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Engaging Members of African American and Latino Communities in Preventive HIV Vaccine Trials

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Abstract

Background—African Americans (AA) and Latinos in US bear a disproportionate burden of HIV-infection, yet remain underrepresented in HIV vaccine trials. The success in engaging and enrolling AA and Latinos in phase-1 and phase-2 vaccine trials at two research sites in New York City is described.

Methods—A retrospective analysis of 1683 HIV-uninfected individuals who completed ≥ 1 stage of the screening process from 2002–2006. Data on sociodemographic, behavioral characteristics, medical eligibility and enrollment in NIH-sponsored vaccine trials were collected.

Results—7.5% of screening participants completed enrollment; 33% were AA, 24% Latino. The proportion of enrollees did not differ significantly by race/ethnicity. Low-risk vs. high-risk AA (49% vs. 23%, $p=0.006$) and high-risk vs. low-risk Latinos (31% vs. 13%, $p=0.006$) were more likely to enroll. Among them, loss-to-follow-up was the most common reason for not completing

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screening. In multivariate analysis, older participants, high-risk men and high-risk women were more likely to complete enrollment.

Conclusions—Once potential minority participants are identified and engaged in the screening process, it is possible to enroll them at rates comparable to white participants. Experience at these sites suggests that the challenge in achieving high rates of minority participation is in increasing the initial pool of candidates prescreening for HIV vaccine studies.

Keywords

HIV; HIV vaccines; AIDS vaccines; HIV vaccine clinical trials; ethnic minorities

Introduction

A safe and efficacious HIV vaccine is one of the most important priorities of AIDS prevention research. In order to ensure that the vaccine is applicable across a variety of populations, HIV vaccine trial participants need to reflect the demographics of the epidemic.

In the United States, African-Americans and Latinos have experienced a disproportionate burden of HIV- infection. The HIV case rate in 2006 was 29.3 per 100,000 among Latinos, and 83.7 per 100,000 among African-Americans, compared to 11.5 per 100,000 among whites¹. New York City has the largest number of AIDS cases and the highest AIDS case rate in the US. In 2007, 28% and 52% of the new AIDS diagnoses in New York City were among Latinos and African-Americans, respectively². Therefore inclusion of individuals from these communities in HIV vaccine trials is greatly needed.

Historically, Latinos and African Americans have been underrepresented in HIV vaccine clinical trials. For example, in the VaxGen phase III HIV vaccine efficacy trial conducted among 5,108 men and 309 women, only 6% of enrollees were African American and 7% Latino, making it difficult to interpret subgroup analyses of these populations³. Racial/ethnic minority participants represented only 17% of the overall enrollment in NIAID-funded network HIV vaccine trials from 1988 to 2004. An encouraging trend was noted as minority participation increased to 27% in 2004, mostly due to an increase in African American participation; Latinos, however, comprised only 4% of study participants in 2004.⁴

Underrepresentation of men or women from African American and Latino communities may have implications for generalizability of the clinical trial results to these populations. Furthermore, the acceptance of HIV vaccines by communities will likely be influenced by whether or not those communities participated in the clinical research. From a biologic standpoint, race or ethnicity may influence responses to vaccines given variations in Human Leukocyte Antigen (HLA) or immune responses.^{4-6, 7} Therefore, effective strategies are urgently needed to increase participation of minorities in HIV vaccine research.

Enrollment in HIV vaccine trials involves a process starting with information gathering by the potential volunteer to help make an informed decision about participation and by the research team to help determine eligibility. The process continues with obtaining a medical history, conducting a physical examination, collecting specimens and signing of the final

consent to enroll. In this paper, several questions that are relevant to developing strategies to engage African Americans and Latinos in vaccine trials are addressed. First, what is the success in reaching and engaging African Americans and Latinos in initial discussions about vaccine trials? Is it possible to retain them through the screening process to determine eligibility or are there any differences by race/ethnicity in the proportion of volunteers who fall out in the process? Is it easier to reach and enroll high risk rather than low risk individuals? Are particular recruitment methods more effective in reaching and retaining minorities? To address these questions, we report the experience of two sites with screening and enrolling volunteers into phase 1 and 2 vaccine trials in New York City. To our knowledge, this is the first study to examine the details of the screening and enrollment process into HIV vaccine trials by race/ethnicity.

Methods

Location and Study Population

From October 2002 to April 2006, men and women 18 to 50 years who were HIV antibody negative were recruited into NIH-sponsored preventive HIV vaccine trials at two Project ACHIEVE research sites in New York City: one located in the South Bronx section of New York City, a predominantly African American and Latino community, and one in lower Manhattan at Union Square, a predominantly white neighborhood. Project ACHIEVE is a part of the Laboratory of Infectious Disease Prevention of the New York Blood Center. Project ACHIEVE is funded by the National Institutes of Health (NIH) HIV Vaccine Trials Network (HVTN).

Volunteers were recruited through a variety approaches including: advertisements in gay publications and local newspapers; posters in public places (universities, community groups), outreach (community health fairs, bars and clubs, on the street); and referrals from study participants and staff. Data on the recruitment sources for every participant entering the screening process were collected.

Individuals were enrolled into Phase 1 and Phase 2 studies based on medical and behavioral eligibility. Men and women were eligible for phase 2 studies if they were at high risk defined as having 1 risk factors over the previous 6 months: (1) high-risk women: unprotected vaginal or anal intercourse with a man known to be HIV-infected; unprotected vaginal or anal intercourse with a man who uses injection drugs; exchanged sex for money, drug, services, or gifts; used crack cocaine at least 3 times; (2) high risk men: unprotected anal intercourse with another man and/or anal intercourse with 2 or more male sexual partners. Men in a monogamous relationship with an HIV seronegative partner for >1 year were not high risk. Individuals at low risk for HIV were eligible for phase 1 studies by the absence of high-risk factors.

Medical eligibility criteria differed for phase 1 and phase 2 studies and were stricter for the former. Individuals were eligible to enroll if they had normal medical histories, laboratory evaluations and physical examinations; were willing to provide written informed consent and comply with study procedures; and met behavioral criteria outlined above.

The number of available phase 1 and phase 2 trials and number of participants enrolled at the two New York study sites varied during the study period: in 2002 twelve participants enrolled into two phase 1 trials; 2003 four participants enrolled into one phase 1 trial; in 2004 twenty-two participants enrolled into four phase 1 trials; in 2005, nine and fifty-four participants enrolled into three phase 1 and one phase 2 trials, respectively; and from January to April 2006, twelve participants enrolled into two phase 1 and seventeen participants enrolled into one phase 2 trial.

Prescreening and Screening Procedures

The screening process consisted of six stages. The first stage was a telephone interview using a prescreen questionnaire containing 28 questions about participant's demographic, medical and behavioral risk. Participants who were preliminarily eligible based on the questionnaire were invited to come to one of our research sites for the second stage, a one-on-one vaccine education and discussion visit. The educational materials and visual aides were standardized across both sites. If interested in the study, the individual proceeded to the third stage, review and signing of a screening informed consent form. The fourth stage was a medical history screening and the fifth stage was a physical examination and a blood draw. If the individual remained interested in participating and met study eligibility criteria, he/she proceeded to the final stage, enrollment, defined as administration of the first study injection. The speed (and number of visits) by which participants progressed through the stages was determined by the participant willingness to engage, time availability, staff assessment and eligibility to progress to the next stage. Thus some stages may have occurred at the same visit – e.g., a physical examination and blood draw (stage 5) may have occurred at the same visit as the medical screening (stage 4) if the participant passed the medical screening and was willing to have the other procedures completed at that time. On the other hand, informed consent and protocol specific education (stage 3) may have occurred over more than one visit if desired by the participant. Potential participants could proceed or drop out at any one of the six stages. There was significant diversity among the clinicians and counselors conducting the visits; women, Latinos and African Americans were well represented.

Data Analysis

The main outcome measure was successful completion of the screening process and enrollment into a vaccine trial. A total of 2251 prescreen questionnaires were completed between October 2002 and April 2006. A separate log was kept to record the completion of the stages from prescreening to enrollment. Questionnaire data were merged to the log by first and last initials and date of birth (merged data set n=2533). After reconciling the records and excluding subjects who had only a prescreen questionnaire (n=450) or who were listed in the log but missing the prescreen questionnaire (n=248), a merged database of 1835 individuals with complete data was created. There were 269 duplicate records which were reviewed and handled as follows: for individuals who prescreened more than once (n=89), the earlier prescreen date was chosen and the other record was deleted; duplicate entries were reviewed and complete ones retained (n=28); participants who screened at both of our research sites were deleted from the database. The final merged database of 1683 records was used for analysis. There was no difference in the ethnic/racial distribution (proportion of

African Americans and Latinos) of individuals with only prescreen questionnaires compared to prescreeners with complete data. Including individuals with missing data in the analysis did not significantly change the proportion of African American and Latino completing the prescreen-questionnaire stage (data not shown)

Categorical variables were compared using chi-square or Fisher's exact test. Multivariate logistic models were used to describe the independent predictors of enrollment. Variables included in the final model were those significantly ($p < 0.05$) associated with successful enrollment on univariate analysis.

Results

Characteristics of Screened and Enrolled Participants

Figure 1 outlines the stages of screening and number of participants who completed each stage of the screening process. Out of 1683 individuals who completed the prescreen questionnaire over the telephone, 126 (7.5%) proceeded to the final stage of enrollment.

The demographic characteristics of individuals who completed the prescreen questionnaire and their disposition in the screening process are summarized in Table 1. The largest groups of individuals who contacted the site and completed the questionnaire were white (33.7%) and male (66.7%) and in the 36 to 45 age group (36.5%). The majority of initial contacts were generated from referrals, street outreach and advertisements. Almost one quarter of the individuals initiating the screening process reported prior medical conditions which would exclude them from participating in a trial and 91% had undergone HIV testing in the past.

Overall, 31.3% of the volunteers who completed a prescreen questionnaire were African American and 25.0% were Latino [Table 1]. Individuals from ethnic/racial minorities were successfully retained through the six stages of screening: 33.3% of the enrollees were African-American, and 23.6% were Latino.

Behavioral risk criteria differed among individuals who proceeded through the screening stages [Table 1]. Low risk men (LRM) were more likely than others to complete every stage of screening, with the notable exception of the enrollment visit. While over one-third of individuals completing vaccine education through physical exam visit were LRM, there were only 16% of them among enrollees. High risk women (HRW), on the other hand, once they entered the screening process, were very likely to complete it and proceed to an enrollment visit; a little over 9% of prescreeners were HRW but they constituted almost one-quarter of total enrollments. It should be noted, however, that the number of protocols open to enrollment for low vs. high risk individuals varied during this time period; for example in 2003, only one phase 1 (4 participants enrolled) and no phase 2 trials were available, whereas in 2005, the sites were screening and recruiting participants for three phase 1 and one phase 2 trials (9 and 54 participants enrolled into phase 1 and 2 trials, respectively) [Table 1]. This may account for differences in the screen to enrollment ratios among LRM and HRW.

Multivariate analyses of factors associated with proceeding to an enrollment visit are shown in Table 2. Older participants, high risk men and high risk women were more likely to proceed to enrollment on multivariate analysis. Race/ethnicity was not associated with enrollment. The use of flyers/postcards and website/other strategies were associated with successful enrollment.

Table 3 presents the comparison of high (Phase 2) and low risk (Phase 1) individuals at each stage of screening. Although women were more likely to prescreen for phase 1 trials, the proportion of women participating in Phase 1 vs. Phase 2 trials was not significantly different of all subsequent stages of the screening process [Table 3]. Overall, the largest proportion of participants at every stage of Phase 1 screening was African-American. We were also more successful at recruiting, screening and enrolling African-Americans into Phase 1 compared to Phase 2 vaccine studies: for example, 48.9% in Phase 1 vs. 23.0% enrolled in Phase 2 studies ($p=0.006$). We were less successful, however, enrolling low risk compared to high risk Latinos: only 12.8% of individuals enrolling into Phase 1 were Latinos compared to 31.1% enrolling into Phase 2 studies ($p=0.006$).

Effective recruitment methods differed among participants prescreening for Phase 1 vs. Phase 2 study [Table 3]. Among our Phase 1 prescreeners and individuals completing every stage of the process, advertisements, for example, seemed most effective (26.3% of Phase 1 prescreens), while referrals and outreach were more successful in bringing in Phase 2 individuals. However, the percents enrolled by different recruitment strategies were not significantly different. No significant differences were identified between effective sources of recruitment for men, women and ethnic minority groups enrolling in the vaccine studies (data not shown). Although ethnically-specific or Spanish-language print media were not targeted, the recruitment team engaging in direct street and bar outreach was composed of outreach workers from diverse communities.

Reasons for Screen Failure

The proportion not completing a vaccine education visit was the highest among Latinos (65.6%), and the group of Asian/Pacific Islander, Native American/American Indian and others self-identified as “other” (66.7%) [Table 4]. African Americans were the most likely to fail completing the medical screening visit.

Among participants who did not complete enrollment, 24.8% were ineligible for medical reasons, 16.1% did not meet behavioral criteria, 28.0% were lost to follow-up or did not show, 26.9% refused participation and 4.2% did not enroll for other reasons (age, waitlisted, referred to the other site) [Table 5]. Medical eligibility criteria for enrollment into phase 1 studies were considerably stricter than for phase 2 trials and failure to enroll for medical reasons was more common for phase 1 compared to phase 2 studies (27.2% vs. 19.6%) [Table 5 and data not shown].

The reason for not enrolling differed among volunteers from ethnic/racial groups. Overall, the percent who were lost to follow up or no shows were higher among Latinos and African Americans than whites (32.1% and 29.3% vs. 23.9%, $p<0.0001$), whereas active refusal to

participate was the least common reason for dropping out (20.0% and 15.0% for Latinos and African Americans respectively compared to 40.1% for whites, $p<0.0001$).

For phase 1 trials for which we were least successful enrolling Latinos, the most common reason for failure to enroll this population was loss to follow-up (28.8%), followed by medical ineligibility (26.6%) [Table 5]. Of note, loss to follow-up was higher among Latinos than whites screening for both phase 1 (28.8% vs. 20.6%) and phase 2 trials (37.9% vs. 29.6%). Among African Americans screening for phase 1 and phase 2 studies, medical ineligibility and loss to follow-up were the most common reasons for not enrolling [Table 5]. The percent refusing to participate was lower among African Americans and Latinos for both phase 1 and 2 trials.

Discussion

The experience from two research sites in New York demonstrates that it is possible to recruit, prescreen and retain in the screening process African American and Latino volunteers. Among participants enrolled into vaccine trials at our site, 33.3% were African American, and 23.6% were Latino. There were no significant differences in the percentage of Latinos or African Americans who prescreened and subsequently enrolled in vaccine studies at two New York sites; we noted, however, that the sites were more successful enrolling Latinos into Phase 2 studies and African Americans into Phase 1 studies. Potential reasons for this discrepancy may include use of specific recruitment strategies, such as targeted street outreach in Latino communities, which tapped into high risk subgroups, or differences in the communities' perception of phase 1 and phase 2 trials. It is possible that Latinos are less willing to enroll into early phase 1 trials rather than efficacy trials. Although active refusal to follow up was lower among African Americans and Latinos, loss to follow up during the screening process was more common in both groups compared to whites, and this may represent a form of "passive refusal."

In 1994, the National Institutes of Health mandated better representation of minorities in NIH-sponsored clinical research. Since then, however, enrollment of minorities continues to be a challenge^{8,9}. Previous work has attempted to elucidate barriers to enrollment in HIV vaccine trials. Factors such as concerns about safety of the vaccines, social risks as a result of participation or testing HIV antibody positive after receiving an HIV vaccine and the burden of study follow-up have been cited as potential barriers to participation in the high-risk populations¹⁰⁻²¹. Compounding these barriers is the history of abuses and disenfranchisement of minority participants in medical research. It has been shown that the primary reason for reluctance to participate in HIV vaccine trials among Spanish-speaking Latinos was mistrust and fear of government and government sponsored HIV/AIDS medical research²². African Americans and English speaking Latinos in HIV-related research have cited similar concerns²³⁻²⁶; among African-Americans, mistrust was the strongest predictor of unwillingness to participate in HIV research²⁷. Other potential barriers to participation may be due to limited access to research studies in addition to unwillingness to enroll^{13, 28, 29} and that individuals from ethnic minorities may be less likely to be informed about clinical trials than non-minority participants. Wendler and colleagues, for example, assessed whether minority groups invited to participate in health research were less

likely to consent to participate than non-minority individuals. The authors found only small differences in consent rates by race or ethnicity, but noted substantially lower numbers of individuals invited to participate in research, HIV studies in particular²⁸. Lack of knowledge of HIV vaccine may be an important barrier to participation among these groups. In a national telephone survey, 53% of Latinos and 37% of African Americans had read or heard anything about HIV vaccine research in the prior 12 months. A higher proportion of Latinos (27%) and African Americans (47%) compared to the general population or high-risk men who have sex with men (18% and 13% respectively) thought a vaccine already exists but is being kept a secret.³⁰

Misconceptions about HIV vaccine research exist, but these results suggest that, once given the opportunity to participate, minority groups are equally likely to enroll into vaccine studies. It remains to be seen whether these findings are generalizable to other sites within the HVTN network. The reasons for our success may be due to factors such as location of the two research clinics in culturally and ethnically diverse neighborhoods in South Bronx and lower Manhattan; free standing office space physically detached from a hospital or medical clinic thereby minimizing any potential stigma of participating in a research study; long established history in the community with a strong community education; the screening process and vaccine education carried out over several visits; and our diverse and bilingual staff reflecting the target populations. All of these factors can contribute to creating an environment that facilitates communication and trust between participants and study staff.

Limitations of this study include the retrospective design and the fact that it was limited to only two sites in one city.

Although enrollment rates of Latinos and African Americans at our sites are higher than what has been previously reported for all study sites conducting Phase 1 or 2 trials within the HVTN⁴, much still remains to be done. It appears that in order to raise the overall participation of Latinos and African Americans in vaccine trials at these two sites, a crucial step is to increase the initial pool of individuals prescreening for studies. Targeted strategies for reaching out to individuals, such as low risk Latinos and high risk African Americans, need to be developed. To ensure successful inclusion of minority groups, it is crucial that efforts focus on substantive community education to raise awareness, foster an environment of trust, dispel misconceptions and lay the foundation for culturally relevant recruitment strategies. This could be accomplished through building partnerships with community based minority organizations to strengthen community engagement with researchers. Through these collaborations we can make sure that information about HIV vaccine research is disseminated, our goals are clearly communicated and trust is firmly established.

Recent developments in the HIV vaccine field may pose an even greater challenge to accomplishing this goal. In September 2007, based on the Data and Safety Monitoring Board review of the phase IIB, test-of-concept, efficacy trial in the Americas (the STEP study, HVTN 502/Merck 023), vaccinations in this trial were stopped as statistical criteria for futility had been met³¹. Data released in November 2007 also raised the question of whether there was an increased risk of HIV acquisition conferred by the vaccine in persons with pre-existing immunity to adenovirus type 5³². In wake of these developments,

potential for misconceptions about HIV vaccine research may grow. It is therefore more important than ever to ensure that researchers engage members of the community and its organizations in open dialogue, dissemination of accurate information, and that sight should not be lost of the need to develop an effective preventive vaccine. As we move the field forward and embark on other vaccine trials, it is imperative that we ensure equitable representation of groups most affected by this epidemic and in greatest need of preventive interventions.

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FIGURE 1.
Number of participants at each stage of screening.

TABLE 1
 Characteristics of individuals completing each stage of the screening process for HIV vaccine trials¹.

	Prescreen Questionnaire N=1683 N (%)	Vaccine Education N=675 N (%)	Informed Consent N=514 N (%)	Medical Screening N=454 N (%)	PE/Blood Draw N=273 N (%)	Enrollment N=126 N (%)
Gender						
Female	559 (33.2)	218 (32.3)	176 (34.2)	160 (35.2)	91 (33.3)	52 (41.3)
Male & Transgender ²	1124 (66.7)	457 (67.7)	338 (65.8)	294 (64.8)	182 (66.7)	74 (58.9)
Race/Ethnicity						
White	563 (33.7)	233 (34.8)	169 (33.1)	157 (34.8)	96 (35.6)	44 (35.8)
African American or Black	523 (31.3)	237 (35.4)	189 (37.1)	157 (34.8)	100 (37.0)	41 (33.3)
Latino/Hispanic	419 (25.0)	144 (21.5)	107 (21.0)	99 (22.0)	51 (18.9)	29 (23.6)
Other ³	168 (10.0)	56 (8.4)	45 (8.8)	38 (8.4)	23 (8.5)	9 (7.3)
Age						
18–25 ⁴	378 (22.5)	122 (18.1)	93 (18.1)	86 (18.9)	50 (18.3)	21 (16.7)
26–35	504 (30.0)	202 (29.9)	142 (27.6)	128 (28.2)	79 (28.9)	44 (34.9)
36–45	614 (36.5)	284 (42.1)	235 (45.7)	202 (44.5)	121 (44.3)	55 (43.7)
46–50	187 (11.1)	67 (9.9)	44 (8.6)	38 (8.4)	23 (8.4)	6 (4.8)
Risk Group						
High Risk Men	519 (30.9)	197 (29.3)	144 (28.1)	122 (27)	91 (33.5)	53 (42.4)
High Risk Women	156 (9.3)	69 (10.3)	59 (11.5)	55 (12.2)	33 (12.1)	31 (24.8)
Low risk Men	598 (35.6)	258 (38.3)	192 (37.5)	170 (37.6)	90 (33.1)	20 (16.0)
Low Risk Women	405 (24.1)	149 (22.1)	117 (22.9)	105 (23.2)	58 (21.3)	21 (16.8)
Referral Source						
Ads	347 (20.6)	151 (22.4)	121 (23.5)	109 (24.0)	70 (25.6)	11 (8.7)
Events	210 (12.5)	69 (10.2)	47 (9.1)	44 (9.7)	24 (8.8)	11 (8.7)
Outreach	423 (25.1)	151 (22.4)	113 (22.0)	101 (22.3)	54 (19.8)	34 (27.0)
Flyers/postcard distribution	121 (7.2)	61 (9.0)	48 (9.3)	40 (8.8)	24 (8.8)	15 (11.9)

	Prescreen Questionnaire N=1683 N (%)	Vaccine Education N=675 N (%)	Informed Consent N=514 N (%)	Medical Screening N=454 N (%)	PE/Blood Draw N=273 N (%)	Enrollment N=126 N (%)
Referrals ⁵	430 (25.6)	181 (26.8)	137 (26.7)	120 (26.4)	74 (27.1)	40 (31.8)
Website & Other	152 (9.0%)	62 (9.2)	48 (9.3)	40 (8.8)	27 (10.0)	15 (12.0)
Prior Medical history ⁶	404 (24.0)	104 (15.4)	77 (15.0)	64 (14.1)	39 (14.3)	25 (19.8)
Previous participation in clinical trial	48 (3.2)	17 (2.9)	14 (3.1)	13 (3.3)	8 (3.5)	6 (5.1)
Previous HIV testing	1517 (91.1)	619 (92.7)	476 (93.7)	419 (93.5)	254 (94.4)	122 (99.2)

N's do not add to total subjects due to missing data

¹ Number of phase 1 and phase 2 trials open for enrollment at the two New York study sites: 2002 (2 phase 1 trials); 2003 (1 phase 1 trial); 2004 (4 phase 1 trials); 2005 (3 phase 1 trials and one phase 2 trial); January to April 2006 (2 phase 1 trials and one phase 2 trial)

² 1, 3, 3, 2, 1, 1 and transgender participants completed Pre-screen questionnaire, vaccine education, informed consent, medical screening, PE/blood draw visits, respectively.

³ Other: Asian/Pacific Islander, Native American/American Indian and everyone self-identifying as "other" on the questionnaire

⁴ Includes persons under 18 years of age at prescreening stage only

⁵ Referrals from participants, staff and other

⁶ Defined as: previous history of diabetes, high blood pressure, cancer, Coronary Artery Disease, asthma, hospitalization over the past three years

TABLE 2

Predictors of proceeding to enrollment in Phase 1 and 2 HIV vaccine trials

Variables	Total prescreened	N (%) enrolled	OR	95% CI	p-value
Age					
18–25	378	21 (5.5)	2.22	0.79–6.20	0.128
26–35	504	44 (8.7)	2.90	1.09–7.69	0.032
36–45	614	55 (9.0)	2.86	1.10–7.43	0.031
46–50	187	6 (3.2)	1.0		
Risk Group					
High Risk Men	519	53 (10.2)	3.20	1.79–5.71	<0.0001
High Risk Women	156	31 (19.9)	6.27	3.27–12.05	<0.0001
Low risk Men	598	20 (3.3)	1.0		
Low Risk Women	405	21 (5.2)	1.35	0.69–2.67	0.382
Race/Ethnicity					
White	563	44 (7.8)	1.0		
A-A or Black	523	41 (7.8)	1.15	0.68–1.93	0.608
Latino/Hispanic	419	29 (6.9)	0.75	0.44–1.30	0.306
Other	168	9 (5.4)	0.57	0.22–1.51	0.259
Referral Source					
Ads	347	11 (3.2)	1.0		
Events	210	11 (5.2)	1.36	0.5–3.38	0.511
Outreach	423	34 (8.0)	1.80	0.85–3.81	0.125
Flyers/postcard	121	15 (12.4)	3.12	1.31–7.46	0.011
Referrals	430	40 (9.3)	1.85	0.88–3.90	0.104
Website/Other	152	15 (9.9)	2.76	1.18–6.47	0.019

Other Race/Ethnicity: Asian/Pacific Islander, Native American/American Indian and everyone self-identifying as “other” on the questionnaire

TABLE 3
 Characteristics of Phase 1 vs. Phase 2 participants by stage of screening for HIV Vaccine Trials

	Pre-Screen		Vaccine Education		Informed Consent		Medical Screening		Physical Exam/Blood Draw		Enrollment	
	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II
Total (N)	1114	556	458	210	349	160	312	106	164	106	50	74
Gender %												
Female	37	25**	33	29	34	34	34	37	35	29	44	39
Male & Transgender	63	75	67	71	66	66	66	63	65	71	56	61
Race/Ethnicity %												
White	31	40**	31	42*	29	42*	31	43*	29	45*	28	41*
A-A or Black	35	23	41	24	42	27	39	27	46	24	49	23
Latino/Hispanic	23	28	20	24	21	21	22	22	17	23	13	31
Other ²	11	9	8	9	8	9	8	8	8	9	11	5
Age %												
18-25 ¹	23	21**	19	15*	19	16*	20	17	19	17*	14	18
26-35	28	34	27	36	26	32	28	29	28	30	38	34
36-45	35	39	30	46	45	48	42	50	41	50	38	47
46-50	14	6	13	3	11	4	10	4	9	3	10	1
Referral Source %												
Ads	26	9**	29	9**	31	9**	32	7**	23	7**	14	5
Events	14	9	13	6	11	6	11	7	10	7	12	7
Outreach	22	30	17	31	18	29	18	29	13	28	20	30
Flyers/postcard	8	6	10	8	10	8	9	8	10	7	16	9
Referrals ³	20	37	22	37	21	39	10	41	17	43	22	39
Website & Other	9	8	9	8	9	8	9	8	10	8	16	9
Past Medical history %	15	41**	8	32**	7	33**	6	32**	2	33**	4	31**

Pre-Screen		Vaccine Education		Informed Consent		Medical Screening		Physical Exam/Blood Draw		Enrollment	
Phase		Phase		Phase		Phase		Phase		Phase	
I	II	I	II	I	II	I	II	I	II	I	II
88	97**	91	96*	93	96	92	97*	93	96	100	99
Previous HIV testing %											

p-value for comparing phase I to phase II within each stage

** p 0.0001;
* p 0.05;

¹ Includes 3 individuals under the age 18 who completed a prescreen questionnaire

² Other: Asian/Pacific Islander, Native American/American Indian and everyone self-identifying as “other” on the questionnaire

³ Referrals from participants, staff and other

Not significant: past participation in a clinical trial

TABLE 4
Proportion of individuals who failed to complete a screening stage for HIV vaccine trials

	Total prescreened	Vaccine Education Visit N (%)	Informed Consent visit N (%)	Medical Screening visit N (%)	Physical Exam Visit/Blood Draw N (%)	Enrollment Visit N (%)
Race/Ethnicity						
White	563	330 (58.6)**	64 (27.5)	13 (7.7)*	10 (6.4)	56 (58.3)
A-A or B lack	523	286 (54.7)	48 (20.3)	32 (16.9)	12 (7.6)	62 (62.0)
Latino/Hispanic	419	275 (65.6)	37 (25.7)	9 (8.4)	4 (4.0)	25 (49.0)
Other ^I	168	112 (66.7)	11 (19.6)	7 (15.6)	3 (7.9)	15 (65.2)

N's do not add to total subjects due to missing data. Percents are of those completing the previous stage in Table 1.

p-value compares the proportion who failed by race and ethnicity for each stage;

* p=0.02;
** p=0.002

^I Asian/Pacific Islander, Native Am/Am Indian and Other

TABLE 5
Reasons for failure to enroll into Phase 1 and Phase 2 HIV vaccine trials among ethnic/racial groups

	Medical Ineligibility N (%)	Behavioral Ineligibility	Lost to Follow up/No show	Refused	Other ¹	p-value
Phase 1 Low Risk						<0.0001
White	73 (22.8)	50 (15.6)	66 (20.6)	120 (37.5)	11 (3.4)	
African-American	115 (34.5)	67 (20.1)	85 (25.5)	51 (15.3)	15 (4.5)	
Latino	61 (26.6)	49 (21.4)	66 (28.8)	40 (17.5)	13 (5.7)	
Other ²	19 (18.1)	16 (15.2)	33 (31.4)	31 (29.5)	6 (5.7)	
Phase 2 High Risk						<0.0001
White	30 (15.9)	15 (7.9)	56 (29.6)	84 (44.4)	4 (2.1)	
African-American	20 (20.8)	15 (15.6)	41 (42.1)	14 (14.6)	6 (6.2)	
Latino	26 (21.0)	16 (12.9)	47 (37.9)	31 (25.0)	4 (3.2)	
Other ²	12 (30.0)	2 (5.0)	8 (20.0)	17 (42.5)	1 (2.5)	
Total	359 (24.8)	232 (16.1)	404 (28.0)	389 (26.9)	61 (4.2)	

N not equal to 1557 because of missing values

p-value compares the proportion of failing to enroll for a particular reason by race/ethnicity.

¹ Includes age ineligibility

² Other: Asian/Pacific Islander, Native American/American Indian and everyone self-identifying as "other" on the questionnaire