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Understanding Differences in Enrollment Outcomes among High-Risk Populations Recruited to a Phase IIb HIV Vaccine Trial

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Abstract

Background—The Step Study, a Phase IIb HIV vaccine proof of concept study, enrolled approximately 3,000 persons in Clade B regions. The Atlanta site sought to enroll a diverse population. This prospective cohort study examined key factors associated with participant enrollment.

Methods—We obtained participant information (e.g., sociodemographic, medical) and followed outcomes from 2005 to 2007. Of the 810 potential “Step Study” participants, 340 cases were analyzed.

Results—The recruitment strategy generated strong interest among minorities with 37% eligible following prescreening, yet 25% of the minorities enrolled. However, the percentage of whites increased from 62% eligible (prescreened sample) to 75% enrolled. The regression model was significant with educational level being an enrollment predictor ($p = 0.0023$). Those with at least a bachelor’s degree were more likely to enroll compared to those with a K-12 education or some college (OR = 2.424, 95% CI = 1.372–4.281, $p < 0.01$). White race was also a significant factor (OR=2.330; 95% CI = 1.241–4.375, $p < 0.01$). No difference in enrollment was observed among recruitment approaches, Pearson χ^2 (2, N = 336) = 5.286, $p = 0.07$.

Conclusions—The results from this study indicate that women, minorities, and those with lower educational attainment were less likely to enroll in an HIV vaccine efficacy study at our site. The findings highlight an important consideration on the role of health literacy to sustain participation of eligible minorities in HIV vaccine trials.

Keywords

HIV Vaccine; Willingness-to-Participate; Recruitment; Retention; Women; Minorities

Introduction

In 2007, approximately 33.2 million people were living with HIV/AIDS worldwide.¹ In the US alone, CDC estimates that approximately 56,300 individuals are newly infected with HIV every year.^{2,3} Demand for a safe and effective HIV vaccine exists and research toward that goal continues to be a major public health priority. Ensuring adequate representation in

HIV/AIDS clinical trials of those primarily impacted by the epidemic is a key objective. Racial and ethnic minorities are particularly affected by the epidemic with 48% of new HIV infections in the United States diagnosed among Blacks.⁴ Minority women are also disproportionately impacted by HIV/AIDS.^{4, 5} Thus, women and minorities have been identified as priority populations for domestic HIV prevention efforts.^{6–8}

HIV/AIDS Vaccine Recruitment Issues

Although much is known about the challenges associated with recruitment and retention of high risk populations in HIV vaccine trials, very little is known about the retention issues within the context of an active study enrollment cycle.^{9–14} Previous findings have indicated that “willingness-to-participate” (WTP) declines with the passage of time among groups.^{15–17} Thus, examining the attrition patterns of priority groups in HIV vaccine research is of interest to meet future study enrollment objectives.

We evaluated the sociodemographic and recruitment factors predictive of enrollment in a multisite Phase IIb HIV vaccine clinical trial. We sought to contribute to the evidence for the need for culturally-sensitive approaches in the recruitment process by investigating potential disparities in enrollment at our site. We also examined the role of our integrated marketing communication (IMC) approach on the recruitment process to determine whether specific approaches had an effect on the enrollment outcome. The IMC strategy focuses on key communication objectives (e.g., build study awareness in the community) and it suggests that an equilibrium of effect can be anticipated with alternating use of advertising and other promotional tactics over time.¹⁸

Methods

Study sample

Volunteers were actively recruited for participation in a Phase IIb HIV vaccine study (the Step Study) from March 2005 through March 2007. Our study recruitment approach featured a key message on the urgent need for an HIV vaccine and the campaign advertising included diverse and recognizable community members.¹⁹ Recruitment strategies included a mix of internet/electronic advertising, mass media approaches, and venue-based promotion.

Potential volunteers contacted the study site hotline to conduct a brief pre-screening with outreach staff to determine initial study eligibility. Occasionally, volunteers walked into the study site and the pre-screen was performed in person. Inclusion and exclusion criteria were established by the study protocol for this HIV vaccine study. Eligible potential volunteers were between 18 and 45 years old, HIV negative, and at high risk for infection with HIV-1.²⁰ Eligible participants were referred to study nurses for informed consent and clinical screening. A volunteer was able enroll in the study once both steps were completed successfully.

Data Collection

During pre-screening, potential volunteers consented to participate in an IRB-approved volunteer database for collection of contact information, sociodemographic characteristics, and a short medical and risk behavior profile. Persons were permitted to skip any questions that they did not want to answer. Data were stored in a password-protected, numerically encoded electronic volunteer database. Telephone prescreening took place during normal business hours within a 24-hour period following initial contact. Among those who eventually enrolled in the Step Study at our site (N =130), two elected not to participate in the database study protocol. Our analyses therefore included 128 Step participants (98.5% of site study population).

Measurement

The primary outcome of interest in this analysis was enrollment in the clinical trial. Alternative outcomes included ineligible or eligible but not enrolled (i.e., passive or active refusal of participation). Educational attainment included the following levels: K-12 grade or some college (i.e., vocational or technical training, some college without degree, or associate degree), and bachelor's degree or beyond (i.e., bachelor's degree, masters, doctorate or professional degree). Race/ethnicity included 'White' for those who self-identified as White/Caucasian respondents, 'non-White' for those reporting other than white race including Black/African American, Hispanic/Latino/a, Asian/Pacific Islander, multiracial or 'other' race or ethnicity.

Statistical Analysis

SAS version 9.1 (SAS Institute, Inc., Cary, NC, USA) and SPSS version 15.0 (SPSS, Inc., Chicago, IL., USA) were used for analyses. Descriptive statistics and cross-tabulations were generated for all of the variables of interest. An overall multivariate model (i.e., binary logit regression method) was performed along with similar analyses for the male subgroup. Participant motivation had a large proportion (38.9%) of missing data and therefore was not included in the regression analyses. Significant independent predictors of outcomes were assessed at $p < 0.05$ levels. Differences in categorical sociodemographic information (e.g., gender and enrollment status) were assessed by Chi-square (χ^2) tests and differences in continuous information (e.g., mean age) were assessed by paired t-tests (t).

Descriptive statistics were generated from the recruitment campaign records to assess IMC variables. The variables included occurrence data and type of communication approach in the recruitment cycle (e.g., mass media, electronic/web-based, general community promotion). Recruitment approaches were categorized as general promotion (print material distribution, educational presentations, special community events, word of mouth referral and multiple sources), internet-based (email, listservs, web banners), and mass media (television, radio, mass print advertising). Each category was enumerated (e.g., 1, 2, 3) and frequencies were calculated to assess the overall marketing mix of the campaign. Crosstabulation procedures including chi-square (χ^2) tests were employed to assess the differences in recruitment sources and enrollment outcomes for all participants and for minorities.

Results

Volunteer Contacts, Screening and Enrollment

Of the 810 individuals who initially contacted the study site, most (86.8%, $n=703$) completed the pre-screening process (Figure 1). Another group of 107 potential volunteers either lost interest (90.7%, $n=97$) prior to pre-screening or were unable to be contacted (9.3%, $n=10$). Among those prescreened ($n=703$), 42.2% ($n=297$) were ineligible for reasons including risk-related ineligibility (53.2%, $n=158$), HIV, HBV, or HCV positive status (18.9%, $n=56$), age (9.8%, $n=29$), study commitment difficulties (7.1%, $n=21$), health problems (3.0%, $n=9$), multiple exclusion criteria (3.0%, $n=9$), receipt of previous HIV vaccine from other investigational HIV vaccine study (0.3%, $n=1$), and a lack of English language comprehension (0.3%, $n=1$). The remaining 406 (57.8%) persons were referred for informed consent and clinical screening processes.

Of these 406 eligible volunteers, 46.8% ($n = 190$) did not complete clinical screening. Many of these were unable to be contacted or lost interest prior to completing clinical screening. 216 individuals successfully completed informed consent and clinical screening and of these 66 (30.6%) were found to be ineligible. Reasons for clinical screen ineligibility included

screening laboratory abnormalities (27.3%, n=18), health problems (25.8%, n=17), risk ineligibility (21.2%, n=14), HIV, HBV, or HCV positive status (12.1%, n=8), inability to understand consent (7.6%, n=5), age (3.0%, n=2), and other exclusionary considerations (3.0%, n=2). Of the remaining 150 eligible individuals, 128 volunteers (85.3%) enrolled in the HIV vaccine clinical trial (Figure 1).

Recruitment Tactics

The campaign totaled 409 tactics implemented throughout the recruitment cycle at our site (March 2005 to February 2007). Effort given to web-based recruitment (e.g., email outreach, listserv and web advertising) resulted in about 50% of the overall strategy (n = 206). General promotional activities including in-person outreach, print material dissemination, educational presentations, and special community events comprised a significant proportion of the recruitment endeavor (n = 145 tactics; 35.5% of campaign approach). Finally, the investment in mass media was limited, resulting in 14.2% (n=58 tactics) of the overall effort.

Characteristics of the Study Population

The study population (N = 340) included the volunteers who successfully enrolled in the trial (n=128) and potential participants who did not clinically screen or enroll (n= 212) (Table 1). The non-enrolling group is comprised of both the group of eligible persons who completed the clinical screening, but decided not to participate (n=22) as well as the group of potentially eligible volunteers who, after pre-screening, did not proceed to clinical screening (n=190).

The study population was comprised predominantly of men 82.9% (n=282), and most reported homosexual orientation (n=238, 70.0%). Nearly two-thirds (n=211, 62.1%) of the study population were White and 30.6% self reported as Black (n =104). Attained educational level for 134 (39.4%) was having K-12 or some college and others reporting having earned a college degree or achieving post-graduate educational status (n=110, 32.4%). Many reported altruism (n= 75, 22.1%) and scientific or medical contribution (n = 59, 17.4%) as their motivation for participating in an HIV vaccine clinical trial. At the prescreening interview, potential participants indicated that they became interested in the study through mass media outreach such as newspaper, magazine, and transit television ads (n=132, 38.8%). Others were introduced to the study via general promotion (n = 115, 33.8%) and internet-based approaches (n = 89, 26.2%).

Enrollment Sociodemographics and Recruitment Factors

The mean age for the non-enrolled population was 34.0 years and for the enrollee group was 34.5 years (p=0.64). Nine women enrolled in the trial of the 58 females in the study population. A statistical association was observed between gender and enrollment ($\chi^2 = 14.59$, $p < 0.01$). Similarly, 32 racial or ethnic minorities enrolled in the Step Study of the 127 in the sample. A statistical association between race/ethnicity and enrollment exists in this study population ($\chi^2 = 13.89$, $p < 0.01$).

An analysis of educational attainment of enrolled and non-enrolled members of the sample revealed that the proportion of enrollment was largest among those with at least a college degree ($\chi^2 = 19.26$, $p < 0.01$). Sexual orientation was also associated with enrollment ($\chi^2 = 25.60$, $p < 0.001$) with male MSM volunteers comprising the largest proportion of study participants (n=110, 85.9%).

Evaluation of the recruitment approaches (i.e., general, internet, or mass media) on enrollment outcomes was assessed with two-way contingency analysis. No significant

differences were observed, Pearson χ^2 (2, N = 336) = 5.286, p = 0.071. Recruitment source also did not have a relationship to the enrollment outcomes for 127 minorities who were eligible but did not enroll or among those minority volunteers who enrolled (n = 32), Pearson χ^2 (2, N = 124) = 3.266, p = 0.195.

Predictive Enrollment Model

Multiple logistic regression analyses were used to determine the overall predictive ability of personal characteristics (e.g., gender, race, and educational attainment level, along with reported recruitment method) on the likelihood of enrollment among those eligible. These factors were selected to ensure parsimony of model measures. Given the large proportion of missing data on the participant motivation variable (38.9%), the data were excluded from regression analyses.

The overall model was significant with education being a significant predictor for enrollment (p = 0.0023). Those with a bachelor's degree or beyond were significantly more likely to enroll compared to those with a K-12 education or some college (OR = 2.424, 95% CI = 1.372–4.281). In addition, white race was a significant overall predictor for enrollment (OR = 2.330; 95% CI = 1.241–4.375, p = 0.0085).

Among the subgroup of males who enrolled compared to those who did not (n = 119, 42.5% of subgroup sample of 280), the overall findings are similar with respect to educational attainment (i.e., bachelor's degree or higher) compared to those with K-12 or some college (OR = 2.088, 95% CI = 1.142–3.820, p = 0.0169). With respect to race, white men were also more likely to enroll than non-white men (OR = 2.130, 95% CI = 1.046–4.339, p = 0.0372). A subgroup analysis for women (n = 9, 15.52% of 58) revealed no significant differences with respect to recruitment tactic, educational attainment, and race factors on enrollment.

Discussion

The goal of this study was to examine differences between those who enrolled in an HIV vaccine trial and others who were eligible for clinical screening or enrollment but who did not continue in the process. This empirical investigation is unique in its orientation as it provides a case study perspective of participant accrual and attrition within the context of an HIV vaccine trial enrollment cycle.^{13, 15–17} Clear differences exist in the clinical screening and enrollment patterns of the priority populations. Of particular concern was the loss of priority populations for HIV vaccine research, such as women and minorities, from the pre-screening stage to enrollment. We were also interested in evaluating the effects of our IMC strategy on enrollment. The findings contribute to our understanding of recruitment methods that generate attention among minorities interested in HIV vaccine research study participation.

There is a meaningful relationship of race and greater educational attainment on likelihood of enrollment for men. White men were more likely to enroll than non-Whites. Those with higher educational achievement level were more likely to enroll in the study. This suggests a higher level of health literacy may play a role in participant motivation to enroll. Other concerns such as recruitment methods did not explain the outcome differences.

In addition to educational attainment, other issues may have impacted our ability to successfully enroll eligible minority men such as the potential for social harms (e.g., stigmatization, negative reactions from family or friends), fear and mistrust, or potential for vaccine-induced positive HIV antibody test.^{21–25} Previous behavioral research at our site with similar target populations suggested that we needed to build a diverse volunteer and clinical staff pool in order to gain the trust of minority men considering participation.^{26, 27} In

addition, the minority men who participated in our earlier pre-Step interviews expressed a desire for information addressing key misconceptions (i.e., the vaccine does not contain HIV), and indicated a need for sufficient compensation to offset time and travel costs associated with participation.^{26, 27} These issues may warrant further investigation to facilitate enrollment of similar populations in future Phase II or III HIV vaccine studies at this site.

Of the 49 women who were eligible for the study from the prescreen pool of 58 females, most were Black/African American and were recruited primarily through mass media and street outreach tactics. However, we enrolled far less than anticipated of those who were determined to be eligible, and the predictive model for this group offered no insight about the reasons why this occurred. We do believe that other factors not measured in this study may have influenced the result with the female group, but we remain cautious given the small sample size. However, it should be noted that there was a centralized push from the study sponsors to limit the female recruitment for this protocol to sites with a track record of recruiting high-risk women. Our efforts to aggressively recruit this population were therefore limited throughout the sample accrual period. Barriers for enrollment that have been identified in other studies of high risk women have included lack of childcare, the distance of the site from neighborhood recruitment vicinity, time requirements, informed consent comprehension, and clinical staff ethnic composition.^{7, 8, 27–31}

We acknowledge the limitations inherent in this study. The most important limitation is the small sample size. Despite there being adequate numbers in each group, consent for participation in the volunteer database allowed for skipping questions, resulting in some missing data on key variables including participant motivation. Recall bias may have also been a factor with some respondents, particularly on the recruitment measures. Some participants may not have accurately recollected the recruitment source in the prescreen interview. Finally, our results reflect one site's experience in the Step Study and may not be reflective of the occurrences at the other 33 sites included in the trial. However, we do not believe that these issues resulted in any form of systematic bias in the analyses.

The results from this study indicate that women, minorities, and those with lower educational attainment were less likely to enroll in an HIV vaccine efficacy study at our site. The IMC approach was useful for recruitment, as it generated many prescreen interviews from a diverse cohort and it built a sufficient pool of eligible participants to exceed our site's enrollment goal. The findings highlight an important consideration on the role of health literacy to sustain participation of eligible minorities in HIV vaccine trials.

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FIGURE 1.
Recruitment-to-enrollment volunteer flow chart.

Table 1

Characteristics of eligible participants, not enrolled participants, and enrolled volunteers

Characteristic	All Participants (N=340)	Not Enrolled Participants (N=212)	Enrolled Volunteers (N=128)
Age			
Age (Mean)	34.2	34.0	34.5
<i>Missing</i>	103	101	-
Gender			
Female	58 (17.1%)	49 (23.1%)	9 (7.0%)
Male	282 (82.9%)	163 (76.9%)	119 (93.0%)
<i>Missing</i>	-	-	-
Race/Ethnicity			
Asian/Pacific Islander	3 (0.9%)	3 (1.4%)	-
Black/African American	104 (30.6%)	81 (38.2%)	23 (18.0%)
White/Caucasian	211 (62.1%)	115 (54.2%)	96 (75.0%)
Hispanic/Latino/a	9 (2.6%)	5 (2.4%)	4 (3.1%)
Multiracial	7 (2.1%)	4 (1.9%)	3 (2.3%)
Other	4 (1.2%)	2 (0.9%)	2 (1.6%)
<i>Missing</i>	2	2	-
Sexual Orientation			
Heterosexual	49 (14.4%)	44 (20.8%)	5 (3.9%)
Homosexual	238 (70.0%)	128 (60.4%)	110 (85.9%)
Bisexual	49 (14.4%)	36 (17.0%)	13 (10.2%)
<i>Missing</i>	4	4	-
Education			
K – 12	56 (16.5%)	46 (21.7%)	10 (7.8%)
Some College (Vocational/Technical, Associates)	78 (22.9%)	54 (25.5%)	24 (18.8%)
Bachelors Degree	73 (21.5%)	36 (17.0%)	37 (28.9%)
Post-graduate Training (Masters, Doctorate or Professional Training)	37 (10.9%)	18 (8.5%)	19 (14.8%)
<i>Missing</i>	96	58	38
Recruitment			
General Promotion/In-Person Outreach (special events, multiple approaches, print material, word of mouth, etc.)	115 (33.8%)	67 (31.6%)	48 (37.5%)
Electronic Materials (websites, emails, listservs)	89 (26.2%)	50 (23.6%)	39 (30.5%)
Mass Media (newspaper, radio, TV ads)	132 (38.8%)	92 (43.4%)	40 (31.3%)
<i>Missing</i>	4	3	1
Motivation			
Altruism	75 (22.1%)	45 (21.2%)	30 (23.4%)
Compensation	23 (6.8%)	19 (9.0%)	4 (3.1%)
Personal Connection to the Cause	19 (5.6%)	9 (4.2%)	10 (7.8%)

Characteristic	All Participants (N=340)	Not Enrolled Participants (N=212)	Enrolled Volunteers (N=128)
Scientific or Medical Contribution	59 (17.4%)	32 (15.1%)	27 (21.1%)
Other (Reason not specified)	31 (9.1%)	28 (13.2%)	3 (2.3%)
<i>Missing</i>	133	79	54