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Time will tell: community acceptability of HIV vaccine research before and after the "Step Study" vaccine discontinuation

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Abstract

Objective—This study examines whether men-who-have-sex-with-men (MSM) and transgender (TG) persons' attitudes, beliefs, and risk perceptions toward human immunodeficiency virus (HIV) vaccine research have been altered as a result of the negative findings from a phase 2B HIV vaccine study.

Design—We conducted a cross-sectional survey among MSM and TG persons (N = 176) recruited from community settings in Atlanta from 2007 to 2008. The first group was recruited during an active phase 2B HIV vaccine trial in which a candidate vaccine was being evaluated (the "Step Study"), and the second group was recruited after product futility was widely reported in the media.

Methods—Descriptive statistics, *t* tests, and chi-square tests were conducted to ascertain differences between the groups, and ordinal logistic regressions examined the influences of the above-mentioned factors on a critical outcome, future HIV vaccine study participation. The ordinal regression outcomes evaluated the influences on disinclination, neutrality, and inclination to study participation.

Results—Behavioral outcomes such as future recruitment, event attendance, study promotion, and community mobilization did not reveal any differences in participants' intentions between the groups. However, we observed greater interest in HIV vaccine study screening ($t = 1.07$, $P < 0.05$) and enrollment ($t = 1.15$, $P < 0.05$) following negative vaccine findings. Means on perceptions, attitudes, and beliefs did not differ between the groups. Before this development, only beliefs exhibited a strong relationship on the enrollment intention ($\beta = 2.166$, $P = 0.002$). However, the

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effect disappeared following negative trial results, with the positive assessment of the study-site perceptions being the only significant contributing factor on enrollment intentions (β = 1.369, *P* = 0.011).

Conclusion—Findings show greater enrollment intention among this population in the wake of negative efficacy findings from the Step Study. The resolve of this community to find an HIV vaccine is evident. Moreover, any exposure to information disseminated in the public arena did not appear to negatively influence the potential for future participation in HIV vaccine studies among this population. The results suggest that subsequent studies testing candidate vaccines could be conducted in this population.

Keywords

AIDS; men-who-have-sex-with-men; recruitment; community engagement; willingness to participate

Introduction

This study examines whether attitudes, beliefs, and risk perceptions of men-who-have-sex-with-men (MSM) and transgender (TG) persons toward human immunodeficiency virus (HIV) vaccine research have been altered in the past few years against the backdrop of important scientific findings in the field.[1] Specifically, this study investigates whether intentions to volunteer for future HIV vaccine efficacy studies have been influenced by the results from 2 major vaccine trials. In September 2007, an interim Data Safety and Monitoring Board (DSMB) review of a phase 2B study being conducted with a candidate vaccine (the Step Study; HIV Vaccine Trials Network [HVTN] 502/Merck V520-023) concluded that the study had reached the futility end point, and thus, the study vaccinations were discontinued. Shortly thereafter, a concomitant study conducted in South Africa with the same product was also stopped (the "Phambili Study"). With new HIV vaccine trials currently under progress and others anticipated in the near future, this study contributes to the larger dialog with direct measure of a target audience viewpoint on HIV vaccine research before and after the release of the Step-Phambili results. For this reason, we selected MSM and TG male-to-female persons as a priority population because their participation is sought in domestic HIV vaccine trials.

Background

The Step Study commenced in late 2004, was considered the most promising candidate HIV vaccine.[2] In this phase 2B ("proof of concept") study, an Ad5 vector candidate vaccine with gag-pol-nef inserts that had shown promise in animal models was studied. The study enrolled 3,000 persons at risk for HIV infection, including MSM and TG individuals, at sites throughout North and South America, Caribbean, and Australia (HIV clade B regions). Our site in Atlanta, Georgia enrolled 130 participants of the total study sample.[3]

On 18 September 2007, the DSMB responsible for oversight of the Step Study concluded that the study had reached its futility end points and that the Ad5 vector candidate vaccine with gag-pol-nef inserts was ineffective.[4] A primary aim of the study was to determine if the vaccine would prevent primary HIV acquisition or had the potential to suppress HIV load in subjects who become infected during the trial period.[5] Vaccination of the enrolled participants was subsequently halted at all sites. The results were unanticipated as the vaccine appeared to be safe and immunogenic in phase 1 testing.[6]

By February 2007, an associated study entitled "Phambili" was under progress in South Africa with a similar goal of enrolling a large cohort of HIV negative, healthy volunteers for

phase 2B efficacy testing.[7] The study utilized the same gag-pol-nef strategy as the Step Study product. While the Step DSMB met on 18 September 2007, the Phambili study was actively recruiting participants, whereas the Step cohort had already been accrued. The Phambili recruitment efforts quickly ceased in fall 2007 following independent DSMB review of data, suggesting futility of the candidate vaccine.[8]

Dissemination of study findings

The status of the Step and Phambili studies was widely reported in the international press, including highly visible print and online media outlets such as the *New York Times*, *Baltimore Sun*, *Los Angeles Times*, *The Times* (London), and *Washington Post*, among other syndicate pieces.[4,9] Online news was immediately available following the HVTN and Merck and Co., Inc's press release dissemination on 21 September 2007, with pieces appearing on Yahoo! Business, British Broadcasting Corporation News, and Bloomberg Web sites via the Associated Press contribution.[10]

The Atlanta local press on the Step Study outcome was first covered by the *Southern Voice*, a local gay and lesbian media outlet with online and print news reaching over 100,000 Atlanta-area readers.[11] Our study participants offered ongoing interviews with the press on their experiences in the Step Study that were subsequently published.[11–13] Other pieces appeared later in Atlanta's most visible daily newspaper, the *Atlanta Journal Constitution*, including an opinion-editorial on HIV vaccine research by our site investigators.[14]

Community attitudes

Our previous findings indicated the importance of building a favorable study-site image and gaining familiarity in the community to aid in the promotion of HIV vaccine research on an ongoing basis with priority populations (eg, women and minorities).[15,16] Among the MSM and TG subgroups, we identified that those with a positive impression of the clinical research site conducting HIV vaccine trials and having accessibility to HIV vaccine-related informational activities were important factors driving their interest in the cause, among other concerns such as trial and product-related safety and perceived social support and potential harms assessed in our models.[15] Having identified the critical pathways to successful engagement of our target populations including MSM, our programmatic efforts have focused on improving attitudes toward health research and HIV vaccine development. In addition, we found that focusing on the personal relevance of the effort, addressing study participation risk concerns, and fostering positive attitudes toward local clinical research endeavors all have an impact on participation.[16,17] Our models indicate that alignment of these factors is critical in generating support for, and interest in, HIV vaccine research efforts with target populations for phase 1 and 2 studies.[16,17]

This investigation responds to the call for greater understanding of community perceptions as new trials are planned with different candidate vaccine strategies.[4] In effect, our team in the study asked, "Is the community ready for participation in new studies?" We hypothesized that the findings from the Step and Phambili studies might cause short-term negative shifts in attitudes and study volunteerism intentions. Prospective measures obtained over a period of 6 months with MSM enabled our team to ask if we are ready for the next wave of HIV vaccine research in the community.

Methods

Study sample

Our site continuously measures community attitudes and perceptions to gauge progress on HIV vaccine community engagement. For this study, we selected MSM and TG persons

(male-to-female), whose participation has been and will remain vital to HIV vaccine research in the United States.[18–23] Data from August 2007 through January 2008 are included in this analysis.

Our study population was derived from a larger sample accrued via venue-based sampling methods. These methods have proven successful in obtaining representative cross-sectional survey samples.[24] Venues were selected by the study staffs and the Atlanta Prevention Research Community Coalition (APRCC) partners. This coalition effort was undertaken by our site's community advisory board members to increase awareness of HIV prevention research, promote the personal relevance of the effort, and enhance public trust in research endeavors. The study staffs determined the suitability of venues based upon discussions with APRCC leaders, observation of target population at the locations, and other considerations (eg, safety). The sampling frame for this study ultimately included 16 locations that demonstrated the potential to recruit an adequate number of eligible study participants within venue-specific-day-time periods. Venues included social network meetings and community forums, bookstores, "pride" events, health fairs, churches, bingo gatherings, and others.

The overall sampling strategy allowed for recruitment to occur at various times and days of each week and during randomly selected blocks of time. Project assistants were given assignments to perform recruitment and anonymous and confidential data collection based on master schedule of monthly activities. At each venue, team members randomly approached members of attendee populations about the survey. For those who met eligibility criteria and consented to participate in the study, the study staff directed them to a semi-private area or nearby quiet spots (such as picnic tables) in outdoor locations to complete the self-administered paper questionnaire.

The recruitment area was limited to the 22-county metropolitan area constituting greater metropolitan Atlanta, Georgia. Persons were eligible for this study if they were at least 18 years of age and could read and speak English. Approximately, 200 people were invited to participate in the study. Of these, 176 were eligible and provided written informed consent (yielding a response rate of 88%). A T-shirt, logo visor, or health promotion incentive valued up to $10, such as a bag with condoms and safe sex items, was offered for participation in this study. The study was approved by the institutional review board of Emory University.

Survey instrument

The survey was developed by the researchers on the basis of previously validated questionnaires and behavioral research conducted by our team with diverse populations, including MSMs.[25] In addition to sociodemographic characteristics, event or activity assessment, previous HIV vaccine research involvement (eg, past attendance or study volunteerism), and other independent variables (eg, participation in other community organizations), participants were asked a series of outcome questions on participation intentions. These included the likelihood of future attendance, promotion of HIV vaccine research in the community, mobilization of others, and potential for study screening and enrollment. We specifically asked about the interest in screening and enrollment as these are discrete process points within clinical trials for which attrition had been observed among our site's minority MSM recruits to the Step Study.[3] Intentions were gauged on a 0–10 point scale, with 0 representing "definitely not" and 10 indicating "definite" intention to engage in the behavior in the next 6 months. These continuous outcome measures were transformed for subsequent analyses into ordinal variables representing "very likely or definitely", "neutral", and "definitely not or very unlikely" to correspond with the direction of the response options of scaled items. Given the overall mean enrollment intention score of 4.55

(standard deviation [SD] = 3.3) and no indication of kurtosis (−1.12) or skewness (0.75), we performed percentile splits where continuous values of 0–3 represented “definitely not or very unlikely” intentions, 4–6 indicated “neutrality”, and 7–10 represented “very likely or definitely” on the ordinal scale.

The instrument contained additional psychosocial measures from a modified theory of reasoned action, including behavioral beliefs, attitudes, outcome evaluation (eg, perceived risk of study participation and product safety concerns), organizational involvement, normative influences including perceived social stigma, and social activism congruence with the HIV vaccine research cause.[17,28,29] Each item on the scale was rated by the study participants on a Likert scale of 1–5, with 1 representing strong agreement and 5 indicating strong disagreement. Response categories were later collapsed into binary variables due to response skewness, with values of 1–3 representing agreement and 4–5 indicating disagreement with each item.

“Behavioral Beliefs” included 7 items measuring agreement with community benefit of HIV vaccines, individual benefit of health research, study participation to prevent acquired immunodeficiency syndrome, and involvement as a means to increase community trust in the HIV vaccine effort. “Attitudes” included 5 items relating to motivations such as altruism, being involved, medical benefits associated with HIV vaccine study participation, and HIV concern.[30] The “Outcome Evaluation” domain included 5 items, detailing reported logistical barriers to study participation such as lack of time and travel inconvenience, fear of needles, product-related concerns including potential to experience vaccine-induced seropositivity, and general social harm-related risks associated with involvement.[31–33] The “Organizational Involvement” factor included 3 questions relating to favorable social identification with the clinical trial site’s efforts. The latent appeal of HIV vaccine research as a social-justice endeavor addressing health disparities by empowered individuals is captured within the “Social Activism Congruence” realm with 4 questions.

Data analysis

Descriptive statistics were tabulated to analyze responses for demographic characteristics, outcomes, and survey items. Binary variables were created for the groups based on the dissemination date of the initial Step Study press release (group 1: before 21 September 2007 vs group 2: that date through 26 January 2008). Initial chi-square tests were performed to ascertain differences between the groups on sociodemographic characteristics and participatory behaviors. To test our hypotheses, we assessed differences on outcomes and on the 5 domains with *t* tests. We conducted ordinal logistic regressions to examine the influences of the above-mentioned factors on a critical outcome, future HIV vaccine study participation. For main effects, a *P* value of ≤0.05 was considered statistically significant. SPSS version 15.0 was used for all analyses.

Results

Sample characteristics

One hundred and seventy-six MSM including 11 TG persons were recruited in the study, with 83 in group 1 and 93 in group 2 (overall mean age = 39.1 years). A nearly proportionate racial or ethnic balance was observed with 72 individuals self-identifying as White or Caucasian (N = 72, 42.4%) and 73 self-identifying as Black or African American (N = 73, 42.9%). The enrolled population also included 8 persons who self-identified as Hispanic (N = 8, 4.7%), 12 multiracial (7.1%), 4 Asian or Pacific Islander (2.4%), and 1 Native American (0.6%). A large percentage of respondents reported having earned a bachelor’s degree (N = 56, 32.7%), with an additional 37 having attained a high school

education (21.6%), 32 with technical degree (18.7%), 27 having earned a master's degree (15.8%), and 19 with a doctoral degree (11.1%). Similarly, a range of household incomes were reported including many earning ≤$40,000 per year (N = 76, 43.9%), which is comparable to the US Census Bureau's estimated median income level of $34,770 for Atlanta as of 1999.[35] The remainder of the sample had incomes of $40,001–$60,000 (N = 27, 15.6%), $60,001–$80,000 (N = 33, 19.1%), $80,001–$100,000 (N = 10, 5.8%), and ≥ $100,000 (N = 27, 15.6%).

Chi-square tests were performed to identify the existence of any characteristic differences between the groups. The MSM "before" and "after" groups were balanced on age (χ^2_4 = 1.556, P = 0.817), educational attainment (χ^2_4 = 8.122, P = 0.087), income (χ^2_4 = 6.897, P = 0.141), and previous HIV vaccine event involvement (χ^2_2 = 0.105, P = 0.949). Their perception of the research site was also similar, a measure indicating no difference between groups in their regard for the organization (χ^2_2 = 0.065, P = 0.968).

Internal consistencies

The instrument exhibited excellent psychometric properties. Reliabilities for the scales for each population were moderately high to very strong, with Cronbach's α values of 0.740–0.910, close to internal consistency values obtained with similar populations.[16,17,28] The values for each scale were "Attitudes" (α = 0.740), "Behavioral Beliefs" (α = 0.849), "Outcome Evaluation" (α = 0.822), "Organizational Involvement" (α = 0.811), and "Social Activism Congruence" (α =0.910).

Assessment of dependent and independent variable means

Five study outcomes were assessed, including likelihood of future attendance at partner-organized HIV vaccine awareness and education events, intention to organize community members to action on HIV vaccine research, promotion of HIV vaccine research in the community, and intention to screen and/or enroll in future HIV vaccine studies. Bivariate correlation matrices comparing outcome means indicated the potential for multicollinearity (≥0.80) for HIV vaccine study screening and enrollment intention among MSMs (r = 0.85, P < 0.01). In effect, the study population viewed the screening and enrollment participatory outcomes as fairly synonymous.

Two significant relationships were observed on the screening and enrollment intention outcomes. In our sample, we observed greater interest in HIV vaccine study screening (t = 1.07, P < 0.05) and enrollment (t = 1.15, P < 0.05) among members of group 2 (Table 1).

Regression models

Ordinal logistic regression analysis was performed for the study enrollment outcome to ascertain the differential impact of the psychosocial factors on study volunteerism in the prerelease and postrelease of the Step Study data. We selected the study enrollment outcome given the evidence of multicollinearity between screening and enrollment. We tested our models to determine if the ordinal assumptions were met and if these assessments yielded good results (group 1: χ^2_6 = 22.053, P < 0.001 and group 2: χ^2_6 = 24.201, P < 0.001). Additionally, goodness-of-fit tests were performed for the group 1 model (Pearson χ^2_{42} = 48.000, P = 0.243) and the group 2 model (Pearson χ^2_{42} = 56.193, P = 0.070), indicating excellent fits in both instances.

The ordinal regression models highlighted the decisional factors including all scales previously described affecting the enrollment intention before and after the Step-Phambili results were publicly announced. The overall group models were highly significant models for group 1 (Wald χ^2_1 = 5.408, P = 0.02) and group 2 (Wald χ^2_1 = 17.489, P < 0.01). For

group 1, the only factor that exhibited a strong relationship on the enrollment intention was the "Behavioral Beliefs" variable (β = 2.166, *P* = 0.002). However, the effect disappeared with group 2, with the positive assessment of the study site ("Organizational Involvement") being the only significant contributing factor on enrollment intentions (β = 1.369, *P* = 0.011; Table 2).

Discussion

This study illustrates the extent to which the important HIV vaccine findings have an impact on the attitudes, perceptions, and future behaviors of targeted populations that have been engaged in HIV vaccine research. Overall, positive shifts were observed among the groups on key participatory intentions including future enrollment in HIV vaccine studies. Our population findings show slightly greater enrollment intention among these groups in the wake of negative efficacy findings. The willingness of the community to consider participation in HIV vaccine research is evident from the comparison results. Moreover, any exposure to information disseminated in the public arena did not appear to negatively influence the potential for future study enrollment among this population.

A note of caution is advised in interpreting changes among this population as study enrollment had concluded for the Step Study when the survey was conducted. Therefore, it is possible that the low mean value of enrollment intention for group 1 (mean = 3.94, SD = 3.12) on a 10-point continuum scale is reflective of the time period at which our site was not recruiting new MSMs or TG persons to HIV vaccine studies, and therefore, opportunity to participate was limited for the foreseeable future. Similarly, the environment was constant for group 2 as new HIV vaccine studies were planned but not open for recruitment. The slightly greater mean value for study enrollment observed with group 2 of this population (mean = 5.09, SD = 3.43) indicates some neutrality on the scale with respect to the involvement in future HIV vaccine research studies. In effect, it could be argued that persons in group 2 indicated a moderate likelihood of enrolling in future HIV vaccine studies until more information was gleaned from Step results or if more information about future trials was presented. In addition, the population may have been noncommittal in the absence of information about new candidate HIV vaccine product attributes and study-protocol details.[22,25,35] Nonetheless, the evidence suggests that any exposure to HIV vaccine information in this timeframe did not adversely affect people's intentions to participate.

An important finding from this group is the importance of their positive assessment of our clinical trial site on enrollment intention in the group 2 regression model. Therefore, it is vital that association with the site remains favorable and "top-of-mind" as a volunteer organization of choice. It is possible that our simple, relevant, and responsive approaches to communicating risk in HIV vaccine research are favorably regarded by this population. The non-significant change in mean value for the "Organizational Involvement" factor in the post-Step era may also signify stable perceptions in the organization with its model of continuous community engagement featuring regularly updated news on the Step Study and other HIV vaccine efforts. We believe that our outreach model in effect served as our organizational "insurance policy" against public backlash during this very difficult time period in the field of HIV vaccine research.

Limitations

The study findings are limited by several factors, including the inherent limitations of a cross-sectional study design. The design does not allow for causal conclusions to be drawn. In this study, intentions were evaluated. A body of research has demonstrated that intentions

are moderately good predictors of future behavior.[36–38] However, it would be highly beneficial to the field to examine the role of intentions to actual enrollment outcomes of the target groups. This would offer additional insight on the factors that are truly motivating on achievement of each of the outcomes of interest. Additionally, the venues where the participants were recruited may have resulted in bias, reducing our ability to generalize the results. Clearly, the people attending APRCC functions may have already had a vested interest or, at least, curiosity, in the HIV vaccine cause. The use of a small sample consisting of MSMs and TGs within specific venues may not be representative of other venue-based functions or all MSM or TG populations.

Although we did not track media consumption patterns among the population in this study, and therefore, cannot be certain of media exposure patterns, our previous formative work in advance of the Step Study indicated that the target audiences gathered news and information from the sources that reported on the trial outcomes. Because we did not anticipate the sudden discontinuation of vaccinations in the Step Study, we did not ask participants about their trial awareness. Thus, we were unable to determine what the groups actually knew about the study in this post hoc analysis.

It should also be noted that participation bias in a study of HIV vaccines and health behaviors is particularly likely (ie, it is conceivable that people having strong negative beliefs and attitudes on HIV vaccine research may be the least inclined to complete the study questionnaire). Thus, even though the study achieved a response rate of 88%, participation bias may have affected our findings. Nonparticipation of low-literacy or non-English speaking MSM immigrant populations may have also biased the results. As with any self-administered questionnaire, self-reported data may not be entirely accurate, and therefore, should be viewed with caution. However, it is not anticipated that any of these limitations resulted in large or systematic errors in data collection.

Conclusion

The results from this study suggest that attitudes, beliefs, perceptions, and intentions of MSM and TG persons to enroll in future HIV vaccine research did not experience substantial shifts in the wake of the Step-Phambili result dissemination. The findings show slightly greater enrollment intention among MSM in the wake of negative efficacy findings from the Step Study. Thus, we can conclude that our community-engagement model maintained a positive public perception despite a disappointing vaccine outcome. In effect, our model has effectively positioned us for the next wave of HIV vaccine recruitment.

Our findings, therefore, have important programmatic implications for sustainment of community engagement in HIV vaccine research via a coalition of partnership organizations. By working alongside organizations that are trusted by community members, they bring enormous credibility to the endeavor.[19] Thus, agencies with stable histories in the community and for whom HIV vaccine research is a concern serve as ideal allies in this endeavor.

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Table 1

Observed differences among MSM and TGs (N = 176)

	Before	After	Before[a]	After[a]	Mean difference
	N	N	Mean (SD)	Mean (SD)	
Outcomes					
Future attendance at HIV vaccine activities	77	85	8.57 (2.00)	8.00 (2.52)	−0.57
Community mobilization	78	83	5.60 (2.94)	5.55 (3.05)	−0.05
Study screen	77	80	4.29 (3.32)	5.36 (3.40)	1.07*
Study enrollment	71	79	3.94 (3.12)	5.09 (3.43)	1.15*
HIV vaccine research promotion in community	76	85	6.46 (3.19)	6.34 (3.02)	−0.12
Community engagement factors					
Attitudes	79	88	8.47 (2.52)	8.43 (3.31)	−0.04
Behavioral beliefs	77	86	12.97 (4.10)	12.43 (4.82)	−0.54
Outcome evaluation (risk perception)	80	91	17.49 (4.29)	16.49 (4.79)	1.00
Organizational involvement (study-site assessment)	79	88	10.33 (2.66)	9.65 (2.61)	−0.68
Social activism congruence	80	85	16.06 (4.01)	16.18 (4.83)	0.12

*$P < 0.05$.

[a]"Before" data collected prior to 21 September 2007. "After" data collected subsequent to 22 September 2007.

Abbreviations: MSM, men-who-have-sex-with-men; TGs, transgenders; SD, standard deviation; HIV, human immunodeficiency virus.

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Table 2

Ordinal logistic regression model for HIV vaccine trial enrollment potential with independent variables[a]

	Group 1 (N = 83)	Group 2 (N = 93)
Model significance	$\chi^2_6 = 22.053$; $P \leq 0.001$	$\chi^2_6 = 24.201$; $P \leq 0.001$
Nagelkerke R^2	0.322	0.314
Enrollment intention	Wald $\chi^2_1 = 5.408$; $P = 0.02$	Wald $\chi^2_1 = 17.489$; $P < 0.01$
Attitudes (strongly disagree/disagree)	−1.264 (0.150)	−0.071 (0.921)
Behavioral beliefs (strongly disagree/disagree)	2.166 (0.002)***	1.093 (0.076)
Outcome evaluation (strongly disagree/disagree)	−1.183 (0.108)	0.115 (0.861)
Organizational involvement (strongly disagree/disagree)	0.449 (0.408)	1.369 (0.011)
Social activism congruence (strongly disagree/disagree)	0.671 (0.358)	0.975 (0.130)

** $P \leq 0.05$;

*** $P \leq 0.01$.

[a] By convention, referent group comparisons are presented with level indicated in parentheses for each variable.

Abbreviation: HIV, human immunodeficiency virus.