Journal of
AIDS & Clinical Research
ISSN: 2155-6113

Ma et al., J AIDS Clin Res 2014, 5:11
DOI: 10.4172/2155-6113.1000361

Research Article Open Access

Predictors of Willingness of Participate in HIV Vaccine Trials among African Americans

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Abstract

African Americans in the United States (U.S.) are disproportionately affected by HIV. Developing an HIV vaccine is an important part of the HIV prevention and treatment toolkit and may help contribute to ending the HIV epidemic. To date, HIV vaccine trials have not engaged representative numbers of African Americans. We evaluated the willingness of African Americans to participate in HIV vaccine trials and identified correlates of willingness to participate (WTP) by surveying African Americans at low- and high-risk of HIV infection in a multi-site, cross-sectional study. We enrolled 1,452 participants; 59% heterosexual women; 21% heterosexual men; 20% men who have sex with men (MSM). Over half of participants (58%) expressed some level of WTP in HIV vaccine trials. Multivariable analyses revealed several variables were positively related to WTP: HIV risk behavior, knowing someone with HIV/AIDS, social support for trial participation, high perception of risk, perceived protection if in a trial, altruism, and greater tolerance for the ambiguous nature of trials ($p<0.01$). Emphasis on contextual factors related to personal HIV experiences, including knowledge of someone with HIV, and community support for research, may provide effective strategies for engaging African Americans in future HIV vaccine trials.

Keywords: HIV; Vaccine; Clinical trials; African Americans; Willingness; Participation

Introduction

Substantial racial/ethnic disparities in human immunodeficiency virus (HIV) infection exist in the United States (U.S.), and African Americans are disproportionately affected by HIV infection. As such, African Americans are important partners for HIV prevention research if we are to effectively reduce the burden of HIV in highly affected communities [1]. The National Institutes of Health (NIH) Revitalization Act established guidelines for the inclusion of racial/ethnic minorities in all NIH-supported human subjects research unless a compelling rationale is provided for their exclusion [2]. Yet, achieving adequate representation of minority and marginalized groups in clinical trials has sometimes been challenging and has resulted in ambiguous efficacy results [3]. For example, the first phase-III efficacy trial of an HIV vaccine, AIDSVAX B/B[1], indicated the vaccine was not efficacious for preventing HIV infection [4,5]. However, the protective efficacy of AIDSVAX B/B was initially reported to be 66.8% among black, Asian, and mixed-race participants; and 78.3% among African Americans alone [4,5]. Because the majority of AIDSVAX trial participants were white (86%) and male (94%), the trial lacked adequate statistical power to address pertinent questions regarding vaccine efficacy, immunologic responses, and behavioral risk among racial/ethnic subgroups and women [4,5]. The recent RV-144 HIV vaccine regimen conducted in Thailand had a modest efficacy of 31% [6], but the sample was not designed to address any racial/ethnic differences. However, the RV-144 trial has generated new enthusiasm for HIV vaccine researchers working with broadly neutralizing antibodies capable of neutralizing different HIV strains [7,8].

Numerous barriers have been suggested that may preclude the participation of African Americans in clinical trials and human immunodeficiency virus (HIV) prevention research. These barriers have been categorized into four broad categories: 1) characteristics of potential participants, 2) health care system issues, 3) knowledge, perceptions, and attitudes toward HIV and research, and 4) personal and temporal factors related to clinical trial participation [9-16]. Barriers within these categories include low perceived risk and education, limited access to and utilization of health care, racial disparities in service delivery and location (e.g., hospital versus community clinic), language and cultural barriers, distrust of the medical establishment, lack of knowledge about clinical trials, and lack of incentive for research participation [9,17-20].

Although knowledge regarding clinical trials has not been shown to be positively related to willingness to participate (WTP) [14,21,22], educating individuals about the nature, purpose, and procedures of medical research is ethically essential and likely related to the successful recruitment of HIV clinical trial participants [23,24]. A lack of knowledge about HIV clinical trials has been documented in multiple communities [25,26], indicating the need to provide information, dispel misinformation, and to build trust among those communities targeted for trials. Increased understanding of the impact of trial-

[1]AIDSVAX is an experimental preventive HIV vaccine that is made up of a synthetic copy of the surface protein of HIV called gp120. Because AIDSVAX is made up of synthetic or genetically engineered materials that lack all the elements required for infection, it cannot cause HIV infection. The vaccine that was tested in North America and Europe – AIDSVAX B/B – was designed to protect against subtype B, which is the HIV strain prevalent in those areas as well as Central America, South America, Australia and New Zealand.

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Received August 04, 2014; **Accepted** September 27, 2014; **Published** October 10, 2014

Citation: Ma M, Toni Young A, Durham M, Kibler JL, Gaul Z, et al. (2014) Predictors of Willingness of Participate in HIV Vaccine Trials among African Americans. J AIDS Clin Res 5: 361. doi:10.4172/2155-6113.1000361

related information on WTP among African Americans will inform health education approaches tailored for HIV prevention trials.

Distrust of the medical establishment by African Americans has been ascribed in part to racist attitudes, theories, and practices of physicians in the early 1800s [27], and to the United States Public Health Service funded *Tuskegee Study of Untreated Syphilis in the Negro Male* [28], which has come to symbolize ethical misconduct in clinical research [28,29]. The Tuskegee Study, widely criticized for providing inadequate informed consent and medical treatment, is perhaps the most frequently cited factor for distrust of the medical establishment among African Americans, especially those in the southeastern United States [27,29-32]. In the context of HIV, genocidal conspiracy beliefs have been observed among moderate segments of the African American communities [33,34], and has been cited as a major barrier to HIV prevention among these communities [30]. While there is substantial literature suggesting that historical factors such as slavery and the Tuskegee Study may inhibit the participation of African Americans in clinical trials, other personal and temporally relevant factors may also be related to clinical trial participation. For example, altruism, perceived and actual risk of HIV infection, knowing someone who is HIV-infected or who has AIDS, the desire to protect oneself from HIV infection, perceived normative support for trial participation, and tolerance for the ambiguous nature of clinical trial participation (e.g., blinding, unknown efficacy, potential for vaccine-induced seropositivity) have been shown to be related to WTP in clinical trials [12,25,35-38]. Evaluating the relative contribution of negative historic events and distrust to WTP in trials, as well as the temporally relevant factors in the context of HIV, may provide a more comprehensive understanding of WTP among African Americans that can inform strategies for achieving diversity in future trials, improve the generalizability of results, and benefit the public health of African American communities. Although advances have been made in the evaluation of barriers to WTP in clinical trials, most studies have focused on a limited set of predictors. The objective of the present study was to evaluate the willingness of African Americans to participate in phase II HIV vaccine trials and to identify correlates of willingness to participate (WTP) among African Americans using an expanded group of predictors.

Methods

Participants

African American men and women living in three cities: 1-Jackson, Mississippi, 2-Washington, District of Columbia (DC), and 3-Oakland, California, were enrolled from November 2005 through July 2006 and queried about issues related to willingness to participate in HIV vaccine trials. Background demographic and social data for the 3 recruitment cities are shown in Table 1. Of note, each location had between 28%-79% African American populations and HIV prevalence rates of between 268 - 559 persons living with diagnosed HIV infection per 100,000 population (Table 1). Participants were recruited through convenience sampling at community events, beauty salons, and barber shops, block parties, bars, public parks, service organization venues, and community-based clinics across all 3 sites. Because the goal of the study was to evaluate the willingness of eligible African American participants to enroll in HIV vaccine trials, vaccine trial eligibility criteria were used to screen individuals for the study. Individuals were eligible if they self-identified as black or African American, or multiracial with black or African American heritage, and 18-70 years of age. Persons were also eligible if they were residents of one of the three study catchment areas, had not previously participated in a HIV vaccine trial, were HIV-seronegative and willing to be tested for HIV antibodies, and had not been diagnosed with cancer, active liver disease or illnesses requiring immunotherapy such as interferon or steroids.

Characteristic	Jackson, MS	Washington, DC	Oakland, CA
Total population	173,514	601,723	390,724
African Americans	79.4%	50.7%	28.0%
Median household income	$30,219	$66,583	$48,196
Employment	60.7%	69.0%	66.8%
Below poverty level	26.8%	13.9%	19.5%
Health insurance coverage	78.4%	94.1%	83.1%
HIV prevalence rate[3]	558.8	549.0	267.9
HIV vaccine trial experience[4]	No	Yes	No

[1]Centers for Disease Control and Prevention. HIV Surveillance Report, 2011; vol. 23. http://www.cdc.gov/hiv/topics/surveillance/resources/reports/. Published February 2013.Accessed August 27, 2014.
[2]United States Census 2010. 2010 Census Interactive Population Search. http://www.census.gov/2010census/popmap/ipmtext.php?fl=28. Accessed August 27, 2014.
[3]Persons living with diagnosed HIV infection, year-end 2010. Rates are per 100,000 population.
[4]ClinicalTrials.gov. http://clinicaltrials.gov/ct2/help/how-use-search-results. Accessed August 27, 2014.
Table 1: Demographic and social characteristics[1, 2] of the 3 U.S. cities from which persons were enrolled for African Americans' willingness to participate in HIV vaccine trials study.

Study instruments were administered on-site using AudioComputer-Assisted Self-Interview (ACASI) software (NOVA Research: Questionnaire Development System version 2.1; NOVA, 1998). After individuals were determined to be eligible for the study, informed consent was obtained, and participants were oriented to the computerized interview. Participants completed a practice ACASI and addressed questions with study staff prior to initiating the survey. Staff members were available to answer questions during the interview. The ACASI included a section on WTP and predictors that are described in detail below. Institutional Review Boards at the Centers for Disease Control and Prevention, Jackson State University (Mississippi), the Whitman Walker Clinic (Washington, DC), and Independent Review Consulting, Inc (Oakland, CA) reviewed and approved this study protocol.

Instruments

Willingness to participate in HIV vaccine trials: To assess the influence of trial-related information on WTP in HIV vaccine trials, a computer-administered informed consent-like process presented information using a stepwise approach. Low risk and high risk among participants is defined below. Low-risk participants were presented information about phase-I HIV vaccine trials(i.e., phase-I trials are the first time a vaccine is given to people, are conducted to determine safety, usually involve about 100 people, require 12-18 months of follow-up). Following the presentation, participants were asked about their WTP in phase-I trials. Similarly, low- and high-risk individuals were presented information about phase-II trials (i.e., if a vaccine appears to be safe in phase-I trials, phase-II trials are conducted to learn more about safety and protective responses in the body. Hundreds of people are needed for phase II trials which can last 2-3 years) [39]. After this, WTP was again assessed. Finally, high-risk individuals were presented information about phase-III trials (i.e., if phase-II trials indicate that a vaccine is safe and causes the body to react in a way that might protect against infection, then phase-III trials are conducted. Phase-III trials test to see if a vaccine protects people from HIV. Thousands of people at high risk for HIV are needed for phase-III trials, which can last from 3-5 years); [39] subsequently, WTP was again assessed. Because phase-II trials include both low and high risk participants, willingness

to participate in phase-II trials was the outcome variable in the WTP analyses for the current study.

HIV risk behavior: Participants were asked with how many HIV-infected, HIV-uninfected, and HIV-unknown serostatus men and women they had sex with in the three months prior to study enrollment, along with questions on frequency of sex and condom use. Participants were also asked if they had sex with anyone known to have had a sexually transmitted infection (STI) or injected drugs; had a sexually transmitted infection themselves; or exchanged sex for money, drugs, or shelter. Women were also asked if they recently had sex with a man who had been in prison. Participants also responded to questions on injected drug use and crack cocaine smoking. Participants were classified to be at low risk of HIV infection if they were in a mutually monogamous relationship with an HIV-uninfected partner during the past year or did not report any of the following: smoked crack, exchanged sex for money or drugs; had sex with more than two partners and reported infrequent condom use; had sex with another man (men only); had sex with a HIV-infected partner, injecting drug user, a partner with a recent sexually transmitted infection or who had recently been in prison (women only). Any participant reporting any of the preceding behaviors or circumstances were classified as high risk.

Sexual identity: Participants responded to a series of questions on sexual identity as well as gender of sex partners. Men were categorized as "men who have sex with men" (MSM) if they self-identified as homosexual, MSM, or reported having sex with another man in the past 3 months.

Access to medical care: Participants indicated the extent to which they had access to medical care by selecting one of the following: (a) I have all the medical care that I need, (b) I have good medical care but not all that I need, (c) My access to medical care is very limited, (d) I rarely get good medical care, and (e) I have no access to medical care.

Knowledge of clinical trials, HIV vaccine trials, and the tuskegee syphilis study: To assess knowledge of clinical trials generally and HIV vaccine trials, 17 questions were administered (True/False/Don't know) addressing the purpose of trials, informed consent, representation of African Americans in trials, HIV antibody testing requirements, risk of infection from study vaccine, and the need to practice safe sex if in a trial. Participants were also asked if they had ever heard of the Tuskegee Syphilis Study (Yes/No) and if so, seven additional questions were administered regarding specific knowledge about the study (True/False/Don't know).

Multidimensional vaccine attitude inventory (MVAI): A subset of the MVAI (14 items) was used to measure four constructs previously shown to be related to WTP in HIV vaccine trials [36]. The constructs assessed include *genocidal conspiracy beliefs* (3 items, α=0.78), *perceived decreased risk of HIV infection* (4 items, α=0.78), *altruism* (3 items, α=0.72), and *Tolerance for the ambiguous nature of trials* (4 items, α=0.78). For all items, participants responded using a 5-point Likert-type scale.

Barriers to research participation questionnaire (BRPQ): A 17-item instrument developed by Kibler and Brisco [40] was used to measure five constructs that may be associated with WTP in HIV prevention trials [9]. The constructs assessed by the BRPQ include *mistrust* toward researchers' motives and government sponsorships of research, *incentives* for participation, *role overload* (perception of serving in multiple social or occupational roles), *religious beliefs* that may be inconsistent with participation in scientific research, and *health beliefs* that could affect sentiments toward research. Psychometric examination of the BRPQ has indicated support for the five factors through confirmatory factor analysis, as well as good three-week test–retestreliability (r=0.80) and marginal internal consistency (α=0.63) [40]. The BRPQ uses a five-point Likert type scale for responses.

Knowing someone with HIV/AIDS and social support for trial participation: Participants were asked if they knew anyone who was infected with HIV or who had AIDS (2 questions). Social support for trial participation was assessed by combining three 5-point Likert-type items addressing whether friends, family, and sexual partners would support their decision to participate in HIV vaccine trials (α=0.91).

Perceived risk of HIV infection: Perceived risk was assessed using three Likert-scale response questions:1-"How likely do you think it would be for you to become infected with HIV in the next 5 years?"; 2-"Do you believe that you are at low, medium, or high risk for becoming HIV infected?"; and 3-"My current sexual partner(s) place me at-risk of becoming infected with HIV." Responses to the questions were summed to derive an index score of perceived HIV risk.

Data analyses

Chi-square tests of independence for categorical variables and one-way analysis of variance for continuous variables were utilized to compare participants in three US cities on demographic variables. Because the dependent variable, WTP in HIV vaccine trials, is an ordered response variable, ordinal regression analyses were employed to assess the correlates of each independent variable to WTP in HIV vaccine trials. Initially, the bivariate relationships of the covariates to WTP in HIV vaccine trials were assessed by conducting separate ordinal regression analyses for each independent variable: HIV risk, sexual identity, study site, access to health care, knowledge about clinical trials, knowledge of HIV vaccine trials, awareness of the Tuskegee syphilis study, HIV/AIDS genocidal conspiracy, mistrust, knowing someone with HIV/AIDS, social network support for trial participation, perceptions of HIV risk, perceived protection in trial participation, altruism, incentive for trial participation, role overload, tolerance for ambiguity, religious beliefs precluding research participation, and health beliefs precluding research participation. Independent variables that were significantly related to WTP in the bivariate analyses ($p<0.05$) were retained for the multivariable analyses. Positive beta coefficients indicated a positive association with WTP, and negative beta coefficients indicated a negative association with WTP.

Results

Of 1,859 individuals screened for the study, 1,665 (89.6%) were eligible to participate. Reasons for ineligibility included HIV infection (3.7%); a health condition other than HIV that would result in ineligibility for an actual HIV vaccine trial (2.6%); living outside of a study site catchment area (2.8%); participation in a previous HIV vaccine trial (0.7%); not being of black or African American descent (0.6%); unwilling to test for HIV antibodies and thus not eligible to participate in an actual trial (0.3%); and not meeting the age requirements for participation (0.3%). Valid and complete ACASI records were obtained from 1,452 (87.2%) of the 1,665 eligible individuals.

Descriptive results

Participant characteristics are summarized in Table 2. There were significant differences in age across the three study sites with participants in Oakland being the oldest and Jackson being the youngest ($p<0.01$). Of note, most participants reported ≤ high school education, with those from Oakland being the least likely to have completed high

school (p<0.01). Approximately half of participants reported an income of <$10,000 per year, with those from Oakland reporting lower income than participants from the other sites (p<0.01). While the majority of the participants were single, more participants from Jackson reported being married (p<0.01). Overall, self-reported HIV risk behavior was similar across sites. However, participants from Oakland were more likely to report smoking crack cocaine (p<0.01), DC participants reported a higher rate of having sex with partners who injected drugs (p<0.05), and those from Jackson were more likely to report having had an STI (p<0.05).

Predictor variables

Knowledge about clinical trials was fairly good; 76.6% of the questions about clinical trials were answered correctly (Table 3).

	Study Site			
Variable	**Jackson, MS (n = 570)**	**Washington, DC (n = 543)**	**Oakland, CA (n = 339)**	***p*†**
Mean Age (SD)	30.2 ±10.1	36.7 ± 12.3	40.7 ± 11.6	<0.01
Education				
<High school	16.1%	15.7%	27.8%	
High school	63.8%	74.6%	61.5%	
College graduate	16.3%	7.6%	9.5%	<0.01
Graduate School	3.7%	2.2%	1.2%	
Marital Status				
Single	76.5%	72.4%	72.3%	
Married	14.4%	9.2%	9.7%	
Divorced, Separated, or Widowed	9.2%	18.4%	18.0%	<0.01
Income				
<$10,000	45.3%	43.1%	64.6%	
$10,000 - $19,999	19.6%	13.6%	18.6%	
$20,000 - $34,999	18.8%	20.1%	5.6%	
$35,000 -$49,999	10.0%	13.6%	7.1%	<0.01
≥ $50,000	6.4%	9.5%	4.2%	
Injected drugs	3.2%	5.7%	5.3%	NS
Smoked crack cocaine	8.4%	10.3%	25.7%	<0.01
Sex partner had STI	5.9%	6.0%	3.7%	NS
Sex with IDU	3.9%	7.8%	5.3%	<0.05
Had STI	6.5%	3.8%	3.0%	<0.05
Exchanged sex for drugs or money	8.4%	12.3%	9.8%	NS
Sex partner recently in jail (women only)	20.3%	18.6%	24.7%	NS

Note. STI - sexually transmitted infection; IDU - injecting drug user; NS - non-significant; SD-standard deviation; †χ^2 test of independence

Table 2: Demographic and HIV risk characteristics of African Americans enrolled from three U.S. cites. (n=1,452).

Variables	Statistics	Scale
Participant characteristic		
HIV Risk		
Low	53.0%	Percent of Participants
High	47.0%	
Sexual Identity		
Heterosexual men	21%	Percent of Participants
Men who have sex with men	20%	
Heterosexual women	59%	
Healthcare system issue		
Adequate healthcare access	2.3 ± 1.2[a]	1=Complete Access, 5=No Access
Knowledge, perception, and attitude toward HIV and Research		
Knowledge about clinical trials	76.6%	Percent Correct Responses
Knowledge about HIV vaccine trials	66.4%	Percent Correct Responses
Awareness of the Tuskegee Syphilis Study	41.4%	Percent of Participants
HIV/AIDS genocidal conspiracy	2.8 ± 1.1[a]	1=Strongly Disagree, 5=Strongly Agree
Mistrust	3.1 ± 0.8[a]	1=Strongly Disagree, 5=Strongly Agree
Personal and temporal factors related to clinical trial participation		
Know someone infected with HIV/AIDS	55.9%	Percent of Participants
Social network support for trial participation	3.2 ± 0.5 [a]	1=Strongly Disagree, 5=Strongly Agree
Perceptions of HIV Risk	1.6 ± 0.6[a]	1=Low Risk, 4=High Risk
perceived protection in trial participation	2.7 ± 0.8[a]	1=Strongly Disagree, 5=Strongly Agree
Altruism	3.4 ± 0.8[a]	1=Strongly Disagree, 5=Strongly Agree
Incentive for participation	3.1 ± 0.4[a]	1=Strongly Disagree, 5=Strongly Agree
Role overload (serving in multiple social or occupational roles)	2.4 ± 1.0[a]	1=Strongly Disagree, 5=Strongly Agree
Tolerance for ambiguity	3.1 ± 0.8[a]	1=Strongly Disagree, 5=Strongly Agree
Religious beliefs precluding research participation	3.3 ± 0.9[a]	1=Strongly Disagree, 5=Strongly Agree
Health beliefs precluding research participation	2.0 ± 0.7[a]	1=Strongly Disagree, 5=Strongly Agree

Note. *a*=Mean±SD

Table 3: Summary scores of predictor variables for African Americans' willingness to participate in HIV vaccine trials enrolled from three U.S. cites. (n=1,452).

Variables	β	Standard error	p value
HIV Risk	.42	.11	<0.01
Adequate healthcare access	.12	.05	<0.01
Knowledge about HIV vaccine trials	.01	.01	.581
HIV/AIDS genocidal conspiracy	-.24	.06	<0.01
Mistrust	-.07	.01	<0.01
Know someone infected with HIV	.20	.11	.059
Social network support for trial participation	.58	.12	<0.01
Perception of HIV Risk	.20	.09	<0.05
Perceived protection in trial participation	.36	.07	<0.01
Altruism	1.14	.09	<0.01
Role overload(serving in multiple social or occupational roles)	-.09	.05	.096
Tolerance for ambiguity	-.43	.07	<0.01

Note. Model X^2 = 494.89 (p <.001)

Table 4: Ordinal regression analysis with significant predictors of willingness to participate in vaccine trials for African Americans enrolled from three U.S. cites. (n=1,452).

Participants were less familiar with HIV vaccine trials with 66.4% of these questions being answered correctly. The vaccine trial concepts most misunderstood, indicated by incorrect or "don't know" responses included: (1) the purpose of HIV vaccine studies is to find a cure (86%), (2) minorities are over-represented in HIV vaccine trials (55%), (3) a preventive vaccine may stop an individual from becoming infected with HIV (48%), (4) trial participants are encouraged to engage in high-risk behavior (40%), and (5) a vaccine has already been developed that prevents HIV infection (36%). More than one-half (58.6%) of study participants had not heard of the Tuskegee Syphilis Study. Results concerning participant attitudes toward scientific research and mistreatment of African Americans, participant characteristics, healthcare system issue, and personal and temporal factors related to clinical trial participation are also depicted in Table 3.

Willingness to participate in Phase II vaccine trials

The data revealed 7.6% of the participants indicated they were definitely, 19% probably, 31.4% might be, and 42% not at all WTP in vaccine trials. Although there were demographic and HIV risk characteristic differences among participants across the three study sites, participants did not differ in WTP across study sites.

Bivariate and multivariable analyses

Bivariate analyses revealed that greater WTP was associated with higher HIV risk, less healthcare access, greater knowledge of HIV vaccine trials, less belief in the HIV genocidal conspiracy, less mistrust of the government and research, knowing someone infected with HIV, stronger social network support for trial participation, greater perception of risk, greater perceived protection in trial participation, greater altruism, less role overload, and tolerance for ambiguity (ps<0.01). These significant correlates were entered in the multivariable ordinal regression analysis (Table 4). Nine variables emerged as independent predictors of greater WTP in Phase II vaccine trials: higher HIV risk (p<0.01), inadequate healthcare access (p<0.01), less belief in HIV/AIDS genocidal conspiracy (p<0.01), less mistrust of government and research (p<0.01), greater social network support for trial participation (p< 0.01), greater perceptions of HIV risk (p< 0.05), greater perceived protection in trial participation (p<0.01), greater altruism (p<0.01), and greater tolerance for ambiguity (p<0.01) (Table 4). Marginal significance was observed for knowing someone with HIV/AIDS (p=0.06).

Discussion

This study assessed the willingness of African American men and women at low and high risk of HIV infection to participate in HIV vaccine trials. This study adds to previous literature by evaluating a comprehensive set of correlates, including: 1) participant characteristics, 2) health care system issues, 3) knowledge, perceptions, and attitudes toward HIV and research, and 4) personal and temporal factors related to clinical trial participation. The results suggest all four domains contribute to WTP in vaccine trials among African Americans.

As others have indicated, high-risk participants reported greater WTP in vaccine trials [9,41]. Participants with less healthcare access also reported more WTP. These results are likely due to the perceived health benefit of trial participation. Consistent with the literature [9], historic distrust variables were generally related to WTP, with mistrust and the belief in HIV genocidal conspiracy providing independent negative associations with WTP. Among the four domains assessed, variables likely to be temporally and personally relevant to individuals in the context of HIV emerged as the stronger predictors of WTP. Altruism was the most prominent factor related to WTP, suggesting that helping one's community improve the health of its residents was the strongest motivator for trial participation. Social support for trial participation, perceived behavioral risk of HIV infection, perceptions of decreased risk if enrolled in a trial, and intolerance for the ambiguous nature of trials also showed strong association with WTP in Phase- II vaccine trials.

These findings indicate that, while there has previously been suspicion by some that African Americans might be used inappropriately in HIV-related research [42], such negative feelings were not as prominent among these study participants. Trial sponsors interested in achieving racial and ethnic diversity in future HIV vaccine research should incorporate strategies that appeal to altruistic motivations to help one's community, educate individuals as to their risk of HIV infection, mobilize the community to provide a supportive environment for vaccine trial participation, develop educational and consent processes that minimize the ambiguity associated with trial participation (blinding, unknown efficacy, potential for social harm, potential social reactions, HIV testing), and partner with HIV-infected individuals who may want to appeal to their friends and community to participate in HIV vaccine trials [13]. Popular opinion leaders, including public figures who are HIV infected and willing to disclose their status while they appeal to other African Americans to participate in HIV research and HIV vaccine trials might also help to increase ethnic diversity in future trials [13].

Our study had some notable limitations. While the sample size in this study far exceeded that of previous studies evaluating the willingness of African Americans to participate in HIV-related clinical trials, our non-probability sample precludes the generalization of these findings to other diverse African American communities. However, the lack of differences in WTP across study sites demonstrates the possibility that willingness may not vary by geographic location. Additionally, the evaluation of WTP in a hypothetical HIV vaccine trial may not accurately reflect actual enrollment in trials as pointed out by Buchbinder et al. [25]. However, WTP in hypothetical trials has been shown to be a strong predictor of enrollment in actual trials [21]. Also, our data were collected some years ago. However, more recent HIV vaccine WTP studies have similarly concluded that African Americans are willing to be engaged in this research, given appropriate cultural context [13,41] and even community liaison programs [43].

Despite the limitations, a major advantage of this study was that

it evaluated participant characteristics, healthcare access, historic distrust variables, as well as those that may be more personally and temporally relevant to the individual in the context of HIV. Although not a significant predictor in our study, the Tuskegee Study legacy and distrust of researchers/medical establishment are important factors that cannot be ignored when planning and conducting HIV prevention research and programs in African American communities [33]. In addition to building trust, emphasis on temporally-relevant contextual factors related to personal HIV experiences, including knowledge of someone with HIV, and community support for vaccine trials, may provide an effective strategy for engaging African Americans in HIV vaccine trials and working toward reduced HIV-related disparities.

Acknowledgements

The authors thank the study participants for their willingness to participate in this study and the time they spent providing information to inform public health efforts for HIV prevention. Also, the authors are extremely grateful to Bradford Bartholow, K. Shakira Washington, Carla Dillard-Smith, Gloria Lockett, David Fluker, Lisa Fitzpatrick, Alan Greenberg, and Eleanor McLellan-Lemalfor their generous contributions of time, talent, and commitment to the Minority HIV/AIDS Research Initiative.

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