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An Extended Model of Reasoned Action to Understand the Influence of Individual- and Network-Level Factors on African Americans' Participation in HIV Vaccine Research

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Abstract

In the United States, the number and proportion of HIV/AIDS cases among black/African Americans continue to highlight the need for new biomedical prevention interventions, including an HIV vaccine, microbicide, or new antiretroviral (ARV) prevention strategies such as pre-exposure prophylaxis (PrEP) to complement existing condom usage, harm reduction methods, and

behavioral change strategies to stem the HIV epidemic. Although black/African Americans are disproportionately impacted by HIV/AIDS, their participation in HIV clinical research continues to have unique challenges. We theorize that interaction among multilevel factors creates ideal alignment for minority participation in HIV clinical studies. Thus, we initially set out to test an extended model of reasoned action with 362 participants to understand the interplay of sociopsychological and network-level considerations influencing minority participation in HIV prevention research efforts. In this study, we linked the intrapersonal dimensions of attitudes, beliefs, and normative concerns to community-level components, appraisal of involvement with the clinical research organization, an entity which operates within a networked structure of community partner agencies, and identification with coalition advocacy aims. Various participatory outcomes were explored including involvement in future HIV vaccine community functions, participation in community promotion of HIV vaccine research, and community mobilization. Three-stage least squares estimates indicated similar findings across three models. Significant effects demonstrate the importance of positive attitudes toward HIV vaccine research, favorable health research beliefs, perceived social support for participation, HIV/AIDS issue engagement, and perceived relevance of the clinical research site's mission and values. Identification of these nuanced pathway effects provides implications for tailored community program development.

Keywords

HIV/AIDS; HIV vaccine; African Americans; Community engagement; Willingness to participate

Introduction

In the United States, the number and proportion of HIV/AIDS cases among black/African Americans continue to highlight the need for new biomedical prevention interventions, including an HIV vaccine, microbicide, or new ARV-based prevention strategies such as pre-exposure prophylaxis (PrEP) to complement existing condom usage, harm reduction methods, and behavioral change strategies (Berkley and Koff 2007; Liu et al. 2006; McCormack et al. 2001; Potts 1994; Youle and Wainberg 2003). In 2006, black/African American women constituted 61% of the estimated 54,230 domestic female incident HIV cases, and subgroup estimates among young (ages 13–29) black men-who-have-sex-with-men (MSM) demonstrate a rate 7.1 times greater than for white men in the same age group (Prejean et al. 2008). Southerners living with HIV comprise a large proportion (52%) of the geographic prevalence distribution (Centers for Disease Control and Prevention 2008; Southern States AIDS Directors Work Group 2008).

New biomedical options will expand the set of behavioral, policy and structural approaches, and existing effective medical interventions including administration of antiretroviral therapy to reduce maternal-to-child transmission (Cargill and Stone 2005; Centers for Disease Control and Prevention 2007a, b; Peterson et al. 1992; Sanders et al. 2006). However, any breakthroughs have been elusive. Disappointing results from HIV vaccines, microbicides, cervical barrier methods, and herpes treatment trials were realized in the past 2 years (Landovitz 2007; Miedema 2008; Moore et al. 2008; Weiss et al. 2008). Though male circumcision may be an effective prevention strategy for heterosexual transmission, widespread implementation will be an intensive and complex endeavor (Weiss et al. 2008). Results from pre-exposure prophylaxis studies are also anticipated in the near future (AIDS Vaccine Advocacy Coalition 2008).

Despite the challenges, novel directions have been encouraged for preclinical HIV prevention “technology” research and an existing pipeline of candidate vaccines,

microbicides, and other strategies will be evaluated in upcoming clinical trials (Fauci et al. 2008; Rossi 2008). Future advances in HIV biomedical research will only be realized with the support of communities. The involvement of clinical trial volunteers, their support networks, advocacy groups, other organizational partners, and community advisory boards is necessary to maintain scientific integrity, oversee the protection of human subjects in research, and gain ownership of research efforts (National Medical Association 2001; Porter et al. 1989; Quinn 2004). “Good participatory practices” highlight the role of community members in the cycle of prevention product development (UNAIDS & AIDS Vaccine Advocacy Coalition 2007). Federal guidelines from the National Institutes of Health (NIH) also emphasize the importance of community participation and collaboration in HIV vaccine, microbicide, and prevention trial networks’ activities (HIV Prevention Trials Network 2008).

Although black/African Americans comprise a significant proportion of HIV incident cases in the United States, they remain underrepresented in HIV-related clinical trials with $\leq 26\%$ overall participation rates in Phase I and II HIV vaccine clinical studies (Djomand et al. 2005) and a similarly low participation in therapeutic studies (Gifford et al. 2002). The 1994 NIH mandate specifying the inclusion of women and minorities in federally-sponsored studies underscored the importance of recruiting and retaining black/African Americans on research-related community advisory boards, promoting community organizing, and encouraging study participation (National Medical Association 2001; UNAIDS & AIDS Vaccine Advocacy Coalition 2007). Given the scope and magnitude of HIV/AIDS in black communities, calls to action have been issued to increase support for and participation in biomedical HIV prevention research (Black AIDS Institute 2008; National Minority AIDS Council 2008).

The dynamics driving community involvement in HIV vaccine-related activities have not been a focus of empirical investigation, particularly for priority groups whose participation is sought (Frew et al. 2008c; Newman 2006). The Theory of Reasoned Action (TRA) presents a useful model that may explain how minorities become actively engaged in clinical research endeavors (Morrow et al. 1994). The theory is motivational in nature, with integration of individual (behavioral attitudes) and social (subjective norms) components in the formation of intentions which are predictive of behavioral outcomes (Ajzen and Madden 1986; Fishbein and Ajzen 1975). Meta-analyses have shown that the model is effective at predicting a variety of health behaviors and that planned intentions are a moderately good predictor of behavior accounting for 20–30% of outcome variance (Albarracín et al. 2001; Gibbons 2008; Sheeran 2002). This model has been examined in relation to HIV vaccine acceptability (Gagnon and Godin 2000) and clinical trial willingness-to-participate (Giocos et al. 2007; Kkafaar et al. 2007; Morrow et al. 1994), and other HIV/AIDS prevention studies (Koniak-Griffin and Stein 2006) including condom use (McClaws et al. 1996; Sneed and Morisky 1998).

Although considerable evidence has been accrued in the past few decades on the application of the TRA to an array of health behaviors, only two studies to date have specifically tested the model on willingness-to-participate in HIV vaccine research (Frew et al. 2008a; Gagnon and Godin 2000). One of these studies specifically examined the utility of the model with African Americans (Frew et al. 2008a). Both found that although the model is useful in understanding hypothetical willingness-to-participate, hypothesized normative effects did not materialize in either study. These findings suggest an omission in the model that addresses emotional influences and other affective variables that may contribute to a comprehensive understanding of why minorities become engaged in such efforts. These stem, in part, from recognizing the historical importance of the African American community’s unique experiences with clinical trials and its bearing on future participation

(Corbie-Smith et al. 1999). Thus, positive and negative assessments of clinical studies, research entities, and participatory belief expectancies need to be accounted for in an extended model.

A body of evidence suggests that motivation to participate in biomedical research among minorities is multifaceted, and encompasses an individual's reasoned appraisal of the research endeavor, such as perceived benefit of a new product to self and community, as well as specific affective considerations such as degree of trust in researchers. Studies pertaining to HIV/AIDS volunteerism, clinical trials participation, and other forms of elective health behavior (i.e., bone marrow donation) suggest that decisional pathways are complex in these realms and have strong emotional components (Bagozzi et al. 2001; Curbow et al. 2006; Davis and Randhawa 2006; Reeder et al. 2001). Therefore, an expanded theoretical model that incorporates research site and health cause-related affective judgments may help in understanding why black/African Americans choose to participate in HIV prevention research and become active health research volunteers.

We therefore theorize that there are multiple factors at the individual, network/community, and population levels that interact to create ideal alignment for minority participation in HIV clinical studies. Greater understanding of the individual- and network-level facilitators and barriers to involvement of black/African Americans in HIV vaccine research can yield insight into the development of a powerful multisystem community engagement model. Thus, we set out to test a model of reasoned action that assesses not only the interplay of attitudes, beliefs, and normative concerns, but includes perceptions of the clinical research entity sponsoring vaccine trials as well as perceptions of social activism, in formulating decisions to participate in the search for a vaccine. We linked the intrapersonal dimensions of the traditional TRA model to appraisal of involvement with the clinical research organization, an entity which operates within a networked structure of community partner agencies, as well as to identification with our local prevention research coalition advocacy aims (Fig. 1).

As Fig. 1 indicates, participation in HIV vaccine research among minorities is expected to follow from intentions to participate which in turn are linked to favorable attitudes and norms promoting HIV prevention outcomes. Precursors of participatory attitudes and norms include beliefs outcome evaluations, normative beliefs and motivations to comply with norms. In addition, we expanded the TRA model to include affective components, organizational relevance and social activism, which are expected to help us understand the emotional linkage between individuals and community actors shaping their participation as well as affect behind social activism. We included these variables because of the importance of emotion as a motivating factor in health-related behavior (Leventhal et al. 2003). In addition, the TRA progenitors contend that such variables should function like other external factors. That is, the effects of organizational relevance and social activism on intentions and behavior are likely mediated by the attitudinal and normative components (Ajzen and Fishbein 1980). We therefore proceeded to test the model using this theoretical guidance.

Methods

Participants

From August 2007 through January 2008, venue-based sampling was conducted. This method has proven successful in obtaining representative populations in cross-sectional survey samples (Muhib et al. 2001). Venues were selected by study staff and partner agencies that hosted HIV vaccine-related functions in these settings. The study staff determined the suitability of venues based upon discussions with agency staff, target population observation at the locations, and other considerations (e.g., safety). The sampling

frame ultimately included 21 locations that demonstrated the potential to recruit an adequate number of eligible study participants within venue-specific-day-time periods (VDTs).

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 data collection based on a master schedule of monthly activities. They randomly approached members of attendee populations about the survey. For those who met the eligibility criteria and consented to participate in the study, the study staff directed participants to a semi-private area or nearby quiet spots in outdoor locations to complete the questionnaire.

The recruitment area was limited to Atlanta, Georgia. Persons were eligible for this study if they were at least 18 years of age and could read and speak English. Approximately 400 people were invited to participate in the study. Of these, 362 were eligible and provided written informed consent (yielding a response rate of nearly 90%). A T-shirt 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.

Measures

The inventories developed for this study were constructed based on a review of the literature (Fuchs et al. 2007; Newman et al. 2005, 2006), from our previous research with similar populations (Crosby et al. 2004a, b; Frew et al. 2008b; Salazar et al. 2005) and our existing instruments (Frew et al. 2008c; Priddy et al. 2006), along with other scaling options (Ajzen and Fishbein 1980).

Dependent Variables: Intentions—Three outcome variables were used to measure community engagement in HIV vaccine research. To increase the predictive utility of the model, the three intentions were concretely phrased to capture the likelihood of performing the behavior within a specific timeframe (e.g., “On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of getting others involved in HIV vaccine research in the next 6 months”). Participants were asked to rank their likelihood of contacting organizers about participating in future HIV vaccine trial events, of promoting HIV vaccine research in their community, and of mobilizing others in the cause of HIV vaccine research.

All of the scale inventories used the summative response format, a 5-point Likert scale, to assign meaningful values to an underlying continuum of ratings (Meyers et al. 2006). Response options ranged from 1 (strongly agree) to 5 (strongly disagree). Values were indexed to maintain consistency with the hypotheses with lower scores therefore representing strong negative responses and higher scores indicating strong positive views. The following section details the development of each scale for this study.

Attitudes (5 items; $\alpha=.771$)—The influence of attitudes on the three outcome intentions was explored. We hypothesized that favorable responses to attitudinal items covering HIV vaccine research would increase intentions. Respondents indicated positive attitudes with statement agreement on “I like to do good for others,” “I like getting involved with HIV vaccine research,” “HIV is a serious concern in my immediate community,” “HIV testing is a benefit of an HIV vaccine study,” and “I would benefit from the medical care associated with an HIV vaccine study.”

Subjective Norms (3 items; $\alpha=.849$)—Perceived “social pressure” (Ajzen and Fishbein 1980, p. 246) to perform a behavior or forego it, is reflected in the “subjective norm” construct. In this study, participants were also asked if they thought people, including family and friends, would support their participation. It was hypothesized that favorable social

opinion of research involvement would increase participatory intention. Influential normative concerns were directly measured through items including “Most people who are important to me think I should participate in the HIV vaccine effort,” “Most people who are important to me would approve of my involvement in this cause,” and “Most people who are important to me would support my interest in this cause.”

Behavioral Beliefs (7 items; $\alpha=.881$)—Several questions measured volunteers’ salient beliefs about their role in health research related to HIV/AIDS. It was hypothesized that beliefs about medical research favoring participatory behavior would increase intentions to participate in future activities, and generate greater community mobilization and study volunteerism. The items included “My community would really benefit from an HIV vaccine,” “My actions can inspire others to act,” “I benefit from health science research,” “My participation in an HIV vaccine study would be very good,” “My involvement in this cause will result in more ethical research,” “My involvement in this cause will improve my community’s trust in medical research,” and “I would participate in an HIV vaccine research study because it would help to prevent AIDS.”

Outcome Evaluations (5 items; $\alpha=.824$)—Consideration of outcomes related to study participation was uniquely assessed to understand negative salient beliefs related to volunteerism. Previous studies indicated logistical, physical, and psychological barriers with respect to involvement in HIV vaccine research among ethnic minorities (Newman et al. 2006; Priddy et al. 2006). It was therefore hypothesized that reduced personal concerns, and decreased concern of negative health and social consequences specifically related to HIV vaccine study participation, would more likely result in greater participatory intention. Items therefore included in the scale were “My participation in an HIV vaccine research study would be more trouble than it’s worth,” “Even if I wanted to participate in an HIV vaccine research study, I just don’t have the time,” “Participating in an HIV vaccine research study seems risky,” “I would participate in an HIV vaccine research study, but I don’t like needles” and “I am concerned that an HIV vaccine will cause me to test HIV positive.”

Normative Beliefs (6 items; $\alpha=.806$)—Two aspects of normative beliefs were considered. Those connected to beliefs about the effects of research on a community and beliefs about the effects of one’s own HIV vaccine participation in research for the greater good. It was hypothesized that these motives would influence subjective norms and participatory intentions. Normative beliefs consisted of six questions based on these two dimensions. They include reference to specific individuals within the social realm who may affect individual decision-making. Items on the 5-point scale therefore included “I think my doctor would approve of my involvement in HIV vaccine research,” “I think my work colleagues would approve of my involvement in this cause,” “My immediate family is supportive of my involvement in HIV vaccine research,” “Most people important to me think my involvement in HIV vaccine research is good,” “Most people important to me usually support my interests,” and “If my pastor supported HIV vaccine research, I would be inclined to get involved.”

Motivation to Comply (5 items; $\alpha=.843$)—Individuals might declare a willingness to participate or reluctance to get involved in HIV vaccine research due to general compliance with referent opinion. The theorized influence of family, friends, and others on behavioral performance will exert social pressure to act or engage in avoidance. It was hypothesized that greater self-agency would lead to greater participatory intention. The items measuring this domain therefore include “I tend to be concerned about what people think of me, even if I don’t know them,” “I generally do what my family expects of me,” “I would not want to do something my friends disapproved of,” “If my superiors told me to do something I

disagreed with, I would obey their wishes,” and “Sometimes I do what my friends say to do, even though I know they are wrong.”

Organizational Relevance (4 items; $\alpha=.813$)—“Organizational Relevance” incorporates specific attitudes about HIV vaccine research and belief expectancy based on identification with the aims of the clinical research site (CRS). Drawing upon consumer studies that examine the relationship of brands and product purchases (Traylor and Joseph 1984; Zaichkowsky 1985), “relevance” has been conceptualized as the affective linkage between individuals to a network/community-level entity with whom they identify. Positive appraisal of a clinical research entity has been linked to intentions to participate in future HIV vaccine functions (Frew et al. 2008c). Greater agreement with relevance items on a 5-point Likert scale (strongly agree to strongly disagree) is theorized to increase the likelihood of realizing HIV vaccine research participation. The items for this study therefore include: “Being active with the (CRS) would help me to express who I am,” “Hearing that someone else is involved with the (CRS) tells me a lot about that person,” and “Others would view me favorably if I volunteered for a study at the (CRS),” and “Being involved with the (CRS) helps me to feel empowered.”

Social Activism Congruence (6 items; $\alpha=.918$)—This domain incorporates specific feelings about participatory behavior and belief expectancy. The strength of this identification is expected to align with intention to perform a participatory behavior such as promoting HIV vaccine research. The “purchase decision” measurement work of Zaichkowsky (1985) informed the development of this scale. It is therefore linked to cultural values and identification with an issue of broader community concern. We theorized that positive affect toward HIV vaccine activism may have a strong influence on behavioral intention. The items therefore include: “I experience a sense of community in this cause,” “I feel a sense of belonging through my participation in this effort,” “My involvement is helping to protect the rights of others,” “I am advancing the public’s health and my well-being through my support of this cause,” “Getting involved in the HIV vaccine effort is liberating,” and “I feel a sense of purpose in this cause.”

Data Analyses

Descriptive statistics were generated for all of the variables of interest. Independent predictors of outcomes were assessed at $p \leq .10$ levels given sample size considerations. A three-stage least squares estimation procedure was used to test structural relationships between factors shown in the path model.

SPSS version 17.0 and Stata 10.0 were used to generate statistical analyses because they have the capability to automatically screen data for multivariate normality (i.e., skewness and kurtosis) and to assess outlier cases (Brown 2006). Reliability and validity were assessed using SPSS for all scales to measure their internal consistency.

Missing case data were observed with respect to each outcome from the overall sample ($N=362$) resulting in a reduction of cases appropriate for modeling (attendance, $N=334$; promotion, $N=322$; community mobilization, $N=329$). All scale variables from the instrument were subjected to multiple imputation procedures (i.e., expectation maximization algorithm) (McKnight et al. 2007; Roth 1994). The “Missing Cases” module within the SPSS package was utilized for the multiple mean imputation procedures. A Little’s MCAR test (Missing Completely At Random) was subsequently conducted ($\chi_{4538}^2=5106.217$, $p<0.001$). Imputation of missing values was performed after satisfactory assessment on MCAR test.

Results

Sample Demographics

A total of 362 African Americans agreed to participate in the study. The majority were in the 18 to 39 age group ($n=204$, 57.3%; mean age = 37.0 years). Most respondents were female ($n=229$, 63.3%) and most identified themselves as heterosexual ($n=246$, 68.9%). The sample included six persons who specified transgender status with five male-to-female (1.4%) and one female-to-male (0.3%) in the study population. While just over half of all respondents reported working full-time ($n=191$, 53.2%), a significant majority of participants reported yearly incomes of under \$40,000 ($n=216$, 61.2%) (Table 1).

Internal Consistencies

The results from this study indicate that the construct measures exhibited moderate to high internal consistencies for each outcome assessed (standardized Cronbach's $\alpha=0.771-0.918$). The "attitude" scale ($n=5$ items) achieved the lowest, but moderately good, reliability (Cronbach's $\alpha=0.766-0.771$).

Modeling Community Engagement

The TRA is based on a path model with multiple endogenous (dependent) variables (i.e., attitudes, subjective norms, intentions). Path models with multiple endogenous variables have the potential to violate a number of ordinary least squares (OLS) assumptions that can be resolved by use of two- and three-stage least squares models (Bollen 1996,2001;Kline 2005). The first stage creates "instrumental variables" as new predictive proxies for use in the later stage analyses (Kline 2005, p. 253). The instrumental variables replace problematic causal variables with new predictors. Typically, "problematic" causal variables directly affect endogenous variables and contribute to model disturbances if not addressed (Kline 2005). Therefore, the development of these variables does not have any bearing on the substantive hypotheses as they are excluded from the subsequent equation of endogenous variables (Kline 2005). Stage two analyses yield parameter estimates based on the regression of each of the intentions on the endogenous instrumental variables. Stage three testing examines the system of relationships among behavioral beliefs, outcome evaluation, social activism congruence, and organizational relevance on attitudes as a dependent variable. Similarly, at this level, the relationship among normative beliefs, motivation to comply, social activism congruence, and organizational relevance are also tested with subjective norms functioning as the dependent variable.

It is important to note that the three-stage least squares modeling method relies on Wald tests to ensure stable parameter estimates in lieu of power calculations (Kline 2005). Therefore, we calculated likelihood ratios on all models resulting in stable and valid estimates given the large number of tests, variables, the significance level at $p \leq .10$, and number of participants in the sample (Table 2).

Table 2 presents results of three-stage least squares models. For each outcome, the first set of models contains the system direct and indirect relationships with social activism as a key factor. The second set of models contains the system of direct and indirect relationships using organizational relevance as the key factor. Since three-stage regression consists of a single system of equations (i.e., for the indicated set of variables), goodness-of-fit tests apply only to each level of analysis. Examination of the root mean square error and chi-square are suggestive of well-fitting models in all instances. Regression of the three outcomes on attitudes, subjective norms, social activism congruence and, alternately, organizational relevance, produced varied fits overall, with intent to mobilize the community in HIV vaccine endeavors producing the strongest measure ($\chi_{(3)}^2=136.77$, $p < .05$ and $\chi_{(3)}^2=122.04$,

$p < .05$), promotion of HIV vaccine research the next strongest ($\chi_{(2)}^2 = 109.48, p < .05$ and $\chi_{(3)}^2 = 90.98, p < .05$) followed by likelihood of future attendance at these events ($\chi_{(3)}^2 = 35.68, p < .05$ and $\chi_{(3)}^2 = 36.17, p < .05$). The root mean square error term, used to determine how well the model fits the data, supports these conclusions.

To explore these relationships in more detail, Table 2 presents the tests of individual relationships between the theorized constructs in the models. It includes the least squares estimates of regression coefficients, their standard errors, and significance levels. Overall, the pattern of significant and non-significant path coefficients is similar across the three different measures of intention to engage in action with respect to HIV vaccine research. Positive attitudes about “getting involved with HIV vaccine research” had a significant positive effect on the promotion of HIV vaccine research ($b = .074, p = .020$, model 3), community mobilization ($b = .061, p = .020$, model 5), and the likelihood of future attendance at these events ($b = .053, p = .034$, model 1). Attitudes had positive and significant effects on community mobilization for models with both social activism congruence and organizational relevance tested ($b = .191$ and $.227, p < .001$, models 5 and 6, respectively). Social activism congruence and organizational relevance as well had a direct effect on HIV promotion ($b = .074, p < .001$ and $.052, p < .10$, models 3 and 4 respectively). Similarly, social activism congruence and organizational relevance had a direct effect on HIV community mobilization ($b = .061, p < .01$ and $.047, p < .10$, models 5 and 6 respectively), although only organizational relevance had a direct effect on attendance at future HIV related events ($b = .068, p < .10$, model 2).

Consistent with predictions, behavioral beliefs influenced attitudes toward HIV research, which influenced participant outcomes across all models ($b = .508, .517, .507, .511, .512, .520, p < .05$, all models). Similarly, normative beliefs were a robust predictor of participants’ perceptions of “social pressures” (i.e., subjective norms) influencing intentions to attend future events ($b = .431, .467, p = .031$, models 1 and 2, respectively), promote HIV vaccine research ($b = .441, .477, p < .05$, models 3 and 4, respectively) and mobilize community members ($b = .453, .485, p < .05$, models 5 and 6, respectively). Social activism congruence and organizational relevance were significant predictors of social pressures across models (e.g., social activism $b = .155, .127, .118, p < .001$ in models 1, 3 and 5) while, motivation to comply with others’ expectations, showed occasional significant effects ($b = .050, .040, .058, p < .10$, models 2, 3 and 4, respectively). Attitudes and their constituent precursor beliefs were therefore the most consistent and robust predictors of participants’ HIV vaccine research activities ($b = .431, .467, .441, .477, .453, .485, p < .001$, all models). Social activism congruence ($b = .074, .061, p < .05$, models 3 and 5, respectively) and organizational relevance ($b = .052, .047, p < .10$, models 4 and 6, respectively) were also consistently important influences on participants’ intentions to engage in vaccine research promotion and community mobilizing HIV-related activities. Overall, this indicates the importance of attitudes and individual appraisal of the social conditions of their commitment to HIV clinical research. Interestingly, subjective norms had no effect on intentions to engage in HIV-related activities ($b = .041, .033, -.045, -.016, .040, .060, p \geq .10$, all models) because its influence was overshadowed by social activism congruence and organizational relevance, both robust precursors of subjective norms itself. This suggests that the importance of the cause and the relationship formed to the clinical research entity dominate in the face of mere normative pressures favoring or disfavoring African Americans’ HIV vaccine research participation.

Discussion

The current study is significant because it augments the explanatory power of an established behavioral theory with network-level perceptions to understand the array of factors that may

play a role in realizing greater involvement of priority populations in HIV vaccine research (Giocos et al. 2007). Overall, the study validates the importance of including cognitive and affective appraisal in measurement of community engagement in biomedical research (Frew et al. 2008a).

The model established that seven of eight components were significant in the explanation of three dependent variables including future attendance, promotion of HIV vaccine research in the community, and intention to mobilize others to the cause. The “outcome evaluation” construct was not significant in relation to any of the dependent variables. The results demonstrate the importance of favorable beliefs and attitudes toward biomedical health research and HIV vaccine development. Attitudes are clearly an important predictor of future behavioral intention for all outcomes in this study, and represent an important intervention point for programmatic efforts targeting African Americans.

Social activism and organizational relevance consistently resulted in significant effects. To the extent that respondents see themselves aligned with ideological purposes as well as the mission of the clinical research site, they are more likely to participate in future HIV vaccine functions, promote HIV vaccine research in their communities, and to mobilize others to action on the cause. Thus, the latent characteristics, such as a perceived sense of inclusion and purpose that are associated with community-organized research involvement, resonate with this population. Similarly, appraisal of the research site’s mission, vision, and values in decision-making is realized in the normative context. This result suggests that first impressions or previous interactions with the site may be used as a heuristic for decision making on volunteerism.

In the presence of strong issue and organizational commitments, normative concerns had no significant effect on HIV vaccine research intentions. This shows a degree of appraisal given to perceived sociopolitical and organizational support in deciding whether to engage in advocacy efforts that trumps purely social concerns. Although it is important to promote positive messages on HIV vaccine research that reach family, friends, co-workers, pastors, and significant others to build their support for the cause, it is more effective to mobilize participants through formal networks established by locally embedded agencies where dissemination of positive messages about HIV vaccine trials can be undertaken.

In this study, perceived risk associated with HIV vaccine participation resulted in nonsignificant findings related to the “outcome evaluation” component. Fear of needles, concern related to vaccine-induced seropositivity, time constraints, and risk perception were cited as factors negatively impacting minorities’ trial-related willingness-to-participate (WTP) (Koblin et al. 2000; Newman et al. 2006; Strauss et al. 2001). These issues correspond with vaccine product acceptability studies (Crosby et al. 2004a, b; Frew et al. 2008b). However, in the context of community participatory endeavors supporting HIV vaccine research, such issues did not have an influential effect. It is therefore prudent to recognize this as a potential intervention point to ameliorate such issues that may arise within the context of active study recruitment efforts. Incorporating education on these “barriers to participation” in community programs may facilitate longer-term enrollment objectives (Koblin et al. 2000; Roberts et al. 2005).

It is important to note that the study population included a large percentage of African American women (63.3%). Other studies that have examined clinical research perceptions with similar populations indicate gender differences with respect to clinical trial involvement (BeLue et al. 2006; Smith et al. 2007). African American women have expressed a need for information, clinical site involvement in the community to build trust, and they have expressed the importance of community networks in their engagement in

clinical research (Smith et al. 2007). Moreover, women indicate the importance of developing relationships with clinical staff in their decision-making process, and ascribe value of the clinical effort to families and community in determining whether they should actively become involved in the research (BeLue et al. 2006). Previous efforts to assess clinical research participation among African American men suggest that there are greater barriers to participation including concerns about pharmaceutical companies and the government primarily benefiting from their involvement, adequacy of study compensation, potential for side effects, and clinical site reputation, among other factors (BeLue et al. 2006). Although this study could not conduct the analysis by gender due to sample size limitations, future research warrants greater examination of issues that are specific to men, women, and transgender individuals.

This study adds to the literature with information gathered among those attending HIV vaccine-related functions. As favorable attitudes, perceptions, and beliefs are theorized to be critical predisposing factors influencing future behavioral outcomes (Ajzen 1991; Fishbein and Ajzen 1975), these attendees have the potential, at a minimum, to serve as allies in expanding needed social support for HIV vaccine research (Allen et al. 2005). The results from this study offer evidence to reinforce this notion.

Limitations

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. The study was concerned with relational modeling of various theoretical constructs thereby only allowing for covariant evaluation. In this study, intentions were evaluated. A body of research has demonstrated that intentions are moderately good predictors of future behavior (Ajzen and Fishbein 1980; Albarracin and Wyers 2000; Halpern et al. 2001). However, it would be highly beneficial to the field to examine the role of intentions to behavior among those at HIV vaccine functions. This would offer additional insight on the factors which 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 and reduces our ability to generalize the results. Clearly, the people attending our organized community 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 African Americans within specific venues may not be representative of other venue-based functions.

It should also be noted that participation bias in a study of HIV vaccines and health behaviors is particularly likely (i.e., 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 approximately 90%, participation bias may have affected our findings. Non-participation of low-literacy or non-English speaking Black 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.

This study introduces contextual variables to the TRA model by operationalizing social activism congruence and organizational relevance with scales that achieved very good reliability. Future research warrants additional investigation of these constructs to establish their reliability and discriminant validity with respect to other clinical research behavioral outcomes (e.g., acting as a community advisory board member at a site conducting HIV vaccine research).

Implications

This study explored the interplay of cognitive and affective mechanisms with respect to decision-making on HIV vaccine participation among Black/African Americans. The assessed variables reflecting motivation demonstrated predictive validity toward various forms of involvement in HIV vaccine research endeavors. The model components indicate consistent effects associated with the factor relationships for all of the tested outcomes. The extended TRA model is therefore useful in understanding the complex interplay of factors that influence HIV vaccine involvement with this population.

The results from this study suggest that our priority populations may be influenced to become involved in HIV prevention research. Sponsored functions within community venues had large numbers of African American attendees. Future attendance can be achieved via favorable attitudes with messages focusing on the importance of health research and the relevance of HIV vaccine development in ending HIV/AIDS. In addition, the role of the partners in identifying appropriate spokespersons, locations, scheduling, and types of activities have been beneficial in shaping attitudes toward the cause among diverse segments.

Generating positive promotion and greater community mobilization about HIV vaccine research within Black/African American communities are activities that stem from positive attitudes toward health research and HIV vaccine development, as well as favorable appraisal of sociopolitical involvement in HIV issues specifically embedded in participants' relationship with the clinical research site. The findings have programmatic implications for the initiation of community engagement via a coalition of partnership organizations. By linking individuals to organizations and, in turn, cultivating relationships between clinical research entities and those community organizations, effective coalitions can be formed. With experience in building trusting relations among their respective communities, the partners therefore bring enormous credibility to the endeavor (Brown-Peterside et al. 2000). Recognition of HIV/AIDS as an important issue signifies a normative concern for each organization. Bringing HIV vaccine research to the agency agenda therefore signifies the importance of new prevention options to reduce HIV transmission. Thus, agencies with stable histories in the community and for whom HIV prevention is a concern continue to serve as ideal allies for building trust and facilitating collective collaborative action.

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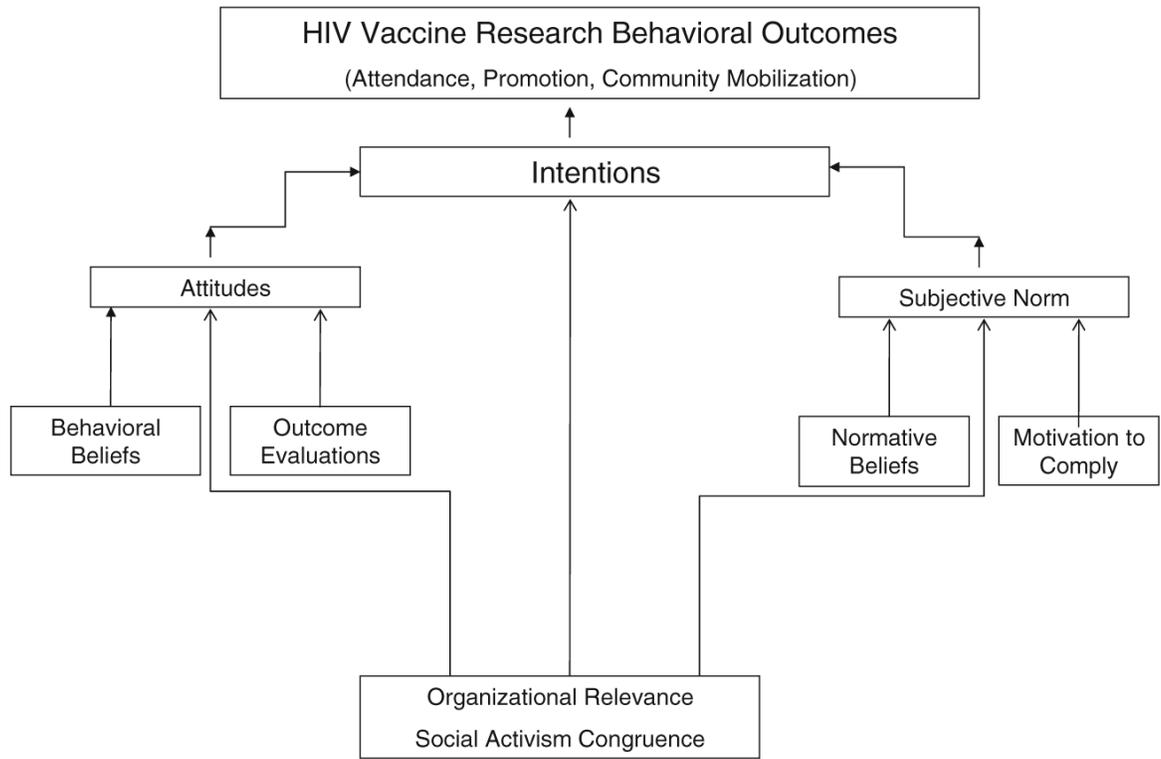


Fig. 1.
Community engagement conceptual model

Table 1Sample demographic characteristics (*n*=362)

Characteristic	Frequency (%)
Age (mean = 37.0 years old)	
18–29	104 (29.2)
30–39	100 (28.1)
40–49	100 (28.1)
50–59	45 (12.6)
60 and over	7 (2.0)
Gender	
Male	127 (35.1)
Female	229 (63.3)
Transgendered: M → F	5 (1.4)
Transgendered: F → M	1 (0.3)
Sexual orientation	
Straight (heterosexual)	246 (68.9)
Lesbian, Gay, Bisexual, Queer, Questioning (LGBQQ)	111 (31.1)
Educational attainment	
K-12 grade	123 (34.0)
Technical/Vocational/ Associates	104 (28.7)
Bachelor	81 (22.4)
Master's	42 (11.6)
Doctorate	12 (3.3)
Employment status	
Employed full-time	191 (53.2)
Employed part-time	52 (14.5)
Unemployed	77 (21.4)
Other	39 (10.9)
Household income	
Less than \$40,000	216 (61.2)
\$40,001–\$60,000	63 (17.8)
\$60,001–\$80,000	37 (10.5)
\$80,001–\$100,000	13 (3.7)
Over \$100,000	24 (6.8)

Table 2
Three-stage least squares parameter estimates, standard errors and *p*-values for predictors of HIV vaccine research attendance, promotion, and community mobilization among Black/African American participants

	Future attendance		Vaccine research promotion		Community mobilization	
	Model 1 Social activism congruence b (SE)	Model 2 Organizational relevance b (SE)	Model 3 Social activism congruence b (SE)	Model 4 Organizational relevance b (SE)	Model 5 Social activism congruence b (SE)	Model 6 Organizational relevance b (SE)
Attitudes	.126(.053) *	.148(.051) **	.188(.036) ***	.230(.036) ***	.191(.038) ***	.227(.037) ***
Subjective norms	.042(.067)	.033(.066)	-.045(.046)	-.016(.046)	.040(.046)	.060(.046)
Social activism	.053(.034)	-	.074(.020) ***	-	.061(.020) **	-
Org. relevance	-	.068(.038) #	-	.052(.028) #	-	.047(.028) #
Constant	6.276(.471) ***	6.491(.487) ***	1.466(.341) ***	1.354(.341) ***	.362(.337)	.253(.337)
Model χ^2 (df = 3) **	35.68	36.17	109.48	90.98	136.77	122.04
RMSE	1.52	1.52	1.96	1.08	1.05	1.08
Likelihood ratio χ^2 (df = 1)	2.23 (<i>p</i> = .135)	3.00 (<i>p</i> = .083)	13.74 (<i>p</i> = .001)	3.67 (<i>p</i> = .055)	8.27 (<i>p</i> = .004)	2.72 (<i>p</i> = .099)
Attitudes						
Behavioral beliefs	.508(.023) ***	.517(.020) ***	.507(.023) ***	.511(.021) ***	.512(.023) ***	.520(.021) ***
Outcome evaluation	.021(.018)	.023(.018)	.022(.018)	.024(.018)	.015(.018)	.015(.018)
Social activism	.035(.025)	-	.028(.021)	-	.026(.022)	-
Org. relevance	-	.035(.030)	-	.051(.031) #	-	.036(.031)
Constant	1.324(.422) **	1.457(.390) ***	1.493(.390) ***	1.404(.393) ***	1.578(.393) ***	1.550(.395) ***
Model χ^2 (df=3) **	865.54	866.89	829.66	838.62	822.38	827.81
RMSE	1.37	1.38	1.39	1.39	1.38	1.38
Subjective norms						
Normative beliefs	.431(.031) ***	.467(.031) ***	.441(.032) ***	.477(.031) ***	.453(.032) ***	.485(.031) ***
Motivation to comply	.030(.021)	.050(.022) *	.040(.021) #	.058(.022) **	.032(.022)	.051(.023)
Social activism	.155(.030) ***	-	.127(.026) ***	-	.118(.026) ***	-
Org. relevance	-	.137(.042) **	-	.133(.043) **	-	.131(.044) **
Constant	2.774(.599) ***	3.560(.593) ***	3.179(.561) ***	3.130(.598) ***	3.276(.573) ***	3.136(.611) ***

	Future attendance		Vaccine research promotion			Community mobilization		
	Model 1 Social activism congruence b (SE)	Model 2 Organizational relevance b (SE)	Model 3 Social activism congruence b (SE)	Model 4 Organizational relevance b (SE)	Model 5 Social activism congruence b (SE)	Model 6 Organizational relevance b (SE)		
Model χ^2 (df=3)	423.43 **	391.60	423.30	391.54	429.53	405.58		
RMSE	1.72	1.76	1.74	1.78	1.72	1.75		
Number of cases	334	334	329	329	322	322		

* $p < .05$
 ** $p < .01$
 *** $p < .001$
 # $p < .10$