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Socioecological influences on community involvement in HIV vaccine research

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ABSTRACT

Objective: This study investigated socioecological factors influencing HIV vaccine research participation among communities living in geographic areas with high HIV prevalence and high poverty rates.
Methods: We surveyed a sample of 453 adults $\leq$18 years from areas of high poverty and high HIV prevalence in metro Atlanta and differentiated the effects of individual-, social/organizational-, and community-level characteristics on participation in HIV vaccine research via multilevel modeling techniques that incorporated questionnaire, program, and census data.
Results: Models that adjusted for both individual-level covariates (such as race, gender, attitudes, and beliefs concerning HIV research), social/organizational- and community-level factors such as local HIV prevalence rates, revealed that the extent of HIV prevention-related programs and services in census tracts contributed to individuals' likelihood of participation in an HIV vaccine study. Additionally, neighborhood-based organizations offering HIV medical and treatment programs, support groups, and services (e.g., food, shelter, and clothing) encourage greater HIV vaccine research participation.
Conclusions: The findings support the hypothesis that community-level factors facilitate participation in HIV vaccine research independent of both individual- and social/organizational-level factors.

1. Introduction

With over 50,000 new HIV infections estimated to occur annually in the United States, the HIV/AIDS epidemic is far from over [1]. The number and proportion of HIV/AIDS cases among specific groups continue to highlight the need for new biomedical prevention interventions, including an HIV vaccine, microbicide, or pre-exposure prophylaxis (PrEP) to complement existing behavioral prevention strategies [2–6].

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 [7–11]. Both encouraging and disappointing results from HIV vaccines, microbicides, pre-exposure prophylaxis, cervical barrier methods, and herpes treatment trials were realized in the past few years with priority groups at risk for HIV infection [12–18]. Yet even with positive developments in HIV biomedical research, recruitment challenges endure as the existing pipeline of candidate biomedical prevention options will need to be evaluated among those racial and ethnic groups who are disproportionately affected by HIV in the US but who have also been historically underrepresented in clinical trials. Moreover, as new biomedical strategies are tested in study protocols, potentially even larger cohorts will be needed as risk status is ameliorated and new standards of care are adopted [19,20]. Among those most needed in future domestic HIV biomedical prevention studies are men-who-have-sex-with-men (MSM), especially black/African American men, and minority women living in areas of high poverty and HIV prevalence [21]. Therefore, it is critical to invest in effective community engagement and recruitment approaches to yield support and participation from these groups to achieve HIV biomedical prevention research aims.

Although racial and ethnic minorities, particularly 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$26% overall enrollment rates in Phase I and II HIV vaccine clinical studies compared to whites who comprised 87% ($N = 2323$) of Phase I and 73.8% ($N = 783$) of Phase II HIV Vaccine Trials Network (HVTN), AIDS Vaccine Evaluation Group (AVEG), and HIV Network for Prevention Trials (HIVNET) trial participants [22]. Therapeutic HIV studies have experienced similar challenges with

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enrollment of non-white minorities in studies, both as a function of under recruitment of these groups and individual (un)willingness-to-participate in studies [23]. 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 and Hispanics on research-related community advisory boards, promoting community organizing, and encouraging study participation [24,25]. Given the scope and magnitude of HIV/AIDS in minority communities, calls to action have been issued by community leaders and national AIDS organizations such as the Black AIDS Institute (BAI), National AIDS Education and Services for Minorities, National Minority AIDS Council (NMAC), SisterLove/SisterSong, and others to increase support for and participation in biomedical HIV prevention research [26,27].

Motivation to participate in biomedical research among minorities is multifaceted and operates at multiple levels. It is widely accepted that a number of socioecological factors influence health behaviors [28,29]. The socioecological framework integrates multi-level factors including community-level factors (e.g., racial distribution, HIV prevalence), social/organizational-level (e.g., accessible testing sites, community education programs), and individual-level factors (e.g., attitudes, gender) [30,28]. Previous studies have demonstrated decisional pathways are complex in HIV/AIDS research participation and individual-level influences have a significant role in promoting involvement [31,32]. It has been argued that microlevel theories typically utilized in explaining research participation are compromised in their ability to predict intention and behavior in the face of alternative options [33]. Thus, these models may have limited explanatory power to understand the complexity of the relationships in the broader socioenvironmental milieu. How contextual factors and community characteristics interact with individual- and social/organizational-level influences to effectively promote HIV prevention research participation remains to be explored.

We therefore theorize there are multiple factors at the individual-, social/organizational-, and community-levels interacting to influence participation in HIV biomedical studies. Greater understanding of how individuals respond to the call to volunteer for HIV biomedical research within their communities can yield insight into the development of a powerful multisystem community engagement and study recruitment model. Thus, we set out to assess the interplay of individual characteristics, including race and gender, and psychosocial factors such as attitudes and beliefs toward HIV prevention research. We also considered perception of study volunteerism at the local clinical research organization via our measure of “organizational relevance as a psychosocial variable” [31,32]. This construct reflects connection or engagement of individual’s values and commitment to the organization which is a networked coalition entity among other local operations also engaged in AIDS-related work [34]. Finally, we examined community-level factors such as HIV prevalence and provision of local HIV prevention services to understand the formation of motivation to participate. Given the theorized influence of macrolevel factors on health behaviors, we expected community-level factors would influence community involvement independent of other individual and compositional factors commonly associated with participation such as race and ethnicity, gender, and beliefs and attitudes related to motivation.

2. Materials and methods

2.1. Participants

From August 2007 to January 2008, venue-based sampling was conducted in the metro Atlanta area in areas of high poverty and high HIV prevalence [35]. Venues were selected by study staff and partner agencies, who had hosted HIV vaccine-related functions. 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 specified venue-day-time periods (VDTs).

The sampling strategy allowed for recruitment to occur at various times and days of each week 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 self-administered, paper questionnaire. The questionnaire took approximately 20 min to complete.

Persons were eligible for this study if they were at least 18 years of age and could read and speak English. Approximately 540 people were invited to participate. Of these, 453 were eligible and provided written informed consent (yielding a response rate of 83.9%). 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. The Emory University Institutional Review Board approved this protocol.

2.2. Measures

The inventories developed for this study were constructed based on a review of the literature, from our previous research with similar populations and our existing instruments, along with other scaling options [34–37]. The measures utilized for this study have been previously reported and were determined to be reliable and have been validated with similar populations [36–40].

2.3. Dependent variable

We selected HIV vaccine community participation as the dependent variable, focusing on involvement in HIV vaccine research as it is typically more difficult to achieve participation in biomedical research compared to other HIV prevention efforts. HIV-related research participation was measured by asking respondents: “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”. Kurtosis estimates were examined to determine normality of the distribution and the Shapiro–Wilk test was subsequently performed to assess skewness with nonsignificant normality ($z = -0.23$). Similarly, the kurtosis estimate on the raw scaled outcome was also acceptable ($z = -0.90$). Given that the raw outcome score displayed a greater degree of normality and acceptable clustering, the variable was subsequently rescaled from 1 (definitely not/not very likely) to 5 (definitely so/very likely) using percentile splits. The resulting kurtosis score remained relatively similar ($z = -0.99$) to its previous version ($z = -0.90$), as did its degree of skewness ($z = -0.28$).

2.4. Individual-level and psychosocial covariates

In addition to demographic variables including race, income, gender, and age, we examined the role of psychosocial variables (see Table 1). Drawing from the theory of reasoned action schema, we assessed attitudes toward HIV vaccine research [41]. In addition, behavioral and normative beliefs were examined. Consideration of social norms was also critical given historical and cultural consideration of clinical study participation in minority communities