



What can HIV vaccine trials teach us about future HIV vaccine dissemination?

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Summary This investigation explored commonalities and differences in barriers and motivators to HIV vaccine trial participation and acceptability of future U.S. Food and Drug Administration (FDA)-approved HIV vaccines in order to identify implications of clinical trials for future HIV vaccine dissemination. Fifteen focus groups were conducted with 157 predominantly ethnic minority and low income participants recruited using venue-based sampling in Los Angeles. Data were analyzed using narrative thematic analysis. Barriers and motivators in common across willingness to participate (WTP) in HIV vaccine trials and future HIV vaccine acceptability (e.g., concerns about vaccine-induced infection, false-positives, side effects, efficacy, mistrust and stigma) suggest clinical trials present significant opportunities to develop and evaluate empirically based interventions to support future HIV vaccine dissemination. Barriers specific to HIV vaccine acceptability (e.g., concerns about duration of protection, cross-clade protection, cost and access) also indicate the need for formative research focused specifically on future dissemination. Protection motivation, common to WTP and acceptability, highlights the need to provide and evaluate prevention counseling and education in clinical trials, which may form the basis of evidence-informed preventive interventions to be launched in tandem with dissemination of partial efficacy HIV vaccines.

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Introduction

A new era in preventive HIV vaccine research and development is underway with increased funding and coordination of research efforts, and a doubling of candidate vaccines in clinical trials [1]. Nevertheless, wide gaps are forecasted between projected need and future uptake of HIV vaccines

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[2] with significant challenges for HIV vaccine acceptability [3–5].

Suboptimal uptake of widely available, highly safe and efficacious vaccines (e.g., influenza, pertussis [6]) in the United States (U.S.) for diseases unencumbered by the stigma and risk behaviors associated with AIDS [7] highlight the importance of preparing for future HIV vaccine dissemination [4,8]. In particular, communities in the U.S. most impacted by HIV – e.g., African Americans and Latinos – are among those with the lowest levels of coverage for existing vaccines [6] and the least utilization of HIV medications [9]. The potential for increased risk behaviors in response to HIV vaccine availability also threatens to counteract the benefits of partially efficacious HIV vaccines [10–12]. Limited research focused on HIV vaccine acceptability among vulnerable communities raises a number of challenges for future dissemination based on possible vaccine characteristics (e.g., level of efficacy, side effects) as well as attitudes toward HIV vaccines [5,12–16].

HIV vaccine dissemination is likely to raise formidable sociobehavioral challenges beyond the more circumscribed realm of clinical trials [4]. Nevertheless, numerous investigations focused on HIV vaccine trials, particularly stated willingness to participate (WTP), reveal a variety of barriers to participation (see [17] for a review). This relatively extensive body of research may serve to elucidate some of the difficulties for future vaccine acceptability and further may provide an empirical basis to support HIV vaccine dissemination interventions. However, the potential relevance of factors associated with WTP – and of HIV vaccine trials, in general – to future HIV vaccine acceptability has not yet been evaluated. The purpose of this investigation is to identify commonalities and differences in barriers and motivators to HIV vaccine trial participation, and acceptability of future U.S. Food and Drug Administration (FDA)-approved HIV vaccines, respectively, in order to identify implications of clinical trials for future HIV vaccine dissemination.

Methods

Fifteen focus groups were conducted – nine in English, six in Spanish – with 7 to 13 participants per group ($N=157$). Groups were largely homogenous by design in terms of gender, sexual orientation, language and ethnicity. Participants were recruited from venues in Los Angeles providing services to communities at heightened vulnerability to HIV infection: needle exchange programs ($n=3$), community clinics serving low socioeconomic Latinos ($n=2$) and African Americans ($n=1$), and gay community centers ($n=3$), including a social service agency for lesbian, gay, bisexual and transgender homeless youth.

Eligibility criteria were 18 years of age or older, not an employee of the recruitment site and fluency in English or Spanish. Participants received \$30 for engaging in a 75- to 90-min focus group. All participants provided individual written informed consent. The study was approved by the IRBs of UCLA and University of Toronto.

Data collection

Two parallel semi-structured focus group interview guides were constructed [18], one focused on HIV vaccine trials (6 groups; $n=58$) and one focused on hypothetical future preventive HIV vaccines (9 groups; $n=99$; including 1 group [$n=8$] for youth aged 18–23 years). The interview guides and all study materials were translated into Spanish, back-translated into English, and revised in Spanish [19]. Questions and probes elicited respondents' knowledge, concerns and motivations regarding willingness to participate (WTP) in an HIV vaccine trial or acceptance of a future HIV vaccine (acceptability). Debriefing was conducted at the end of each group.

Data analysis

Focus groups were digitally recorded and transcribed verbatim. Spanish-language groups were transcribed in Spanish and translated into English for analysis. Narrative thematic analysis and a constant comparative method were used to identify major themes [20], with Ethnograph software. Line-by-line, focused and theoretical coding were used to identify, refine and ensure saturation of codes [20]. Disparities in coding were resolved by consensus among three investigators. Separate findings from acceptability focus groups [12,15] and WTP groups [21,22] have been previously reported; the present study capitalizes on the use of parallel interview guides to compare and contrast findings across the two sets of focus groups. Each guide consisted of the same question stems – for example, “What are concerns that you or your community might have about...” – with one guide finishing the question with “participating in an HIV vaccine trial?” and the other with “getting an approved HIV vaccine?”

We conducted *t*-tests and chi-square tests to compare demographics between participants in the two sets (WTP and HIV vaccine acceptability) of focus groups.

Results

Social and demographic characteristics of participants are presented in Table 1. Overall, about one-fourth (27%) were African American, half (51%) Latino, 19% White and 3% other race/ethnicity. Nearly half (47%) were women. Most participants (51%) had an annual income of \$10,000 or less. Participants in WTP groups were slightly older (3.3 years) than those in acceptability groups. Both sets of groups had a majority of Latinos; significant differences were observed by ethnicity, with the proportion of African Americans greater in the WTP groups and the proportion of Whites greater in the acceptability groups. All other sociodemographic characteristics were the same across the two sets of groups, although more participants did not identify their sexual orientation in the WTP groups. The youth group was mixed gender (5 male, 3 female) and ethnicity (4 African American, 2 White, 2 mixed/other).

Two overarching sets of themes were explored, barriers and motivators, which are organized into three domains: themes common to WTP (in an HIV vaccine trial) and accept-

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