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Selectively willing and conditionally able: HIV vaccine trial participation among women at "high risk" of HIV infection

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ABSTRACT

Efficacy studies of investigational HIV vaccines require enrollment of individuals at 'high risk' for HIV. This paper examines participation in HIV vaccine trials among women at 'high risk' for HIV acquisition. In-depth interviews were conducted with 17 African-American women who use crack cocaine and/or exchange sex for money/drugs to elicit attitudes toward medical research and motivators and deterrents to HIV vaccine trial participation. Interviews were digitally recorded and transcribed; data were coded and compiled into themes. Most women expressed favorable attitudes toward medical research in general. Motivators for trial participation included compensation; personal benefits including information, social services, and the possibility that the trial vaccine could prevent HIV; and altruism. Deterrents included: dislike of needles; distrust; concern about future consequences of participating. In addition, contingencies, care-giving responsibilities, and convenience issues constituted barriers which could impede participation. Respondents described varied, complex perspectives, and individual cases illustrate how these themes played out as women contemplated trial participation. Understanding factors which influence vaccine research participation among women at 'high risk' can aid sites to tailor recruitment procedures to local contexts. Concerns about future reactions can be addressed through sustained community education. Convenience barriers can be ameliorated by providing rides to study visits when necessary, and/or conducting study visits in accessible neighborhood locations. Women in this sample thought carefully about enrolling in HIV vaccine trials given the structural constraints within which they lived. Further research is needed regarding structural factors which influence personal agency and individuals' thinking about research participation.

1. Introduction

Testing the efficacy of candidate HIV vaccines requires the enrollment of persons at 'high risk' for HIV acquisition into clinical trials [1]. In the United States, most of these trials have been conducted among men who have sex with men (MSM). The U.S. HIV epidemic has shifted to increasingly affect women, in particular African-American women [2]. In order to accurately interpret vaccine effectiveness among diverse populations, women and ethnic minorities are encouraged to participate in clinical HIV vaccine research [3,4]. However, little is understood about the factors which influence African-American women's decisions to participate in such trials.

A significant body of research has examined willingness to participate (WTP) in clinical research, and part of this has focused on ethnic minorities [5,6], in particular African Americans. Barriers to participation include distrust of the medical community based on the history of U.S. racial discrimination, the history of research abuses of African Americans, and contemporary discriminatory experiences within the healthcare system [7–13]. Poor women in particular have been subject to unethical medical and research procedures, including forced sterilization and involuntary drug testing during pregnancy, conducted disproportionately among Black women [11].

Research on WTP in clinical HIV vaccine trials has focused on groups significantly impacted by HIV/AIDS [1,12]. Motivators have included altruism, helping to end the HIV/AIDS epidemic, and personal benefits such as HIV testing, HIV information, protection from HIV, medical care and financial compensation [3,14–21]. Deterrents included concerns about safety, side effects, contracting HIV from the vaccine, vaccine-induced seropositivity (VISP), trust, confidentiality, social stigma, discrimination, family member concerns, insurability, study design, and pragmatic obstacles to participating [4,12,14,15,17,22,23]. However in actual HIV vaccine trials, some

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Table 1
Examples of topic areas and questions from the interview guide.

Establishing rapport and demographic questions
Can you tell me a bit about yourself?
Perceptions of neighborhood-based recruitment strategies
Have you seen or heard about the recruitment van/mobile unit?
What have you heard about this van?
Why do people/you go to the van?
General perceptions of research
Can you tell me what people in this neighborhood/you think of research?
How common is participation in research in your community?
What kinds of research studies would you participate in? Why?
General perception of HIV vaccine research
What do you think of when you heard the word "vaccine"?
What are reasons why people/you would want to participate in an HIV vaccine study?
Perception of participating in actual HIV vaccine research study
Did you have any concerns about going on the van for pre-screening?
When you left the van, did you have the same concerns? Did you have new ones?
Did they give you an appointment for a screening visit? Did you go to it?
What did you think about the informed consent process?
General perceptions of HIV prevention
Do you believe HIV/AIDS is an important issue in your neighborhood?
What resources are available to you to help protect yourself from disease?

sites recruiting diverse populations have reported lower rates of enrollment among women and minorities [3,24], suggesting that factors influencing minority women's participation may be systematically different from those of other groups [25]. This study examines factors associated with participation in an actual HIV vaccine trial among African-American women in Philadelphia.

2. Materials and methods

As part of a multi-site trial by the HIV Vaccine Trials Network (HVTN), Philadelphia was one of several sites targeting women [26]. This site recruited women at 'high risk' of HIV infection due to drug and/or sexual risk behaviors occurring in neighborhoods with high HIV prevalence, which were predominantly African American. Women were pre-screened for behavioral eligibility for participation in the vaccine trial on a mobile assessment unit (MAU) in community locations accessible to drug-using women. Eligible women were invited to a screening visit in our clinical offices. Few challenges were involved in pre-screening activities; however, many eligible participants missed screening and enrollment appointments.

In 2005–2006, in-depth interviews were conducted among 17 African-American women who had pre-screened eligible for the vaccine trial to inform recruitment efforts. All used crack cocaine and/or exchanged sex for money or drugs. Respondents were recruited in-person via purposive sampling in neighborhoods where recruitment took place, at mobile recruitment sites, or in the vaccine trial site's clinical offices based on their ability to provide rich information from a range of perspectives about the main research questions [27] of how women view research and why they do/do not participate in trial activities.

This study was approved by the University of Pennsylvania Institutional Review Board. All participants gave informed consent. Confidential semi-structured interviews were conducted in an open-ended manner by trained interviewers/ethnographers (one white female and one black male) in private spaces in the MAU or research office. Interviews lasted an average of 44 min, and participants received $20 and two public transportation tokens. See Table 1 for an overview of main research questions. Data were collected until interviews generated little new information regarding the main research questions [28]. Interviews were digitally recorded and transcribed verbatim.

Table 2
Characteristics of sample ($N = 17$).

Characteristic	Number	Percent
Sex		
Female	17	100
Race/ethnicity		
African American	17	100
Education		
High school diploma/GED	11	64.7
Less than high school	6	35.3
Participation status		
Pre-screened	17	100
Screened	5	29.4
Enrolled	1	5.9
Willing to participate in trial		
Yes	9	52.9
No	4	23.5
Undecided	4	23.5

	Mean
Age	36.4

Table 3
Willingness to participate and study status.

Number	Age	Willingness	Screened	Enrolled	Reason not enrolled
1	37	Not willing	No	No	NA
2	33	Not willing	No	No	NA
3	36	Not willing	No	No	NA
4	33	Not willing	No	No	NA
5	38	Willing	No	No	NA
6	42	Willing	No	No	NA
7	40	Willing	No	No	NA
8	33	Willing	No	No	NA
9	40	Willing	No	No	NA
10	40	Willing	No	No	NA
11	31	Willing	No	No	NA
12	36	Willing	Yes	No	Medically ineligible
13	37	Willing	Yes	Yes	NA
14	27	Undecided	No	No	NA
15	39	Undecided	Yes	No	Medically ineligible
16	45	Undecided	Yes	No	Refused vaccination
17	31	Undecided	Yes	No	Fear of VISP

Multiple reads were conducted of all transcripts by the first and second authors to identify primary themes based on the study goals. Summaries were written of each interview, and preliminary findings were discussed among trial recruitment staff experienced in working and/or living in the neighborhoods where recruitment took place. A code list was generated based on these processes. Codes were applied to relevant text segments by the first author using ATLAS.ti qualitative data management software [29]. Coded quotations were subsequently reviewed within the context of the full interview to verify their interpretation.

3. Results

The majority of the sample ($N = 17$) were over 30 years of age (mean = 36.4 years) (see Table 2), and nearly evenly divided between those who reported being willing and those either undecided or unwilling to participate in the vaccine trial (see Table 3). Only one went on to enroll in the vaccine study. The majority of interviewees expressed positive views of medical research in general, for its ability to lead to cures and treatments for illness, and some had participated in research in the past. However, a minority held negative views and discussed reasons to view research with caution.