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

Chelsea D. Voytek[a], **Kevin T. Jones**[a], and **David S. Metzger**[a]
[a]HIV/AIDS Prevention Research Division, University of Pennsylvania

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, caregiving 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.

Chelsea D. Voytek, MPH (Corresponding author / address for reprints) HIV/AIDS Prevention Research Division University of Pennsylvania 3535 Market Street, Suite 4000 Philadelphia, PA 19104 USA Phone: 001-215-746-3711 Fax: 001-215-746-7377 chelseav@mail.med.upenn.edu .
Kevin T. Jones, MEd, MPH HIV/AIDS Prevention Research Division University of Pennsylvania 3535 Market Street, Suite 4000 Philadelphia, PA 19104 USA Phone: 001-215-746-7304 Fax: 001-215-746-7377 kevintj@mail.med.upenn.edu
David S. Metzger, PhD HIV/AIDS Prevention Research Division University of Pennsylvania 3535 Market Street, Suite 4000 Philadelphia, PA 19104 USA Phone: 001-215-746-7346 Fax: 001-215-746-7377 dsm@mail.med.upenn.edu

Contributors/Authorship: David S. Metzger and Chelsea D. Voytek conceived the study. Chelsea D. Voytek designed the study; collected, coded, and analyzed data; and drafted the article. Kevin T. Jones collected and analyzed data, and revised the draft critically for important intellectual content. David S. Metzger contributed to data analysis and revised the draft critically for important intellectual content. All authors approved the final version for submission.

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Keywords

HIV vaccine; research subject recruitment; willingness to participate; African-American women; drug use; qualitative research

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 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 minutes, 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.

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.

3.1 Motivators for trial participation

Major motivators included financial compensation, perceived personal benefits, protection from HIV, and altruism.

3.1.1 Compensation—All respondents in this sample cited financial compensation as a motivator. A few suggested that responding to interview questions was an acceptable, alternative to other common income-generating activities in their neighborhoods.

> What's to taking a little couple of minutes out their time to come down here to answer questions for money instead of standing out there tricking?…So I think it benefits some of the girls out there to come here.

33 y.o. woman

One woman learned of the study from a friend when she was cooking a big dinner for her daughter's birthday and needed money to complete the meal:

> I said [to my friend], "What I got to do? What kind of shit am I getting myself into up in there?" She said, "No, it's a survey. They just ask you about your sexual preference, your choice of high and stuff like that." I said, "Oh, that's no problem."

39 y.o. woman

3.1.2 Personal benefits—While most interviewees approached the study initially because of the compensation, several were also motivated by additional perceived benefits. These included the opportunity to gain information on health and HIV/AIDS, and the opportunity to talk to a supportive person.

> People are just trying to get to know what is going on with their health, basically. That's how I look at it…When I went there… I was thinking about the tokens, money in my pocket to eat with, and knowledge.

36 y.o. woman

> At the time I just was stressing…I needed to talk to somebody, so it wasn't all about the money because I had money.

33 y.o. woman

Several women perceived that contact with the research project could increase access to social services and other benefits. Some believed the trial could provide a "wake up call" about their current risky/unhealthy behaviors.

> When you run the streets… these studies… give people the incentive like to do better…Because… the more information you get…it starts to embed in you and then you start to think …Being updated on the AIDS virus … gives me the incentive maybe to just… take my time and think about some of the shit that I do.

40 y.o. woman

A few were motivated partially by the idea that the trial vaccine might help prevent them from getting HIV:

> I've dated guys that have shot drugs…and…who knows? I may come up with the virus couple of years from now… (I'd participate) I guess just so I won't get the virus.

40 y.o. woman

3.1.3 Altruism—Another motivator was the opportunity to help others prevent HIV. About half of the sample mentioned having close friends or family members who were living with HIV or had died of AIDS, which in some cases influenced respondents' WTP.

> About 50 some percent is about the dollars, really. But…for me… I'd have to say less than 50… because I have a family member that I love very dearly that has contracted HIV and is full blown now…It's destroying him.

37 y.o. woman

3.2 Deterrents to trial participation

Major deterrents regarding further trial participation included dislike of needles, distrust, concern about potential future consequences, contingencies, commitments, and convenience factors.

3.2.1 Needles—Needle aversions applied to blood draws as well as injection with the trial vaccine. Most women were willing to participate in research involving surveys or interviews, but several would not participate in a clinical study.

> No swabs, no needles…don't put nothing on my skin…The only thing the university get out of me is a conversation.

45 y.o. woman

3.2.2 Distrust—A minority was distrustful of recruitment activities and/or the vaccine trial, and some described themselves as being skeptical by nature.

> I really thought they was just taking people that didn't know no better off the streets to give them information that we're not really sure about…because we're addicts and we don't really know what we're getting ourself into.

35 y.o. woman

One participant discussed the historical Philadelphia prison experiments which were associated with the University of Pennsylvania [30], and two knew others who participated frequently in research and looked ill, which they blamed at least partly on research. However, distrust was most commonly voiced regarding the trial vaccine. Some respondents had doubts about what was known or being disclosed about the vaccine, and they wondered whether it contained HIV or could cause HIV infection.

> I don't know what they're injecting you with…It could be a placebo. (Or) it could be HIV.

45 y.o. woman

Several expressed wariness about being used as a "guinea pig", "lab rat", "test dummy", or "research monkey" for this reason.

> I ain't no guinea pig… I'm not getting stuck with no needles or…no vaccination that they don't even know what it is. They don't know if it's preventing AIDS or not. So I'm supposed to take a chance?

33 y.o. woman

3.2.3 Future consequences—Some respondents worried about potential short-term side effects. One woman (age 33) said that, "the symptoms that come with it" were "probably what would make me not really want to do certain researches [sic]…'Cause… I don't like feeling sick at all." When asked whether she would participate, she said, "I ain't decided yet…I want to take this (consent form) home to my mom, let her read this and what you was telling me… and see what we come up with." Others feared unforeseen severe reactions that could have significant repercussions in the future:

> I can't do it…Because ten years from now… I might be sick from that stuff…I don't want to sacrifice myself.

45 y.o. woman

In addition, some interviewees expressed concern about known potential consequences of participating, such as VISP.

3.2.4 Contingencies, commitments, and convenience—Beyond beliefs and perceptions that influenced WTP, some respondents described barriers which could impede their participation in the trial. Unexpected events such as illness, incarceration, oversleeping, or forgetting about a scheduled appointment could prevent respondents from attending appointments. When asked why she did not attend an office visit, one woman replied:

> After seeing you, I lost the paper and I didn't know what I was supposed to do from there… And I told you before, I was in the hospital and then I went to jail.

28 y.o. woman

Meetings with parole officers and court dates could have a similar effect. A few interviewees were caregivers to children or older relatives, and these commitments could also interfere with study appointments.

> They gave me another appointment…I wasn't able to go to…Because I had…a doctor's appointment I had to go to with my oldest daughter.

33 y.o. woman

> It's not hard (to get to the office). It's just that I watch my aunt every day now… The nurse comes for about an hour and half. I watch her until…somebody else comes and takes my place…just about all day.

40 y.o. woman

Convenience (location and time) was also a consideration among this sample. This is perhaps even more important because of the contingencies and commitments discussed above, which might further limit the time women could be away from their neighborhoods and the economic or care-giving activities they engage in there, and consequently the distance they could travel conveniently.

> …how far I may I have to go, what days would I be home, what time you want me there…Convenience, that's all that matters.

28 y.o. woman

3.3 Individual cases

To illustrate the complexity of respondents' views and the sometimes unpredictable ways in which they played out, we will discuss three individual cases. Each refers to themes reported above in isolated descriptions, then shows how these themes linked to one another as women grappled with decisions of whether to enroll in the trial, as well as factors beyond their control which may have limited their participation.

3.3.1 "Karen"—"Karen", age 39, was at first adamantly opposed to participating in the vaccine trial, though she reported that her experiences with recruitment had been "alright" and that research in general was "very good". She remembered the Philadelphia prison experiments, and felt that AIDS was created by people whose job is to create "germs and stuff".

> I truly believe it is a man-made disease. That's why I will not take any investigational medicine because I'm afraid.

She came to the clinical office because she wanted to learn more; she elaborated:

> You give me ten dollars, I want to know why…you're giving me this money… And it wasn't about the (compensation)…I'm greedy for knowledge; I'll put it to you like that.

"Karen" said she understood the concepts of control group and how the vaccine trial was designed, because she reads a lot. Then, despite her earlier statements, she began to express interest in participating in the trial:

> Now…I'm really pulling with myself to take it, try it… and it's a hard, hard decision.

And later:

> It's going to take me a lot of thought…and I'm going to go home and go over these papers with a fine-toothed comb…because I can do things better on my own time

> by myself…this is something that I would have to talk to my boyfriend about and my family…before I just go ahead off and do it…because I don't know what my reaction may be; I might die.

"Karen" came in the following week, screened, and was determined medically ineligible for the trial. It is unclear if she would have enrolled otherwise.

3.3.2 "Lisa"—"Lisa", age 31, had positive experiences with the same researchers in the past and said she would participate this time for the "help" available at the study:

> Like they there to help you…But they also…trying to find some things out about us too… coming to some type of conclusion and some type of science…I don't feel like I'm no research monkey…but… people …be saying that on the street.

She went on to say, about participating in research studies:

> I have gotten a lot out of it…because I was in a (study) before… they had assisted me in getting clean before I relapsed…They helped me with my housing…And then…I still benefit from it as far as… if there was something going on, I could just ask anybody in here for assistance. I really believe that if I were in need, they would assist to the best of their capability.

However, she went on to talk about issues which would deter her from participating in an HIV vaccine trial.

> In the (informed consent) form it states that if you went some place else to take a HIV test, it's like 99.5% possible that you could turn up HIV positive even though you really…wouldn't be HIV positive…I'm not gonna accept something like that…'cause…when… it is noted that you have HIV, you go through a lot. The Health Department comes to see you…employers might not want you…you could be trying to do anything and that just 'you have HIV' thing… ruin everything.

Prior to the interview, "Lisa" was making urgent calls to have her children picked up from school during a public transportation strike at the time. She said, "only thing I think real hard on is my kids, like my house and stuff like that. Anything that's like life situation." Finally, after screening, and multiple conversations with staff, "Lisa" decided not to enroll in the trial. Her primary reason was the risk for VISP.

3.3.3 "Denise"—"Denise", age 37, learned about the study from a friend and described positive experiences with the recruitment process. She had participated in other studies in the past. Her uncle was at the time dying of AIDS, and she said she would participate to get information on HIV/AIDS prevention and care, and in the hope that the trial vaccine would protect her from HIV/AIDS:

> I be promiscuous too. So (if)… it could prevent me from getting it, I'd rather do the research…Anything to prevent me from straight up signing my death certificate.

When asked about reasons why she would not participate in research, she replied:

> You know how they say some vaccines, like… the flu shot, how it can give you the flu? …That why I asked about three, four times, "will this vaccine give me the virus?"…That's my concern.

Though she lived far from the clinical office, and initially expressed anxiety since she was unfamiliar with the area, "Denise" screened and enrolled in the vaccine trial. She is the only person in this sample who accepted the trial vaccine.

4. DISCUSSION

The data reported here describe a diversity of perspectives about HIV vaccine trial participation. Rather than eliciting dichotomous views regarding being willing or unwilling, respondents' views were complex, and a range of issues factored into decision-making with the potential that women would opt out at various points. Many motivators and deterrents were similar to those found in other studies regarding participation in HIV vaccine [3, 12, 14, 17, 19], suggesting that many groups have similar considerations overall, though the degree to which these considerations ultimately influence participation may differ. Most held positive views of the study's recruitment procedures, and mentioned various motivators for participating. However, the majority were ultimately deterred by concerns about research procedures, potential consequences of participation, and/or their ability to attend study appointments.

Our findings show that women in this sample think carefully about enrolling in HIV vaccine trials given the structural constraints within which they live. Uncertainties about unforeseen consequences of participation may be particularly important among women with few economic or social resources to fall back on if they experience a medical problem. Poor women may be particularly concerned about the potential for illness that may lead to a loss of ability to support their selves and/or fulfill their familial responsibilities [4] in the short or long term. Perhaps this figured into their far-sighted thinking about potential future consequences of trial participation. Participants in previous trials have experienced negative social impacts related to personal relationships, and even areas with high AIDS case rates may not have high community-level knowledge about HIV vaccine research [31]. Several respondents said they would talk about participating with loved ones before making up their minds, but unfortunately many women's comments implied the presence of research distrust and/or misinformation among their social networks.

Though these women's decisions about research participation appeared largely to be in line with current standards of autonomy, in some cases motivations were based on false assumptions or alternative interpretations of study procedures. A minority were motivated to participate by the hope that the investigational vaccine could help prevent them from getting infected with HIV. This has been reported to be an issue in previous HIV vaccine trials [19, 20, 32, 33]. Though the informed consent process for screening explicitly stresses that it is not known if the trial vaccine will prevent HIV or not, those who only behaviorally screened may not have had as detailed of discussions. In addition, several people perceived that there were social services to be gained from engagement with the vaccine trial. Though informed consent emphasizes that participants "receive no direct benefit" from participating, some women believe that research interactions do benefit them. Being motivated to participate in an HIV vaccine trial by potential personal benefits has been reported as more frequent among women, people of color, those with lower educational attainment, and those reporting unprotected anal or vaginal intercourse in the last 6 months [19]; it was also reported as a motivator among non-Black MSM [20].

The fact that these women perceive that they need to take part in research to obtain information, support, or social services may belie a lack of comprehensive HIV/AIDS information, as well as other available services which they feel comfortable accessing, in their communities and/or the difficulties of maintaining supportive relationships in a drug-using context. The degree to which poor women may rely on research to fill in for absent public services raises questions about the voluntary nature of research participation. As Colfax et al. have argued, public health efforts to ensure that potential HIV vaccine trial participants have access to HIV prevention services and medical care outside of clinical trials may alleviate such tensions [19].

While several participants asserted that they were not solely motivated to take part in the study by money, in some cases, the way they talked about the compensation suggests that it was significant in their lives, and may have been difficult to turn down. For example, when women talked about having money to eat with or to cook a child's birthday meal, this small compensation becomes quite meaningful. Many of these comments were specific to the compensation received for a short pre-screening interview in a community-based location. Judging from the relatively low rates of follow-up, the various considerations involved in participating further in the HIV vaccine trial may have outweighed the influence of compensation on participation.

Limitations in this study include the small sample. Results cannot represent all women eligible to participate in the HIV vaccine trial. Interviewees were recruited, in most cases, when it was not clear whether they would continue, or be eligible to continue, participating in the vaccine trial; therefore, the perspectives of women who screened and enrolled, as well as people who did not participate in trial activities at all, are not well represented. Member checking was not conducted, which is also a limitation. However, per our study aims, results provide rich data on the beliefs and understandings with which women consider participation in HIV vaccine trials. Although the questions asked in this study were not directed at understanding WTP in trials of other biomedical HIV prevention interventions, it is likely that similar factors could apply to women's WTP in other biomedical intervention trials.

4.1 Conclusions

Understanding factors which influence vaccine research participation among women at 'high risk' can aid sites to tailor recruitment procedures to local contexts. The goal is not to convince unwilling women to take part, rather to address concerns and barriers to make clinical research better understood and more convenient to women at risk for HIV acquisition. Concerns about future reactions can be addressed through sustained community education and informed consent which continues to address safety and side-effects of relevant HIV vaccine studies. Convenience barriers can be ameliorated by providing rides to office visits when necessary, and/or conducting clinical study visits in more accessible neighborhood locations. While distrust did not preclude most respondents from learning more about the study, it remains salient among African-American women and their social networks and must continually be addressed in clinical trials, as well as future vaccine rollout if and when a safe and effective HIV vaccine is found.

Further research is needed regarding community-level influences on WTP in HIV vaccine research and the structural factors which influence personal agency and individuals' thinking about research participation, particularly in light of the tenuous financial situations that the women in this study were living in. Researchers must continue to interrogate the ethical dimensions of recruitment practices and research participation when recruiting impoverished and socially marginalized people into research.

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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?

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 vaccinaton
17	31	Undecided	Yes	No	Fear of VISP