

Why Blacks Do Not Take Part in HIV Vaccine Trials

Demetrius L. Moutsiakis, MD, MPH and Nancy P. Chin, PhD, MPH

Buffalo and Rochester, New York

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Background: AIDS is still a major cause of death. To combat this disease, researchers are developing a vaccine. Although blacks account for most new infections in the United States, they account for a low percent of experimental vaccine recipients. This study, conducted in a mid-sized U.S. city where vaccine trials are held, seeks to learn why.

Methods: We conducted 11 in-depth ethnographic interviews. Two groups were targeted: blacks who had not participated in HIV vaccine trials and blacks who had.

Results: Overall, three major causes of nonparticipation were identified: misinformation, fear/mistrust and stigma. Factors that favored participation included having close friends with HIV and being homosexual.

Conclusions: HIV is considered by many blacks to be a gay, white disease. Steps to increase participation must include efforts to destigmatize the condition and disseminate accurate information. Efforts to address historical causes of mistrust through "education" alone are insufficient. Trust needs to be earned through long-term relationships with black communities.

Key words: HIV vaccine trials ■ African Americans ■ mistrust

© 2007. From the Department of Community and Preventive Medicine, University at Buffalo (Moutsiakis), Buffalo, NY; and Department of Community and Preventive Medicine, University of Rochester, Rochester, NY (Chin). Send correspondence and reprint requests for *J Natl Med Assoc.* 2007;99:254-257 to: Dr. Nancy P. Chin, University of Rochester, Department of Community and Preventive Medicine, Rochester, NY; phone: (585) 273-2586; e-mail: nancy_chin@urmc.rochester.edu

INTRODUCTION

Acquired immune deficiency syndrome (AIDS) remains a major cause of death throughout the world.¹⁻³ Efforts to develop a vaccine have been a key to halt the virus that causes this disease.⁴ Traditional approaches such as whole, killed or attenuated

live virus appeared inadequate; the accidental introduction of live virus could mean an adverse event not only for the vaccine recipient but also for a large cohort of sexual or IV-drug using partners.⁵ Current approaches using such factors as recombinant protein, synthetic peptide or recombinant live vector vaccines have been used safely⁶ and are currently in clinical trials.

Vaccine efficacy must be tested in a variety of groups. Consider *hemophilus influenzae B* (HiB) conjugate vaccine capsular polysaccharide (PRP): estimated initially to have >90% efficacy in Finnish infants,⁷ it was found to have only 35% efficacy in Alaskan natives.⁸ Similarly, Navajo children experienced significantly less responsiveness to PRP outer capsule than white children.⁹

Despite their being affected by human immunodeficiency virus (HIV) more than whites, blacks in the United States do not take part in HIV vaccine trials at the same rate as whites.^{10,11} African Americans currently account for roughly 14% of the population,¹² but 47% of the total AIDS-related deaths in 2000,¹³ 49% in 2001¹⁴ and 51% in 2002.¹⁵ Nevertheless, blacks are consistently underrepresented in vaccine trials.^{16,17} According to a report of the National Institute for Allergy and Infectious Disease (NIAID) AIDS vaccine trials, out of >1,300 volunteers, only 115 (9%) were black.¹⁸ In another study, there were only eight blacks in a sample of 140 subjects.¹⁹

The hypothesized causes for low enrollment of blacks in HIV vaccine trials can be divided into two categories: those common to all clinical trials, and those unique to HIV vaccine trials. Mistrust by blacks of medical research is due in part to the Tuskegee Study of Untreated Syphilis in the Negro Male (Tuskegee Syphilis Study); other sources may include the legacy of slavery.^{20,21} Furthermore, in ≥ 1 clinical trial of HIV medications, the odds of participation by blacks were about one-half that of whites.²²

As a result of Tuskegee and the National Research Act that followed, institutional review boards were created to protect the rights of human research subjects.²³ It was stipulated that, for a study to be generalized to a

population, its participants must be representative of all within that population. Now, when results of a study with insufficient minority representation are published, they are published with the caveat that the findings may not be generalized.^{24,25}

Additional causes of underenrollment are conspiracy theories. In a 1994 study, 20% of blacks as compared to 4% of whites agreed with the following statement: "The government is using AIDS as a way of killing off blacks."²⁶ In 2003, the authors report that 52.9% of blacks believe "there is a cure for AIDS, but it is being withheld from the poor."²⁷ Until such conspiracy theories can be dispelled, difficulties in increasing participation will continue.

The purpose of this paper is to learn why, in a city conducting HIV vaccine trials and attempting to address barriers to minority recruitment, blacks still do not take part in HIV vaccine trials. The paper also seeks to identify steps to increase their participation.

METHODS

To learn why blacks do not take part in HIV vaccine trials, in-depth ethnographic interviews were conducted from May to November 2004 in a mid-sized U.S. city currently conducting HIV vaccine trials. Two groups were targeted: blacks who had participated in HIV vaccine trials (V) and those who had not (N).

Criteria for participation included the following: the subject must be black, be ≥18 years of age, be willing to spend the required time to conduct the interview and verbally consent to being interviewed. The first group comprised subjects, regardless of HIV status, who had not taken part in any HIV vaccine trial. The rationale for including subjects in the first group was simple: because it is at least theoretically possible to recruit HIV patients in a vaccine trial, their a priori exclusion appeared unwarranted. The second group comprised subjects who had participated in ≥1 HIV vaccine trial. Participants were recruited and interviewed at both

medical and nonmedical sites.

Open-ended interviews of blacks inquired about such topics as knowledge and impressions of clinical trials and vaccines, personal experiences with HIV/AIDS, potential causes of poor recruitment of blacks for HIV/AIDS vaccine trials, steps to increase participation by blacks in HIV/AIDS vaccine trials, and the opinion of friends and family regarding participation. In addition, blacks who had participated were asked about their experiences with HIV/AIDS vaccines and reasons for taking part in vaccine trials.

All interviews were recorded with the permission of the respondent. The authors independently analyzed the transcripts for recurring themes, events and concepts, and grouped them in overarching explanatory themes. New follow-up questions were added to the interview guide as unanticipated issues arose from the data. Sampling was purposive, rather than random, and sought to identify a wide variation in experiences.

RESULTS

Participant characteristics are shown in Table 1. Attempts were made to include a wide spectrum of volunteers, rather than simply medical personnel. As can be seen from the table, volunteers came from a diverse background. Overall, three causes of poor participation by blacks in HIV vaccine trials were identified: misinformation, fear/mistrust and stigma.

Misinformation

Feelings regarding clinical trials from blacks who had not participated in HIV vaccine trials ranged from confusion to frustration and uncertainty. N2 stated: "I don't quite understand these clinical trials. Can you explain it?" N8 stated: "I think [clinical trials] are important, [but] that general information needs to be more user friendly. Language and jargon have the tendency to intimidate people." Few nonparticipants outside the medical profession knew much about clinical

Table 1. Demographic data for participants

	Age	Gender	Marital Status	Socioeconomic Status	Took Part?	Education Level
N1	59	M	Single	Low	No	HS
N2	45	F	Divorced	Low	No	HS
N3	27	M	Married	Low	No	HS
N4	33	F	Married	High	No	MD
N5	29	M	Single	Middle	No	BS
N6	27	F	Single	High	No	MD CAND
N7	25	F	Single	High	No	MD/PhD CAND
N8	50	M	NA	Middle	No	AA
V1	38	F	Single	Middle	Yes	ABA
V2	63	M	Single	Low	Yes	HS
V3	65	M	Single	Middle	Yes	MSW

NA indicates data not available; Highest education level achieved indicated as high school (HS), associate's degree in arts (AA), associate's in business administration (ABA), bachelor's degree in science (BS), master of social work (MSW), doctor of medicine (MD) or doctor of philosophy (PhD). CAND indicates candidate for said degree.

trials in general or HIV vaccines in particular. N5 mistakenly believed: "With the vaccine, you want [to treat] the people that are already sick." Even those blacks with a strong medical background were still very reluctant to participate in HIV vaccine trials.

Blacks who had participated in HIV vaccine trials also had limited knowledge of clinical trials. Knowledge of vaccine protocol appeared good, though. V3 stated: "The injection is made in the laboratory. I have no fear of contracting HIV." V1 added: "I went beyond my fear and got the information for myself." Both V1 and V2 consider misinformation a factor limiting participation.

Fear/Mistrust

Fear came in many guises. N2 stated: "I just don't like being shot. I don't like needles." N4 stated: "[Experimental vaccines] are a bit of a quandary, because the vaccine has to be proven safe [first]." N8 stated: "When you look at slavery ... blacks were called three-fifths human beings. It was easy to deprive African Americans of treatment." He continued: "It is also mistrust. [People] feel like they do not participate in many of the studies because of years and years of racism." N3 stated: "Why would [blacks] start trusting [whites] ... after they lynched us, burned us, murdered us ... being in the Tuskegee experiment." Those who took part in HIV vaccine trials stated: "I got some very negative responses like 'Oh, you don't know what you're getting into.'" [V1] or "They were primarily concerned that I was being used as a guinea pig."

Several had mentioned conspiracy theories. N1 stated: "[Conspiracy theorists think] the vaccine is going to make them sick ... they are going to catch [HIV]." Members in all groups mentioned the term "guinea pig," usually when describing attitudes of others. N3 stated: "Guinea pigs are considered expendable." N6 added: "I don't want to be the guinea pig!" V2 stated that conspiracy theories were a factor limiting black recruitment. However, V1 said: "I was never a guinea pig. I always had a choice to do this. I made the decision."

Stigma

Several people felt a stigma associated with participation. The stigma was a complex intertwining of the disease itself and being gay. N8, a heterosexual who contracted HIV through IV drug abuse, stated:

AIDS bothers them because [of] the current stigma around AIDS. Many African Americans look upon it as a gay disease. In the African-American community, people talk about people in a negative way about HIV. Black political leaders need to talk about it openly."

V3 stated:

The stigma was that there was something wrong with me ... they would catch the disease [from me]. A lot of people just didn't want to believe that I was homosexual. First of all, you're black. They couldn't believe I was homosexual because my father was a minister. They have to pray for me, because clearly it's the devil that has gotten into me.

Factors Favoring Participation in HIV Vaccine Trials

Reasons for participating seemed to center around a sense of purpose. V3 stated: "For me, [the HIV vaccine trial] is a memorial to my friends who died from the disease ... to do something to help eradicate the disease." V2 stated: "I thought about my brother who died with AIDS." Those who participated identified several persons who had died of HIV/AIDS. V3 stated: "I certainly had lots of friends who died of AIDS." V2 reported at least one brother and his male partner both died of HIV/AIDS.

All three that had participated in HIV vaccine trials were openly homosexual and HIV negative. By contrast, all who had not taken part self-identified as heterosexual. When asked how HIV affected her, N6 replied: "Personally, it has not." Of all who had not taken part in HIV vaccine trials, only N8 identified persons, including himself, as HIV positive. "I have lost so many friends, a brother ... so many senseless deaths." N8 noted, however: "Many years ago, I was infected by intravenous drug use."

Steps to Increase Participation by Blacks in HIV Vaccine Trials

Blacks who had not participated in HIV vaccine trials mentioned several possible steps to increase participation. These included distribution of materials at church meetings, clubs and buses, and presentations at town meetings. N8 mentioned "a separate outreach component where [an African-American peer] actually goes to the churches, the barber shops, and recruits people."

Those who had participated mentioned their being used as spokespersons in the black community at large. V3 stated: "When people come in for AIDS information, or AIDS testing ... it is a great opportunity to talk to them about being part of a trial." He continued: "I would start one step back from the actual recruitment ... by trying to promote good will among blacks in the community, to ameliorate or do away with the historical mistrust."

DISCUSSION

Participants identified three reasons blacks do not take part in HIV vaccine trials: misinformation, fear/mistrust and stigma. Misinformation related to both HIV and vaccine trials. One example of misinformation is the notion of HIV being a white, gay disease, despite the fact that over half of all new cases in this country are black, and many of those the result of IV drug abuse.²⁸

Fear came in many guises; the resulting mistrust by blacks continued to play a major role.²⁹ Stigma was associated with a black person's taking part in an HIV vaccine trial and being gay.

Several persons have suggested flyers, church meetings, youth groups or incentives to increase participation. While all these efforts have merit and deserve attention, all suffer from the same flaw: they do little to ameliorate either historical mistrust or misinformation. These must be addressed.

One possibility has black, HIV-positive heterosexuals speaking to youth groups to let them know that HIV is a disease not simply of gay, white males but of blacks and whites, gay and straight. HIV is colorblind. HIV does not care if one is gay or straight.

Some more results were obtained from this study. For example, being heterosexual could be considered a negative risk factor for participation in an HIV vaccine trial, despite the fact that many new HIV cases among blacks are among IV drug users and their partners. In addition, extensive medical knowledge may be a hindrance to participation. Although the sample admittedly was small, not a single medical professional in the vicinity who spoke to me volunteered to take part in an HIV vaccine trial. By contrast, none of the volunteers who had taken part in HIV vaccine trials demonstrated extensive knowledge of clinical trials.

There were several limitations to this study. First, the sample size was small. As a result, the findings may not extend outside the target city. Since finding blacks who had taken part in HIV vaccine trials proved difficult, the ability to generalize their findings to either the black population or the nation fell into question. Some have asserted that quantitative data are the only data of interest; there is no role for qualitative studies. What we need first is hypothesis generation. Qualitative data are needed for hypothesis generation; quantitative data are then used to test hypotheses.

Despite these limitations, this study raises important points. The cause of poor participation by blacks in HIV vaccine trials is some combination of misinformation, fear/mistrust and stigma associated with the mistaken notion of HIV as a gay, white, male disease. One way to address this issue is to recruit heterosexual, HIV-positive blacks who could provide not only cautionary evidence of the dangers of HIV infection but also a famous face that one could fight for. More study and more action must be done. Status quo is not an option.

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