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Breaking the Silence: What Homeless 18- to 24-Year-Olds Say about HIV Vaccine Trials

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Abstract: Development of a global HIV vaccine will require enrollment of a large number of adults and adolescents in clinical trials. Involvement of homeless young adults in these trials will be particularly important because they often practice high-risk behaviors and are disproportionately infected by HIV. This qualitative study explores factors that might affect future participation of homeless 18- to 24-year-olds of diverse racial/ethnic backgrounds in HIV vaccine trials (HIVVTs). Twenty males and females attended focus groups. Participants expressed concern about seroconversion, the trustworthiness of the researchers and/or government agencies conducting trials, vaccine side effects, and possible negative behavior change as a result of being vaccinated. Understanding the personal perspectives of high-risk young adults will enable researchers to tailor protocols to their individual needs and cultural values and, in so doing, potentially enhance willingness to participate in HIVVTs.

Key words: HIV vaccine, homeless young adults, vaccine trials.

In 2003, about 50% of new HIV infections worldwide were among 15- to 24-year-olds, and 12.4 million adolescents and young adults, at least half of them female, were living with HIV/AIDS.¹ Including this population in clinical trials is an important step toward promoting its immediate access to an effective AIDS vaccine when available.² Expert consultants to the Centers for Disease Control and Prevention have recommended that young adults at high risk for HIV infection be targeted in preparation for HIV vaccine implementation.³ The Adolescent Medicine Trials Network for HIV/AIDS Interventions, funded by the National Institutes of Health, is mandated to develop and conduct therapeutic and vaccine trials involving pre-adolescents, adolescents, and young adults up to 25 years of age.⁴

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Although adults have participated in several studies examining HIV vaccine preparedness, a comprehensive literature review found little research in this area focused on homeless young adults. Yet, understanding the attitudes and beliefs of this population about participation in HIV vaccine trials (HIVVTs) and the potential effects of their involvement on risk behaviors is crucial for planning and implementing effective clinical trials. This study explores factors that might affect future participation in HIVVTs of homeless 18- to 24-year-olds of diverse racial/ethnic minority backgrounds.

Limited available data suggest HIV rates are disproportionately high for homeless adolescents and young adults. In a New York study, 5.3% of homeless 15- to 20-year-olds were reported to be HIV positive, compared with .06% of age-matched non-homeless peers.⁵ Rates as high as 12% (19.5% of males) were found for homeless 14- to 20-year-olds in a clinic-based San Francisco study.⁶ Similar seroprevalence rates have been reported for 14- to 24-year-old street youth in Hollywood, California.⁷

Several factors place homeless adolescents and young adults at increased risk for HIV infection. Of a sample of runaway and homeless 12- to 19-year-olds in three cities, 98% were sexually active; survival sex (i.e., sex exchanged for food, shelter, drugs, or protection) was common; and 75% said they had had sex while under the influence of alcohol or drugs. Substance abuse rates ranged from 70–90%, increasing with age and duration of homelessness.⁸ In Los Angeles, the site of the present study, previous research has shown that 71% of homeless people ages 12–23 years have a drug and/or alcohol abuse disorder; 30% use injection drugs, and 59% of the latter group report sharing needles.⁹

Few studies examining interest and willingness to participate (WTP) in HIVVTs have specifically targeted adolescents and/or young adults. Factors influencing willingness to be vaccinated for HIV have been explored with college students^{10–13} and adolescents attending community health clinics.^{14,15} Self-administered questionnaires have frequently been administered to predominantly White samples, limiting generalizability of findings and the opportunity to understand issues from the perspective of participants. Health beliefs such as perceived HIV susceptibility, non-membership in a traditionally defined risk group (e.g., gay men), and fear that the vaccine could cause AIDS reportedly are independent predictors of intent to be vaccinated.^{13,16} Vaccine characteristics such as efficacy, type, and cost strongly influence acceptability.^{11,14} Likelihood of getting immunized for HIV correlates negatively with perceived stigma of being vaccinated, and positively with prior sexual activity.¹¹ HIV-related risk behaviors also are expected to increase among adolescents receiving an efficacious vaccine.¹⁵

Murphy and colleagues¹⁷ evaluated use of a simplified consent form developed for adolescents, compared with the standard version of the HIVNET prototype HIV vaccine process. Data from 15- to 19-year-olds in three cities revealed that those who received the simplified version had significantly higher comprehension scores. However, the key concept that the vaccine cannot cure HIV was not clearly understood by either group, and WTP decreased overall from 80% to 60% from pre- to post-presentation, possibly due to a better understanding of potential risks such as false positive HIV tests.

Research examining interest and WTP in HIVVTs in adults has included gay and bisexual men, injection drug users (IDUs), and high-risk women.^{18–23} Findings show that WTP in a hypothetical HIVVT may be influenced by many factors. Among former

participants (N=2,531) in vaccine preparedness trials who were later invited to be screened for a phase 2 HIV vaccine trial, refusal to participate was higher among African Americans, and lower among people older than 40 years, having higher education, or reporting six or more sex partners in the prior six months.¹⁸ Participants from all racial/ethnic groups expressed concerns about vaccine-induced seropositivity, vaccine safety, and potential social harm (e.g., loss of employment, insurance problems, negative reactions from family and friends). African Americans, in particular, expressed a high level of mistrust of scientific research. Motivations for enrollment included a desire to help find a vaccine that works, and helping the community.¹⁸ Findings from other studies similarly show that altruism and being uninsured or covered only by public insurance are motivators for participation in HIVVTs,¹⁴ whereas fear of serious health problems or potential HIV infection is associated with decreased WTP.²⁴

Results of a cross-sectional survey involving a multiethnic adult sample revealed that efficacy had the greatest influence on acceptability of eight hypothetical HIV vaccines, followed by cross-clade protection (i.e., vaccine effective against multiple strains of the virus), side effects, and duration of protection.²⁵ Likewise, low-income adults (predominantly African American and Latino) who participated in focus groups expressed concerns about vaccine efficacy and characteristics, vaccine-induced HIV infection, physical side effects, study demands, stigma, and mistrust of government.²⁶ Motivators for participation were protection against HIV infection, economic considerations (free insurance and/or medical care, monetary incentives), and altruism. Adults, like adolescents, expect increased risk behaviors as a result of vaccination.²⁷

Low-income and homeless minority adults in Los Angeles participated in focus groups as part of a community-based participatory research (CBPR) study.²¹ They expressed interest in participating in future HIVVTs and the desire to have their voices heard by researchers early in the design of vaccine studies.²¹ Their concerns reiterated those reported in other studies (e.g., impact of the vaccine on physical health, possible seroconversion and associated stigma, increased sexual risk behaviors, trustworthiness of government-sponsored research). Motivating factors included access to care, compensation, and altruism.

Methods

A CBPR approach was employed in designing and implementing this study. First, we consulted a Community Think Tank on HIVVT attended by over 50 professionals from the community and the University of California, Los Angeles (UCLA), including academic researchers, administrators, community organizers, and peer advocates. Participants provided a broad range of community perspectives on 1) research questions to be asked, 2) barriers to and facilitators of participation HIVVTs by low-income and minority people in Los Angeles, 3) ways to promote cultural sensitivity in education and intervention programs, and 4) types of questions important to pose in a semi-structured interview guide (SSIG) for use in focus groups. Based on this input, a draft SSIG was developed, and a community advisory board (CAB) composed of four community members and four UCLA investigators was formed. The community representatives were a physician who directed a homeless medical clinic, two workers with expertise

in organizing interventions for high-risk homeless populations, and a peer educator who worked with homeless people. Members of the CAB assisted the researchers in finalizing recruitment site selection and in refining the SSIG, which was pilot-tested with volunteers and revised for cultural sensitivity and linguistic appropriateness.

Participants and setting. Three focus groups were conducted with a total of 20 homeless young adults recruited from 2 drop-in shelters in Hollywood, California. Eligibility criteria included being 18–24 years of age and engaging in one or more of the following high-risk activities within the past 6 months: 1) intravenous drug use, and/or exchange of sex for money or other things; 2) 3 or more sexual partners; 3) sex with an HIV positive person; 4) diagnosis of an STD; and 5) for males, unprotected sex with other men. The participants were 75% male ($n=15$), 20% female ($n=4$), and 5% (one individual) identified as transgendered. Mean age was 20.45 years ($SD=1.47$), and the group was racially/ethnically diverse: 35% African American ($n=7$), 35% White ($n=7$), 25% Other (2 Belizean, 2 multi-ethnic, 1 Tahitian), and 5% Hispanic ($n=1$). Reported risky behaviors in the prior 6 months included unprotected sex with an HIV positive person (15%), diagnosis of an STD (35%), IDU (45%), males having unprotected sex with other males (60% of male participants), and unprotected sex with multiple partners (90%). In addition, 30% reported having had a partner who used injection drugs; 35% indicated they had been forced to have sex on some occasion(s) in the past; 30% were currently in a relationship; and 85% were unemployed.

Data collection procedures. At each site, fliers were posted with information about the focus groups. Interested individuals were invited to attend an information session, at which the project was explained and potential participants were screened for eligibility. During the screening, conducted privately to ensure confidentiality, demographic data were collected using a questionnaire read individually to the participant by a research staff member.

Focus group participants were then randomly selected from the pool of eligible individuals and written informed consent obtained according to approved procedures of UCLA's institutional review board. The focus groups, each having 6–8 participants, were led by trained facilitators. Participants were told that the purpose of the study was to gain an understanding about homeless young adults' attitudes and concerns about participation in HIVVTs. Factual information about HIVVTs (e.g., vaccine characteristics, side effects) was presented at the conclusion of the focus group in order to elicit responses reflecting participants' knowledge at baseline. The 90-minute sessions were audiotaped for later transcription.

The facilitators used the open-ended questions in the SSIG (see Box 1) to guide discussions in the three focus groups. Discussions first focused on attitudes and feelings about participation in HIVVTs, followed by views about being vaccinated once a vaccine is available to the public. Ethnographic observations, guided by methods developed by Johnson and Sackett,²⁸ were recorded on-site, followed by more detailed note writing within 24 hours.

Data analysis. After completion of all focus groups, the audiotapes were transcribed and content analyzed. Inter-rater reliability for content analysis, as assessed by a two-member independent panel, was 88%. Data management and analysis methods, developed by Hymes,²⁹ included reading and re-reading of field note data and transcriptions,

Box 1.**SAMPLE SEMI-STRUCTURED INTERVIEW
GUIDE QUESTIONS**

Topic	Question(s)
Motivations to participate in an HIVVT ^a	<ul style="list-style-type: none"> • What do you know about HIV Vaccine Trials? • What might be some of the reasons that you would want to participate in an HIV Vaccine Trial? • If an HIV/AIDS vaccine trial were available tomorrow, what are some concerns you might have about being a participant in the trial?
Thoughts about a future HIV vaccine	<ul style="list-style-type: none"> • What might be some of the reasons that you would want to be vaccinated against HIV/AIDS [if the US government tomorrow approved the vaccine]? • If an HIV/AIDS vaccine were available tomorrow, what are some concerns you or people like you might have about being vaccinated? • If a vaccine against HIV/AIDS were available tomorrow, do you think you or people like you would change your/their sexual or drug use behaviors? If yes, why? If no, why not?
HIVVT = HIV Vaccine Trial	

coding, and breaking down of information into data segments. Data were sorted into clusters according to emerging categories, re-examined, and combined into themes. Ethnograph Software³⁰ was used for qualitative data storage and analysis.

Results

Reasons for participating in a HIVVT. A desire to help others was the most common reason given. A 20-year-old Belizean male expressed this idea eloquently: “If there was a trial I knew about that needed people to participate, I would ‘cause of the simple fact that you can’t be selfish in the world. . . .” Unsurprisingly, for some homeless participants living in poverty, reimbursement would be an important incentive: “For me it would have to be monetary compensation. I don’t care what the side effects are, as long as I know I’m going to be taken care of. . . .” (18-year-old Belizean male). The combination of helping others and receiving compensation was viewed as particularly attractive by the homeless young adults.

Types of information desired before deciding whether to participate. *Risk factors.* Several participants wanted information about the risk factors associated with joining a trial before deciding whether to enroll. For a 20-year-old Latino male, it was important to know, “. . . what the side effects are, if any, what they believe they are, what it has caused in other people.”

Background information. Many wanted information about the stage of the trial, prior results, who might benefit, credibility of the researchers, and content of the vaccine. Individual strategies for obtaining background information were also identified; e.g., a 20-year-old African American male stated, “I would look into the encyclopedia and the papers and test[s] . . . on animals before I would even consider anything like that.” Specific details about trials were a concern as well. A 21-year-old African American male, apparently believing the vaccine was intended for those already HIV positive, would want to “. . . go through an orientation, be shown documents that they was really diagnosed with the HIV virus . . . for me to even take it, the vaccination.” Some wondered about the monitoring of HIVVTs. “I would want to know who is testing me? Are you certified? Are you legit?” (20-year-old Belizean male).

Concerns about participating. *Contracting HIV.* Several participants worried they could contract HIV as a result of being vaccinated. The source of this concern was the notion that a live HIV virus would be used. A 20-year-old African American male worried about this:

They are going to inject it [HIV virus] into you so there is a chance that your body can't overpower the virus and build up antibodies or the virus can take over your white blood cells then you'll be infected with the HIV virus.

Government/researcher trustworthiness. A 20-year-old Belizean male said, “My main concern . . . would be why [are they] testing it on regular people? Why not test it on government people, people in the military?” Several expressed concerns about the honesty of the government as well as of researchers:

I really don't know if I can even trust the government because they like to lie and they [would] just be trying to get me to do trial vaccinations. They be trying to throw lies at you . . . trying to say it's 100% accurate, when actually not everything is accurate all the time. (21-year-old Euro-American [Euro] female)

Distrust of researchers' motives for conducting an HIVVT was also expressed: “If the people that were administering this trial weren't really doing it to better us. They were just doing it for money or just recognition. I would just be concerned that I would be doing it for nothing” (20-year-old Tahitian female).

Worry about inequities in treatment based on race and gender was another concern:

I would want to make sure that everyone was getting the same test, not, like, because he's Black, he's going to get different testing, 'cause I'm White I'm going to get a different test. (19-year-old Euro female)

Side effects. Some participants were concerned about the side effects of a trial vaccine; for example, one wondered “. . . whether or not it would cause permanent damage to any of my systems or would it like cause skin discoloration or anything” (22-year-old Euro male). The possibility of vaccines causing varying side effects on different individuals was identified: “Everybody’s body is different toward the vaccines . . . and they have different side effects for everybody” (21-year-old Euro female).

Access to health care. Participants were also concerned about who would pay for any associated health care costs. A 21-year-old Euro female stated, “I hope the government would be ready to pay my hospital bill, ‘cause I’m doing this to help them out. I’m trying to help the government out, they can help me out.” Similar sentiments were expressed by a 20-year-old African American male: “If they want to run these tests they should be willing to pick up the bill [for health care]. . . .”

Sources of information regarding HIVVTs. Participants had a wide range of opinions about where to get information. Identified sources included the Internet, medical personnel (e.g., caseworkers, doctors, clinic personnel, therapists), and HIV/AIDS organizations. An 18-year-old Euro male said, “I would go to the Internet first, ‘cause that would give you all the perspectives possible quickly, just to get an overview of who is doing what.” A 20-year-old Tahitian female said: “I would want to talk to . . . the scientist[s], the researchers, the people that are going to act . . . the ones that would know the most about it, about what it’s going to do to my body, about what it means and all.”

Willingness to be vaccinated if an actual HIV vaccine existed, and related concerns. Most participants indicated they would wait to see what happened to other people before being vaccinated themselves. Some participants wanted more information before deciding whether they would be willing to be vaccinated. Discussion focused on some of the same issues raised in relation to participation in an HIVVT, including knowledge of the risks and benefits of being vaccinated, particularly side effects, and content of the vaccine.

The lack of WTP if an actual vaccine were available, expressed by two participants, was related to distrust of medical personnel: “I don’t like doctors and they mess up a lot and so I really wouldn’t want to take the risk or whatever” (19-year-old Euro female). Feelings of distrust of the government again arose in discussions about the actual vaccine.

In response to a question about how effective participants would want an actual vaccine to be in order to be vaccinated, answers ranged from 1% to 100%. Most wanted a vaccine to be at least 85% effective, but a 20-year-old Latino male argued: “One percent, as long as the side effects aren’t horrible. . . . It’s better having a chance of 1 out of 100 of not getting it at all than nothing, zero.” In contrast, a 20-year-old African American male said, “I would want 100% accuracy because I’m not a guinea pig.” In terms of lengths of desired protection, responses ranged from 6 months to life.

Participants who would want to be vaccinated if an actual vaccine existed gave a variety of reasons: most commonly, a desire for self-protection or protection so they could be there for others in their lives. A 21-year-old Euro female stated, “What would really make me want to take the vaccination against it is being able to watch the kids

raised. I want to be there for the rest of their lives. . . .” Some respondents indicated they would want to be vaccinated if HIV became more virulent or easier to contract.

How behavior might change after receiving an approved vaccine. The majority of participants believed sexual risk behavior would change negatively if an actual HIV vaccine were available, e.g., by becoming more sexually active, increasing the number of sexual partners, and having unprotected sex. Some felt behavior would not change, and a few believed positive behavior change would occur (e.g., less drug use and sharing of needles). A 20-year-old African American male stated, “People are very cautious right now, so it would be like a burden, a weight, lifted off their shoulders and they would feel that they could just run around. Go out without having to worry about consequences. . . .” A 19-year-old Euro female felt people “would get this attitude like they could do whatever they want, yeah, they’re invincible basically.” The potential problem of adolescents and young adults acquiring other sexually transmitted diseases (STDs) after vaccination was discussed. In contrast, a few participants agreed that because there are still other STDs, individuals would continue to use protection. “The other incurable [*sic*] STDs would still be here, you know, pregnancy [too], so people would like to keep themselves a little bit in check” (18-year-old Belizean male).

Discussion

Our findings suggest that homeless young adults share the same concerns as other adults and adolescents regarding WPT in a HIVVT: anxiety about the trustworthiness of researchers and/or government agencies conducting trials; possible negative behavior change as a result of being vaccinated; and concerns about various factors related to HIVVT design, including the impact of the vaccine on participants’ health, seroconversion, and costs for related health care, if needed. Additionally, they expressed unique interest in the process for monitoring participants in HIVVT and recognized that side effects of vaccines may differ among individuals. Creative strategies for obtaining information about trials were identified in relation to decision-making about participation, including use of technology (Internet) and health care professionals. Despite uncertainties about enrollment in an HIVVT, many participants showed interest based on feelings of altruism and desire for compensation. The latter motivation is likely related to survival needs associated with living in impoverished conditions.

Challenges to conducting HIVVTs with this population include 1) the lengthy follow-up requirements, often problematic with young adults in transition or without stable social environments; 2) the possible impact of vaccine-induced seropositivity, which may be particularly detrimental to those who lack health insurance and regular employment; and 3) an inadequate infrastructure for health care, particularly for members of racial/ethnic minorities.³¹ Protocols must be in place for addressing the problem of individuals who may test HIV positive at the time of screening for the HIVVT, as well as those who may become HIV positive during the trial, as a result of exposure either pre-trial or during the trial itself.

The potential for undue harm to communities of high-risk young adults exists if, as anticipated by some, vaccination leads to an increase in sexual risk-taking behaviors. In tailoring HIV vaccine efforts for this community, risk reduction strategies, includ-

ing the message that vaccines will not replace safe sexual behavior, will have to be repeatedly emphasized from the planning to the completion and follow-up phases of the clinical trials.

Homeless young adults constitute a vulnerable population that requires special protection in research. Necessary steps must be taken to ensure their understanding of any study (e.g., designing consent forms at appropriate literacy levels) and related personal risks (e.g., presenting factual and easily understood information on the risks and benefits of vaccination and on level of efficacy). Incentives such as financial gifts have the potential to serve as a coercive force among homeless young adults, thus researchers must ensure participation is truly desired. The research of Murphy and associates on informed consent¹⁷ demonstrates how comprehension of 15- to 19-year-olds may be improved with clear and simple presentation of information on HIVVT. Mechanisms also must be developed to protect participants from stigmatization and prejudice (e.g., offering study sites for HIV testing that accurately distinguish actual HIV infection from vaccine-induced seropositivity; providing services for screening and treating STDs; launching public campaigns about the nature of HIV vaccines and their side effects).

Additional special issues unique to homeless young adults must be addressed if clinical trials are to be successful. Convenient and friendly access and follow-up points must be established. Social marketing and recruitment for clinical trials should be conducted at community sites where homeless young adults gather (such as temporary shelters or other frequently occupied lodgings, neighborhood free health clinics, and drop-in centers). Because this population lives in poverty and lacks stability, integrating special services that increase its resources may be particularly appealing (e.g., free health care, job training, clothing, or shelter). This will require government support and related change in public policy about resources for homeless young adults and other vulnerable individuals. Further, scheduling of data collection must be flexible and interventions specially designed to be culturally sensitive.

A fundamental requirement for launching any clinical trial, whether the intended participants are permanent or transient residents, is the establishment of trust in the community. The use of CBPR methods in an HIVVT may help build trust, enhance understanding of the trial, and facilitate development of an infrastructure to support successful implementation and completion. Researchers using CBPR must be willing to form partnerships in the community and to share responsibilities with these community partners. A CAB that includes representatives from the target population should be formed in the planning phase of any HIVVT. Hiring and special training of high-risk young adults from the community for roles as recruiters and peer educators might enhance enrollment and improve retention rates. Their involvement might help to counterbalance distrust of researchers and government-sponsored trials and, most importantly, give community members a voice on the research team.

Limitations. The small size and the nature of the sample limit our ability to generalize findings. Additionally, females were underrepresented among the participants in this study.

Considering both the findings and limitations of this study, several recommendations are offered for future studies. Researchers should conduct a series of focus groups,

stratified on potentially important participant characteristics. Conducting in-depth interviews following focus groups will allow exploration of specific themes in more detail and enhance understanding of the complex social and economic contexts that homeless young adults face and how these affect HIV risk behaviors and WTP in trials. Investigations also should focus on examining participants' feelings about specific vaccines or HIVVT protocols and on how current ethical issues may be addressed.

Conclusion

Findings from this study will help to inform future HIVVTs with homeless young adults, particularly understanding of factors influencing decision-making, behavioral issues, and need for comprehensive orientation to trials. Understanding the personal perspectives of this population will enable researchers to tailor protocols to their individual needs and cultural values and, thereby, potentially enhance WTP in HIVVTs.

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