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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 predominately 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.

Keywords

HIV vaccines; Clinical trials; Willingness to participate; Acceptability; Ethnic minorities; Qualitative research

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

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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 countervail 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-ability (of future FDA-approved HIV vaccines); those specific to WTP; and those specific to acceptability.

Barriers and motivators common to WTP and acceptability

Nine barriers and motivators were common to WTP and acceptability (see Table 2).

Barriers in common—Barriers common to WTP and acceptability were: (1) fear of vaccine-induced HIV infection, (2) false-positives, (3) side effects, (4) partial vaccine efficacy, (5) mistrust, (6) AIDS stigma, (7) low perceived HIV risk, and (8) relationship concerns.

Fear of vaccine-induced HIV infection: Despite the fact that current experimental HIV vaccines are synthetic/recombinant products incapable of inducing HIV infection, respondents in both sets of focus groups expressed fear that the vaccine would infect them with HIV. Respondents in the WTP groups reported that fear of accidental HIV infection from an experimental vaccine would pose a barrier to their participation in a clinical trial. Fear of vaccine-induced infection was also raised as a barrier to acceptability of an approved HIV vaccine, based on an understanding that a vaccine induces immunity by introducing a small dose of a viral agent or disease to the human host.

False-positives: Fears that a false-positive test result might signify actual HIV infection and concerns about adverse social consequences of testing HIV-positive arose in regard to HIV

vaccine trials and approved HIV vaccines. While some respondents tentatively accepted that a "special" test could distinguish actual HIV infection from a vaccine-induced immune response, many were skeptical or distrustful of such a test and others were confused. Concerns about adverse social consequences due to testing HIV-positive that were common to WTP and future acceptability included difficulty qualifying for health insurance, discrimination in employment and difficulties with immigration and travel to the U.S.

Side effects: Concerns about side effects were expressed primarily as fear of injury, such as "your liver, your kidneys could be harmed" or "will it make me lose my hair?" Participants also raised apprehensions about the availability of monetary compensation and health care to address problems that might arise after the conclusion of a vaccine trial or years after receiving a government-approved vaccine. Women raised concerns about possible teratogenic effects of both experimental and approved HIV vaccines, and fears of reproductive difficulties and transmission of vaccine-induced infection through breast milk.

Partial vaccine efficacy: Concerns about efficacy were expressed in regard to both experimental and approved HIV vaccines. Respondents stated, albeit paradoxically, that they would be hesitant to participate in a trial of an HIV vaccine that had uncertain efficacy. In the case of an approved vaccine, respondents generally expected the vaccine to be 100% effective in preventing HIV infection and expressed low acceptability of "partially effective" HIV vaccines.

Mistrust: Mistrust was reported in fears of being experimented on without one's consent and in regard to those sponsoring and implementing HIV vaccine trials, including the U.S. government and pharmaceutical companies. Similarly, mistrust of vaccine manufacturers, scientists, government and the U.S. Food and Drug Administration (FDA), in particular, were raised around a future approved HIV vaccine. Mistrust of an approved vaccine was described in terms of incompetence (e.g., unintentional medical errors), lack of integrity in biomedical research (e.g., conflicts of interest), and conspiracy theories (e.g., AIDS, and HIV vaccines, as a form of genocide).

AIDS stigma: Respondents expressed concerns about others' perceptions of their motivations for volunteering for an HIV vaccine trial or seeking out and/or accepting an approved HIV vaccine; either scenario was seen as carrying the stigma associated with risk behaviors for HIV infection and "risk groups" (i.e., gay men, injecting drug users and sex workers). Concerns about stigma were also expressed regarding venues for clinical trials and dissemination of future HIV vaccines, including the discreteness of the location (e.g., non-HIV-identified) and ability to maintain confidentiality.

Low perceived HIV risk: The perceived necessity for and importance of HIV vaccine development and dissemination - and thus WTP and acceptability - were diminished by low perceptions of individual and/or community risk for HIV infection. Female respondents, particularly Latinas and African Americans, explained that heterosexual women often do not perceive themselves to be at risk for HIV infection due to lack of awareness or denial of their husband's or partner's risk behaviors. Among both heterosexual men and MSM, some construed vaccine trials as a form of preventive intervention; thus low perceived risk for HIV infection obviated the need for participation: "If you are not doing things that expose you to the risk of HIV, why get in a preventative program?" Low perceived HIV risk also emerged as a threat to HIV vaccine acceptability among men: "the immediacy of the threat has changed, so people don't feel as personally threatened by it."

Relationship concerns: HIV vaccines, including discussions about volunteering for an HIV vaccine trial or seeking an approved HIV vaccine, were reported as potentially evoking mistrust

in intimate relationships. Female respondents in particular expressed concerns about the potential reactions of their family and partner to their joining a trial or being vaccinated. Latinas articulated concerns that invoking an HIV vaccine would be perceived as an accusation about their partner's infidelity or "evidence" of their own extramarital relationships, either of which would create relationship difficulties.

Motivators

Protection from HIV infection: HIV vaccine trial participation was envisioned by some as a means of reducing risk for HIV infection or a form of "prevention program", while uptake of an approved vaccine was seen as particularly beneficial for persons at elevated risk. Women raised the ability to protect their children from HIV infection as a motivator for supporting HIV vaccine development and accepting childhood HIV vaccination in the future.

Barriers and motivators specific to WTP

Five barriers and motivators were specific to WTP (see Table 3).

Barriers to WTP

Uncertainty about vaccine characteristics: Respondents indicated concerns about the composition of experimental vaccines (e.g., live HIV and possible vectors) and route of administration as barriers to WTP. A minority of respondents cited fear of needles; however, fear of vaccine-induced infection was reported in every group.

Study demands: Logistical demands imposed by an HIV vaccine trial, including the number and frequency of study visits, and the duration and location of the trial were cited as potential barriers to participation. Some respondents indicated WTP in low demand situations (e.g., going to a clinic "once versus three times" and less "hassle getting to the trial headquarters") but expressed wariness of a multi-year commitment with frequent clinic visits.

Motivators for HIV vaccine trial participation

Altruism: Respondents reported motivations to engage in a trial in order to help humanity, their community, and to be a part of advancing research to end the AIDS epidemic.

Free medical care/insurance: The provision of free medical care through a clinical trial, even care tied only to possible vaccine complications, was a motivator for WTP. Respondents also discussed the availability of health and life insurance for possible damage wrought by an experimental vaccine as incentives for trial enrolment.

Monetary incentives: Financial incentives were raised as a motivator for trial participation, with the ideal amount varying widely depending on the level of perceived HIV risk and socioeconomic status. Both injection and non-injection drug users indicated that if they were in need of drugs, a small incentive would be sufficient inducement to join a trial.

Barriers and motivators specific to HIV vaccine acceptability

Six barriers and motivators were specific to HIV vaccine acceptability (see Table 4).

Barriers to HIV vaccine acceptability

Duration of protection: Respondents raised concerns about the number of years of protection an HIV vaccine might offer. Many expected lifetime protection as a benchmark, while others were concerned about any single vaccine's ability to protect against an evolving virus. Concern about limited protection was also discussed in terms of possible negative consequences of

getting an initial, partially efficacious vaccine that might prevent one from reaping the benefits of a more efficacious vaccine that might be developed in the future.

Cross-clade protection: Specific concerns were raised about the ability of an HIV vaccine to protect against more than one viral clade. Respondents related cross-clade protection to a false sense of security in feeling completely protected against HIV infection by any one vaccine.

Cost and access: Some respondents presumed that if an HIV vaccine were available, the U.S. government along with health insurers would cover the cost, and thus were not concerned about cost. Others expressed concerns about their ability to pay for HIV vaccines and around possible restrictions in terms of for whom a vaccine would be provided. Fears were raised about being excluded from vaccine access based on stigma and discrimination against injecting drug users, gay men and people of color.

Motivators for HIV vaccine acceptability

Unprotected sex: The ability to engage in unprotected sex without the risk of HIV transmission was discussed as a motivator for HIV vaccine uptake—in addition to motivations based on gaining added protection against HIV infection (e.g., in case a condom breaks). Dimensions of this motivation included the ability to forego condom use and to have more sexual partners, reduced anxiety around sex, and obviating concerns about the HIV serostatus of potential sexual partners. Women raised the ability to conceive a child without worrying about HIV infection as a motivator for HIV vaccine acceptance.

Vaccine endorsement: Endorsements of HIV immunization from respected sources, including family doctors, local clinics and media, and celebrities affiliated with ethnic minority communities and youth emerged as a motivator for future HIV vaccine uptake.

Improving overall health: Vaccines were discussed as being part of sound health care practices and a means to improve overall health and well being.

Discussion

This investigation identified a number of concerns and motivators in common across willingness to participate (WTP) in HIV vaccine trials and acceptability of future FDA-approved HIV vaccines among adults at heightened vulnerability to HIV infection. Several concerns (e.g., fear of vaccine-induced infection, concerns about false HIV-positives) common to WTP and future HIV vaccine acceptability suggest HIV vaccine trials may represent sources of sociobehavioral data to support the design of proactive interventions to facilitate future HIV vaccine dissemination. Educational, social marketing and sociobehavioral interventions that prove effective within the context of clinical trials may not only facilitate and improve the safe and ethical implementation of subsequent HIV vaccine trials; they may support the much more monumental task of disseminating HIV vaccines to millions of people.

Nevertheless, concerns about a vaccine's level of efficacy, duration of protection, cross-clade protection, and cost arose as specific aspects of HIV vaccine dissemination beyond the realm of clinical trials [5]. Formative research focused on addressing consumer preferences and concerns that may influence future vaccine uptake may be vital to ensuring the success of HIV vaccines on an epidemic level [4,8]. For one, social marketing interventions might highlight the benefits of partially efficacious HIV vaccines, particularly among communities at risk. Trepidation about lack of access to HIV vaccines due to prohibitive costs indicates a role for structural interventions, including cost subsidies and ensured access through public clinics for low income individuals.

Importantly, some of the perceived factors common to WTP and acceptability of approved HIV vaccines were inaccurate. Concern about the partial efficacy of an investigational vaccine suggests misconceptions among persons eligible to enroll in a randomized placebo-controlled trial. In fact, the hope of gaining protection against HIV infection as a result of participating in a trial (i.e., protection motivation) was reflected in a stated desire to participate only in clinical trials of experimental vaccines that "work". These misconceptions reinforce the importance of ensuring that trial participants understand the necessarily uncertain nature of experimental vaccine efficacy as well as the possibility of receiving a placebo. In terms of the dissemination of future HIV vaccines, evaluation of approaches to providing education around uncertain vaccine efficacy in the context of clinical trials may provide data to support educational interventions to promote behavioral prevention in the likely scenario of deployment of a partially efficacious vaccine [15,23,24]. Similarly, materials that prove effective in educating trial participants about false-positives, vaccine side effects and the impossibility of vaccine-induced HIV infection may build evidence for interventions to support future HIV vaccine dissemination.

Evidence of mistrust as a barrier to both WTP and future acceptability suggests that interventions to mitigate a legacy of mistrust of government and medical research (e.g., Tuskegee Study of Untreated Syphilis) may increase participation of ethnic minorities and women in HIV vaccine trials [21,22,25]. Educational and social marketing interventions to increase understanding of and informed participation in HIV vaccine trials, in turn, may support a longer term strategy to build trust in future FDA-approved HIV vaccines as well as other innovations in HIV chemoprophylaxis [4].

A number of concerns were raised exclusively in the context of women's focus groups. Women, and particularly Latinas and African Americans, reported that mere discussion of HIV vaccine trials might evoke mistrust and suspicion with their partner or family, and might similarly evoke mistrust and stigma in the case of approved HIV vaccines. Women across all demographics expressed concerns about teratogenic effects of HIV vaccines, as well as motivations for uptake based on ability to protect their children. These findings support the need for gender-specific interventions to enhance informed WTP and future HIV vaccine acceptability among women [26].

Finally, motivators (e.g., altruism, free medical care) and barriers (e.g., false-positives, AIDS stigma) raised in regard to WTP indicate complex rather than unilateral reactions to volunteering. Persons who screened into an actual HIV vaccine trial yet declined to enroll similarly expressed ambivalence; altruistic intentions may be overwhelmed by anticipated social harms of HIV vaccine trial participation [27]. The recent failure of an investigational vaccine in a Phase IIb trial that may have *increased* susceptibility to HIV infection among those who received the test vaccine compared to placebo [28] may engender renewed concerns about potential physical harms associated with HIV vaccine trials; it also reinforces the importance of ongoing sociobehavioral research conducted in the context of biomedical HIV prevention trials.

Limitations to this study include the use of purposive venue-based sampling, which circumscribes generalizability. Nevertheless, our primary purpose was to explore in depth the perspectives of persons likely to be targeted in initial dissemination of FDA-approved HIV vaccines. We were successful in recruiting a low socioeconomic, predominantly ethnic minority and mixed-gender sample across nine different venues of three broad types from vulnerable populations often deemed "hard to reach". The venue-based sampling strategy was modeled on likely methods for future HIV vaccine dissemination targeting vulnerable communities, which also mitigates limitations on generalizability. Focus groups also pose methodological limitations as they do not necessarily represent each individual's distinct

concerns. We conducted homogeneous groups by gender, ethnicity, language and sexual orientation to encourage comfort and candor among participants; and groups were led by culturally and linguistically diverse, trained co-facilitators who were capable of managing group dynamics. Additional focus on concerns among youth, important candidates for HIV vaccine trials and future HIV vaccine dissemination, is a vital direction for further research. Finally, hypothetical WTP and HIV vaccine acceptability may not translate into actual behavior. However, stated WTP, while imperfect, was the best predictor of actual participation in an HIV vaccine trial in two different investigations [29,30]. Additionally, the purpose of this investigation was not to predict trial enrollment or vaccine uptake but to elicit an array of concerns and motivators among adults from vulnerable communities for whom HIV vaccines are most urgently needed.

In conclusion, this investigation suggests a number of concerns and motivators specific to HIV vaccine accept-ability, which supports the importance of sociobehavioral research conducted beyond the circumscribed realm of clinical trials. Nevertheless, the many concerns and motivators in common across WTP and acceptability of future FDA-approved HIV vaccines suggest that rigorous sociobehavioral research conducted in conjunction with HIV vaccine trials, in addition to facilitating informed enrollment in safe and ethically conducted trials, may provide an empirical basis for targeted sociobehavioral interventions to ensure the effectiveness of future HIV vaccines in controlling the epidemic.

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Table 1

Demographic characteristic by focus group topic

Characteristic	Willingness to participate in an HIV vaccine trial[a] (*n* = 58) N (%)	HIV vaccine acceptability[a] (*n* = 99) N (%)
Age (mean)[b]	36.3	33.0
Race/ethnicity[b]		
Black/African American	20 (35)	20 (22)
Hispanic/Latino	32 (56)	39 (44)
White	3 (5)	25 (28)
API[c], Native American, other	2 (4)	5 (6)
Gender		
Male	36 (63)	52 (53)
Female	21 (37)	47 (47)
Sexual orientation[b]		
Heterosexual	23 (40)	38 (43)
Gay/Lesbian	21 (37)	27 (30)
Bisexual	2 (4)	18 (20)
Refuse to answer	11 (19)	6 (7)
Relationship status		
Single	41 (72)	61 (69)
Partnered/Married	10 (18)	20 (22)
Divorced	4 (7)	3 (3)
Widowed	2 (3)	0 (0)
Refuse to answer	0 (0)	5 (6)
Employment		
Full-time	19 (33)	26 (29)
Part-time	6 (11)	14 (16)
Unemployed	31 (54)	45 (51)
Refuse to answer	1 (2)	4 (4)
Annual income ($)		
0-10,000	33 (58)	42 (47)
10,001-20,000	10 (18)	15 (17)
20,001-30,000	3 (5)	7 (8)

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Characteristic	Willingness to participate in an HIV vaccine trial[a] (*n* = 58) N (%)	HIV vaccine acceptability[a] (*n* = 99) N (%)
>30,000	4 (7)	9 (10)
Refuse to answer	7 (12)	16 (18)
Health insurance		
Health insurance	24 (42)	44 (49)
No health insurance	30 (53)	45 (51)
Refuse to answer	3 (5)	0 (0)

[a] One participant in the willingness to participate focus groups and 10 in the vaccine acceptability groups did not turn in completed questionnaires.

[b] $p < 0.05$.

[c] API = Asian/Pacific Islander.

Table 2

Barriers and motivators common to willingness to participate in an HIV vaccine trial and acceptability of an approved HIV vaccine and representative quotations from participants

	Quotations from participants in willingness to participate focus groups	Quotations from participants in HIV vaccine acceptability focus groups
Barriers		
1. Fear of vaccine-induced infection	"…they would be scared…because they know they will die with the virus." (African American woman)	"I would have to think twice about it because of the possibility of getting infected." (Latino MSM)[a] "…primary concern…getting HIV from the vaccine" (MSM)
2. False-positives - fear of infection	"If they tell me I am HIV positive, I am going to be so scared." (Latino male)	"So, as a technicality, you are HIV-positive?...and you can give it to somebody?" (MSM) "I would think that I didn't have it before you gave me the vaccine, but now I got it…You gave it to me." (Youth)
- social consequences	"You might not be able to qualify for insurance" (Male IDU)[b]	"Even insurance wise, if you got tested with your doctor and you didn't ask for the test, that told the insurance company that you…are a risk." (MSM)
3. Side effects	"Is it going to give me kidney failure or heart failure?" (MSM) "What happens when, if you take part in the study, and you have side effects later, and you won't be able to do your job?" (Latino MSM)	"Would it damage your reproductive system?...Your offspring?" (Female IDU) "How do they know that there will be no side effects? These things are so different on every person." (MSM)
4. Partial vaccine efficacy	"How will they know if it works on me?" (Latino male) "…it [WTP] would all depend on if they they gave me a placebo or not." (MSM)	"It would have to be in the upper 90s" [% efficacy] (Male IDU)
5. Mistrust	"There is no real trust in the government." (Latino MSM) "I think the less that is said about the government the better…the more you use the [word] government, the more you will scare people away." (MSM)	"Who is making it anyways? Because if it's the government, we know we can't believe them anyways." (Male IDU)
6. AIDS stigma	"I think that some [HIV]-negative people, would do it, but I don't think they would let people know that they are doing the study. It is not something you share…many people are not educated about that." (MSM)	"Who are giving the vaccines? What clinics? They are going to point and say, 'Oh, that one, who knows, what she is doing because look she's going into the AIDS clinic.'" (Latina)
7. Low perceived HIV risk	"Men would say, 'No way, I will never have that, not me'…because they feel strong, manly, they think they would not get it." (Latino male)	"If you do the right things you're not going to get the bad disease. If you're not going to get it, why take a vaccine for it?" (Female IDU) "You have to weigh in the factor of how high at risk are you?" (MSM)
8. Relationship concerns	"If I have a partner and if I get the vaccine, it would mean that I'm going to be with several people." (Latina)	"If the woman goes and says, 'I am going to get the injection.' And he is going to say, 'Why Are you getting the injection? Are you having an affair?"' (Latina)
Motivators		
1. Protection	"I think that if we all knew that…we would be immune against HIV, we all would say'Yes.'" (Latina) "If the vaccine will prevent you from all the suffering and pain, from all that really happens to people with the disease, or if it will save you from dying…It is a great thing." (Latino MSM)	"Knowing the circle of people I know…the fact that they can probably avoid something [HIV], I would say about 75% of them would probably start going [to get vaccinated]." (MSM) "I have a friend that has a serodiscordant boyfriend. He would get vaccinated in order to be closer to each other." (Latino MSM)

[a] MSM = men who have sex with men.

[b] IDU = injection drug user.

Table 3

Barriers and motivators specific to willingness to participate in an HIV vaccine trial and representative quotations from participants

	Quotations from participants in willingness to participate focus groups
Barriers	
1. Uncertainty about vaccine characteristics	"What would they inject me with?" (Latina) "Maybe they are afraid of needles." (African American female)
2. Study demands	"I would prefer going once versus three times." (African American male) "Less is always better." (MSM)[a]
Motivators	
1. Altruism	"They need someone to try the cure, to see if it works. I would do it because it would help them find a cure for this disease." (Latino male) "I feel like if I'm participating in an HIV vaccine trial, possibly to help someone in the future, that's why I would do it." (Latina)
2. Free medical care/Insurance	"I think for some people there would have to be some kind of insurance. . .If I took the placebo and I had risky sex and came out positive. I would need some kind of insurance that I will be taken care of." (MSM) "Will we have some health insurance? Will they take care of our health? There might be side effects. . .maybe our careers would be affected, too. It would be great having the support, and health care, we would be more at ease." (Latina) "They should give health care and doctors - that way you can go somewhere and get checked if you don't feel well." (Latino MSM)
3. Monetary incentives	"You may have to spend a lot of money - paid visits are best." (Latina) "Only if the money was right." (Male IDU)[b]

[a] MSM = men who have sex with men.

[b] IDU = injection drug user.

Table 4

Barriers and motivators specific to acceptability of an approved HIV vaccine and representative quotes from participants

	Quotations from participants in HIV vaccine acceptability focus groups
Barriers	
1. Duration of protection	"What happens if the strain changes and you need to get another vaccination three years down the line and all of a sudden. . .you. . .have. . .too much of this in your body?" (MSM)[a] "[Is it] once in your life?... do I have to come back each month or each year or what?" (Youth)
2. Cross-clade protection	"The [HIV] virus from the United States is different than the virus from other countries. . .so if people come from other countries, they will infect others with a different virus." (Latina) ". . .if people were to get vaccinated, would they then assume that they were completely safe when they might actually be able to be exposed to a different strain?" (Female IDU)[b]
3. Cost and access	"If it wasn't free, I wouldn't be able to afford it." (Male IDU) "If it was free, I wouldn't trust it because then I think that they were trying to reverse it and make you sicker." (Male IDU) "Who would get the vaccine. . ..Like in Africa millions of people are dying. How is it going to be distributed?" (Latina)
Motivators	
1. Unprotected sex	"I would get vaccinated so that I don't get HIV and to practice sex without condoms." (Latino MSM) "There will be more promiscuity. . .more sexual freedom in regards to 'try anything you want.'" (Latino) "A lot of my friends have died already [of HIV/AIDS]. . .We've had friends affected and. . . I'm not sure I feel like continuing to practice safe sex." (MSM) "Feel. . .safe about having unprotected sex. . .peace of mind." (MSM)
2. Vaccine endorsement	"If my doctor, who I trust, recommended that I do it, I would do it." (MSM) "I would trust the radio, especially if it was on 92.3 - The Beat. I would trust the radio. That's me." (Youth)
3. Improving overall health	"I would take the vaccine because I want to stay alive as long as I can." (Female IDU) "My friends and I would do it because we are already infected and we want a cure." (Latino MSM) "for health reasons." (Female IDU)

[a] MSM = men who have sex with men.

[b] IDU = injection drug user.