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Enhancing HIV Vaccine Trial Consent Preparedness Among Street Drug Users

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Abstract

This research used open-ended and true-false questions to assess the preparedness of 96 ethnically diverse, economically and socially marginalized adult street drug users to consent to participate in HIV vaccine trials (HVT). Specific areas of consent vulnerability included misconceptions about: (1) the recuperative value and risk of vaccines in general; (2) the presence of the HIV virus within the vaccine and the possibility of contracting or transmitting HIV as a consequence of participation; (3) inclusion criteria and experimental blinds; and (4) distrust in the medical and research establishments. A brief HVT lesson administered to 30 participants was effective in correcting specific HVT knowledge misperceptions and increasing certain, but not all areas of HVT trust. Assessment of post-lesson responses to ethics-relevant questions provides information on respondents' attitudes toward AIDS safe behavior, research risks and benefits, monetary compensation, and willingness to participate. Implications for enhancing informed consent for HVT involving active drug users are discussed.

Keywords

intravenous drug use; HIV risk; vaccine trials; informed consent; trust; ethics; addiction

Injection drug users (IDUs) account for almost one-third of HIV/AIDS cases in the U.S. (Centers for Disease Control & Prevention, 2009). Despite successful harm-reduction efforts such as needle exchange programs, community interventions, and methadone maintenance, the acquisition and transmission rates within this population remain high. Concern that IDUs are a source for widespread HIV acquisition and transmission derives from the common occurrence of sharing contaminated injection equipment, involvement in sex work, and trading sex for drugs. While HIV vaccine investigators continue to produce breakthroughs in the battle against HIV/AIDS (Dolin, 2009), the development of a universally effective HIV vaccine based on variations in viral genetic diversity is particularly challenging for IDUs because of differences in the course of infection via sexual transmission and injection, the as-yet-undetermined effect of extended drug use on the epidemic strains of the virus, and differences in immunological barriers to the virus (Beyrer, 2002; Lau et al., 2008). Additionally co-morbidities of drug abuse including poor nutritional status, local and systemic infection, psychiatric disorders, poverty, a history of incarceration, and the potential for drug interactions with the vaccine are sufficiently different from other HIV risk populations to question generalization of HIV vaccine trials (HVT) involving non-drug users (Suntharasamai et al., 2009). Thus, participation of IDUs in vaccine trials is critical to the development of vaccines effective for the IDU population.

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When designing HIV vaccine clinical trials, investigators, private and public sponsors, and institutional review boards (IRBs) must consider both the potential benefits to the IDU population of research leading to the discovery of an effective HIV vaccine and the characteristics of this population that may require special ethical considerations for ensuring informed, rational, and voluntary consent. The lack of education, marginal housing, unemployment, health care disparities, engagement in illegal behaviors, social stigma, fear of HIV/AIDS and co-morbid psychiatric disorders pervasive in this population present potential barriers to understanding elements of research design, participant response to monetary compensation, and participant protections described during informed consent in economically and socially developed and developing countries (Buchbinder et al., 2004; Higgs, Moore, & Aitken, 2006; Irwin & Fry, 2007; Koblin et al., 2000; Mills et al. 2004; Striley, Callahan, & Cottler, 2008).

HIV vaccine clinical trials are currently being conducted across the United States and worldwide, including South Africa, India, Peru, and Brazil (Excler et al., 2008; Middelkoop et al., 2008; HIV Vaccine Trials Network, 2010). In the first part of this decade, ethical debate surrounding HVTs focused on placebo-controlled trials in developing countries and the responsibility of investigators towards participants who acquired HIV during the course of the trials (UNAIDS, 2007). More recently, there has been a growing research focus on vaccine trial preparedness aimed at increasing the feasibility of studies by incorporating community perspectives into trial design, recruitment, retention, and informed consent (Dhalla et al., 2007; Djomond et al, 2008; Excler et al., 2008; Lagakos & Gable, 2008; Maher et al., 2010; Valente et al., 2009). Such research is necessary to address the continuing problem of low enrollment and retention in HVTs (Buchbinder et al., 2004; Dhalla et al., 2007; Maher et al., 2010).

HIV preparedness studies, largely conducted outside of the United States, have shed light on the knowledge and attitudes of target groups, especially as they relate to barriers to trial participation and intervention uptake. HVT consent preparedness is one component of this broader agenda. An underlying assumption of the HVT consent preparedness approach is that the ability of prospective participants to understand the specific study information provided during informed consent may be facilitated or impeded by previous knowledge (or misconceptions) regarding HIV, vaccines, and clinical trials in general, as well as HIV vaccines and HVT clinical trials specifically, and overall trust or mistrust in the responsible conduct of medical research. For example, in one of the first studies to address this question, Meyers et al. (1994) reported that although the majority of IDUs had direct experience receiving a vaccine for themselves or their children, about half were confused about the preventive versus curative purpose of vaccines, with 30 percent responding they did not know what a vaccine was. Adding to ethical concerns, the study found 22 percent of IDUs believed participation in a vaccine trial could make them “AIDS safe,” giving them greater latitude in engaging in HIV risk behaviors (Vlahov et al., 1994).

Misconceptions about HVT are not the only barriers to informed participation. Medical and research mistrust also play significant roles in IDU's responsiveness to HVT recruitment (Mills et al., 2004). Individual and collective histories of inadequate health care and familiarity with community narratives on research misconduct involving economically disadvantaged racial/ethnic minorities and other vulnerable groups has been found to contribute to lower levels of research trust within marginalized African American, Hispanic, and non-Hispanic white populations (Boulware et al., 2003; Brooks et al., 2007; Corbie-Smith et al., 1999; Crawley, 2001; Fisher et al., 2008; Fisher & Wallace, 2000; Gamble, 1997; McDonald et al., 2008; Meyers et al., 1994).

Educational efforts toward increasing understanding and reducing misconceptions about HIV vaccine trials are an important step forward in ensuring informed participation of IDUs in such research. There have been few such efforts involving IDU populations in the U.S. and these have been conducted within the context of large-scale studies on other aspects of HIV prevention. For example, as part of the HIV Network for Prevention Trials (HIVNET), Coletti et al. (2003) pioneered an 18-month, large-scale, two-session HVT prototype informed consent process for individuals at high risk for HIV infection participating in a prospective study of HIV seroincidence. Twenty-two percent of the participants were IDUs. The investigators reported that sessions yielded substantial and sustained increases in understanding of essential components of participation in HIV vaccine trials. However, increased HVT understanding did not affect willingness to participate (WTP) in a future vaccine trial. The authors suggested that the lack of association between HVT understanding and WTP was due in part to the high rates of willingness to participate in their sample.

In summary, there is a paucity of empirical data on the nature of and factors influencing HIV vaccine trial consent preparedness among marginalized street drug users in the United States who have not been involved in previous forms of HIV research. The research reported here, examined the following three questions:

- What are the HVT consent preparedness strengths and vulnerabilities of marginalized urban street drug users?
- Can a brief lesson on the purpose and nature of HVTs increase consent preparedness and trust among members of this population?
- What are the ethically relevant misconceptions, fears, and concerns that continue to influence IDU's attitudes toward HVT participation following exposure to the lesson?

Method

Participants

A total of 96 active male and female drug users, mean age 40 years and one month (standard deviation 8.59 years; range 21–57 years) participated in this study. The majority of participants self-identified as non-Hispanic black, non-Hispanic white, or Hispanic (majority were Puerto Rican). Detailed demographic data are provided in Table 1 of the Results section. Inclusion criteria included (a) having tested negative for HIV or never been tested; (b) use of illegal or non-prescription drugs other than alcohol, marijuana, or prescription methadone within the past 30 days; (c) history of intravenous drug use; and (d) English proficiency. Recruitment was conducted using street outreach in areas commonly frequented by IDUs. Screening questions covered inclusion relevant and non-relevant information to avoid biasing prospective participants' responses. Individuals who met inclusion criteria were given an appointment to participate in the research at local offices rented for the purposes of the study.

Measures

Demographic and Healthcare Questions—Demographic information included data on drug use, employment, education, housing, incarceration, HIV risk behaviors, and vaccine and medical treatment. On a 4-point Likert-type scale (1 = poor, 4 = excellent), participants were asked to rate the healthcare services they received. They were also asked how much they worried about getting HIV/AIDS (0 = not at all, 2 = somewhat, 3 = a lot). In addition, they responded to a multiethnic health disparities scale, which assesses endorsement of six reasons for poor quality healthcare, including racial/ethnic

discrimination, difficulty speaking English, inability to pay, lack of trained professionals, rejection because of insurance or relevant health services (Blendon et al., 2007).

Open-Ended Questions—Prior to administration of relevant true-false questions, participants responded to two open-ended questions: (1) What is your understanding of the term “vaccine” or “vaccination”? (2) An HIV vaccine study is a type of research. Sometimes it is called an HIV vaccine clinical trial study. What do you think is the purpose of an HIV vaccine clinical trial research study?

True-False Consent Preparedness Questions—The wording of each true-false item analyzed for this study is provided in Tables 2, 3, and 5 in the Results section. Vaccine knowledge (three items: preventive versus curative nature of vaccines in general, and level of vaccine risk), HIV knowledge (three items: health effects of virus and needle sharing, and use of condoms as risk and preventive behaviors, respectively), and HIV mistrust (four items: HIV is man-made, a vaccine and cure exists, the health department is working to prevent the spread of HIV) were measured with true-false items adapted from Brooks et al. (2007). True-false items tapping knowledge about and trust concerning the implementation of HIV vaccine trials (HVT) were adapted from Coletti et al. (2003) and Meyers et al. (1994). There were 13 consent relevant HVT knowledge questions tapping understanding of the purpose of an HVT trial, inclusion criteria, random assignment to vaccine or placebo and experimental blind, the nature of the vaccine (Does it contain the HIV virus? Can it cause transmission to others?), and side effects (false positives). There were five items tapping HVT trust in the government, investigators, and pharmaceutical company research sponsors.

As described below, 30 participants received a brief HVT lesson immediately followed by retesting of HVT knowledge and trust items. These participants also responded to 14 true-false items tapping AIDS safe-behavioral responses to HVT participation, perceived participation risks and benefits, adequacy of informed consent, voluntariness, and monetary compensation (Brooks et al., 2007; Mills et al., 2004). Overall positive attitude toward participation was evaluated with a modified version of a 4-point paired-item scale developed by Dormandy et al. (2006). Willingness to participate was assessed by a 4-point Likert scale (1 = definitely would not participate, 4 = definitely would participate).

Brief HIV Vaccine Trial Lesson—The brief (five-minute) lesson administered to 30 participants consisted of 12 colorful PowerPoint slides that included both text and pictorial illustrations. Information was drawn from the National Institute of Allergy and Infectious Diseases fact sheets and brochures (National Institute of Allergy and Infectious Diseases, 2009). Information included: definition of vaccine; purpose of HIV vaccine clinical trials including explanations of placebo, randomization, potential side effects, participation eligibility (HIV negative), and the fact that researchers “do not know if the vaccine works until the study is over”; the nature of participation (one to two year length, 6 to 20 visits, monetary compensation); how blood tests for antibodies and HIV serostatus are used to assess vaccine effectiveness; the probability of false positive HIV tests for individuals who are given the vaccine and how accurate diagnosis will be obtained; correction of common misconceptions (the vaccine does *not* contain the HIV virus, participants can *not* get or transmit HIV to others from taking the vaccine); and the voluntary and confidential nature of participation.[1]

[1]The brief lesson can be downloaded at www.fordham.edu/ethicsdownloads.

Procedure

The research was approved by the Fordham University Institutional Review Board and a PHS Certificate of Confidentiality was obtained. The HIV vaccine clinical trials (HVT) lesson and all questions were presented in written form and read to participants to accommodate low literacy rates in this population. After informed consent, all participants responded to demographic and healthcare questions, followed by open-ended and true-false questions assessing vaccine knowledge, HIV knowledge, HIV mistrust, HVT knowledge, and HVT trust.

After completing the above questionnaires, the last 30 participants to be recruited for the study received the HVT lesson immediately followed by re-administration of the true-false HVT knowledge and trust items. This in turn was followed by the series of questions on ethically relevant attitudes toward HVT participation. Finally, these participants were asked if they would participate in this type of study. Participants were compensated $25 plus travel for their participation.

Results

Study Population

Table 1 provides demographic and healthcare information for all participants. Overall, the majority of participants engaged in HIV high-risk behaviors including needle sharing and failure to use condoms during sex. Heroin and cocaine were the most frequently reported drugs used over the past 30 days. Most were unemployed. During the past month, participants reported taking in an average of $750 per month primarily through welfare, family, pick-up jobs, or illegal activities such as boosting (theft), selling or running drugs, and sex work. Only 5% of individuals reported having prior experience participating in research. Most had received a vaccine during their lifetime and had received health care within the past 12 months. Participants assessed healthcare services in the U.S. as poor to fair, and on average endorsed two out of six health disparity items. Major reasons endorsed for receiving poor health care were inability to pay for care, and professionals' lack of training. Average scores on worry about getting HIV/AIDS were in the “somewhat” to “a lot” range.

Vaccine Knowledge, HIV Knowledge, and HIV Mistrust

Open-Ended Questions—In their response to the open-ended question, 82% of respondents spontaneously described a vaccine as an injection to “prevent,” “protect,” or “immunize” one against disease. Another 4% described it as an injection to stay “healthy” or “strong.” Only five participants thought it cured or reduced symptoms of a disease and the remainder said they did not know or gave uncodable responses. In response to the open-ended question about HVT, 38% of participants defined the purpose as testing whether a vaccine to protect against HIV works; 11% described it as a means of gathering information to better understand HIV, whereas 25% thought the purpose was to find a cure for HIV. The remainder said they did not know, or provided uncodable responses.

True-False Responses—The proportion of participants endorsing true-false items is provided in Table 2. The majority of participants endorsed the statement that “vaccines protect individuals from getting a disease.” However, more than half believed a vaccine could help someone already infected with HIV, and considered a vaccine with mild side effects unsafe. The majority of participants (72%) accurately responded to all four HIV knowledge items. More than half of the participants thought a vaccine and a cure for HIV existed that was being withheld from the public, and 29% thought it was a manmade virus.

Yet, a majority thought the health department was doing all it could to stop the spread of HIV/AIDS.

Cumulative scores were constructed based on the number of correct items endorsed (incorrect items were reversed scored) for vaccine and HIV knowledge, respectively, and for items endorsing HIV mistrust (trust items were reversed scored). Neither gender nor ethnicity significantly affected how many correct items were endorsed, with the exception of HIV knowledge where males (M = 3.8, SD = .35) had significantly higher scores than females (M = 3.56, SD = .57), $F_{1, 93} = 9.13$, $p < .004$. Among the knowledge and attitude variables, HIV mistrust was negatively correlated with HIV knowledge ($r_{96} = -.25$, $p < .05$) and positively correlated with the total number of health disparities items endorsed ($r_{96} = .22$, $p < .05$).

HVT Knowledge and HVT Trust

HVT Knowledge—As illustrated in Table 3, the majority of participants understood the purpose of an HVT, the use of a placebo-control, and the use of blood tests and incidence of HIV as outcome measures. Just over half understood that participants would not know their group assignment, but a majority thought that the trial doctor would. Approximately 40–50% of respondents were unaware that participants needed to be HIV negative and that the HIV vaccine would cause false positive HIV test results. The same percentages endorsed misconceptions that during participation they might be injected with the HIV virus, contract or transmit HIV to others, and that the experimental vaccine would protect them from getting HIV.

Half the respondents endorsed at least two out of the five HVT trust items. However, as illustrated in Table 3, endorsement of trust items never exceeded 50%. Their responses indicated a lack of trust in government monitoring of experimental vaccine safety, the honesty with which government- and sponsor-funded research would be reported, and the integrity of researchers and their respect for participants as persons rather than as guinea pigs.

Associations Among Demographic, Healthcare, Knowledge, and Trust Variables—Cumulative scores based on correct HVT knowledge items and HVT trust items were significantly correlated with one another, $r_{96} = .33$, $p < .001$. Most demographic factors, including gender and ethnicity, were unrelated to cumulative scores created by summing correct answers for HVT knowledge and for answers indicating trust for HVT trust. Table 4 provides information on those variables that were significantly correlated with at least one of the HVT scores.

Pre-post Lesson Differences on HVT Knowledge and HVT Trust

Nature of Sample—Responses from the 30 participants who received the lesson did not differ significantly from the remaining 66 participants on most demographic variables and cumulative measures of vaccine knowledge, HIV knowledge, HIV mistrust, or HVT knowledge. The proportion of participants identifying as Hispanic was equivalent for the non-lesson and lesson groups. However, there was a significant difference in the proportion of non-Hispanic black and white participants ($\chi^2_3 = 16.70$, $p < .001$). The non-lesson sample had less non-Hispanic black participants then the lesson group (21% versus 60%) and higher proportions of non-Hispanic white participants (54% versus 17% for non-lesson and lesson groups, respectively). The lesson group were somewhat less likely to live in marginalized housing (58% versus 28%; $\chi^2_1 = 7.89$, $p < .05$), share needles (51% versus 30%; $\chi^2_1 = 3.86$, $p < .05$), or engage in sex without condoms (68% versus 47%; $\chi^2_1 = 4.03$, $p < .05$), and had

significantly lower scores on HVT trust (M = 1.20, SD = 1.34) than the non-lesson group (M = 1.98, SD = 1.62) [$F_{1,95} = 5.34$, $p < .05$].

Pre-Post Lesson HVT Responding—Cumulative scores for pre- and post-lesson responses to HVT knowledge and HVT trust were constructed for the 30 participants who received the brief HVT lesson. Dependent *t*-tests demonstrated that exposure to the lesson produced a significant advantage in HVT knowledge [M = 7.86, SD = 1.90 and M = 11.38, SD = 2.04 for pre- and post-lesson, respectively; $F_{1,28} = 505.49$, $p < .001$, Partial Eta Squared = .95, observed power = 1]. The lesson also increased levels of HVT trust [M = 1.20, SD = 1.35 and M = 1.87, SD = 1.72 for pre- and post-lesson, respectively; $F_{1,28} = 57.66$, $p < .001$, Partial Eta Square = .67, observed power = 1].

As illustrated in Table 5, the lesson's effect was greatest for increasing the proportion of respondents understanding that: (a) participants in an HVT must be HIV negative [$t_{29} = 4.47$, $p < .001$]; the vaccine would produce HIV false positive test results [$t_{29} = 5.11$, $p < .001$]; and neither the participant nor the doctor would know the assignment condition [$t_{29} = 4.35$, $p < .001$ and $t_{29} = 6.69$, $p < .001$, respectively]. The lesson also significantly reduced false beliefs that the vaccine contained the HIV virus [$t_{29} = 2.54$, $p < .05$] and that those receiving the vaccine could then transmit HIV to others [$t_{29} = 3.89$, $p < .001$]. Furthermore, the lesson was effective in increasing participants' beliefs that researchers would fully explain the risks of participation [$t_{29} = 2.26$, $p < .05$] and that study results would be reported honestly if the research was funded by the government [$t_{29} = 2.26$, $p < .05$]. However, the majority continued to believe scientists used them as guinea pigs and that pharmaceutical company–funded research would not be reported honestly.

Post-lesson Attitudes Toward Participation

The majority of respondents exposed to the brief HVT lesson held positive attitudes toward participation (M = 3.18, SD = .92). As illustrated in Table 6, few active drug users who received the HVT lesson believed HVT participation would increase HIV risk behaviors and most endorsed statements describing the potential for direct and indirect research benefits. Moreover, few were concerned about side effects of placebo and blood tests; although more than half expressed concern about taking non-FDA approved experimental vaccines. Although the majority of participants thought drug users would understand the HVT consent information, many believed the effects of addiction might make it difficult to understand assignment to a placebo condition. Few thought refusal to participate would result in denial of services. However, responses varied to questions on the effect of monetary compensation on voluntary participation: many believed monetary gains would outweigh safety (45%) or other concerns (77%) in participation decisions. Finally, 81% reported they would probably or definitely participate in HVT research. The participation decision was not significantly correlated with either post-lesson HVT knowledge or trust, but was negatively associated with health disparities ($r_{27} = .43$, $p < .05$).

Discussion

The ethics of conducting HIV vaccine trials (HVT) in developing countries has stimulated national and international commentary. Less attention has been paid to the ethical challenges of HVT recruitment of intravenous drug users (IDUs) living in the U.S., especially those with little prior research participation experience. This research was designed to highlight and stimulate additional research on the consent preparedness and ethically relevant attitudes that may influence HVT participation decision-making among economically and socially marginalized IDUs.

Vaccine Knowledge, HIV Knowledge, and HIV Mistrust

General knowledge about vaccines and HIV are important to an understanding of the purpose and nature of an HIV vaccine trial (HVT). Although both open-ended and true-false item responses indicated the majority understood the purpose of a vaccine was to prevent disease, half erroneously believed it could also help those who had already contracted the disease. Moreover, half of the participants viewed vaccines as unsafe if they produced what physicians, investigators, and institutional review boards (IRBs) have traditionally viewed as "minor side effects" (e.g., headaches, fever). This finding calls for further examination of whether descriptions of risk in informed consent for HIV vaccine clinical trials are interpreted differently by the science and medical establishments, IDUs, and other marginalized groups (Klitzman, 2008; Lazovski et al., 2009).

The majority of participants were knowledgeable about HIV symptoms and risk behaviors. However, in items tapping HIV mistrust, almost a third believed HIV to be a manmade virus intended to eliminate certain groups of people and more than half believed both a cure and effective vaccine for HIV exists but is being withheld from the public. These findings are consistent with reports of similar beliefs among ethnically diverse marginalized drug users and racial/ethnic minority populations in the United States (Allen et al., 2005; Corbie-Smith, 1999; Fisher et al., 2008; Gamble, 1997; Priddy et al., 2006).

HVT Knowledge and Trust

Data on true-false responses to questions tapping specific HIV vaccine trial (HVT) knowledge highlighted both strengths and vulnerabilities in street drug users' HVT consent preparedness. A majority of participants were aware that an HVT study was designed to test the effectiveness of an experimental vaccine, that some participants might be assigned to a placebo group, and that effectiveness would be measured through blood tests and comparisons between experimental and control group. However, similar to their misconceptions about vaccines in general, more than half believed the experimental vaccine was designed to cure or help alleviate symptoms of HIV/AIDS. There were also indications that participants might be confusing the goals of research with those of treatment. For example, although a majority knew the purpose of an HVT study was to test whether the experimental vaccine was effective, almost half believed assignment to the experimental group would nonetheless protect them from getting HIV. Moreover, while most understood that participants would be naïve with respect to assignment to experimental or placebo condition, the majority believed group assignment would be known by the trial doctor. These findings are consistent with previous work, suggesting that the therapeutic misconception (the conflation of the investigator's research and physician roles; Appelbaum, Lidz, & Grisso, 2004) influences attitudes of street drug users toward clinical trial participation (Fisher et al., 2008).

The true-false data revealed additional misconceptions about HVT that could jeopardize the adequacy of both participation consent and recruitment. Many thought that participation in an HVT meant they might be injected with the HIV virus and that participants could thus contract or transmit HIV to others. This misconception may be explained by the inverse relationship found between cumulative scores on vaccine knowledge and HVT understanding. That is, individuals familiar with vaccines in general (many of which contain some version of the disease as a means of building up immunity) may be more susceptible to generalizing this knowledge to beliefs that the experimental HIV vaccine contains the HIV virus.

The true-false questions also surfaced respondents' distrust in the integrity of the science establishment. A majority did not believe the government would make sure experimental

vaccines were safe before they were tested, nor that results of HVT studies would be reported honestly if funded by the government or pharmaceutical companies. Consistent with other studies underscoring the relationship between everyday experiences with poor healthcare services and attitudes toward research participation (Fisher et al., 2008; Fisher & Wallace, 2000), HVT trust was inversely related to the number of health disparities endorsed by the participants.

Gender and Ethnicity—In this study, the relationship of gender and ethnicity to HVT ethically relevant knowledge and trust were minimal as were most other demographic characteristics. The data are consistent with other large-scale studies that fail to find gender or ethnic influences on IDUs' willingness to participate or their response to HIV educational efforts (Golub et al., 2005; Sobieszcyk et al., 2009). These findings suggest that the shared effects of poverty, under-education, marginal living conditions, social stigma, and engagement in illegal drug activities may serve to homogenize healthcare experiences, medical and research knowledge, and trust in ways that override experiential differences due to gender and race/ethnicity (Fisher et al., 2008).

Effectiveness of the Brief HVT Lesson

The brief lesson constructed for this study, enhanced consent preparedness for specific features of HVT designs including inclusion criteria, random assignment to placebo, the likelihood of false-positive HIV test results, and the experimental blind. The lesson also reduced misconceptions that participants would be injected with the HIV vaccine and increase the likelihood they could transmit HIV to others. Following the lesson, participants were also less likely to believe the investigator would not know specific participant group assignments, thereby potentially reducing the potential for therapeutic misconception among this population.

Exposure to the lesson also increased expectations that researchers would be honest with participants about HVT participation risks and provide truthful reports about the results of government-sponsored studies. However, exposure to the lesson did not alter beliefs that scientists used drug addicts as guinea pigs, that the government could not be trusted to insure the safety of experimental vaccines, or that industry would fail to honestly report study results. These findings draw further attention to difficulties in remedying the high levels of mistrust in the healthcare system and clinical trials in general among marginalized groups in the United States (Boulware et al., 2003; Brooks et al., 2007; Crawley, 2001; Meyers et al., 1994; Mills et al., 2004; Newman et al., 2008).

Ethically Relevant Attitudes toward Participation

Some in the science community have raised concerns that participation in HVTs might inadvertently increase HIV risk behaviors if participants wrongly assume that trial participation render them “AIDS safe.” The attitudes expressed by participants in the present study did not support this concern. These findings are consistent with a study by van Griensven et al. (2004) reporting no increase in HIV risk behaviors among IDUs participating in an HVT in Thailand. Clearly, additional behavioral data is needed to assist investigators and IRBs in determining whether the possibility of “AIDS safe” behaviors should be considered a research participation risk in HIV vaccine trials.

Participation Benefits and Risks—This study provides a window into how socially and economically marginalized IDUs evaluate the benefits and risks of HVT participation. Almost all respondents thought the results of the study could benefit addicts in the future and that participants would benefit from the chance to be protected from HIV and from study-provided HIV counseling. Although baseline responses suggested many participants

evaluated vaccine side effects such as blood tests and headaches as potentially high risk, the percentages of individuals judging side effects as dangerous was dramatically reduced following exposure to the lesson. At the same time, many respondents believed it was a risk to take an experimental vaccine that had not already been approved by the FDA. This suggests that to enhance informed consent preparedness, the relationship of clinical trials as a precursor to FDA vaccine approval and the regulations protecting individuals who agree to participate in clinical trials for experimental vaccines should be added to the brief lesson format.

Consent Capacity—Following the lesson, the majority of respondents thought most people addicted to drugs would understand the description of the study before making a participation decision. While such attitudes were not measured prior to receiving the lesson, the finding does suggest that a clearly worded brief educational presentation may not only increase consent preparedness, but also confidence in making an appropriate consent decision. Almost half the participants believed long-term drug addiction may make it difficult for individuals to understand they may receive a placebo in an HIV vaccine trial. This finding is consistent with suspicion about random assignment to experimental or placebo conditions evidenced in a similar sample of street drug users who responded to a video vignette of an informed consent conference for an RCT for a new cocaine addiction treatment (Fisher et al., 2008).

Voluntary Participation and Monetary Compensation—Monetary compensation has been found to increase recruitment and retention for street addiction research in general and HVT participation in particular (Fry & Dwyer, 2001; Golub et al., 2005; Grady et al., 2008; Jenkins et al., 2000; Maher et al., 2010; Oransky et al., 2009; Seal et al., 2003; Slomka et al., 2007). Some have raised concerns that cash payments for participation in drug addiction research can distorts prospective participants' evaluation of drug use dangers by providing funds that can be used to purchase drugs (Fisher, 2004; Gorelick, Pickens, & Bonkovsky, 1999; McCrady & Bux, 1999). Others have argued that to deny compensation to this population can reinforce financial inequities between drug abusing and non-abusing populations or deny them the right to apply their own value system to life risk decisions (Levine, 1988; Fisher, 1999). Furthermore, studies have found that drug users reject paternalistic approaches to limit monetary compensation for addiction and other types of research as efforts to limit their autonomy or as overly simplistic views of drug addiction habits (Oransky et al., 2009; Seddon, 2005; Singer & Couper, 2008).

Results from the present study raise additional questions about the impact of monetary compensation on voluntary participation. While most participants believed that money would not put undue pressure on drug users to participate in a study they thought was dangerous, a similar proportion thought the offer of compensation would erase such safety concerns. Emanuel (2005) proposed compensation be defined as coercive only when it distorts prospective participants' reasoning to the degree that they take risks they would not ordinarily be willing to take. However, the science establishment has yet to operationalize “clear reasoning” or “risk of serious harm” (Ripley, 2006) within the context of drug addiction. For example, there is a paucity of empirical work on how the need for money to procure drugs to satisfy cravings and avoid withdrawal symptoms or to pay for food, clothing, or shelter affects participants' risk-benefit calculations. Thus ethical decisions about monetary compensation for IDUs' participation in HVT and other studies must continue to grapple with the dual responsibility of ensuring that drug using populations receive fair compensation for their research participation while making sure such compensation does not jeopardize the voluntary nature of their participation (Fisher, 2004; Fry et al., 2006; Oransky et al., 2009).

Willingness to Participate

Previous research indicates trust, confidentiality, side effects and safety concerns, social stigma, and other factors as recruitment barriers to HVT; however, rates of expressed willingness to participate are far greater than actual participation (Halpern et al., 2001; Koblin et al., 2000; Priddy et al., 2006). In the present study, attitudes toward health disparities predicted participation willingness. Surprisingly, neither HVT knowledge nor trust significantly influenced the participation decision. Although participants in this study were responding to a hypothetical decision, this finding may be cause for concern, since it suggests that for marginalized IDUs, understanding during informed consent may not strongly influence HVT participation decisions. The current body of research points to the need for more empirical data on the links between pre-recruitment attitudes and participation choices.

Best Practices

This study adds to the small but growing body of literature on consent preparedness for participation in HIV vaccine trials among economically and socially marginalized intravenous drug users in the U.S. Participant misconceptions about vaccines in general and HVT research in particular suggest that without educational efforts, members of this population may be experientially unprepared to provide fully informed consent for HVT participation. The post-lesson findings further suggest that brief educational interventions are a practical and effective way to increase consent preparedness during street recruitment or as part of consent procedures involving economically and socially marginalized illegal drug users with little research experience. Based on areas in which respondents indicated the most misconceptions, best practices in preparing members of this population for HVT consent decisions should include education on: (1) the preventive rather than recuperative nature of vaccines; (2) the relationship of clinical trials to the FDA approval of vaccines; (3) clarification regarding the investigator blind as well as uncertainty about the effectiveness of the experimental vaccine, which in turn may help reduce therapeutic misconceptions; and (4) correction of common misconceptions that the vaccine contains the HIV virus and can cause participants to contract or transmit HIV.

The findings of this study are consistent with previous research highlighting the barrier mistrust presents to HVT recruitment. Low enrollment levels, in turn, create significant barriers to the development of a vaccine effective for this population. The preliminary finding that HVT trust, though not directly addressed in the lesson content, was nonetheless increased following the lesson suggests that providing prospective participants with the knowledge needed to make an informed decision is perceived as a sign that the research team is dedicated to respectful and honest communication. This is underscored by the many unexpected times participants in the present study thanked the field researcher for providing them with information about the current status and nature of HIV vaccine development and research. The changing levels of trust found in this study is consistent with the portrayal of trust in research as a dynamic concept, continuously changing and based on reciprocity and respect (McDonald et al., 2008)

Limitations

The sampling procedures and exploratory nature of this study suggest a need for caution in generalizing the results of this study to other IDU populations. For example, the preliminary nature and relatively small sample size used to examine the effect of a brief HVT lesson and post-lesson participation attitudes requires replication before such findings should be considered generalizable. Since the samples represented IDUs living in ethnically diverse New York City where access to health care and recruitment for addiction research may be

higher than in other locales in and outside the U.S., the generalizability of the findings to this densely populated urban environment is limited. However, the evidence suggests that the knowledge and attitudes toward HVT among the urban poor IDUs participating in this study may not be different from that found in other high-risk populations worldwide. For example, Priddy et al. (2006), surveying a multi-ethnic college population, found percentages similar to those reported in the present study for: (a) knowledge of HIV symptoms and placebo controls; (b) misconceptions about the vaccine's composition and effect on HIV test results; and (c) suspicions of an HIV government conspiracy.

Previous studies aimed at enhancing consent preparedness in the U.S. have involved diverse high-risk populations already involved in other forms of HIV prevention studies (Coletti et al., 2003; Colfax et al., 2005). This has the advantage over the present study in providing more time-intensive lessons, evaluations of knowledge retention over time, and medical assessment of HIV serostatus. This limitation is balanced in part by the present study's focus on the effectiveness of a brief lesson for IDUs who represent a population with little research experience or previous contact with research team members.

Research Agenda

This preliminary investigation suggests several areas for future research. First, the data underscore the salience of non-research-related healthcare experiences on levels of research mistrust. The findings also highlight the need for federal efforts to reduce health disparities among U.S. racial/ethnic and other minority groups as an essential step toward increasing confidence in the integrity of HIV vaccine trial investigators and sponsors. Additional studies are needed to fully understand the relationship between health disparities and recruitment barriers to inform social policy and move federal funding in a direction that recognizes the need for the integration of health research and health services.

Consistent with previous research within and outside the U.S., this study found a high percentage of participants expressing willingness to participate (WTP) (Coletti et al., 2003; Dhalla et al., 2007; Golub et al., 2005; Koblin et al., 2000; Meyers et al., 1994; Yin et al., 2007). Such high rates of WTP are in striking contrast to actual low participation rates reported for HVT trials and in immunization rates for currently available vaccines for preventable infections within this population (Baral et al., 2007; Buchbinder et al., 2004; Sobieszczyk et al., 2009). Additional studies are needed to better understand the extent to which the discrepancy between stated and actual HVT participation rates among IDUs reflects social desirability or other demand characteristics of measures of WTP, family, and other social influences on the actual participation decision, or additional participation barriers that occur between the occasionally lengthy screening procedures and the beginning of a vaccine trial.

Finally, the paradoxical nature of our participants' responses to the influence of monetary compensation on recruitment calls for additional investigation of how socially and economically marginalized individuals addicted to illicit drugs decide to take research risks in the context of research payments. Singer and Couper (2008), for example, found no interaction between level of payment and willingness to assume research risk in hypothetical cases presented to a diverse sample over the Internet. Population-specific adaptation of Singer and Couper's procedures for active drug users is one fruitful avenue to continue to empirically inform ethical decisions regarding payment plans for research participation.

Educational Implications and Goodness-of-Fit Ethics

Informed consent for HIV vaccine trials (HVT) involves a series of interrelated concepts, many of which may be unfamiliar to impoverished persons with addictions, marginal levels

of education, and lack of access to quality health care. At the same time, as evidenced in this study, these individuals have consent strengths and the capacity to understand the various elements of HVTs when they are clearly explained. The study thus has implications for education for those developing informed consent procedures to enroll street drug abusers in HVT research and IRBs reviewing the adequacy of consent procedures for this population. The findings suggest that for HVT studies with marginalized populations, the responsible conduct of research requires investigators to be trained in strategies to: (1) generate knowledge of the consent assets and weaknesses of the population, including misconceptions that may be a consequence of health disparities and medical mistrust; and (2) develop knowledge-enhancing methods to reduce these misconceptions.

These training recommendations draw from Fisher's goodness-of-fit ethics (GFE) conceptual framework, which calls for consent procedures fitted to the knowledge, interpersonal, and experiential needs of research participants specific to the research designs (Fisher, 2002, 2003; Fisher & Ragsdale, 2006). GFE views consent preparedness as a product of the relationship between participants and the consent context. This ethical framework shifts assumptions regarding consent preparedness away from an exclusive focus on a prospective research participant's knowledge deficiencies to: (1) an examination of those aspects of the consent setting that are creating or exacerbating consent vulnerability; and (2) consideration of how the setting can be modified to produce a consent process that best reflects and protects the consumer's hopes, values, concerns, and welfare (Fisher & Goodman, 2009; Masty & Fisher, 2008). Applied to HVT, goodness-of-fit ethics defines consent vulnerability in terms of a susceptibility to misconception and mistrust that does not rest solely upon the psychological or social characteristics of marginalized street drug users. Rather, it must include consideration of the degree to which an individual's ability to provide informed, rational, and voluntary consent is dependent upon the specific actions of scientists within a specific experimental context (Fisher, 1999). For HVT studies involving marginalized street drug users, GFE will often involve remedial efforts to enhance consent preparedness coupled with efforts to attain mutual understandings and trust between investigators and participants.

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Biography

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TABLE 1

Demographic and Health Care Information Represented by Number of Participants and Percentages (N = 96).

Demographic Variables	N (%)	Health Care Variables	N (%)
Male	43 (45)	Tested for HIV	92 (96)
Race/ethnicity		Received health care in past 12 months	95 (99)
non-Hispanic black	32 (33)	Have you ever received a vaccine?	96 (100)
Hispanic (majority were Puerto Rican)	22 (23)	Worry about getting HIV/AIDS	
non-Hispanic white	41 (43)	Not at all	
Other	1 (1)	Somewhat	95 (96)
High school degree/GED	63 (66)	A lot	
Employment status (unemployed)	86 (90)	Health disparities	
Served time in prison	69 (72)	Professionals' lack of training	57 (59)
Homeless or in marginal housing	46 (48)	Inability to pay	38 (40)
Drugs used in past 30 days		Racial/ethnic discrimination	39 (41)
Cocaine	69 (72)	Do not take health insurance	40 (42)
Heroin	87 (91)	Services not offered	38 (40)
Barbiturates	35 (36)	Difficulty speaking English	
Marijuana	33 (34)	HIV risk categories	3 (3)
Other opiates	24 (25)	MSM (men who have sex with men)	7 (16)
Crack	16 (17)	WSM (females at heterosexual risk)	40 (78)
Alcohol use	63 (66)	IDU within past year	93 (97)
		Shared needles within past year	43 (45)
		Never or rarely use condoms	42 (44)

Note: Missing date resulted in some percentages not equaling 100.

TABLE 2

Number and Percentage of Participants Endorsing True-False Items Representing Vaccine Knowledge, HIV Knowledge, and HIV Mistrust (N = 96).

True-False Items	N (%)
Vaccine Knowledge	
A vaccine can protect you from getting a disease.	86 (90)
A vaccine does not help someone infected with a disease.	51 (53)
A vaccine is considered safe if it causes only minor side effects such as headache, arm pain, or a low fever.	61 (64)
HIV Knowledge	
HIV makes it more difficult for your body to fight other diseases.	96 (100)
HIV can be cured with medicine.[a]	84 (88)
You can get HIV by sharing needles with other drug addicts.	93 (97)
Using condoms can protect you from getting HIV.	81 (84)
HIV Mistrust	
HIV is a manmade virus that was created to get rid of certain groups of people.	28 (29)
An effective HIV vaccine already exists but has been withheld from the public.	56 (58)
The health department is doing all it can to stop the spread of AIDS.[a]	61 (64)
There is a cure for AIDS but the government is keeping it from the public.	50 (52)

[a]Reversed scored when calculating cumulative score.

TABLE 3

Number and Percentage of Participants Endorsing True-False Items Representing HIV Vaccine Trial (HVT) Knowledge and HVT Trust (N = 96).

True-False Items	N (%)
HIV Vaccine Trial (HVT) Knowledge	
Researchers conducting the vaccine study do not know whether the vaccine can protect people from getting HIV.	81 (84)
Vaccines must be tested by clinical research studies in order to know if they work.	84 (87)
In an HIV vaccine study, some people receive the experimental vaccine and some receive a placebo (a sugar pill or injection of a liquid that is not medicine).	82 (85)
Researchers will know whether the vaccine works by blood tests that will show whether my immune system is responding to the vaccine.	86 (90)
Researchers will know whether the vaccine works by comparing whether people who were given the vaccine were less likely to get HIV then those who were given the placebo.	77 (80)
If I participate in an HIV vaccine trial, I will know whether I am receiving the experimental vaccine or the placebo.[a]	45 (47)
If I participate in an HIV vaccine trial, the doctor will know whether I received the vaccine or the placebo.[a]	81 (84)
Only people who do not have HIV can participate in an HIV vaccine study.	50 (52)
An HIV experimental vaccine will cause you to test positive for HIV even though you do not have HIV.	49 (51)
In an HIV vaccine clinical trial, I may be injected with the HIV virus.[a]	43 (45)
A participant in an HIV vaccine trial can get HIV from the vaccine.[a]	36 (38)
If I participate in an HIV vaccine trial, the vaccine might make it possible for me to transmit HIV to others.[a]	40 (42)
People who get the experimental vaccine in a research study will be protected from getting HIV.[a]	46 (48)
HIV Vaccine Trial (HVT) Trust	
I trust the government to make sure that vaccines they want to test are safe before they test it on people.	45 (47)
Scientists think it is more acceptable to use drug addicts as guinea pigs for HIV vaccine studies than people who are better off.[a]	66 (69)
Drug addicts can trust that researchers will be honest with them about the risks of participating in experimental vaccine studies.	39 (41)
The results of experimental vaccine studies will be reported honestly if it was paid for by government.	37 (39)
The results of experimental vaccine studies will be reported honestly if it was paid for by a pharmaceutical (drug) company.	16 (17)

[a]Reversed scored when calculating cumulative score.

TABLE 4

Demographic, Health Care, and Knowledge Variables Significantly Correlated With Cumulative Scores for Either HVT Knowledge or HVT Trust (N = 96).

Variables	HVT Knowledge	HVT Trust
Education (GED)	.21*	−.15
Condom use	−.12	−.23*
Needle sharing	.23 *	−.13
Tested for HIV	−.33***	.07
Worry about HIV/AIDS	−.22*	−.09
Health disparities	−.24*	−.24*
Ratings of healthcare received	.15	.39***
Vaccine knowledge	−.24*	−.46***

Note:

* $p < .05$,

** $p < .01$,

*** $p < .001$

TABLE 5

Number and Percentage of Participants Endorsing True-False Items on HIV Vaccine Trial (HVT) Knowledge and HVT Trust Before and After an HVT Lesson (N = 30).

True-False Items	Pre-lesson	Post-lesson
HIV Vaccine Trial (HVT) Knowledge		
Researchers conducting the vaccine study do not know whether the vaccine can protect people from getting HIV.	25 (83)	26 (87)
Only people who do not have HIV can participate in an HIV vaccine study.	12 (40)	26 (87)***
An HIV experimental vaccine will cause you to test positive for HIV even though you do not have HIV.	11 (37)	27 (90)***
In an HIV vaccine study, some people receive the experimental vaccine and some receive a placebo (a sugar pill or injection of a liquid that is not medicine).	24 (80)	30 (100)
In an HIV vaccine clinical trial, I may be injected with the HIV virus.[a]	10 (33)	3 (10)*
Vaccines must be tested by clinical research studies in order to know if they work.	26 (88)	26 (87)
A participant in an HIV vaccine trial can get HIV from the vaccine.[a]	10 (33)	4 (13)
People who get the experimental vaccine in a research study will be protected from getting HIV.[a]	11 (37)	6 (20)
If I participate in an HIV vaccine trial, the vaccine might make it possible for me to transmit HIV to others.[a]	13 (43)	1 (3)***
If I participate in an HIV vaccine trial, I will know whether I am receiving the experimental vaccine or the placebo.[a]	19 (63)	4 (13)***
If I participate in an HIV vaccine trial, the doctor will know whether I received the vaccine or the placebo.[a]	28 (93)	8 (27)***
Researchers will know whether the vaccine works by blood tests that will show whether my immune system is responding to the vaccine.	28 (93)	28 (93)
Researchers will know whether the vaccine works by comparing whether people who were given the vaccine were less likely to get HIV than those who were given the placebo.	22 (73)	24 (80)
HIV Vaccine Trial (HVT) Trust		
I trust the government to make sure that vaccines they want to test are safe before they test it on people.	9 (30)	13 (43)
Scientists think it is more acceptable to use drug addicts as guinea pigs for HIV vaccine studies than people who are better off.[a]	22 (73)	22 (73)
Drug addicts can trust that researchers will be honest with them about the risks of participating in experimental vaccine studies.	8 (27)	14 (47) *
The results of experimental vaccine studies will be reported honestly if it was paid for by government.	5 (17)	12 (40)*
The results of experimental vaccine studies will be reported honestly if it was paid for by a pharmaceutical (drug) company.	6 (20)	7 (23)

[a]Reversed scored when calculating cumulative score.

*$p < .05$,

**$p < .01$,

***$p < .011$

TABLE 6

Number and Percentage of Participants Responding to True-False Items Representing Endorsement of Ethically Relevant Aspects of HIV Vaccine Trial (HVT) Participation Following a Brief HVT Lesson (N = 30).

True-False Items	N (%)
Risk of "AIDS-safe" Behaviors	
If I was participating in an HIV vaccine study, I'd probably share needles or have unsafe sex more often.	0 (0)
If I was participating in an HIV vaccine study, I would feel less concerned about getting HIV from others.	2 (7)
Most drug addicts who participate in this study will continue to share needles or have unprotected sex because they think the vaccine will protect from getting HIV.	8 (27)
Participation Benefits	
Participating in this study will benefit drug addicts because it is a chance to get protection from getting HIV.	25 (83)
Participating in the study will benefit drug addicts because it is a chance to get counseling about how to avoid getting HIV.	27 (90)
The study will benefit other drug addicts in the future because it will find out if the vaccine works.	28 (93)
Participation Risks	
The placebo could have serious side effects.	8 (27)
Getting the blood tests each week is dangerous to the drug addicts' health.	3 (10)
Drug addicts should not take the experimental vaccine if it is not already approved by the FDA.	19 (63)
Consent Comprehension	
Most people addicted to drugs will understand the researcher's description of this study before they decide whether to participate.	26 (87)
The effects of addiction will make it difficult for long-time drug addicts to understand they may get a placebo rather than the experimental medicine.[a]	12 (40)
Voluntariness	
Drug addicts should worry that if they say no to participate in the vaccine trial, other doctors at the clinic will not treat them.[a]	4 (13)
No matter how much money is offered, if people with drug addictions thought the experimental vaccine study was dangerous, they would refuse to be in it.	16 (55)
If there is money being offered, drug addicts won't care about the risks of being in the study.[a]	23 (77)

[a]Reversed scored when calculating cumulative score.