Assessing and Enhancing HIV Vaccine Trial (HVT) Consent Preparedness Among Street Drug Users

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HIV Prevention Research Ethics Institute
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HIV Vaccine Trials and Justice

- Is it fair to study HIV vaccine in drug using impoverished populations in the US?

- Are we asking this population to carry an unjust burden of experimentation that we are not asking of better off populations that will benefit from the results of the study?
HIV Vaccine Trials and Justice

- Injection drug use accounts for 1/3 HIV cases in US
- Increased risk from IDU, sex work, & unprotected sex
- Difficult to develop a universally effective vaccine without testing its efficacy in IDUs...

Course of infection through sexual transmission and injection
Effect of street drugs on viral strains
Differences in immunological barriers
Drug-drug interactions
Comorbidities
General Consent Vulnerabilities

- Health disparities
- Education
- Cognitive impairments
- Co-morbid mental health disorders
- Poverty
- Social Stigma
- Legal risk
HVT Consent Vulnerabilities

• Misconceptions

HIV acquisition and transmission
Purpose of vaccine (preventive v. curative)
Nature of HVT (injection of virus; increased risks; AIDS safe)

• Mistrust

Group stigma
History of research abuses
Health disparities
Goodness-of Fit Ethics

- Consent vulnerability = joint product of participant characteristics and the research context.
- Shared burden for consent vulnerability.
- Increase consent capacity by fitting research and consent context to participants strengths and vulnerabilities

Research Ethics Questions

• What experiences, knowledge and attitudes characterize HVT consent preparedness among marginalized persons who use street drugs?

• Can a brief lesson fitted to this population’s needs correct misconceptions and increase HVT relevant knowledge?

• Can a brief lesson reduce research mistrust?
Procedure

• Street recruitment
• Informed consent
• Demographics
• Health care experience & attitudes
• Baseline measures N = 96
• Lesson N = 30
• Post-lesson measures N = 30
• Compensation $25
96 HIV Negative Street Drug Users

Demographics
• 45% Male
• 21 - 57 years, M = 40
• 90% unemployed
• 48% homeless/shelter
• 66% high school degree
• 72% time in prison

Ethnicity
• 33% Black non-Hispanic
• 23% Hispanic (Puerto Rican)
• 43% non-Hispanic White
• 1% other

Commonly used drugs
• 97% IDU past year
• 72% cocaine
• 91% heroin
• 36% marijuana

HIV attitudes & risk factors
• 45% shared needles
• 44% rarely use condoms
• 96% worried about HIV
• 16% men MSM
• 78% women WSM
Health Care Experience

Healthcare
- 96% tested for HIV
- 99% received health care past 12 months
- 100% were vaccinated

Reasons for Perceived Health Disparities (Blendon et al, 2007)
- 59% professionals lack training
- 40% inability to pay
- 41% racial/ethnic discrimination
- 42% not take my health insurance

How much do you worry about HIV? 96% somewhat (Scale 0 – 3)
11 True False Questions Tapping HIV & Vaccine Knowledge

HIV KNOWLEDGE 84 – 100%

VACCINE KNOWLEDGE

• Vaccine is a treatment for people infected with a disease 47%

MISTRUST

• HIV is a manmade virus created to get rid of certain groups 29%
• An effective HIV vaccine has been withheld from the public 58%
• The government is keeping a cure for AIDS from the public 50%
HVT Knowledge and Misconceptions

KNOWLEDGE 80% - 90%

- *Equipoise, placebo, blood tests*

MISCONCEPTIONS 40% – 84% (5 items)

- Participants and doctors will know whether they are given vaccine or placebo
- Individuals with HIV can participate in an HVT
- An HIV vaccine will NOT produce false positive HIV tests
- The vaccine contains the HIV virus
- The vaccine increases acquisition and transmission of HIV
HVT Mistrust

53% - 83% of Respondents:

- Gov’t does NOT test the safety of a vaccine before giving it to participants
- Scientists use addicts as guinea pigs for vaccine for “better offs”
- Scientist will NOT be honest about HVT risks
- Vaccine studies sponsored by the gov’t or pharmaceutical companies will not report results honestly
HIV Vaccine Research

- Researchers are testing whether new medications can prevent HIV

- These research studies are called Experimental HIV Vaccine Studies or HIV Vaccine Clinical Trials

- For each study, researchers do not know if the vaccine works until the study is over
What is a Vaccine?

- A vaccine is a drug that prevents people from getting a disease, like hepatitis or polio.

There is **NO** vaccine for HIV
Researchers test whether the new vaccine works by comparing its effects to a placebo

- Half the people who agree to participate receive the experimental vaccine
- Half receive a placebo (a sugar pill or an injection that does not contain any medicine)
Randomization

• Everyone who volunteers has an equal chance of being in the experimental vaccine or placebo group.

• This is called randomization and it is like a coin toss. Neither volunteers nor researchers can choose which group people will be in.

• Neither the volunteer or the researchers know who is getting the vaccine or placebo until the study is over.
Side Effects of the Vaccine

- Side effects from the experimental vaccine are usually short-term and mild such as arm soreness, fever, headache or tiredness.
Who Can Participate?

- Because the purpose of a experimental vaccine is to prevent people from getting HIV,

- Only people who are HIV negative can participate.

- Therefore, to qualify to be in the study everyone must take an HIV test.
What Can I Expect if I Participate?

• Experimental vaccine studies usually last for 1 or 2 years and requires about 6 – 20 visits.

• Most visits require participants to take a blood test and visits last anywhere from 30 minutes to 3 hours.

• Participants are paid between $50 - $150 or more a visit depending on how long the visit lasts.
How Will Researchers Know Whether the Vaccine Works?

Blood tests will tell whether people getting the vaccine build up antibodies that can fight the HIV virus.

At the end of the study researchers will see whether people who received the vaccine were less likely to get HIV than those who received the placebo.
The Vaccine **DOES NOT** Contain the HIV Virus

- The vaccine is made from artificial material and does not contain the HIV virus. The vaccine is designed to make the body build up its own defenses against the HIV virus.
YOU **CANNOT** GET HIV FROM THE VACCINE

YOU **CANNOT** TRANSMIT HIV TO OTHERS IF YOU TAKE THE VACCINE
False Positive HIV Tests

• Since one way doctors usually diagnosis HIV is to test the body defenses to the virus, people who participate in an HIV vaccine study may test positive for HIV even though they do not have HIV.

• Researchers will use special tests during the study that will provide correct test results.
Participation is Voluntary & Confidential

• Participation in these studies is always voluntary and all the facts about the study are explained to each person before they are asked if they want to participate.

• All information is given the same confidentiality protection as other medical records.
## Did Lesson Reduce Misconceptions?

<table>
<thead>
<tr>
<th>Item</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant blind</td>
<td>63%</td>
<td>13%</td>
</tr>
<tr>
<td>Investigator blind</td>
<td>93%</td>
<td>27%</td>
</tr>
<tr>
<td>HIV+ can participate in HVT</td>
<td>60%</td>
<td>13%</td>
</tr>
<tr>
<td>HVT produces false-positive HIV test</td>
<td>37%</td>
<td>90%</td>
</tr>
<tr>
<td>Vaccine contains HIV</td>
<td>33%</td>
<td>10%</td>
</tr>
<tr>
<td>Can get HIV from HVT</td>
<td>33%</td>
<td>13%</td>
</tr>
<tr>
<td>HVT increases chance of transmission</td>
<td>43%</td>
<td>3%</td>
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## Did HVT Lesson Reduce Mistrust?

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<thead>
<tr>
<th>Item</th>
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<tbody>
<tr>
<td>Gov’t does not test safety before giving vaccine</td>
<td>70%</td>
<td>57%</td>
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<tr>
<td>Scientist will NOT be honest about HVT risks</td>
<td>73%</td>
<td>53%</td>
</tr>
<tr>
<td>Vaccine studies sponsored by the gov’t will not report results honestly</td>
<td>81%</td>
<td>60%</td>
</tr>
<tr>
<td>Scientists use addicts as guinea pigs for vaccine for “better offs”</td>
<td>73%</td>
<td>73%</td>
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# Post-Lesson Questions

<table>
<thead>
<tr>
<th>Ethics Relevant Questions</th>
<th>%</th>
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<tbody>
<tr>
<td>“AIDS-safe” increase in risk behaviors (participant)</td>
<td>0 – 7%</td>
</tr>
<tr>
<td>“AIDS-safe” increase in risk behaviors (Other drug users)</td>
<td>27%</td>
</tr>
<tr>
<td>Participation benefits: HIV Protection, counseling, benefit others</td>
<td>83-90%</td>
</tr>
<tr>
<td>Participant risks: Placebo &amp; weekly blood tests</td>
<td>27-10%</td>
</tr>
<tr>
<td>Participant risks: Not take vaccine unless FDA approved</td>
<td>63%</td>
</tr>
<tr>
<td>Consent: Most will understand consent</td>
<td>87%</td>
</tr>
<tr>
<td>But long term addicts may not understand placebo</td>
<td>40%</td>
</tr>
</tbody>
</table>
### Voluntariness

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Drug addicts should worry that if they say no to participate in the vaccine trial, other doctors at the clinic will not treat them</td>
<td>13%</td>
</tr>
<tr>
<td>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</td>
<td>55%</td>
</tr>
<tr>
<td>If there is money being offered, drug addicts won’t care about the risks of being in the study</td>
<td>77%</td>
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Implications for Goodness of Fit Practices

• A brief intervention significantly increases street drug users understanding of consent information

• Under GFE investigators have a responsibility to include educational procedures in consent practices

• Understanding consent information is not the same as believing in the honesty of the information provided

• Such procedures may be necessary, but not sufficient in the context of health disparities and systemic discrimination