

Quantitative Research Example for Institute Presentation

Enhancing HIV Vaccine Trial Consent Preparedness Among Drug Users

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Purpose of the Study

- To examine the HVT consent strengths and vulnerabilities of marginalized urban street drug
- To determine if a brief lesson can increase consent preparedness and trust in HVT among members of this population

Background/Rationale

- Despite great strides in harm reduction efforts, Injection drug users continue to account for almost 1/3 of HIV/AIDS cases in the U.S.
- Differences in infection through sexual transmission and injection, effect of drug use on strains and immunological barriers, drug-drug interactions, poor nutrition, and other factors question generalizability of HVT involving non-drug users
- Poverty, lack of educational and health care opportunities, social marginalization, mistrust, and psychiatric disorders raise questions about HVT consent preparedness for this population.

Specific Aims

- AIM 1: To examine the HVT consent preparedness strengths and vulnerabilities of marginalized urban street drug users.
- AIM 2: To evaluate the effectiveness of a brief lesson on the purpose and nature of HVTs to increase consent preparedness and trust among members of this population.
- AIM 3: To determine which ethically relevant misconceptions, fears, and concerns continue to influence IDU's attitudes toward HVT participation following exposure to the lesson.

Hypotheses or Anticipated Themes

A brief HVT lesson will reduce the following HVT misconceptions:

- The HIV vaccine contains the HIV virus
- Trial participation can increase risk of transmission to their partners.
- The investigators know that the vaccine will work
- A cure exists that is kept from poorer populations
- The blood tests can transmit HIV
- Assignment is not random; everyone gets the vaccine
- The vaccine is a cure for HIV

Barriers to HVT Consent Preparedness will Include:

- Discrimination in health services
- Poor understanding of HIV acquisition and transmission
- Confusion regarding inclusion criteria, nature of placebo controlled trials etc

Study Population

- 100 economically marginalized male and female drug users self-identifying as African American, Hispanic, and Non-Hispanic White.

Inclusion Criteria

- Having tested negative for HIV or never tested;
- Use of illegal or non-prescription drugs other than alcohol, marijuana, or prescription methadone within the past 30 days;
- History of injection drug use
- Proficiency in English

Research Design

- All participants respond to questionnaires on: demographics, health care disparities, understanding of HIV acquisition and transmission, vaccines in general and HIV vaccine specifically, HVT research methods, and trust in government, research, pharmaceutical companies
- Half participants receive the HVT lesson
- All participants retested on HVT knowledge and trust items and willingness to participate in HVT

Measures/Methods

- Demographics and Health Disparities Likert type items (Blendon et al., 2007)
- Pre-Post Test Open-ended and True-false items: vaccine knowledge, HIV knowledge, HVT knowledge (risk/benefit, use of blood tests, randomization, confidentiality, compensation), HIV & HVT mistrust, informed choice, willingness to participate (adapted Brooks et al, 2007; Dormany et al, 2006; Coletti et al, 2003; Myers et al, 1994)
- 12 colorful PowerPoint slides that including text and pictorial illustrations drawn from the NIAID (2009) fact sheets on HIVT

Procedures

- Recruitment will use street outreach in areas commonly frequented by IDUs.
- Screening questions include relevant and non-relevant information to avoid biasing responses
- Interviews conducted in local offices
- Informed consent will be obtained
- Questions will be read and answers recorded by the interviewer
- \$25 compensation
- All participants receive NIAID population sensitive fact sheets on HIV and HIVT at end of study

Analytic Strategies

- AIM 1: Descriptive statistics on knowledge and attitudes and correlations to examine demographic, health care, general HIV and vaccine knowledge scores associated with HVT scores
- AIM 2: A 2 (lesson vs non-lesson group) x 2 (pre-post test knowledge/attitudes) MANOVA
- AIM 3: Multiple regression assessing pre-test factors influencing post-test improvement in enhancement group

Community Consultation/Dissemination Plan

- CAB review and modifications to video script and focus group probes
- CAB review of content analysis and interpretation
- Distribute “newsletters” to recruitment sites summarizing results

Project Challenges

- Are HIV status self-reports sufficient? Is previous history of IDU sufficient?
- True-false questions and participation questions not in format of an “informed consent” form;
- Is partner status important?
- Should control group receive a different topical “lesson”?
- Other?