

Preparing for and conducting a successful HCV vaccine trial with injection drug users: The VIP Study



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Background

- The **Vaccination Is Prevention (VIP) Study** is a phase I/II trial testing a preventive HCV vaccine in San Francisco and Baltimore.
- Conducting successful clinical trials of biomedical prevention interventions in IDU requires community involvement and a supportive clinical infrastructure.
- IDU are often 'hard-to-reach' and difficult to follow; knowledge of and experience with this population is critical to success.
- Our client-centered approach is culturally competent and informed by the needs of the injection drug user community.

Preparing the Community

- We surveyed young (<30) IDU to gauge understanding of, and willingness to participate in a randomized trial testing an experimental HCV vaccine.
 - A substantial proportion (88%) reported being definitely (44%) or probably (44%) willing to participate.
 - Knowledge of vaccine trial concepts was low.

Preparing the Community

- To address knowledge gaps, we held information sessions with IDU and community-based providers working with IDU prior to initiating the trial
- Ongoing sessions aid in participant recruitment as well as provide an opportunity for the research team to forge community partnerships.
- Key concepts such as blinding, randomization, study objectives, and the properties of the experimental vaccine are discussed. Special attention is given to myths surrounding vaccines and clinical trials.
- Our experience with conducting research, HCV counseling/testing, and health resource/referral networks are highlighted, illustrating our connection with the IDU community.

Conducting the trial

Factors contributing to the early success of the VIP Study include:

- Intensive recruitment and retention efforts: a case-management outreach approach tracks participants with phone, social media and personal visits.
- Use of an Informed Consent (IC) Comprehension tool reviewed with participants prior to enrollment to ensure essential trial concepts are understood.
- A memory aid tool designed specifically for the population, to assist in identification of adverse events.
- Outreach to local community providers and stakeholders is ongoing and positive. Many participants are referred by community-based providers.

Lessons Learned

- Conducting a successful clinical trial for an HCV vaccine with IDU requires strong internal and external support.
- Essential components include:
 - Educational activities
 - Community buy-in
 - A culturally-competent staff
 - An accessible clinic
 - Aggressive outreach strategies to meet recruitment and retention goals

Thank you

- Questions?
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