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.
- We describe preparatory and ongoing work in San Francisco for the VIP Study in a population normally excluded from clinical trials: injection drug users.
- Our approach is client-centered, culturally competent and informed by the needs of the injection drug user community
- 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

Preparing the community

- We surveyed IDU to gauge understanding of, and willingness to participate in a trial testing an experimental HCV vaccine.*
- We held information sessions with IDU and community-based providers working with IDU prior to initiating the trial to disseminate goals and objectives of the VIP Study.
- 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 were discussed. Special attention was given to myths surrounding vaccines and clinical trials.
- Our experience with conducting research, HCV counseling/testing, and health resource/referral networks was highlighted, illustrating our connection with the IDU community
- Trial staff were trained and sensitized to issues impacting safety monitoring, including psychosocial factors, and long-term retention and making visits client-centered.

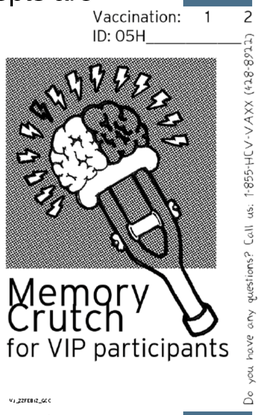
*Levy, et al. *Vaccine*. 2010

Establishing success

- IDU are willing and interested in participation, and enrollment is ongoing.
- 68 participants meeting all evaluation criteria are targeted for phase I.
- Phase II will start upon approval from an independent data safety monitoring group

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

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



Community-based and centered

The clinical trial site, while a recognized entity of the University, is an outpatient research clinic catering to low-income and marginalized communities. Located in the Tenderloin community of San Francisco, the clinical site Its location in Training for clinical staff has resulted in improved cultural sensitivity, phlebotomy and a referral system that meets the physical and social service needs of IDU.

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

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