Herding Birds – The Recruitment and Retention of a Highly Disenfranchised Population

Caycee K. Cullen¹, Alice K. Asher, RN, Ph.D.(c)¹, Ellen S. Stein, MPH¹, Paula J. Lum, MD², MPH², Kimberly Page, PhD, MPH³

¹Global Health Sciences, University of California, San Francisco
Department of Medicine, University of California, San Francisco
³Division of Epidemiology, Biostatistics & Preventive Medicine, University of New Mexico Health Sciences Center
Background

• The **Vaccination Is Prevention (VIP) Study** is a placebo-controlled randomized clinical trial testing the safety, efficacy, and immunogenicity of a HCV preventive vaccine among PWID in San Francisco and Baltimore.

• At enrollment, participants are aged 18-45, HCV- and HIV-negative and have injected drugs in the last 90 days.

• Subjects are randomized to receive experimental vaccine or placebo, and are followed for up to 29 months for adverse event monitoring, health and immunological outcomes.
ARE YOU:

- 18 to 45 years old and in general good health
- Recently injected drugs?
- Planning to be in the Bay Area for 6 months or more?
- Hep C and HIV negative?
- Ready to help CONQUER Hep C?

Then you may be eligible to participate in a Phase I Study! RIGHT NOW the VIP Study (Vaccine Innovation and Prevention) is testing a vaccine called VPI-5030 for the prevention of chronic hepatitis C infection.

*Call or stop by to see if you are eligible.*

VACCINATION IS PREVENTION

1-855-HCV-VAX

VIP Study
544 Market St, SF
(415) 553-8030

VIP Study
964 Market St, SF
(415) 553-8030

BHOMBO AMERICA
People who inject drugs (PWID) are commonly excluded from participation in clinical trials of biomedical interventions due to assumptions about poor health and non-adherence.

PWID are at highest risk of transmission of blood borne viruses, including hepatitis C virus (HCV). Including PWID in clinical research is necessary to identify optimal HCV prevention interventions.

PWID are often ‘hard-to-reach’ and difficult to follow; knowledge of and experience with this population is critical to success.

We describe the recruitment and retention methods utilized by the San Francisco site, and draw conclusions on their success.
Methods

- The research site is located in the Tenderloin, a low-income neighborhood with high numbers of PWID.
- An in-depth outreach plan was developed to guide recruitment of study population, strategically targeting neighborhoods frequented by PWID.
- An aggressive retention plan was created to minimize possible bias associated with loss-to-follow-up and aims to achieve high retention.
- Two outreach workers conduct street based recruitment and retention activities 15 hours/week.
- A toll free phone number with 24-hour staffing allows potential participants to screen at any time.
Methods - Recruiting

- **The street** - Outreach workers map routes on foot and bike to identify the best street venues for recruitment and appropriate times for street outreach as well as establish a street presence where PWID congregate.

- **Secondary recruiters** - Presently enrolled participants are trained to refer people to the study and inform outreach workers of new places to go to maximize recruiting efforts.

- **Education** – VIP staff work with agencies who serve PWID, i.e. syringe exchange programs (SEP) and community clinics, to provide hepatitis C (HCV) prevention education trainings for staff and clients that include study aims, goals and eligibility criteria.

- **Collaboration** – Outreach workers draw on pre-existing relationships with staff at homeless drop-ins and street-based health providers for direct referrals.

- **Flyering** – Outreach workers post flyers at SROs, clinics, key street locations, SEPs, alleys, parks, public bathrooms, shelters, bars, and any other places a PWID is likely to be.
ARE YOU:
- 18 to 60 years old and in general good health?
- Recently traveled abroad?
- Planning to travel to the U.S. within 30 days?
- Current C hangover or fever?

If yes, call V.F.

RESEARCH STUDY: Right now the VIP Studyell be conducted in hospital. if a

*Call or stop by if you are available*

1.855.MCV.VAXX(243-8239)
Methods - Retention

- **Contact forms** – At enrollment detailed contact information is collected including: address, email, phone number, social media, and family contacts. Importance of adherence is emphasized.
- **Location** - Participants are seriously queried about where they spend time and various social services accessed.
- **Photo** – With permission, a face shot is taken.
- **Database** – All information is stored on a secure database. Tracking notes are added to document updated participant information
- **Reminders** – Participants receive study reminders by street contact, cell phone, email, home visits, text messages or social media.
- **No show** – If a participant misses an appointment, all contact information given is used to make every effort to get that person in. Calls to local jails, hospitals, and the medical examiner’s office are made if necessary.
- **Smart phones** – 3 of the 5 VIP staff carry study smart phones and are available to field calls/texts and access the database beyond the work day.
**Pete Davidson**

DOB: 10/20/68 (age 46)  
Gender: M  
Mom: Hazel  
Dat: John

VIP: M4/12

Next visit was VIP V02 due between 2/14/12 and 3/18/12 but is **OVERDUE**.

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**Log out**
Rooms: $40 Special
Inquire Within 618-6824
VACCINATION IS PREVENTION

YOUR NEXT APPOINTMENT IS ON Tuesday Jan. 20th
Results

• The VIP Study began enrolling in March 2012 and is expected to complete in 2016.
• The enrollment goal for the two study sites is 450 participants over 4 years.
• Retention numbers are reviewed weekly, documented on spreadsheets, and used to inform staff of participant status, including drug treatment or incarceration.
• Outreach workers document recruitment contacts and use data to target efforts to reach new participants.
• To date we have seen 80% retention over the course of the study.
• Incarceration, relocation, and involvement in residential drug treatment programs are the primary reasons for early withdrawal from study participation.
Conclusions

• Despite being a highly mobile, hard-to-reach population that often is reluctant to access medical care, PWID in VIP have demonstrated the ability to adhere to a placebo-controlled randomized vaccine study protocol.

• While significant staff time is spent on retention activities including street searches, phone calls, social media contact, and home visits, participants report enjoying frequent contact with VIP staff. Participants develop a sense of responsibility to VIP, demonstrate reliability, and take their research participation seriously.

• Our work demonstrates that PWID can be successfully enrolled and retained in a demanding clinical trial requiring multiple study visits over a long period of time.

• Our methods offer a successful recruiting and retention framework for PWID involvement in future studies.
Thank you

Questions?
Contact Caycee Cullen
1-415-298-3108
Caycee.Cullen@ucsf.edu