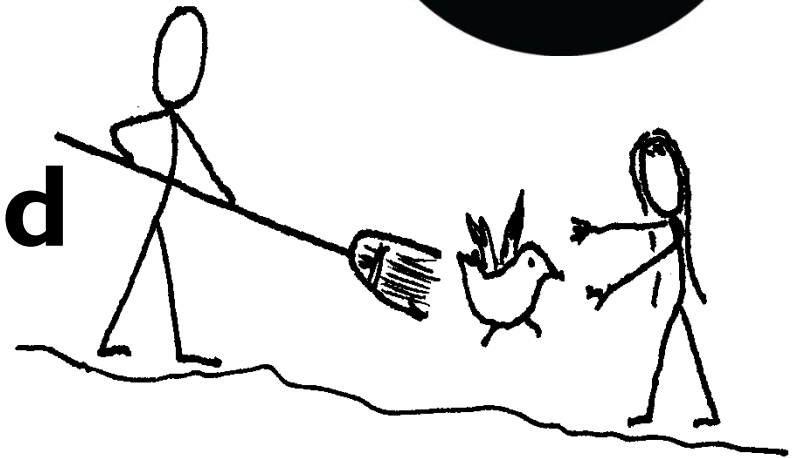


Herding Birds – The Recruitment and Retention of a Highly Disenfranchised Population



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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 the next 6 months?
- Hep C and HIV negative?
- Ready to help CONQUER Hep C?

Then you may be eligible to participate in a PAID
STUDY! RIGHT NOW the VIP Study (Vaccine
Prevention) is testing a vaccine meant to prevent
chronic hepatitis C infection.

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



1.855.HCV.VAXX

964 Market St.
(between 10th & 11th)
San Francisco, CA 94102
Open Hours: Mon-Fri 10am-5pm, Sat 10am-3pm

VIP Study
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BROWNE
AMERICA





Background

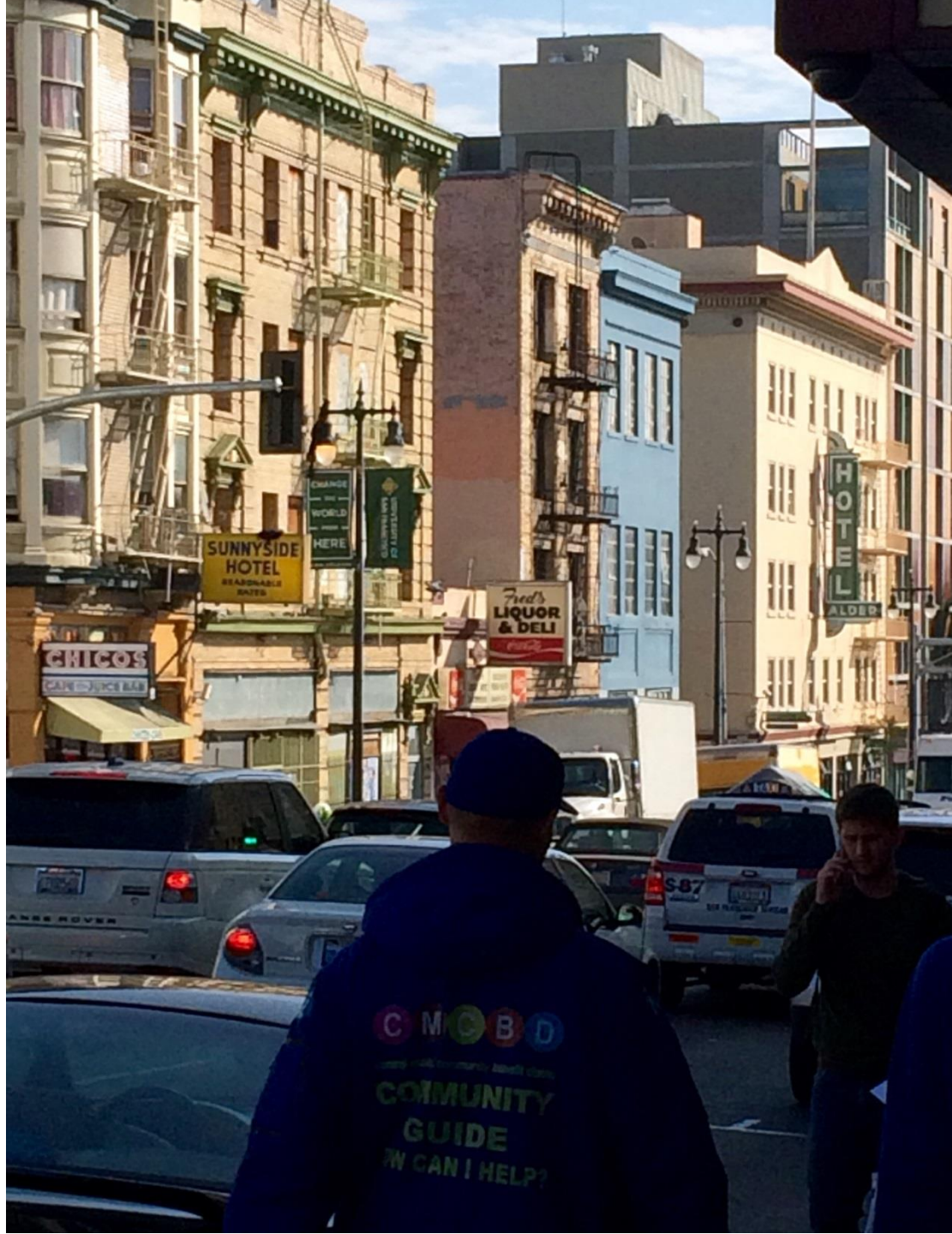
- People who inject drugs (PWID) are commonly excluded from participation in clinical trials of biomedical interventions due to assumptions about poor health and non-adherence.
- PWID are at highest risk of transmission of blood borne viruses, including hepatitis C virus (HCV). Including PWID in clinical 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.







Panhandling Prohibited
on Traffic Medians or in Roadway
SAN FRANCISCO MUNICIPAL POLICE CODE

Small illegible sign on the utility pole.

HOLIDAYS AND HONOR

Live Musically

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 49 years old and in general good health?
- Recently injected drugs?
- Planning to be in the Bay Area for 2+ years?
- Hep C and HIV negative?
- Ready to help CONQUER Hep C?

Then you may be eligible to participate in a PAID RESEARCH STUDY! RIGHT NOW the VIP Study (Vaccination to Prevent) is testing a vaccine meant to prevent chronic hepatitis C infection.

Call or stop by to see if you are eligible

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8:30am-noon and 1pm-3pm

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5-10-25

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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

[05HSE000](#)

10/20/68 (age 46)

Gender: M

Mom: Hazel

Dad: John

VIP: 3/4/12



Next visit was VIP V02 due between 2/14/12 and 2/18/12 but is **OVERDUE** -- [Show UFO version](#)

Place for important notes [see link](#)

Visit date	Visit Type	Consenter	Event	Outcome	Interview
2/12/12	V01	Alice		-	
2/18/12	V00	Alice			
2/18/12	V02 pre-screen	Alice			

[Document vaccination](#)

[Serology](#)

Date	Site	Shot#	Type
2/18/12			VIP Vaccine

5/9/12 Pete General medical notes

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68

Site
S

good clean quiet
* ROOMS *
→ * →
Rent \$40⁰⁰
"out the door"
Special!!

68

VACANCY
WEEKLY
MONTHLY

INQUIRE WITHIN 678-6824

SP 349

VACCINATION IS PREVENTION

YOUR NEXT APPOINTMENT IS ON

Tuesday Jan. 20th

AT

115

KEEPING YOU!

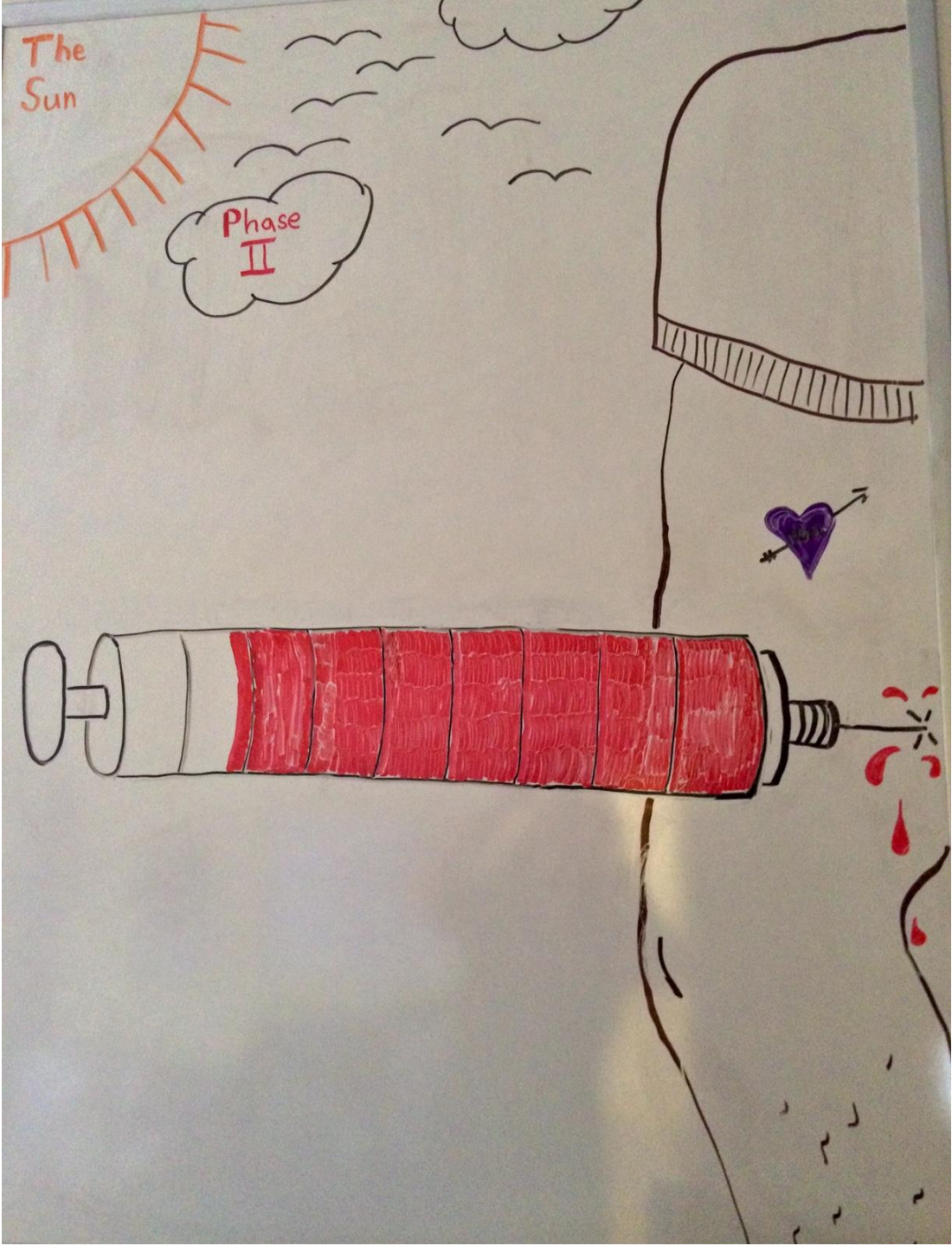






Results

- 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 spread sheets, 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.





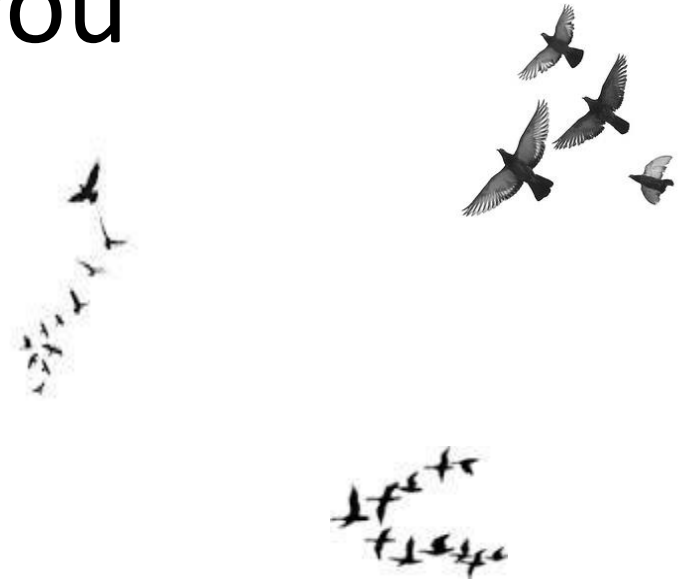
Conclusions



- 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

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