Willingness to Participate in Preventive HIV Vaccine Trials among Young IDU: The UFO VAX Study

Jamye L. Ford, Alan Paciorek, BSc., Judith A. Hahn, Ph.D., Kimberly Page Shafer, Ph.D., M.P.H., Paula J. Lum, M.D., M.P.H.
Department of Medicine, University of California, San Francisco

Contact:
Jamye L. Ford
3180 18th St., Suite 207
San Francisco, CA 94110
415.215.1502
jford@php.ucsf.edu

Background

- Young injection drug users (IDUs), particularly young men who have sex with men and inject drugs (MSM-IDU), are at high risk of HIV infection.
- A safe, effective, and affordable vaccine is the world's best hope for controlling the HIV epidemic.
- High-risk drug users in the U.S. are underrepresented in HIV vaccine efficacy trials.

Study Questions

- How much do young IDU in San Francisco know about preventive HIV vaccine trials?
- Are young IDU willing to participate in HIV vaccine trials?

Methods

- Cross-sectional study of young IDU in San Francisco
  - Age under 30 years
  - Injecting drug use in last 30 days
  - HIV-negative or unknown
- Street-based recruitment, 8/04–2/06
- Structured interview: sociodemographics, drug use and sexual behavior, knowledge of HIV vaccine trial concepts, and willingness to participate in an HIV vaccine trial.
- HIV, HBV, and HCV risk reduction counseling, testing, and referral.
- $10 at time of interview and phlebotomy, $20 at time of results disclosure (1 week later).

Outcome:

Knowledge of preventive HIV vaccine trial concepts

- Eight statements from the HIV Network for Prevention Trials (HIVNET) about HIV vaccine trial concepts.
- Participants were asked if they agreed or disagreed with or were unsure of each statement.
- Correct answers were provided after participants responded to all 8 statements.
- A cut-off of 5 or more correct responses were used in this analysis.

Outcome:

Willingness to participate in an HIV vaccine trial

- "How willing would you be to join a study of a vaccine to prevent HIV infection, if the study were to start tomorrow?"
- Responses measured on a 4-point scale:
  - Definitely not
  - Probably not
  - Probably will
  - Definitely will
- Participants answering "probably will" or "definitely will" were considered willing to participate in this analysis.

the UFO STUDY

Selected characteristics of young IDU in San Francisco: Associations with knowledge of HIV vaccine trial concepts and willingness to participate in an HIV vaccine trial (N=271)

Characteristic	N(%)	Correct 5+/8 HIV Trial Statements N (%)	OR [95% CI] Correct 5+/8 HIV Trial Statements	Willing N (%)	OR [95% CI] Willingness
Age (median IQR)	22 [20,24]	--	--	--	--
White	202 (75)	49 (24)	1.52 [0.75,3.06]	153 (76)	0.87 [0.45,1.67]
MSM (Reference)	32 (12)	8 (25)	1.0	27 (84)	1.0
Female	76 (28)	14 (18)	0.68 [0.25,1.82]	61 (80)	0.75 [0.25,2.28]
Male non-MSM	163 (60)	39 (24)	0.94 [0.39,2.27]	119 (73)	0.50 [0.18,1.38]
Completed High School	178 (66)	44 (25)	1.46 [0.78,2.75]	132 (74)	0.69 [0.37,1.27]
Employed last 3 months	100 (37)	20 (20)	0.79 [0.43,1.44]	72 (72)	0.67 [0.38,1.18]
Start injecting age 18 yrs or older	128 (47)	28 (22)	0.93 [0.53,1.65]	96 (75)	0.86 [0.49,1.52]
Years Injecting (median IQR)	5 [2,8]	--	--	--	--
Daily injection	261 (96)	59 (23)	1.17 [0.24,5.65]	198 (76)	0.35 [0.04,2.81]
Heroin injection last 3 months	218 (80)	51 (23)	1.31 [0.62,2.80]	167 (77)	1.06 [0.53,2.14]
Methamphetamine injection	169 (62)	34 (20)	0.70 [0.39,1.25]	132 (78)	1.28 [0.73,2.27]
Borrowed or lent rig last 3 months	112 (41)	21 (19)	0.69 [0.38,1.24]	91 (81)	1.60 [0.89,2.89]
Always use condoms, n=225	39 (17)	15 (38)	2.69 [1.28,5.66]	28 (72)	0.72 [0.33,1.57]
Ever tested for HIV	201 (75)	45 (22)	0.97 [0.51,1.86]	150 (75)	0.67 [0.34,1.33]
Perceived HIV risk of 5+ on 10 point scale	72 (27)	13 (18)	0.69 [0.35,1.38]	58 (81)	1.42 [0.73,2.78]
HIV vaccine trial 5+/8 correct answers	61 (23)	--	--	46 (75)	0.93 [0.48,1.81]

Results

HIV vaccine trial knowledge questions & responses

		Agree N (%)	Disagree N (%)	Unsure N (%)
1.	Preventive HIV vaccine studies enroll people who are HIV-positive and HIV-negative.	142 (52)	35 (13)	94 (35)
2.	Some participants in HIV vaccine studies will get a real vaccine, and some will get a placebo (an inactive substance).	120 (44)	60 (22)	91 (34)
3.	Only vaccines known to be at least 50% effective at preventing HIV are tested in HIV vaccine studies.	50 (18)	46 (17)	175 (65)
4.	Once a large scale HIV vaccine study begins, we can be sure the vaccine is completely safe.	75 (28)	125 (46)	71 (26)
5.	Participants are told whether they got the HIV vaccine or the placebo at the end of HIV vaccine studies.	116 (43)	56 (21)	99 (36)
6.	HIV vaccines will never affect a person's HIV test results.	56 (21)	104 (38)	111 (41)
7.	An HIV vaccine can infect a person with HIV disease.	43 (16)	149 (55)	79 (29)
8.	People in vaccine studies know whether or not they got the placebo because only the vaccines cause side effects.	43 (16)	130 (48)	98 (36)

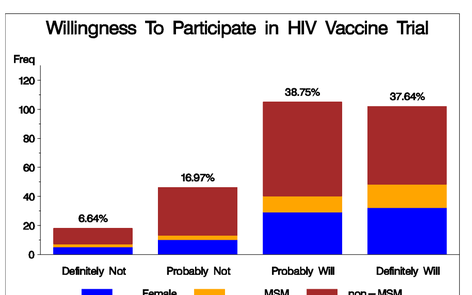
- Fewer than one-fourth (23%) of respondents correctly answered ≥5 knowledge questions about key vaccine trial concepts.
- Participants frequently answered "unsure" to each of the eight questions (range 29–64%).
- The question with the largest percentage of correct answers (55%) and the smallest percentage of "unsure" responses was "An HIV vaccine can infect a person with HIV disease."

Knowledge analysis

- Participants who reported always using condoms were more than twice as likely as those using condoms inconsistently to correctly answer ≥ 5 questions about key HIV vaccine trial concepts; OR 2.69 with 95% CI [1.28,5.66].
- HIV vaccine trial knowledge was not associated with with age, sex, education, recent employment, age at first injection, frequency of injection, drug of choice, recent borrowing or lending syringes, condom use, prior HIV testing, or perceived risk of HIV infection.

Willingness analysis

- Willingness to participate in an HIV vaccine trial was not associated with age, sex, education, recent employment, age at first injection, frequency of injection, drug of choice, recent borrowing or lending syringes, condom use, prior HIV testing, or perceived risk of HIV infection.
- There was no association between knowledge of vaccine trial concepts and willingness to participate in a preventive HIV vaccine trial.



- Most participants (76%) were definitely or probably willing to join an HIV vaccine trial if it started tomorrow.

Conclusions

- Young street-recruited IDU in San Francisco report high HIV-related risk behavior.
- While most young IDU are willing to participate in HIV vaccine trials, knowledge of key vaccine trial concepts is extremely low.
- Improving young injectors' basic understanding of vaccine trials is an essential step to ensuring their informed consent and participation in any future clinical trials of an HIV or HCV vaccine candidate.

Acknowledgements

- Many thanks to UFO VAX field staff: Erin Antunez, Alya Briceno, Shanel Coleman, Caycee Cullen, Peter Davidson, John Day, Sugar Edwards, Ro Giuliano, Lydia Guterman, Gina Hobson, Caroline Maroten, Ted Miller, Peter Morse, Kim Pierce, Kyle Ranson, Stacey Rubin, Jason Storm, Nickie Tilsner, Parousha Zand.
- Collaborators:
  - Adult Immunization Clinic (AIC) of the San Francisco Department of Public Health
  - Berkeley Free Clinic, Inc.
  - Haight Ashbury Youth Outreach Team (HAYOT) of the Haight Ashbury Free Clinic, Inc.
  - HIV Prevention Project of the San Francisco AIDS Foundation
  - San Francisco Needle Exchange (SFNE)
  - Street Outreach Services
- Funded by the National Institute of Drug Abuse, R01 DA017476

PositiveHealthProgram HIV/AIDS Division at SFGH

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