

Communicating Disappointing Results with Study Participants and Community

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HIV VACCINE
TRIALS UNIT ● SEATTLE

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Step Trial

- Phase IIb Test of Concept study
 - Multicenter, Double-Blind, Randomized, Placebo-Controlled
 - 1:1 vaccine : placebo
 - Vaccinations at 0, 1 and 6 months
 - Enrollment Period: April 2005–January 2007
 - 119 high-risk men who have sex with men (MSM) enrolled in Seattle using the following criteria:
 - 1) unprotected anal intercourse with another man and/or
 - 2) anal intercourse with 2 or more male sexual partners
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- Scheduled Data & Safety Monitoring Board Interim Analysis:
 - Vaccine was not efficacious in the trial population
 - Vaccinations should be stopped
 - Seattle site: all vaccinations already completed
- Sent press releases, local articles
- Notified IRB, community based organizations, Community Advisory Board
- Notified volunteers:
 - Calls, emails, letter #1 and in-person visits
 - Email preferred contact method for 108/111 volunteers reached

- DSMB Findings:
 - More HIV infections found among men in the vaccine group vs. placebo group
 - South African Study unblinded
 - All studies discontinued vaccinations
 - Volunteers:
 - Letter #2 sent
 - Seen for regularly scheduled study visits
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- Seattle Unblinding
 - 111/119 volunteers unblinded
 - Calls, letters, emails and in-person notification
 - 8 lost to follow-up/moved: notification letters sent
 - Mixed reactions
 - Very concerned
 - Relieved if they had received placebo
 - Few questions from volunteers
-

Slide 5

U42

pjs: changed oral text below to read "unblinded",

"Volunteers were then given detailed information on updates regarding the study, such as their treatment assignment (vaccine or placebo) and their ad5 status."

and then "Clinicians who unblinded the volunteers observed mixed reactions: few expressed etc etc"

User, 9/3/2008

Unblinding Communication

Unblinding Methods	n	%
Clinic visit	72	61
Phone	35	29
Letter	2	2
Email	2	2
Lost to follow-up	8	7
Total	111	

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U43

pjs: I realize the notes below are for oral presentation but I did some cleaning up of grammar and construction anyway. My program does not allow for editing directly on the text, but several changes were made.

User, 9/3/2008

- Unblinding continued
 - Community Forum announced
 - Flyers, e-vites, calls to volunteers
 - Attendees: Public health, CBOs, staff and 2-3 volunteers
 - Many volunteers felt attendance not necessary because of individual meeting with their clinicians
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Slide 7

U45

pjs:reworded oral text.
User, 9/3/2008

January 2008

- Unblinding completed
 - 108/119 volunteers were emailed a 4-question survey to ascertain degree of satisfaction with communication of study results
 - Volunteers who did not specify email as a way to receive information were contacted by phone
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Dear Study Volunteer,

Happy New Year!

I am writing to check in with you to see if you have any further questions or concerns about your participation in the Step Study. Your continued participation is important to us, so we want to make sure all your questions and concerns are addressed adequately.

Please reply to this email with one of the following answer choices below, so that we can best plan to meet your communication needs.

A - I do have further questions or concerns and would appreciate a "participant only" forum to best address them.

State your preference for a weekend or weeknight forum.

B - I do have further questions or concerns and would appreciate an Internet based (chat room/web telecast) forum to best address them.

State your preference for a weekend or weeknight forum.

C - I do have further questions or concerns and would appreciate _____ (*insert other method of delivery*) to best address them.

D - I do NOT have any further questions and concerns and feel that your clinic has addressed these adequately.

Slide 9

U46

pjs: smoothed this out a bit
User, 9/3/2008

Survey Results

Communication	n	%
Participant-only forum	4	8
Internet-based forum	0	--
Other	2	4
No further questions/concerns	44	88
Total	50	

Response rate: 50/108 (46%)

- Volunteer follow-up
 - No participants self-disclosed dissatisfaction with how results were communicated
 - 111/119 (93%) continue to be followed
 - Reasons for no follow-up:
 - Moved
 - Transferred to other study site
 - Lost to follow-up
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Conclusion

- Volunteers' feedback to clinicians and through the survey indicates the clinic had adequately addressed these questions and concerns
 - Combined communication methods may have resulted in participant satisfaction
 - Staff dedication and care of the volunteers may have contributed to the volunteer satisfaction with the dissemination of the disappointing study results
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HIV Vaccine Trials Unit & HIV Prevention Trials Unit

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Merck

HIV Vaccine Trials Network

Seattle HIV Vaccine Trials Unit study volunteers!
