
HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

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Recruitment and Community Education

Understanding the similarities and differences

Dennis Torres

In 1992, I joined the Community Advisory Board (CAB) of the Seattle AIDS Vaccine Evaluation Unit (AVEU). My role as a CAB member was to serve as an advocate for those participating in the trials or those interested in participating. I chose two ways in which to provide this service; one was to assist in community education and the other was to assist with recruitment into the studies.

In assisting staff with community education, I had the opportunity to educate my colleagues and peers, speak to community groups and review materials. I felt my role was to get as much information as possible to as many people as possible about the research being conducted. As I reviewed the materials, I learned to ask that the research being conducted be better explained so that I could tell others about it in language that made sense. I never felt pressured into doing any of this. I just knew that the more information provided, the better prepared the community would be for HIV vaccine research studies.

I always felt that by assisting in community education I was assisting in recruitment into the studies. Once the information was out in the community people could then choose to participate or not.

In 1996, Dr. Connie Celum, the Principal Investigator (PI) for the Seattle HIV Network for Prevention Trials (HIVNET) asked me to consider joining the staff as their Community Education Coordinator. In describing the position, she said that my job would be to get appropriate and adequate information regarding HIV prevention research out to the Seattle community, specifically people at high risk for HIV. She described the job as one in which I would be laying the groundwork for future recruitment into a variety of studies to be conducted by the site. My job became an extension of what I had done as a CAB member. With that job description in mind, I accepted the job and have been community educator for the last four years.

Connie and I both agree that community education and recruitment are complimentary. Although I am not the recruiter for the site, I oversee the recruitment staff and their plan. Good community education work should open the

doors for recruiters to be able to do their job at a variety of sites within the targeted community. Community education goes beyond laying the groundwork for recruitment for trials by ensuring community awareness and acceptance of a trial, which are essential for developing culturally appropriate and ethically sound trials.

Skilled community educators and recruiters are uniquely placed to inform the community about AIDS prevention research in general, the clinical trials process, and specific interventions such as vaccines.

Recruitment is not a dirty word. It is NOT the process of tricking someone into being in a study. Clinical trial research requires volunteer participants. The best study participants are those who understand the research, the possible risks involved, the procedures that will be followed, and their rights if they decide to enroll. These are the participants who will then, in turn, be the best advocates in the community for the study in which they are enrolled and for other research done at the site.

Community educators and recruiters, with the assistance of CAB members, should bring the community perspective to the formulation of research questions or protocol design. We can help address the question of feasibility, i.e. if we ask study participants to do X, is anyone likely to enroll? We should also be good at reminding the PIs to be realistic about the number and timing of study visits, how restrictive inclusion/exclusion requirements can be, etc.

Education and recruitment are not at cross-purposes. Informed consent requires becoming educated about the research that participants will be taking part in. Community educators can assist the recruitment process by: writing/developing/reviewing recruitment materials, speaking/writing about the importance of HIV prevention research, reviewing site recruitment plans and encouraging community members to consider volunteering.

It is not a question of either/or. Paul Verano, the Seattle site recruiter and I continue to work well together and look forward to continued collaboration. The success of the research depends greatly on both of us doing our work well. ❖

Community Education =
Community relations
+ media relations
+ recruitment

RESOURCES FOR HIV VACCINE INFORMATION

ON THE WEB:

AIDS Clinical Trials Information Service www.actis.org
ACTIS is a service of the US Department of Health and Human Services

AIDSFONDS www.aidsfonds.nl
This Dutch AIDS organization posts useful AIDS vaccine information on its website in support of its mission to "work toward a world without AIDS."

AIDS Vaccine Advocacy Coalition www.avac.org
AVAC is an advocacy group in the US that publishes an annual review of progress in HIV vaccine development.

Capitol Area Vaccine Effort www.aidsvaccine.org
DC volunteers organized around trial participation

Centers of Disease Control and Prevention www.cdc.gov
The US government's disease control and prevention agency's web-site.

Global Alliance for Vaccines and Immunization
www.vaccinealliance.org
GAVI provides information about delivery of vaccines with a particular focus on poor countries.

Grupo Pela Vidada www.pelavidda.org.br
The website of the Brazilian PWA organization provides information in English and Portuguese.

HIV Prevention Trials Network www.hptn.org
Evaluates prevention approaches through randomized controlled trials

International AIDS Vaccine Initiative www.iavi.org
IAVI is working to accelerate the development and distribution of AIDS vaccines for people around the world.

International Council of AIDS Service Organizations
www.icaso.org
ICASO promotes and supports the work of community AIDS organizations around the world.

Joint United Nations Programme on HIV/AIDS (UNAIDS)
www.unaids.org
UNAIDS produced the publication 'Ethical Considerations in HIV Preventive Vaccine Research: A UNAIDS Guidance Document' which can be downloaded

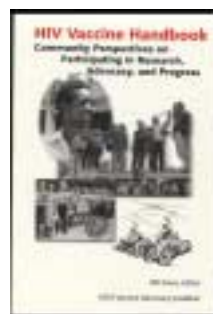
Medical Research Council of South Africa www.mrc.ac.za
This site contains information about the South African role in HIV vaccine development

National Institute of Allergy and Infectious Diseases/NIH
www.niaid.nih.gov/aidsvaccine
NIAID is a research institute of the US government.

Pasteur Institute www.pasteur.fr
A leading HIV vaccine research organization in France

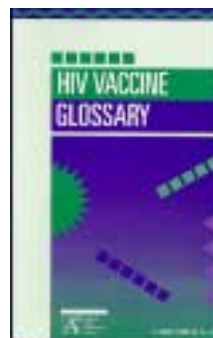
University of California at San Francisco
<http://hivinsite.ucsf.edu>
UCSF's HIVinsite web page contains extensive information, including some in Spanish

FREE publications that you can order from the CDC, ACTIS or the NIH:



*HIV Vaccine Handbook
Community Perspectives on
Participating in Research,
Advocacy and Progress.*
Edited by Bill Snow
AIDS Vaccine Advocacy
Coalition

For your free copy, please
call the National Prevention
Information Network
1-800-458-5231
Inventory item D305



HIV Vaccine Glossary
Produced by the AIDS
Clinical Trials Information
Service

For a free copy, contact
ACTIS
1-800-874-2572
actis@cdcnao.org



Understanding Vaccines
Produced by NIH/NIAID

For your free copy, contact
Claire McCullough in the
NIAID Office of
Communications.
(301) 496-5717
cmcculloug@niaid.nih.gov

COMING SOON...

The HVTN's very own
web site!!! Look for
details in next month's
CAB bulletin.



The Participant's Bill of Rights and Responsibilities

A community perspective

Tom Gibson, Robb Akridge- Global CAB members

Airlines have a customer's bill of rights. The concept is simple, the customer (who is paying for a service) is compensated if the airlines is shown to have violated their client-business agreement. Moreover, private HIV vaccine manufacturers, such as VaxGen, have an extensive participants' bill of rights. So why can't a vaccine volunteer in a publicly-funded research trial who is providing a tremendous service (often blood, sweat, tears and at times even rectal biopsies) have similar rights? I guess it all starts with a small section of a protocol called the Consent Form. It is in this document that "responsibility" is spelled out. Who will be responsible if the experimental vaccine causes material physical, mental or social harm to the volunteer? It must be pointed out that the chances of this happening are very low. In fact in the some 10+ years of AIDS vaccine research in which thousands of volunteers have received a vaccine or placebo, the number of proven episodes can be counted on one hand. However, it is the unknown episodes and the possible legal ramifications that could result that have prevented a bill of rights from being adopted. It was originally the volunteers' responsibility to handle their own medical expenses if they had a major side effect "proven to be related to the vaccine."

Long before we became involved with the AIDS vaccine program, a bill of rights was proposed by the National CAB. The draft of the bill of rights was circulated among local CABs, trial sites and the NIH. In fact, the proposed bill of rights was discussed at the highest level: the Scientific Steering Group of HIVNET. Even Peggy Johnson, Associate Director of the Vaccine and Prevention Research Program at DAIDS, had the opportunity to review and discuss the draft of the participant's bill of rights.

As proposed, the bill of rights would, among other things, make the trial sponsors financially responsible for such side effects. The question is who should take the financial hit. If this was a simple "one horse town" system we could easily assign financial responsibility; however, we are dealing with three major entities ...the pharmaceutical companies, the NIH and the academic institutions, all of which have multiple departments with their own battalions of attorneys. None of which are willing to take broad responsibility for someone's medical care primarily because it is not really known what type of side effects can be proven to be directly related to vaccination. They fear opening Pandora's box to any and every medical complaint as being vaccine related. We can't blame them ...medical care is expensive.

It has been interesting, however, to see that on two

occasions, after demands were made by local and national CABs, the pharmaceutical companies did change the wording of the consent form to show that they would be responsible for certain medical expenses of the volunteers. After the first episode, it was assumed that subsequent manufacturers would absorb medical expenses as a result of vaccination. However the wording of the consent form was switched back on later protocols to the volunteer being responsible.

Although this financial responsibility as a result of vaccination is a major sticking point, it is only a small component of the participants' bill of rights. The majority of the document has more to do with respect for the volunteers, and how they should be treated considering that they are giving up their body to the unknown. A full copy of the current version of the participants' bill of rights supported by the national HVTN CAB can be attained by contacting Siobhan Malone at the address listed on the back of this bulletin. Disappointingly, after several years of negotiating a standard, concise and reasonable participants' bill of rights, the question remains.... who will take responsibility? ❖

From Steve Wakefield, Director of Community Education

Protection of research subjects is one of the highest priorities of those involved in the HIV Vaccine Trials Network. Our HVTN policy manual reads, "At all levels including design, informed consent process, and the implementation of study protocols, efforts will be made to ensure that every precaution is taken to minimize potential harms to trial volunteers."

One of the important legacies of NIH sponsored research is that through a variety of mechanisms all participants to date have expressed satisfaction with the steps taken to mitigate medical and social harm.

A process has recently started to ensure that the HVTN can adopt a network wide "Participant's Bill of Rights". This process will start with conversations in the natural affinity groups of the network: investigators, clinic coordinators, community educators and recruiters, and community advisory board members. Each group will have representatives to serve on a task force to create the HVTN document.

The concerns identified in the article by CAB members Rob and Tom provide a place to start the discussion. Consideration must be given to a document that is a "Participants Bill of Rights and Responsibilities". There must be a clear process for ensuring that informed consent templates include the network's guidance. Site staff must review with local authorities for compliance with institutional regulations as well as any local jurisdiction that may affect implementation. The HVTN will also have to decide whether or not to continue specific mechanisms used in the past, such as the ID Card.

Because the safety of our volunteers is necessary, we will try to complete this process by the winter meeting in February. Please feel free to contact Steve Wakefield with your suggestions. ❖

The various protocols and their respective community representatives

Where you see this symbol ☺, we need a community representative like you. There's lots of room for interested CAB members to get involved in HVTN protocol teams and the CAB Protocol Working Group. Just let us know which protocol interests you and we'll get you on board. Contact us for further information. ❖

PROTOCOL	DESCRIPTION	CAB rep(s)
HVTN Protocol 501 (same as HVTN 301)	A Phase III efficacy trial of live recombinant canarypox ALVAC-HIV vCP1452 with and without AIDSVAX B/B in HIV-1 uninfected adult volunteers	Tom Gibson Raymond Hulse
IL2 Protocol	Phase I trial to evaluate the safety and immunogenicity of ultra low dose IL-2 as an HIV vaccine adjuvant.	Carole Stock ☺
AVEG Protocol 031	Phase I safety and immunogenicity trial of the facilitated HIV-1 gag-pol DNA vaccine (apl-400-047, Appolon, Inc) given intramuscularly by needle and syringe or Biojector 2000 needle-free jet injection system in HIV-1 uninfected adult volunteers	Debra Newman ☺
AVEG Protocol 033	A multicenter, randomized, placebo-controlled, double blinded, Phase 1 trial to evaluate the safety and immunogenicity of live recombinant canarypox ALVAC-HIV vCP205 combined with gm-csf in healthy, HIV-1 uninfected volunteers	Debra Newman ☺
AVEG Protocol 038	A multi-centered, Phase 1 trial to evaluate the memory responses to a single boosting vaccination with ALVAC-HIV vCP205 in volunteers who have previously received poxvirus-based vaccines	Nick Ferrario ☺
HVTN Protocol 039 (same as AVEG 034B)	Phase I trial to evaluate the safety, immunogenicity, and dose response of the live recombinant canarypox ALVAC-HIV vaccine, vCP1452, in HIV-1 uninfected adult volunteers	Allegra Cermak ☺
HVTN Protocol 802	A study of the effects of combination antiretroviral therapy with an emphasis on virologic and immunologic responses, in volunteers who develop HIV-1 infection subsequent to enrollment in HVTN 501	William Snow ☺
HIVNET Protocol 026	A Phase I safety and immunogenicity trial of live recombinant canarypox ALVAC-HIV (VCP300) and HIV-1 SF-2 rgp120 in HIV-1 uninfected adult volunteers	Monica Barbosa ☺
HVTN Protocol 203	A Phase II clinical trial to evaluate the immunogenicity and reactogenicity of a combined regimen using the ALVAC vector vCP1452 and AIDSVAX. B/E, B/B	Raymond Hulse Peter Emau
HVTN Protocol 03 (same as VEE Protocol)	Phase I safety and immunogenicity trial of an HIV subtype C gag-VEE replicon particle vaccine (HIV-1-VRP, AlphaVax) in HIV-1 uninfected adult volunteers	Janelle Thompson ☺
TBC-3B (same as AVEG 014D)	A multicenter, randomized, placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of an escalated dose of the Therion recombinant vaccinia-HIV-1 IIIB env/gag/pol vaccine (TBC-3B)	☺ ☺
ALVAC vCP 1452 BX08 primary isolate subtype B	Phase I study of vCP1452 based on a primary isolate, boosted with a primary isolate subunit vaccine.	Robb Akridge ☺
HVTN Protocol 403	An evaluation of virologic, immunologic, and clinical parameters of participants enrolled in HIV Phase I and II vaccine protocols who develop HIV-1 infection subsequent to trial enrollment	☺ ☺
SKB Bio vaccine	Phase I trial of a new recombinant vaccine based on regulatory proteins	Carole Stock ☺

CALENDAR OF EVENTS

PROTOCOL WORKING GROUP CAB CONFERENCE CALL:

October 3rd, 2000 7pm EST, 4pm PST. **CANCELLED**

GLOBAL CAB CONFERENCE CALL:

October 12th, 2000 7pm EST, 4pm PST

THE UNITED STATES CONFERENCE ON AIDS

October 1-4, 2000 Atlanta, Georgia

NATIONAL AIDS TREATMENT ADVOCATES FORUM
(NATAF) November 9-12, 2000 Dallas, Texas

HVTN FULL GROUP MEETING OCTOBER 3-5, 2000

Renaissance Park 55 Hotel, San Francisco, California

(CAB specific events occur October 3rd and 4th)

Please send suggestion, questions and article submissions to:
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Seattle WA 98109-1024
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