
HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

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NIH Communications Group and HVTN Community Educators/Recruiters Joint Meeting

On February 12, the HVTN Community Educators and Recruiters met with NIH's National HIV Vaccine Communications Steering Group. This was the first time that these two bodies met to explore their shared goals: to develop broad societal support for HIV vaccine research and development and to provide a supportive environment for study volunteers to participate in HIV vaccine trials.

Both groups recognized the importance of focusing on communities most affected by HIV/AIDS. The two groups also agreed that the HVTN sites and NIH's campaign must create not only a supportive environment for large research studies within the next 18-24 months, but also that it should begin to provide long-term, sustainable support that will endure until a vaccine is licensed and available over the next decade. There was a joint review of a task order for a potential NIH contractor to promote education, attitudinal change, and community support for a program to provide HIV vaccine communications.

RESULTS:

- 1) The group set in motion activities for this year's HIV Vaccine Awareness Day on May 18.
- 2) It was agreed that an HVTN Global CAB member and a Community Educator/Recruiter, with alternates, will serve as liaison members to the NIH HIV Vaccine Communications Steering Group.

The group also agreed to the following principles to guide the collaboration:

- ⇒ The education and outreach efforts of the HVTN Community Educators and CABs will focus on potential trial volunteers and their immediate support networks. The communication and education efforts of the National HIV Vaccine Communications Steering Group will focus on a national media and public relations campaign designed to create a supportive environment for the nationwide conduct of HIV vaccine trials.
- ⇒ Both groups will strive to produce clear, consistent and appropriate messages that communicate the need, urgency and the process for developing a vaccine to prevent HIV infection or disease.

- ⇒ The Steering Group will solicit input and feedback from the HVTN Community Educators and CABs on all media and communications materials, tools, and activities PRIOR to implementation or distribution.

At the end of the joint session, the group provided an update to Dr. Peggy Johnston, Associate Director, Vaccine and Prevention Program, DAIDS. Dr. Johnston noted that she and Dr. Larry Corey had met with Dr. Fauci regarding leadership in communicating on HIV vaccine development. ☘

Community Educators/Recruiters' Training

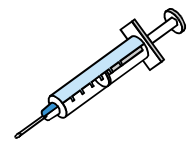
The Community Educators/Recruiters (CER) spent the remainder of their time in New York in training sessions. Most of the time was spent reviewing new HVTN development sheets for writing a community education plan. The objectives of an HIV Vaccine Trials Unit (HVTU) Community Education Plan include:

- ◆ recommending action steps the HVTU will undertake over the coming 18 months to:
 - ◇ increase awareness of HIV vaccine research,
 - ◇ build local support for vaccine trials,
 - ◇ improve vaccine trial recruitment and retention, and
 - ◇ decrease opportunities for misunderstandings about vaccine research.
- ◆ writing an 18-month implementation plan with a June 2000 start date or as determined by the site Principle Investigator (PI).
- ◆ recognizing that informed support of affected communities is essential to successful HIV vaccine research efforts, and conversely, that the lack of information about vaccine research may lead to mistrust and misunderstanding in those communities.

CER training attendees were able to share success stories, meet with international advocates at the International AIDS Vaccine Initiative (IAVI) who are working on HIV vaccine access issues, and look at the landscape of activity which has engaged others around vaccine development. Some of the topics covered were:

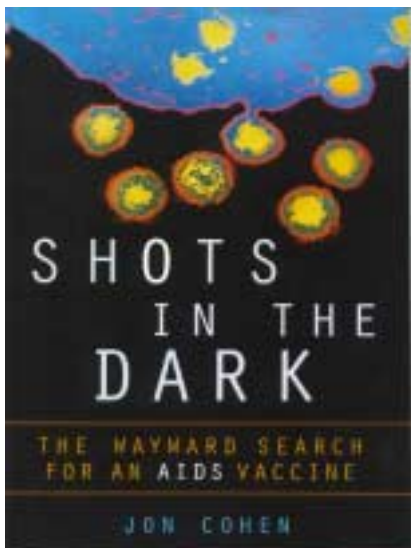
- * the AIDS vaccine ride (www.vaccineride.org),
- * the impact of VaxGen results,
- * the impact of Merck and other private industry trials,
- * response to unexpected national and international news,
- * response to anti-vaccine movements in America,
- * partnerships with international sites, and
- * a proposed international internship program. ☘

HIV Vaccines Currently in Trials



To date, over 60 phase I/II trials of 30 candidate vaccines have been conducted worldwide. The table below gives an idea of some of the products currently being tested in clinical trials around the world. The funding agencies for these trials range from government institutions like the National Institutes of Health (NIH) to public/private sponsors like the International AIDS Vaccine Initiative (IAVI). Over the past 13 years, many different products have been tested, and there are many products in development for testing in human trials in the near future. Tremendous progress has been made and with enough effort and support from governments, funding agencies, the scientific community, pharmaceutical companies, and the general public, we will make possible what was thought impossible for so long- a vaccine against HIV. ☼

Company/Institution	Product tested	Phase of trial
Aventis Pasteur	vCP205	Phase II ongoing
	vCP 1433	in Phase I
	vCP1452	in Phase I, Phase II planned
	lipopeptides	Phase I (France)
	vCP1521 (E)	in Phase I/II
	gp160	in Phase I/II
	gp160-did (E)	in Phase I
Cell-Sci	HGP30W peptide	in Phase I/II (U.S./Europe)
Chiron	gp120 (B)	Phase II completed
	gp120 (B)(E)	Phase II (Thailand)
	p24	in Phase I
Merck	DNA	in Phase I
Oxford University/University of Nairobi	Clade A DNA	in Phase I (U.K./Nairobi)
Therion	TCB-IIIB: vaccinia-env,gag,pol	in Phase I
VaxGen	AIDSVAX gp120 (B/B)	Phase III (U.S.)
	AIDSVAX gp120 (B/E)	Phase III (Thailand)
Wyeth-Lederle	APL-400-047: DNA-gag,pol	in Phase I
	APL-400-003: DNA-env,rev	in Phase I
	gp120 C4-V3 polyvalent peptide	in Phase I



BOOK REVIEW

Shots In The Dark by Jon Cohen provides a ten year perspective on HIV vaccine development and suggestions for future progress. In the book, Cohen notes, "The solution to the dilemma is to combine all of these sources into one well-funded, goal-oriented, targeted research program that exists solely to speed every potential promising lead."

The book also calls for a "March of Dollars" that would "have its own money, in the neighborhood of \$1 billion, donated by philanthropists and foundations to solve the problem."

Perhaps your local CAB and staff could host a book club evening to talk about this new work. ☼

SEATTLE/LIMA HVTU COLLABORATION

By *Dennis Torres*

Greetings from the Pacific! The University of Washington (UW), the Fred Hutchinson Cancer Research Center (FHCRC) and its partner, the Universidad Cayetano Heredia in Lima, Peru are proud to be part of the HVTN. We like to think of ourselves as two sides of the Pacific represented in the North by our Seattle site and in the South by our Lima site.

The UW has a long history of collaboration with other medical institutions throughout the world. With our work in sexually transmitted diseases, we began a very close partnership with the Peruvian Ministry of Health. As the HVTN and HIV Prevention Trials Network (HPTN) were being formed, the Seattle Principal Investigators, Drs. Connie Celum and Julie McElrath thought it a great opportunity to bring Peru on board to participate in vaccine and other HIV prevention research.

Peru is the 5th most populous country in Latin America and Lima, its capital, has a population of over 7 million people. Peru is a country rich in history and proud of its Inca heritage. Lima has an HIV prevalence of close to 14% and, like Seattle the epidemic, seems to have affected gay and bisexual men the most.

In 1995, the Peruvian Ministry of Health began doing research work with gay and bisexual men throughout the country. In Lima alone, they screened over 8,000 men and created a cohort of 3,000 men which became known as the *Grupo Alaska*—the name comes from a Spanish rock band that sings a song known for its gay positive message. The research goal was to identify where gay and bisexual men frequent, and what HIV knowledge they had and needed. The work was done at a variety of sites that included Via Libre, a non-governmental organization (NGO) for sexual minorities in Lima and at eight Ministry of Health clinics throughout the city. In order to make the clinics more accessible and friendly to gay and bisexual men, the Ministry hired patient advocates and stationed them at the entrance. The advocates were peers of the men in the cohort who had assisted in the recruiting, and were able to sensitize staff to the needs of the men in the cohort. The final goal was two-fold: the Ministry was able to conduct its research and develop appropriate services for gay and bisexual men; and gay and bisexual men are now aware that these community clinics are there for them too.

Last month some of the Seattle staff was able to visit the Lima site to assist with details as they prepare to start their first trial under the auspices of the HPTN. We were very impressed at how much they have accomplished with so few financial resources. The Lima site has proven that collaboration does work. They created a community-based



The PI, Jorge Sanchez, staff and CAB of the Lima, Peru site are pictured here with their Seattle HVTU visitors Dennis Torres, and Connie Celum.

organization and called it *Impacta*. They converted a house into their offices and lab in a section of Lima near the beach called Miraflores. The first trial is very similar to HIVNET's Vaccine Preparedness Study. They will enroll 500 men in six months, screen them for HIV and STDs and have them come in every 6 months for 18 months. They hope to reach a retention rate of greater than 90%. Men will be enrolled in two other sites other than Impacta. These are Via Libre and a community clinic in the center of Lima known through the Grupo Alaska as a clinic that serves gay and bisexual men. This trial will prepare the Lima site for the possible HVTN phase III efficacy trial to be done in sometime in 2002.

The Seattle staff on the visit were also able to attend the site's first CAB meeting! The site invited representatives from all the HIV/AIDS NGOs, as well as gay organizations. It was quite interesting to hear from the community folks gathered there as they presented many of the same CAB issues that our Seattle CAB deals with. Some of the concerns they brought up included: HIV testing issues after vaccination; questions on what would be available to those who sero-convert; and what recourses existed for vaccine related injuries. I explained that the Seattle CAB, in conjunction with the HVTN Global CAB, are working to resolve all of those issues and that consistently putting pressure around those important issues is an essential role for all CABs.

The week ended with a celebration at an auditorium in the center of Lima very near to the participating clinic and to many gay bars. The turnout was amazing as we thanked the Grupo Alaska cohort participants and explained how we would like them to consider participating in this new trial. There were over 250 men at the event and it was hosted by two of the most popular drag queens in Lima. Gay culture seems to be the same all over the world!

So we seem very busy both here in Seattle and at the Lima sites given that we are units in both the HPTN and HVTN. As we prepare for all this hard and rewarding work, the one great constant has been the positive response from the communities that we work in. We owe a great many thanks to the over 850 Seattle and Puget Sound area volunteers that have assisted us in the more than 22 trials we have done. We also owe many thanks to all the dedicated CAB members we have had throughout the years.

Until there's a vaccine— the Seattle and Lima HVTU staff. ☘

A Task for the Network

At the recent meeting of HVTN Investigators in Chicago, Steve Wakefield led a discussion of ethical issues for Phase I trials, during which it was noted that we, as a network, need documentation that presents the HVTN's ongoing commitment to high ethical standards. As a first step, it was suggested that the CAB develop checklists for the investigators and for themselves to help guide discussions in this documentation process. Carole Stock agreed to lead the Global CAB in this process. Steve drafted the attached list to begin the CAB dialogue. It is based on the discussion document "Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials" by Linda M Richter, Graham C Lindegger and Quarraisha Abdool Karim. For a copy of the complete article, go to www.hs.unp.ac.za/mind/icunaids.htm

HVTN Investigators' Ethics Checklist

DRAFT

- ✓ Identify major ethical issues emerging from the study
- ✓ Articulate a commitment to ethical standards
- ✓ Identify community leaders and representatives; arrange discussions regarding implementation of the research in the local community
- ✓ Draw up agreements regarding partnership in trial or trials
- ✓ Establish terms of reference for research counselors and support or advocacy counselors
- ✓ Establish and support a Community Advisory Board
- ✓ Establish a strategy to ensure that members of the scientific team are acquainted with local and cultural issues of relevance to HIV vaccine research
- ✓ Identify major components of information which will need to be transmitted to trial participants, discuss components with CAB; finalize components to be included in information to participants
- ✓ Arrange community meetings to facilitate understanding of components identified
- ✓ Arrange preparation of informational materials and/or video for participants in collaboration with research counselors and CAB
- ✓ Prepare informed consent forms
- ✓ Oversee informed consent procedures with potential participants
- ✓ Receive feedback from research and support/advocacy counselors regarding informed consent procedures and modification thereof
- ✓ Ensure evaluation of ongoing willingness to participate

It's CARNIVAL Time!



CALENDAR OF EVENTS

CAB PROTOCOL WORKING GROUP CONFERENCE CALL:

Wednesday March 7, 2001 12 p.m. EST, 9 a.m. PST. **NOTE NEW DATE**



GLOBAL CAB CONFERENCE CALL:

Thursday March 8, 2001 7 p.m. EST, 4 p.m. PST



COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:

Tuesday March 20, 2001 12:00 noon EST, 9:00 a.m. PST



INTERNATIONAL WORKING GROUP WORKSHOP

March 14-17, 2001 Brazil

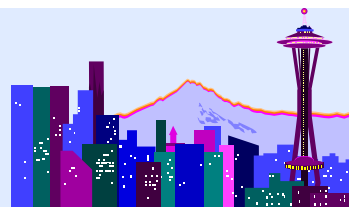
HVTN FULL GROUP MEETING

MAY 9-11, 2001 WASHINGTON D.C.



4TH ANNUAL HIV VACCINE AWARENESS DAY

May 18, 2001



Save the Date:

CAB Retreat in Seattle, WA
August 16-18, 2001

Please send suggestion, questions and article submissions to:
Siobhan Malone- Community Project Coordinator
HVTN/FHCRC, 1100 Fairview Avenue North
PO Box 19024, M/S: MW 832
Seattle WA 98109-1024
Siobhan@ssharp.org
Tel: 206-667-6350 Fax: 206-667-6366



HIV VACCINE
TRIALS NETWORK