

HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

Volume 2, Issue 8 September 2001

First-ever CAB Retreat

By Jim Thomas, Global CAB co-chair

Some 50 people, including staff, gathered in Seattle at the Fred Hutchinson Cancer Research Center, Thursday, August 16 through Friday, August 18, 2001, for the first-ever Community Advisory Board retreat of the HIV Vaccine Trials Network (HVTN). In attendance were CAB members from Brazil, China, Haiti, Peru, South Africa, Trinidad and Tobago, and the United States.

The retreat was an exciting event as it was the first time an HIV vaccine research network had held a stand-alone meeting for its CAB members.

The retreat began on Thursday evening with an introduction that included new member orientation and an overview of the HVTN structure and functions.

The following morning Dr. Larry Corey, who heads the HVTN, visited the retreat primarily to discuss the Participants Bill of Rights and Responsibilities and provision of medical care for anyone injured in a study.

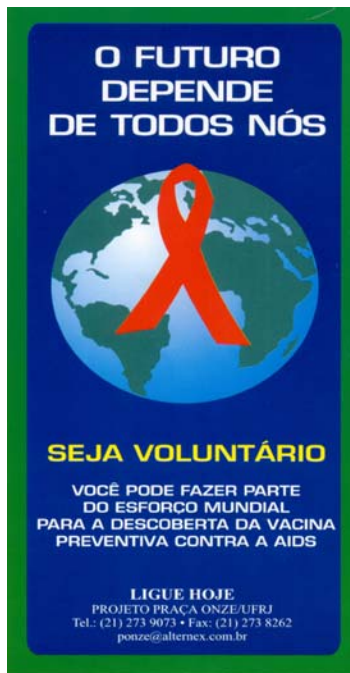
Following Dr. Corey's presentation, Derrick Mapp, from the San Francisco CAB, and David Lee, a protocol specialist at SCHARP, gave a presentation on reviewing and understanding protocols. The goal of the session was to enable CAB members to more effectively participate in the development of protocols, there by ensuring that community concerns and needs are taken into account from the very early stages of protocol development. Participants broke out into small groups to discuss various aspects of review, and then reported back to the full group their specific findings.

Mary Allen, from the Division of AIDS, gave a very helpful basic vaccine science overview. Bill Snow, from the San Francisco CAB, followed with a session covering how CAB members can be most effective. The group examined the role of local CABs and the Global CAB, and the resources available to CAB members on science, ethics, politics, and general background information.

After team-building on Friday evening with a trip to Tillicum Village, Steve Wakefield started off Saturday morning with a presentation on the vaccine research "landscape," reviewing who is involved beyond the HVTN and the kinds of activities in which they are engaged.

The group then identified a variety of topics on which they wished to hold small roundtable groups. After these breakout groups met, they reported back to the whole group their discussion and ideas. The topics included: the global sense of the HVTN; increase in scientific representation; mentoring programs; CAB Bulletin Board/E-tools; and the October meeting with Investigators.

Rose McCullough, a CAB member and Executive Director of the AIDS Vaccine Advocacy Coalition (AVAC), gave an informational presentation on AVAC and spoke about the activities of the organiza-



The future depends on all of us.



tion in the context of opportunities for advocacy.

Finally, Hamilton Richardson, from the Johns Hopkins University CAB, led a spirited discussion on diversity issues. Areas of focus included the need for diversity in local CABs and in trial participation, and how sites can reach out to groups that are traditionally harder to engage in research.

Best of all, the retreat will soon be coming to you in three different ways. First, extensive handouts, available from those on your CAB who attended the retreat, accompanied virtually every presentation. Andrew Campbell at my own local CAB in St. Louis copied the entire notebook provided to participants and gave each CAB member a copy.

Secondly, each person in attendance agreed to provide two training sessions for their local CAB from materials provided at the retreat.

Thirdly, there are plans for future regional CAB retreats so that more local CAB members can attend. ☘



Conference Overview

By *Community Education Program Staff*

From September 5 through 8, 2001, researchers, clinicians, advocates, policy-makers, and public health experts gathered in Philadelphia for three days of plenary sessions, poster sessions, slide presentations, and symposia highlighting the latest and most interesting information regarding the development, delivery, evaluation, production, and implementation of AIDS vaccines and immunotherapies.

AIDS Vaccine 2001, an international biennial conference sponsored by *Foundation for AIDS Vaccine Research and Development*, was created to provide a setting for the presentation of the latest basic, clinical, and public health data relevant to AIDS vaccine development; and an opportunity for informal and formal discussions to facilitate international and interdisciplinary collaborations in the field of AIDS vaccinology.

The conference began with three very poignant speeches. William Foege, from the Rollins School of Public Health of Emory University and Senior Health Advisor for the Bill and Melinda Gates Foundation, spoke about “The Global Need of an AIDS Vaccine.” He focused on the collective obligation to use science for the betterment of health globally, and urged all to look beyond science to ensure that the ethics, politics, law, and infrastructure are developed so that access and implementation are possible once science has come up with an effective vaccine.

After Dr. Foege, Dr. Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), spoke about “NIAID and Vaccine Research: Science and Policy.” The keynote lecture was delivered by His Excellency Paul Kagame, President of the Republic of Rwanda. Kagame addressed the issues surrounding AIDS in Africa and the need for partnerships. He stated “let this first conference of AIDS vaccines offer hope to the inhabitants of the globe.”

The following three days of the conference were filled with exciting sessions. Below are excerpts from some of the presentations.

Plenary: Therapeutic Vaccines and Immune Responses

The primary objective of the HVTN is to find an effective preventative vaccine. However, many of the products tested in the HVTN will also be examined in clinical trials by the Pediatric and Adult AIDS Clinical Trials Group and others. HVTN CAB members are familiar with ALVAC-HIV vCP1452 used in protocols 026 and 203. There are two studies in progress to see if persons who already have been successful in controlling HIV and reducing viral load can have a clinical benefit from a vaccine. This would mean the vaccine would control viral load after HIV treatment is withdrawn for a certain time period. AACTG A5068 is being conducted at multiple sites to evaluate ALVAC-HIV vCP1452 only. AACTG A5024 is being conducted at New York Hospital and Cornell Medical Center to evaluate ALVAC-HIV vCP1452 and/or interleukin-2 (IL-2). (For more details, go to www.actis.org and search under “ALVAC”)

Data on an Aaron Diamond study was also presented at the conference. The information was from a safety and immunogenicity study of ALVAC 1452 with rgp160 in a cohort of newly HIV-1-infected sub-

jects. Thirteen of the 14 patients who completed the vaccination had increased antibody response to gp120 and p24. With other important immunologic responses the team concluded that canarypox vCP1452 and rgp160 are safe and immunogenic to use in HAART treated patients. The clinical benefits still needs to be evaluated with larger controlled trials.

As was noted by many presenters, we still do not know the correlates of protection. This is one reason why we hope that the science tells us to move forward with Phase III trials, such as HVTN 501, in the coming months.

Slide Session: Human Trial II

Drs. Buchbinder (San Francisco HVTU) and Celum (Seattle HVTU) were co-authors on a study presented by Dr. Brad Bartholow of the CDC vaccine branch. They found that despite concerns that participants in AIDS vaccine trials might feel a false sense of security and engage in more risky sexual behaviors, the results of a subset of current VaxGen participants show an actual reduction in risky behavior. It was noted that 12 months into the trial, male participants were less likely overall to engage in unprotected anal intercourse. Perceptions about whether they were receiving the vaccine or the placebo did not appear to influence the behavior of either men or women.

Symposium: Global Challenges for Vaccine Implementation

Bill Snow, HVTN CAB representative to the Scientific Steering Committee, Board member for the AIDS Vaccine Advocacy Coalition, and frequent contributor to the CAB Bulletin, organized the session which focussed most on community issues.

In this session, Dr. Jose Esparza provided a historical context for viewing the global challenges for HIV vaccine development. Jose pointed out that several new site development initiatives are being implemented, including: (1) WHO/UNAIDS is promoting the development of the *African AIDS Vaccine Programme* (AAVP), a network of African scientists working to promote and facilitate HIV vaccine research and evaluation in Africa, through capacity-building and regional and international collaboration; (2) in collaboration with WHO-UNAIDS, several African countries are in the process of developing National AIDS Vaccine Plans; (3) the HIV Vaccine Trials Network (HVTN) established seven international sites in Latin America/Caribbean, Africa and Asia, and is in the process of expanding the number of international sites; (4) the U.S. Military HIV Research Programme is extending its activities to several East African countries; (5) and other organizations, including the U.S. Centers for Disease Control and Prevention (CDC), the French Agency for Research on AIDS (ANRS), the International AIDS Vaccine Initiative (IAVI), and the European Community are also contributing to site development in different developing countries.

Steve Wakefield and Janet Frohlich provided conferees with a look at many of the issues familiar to HVTN site CABs. Janet highlighted work in the South African township of Hslabisa. This is a community in the process of preparing for Phase III trials. The process began by providing the community with a simple understanding about research and mapping projects to determine who might be eligible for research. They have built a partnership that serves as a visible field of hope for a small village ravaged by the HIV and AIDS epidemic. Janet noted that

the hope for a future vaccine engages the community through the use of a participatory management approach.

David Gold of IAVI provided a look at the important work that must happen now to ensure access to and distribution of a future effective vaccine. Dr. Ezekial Emmanuel noted the ethical challenges, citing many of those provided to the HVTN by his colleague Dr. Christine Grady as noted in *CAB Bulletin* Volume 2, Issue 6, page 2.

Slide Session: Access and Implementation

This session focused on issues pertaining to access to and implementation of vaccine trials. The slide presentation covered a range of subjects from improved injection drug user (IDU) adherence, to vaccine schedules with cash incentives, to increased involvement of women in HIV trials. Alex McNess, the presenter from the IDU vaccine adherence study, concluded that a \$20 cash incentive is not enough to be considered coercive and his data noted cash incentives are far cheaper than outreach and much more effective in retention. Jorge Beloqui, CAB participant at the Brazil site in Sao Paulo, presented findings that show linking non-governmental organizations (NGO's) to vaccine education helped communities overcome suspicions of government and the "guinea pig" issue. Jorge also noted that this linkage helps make HIV vaccines part of a larger national dialogue. Bridget Haire and Elenor McClellan both focused on the importance of increasing women's involvement in trials. Targeted and innovative approaches were found necessary to engage women in a dialogue about potential trial participation, noting as well that the existence of a supportive staff sensitive to women's issues improves enrollment and retention.

In a related abstract presented in the poster session, "Phase III Efficacy Trials," Dr. Rick Novak of the Chicago HVTN site spoke about data from women in the VaxGen study and noted that women trial participants are more often minorities, are less educated than the men, are more likely to perceive protection against HIV infection from the vaccine than men, and value monetary incentives more than men. These factors must be addressed in future vaccine trials designed for sexually at risk women.

Symposium session: The AIDS VAX B/B Phase III Efficacy Trial in North America and the Netherlands

In preparation for the AIDS VAX B/B interim analysis of the first Phase III trial, Donald Francis from VaxGen, Inc., reviewed the safety data for the gp120 based on the HIV-1 envelope protein. To date, there have been 26,000 doses given in 7,000 volunteers. Only mild reactivity, has been reported, with no increase in rates of infection, and no apparent disease acceleration in those who seroconvert with the vaccine. This fall, there will be an interim analysis by the Data Safety and Monitoring Board (DSMB) to do the usual six-month safety tests as well as the first interim efficacy analysis. Donald pointed to company efforts to ensure that trial participants have realistic expectations and continue to participate, despite media analysis of this event.

Wrap-up: AIDS Vaccine 2003: The Future?

The closing session was convened by Dr. David Baltimore from the California Institute of Technology in Pasadena. The panelists included:

Kevin De Cock, *CDC, Nairobi, Kenya*

Jaap Goudsmit, *Academic Medical Ctr., U. of Amsterdam, The Netherlands*

David Ho, *Aaron Diamond AIDS Research Center, New York, NY, USA*

Margaret Johnston, *NLAID, NIH, Bethesda, MD, USA*

Michel Kazatchkine, *Agence Nat'l. de Recherches sur SIDA (ANRS), Paris*

Gary Nabel, *NLAID Vaccine Research Center, NIH, Bethesda, MD, USA*
Yiming Shao, *National AIDS Reference Laboratory, National Center for AIDS Prevention and Control, China*

Dr. Baltimore opened the last session by asking the panelists two questions:

- What surprised you here at the AIDS Vaccine 2001 Conference?
- Where are we headed with HIV/AIDS vaccines?

Each of the panelists addressed the question and discussed pertinent issues. While some were surprised by the lack of discussion at the conference around adjuvants, others were impressed by the number of presentations showing the range of different vectors being used.

Kevin DeCock was encouraged by the results presented from monkey data and expressed concern over the distance between encouraging animal data and the lack of commitment and aggressive push into Phase III trials, especially in areas where incidence rates are the highest. He believes that there is only so much monkey data that can answer questions, and that many questions cannot be answered until we move into human trials.

Gary Nabel believed that the novel lessons from the meeting came from the collective information, and reiterated that the two most important criteria for moving forward with Phase III trials were that they be both scientifically rigorous and ethical.

Yiming Shao focused on the need to enhance partnerships between developing and developed countries, and Jaap Goudsmit expressed his concern that AIDS vaccines may become too politicized, and hence the science too burdened by political wrangling to move forward quickly.

Michel Kazatchkine pointed out that up until now the process for moving to a Phase III trial has been very loose. He asked the question "Who has the right to do a Phase III trial? Can it continue that whoever has the money and a product, can do a trial?"

Margaret Johnson reiterated the imperative to move safe vaccines forward, pointing out the need to learn more about the correlates of protection that only efficacy trials can define. She also expressed concern that, in this meeting and future ones, pounding on the clade issues could impede the pushing forward of science and vaccine development.

The basic summary of the last session focused on the future of HIV vaccine science. The key issues thought to be most important in the coming years included:

- Figuring out the clade question.
- Discovering immunological models to more efficiently move new vaccines into human trials.
- Ensuring the possibility for head-to-head comparisons of trial data.
- Improving collaboration between the Northern and Southern hemispheres for conducting trials.
- Understanding the question of who has the right to run a trial, and whether or not there needs to be some sort of a global, overarching regulator.
- Making sure all countries involved in trials feel a sense of gain in the cooperation. ☘

For more information on the
AIDS Vaccine 2001 conference, visit:
<http://63.84.172.40/>

If you missed the *USA Today* article featuring two of our very own, Mary Allen and Sandra Wearins, search *USA Today's* online archives for Steve Sternberg's article "Closer to AIDS vaccine?" at <http://pqasb.pqarchiver.com/USAToday/>

International Community Educator's Meeting

August 16, 2001, Seattle, WA

As language and time barriers have often kept the HVTN's international sites from getting non-staff members involved in the Global CAB, retreat participants from the HVTUs in Brazil, Haiti, Trinidad & Tobago, South Africa, and Peru included one CAB member and one staff member—the community educator. Known to take advantage of great opportunities, the Community Education Program invited the international Community Educators to come a day early in order to meet, as the U.S. Community Educators/Recruiters did in New York last February, to discuss development of community education plans and other issues specific to the non-U.S. sites.

The first session of the morning was led by Siobhan Malone. After giving the Community Education Program's view of their roles and responsibilities and those of the community educators, the group was asked to respond and come up with their definition of the roles and responsibilities for themselves and for the Program.

Andrew Lambert then led the group in a discussion regarding the formation, functioning, and development of a successful CAB. The international Community Educators broke out into small groups, looking at a number of questions that inspired each person to think about their own experiences with their local CAB. Each group then presented their successes and challenges. This was a helpful session in that it allowed people to rethink the role of their CAB, and allowed people to share with other sites ways of improving many aspects of how CABs are formed and how they function. The ultimate goal of this session was to equip Community Educators with some tools to take back to their sites to help improve, diversify and strengthen CAB involvement in the Network and on vaccine issues in general.

The last session focused on the importance of writing a community development plan. These plans, if seen as more than an administrative exercise, can be useful in setting goals and expectations for the future, increasing community participation, and strengthening community ownership of the site's activities. The group went through the basic exercise of putting a plan together and then received a template that would facilitate writing all the various sections.

The international sites realized that there are many issues that are common among non-U.S. sites and have suggested having future discussions and meetings that focus on "south to south" issues. The sites put forward their immediate needs from the HVTN Core, and concluded the meeting by jointly calling for future development of international collaborations. ☘



CALENDAR OF EVENTS

CAB PROTOCOL WORKING GROUP CONFERENCE CALL:

Saturday, October 6, 2001, 12 p.m. E.D.T./ 9 a.m. P.D.T.



GLOBAL CAB CONFERENCE CALL:

Thursday, October 11, 2001, 7 p.m. E.D.T./ 4 p.m. P.D.T.



COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:

Tuesday, October 30, 2001, 12 noon E.D.T./ 9 a.m. P.D.T.



HVTN FULL GROUP MEETING

October 14–17, 2001, Seattle, WA

GCAB: October 14, 3p.m.–6p.m.

CER: October 17, 1p.m.–5p.m.



HIV Prevention and Vaccine Conferences:

12TH INTERNATIONAL CONFERENCE ON AIDS AND STDs (AFRICA)

December 9–13, 2001, Ouagadougou, Burkina Faso

9TH CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS

February 24–28, 2002, Seattle, WA (Abstract deadline: Oct. 26, 2001)

2002 COMMUNITY PLANNING LEADERSHIP SUMMIT FOR HIV PREVENTION

March 6–9, 2002, Chicago, IL (Abstract deadline: October 12, 2001)

WORLD AIDS DAY...

December 1 is not too far away. Sites should be finalizing plans for this year's event. The theme for 2001 is "I care. Do you?"

Please send suggestions, questions, and article submissions to:

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