
HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

Volume 2, Issue 6 June/July 2001

HVTN Full Group Meeting Debrief

Arlington, VA, May 9–11, 2001

The HVTN Full Group Meeting in Arlington, VA on May 9–11 was an opportunity for all to soak up some of the latest scientific findings regarding specific vaccine development strategies. Special sessions also provided the over 300 participants a chance to better understand some of the challenges facing the sites outside the U.S., and some of the ethical issues surrounding the proposed protocol for a Phase III trial (see pink box on page 2).

The first day of the meeting was taken up by small meetings of the various committees and working groups. The Phase III Trials Committee and the International Working Group held open sessions where topics such as “Recruitment of High-Risk Heterosexuals” and “U.S. Approval Processes for the Conduct of International HIV Vaccine Trials” were discussed.

Both Thursday and Friday were long days packed with plenary sessions addressing cutting edge scientific findings and industry programs centered around HIV vaccines. Many closed protocol and development team meetings also occurred during these two days. Thursday's plenary speakers included Dr. Robert Gallo, co-discoverer of the virus that causes AIDS, and Emilio Emini from Merck. Dr. Emini described his company's progress toward production of an effective DNA vaccine.

Friday morning began with an invigorating speech by Dr. Anthony Fauci regarding funding and future HIV vaccine research. The plenary sessions that followed included recent investigations targeting the acute phase of HIV infection, and vaccines designed to prevent HIV transmission across mucosal tissues. The session wrap-up included presentations by Dr. Larry Corey, on the vaccine pipeline, and Dr. Steve Self, on the proposed standardization of Phase I/II vaccine trials. Dr. Self reported on the HVTN's move to standardize the series of Phase I and Phase II trials required to provide critical safety and immunogenicity evaluation of candidate HIV vaccines prior to an efficacy evaluation. This standardization, according to Dr. Self, will improve the efficiency of the network and shorten the timeline for this early clinical evaluation of candidate vaccines. The trial design guidelines involve a sequence of three trials. The first trial provides initial safety data across a range of doses. The second trial selects the specific schedule of immunization

and other aspects of the vaccine regimen that will most likely produce the best immunogenicity response from the vaccine candidate. The third trial provides a precise characterization of the immunogenicity profile of the optimized regimen on which will be the basis for a decision to initiate an efficacy evaluation.

On Friday afternoon, CAB members met for five hours to discuss a range of issues. Drs. Larry Corey and Michael Keefer joined the first part of the meeting to debrief the CAB on some of the important scientific issues that were addressed in plenary sessions. They also responded to questions, including those regarding injury provisions for trial participants. Dr. Corey assured the CAB that he and Dr. Johnston of the NIH had been discussing the issue and would continue to work on it until an acceptable solution is found.

Steve Wakefield gave a presentation updating the group on the activities of the Community Education Program. He talked about the program's success in getting community participation on all protocol teams and scientific committees in the Network. He also talked about the CAB Bulletins, the updated HVTN web-site, and the progress made in the development of smooth-functioning, diverse CABs at all Network sites. The presentation also covered the important points that CABs should be aware of in the HIV vaccine landscape, including other HIV vaccine trials; upcoming conferences and news-worthy events; information on the web; treatment issues; other prevention campaigns; and anti-vaccine movements. Steve concluded the presentation with a look at some of the community challenges that will need to be addressed by local CABs as HIV vaccine research grows and becomes a more visible issue world-wide.

Tom Gibson updated the group on the Participant's Bill of Rights and Responsibilities. He shared copies of the latest draft, letting the GCAB know that the Working Group had not made any major changes, and that the document was almost ready to go to the Scientific Steering Committee for final review.

Monica Barbosa, the CAB liaison from the HVTU in Brazil, spoke about the upcoming United Nations General Assembly Special Session in New York this June. She urged the CAB to get involved and show their support, as a group, for an appropriate Declaration of Commitment that includes important steps that member states need to take to encourage and hasten HIV vaccine research.

After hours of discussion, the meeting ended with long to-do lists and members reinvigorated to do important work at their sites and on the Global CAB. ☘



HVTN 501 Ethics Workshop



One feature of the May Full Group meeting in Arlington was a panel discussion of the HVTN Protocol 501 draft outline—the first phase III trial for the Network. External advisors and friends of the network helped identify the ethical issues for consideration in this specific trial. Panelists included: Arthur J. Ammann, Global Strategies for HIV Prevention; Christine Grady, NIH; Jose Esparza (Switzerland), UNAIDS; and Janet Frohlich (South Africa), HPTN Community Science Working Group Co-chair. Dr. Susan Buchbinder, as the Protocol 501 Chair, provided scientific leadership, and Steve Wakefield moderated the discussion.

Participants commented, suggesting that ethical considerations guide continued development of the actual draft protocol document for this trial, which will be conducted in the U.S., the Caribbean and South America.

Dr. Grady provided a framework for the group's consideration of the current ethics environment with multiple guidance documents. The seven elements of ethical research that she outlined included:

- Valuable scientific question (Value)
- Rigorous scientific methodology (Validity)
- Fair subject selection
- Favorable balance of risks and benefits
- Independent review
- Informed consent
- Respect for enrolled subjects

A more in-depth coverage of these concepts can be found in the *JAMA*, May 24/31, 2000—Vol 283, No. 20 article “What Makes Clinical Research Ethical?” by Ezekiel J. Emanuel, M.D., Ph.D.; David Wendler Ph.D.; Christine Grady, Ph.D.

Dr. Esparza highlighted considerations from the UNAIDS Guidance Document, *Ethical Considerations in HIV Preventive Vaccine Research*, issued in May of 2000, that directly relate to this protocol. (A link to the document can be found on the HVTN web-site under “Resources.”)

Dr. Amman and Janet Frohlich helped attendees understand the impact of HVTN decisions on communities where the understanding of research may vary considerably. Each raised significant issues. Some of those that will require additional consideration by HVTN CAB and Investigators in helping the HVTN 501 Protocol Team move forward include the following: How will we balance individual benefit versus community benefit?; Can we ensure an informed consent process where persons fully understand the risk-benefit ratio?; How will the HVTN handle new scientific information as the trial progresses?; What can we put in place to help trial participants understand the value of research that helps us develop “correlates of immunity”?; How will the trial benefit the population from which subjects are drawn?; What are the steps to ensure

post study availability of an efficacious vaccine?; What treatment will be provided to those who become infected during the trial?; Can the HVTN develop a uniform research plan, with an appropriate response to the treatment issue, that is responsive to today's reality at each locale and can be adjusted as the standard of care changes globally?

The panel noted the excellent work to date. They also recognized that our ethics must meet the substantial scientific challenges in vaccine development while at the same time ensuring collaboration and cooperation in a global environment. ❀

Baltimore Vaccine Day Celebration

By John Bunting GCAB

Baltimore held its fourth annual Vaccine Day Celebration on June 17, 2001 to commemorate our commitment to finding an HIV vaccine, our appreciation of vaccine trial participants, and our outreach to communities most impacted by AIDS. The event was held at New Shiloh Baptist Church, home to a large African-American congregation in West Baltimore. The organizing committee, jointly comprised of Community



Advisory Board members and staff from Johns Hopkins and the University of Maryland, decided to encourage people from the faith community and African-

Americans to attend. The marketing activities and the program itself were structured to attract those populations. In addition, trial volunteers and AIDS service providers were invited. The more than two hundred attendees, mostly African-Americans, attested to the accomplishment the committee's goal.

After a meet-and-greet reception and dinner, two keynote speakers from Sisters Together and Reaching (STAR) and Baltimore Prevention Coalition (BPC) gave testimony about their long involvement in the struggle against AIDS and the need for people to be well-informed about HIV vaccine trials, treatment, and prevention. Major themes in their remarks included the necessity for everyone to be educated about clinical trials, to ask questions of trial sites and organizers, and to ensure that community needs are being met at every level of trial design and participation. A question and answer segment that followed demonstrated the attendees' commitment to learning about HIV vaccine trials and holding investigators responsible for informing the public about every aspect of trial protocols.

Edna Reynolds, an active member at Project Arise, Sacred Zion Church, commented: “I learned more about vaccines. I was glad that this program involved the faith-based community. I was surprised at

(Continued on page 4)

Trinidad & Tobago CAB

By Yolanda Simon and Petula Lee

The Trinidad and Tobago Community Advisory Board was born as a result of the proposed Vaccine Trial Preparedness exercise in Trinidad and Tobago in mid-1998. The Medical Research Foundation hired Claudette Francis and Yolanda Simon as Liaisons Officers to begin the process, and some of our foundation members were recruited, (our first Convenor Ms. Beulah Duke who has done yeoman's service, for instance, was one of them). People were recruited from all the Non Government Organisations (NGOs), Community Based Organisations (CBOs), Medical Associations, churches, and other interested groups and individuals.

By July 1998, we had things moving smoothly after sitting together for hours working on our mission statement, philosophy statement, goals and objectives, the roles and responsibilities of CAB members, criteria for membership, and the requirements/standards for individual members. Now that was a lot, and we still had more to do.

Finally, on Thursday September 24, 1998, we formally launched the Trinidad and Tobago Community Advisory Board (TTCAB). We had some positive media coverage about which we felt good—mission accomplished. Little did we know that *"de journey now start."*

Having decided that our focus should be education, advocacy, networking and community participation, we began by hosting a media workshop to inform and educate members of all the media houses in T&T. This was followed by a series of town meetings and workshops at churches, schools, and the military. We also held discussions with the Ministry of Health. There were monthly meetings for our membership, at which an hour or so was used for our own education and information updates.

It is our belief that there is urgent need for an HIV Vaccine and we will support any legitimate activity which allows for the development of a safe and effective vaccine for the control of HIV/AIDS. The idea of "vaccine trials in Trinidad and Tobago is/was brand new, and we have already had our fair share of hiccups, but we are committed to addressing the needs and concerns of the community, infected and affected individuals. Our solidarity with all agencies involving HIV/AIDS prevention and our obligation to act with compassion for those at risk of infection makes us determined to fight stigmatization and discrimination against all persons living with HIV/AIDS.

We are also committed to education, and to addressing misinformation by providing accurate information. We also recognize that poverty, discrimination, and stigmatization are contributing factors in the spread of the epidemic, and that it impacts adversely on individuals, family, and community life and is hindering social and economic development in our twin island republic. We therefore intend to mobilize ourselves (the CAB) and the nation in general through a series of capacity building workshops, lectures, town meetings, etc.

HIV/AIDS has not only caused grave physical and emotional suffering, but more times than not results in discrimination, especially at the workplace. Our society faces obstacles that hamper prevention, care, and support efforts. The CAB realizes that these are inseparable and must be integral components of any effective approach to combating infection and disease. We also believe that all initiatives must include persons infected and affected, along with an effective, committed political directorate.

The TTCAB is a part of a network of persons living with HIV/AIDS, NGOs, CBOs working together in an effort to foster partnerships as a response to the pandemic.

We understand that we still have a long way to go and many hurdles to overcome, but we have one common head. We resolve to understand and to address specific HIV/AIDS issues and concerns, to advocate on behalf of our brothers and sisters as we work together in the spirit of social tolerance and solidarity.

Finally, I will quote a few lines from our Declaration:

"We, the members of the Trinidad and Tobago Community Advisory Board (TTCAB), hereby declare that we are mindful that the HIV/AIDS epidemic constitutes a threat to human life and negatively affects our nation" and as such we will be "a force for change." ❀



Medical Research Foundation of T&T Staff and CAB member (left to right): Jenny Kwang, Felitia Campbell, Petula Lee, Avion Quava, and Dr. Harry Smith

CONGRATULATIONS to the Medical Research Foundation of Trinidad and Tobago HVTU for vaccinating their first trial participant in the HVTN/HIVNET 026 trial on June 20, 2001. At the end of the visit the participant said, "During the screening I was excited, but today after getting the vaccine I feel proud."

(Continued from page 2)

the questions that came from the audience. What this revealed to me is that there is a lot to learn in the African-American community about the HIV vaccine issue. If the African-American community is ever going to participate in vaccine work, there will need to be more forums such as this.”

Inspirational songs by the New Shiloh Baptist Church Choir gave the audience an uplifting demonstrated by the clapping of hands and voices singing praise. It seemed everyone in the room was moved by the music and the promise of a new vaccine supported by all communities.

Theron Scott, Community Education/Recruitment Coordinator at Hopkins and one of the event organizers, was very pleased with the evening turnout and success. “This was a great opportunity for HIV vaccines to be taken to the community where people could ask questions and be heard. A lot has been accomplished this evening and I am very glad I could be part of it.”

Another prevailing thought shared by many of the event organizers came from Dr. William Blattner, Principal Investigator from the Institute of Human Virology at University of Maryland. “This day spoke of partnership: achieving the common goal of understanding and overcoming barriers to developing an effective vaccine. It was important that the Community Advisory Boards of Maryland and Hopkins sponsored this event and that the leadership and staff of these institutions united to demonstrate a commitment to work together toward this common goal.” ❀

New Staff...

We would like to welcome Andrew Lambert as the newest member of our Community Education Program here at the HVTN. Andrew will be working as the Community Education International Projects Manager. He was born in the Seattle area, but has lived, studied, and worked for almost seven years overseas in Europe, Latin America, and West Africa. He has a BA in International Studies and a Masters in Community and Environmental Planning, both from the University of Washington. He has a tremendous amount of experience in developing countries, most notably working and living with the local populations, learning their languages, customs, culture, and systems of organization.

Andrew did a two-year stint with the Peace Corps in Guinea, West Africa as an English teacher and grass-roots community development organizer. He has recently come back from the Ivory Coast where he was a Fulbright grantee doing research on the impediments to community-based planning and development. He speaks French, Spanish, Portuguese, and has a basic understanding of two different local West African languages (Fulani and Sousou). He will be a great asset to our organization as we continue to work in and expand into other parts of the world. ❀



Phone #: (206) 667-7151
Email: alambert@hvtn.org

CALENDAR OF EVENTS

CAB PROTOCOL WORKING GROUP CONFERENCE CALL:

Saturday, August 4, 2001, 12 p.m. E.D.T./ 9 a.m. P.D.T.

Wednesday, September 5, 2001, 12 p.m. E.D.T./ 9 a.m. P.D.T.



GLOBAL CAB CONFERENCE CALL:

Thursday, August 9, 2001, 7 p.m. E.D.T./ 4 p.m. P.D.T.

Thursday, September 13, 2001, 7 p.m. E.D.T./ 4 p.m. P.D.T.



COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:

Tuesday, August 21, 2001, 12 noon E.D.T./ 9 a.m. P.D.T.

Tuesday, September 18, 2001, 12 noon E.D.T./ 9 a.m. P.D.T.



CAB RETREAT

August 16–18, 2001, Seattle, WA

HVTN FULL GROUP MEETING

October 15–17, 2001, Seattle, WA



HIV Prevention and Vaccine Conferences:

2001 NATIONAL HIV PREVENTION CONFERENCE

August 12–15, Atlanta, GA

AIDS VACCINE 2001

September 5–8, Philadelphia, PA

2001 US CONFERENCE ON AIDS

September 13–16, Miami Beach, FL

*Please send suggestions, questions, and article submissions to:
Siobhan Malone, Community Project Coordinator
HVTN/FHCRC, 1100 Fairview Avenue North
P.O. Box 19024, Mailstop: MW832
Seattle, WA 98109-1024
siobhan@hvtn.org
Tel: 206-667-6350 Fax: 206-667-6366*



HIV VACCINE
TRIALS NETWORK