The 2008 World AIDS Conference highlighted the need to work together in the search for an effective tool that will put an end to HIV.

Throughout the conference, presenters emphasized how quickly the epidemic is advancing. If the virus continues at this rate (in 2007 there were 2.7 million new infections), it will be increasingly difficult to guarantee access to antiretrovirals to everyone who seroconverts. Given the high cost of ART, it will not be sustainable for countries to supply treatment to people living with HIV/AIDS. For this reason, Peter Piot, executive director of UNAIDS, urged greater investment in prevention interventions. Along the same lines, political leaders, activists, and scientific and technical presenters also stressed the need for greater investment in broad prevention research, including vaccines, microbicides, PrEP, circumcision, etc.

Many sessions echoed the message that continuing to advance vaccine science is imperative in order to stop the HIV epidemic. Political leaders of countries that are both severely affected by HIV and compromised in their research capacities called for greater activism. They stressed the need for involvement of more local researchers in the development of a preventive vaccine and increasing financial support for these efforts.

There was also great support for the role of community education, because it is the only way to increase awareness about HIV in a variety of populations. Community Advisory Boards can play a role in achieving greater involvement in communities. Communities should make sure that this activism is present and felt at the next global AIDS 2010 conference in Vienna.

The sessions on prevention research emphasized the need to involve community leaders in all aspects of study development, from initial design through implementation. The Community Advisory Boards that support the HVTN investigation units have gained valuable experience that can be shared with other networks. The HVTN CABs can show that social participation in biomedical research facilitates and enriches the investigative process.

Finally, we left with three conclusions from this World AIDS Conference:

1.  It is possible to find a vaccine against AIDS and research must continue: creating an effective vaccine is a long road, full of obstacles, but it is a road that we should walk if we want to put an end to this epidemic.

2.  The Step Study was one of the best achievements in vaccine research because it was well designed, and it provided valuable information for the design of future studies.

3.  We should promote and demand the development of adequate plans for health research. We must demand more investment in vaccines.

Universal Access to an HIV Vaccine, NOW!

Eduviges Cuello Paredes
Santo Domingo CAB, República Dominicana
preceded by a period of networking, which seems to help build a sense of camaraderie among the community members. Principal Investigators and staff persons from each research unit also attend, including clinic coordinators and community education and recruitment staff. Light food is provided at every meeting. Community participation on the CAB varies from year to year. Our goal is to have the membership of the CAB represent local communities most affected by HIV/AIDS including people living with HIV and people who have participated in research studies.

Community Engagement

Every CAB member brings unique time and talent to the table and is a valued asset to the CAB mission: “A World Without AIDS.” Many of our CAB members provide visibility for the clinical trials unit (CTU) within their organizations. Others have facilitated new alliances for the unit and some members volunteer and do community outreach and education. One of our CAB strengths lies in having individuals with an established network of contacts who make inroads for the CTU among stakeholders of target communities. Similarly, some agencies at the table provide our site with additional visibility to broad population groups. A few examples are provided in the following paragraph.

In addition to being the Ryan White Coordinator for the Rochester NY Region, Patricia Zacharias is also a facilitator for the Rochester Area Task Force on AIDS. RATFA is a collaboration of more than 240 health and community based organizations, and Patricia adds updates about HIV vaccine research to the newsletter distributed to all of these agencies. CAB member Jackie Dozier of BMLMHC, Inc. was recently applauded by the Black AIDS Institute for her community engagement events, which provide a safe meeting place for African American and Latina women to gather and share HIV prevention information. These events target women who don’t realize their risk factor for HIV but who live in at-risk neighborhoods. There are many other CAB members contributing in valuable ways, including forging connections with the United Nations Association of Rochester and with local key organizations and universities. We thank them all for their hard work and dedication!

Educational Topics

Typically, at the June CAB meeting, Rochester CAB members discuss the year’s educational topics and presentations and identify topics they would like to consider for the following academic season. Some recent topics include:

“The HPV Vaccine—Challenges & Triumphs.” (Invited Guest Speaker)
“Treatment as Prevention” (CAB Member)
“CABs—Origin & Purpose” (CAB Member)
“HIV Clades” (CAB Member)
“Long-term non-progressors” (CAB Member)
“A Step Study Update – What We Know So Far” (PI)
“Mucosal Immunity” (Invited Guest Speaker)
“Pre-existing Immunity” (Co-Investigator)
“CAB Leadership” (CAB Member)
“Protocol Participation by CAB” (CAB Member)
“PAVE 100 – What Is It & What Lies Ahead?” (PI)

Annual Local Retreat

The CTU hosts an annual local CAB retreat. The retreat provides an opportunity for in-depth discussions on three of the heartier topics selected by CAB members. The site arranges for speakers and provides a continental breakfast and a buffet luncheon. Past retreats were in collaboration with local AIDS Service Organizations including AIDS Rochester Inc., MOCHA Project Inc. and AIDS Community Health Center, Inc.

Ongoing Communications

HVTN messages geared to CAB members are typically forwarded to CAB members as they are received by the staff liaison. This includes messages that attempt to clarify or update community persons about scientific or statistical information regarding HIV/AIDS, or news geared to the community about a particular study and the need for local CAB members to serve on HVTN Protocol Committees.

In closing we would like to publicly thank our CAB Chair, the CAB Executive Committee, and each and every CAB member for their continued dedication to HIV prevention and their individual and collective support for AIDS treatment and HIV vaccine research.
Since 2003, different trials have taken place at the VIC: three HIV preventive vaccine Phase I trials and one Phase I/II trial, one HIV therapeutic vaccine Phase I trial, one malaria Phase I and one IIa trial, one tuberculosis Phase I/II trial, and one preventive/therapeutic Phase I HCV trial. A slight majority of women (57%) have been recruited in these trials. The VIC is also undertaking allergy-related trials.

In June 2007, the Lausanne CAB was formed with seven founding members from different backgrounds. The main goals of the CAB have been set as follows:

- The CAB acts as a spokesperson for civil society, in order to open a dialogue with scientific researchers working in the field of HIV/AIDS. The goal is to identify the questions or misconceptions that the population may have, in order to continuously improve the quality of the information provided by the researchers.
- The CAB informs the community on the different strategies and developments on HIV/AIDS vaccine research.
- The CAB participates in events linked with themes around HIV/AIDS.
- The CAB reviews and makes recommendations to the VIC staff on all the documents meant for future trial participants, in order to guarantee clarity, and ethical standards of the information given to participants.

The CAB meets approximately six times a year. This first year has been focused on training the CAB in different aspects of clinical research, as well as holding discussions within the CAB about the protection of the trial participants and their rights. As a means of describing our CAB, we have presented a little bit about them, in alphabetical order below:

Corinne, who is the Global CAB member, is involved in multiple fields of public health, leading and evaluating complex projects. Through her work, Corinne has developed a passion for bioethics, and teaches bioethics in high schools and universities. In her free time, Corinne is also a clown! In her commitment as Global CAB member, she will defend ethical values, equity and solidarity.

For Daniel, participating in the development of an HIV vaccine is a way of accomplishing something real against this sickness. Daniel has already participated in two clinical trials. Having lived for three years in Africa, Daniel has been confronted by the hard reality of AIDS and its consequences on people’s lives. Daniel comes from a nursing background.

Deborah is the spokesperson for the “Groupe sida Genève,” which is one of the main associations in Geneva offering prevention work and support services for people living with HIV and AIDS. Deborah is also an HIV and AIDS Human Rights coordinator, and manages lobbying and advocacy projects to fight discrimination and promote human rights in the context of the epidemic.

Jean-Philippe is the coordinator of Point Fixe, an association active in communicating about issues regarding HIV and AIDS. As coordinator of this association, Jean-Philippe believes it is important to support the dialogue between the community, researchers and volunteers, healthy or HIV positive, participating in trials for preventive or therapeutic vaccines.

Monique has spent many years working in HIV prevention and the field of sexual and reproductive health. She has trained educators, and was recently recognized by Swiss universities for this work. She is currently coordinating activities between sexual education, family planning and the HIV and AIDS network. She is also politically active in the parliament at the regional level.

Sabrina has just finished her studies in social sciences. She has been working part time at PLANeS, the Swiss Foundation for sexual and reproductive health, particularly in the development of a youth project. Being part of the CAB is a chance to be connected to a network of people from different backgrounds, to be able to give her own opinion and to dialogue with the world of vaccinology research. Sabrina was just elected coordinator of the CAB.

Sandrine is a consultant at the International Bureau of Education/UNESCO for the HIV and AIDS education program. Sandrine has worked as a nurse and studied International Relations, with a focus on economic and social human rights. She currently travels in developing countries, giving conferences on educating children and adolescents about HIV and AIDS, including issues such as stigmatization and discrimination.
Community Connections

SAO PAULO, BRAZIL
Recently, the Sao Paulo CAB has held several different community events. Pictured in the top two photos at left is a CAB training led by Marcia Rubia, the CAB member who attended the 2008 HVTN CAB Retreat. At this training, Alexander Menezes from the International AIDS Vaccine Initiative (IAVI) facilitated a discussion around Community Participation in HIV Vaccine Research. He shared information about the development, involvement, and variety of CABs in HIV vaccine research. Further, he discussed the tradition of advocacy and activism in each region. It was a very interesting day!

Additionally, the Sao Paulo CTU organized a public consultation with community members to review good participatory practice guidelines for HIV research. Finally, the site was involved in the Seminar on Biomedical Prevention Trials, conducted by a local HIV agency with support from the Sao Paulo site. Research was presented on HIV vaccine trials, including the STEP Study, as well as future PrEP studies and research on circumcision acceptability.

SAN JUAN, PUERTO RICO
(right photos)
CAB members at the Puerto Rico site meet to discuss upcoming protocols in their community.

BOSTON, MASSACHUSETTS, USA
(left column)
These photos are from an outreach event during Cyndi Lauper’s True Colors tour in July. In each city of the tour, tour organizers invited AIDS Service Organizations and other CBOs to set up a free booth and hand out information. Boston Recruiters Jake Tinsley and Coco Alinsug did the outreach that day. Jake Tinsley, Senior Recruiter for the Fenway Institute, even got to have a picture taken with Cyndi Lauper herself! Coco Alinsug, Recruitment Coordinator, was also photographed at the event, staffing the site’s info table. There was lots of interest in HVTN studies that day!

Alexandre Menezes, from IAVI, speaking with the Sao Paolo CAB.

CAB member Marcia Rubia leading a CAB training.

Site training with guests from IAVI, with educators Gabriela Calazans (Sao Paulo) and Monica Barbosa (Rio).

Community discussion on participatory practice in HIV research.

CAB members in San Juan, PR

Rock star Cyndi Lauper with Jake Tinsley, Fenway Recruiter.

Coco Alinsug working the tables during Cyndi Lauper’s tour.

CAB members in San Juan, PR
Community Connections

Santo Domingo, Dominican Republic

In July, the CTU held a dinner at The Lina Hotel as a retention activity with site staff and volunteers. Part of the evening included a performance by the recruiters about avoiding STIs. A happy afternoon was also spent with the children of trial volunteers and CAB members at the Children’s Trampoline Museum. This retention activity was organized to create a familiar and relaxing environment for the volunteers and their children. Over 200 people attended that day.

Durban, South Africa

Over the South African winter, the Durban site held two retention events. Over two hundred participants attended on a day during Youth Month in June, nearly of 50 of whom were part of the Phambili trial, as well as close to 150 participants from a microbicide trial. In addition to a general thanks to participants, the main theme was a discussion of the problems caused by co-enrollment.

The site also participated in National Arbor Day, during which they planted trees together at the site, signifying their commitment to the cause of finding an HIV Vaccine.
The next Phase II trial from the network, HVTN 505, is currently being developed. CAB representatives for this protocol team are Rick Church of New York City and Richard Trevino of Boston. Community Educator representatives are Gavin Morrow-Hall of San Francisco and Kat Davis of Nashville.

The study vaccines in this trial will be a DNA prime and an Adenovirus 5 (Ad5) boost. Both study vaccines have been developed by the Vaccine Research Center of the US National Institutes of Health. While this vaccine regimen uses an Adenovirus 5 vector, it is a different vector than the one used in the Step and Phambili trials. The Adenovirus vector was constructed differently, and it carries different copies of HIV genes.

HVTN 505 is currently planned to enroll 1350 men who have sex with men in the United States. They must be fully circumcised and they must not have any pre-existing antibodies to Ad5. These two criteria are important for increased safety, as men in the Step Study who were Ad5 negative and circumcised were not found to have any enhanced susceptibility to HIV infection. Safety of the participants is always key in HVTN trials, and safety monitoring will be enhanced in this trial. Building on what we learned in the Step Study, preliminary plans include regular review by the Data and Safety Monitoring Board, and visits scheduled more frequently to allow for additional risk reduction counseling.

As you may recall from the last CAB Bulletin, we were waiting for NIAID director Anthony Fauci to decide whether or not the revised protocol known as PAVE 100A would be approved to move forward. In his announcement on July 17, Dr. Fauci noted that PAVE 100A would not move forward, but that the VRC vaccine regimen deserved further study. Dr. Fauci said he would be interested to see a proposal for a more focused trial using this regimen that would help show whether this T-cell vaccine could lower viral load among vaccinees who later became infected with HIV.

The HVTN put together such a proposal, and were given approval to move ahead with protocol development. The new protocol is chaired by Dr. Scott Hammer. The protocol team met for a face-to-face meeting to fully flesh out the protocol during the first week of November. The trial is planned to have equal numbers of vaccine and placebo recipients. Those who are randomized to receive vaccine will get one shot of the VRC DNA vaccine at three times: the first study visit, one month later, and two months later. This priming series will be followed by a single boost vaccination with the VRC Ad5 vaccine six months after the first injection. Participants in the placebo group will receive four shots of the placebo at the same timepoints.

We will provide further updates about the protocol in the next issue, once the full protocol is available.

Key messages from the HVTN

One of the best ways to talk about any issue is to develop key messages and then use them consistently. When a large number of people talk about a topic in the same way over and over, there is a better chance that the people listening will really hear the message. Here are the key messages the HVTN uses when talking about HIV vaccine research and the HVTN. If you have questions about any of these messages, please talk to your community educator or your Principal Investigator.

**A vaccine is critical for ending the AIDS epidemic**
- Finding a vaccine is a long-term process that involves many studies, each designed to learn specific information.
- A comprehensive program to fight AIDS must include prevention, treatment and research.

**Every trial is designed with safety as a primary objective**
- Many studies need people who are at risk of HIV infection. As participants, they receive counseling to reduce their risk of infection, condoms and lubricant, and connections to other prevention services in the community.

**The process of finding an HIV vaccine requires the commitment of thousands of people**
- It will take time to find an effective HIV vaccine.
- Community members and community organizations are a critical part of this process.
- The HVTN remains committed to finding an HIV vaccine that works for all people around the world.

**Each trial is designed to answer specific scientific questions**
- Scientific discovery requires many studies. Each study may reveal a small bit of information that can help solve the puzzle.
The GCAB and its working groups

We often refer to the GCAB, which is the group of representative CAB members from local sites that come together to advise the Network as a whole. The GCAB, however, has many subgroups, and as many of these groups have changed or been added in the past year, you will find a description of all these groups below. CAB members are invited to participate in various working groups at the HVTN. Participation in some of these groups is through election to a representative position by the local CAB or by the GCAB, while participation in others is purely voluntary, and any CAB member may join the group. Please see the back page of the Bulletin for the call schedules.

The **Global Community Advisory Board (GCAB)** comprises one elected CAB member from each network site and the CAB representatives to key Network working groups, as well as regular participants in the EWG and SWG. The GCAB serves as the community advisory group for the HVTN as whole, just as the local CABs advise their sites. The group holds a monthly call, and meets ad hoc when its advice is needed quickly. Currently the group is co-chaired by Rick Church from the New York City CAB and Phineas Malahlela from Soweto, South Africa and supported by Lisa Bull at HVTN Core.

The **Ethics Working Group (EWG)** is the one working group open to all in the Network, although it is chaired by and predominantly composed of CAB members. The group is open to any who are interested. The EWG holds monthly calls to discuss and advise on policies of the HVTN that relate to ethical conduct of HIV vaccine trials. CAB members chairing this group are Gloria Malindi from Soweto, and Quincy Green from Philadelphia, U.S.A. CEU support comes from Carrie Schonwald; please contact Carrie at cschonwa@fhcrc.org if you are interested in joining the EWG.

The **Community Partners (CP)** is a collaboration of both community members and staff from the six DAIDS-funded global HIV networks. CP is administered out of the offices of HIV AIDS Network Coordination (HANC) in Seattle, Washington. The GCAB elected four HVTN community representatives to hold positions in this group: Hamilton Richardson (Baltimore); Edd Lee (New York); Gloria Malindi (Soweto); and Nancy Mae Anderson (Kingston). Carrie Schonwald is the CEU staff

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**Continued on page 8**

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**GCAB letter**

A letter from the Co-Chairs of the Global Community Advisory Board:

Dear CAB members,

At the HIV Vaccine Trials Network (HVTN), the Global Community Advisory Board (GCAB) is a collection of representatives from each Community Advisory Board at research sites in 27 cities across the globe. The GCAB holds monthly conference calls and semi-annual face-to-face meetings to engage the community representatives and to create direct communication throughout all of the research sites.

GCAB members are volunteers from diverse communities across the globe who represent the voices and concerns of vaccine study participants and their related communities. GCAB members volunteer their time and resources to gather community input at their local research site and share their advice with HVTN leadership in the interest of improving HIV vaccine study design, implementation and participation. The GCAB plays a crucial role in communicating information in both directions, from local research site communities to the HVTN leadership and also back from the HVTN to the stakeholders in local communities. The GCAB is dedicated to ensuring that safe, confidential, and beneficial clinical studies are practiced across all sites in the HVTN. This work is achieved most effectively through open collaboration and partnerships between the GCAB and scientists, government leaders, vaccine research staff, and other HIV prevention organizations. Our GCAB members share a desire to secure the best vaccine studies with the greatest benefits for our communities.

Sincerely,

Rick Church, New York
Phineas Malahlela, Soweto
Community Working Groups of the GCAB

Continued from page 7

member on this group. The CP are developing a guide for DAIDS on community engagement, including the challenges currently faced by each of the six networks.

Scientific Working Group The SWG is composed of CAB members and Community Education and Recruitment staff who serve on protocol teams, community representatives on Network committees, and any other CAB members who are interested in HIV vaccine science. The group works to increase scientific knowledge among community members and to identify cross-protocol issues that are of interest to or that impact communities. Issues that require advocacy from community members are brought to the Global CAB for further action. Topics for wider CAB training are identified, and the group helps to strategize regarding ways to provide such training. New members are always welcome. This group is chaired by Dave Crawford from the Chicago CAB, supported by Gail Broder from the CEU; send Gail an email at gbroder@hvtn.org if you are interested in joining this group.

Scientific Priorities. This subgroup of the SWG is charged with examining the HVTN scientific agenda and the priorities of the HIV vaccine field overall in order to raise community issues and perspectives. With the leadership of Scientific Priorities, topics are identified and brought to the SWG and/or GCAB for discussion, training, or other appropriate action. The group is composed of 5 experienced CAB members who have demonstrated their interest in and understanding of the science throughout their years of involvement: Dave Crawford (chair), Jim Thomas, Jeff Gustavson, Steve Muchnick, and Bill Snow. Gail Broder provides staff support. Participants who are part of the SWG and knowledgeable of the foundations of HIV vaccine science are welcome to talk to Gail about joining the group.

The Scientific Literacy subgroup of the SWG started in 2007 by polling CAB members on what scientific topics they think are most important for CAB members to have knowledge of. The survey was circulated at the Nov. 2007 and May 2008 HVTN meetings. The group convened in July 2008 to review the survey results and begin their work. They have agreed that there are at least two tiers of scientific literacy for CAB members: a core area that all CAB members should know about plus peripheral topics, that might be interesting and/or relevant to a smaller group of CAB members. The intent is to create a curriculum that CAB members could use to build their own knowledge and confidence in discussing HIV vaccine science. The group’s members are Steve Muchnick (chair), Gloria Malindi and Michele Bailey, with staff support provided by Gail Broder.

Conferences and announcements

The next HVTN Conference will take place this year on November 18-20, 2008 in Seattle, WA.

AIDS Vaccines 2008 will take place in Cape Town, South Africa on October 13-16, 2008.

Calendar of events

If you are interested in joining one of these calls, please email Genevieve Meyer (gmeyer@hvtn.org).

CAB Scientific Working Group conference call:
Held the second Friday of every month at 8 am PST
No call in November
Friday, December 5th, 8 a.m.PST/11 a.m. EST

Global Ethics Working Group call:
Held the fourth Thursday of every month at 8 am PST
No call in December
Thursday, January 22nd, 8 a.m. PST/10 a.m. EST

Global GCAB conference call:
Held the second Thursday of every month at 8 am PST
Thursday, November 13th, 8 a.m. PST/11 a.m. EST
Thursday, December 11th, 8 a.m. PST/11 a.m. EST

Global Community Education/Recruitment call:
Held the third Tuesday of every month at 9 am PST
Tuesday, January 20th, 9 a.m. PST/11 a.m. EST
Tuesday, March 17th, 9 a.m. PST/11 a.m. EST

Community Advisory Boards (CABs) are one way that the HVTN involves community in the research process. CABs consist of volunteers from diverse backgrounds who work with local research units and advise the site from a community perspective. Community input has been invaluable to the broad community education efforts, as well as to the development of this bulletin.

Send suggestions, questions, and article submissions to:
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