

The CAB Bulletin

July/August 2006 Volume 7 • Issue 2

HIV Vaccines and the Community



HIV Vaccine Awareness Day 2006

HIV vaccine trial units (HVTUs) spread the word about HIV vaccines in many ways. Pictured above, clockwise from the upper left, are a few of the events: 1 & 2. The Malawi site focused on expanding support for vaccine trial participants. They held a march with about 200 people and a rally of about 1,000, as pictured. 3. In Botswana, the site set up a table in a plaza and passed out information to the public. 4. Pictured here are the winners from the third annual HVAD comic book competition in Lima. The Lima site also conducted an outreach ‘intervention,’ in which 38 youth representatives and two drag queens handed out information on a main street, and they held a participant appreciation event. 5. Iquitos had a full schedule, with 10 days of press conferences, outreach and educational events, a health fair, and a rock concert that included presentations by youth groups (as pictured). 6. The New York site held a breakfast buffet for participants. Pictured are Denise Goodman, Community Educator; a participant; and Debbie Lucy, Bronx Site Coordinator. Seattle worked with its CEOPP partners on a series of events, including Gay Bingo night, an outreach extravaganza, and training for HIV educators (see the photo from Gay Bingo on page 5). ☘

In this issue

The HVTN has been busy this year—for details on just how busy, check out the Network overview on Page 6 in the Full Group update.

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Step Study Recruiter Workshops

by Gail Broder, HVTN Core, Domestic Projects Manager

The Step Study (HVTN 502/Merck 023) is the second collaborative trial between the HVTN and Merck. It is also the first “proof-of-concept” or Phase IIB trial conducted by the HVTN. Operationally, it is the first time the HVTN has asked sites to recruit people who are at high risk of becoming HIV-infected through their sexual behavior. Based on the local epidemic and experience with target populations, each site participating in the trial was assigned to recruit either men who have sex with men (MSM) or high risk women (HRW) such as commercial sex workers or women who trade sex to obtain drugs. The shift to recruitment work with Phase II populations was challenging for many sites, and initial recruitment numbers were below target. Core realized that sites could benefit from additional support and time to strategize together, so the Community Education Unit (CEU) held two recruitment workshops last winter, one each for MSM and HRW sites.

The first workshop was tailored to sites recruiting MSM and was held in Chicago in January. The second workshop was for sites recruiting HRW and was held in the Dominican Republic in March. The CEU staff worked closely with Community Educators in planning the agendas for both workshops. Unlike past CER workshops, these workshops needed to involve the outreach workers who were actually going out in the field, many of whom are part-time employees. These staff members don't typically participate on conference calls or email lists, since they are more likely to work in a bar or on the street than behind a desk. Recruiters also tend to have high energy and dynamic “people skills,” so the workshops were planned to be highly interactive and

experiential. Another consideration was planning the workshop so that interpretation and translation in Spanish and Portuguese was integrated enough to allow equal participation from all sites.

The agenda of the Chicago workshop covered topics that were specific to the needs of the outreach workers, including developing the interpersonal skills needed to approach strangers and start a conversation; using data collection tools; and polishing answers to questions about the Step Study and research in general.

A highlight of the workshop was the opportunity to go out into the street and into nightclubs to practice what had been learned. A Human Scavenger Hunt sent teams out into the streets and clubs of Boystown in Chicago. Each team had to find people who could answer a question or who matched a description from a list of 22 characteristics. These characteristics included someone who could define “vaccine,” someone who knew where to get tested for HIV, someone who had been vaccinated against anything in the last three months, and someone who had traveled to a country where the HVTN has a site. No one person could respond to more than one characteristic, so each team needed to find at least 22 people. Every team finished the hunt with all 22 characteristics found.

Another highlight was a session on how to use the Internet. Jake Tinsley, Darren LeBlanc, and Jim Maynard demonstrated the Internet techniques they have used to recruit participants in Boston. These techniques included placing banner ads on “hook-up” websites like www.manhunt.net and sharing information on chat rooms and personal webpages on sites like

www.myspace.com. They also modeled attire they might wear when recruiting, including t-shirts with specific messages, leather accoutrements, and high-style drag outfits.

At the workshop for sites recruiting women engaged in high-risk behavior held in the Dominican Republic, a number of staff from Merck's Step Study sites joined HVTN staff members. Agenda highlights included discussing attractions and barriers to research participation among women at high risk, partnering with community-based organizations, and bringing interested volunteers into the clinic.

This group also went out into the field. The Santo Domingo site is made up of a clinical site and two partner organizations that represent and comprise former and current sex workers. The groups, both staff and volunteers, were excellent hosts. They arranged to take workshop attendees out in vans to visit recruitment venues, including bars and street hangouts. Attendees were then able to compare and contrast the environment and challenges of work in Santo Domingo to the situation at their own sites, which led to good conversation.

Additionally, participants attended a session in which they communicated with someone who spoke a different language or languages. The goal was to convey autobiographical information without sharing a common language. This exercise served in part as an introduction to the challenges inherent to incorporating translation and interpretation, as English, French, Portuguese and Spanish speakers all worked together throughout the workshop. Also, the language session helped attendees begin a dialogue about working

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New Informed Consent Template

By Renee Holt, Regulatory and Clinical Affairs Manager

Recently, an Informed Consent Task Force was convened to take on the challenge of trying to shorten, improve, and update the Informed Consent. At 14 pages, you still may not be able to call the Informed Consent a short document, but it has been simplified and is hopefully easier to read and use.

The major changes were as follows: moving from a question-and-answer format to numbering a “topic sentence” for each section (so that by skimming through the numbered topic sentences, one reads an outline of the whole document); taking out the list of acceptable birth control methods and the table of study procedures (sites can use those sections or not based on what they feel is best for their study participants); changing the language “False positive antibody test” to “Positive HIV antibody test caused by the vaccine;” and simplifying the standard consent language.

It is always difficult to balance attempts to keep the document short and understandable with the need to be transparent about all aspects of the trial and to conform with regulations. We therefore appreciate the time and effort everyone put into the Shortened Informed Consent face-to-face meeting. Pedro Goicochea represented the Community Educators, and we especially thank the CAB representatives, Father Patrick Cunningham from Jamaica and Linda Sawin from Seattle, who volunteered to take on the document line-by-line. The new Informed Consent was approved in time to be used in the most recent protocol, HVTN 067. If you would like to see a copy of the new version, please contact Lisa Bull at lbull@hvtvn.org. ☘



Above, Hugo Sanchez (Lima), William Torres (San Juan), Blue Williams (San Francisco), and Tyler Juel (Seattle) worked to keep the blood flowing as they cruised the cold streets of Chicago looking for warm bodies who could answer the questions in their scavenger hunt. Below, Sean Lawrence of New York and Elmerlene Robertson, Regina Harden, and Yolanda Newman of Chicago all relax on the beach in Santo Domingo after their workshop, happy to be somewhere warmer than Chicago!

Workshops continued from page 2

with people whose languages and experiences differ from their own.

Ultimately, the workshops were a great success. Trainees commented on the value of realizing that they were part of a larger network, and that they had colleagues doing similar work with whom they could share ideas and advice. Many people commented that they enjoyed having the chance to learn from each other during the interactive sessions. Attendees learned that as unique as each site and community may be, there are also many commonalities among both recruiters their target populations. Being able to share ideas in a face-to-face environment across languages was a valuable experience that was really appreciated by all! ☘



Two of our fine Community Education staff are leaving in the month of August. Jen Sarche from San Francisco is moving on to do contract work and other yet-to-be-identified endeavors. Darren LeBlanc, Community Education and Outreach Coordinator from the Fenway Community Health clinic in Boston, is returning to school to get his BSN. A big thank you to both of you for your very hard work over the years, and good luck in your new experiences!

A letter from Steve Wakefield

Words cannot express my gratitude to each member of the HVTN family for the support that I have received over the past six years. Together we have created a community engagement program that really helps this network. Community members, both volunteers and staff, are involved in every aspect of HIV vaccine research within the HVTN. Community leadership on ethics, public and participant education and the rights and responsibilities of being in a study have helped us conduct very successful trials with rapid enrollment and appropriate retention.

This letter is intended to help you understand why the HVTN is looking for a new Director for the Community Education Unit and why I would even consider moving on from the leadership position that I've occupied. While we have done our work, the HIV epidemic continues to rage in the United States with new infection rates just as high today as they were when I joined the HVTN in February of 2000. The people most impacted in the United States are African Americans and Hispanics/Latinos.

So, as I asked both myself and HVTN leadership, how can an HIV research organization, committed to finding a vaccine that works for all people, succeed? We need to focus our attention on those most affected; the HVTN recognizes it is essential to include those who would most benefit from a vaccine in clinical trials. Successful trials must include sufficient numbers of people to detect any differences in effectiveness by race, gender, or ethnicity.

African American (AA) and Hispanic/Latino (H/L) women are, respectively, 25 times and 6 times more likely to become HIV infected than their white counterparts. Young men of color who have sex with men continue to have disproportionate rates of new infections in numbers that continue to confound researchers. Historic barriers to access to care, as well as prevalence of other health disparities, could limit acceptability

of an effective HIV vaccine.

Since February 2003, we have lived with the lesson learned from the VaxGen study: we need enough data from sufficiently diverse participants to make clear conclusions about efficacy in all subgroups. Some may remember there was not enough diversity in VaxGen's population to detect differences by subgroups.



Steve Wakefield, former Associate Director of Community Education; now current Legacy Project Director.

I have moved from my former HVTN position into a newly created position, the Legacy Project Director. The HVTN Legacy Project has been created to increase enrollment in clinical trials of those from populations most affected by HIV disease in the United States today: women of color and young men of color who have sex with men. We also hope to use the project to provide insight into the impact of historic health disparities and co-morbidities on HIV risk.

The project will be guided by a working group currently being developed. This group will comprise CAB members, community educators and recruiters, clinical staff, and investigators. We will also invite people from NIH's communications and minority outreach efforts to join us so there is better coordination of efforts. An external advisory group has already met, and we hope to engage them in helping HIV

vaccines to have greater visibility within some of the target populations.

As an initial step, a request for proposals will be sent to the US HVTUs this summer seeking creative efforts in three pilot project areas:

Area I

Activities that strengthen community partnerships through relationships with community-based organizations and AIDS service organizations for sustained AA and H/L relationships.

Area II

Activities that increase staff diversity and capacity for culturally appropriate, client-centered engagement at US HVTN research sites.

Area III

Activities that increase visibility of HVTN trials with media and key community opinion leaders.

We sincerely hope to find evidence-based ideas that will further extend the good work sites have done to include minority groups in trials. Future programs developed under the Legacy Project may include a peer education program and a variety of outreach programs for local faith and media groups.

The measures being considered for the Legacy Project provide a blueprint for building bridges of trust to overcome the disparities that threaten the effectiveness of the search for a vaccine that will end the AIDS pandemic. Building durable partnerships may require a substantial commitment of resources—potentially at a significantly greater level of investment than traditional university-based clinical trials require. I know we can make a difference and hope you will join me in creating a new legacy. You have supported me in the past and I need your help with this new endeavor as well.

Sincerely,

Steve Wakefield

The importance of participant diversity in HIV clinical trials

by Gail Broder, HVTN Core, Domestic Projects Manager

Of all the challenges facing HIV researchers, one of the most significant is how to include persons of all genders and all racial and ethnic backgrounds in clinical trials. This challenge has emerged in many areas of medical research, but it is more pronounced in HIV research, in which women and people of color have historically been under-represented.

There are many barriers to ensuring diversity in clinical trials. These barriers include cultural and language issues, social stigma around HIV and the behaviors by which it is transmitted, and a history of ethical violations in research. Addressing these concerns does not happen overnight, but rather one person at a time, with lots of hard work. We also know that we must begin the work of addressing people's concerns early, before research in a particular location even begins. People need time to listen to the research messages, meet the researchers and other staff members, ask questions, and make decisions about whether participating in a trial is something they want to do.

Community education efforts strive to move communities along a continuum, beginning with raising awareness and gradually moving ahead to knowledge, a willingness to participate, and, eventually, support for the research agenda. We seek to create communities in which people understand the importance of the research agenda and are supportive of those who choose to volunteer. Even if some people decide that trial participation is not appropriate for them personally, it is important to create an environment that will be supportive for all, whether they choose to volunteer or not.

We often hear the question, "Why do I keep hearing about the need for women and minorities to participate?" There are some diseases where we already know that ethnicity matters. For example, African Americans are more susceptible to Sickle Cell Anemia, and Jewish people of Eastern European descent are more susceptible to Tay Sachs disease. We don't know yet if race or ethnicity makes a difference for HIV, so we need to involve people of many backgrounds

in our research to make sure that the products will be safe and will work in diverse populations. This is true for all HIV research, whether the study product is a preventive or therapeutic vaccine, a vaginal or rectal microbicide, or an anti-HIV drug. Finally, diversity issues are important in behavioral intervention studies to catch differences that are due to cultural norms.

We also are not sure whether gender matters. In the first Phase III trial (7,400 participants) of a preventive vaccine against herpes simplex virus type two, the type that typically affects the genitals, results appeared to indicate that the vaccine might be effective for women but not for men. However, there were not enough women enrolled in the trial to make this conclusion with certainty. As a result, researchers are now conducting another Phase III trial with 7,550 women to assess the vaccine's effectiveness in women. Think of the time and money that could have been saved if only the first trial had enrolled enough women!

As the herpes vaccine trial demonstrates, we need to include women in HIV research so that scientists can examine how their immune responses may differ from those of men. Examples of these differences include the hormonal effects of estrogen and the different dosages that women might require (since their body mass is typically lower than men's). Similar questions must also be addressed for transgender individuals. Including people of many backgrounds underscores why we conduct research in cities around the globe. Working globally helps researchers take into account how nutrition, living conditions, and other lifestyle factors impact the immune system and how these factors might relate to the effectiveness of a study product.

At the HIV Vaccine Trials Network, we believe that by working with diverse communities, earning their trust and their respect, we can create relationships that will ultimately benefit the communities themselves. Community Advisory Board members can play an important role in shaping these relationships. These

may include:

- Advising research staff members on appropriate strategies for outreach and recruiting in various communities;
- Reviewing the cultural competence of proposed advertising/study materials;
- Helping researchers identify gatekeepers and other key members of the community; and
- Making introductions: in some cases, the research staff members may not be the appropriate people to meet with a particular group, and CAB members can help to open doors and make connections that will facilitate a more productive interaction.

We must work to ensure that the history of under-representation of women and people of color in HIV research is not carried into the future. Instead, we want to create a new legacy of equal representation, where all are seated at the table. Advancing the HIV research agenda is something that scientists can't do alone, and it is the partnerships created now that will enable the delivery of successful interventions, both preventive and therapeutic, to all populations when they become available.

This article appeared on the website AIDS Research Community Handbook at www.researchadvocates.org/article016.htm. ☞



The Seattle outreach team poses for a photo at Gay Bingo, a monthly Seattle event. For HVAD, the evening's theme was HIV vaccines, and the games—including several designed so that winners made a 'V' on their cards—were interspersed with information sessions.

Update on Network progress from the Full Group Meeting

This past May, the final HVTN Full Group Meeting was held. Don't be alarmed—there will still be an annual fall and spring meeting for the HVTN. In the future, however, these meetings will be called HVTN Conferences. As the Network has grown, the meetings have evolved as well, and this name better represents the intent and activity of these meetings in their current form.

In May, however, it was still the HVTN Full Group Meeting, and the

In Memory: Octavio Valente, Jr.

Octavio Valente, Jr., a CAB member from Rio de Janeiro who served many roles in the Network, passed away on March 21, 2006. Very involved in the HVTN, Octavio also served as a leader in HIV/AIDS community advocacy work around the world. Most recently, he served as President of Pela Vidda, a Brazilian AIDS advocacy organization. Octavio believed strongly in responding to the epidemic comprehensively and working to unite treatment, prevention, and vaccine research efforts.



The HVTN remembers Octavio as a beloved and respected long-time member of its community. In his honor, the Octavio Valente, Jr., Volunteer Service Award has been instituted (see page 7 for more on this award). We at the HVTN will miss his kind smile, his thoughtful contributions, and his spirited energy.

Doing the numbers: Facts from the HVTN in 2005

Participants enrolled: 1,139

Participant visits : 6,118

Participant diversity: 31% black, 14% Hispanic, 46% women

Protocol development takes about six months.

Protocol implementation takes about nine months.

agenda was certainly full. The focus of the plenary sessions was on the Network itself, and speakers presented past Network accomplishments and plans for moving forward. On the rest of the page you will find highlights from the meeting, but keep in mind that you can find out more by going to the HVTN website and looking for Full Group Meetings/Presentations. This information is on the private side of the website, so you will need the password from your site if you don't already have it. Your Community Educator can help you locate the presentations if you have any trouble, or can print them out for you.

Where we've been

We are meeting most of our milestones, and we are starting to answer some interesting questions. HVTN Director Larry Corey called the work we are doing right now the most important work we have undertaken so far. We are developing more streamlined ways of working, and we are building a strong knowledge base both operationally and scientifically.

As of August 1, the Step Study has enrolled almost 2,000 people, including over 1,400 that the HVTN has enrolled. The study vaccine has been generally well tolerated, and the HIV infection rate so far is consistent with projections. Our site staff continue to work hard to meet enrollment goals by the end of the year—and they deserve a hand for all their hard work! Site staff are also working hard on our second Phase II trial, HVTN 204. This trial is proceeding smoothly, with enrollment finished

in the US and underway in Africa.

The Non-Human Primate Symposium in April allowed scientists to discuss the ways in which animal models can be effectively used to establish immunogenicity data. The decision was made that current systems of research do not maximize the information that is obtained. The symposium allowed scientists to generate new ideas about how to proceed, including plans for establishing a greater match between human and animal models and discussion of how to best analyze results to generate maximum applicable knowledge.

Where we're going

We are moving towards initiation of HVTN 503, the first efficacy trial of an HIV vaccine to be conducted in Africa (the product is the same as in the Step Study). The trial will be conducted in South Africa. Its primary focus will be to evaluate the safety profile of the product and to provide information about the potential efficacy of a product derived from clade B HIV administered to a population in which clade C is most common. This information will help clarify the importance of clade variation in HIV vaccine design.

Strong progress has been made toward initiating adolescent HIV vaccine trials. Working in collaboration with the Adolescent Trials Network (ATN); the Infant, Maternal, Pediatric and Adolescent AIDS Clinical Trials Network (IMPAACT); and our HVTN colleagues in South Africa, the HVTN is in the process of articulating and establishing the groundwork needed to proceed with adolescent trials.

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Full Group continued from page 6

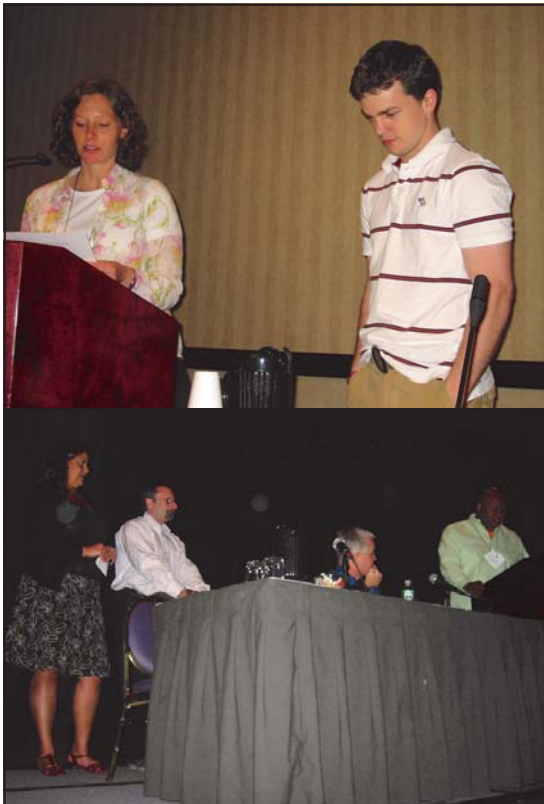
The Phase I trials process at the HVTN is currently being rethought and improved. Scientists are working on planning new trials and are deciding how to best compare and combine products. At the same time, there is work to establish better ‘filters’ to evaluate which products should proceed. Finally, the standard Phase I trial schema is being altered to allow for clearly delineated Phase IA and Phase IB groups. Small, easily handled IA trials allow initial data to be collected so that investigators can decide what should progress to the larger IB trials, in which more immunogenicity can be established. This plan calls for streamlining and expediting the process of finalizing trial data.

In order to utilize each part of the trials process in the most expeditious way possible, the Network is also trying to develop a more diverse group of laboratory assays that will better predict the efficacy of a study vaccine product.

The HVTN is turning to its researchers to brainstorm the best possible ways to move the Network forward. The HVTN seems to be in an adolescent stage—it has reached a level of maturity, but it is still changing, learning, and growing quickly. ❧



The Full Group Meeting, clockwise from upper left: Lucky Barnabas plays the drum during a CER Workshop session on presenting HIV vaccine information creatively. Dr. Mickey Lally of Providence uses a fishbowl, fluorescent plastic fish, and paper umbrellas to describe vaccines and adjuvants. Chicago CAB member Yaa Simpson with GCAB co-chair Lenny Jackson (Baltimore). Adolescent CAB members from South Africa who were invited as plenary session speakers also brought beadwork from their CABs to sell as a fundraiser for their CAB activities; this beautiful necklace was one of several pieces sold.



Three appreciation awards

Introducing the Octavio Valente, Jr., Volunteer Service Award

Every year, the Network Evaluation Subcommittee has recognized two HVTNers for outstanding work in the Network. This year, a third recognition was added: the Octavio Valente Jr. Volunteer Service Award is to be given annually to a CAB member who demonstrates a level of commitment and conscientious care that is similar to the work of our friend, Rio de Janeiro CAB member Octavio Valente, Jr., who passed away earlier this year.

This year, the inaugural Octavio Award went to Robert Reinhard. Dedicated, thoughtful, and generous with his knowledge, Robert Reinhard works tirelessly for trial participants and the people and communities in need of a vaccine. We are happy to honor both men this year. Presentation of the award is pictured at bottom left.

The Network Service Award was given to Dr. Jonathan Fuchs from San Francisco for his leadership and care in developing training programs for the HVTN. Josh Barnes, CER from Nashville, was chosen for the Network Citizenship Award for his energetic and committed leadership as co-chair of the Community Educators and Recruiters. The photo above left shows Josh receiving his award from Katy Turner Brooks, Chief of Network Evaluation. ❧

Updates and news

Grant renewal news

As many of you know, the Division of AIDS (DAIDS) of the US National Institutes of Health (NIH) is restructuring HIV/AIDS clinical trials networks to streamline the search for safe and effective treatments and prevention strategies, including HIV vaccines. Their hope is to produce a more integrated, collaborative, and flexible structure that emphasizes studies of highest priority.

The new networks were announced in late June. The HVTN will continue to operate with few changes at the Core level. Sites will learn later this year about their levels of funding and which networks they will join. Current trials will all be completed without interruption. The whole process should be invisible to participants but there may be a need for CABs and

community staff to explore new ways of working across prevention and treatment studies. The CAB Bulletin will provide updates as they become available.

Gates Foundation grants

Recently, media across the world announced grants made by the Gates Foundation to support HIV vaccine science. Together, the grants create a new collaboration that will support HIV vaccine research. We are pleased to note that two of the 16 awards were given to HVTN researchers.

Dr. Julie McElrath, head of the HVTN Laboratory program, received a grant to lead a group of researchers in investigating adjuvants. Adjuvants are substances that can help a vaccine product work more efficiently. Several HVTN trials currently use various adjuvants in addition to the primary

vaccine study product.

Dr. Steve Self, who heads SCHARP (the Statistical Center for HIV/AIDS Research and Prevention), will lead a team that will coordinate statistical analysis of work done by the 168 scientists that make up the Gates Foundation's new collaboration of awardees. This effort will help ensure that data from many sources are comparable and cumulative.

AVAC HIV Vaccines Clearinghouse

The AIDS Vaccine Advocacy Coalition (AVAC) recently announced the initiation of the AIDS Vaccine Clearinghouse, a library of information about HIV vaccines. Please check out this valuable resource; AVAC has provided a wealth of information in a well-organized and useful format. Go to www.aidsvaccineclearinghouse.org. ☘

Conferences and announcements

The next HVTN Conference will be held October 18-20, 2006, in Seattle, Washington. This fall Conference is expected to be smaller in scale and scope than previous fall meetings. Session topics, intended audiences, and breakout meetings held before and after the conference will be announced by early fall.

AIDS 2006 is a conference for everyone involved in combating the HIV/AIDS epidemic: researchers, healthcare workers, civil society, governments, UN organizations, activists, donors, industry, the media, and people living with HIV/AIDS. This year's theme is "Time to Deliver," and the 2006 location is Toronto.

AIDS Vaccines 2006 is a meeting for scientists from all fields with an interest in the development of vaccines against HIV. This year, the meeting will be held in Amsterdam beginning August 29. The website is www.aidsvaccine06.org. ☘



Calendar of events



CAB Protocol Working Group conference call:

Friday, August 4, 8 a.m. PST/11 a.m. EST

Friday, September 1, 8 a.m. PST/11 a.m. EST

Global GCAB conference call:

Thursday, August 10, 8 a.m. PST/11 a.m. EST

Thursday, September 14, 8 a.m. PST/11 a.m. EST

Global Ethics Working Group call:

Thursday, August 24, 9 a.m. PST/12 p.m. EST

Thursday, September 28, 9 a.m. PST/12 p.m. EST

Community Education/Recruitment coordination call:

Tuesday, August 15, 9 a.m. PST/12 p.m. EST

Tuesday, September 26, 9 a.m. PST/12 p.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 the development of this bulletin.

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