Do I belong? Confessions of a First Timer at the HVTN Conference

By Laurie Kavanagh

The November 2008 Full Group Meeting was my first exposure to the diverse world of the HVTN. As a CAB member and volunteer at the Seattle site for only a few months, my comprehension of medical terminology and HVTN processes was a thin foundation. I knew that the information presented at the meeting would either crack or strengthen this base. There were times when my base was fractured by voluminous technical verbiage, fissures which were later filled in when I had time reflect, ask questions of my fellow conference attendees, and participate in the rapporteur sessions. I found these moments critical to my experience because they reassured me of my place at the conference. They confirmed that I didn’t have to understand every last bit of information in order to play a role in sessions and in the HVTN itself.

I was surprised by just how much I learned during the presentations, especially those that were technically frontloaded. Outside the meetings I found myself bursting with knowledge and confidently using scientific terms in discussions with friends and coworkers. I think they learned more about circumcision and HIV transmission than they thought possible! Excited to learn even more so that I could share with others, I eagerly returned each morning to see what else I could absorb. Continued on page 7

What’s Happening with HVTN 404 & HVTN 802?

By Richard Newman, Clinical Trial Manager, HVTN Core

To reduce the risk of HIV infection, each HIV vaccine trial participant is counseled extensively on how to avoid getting infected with HIV. Regardless, a small number of trial participants get infected every year.

In the July/August 2007 CAB Bulletin, San Francisco CAB member Jeff Gustavson provided an overview of two studies which were being developed to follow people who get infected with HIV after enrolling in an HIV vaccine trial. Now that these studies have been implemented and participants are being enrolled, we are providing this update.

For a further background and overview of these trials please see the July/August 2007 CAB bulletin available online at http://www.hvtn.org/community/bulletin.html

HVTN 404

HVTN 404 is designed to enroll people who participated in early phase HIV vaccine trials, such as phase 1 and 2a trials, and vaccine preparedness studies, such as HVTN 906 or 907, who then become infected with HIV.

Early phase trials are limited to people who are unlikely to get infected with HIV. Therefore this study is not expected to enroll enough participants to allow for a statistically significant analysis. However, because HIV infections do occur among these “low-risk” volunteers, the trial is expected to enroll enough participants to compile a history of observation which will allow researchers to plan for future studies. Continued on page 7

Congratulations!

On World Aids Day 2008, Cape Town CAB member Nombeko Mpongo was honored with the Community Involvement award from the Africa Centre for HIV/AIDS at Stellenbosch University. Ms. Mpongo was very proud to receive this award as it strengthened her commitment to her work in HIV/AIDS prevention, care and treatment. In spite of the many political constraints she often confronts, she feels that the more you are able to connect with people, the more you gain their trust and can achieve amazing things.

We at the HVTN are very proud of her achievements as well!
Community Partners in South Africa, Learning and Sharing Across Cultures
By Hamilton Richardson, Baltimore CAB member and Community Partner Representative for the HVTN

Hamilton was invited to South Africa to meet with the CABs from the 6 DAIDS-funded networks and attend the AIDS Vaccine 2008 conference, October 13-16, 2008 in Cape Town, South Africa.

When I first arrived in Cape Town I was struck by the beauty of this modern city and surprised by how much the inner harbor reminded me of San Francisco, California’s seaside. I was also very taken by the diversity that exists between the city and the surrounding townships. Throughout the trip I was overwhelmed by the universal kindness I felt from the people I interacted with.

My first visit was to the Desmond Tutu Foundation in Cape Town, whose CAB had been meeting for about a year. I listened as they planned their World AIDS day event, then we discussed ways they might be able to network and share lessons learned from other local network CABs.

Over the next several days I attended the AIDS Vaccine 2008 Conference 2008. For the first time, the South African Minister of the Presidency, Dr. Mantombazana Tshabalala-Msimang, acknowledged publicly that AIDS comes from HIV, which the previous administration was not willing to do. Everyone in the audience applauded loudly, and you could feel the excitement in the air. I imagined the relief of HIV scientists and researchers whose work in the country will now be that much better supported. It was also reassuring to hear Dr. Fauci, the director of NIAID, reaffirm his agency’s commitment to vaccine research. However, I was most excited that many of the workshops and plenary sessions emphasized the importance of community involvement and engagement at all stages of the vaccine research process.

During the second day of the conference all of the attendees were invited to a local winery. We got to know each other much better after an evening of eating, dancing and face painting. Before leaving Cape Town, I also had the pleasure of visiting with the HVTN CAB at the Emavundleni Clinic in New Crossroads where we talked about future HIV vaccine trials.

The next stop in my trip was a visit to the IMPAACT (International Maternal Pediatric Adolescent AIDS Clinical Trials) CAB at the University of Stellenbosch. After the meeting I was delighted to watch a lively song and dance performance put on by the very talented CAB members. Later I joined these CAB members on a visit to some of the townships around Cape Town. Since South Africa has free public health care, I was excited to visit one of the many free health clinics on this outing.

When I arrived in Durban, Angela Macharia from IMPAACT and I visited Community Partners member Neetha Moran’s HIV Prevention Research Unit. What a great meeting we had with their local CAB! I could tell it was a very passionate group by all of the questions they had about Community Partners. Next we met with the HVTN CAPRISA CAB which included about 40 members who represent the HVTN and other research networks.

Angela and I then traveled to Johannesburg to meet with the IMPAACT CAB located at the Chris Hani Baragwaneth Hospital in Soweto, the largest in Africa. This hospital has a rich history that goes back to apartheid. We talked about the need to have the same standard for determining at what virus level a volunteer would start anti-retroviral therapy (ART) across all trial sites internationally, regardless of a particular country’s own standard. Since our meeting, IMPAACT has changed the language in the one of their protocols (Promise) that now reflects the community’s concerns for developing a universal standard of care.

(Left) Conference attendees enjoy an evening of local food and dance at a nearby winery.
The Nashville CAB lights the way for HIV Prevention
Prepared by Community Educator Kat Davis in collaboration with site CAB members

The Community Advisory Board at the Nashville, Tennessee site is a small group of people with great diversity and great commitment to HIV Vaccine Trials. We currently have about 12 regular attendees that come from all walks of life. Our members have said that being on the CAB gives them a connection and appreciation for people that are different from them because everyone is working together for a common goal.

Our NIAID-funded Local Partnership Project (LPP) collaborator is Planned Parenthood of Middle and East Tennessee. One of the CAB’s favorite events of 2008 was a Health Fair and Fish Fry for HIV Vaccine Awareness Day in May. Planned Parenthood received funding from the Academy for Educational Development (AED) to hold the event. They invited health agencies from around the Nashville area to display and give away information about their organizations. A local radio station broadcast live from the event. During their broadcast, they encouraged listeners to come get tested for HIV.

Upon arriving at the event, each visitor was given a punch card. For every table visited, they would receive one punch on their card. Once they visited the Vaccine Unit’s table, plus four others, they could receive one of the backpacks that HVTN Core had provided. The event was a great success. Many families from the area came that day. This event was enjoyable because it allowed our relationship with our Local Partner to develop and allowed the CAB to see how and why the organizations are connected. It also took place in a great location that allowed us to reach out to community members that are rarely reached by conventional recruitment methods.

Right now we have identified retention of new CAB members as an area for improvement. Many of our CAB members have been involved for 5 years or more. When new members come to meetings, it can be difficult to train them and make them feel comfortable. Sometimes they are overwhelmed with information or administrative items and they don’t feel as though their input matters. In 2008, our CER created a CAB packet to give to new members at their first meeting.

This packet includes information about our CAB and the members, a roster, a calendar, an overview of the HVTN, the role of communities in HIV prevention, the protocol review process and some sample outreach materials. It helps to familiarize them with the CAB, the vaccine trials, and what our purpose and mission is. This helps get new members plugged in, but we will continue working on improving retention in 2009.

We have come up with several ways to try to improve our new member retention for 2009. The first goal is to get the Principal Investigator (PI) and Co-Investigator more actively involved in the CAB. Currently the meetings are run by the CER and an elected CAB Chair. Our Co-Investigator, Dr. Greg Wilson, attended our January CAB meeting to discuss an educational series he wants to begin for new members. In February, he will be giving the CAB a presentation that will be used in the future for an orientation for new members. This could be held quarterly and would allow people who are interested to get information before they attend a meeting. This would give them a greater understanding when they attend a meeting for the first time. Dr. Wilson has offered to give educational presentations to the CAB about topics they choose. This would give us some opportunities to do joint CAB meetings with the two other CABs in town (which represent the AIDS Clinical Trials Group and the Comprehensive Care Center, an AIDS care provider) and encourage camaraderie between them.

Our second goal is to create a CAB brochure. This would have some basic information about the CAB and how to get involved. It would be a great tool to use at outreach events. The CAB is a good way for people to volunteer, even if they are not eligible for a trial. It can also be given to people at their pre-screening education sessions before they join a trial. Since those individuals are already interested in getting involved with HIV/AIDS, having more information about the CAB might encourage involvement in both the trials and the CAB.

Over the last couple of years our site has experienced multiple staff changes, as well as changes in the HVTN and the HIV vaccine trial environment. Still, our CAB has remained wonderfully dedicated through these times. We really appreciate everything that they contribute to our site and the CERs truly could not do this job without them! 🎉

Kat Davis (left), Nashville Educator with Ashley McCarty and CAB member Mark Hubbard at their booth during HIV Vaccine Awareness Day
WORLD AIDS DAY 2008

KINGSTON, JAMAICA

The Epidemiology Research and Training Unit/ Clinical Research Site (CRS) participated in the National World AIDS Day event held on December 1, 2008. The event was held on the lawn of the historic Devon House, and organized by the Ministry Of Health through the National HIV/STI Control Programme. The theme was “Youth Take the Lead” and took the form of an expo that featured HIV prevention work being carried out by several government and non-government organizations.

The site had a booth display with educational materials and incentives such as the HVTN drawstring bags, cups, t-shirts, and pens. Visitors to the booth were given the opportunity to win the incentives by answering simple questions about HIV vaccines after they read the educational materials. The GHESKIO Haiti site video was shown to help give a visual representation of what the vaccine trials are about. Approximately 250 persons visited the booth, run by CRS staff and CAB members. The response of the public to the information about HIV vaccine trials was tremendous. Visitors wanted to know all they could about HIV vaccines and what the trial process is like. Some even indicated they were willing to participate in an HIV vaccine trial.

SOWETO, SOUTH AFRICA

Churches taking part in the fight against HIV/AIDS

The slow response of churches during the early years of the AIDS pandemic in South Africa has since changed. Churches are now becoming more aware and proactively involved in leading their entire communities to combat AIDS. The Churches also believe that prevention of HIV infection is the key to controlling it in the long term. On December 11, 2008 the Anglican Church Dioceses based in Orlando, a township of Soweto, successfully organized an HIV/AIDS awareness campaign that focused on: HIV/AIDS education, HIV/AIDS vaccines education, voluntary counseling & testing (VCT), and referrals.

The campaign was led by Mrs. Gloria Malindi (left) coordinator of HIV/AIDS Ministry and the Soweto site Chairperson of the Community Advisory Board (CAB). Approximately 60 people from different churches and general members of the community attended the event.

After a presentation on HIV/AIDS and vaccine education, people were encouraged to test for HIV. Over two dozen people took part in the VCT provided by New Start, a mobile caravan. In general, people responded positively to the vaccine information although there were some concerns around the safety of vaccines and HIV false positive results. Mrs. Malindi briefly addressed this topic then referred guests to the site clinic for more information.

The campaign was a success because of the support from the Anglican Church, Soweto CAB members and local community-based organizations. It is imperative that local networking and collaboration happen with faith-based organizations to strengthen the impact of the local response to AIDS.
WORLD AIDS DAY 2008

PORT AU PRINCE, HAITI

For the 2008 World’s AIDS Day, the GHESKIO site in Haiti led several community outreach events.

On Saturday, November 29, 2008 Dr. Mireille Peck, Community Educator from the GHESKIO Center, visited the Delmas Protestant Church and gave a presentation on AIDS awareness and how to get engaged in the struggle against this disease. Over 75 community members attended and asked some very thoughtful questions including: “Is AIDS a natural disease or a punishment of God?” They also asked whether vaccine trials only took place in developing countries and what the specific interest was in having Haiti participate in vaccine research.

The following Monday, December 1, Dr. Peck joined students at the local Excelsior College for an informational session on vaccine trials. This time there were 49 students in attendance. They, too, had great questions for Dr. Peck, such as whether an HIV positive result caused by the vaccine meant a participant really had HIV and whether the vaccine would increase someone’s risk of getting infected with HIV.

SÃO PAULO, BRAZIL

To celebrate World AIDS Day, the São Paulo site arranged a movie night for its trial participants. This event, the last of 2008 for the site, took place in a nearby cinema located in the Lasar Segall Museum. The activity, called “Cine Vacinas,” (Vaccine Cinema) was free for the participants. The film of the night was “The Constant Gardener” directed by Fernando Meirelles, one of the most internationally recognized Brazilian movie makers of today. This important film calls attention to an unethically conducted research trial of an experimental tuberculosis drug. After the movie, the São Paulo Principal Investigator, Dr. Artur Kalichman and Community Education Coordinator, Gabriela Calazans, led a discussion. They spoke about the importance of ethical standards for human participation in biomedical research and how these standards contribute to the well-being of the community and the advancement of health research. All 16 participants who attended the showing received a snack kit and an HVTN backpack as thank you gifts to recognize their efforts in fighting the AIDS epidemic. Each backpack contained a copy of the Portuguese version of IAVI’s immunological system poster. This event was possible thanks to the partnership between the site (and São Paulo Center of Reference and Training in STD/AIDS where the São Paulo trial site is located) and the Lasar Segall Museum.
The HVTN Legacy Project works to increase clinical trial enrollment among the populations most impacted by HIV in the United States, such as Latinos and African Americans, especially women and young men who have sex with men (MSM). The project also hopes to provide insight in order to address the historic health disparities in these populations. Legacy does this by providing funding, support, and data analysis for site-specific outreach projects with these communities. Lessons learned in the following two projects will inform work that is done by other US sites.

Legacy Project at the University of Alabama, Birmingham

Despite a long history of fighting for racial justice, Alabama will be forever linked in America’s collective memory to the Tuskegee Syphilis Study. Just a few miles from Tuskegee is the University of Alabama (UAB) vaccine trial site. Birmingham is a city of close-knit communities where people know each other well, which can be a great support to some, but also means that stigma against those known to be infected with HIV can linger. African American women are among those at highest risk for HIV infection, a population traditionally underrepresented in clinical trials. The Legacy Project works with the site to help change this by working to identify a population of high risk women who could be successfully recruited to join HIV vaccine trials.

The goal of the project at UAB is to strengthen partnerships between community-based street outreach programs, agencies that provide healthcare for the homeless, and the Alabama Vaccine Research Clinic (AVRC) to see if these partnerships can be used to recruit participants. Another goal is to learn from Community Outreach Workers and project participants what is needed to maintain long term retention of high risk women. These are women who live in communities ravaged by a number of economic and social problems that may make future HIV vaccine trial participation difficult.

Led by Drs. Joseph Schumacher and Paul Goepfert, the project will 1) estimate HIV prevalence (people living with HIV), 2) assess 12-month retention rates, and 3) estimate the HIV rate of new HIV infections (incidence). Women identified through these partner organizations will be recruited and followed for one year. Several recruitment methods being used in this project include 1) the use of mobile outreach vans that go into identified neighborhoods, 2) providing HIV rapid testing on the van, and 3) working with the women to refer others. These methods will be evaluated to see if they reduce the barriers to participation that have been observed with traditional clinic-based recruitment used in the past.

Legacy Project at Columbia University, New York

New York is well known for its excitement and cultural diversity. Unfortunately, it is also known as a city with some of the highest rates of HIV/AIDS in the United States. Columbia University Medical Center is located in Washington Heights, a community with a high number of Latinos at risk of HIV-infection. The Columbia site collaborates with the Alianza Dominicana HOPE Program, a community-based organization instrumental in serving the Washington Heights’ HIV/AIDS affected community. For years, Alianza staff and Washington Heights’ community members have been reluctant to support HIV vaccine research. The focus of the Legacy Project at this site is to increase the representation of Latinos enrolled in HIV vaccine trials.

In order to build better relations with Alianza, the Columbia unit has provided support beyond typical community education efforts. A Columbia recruiter works with Alianza to prepare HIV-prevention packets, and has been instrumental in getting Alianza to be invited to do HIV testing at health fairs. The Columbia site has also provided staffing support at events sponsored by Alianza. The next steps are to hold more educational sessions with Alianza staff and Latino community members, and to help Alianza design culturally specific informational materials on HIV vaccine trials.

The project hopes to find out what factors have historically deterred Latino community members and what will mobilize them to support and participate in HIV vaccine research. Another goal is to evaluate the use of a community based organization as a partner in vaccine trial recruitment efforts. The project should demonstrate that building true partnerships with community organizations helps to meet the needs of both the researchers and the organization.

Legacy Project Staff and Advisors, clockwise from top left:

Dr. Sonya Arreola, Scientific Director
Reverend Edwin Sanders, Chair, Legacy Project Advisory Group
Kaijson Noilmar, Legacy Project Coordinator
Steve Wakefield, Legacy Project Director
For implementation of HVTN 404, the HVTN prioritized clinical research sites at which at least one person had been infected while participating in an early phase vaccine trial. As of February 2009, five participants had been enrolled in HVTN 404 at the sites indicated in the table below.

**HVTN 802**

HVTN 802 is open to participants of phase 2b and phase 3 efficacy trials, which currently includes participants of HVTN 502 (Step) and HVTN 503 (Phambili). However, the protocol team expects other future efficacy studies will have potential participants eligible for HVTN 802.

Most infections occur among participants of later phase HIV vaccine trials because these trials are limited to people who have a greater chance of getting infected with HIV, such as people who have many sex partners or engage in other high-risk sexual behaviors. While few participants are expected to enroll in this study, it is hoped that HVTN 802 will inform researchers about a future vaccine focus, and will also ensure close monitoring of later phase trial participants who become HIV-infected.

Participants only enroll in HVTN 802 after they begin anti-retroviral therapy (ART). The purpose of the study is to compare the outcome of ART treatment in the participants who had originally received a vaccine to those who had received a placebo and to see the effects of the vaccine product on the progression of HIV. Participants will be followed for up to 5 years or until two different ART regimens have failed them, which is not uncommon. In contrast, HVTN 404 follows HIV infected participants for up to 7 years or until they begin ART.

As of February 2009, three participants had been enrolled in HVTN 802 at the sites indicated in the table below.

| Number of participants enrolled as of February 2009 |
|-----------------|-----------------|
| Site            | HVTN 404        | HVTN 802        |
| Atlanta         | Not activated   | 0               |
| Birmingham      | 0               | Not activated   |
| Bronx           | 0               | 0               |
| Cape Town       | 1               | 0               |
| Chicago         | Not activated   | 0               |
| Columbia        | 0               | 0               |
| Fenway          | 0               | Not activated   |
| Iquitos         | 2               | 0               |
| Miraflores      | 0               | 1               |
| Nashville       | 0               | Not activated   |
| Rochester       | 0               | Not activated   |
| San Francisco   | 1               | 0               |
| Seattle         | 0               | 2               |
| Soweto          | Not activated   | 0               |
| Union Square    | 1               | 0               |

Note: This table only lists sites that have activated for at least one of the two studies; additional sites are in the process of being activated for one or both studies.

**Do I belong? continued from page 1**

One repeating theme of the CAB breakout sessions was that our communities need to be connected, not just informed. Community education serves as the cornerstone linking populations that sit on the periphery of understanding HIV and trusting vaccine trials. Therefore, the degree to which site staff and CAB members feel informed, invigorated, and supported directly impacts the level to which they share knowledge with their community. I appreciate that we analyzed ways to strengthen the underlying connection with, and involvement of, our local communities and look forward to expanding this focus.

In conclusion, I feel very fortunate to have participated in the 2008 HVTN conference and to have interacted with so many dedicated and passionate people. There was a palpable energy throughout the conference, which seems grounded in the desire to make a difference and to positively impact our communities. I hope that members of our HVTN community are able to nurture this for themselves and for the cause of finding an HIV vaccine.

Laurie Kavanagh joined the Seattle CAB in September 2008. You are welcome to email her at lkavanag@fhcrc.org
New CAB Bulletin Format

By Genevieve Meyer

The CAB Bulletin will continue to be created on a quarterly basis. However, the format is changing. Instead of four 8-page issues, there will now be two 8-page issues coming out in September and March. There will also be two smaller issues that will go out the month after each HVTN conference (June and December). The September issue will capture events from HIV Vaccine Awareness Day, Gay Pride events and other site activities. The March issue will cover World AIDS Day as well as site activities. Each of the larger issues will also feature a particular site’s CAB. I look forward to getting to know each site better in the process.

We have all made many adjustments since Lisa Bull’s departure. One such transition is that I am taking over as editor of the CAB Bulletin. Lisa is already very missed, but we hope she is happy in her new position and with her new baby! Please feel free to email anytime with questions, comments or submission ideas for the Bulletin (gmeyer@hvtn.org). I welcome your feedback! ✉

Spanish Language CAB Calls

By Carrie Schonwald

It has been clear for some time that there was a need for a Spanish-language call so that CAB members from Latin America who speak only Spanish, or Portuguese and Spanish, could stay as up to date on network information as English-speaking CAB members. The Spanish-language CAB call has existed for about a year, and is now a fully functioning sub-group of the GCAB with official representation from all of the Spanish-speaking sites. Recently, Jose Carlos Veloso of the São Paolo, Brazil CAB and Carmen Rosa de la Cruz from the Dominican Republic site were elected co-chairs of this group. In addition, several committed US CAB members have offered their time as bilingual interpreters. They will rotate on a monthly basis, participating on the Spanish CAB call, and will then write a summary of issues brought up on that call in English so that it can be shared with the GCAB. We at the Community Education Unit are very excited to have found new ways to bridge the distances of geography and language! ✉

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:**
*First Friday of every month*
- Friday, April 3rd, 8 a.m. PST/11 a.m. EST
- Friday, May 1st, 8 a.m. PST/11 a.m. EST

**Global Ethics Working Group call:**
*First and last Tuesday until May*
- Tuesday, March 24th, 9 a.m. PST/12 a.m. EST
- Tuesday, April 7th, 9 a.m. PST/12 a.m. EST

**Global GCAB conference call:**
*Second Thursday of every month*
- Thursday, March 12th, 8 a.m. PST/11 a.m. EST
- Thursday, April 9th, 8 a.m. PST/11 a.m. EST

**Spanish Language CAB Call:**
*Second Tuesday of every month*
- Thursday, March 19th, 9 a.m. PST/12 a.m. EST
- Thursday, April 16th, 9 a.m. PST/12 a.m. EST

**Global Community Education/Recruitment call:**
*Third Tuesday of every other month*
- Tuesday, March 17th, 9 a.m. PST/12 a.m. EST
- Tuesday, May 19th, 9 a.m. PST/12 a.m. EST

The next HVTN Conference is May 12-14, 2009 in Washington DC

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.

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