Those who attended the Full Group Meeting were introduced to the new manager of the HVTN Community Education Unit (CEU), Niles Eaton. Niles may be new to the CEU but he is certainly not new to community education or to the HVTN. Niles has spent the last seven years as a Clinical Trials Manager and is incredibly knowledgeable about site operations and structures. Prior to joining the HVTN, Niles spent seven years as a study coordinator and research manager at the Seattle HPTN site. In that role, he was an integral member of the site’s community education and recruitment team. The CEU is very excited about the addition of Niles to the team! This transition in CEU leadership is part of a larger reorganization within HVTN Core. Specifically, this change will align the CEU with the day-to-day activities of the Scientific Operations Unit, which houses the clinical trials managers and all of the protocol development and implementation work. Part of this reorganization means that Steven F. Wakefield, our previous manager, will expand his role with external relations, community advocacy for HIV vaccine trials, and HVTN Legacy Project activities. Wakefield will also continue to serve as an advisor to the CEU.

Editor’s note on the CAB Retreats: From April 9-11, 2010 the CEU conducted a U.S./Swiss CAB Retreat in Seattle, Washington. It was similar in format to the South African CAB retreat (see article by Siyabonga Nzimande in this issue): a train-the-trainer approach where CAB members worked with staff from the CEU to present on topics such as an Introduction to Vaccinology, Introduction to Research Ethics, How to Read a Protocol, Vaccine-Induced Seropositivity, and many more. Originally scheduled for June, 2010, the Latin American and Caribbean CAB Retreat will take place in late 2010 or early 2011.

We arrived separately and we ranged in age, race, creed and color. We were gay, bi, straight, single, married (legally and one-day-soon-to-be). We came from distinct career paths: students, prison liaisons, guidance counselors, hospital staff, retail salespeople, political staff, community workers, and more. Each from a unique city in the United States (Seattle, San Francisco, Los Angeles, Birmingham, Nashville, Chicago, Washington DC, Rochester, New York City, Atlanta, and Boston) and one from Lausanne, Switzerland. One by one, we arrived for a once-in-a-lifetime experience; to learn more about what we each do in our own cities. We all had two important things in common: we were volunteers, and we were part of a world-wide effort to eradicate HIV/AIDS.”

Reese Isbell, San Francisco CAB member

“We all had two important things in common: we were volunteers, and we were part of a world-wide effort to eradicate HIV/AIDS.”

Reese Isbell, San Francisco CAB member

...continues on page 7

From Unique Paths, Hope Takes Action—
Reflections on the U.S./Swiss CAB Retreat

By Reese Aaron Isbell, San Francisco CAB member

U.S. and Swiss CAB members in Seattle for a three day CAB retreat, April 2010.
This year’s South African Regional CAB retreat was one of the most exciting platforms created by the HVTN for South African CAB members. In the past, when there was only one international CAB retreat (taking place in the U.S.) only one CAB member from each site got to interact with the HVTN staff and other attendees. At this year’s regional retreat, two CAB members from each of the five South African sites were able to attend, making the regional CAB retreat an excellent format for all those in attendance.

The CAB retreat took place in Soweto, which is in Gauteng Province in South Africa, near Johannesburg. (Soweto is an abbreviation of South West Township). The Soweto HVTN clinical research site, the Perinatal HIV Research Unit [PHRU] of the Chris Hani Baragwanath Hospital, hosted the 3-day retreat.

Two CAB members from each site were present at the retreat; some of the CAB members were from the adolescent CAB of the selected sites. There was a high energy level amongst the CAB members and everybody actively participated in the retreat workshop activities.

*What did I learn?* First, I learnt people management skills from the HVTN staff. I have never seen so much care and support when it comes to people management: for some reason I felt like a king because I was treated with so much passion and respect from the HVTN staff. I actually felt like I was important as a community representative for a clinical trial. I now understand better what it means for me to be a CAB member.

Moreover, I learnt a lot about HVTN values around clinical research. I also gained more knowledge about Vaccine-Induced Seropositivity (VISP), which I had understood to mean “false positive.” Actually, VISP means that vaccines can produce antibodies, which show up on HIV antibody tests (commonly used for HIV detection); these aren’t actually false results since the tests are doing what they are supposed to do. But, this is why it’s important to get appropriate testing at the clinic site. The site uses different tests and different methods of interpreting the tests to determine an accurate result.

*What have I brought back to my local CAB and community?* I have planned and implemented training for CAPRISA CAB members on VISP, Research Ethics, and How to Read a Protocol, which I had learned more about during the retreat. I have also planned to work with my clinic to advocate around VISP; we will be visiting local VCT clinics and educating them about VISP.

I want to give many thanks to the HVTN and CAPRISA for allowing me to represent the site. I am looking forward to future working relationships with HVTN staff and CAB members.

“I actually felt like I was important as a community representative... I now understand better what it means for me to be a CAB member.”

Siyabonga Nzimande, CAPRISA CAB member
From February 16 – 19, I attended CROI 2010 (the 17th annual Conference on Retroviruses and Opportunistic Infections) in San Francisco, California, which brought together 4,000 scientists and physicians, including about 350 young investigators, plus 25 community members including Mark Hubbard from the Nashville, Tennessee CAB and me. There were also dozens of HVTN investigators and a few other Core staff there, including Dr. Larry Corey and Steven F. Wakefield.

CROI is an annual four-day conference of very intensive science and a minor amount of politics. The science covers everything from treatment issues to prevention of all types, and basic science. This year’s conference included three invited lecturers, six plenary talks, dozens of break-out sessions and over a thousand posters.

The politics included a presentation by Ambassador at large, Eric Goosby. Dr Goosby, appointed last summer as President Obama’s Global HIV/AIDS Coordinator, was right at home, having completed his M.D. at the University of California, San Francisco, and having served as Associate Medical Director of San Francisco General Hospital’s AIDS Clinic before going into government work in 1991. He spoke about the history and future of the President’s Emergency Plan for AIDS Relief (PEPFAR) along with two colleagues from non-western countries.

Dr. Anthony Fauci, Director of NIAID, gave a talk about the scientific challenges of HIV. After more than 25 years of HIV research, we know more about HIV than any other virus, yet we still do not have the means to stop its spread with a vaccine or any other effective biomedical intervention. He was cautiously optimistic about what we might learn from RV144 (the “Thai Trial”; see article in CROI), but emphasized the need to test for and treat HIV as widely as we can. However, I found this paradigm more effectively expressed by Dr. Julio Montaner, Clinical Director of the Centre for Excellence in HIV/AIDS at the University of British Columbia, as “seek, test, treat, and retain.”

While there were many advantages to attending a conference in my hometown, one thing I found frustrating about this meeting (and the last CROI I attended in Boston in 2008) is that there are usually at least four sessions that I am interested in, offered at the same time! Nonetheless, both meetings were well worth the time, because of what I have learned and for the new contacts I have made. I am already getting excited to see what will be on the agenda for next year’s conference, which will return to Boston.

To learn more about CROI and the 2010 conference in San Francisco, visit: http://retroconference.org/2010/

GCAB Co-chair elections — It’s that time again!

It seems like only a few months ago that Rick Church and Phineas Malahlela were elected as Global Community Advisory Board (GCAB) co-chairs, yet their two-year term has already come to an end. This year, instead of seeking two new chairs, the GCAB and Community Education Unit (CEU) returned to the original system of electing one new co-chair each year so that there is continuity of leadership as new leaders take the reins. In order to move forward with this system, one co-chair would continue for another year and the other step down. Rick decided to pass the torch and vacate the U.S. co-chair position. Phineas expressed his willingness to continue as the international co-chair until 2011. The CEU would like to thank Rick personally for all his hard work as GCAB co-chair and looks forward to continuing to work with him on the HVTN 505 Protocol team.

Earlier this spring, the GCAB representatives found themselves... continues on page 8
Twice a year the HVTN convenes a Network-wide meeting to share new developments in vaccine science and conduct face-to-face meetings of network committees, protocol teams and community constituents. At the recent meeting in Washington DC, the plenary sessions featured presentations of interest to both scientists and laypersons alike. Kicking off the meeting was a Symposium on Non-neutralizing Antibodies in HIV followed by an afternoon plenary on the Neglected Epidemic of HIV in MSM, which looked at the needs and challenges of HIV prevention with this population. Presentations highlighted transmission trends outside of the U.S. and Europe, including highlights of specific trends in the U.S. and in Sub-Saharan Africa, and a review of PrEP studies in MSM and heterosexual populations. If you were not able to attend the FGM, you may enjoy the slides from these presentations, which are posted on the HVTN website and would make for a great discussion with your CAB.

During the HVTN Data Forum on Wednesday, Dr. Rick Koup from the NIAID Vaccine Research Center presented on Env binding antibodies after DNA-Ad5 vaccination. Dr. Koup’s study was of particular interest because he was looking to see whether the VRC DNA and the VRC Ad5 vaccine regime used in HVTN 204 generated antibodies of a similar level to those found in the Thai trial. This finding is of interest because HVTN 505 (open in the U.S.) uses the vaccine regimen used in HVTN 204, which finished enrollment in 2007. Although it is unclear whether antibodies are the key to the modest protection in the Thai trial, HVTN 505 is not currently designed to look at protection from infection (as a primary objective). Dr. Koup’s findings could mean that similar results to the Thai trial might be expected from HVTN 505.

For a great review of the role of antibodies, both binding and neutralizing, view Viv Peut’s slides summarizing this presentation for the Science Tutorial, posted on the HVTN website.

HVTN 505 was a key focus of the meeting. Six sessions were dedicated to various aspects of the trial: operations, trial management, recruitment, community engagement, use of social media, and planned site expansion. The Network recognizes that this trial has proven more challenging to enroll than could have been predicted and that the current US sites have been putting forth their greatest efforts to improve the pace of enrollment. In order to add to the Network’s current capacity for enrollment, the protocol team has been working with HVTN leadership and DAIDS to identify potential clinical research sites that could be brought on rapidly to further support recruitment efforts. Staff from HVTN Core visited these sites during May and early June to assess their infrastructure and capacity, an announcement of the new locations will be made in the upcoming months.

Adaptive Trial Designs

By Genevieve Meyer and Carrie Schonwald of the Community Education Unit.

One of the many innovative ideas presented during the Conference was the concept of Adaptive Trial Designs (ATD), moderated by Dr. Steve Self, director of Biostatistics and Data Management at SCHARP (Statistical Center for HIV/AIDS Research & Prevention). ATD is a model for “us[ing] the information generated within a trial to modify the trial to become even more effective.” Rather than waiting for a trial to conclude, assessing the data, then applying the findings to future trials (which requires considerable time and resources), this model allows for real-time modifications of open trials (such as adding or removing a study arm) based on pre-
determined interim analyses of study data. The idea of modifying a trial based on interim analysis is somewhat common in phase 1 studies and in pharmaceutical trials; however, it poses greater operational challenges for a phase 2 or phase 3 vaccine study.

During the plenary session on this topic, Dr. Glenda Gray spoke about issues to consider if a trial like this were implemented in her home country of South Africa. One major area of consideration would be community education: how can we talk about this type of trial design with communities and what will it mean if one study arm is stopped short because it is not found to be efficacious, while another study arm continues? Other steps include creating solid systems for data collection, implementing real-time sampling, and putting preventive mechanisms in place to avoid co-enrollment issues (when participants are enrolled in more than one trial at the same time).

The overall benefits of ATD are that it allows for predetermined changes during a trial, quicker removal of ineffective vaccines, and the possibility of identifying immune correlates sooner than waiting for the trial to conclude. However, this also raises an important role for CABs in looking at ways to implement community education about ATD and in ensuring that the informed consent process addresses the various ways a trial could unfold. The HVTN will continue discussing the merits of this model and how to address operational challenges before deciding whether or not to implement an ATD in the next few years.

If you would like to learn more about the use of Adaptive Trial Designs, here are a few helpful references:


One of the true highlights of this meeting, and every HVTN meeting, is the reception and dancing!
Each May, the Community Education Unit (CEU) honors a CAB member for his or her commitment to the HVTN at a local and Network level. The award is named after Octavio Valente Jr. from Rio de Janeiro, a CAB member and friend who worked tirelessly in HIV prevention until he eventually succumbed to the disease. This year the CEU was delighted to present Gloria Malindi of the Soweto site with the award. Gloria, a long-time dedicated CAB member, is highly committed to her local CAB. She is the current co-chair of the EWG, and an HVTN representative to Community Partners (a DAIDS cross-network working group) in addition to being a former co-chair of the GCAB.

Each Spring, the Network Evaluation Committee seeks nominations for Network Citizenship and Network Service awards. The awards are presented during the May Full Group Meeting. This year, Community Educators Gabriela Calazans from São Paulo and Jim Maynard from Boston each received the Network Citizenship Award in recognition of their consistent, reliable, and quality performance of site duties and activities. The Network Service Award is given to individuals who have creatively responded to a particular challenge arising in their site work, and by which value has been added to the site and to the HVTN as a whole. Dr. Marie-Marcelle Deschamps, Co-Investigator at Gheskio in Haiti, was the recipient of the Network Service Award, in recognition of her passionate leadership at Gheskio during and after the recent earthquake.

On day two of the conference, attendees were touched to learn of the impressive efforts of Gheskio staff during their ongoing post-earthquake recovery. Dr. Bill Pape, the Principal Investigator of the site, discussed the daily challenges of providing for the basic survival needs of over 6,000 displaced people camping on their property, of keeping patients on track with their HIV and TB medications, and of maintaining contact with and even increasing recruitment of trial participants. The staff, many of whom have worked at the site for over two decades, have gone beyond the scope of their jobs to provide for their fellow citizens. In addition to medical intervention on an impressive scale, they have been helping to meet basic needs, uniting children with parents, and all while dealing with their own personal losses during and after the earthquake. Community Educator Dr. Mireille Peck was among those acknowledged for her work in the recovery efforts. She alone was responsible for child vaccinations at the refugee camp. At the end of Dr. Pape’s presentation, the HVTN presented him with a check for $10,000 towards Gheskio’s ongoing recovery efforts.

Dr. Pape’s slides on the recovery efforts in Haiti are posted with the other conference slides. To learn more about the ongoing post-earthquake recovery efforts at Gheskio, visit: http://weill.cornell.edu/globalhealth/
Reflections on the U.S./Swiss CAB Retreat continued from page 1

and we were part of a world-wide effort to eradicate HIV/AIDS. I can’t tell you all their stories, but I can tell you mine. I’m the one from San Francisco.

Several years ago, while meandering through the Castro neighborhood of San Francisco, I was approached by a cute guy with a clipboard. I had previously been in his shoes, canvassing for votes, promoting a cause, or sometimes just trying to meet cute guys. I figured I should listen to what he had to say. He asked me if I’d consider being part of an HIV vaccine trial and I accepted. So began my two-year stint as a trial participant, which led to my joining the San Francisco Community Advisory Board (called a Community Advisory Group [CAG] in San Francisco).

“I have a college degree and passed some basic biology classes years ago, but I am definitely not a scientist.”

Reese Isbell, San Francisco CAB member

Let me be clear, I am not a scientist. I have a college degree and passed some basic biology classes years ago, but I am definitely not a scientist. I love to watch a good nature show on TV, but my knowledge of medical research is extremely limited. So the first thing I noticed about the meeting of my CAB was that there was a lot of science. At first I thought I wasn’t in the right room. I was surrounded by scientists and AIDS activists who had studied this stuff for years, and it just wasn’t my area of expertise.

I have now been with the CAB for several years and I still sometimes glaze over a bit when we have heavy science parts of the meeting. However, now I am less anxious about the science because I know that I’m there to represent my local community not as a scientist, but as a person who cares deeply about HIV research and its impact on my community.

One day my site told me they wanted me to go to a meeting of CAB members from different HVTN sites. I didn’t even realize there were other groups like ours. When I got to the HVTN US and Swiss CAB Retreat, the first thing I noticed was that perhaps I was in the wrong room again. There was quite a bit of heavy science that was way beyond my rudimentary knowledge gained from watching nature shows on TV. I wanted to leave and apologize for not being what they were hoping I would be.

But then, there they were: assurances that I wasn’t in the wrong room. We were needed in this room. It turns out that we, non-science people, can help science advance just by being our basic-biology selves.

Well, now I know I can do that. In fact, we all can do that. The local CABs have a valuable role in the multi-layered, worldwide system of HIV/AIDS research. I recognize now that my role, as small as it may seem to me, is part of a larger picture that is slowly and dedicatedly changing the world for the better. From our first days of being recruited on the streets or through friends, or school, or happenstance, to years later finding new ways to advance science, I and my fellow international CAB members are finding Hope Taking Action.
GCAB Co-chair elections  continued from page 1

Kate Miller, new GCAB co-chair

Send suggestions, questions, and articles submissions for the CAB Bulletin to:
Genevieve Meyer, Editor
gmeyer@hvtn.org
Tel: 206 667-5300
Fax: 206 667-6366
HVTN/FHCRC, 1100 Fairview Avenue North, LE-500
PO Box 19024 Seattle, Washington 98109-1024

Layout: Deborah Cughan
Translation: Translation of the CAB Bulletin from English to Spanish and French provided by Infinity Translation Services.
www.infinitytranslations.com

The polls closed in April and the CEU is very excited to announce that Kate is the new U.S. GCAB co-chair. Kate has served on the Chicago CAB for three years. She has a history of working with people who live on the street and currently works for an organization that provides legal services for HIV-positive individuals. Kate has had the unfortunate experience of watching many people die in the early years of the HIV epidemic, both in the U.S. and in Ghana where she lived for two years. However, she has also had the opportunity to watch many people endure HIV with great spirit, which further encourages her commitment to HIV prevention and vaccine discovery efforts. In addition, Kate speaks Spanish and is eager to participate on the Spanish language CAB calls.

Kate stepped into her new duties at the HVTN Full Group Meeting, where she was able to meet Phineas in person for the first time. Please join the CEU in welcoming Kate as GCAB Co-Chair!

About CABs
Community Advisory Boards (CABs) are one way that the HVTN involves community members 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 community education efforts, as well as to the development of this bulletin.

Missed an issue?
If you have missed an issue of the CAB Bulletin, all of our past issues are archived on the HVTN website community pages (no password required!). View past issues including featured clinical research sites, scientific updates, CAB experiences and much more. http://www.hvtn.org/community/bulletin.html

Upcoming Events
If you are a U.S. CAB member, don’t forget to talk to your site about plans for Pride festivals, Juneteenth, National HIV Testing Day, and all of the other upcoming HIV awareness days. (http://www.hhs.gov/aidsawarenessdays) We will feature site activities from HIV Vaccine Awareness Day in the next issue!

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

Global GCAB call
Second Thursday of every month
Thurs., July 8th, 8 a.m. PT/11 a.m. ET
Thurs., Aug. 12th, 8 a.m. PT/11 a.m. ET

Global Ethics Working Group call
First Tuesday of every month
July call has been cancelled
Tues., Aug. 3rd, 9 a.m. PT/12 p.m. ET

CAB Scientific Working Group Call
First Friday of every month
Fri., July 2nd, 8 a.m. PT/11 a.m. ET
Fri., Aug. 6th, 8 a.m. PT/11 a.m. ET

French Language CAB call
Second Wednesday of even months
Wed., June 9th, 9 a.m. PT/12 p.m. ET
Wed., Aug. 11th, 9 a.m. PT/12 p.m. ET

Spanish Language CAB call
Third Thursday of odd months
Thurs., July 15th, 9 a.m. PT/12 p.m. ET
Thurs., Sept. 16th, 9 a.m. PT/12 p.m. ET

African Regional CAB call
Third Thursday of even months
Thurs., June 17th, 9 a.m. PT/12 p.m. ET
Thurs., Aug. 19th, 9 a.m. PT/12 p.m. ET

Thank you to the many people who helped with this issue: Carrie Schonwald, Gail Broder, Niles Eaton, Dave Crawford, Viv Peut, Erik Schwab, Sarah Alexander