Transgender Inclusion: Considerations for sites

By Gail Broder, Community Education Unit, HVTN Core, on behalf of the Transgender Working Group

In 2007, the Global CAB sent recommendations to the HVTN’s Scientific Steering Committee (SSC) about making HVTN trials more accessible to transgender participants. The SSC then decided to form a working group to review these recommendations and determine what changes could be made. Initial efforts included revisions to the HVTN protocol and consent form templates to make the language more inclusive. HVTN 505, a study recruiting persons at high risk for HIV infection, provided an opportunity to include transgender women (male to female), also known as “transwomen,” assuming they fit the eligibility criteria.

To help sites think about the needs and issues that transgender people deal with in their lives, a panel discussion took place at the May 2009 HVTN Conference. The panelists were Jeffrey Johnston, a female to male transgender man who is involved in community health planning in the Washington DC area, and Brian Watson, the Program Director for Transgender Health Empowerment, a community-based organization that serves the transgender community of Washington DC. Transgender Inclusion continues on page 5

My First HVTN Conference

By Robert Divito, Atlanta CAB member

I have been an Emory University Hope Clinic CAB member for over five years. But up until this year, I had never been able take the time off from work to attend an HVTN Conference. I am so glad that I was able to have this meeting be my first. There were important and game-changing topics addressed; for example, the impact of male circumcision on reducing HIV transmission, which we learned played a role in the Step Study results. With such international attention on the HVTN since the vaccinations were stopped in the Step Study, it was great to hear the lessons learned from the investigators and researchers who continue to analyze and data on factors such as circumcision and the role of Adenovirus 5 as a vaccine vector. The data presented and the discussion around it really helped me see the powerful exchange of information and ideas that goes on at these conferences, which really helps the scientific community in developing their ideas for future vaccines and vaccine studies. With my new understanding of the exchanges that take place at these conferences, I am now able to talk more knowledgeably with my local CAB members. I plan to help them understand the important information learned from Step and other studies presented and what this information means for upcoming HIV vaccine trials.

My First HVTN Conference continues on page 6
In September 2001, the Asociacion Civil IMPACTA Salud y Educacion created a CAB in order to strengthen community support for HIV/AIDS prevention and treatment studies in Lima. A diverse group of organizations and individual community representatives participated in the creation of the group. The 11 member CAB includes community educators, activists from the MSM and transgender communities, study volunteers, people living with HIV/AIDS and representatives from the Ministry of Health at both a regional and national level.

Last year the CAB implemented a plan for improving community engagement. They are currently working on the 2009 plan. The plan’s objectives were to:

1. Implement a survey to collect community perceptions about biomedical studies.
2. Promote the importance and visibility of the CAB and its role in protecting the human rights of participants through communication materials.
3. Work with the investigators to inform the community about the advances and results of recent studies.
4. Strengthen the CAB’s relationship with other community institutions.

Currently the CAB is reviewing the information gathered from the survey. The survey responses will provide insight for the development of community forums and for the creation of informational materials. The group also relies on a web page that includes communication materials that support their activities.

The CAB typically meets twice a month. The CAB president leads the meeting; the secretary records the activities and disseminates the minutes. Recently the CAB reviewed materials for HVTN 205 and discussed a recent study of neuropathy (peripheral nerve damage associated with an underlying disease, or treatment given, for a particular disease) in HIV patients. The study, sponsored by the University of Washington in Seattle, examined the prevalence and possible causes of neuropathy in adults with HIV. Both the Lima site and the Iquitos site took part in this study.

On March 28th the site hosted CAB members and trial participants at an appreciation luncheon at the “Peña de Rompe y Raja” in the popular Barranco district. There were exciting performances by local entertainers Guajaja and Zoila Montedoro as well as traditional regional Peruvian dancing. Throughout the event, guests enjoyed good food, dancing, listening to music and just relaxing together. At one point during the meal, several CAB members, including the president Cristina Magan, offered words of support to the participants. At the end of the event, the site gave participants a souvenir, a stylish red HVTN/IMPACTA aluminum water bottle, in recognition and thanks for their ongoing support of vaccine studies.
I am no longer brand new to the HVTN, or to the world of science. I should be able to sit through a scientific plenary session at an HVTN conference and know what the presenters are talking about, right? Wrong! During the HVTN conference, I found myself sitting through the Data Forum thinking about how the charts with bars and dots look more like modern art that I would like to hang on my wall than anything I could ever actually make sense of. That, however, was exactly what I was supposed to do. As a community rapporteur I was tasked with first listening to, then explaining the key concepts of these presentations to community members during the Rapporteur Wrap Up session.

The first two presentations felt fairly comfortable to me. Dr. Susan Buchbinder talked about new data that had been analyzed from the Step Study. We learned that not being circumcised remained a significant risk factor for the participants who contracted HIV in both the vaccine and placebo groups. They also found that about 6 months after their first study visit, participants’ initial reduction in risk behaviors seemed to level off and did not appear to further decline. What I found most interesting was the new data about Adenovirus 5 (Ad5), a deactivated virus used to deliver the HIV vaccine into the body (a vector). Ad5 was initially thought to be associated with an increased risk of HIV infection for participants who:

- had immunity to Ad5 before receiving the vaccine, and
- were exposed to HIV shortly after receiving the vaccine.

However, this association did not appear to last as the time between vaccination and exposure to HIV increased (exposure to HIV due to behavior, not the vaccine product).

The next presentation also supported these findings. Dr. Glenda Gray’s data about the Phambili trial, which used the same vaccine product as the Step trial, showed no association between Ad5 levels and risk of HIV infection in South African participants. For their female participants, they learned that older women seemed to be at higher risk for getting HIV than women under age 25. This is the opposite of what they had originally expected. Data on the male participants revealed that 30% were circumcised before enrolling, and another 20% decided to get circumcised during their time in the study. Both alcohol and drug use continue to play a role in increased risk and were emphasized as areas for directing more prevention interventions.

When the presentations changed from clinical study data to more abstract scientific topics, anxiety suddenly overtook me. Words like sieve and epitope started banging around in my head. I thought a sieve was a useful cooking tool, but I knew that couldn’t be what they were talking about. I knew epitopes were pieces of proteins, but I didn’t understand their importance. And what about a gag response? I knew Dr. Nicole Frahm was certainly not talking about throwing up after smelling something rotten. How did all of these terms relate to finding a vaccine? I was lost. I left the plenary feeling frustrated and confused, worried about how I would ever be able to share this information during the Rapporteur session.

The next day our group sat down with Dr. Mike Keefer, the investigator in our group. I really wanted to understand what Dr. Jim Mullins and Dr. Peter Gilbert were talking about when they mentioned a “sieve effect”. Their data showed that while the vaccine could not completely block HIV infection, it was having an effect on blocking variants, or pieces of the HIV virus. In essence it provided a sieve, or net, to potentially slow the progression of the virus. In order to determine which pieces of the viruses were being impacted, Dr. Mullins’ lab took the information about the HIV viruses contracted during the Step Study and worked to identify all of the small viral pieces or epitopes (bits of proteins on the HIV virus structure) of those particular HIV strains.

A Rock in the River, continues on page 5
In planning for each HVTN Conference, the Community Education Unit incorporates suggestions from CAB members and Community Educators/Recruiters to make sessions meaningful to those attending. We heard from all of you that it would be useful to have general community meetings, but also regionally specific sessions. We held an African CER/CAB meeting, a US CER meeting and both CAB and CER meetings for Latin America and the Caribbean (LAC).

At the African meeting we discussed ways of increasing both telephone and face to face communications across South African sites. Similarly, the LAC CAB members strongly desire a regional conference, and we discussed what this might look like and how to accomplish it. The LAC CER meeting was dedicated to recruitment issues of high risk women at the HVTN 907 sites. The US CER meeting focused on the history of the exploitation of African Americans in clinical research and how this can be addressed in community presentations. There was also interest in creating similar presentations for other populations that have been historically exploited in medical research.

Overall, the regional meetings allowed both CERs and CABs the opportunity to focus on issues of greatest relevance to their sites, and appeared to be a successful tool in moving our work forward.

Congratulations!

Reverend David Galetta was the winner of this year’s Network Service Award. As Cape Town’s longest standing CAB member, David has worked on HIV issues for years. When called on by the University of Cape Town (UCT) Research Ethics Committee (REC) to represent his community he showed remarkable interest, responsibility and commitment. As a result, the UCT REC has asked him to serve on the REC as a community representative. Recently he was elected to the Global CAB of the HVTN and selected as a representative for the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention this July in Cape Town. David also contributes his energy as the CAB participant serving on the HVTN Network Evaluation Committee.

Rick Church was awarded this year’s Octavio Valente Jr. Award for Volunteer Service from the HVTN Community Education Unit. Rick is a CAB member for the Columbia University and New York Blood Center clinical sites. Among his other activities in the HVTN, Rick currently serves as the co-chair of the Global CAB. He served on the protocol team for HVTN 065, and served as the HVTN CAB member on the PAVE 100 protocol team. Rick has continued as a member of the 505 protocol team, and its Community Affairs Working Group. This has involved an extraordinary commitment of time and effort, far beyond the usual responsibilities of serving on a protocol team, in addition to his commitment to his local CAB, full time employment, and graduate school.

Regional sessions at the HVTN Conference

By Carrie Schonwald, Community Education Unit, HVTN Core

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Overall, the regional meetings allowed both CERs and CABs the opportunity to focus on issues of greatest relevance to their sites, and appeared to be a successful tool in moving our work forward.

Thank you!

To everyone who gave input and helped look over the final touches for this bulletin: Carrie Schonwald, Gail Broder, Shelly Karuna, Sarah Alexander, Erik Schwab, Malkah Duprix, Emily Dossett & Ben Meyer.

Translation from English into Spanish and French by Infinity. www.infinitytranslations.com

Editor’s note: In the last bulletin I mentioned a new bulletin format, two 8-page editions (Sept. and March) and two 4-page editions (Dec. and June). However, there were so many wonderful pieces to include this time that I decided to create a 6-page bulletin, just this once. We will return to the regular format in September.
While the concept was becoming a little clearer to me, I still did not feel I truly understood the significance of this discovery. Then someone else explained it to me another way.

If HIV is a river flowing out of control, the scientists have not yet been able to find a vaccine that will provide a dam, but they are starting to place large enough rocks in the river to impact the river’s flow. They have begun to identify the particular epitopes that were affected by the vaccine and are now able to focus on improving those responses. The type of vaccine that is causing this impact, placing a rock in the river, is one that causes a T-cell response. In this case, the goal of the sieve is to identify which rocks will work to slow, then ultimately stop the flow of water, and find ways to get more of them in place. T-cell vaccines focus on stimulating particular T-cells of your immune system, such as CD8+ cytotoxic T lymphocytes (CTLs), to recognize HIV as an intruder and begin to fight it off. This is done by targeting the epitopes that hang onto the outside of the virus. This is the type of vaccine that was used in Step and the direction that much of vaccine science will continue to pursue.

The work presented in Dr. Mullins’ and Dr. Gilbert’s sieving data was looking at HIV epitopes, which are pieces of HIV proteins. Yet vaccine science is looking at multiple ways to combat HIV, whether through targeting pieces of the virus, or targeting a complete HIV gene protein as in the research of Dr. Nicole Frahm. Dr. Frahm found that there is actually a trend towards reducing viral load when vaccines target responses specifically to the gag gene, and that vaccine designs should focus on increasing these responses rather than responses to other HIV genes like pol, nef, or env. Wow, I thought, it seems the scientists really have made huge steps towards outsmarting this disease, which is something everyone can be excited about!

I may never understand all of the dots and lines used on the charts during a scientific plenary, and I realize that’s OK. It’s also OK to ask someone to try to explain the information in another way. I do take comfort in knowing that once the information is broken down for me a second, third or tenth time that I really can understand the excitement behind the science and what these steps mean for the future of HIV vaccines.

The original PowerPoint presentations are available on the HVTN member pages: http://www.hvtn.org/meeting/may09.html
My First HVTN Conference  continued from page 1

I imagine it will be challenging for our clinic to enroll participants for HVTN 505 the given the specific eligibility criteria for this trial and all the buzz that still surrounds the Step Study. But I also know that they will succeed in enrollment, especially with the support of the CAB members who are passionately helping to educate and promote this study in their communities.

As with many meetings I’ve attended since becoming involved in HIV prevention work, this meeting had its contentious moments. With so many passionate people coming together in one space, there were bound to be disagreements on approach or language. But, I wouldn’t have it any other way. I would rather that emotions spill over a bit and are heard and addressed, than to be in a room where no one was passionate about the work nor felt comfortable raising their voice. I am so glad that people are using their passion to fight HIV in this professional arena. Seeing their commitment has reenergized me to continue to do my part in putting an end to HIV.

### 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*  
  Thursday, June 11th, 8 a.m. PST/11 a.m. EST  
  Thursday, July 9th, 8 a.m. PST/11 a.m. EST

- **Global Ethics Working Group call**  
  *First Tuesday of every month*  
  Tuesday, July 7th, 9 a.m. PST/12 p.m. EST  
  Tuesday, August 4th, 9 a.m. PST/12 p.m. EST

- **CAB Scientific Working Group call**  
  *First Friday of every month*  
  July’s call will be rescheduled  
  Friday, August 7th, 8 a.m. PST/11 a.m. EST

- **Spanish Language CAB call**  
  *Second Tuesday of every month*  
  Thursday, June 18th, 9 a.m. PST/12 p.m. EST  
  Thursday, July 16th, 9 a.m. PST/12 p.m. EST

- **French Language CAB call**  
  *Second Wednesday of even months*  
  Wednesday, June 10th, 9 a.m. PST/12 p.m. EST  
  Wednesday, August 12th, 9 a.m. PST/12 p.m. EST

### HVAD

If you would like your HIV Vaccine Awareness Day (HVAD) photos or event description included in the next CAB Bulletin, please send items to Genevieve (gmeyer@hvtn.org) by **July 15, 2009**.

### About CABs

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 for the CAB Bulletin to:

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