South African CABS: Crucial to HVTN Site Expansion Community Engagement

By Carrie Schonwald, HVTN Community Engagement Unit

In response to having some of the highest HIV prevalence and incidence rates on the planet, South Africa has developed a world-class HIV research infrastructure. They have brilliant scientists surrounded by communities who live every day with the devastating impact of this epidemic. This combination makes for a country that is deeply dedicated to HIV research. For these reasons and more, the HVTN is planning a large site expansion process over the next few years in South Africa and several other southern African countries. To plan for successful community engagement, the Community Engagement Unit (CEU) at HVTN Core will be relying upon South African CAB members’ knowledge of their communities to inform community engagement plans for expansion sites.

To this end, members of the HVTN Core CEU spent three weeks in October traveling in South Africa to observe the models of community engagement used by staff and CAB members at our

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Transgender Training Continues

Gail Broder, HVTN Community Engagement Unit

At the recent HVTN Conference, the Network continued its efforts to include transgender persons in HIV vaccine studies. Following the successful cultural responsiveness training held in June in Washington, DC, the October 2012 training focused on the needs of clinicians to understand and respond to the medical issues faced by some transgender participants. The program, organized by the HVTN’s Training Unit and a planning group of HVTN Core staff and site staff representatives, featured two local Seattle clinicians, Dr. Carolyn Fuller, ND and Dr. Linda Gromko, MD. Jonathan Fuchs, MD, of the San Francisco site, moderated the program.

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In 1998 the GHESKIO CAB was created in preparation for HIV vaccine trials starting at the site. In 2003, the CAB expanded its scope to include the AIDS Clinical Trials Group (ACTG) as well. The CAB sought to have full representation of the community, so they organized monthly meetings that allowed for members of different sectors of society to attend.

Currently the CAB comprises 26 active volunteers who represent People Living with HIV, media representatives, youth, those who are illiterate, lawyers, doctors, students, former study volunteers, teachers, religious leaders (Voodoo, Catholic, Baptist), human rights activists, and sex workers.

The CAB considers itself a group of advisors, advocates and activists with a mission of linking GHESKIO and the community, acting as a liaison between the two. Throughout their 14 years as a CAB they have reached over 500,000 community members through 150 CAB meetings, 280 workshops, and regular community outreach. In addition to participating in annual HVTN and ACTG meetings, they also send representatives to the Annual Haitian Medical Society Congress and to Association of Public Health meetings. The CAB presence is also evident in the materials they have developed and distributed, including posters, pamphlets, postcards, calendars, community practice guides and CAB handbooks.

But what is unique about this CAB is their dedication not just to the research, but to their community overall. In January 2010, after a devastating earthquake left much of Haiti in shambles, over 7,000 internally displaced persons (IDPs) took refuge on the GHESKIO campus. Overwhelmed by the need for support, the site Principal Investigator called on CAB members to help organize the IDP community to access services — potable water; programs for micro-credit; prevention of TB, STIs and gender-based violence — and to organize vocational and primary schools. As if this weren’t enough, for months following the earthquake, a cholera outbreak made many of the GHESKIO refugees sick. Once again the CAB jumped in to help inform and educate the IDPs about cholera. They taught them how to prevent and treat the infection in order to minimize damage to the community.

It is this spirit of community, this dedication and resilience that has kept this CAB strong after all these years. Their dedication is contagious; it reaches beyond their CAB and to the study volunteers who wholeheartedly commit to the cause.

“I am Haitian, I am poor, I don’t have money, but I can use my time and my blood to help find an effective product to fight AIDS. By doing so, I will prove how rich I am.”

GHESKIO CAB member and study volunteer.
1) At-large CAB member Hamilton Richardson, always excited to meet new CAB members; 2) Dr. Magda Sobieszczyk discusses what the licensure of Truvada as Pre-exposure Prophylaxis (PrEP) means for HVTN 505 during the General Community Session; 3) CER Coco Alinsug (left) and CAB member Kirsten Freni of The Fenway Institute in Boston, MA enjoying a relaxing moment; 4) Seattle CAB member Caitlin Jirovsky describing her CAB’s activities and methods during the CAB Breakout Session; 5) Seattle’s Sisters of Perpetual Indulgence, Seattle CER Ro Yoon (center) and friends at the HVTN reception; 6) Denver CAB member John Jaruzel describing his CAB’s transition from representing the just the ACTG, to both ACTG and HVTN during the CAB Breakout session; 7) One of many beautiful glass art arrangements at the Chihuly Garden and Glass museum where the HVTN reception was held.

Photos by Soyun Im


**ONGOING AND UPCOMING HVTN STUDIES**

*Genevieve Meyer, HVTN Community Engagement Unit*

In March 2010, we printed an article on “Understanding HIV Clinical Trials” ([hvtn.org/community/bulletins/Q12010.pdf](http://hvtn.org/community/bulletins/Q12010.pdf)) in which we described the different phases of trials (also called “studies”) and what is unique about each phase. In looking over these tables of current and future studies, we recommend that you take advantage of that past issue as a helpful reference to terminology in addition to information about previous studies.

<table>
<thead>
<tr>
<th>STUDY (PROTOCOL) NAME: STUDY PHASE (NUMBER OF PARTICIPANTS)</th>
<th>PRODUCTS USED</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVTN 087: phase 1 (n=100) Opened May, 2012</td>
<td>DNA vaccine with IL 12 adjuvant given with electroporation followed by an rVSV vaccine boost.</td>
</tr>
<tr>
<td>HVTN 096/EuroVac 04: phase 1 (n=96) Opened August, 2012</td>
<td>NYVAC, AIDSVAX B/E, DNA.</td>
</tr>
<tr>
<td>HVTN 505: phase 2b (n=2500) Opened June, 2009</td>
<td>DNA vaccine and rAd5 vector vaccine boost.</td>
</tr>
<tr>
<td>HVTN 910: observational study (n as many people as choose to enroll) Opened December, 2011</td>
<td>No study product.</td>
</tr>
</tbody>
</table>

**These are studies that are still in the planning phase, but likely to open in 2013 or 2014**

<table>
<thead>
<tr>
<th>STUDY (PROTOCOL) NAME: STUDY PHASE (NUMBER OF PARTICIPANTS)</th>
<th>PRODUCTS USED</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVTN 092: phase 1 (n=204) Expected to open in January 2013</td>
<td>Clade C DNA with a clade B NYVAC vaccine boost.</td>
</tr>
<tr>
<td>HVTN 095/MTN 022: phase 1 (n=108) Expected to open in Spring 2013</td>
<td>IPPOX/Eurovac DNA, with vaginal microbicide (Tenofovir gel) &amp; oral PrEP (Truvada pills).</td>
</tr>
<tr>
<td>HVTN 097: phase 1 (n=100) Expected to open in mid-2013</td>
<td>ALVAC pox prime and AIDSVAX B/E protein boost.</td>
</tr>
<tr>
<td>HVTN 098: phase 1 Part A: n = 66, expected to open in September 2013 Part B: n = 66, expected to open in mid-2014</td>
<td>PENNVAX + IL12, with intradermal or intramuscular electroporation.</td>
</tr>
<tr>
<td>HVTN 099: phase 1 (n=180) Expected to open in October 2013</td>
<td>CHAVI DNA+NYVAC, mosaic inserts.</td>
</tr>
<tr>
<td>HVTN 506 (phase 1- 2B). This is also called the “Research Track” study. Expected to open in late 2013</td>
<td>DNA and NYVAC products (like in 092, 095, 096) plus Proteins gp 120 and the MF59 adjuvant (like in HVTN 100).</td>
</tr>
<tr>
<td>HVTN 100 (phase 1). If the phase 1 study goes well, it will roll into a larger efficacy study. Expected to open in 2014</td>
<td>ALVAX pox prime with protein boost and MF59 adjuvant.</td>
</tr>
</tbody>
</table>

**Product abbreviations and descriptions:**

- **MVA** = Modified Vaccinia Ankara, used as a vector. MVA is a pox virus related to smallpox.
- **MF59** = A type of adjuvant. It is already licensed in several countries and is used in some flu vaccines.
- **rAd5** = Recombinant adenovirus type 5, used as a vector.
- **rVSV** = Recombinant Vesicular Stomatitis Virus, used as a vector.
- **IL-12** = Interleukin 12, used as an adjuvant.

"Understanding Clinical Trials", article from March 2010 CAB Bulletin
So what’s new at the HVTN? Here are some studies that are currently enrolling or just finishing enrollment. Product names that are bolded are defined below.

A special thank you to the following people for their consultations regarding article: Carter Bentley, Gail Broder, Jim Kublin, Niles Eaton and Reena Gulati.

**Purpose of the Study**

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Location(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVTN 100</td>
<td>Nashville, TN; New York, NY; Rochester, NY; Philadelphia, PA</td>
</tr>
<tr>
<td>HVTN 506</td>
<td>Lausanne, Switzerland</td>
</tr>
<tr>
<td>HVTN 099</td>
<td>All US sites plus 7 expansion sites</td>
</tr>
<tr>
<td>HVTN 098</td>
<td>All active HVTN sites qualify</td>
</tr>
</tbody>
</table>

**Locations Where Study Takes Place**

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Location(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVTN 095/MTN 022</td>
<td>New York, NY; Philadelphia, PA; San Francisco, CA; and Lausanne, Switzerland</td>
</tr>
<tr>
<td>HVTN 092</td>
<td>Soweto (Johannesburg), Klerksdorp, Cape Town, South Africa</td>
</tr>
<tr>
<td>HVTN 097</td>
<td>Part A: Atlanta, GA; Nashville, TN; Rochester, NY; Seattle, WA. Part B: Birmingham, AL; San Francisco, CA.</td>
</tr>
<tr>
<td>HVTN 098</td>
<td>Sites not yet determined.</td>
</tr>
<tr>
<td>HVTN 095</td>
<td>Part A: All current South African sites, plus several new South African sites. Part B: All active US sites qualify.</td>
</tr>
<tr>
<td>HVTN 092</td>
<td>All active HVTN sites qualify</td>
</tr>
</tbody>
</table>

**Product Abbreviations and Descriptions, Continued:**

**Helpful terms for understanding vaccine products:**

**Definitions from hvtn.org/resources/glossary.html**

- **Adjuvant** - a substance that may be included in a vaccine to improve the body’s ability to fight disease or infection.
- **Vector** - a bacterium or virus that does not cause disease in humans and is used in genetically engineered vaccines to transport genes coding for antigens into the body to induce an immune response.
- **Clade** - a subtype or strain of HIV. Different HIV clades exist in various regions of the world.
- **Recombinant** - an organism whose genome contains integrated genetic material from a different organism. Also used in relation to compounds produced by laboratory or industrial cultures of genetically engineered living cells. Recombinant compounds often are altered versions of naturally occurring substances.
- **Recombinant vaccine** - vaccine that uses genetic material from a disease-causing organism to produce an immune response. For instance, an HIV recombinant vector vaccine uses a vector (a weakened virus or bacterium) to transport genetic material from man-made HIV proteins into the body.
current HVTN trial sites. Additionally we spent time learning from the work of Masikhulisane (the community engagement arm of SAAVI, the South African AIDS Vaccine Initiative) which has been a leader in HIV vaccine research-related community engagement in South Africa for many years.

Site expansion

There will be two tracks of HIV vaccine trials occurring in South Africa over the next several years: research and licensure (also called “development”). In addition to the three trial sites that the HVTN currently works with in South Africa — Desmond Tutu HIV Foundation (DTHF) in Cape Town, Perinatal HIV Research Unit (PHRU) in Soweto near Johannesburg, and the Aurum Institute in Klerksdorp — these two tracks will necessitate expanding the network by more than 20 new sites, predominantly in South Africa, and also in a handful of other countries in southern Africa. (See June 2012 CAB Bulletin “On the road to vaccine licensure…”)

The communities where HVTN currently has trial sites are very well informed and engaged, thanks to the tireless work of the site staff and CABs in those areas. However, our network will be venturing into new communities. These communities may potentially be aware of the importance of clinical research and are likely very aware of the tragedies of the HIV epidemic. However, they may not be as informed about HIV vaccine research, since it has not been previously conducted in their areas. This is where we hope to build upon the expertise of our current sites and CABs.

At PHRU, we attended a meeting of the full CAB and had a rich discussion about the relationship between traditional healing and clinical research. Traditional healers in South Africa are community leaders and their voice is well respected by their communities. We learned from the CAB that further opening the channels of communication between clinical researchers and traditional healers will be an important part of HVTN site expansion community engagement work to help support mutual respect and understanding between these groups.

In Cape Town, we also met with the full CAB at DTHF. This CAB is large and diverse, with members who have been on the CAB for many years as well as new members who are excited and engaged in the work of this group. They had a lively discussion about events they have been planning as well as some CAB structural issues. Seeing how the various CABs are structured and address issues is important to our expansion work as it provides relevant models for how new CABs could conduct their work.

Our final site visit was to the Aurum Institute, where we met with the Executive Committee of their CAB. They gave a beautiful presentation on the events they organized as well as on the challenges they encounter. For example, they have found that many “people are interested in HIV testing and jobs, not the (educational) message conveyed.” These observations along with many others provided us great insight into the obstacles that HVTN will face in the coming years engaging communities for HIV vaccine research.

Over the course of three weeks in South Africa, we attended these three CAB meetings and two excellent Masikhulisane workshops. At each one, we gathered key information that will form the basis of our community engagement work in southern Africa.

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Dr. Fuller’s presentation focused on communication skills to enhance the participant’s experience in the research clinic. She noted that many transgender people have had unpleasant experiences in dealing with the medical community. Examples range from providers and staff who show disrespect by not using a patient’s preferred name or pronoun, to providers who conduct unnecessary genital exams. Clinicians must recognize that there may be unspoken barriers to overcome as they build a relationship with a transgender participant. She noted the importance of not making assumptions, and of asking questions about current gender identity, preferred pronouns, and how the individual would like to be addressed. She also noted the importance of making sure that all clinic staff, not just clinicians, use the preferred name and the appropriate pronoun of the participant.

Dr. Gromko provided an overview on the basics of transgender care, including hormone therapy for both MTF* and FTM* individuals, and common surgeries that some individuals choose to undergo as part of their gender transition.* (*See glossary below) These include facial feminization surgery, breast augmentation (MTF) or chest surgery (FTM) (also known as “top surgery”) and other procedures. She noted that many transgender individuals do not choose to have gender reassignment (“bottom”) surgery, because of the risks involved and/or the cost (not often covered by insurance). Some people may choose to use a range of biomedical interventions in their transition, while others do not choose to use any at all. It is important to not assume that all transgender people wish to use hormones or wish to have surgery. Rather, one should acknowledge the path of transition that each individual determines for themselves.

Many of the workshop attendees noted that the speakers were very knowledgeable and their presentations were very informative, really helping the audience to understand the basics of clinical care for transgender people. Others appreciated the helpful tips and real-world experience shared by both the presenters and the other workshop attendees during the question and answer period. It was clear that the workshop met the needs of many clinicians who have limited experience working with transgender people, and the comments on the workshop evaluations provided great suggestions for follow-up trainings.

In addition to the presentations, workshop materials included a myth-busting fact sheet, a resource list including recommended websites and videos, a bibliography of journal articles and research summaries, and a glossary (see below). Complete materials and the speakers’ slides are posted online: hvtn.org/meeting/oct2012.html.

TRANSGENDER GLOSSARY OF TERMS

MALE-TO-FEMALE (MTF OR M2F):
A person whose sex assigned at birth was male, and who lives, presents or transitions to female. Another term for this is Transwoman. These individuals are likely to prefer use of female pronouns: she, her, hers.

TRANSITION:
The process of medically, legally and socially changing from one gender to another. Transition may or may not include the use of medical treatment or surgery to change a person’s anatomy. This decision is unique to each individual.

FEMALE-TO-MALE (FTM OR F2M):
A person whose sex assigned at birth was female, and who lives, presents or transitions to male. Another term for this is Transman. These individuals are likely to prefer use of male pronouns: he, him, his.

MTF, FTM, and transsexual are terms that typically refer to individuals who subscribe to the gender binary of “woman vs. man” or “she vs. he,” regardless of whether the individual chooses to undergo medical treatment or surgical procedures.

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Transgender training continues
South African CABS

The only “experts” on community engagement are people who live and work in those communities. With this in mind, we explained to each group that our expansion will not succeed without their participation and support. We will be relying on their expertise to directly guide our creation of messages, materials and trainings.

There are many measures by which a vaccine trial may be considered a success. One measure is looking at how well the products “worked” in developing an immune response or preventing HIV infections. However, this is not the sole measure of success. In part, each trial is considered “successful” if the communities it was conducted in are more informed and invested in HIV vaccine research than they were before the trial. This community investment is an achievement the HVTN cannot reach without our CABs. Beyond South Africa, each CAB member throughout our network is an expert on the needs and perspectives of his or her community, and that is knowledge that can sometimes be transferred to other contexts.

We will ask all HVTN CABs to be a part of the South African expansion by sharing their knowledge with us and with new CABs as they join the Network to continue to ensure that sites are doing everything they can to engage, educate and support their communities in the vaccine research process.

Send suggestions, questions, and article submissions for the CAB Bulletin to:

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www.infinitytranslations.com

Missed an Issue?
View past issues of the CAB Bulletin at www.hvtn.org/community/bulletin.html. No password required!

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 them from a community perspective. Community input is invaluable to community education efforts, as well as to the development of this bulletin.

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

GLOBAL GCAB CALL*
2nd Thurs of every month
_Thurs., January 10th: 8 a.m. PT/11 a.m. ET_
_Thurs., February 14th: 8 a.m. PT/11 a.m. ET_

SPANISH LANGUAGE CAB CALL
3rd Thurs of odd months
_Thurs., January 17th: 9 a.m. PT/12 p.m. ET_
_Thurs., March 21st: 9 a.m. PT/12 p.m. ET_

SCIENTIFIC WORKING GROUP CALL
1st Fri of every month
_Fri., January 4th: 8 a.m. PT/11 a.m. ET_
_Fri., February 1st: 8 a.m. PT/11 a.m. ET_

AFRICAN REGIONAL CAB CALL
3rd Thurs of even months
_Thurs., February 21st: 9 a.m. PT/7 p.m. RSA_
_Thurs., April 18th: 9 a.m. PT/7 p.m. RSA_

*Please note that the GCAB call is only open to GCAB representatives and alternates at each site. All other CAB calls are open to any and all CAB members.