A message from Dr. Jim Kublin, HVTN Director

The HVTN has undergone major shifts over the years. In 2006, we projected that by 2010 there would be at least 15,000 people enrolled in HVTN studies. The Community Relations and Education Unit (CEU) grew at this time to support this volume of recruitment and education at the sites. The Legacy Project (LP) was established the same year to provide a focused effort on changing attitudes and awareness of HIV vaccine research among the African American and Latino communities in the United States. It made sense for the Legacy Project to operate as a separate unit so that it had the focus it needed without being overwhelmed by the rest of the community work.

Our path forward changed dramatically in 2007 with the Step Study results. The subsequent shift in our scientific agenda created a need for operational changes at Core for a variety of groups, including the CEU. The LP and CEU have now been consolidated into a single unit under the leadership of Steven Wakefield. Unfortunately this meant the loss of Enid Moore. We thank Enid for her contributions over the past two and a half years as the Associate Director of the CEU and wish her well in her future endeavors.

I am grateful that Wakefield has agreed to assume this leadership. He established the concept of community education for HVTN. He has relationships throughout the world with a wide variety of HIV researchers, advocacy groups and community-based organizations. He has the respect of all of our collaborators.

I look forward to working with Wakefield and with you as we continue our efforts to engage communities around the world in working to find a vaccine and helping to end the AIDS epidemic.

Sincerely,
Jim Kublin

Welcome ARA and VRC

Two new sites have joined the HVTN for HVTN 505: the AIDS Research Alliance (ARA) of Los Angeles (LA) California and the Vaccine Research Center (VRC) of Bethesda, Maryland (Washington DC metro area).

The VRC (developers of the vaccine being used in HVTN 505) first started conducting clinical trials in 2001 and is part of the National Institute of Allergy and Infectious Diseases (NIAID). The CAB engaged by the VRC (the Capitol Area Vaccine Effort or CAVE) was formed almost seven years ago to serve HIV vaccine trial sites in the metro DC area.

Continues on page 5
Dedication Defines the Dominican Republic CAB

Written by Community Education Coordinator Lic. Hoisex Gomez with input from the CAB,
Translation from Spanish to English by Genevieve Meyer

“If I have time, I use it to educate others, so that they may prevent HIV, so that they may support and respect those who live with HIV, or simply so that they can collaborate in the search for a vaccine against this virus. This gives meaning to our lives.” Gustav Weise, CAB Coordinator

**Commitment** is the word that defines the work of each member of the Dominican Republic CAB at the Vaccine and Research Unit (La Unidad de Vacunas e Investigación de República Dominicana). Their efforts range from educating the public about the HIV pandemic, modifying false beliefs and cultural practices that limit the prevention of new infections, to developing respectful attitudes and support for those living with this virus and to motivate people to collaborate in HIV vaccine research as a volunteer or an activist.

**Respect** is the common value that has allowed for collaboration amongst these 17 people of different ages, educational levels, political leanings, life experience and social commitments. Each institution represented on the CAB works with specific populations or political institutions and responds to a broad range of societal needs. The nine institutions include:

- Movement of United Women (MODEMU) - advocates for the rights of commercial sex workers.
- Colleagues Living with HIV (COVIH) - a collective of former sex workers living with HIV who care for each other and offer support to other people living with HIV/AIDS.
- Solidarity Program with HIV in the Gospel (PROSOLIDARIDAD) - brings together non-Roman Catholic Christian denominations committed to the fight against HIV/AIDS.
- Life Program - an HIV prevention program that works with teens and youth of ecclesiastical groups.
- Foundation of Young Catholics (FUNJOCA) - works with youth in the Catholic Church so that they develop an ongoing commitment and national response to the HIV pandemic.
- The Dominican College of Bio-analysts (CODOBIO) - involved with training clinical lab professionals about HIV themes and vaccines.
- The Dominican College of Lawyers - leverages their legal expertise to safeguard and guarantee the rights of research volunteers.
- Education Sector - works in adult education in the formal system.
- Volunteers in Vaccines - represents volunteers who participate in different research protocols and who guarantee that ethical guidelines are followed throughout the process.

For two hours each month, the joy and passion of each of these members creates an atmosphere of warmth, commitment and positive energy. The diversity of perspectives, disagreement and agreement all enrich the quality of the tasks to which they have committed themselves.

Photos, clockwise from top left:
1. CAB member Eduviges Cuello was recognized by the Secretary of the State for Youth for her contribution to HIV vaccine activism.
2. CAB member Gustav Weise leading a discussion on HIV vaccines with a neighborhood group

Continues on page 8
HVTN 505 Launches in US

Community Engagement Events
Kaijson Noilmar

Fall is nearly upon us in the north and the HVTN 505 sites are now in full swing with recruitment, and enrollment. Prior to opening the trial, the HVTN Community Engagement Team (CET), a collaboration of the Community Education Unit, the Communications Unit and the Legacy Project, worked diligently to create a strategic community engagement plan focusing on building partnerships and relationships with individuals and organizations in the U.S. cities where HVTN 505 will take place.

The plan calls for hosting a community event, such as a town hall meeting or community forum, at each trial site. Preparing such an event is no small task. First there is an initial planning call with the site staff and their key collaborators and HVTN Core, followed by further meetings with key partners to develop a shared vision for outreach and implementation of the event. The local NHVREI* partners and staff from the CET both lend support to the planning efforts.

The first site to conduct a community event was the University of Pennsylvania, which worked closely with the Colours Organization and other key organizations in the area to host a community forum. This well-attended event packed Ms. Tootsie’s Restaurant and Bar with a diverse mix of attendees. One of the most exciting surprises of the event was the number of young people who attended. Lawrence Frazier, the Community Coordinator of the Colours Organization, said he looked forward to “exploring other ways to create conversations and actions across communities.” Boston, Rochester, Los Angeles and San Francisco will be the next sites to hold community events.

With only a few events completed, the HVTN, sites and stakeholder partners have already learned that when they come together to develop a shared vision, the result is often greater than the event alone. The shared vision then helps to develop strong and long-lasting relationships that help guide this important work to create better informed communities and greater support to participants who play such a critical role in the quest for an effective HIV vaccine.

*NHVREI, which stands for NIAID HIV Vaccine Research Education Initiative, contributes funding to local organizations that partner with the U.S. clinical trial sites to support their outreach and community education. NIAID is the National Institute of Allergy and Infectious Diseases part of the National Institutes of Health, which supports the HVTN through a cooperative agreement.

HVTN 505 Launch Party in Boston
Jim Maynard

To celebrate the launch of HVTN 505, the Fenway site organized a party on Friday, June 26th at Fran’s Place, a large gay club in Lynn, MA on the North shore of Boston. Recruitment Coordinator Coco Alinsug hired a dance troupe, provided Chinese food, and even gave away a door prize. Through Coco’s recruitment efforts, the club was packed. Overall it was a great event and staff were able to schedule multiple screening appointments for 505.

Recruiting Communities for HVTN 505
Genevieve Meyer

Over the weekend of July 10-12, nearly 40 recruiters met in Chicago, Illinois for a workshop designed to hone their outreach skills for HVTN 505 recruitment. Session themes ranged from the science of HVTN 505 and how the vaccines differ from the vaccine in Step, to hands-on and peer-led sessions to prepare recruiters for the variety of questions and situations that might come up in the field. There were role-plays, an Internet training, a training on interpersonal skills, one on retention strategies, a session on working with transwomen and even a practice outreach activity in the Boys Town neighborhood of Chicago. Presentations, handouts and resource articles from the workshop are available on the HVTN member website:

http://www.hvtn.org/members/groups/ce/meeting/

To learn more about HVTN 505, please visit our official website for the study: www.hopetakesaction.org
HIV Vaccine Awareness Day (HVAD) May 18, 2009

Durban, SA
Students at Wiggins Secondary School were presented with a certificate by the CAPRISA site in Durban for their participation in an HIV vaccine research seminar. An award was given to the student who did the most research on HIV vaccines and general vaccine studies. Approximately 1300 students, 200 parents and 36 teachers attended.

Cape Town, SA
The Emavundleni site in Cape Town organized a Fun Walk to raise awareness for HIV prevention. Nearly 200 people including key stakeholders from over 20 regional community-based organizations attended. The site distributed trophies to the 1st, 2nd and 3rd place winners and t-shirts to the first 50 winners of the walk. All participants were treated to a snack pack with fruit, juice, chips and chocolate. To follow-up from the walk, the community educators sent ‘Thank you’ notes to the organizations that participated, which included an invitation to consider partnering with the site on future projects.

Kingston
The Epidemiology Research and Training Unit in Kingston recognized HVAD 2009 by hosting a seminar for members of the CAB and ethics committee. There were also representatives from the Kingston & St. Andrew Health Department, the Comprehensive Health Centre, as well as a media representative. The seminar included presentations on: Recruitment, Education and Retention process in Jamaica; the role of the CAB; Male Circumcision: Is it Relevant in Today’s World?; HIV vaccine concepts implemented to date and results. In the photo above, co-investigator Dr. Jacqueline Duncan explains different HIV vaccine designs.

Pretoria
This year for HVAD, the Medunsa site in Pretoria hosted more than 200 CAB members and local stakeholders from NGOs, schools and the greater community for an afternoon of music and performances by local entertainers, delivering messages about HIV vaccines, research and development. The goal of the event was to promote the urgent need for a vaccine to prevent HIV and AIDS and also to acknowledge and thank the thousands of volunteers, community members, health professionals, supporters and scientists who are working together to create such a vaccine. After a presentation on HIV/AIDS and vaccine education, people were encouraged to become partners with the researchers through community involvement or trial participation. The event was very successful in that many people expressed interest in participating in an upcoming study.
Gay Pride Celebrations

On Sunday evening, June 14th Fenway Health helped to sponsor one of the Boston Black Pride events during Pride Weekend. The Spyce Pool Party and Barbeque drew some 50 people to an evening of fun in the water, featuring a great DJ and a mouth-watering barbeque. Further adding to the excitement of the event, one lucky guest got to take home an iPod Shuffle as a door prize provided by the Fenway site. Later that weekend the site staff attended the Stuart Street Block party that drew hundreds of MSM to a day of fun in the “almost sun” of Boston.

Below: Legacy Project Coordinator Katjison Noilmar (blue shirt) chatting with a community member during Fenway’s Pool Party

Birmingham

On Saturday June 13th, staff & CAB members at the University of Alabama site participated in the Pride Parade in Birmingham, Alabama. Many CAB, staff, and community members contributed their time and talent to help create a float for the parade that provided lights, music and entertainment to a crowd of nearly 2000 people. This event provided the site with the opportunity to display our banners for the Hope Takes Action campaign, launching our 505 recruitment and increasing our visibility within the community.

ARA and VRC  

continued from page 1

It currently has ten members and is being revitalized with returning and new members for HVTN 505. Learn more at www.vrc.nih.gov

AIDS Research Alliance has twenty years of experience conducting HIV/AIDS clinical trials in both HIV-infected and HIV-uninfected populations. Their current studies range from the Step Study rollover (HVTN 504), to a trial looking at the effects of pomegranate juice on quality of life in HIV-infected individuals. Their CAB was recently reactivated with new and returning members and will serve as the CAB for HVTN 505. As of July the CAB had eight members; half veterans and half newcomers. You can learn more about their work by visiting www.aidsresearch.org

These are both very experienced sites with a great deal of knowledge and skill to share with the network and we welcome both ARA and VRC and their CABs to the HVTN!

Los Angeles

Staff and volunteers from ARA and Being Alive took to the streets of West Hollywood in LA for HVAD. Holding signs, passing out “I Support HIV Vaccine Research” stickers and soliciting honks from drivers supporting our cause, the ARA launched its vaccine awareness campaign with a bang.
Iquitos and São Paulo Examine UNAIDS & AVAC’s Good Participatory Practice Guidelines

By Genevieve Meyer

In November of 2007 UNAIDS and the AIDS Vaccine Advocacy Coalition (AVAC) published a document entitled “Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials” (GPP) which “are guidelines designed to provide systematic guidance on the roles and responsibilities of trial sponsors and trial implementers towards participants and their communities.” The creators of the GPP intended it to be a “living” document, open to ongoing discussion and evaluation. In June 2008, AVAC awarded 12 grants to community organizations and clinical sites around the world to conduct in-depth Community Consultations (CC) to discuss the document and generate ideas around its implementation. In May of 2009, once all 12 groups had conducted their CC, they met in Johannesburg, South Africa to discuss their respective results. Currently AVAC is working to review, analyze and synthesize the results into one comprehensive report, due out later this year. In the meantime, the Sao Paulo and Iquitos sites would like to share a preview of their findings.

The Iquitos Experience
By Dr. Martin Casapia, PI, Dr. Juan Carlos Hinojosa & Lucia Ruiz, Community Educators

Last November the Asociación Civil Selva Amazónica in Iquitos, Peru invited more than 100 community members join their CC. The community members, which included some members of the CAB, comprised six groups: commercial sex workers, men who have sex with men (MSM), health workers, the general public, people living with HIV and representatives from local NGOs (non-governmental organizations).

Overall, the participants felt that the GPP guidelines were a very useful tool, especially to help investigators better understand how to integrate community participation in all areas of biomedical HIV prevention studies. The group also suggested the document be revised to:

- Use clear, simple, non-technical language throughout;
- Include figures and flowcharts;
- Be accessible to people of all education levels;
- Combine parts I and II into one section. Currently both parts address issues of implementation of the guidelines;
- Take into account the cultural diversity within the various community groups.

Finally, once the guidelines are in broad circulation, the group recommended developing social science research studies to evaluate the experiences of using the guidelines in the field. They felt that dissemination of this information would help strengthen connections between research institutions and community members in order to reach the many diverse populations who play an essential role in clinical trials.

The São Paulo Experience
By Gabriela Calazans, Community Educator

Last September, CAB members from São Paulo and Rio de Janeiro, members of the Brazilian National HIV/AIDS Vaccines Technical Advisory Committee, vaccine advocacy organizations, and coordinators of the São Paulo State AIDS NGO Forum gathered for a CC, developed by the São Paulo HIV Vaccine Trials Unit in partnership with a Brazilian AIDS NGO called GIV (Grupo de Incentivo à Vida).

During the two day meeting, the GPP document was discussed at length. In general, the group felt the guidelines presented a good model for systematizing participatory practices in clinical trials. They also suggested that because guidelines for good participatory practice seem so universal, that they should also be applied to AIDS treatment and care research, as well as other health issues. They also recommended that the Brazilian branch of UNAIDS formally disseminate the GPP guidelines to the Brazilian Commission on Research Ethics (CONEP), local Ethics Committees, all the committees connected with the Brazilian Program on STDs and AIDS, and the Brazilian Vaccine Committee, with particular focus on Brazilian AIDS activists and clinical researchers. The group further advocated for the support and creation of a Brazilian document establishing local guidelines and regulations on participatory practices. Several suggestions for modifications to the current version of the GPP also came out of the consultation. These included:

- Modifying the language of CABs “acting as ambassadors”. The Brazilian advocates were concerned the word ambassador might easily be interpreted to mean that CAB members must always positively promote vaccine research.
New Protocols Under Development

By Genevieve Meyer

We’ve been busy! Since January of 2009, numerous protocols have gone through the interdisciplinary face-to-face development process and are now progressing through DAIDS, FDA, and local regulatory reviews. The table below shows many of the HVTN studies that are in the works.

<table>
<thead>
<tr>
<th>Trial number</th>
<th>About the Study (participating sites)</th>
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<tbody>
<tr>
<td>HVTN 080</td>
<td>This study which tests a Univ. of Pennsylvania DNA vaccine (also used in HVTN 070) will evaluate whether the body responds to the product better when administered with electroporation than with standard injection methods. <em>(Philadelphia, Nashville, Rochester)</em></td>
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<tr>
<td>HVTN 082</td>
<td>This study compares immune responses in identical twins to those of fraternal twins to determine how much host genetics influence immune responses using VRC’s DNA &amp; rAd5 regimen (used in HVTN 204 and 505). <em>(Brigham, Fenway, Seattle, San Francisco)</em></td>
</tr>
<tr>
<td>HVTN 083</td>
<td>This study tests partially overlapping env genes (heterologous inserts) from clade A and B, in different prime/boost combinations of VRC’s rAd5 and rAd35 vectors (heterologous vectors) to see if immune responses can be targeted to specific pieces of HIV that are present in a broad range of HIV strains and to see if a better type or magnitude of T cell response can be elicited. <em>(Sites to be announced)</em></td>
</tr>
<tr>
<td>HVTN 084</td>
<td>This study examining antigenic competition, is designed to see if T cell responses to different HIV proteins compete with each other. It will evaluate whether the body responds differently to the Gag-Pol fusion protein when Env is present or absent in VRC’s rAd5 vaccines. <em>(Sites to be announced)</em></td>
</tr>
<tr>
<td>HVTN 085</td>
<td>This study will examine whether giving different vaccine components in different locations on the body can improve responses over giving the entire vaccine in one location using VRC’s rAd5 vaccines. <em>(Sites to be announced)</em></td>
</tr>
<tr>
<td>HVTN 908</td>
<td>This companion study to HVTN 205 will look at innate immune responses; participants in 205 will be asked to co-enroll in this study, which involves extra blood draws at early time-points following vaccination. <em>(Seattle, Birmingham, San Francisco)</em></td>
</tr>
<tr>
<td>HVTN 910</td>
<td>This study provides post-study HIV testing for participants with vaccine-induced antibodies from their participation in a HVTN vaccine trial. <em>(All sites)</em></td>
</tr>
<tr>
<td>Ancillary Study - HVTN 503 Partners</td>
<td>This prospective ancillary study to HVTN 503 will assess the feasibility of recruiting partners of vaccine trial participants for other future studies that address topics such as secondary transmission. <em>(All Phambili sites)</em></td>
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Good Participatory Practice Guidelines continued from previous page

However, the role of CAB members is to be a link between the community and the site, a role in which they should feel comfortable openly expressing any concerns about a trial or about HIV research in general.

- Discussing the idea of whether a community is even interested in participating in a particular trial. The guidelines as they are currently written assume that communities would always want to participate.
- Recognizing that one positive outcome of the application of the GPP is that a community might decide not to support a trial, especially if it does not meet local interests and demands, or if the sponsor does not support the investigator with community engagement.
- Combining the principles of “shared responsibility” and “participatory management” into a principle of “reciprocity” which takes into account a balanced commitment on the part of the researcher and of the broader community.
- Revising the Portuguese translation of the GPP, which in its current form is not useable.

At the last HVTN Conference in May, 2009, these recommendations were presented to the Community Educators and Recruiters and discussed in the context of whether and how to use the guidelines to evaluate practices of the HVTN.

If you or your CAB would like to learn more about the development of the GPP Guidelines and the twelve groups who led CCs, visit AVAC’s website [http://www.avac.org/gpp.htm](http://www.avac.org/gpp.htm)
**Perseverance**, flexibility and creativity are all qualities that distinguish their work and strengthen the connection between community and the research team. These qualities are ever present when they go into neighborhoods with a computer, a projector and a bed-sheet as a make-shift screen to conduct “community conversations,” offer conferences in the universities or professional unions, bring the theme of vaccines to social forums, or accompany the principal investigator to radio, television, and press events.

**Dedication** to shaping and polishing themselves in their roles has been key to success with this group. Whether they are spending hours reading trial-related documents or participating in workshops, conferences and retreats, they are opening themselves to new ideas. The old members take time to educate the new members and take them under their wing.

To fight for a future without new HIV infections is to believe that only the alliance between a pro-active community and the respectful commitment of professionals and scientists of the HVTN is what will pave the way for an HIV vaccine.

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**Announcements**

**CAB Conference Calls**

*If you are interested in joining one of these calls, please email Genevieve Meyer (gmeyer@hvtncab.org)*

- **Global GCAB call**
  - *First Monday of every month*
  - September 7th, 8 a.m. PT/11 a.m. ET
  - October 5th, 8 a.m. PT/11 a.m. ET
  - November 2nd, 8 a.m. PT/11 a.m. ET

- **Global Ethics Working Group call**
  - *First Monday of every month*
  - September 7th, 9 a.m. PT/12 p.m. ET
  - October 5th, 9 a.m. PT/12 p.m. ET
  - November 2nd, 9 a.m. PT/12 p.m. ET

- **CAB Scientific Working Group call**
  - *First Friday of every month*
  - August 7th, 8 a.m. PT/11 a.m. ET
  - September 4th, 8 a.m. PT/11 a.m. ET
  - October 2nd, 8 a.m. PT/11 a.m. ET

- **French Language CAB call**
  - *Second Monday of every month*
  - September 14th, 9 a.m. PT/12 p.m. ET
  - October 12th, 9 a.m. PT/12 p.m. ET

- **Spanish Language CAB call**
  - *Second Wednesday of every month*
  - September 9th, 9 a.m. PT/12 p.m. ET
  - October 7th, 9 a.m. PT/12 p.m. ET

- **U.S. National HIV/AIDS Awareness Days**
  - Sept. 18 - National HIV/AIDS and Aging Day
  - Sept. 27 - National Gay Men’s HIV/AIDS Day
  - Oct. 15 - National Latino AIDS Awareness Day

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**To everyone who gave input and helped put this bulletin together:** Gail Broder, Carrie Schonwald, Sarah Alexander, Steve Wakefield, Erik Schwab, Malkah Duprix, Carter Bentley, Cecilia Morgan, Margaret Wecker & Lori Miller at AVAC.

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**Translation of the CAB Bulletin from English into Spanish and French by Infinity Translation Services.**

[www.infinitytranslations.com](http://www.infinitytranslations.com)

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**Send suggestions, questions, and article submissions for the CAB Bulletin to:** Genevieve Meyer, editor.

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HVTN/FHCRC, 1100 Fairview Avenue North, LE-500 PO Box 19024 Seattle, WA 98109-1024

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**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.

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**About CABs**

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