

The CAB Bulletin

HIV Vaccines and the Community



HIV VACCINE
TRIALS NETWORK

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Seven New Sites Take On HVTN 505!

It's official: 7 new sites will join the Network to add capacity for recruitment for HVTN 505. We have learned that recruitment is most effective when it involves one-on-one face-time between potential participants and recruiters.

Therefore, to expand on the valiant efforts of our current HVTN 505 sites, we are now delighted to welcome CARE-ID in Annandale, Virginia; Case Western Reserve in Cleveland, Ohio; University of Texas Southwestern in Dallas, Texas; University of Colorado Health Science in Denver, Colorado; Baylor University in Houston, Texas; New York University in New York City; and Orlando Immunology Center in Orlando, Florida to the HVTN 505 family.

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Annandale, Virginia

The Clinical Alliance for Research and Education of Infectious Diseases (CARE-ID), founded in 1980, is located in Annandale just outside of Washington, DC. The founders and current co-PIs are Drs. David Wheeler and Donald Poretz. The majority of the clinical trials held at CARE-ID are HIV related, though numerous trials have also been conducted on malaria, herpes zoster, and other sexually transmitted diseases such as human papilloma virus. Vian Yousify and Tiriq Craig will be the primary staff working on community education and recruitment. The site is also hiring an additional recruiter.

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Expansion Sites Immersed into HVTN 505

by Carrie Schonwald, Community Education Unit

On July 29th and 30th, the Community Education Unit at Core gathered a group of 22 staff involved in community education and/or recruitment and CAB members from the HVTN 505 expansion sites for a very full training. The goal of the training was to bring the new sites to a point where they were ready to embark on the adventure of educating and recruiting for HVTN 505 in their communities. One challenge to preparing the new sites for this trial is that while all of the new sites are clinical research sites, most of them have not conducted vaccine trials and several of them have never been part of a DAIDS network, though others have already been an ACTG or other network site for some time. The same is true for CAB involvement: some sites have

active CABs while others are just forming one.

During the training, we covered topics such as an overview of 505, recruitment, how to track data, VISP (vaccine-induced seropositivity), and discussed race and ethnicity in vaccine research. In addition to Community Education Unit staff and other Core staff presenting on fundamental topics, we had wonderful guest speakers. Gavin Morrow-Hall, Community Educator



CAB members and community education & recruitment staff in Seattle for a two-day workshop on HVTN 505.

from the San Francisco site, spoke about his experience as a recruiter and educator and shared some hard-earned wisdom with his new colleagues. We also had a

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News from the International AIDS Conference in Vienna, July 18-23, 2010

By Gail Broder of the Community Education Unit

My time at the International AIDS Conference began with a pre-conference workshop for young and early career investigators regarding the UNAIDS Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials. The workshop was organized by AVAC, the Global HIV Vaccine Enterprise, OCTAVE, and UNAIDS. The attendees included several HVTN colleagues who work with communities, including Gabriela Calazans from Sao Paulo, Udom Likhitwonnawut from Chiang Mai, Rosario Leon from Lima, and Jennifer Sarche from San Francisco. The workshop included interactive case studies about experiences of current research like the iPrEx study on pre-exposure prophylaxis (PrEP). The group also discussed next steps, such as how to get the GPP guidelines to be a requirement for research conduct, similar to Good Clinical Practice or Human Subjects Protection training.

The next day, I attended a session hosted by the AIDS Vaccine Enterprise held at the Messe Wien Conference Center, which hosted more than 19,000 AIDS 2010 conference attendees. During the session we heard from a range of speakers, including vaccine researchers, collaborators, and community members, about "The Search for an HIV Vaccine: Where are we, where are we going, and how can we get there faster?" I was inspired by some of the leaders in prevention research, such as Jose Esparza, Senior Advisor on HIV Vaccines at the Bill & Melinda Gates Foundation, who reminded us that "We do science not for the sake of science, but for the people who need an HIV vaccine." Peter Piot (the former head of UNAIDS and current Director of the London School of Hygiene & Tropical Medicine) told us that the world was ready for a "game-changer," and that had to be an HIV vaccine. In the first panel discussion, Dr. Robin Shattock of St. George's Hospital Medical School at the University of London noted that future vaccine trials will need to look carefully at synergy with other prevention methods and address the larger prevention issues. Alan Bernstein, the director of the Enterprise, concluded this discussion by noting that "Trials cannot and will not be successful without significant engagement of communities, and researchers must acknowledge the centrality of communities to the research environment." Gabriela Calazans, community educator from the HVTN clinical trials site in Sao Paulo, Brazil, joined the second panel to talk about the way forward for research, the importance of community engagement and the need for implementation of the GPP guidelines.

The opening ceremony of the conference featured a full lineup of dignitaries, and included the first of many protests throughout the week. Activists called for nations



Jennifer Sarche, Director of Community Programs from the San Francisco site, facilitating a discussion on AVAC's Good Participatory Practice Guidelines.



"Condomize" one of the many prevention campaigns displayed at the Global Village.

to fulfill their funding commitments to the Global Fund for AIDS, Tuberculosis and Malaria, and featured slogans like "Broken Promises Kill" and "No U-turn: Fund the Fund." Marchers advocating for the rights of sex workers and other women carried red umbrellas and distributed buttons saying "Only rights can stop the wrongs." These human rights themes were reiterated loudly throughout the week, as various groups pointed out the challenges experienced by drug users in Eastern Europe and Central Asia, men who have sex with men around the world, those living with HIV and co-infected with TB, and youth. The Vienna Declaration is one example of this demand for human rights, calling for a shift to evidence-based interventions for drug users instead of plans based on ideology. (People are welcome to read and sign on to the Vienna Declaration at <http://www.viennadeclaration.com/>.) On Tuesday evening, July 20, there was a human rights march through the streets of Vienna, filled with banners and slogans from all of these groups and more, not to mention the sounds of drums, South African horns called *vhuvhuzelas*, whistles, and thousands of voices. The march concluded symbolically in Heroes Square, surrounded by the beautiful Hofburg Palace, where singer Annie Lennox gave a concert for the assembled crowd.

Another theme throughout the week was a new understanding that HIV treatment drugs can work toward prevention in two distinct ways. One way is for an HIV negative person to take HIV treatment drugs to prevent HIV acquisition (such as the idea behind PrEP, currently being studied). In addition, there is now

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Three New Phase 1 Studies Under Development, Two Others Open in the Field

HVTN 088 This June, HVTN 088 went through the face-to-face meeting process and is now moving through the DAIDS review process. HVTN 088 seeks to re-enroll participants from HVTN 049 who received envelope sub-unit protein vaccines given with MF59 adjuvant, and give them a boost vaccination with a Novartis clade C gp140 protein vaccine product with the same adjuvant.

HVTN 089 uses a VRC Adenovirus 5 product and will study innate immunity in female participants. The study involves in-patient blood draws hourly for 24 hours following vaccination in order to perform multiple immune response tests. HVTN 089 is scheduled for submission to DAIDS in early October.

HVTN 090 is a phase 1 study of a vaccine developed by Profectus. It uses Vesicular Stomatitis Virus (VSV) as the vaccine vector. This is a first-in-humans study that will establish the safety and the maximum tolerated dose of the vaccine. Pending the outcome of HVTN 090, the HVTN plans to give the VSV vaccine as a boost to participants in HVTN 087, which gives a DNA vaccine made by Profectus as the prime. HVTN 090 will go through the face-to-face process in early September.

HVTN 503 Ancillary study, called siPhambili, meaning “we are moving ahead” in Xhosa, opened in mid-August at the HVTN sites in Klerksdorp, Soweto and Cape Town. This study will enroll the partners of participants from HVTN 503 (the Phambili study). siPhambili is designed to assess the feasibility of recruiting partners of individuals who are enrolled in vaccine trials, as preparation for development of future partner-augmented studies such as secondary transmission studies.

HVTN 205 recently underwent a complete protocol amendment and has now reopened in the U.S. This phase 2 study, which involves GeoVax DNA and MVA, now includes an additional trial arm in which participants will receive an MVA prime and MVA boost. The protocol amendment also included the updated DAIDS low-risk eligibility criteria.

To read more about studies in the field and under development, check out the March 2010 CAB Bulletin: <http://www.hvtn.org/community/bulletins/Q12010.pdf>

The News from Vienna continued from page 2

evidence that an HIV positive person taking ART will reduce the amount of virus in his or her body and be less likely to spread the disease to a partner. Several scientists presented data showing the benefits of initiating ART earlier, including for those who are co-infected with TB or who use intravenous drugs. Michel Sidibé, Director of UNAIDS, noted that “Treatment works for the three P’s: the Patient, the People, and the Pocket.” This was reinforced by the rapporteurs on the final day of the conference, who noted data showing the health benefits of providing ART to drug users and to those who are co-infected with TB, as well as the decrease in transmission rates from these infected individuals to others.

Like past AIDS Conferences, this one was full of information sharing, networking, learning and fun. The Global Village was alive with presentations, movies, performers, rallies, artwork, and informal gatherings. The needs of deaf and blind communities were acknowledged this year, with the inclusion of sign language interpretation for many sessions. Thousands of posters were displayed, including two from the HVTN which highlighted the work of the Legacy Project and one which explained our model for training recruiters for HVTN 505.

By far the most exciting event of the week was the presentation of the data from CAPRISA 004. The husband-and-wife team of Drs. Salim and Quarraisha



Gail Broder standing in front of an HVTN poster “Training Recruiters for Preventive HIV Vaccine Trials”

Abdool Karim presented the results of their landmark trial of a vaginal microbicide gel containing 1% Tenofovir. They announced that the study had reduced the number of HIV infections among women at high risk by 39%, which was statistically significant at $p=.017$ (anything less than .05 is considered significant). This announcement resulted in an extended standing ovation and applause. Also exciting was news that use of the gel was associated with a reduction in new infections of Type 2 Herpes (HSV-2) by 51%. Another way to understand the results is to think about the things that were not observed: there was no Tenofovir drug resistance, there was no increase in side effects overall, there were no safety concerns among participants who became pregnant, and there was no increase in risk behaviors while participants were using the gel. Additional studies will be needed to determine if the gel can be used by other populations and in other parts of the world, or if the gel can be used

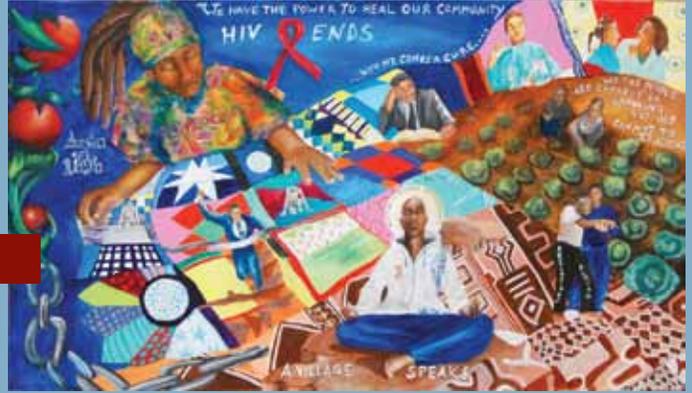
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HIV Vaccine Awareness Day- May 18th Around the Globe

Chicago



Kuumba Kids, an African dance performance ensemble showing their moves at Chicago's HVAD event.



In honor of HVAD in Chicago, artists, residents, and politicians gathered for a ceremony to dedicate a 15 x 30 feet community mural entitled "Austin is Doing Something" (A.I.D.S.) designed by M. Carla Carr. The mural will be the centerpiece of a planned community garden.

Cape Town



The Desmond Tutu HIV Foundation in Cape Town conducted a community drive in collaboration with its CAB to promote HIV prevention. They also distributed condoms and information flyers on HIV prevention research information.



On July 5th, Cape Town CAB member Nombeko Mpongo took part in the annual South African AIDS Artist Awareness Concert. She was one of three openly HIV positive women who performed a short play based on their real life experiences of living with HIV.

Nashville



Local drag performer Nicole proudly wearing a Vanderbilt T-shirt honoring the 1000 volunteers who have participated in HIV vaccine studies at their site during an HVAD event at PLAY Dance Bar, in collaboration with Nashville Cares, a local AIDS Service Organization.

Klerksdorp



The KOSH site in Klerksdorp commemorated in the spirit of the World Cup which was only 3 days away.

Nashville



Vanderbilt's prominently displayed billboard, honoring and inviting vaccine volunteers, was visible to everyone attending the Gay Pride after-parties.

San Francisco



Left: "What Will it Take to Find an HIV Vaccine? People like you."

Below: The HIV Research Section at the SF Dept of Public Health celebrates Gay Pride 2010 with friends, free underwear, and healthy information.



GAY PRIDE ACROSS THE US

Boston

Right: The "Humpa Loompas" of Fenway Health out during the Pride parade.

Below: Boston's first HVTN float debuted at 2010 Pride with the help of MTV's *The Real World- Brooklyn* reality TV star Herman Scott acting as Fenway's Celebrity Marshall.



Birmingham

Birmingham staff along with CAB members participated in Pride festivities by teaming up with the Magic City Sisters of Perpetual Indulgence. UAB captured the title of Best Float with "Together we can... create a world without HIV."

The National HIV/AIDS Strategy Arrives

by Mark Hubbard, Nashville CAB member

Editor's note: On July 13th, Mark Hubbard had the opportunity to visit the White House and hear President Obama discuss the new National HIV/AIDS Strategy. This article is an adaptation of a blog entry that Mark wrote for the blog Lifelube (<http://bit.ly/9d9qmb>) following that experience. Lifelube is a U.S.-based advocacy website targeting men who have sex with men. The opinions expressed here do not necessarily reflect those of the HVTN.

*"Vision: The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination." **

On Tuesday, July 13, 2010, the Obama administration began what many advocates would consider to be atonement for mortal sins perpetrated by every other presidential administration since AIDS was first recognized. I was honored to be one of many individuals from the community present. A blueprint for addressing the domestic epidemic, the new National HIV/AIDS Strategy outlines challenges faced, steps to be taken, and five-year goals in a reasonably comprehensive and detailed manner. That day, a line from "Jeffrey" (an off-broadway musical and movie romance about two men in a sero-discordant relationship) came to mind and I thought, "this historic action cannot reverse the losses created by years of inaction, neglect, distraction, and dogma (vs. science)-driven policy, but it is the *opposite* of those losses."

Promises made by the administration during the election and at last August's National HIV Prevention Conference have been kept. A healthcare reform bill was passed, the travel entry ban was lifted, and the community was consulted. Most importantly, a National HIV/AIDS Strategy is now a matter of public record. The goals are straightforward: we must reduce new HIV infections, increase access to care and optimize health outcomes for persons living with HIV, reduce HIV-related health disparities, and achieve a more coordinated national response to the epidemic in the US.

I view the documents as brilliant — they're grounded in current data and science, the administration appointed the right people from within our midst to lead their development, and most importantly, they have the community as co-authors and editors. There is some tiptoeing (particularly the notable lack of mention of anything anal or rectal) but they speak plainly about controversial issues. Stigma and social justice are given their due. One activist reported crying in response to the unabashed use of the phrases "gay and bisexual men," "condoms," and "syringe exchange"; another remarked,



Nashville CAB member Mark Hubbard with Jeff Crowley, Director of the Office of National AIDS Policy and Senior Advisor on Disability Policy at the White House



Mark Hubbard at the National HIV/AIDS Strategy press conference with President Obama speaking in the background.

"after 30 years we've finally become a grown-up, adult nation."

When I had the chance, I shook President Obama's hand, looked him in the eye, and simply said, "Thank you." Having grassroots community attend these events made a profound statement to me implying: We couldn't have and can't do this without all of you. That's the point; it's also the challenge. We have a blueprint, but remodeling has just begun. We'll continue to face political and financial challenges. We must better address other aspects of the epidemic more specifically, especially research.

*"...safe and effective vaccines and microbicides are not yet available and investments in research to produce safe and effective vaccines and microbicides must continue." **

Perhaps the next conversation should involve creating a succinct National HIV/AIDS Research Agenda. Based on the Office of National AIDS Policy's (ONAP) contention that prevention resources must be targeted to address disparities and to help the most affected communities, such an agenda must address the failure to equitably fund anorectal-focused research. It must commit to an infusion of resources that will bring our scientific knowledge of the rectal compartment, lubricants commonly used for anal sex, anorectal transmission, and new rectal-specific prevention technologies into parity with our knowledge of the vaginal compartment, products, transmission, and technologies.

* National HIV/AIDS Strategy Information can be found at www.whitehouse.gov/ONAP and www.nationalaidsstrategy.org.

Expansion Sites Immersed into HVTN 505 *continued from page 1*

profound presentation by Aidan Key, a female-to-male transgender man, who spoke in great depth about his work in the transgender community and his personal experiences as a transgender man.

By the end of two days, there was definitely mixed emotion in the room on the part of the workshop participants: excitement at being a part of discovering an HIV vaccine, but also anxious about the hurdles to come. However, we at Core finished the training feeling very excited about the skills, enthusiasm, sensitivity and energy of all of these new additions to the HVTN and to the HIV vaccine effort. We know that the combination of current 505 sites with the infusion of new sites will make outreach around the country an

education and recruitment force to be reckoned with. Welcome aboard, new sites!



Carrie Schonwald of the Community Education Unit leading a discussion on the informed consent process.

Seven New Sites Take On HVTN 505! *continued from page 1*

Cleveland, Ohio

The site at Case Western Reserve University has a successful history of working with the AIDS Clinical Trials Group (ACTG) on treatment trials, and recently began working with the Microbicide Trials Network (MTN) on microbicide trials as well. The site is under the leadership of Dr. Michael Lederman and co-investigator Dr. Benigno Rodriguez. Bob Bucklew is the manager of community outreach efforts and supports the CAB, and at this writing the site was working to add additional recruiters to the team.

Dallas, Texas

Founded in January 2000, the University of Texas (UT) Southwestern HIV/AIDS Research Unit has years of experience conducting HIV clinical research through the ACTG and pharmaceutical studies. This will be the first clinical prevention study for the site, led by investigator Dr. Mamta Jain and clinical research manager Tianna Petersen. Also joining the team is recruiter Chris Miklos, study coordinator and counselor Jesse Tarbutton, and a long-established CAB.

Denver, Colorado

Located at the University of Colorado Health Science Denver campus, the Denver site was active during the Step Study and continues to be a top recruiting site for the ACTG. Headed by Principal Investigator Dr. Tom Campbell since 2004, and clinic coordinator Graham Ray since 1990, the team caring for HVTN 505 participants is very experienced. Dan Eide was recently hired to lead the community education and recruitment efforts. This site already has a CAB and looks forward to incorporating vaccine research into its agenda.

Houston, Texas

Baylor University is home to the new site in Houston, led by Dr. Hana El Sahli. This site has experience working as a Vaccine and Treatment Evaluation Unit (VTEU) with NIAID's Division of Microbiology and Infectious Diseases, and was part of last year's effort to test the H1N1 flu vaccine. Janet Wells will be the community educator, and the site is working to form a CAB. At this writing, the site was interviewing for recruiters to add to the team.

New York, New York

The Men's Sexual Health Project (M*SHP), run by the Bellevue Hospital Center and New York University (NYU) School of Medicine, is under the direction of Dr. Demetre Daskalakis. M*SHP has a long history of conducting epidemiologic and clinical research among patrons of commercial sex venues, as well as immunologic and treatment studies (as an ACTG site) with persons who have acute and early HIV infections. Richard Silvera and Michael Ramos will be conducting the majority of community education and recruitment efforts for HVTN 505. The site has a well-established CAB to support its work on HVTN 505.

Orlando, Florida

Orlando Immunology Center (OIC) has a long history as an independent immunology clinic, serving patients with a range of medical needs. Led by Dr. Edwin DeJesus, OIC is starting its first collaboration with NIAID and the Division of AIDS by joining HVTN 505. Saul Leon will be facilitating the newly formed CAB and will assume community educator and study coordinator responsibilities, Keith Barsky will be their primary recruiter.

rectally as well as vaginally. My favorite quote to sum up the mood of the crowd came from Sheena McCormack of the British Medical Research Council, who noted that while the vaccine results from Thailand had given everyone a warm glow, these CAPRISA 004 results were like a hot flash!

Attention is now turning to the planning of the AIDS 2012 conference in Washington DC, the first time the meeting will be in the US since the San Francisco conference in 1990. While the US is to be credited for lifting its travel ban against HIV-infected people, thus allowing the conference to return to the US, you can bet

that this meeting in the nation's capitol in a presidential election year will heighten the political news surrounding the conference. Who knows what the scientific news of the day will be in 2012, but I know we all look forward to that next achievement, that next step that brings us closer to the end of this epidemic.

For more information on the conference, or to view abstracts, visit: <http://www.aids2010.org/>

For more information on CAPRISA 004, visit <http://bit.ly/bfwfE7> or <http://www.avac.org/ht/a/GetDocumentAction/i/29403>

Send suggestions, questions, and articles submissions for the CAB

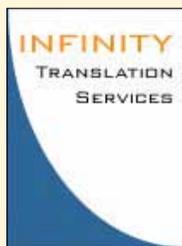
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About CABs

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

HVTN Conference, November 15-17, 2010 Seattle, Washington

CAB Conference Calls

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

Global GCAB call *Thurs., Oct. 14th, 8 a.m. PT/11 a.m. ET*
Second Thursday of every month *November call will be rescheduled*

Global Ethics Working Group call *Tues., Oct. 5th, 9 a.m. PT/12 p.m. ET*
First Tuesday of every month *Tues., Nov. 2nd, 9 a.m. PT/12 p.m. ET*

CAB Scientific Working Group Call *Fri., Oct. 1st, 8 a.m. PT/11 a.m. ET*
First Friday of every month *Fri., Nov. 5th, 8 a.m. PT/11 a.m. ET*

French Language CAB call *Wed., Oct. 13th, 9 a.m. PT/12 p.m. ET*
Second Wednesday of even months *Wed., Dec. 8th, 9 a.m. PT/12 p.m. ET*

Spanish Language CAB call *Thurs., Sept. 16th, 9 a.m. PT/12 p.m. ET*
Third Thursday of odd months *Thurs., Nov. 18th, 9 a.m. PT/12 p.m. ET*

African Regional CAB call *Thurs., Oct. 21st, 9 a.m. PT/12 p.m. ET*
Third Thursday of even months *Thurs., Dec. 16th, 9 a.m. PT/12 p.m. ET*