

The CAB Bulletin

HIV Vaccines and the Community



HIV VACCINE
TRIALS NETWORK

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My First Time

By Dino Martino,
Orlando, FL CAB member.

With nervous excitement I accepted the offer to attend my first HVTN conference. As a member of the newly formed CAB in Orlando, this was another “first time” opportunity in a series of events that I have had the pleasure to be a part of in support of the work of the HVTN.

As a pharmacist for nearly two decades, scientific conferences are not new to me; still, each one brings a new prospect for growth both professionally and personally. So with wide eyes and an open mind I stepped into the first of many meetings that would enlighten me, give me pause, and challenge me. HVTN for First Timers on the first morning was a great primer for what lay ahead. In addition to learning more about the structure of the HVTN, I enjoyed learning from the questions and concerns voiced by other attendees. While barely comprehending the concepts and complex science being presented during the plenary sessions, I could not help but revel in the creativity and genius of those presenting. It’s one thing to learn about research in journals, but

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Orlando CAB member, Dino Martino.

Planning for PrEP

By Genevieve Meyer, HVTN Community Education Unit

On November 23rd, 2010, the results of the iPrEx study were released. The 2,499-person study demonstrated that a daily dose of oral Truvada®, (a combination of two antiretroviral medications, emtricitabine and tenofovir) could reduce new infections of HIV in gay men, transwomen and other men who have sex with men (MSM) by an average of 43.8%. The HVTN salutes the sponsors, study team, and volunteers in the 11 sites throughout Brazil, Ecuador, Peru, South Africa, Thailand and the United States who contributed to this study’s success.

The results of the iPrEx study have added increased vigor to the HVTN’s search for a safe and effective HIV vaccine. One central question being asked at the HVTN right now is what these results mean for participants in HVTN 505, a study which is also enrolling MSM and transwomen who are at risk of contracting HIV.

The Network has set up a working group to solicit feedback from community stakeholders about possible changes to HVTN 505 based on the iPrEx results. This process will initially involve a series of conference calls, to be completed by late

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Engaging Transgender Women

By Michele Andrasik¹, Annet Davis-Vogel², Marcus Bolton³, Borris Powell⁴, Gail Broder¹, Erica Avant³, Aamina Morrison² and Kevin T. Jones². 1. HVTN Core 2. University of Pennsylvania 3. Emory University, Hope Clinic 4. HANC Legacy Project

The U.S. Community Session at the HVTN November Conference focused on increasing understanding and knowledge about reaching out to and engaging male to female transgender individuals. The workshop began with opening remarks by Borris Powell of the Legacy Project who provided an overview of why community engagement with consciousness is essential for recruitment. His remarks were followed by in-depth presentations of engagement models currently used by two HVTN 505 sites.

Erica Avant and Marcus Bolton from the Emory University Hope Clinic (Atlanta) presented their model, which illustrates the effectiveness of hiring a transgender staff person, building strong relationships with community leaders and providing regular cultural competence trainings for site staff. Marcus explained the

Clinic’s engagement model and stressed the importance of building relationships with other community-based organizations (CBOs) and

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Aamina Morrison of TIPS in Philadelphia speaking on the diversity of the transgender community.

Planning for PrEP *continued from page 1*

December, 2010. Groups both inside and outside the network are being solicited for feedback and include CAB members, Community Educators and Recruiters, Network personnel and NHVREI partners. On a local level, sites are soliciting input from participants about what the iPrEx results mean to them. Updates to this feedback process will be available on the HVTN website at: <http://www.hvtn.org/community/iprex.html>.

More immediately, HVTN sites were provided with a letter for distribution to HVTN 505 participants notifying them of the iPrEx study results. The letter included resources about the study, who to call locally if they had questions, and a reminder that they would be re-contacted if any changes were made to 505.

Some people may ask why the HVTN is paying so much attention to the results of a trial testing a non-vaccine method of HIV prevention. One reason is that the Network has an ethical obligation to provide the best proven standards of prevention to participants, as they become available. In this case, Truvada, commonly used to treat HIV, is already a licensed product and widely available on the market. Because of the positive findings in the iPrEx study, the HVTN 505 protocol team has to assess new considerations. For example, does the study need to be modified at all to account for individuals who wish to enroll in 505 and report having taken Truvada in the recent past? Currently they would be excluded from enrolling.

The HVTN 505 protocol team will be working hard over the next few months to consider all of the possible implications for interactions of pre-exposure prophylaxis (PrEP) and vaccines. Yet the entire field of HIV prevention has many more questions to address.

The findings from the iPrEx study show effectiveness in reducing HIV infection in MSM and transwomen. But more studies are needed to evaluate the effectiveness of PrEP in other populations such as women, injection drug users (IDU) and heterosexual men, not to mention studying the long-term effects of taking the medication as prevention, and addressing questions about adherence and cost.

Participants in the iPrEx study were counseled that the effect of PrEP as prevention was unknown and to protect themselves using other risk reduction methods. Will adherence improve once participants know that the product is effective? If adherence improves, will it increase the overall effectiveness? Finally, who will pay for this medication? A monthly supply of Truvada for HIV treatment for someone without comprehensive insurance can reach US \$1400. The

cost of this medication alone is yet another reason why finding an effective HIV vaccine remains at the forefront of biomedical HIV prevention efforts, and why the mission of the HVTN remains as important as ever.

To stay up to date on HVTN activities, visit our website, www.hvtn.org, or by follow us on Twitter @HelpEndHIV.

Additional Resources:

To learn more about the iPrEx study, visit- <http://www.niaid.nih.gov/news/newsreleases/Pages/default.aspx>; www.globaliprex.net <http://www.youtube.com/watch?v=wrdfwzTl-Oc>.

For information about how these results affect the HIV prevention field, go to the AVAC website at <http://www.avac.org/ht/d/sp/i/3619/pid/3619>.

What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an experimental approach to HIV prevention where HIV treatment drugs are given to HIV uninfected persons to try to protect against infection.

My First Time *continued from page 1*



Keith Barsky, recruiter at the new Orlando site with longtime Chicago CAB member, Dave Crawford.

to hear first-hand from the scientists themselves is a true treat. Attending the iPrEx session and seeing some preliminary data just days before the results were released was surreal.

Apart from the wealth of information presented about studies currently underway at the HVTN, probably the most constructive feature of the conference was the interaction and networking with the other attendees. The General Community Session was one of the highlights of the conference for me. This diverse group of Com-

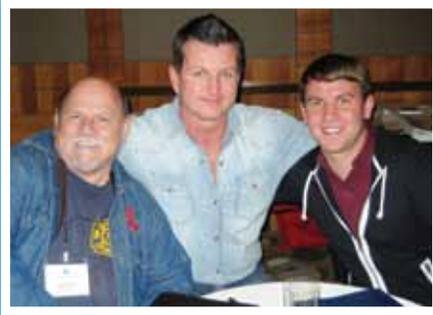
munity Educators, CAB Members and NHVREI partners was inspirational. It was quite possible to have someone from South America seated on your left and someone from South Africa on your right. The knowledge and experience of this dedicated group of individuals was immeasurable. Here, I was given the ability to build on the success of others, and the wisdom to avoid and overcome the hurdles they faced.

I ended my time at the conference with one powerful and positive

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HVTN Conference

From left to right:
Butch McKay,
Jim Higginbotham
and Edward Todd
of the Birmingham
site.



(l) Chia Thach
(CAB) and
(r) Kingdom
Mufhandu (CER)
of Rochester
with Alejandra
Diaz of the New
York CAB.



A captive audience
during the General
Community Session.



Iquitos staff and
CAB members are
all smiles between
sessions at this
year's HVTN
conference.



From left to right: Seattle CAB
members Lisa White and Victoria
Chinnell with Boston-Fenway
educator Jim Maynard.



GCAB co-chair Phineas Malahlela (left)
with Michael Hodge (right), educator
from New York.



Chip Lohner of the newly
formed Dallas CAB.

November 15-17, 2010, Seattle, Washington

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observation. There was no difference in the level of enthusiasm and commitment from the people I was surrounded by. Whether they were neophytes like me or veterans participating in CABs for over 10

years, everyone shared the same passion. It was with this passion that I returned to Florida with ideas to further engage the community about HVTN 505: dispelling misconceptions and advising the site about finding

volunteers to participate in trials to find a safe and effective HIV vaccine and to put an end to this disease.

Dino Martino joined the newly formed Orlando CAB in September 2010.

nourishing those relationships over time. Erica discussed the importance of having a transgender advocate on staff at the site to ensure that the transgender community has a representative who will make certain that their needs are addressed. She noted that for many transwomen, it can be a struggle just to survive from day to day. Therefore, addressing these needs by providing support, services, and education is paramount. The Hope clinic provides a range of services which include linkages to health care and social services, training for life (educational and vocational skill-building), and referrals for mental health services.

Aamina Morrison, Kevin Trimell Jones, and Annet Davis-Vogel from the Philadelphia site presented their model built on establishing a community partnership between the research site and the Trans-Health Information Program (TIPS). The Philadelphia site has fostered a strong relationship with TIPS, a local CBO serving the transgender community and staffed entirely by members of the transgender community. Aamina, the TIPS Health Education Coordinator, discussed the importance of being aware of the diversity within the transgender community and being

accepting of all identities. She stressed the importance of building relationships with the transgender community and specifically within the transwomen community, respecting and acknowledging that the transgender female identity is separate from the larger MSM or gay community identity. Aamina also discussed the importance of encouraging and respecting transgender women, and advocating that transgender women speak up and have a voice for themselves.

“Many transgender women wonder, ‘Why are you thinking about us now?’”

Michele Andrasik, the HVTN social scientist, provided a summary statement followed by a question and answer period moderated by Gail Broder of the Community Education Unit. During the Q & A, Aamina and Erica pointed out that the community of transgender women has been ignored and discounted for so long that there may be some resistance toward attempts to reach out because of mistrust and fear. Many transgender women wonder, “Why are you thinking about us now?” The women urged the audience to understand that the best way to engage transgender women is to truly care about what happens to them and to demonstrate this by listening, being present and building lasting relationships.

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

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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.

CAB Conference Calls

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

Global GCAB call
Second Thursday of every month

Thurs., Jan. 13th, 8 a.m. PT/11 a.m. ET
Thurs., Feb. 10th, 8 a.m. PT/11 a.m. ET

Global Ethics Working Group call
First Tuesday of every month

Tues., Jan. 4th, 9 a.m. PT/12 p.m. ET
Tues., Feb. 1st, 9 a.m. PT/12 p.m. ET

CAB Scientific Working Group Call
First Friday of every month

Fri., Jan. 7th, 8 a.m. PT/11 a.m. ET
Fri., Feb. 4th, 8 a.m. PT/11 a.m. ET

French Language CAB call
Second Wednesday of even months

Wed., Feb. 9th, 9 a.m. PT/12 p.m. ET
Wed., Apr. 13th, 9 a.m. PT/12 p.m. ET

Spanish Language CAB call
Third Thursday of odd months

Thurs., Jan. 20th, 9 a.m. PT/12 p.m. ET
Thurs., Mar. 17th, 9 a.m. PT/12 p.m. ET

African Regional CAB call
Third Thursday of even months

Thurs., Feb. 17th, 9 a.m. PT/12 p.m. ET
Thurs., Apr. 21st, 9 a.m. PT/12 p.m. ET