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# HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

Volume 1, Issue 1 August 2000

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## WELCOME

*Building relationships between the HVTN and Community*

**Steve Wakefield**

*Director of Community Education for the HVTN*

As we begin to iron out the details of our new network of vaccine trials sites, we want to ensure that a special commitment to community education is made early on in the process. This Bulletin is one of several tools we hope to develop in order to support the tasks of the Community Advisory Boards (CABs), who form a crucial link between the HIV Vaccine Trials Network (HVTN) and the community. The monthly issues of the Bulletin are designed to help keep a steady flow of information between all those involved in the massive effort to create an HIV vaccine. Our goal is to make this Bulletin the voice of the community-- an area where important information concerning vaccines and the community can be found. In order to do so, we need your input. We welcome, the members of the older established CABs as well as members from the newly developed ones to share with us the important community education information/ strategies and lessons learned from their site. ♦

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## The Alphabet Soup of the Old and New Networks

*Getting to know the HVTN and HPTN as they relate to the HIVNET and AVEG and continue to involve CABs*

Part of the mission of this Bulletin is to familiarize Community Advisory Board (CAB) members, and the community in general, with the networks that have been formed to help in the process of developing an HIV vaccine. Getting through the alphabet soup of acronyms can be a challenge, but a rewarding one at that. Grab a spoon and jump in!

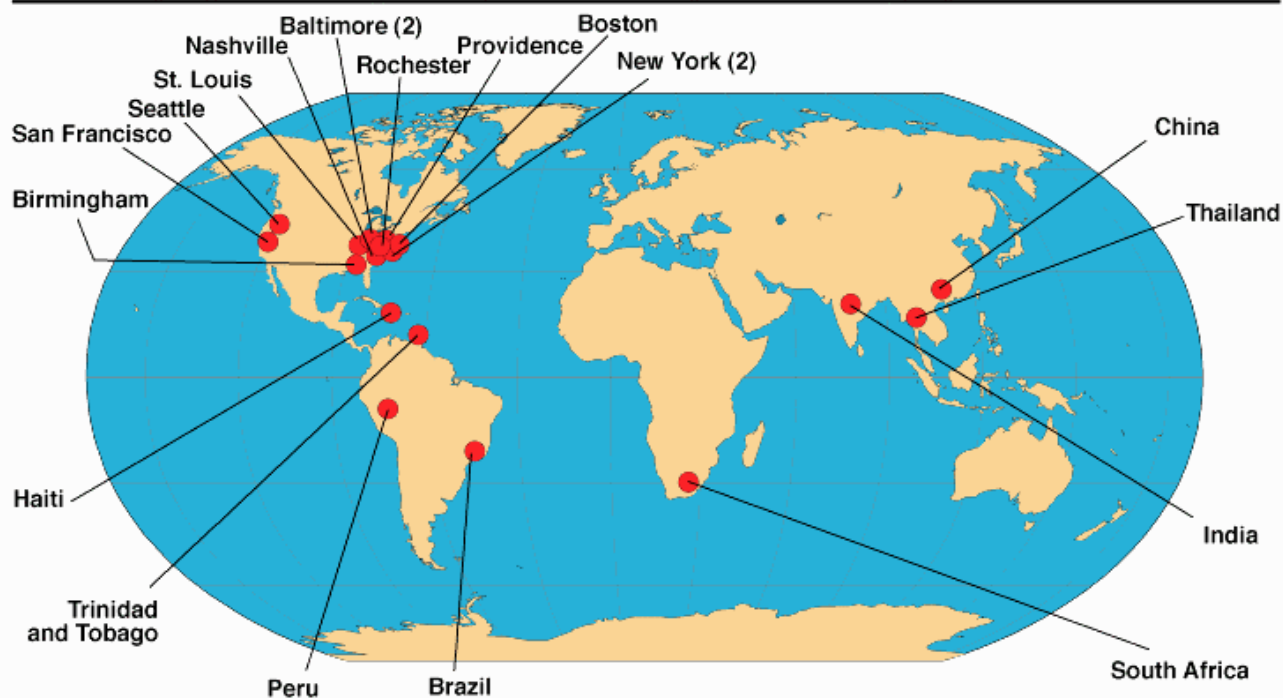
As governments, academia and the private industry get more involved in the search for an HIV vaccine, two networks, known as the HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN) have been developed to help coordinate the effort nationally and internationally. The HVTN is a newly established, clinically based network to develop and test preventive HIV vaccines. Both the HVTN and the HPTN build upon the findings and accomplishments of the AIDS Vaccine Evaluation Group (AVEG) and the HIV Network for Prevention Trials (HIVNET). AVEG carried out early stage testing of vaccine candidates while the HIVNET conducted trials of HIV vaccine and other prevention strategies such as perinatal, microbicides, barriers, STD's and behavioral interventions.

Funded by the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), the HVTN consists of several national and international clinical units (see map on pg. 2). These sites are coordinated by a Leadership Group that includes a Core Operations Center, the Statistical Center for HIV/AIDS Research and Prevention (SCHARP), and a Central Laboratory. The HVTN will conduct all phases of clinical trials including testing vaccine efficacy and evaluating candidate vaccines for safety and the ability to stimulate immune responses.

As the fight against HIV/AIDS continues, investigator-driven research is an important step in the search for a vaccine. With certain trials having already begun and others on their way, it is important, now more than ever, for people to get involved in the community education efforts.

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# NIAID HIV Vaccine Trials Network (HVTN) Domestic and International Sites



## Community Representatives for the HVTN Sites:

SITE	CAB REPRESENTATIVES
U. of Alabama	Debra Newman
Memorial and Miriam Hospital of Rhode Island	Stephanie Howie
Fenway Community Health	David Gray, Jon Jon Figueiroa
Johns Hopkins University	Hamilton Richardson, John Bunting, David Mariner, Rose McCullough
Trinidad and Tobago	Yolanda Simon (Staff)
South Africa	Janet Frohlich (Staff)
New York Blood Center	Denise Goodman (Staff)
U. of Rochester Medical Cntr	Nick Feraio, Bob Ingram
Brazil	Monica B. De Souza (Staff)
San Francisco Dept. of PH	William Snow, Darnell Durio
Seattle	Peter Emau, Janelle Thompson Carole Stock, Robb Akridge
St Louis U School of Med	Jim Thomas
Vanderbilt U. School of Med	Raphael Crawford
Haiti	Mireille Peck, MD (Staff)
At-large	Raymond Hulse
At-large	Tom Gibson
At-large	Allegra Cermak
At-large	Rosalind Porter

## Clinical Trials Update

I think you have all heard that we have delayed the start of any further canary pox studies until new higher titer lots of the vaccine have been produced. Aventis has been hard at work at this and it appears new lots for this study will be available this week – with a potential start date of September.

This puts the timeline for a Phase III trial into early 2002 – if the vaccine qualifies.

I think you know that we have initiated several discussions and processes regarding evaluating the ethical and local issues involving our proposed Phase III trial. It seems to me these are best done with the specifics of the protocol (at least in its initial drafts) available. As such we expect to reinstate these discussions in earnest in February of 2001 – when we have a better idea of whether the canarypox regimens will move forward.

Thank you for your support.

Lawrence Corey, M.D

*In future bulletins we will begin profiling a different HVTU CAB in every issue. Look for it here!*

## **DURBAN UPDATE**

*by Steve Wakefield*

By now many have forgotten that there was an "International AIDS Conference" this year. However, those of us who were fortunate enough to participate are still trying to find ways to convey the impact of this event. Others have used words like "pilgrimage", "epiphany" and "life-changing" to describe the first ever conference in a developing nation. For me, it was a return to unity between the scientists and community as we took time to broaden to a more global perspective of the epidemic. I look forward to updates next month from CAB representatives. I do want to share a few highlights that may have been missed by the media:

\* Nelson Mandela, who gave the closing speech said, "We need to break the silence, banish stigma and discrimination, and ensure total inclusiveness within the struggle against AIDS" as the conference summary.

\* An HIV Positive, openly Gay Supreme Court Justice delivered the first Jonathan Mann Memorial Lecture. It appropriately honored Dr. Mann's commitment to the link between human rights and health. South African Edwin Cameron's discussed his triple HAART (highly active antiretroviral therapy) that costs US \$4,800 annually; he noted "I exist as a living embodiment of the iniquity of drug availability and access in Africa... I am here because I can pay for life itself."

\* Dr. Anthony Fauci, MD, discussed very early experimental "structured treatment interruption" (STI) studies; the press missed his "don't try this yet" caution and admonition.

\* Prominent HIV Researcher Dr. David Ho pointed to a picture of an HIV virion and said, "This is the cause of AIDS." It was the first time I had ever seen an audience applaud HIV; Dr. Ho discussed the findings of several research groups that very low level HIV replication occurs even when HAART leads to an undetectable RNA viral load in blood plasma.

\* HVTN's Dr. Mauro Schechter from Brazil reviewed statistics that have serious implications for resource-poor countries; wider use of preventive antibiotics for AIDS opportunistic infections would likely lower worldwide death rates from AIDS. ♦

Community participation, including CABs, played an important role in the AVEG and HIVNET groups. Both local and national CABs have worked hard to ensure that the perspectives of the community, people at risk for HIV, and people targeted for recruitment as study participants are all included in the design and conduct of the studies. Composed of trial volunteers, family members, local prevention experts, health care workers, and community leaders, the CABs have provided advice on scientific and ethical matters regarding study design, recruitment, and protection of research subjects.

This participation will continue to be an important part of the new HPTN and HVTN. As Dr. Larry Corey, HVTN Principal Investigator, recently noted, "To achieve and maintain broad participation in the HVTN by community representatives from diverse constituencies, we must build on the work that was accomplished through local and national CABs..."

The development of an HIV vaccine will be a long and difficult process. Multiple efficacy trials may ultimately be required before a safe, effective and affordable vaccine is available for widespread public health use. New sites, new strategies, and the integration of sites which serve persons with diverse levels of risk for infection will not be easy. It will be possible, if all involved—scientists in industry and academia, community members, old and new network staff and NIAID staff---continue to work toward the same goal. ♦

## **The National Vaccine Communications Steering Group**

NIAID has convened a National HIV Vaccine Communications Steering Group (NVCSG) to stimulate and enhance the national dialogue concerning HIV preventive vaccines. The challenge of this group is to guide NIH's national communications strategy that builds a supportive and sustainable environment for HIV vaccine development. The NVCSG has determined its first messages will target those individuals and institutions which serve as information resources and social supports for those who might participate in large-scale clinical trials. Steve Wakefield will work with the group to ensure these efforts also facilitate recruitment and retention for HVTN trials.

Steering Group membership represents the diversity of communities affected by the AIDS pandemic and currently includes representation by leaders in fields such as communications, the media, social marketing, community education and organizing, health care, advocacy, public policy, and HIV prevention. We will have a chance at the October meeting to look at draft plans as well as discuss interaction with the network. ♦

## CALENDAR OF EVENTS

PROTOCOL WORKING GROUP CAB CONFERENCE CALL:

September 5<sup>th</sup>, 2000 7pm Est., October 3<sup>rd</sup>, 2000 7pm Est.

GLOBAL CAB CONFERENCE CALL:

September 14<sup>th</sup>, 2000 7pm Est, October 12<sup>th</sup>, 2000 7pm Est.

HVTN FULL GROUP MEETING OCTOBER 3-5, 2000

Renaissance Park 55 Hotel, San Francisco, California

(CAB specific events occur Oct 3<sup>rd</sup> and 4<sup>th</sup>)

THE UNITED STATES CONFERENCE ON AIDS

October 1-4, 2000 Atlanta, Georgia

NATIONAL AIDS TREATMENT ADVOCATES FORUM

(NATAF) November 9-12, 2000 Dallas, Texas

## The HVTN Community Education Plan

- Support strategies for developing education and ethical standards.
- Through collaboration and consultation:
  - \*ensure the ethical and scientific quality of proposed research
  - \* ensure relevance to the affected community
  - \* evaluate acceptance by the affected community
  - \* involve community representatives in design, development, implementation, and distribution of results
- Establish processes for arriving at standards and best practices at international, national and local levels. ♦

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*Please send suggestion, questions and article submissions to:*

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**HIV VACCINE  
TRIALS NETWORK**

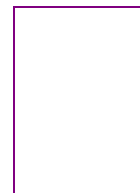
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