

HIV VACCINES AND THE COMMUNITY

The Community Advisory Board Bulletin

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NYC HVTU Sets Standard for Recruiting and Retaining Hard-To-Reach Women

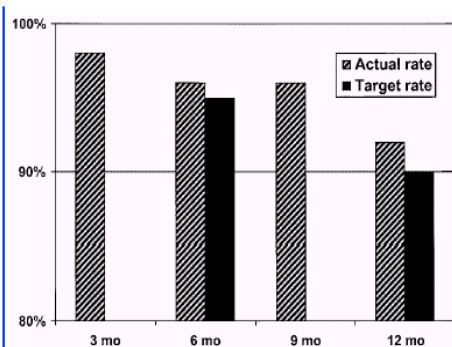
By Steve Wakefield, Director of Community Education

Project Achieve, profiled in this issue of the CAB Bulletin (see Page 3), has conducted HIV prevention research trials since 1993. Pamela Brown-Peterside and other members of the team were recently featured in a Field Action Report of the *American Journal of Public Health* (September 2001, Vol91, No. 9)

The women's site in South Bronx, New York City has long been a champion of including "hard-to-reach" populations in vaccine and prevention trials. The article in the *American Journal of Public Health* describes efforts that contributed to successful recruitment and retention of women in vaccine and vaccine preparedness trials.

The staff activities detailed in the article point out the importance of forming a relationship with cohort members and developing a flexible enough operating style to respond to the various issues faced by the women in the study. This is evident in their recruitment strategies, including street outreach, tabling in clinics and at health fairs, and using the advice of the CAB in developing and placement of flyers and advertisements. The staff also helped define appropriate linkages for women after counseling and testing. HIV-infected women were referred to primary care. HIV-uninfected women were referred for appropriate social services and, when appropriate, were given an opportunity to participate in trials that provided counseling, testing, male and female condoms, and other harm reduction supplies. Support for participants also took the form of a listening ear, a shoulder to cry on, and assistance in access to a range of services from housing to drug treatment to employment.

Ninety-two percent of women enrolled in the vaccine preparedness study remained in the study after one year.



Note. Contact at 3-month and 9-month time points occurred by phone or mail only.

FIGURE 1—Retention rates at each contact or visit (n=164): Project ACHIEVE, New York City, 1998.

American Journal of Public Health | September 2001, Vol 91, No. 9

Project Achieve is currently involved in two multi-site vaccine trials. At the time the article was submitted, the retention rate for the phase II trial was one hundred percent and ninety-five percent after twelve months for a phase III cohort.

The NYC HVTU experience challenges us to look at our trials and our Community Advisory Boards in a way which refutes many preconceived ideas about retention. With appropriate effort, women at high risk for HIV infection can contribute to the search for an HIV vaccine.

Our hats are off to the NYC HVTU and the women who recognize their rights and responsibilities! ☘

CONGRATULATIONS!

The Rio de Janeiro HVTU vaccinated their first participant in the HIVNET/HVTN 026 trial on November 5, 2001.



WORLD AIDS DAY, DECEMBER 1, 2001

VISIT WWW.UNAIDS.ORG

WORLD AIDS CAMPAIGN 2001

I care... do you?

"We must involve young people living with HIV/AIDS in the struggle against the epidemic. They, after all, know best what it means to live with AIDS."

Kofi Annan
Secretary General
of the United Nations

"Stop, listen and learn all you can about HIV/AIDS. Prevention and life - it's your choice!"

Joey DiPaolo, AIDS educator
living with HIV

UNAIDS

PROTOCOL 039: A CAB REPRESENTATIVE'S OVERVIEW & UPDATE

Paul O'Malley, Protocol 039 CAB Representative

After many months of planning, the HVTN is about to launch the Phase I Trial to evaluate the safety, tolerability and immunogenicity of high dose live recombinant Canarypox ALVAC-HIV vaccine (vCP1452) in healthy, HIV-1 uninfected adult participants. The plan is to enroll 30 study participants in the first month. Hopefully, the enrollment of 110 study participants will be completed in approximately 3-4 months. This timeline may be slightly extended due to holiday season associated delays, planned interruption for the interim analysis of safety/adverse events data, and competition for study participants with Protocol 041, which only administers one injection.

By late summer 2002, Day 182 or 6-month follow-up CTL immune response study data should be available for review and analysis. Protocol 203 - Day 182 CTL immune response study data will be available for analysis prior to this time. If Protocol 203 shows very robust CTL responses (50% or better) at the 6-month follow-up, then Protocol 039 will be less important and not crucial for the planned Phase III trial in 2002. However, that scenario is highly unlikely knowing the prior CTL immune response data with the Canarypox vaccine. If the Protocol 039 trial shows a robust CTL immune response and Protocol 203 does not, there is a real possibility that the Phase III trial will not go forward as currently planned.

Community Advisory Board input and involvement has been particularly important in the planning stage of this unique trial and will continue to be so as the trial progresses. This trial is unusual due to the large volume of the vaccine dose which requires two injections into the anterior thigh and because it is highly unlikely that the thigh will be used as the injection site in a subsequent Phase III trial. If this vaccine product is found to be a successful candidate for a Phase III trial, a reconfiguration of the vaccine would be required for an upper arm injection. This is necessary for practical purposes, an easier site of injection coupled with a smaller volume of vaccine will be required for vaccinating larger populations.

Given these factors and the potential for an increase in side effects especially at the injection site due to the volume of the vaccine dose, our protocol team still decided that the implementation of this safety and immune response trial should occur. The trial is necessary and very important for the further development of the Canarypox product as a potential candidate for a Phase III Efficacy trial.

My role as a CAB representative on this protocol is now in transition. During the planning stage as the laymen in a group of researchers, I believed my primary ethical and moral responsibility was to assist the

HVTN 039 – United States Trial at 11 HVTUs

Randomized, double-blind trial of safety, tolerability and immunogenicity. The results of this study are expected to determine if HIV-1 specific CD8+ T cell responses will increase when vaccinating with a higher dose.

Product: ALVAC-HIV (vCP1452) [Aventis Pasteur]

110 Participants – 60 persons one group, 40 persons another group and 10 persons in a placebo third group.

Participants: Healthy, HIV-uninfected men and women, 18-60 years of age (no more than 10% will be older than 50 years of age) at lower risk for HIV infection.

researchers in making sure that the study participants' informed consent process was truly informative and clear as to the potential risks and benefits of participating in this trial. The informed consent form and accompanying informational materials must reflect in a very straightforward and concise manner the more complex, detailed, and broader contents of the study protocol. The training of the health care providers and public health educators who will conduct and promote this trial was also of special concern during the planning phase. The accuracy, clarity, and consistency of the education materials, informed consent process, risk reduction counseling, procedures regarding the recognition and proper reporting of side effects, the broader community education and informational campaign etc., are crucial when multiple sites are conducting a trial.

Now that the trial is beginning, I believe that my role should also include assisting the HVTN in justifying the importance of this trial to the community, as well as monitor the trial as it progresses for compliance with the procedures, agreements, rules and regulations that were agreed upon during the planning phase. Finally, my continued role is to provide observations, give advice, and assistance when necessary to the research team, site staff, and local CABs as the need arises.

It has been a wonderful learning experience and a pleasure working with a group of very knowledgeable and dedicated researchers. I believe the team has a genuine desire to help humanity control the spread of HIV infection and to conduct highly ethical research. I felt that my input and extra "set of eyes" during the development and completion of this protocol was most welcome. I hope to give you a successful update on this trial later next year. ☘

Greetings from the New York City HVTU

By Denise Goodman, Community Relations Coordinator for the New York City HVTU and HPTU

As the song says, “If I can make it here, I’ll make it anywhere.” NYC is forever the land where dreams begin. Our city amazes us by its diversity, energy, and passion. The entire world thinks of NYC, especially since September 11, 2001. We want you to know that New Yorkers are still making it happen here and that our work at the HVTU continues to make significant inroads in the Big Apple HIV prevention effort.

We have a lot of HIV prevention work to do here. Though NYC contains only 3% of the United States’ population, it contains 16% of all U.S. AIDS cases. It is estimated that between 5,000 and 10,000 individuals are infected with HIV in NYC annually. (Source: The New York City HIV Prevention Plan, 2000, Volume 1). Our goal is to complement the efforts of existing HIV prevention programs and to engage the community in the work towards identifying an effective HIV vaccine. The HVTU faces many challenges to community education and recruitment. NYC is the largest city in the United States with approximately eight million residents. “NYC leads the nation in cultural diversity: 28% of the population is foreign born, and approximately 300 different languages are spoken in city homes.” (Source: *ibid.*) To do this work we rely on a strong foundation of talented staff, engaged community, and inspiring volunteers.

Staff

The NYC HVTU is a partnership between Columbia University and Project Achieve of the New York Blood Center with three trial sites in Manhattan and the Bronx. Our staff goes above and beyond to get the job done. Our office hours span from 8:00 am until 9:00 p.m. and we even offer Saturday appointments! Counselors and recruitment staff alike make house calls to contact volunteers and complete study visits. We pride ourselves on keeping retention high and paperwork errors low. All the while we keep our humanity up front, visible by the warm greetings and friendly rapport among staff and volunteers.

Community

Project Achieve has maintained a Community Advisory Board since 1994 and supported community relation efforts through a minimum of one full-time staff position since 1997. Since 2000, the CAB has served both the NYC HVTU and HPTU. There are 15 active CAB members, three of whom have been on the CAB for 5+ years. Our CAB members advise us on study implementation, recruitment, retention, and community education needs. Our CAB members have spoken internationally, nationally, and locally on community involvement in HIV vaccine research. As well, we are supported in our work by numerous community-based organizations including the NYC HIV Prevention Planning Group, Harlem United Community AIDS Program, and Community Research Initiative on AIDS. In so many ways

we’ve seen that an involved community makes for better research results.

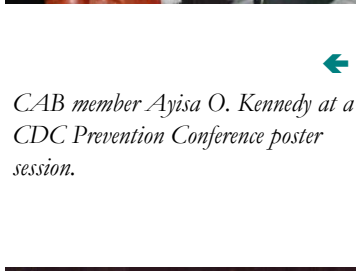
Volunteers

Our participants from our various prevention research studies now number over 1800 men and women and is diverse demographically, largely residing in either Manhattan (49%) or the Bronx (25%). Almost half of our participants are people of color – 24% African-American and 18% Latino and these numbers are in keeping with the demographic profile of the neighborhoods we serve. Forty-three percent of participants are under the age of 30, a population at increased risk of HIV infection. Several of our volunteers have progressed from study to study or gone on to work in the social service field.

So when you make it to the city that never sleeps, please come visit. Our staff, community, and volunteers welcome you. ☘



➔ Pictured left to right: John Sefakis, CAB member; Leab Strook, Clinician; and Bonnie Um, Regulatory Affairs Liaison.



← CAB member Ayisa O. Kennedy at a CDC Prevention Conference poster session.



➔ Michael Camacho, Recruitment Coordinator; Kent Curtis, Site Coordinator; Carolyn Booher, Office Coordinator.



← Denise Goodman, Community Educator and Beryl Koblin, Principal Investigator.



➔ CAB members Columbus Gaskins and Omosupe Jackson.



Global CAB Election

At the October 2001 HVTN Full Group Meeting in Seattle, the Global CAB (HVTN's community advisory board made up of representatives from each of the HVTU CABs) kicked off elections for new co-chairs. It was decided that Jim Thomas would remain in an advisory role to the co-chairs, leaving two leadership positions available. On the Global CAB conference call at the beginning of this month, the newly elected co-chairs were announced— Homero Gomes and Pete Delate.



Homero Alberto Gomes da Silva, Sao Paulo, Brazil



Peter B. Delate, Washington D.C., USA

Homero Gomes (Homero Alberto Gomes da Silva) is from the Centro de Referencia e Treinamento DST/AIDS CAB in Sao Paulo, Brazil. He is a law student specializing in International Law and Human Rights, and is a prodigious student of languages. Beyond his native language of Portuguese, Homero also speaks Spanish, English, and French. He has been an active volunteer with GAPA SP, the oldest AIDS organization in Brazil.

Pete Delate's local CAB is CAVE (Capital Area Vaccine Effort) in Washington, D.C. and while he is an HVTN representative from Johns Hopkins, the CAVE CAB members also represent other entities in the D.C. area such as the National Institutes of Health's new Vaccine Research Center. Pete has been a member of CAVE for just over 2 years.

During the day, Pete is in hospital administration working to establish compensation/human resources policies/programs for one of the largest hospitals in the Washington metro D.C. area—the Washington Hospital Center. In addition to working with AIDS Support Group (ASG) of central Virginia, an organization he helped establish, Pete volunteers with the NAMES Project (The AIDS Memorial Quilt). ☘

PROTOCOL REPRESENTATIVES NEEDED

CAB members are needed to serve on new protocol teams. We need 4 volunteers immediately and several in the first quarter of 2002. Attendees of last summer's CAB retreat should be able to provide some initial training on how-to-read a protocol. If you are ready to volunteer, contact Steve Wakefield for orientation and support. ☘

CALENDAR OF EVENTS



CAB PROTOCOL WORKING GROUP CONFERENCE CALL:
Saturday, December 8, 2001, 12 p.m. E.T./ 9 a.m. P.T.



GLOBAL CAB CONFERENCE CALL:
Thursday, December 13, 2001, 7 p.m. E.T./ 4 p.m. P.T.



COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:
Tuesday, December 18, 2001, 12 noon E.T./ 9 a.m. P.T.

HIV Prevention and Vaccine Conferences:

12TH INTERNATIONAL CONFERENCE ON AIDS AND STDs (AFRICA)
December 9–13, 2001, Ouagadougou, Burkina Faso

9TH CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS
February 24–28, 2002, Seattle, WA

2002 COMMUNITY PLANNING LEADERSHIP SUMMIT FOR HIV PREVENTION
March 6–9, 2002, Chicago, IL



14 January 2002: ABSTRACTS DEADLINE
1 February 2002: SCHOLARSHIPS DEADLINE
Visit www.aids2002.com for more conference details.

Please send suggestions, questions, and article submissions to:
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HIV VACCINE
TRIALS NETWORK