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Over the past few months, many community members have been involved in discussions about the next steps that the HIVTN will take. One of these discussions is around whether or not we will proceed with the Pave trial, but there have been many other important decisions to make as well. Hopefully, this issue of the CAB Bulletin will help draw a map for you of the many issues that are being considered, and the different ways in which the HIVTN’s work is shifting in response to the STEP trial data.

As I have sat in the many meetings that have been held recently, one thing that has impressed me is how often I have heard researchers bring up the important role that community will play over the coming year. Our CAB members are one of the HIVTN’s most valuable assets, and I hear appreciation for your efforts being echoed regularly. Many of you have worked to convey your opinions and questions on the recent PAVE-related calls and through written surveys and questions. We at Core will continue to reach out to all of you, and hope that you will continue to keep us aware of what is being discussed in your communities and in your CABs. Please know that we welcome emails, faxes, letters and phone calls at any time. We are also happy to hear from you through your Global CAB representative on the monthly calls. One of my jobs is to make sure that your voices are represented in discussions throughout our Network, and the more detail I hear about, the better I can do my job.

The scientific questions that the researchers are looking to unravel are complicated. Over the next few months, those of us in the Community Ed Unit here at Core, your Community Educators, and your PIs will be working to help try to explain the new trials, research projects, and discussions that are happening in the Network. We also have several ways in which you can learn more, if you are interested. We will periodically hold calls that will be open to all CAB members to share information. Your GCAB representative will be an excellent resource, and a list of all the GCAB representatives is on page 3. The Scientific Working Group is made up of CAB members who are interested in learning and discussing the science of the Network in more depth. If you are interested in ethical issues that the HIVTN is facing, consider joining a call with the Ethics Working Group, a group led by and mostly consisting of CAB members (although staff are welcome to join as well). Anyone is welcome to join either group, and more details on these calls are available on the last page of this and every Bulletin.

Thanks to all of you for your efforts and dedication,

Enid Moore, Associate Director of Community Education, HIVTN
Changes in perspective at the HVTN

Many of the true discoveries in science come not from hitting the bulls-eye exactly, but by stumbling over new and unexpected information. The results from the STEP Study were unexpected as well as disappointing and disturbing. The HVTN is now working to apply the resulting new perspectives to adjust our future work. There is optimism that the new perspectives and information we have learned will help move us another step further in the process of finding a vaccine against HIV.

Jim Kublin, the HVTN Director, has articulated the new challenges that the HVTN will be taking on. The HVTN is developing a revised list of key clinical research topics, many of which are outlined on page 3. As critical questions are becoming clear in the wake of the STEP Study, there is also an identified need to make changes to the infrastructure used for clinical trials. This will include new standard assays and a comprehensive platform that will enable possible vaccine candidates to be developed efficiently and with clear criteria for advancement. Finally, there will be more focus on the specific issues that will be answered through efficacy trials. Instead of focusing more broadly on possible efficacy, there will be additional detailed attention to issues such as conferred immunity, cofactors that might affect efficacy, and protection.

Traditionally, vaccine and other drug research has been done with a focus on the ultimate licensure of a product. While this remains our committed goal, it is clear that it will be helpful to ask a broader array of questions than we have asked in the past. In one sense, this is a small change, as the HVTN has always looked to the range of information that can be learned from a trial, and it has long been expected that all of our current trials will each only be a step in the direction of an effective vaccine. We have said all along that each trial is one piece of the puzzle. At the same time, for researchers there is a shift happening in how they are thinking about and structuring protocols, and as a part of this shift the HVTN has developed the catch-phrase “the excitement is in the science.” We have always said that the vaccine products may very well not work, and that it is likely that it will take several large-scale trials to find our way to an effective vaccine. Now, however, we need to work to put even more emphasis on the accumulation of information, and to make sure that people know that their participation in a trial is to advance science. We need to communicate that at this time there is little chance that the vaccines being tested will be the pot of gold at the end of the rainbow.

As we continue to look at how we can learn and grow, we will also be focusing on ways that we can learn more about the behavioral aspect of the research we do. We will continue to be looking for community input on our progress and intentions. We look forward to hearing your feedback as our work continues.

The 2008 HVTN Scientific Agenda

In light of what has already been learned from STEP and Phambili, the HVTN leadership has talked extensively about the need for an updated HVTN Scientific Agenda. Below is an outline of the new focus behind HVTN research.

To better understand the data from STEP and Phambili, and to use these data to help define and evaluate suggested improvements in T-cell based vaccines.

Statisticians and lab scientists continue to look over the data and participants’ samples from STEP and Phambili to understand more about what happened. On page 3, 6 and 7 of this Bulletin are more details about the ongoing studies and researchers’ questions. STEP and Phambili continue to be important studies, as the information that is being gathered from these trials is expected to notably increase our information about how the immune system reacts to T-cell based vaccine products. This information will then help to make decisions in trials of future vaccines.

To conduct a series of trials to define how to increase T-cell breadth and in vivo biological function (immune responses in people) after vaccination.

At this point in time, there are no new neutralizing antibody vaccine products ready for clinical trials in the HVTN. Work is being focused on understanding more about the mechanisms behind T-cell vaccines, which is the category into which the Merck and Pave vaccine products fall. Ultimately, researchers expect that an effective vaccine might use both strategies. Information from STEP and Phambili are helping researchers form new questions to ask. The vaccine products currently in the HVTN pipeline can then be put into trials that are planned to answer these new questions—and that will, in turn, generate additional new questions.

To foster a cyclical process between human and nonhuman primate studies that should allow the field to evaluate suggested improvements to vaccine concepts.

The STEP Study allowed researchers to learn more about ways in which nonhuman primate research relates to human results. Researchers in both fields are now looking for ways in which they can develop more discussion about how nonhuman primate studies can be structured to allow for the most useful data for human trials, and how information from human trials can be produced that will then help structure research with the primates. The more researchers in related fields collaborate, the more they can benefit each other.
Key Scientific Questions

At the May 2008 HVTN Conference there was discussion of some of the many new areas of interest currently being pursued by those in the HVTN and our collaborators, including the following:

Collaborations—There is a new emphasis on working more closely with others doing research in the vaccine field. With more active dialogue, it will be possible to help each other design studies that will maximize the applicable information that can cross fields. This will help to improve the relationship between conceptual models and clinical trials, for instance, or between animal models and clinical trials.

Expansion of HVTN lab program—There has been an ongoing goal of further developing relevant assays (tests) that will help indicate if a study vaccine is working. The clear need for new assays has become even more apparent after STEP. The lab program will also be expanding their analytical capabilities.

Using current vaccines to prepare for future trials—Researchers hoped that the STEP Study might lead to an effective vaccine, but expected that it might be one step along the path. Now that we know that is true, researchers are hoping to use current study vaccines to better understand 1. what signs might relate, or “correlate,” to beneficial immune responses; 2. what vaccine schedules produce the best results; 3. what epitopes lead to the best immune responses; and a host of other questions. Developing this information at the same time that others work towards new vaccine products would help researchers improve products and design trials for the next era of efficacy testing.

Epitope breadth and diversity—Epitopes are regions on an antigen, in this case HIV, that elements of the immune system “connect” to. Each study vaccine contains proteins that tell the body what HIV epitopes look like so that the immune system learns what to recognize and latch onto. The HVTN has increased interest in finding ways for future study vaccines to hold more HIV epitope information that represent as many strains of HIV as possible.

Genetic information—There is a desire to know more about which elements of people’s genetic information influence their reaction to HIV and the course of their infection. This would give more clues about how to focus the work of a study vaccine. Researchers might add to their knowledge by looking in more detail at how people’s CD8 and CD4+ T-cells work, or by doing studies with twins, for instance.

Understanding immune responses—There are many questions that researchers want to develop answers to, including the following: What role does pre-existing immunity play? What impact do different vectors have on the immune response? What specifically happens at mucosal sites and in the blood and how does it vary? Do changes in vaccination schedule affect immune response? Do adjuvants improve uptake, or are there other methods that help, such as electroporation?

GCAB co-chairs and GCAB reps

In April of this year, Rick Church from the NY CAB and Phineas Malahlela of the Soweto CAB became the new chairs of the Global CAB. Rick has been on his CAB for 5 years and has served as GCAB representative for 2 years. He is also on the Scientific Working Group and serves as a CAB representative on HVTN 065 and on PAVE. Phineas has been on his CAB for 7 years, and has been a GCAB representative for 6 years. He also serves as the CAB representative for HVTN 066 and on a recent HPV study in South Africa. He has also served as a representative on the Adolescent Trials Coordinating Group.

Phineas and Rick take over from Gloria Malindi of Soweto and Leonard Jackson of Baltimore, who helped lead the GCAB through the Recompetition and the first news from the STEP Study. Many thanks go out to our outgoing GCAB co-chairs, and cheers to our new co-chairs!

Below is a list of the GCAB representatives and their alternates reported from each site:

Ian Maki, Seattle
Fred Lopez and Jeff Gustavson, San Francisco
Rick Church and Neil Montero, New York
Steve Csipke and Chuck Giavaniello, Boston
Roberto Burgos and Don Bruner, Rochester
Butch McKay and Jim Higginbotham, Birmingham
James Manning and Mark Hubbard, Nashville
Timothy Gustavson, Atlanta
Michele Bailey and Rachel Middlesteadt-Ellerson, Chapel Hill
Kate Miller and David Crawford, Chicago
Lora Pearson, Kevin Quirk and Quincy Greene, Philadelphia
Mauro Nunes and Antonio Carlos Cerezzo, Rio de Janeiro
Jose Carlos Veloso da Silva and Aura Abbade, Sao Paulo
Gustav Wiese, Santo Domingo
Emmanuel Benoit and Rodrigue Jeanit, Port-au-Prince
Patricia Watson and Mark Clifford, Kingston
Carmen Montalvan Inga and Erick Murayari, Iquitos
Jose Luis Cairo and Jorge Apolaya, Lima
Juan Hernandez, San Juan
Nombeko Cynthia Mpongo, Cape Town
Maxwell Mncube, Durban
Banele Faku, Klerksdorp
Phineas Malahlela and Gloria Malindi, Soweto
HIV Vaccine Awareness Day around the world!!!

On May 18th, 2008, the world celebrated HIV Vaccine Awareness Day. Each HVTN HVTU did this in its own way. Some celebrated on May 18th and many celebrated later in the month—but all celebrated with compassion, humor and determination. On these two pages, the Core CEU would like to share a few proud samples of the fantastic work done by the HVTUs and their CAB members.

Nashville, Tennessee, USA
We collaborated with our LPP (Planned Parenthood) on a big HVAD event. It was a Fish Fry/Community Health Fair. We had about 300 people come throughout the day. There was free fish, and dessert for everyone, as well as lots of organizations providing health screenings and information at booths. If people visited all the booths they got a goodie bag as well (the Be A Leader backpacks full of goodies).

Rochester, New York, USA
The primary event for HIV Vaccine Awareness Day 2008 in Rochester was a collaborative effort co-sponsored by AIDS Rochester Inc., Muther’s Club, stage performer “Ambrosia Salad” and the Gay Alliance of Genesee Valley (GAGV). The event included a drag show conducted by one of Rochester’s popular performers staged at one of the city’s more popular gay bars. Ambrosia Salad demands attention everywhere she performs, and this time she engaged the audience on the subject of vaccine research. The event was marketed to area college students by the GAGV Campus. Out organization. GAGV is Rochester’s LPP agency. Muther’s nightclub was filled to capacity and periodic announcements from Ambrosia kept the staff busy at the vaccine information table. Once again, the glow-in-the-dark-necklaces provided by HVTN were also a big hit!

Lima, Peru
On a foggy day on May 15th, volunteer educators, under the direction of Martin Lacherre, our new community educator, went to one of the most populous districts in Lima to spread information about vaccine trials. We started at one of the most well-traveled avenues of the city (cars, buses, bikes, moto- axis and pedestrians). At 11 am our banner was set up at the bridge, with the volunteers ready to speak face to face about HIV, the importance of doing trials in Perú and of participating as volunteers. We spoke to the general public on the street, and, most importantly, on the buses. All people received a special edition of our Comic Contest book and an HVTN backpack—they loved the giveaways. The drivers received a t-shirt with our slogan “Dream of a world without AIDS.” In two hours, our volunteers gave out education materials on 35 public buses and other forms of transportation to nearly one thousand people. They also spoke of our wish: To live in a world without AIDS.
In Haiti Awareness Day coincided with National Flag Day. The CEU & CAB organized an all-day activity. In the morning we participated in a national parade and in the afternoon we held a conference, together with two NGOs (World Relief and World Concern).

Puerto Rico took the opportunity to promote HIV vaccine awareness at a Gay Pride Parade, utilizing HVTN backpack giveaways to engage the public.

The main activity for HVAD 2008 was a church service at which about 260 persons were in attendance, including staff and participants. A prayer for HVAD, written by CAB member Rev. Patrick Cunningham, was read. The prayer was distributed to churches in the Kingston area during the week prior to HVAD so that it could be read on Sunday May 18th.

The following is an excerpt of that prayer:

“We pray for all who are involved in the research for a vaccine to combat the HIV/AIDS pandemic. Give them wisdom, skill and direction in this undertaking that their efforts may be successful.

Increase our love and decrease stigma and discrimination, so that together we may work towards the discovery of a vaccine that will prevent the spread of HIV and AIDS and the creation of an accepting environment for persons living with HIV and AIDS.”

Also at the service, trial participant and CAB member Paulette Rowe spoke about her experience in the HVTN 204 vaccine trial. Our site PI, Professor J. Peter Figueroa, thanked volunteers, staff, and the community for their support and took the time to emphasize that vaccine development is challenging and takes many years.

The backpack giveaways we had from HVTN were perfect for our event! MeCRU used the vaccine awareness event to create contact with young people in schools by spending the whole week making introductory presentations of HIV vaccines. The learners gobbled up every piece of information. The focus was also extended to youth out of school, as well as reaching out to youth with other sexual preferences. We received an overwhelming response.

After close to seven hundred contacts, we have enough young people to refer to organizations that will participate in constituting an Adolescent CAB. It is exciting to have some leftover bags because we plan to use them as a token of appreciation for participation in adolescent activities as soon as the CAB is formed.

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In the review of Step Study data, it was surprising to learn that, among the first 30 participants who became infected with HIV, only one was a woman. Sites felt they had enrolled women at very high risk. Women did report having unprotected sex with numerous partners, and this is confirmed in part by the high number of pregnancies. However, only 5% reported known HIV-infected male partners. Low HIV prevalence in the sexual networks of these women may also be a factor in the unexpectedly low rate of HIV infection.

HVTN 906 and 907 are intended to help us better understand infection rates among the women we work with and to better characterize strategies to recruit and retain them for vaccine trials. These two trials are observational and will not involve vaccinations. The secondary objective is to determine whether the HIV incidence rate in each local cohort is at least 1%.

HVTN 906 will be in the United States (New York, Philadelphia and Chicago) and HVTN 907 will be in the Caribbean (Haiti, Dominican Republic, and Puerto Rico). Both studies will seek to enroll women at the highest risk for HIV infection and will conduct HIV and pregnancy testing every 6 months for 18 months. There are some minor differences between the studies relative to the populations worked with in the different locations. The studies are expected to begin in the fourth quarter of 2008.

HVTN 205 is a Phase II trial to evaluate the safety, tolerability and immunogenicity of a prime-boost regimen using a DNA vaccine as the prime and an MVA vaccine as the boost. Both vaccines come from GeoVax, a biotech company in Atlanta, Georgia. The vaccine combination is designed to cause both antibody and T-cell responses. Data from HVTN 065, the phase I study that used these same products, have shown the vaccines to be well tolerated, and data from Part A participants showed strong immune responses (Part B is ongoing at this time).

The study will enroll 225 participants age 18-50 at ten sites in the US and Peru. The trial will seek to enroll participants at low risk of HIV infection. Exclusion criteria will include certain indications of possible heart complications and past smallpox vaccination, since MVA is related to smallpox. People who have engaged in behaviors in the last six months that would elevate their risk for exposure to HIV may be excluded. More details will be available in the exclusion criteria of the protocol.

While originally planned to begin in September, 2008, the protocol has been delayed. The vaccines still need to be vailed, and then stability testing must be done. It is not yet clear when the vaccines will be available for distribution to our sites. It is hoped that the study will open in the fourth quarter of 2008.

HVTN 205

Dr. Larry Corey’s Bottom Line

The need for a vaccine has not gone away

History has taught us that persistence is needed to solve difficult problems

The scientific community should not give up on solving the world’s major health problems

The HVTN will persist as long as the world feels an HIV vaccine is needed

Pave

At the AIDS Vaccine Research Subcommittee (AVRS) Meeting in Washington DC on May 30th, the recommendation was made to proceed with the Pave 100A trial. The final recommendation was 22 in favor and 3 against. The recommendation was made to Tony Fauci, Director of the NIAID, who is now contemplating the input he has been given. He will make a decision sometime in the next few months. If Dr. Fauci decides not to proceed with the Pave 100A trial at this point in time, that will be a final decision. If he decides to support proceeding with the trial, the protocol for Pave100A will then be written and submitted to the FDA, which is the typical development process. FDA approval is needed for all new trials. The HVTN would most likely not know whether the FDA gives approval or not until the end of the year.

If the decision is made to go ahead with Pave 100A, there will be considerable community education work to do to make sure that communities are informed and aware. Much of this work is necessary whether or not Pave moves forward, and some of it is very specific to the Pave trial itself. Over the next months, there will be a lot of work to develop educational messages, provide support for sites and their Community Educators, and to keep a flow of accurate information going out into the communities.

Part of the work that will be done will be working with the non-US sites that will not be starting Pave at this time. It is important that we get the message out that this decision is being made in order to keep participants as safe as possible, and that work will continue to ensure that any licensed vaccine is effective for all communities in need. Changes in the trial plans do not indicate any less commitment by the HVTN to working with all affected communities.
**HVTN 905**

The STEP Study has led researchers to think creatively about several different elements of the HVTN. Out of this new thinking has come the realization that sometimes trial results will lead to new and unexpected questions. HVTN 905 was developed to allow the HVTN to react quickly to changing areas of interest. If, as is the case with the STEP Study, researchers want to expand the questions that they ask in a study, HVTN 905 serves as a template to quickly draw together a protocol. In this way, small projects that ask very particular questions relative to an ongoing trial can be put together as efficiently as possible. The initial projects pursued through 905 will be related to the STEP Study.

The first two research projects in HVTN 905 will be following up on the need for more information about the Merck study vaccine used in STEP, Phambili, and HVTN 071. One of these research projects is being called the Mucosal Research Project, and it involves getting mucosal tissue samples from vaccine and placebo recipients from the STEP Study and Phambili, and possibly from participants in HVTN 071 as well. Participants who are willing to be in this study may be asked to undergo a sigmoidoscopy and/or rectal sampling, study may be asked to undergo a sigmoidoscopy and/or rectal sampling, tissue samples from vaccine and placebo recipients from the STEP Study and Phambili, and possibly from participants in HVTN 071 as well. Participants who are willing to be in this study may be asked to undergo a sigmoidoscopy and/or rectal sampling, cervical sampling, or donation of foreskin tissue. Eight US sites and three South African sites will be participating in some aspects of this project.

The second project is a repository study through which the HVTN is working to assemble a large collection of blood samples that will allow further work to be done as new assays are developed and new questions are formed about the Merck vaccine product. This project will take place at eight US sites and in Peru. Some participants will be asked to consider leukapheresis, a longer process than a standard blood draw that allows more white blood cells to be collected.

**STEP Study and Phambili Updates**

**A Scientific Success:** The STEP and Phambili trials have already successfully contributed key information to the field of HIV research. The information is helping to define the questions and issues that will shape the next generation of research. The HVTN continues to have a deep appreciation for the participants who are remaining committed to follow-up in these trials, as the field will benefit greatly from continued information from these two studies.

**Ongoing STEP Research:** Research on data from the STEP Study is ongoing. Laboratory studies are focusing on possible mechanisms that would explain the potential increase of HIV infection among certain groups of participants who received the study vaccine. They are also analyzing possible reasons why the study vaccine did not provide protection overall. There is some indication that, among a few participants who had an initially strong reaction to the vaccine, the study vaccine may have controlled the virus to some degree among participants who got infected at a later point. This is just a hint in the numbers, and researchers are waiting for more information on this. Work is underway to learn more about the HIV strains found in those who became infected. In some cases, tissue samples and leukapheresis (larger blood draws) are being done on participants to learn more about epitopes, genetic information, and markers of immune system responses. Researchers are also waiting for more data on HSV-2 (genital herpes) status of participants and on the sexual networks that may have been in place among groups of participants. Statisticians continue to look at the data in different groupings, called “multivariate analysis,” to understand more about what might have happened. As more information becomes available through study follow-up, researchers may be able to look at certain questions in more detail.

**HVTN 504:** While there are strong scientific reasons to continue to follow STEP Study participants, the main reasons for doing so have changed. This led the protocol team to decide that it would be most ethically appropriate to roll STEP participants into a new trial, HVTN 504. This will allow for the re-consent of participants, which will provide participants with all the updated information. In HVTN 504, all participants will be followed either through December, 2009 or until their participation in STEP and 504 reaches four years total, whichever comes first. All other study procedures will remain the same. Visits will be increased to every 3 months, which will allow for more counseling, increased monitoring of any HIV infections, and more precise behavioral reporting. Additionally, the trial will be coordinated through the HVTN and the data managed by SCHARP.

**Phambili:** As Phambili was in a different stage when vaccinations were stopped, the trial will be modified but it will remain the same trial. As in HVTN 504, visits will be increased to every 3 months. As of January 22, 2008, there were 11 HIV infections in Phambili, 10 of which were in women. Seven of these were in the vaccine arm. Participants are continuing to be followed, and data analysis will begin when 30 trial participants have become infected.

**Circumcision:** Work is underway to try to understand more about whether and why circumcision status may have been linked to acquisition risk. In Phambili, circumcision was offered to all uncircumcised men due to evidence that circumcision lowers the rate of HIV infection among men engaging in heterosexual sex. One in 5 men decided to proceed with circumcision. This has been done with minimal side effects, and has proved to be easy to implement.
The CAB Retreat

Genevieve Meyer

This July HVTN welcomes Genevieve Meyer as the newest member of the Community Education Unit. She will be working as the Administrative Coordinator, providing technical, administrative, and program support to the division.

Genevieve holds a Master’s degree in International Studies with a concentration in global health as well as a Master’s degree in Social Work from the University of Denver. Before entering the global health field she spent a year teaching English in Mexico, taught for a year in France, and lived in Israel and Gabon. Most recently she served as the Director of Communications at the Global HELP Organization, a Seattle-based non-profit that produces low-cost medical publications for doctors in low-income countries.

After nearly a decade of international and domestic exploration, Genevieve is excited to call Seattle home again and enjoys reconnecting with her native Northwest roots, including recycling and water sports. On sunny days you can often find her exploring the International District eating Vietnamese sandwiches while shopping for exotic fruits, unidentifiable tubers and interesting kitchen gadgets.

Conferences and announcements

Conference calls to update the community regarding the Step Study, Phambili and PAVE will occur as needed. Please stay in touch with your Community Educator regarding announcements concerning upcoming calls.

The next HVTN Conference will take place this year on November 18-20, 2008 in Seattle, WA.

AIDS 2008 will take place in Mexico City, Mexico August 3—8th, 2008, and AIDS Vaccines 2008 will take place in Cape Town, South Africa on October 13—16th, 2008.

Calendar of events

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

CAB Scientific Working Group conference call:
Friday, July 11th, 8 a.m.PST/11 a.m. EST
Friday, August 1st, 8 a.m. PST/11 a.m. EST

Global GCAB conference call:
Thursday, July 10th, 8 a.m. PST/11 a.m. EST
Thursday, August 14th, 8 a.m. PST/11 a.m. EST

Global Ethics Working Group call:
Thursday, July 24th, 7 a.m. PST/10 a.m. EST
Thursday, August 28th, 7 a.m. PST/10 a.m. EST

Global Community Education/Recruitment call:
Tuesday, July 15th, 9 a.m. PST/11 a.m. EST
Tuesday, September 16th, 9 a.m. PST/11 a.m. EST

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

Send suggestions, questions, and article submissions to:
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Second Quarter 2008