
HIV VACCINES AND THE COMMUNITY

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The HVTN 501 Decision

The HIV Vaccine Trials Network (HVTN) and its collaborators (NIH and industry) have reviewed preliminary data from HVTN 203, a trial to test the safety and immunogenicity of a combination of Aventis Pasteur's ALVAC-HIV (vCP1452) and VaxGen's AIDSVAX B/B. The safety profile of the vaccine combination was confirmed, but its immunogenicity did not indicate sufficient cellular response to qualify for a planned Phase III trial, known as HVTN 501.

HVTN 501 was to have tested a prime boost strategy at sites throughout the Western Hemisphere. It was designed to evaluate the critical question of how well measures of cellular immune response correlate with protection from HIV infection, as well as whether these specific vaccine candidates prevent HIV infection.

"The data indicate that the T cell responses do not meet the stringent standards of the HVTN 501 trial design," said Dr. Larry Corey, principal investigator for the HVTN. "We hope to continue testing this and other ALVAC vaccines to determine whether they are more immunogenic in different doses, in different populations, and in combination with other candidate HIV vaccines. The canarypox vector did demonstrate significant immunogenicity compared to placebo injections. However, the criteria that were established to move forward to a trial that would determine if CD8+ T cell responses were associated with reducing the risk of acquiring HIV were not achieved."

HVTN 203 enrolled 330 persons at sites in 10 U.S. cities. The trial design allowed HVTN investigators to determine what levels of CD8+ T cell response to HIV-1 this vaccine combination could achieve. In addition, the trial sought to identify what dose and schedule of the two vaccines would best achieve these levels. The ALVAC vaccine did elicit CTL responses and did behave similarly to other ALVAC vaccines, but it did not achieve the levels of response required by the 501 trial design.

Implications for HVTN trials: The HVTN will continue current trials using vCP1452, as these trials can help answer important scientific questions.

- HVTN 203 will continue to completion in order to better understand the safety and immune response profile of vCP1452 when compared with other fowlpox products.
- HVTN 039 will continue at U.S. sites, as it will tell us what happens when a higher dose of vaccine is used.
- HVTN 026 will continue because it will tell us if the same immune response and safety profile seen after years of U.S. study are also applicable for people in the Caribbean and South America.
- HVTN 042 will start soon, because it can tell us how well vCP1452 works when combined with another new product, called a lipopeptide.

The HVTN, the NIH, and the product manufacturers are committed to continued collaboration to find a vaccine that will stop the over 14,000 daily new HIV infections worldwide. ☘

Assessing the Impact

By Steve Wakefield, Associate Director for Community Relations and Education

This February, the road to an HIV vaccine took an unexpected turn—it was decided that HVTN 501 would not be pursued. We learned from the newspaper, an e-mail, or announcements made at the Retrovirus Conference that the data from HVTN 203 would not support a decision to move forward with the correlates of immunogenicity trial design planned for HVTN 501. "Shock," "confusion," "disappointment," and many other words were used to describe the feelings about and reactions to the news that a phase III trial would be delayed. In some, old arose old fears arose that an HIV vaccine really was not possible. Others worried about the scientific questions the trial was to address that will go unanswered for several more years. While some questioned the reasons behind the decision, most of us realize that it was made by knowledgeable scientists and driven by scientific determinants.

Concerns were raised about the decision-making process in general, especially the ways in which HVTN partners were notified. As a large, collaborative network, the HVTN has a responsibility to ensure fluid internal communications among all members, from the principal investigators to the trial participants. Network investigators will meet in Miami this March to look at the implications and impact of this news.

The February/March issue of the CAB Bulletin seemed to me an appropriate place to note some of the implications and lessons learned from the HVTN 501 decision since Community Advisory Board members, Community Educators and Recruiters will not meet again, as a group, until May.

One of the key lessons learned is the need to improve how information is communicated between various HVTN partners. We must improve our ability to ensure that site investigators have an opportunity to provide their staff, CAB members, and other key persons with information prior to public press announcements. In this instance, a reporter posted news of an NIH decision before HVTN investigators had gathered.

This news leak and the Retrovirus Conference announcement made for particularly difficult information flow to HVTN trial participants. Participants in HVTN/HIVNET 026 could have been better served by hearing the information after scientists leading the trial in the

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La decisión del HVTN 501

La HIV Vaccine Trials Network (HVTN) y sus colaboradores (NIH y el sector) han analizado los datos preliminares del HVTN 203, un estudio clínico para probar la inocuidad y capacidad inmunógena de la combinación de las vacunas ALVAC-HIV (vCP1452) de Aventis Pasteur y AIDSVAX B/B de VaxGen. Se confirmó el perfil de seguridad de la vacuna combinada, pero su capacidad inmunógena no indicó una respuesta celular adecuada para calificar para el estudio clínico de fase III previsto, conocido como HVTN 501.

El objetivo del HVTN 501 hubiera sido probar una estrategia de primo-inmunización/refuerzo en lugares dispersos por el Hemisferio Occidental. El estudio clínico se diseñó con la finalidad de evaluar preguntas críticas: cuál es la eficacia de correlación entre las mediciones de la respuesta celular inmunitaria y la protección contra la infección por VIH, y si estas vacunas experimentales específicas previenen la infección por el VIH.

“Los datos indican que las respuestas de los linfocitos T no satisfacen las exigentes normas del diseño del estudio clínico HVTN 501”, explicó el Dr. Larry Corey, investigador principal de la HVTN.

“Esperamos continuar haciendo pruebas con ésta y otras vacunas ALVAC para determinar si tienen una mayor capacidad inmunógena en otras dosis, en diferentes poblaciones y en combinación con otras vacunas experimentales contra el VIH. El vector de la viruela aviar (canarypox) sí demostró una capacidad inmunógena significativa al ser comparado con inyecciones de placebo. Sin embargo, no se lograron los criterios que se establecieron para continuar con un estudio clínico que determinaría si las respuestas de CD8+ linfocitos T se asocian con la reducción del riesgo de adquirir el VIH.”

El HVTN 203 contó con 330 voluntarios en 10 ciudades de Estados Unidos. El diseño del estudio clínico permitía a los investigadores del HVTN determinar qué niveles de respuesta CD8 + linfocitos T ante el VIH-1 se podría lograr con esta combinación de vacunas. Además, el estudio clínico buscaba identificar qué dosis y régimen de las dos vacunas sería el mejor para lograr esos niveles. La vacuna ALVAC provocó respuestas de los linfocitos citotóxicos T (CTL) y se comportó de manera similar a otras vacunas ALVAC, pero no logró los niveles de respuesta requeridos por el diseño del estudio clínico 501.

Repercusiones para los estudios clínicos de la HVTN: La HVTN continuará los estudios clínicos en curso utilizando vCP1452, pues pueden ayudar a aclarar interrogantes científicos importantes.

- El HVTN 203 continuará hasta su finalización a fin de entender mejor el perfil de seguridad y la respuesta inmunitaria de vCP1452 en comparación con otros productos de viruela aviar.
- El HVTN 039 continuará en centros estadounidenses con la finalidad de revelar qué ocurre cuando se utiliza una vacuna de dosis más elevada.
- El HVTN 026 continuará porque aclarará si el mismo perfil de seguridad y respuesta inmunitaria que se han observado durante años de investigación en Estados Unidos también corresponden a la población caribeña y sudamericana.
- El HVTN 042 comenzará pronto y su finalidad será esclarecer la eficacia de vCP1452 cuando se utiliza en combinación con otro producto nuevo, denominado lipopéptido.

La HVTN, el NIH y los fabricantes del producto están comprometidos a continuar colaborando a fin de encontrar una vacuna que ponga el alto al elevado número de infecciones de VIH que ocurren diariamente (más de 14.000) alrededor del mundo. ☞

Consecuencias del impacto

Por Steve Wakefield, Director Adjunto de Relaciones con la Comunidad y Educación

En el mes de febrero del año en curso, la vacuna contra el VIH sufrió un vuelco inesperado: se decidió suspender el estudio clínico HVTN 501. La noticia pudo haber llegado a través del diario, de algún mensaje de correo electrónico o por los avisos que se hicieron en el Congreso sobre el retrovirus: los datos obtenidos del HVTN 203 no respaldarían la decisión de desarrollar el estudio clínico de correlatos de capacidad inmunógena planificados para el HVTN 501. “Asombro”, “confusión” y “decepción” son algunas de las palabras que sirvieron para describir las reacciones ante la noticia de que se demoraría un estudio clínico de fase III. Para algunos resurgieron los temores añejos de que la vacuna contra el VIH realmente no es posible. A otros les preocupó que los interrogantes científicos que se aclararían en el estudio clínico continuarán sin respuesta por varios años. Si bien hubo quien cuestionara los motivos de la decisión, casi todos reconocemos que fue una decisión tomada por científicos expertos guiados por factores determinantes científicos.

Se preguntó acerca del proceso de la toma de decisiones, en particular se lamentó la manera en que se informó a todas las instituciones y empresas afiliadas a la HVTN. La HVTN, una gran red de colaboradores, tiene la obligación de asegurar que la comunicación interna entre todos los miembros, desde los investigadores principales hasta los participantes, se realice de una manera fluida. Los investigadores de la red se reunirán este marzo en Miami para estudiar las repercusiones y el impacto de esa noticia.

Dado que los miembros de la Junta Asesora de la Comunidad, los educadores de la comunidad y los reclutadores no se reunirán antes de mayo, el número de febrero/marzo del boletín CAB me pareció un lugar apropiado para destacar algunas de las repercusiones y lecciones aprendidas a partir de la decisión referente al HVTN 501.

Una de las lecciones aprendidas es que es imprescindible mejorar las vías de comunicación entre las diferentes partes de la red HVTN. Habrá que encontrar una mejor manera de asegurar que los investigadores de campo tengan la oportunidad de transmitir a su personal, a los miembros de CAB y a otras personas importantes, la información pertinente antes de que se anuncie a la prensa. En este caso, un reportero informó de una decisión del NIH antes de que se reunieran los investigadores de la HVTN.

Esta fuga de noticias y el anuncio del Congreso sobre el retrovirus realmente entorpeció el flujo de la información destinada a los participantes del estudio clínico de la HVTN. Hubiera resultado más útil a los participantes del HIVNET 026 de la HVTN enterarse después de que los investigadores a cargo del estudio clínico en el Caribe y Sudamérica hubiesen tomado decisiones acerca de la seguridad continua y la información operativa para cada país. Se pudo haber avisado a los participantes de Estados Unidos inscritos en el HVTN 039 que la información referente a una dosis de la vacuna que es seis más veces más potente es más importante que nunca. Sin embargo, no hay que permitir que estos dos asuntos eclipsen la importancia de que los individuos que participan en el HVTN 203 entiendan la necesidad imperiosa de acudir a todas sus citas a fin de confirmar los datos obtenidos a par-

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La décision au sujet de HVTN 501

Le HIV Vaccine Trials Network (HVTN) et ses collaborateurs (les NIH et l'industrie) ont examiné des données préliminaires issues de HVTN 203, un test destiné à tester la sûreté et l'antigénie d'une combinaison de l'ALVAC-HIV (vCP1452) d'Aventis Pasteur et de l'PAIDSVAX B/B de VaxGen. Le profil de sûreté de la combinaison de ces vaccins a été confirmé, mais son antigénie n'a pas indiqué de réaction cellulaire suffisante pour répondre aux conditions nécessaires à un test de Phase III, c'est à dire le HVTN 501.

Le HVTN 501 devait tester une stratégie de primo-immunisation/rappel dans des lieux situés dans l'hémisphère occidental. Ce test a été conçu pour évaluer la question cruciale, à savoir le degré de corrélation des mesures de la réaction immunitaire des cellules avec la protection contre l'infection par le VIH, et également si ces candidats vaccins spécifiques empêchent l'infection par le VIH.

« Les données indiquent que les réactions des cellules T ne répondent pas aux normes rigoureuses du plan de test du HVTN 501 », a déclaré Dr Larry Corey, principal investigateur du HVTN. « Nous espérons poursuivre ce test, ainsi que les tests d'autres vaccins ALVAC, pour déterminer s'ils sont plus immunogènes lorsqu'ils sont administrés en différentes doses, auprès de différentes populations et en conjonction avec d'autres candidats vaccins du VIH. Le vecteur canarypox a démontré une antigénie substantielle par rapport aux injections de placebo. Toutefois, les critères qui avaient été établis pour effectuer un test qui déterminerait si les réactions des cellules T CD8+ étaient associées à la réduction du risque d'acquisition du VIH n'ont pas été obtenus. »

Un total de 330 personnes se sont inscrites pour participer au HVTN 203 dans dix villes des États-Unis. Le plan de test a permis aux investigateurs du HVTN de déterminer les niveaux de réaction des cellules T CD8+ au VIH-1 que permettait d'obtenir cette conjonction de vaccins. Le test avait en outre pour objectif d'identifier la dose et l'administration des deux vaccins qui permettraient le mieux d'obtenir ces niveaux. Le vaccin ALVAC a permis d'obtenir des réactions des cellules T tueuses et s'est comporté de manière similaire à d'autres vaccins ALVAC, mais il n'a pas produit les niveaux de réaction requis pour le plan de test 501.

Les implications pour les tests du HVTN : Le HVTN poursuivra ses tests actuels en utilisant le vCP1452, car ils sont susceptibles de fournir des réponses à d'importantes questions scientifiques.

- Le HVTN 203 se poursuivra jusqu'à la fin pour mieux comprendre la sûreté et le profil de réaction immunitaire du vCP1452 par rapport à d'autres produits fowlpox.
- Le HVTN 039 se poursuivra aux États-Unis, car il nous permettra de savoir ce qui se produit lorsqu'on utilise une dose plus forte de vaccin.
- Le HVTN 026 se poursuivra, car il nous permettra de savoir si la même réaction immunitaire et le même profil de sûreté que l'on a observés au bout d'années d'études aux États-Unis s'appliquent également aux populations des Caraïbes et d'Amérique du Sud.
- Le HVTN 042 démarrera prochainement, car il nous permettra de connaître les résultats que donne le vCP1452 lorsqu'on le combine à un autre nouveau produit, à savoir un lipopeptide.

Le HVTN, les NIH et les fabricants de produits sont voués à une collaboration continue pour trouver un vaccin qui mettra fin aux plus de 14 000 nouvelles infections du VIH qui se produisent chaque jour dans le monde entier. ☘

Évaluation de l'impact

Par Steve Wakefield, Directeur associé, Relations et éducation des collectivités

En ce mois de février, la recherche d'un vaccin du VIH a pris un tour inattendu—il a été décidé de ne plus poursuivre le HVTN 501. Nous avons appris par les journaux, le courrier électronique ou encore par des annonces faites au cours de la Conférence sur les rétrovirus, que les données issues du HVTN 203 n'étayeraient pas la décision de poursuivre les corrélations du plan de test antigénique prévu pour le HVTN 501. « Choc », « confusion », « déception » et nombre d'autres mots ont décrit les sentiments et réactions à la nouvelle qu'un test de phase III serait retardé. Certains ont revécu leurs anciennes craintes qu'il n'était vraiment pas possible de trouver un vaccin du VIH. D'autres ont craint que les questions scientifiques que devait aborder le test resteraient sans réponse pendant plusieurs années supplémentaires. Tandis que certains questionnaient les raisons qui étaient à l'origine de la décision, la plupart d'entre nous avons réalisé qu'elle avait été prise par des scientifiques avertis et qu'elle était suscitée par des facteurs scientifiques déterminants.

Des inquiétudes ont été soulevées au sujet du processus de décision en général, et en particulier sur la façon dont les partenaires du HVTN avaient été avisés. En tant que vaste réseau de collaboration, le HVTN a la responsabilité d'assurer la fluidité des communications internes entre tous ses membres, qu'il s'agisse des principaux investigateurs ou des participants aux tests. Les investigateurs du réseau se réuniront à Miami ce mois de mars pour étudier les implications et l'impact de cette nouvelle.

Le numéro de février/mars du CAB Bulletin m'a semblé être un espace approprié pour faire remarquer un certain nombre d'implications et de leçons à tirer de la décision relative au HVTN 501, étant donné que les membres du Conseil consultatif communautaire, les animateurs socio-éducatifs et les recruteurs ne se réuniront pas en groupe avant mai prochain.

L'une des principales leçons que nous avons apprises a trait au besoin d'améliorer le processus de communication de l'information aux différents partenaires du HVTN. Nous devons améliorer les moyens que nous avons d'assurer que les investigateurs sur le terrain peuvent fournir des informations à leur personnel, aux membres de CAB et à d'autres personnes clés, avant que ces informations ne soient divulguées dans la presse publique. Dans ce cas particulier, un reporter a communiqué la nouvelle d'une décision des NIH avant la réunion des investigateurs du HVTN.

Cette fuite dans la presse, ainsi que l'annonce de la Conférence sur les rétrovirus, ont rendu particulièrement difficile la communication des informations aux participants au test du HVTN. Les participants du HVTN/HIVNET 026 auraient pu être mieux servis en entendant ces informations après que les scientifiques qui dirigeaient le test aux Caraïbes et en Amérique du Sud aient pris des décisions relatives à la sûreté continue et aux informations opérationnelles pour chaque pays. Les participants au HVTN 039 sur les sites américains auraient pu être avisés que les informations relatives à une dose de vaccin qui est six fois plus forte sont plus importantes que jamais. Ne laissons pas l'un ou l'autre de ces faits éclipser l'importance de faire comprendre aux personnes participant au HVTN 203 qu'elles doivent compléter toutes leurs visites afin de confirmer les données, recueillies dès

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A decisão do HVTN 501

A HIV Vaccine Trials Network (HVTN) e seus colaboradores (NIH e setor) examinaram os dados preliminares do HVTN 203, um estudo para testar a segurança e a imunogenicidade de uma combinação da vacina ALVAC-HIV (vCP1452) produzida por Aventis Pasteur e da vacina AIDSVAX B/B produzida por VaxGen. O perfil de segurança da combinação de vacinas foi confirmado, mas sua imunogenicidade não indicou uma resposta celular suficiente que se qualificasse para o ensaio de fase III planejado, conhecido como HVTN 501.

O HVTN 501 deveria ter testado uma estratégia "prime-boost" em centros localizados em todo o hemisfério ocidental. Ele foi projetado para avaliar a questão fundamental do modo como as medidas de resposta imunológica celular correlacionam-se com a proteção contra a infecção por HIV, e se estes candidatos específicos a vacinas evitam a infecção por HIV.

"Os dados indicam que as respostas de célula T não atendem aos padrões estritos do projeto de estudo do HVTN 501", afirmou o dr. Larry Corey, pesquisador principal da HVTN. "Esperamos continuar a testar esta e outras vacinas ALVAC para determinar se são mais imunogênicas em doses diferentes, em populações diferentes, e em combinação com outros candidatos a vacinas anti-HIV. O vetor canaripox demonstrou uma imunogenicidade significativa em comparação com injeções de placebo. Entretanto, não se alcançaram os critérios estabelecidos para se passar para um estudo que determinaria se as respostas de células T CD8+ estariam associadas a uma redução do risco de contrair o HIV."

O HVTN 203 contava com 330 pessoas inscritas em centros situados em 10 cidades dos EUA. O projeto do estudo permitiu aos pesquisadores da HVTN determinar os níveis de resposta da célula T CD8+ ao HIV-1 que essa combinação de vacinas poderia alcançar. Além disso, o estudo procurou identificar qual dose e qual programa das duas vacinas seriam melhores para alcançar estes níveis. A vacina ALVAC conseguiu obter respostas de CTL (linfócitos T citotóxicos) e comportou-se de modo semelhante a outras vacinas ALVAC, mas não obteve os níveis de resposta exigidos pelo projeto de estudo 501.

Implicações dos estudos da HVTN: A HVTN dará continuidade aos estudos atuais usando a vacina vCP1452, pois estes estudos podem ajudar a responder questões científicas importantes.

- O HVTN 203 continuará até o final para que se possa entender melhor o perfil de segurança e de resposta imunológica da vCP1452 quando comparado com outros produtos de pox aviário.
- O HVTN 039 continuará nos centros dos EUA, e nos informará sobre o que ocorre quando se usa uma dose maior da vacina.
- O HVTN 026 continuará porque nos informará se o mesmo perfil de resposta imunológica e de segurança vistos após anos de estudo nos EUA também se aplicam a indivíduos no Caribe e na América do Sul.
- O HVTN 042 terá início brevemente, pois pode nos informar como a vCP1452 funciona quando combinada com outro novo produto, chamado de lipopeptídeo.

A HVTN, o NIH e os fabricantes dos produtos comprometem-se a dar continuidade à colaboração para encontrar uma vacina que interrompa a ocorrência diária de mais de 14.000 novas infecções por HIV. ❧

Avaliação do impacto

Por Steve Wakefield, Diretor Adjunto de Relações Comunitárias e Educação

Neste último mês de fevereiro, o caminho para uma vacina anti-HIV deu uma reviravolta inesperada - decidiu-se pelo não-prosseguimento do estudo HVTN 501 (HVTN - Rede de Avaliação de Vacinas anti-HIV). Soubemos através dos jornais, e-mail e declarações feitas por ocasião da Conferência de Retrovírus que os dados pertencentes ao HVTN 203 não bastariam para a decisão de se prosseguir com os correlatos do projeto de pesquisa de imunogenicidade planejados para o HVTN 501. "Choque", "confusão", "desapontamento", e muitas outras palavras foram usadas para descrever os sentimentos e reações causados pela notícia de que o estudo de fase III seria adiado. Em algumas pessoas, isso reacendeu o antigo receio de que uma vacina anti-HIV na realidade não fosse possível. Outras pessoas preocuparam-se sobre as questões científicas que o estudo visava tratar, e que permaneceriam sem resposta por mais alguns anos. Ainda que algumas pessoas questionassem os motivos por trás da decisão, a maioria de nós estava ciente de que a decisão havia sido tomada por cientistas abalizados e fundamentada por determinantes científicos.

Manifestou-se inquietação sobre o processo decisório de um modo geral, especialmente sobre as formas pelas quais os parceiros da HVTN foram notificados. Como uma grande rede colaborativa, a HVTN tem a responsabilidade de garantir a fluidez das comunicações internas entre todos os membros, desde os principais pesquisadores até os participantes do estudo. Os investigadores da rede se reunirão em Miami neste mês de março para examinar as implicações e o impacto desta notícia.

A edição de fevereiro/março do CAB Bulletin pareceu-me um local adequado para tratar de algumas das implicações e lições aprendidas com a decisão sobre o HVTN 501, especialmente desde que os membros do Conselho de Assessoria Comunitária, os educadores comunitários e recrutadores não se reunirão novamente, como um grupo, até maio.

Uma das lições aprendidas foi a necessidade de aperfeiçoar o modo como as informações são veiculadas entre os diversos parceiros da HVTN. Devemos aperfeiçoar nossa capacidade para garantir que os investigadores dos centros tenham a oportunidade de transmitir informações a seus funcionários, membros da CAB e outras pessoas centrais antes de as declarações chegarem à imprensa. No caso em questão, um repórter publicou as notícias de uma decisão do NIH (Institutos Nacionais de Saúde, EUA) antes de os investigadores da HVTN serem informados.

O vazamento de informações e a declaração feita durante a Conferência de Retrovírus resultaram em um fluxo de informações particularmente difícil para os participantes do estudo da HVTN. Teria sido melhor se os participantes do HVTN/HIVNET 026 tivessem sido informados após os cientistas que lideravam o estudo no Caribe e na América do Sul decidirem-se sobre a continuidade das informações operacionais e sobre segurança para cada país. Poderia se informar aos participantes nos centros dos EUA inscritos no HVTN 039 que os dados referentes a uma dose de vacina que é seis vezes maior são mais importantes do que nunca. Não deixemos que nenhuma dessas coisas diminua a importância de as pessoas do HVTN 203 entenderem a ne-

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Coordinating Efforts

By Andrew Lambert, Community Education International Projects Manager

As the HVTN and HIV Prevention Trials Network (HPTN) continue to grow and expand throughout the world, so do community education efforts surrounding HIV/AIDS. Community groups have emerged at various times during this epidemic rallying around what they believed to be a single cause—to end this horrible epidemic. As the prevention and vaccine trials networks separated, so too did the perception of one community voice. There has been, however, a heightened awareness and desire by many community groups to keep the community education efforts united in order to combat all fronts of the HIV/AIDS pandemic at the same time, so as not to lose focus of our one common goal.

When it comes to encouraging community participation in research, in trials, and in the network, the HVTN continues to promote the idea that there are various ways in which Community Advisory Boards can be developed or even defined. Often times, a trial site may only be conducting vaccine trials, and thus the CAB works exclusively with topics related to HIV vaccines. Other sites might be involved in both vaccine and prevention trials, and have therefore combined their community education and CAB development efforts to incorporate all topics related to the HVTN and HPTN. And finally, some sites work with both networks but have created two separate CABs. We encourage CABs to stay involved and up to date on all research taking place in all fields of HIV/AIDS. For this reason, the HVTN and the HPTN Community Education Programs have begun to work more closely together.

The discussion of how to combine the HPTN and HVTN community education and CAB development efforts at a network-wide level has come to the forefront as the two networks continue to incorporate new trial sites around the globe. During a recent trip to Durban, South, Africa, I met with scientists, clinicians, and community educators from both networks to discuss plans for creating a Community Advisory Board, or similar group, that would function as the voice of the community in which both HPTN and HVTN trials would be taking place. The consensus was that in a place like South Africa, with already highly developed community participatory and advisory structures, it would be detrimental to the communities and to HVTN and HPTN efforts to artificially create new community groups, and then to divide them up by either vaccine or prevention focus. This discussion highlighted the importance of Community Education Programs from both networks working together so as not to repeat efforts. In this environment, we have made great efforts toward combining our skills, experiences, and knowledge so as to more quickly develop and promote community involvement and education at joint HVTN and HPTN sites.

With these goals in mind, Steve Wakefield and I (from the HVTN) met with the HPTN community education staff (Stella Kirkendale, Rhonda Beamon and Wayne Wilson), January 28-29, 2002 at Family Health International in North Carolina. For two days, we discussed the successes and difficulties that our trial sites have experienced in

working with the Networks. By the end of the second day, we had created a list of topics to focus on this year, including quarterly reporting/evaluations synchronization, trainings on cross-cutting issues, creating joint training modules, and providing educational materials for topics such as informed consent. We see these as first steps towards an increasingly coordinated effort by the two Networks that will pass along efficiencies and a larger pool of information to our partners at the trial sites, who are the lifeline of our community education efforts. ☘



HVTN/HPTN January meeting (left to right): Steve Wakefield, Rhonda Beamon, Stella Kirkendale, Andrew Lambert, and Wayne Wilson.

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Caribbean and South America had made decisions regarding continued safety and operational information for each country. Participants at U.S. sites enrolled in HVTN 039 could have been told that information about a vaccine dose that is six times higher is more important than ever. Let's not allow either of these to overshadow the importance of persons in HVTN 203 understanding the need to complete all visits to in order to confirm the data gathered from the early evaluation that served as the basis for the HVTN 501 decision.

The continued safety and immunogenicity data has implications for other trials as well. The HVTN will soon start a trial using the same product in conjunction with lipopeptides. Other networks are also planning trials using this product with special populations such as adolescents.

This delay in moving to a large-scale trial increases the urgency of evaluating other candidates in Phase I and Phase II trials. We plan to start a multi-country trial with Merck late this summer. Other multi-country trials using multi-clade products developed at NIH's Vaccine Research Center will soon follow.

We must continue to ask ourselves, "What does it take for our communities to be ready for HIV vaccine research?", "How can we help communities understand that it will take many trials to find an effective vaccine?", and "What can we do at each locale to support trial participants in understanding the value of their contribution to science?"

Despite the fact that the prospect of a Phase III trial in this Network will be delayed by a few more years, our work to educate our communities must continue with the same momentum. ☘

Vaccine Resources on the Web

By *Siobhan Malone, Community Project Coordinator*

As development and testing of HIV vaccines increases, so do the number of sources of information. This is a good thing. We want there to be as many resources out there as possible in order to increase awareness and understanding of an important, and not always easy to understand topic. But sifting through it all, especially web-based information on a 56k modem, is not always easy. With our super-speedy connection here at the Core office, I decided to go through all 26 HIV vaccine-related web-sites and rank them in order of usefulness. In each of the categories below, I have listed my top two picks for sites that provide ample information on the topic.

The top two sites for *comprehensive HIV vaccine information*:

★ NIAID

★ IAVI

Top two sites for *HIV vaccine policy/community involvement*:

★ ICASO

★ AVAC

Top two sites for *HIV vaccine science*:

★ Vaccine Research Center

★ UCSF's HIVinsite

Top two picks for *HIV vaccine documents and articles*:

★ UNAIDS

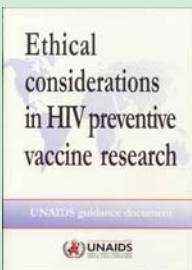
★ WHO-UNAIDS HIV Vaccine Initiative

Top two sites for *HIV vaccine features in the news*:

★ AIDScience

★ HIV and Hepatitis.com

If you know of other sites not listed among those to the left that contain useful HIV vaccine information, please let me know so that I can update this list. We are especially interested in finding out about Spanish, French, or Portuguese language sites. ☘



Ethical Considerations in HIV Preventive Vaccine Research, UNAIDS Guidance Document

Now available in four languages: French, Spanish, English, and Russian.

<http://www.unaids.org/publications/documents/vaccines/index.html>

AIDS Clinical Trials Information Service www.actis.org ACTIS is a service of the US Dept. of Health and Human Services.
AIDScience www.aidscience.com ★ AIDS Prevention and Vaccine Research.
AIDS Vaccine Advocacy Coalition www.avac.org ★ AVAC is an advocacy group in the U.S. that publishes an annual review of progress in HIV vaccine development.
American Foundation for AIDS Research www.amfar.org Supports AIDS research, AIDS prevention, treatment education, and the advocacy of sound AIDS-related public policy.
Capitol Area Vaccine Effort www.aidsvaccine.org Washington D.C. volunteers organized around trial participation.
Centers for Disease Control and Prevention www.cdc.gov/hiv/vaccine.htm The U.S. government's disease control and prevention agency.
Global Alliance to Immunize Against AIDS www.gaiavaccine.org GAIA is a non-profit foundation for a global AIDS vaccine.
HIV and Hepatitis.com www.hivandhepatitis.com/hiv_vacc.html ★ A resource for HIV vaccine-related news articles.
HIV Vaccine Trials Network www.hvtn.org HVTN is an international program to develop and test HIV vaccines.
International AIDS Economics Network www.iaen.org IAEN focuses on how to fund development and access to vaccines.
International AIDS Vaccine Initiative www.iavi.org ★ IAVI is working to accelerate the development and distribution of AIDS vaccines for people around the world.
International Council of AIDS Service Organizations www.icaso.org ★ ICASO promotes and supports the work of community AIDS organizations around the world.
National AIDS Trust www.nat.org.uk NAT, a U.K. based organization, aims to promote a wider understanding of HIV and AIDS.
National Institute of Allergy and Infectious Diseases/NIH ★ www.niaid.nih.gov/aidsvaccine NIAID is a research institute of the U.S. government.
Pasteur Institute www.pasteur.fr A leading HIV vaccine research organization in France.
SA HealthInfo www.sahealthinfo.org/Modules/HIV_AIDS/hiv_aids.htm The South African Health Knowledge Network.
UNAIDS www.unaids.org ★ The Joint United Nations Programme on HIV/AIDS.
University of California at San Francisco http://hivinsite.ucsf.edu ★ UCSF's HIVinsite web page contains extensive information, including some in Spanish.
Vaccine Research Center (VRC) www.vrc.nih.gov/VRC/ ★ The Dale and Betty Bumpers Vaccine Research Center at NIH.
VaxGen www.vaxgen.com A private company developing HIV preventive vaccines.
WHO-UNAIDS HIV Vaccine Initiative www.who.int/HIV-vaccines/ ★ A joint activity of the World Health Organization and the United Nations Programme on HIV/AIDS.

Fenway Community Health

By Benjamin Perkins, Community Relations Coordinator*

Fenway Community Health, part of the Harvard University HVTU, is located in Boston, Massachusetts. Although Fenway's Research and Evaluation Department now manages more than two dozen projects and collaborations, it was the need to better understand the AIDS epidemic that served as the catalyst to its beginnings in the early 1980s. Today, the department is recognized around the country as one of the leading community-based HIV/AIDS research facilities. Expanded efforts in lesbian research and new initiatives in community and program evaluation, as well as gay, lesbian, bisexual, and transgender (GLBT) health, continues to enhance the national recognition of Fenway as a research leader among community health organizations. Fenway is also an HPTN site, coordinating MSM (Men Who Have Sex With Men) prevention at Fenway, microbicide and women's health research at Brown University in Rhode Island, and new collaborations with a Non-Governmental Organization in Chennai (Madras) in southern India.

Fenway was New England's first HIVNET site, enrolling 14 men in the first prime-boost study in New England, and 122 men in the Vaxgen Phase III study. As a member of the Harvard HIV Vaccine Trials Unit, Fenway contributes to HIV vaccine trials that also include Brigham & Women's Hospital, and Miriam Hospital in Rhode Island. Fenway's first vaccine study within the HVTN, Protocol 203, continues on schedule. Fenway is following seven participants in this study, who will be followed for 18 months. As of March 2002, we've also enrolled participants in Protocol 039, a Phase I study, and we have actively begun recruiting and enrolling for another Phase I study, Protocol 041.

Staff

The pride of Fenway's work is reflected in our recruitment and retention staff and coordinators, Darren LeBlanc, Michael Lobo, Matthew Mimiaga, and Christine Borges. Through constant recruitment and visibility, our studies maintain a retention level of more than 90%, and even bring participants together with social events, like our Explore! Valentine's Day Dance. The event was a huge success, bringing together members of Explore! for a night of dancing complete with raffles that included items such as free massage and haircuts, amidst balloons, streamers, and of course, Cupid's arrows.

In the Community

Since 1984, Fenway Community Health has presented community perspectives and provided informed commentary about the conduct of studies through its active program of community education, including the establishment of an independent Community Advisory Board (CAB) in 1994. Presently, the CAB serves both Fenway and Brigham & Women's Hospital. Providing input on appropriate risk reduction education and counseling methods, along with recruitment and retention activities, CAB members are an incredible asset in shaping studies. Working together with Research and Evaluation, the CAB has established strategies for measuring risk behavior and developed approaches to inform and achieve community support for future biomedical and behavioral studies. Recently, the Fenway-Brigham CAB members met for their first-ever CAB retreat, in scenic Essex, Massachusetts. The

retreat gave CAB members the opportunity to get to know each other better, as well as to begin the exciting process of articulating their mission, goals, and action steps for the coming year.

Volunteers

For over 15 years, Fenway has been conducting studies of the natural history and transmission of HIV, and throughout that time, volunteerism has been a part of the Fenway spirit. From our research studies to major fundraisers like the Northeast AIDS Ride, men and women—regardless of sexual orientation—have come together at Fenway to further the causes of the GLBT community.

Finally, if you're ever in Boston, please don't hesitate to give stop by and say hello. We'd love to give you a tour of our fair city, and take you out for some world-famous New England Clam Chowdah! ☘



CAB co-chair Mark Cayabyab and CAB member Kevin Shancady make a presentation at the general CAB meeting.

**Special thanks also to Kenneth Mayer, Darren LeBlanc, Rodney VanDerwarker, and Jim Tella for their contributions.*

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cessidade de completarem todas as visitas, de modo a confirmar todos os dados reunidos desde o início da avaliação e que serviram como base para a decisão sobre o HVTN 501.

A continuidade da segurança e os dados sobre imunogenicidade têm implicações em outras pesquisas também. A HVTN dará início em breve a um estudo usando o mesmo produto em conjunto com lipopeptídeos. Outras redes também estão planejando estudos usando esse produto com populações especiais, tais como adolescentes.

Este atraso para se passar para um estudo de larga escala aumenta a urgência de se avaliarem outros candidatos em estudos de fase I e de fase II. Estamos planejando dar início a um estudo em diversos países com a Merck no início do segundo semestre. Serão realizados, logo após, outros estudos com vários países participantes usando produtos multi-clade desenvolvidos no Centro de Pesquisa de Vacinas do NIH.

Devemos continuar a nos indagar, "O que é preciso para que nossas comunidades estejam prontas para uma pesquisa de vacina anti-HIV?", "Como podemos ajudar as comunidades a entender que será preciso diversos estudos até se achar uma vacina eficaz?", e "O que podemos fazer em cada centro para ajudar os participantes do estudo a entender o valor de sua contribuição para a ciência?"

A despeito do fato de que os planos para um estudo de fase III nesta Rede serão adiados por mais alguns anos, precisamos dar continuidade ao trabalho de educar nossas comunidades com a mesma dedicação. ☘

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tir de la evaluación inicial que sirvió como punto de partida para la decisión referente al HVTN 501.

La seguridad continuada y los datos referentes a la capacidad inmunológica también tienen trascendencia en otros estudios clínicos. La HVTN pronto comenzará un estudio clínico en el que se utilizará el mismo producto con lipopéptidos. Otras redes también están planeando estudios clínicos en los que este producto se utilizará con poblaciones específicas, como los adolescentes.

La demora en avanzar a un estudio clínico de gran escala hace aún más apremiante evaluar otras vacunas experimentales en los estudios clínicos de fase I y fase II. Tenemos previsto comenzar un estudio clínico multinacional con Merck a finales de este verano. Le seguirán otros estudios clínicos multinacionales en los que se utilizarán productos multiclados elaborados en el Centro de Investigación de Vacunas del NIH.

Debemos preguntarnos continuamente “¿qué se requiere para que nuestras comunidades estén preparadas para la investigación de la vacuna contra el VIH?”, “¿qué podemos hacer para ayudar a que la comunidad entienda que se requerirá un gran número de estudios clínicos para encontrar una vacuna eficaz?” y “¿qué podemos hacer en cada localidad para apoyar a los que participan en el estudio clínico y hacerles entender el valor científico de su contribución?”.

No obstante la demora de varios años que sufrirá el prospecto de un estudio clínico de fase III en esta Red, nuestras actividades de educación de la comunidad no deben perder su ímpetu. ☘

(Continued from page 3)

le début de l'évaluation, qui ont servi de base à la décision relative au HVTN 501.

Les données de sûreté continue et d'antigénie ont également des implications pour d'autres tests. Le HVTN démarrera prochainement un test qui utilisera le même produit en conjonction avec des lipopeptides. D'autres réseaux prévoient en outre d'effectuer des tests qui utiliseront ce produit sur des populations particulières, notamment des adolescents.

Étant donné le délai d'exécution d'un test à grande échelle, l'évaluation d'autres candidats aux tests de Phase I et Phase II prend un caractère plus urgent. Nous prévoyons de démarrer avec Merck un test qui aura lieu dans plusieurs pays à la fin de l'été prochain. En outre, d'autres tests qui utilisent des produits multi-clades mis au point au Centre de recherche sur les vaccins des NIH seront réalisés prochainement dans plusieurs pays.

Nous devons continuer de nous demander : « Que faut-il faire pour que nos collectivités soient prêtes à la recherche d'un vaccin du VIH ? », « Comment pouvons-nous aider les collectivités à comprendre qu'il sera nécessaire d'entreprendre de nombreux tests pour trouver un vaccin efficace ? », et « Que pouvons-nous faire dans chaque localité pour aider les participants aux tests à comprendre la valeur de leur contribution à la science ? »

Même si un test de Phase III dans ce réseau doit être retardé de plusieurs années supplémentaires, notre travail d'éducation des collectivités doit se poursuivre avec le même élan. ☘

The CAB in Haiti is busy as always. Pictured above and to the right is a postcard (one among many pieces the CAB has recently developed) that reads— *CAB/GHESKIO Haiti: Volunteers involved in the fight against AIDS. "There is more happiness in giving than in receiving."* ☘

CALENDAR OF EVENTS

CAB PROTOCOL WORKING GROUP CONFERENCE CALL:

Saturday, April 6, 2002, 12 noon E.T./ 9 a.m. P.T.

Wednesday, May 1, 2002, 12 noon E.T./ 9 a.m. P.T.

GLOBAL CAB CONFERENCE CALL:

Thursday, April 11, 2002, 11 a.m. E.T./ 8 a.m. P.T.

Thursday, May 9, 2002, (to be re-scheduled).

COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:

Tuesday, April 15, 2002, 12 noon E.T./ 9 a.m. P.T.

Tuesday, May 21, 2002, 12 noon E.T./ 9 a.m. P.T.

HIV Prevention and Vaccine Conferences:

HVTN FULL GROUP MEETING

May 7-9, 2002, Alexandria, Virginia

→ May 6: CAB and CER meetings

→ May 10: NIH-sponsored CAB ethics workshop



Visit
www.aids2002.com
for conference details.



Comme toujours, le CAB Haiti est très occupé. Voici une carte postale qui fait partie d'une nouvelle production de matériaux éducatifs.

En décembre, le CAB Haiti a organisé douze activités de sensibilisation et deux représentations théâtrales.

Please send suggestions, questions, and article submissions to:

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HIV VACCINE
TRIALS NETWORK