GOODBYE AND HELLO: 
the HVTN CAB Bulletin transitions to the Community Compass

Genevieve Meyer

It has been a pleasure serving as the editor of the CAB Bulletin since 2009. During this time I have worked with many of our sites developing articles that showcase the accomplishments of their CABs. I’ve worked with HVTN scientists who have patiently and enthusiastically helped to translate their scientific discoveries into language that a layperson could understand. I am also proud to have introduced the Spanish and French editions of this publication, and excited that the new publication will soon be translated into Portuguese as well. Editing the Bulletin is a team effort and I could not have done this without many staff within HVTN Core who contributed as writers, editors, advisors and designers over the years, with special thanks in particular to Gail Broder and Erik Schwab.

But now is the season for change. Last year the HVTN was awarded a new 7 year grant with the US National Institute of Allergy and Infectious Diseases, and our sites went through an award process as well. We now work with 12 sites in southern Africa, 8 of them new to the HVTN, along with new sites in Beijing and Cleveland. So as I shift my efforts to our site expansion work in the southern African region, I am pleased to transition the editorial responsibilities of the CAB Bulletin over to my very capable colleague Adi Ferrara. Adi has worked for the HVTN since 2010 as a technical editor and science writer, and she is the Managing Editor of the HVTN News. Another part of this transition is expanding the scope of the CAB Bulletin to a general HVTN community newsletter called the Community Compass. You will notice that our graphic designer Lisa Donohue has created a beautiful new layout to highlight the new features of this publication. These are exciting times for HIV vaccine research, the HVTN, and our new colleagues and sites. I hope you enjoy this new publication as one convenient way to stay current and connected with all this new information.

...Continued on page 2
TRANSITIONS: HELLO!

Adi Ferrara

I am happy to have this opportunity to introduce myself and our new HVTN publication, Community Compass. I would like to start, however, by expressing my deep admiration and appreciation of Genevieve, who has done so much for the HVTN, our sites, and our community, including her leadership of the CAB Bulletin. The southern Africa sites are lucky to get her undivided attention and vast experience, but we’ll sure miss her here!

My name is Adi Ferrara, and I’ve been with the HVTN since 2010. I’m responsible for the Network’s scientific newsletter, the HVTNews, and have worked on many protocols, Face-to-Face protocol team meetings, and document templates. I have probably interacted with some of you in meetings or through emails, and hope to get to know you better through this publication.

The Community Compass is, first and foremost, the community’s newsletter. We want this publication to be the community face of the HVTN, especially as we grow and move into new types of studies as the field moves forward.

As your newsletter editor, I want to encourage you to send me (aferrara@fhcrc.org) your thoughts and suggestions for articles or features. I would specifically love to get any news relating to community events at your site, honors your site receives, mentions in local media, etc. Please help those of us in Seattle make this publication a truly global HVTN community publication!

I would also like to reassure CAB members that there will be a permanent CAB Corner in this newsletter, starting with this issue, so please let me know if there are items you’d like to see in this dedicated space!

I am very excited to launch this newsletter and hope you’ll like it as much as I do. Welcome to all readers at our sites and beyond! ☀️

(above) Adi Ferrara having a blast at Disney World’s Animal Kingdom.
IN THE SPOTLIGHT

Case Western Reserve University Clinical Research Site

By Bob Bucklew, Outreach Coordinator, Case Western Reserve University CRS

We are quite pleased with the opportunity to introduce our city, Cleveland, Ohio, and our site, the Case Western Reserve University Clinical Research Site, to the HVTN community.

Cleveland is a medium-sized city located in the Great Lakes region of the US Midwest bordering on Lake Erie. Racially, ethnically and culturally diverse and with a long progressive history, Clevelanders pride themselves in their civic engagement and volunteerism. Like many of the cities in our region, Cleveland has undergone economic hard times and social displacement over much of the last thirty years. Yet the tenacity of its citizens’ belief in our City continues to birth new and exciting prospects. Cleveland offers something for everyone. Perhaps this is most apparent by our hosting of the worldwide Gay Games in August 2014 and the recent announcement that Cleveland will be the site of the Republican Party’s 2016 presidential convention: diversity indeed.

One additional point of pride for many Clevelanders is our medical and research institutions, including our site’s home, Case Western Reserve University and University Hospitals of Cleveland. The Case site was originally established in 1987 as a founding site of the HVTN’s sister network, the AIDS Clinical Trials Group (ACTG). During most of our history, the site concentrated on treatment trials for people living with HIV. We are still a very active site within the ACTG. The site shares clinic space with the University Hospitals’ John T. Carey Special Immunology Unit, one of the largest HIV clinics in the Midwest.

The expansion of our clinical trials work to HIV prevention strategies came in 2007 when we joined the newly formed Microbicide Trials Network. The differences between conducting treatment trials and prevention trials became apparent quite quickly. Our long-nourished relationships with the HIV-positive community and medical providers were no longer sufficient to reach our enrollment goals. New outreach and education efforts and initiatives were needed to connect with new communities and new populations.

Over the next years, several exciting but challenging trials opened at our site, working with a wide variety of populations to conduct outreach, education and recruitment: low-risk heterosexual, sexually-active women in a vaginal gel/PrEP study; monogamous, heterosexual couples in a vaginal gel coital (sex) study; post-menopausal women in a vaginal ring trial; MSM, transgender men and women who have sex with men, and heterosexual women in a PrEP trial; and MSM and transgender women who have sex with men in the HVTN505 vaccine trial.

One important reason for the Case site’s success over the years has been the dedication and support of the members and friends of our Community Advisory Board. Established in 1991, our CAB, like our site, concentrated on treatment research. Since our expansion to prevention trials, our CAB has established ad hoc committees... Continued on page 11
CROI 2014 REPORT

Steven S. Muchnick, PhD

The 2014 Conference on Retroviruses and Opportunistic Infections (CROI) was held March 3-6 in Boston, Massachusetts. The conference focused primarily on HIV-1 (including cure research) and related opportunistic infections, notably tuberculosis (TB) and hepatitis C (HCV). It also included sessions on nonhuman primate research and public policy issues. There were over 4000 participants including physicians, researchers, and media representatives from around the world, as well as 24 community educators, including myself. As a scholarship recipient at this conference, I am required to share what I learned from the conference, and the HVTN has given me this forum to share some conference highlights.

Following are summaries from presentations in several areas likely to be of interest to this newsletter’s readers.

VACCINES

ADVANCES IN HIV PREVENTION: VACCINES

To date, the one notable (and surprising) success in the HIV vaccine field was RV144 (the “Thai Trial”), which showed a modest degree of protection in vaccinees. Results from a follow-up study, RV305, were discussed at CROI 2014. “RV305...tests three late-boost regimens in RV144 trial participants who received the full vaccination schedule at two sites in Thailand,” according to the U.S. Military HIV Research Program (USMHRP), which conducted both RV144 (with the Thai Ministry of Health) and RV 305. Study participants in RV305 received the same two vaccines used in RV144 (either one by itself or both in a series) or a placebo. The results will help determine the most appropriate vaccination schedule for a planned efficacy trial.

A second vaccine presentation concerned an analysis that was done of CD4 T-cell responses in participants from 7 HIV vaccine studies performed by (or in cooperation with) the USMHRP, including RV144. The vaccine regimens and delivery methods varied, including several types of vaccine vectors and several different HIV inserts. All these vaccines induced CD4 T-cell responses, but the sizes and types of responses varied significantly from one to another. Additionally, vaccine-specific immune responses varied drastically from those developed through natural HIV infection. It is hoped that further understanding of the responses will help in the design of future vaccines.

PREVENTION

ADVANCES IN HIV PREVENTION: PRE-EXPOSURE PROPHYLAXIS AND TREATMENT AS PREVENTION

CROI 2014 covered a range of issues regarding oral pre-exposure prophylaxis (PrEP).

PrEP is essential in developing countries, because these areas often have a high burden of new HIV infections. On the other hand, managing adherence in these settings has so far proved to be particularly challenging in prevention studies. The differences between consistent and inconsistent use of PrEP help explain the outcomes seen in different PrEP trials.

Numerous studies in the U.S. have revealed a lack of knowledge among adolescents and older youths in schools and community settings about HIV generally, and PrEP specifically. Groups are often misinformed, and this has caused PrEP use to be stigmatized. There is a major need for better education about PrEP and its correct usage in these settings.

Treatment as prevention has shown remarkable success as an approach to HIV prevention. The PARTNER study of Treatment as Prevention (TasP) looked at use of antiretroviral therapy taken by the HIV-infected partner in 767 discordant (1 partner is HIV+, the other HIV-) couples. Of these couples, 60% were heterosexual and 40% were gay-male couples. The study was conducted at 75 sites in 14 European countries and included more than 30,000 sex acts between people who often did not use...Continued on page 10
Octavio Valente, Jr. was a dedicated CAB member from Rio de Janeiro, Brazil who passed away on March 21, 2006. Octavio served many roles in the HVTN and in the HIV/AIDS community through his advocacy, dedication and spirited energy. In his honor, this service award is given to a CAB member who has demonstrated exemplary leadership and dedication in the HVTN.

This year’s award recipient is the Rev. David Galetta, Cape Town’s Emavundleni CAB member since 2004, and the Global CAB Co-chair since 2011. He is a past recipient of the HVTN’s Network Citizenship Award for exemplary contributions and citizenship. Rev. Galetta holds a post-graduate degree in International Research Ethics from the University of Cape Town.

Rev. Galleta’s citation recognizes his “unwavering support to his fellow CAB colleagues around the globe, bringing his years of CAB experience, patience, and CAB development know-how.”

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Principal Investigator,
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DR. ARTUR KALICHMAN
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From breakout sessions through award presentations, participants at the HVTN’s spring Full Group Meeting worked hard during 2.5 busy days, and let loose at a fun and friendship-filled reception.
The HVTN’s Full Group Meetings and Welcome Receptions are essential in allowing colleagues from around the world to connect in person.
The HVTN spring Full Group Meeting in Washington DC started on a note of “optimism with an edge.”

HVTN Principal Investigator Dr. Larry Corey opened the Network’s first meeting of the new grant cycle with remarks expressing optimism for the future of the HIV vaccine field. Dr. Corey did point out, however, that it has been 5 years since the results of the Thai study (RV144) were published, and the HVTN’s follow-up phase 1 studies (part of a collaborative effort of the group called P5, see below) will not be starting until 2015. This means that we may not see results from any large scale, phase 3 efficacy studies until roughly 11 years after the RV144 results – hence the “edge.”

An important theme in this year’s meeting was finding correlates of protection. This will also be a major part of all of the Network’s studies moving forward. Correlates of protection are the parts of the immune response that protect against HIV once an effective vaccine is given to a person. From the RV144 study, the only vaccine study that has shown a reduction in new infections among people who got the vaccine regimen, we know of 2 antibodies that appeared at different levels in people who were protected from HIV by the vaccine regimen, compared to people who became infected. What we don’t know is if the levels of these antibodies changed because of the study vaccines and, more importantly, if that change is what protected people, or if the difference was unrelated to the vaccines. If we can prove that the levels of antibodies changed because of the vaccines, and that change is what helped to protect people, we will have our correlates of protection. (It is important to remember that there may be other correlates of protection besides the ones we suspect in the RV144 trial.)

Correlates of protection are important because they make studies move faster. If we have a vaccine that works in one population, we will not have to do very long and expensive studies for every other population. Instead, we can look for correlates of protection and determine very quickly if the vaccine would work in a new population. Long efficacy studies mean more time lost and more people getting infected, and we want to avoid that. Since different populations may be infected by different strains of the virus, one vaccine may not work for everyone, so knowing the correlates may also enable us to modify the vaccine for other populations more easily.

Other areas of development Dr. Corey highlighted included the P5 efforts in southern Africa, and the collaboration between the HVTN and the Chinese Center for Disease Control and Prevention (China CDC), as well as promising vaccine...Continued on page 9
candidates in development.

The P5 is the Pox Protein Public Private Partnership, a group of public and private organizations and companies that set as its main goal to build and improve on the results of RV144, which used a canarypox and protein vaccine regimen. Members of the P5 include the HVTN, the Bill and Melinda Gates Foundation, the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Military HIV Research Program, Novartis Vaccines, Sanofi Pasteur, and the South African Medical Research Council.

The HVTN and NIAID are also partnering with the China CDC to carry out clinical trials of a new experimental vaccine combination, which includes DNA and pox vaccines developed by the Chinese, along with a new protein vaccine being developed by NIAID. The first clinical trial of the protein vaccine will be done in the United States and later trials to test combination vaccine regimens will be done in China.

Dr. Corey's opening talk was followed by a plenary session on correlates of protection, emphasizing the importance of this topic as the first item on the meeting's agenda.

HVTN MATERIALS UPDATE

We have a new handout! “HIV Vaccine Myths and Facts” is available on hvtn.org in the “PARTICIPANTS” section.

EXPLORING HVTN.ORG

In the PARTICIPANTS section of the newly designed hvtn.org you’ll find volunteer profiles and YouTube videos from past and current study volunteers. Check it out!

SOCIAL MEDIA

During the HVTN Conference attendees shared their thoughts and experiences via Twitter (tagged #hivvax):

- So proud of our Med Director Dr. Janine Maenza. She won Citizenship Award at HIV2015. Congrats! pic.twitter.com/b6EE6KtCs
- Adri Ferrara @AdriFerrara Jun 3
- I am always amazed at the depth of scientific curiosity in our investigators, and the questions they answer to advance the field. #HIVvax
- Seattle HIV Vaccines @HIVVAX Jun 3
- Today at the HIVVAX Conf, we hear from the RAAMP scholars: a program to engage more medical students in our research. #hiramp
- Adri Ferrara @AdriFerrara Jun 4
- The data from the HIVVAX is a reminder that no study is a failure in this field – we learn from the responses to every regimen. #HIVvax
- HIV Vaccine Trials @HelpEndHIV Jun 3
- Research innovations bring hope for treatment and AIDS prevention. Use of monoclonal HIV antibodies in phase 1 trials #HelpEndHIV

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http://www.hvtn.org/content/dam/hvtn/participants/myths/myths-facts-handout-2014.pdf
condoms. During the follow-up period of the study, none of the HIV-negative partners became infected if their HIV-positive partner had an undetectable viral load. The principal investigator of PARTNER indicated that if the same patterns continued over time, there would be less than a 5% chance that an uninfected partner would become infected over 10 years and that the chance might, in fact, be zero. These low numbers might change if risk behaviors changed in one or both partners.

My take-away messages: Providing PrEP and aggressive treatment to those in need who wish to take it will reduce the incidence of HIV infection. Greater education about how to use both strategies effectively is essential in both developed and developing countries.

PEPFAR & THE GLOBAL FUND AT TEN YEARS

The President’s Emergency Plan for AIDS Relief (PEPFAR) was established by U.S. President George W. Bush. The Global Fund to Fight AIDS, Tuberculosis, and Malaria has 54 donor countries.

Stefano M. Bertozzi, MD, PhD, outgoing director of PEPFAR, spoke about its history, present, and future plans. His most important point was that PEPFAR’s effectiveness needs to be measured not in money spent or planned spending but, rather, in the “bang for the buck,” that is, what is achieved for each dollar spent. PEPFAR currently has programs in 22 African countries and in 31 other countries around the world. As of the end of September 2013, PEPFAR supported:

- antiretroviral therapy (ART) for 6,700,000 people;
- over 4,200,000 voluntary medical male circumcisions; and
- care and support for 17,000,000 people.

In 2013 alone, PEPFAR funded HIV testing and counseling for over 57,700,000 people, including 12,800,000 pregnant women. PEPFAR is the largest donor to the Global Fund, providing 33% of its funding.

The Global Fund has funded programs that:

- provide over 6,000,000 people with ART;
- have diagnosed and treated over 11,000,000 cases of TB; and
- have distributed 360,000,000 bed nets to keep out malaria-causing mosquitoes.

PEPFAR and the Global Fund are the world's largest and most effective programs by which developed countries help developing countries fight HIV, TB, and malaria, though it is clear that an HIV vaccine remains an urgent need in this effort for both developed and developing countries.

The conference concluded with an announcement that CROI 2015 will be held in Seattle on February 23-26. Its General Chairman will be HVTN Co-PI Dr. Scott Hammer.

to oversee specific prevention trials, such as vaginal microbicide trials and HVTN505. These committees have allowed a subgroup of interested community members to concentrate on and provide support in areas of special interest. The additional work required of a CAB with expansion into multiple networks can be challenging. The site outreach team, in close consultation with the CAB leadership, is working to provide CAB members and friends with better and more accessible education materials to assist them in learning new research areas and specific protocols.

Our outreach team and activities have undergone many changes since we became a site that works with both HIV treatment and prevention networks. We currently have three outreach team members, Brooke Willis, Dan Kilbane, and Bob Bucklew. Attendance at community events (we love going to Cleveland Pride, the Asian Festival, and the Cleveland International Film Festival, to name a few), speaking to groups, distributing flyers around town, responding to contacts and providing one-on-one education sessions keeps us busy interacting with hundreds of Clevelanders.

While focused on education about and enrollment in clinical trials, we are actively involved in Greater Cleveland’s other HIV activities and initiatives. Not only do the Site’s resources in personnel and finances contribute to the HIV efforts in Cleveland, our participation in non-research efforts engenders a feeling of true partnership with the Site throughout much of the community. From distributing materials on HIV testing days to transit commuters, to sponsoring an evening for the upcoming Campaign to End AIDS Leadership Summit, which will take place in Cleveland in October, we remain a vital, active part of the community.

As much as we never get tired talking about ourselves, we look forward to learning more about and from our sister sites in the HVTN.

In the Spotlight: Cleveland ...

Case Western Reserve University Clinical Research Site Staff: (back row, from left): Paul Blakely, Brooke Willis, Dan Kilbane; (from row, from left): Emily Zottola, Jane Baum, Trisha Walton, Bob Bucklew, Kristen Allen, Michelle Gallagher

To read other featured profiles on sites within HVTN, visit the TEAM section at hvtn.org/en/team.html and look for the “Featured Profile” link for the latest site profile.
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ABOUT COMMUNITY COMPASS
The Community Compass aims to keep the HVTN community informed about the Network’s research, site activities, and advances in the field of HIV Prevention and Vaccination. We encourage community members to submit news and event reports to this newsletter, and make this a true community sharing platform.

The HIV Vaccine Trials Network is an international collaboration of scientists and educators. Support for the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health, an agency of the U.S. Department of Health and Human Services. The Network and NIAID have a close, cooperative working relationship, with shared attention to intellectual and scientific issues.