COMMUNITY COMPASS
A PUBLICATION OF THE HIV VACCINE TRIALS NETWORK

A Letter from the HVTN’s Executive Management Team

Dear Community,

This May, at the HVTN’s annual Full Group Meeting in Washington DC, one of our most successful plenary sessions focused on the intersection of community engagement and advocacy. I want to give a shout out to Wakefield, Director of External Relations, for pulling the speakers together and organizing the symposium.

The forum began with Mitchell Warren from AVAC* speaking about AVAC’s commitment to advocacy, communication, and capacity building for community members. Wakefield spoke about the HVTN’s view of community engagement, which reaches well beyond Community Advisory Boards to broad stakeholder engagement.

The HVTN has held a number of forums in which stakeholders (community members, governmental and non-governmental organizations, and regulators) weigh in on trial

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HVTN 702 is a “Go”
UHAMBO CONTINUES

Genevieve Meyer, HVTN Community Engagement Unit, with contributions from Dr. Nicole Grunenberg, MD, HVTN Clinical Trials Physician and Protocol Team Leader

At the recent HVTN Full Group Meeting in Washington, DC, the exciting news was delivered that HVTN 702, a pivotal phase 2b/3 HIV vaccine efficacy trial, had received the “green light” to move forward. “It should give the world great hope, it should give the world courage, that scientists are committed to finding an HIV vaccine and that we’re on to the next step,” notes Dr. Glenda Gray, study chair for HVTN 702.

The decision to move forward with this study was based on a smaller phase 1/2 safety study called HVTN 100. HVTN 100 used a combination of an ALVAC and a protein vaccine, similar to what was given in RV144, the groundbreaking HIV vaccine efficacy trial conducted in Thailand, which showed 31.2% protection. The results of RV144 were promising, but not effective enough to move the products to licensure and public distribution.

HVTN 702 is the next step in the journey towards a licensed vaccine. The study will use similar ALVAC and protein vaccines that have been modified from RV144 to match the most common strain of HIV found in South Africa. In addition, the protein vaccine contains an adjuvant called MF59, which should help improve the vaccine’s strength. Lastly, one more injection visit has been added to the

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The HVTN does not do research in communities; it does research with communities. This has been the guiding principle that has been the foundation of our network since it began, and it is never more evident than in our AMP studies in the Americas and sub-Saharan Africa: HVTN 704/HPTN 085 and HVTN 703/HPTN 081. The protocol team covers both studies and it includes 4 Community Engagement staff representing both networks, 3 Community Advisory Board members and 2 Community Educators/Recruiters representing the 3 regions: North America, South America and Africa. Underscoring principles of Good Participatory Practice, community representatives contribute to all stages of protocol development to help ensure that community has a strong and effective voice in shaping the design and conduct of these pivotal studies.

Recognizing the importance of community in these studies over the next 5 years, our two networks decided to hold a series of stakeholder engagement meetings in regions where the trials will be conducted. On March 31–April 1, the first of these meetings for the sub-Saharan Africa region was held in Cape Town, South Africa. It drew together over 80 people including the Principal Investigators and Community Educators/Recruiters from all 15 of the sub-Saharan African research sites conducting AMP. The South Africa–based sites also invited key community stakeholders including representatives from governmental and nongovernmental organizations, public health advocates, institutional review board members, community officials and traditional and/or spiritual healers. This meeting was co-sponsored by the South African Medical Research Council and its focus was geared toward study roll-out in the South Africa. Meeting participants received detailed information on the study’s science and design and had ample time to ask questions and offer their community expertise. Stakeholders reflected on facilitators and barriers to enrollment in their communities and brainstormed effective ways of engaging their communities to help them understand how important this study is in the battle against HIV! A second session is planned for early August and will include stakeholders from the rest of the sub-Saharan sites.

Enrolling a study of this importance with 1500 women in 7 countries will take more than hard work and scientific expertise. The battle against the spread of HIV in our communities requires dedication, commitment, and passion — all essential characteristics that stakeholders bring to the table. Together we can stop HIV!

I was over the moon at the conclusion of the meeting recognizing that the planning team had successfully met its objectives: dialogue was established with community stakeholders, and they were provided a platform to raise questions about the AMP study and offer implementation recommendations!! I was very pleased when it was recommended that another stakeholder meeting be convened. That was confirmation for me that we’d definitely met our objectives!

Rhonda White, Senior Community Program Manager
HIV Prevention Trials Network.
MEET JOSE LUIS AND DIEGO!

Genevieve Meyer, HVTN Community Engagement Unit

During our recent AMP Study training workshop in Washington, DC, I had the pleasure of getting to know 2 staff members from one of our newest AMP sites: Via Libre in Lima, Peru.

Meet Jose Luis Castro and Diego Torres. Jose Luis (JL), the site’s community educator, has worked at the site for 8 years. Diego (D) has worked at the site for 2 years as a recruitment and retention officer.

Genevieve (G):

So what brought you to this work?

JL: I think the whole idea of antibodies is interesting. Since the earlier phase 1 studies showed good results, I’m excited about what we may learn from this phase 2b study. We’re all hopeful that the antibodies will show favorable outcomes and that we will soon have new prevention tools; the community has high hopes.

D: It was actually one of our clients who told me about the HIV vaccine work at Impacta (also an HVTN site in Lima), and this is what first got me excited about this area of prevention research, and then I learned about AMP. PrEP is a helpful tool, but for people who don’t want to take a pill, it would be great if there was something else you could take. The AMP study is an important step towards ending HIV.

G: Since the Via Libre site is new to the Network, can you share with us something you’d like people to know about the site itself?

JL: Via Libre is like a family and you feel at home. The site has a strong commitment to the community to maintain confidentiality of patients and participants, and that’s why it’s been around for 26 years. It’s a referral agency for the government, and has maintained its good reputation because of its well-trained doctors, nurses, and community staff and that is known and felt in the community.

D: When you come to Via Libre you feel you can trust and be comfortable interacting with the staff, and that you’ll get results. Via Libre has 3 main parts: a clinic, social services, and a research side; the services are really comprehensive. As JL said, it’s a big family and we work hard so that everyone feels comfortable. Not only do we work with the clients, but we will meet with someone’s whole family — whatever it takes so that everyone becomes the best version of themselves.

G: It sounds like an amazing site! We are very excited that Via Libre will be participating in this important study. So tell us, when you’re not working, what do you like to do for fun? What are you passionate about?

JL: For me it’s a group I started 2 years ago called “Casa Diversa” which is a community space for gay guys, a place of friends. We work to achieve respect and equal rights for our community because we are often discriminated against or excluded in my country. The group focuses on issues like activism, leadership, human rights, and health. The goal is to coordinate and work with our public health departments so they take these issues into account when planning their programs and so that they come to us for advice. We also want the government to invest more in these issues. So this is what I do in my spare time and I’m very passionate about it.

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Iquitos, Peru: The Asociacion Civil Selva Amazonica organized a youth flash mob using dance as a way to raise awareness about HIV vaccines, the AMP Study and their hope of finding alternative ways to end HIV soon.

Medunsa, South Africa: The MeCru site held a community event focused on how vaccines have helped to get rid of many illnesses such as small pox, and stressed the urgent need to find an HIV vaccine. They invited local stakeholders, health care workers from the university and hospital, university staff, and students to attend the event. They provided HIV counselling and testing, distributed flavored condoms, and administered flu vaccines.

San Francisco, California: Bridge HIV celebrated HVAD at Cal State University, East Bay. Their bnAb superheroes from the “League of a Three” played HIV, vaccine, and AMP Study trivia games with students.

Maputo, Mozambique: Edna Viegas, clinical investigator and scientific director of CISPOC, speaking about the impact of HIV and the importance of an HIV vaccine, to an audience of around 800 people at one of the most important bus stations in Maputo.

Lima, Peru: The Impacta sites raised awareness for HVAD through promotion of their Vacuman campaign.

Durban, South Africa: Research nurse Mandisa Msomi welcoming study participants and CAB members to the site’s HVAD event at the CAPRISA eThekwini site.
**LEFT:** Dr. Shelly Karuna, HVTN Director of Clinical Development & AMP Protocol Team Leader, providing an overview of the many steps and players involved in getting the AMP Studies launched so efficiently on such a tight timeline. **BELOW:** Neetha Morar, Senior Research Manager of the HIV Prevention Research Unit in Durban, speaking at the General Community Session about how her sites work to keep current and former study participants engaged in research.

**LEFT:** Nombeko Mpongo from the Desmond Tutu Emavundleni Research Centre CAB talking about the personal and professional intersection of her role as a CAB member. **RIGHT:** Dr. Kathy Mngadi, Principal Investigator of the CAPRISA eThekwini site, sharing her site’s perspective on the role of the investigator in supporting community engagement.

**LEFT:** DaShawn Usher, Community Educator from the New York Blood Center, highlighting some of the most effective strategies used to engage communities for the AMP Studies.

**FULL GROUP MEETING**

**HIV VACCINE TRIALS NETWORK**

**MAY 18 - 20, 2016**
COMMUNITY INDICATORS SURVEY (CIS)
A reflection on the relationship between a clinical research site and its CAB

Lisa White  *Lisa is the outgoing CAB representative to the HVTN’s Network Evaluation Committee. She is currently a CAB member of the HIV Vaccine Trials Unit in Seattle, Washington.*

From protocol design to study implementation to result distribution, the Network strives to maintain a healthy partnership with the communities where its research sites are located. For this reason, each clinical research site supports a local Community Advisory Board (CAB). Every year, the HVTN assesses the relationship between clinical research site staff and their CABs. But measuring the quality of this relationship is not simple. What are the metrics of a healthy partnership between researchers and community? The Community Indicators Survey (CIS) is one tool that the Network uses to assess this dynamic relationship.

The survey tries to capture the nature of the interaction between a site and its CAB through both quantitative and qualitative questions. Importantly, site staff and CAB each complete the survey independently of one another and submit their results to the Network Evaluation Committee (NEC). The NEC reviews and compares CAB and site responses then sends sites a summary of responses including any major differences between the 2 versions. Sites are encouraged to discuss the responses with CAB members and brainstorm ways to improve or strengthen the relationship when needed. This approach gives the site an opportunity to celebrate areas of strength, and highlight areas needing more attention. For sites the survey is a tool for self-evaluation and reflection; for the Network it provides a window into the CAB/site relationship and an opportunity to step in and advise or guide when appropriate.

Based on feedback from CAB members and site staff, the survey was revised in 2015 to better explore the nature of the CAB/site relationship. After eliminating redundant questions and simplifying the format, the revised survey now also covers CAB recruitment and retention goals, as well as site activities designed to support CAB efforts.

Ultimately, the survey serves to provide a broad view of the relationship between each research site and its CAB and to be a reflection of research and the community at large. It sheds light on issues that the site, CAB and Network may not otherwise be aware of. The NEC is always seeking new ways to strengthen this tool and the questions within.

For questions about the NEC or the Community Indicator Survey, please email: Vtn.evaluation@hvtn.org
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shape issues. For example, before and during large vaccine efficacy trials, HVTN has engaged with multiple stakeholders to build and deliver comprehensive prevention packages for all HVTN participants. HVTN has worked with AVAC in developing the blueprint for active engagement with community, and for translating vaccine science into digestible pieces for multiple communities. Both HVTN and AVAC recognize the importance of engagement with community, before, during and after trials.

We also heard from an investigator (Dr. Kathy Mngadi), a CAB member (Nombeko Mpongo) and a Community Liaison Officer, (Ross Malamatsho), all from different regions of South Africa. The theme that ran through all 3 presentations was the teamwork required to fully engage community. Although each team member has a different role to play, there is tremendous overlap in terms of community education and input for each trial. Their tremendous commitment to their communities brings us closer to a safe and effective HIV vaccine every day!

And that takes us to thanking you, our community partners. You provide so much input and support to the work we do, through your involvement on Community Advisory Boards, as study participants, serving on protocol teams, and attending community forums. We always learn new things in our partnership with community, so please reach out to us at any time with ideas or feedback. Working with you is truly one of the highlights of our efforts in the HVTN! ☺

Sincerely,
Susan

Dr. Susan Buchbinder is the Director of Bridge HIV, Population Health Division of the San Francisco Department of Public Health. She is also the site principal investigator representative to the HVTN’s Executive Management Team.

*AVAC- Global Advocacy for HIV Prevention (www.avac.org)

regimen (5 injection visits, instead of 4 in RV144) with the goal of prolonging any protective effect. “If we can find something that can be administered once off, twice off, maybe even 3 or 4 doses, but once, you know, done, that is incredibly empowering.”* Dr. Linda-Gail Bekker is the study chair for HVTN 100 and a study co-chair for HVTN 702.

Before HVTN 702 could move forward, we needed to see if this vaccine combination could produce at least comparable results to those in RV144 in 4 key types of immune responses. HVTN 100 was the study that proved this theory. But HVTN 100 was a small trial designed to assess safety and immune responses, not whether the combination could prevent HIV. A large efficacy trial is now needed to see if these vaccines can actually help prevent HIV infection. This is what HVTN 702 is designed to do. It will be the first major HIV vaccine efficacy trial in 7 years.

Sub-Saharan Africa bears a disproportionate burden of disease, and South Africa is at the heart of it with more than 6 million people currently living with the virus. If we can show that this vaccine combination is at least 50% efficacious at the 2 year mark, it could lead to the first licensed preventive HIV vaccine and would have the potential to prevent thousands of new infections each year.

HVTN 702 is expected to open around November, 2016 and will enroll 5400 men and women across 15 sites in South Africa. ☺

To learn more about this exciting journey, visit: www.niaid.nih.gov/news/newsreleases/2016/Pages/HVTN702.aspx

www.Uhambo.org.za

1 “HIV vaccine trial to take place in South Africa later this year,” CCTV Africa 21 May 2016

Professor Glenda Gray is the President of South African Medical Research Council, the study chair for HVTN 702, a Principal Investigator of the HVTN; & the Non-executive Director of the Perinatal HIV Research Unit, Chris Hani Baragwanath Hospital, Soweto, South Africa

2 www.statssa.gov.za/publications/P0302/P03022015.pdf
Dear readers, colleagues and friends,

It has been a pleasure to work with many of you over the years. So with heavy heart I write to announce that after 8 years at the HVTN, I will be leaving in August to start the next chapter in my life, which means transferring to a job that keeps me in Seattle full-time.

As CERs, CAB members and the community at large you are the heart of what we do. Without community support, without our dedicated education, outreach and recruitment staff, without our CABs, we wouldn’t be able to conduct our studies. We all do this work because we want to see an end to HIV and your contributions are an essential part of this process.

Seeing your commitment—both at a network level and at a local site-level—has been the most rewarding and exciting part of this job. I learn from you every day and I hope you continue to be our teachers and advisors.

In gratitude,
Genevieve

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MEET JOSE LUIS AND DIEGO

D: For me it’s writing. I love writing. In college I wrote a book called “Phoenix” that shares stories of my life. I’m working on a new book project now. My other passion is independent movies. I belong to a movie group where we watch films then critique them. My favorites are the horror movies.

Jose Luis and Diego, thank you for spending time to share with us about your site, your work and yourselves. The HVTN is thrilled to be working with Via Libre on the AMP study and we are excited to welcome such smart, caring, and fun staff like you to the HVTN family!

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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.

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View past issues of the Community Compass Bulletin (formerly CAB Bulletin) at hvtn.org/en/community/community-compass.html

SEND INQUIRIES ABOUT THIS ISSUE OF COMMUNITY COMPASS TO:
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ACRONYMS & ABBREVIATIONS

ACTG AIDS Clinical Trials Group
CAB Community Advisory Board
CER Community Educator/Recruiter
DAIDS (U.S.) DIVISION OF AIDS
HPTN HIV Prevention Trials Network
IMPAACT International Maternal Pediatric Adolescent AIDS Clinical Trials
MTN Microbicide Trials Network

Translations in Spanish, Portuguese and French provided by Northwest Translations, Inc.
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The HIV Vaccine Trials Network is an international multi-disciplinary collaboration. 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.