A letter from Executive Director Dr. Jim Kublin

Dear Community,

The year 2016 starts with great excitement and promise for the HIV vaccine research community, and I’m honored to be working with you in fulfilling our mission of finding an HIV vaccine for the world.

This year we look forward to starting efficacy studies of the VRC01 antibody (see article on page 2) and HVTN 702, which will build on the results of the Thai study (RV144) with the goal of licensing a vaccine in South Africa. In addition, we have a number of other phase 1 studies to keep the research pipeline enriched with alternative vaccines. Our participants, communities, and research sites will continue to be the foundation for our work and the keys to our success, getting us one step closer to our goals of curbing new HIV/AIDS infections through an efficacious HIV vaccine.

...continues on page 11

MEET PULENG!

TITLE/ROLE: Recruiter and counselor (since September, 2014)
SITE: Perinatal HIV Research Unit (PHRU) Soweto, South Africa

Clinical research is nothing new for this compassionate recruiter. Before working for PHRU’s vaccine research unit, Puleng worked with the FACTS001 team recruiting women for a vaginal microbicide study, and before that, she worked with behavioral HIV prevention studies. She is very hopeful about finding an effective intervention to combat HIV and this hope is what brought her to HIV vaccine research.

When asked about her biggest accomplishment so far, Puleng speaks of her work engaging communities. She works tirelessly to sensitize about issues related to HIV and HIV vaccines. It is perhaps her background in behavioral HIV research that makes Puleng such a star with recruitment. She engages her audience in dialogue about their HIV concerns both for themselves and for their communities. She spends time getting to know people, trying to understand them and their behaviors and the factors that may put them at risk for HIV. Puleng is able to connect with and assess potential participants and brings in those who seem like a good fit for studies. And this strategy is paying off!

...continues on page 3
AMPing up for HIV prevention

Jim Maynard, Director of Communications & Community Engagement

HIV continues to be a major health crisis worldwide with over 2 million1 new infections each year and 1000 per day in South Africa alone2. Our current HIV prevention “toolbox” includes some highly effective tools like condoms and PrEP (Pre Exposure Prophylaxis), yet they have not proved to be enough to adequately curb the epidemic and protect our communities. The HVTN and HIV Prevention Trials Network (HPTN) will be partnering for the first ever proof of concept trials to test a new idea that offers great promise to prevent new infections.

This new idea is called Antibody Mediated Prevention, or more simply, “AMP.” The goal of AMP is to prevent HIV infection using a broadly neutralizing antibody (BNAb) against HIV given through an IV infusion (sometimes called a drip). While a vaccine teaches the body to make antibodies on its own, AMP involves giving the antibody directly to people. The human immune system produces antibodies in response to potential invaders like viruses so that your body can block an infection, or prevent the invader from causing disease.

The VRC01 antibody, discovered by a team of researchers at the NIAID Vaccine Research Center (VRC), was initially identified in a person who had been infected with HIV for over 10 years but had never developed AIDS. Such individuals are known as “elite controllers.” VRC01 has been shown to neutralize (or block) over 90% of the 190 strains of HIV it has been tested against. Because of this, researchers are optimistic that this BNAb could be effective in preventing HIV for populations around the world and not just in a particular region.

Dr. Larry Corey, principal investigator of the HVTN and co-chair of the AMP Studies, said, “We need to know if this antibody will protect against infection. The data from laboratory studies and animal models is very exciting, but we need to know if this ‘holy grail,’ a broadly neutralizing antibody, can actually be protective in people…”

“We need to know if this antibody will protect against infection. The data from laboratory studies and animal models is very exciting, but we need to know if this ‘holy grail,’ a broadly neutralizing antibody, can actually be protective in people…”

–Dr. Larry Corey
This will help us understand how to build vaccines that could cause the right immune responses. These are questions that phase 2b studies can help us to answer.

Our two networks have a history of working closely with community members as full partners in research happening in their communities, and this is especially evident in preparing for the AMP Studies. The protocol teams include 3 CAB members and 2 CERs to ensure community input to the protocols. The AMP Community Working Group was formed with a CAB member and CER from each of the clinical trial sites conducting the trials to give real time feedback on everything from communication tools and recruitment materials to ongoing conduct of the trial at their sites.

US site staff took part in a 4 day AMP training in November 2015, which included a 6 hour cultural sensitivity training to help staff prepare for cohorts they may not have experience in working with such as transgender and MSM community members. Similar trainings are being planned for 2016, one for the South American sites and another for the African sites.

AMP may be an idea that helps us slow down the spread of HIV until we reach our ultimate goal of a safe and effective vaccine! Working together, we can reach that goal.

Meet Puleng!

continued from page 1

Since beginning at PHRU, she has surpassed their target enrollment slots nearly every week.

While many see Puleng as a recruiter and counselor extraordinaire, she describes herself as a very straightforward person with nothing to hide; an “open book” in her words. Still, she admits that one thing she tries to conceal is when she gets emotional about the stories she hears, and how much they weigh on her heart. Fortunately Puleng knows how to keep herself balanced.

While Puleng claims to lead a pretty boring life, raising 3 children and being active in her church seems anything but! When she does make time for fun, it’s going out for junk food at her favorite fast food joint, or listening to some a cappella gospel music.

Finally, when Puleng was asked what advice she would give to someone new to this position, her reply was simple: “Humanity. You must treat individuals with respect and confidence, especially when they are talking to you about issues related to HIV. It is important to be respectful and flexible and to be able to interact well with all - whether male or female, young or old, and with various cultures, objectives and interests. Involve people in conversations about issues that affect their communities.” She often says to people, “I'm a health worker, and HIV is a challenge in our communities. How do you want to be a part of fighting it?” It’s her opening line — but for now, we’ll use it in closing.

—Interviewed by Genevieve Meyer, HVTN


Broadly neutralizing antibodies (BNAbs) against HIV are special antibodies that are able to block or “neutralize” many types or strains of HIV. Antibodies are part of the human immune system that protects someone from disease.
OVERCOMING CHALLENGES WITH RECRUITING LOW AND HIGH RISK POPULATIONS IN SOUTHERN AND EASTERN AFRICA

Nandi Luthuli, Community Education & Training Manager

As sites prepare for upcoming HVTN studies in Southern and Eastern Africa, the challenge of correctly identifying, engaging and recruiting both low risk and high risk populations is becoming increasingly clear. In these regions, where a person resides may be as much of a risk factor as his or her sexual practices. This often poses challenges to our CERs. One challenge lies in how to find “low-risk” participants in a community that may be classified as “high risk” due to the HIV prevalence and incidence in the area. Another challenge is how to begin to assess risk without offending, stigmatizing or causing social harm to any group or individuals.

For example, commercial sex workers are often identified as being at high risk of HIV infection. Yet according to some regional definitions, all heterosexual women are at high risk. It is therefore critical that sites communicate the right messages when recruiting for studies. For example, a site would not want community members to think that all women in a study are sex workers just because the study seeks high risk participants. Similarly, if sex workers are enrolled, it is equally important that they do not feel judged or stigmatized as being high risk.

In light of these concerns, CERs and CAB members in the region have been discussing the types of recruitment strategies that their sites are using to try to tackle these issues and ways that CAB members can assist. Below are the key themes that have emerged:

WAYS THE SITE CAN ENGAGE THE CAB & THE COMMUNITY

Map out your community with the help of your CAB and key community stakeholders. Engage them in helping to identify places and organizations that work with low risk and high risk participants and create a broad stakeholder directory.

(If appropriate) Have representatives from the LGBTIQ* communities on the CAB to help the recruitment team think about strategies to reach these groups.

Engage HCT** service providers to see if you can create a referral system.

Outreach staff can use pre-prescreening questionnaires to assess risk profile when they are out recruiting.

WAYS TO SUPPORT RECRUITMENT & ENROLLMENT AT THE CLINIC

Have information sharing sessions or educational sessions at the clinic with recruited participants to share more information about HIV vaccine research, study participation and VISP.***

Use prescreening questionnaire or protocol to assess risk profile and eligibility.

Give potential participants ample time to discuss participation with their family and friends. Provide materials that they can take home to show to others.

Create a friendly and welcoming environment for all participants. Remember: Retention starts with good recruitment.

* Lesbian, gay, bisexual, transgender, intersex & queer. ** HIV Counseling & Testing. *** Vaccine-Induced Sero-positivity.
“What is VISP?” “How long does VISP last?” “How will VISP affect study participants?” These are just some of the questions that commonly arise when introducing HIV vaccine studies to a new site or new community. At first VISP can seem like a startling concept, but once explained most people feel at ease. In fact, some former trial participants with VISP tell us that the benefits that they attribute to trial participation far outweigh any inconveniences associated with VISP.

So what is VISP? VISP stands for “Vaccine-Induced Sero-Positivity,” but is also known as “Vaccine-Induced Sero-Reactivity” (VISR). When vaccines are given to people (both in research and real-life settings) they teach the body to build up its immune system against a particular disease by creating antibodies that can fend off or block a disease, in our case HIV. Common HIV diagnostic tests look for these antibodies, as opposed to the actual virus. So if someone receives a study vaccine and their body makes HIV antibodies in response, it could complicate their HIV testing. Having an antibody–positive test result due to the vaccine, without having actual HIV infection, is what we refer to as “VISP.” At this time, we do not know exactly which participants will test VISP or how long it will last.

To distinguish VISP from HIV infection, study participants are tested for the virus itself rather than just for antibodies. The HVTN provides this testing through the study sites, or coordinates it through a central HVTN testing service for as long as the participant needs it (see resources at the end of the article). No participant is enrolled without first going through an informed consent process in which VISP is fully explained and discussed.

It is possible that trial participants who have VISP and receive testing in the community could face complications associated with an inaccurate test result in addition to the stress of being told they are HIV infected. For example, they could be denied medical insurance or be inaccurately reported to public health agencies. That is why it is so important to make sure participants understand what VISP is and its potential implications, and to reduce or eliminate any negative impacts that...
**HVTN CONFERENCE 21-23 OCTOBER**

1. Dr. Nyaradzo Mgodi co-chair of the AMP studies, summarizing study plans for sub-Saharan Africa during a layperson lunch session.
2. Discussion about the use of new educational videos during the CER break-out session.
3. At-large CAB member Monica Pule and HVTN principal investigator Dr. Larry Corey enjoying the music at the opening reception.
4. HVTN Core staff (left to right) Jana Bremmeyer, Beth Minnich and Michele Andrasik during the opening reception.

**HVTN AFRICAN REGIONAL CAB WORKSHOP OCT 19-20**

1. At-large CAB member Monica Pule receiving her certificate for completing the 2 day workshop with HVTN staff (left to right: Monica Pule, Gail Broder, Genevieve Meyer and Nandi Luthuli).
2-4 Attendees discussing site-level CAB roles and responsibilities.
5. Aurum-Rustenburg CAB member Koketso Morei reporting back on the outcome of his group’s discussion.

**CAPE TOWN SITE TOURS**

1. VIDD Administrator Curt Malloy (left) and HVTN Senior Director of Operations and Finance, Mike van der Ven (right) during a site visit to the Desmond Tutu HIV Foundation’s Emavundleni (Ema) Research Centre in Crossroads.
2. Portrait of the late Nelson Rolihlahla Mandela on the wall at the Centre.
3. Dr. Surita Roux, site investigator, giving an overview of the site to HVTN staff.
4. The Cape Town area coastline.
5. The Emavundleni Research Centre.
1 Soshanguve, South Africa. The site’s World AIDS Day event was designed to show support for people living with HIV, remember those who have died of AIDS, and engage key populations in HIV awareness. The event was completely organized by CAB members.

2 Lima, Peru. The many volunteers who helped support the site’s annual “Quilts of Love” World AIDS Day event.

3 Cleveland, Ohio. (left to right) Case Western/University Hospitals CAB members Jan Kosmyna, Jeffrey Mazo and Julie Patterson share a moment at the photo booth during the site’s annual World AIDS Day Community Forum.


5 Rochester, New York. For the first time, Rochester’s City Hall and other major buildings downtown lit up red for world AIDS Day. This awareness-building initiative was organized by the Rochester HVTN site (the Rochester Victory Alliance) as well as the Susan B. Anthony Institute. The full story and video can be found here: http://www.whec.com/article/stories/s3979295.shtml

6 Birmingham, Alabama. Mayor Bell, on behalf of the City of Birmingham recognized the HIV/AIDS epidemic, the need for HIV prevention, as well as World AIDS Day 2015 with this city-wide proclamation.

7 Klerksdorp, South Africa. Community Educator Kagisho Baepanye presented at the United Reformed Church during the site’s World AIDS Day events.

8 Chatsworth (Durban), South Africa. World AIDS Day celebration at Chatsworth Child Welfare where Jason Naidoo of the South African Medical Research Council addressed the audience.
THE JOURNEY TO SEKE SOUTH’S HVTN FORMATION
Charles Chasakara, CTU Community Engagement Coordinator; Emilder Chihota, Community Educator

The University of Zimbabwe – University of California San Francisco (UZ-UCSF) Clinical Trials Unit (CTU) was formed in 1994. UZ-UCSF has conducted several NIH-sponsored clinical trials under the HPTN, ACTG, MTN and IMPAACT networks at its 6 Clinical Research Sites. The CTU was selected to work with the HVTN in April 2014, and in September 2014, the Seke South site became a DAIDS-approved protocol-specific site. Seke South is a suburb of Chitungwiza, a densely populated city about 50 kilometers from Harare, Zimbabwe.

The CTU first established a CAB 15 years ago. The journey to form an HVTN CAB started with sensitization of the MTN, HPTN, IMPAACT and ACTG CABs in mid-2014. This process allowed us to solicit volunteers for the HVTN CAB. We then developed selection criteria for new members and designed a community sensitization plan to identify possible members. The volunteers were chosen based on their experience, area of residence, previous contributions towards community engagement, and professional background.

The community surrounding our catchment area is familiar with HIV research in general, but not as familiar with HIV vaccine research. It was imperative for us to plan for stakeholder engagement meetings to sensitize them about the HVTN, HIV vaccines, and vaccines in general before the nomination process began. During this process the team identified 8 critical stakeholder positions to promote diversity and ensure wide representation of the community. Subsequently, the community engagement team had 2 meetings with stakeholders in September 2014 focusing on the role of CAB volunteerism and advocacy. This rigorous process gave birth to a CAB of 12 members representing the health sector, women’s forum, youth, education sector, religious sectors, former research participants, men’s forum, and local authorities. The CAB was constituted on October 10, 2014 and held an orientation for members.

The CAB has since attended 2 Annual Training and Review Meetings on November 28, 2014 and October 30 2015 where they had an opportunity to learn about the CTU’s studies, including upcoming HVTN studies. Some of the issues discussed included why we need an HIV vaccine, the use of live attenuated vaccines, immunogenicity and side effects, HIV research advocacy, and community engagement. In December 2014 and June 2015 the CAB received similar trainings during the CTU training and the HVTN Site Preparation Visit, respectively. In May 2015 an HVTN CAB member gave a presentation on community engagement for HIV vaccine research at the CTU’s annual research day.

Community engagement started in earnest with a community sensitization event in December 2014, attended by approximately 100 women. Later that month, CAB members attended an HPTN stakeholders meeting where they learned about the other research networks’ community engagement activities. We have now sensitized over 4,000 women at 7 interdenominational church meetings, 244 participants from 66 organizations at 4 stakeholders’ meetings, 83 men at a male involvement workshop and 118 participants at a community health promoters’ meeting. Intensified community engagement continues in anticipation of study activation and our CAB will play a crucial role in helping ensure the community is ready.

Seke South’s newly formed CAB plus staff during an HVTN orientation meeting.
VISP might cause. Some participants express concerns that their partners will have trouble understanding VISP and the special testing situation that is required because of it. Site staff are very willing to talk with the partners of study participants (if the participant agrees) to help explain the testing needs. Also, community educators play a key role by informing the community and HIV testing centers about the fact that they may encounter people in their clinics who have been instructed to decline HIV testing in the community because of their study participation and VISP potential.

On a recent HVTN conference call for community educators in the Africa region, 2 former study participants, 1 from the US and 1 from South Africa, agreed to share their experiences with testing VISP. They have agreed to let us use their first names.

Alberta is from the US. She joined an HIV vaccine study in 1997 and has tested VISP ever since. Whenever she is curious about her HIV and VISP status she returns to the study site for testing.

“I don’t have any psychological challenges due to VISP. When I joined the study, I didn’t know a lot about HIV vaccine research... I was also worried if these antibodies were going to do anything to my body but... the more I learn more about HIV vaccines and VISP, the more I realize that it’s not a big deal. I realize now that what I’m doing is helping other people as I’m helping address a global issue – and this has made me more confident in life.”

Barbara is from South Africa. She joined a study in 2008 and currently tests VISP. She has disclosed her VISP status to her family and they’re okay with it. She said she hasn’t had any negative feedback from anyone that she has confided to about VISP. In fact, her friends were excited about her joining and participating in the study and many have joined or have considered joining an HIV vaccine trial. No one has been fazed by VISP or treated her differently because of her VISP status.

When asked if she would recommend for others to join an HIV vaccine trial Barbara responds, “I’d encourage more people to join an HIV vaccine trial. It’s amazing to see what kind of difference one person’s actions can have in this fight against HIV, and participating in an HIV vaccine trial benefits the entire world.”

While it may seem like a challenging topic to tackle, with a bit of effort, providing information and increasing education about VISP in the community can actually help increase awareness and interest about HIV vaccine research more generally. It is only with dedicated volunteers like Alberta and Barbara that we can move this research forward and ultimately find a safe and effective vaccine to prevent HIV.

The HVTN has resources for the public that focus on explaining what VISP is and why it is important to get the correct testing:

http://www.hvtn.org/en/participants/visp-hiv-testing.html


http://www.hvtn.org/content/dam/hvtn/CAB-Bulletin/CAB%20Dec%202011.pdf

There are also resources on the HVTN members’ website for sites to use, including tools such as brochures and sample letters that participants can carry with them to help explain their situation: https://members.hvtn.org/SitePages/VISP.aspx
social media tips & tricks

Jana Bremmeyer, Communications, Marketing and Web Specialist

The world of social media is always changing. Having a strong presence on social media means evolving with these changes and staying ahead of the game! I’ve been in charge of social media for the HVTN for over 4 years. In that time our followers and fan base have grown to the 1000s. In 2015 we reached over 7,600 followers on Twitter!

Here are a few of my tips and tricks for using social media. Keep in mind these are tips that have worked well for us as a network but there may be other considerations and strategies to use at your site.

**Post regularly**
I post every day and sometimes more than once. The more visible you are the more followers you will get.

**Schedule posts**
This trick is great! Facebook has a feature that allows you to schedule posts for a later time. This is perfect for holidays, weekends or days you will not be in the office.

**Post in thirds**
One third of our posts are about work related to the HVTN. One third relate to HIV or vaccine work in general. And the final third are of general interest to our whole audience of followers. (Think broadly of who you’d like to engage, your CAB, the general population, and groups you’d like to recruit or attract.)

**Sync your Facebook and Twitter accounts**
Posts on your Facebook will automatically populate on your Twitter account, reaching both your audiences at once!

**Engage with your followers**
We have a rule on our team to respond to all comments or questions posted to us within 24 hours. Even on the weekend and holidays we keep an eye out for comments and questions that may require a rapid response. Your followers will love the interaction and feeling like they are being heard.

**Respond promptly but intelligently**
If you don’t know the answer, find someone on your team who does and can help you generate a meaningful response. Sometimes our audiences need a little education and that is what we are in the business for! We’ve learned that even responding to negative comments or questions in a timely and intelligent manner leaves the person seeing us in favorable way. So far, even people who have left negative comments have always come back and “liked” our response back to them and continued to engage on our pages.

**Keep your posts short and sweet**
Just as Twitter allows only 140 characters in a tweet, studies show people are more likely to read posts that are under 140 characters.

**Provide pictures and links**
Posts get more “likes” and visibility when they include a link or a picture.

**Have fun with it!**
Running our social media and learning what works and doesn’t work is one of the best parts of my job. Each day brings new stories, articles, pictures, and posts to share with the world about the wonderful work we all do. I hope you have found these tips and tricks helpful. I’ll be following you :)

*The HVTN does not post recruitment-specific materials to its Facebook and Twitter accounts. If your site will be using social media for recruitment purposes, please make sure to check with your local IRB or ethics committee about requirements. You may be able to get several generic recruitment messages approved all at once, then use them in rotation over time.*
I would like to express my deepest thanks for your contributions to our work and your ongoing commitment to the HVTN.

In October, the day before our Full Group Meeting in Cape Town, South Africa, I had the privilege of visiting the Emavundleni Research Centre (Ema), which is supported by the Desmond Tutu HIV Foundation. The Ema clinic runs various clinical studies and engages large numbers of participants and community members from the surrounding Klipfontein/Mitchells Plain Sub Districts in many exciting programs of HIV vaccines and other research.

When I visited the site, I was impressed by the commitment of the staff and especially drawn to their great appreciation for the community engagement aspects of their work. I came to understand that the populations the site works with and supports are in a constant state of change, yet the research site has remained a consistent and trusted resource for the communities. The site hasn’t accomplished this stability on its own but has done so by forging strong partnerships with the community. Over the years I have witnessed this same site–community partnership in many of the other research sites working with the HVTN, and it is a testament to their commitment and vision.

As we enter this critical year of HIV vaccine research, we will continue to rely on our communities to be our guides on how best to message our mission around new and existing studies. We want to make sure messages are clear, complete and consistent. We want you to challenge us to deliver messages that impart the importance and value we place on the people who volunteer for our studies, and that ultimately expresses the truth behind the direction we’re all working toward: the end of HIV. ☺

OVERCOMING CHALLENGES WITH RECRUITING LOW AND HIGH RISK POPULATIONS IN SOUTHERN AND EASTERN AFRICA

of the discussions was that CERs need to be aware of the potential social harms that exist when they are out in the field engaging, educating, and recruiting potential participants into HIV vaccine and prevention trials. CERs also need to strike and maintain a balance between clinical terms for sexual behavior and circumstances that put people at most risk of HIV infection, especially as an individual’s risk profile may change with time. They need to consider how these terms translate and are interpreted by the community so as to prevent any stigma or discrimination that may be associated with participation in an HIV prevention research trial, while continuing to recruit and retain dedicated participants across all phases of trials. ☺
BOB BUCKLEW WINS THE JOAN HARRIS STAFF RECOGNITION AWARD

Brooke Willis Community Educator/Recruiter - AIDS Clinical Trials Unit at Case Western Reserve University

Robert (Bob) Bucklew has served as the Outreach Coordinator for the Case Western Reserve/University Hospitals (CWRU) site in Cleveland, Ohio since May of 2002, and he is the recent winner of a prestigious CWRU School of Medicine award.

Nominated for his service, inclusion and creativity with outreach and community engagement, Bob won the Joan Harris Staff Recognition Award for 2015. Bob is responsible for leading the Unit’s outreach and education efforts in the Greater Cleveland community on issues applicable to both HIV treatment and prevention clinical trials, with a special emphasis on outreach to HIV-positive people and people in traditionally underserved communities. With his expertise and diligence, the CWRU site has been able to meet, and in some cases exceed, goals for recruitment and enrollment with HIV-negative populations for prevention studies. As a coordinator for HVTN, MTN and ACTG studies — as well as the local CAB, protocol teams and DAIDS’ Community Partners — Bob’s work is highly regarded and respected in the HIV/AIDS and prevention arenas locally, nationally, and on an international level. In fact, within the ACTG he was recently awarded the Donna Davis Community Award that is given annually to the most effective contributor to community issues in this network, which is the largest clinical trials organization in the world. Bob has become a widely recognized advocate, guide, and collaborator with a vast swath of the greater Cleveland community and beyond. It is truly a pleasure to work with Bob and we are grateful to have him at the helm of our upcoming HVTN studies.

Bob shows that we are ALL affected by HIV and stigma. http://adaywithhiv.com

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.