LETTER FROM THE EDITOR

Welcome to the newest edition of the HIV Vaccine Trials Network (HVTN) Community Compass, formerly known as the CAB Bulletin.

Since 1988, December 1st has marked an important date in the global response to HIV, World AIDS Day. HIV/AIDS continues to devastate communities globally, and social and structural forces such as poverty, discrimination, intimate partner violence, and social and cultural norms relating to sex/gender, sexuality, and race/ethnicity continue to intersect and increase the risk of HIV. This is not romanticizing; this is the reality. World AIDS Day is a reminder that though we have come very far in reducing the number of new infections and disease progression in many geographic areas, there are still some communities around the world that are heavily burdened by new HIV cases annually, and more work is needed.

We have come very far regarding new and innovative treatments for HIV, primary prevention interventions, and the HIV vaccine study RV144 conducted in Thailand provided renewed optimism in the search for an effective HIV vaccine. The Antibody Mediated Prevention (AMP) studies are taking place around the world to see if these antibodies will work to prevent HIV, and if so, how much of the antibody is needed to prevent infection. This Community Compass issue highlights HVTN 702 and HVTN 705. These two HIV vaccine studies in Southern Africa are groundbreaking and innovative trials that will answer critical questions. HVTN 702 is a study in men and women in South Africa focusing on a particular HIV strain, called clade C, which is found in Southern Africa, and may result in licensure if the vaccine regimen is found to be effective. HVTN 705 is testing a mosaic vaccine regimen, that represents many strains of HIV found around the world, in women in several Southern African countries, and will answer questions about how this approach might work in different parts of the world. The answers from these studies may lead not only to expanded research into the ways we envision vaccines may be used to fight HIV, but may also uncover new pathways that contribute to the development of an HIV vaccine. To learn more about these studies, please continue to turn the pages of this magazine!

For your support of the HVTN wherever you are in the world, for the work that you do in whatever role you have in the HVTN community, and the impact we’ve been able to make in our collective history and communities, together, we want to say thank you! There is so much more work to do to get us to an HIV vaccine, which we continue to believe is the best long-term hope for ending the HIV epidemic. The HVTN Community Compass team wants to be everywhere you are, so please share with us what’s happening at your research sites, institutions, and in your communities, so that we can share it with the world.

Be well,
Stephaun E. Wallace
Editor-in-Chief,
HVTN Community Compass
New CEU Team Member Welcome

By: Nandi Luthuli, HVTN Core, Johannesburg, South Africa

The HVTN’s Community Engagement Unit (CEU) is excited to welcome its newest member, Kagisho “KG” Baepanye, who started on the 3rd of July 2017 and will be working closely with Nandi Luthuli as an HVTN Community Education Training Manager based in Johannesburg, South Africa. Many of you already know KG as a CER at the Aurum Institute in Klerksdorp, but he is better known as the HVTN CER Co-chair for International Sites. KG is a registered nursing assistant who trained at Klerksdorp Tshepong Hospital Complex and worked for the hospital as a chronic nurse in medical wards for 4 years. He worked for the Perinatal HIV Research Unit (PHRU) CRS in Klerksdorp for 4 years conducting recruitment, retention and community education for TB studies. For the past 5 years, he has worked for the Aurum institute where he worked as the Recruitment and Retention Team Leader and later the site’s Community Engagement Manager (CEM). In his former role as a CEM, KG led and managed the site’s community outreach staff, led recruitment and retention efforts, coordinated Community Advisory Board activities, as well as oversaw the CRS’s HIV counseling and testing program. KG graduated from the University of South Africa (UNISA) where he received a Bachelor of Arts degree in Health Science and Social Services. He later completed a Postgraduate Certificate in Management with the Foundation for Professional Development. KG also brings his passion for finding an HIV vaccine that will one day stop the untimely passing of our brothers, sisters and children. He looks forward to joining the HVTN Core family and working to make a difference in the lives of those most impacted by HIV.

* Nandi Luthuli is the HVTN Lead Community Training Manager based in Johannesburg, South Africa.

MEET THE COMMUNITY COMPASS TEAM

Our vision is an informed HVTN community that is aware of current events and activities relating to the HVTN network and its sites, advances in the field of HIV prevention and vaccination, as well as community priorities. We work to accomplish this by providing relevant information and updates to promote awareness, understanding, and support for HIV prevention and HIV vaccines, reaching global communities invested in the response to the HIV epidemic.

We welcome submissions of articles on any topic for publication that is relevant to the HVTN community. Submissions must be exclusive to us, and not appear in any other publication. Submissions must be 500 words or less to comply with our layout and design requirements.

We do our best to read all submissions promptly and will contact you within two weeks if we are interested in publishing your article. Due to space limitations, we may need to hold publishing your article for a future issue. To submit articles for Community Compass, please go to the HVTN Members Site homepage, click on “About”, then click “Community Compass”, then click on “Submit to Community Compass”.

Kagisho Baepanye

HIV VACCINE TRIALS NETWORK | COMMUNITY COMPASS | VOLUME 17, ISSUE 2: JUNE, 2017
HVTN 705/HPX2008: THE IMBOKODO STUDY

HVTN 705/HPX2008 is a collaboration between the HVTN and Janssen Pharmaceuticals, designed to test an HIV preventive vaccine regimen that covers the different types of HIV found across the world.

The study is planned to start in November 2017 across approximately 26 sites in 5 countries in sub-Saharan Africa: South Africa, Zimbabwe, Mozambique, Malawi and Zambia.

This proverb was made famous by a resistance song symbolising the courage and strength expressed by women in African societies. Women in Africa are seen as the foundations of life as symbolized by huge strong rocks!

The protocol was distributed to all the sites in February 2017, and has already been submitted for approvals to some country regulatory bodies and sites’ ethics committees. The study logo has been finalized, and training of community education and recruitment staff took place in Johannesburg from 5th to 7th June 2017, followed by a stakeholder meeting on 08th and 09th June 2017.

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The study is expected to enrol a total of 2600 women between the ages of 18 to 35 years, in recognition of the disproportionate burden of HIV that women in these countries face in comparison to men of the same age group. Enrolment is expected to take up to 14 months with sites starting in a staggered fashion through November 2018. Volunteers will be recruited by outreach teams in the communities in which sites are located and adjacent areas if needed, using a variety of educational, awareness and outreach activities. Research staff will assess potential participants at the sites to ensure they are healthy enough and they meet the study criteria for participating. All volunteers must be HIV uninfected, non-pregnant and be willing to adhere to the study visit schedule.

Each participant will be followed up for between 24 and 36 months (2-3 years), receiving 6 injections over a 12-month period. They will get one injection at enrolment and the third month, and two injections each at months 6 and 12. During follow-up participants will be closely monitored by the research team to ensure their safety and well-being. Vaccines prevent infection by teaching the immune system (the body’s defence system) to recognise and fight HIV, and antibodies to HIV are important in this fight. Although only one vaccine so far has shown some protection (Thai Trial or RV144 ), almost all vaccines tested have resulted in antibodies forming, but they have not been protective. Current rapid HIV fingerprick tests used in government and other clinics work by detecting antibodies to HIV, so people who have antibodies from a vaccine may be misunderstood to be infected. Special tests are done at the research clinic, that can tell the difference between actual HIV infection and VISP. Study participants will be provided with regular HIV testing during the study which will distinguish actual infection and a vaccine reaction. For participants who have VISP at the end of the study, these special tests will be made available for as long as they are needed, even when the study ends or a person moves away from a site. This will ensure that participants are not negatively impacted by VISP following the study closure.

This exciting, ground-breaking study has been in planning for many years, with Janssen testing several components of the vaccine regimen in previous studies to ensure that they are safe and get a response from the immune system. This study will add valuable information to the vaccine research field, and needs strong community support to be conducted successfully at all research sites.

TOGETHER WE CAN END HIV!!

For more information about this study, please go to: www.imbokodo.org.za

* Dr. Kathy Mngadi is the Principal Investigator for the eThekwini CRS in Durban, South Africa and is Co-Chair for the Imbokodo Study. Dr. Susan Buchbinder is the Principal Investigator and Director of the Bridge HIV CRS in San Francisco, CA, USA, and is Co-Chair for the Imbokodo Study.

THE NAME “IMBOKODO” HAS BEEN CHOSEN; THIS IS AN ISIZULU WORD THAT MEANS “ROCK” AND COMES FROM A POPULAR AFRICAN PROVERB WHICH SAYS, “WATHINT’ ABAFAZI, WATHINT’ IMBOKODO!” (“YOU STRIKE THE WOMEN, YOU STRIKE THE ROCK!”).
NASHVILLE, Tenn. — An hour and a half into a rousing Sunday service at the Kingdom Love Worship Center, the Rev. San Jackson paused her preaching to ask Vic Sorrell if he wanted to say a few words.

Sorrell didn’t hesitate. Bounding from his back pew to the pulpit, the white visitor stood before a congregation of African-Americans, their faces politely expectant behind a blur of hand-held fans.

As community engagement manager at the Vanderbilt HIV Vaccine Program, Sorrell gives talks like this many times. But even 36 years into the pandemic, HIV can make for a difficult conversation, one the 39-year-old Sorrell tailors to the audience and the moment, speaking from his heart and trusting he’ll strike the right chord.

“Thank you for being a congregation that says, ‘Come and talk to us,’” he began that June afternoon in East Nashville. “Every one of us is either infected or affected by HIV. The virus knows no color, no socioeconomic status.”

To calls of “Yes!” and “Amen,” Sorrell spoke about an international research study called AMP — for Antibody Mediated Protection — underway at the Vanderbilt University Medical Center and other sites around the world. Run by the HIV Vaccine Trials Network, which is headquartered at Fred Hutchinson Cancer Research Center, HTVN 704/HPTN 085 is enrolling 4,200 volunteers to test an experimental antibody that could potentially protect people from infection by HIV.

The antibody is modeled on one that developed naturally in a person whose immune system had been able to control his HIV infection for years without needing medication, Sorrell explained. Such rare individuals are intensely studied by scientists.

“There’s a chance a vaccine could be created that could cause that antibody response in other people and keep them from getting infected if they are exposed,” he said. “If we had a vaccine, we could truly begin to see the face of HIV changed. Thank you for being willing to support these efforts. Thank you for being the faces of love and community we need.”

As the organ started up again and Sorrell headed back to his pew, Jackson, the pastor, nodded her approval.

“Vic preached,” she said. “You will hear some people say that HIV was God’s curse. Whatever the problem, Jesus sends an answer.”

Just maybe, she seemed willing to consider, this antibody could be that answer.
BUILDING TRUST

The international AMP study got underway in April 2016 when the Vanderbilt HIV program became the first of 47 sites on four continents to enroll a volunteer participant. The trial’s co-leader, the North Carolina-based HIV Prevention Trials Network, reported last week at the International AIDS Society conference that enrollment rates across all sites are running about 20 percent ahead of projections.

That strong response is in no small part due to the efforts of community outreach specialists like Sorrell. Their job is to engage interest and build trust in a clinical trial that is among the largest and most complex either of the two networks has ever conducted. And in few communities is gaining trust more important than among African-Americans.

Sorrell is right that a virus knows no color or socioeconomic status. But because of many of the same barriers that contribute to health disparities in cancers and other diseases, HIV hits African-Americans harder than any other group of Americans. As with whites, black men who have sex with men bear the brunt of the infections. If current infection rates continue, according to the U.S. Centers for Disease Control and Prevention, one in two gay or bisexual African-American men will be diagnosed with HIV in their lifetime.

Let that sink in: one in two.

Geographically, a majority of these new infections will occur in the U.S. South, which today has the highest HIV diagnosis rates, the largest number of people living with HIV, and the highest death rates with HIV as an underlying cause in the U.S. Fueling those figures is a lack of access to quality health care due to poverty, no or inadequate health insurance, and cultural attitudes and beliefs that contribute to distrust of the medical system.

For many minority populations, distrust stems from decades of neglect and even exploitation. The Tuskegee experiment is the most infamous example for African-Americans. Starting in 1932, scientists followed hundreds of black sharecroppers for 40 years to study the long-term effects of syphilis without ever telling the men they were infected or offering them treatment once penicillin proved curative.

FIGHTING STIGMA

Another equally daunting barrier is unique to HIV, according to Dr. Greg Wilson, the AMP study’s lead scientist at the Vanderbilt site.

It’s the stigma still associated with HIV — not wanting individuals in your family to know you’re positive, not having a circle of friends you can talk to,” he said. “Family and church are large issues for African-Americans. You may know that you need to go to a doctor to determine if you have HIV, but there’s a lot of baggage that’s associated with that knowledge and consequences that may come with other people knowing about it — rejection, not only from family but from your church community, which may be your major source of support.”

Barbara Gunn Lartey, the director of community engagement for the Nashville Human Relations Commission and a longtime advocate for people with HIV, agrees that stigma and fear make HIV a taboo topic in many African-American households.

“You still have families who require you to eat on paper plates at Thanksgiving,” Lartey said.

The stigma and shame go deeper than fear of infection.

“For people of color in particular, it’s an issue of your salvation,” she said. “You have voices from the pulpit saying that HIV is punishment for whatever — for being gay, for being promiscuous, for using drugs, for participating in risky behavior. In many cases, the pastor’s perspective can outweigh a parent’s. You feel like you’re being condemned to hell.”

Which brings us back to why Vic Sorrell was at a small African-American church in East Nashville on a Sunday afternoon talking about the AMP study. How he got there is a longer story.

MUSIC CITY DREAMS

Sorrell’s path to the pulpit of HIV outreach was not a straight one. He was nicknamed “Baby Country” when he moved to Nashville at age 17 from a small town in Virginia, determined to be a country music star. The cherubic-faced crooner had been performing on stage since...
he was 6. He had wanted to be Dolly Parton for at least that long — OK, maybe not to be Dolly herself, but to have her talent, her light, her presence.

He enrolled in Nashville’s Belmont University and got a degree in music management and marketing for his parents’ sake. But he also got a band and was well on his way to signing a recording contract when something happened that upended his dream: He fell in love with a man.

The surprise was how unequivocal it felt. There were no longer doubts, no telling himself it was a phase he would outgrow. And it forced a decision.

“The reality of the conservative nature of the country music industry smacked me in the face, and it was made very clear that I needed to decide what I wanted,” Sorrell said. “Did I want to be gay, or did I want to be a country star? For me, being something in the public eye that was not real and was not true was not an option.”

And just like that, the dream he had held since he was 6 disappeared.

He stayed in the music business by working in marketing but spiraled into a personal crisis. He found his way out through Marianne Williamson’s best-selling books on spirituality and decided: “I want my gifts to serve, and I’m willing to have that happen however the opportunities present themselves.”

In the 2008 Great Recession, his fallback marketing job disappeared, but a new opportunity presented itself. A friend who knew his drive to do good mentioned a job opening for an HIV prevention educator at Nashville Cares, the largest HIV services agency in the region.

As a gay man, Sorrell definitely had HIV on his radar, but he had no idea that such a job existed, much less that he could do it. He got an interview. Then he got the job.

Sorrell said the work — by which he means the people he’s met and the partnerships he’s formed at Nashville Cares and later at the Vanderbilt HIV Vaccine Program — has made him who he is today. And who he is today, many argue, is a big part of why the Nashville AMP study is shaping up so successfully.

‘TWO PEAS IN AN ODD-SHAPED POD’

One of his earliest partners was Larkey, who at the time was a case manager and director of women’s programs at Nashville Cares. Larkey’s and Sorrell’s backgrounds could not have been more different.

Larkey grew up in the shadow of Tuskegee. Its legacy was not so much talked about as modeled. Observing her aunts and other elders, Larkey recalled that “your head had to be pretty much hanging off to go to a doctor.”

She first became aware of HIV as a Peace Corps volunteer in West Africa and later when she studied law in South Africa. She was shocked at the widespread misinformation: The virus was believed to have been created by the U.S.; the use of condoms was seen as a ploy to control African population growth. She was shocked again to return home and see the fear, stigma and misinformation surrounding HIV in her own community.

Larkey acknowledges that she and Sorrell are “two very different peas in an odd-shaped pod.” But the two clicked right away.

“It gets my attention when someone says, ‘I don’t have all the answers, but I’m open and willing to learn.’ And that is Vic Sorrell,” said Larkey. “He gets that, at the heart of it, it’s about a person’s humanity. We believe in each other. We believe in this work of lifting up humanity.”

After Sorrell moved to the Vanderbilt HIV unit, he continued working with Larkey to set up programs for Black HIV Awareness Day at African-American churches in Nashville. Earlier this year, he joined her in a musical production about HIV prevention. The musical was written by another key partner, T.K. Hampton, a longtime HIV advocate who works for a Nashville program called Street Works that supports African-American gay and bisexual men. (The show, “YOU Shall LHiV 2 Zero,” was so successful that the
group has been invited to present it at the United States Conference on AIDS in Washington, D.C., in September and at the annual Conference on Retroviruses and Opportunistic Infections, or CROI, in Boston next March.)

Sorrell described that day at the church service or a placebo via an intravenous infusion. If the antibody provides protection against HIV as hoped, information gleaned from the study could help scientists make a vaccine that teaches the body to make such antibodies — long the holy grail of HIV researchers. A vaccine is widely considered the nail in the coffin needed to finally end a pandemic that still causes 40,000 to 50,000 new infections in the United States each year and 1.8 million worldwide.

In the beginning, the study’s organizers feared that the time commitment alone — participants receive a total of 10 30-45 minute infusions, one every eight weeks — would discourage volunteers. That has not been the case.

The only white person in the musical, Sorrell contributes a country version of the title song, talks about the AMP study, and speaks forthrightly about the institutional racism that has contributed to the high rates of HIV among African-Americans. He also describes hard-won lessons on recognizing privileges he never even realized he had.

“When you get up in the morning and the first thing you think of is not the color of your skin, that’s a privilege,” he said during a recent run of the play. “Being given the opportunity to check my privilege is one of the greatest gifts I’ve ever gotten.”

‘I’M GOING TO HATE WHEN THE STUDY IS OVER’

AMP is an ambitious study with an ambitious goal. Each HIV-negative volunteer gets randomly assigned to receive a laboratory-produced version of the antibody

Take Justin Lofton, 25, who works at a Nashville drop-in center for young gay and bisexual African-Americans called My House and who also performs in Hampton’s musical. Lofton volunteered for the study because he believes that such research is key to protecting his community.

“I work with HIV-negative men right now,” he said. “Sometimes I’ll be thinking, ‘Now we’re all negative, but if I count out one, two, one, two, one, two — half of us could get infected with HIV.’

But what keeps him coming back for the infusions are Sorrell and the rest of the study staff.

“They are invested in making us feel like more than a number,” he said. “They’re there outside the clinical role. To me, that feels like a relationship.”

Darnell Peppers, 23, agrees. He met Sorrell at a Nu Phi Zeta party — a non-university affiliated, service-oriented African-American fraternity — and took to him instantly. The fraternity’s motto is “I am my brother’s keeper,” and after reading more about the AMP study online, Peppers started asking himself, “How can I help?” He decided to volunteer for the study.

Thanks to Sorrell and the staff at the Vanderbilt program, Peppers said, “I really feel cared for. I’m going to hate when the study is over.”

So along with enrollment rates that are exceeding expectations has come another surprise: In Nashville, 33 percent of those enrolled are people of color, a higher percentage than any previous study the Vanderbilt HIV program has done.

Continued on next page...
Sorrell lays this success on the key community partnerships that he has formed with Lartey, Hampton, Lofton and others. His talent for building these partnerships has earned him a reputation throughout the HVTN as a pioneer in community engagement.

“My experience has been that even if at first there is a hesitancy to my being there, people eventually understand that my commitment is to however I can assist with what they’re already doing,” he said. “How I can provide resources or any kind of support. Once people have experienced that again and again, a trust is established and I find that there really aren’t barriers to my being there. But it takes time.”

Being a community outreach specialist is not a 9-to-5 job. Evenings, weekends, hot Sunday afternoons in a small church, Sorrell will be there. Again. And again. And again.

“Vic can’t be surpassed in his ability to connect to people,” said Kyle Rybczyk, the Vanderbilt program’s clinic coordinator, who hired Sorrell. “We have a solid reputation in the community for being a program that cares, that’s visible, that shows up — not just when we need people but when they need us.”

As a white man working with communities of color, Sorrell has learned it’s the showing up part that counts. The way to break down barriers is as simple as it is challenging: Open your heart. Be fully present. Repeat.

*Mary Engel is a staff writer at Fred Hutchinson Cancer Research Center. Previously, she covered medicine and health policy for newspapers including the Los Angeles Times, where her editorials were part of a healthcare series that won the Pulitzer Prize for Public Service. She also was a fellow at the year-long MIT Knight Science Journalism program. Reach her at mengel@fredhutch.org or on Twitter, @Engel140.
Jim’s Farewell

Our best long term hope for stopping the spread of HIV is a safe and effective vaccine. For the last 6 years I have had the privilege of being a part of this great work, and for that I am thankful! I have had the opportunity to work with an amazing and talented team here at HVTN Core and together our primary mission has been to support the clinical trial site outreach and recruitment staff. Our 60 plus sites are blessed with CERs/CLOs and other staff whose passion for engaging their local communities has been an inspiration to me and those of us at Core. I have also enjoyed working with community advisory board members who selflessly give of their time and talents to be a living bridge between our trial sites and their own communities. Community is at the heart of the work that we do and we will never reach the goal of an HIV preventive vaccine without the active support of volunteers and others that care about the health of their communities.

As I leave the HVTN and begin a new chapter in my life, I will miss the passion of this great community of believers, of those who believe in the quest for an HIV vaccine. I will also miss the comradery and the laughter of this wonderful group of people, but please know that I will continue to care deeply about our mission. I do not doubt that one day we will have a vaccine and the spread of HIV will be relegated to history. May the days ahead be, for each of us, ones filled with passion, purpose, and unlimited possibilities! Thank you.

Yours,
Jim Maynard
Vanderbilt University collaborates with Black AIDS Institute to host PrEP Summit in Nashville August 2017

“You Shall LHIV 2: Zero” Vanderbilt CRS collaborates with community partners to produce an HIV prevention musical theater production (from l to r: Ebony Gordon, Justin Lofton, TK Hampton, Vic Sorrell and LeDon Campbell) August 2017

Vanderbilt CRS at Nashville Pride June 2017

Atlanta Hope CRS Community Engagement and Recruitment Team (C.E.R.T) at Atlanta Black Pride September 2017 (from l to r: Nicole Kasher, Chloe Jordan, Machel Hunt, Harlan Smith, Javani Williams)
June 2017 AMP Training with Lima, Peru Community Staff (IMPACTA, Via Libre, and San Marcos sites)

Club Outreach in Lima with San Marcos CRS Community Staff September 2017

HPTN Community Team, Our AMP Study Colleagues
Uhambo means journey, and this is the name being used for the journey of hope toward an HIV vaccine to prevent HIV in sub-Saharan Africa. There were 270,000 new HIV infections in 2016 in South Africa alone (UNAIDS, 2017). Uhambo’s journey is a series of research studies that will hopefully lead the region toward the safe and effective HIV vaccine that is so desperately needed.

The journey so far

- 2009: The ancestor to our journey is the “Thai trial”, a study done in Thailand which showed that a combination of two experimental vaccines, named ALVAC + AIDSVAX B/E, was safe and could prevent people from getting HIV. It was the first time a study showed that vaccines to prevent people getting HIV are possible. It also showed that the vaccines had to be improved for more lasting immune responses and protection.

- 2013: The journey moved to South Africa, where a small study called “HVTN 097” showed that the same vaccines that had been used in the Thai trial were also safe in South Africans. South Africans even had slightly better immune responses to the vaccines.

- 2015: The vaccines were adapted for the southern African region. A study called HVTN 100 first used these adapted vaccines, and showed good safety and immune responses in South Africans. HVTN 100 also showed that giving a booster can extend how long the immune responses to vaccines last.

- 2016: In October 2016, South Africa took another bold step forward in the journey of hope toward an HIV vaccine with HVTN 702. In this historic study, the adapted vaccines are now being tested in 5,400 participants across the country to find out if the vaccines are effective. In other words, the big question of HVTN 702 is: do these vaccines have the ability to prevent people from getting HIV? If the vaccines are successful, then in years to come the HVTN 702 results will be submitted to the South African Medicines Control Council to apply for registration in the country. It is possible this could lead to the first ever licensed preventive HIV vaccine regimen.

- There are also other smaller studies that are happening in the southern African region that form part of our journey toward an HIV vaccine. Studies like HVTN 107, HVTN 108, HVTN 111, HVTN 120, and HVTN 126 will give us very important information about how to make the vaccines even better. These smaller studies ask questions about the effect of different adjuvants and about whether a DNA vaccine could have a role to play.

*Dr. Fatima Laher is the Principal Investigator and Director of the PHRU Vaccines Research CRS in Durban, South Africa and is Co-Chair for the Uhambo Study.*
A study that has been widely covered in the news, on television, in newspapers, on the radio, online and at community events is HVTN 702. This study tests a combination of two experimental vaccines aimed at trying to prevent people from getting HIV. One vaccine is a protein vaccine; the other is a vaccine made with a pox virus carrier. Neither of the vaccines use the real HIV virus, and the trial never exposes participants to HIV.

Healthy women and men between 18 and 35 years of age who do not have HIV can be screened to see if they are eligible to join HVTN 702. A person must be willing to undergo medical check-ups and regular HIV counseling and testing in the study. Women cannot be pregnant or breastfeeding. There are also other criteria that must be met in order for a person to be eligible to join the study.

The study opened in October 2016, is planned to enroll for at least 18 months, and is following up each participant’s health for 3 years. Throughout the study, participants are provided with regular risk reduction counselling and access to other approved HIV prevention methods.

Communities have been engaging with local researchers since the first HIV vaccine study in South Africa, and continue to be active. Prevention methods are for communities. Study participants and research staff are part of communities with the singular goal of improving health through vaccine research. Community stakeholders continue to engage with the research development and implementation process, ensuring research ties in with our South African community preferences, needs, customs, traditions, and beliefs.

We asked study staff to tell us their favorite things about working on the HVTN 702 study so far:

- **It’s a pivotal study that is aiming to find a safe and effective vaccine that will protect people from HIV** – Counsellor, CAPRISA site

- **It unites us in the fight against HIV** – Pontso Seithlamo, Kliptown site

- **The study includes women, heterosexual men and men who have sex with men, hence no-one is excluded in having an opportunity to participate and make their contribution toward finding a great HIV prevention method** – Staffer, CAPRISA site

- **The potential to stop new HIV infections** – Kingsley Nukeri, Kliptown site

- **The vaccines could be submitted for licensure in our country!** – Bontle Modibedi, Soweto-Bara trial site. (Sr. Bontle is the first ever nurse to administer these vaccines.)

The journey continues – online...

- The HVTN 702 informed consent video makes informed consent information available to the public [https://vimeo.com/207302012](https://vimeo.com/207302012) or [https://www.youtube.com/watch?v=8KqDbVZ2o8Q](https://www.youtube.com/watch?v=8KqDbVZ2o8Q)

- The study website is [www.uhambo.org.za](http://www.uhambo.org.za)
For the first time, sex workers have learned to advocate with decision makers in our city. Here in Iquitos, my hometown, different NGOs have always been active and held training workshops to educate sex workers and empower them with viable skills. With the NGO Via Libre, the connection was more than familiar; we maintained a constant communication that allowed us to get advice and support at all times. I was one of the people who cared little about that kind of work (advocacy). I saw it as being very difficult since I had to talk and write a lot which was tedious for me. However, as I continued to grow and become empowered I learned to handle an email account and to use other technological tools to strengthen my communication. These skills continue to be useful to me. I feel that it was worthwhile to leave my comfort zone, since now I feel respected both as a leader and as a representative of my community of sex workers.

It’s hard for me to believe that now these workshops are designed and organized to empower sex workers to assert their rights as individuals. Thanks to the success of these programs in Iquitos I have traveled to other cities where I share my experiences. As a sex worker, I learned to accept myself as I am and above all to represent my community, because we sometimes suffer situations of discrimination and mistreatment by bad police for the sole reason of exercising our right to work.

“I feel that it was worthwhile to leave my comfort zone, since now I feel respected both as a leader and as a representative of my community of sex workers.”

Our Association of Sexual Workers of Iquitos, “Sarita Colonia,” is growing and strengthening; in the beginning, we were only five members and now we have 50 members, and we have acquired programming space in the Loreto region. As local and national activists, we lead the group of female sex workers of Iquitos.

* Silvia Torres Canayo is a member of the Association of Sex Workers “SARITA COLONIA” - Loreto Region and is a member of the Community Advisory Council (CAC) of the ACSA-Iquitos CRS in Iquitos, Peru.
space that we share information on new studies and new prevention strategies, such as the AMP study, a novel study with great potential to prevent HIV.

“The recurrent theme is HIV infection. In Peru, HIV infection disproportionately impacts transgender persons, bisexuals, and men who have sex with men, with a prevalence ranging from 12% to 30% in males and trans females respectively.”

Additionally, recreational activities allow socializing, getting to know each other, fraternizing, bonding and building interpersonal relationships. Singing, dancing, and games are excellent ways to make friends, to learn, and to expand our networks. Via Libre organizes an open house at the end of each month and it is open to the public. All are welcome. If you are ever in Lima, Peru, we would love for you to join us so we can shower you with love and appreciation. For more details, you can follow us on Facebook:

www.facebook.com/vialibre.org/

* Jose Luis Castro Chuquillanqui is the lead Community Educator for the Via Libre CRS in Lima, Peru.
The Clinical Trials Unit Principal Investigator, Prof. Gita Ramjee, addressed all the participants and personally thanked them for their contribution toward finding an effective HIV vaccine. The workshop focused on the importance of finding an HIV vaccine in South Africa, as it is burdened with the highest incidence and prevalence of HIV in the world, particularly in KwaZulu Natal. Participants were able to share their experiences, motivations, and challenges about participating in HIV prevention research. The workshop created a platform for everyone to ask researchers questions and make suggestions. Women were excited to see that men have joined studies, as previously many previous studies focused only on women. Many of the discussions were around VISP, pregnancy in trials, PrEP, and general health and wellbeing.

A concern was raised regarding the exclusion of pregnant women participating in HIV vaccine trials, because participants see pregnant women in the clinic. Neetha explained that no one is enrolled into the HIV prevention studies if they are pregnant, however, women sometimes do become pregnant while they are enrolled. It was explained that they will be followed during their pregnancy until they give birth to monitor their safety, but they do not receive any further injections or infusions of study products. Staff also follow-up to ensure that the baby is delivered safely.

The participants expressed appreciation for the health care and support they received from staff members. Participants who are part of the Peer Education Programme had the opportunity to facilitate and speak about their participation in the work they are doing in their communities.

*Neetha S. Morar is the Senior Research and Community Manager and Ishina Hemchund is the Research Assistant at the HIV Prevention Research Unit at the South African Medical Research Council in Durban, South Africa.*
## Legacy Project

The Legacy Project at the Office of HIV/AIDS Network Coordination (HANC) works to support and increase awareness of HIV clinical and behavioral research throughout the United States. Legacy’s primary goal is to promote diversity in HIV research by addressing factors that influence the participation of historically underrepresented communities. The Legacy Project achieves its core mission through strategic community engagement and partnerships, educational initiatives, and scientific investigation.

Additionally, Legacy works to cultivate and enhance collaboration among the National Institutes of Health (NIH) HIV/AIDS Clinical Trials Networks and associated research sites, academic and research institutions, governmental agencies, and community-based organizations. The Legacy Project is committed to capacity building for communities and populations most impacted by the HIV epidemic in the United States.

## The Women’s HIV Research Collaborative

The Women’s HIV Research Collaborative (WHRC) is a cross-network advisory group of the Legacy Project comprised of women leaders from around the U.S. This group provides guidance and leadership in the development, implementation, and dissemination of information about HIV research focused on and responsive to the needs of women and girls in the United States. The WHRC works to raise the visibility of issues related to HIV in women in the US, and promote awareness of scientific research to women in disproportionately impacted communities. The WHRC focuses on advocating for HIV research with women living in the United States, but operates with a comprehensive awareness of the potential for American women to benefit from HIV research conducted internationally. To this end, the WHRC’s focus is domestic, but its interests are global and optimistic.

## Community Partners

Community Partners (CP) is a cross-network body charged by Network Leadership and the Division of AIDS (DAIDS) with promoting effective representation of the many communities within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research.

CP focuses on improving intra- and inter-network community input at all levels. CP’s work includes identifying and developing programs to enhance training and support requirements of local Community Advisory Boards, increasing the representation and participation of community members from resource-limited settings and vulnerable populations, and identifying and addressing challenges to participation in clinical trials.

* Russell Campbell is the Deputy Director of HANC, and Louis Shackelford is the Project Manager of the Legacy Project.
A World AIDS Day Reflection

By: S. Wakefield - HVTN, Seattle, WA, USA

Community responses in times of intense need are often the most effective agents for change. We have had the opportunity to witness the brilliant effect of human beings in action recently during several hurricanes and mass shootings in the US. Advocacy and change have been fueled by historical movements as well, such as the Boipaton massacre in South Africa that prompted local, and eventually global, efforts to end apartheid. Injustice and inhumanity, hate and oppression, have also sounded the clarion bell that demanded and demands unity, and encourages collective gathering for strength and sustained hope in the face of inequalities. As we gather for World AIDS Day 2017, there are advances brought forward by medical science, as well as a continued need for communities to lead the charge for change. For World AIDS Day 2017, let us reflect for a moment on critical points in HIV’s history, while also considering how to increase our efforts, individually and collectively, to get us to an HIV vaccine.

On April 23rd, 1984 at a press conference in Washington, D.C., the identification of the virus we now call HIV occurred, and Margaret Heckler, the U.S. Secretary of Health and Human Services, proclaimed that a preventive vaccine would be ready for testing within two years. Since then, many physicians who had already begun identifying significant health disparities in communities would also start providing care and services to communities underserved by the scientific and medical establishment. These clinicians came from around the world, and needed more than regular public health services to fight this new virus, so they built special clinics. Physicians such as Drs. James McIntyre, Glenda Gray, and Kenneth Mayer worked to establish clinics to ensure communities who were underserved could seek care and services. These clinicians and countless others were also spending time in community settings where they gained valuable insight to fuel innovative scientific inquiry.

Early in this epidemic community members took to the streets. Communities also gathered to share information about any scientific development which seemed hopeful or useful. ACT UP, TAC and other groups fought governments because they were not doing enough, or not doing it fast enough, or not doing it the right way. Community responses brought a sense of passion and urgency to make a difference, processing grief and anger, or because many were afraid their own time might be short due to the mysterious virus. Scientists and providers frequently left their labs or the bedsides of their patients to join marches and demonstrations. Others worked hard from inside hallowed halls to quietly identify ways to accelerate change.

Someone took a failed cancer drug called AZT and discovered it could impact the virus. No one knew how much there was to learn to move beyond toxic doses of this drug. Today, due to working with those governments and dreaded pharmaceutical companies, we have over 40 drugs that are just as smart and different as smartphones are from the rotary dial phones of the 1950s and -60s. Advocates and local advisory boards noted that while we had tools for HIV treatment, HIV prevention was a critical gap that could be filled by distributing condoms and supporting research that might help future generations avoid infection. Some advocates joined with US government-funded research, while others partnered with investigators who came together when government priorities differed on how to resource HIV vaccine research.

In January of 2000, a new National Institutes of Health (NIH) Division of AIDS (DAIDS)-funded network was formed to focus on HIV vaccines, the HIV Vaccine Trials Network (HVTN). The new leadership sought to demonstrate a commitment to answer questions raised by every study through providing specimens, sharing data, developing lab tests and other scientific endeavors. The HVTN noted that study participants made it possible for the scientific community to determine next steps with each product tested. HVTN leadership had heard the cry for “studies with us, not on us,” and was the first DAIDS network to develop a Participants’ Bill of Rights and Responsibilities. Through the HVTN, education and training were provided not just for clinicians but for members of Institutional Review Boards, ethicists, community members and those responsible for public health in the geographic areas where vaccine research occurred. Community advocates and leaders like Butch McKay and Mark Hubbard, who had fought for the participation of volunteers in informing treatment trials, joined people like Hamilton Richardson who had participated in vaccine studies to help shape
the HVTN. These committed advocates knew the same advocacy spirit which prevailed on the street needed to ring loudly in the hallowed halls of science as well.

On February 24, 2003, results were released from the first HIV vaccine efficacy study, VaxGen. The vaccine was ineffective, yet the results were released with a controversial sub-analysis that indicated “possible protection in non-whites.” The VaxGen trial did not enroll adequate numbers of minority participants to yield scientifically valid results broken down by race/ethnicity, which created significant problems when the initial analyses raised the question of differential efficacy among Blacks, Asians, and others. Advocates noted that we needed to learn from this experience and not repeat it. Shortly after this in June 2003, the Global HIV Vaccine Enterprise, a global endeavor that emphasized the need for integration and capacity building around the world, was announced. Some of the top scientists announced unprecedented collaboration and shared strategic planning. Focused on new ways of working, creative public and private partnerships emerged. Years later, Bill Snow, a founder of the AIDS Vaccine Advocacy Coalition (AVAC), led the Enterprise as it embraced the HIV prevention science that has resulted in the organization moving under the auspices of the International AIDS Society. Professor Dr. Linda Gail Bekker, another scientist/advocate and president of the IAS, provided oversight to the transition.

The ongoing debate regarding what is needed most in an HIV vaccine response, t-cells or antibodies, continues. HIV and research myths have continued to have validity despite an army of CAB members and other advocates who immerse themselves in the science and can interpret trial results and progress. Community emphasis on building and leveraging key partnerships to ensure stronger voices and policy support for HIV vaccine research has struggled side by side with an enhanced behavioral research agenda to support engagement in trials. Barriers to participation in HIV preventive vaccine studies have persisted, including historical mistrust of medical providers and research. It may be easier for persons already diagnosed with an incurable illness (HIV) to participate in research than it is for healthy, uninfected persons who do not think of themselves as being at risk to join a study. Vaccine study participants and communities of otherwise healthy individuals are asked to make personal sacrifices for the sake of research. They must commit time, respond to invasive and personal questions, and potentially face criticism from their family, friends, and communities. The vaccines they receive may not provide any level of protection nor offer any immediate or long-term benefits. Many still hold on to unfounded myths such as “you can get HIV from a vaccine,” or wonder how researchers can test a vaccine without intentionally infecting people, while others say they believe a vaccine exists but is being kept secret. Fostering trust and increased understanding of HVTN’s research begins with updates during potential study concept stages, with a goal of moving persons from community awareness of the scientific agenda through engagement during study planning, and community ownership

Continued on next page...
A World AIDS Day Reflection, continued...

throughout the time a study is being conducted. With this in mind, HVTN community engagement partners are in regular contact with local community stakeholders, country level representatives from multiple disciplines, and global HIV prevention stakeholders.

Recent years have seen HIV vaccine trials with surprise outcomes, where communities were armed with enough of the science to offer nonscientific explanations for why those studies ended. On the research side, efforts to develop HIV vaccines capable of eliciting broadly neutralizing antibodies have begun or increased, as well as work on new vectors to provide durable protective immunity in the communities most impacted by the virus. Tremendous scientific progress has occurred since 2009, when results of RV144 were announced, the first vaccine regimen that reduced the number of HIV infections by about 32%. HVTN has led the way to incorporate new proven HIV prevention technologies into its protocols as they have emerged. Medical male circumcision (MMC) and facilitating PrEP access have occurred in real time with protocol modifications. These efforts reflect HVTN’s continued commitment and ability to ensure people recognize a vaccine as the best long-term hope for ending the epidemic while simultaneously building awareness, knowledge, and support for other prevention technologies. HVTN continues to meet its commitment to ensuring trial participants have the best prevention available by maintaining linkages with HIV treatment, cure, and prevention advocates, as well as connections with condom and reproductive health advocates. We regularly participate in social media and listservs like the IRMA (International Rectal Microbicide Advocates) blog by providing clarity about our trials and policies. We also participate in public and private online groups such as Facebook’s Trans MSM: Rethinking Sexuality and Health, designed to support discussions, debates, questions, and concerns that promote fact-based information, understanding, respect, and compassion among transmasculine people who have sex with men (TMSM), and their partners and allies. There is also a new marketing campaign on TASP (treatment as prevention) to ensure people understand the prevention message “Undetectable equals Untransmittable (U=U).”

This time in the history of the HIV epidemic is bittersweet. There are exciting new tools for treatment and prevention, and funded cure research is occurring with remarkable attention across biomedical disciplines. Extraordinary advances in the treatment and prevention of HIV infection bring many to the conclusion that it is possible to end the HIV epidemic through scaling up these interventions. At the same time, there is a lack of resources to provide for those at highest need, and a surge in stigma/discrimination. Politics are once again placing the lives of people in need on the back burner. One new challenge is to be vigilant and hopeful while working with warriors who have been leading the charge. We must do this while developing the next generation of people who can exude unity, gathering for strength and sustained hope.

* S. Wakefield is the Director of External Relations for the HVTN.

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NDLOVU CARE GROUP

By: Renee Meyer, Ndlovu CRS, Elandsdoorn, South Africa

18 October 2017 was a milestone in the history of Ndlovu Care Group. There were a great many reasons to celebrate the inauguration of the new research facility in Elandsdoorn. One of them is that we can proudly say that we have helped illuminate the research and priority needs for scientists from all over the world to see what is happening here, in Elandsdoorn, in Limpopo, in South Africa.

Our community has thrown its back into supporting Ndlovu Care Group to liaise, to work together, and to shape a strong and reinforced partnership to put an end to HIV and AIDS. The community has experienced, for the past 22 years since Ndlovu was established, what it is like to have their backs covered by someone who cares about what is happening at the grass roots level. When no one else seemed to even notice the suffering and anguish people were experiencing, Ndlovu Care Group was always there. And... they never dropped the ball.
Ndlovu is the care group who has convinced thousands of people in the local and surrounding communities to get tested for HIV, and Ndlovu supplied the medication and care necessary to help keep people alive and well. People who were dying have seen their health return and those who faced their final days of life were nursed with compassion and care during their last days when other groups were not willing. This community trusts Ndlovu Care Group, and Ndlovu loves the community.

Ndlovu has compassion for children left as orphans – for them Ndlovu Care Group has:

• Built houses that have become homes;

• Ensured access to care and support, medically and socioeconomically;

• Assisted some to become registered with identification to assist with access to other grants;

• Established nutritional units where children are nurtured back to health and care givers are taught how to care for their kids, pre-schools where children can feel safe and cherished, after school centers – the Ndlovu Chill Hubs – where young people can attend after school classes, attend computer school, read and be safe;

• There also are countless opportunities to excel at sports, with soccer fields, netball, tennis and volleyball courts and even a very classy gym.

This event was important and different because it also demonstrated how a community and a NGO can work together to create positive change in communities. Working together is one clear way to support finally eradicating HIV/AIDS. We were honored today to have many guests whose support in the field of HIV/AIDS has been remarkable and many who pledged their support, thank you very much! Thank you for the Ndlovu Youth Choir and Ralf and the people who made the enormous effort to build a beautiful stage in less than a week, thank you to the people who dug deep into their pockets to make this research facility possible.

Thank you to the community of Dennilton, and thank you to Dr. Hugo Tempelman, all of the researchers everywhere and all the staff members of Ndlovu Care Group.

* Renee Meyer is the Marketing Manager of the Ndlovu CRS in Elandsdoorn, South Africa.

*Note from Editor: The HVTN welcomes the Ndlovu CRS and looks forward to their participation in HVTN 709!
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.

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.

Translations in Spanish, Portuguese and French provided by Northwest Translations, Inc.
www.nwtranslations.com

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