Welcome to the newest edition of the HIV Vaccine Trials Network (HVTN) Community Compass.

For more than 30 years, HIV/AIDS has continued to ravage families and communities in the United States, and around the world. Social and structural factors such as stigma/discrimination, heterosexism, poverty, intimate partner violence, economics, cultural and social norms regarding gender and sex assigned at birth, sexuality, and ethnicity/race are some of the many forces that complicate HIV prevention and treatment strategies. These issues work together to increase the HIV risk for people in many communities. This is not romanticizing; this is the reality. We have come very far in the last 3 decades in reducing new HIV cases and slowing disease progression globally, but many places remain heavily burdened by HIV, so the work must continue. Biomedical HIV prevention research has laid a path toward ending the epidemic, and many biomedical advances have supported this journey. Much of the focus of biomedical HIV prevention has focused on four key areas: vaccines, microbicides, pre-exposure prophylaxis (PrEP) and treatment as prevention. HIV clinical research broadly, however, has produced some significant advances that have supported our achievements thus far in HIV prevention, and I believe will support an eventual end to the HIV epidemic in the future.

Stephaun E. Wallace, Editor-in-Chief
sewallac@fredhutch.org
In 1985, HIV testing in the United States became possible due to the U.S. Food and Drug Administration’s (FDA) licensure of the first commercial HIV antibody test known as ELISA\(^1\). This was an important step, which allowed blood screening to occur by testing for antibodies to HIV. In 1987, the FDA approved the first drug to treat HIV called zidovudine (AZT)\(^2\), and that same year the FDA approved another test to detect HIV antibodies called Western Blot\(^3\). More recently in 2011, a landmark global HIV clinical research study, HPTN 052, showed that among serodiscordant couples (where one partner is living with HIV and the other is not), HIV transmission can be reduced by up to 96% when the partner living with HIV starts HIV treatment early, is adherent to treatment, and is virally suppressed\(^4\) (an undetectable viral load). In 2012, the FDA approved the HIV treatment medication Truvada for use by persons who are HIV negative to prevent sexual transmission of HIV, in a strategy called pre-exposure prophylaxis or PrEP\(^5\). These are truly just a few of the advances that HIV clinical research has supported in the effort to prevent HIV and reduce the burden of HIV around the world.

As always, the best part for us is when we hear from you, the HVTN community. We thank you for your previous feedback and continue to welcome your feedback about how we are doing. We have received numerous responses to the Community Compass Experience Survey, and I would like to take a moment to highlight some of the feedback here. Many of you have indicated that you really enjoy reading the science updates, special feature articles, and photo albums. Everyone who has responded thus far has found the magazine to be a quality publication, and has remarked positively to the updates we have made to the publication. Some of the specific feedback we have received as opportunities for improvement include (but are not limited to) adding more content about HIV, HIV science, site community engagement best practices, and site engagement with CABs; as well as adding an app-based platform. You have my word that we will review all of your feedback and work to incorporate what we can.

Please help us ensure that this publication is representative of our entire global HVTN community! HVTN members (who have access to the HVTN member’s website) can use our newly developed submission page that offers the ability to submit content and articles for inclusion in future issues. More information about this follows on page 5 under the “Meet the Community Compass Team” section.

Thank you for your continued 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 have been able to make in our collective history and communities, together. Though we have come very far in response to the HIV epidemic, we have so much further to go to achieve an effective global HIV vaccine. 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

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\(^2\) AIDSinfo (1987, 20 March) ‘Approval of AZT’

\(^3\) The Henry J. Kaiser Foundation (2014) ‘HIV Testing in the United States’


\(^5\) U.S. Food and Drug Administration (FDA) (2012) ‘FDA Approves First Medication to Reduce HIV Risk’
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Antibodies are one of the natural ways that our bodies fight infection. Giving people antibodies to prevent infection is an accepted medical practice more than 100 years old. For example, doctors give people antibodies to prevent infections like hepatitis A and B and chicken pox. Some antibodies that are used for preventing infections are made in laboratories. Manufactured antibodies have been used to prevent a dangerous respiratory infection in infants called Respiratory Syncytial Virus (RSV), and to prevent and treat diseases such as rheumatoid arthritis and breast cancer.

bnAbs are special antibodies that seem to recognize many strains of HIV from across the globe.

In the HVTN, we began working with broadly neutralizing antibodies (bnAbs) a few years ago. bnAbs are special antibodies that seem to recognize many strains of HIV from across the globe. In lab tests, they are able to attach onto the surface of HIV and block it from being able to attach to a person’s cells to cause an infection. The HVTN first tested passive administration of bnAbs in HVTN 104, and is now working with the HIV Prevention Trials Network (HPTN) to do the AMP Studies, the first efficacy studies to see if one particular bnAb called VRC01 can prevent HIV infection in people.

The next bnAb we are testing is called VRC07-523LS, and once again we are joining forces with the HPTN to conduct the clinical trial. HVTN 127/HPTN 087 is a phase I study that is looking at 3 different doses of the antibody, and also three different ways of giving the antibody. This antibody has been engineered in the lab to make it last longer in the body and to make it better able to neutralize even more strains of HIV, possibly at even lower doses than VRC01. Volunteers will get the antibody 5 times, once every 4 months. Some people will get it by an intravenous (IV) drip, some will get it by a subcutaneous injection (a shot under the skin), and others will get it by a shot in the muscle of the upper arm or in the butt, whichever is preferred. In addition to looking at safety and whether participants are able to get the antibody without being too uncomfortable, this study will also look at how much of the antibody remains in the human body over time, if the immune system responds to the antibody, and if those immune responses are different depending on the dose or how the antibody is given to people.

HV 127/HPTN 087 is a phase I study that is looking at 3 different doses of the antibody, and also three different ways of giving the antibody.

The study opened in January, 2018, and will enroll 124 people. The study is being done at HVTN and HPTN sites in Lausanne, Switzerland; Atlanta, GA; Birmingham, AL; Boston, MA (2 clinics); Chapel Hill, NC; and New York, NY.

*Gail Broder is a Senior Community Engagement Project Manager for the HVTN, and a protocol team member for HVTN 127/HPTN 087.
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”.

On behalf of the HVTN Executive Management Team, we are pleased to announce the additional leadership responsibilities accepted by Dr. Michele Andrasik, as HVTN Director of Social-Behavioral Sciences and Community Engagement. Michele is a clinical health psychologist, Senior Staff Scientist in the Fred Hutch Vaccine and Infectious Disease Division, and an Affiliate Professor in the Department of Global Health at the University of Washington. Her research interests include resilience, social and structural drivers of disease, identifying and reducing barriers to HIV prevention, and qualitative research methods.

Michele received her PhD in Clinical Health Psychology from the University of Miami in 2006, where her work focused on assessing and addressing barriers to accessing care and treatment among low income African American HIV seropositive and HPV seropositive women. She also has Masters Degrees in Health Education and Psychological Counseling from Columbia University. She is highly committed to developing collaborative relationships between researchers and community members and brings extensive expertise utilizing Community-Based Participatory Research approaches, Qualitative Research methods, and working with communities and community organizations, both as a researcher and as a service provider. Prior to her doctoral training, Michele was the Director of AIDS Services for a community-based HIV/AIDS service organization with offices in the New York City boroughs of Brooklyn and Manhattan. She has also served on several community boards and committees in New York, Miami, and Seattle.

With Michele’s background and passion for HIV prevention, we are thrilled about the possibilities to continue to foster and support the general community, community educators, and our critical Community Advisory Boards and their respective members.

Another addition to the HVTN management team is Aziel Gangerdine in the position of Director of Communications. Aziel joins the HVTN after working with the South African Medical Research Council (SAMRC) as the Head of Corporate & Marketing Communications under the leadership of Dr. Glenda Gray. Aziel’s career spans more than a decade in health research communications. He also gained strategic experience in political communication between February 2009 – December 2013 when he served in the dual role of departmental spokesperson and political communication strategist for the portfolio of environmental affairs and development planning in the Western Cape state government in South Africa.

Some of Aziel’s career highlights include: appointed as the youngest head of communication to a state government department in South Africa (2009); served on the FIFA World Cup crisis communications team (2010); strategically relaunched the brand of the SAMRC to reposition them as a national asset in research and development (2015 – 2017); documented the highest ever recorded media coverage in the history of the SAMRC following the implementation of a communication strategy over three years (2016); and strategically designed a five year integrated communication and marketing plan and brand strategy for the BioEconomy South Africa (2017 – 2018). Aziel holds double Bachelor’s degrees with majors in public relations and media studies. Other South African qualifications include a post-graduate qualification in labor law and a diploma in human resources management and training.

Aziel’s expertise in the development of strategic communication plans and rebranding will serve the Network well as we anticipate results from our efficacy studies and prepare for our application to DAIDS for the next funding cycle in the coming year.

Please join us in welcoming Michele and Aziel into their new positions.

*Dr. James Kublin is the Executive Director of the HVTN.*
In 2018, the HVTN will continue:

Several early phase studies to assess the safety and immune responses to vaccine and broadly neutralizing antibody candidates.

**HVTN 703/HPTN 081 and HVTN 704/HPTN 085 (The AMP Studies)**
Evaluating the use of a broadly neutralizing antibody (bnAb), VRC01, to reduce HIV infection in HIV-uninfected men and transgender people who have sex with men, and among women.

**HVTN 702**
Evaluating the use of a clade-specific combination vaccine regimen to reduce HIV infection in HIV-uninfected persons in South Africa.

**HVTN 705/HPX2008**
Evaluating the use of a combination vaccine regimen containing a mosaic vaccine targeting global HIV strains to reduce HIV infection in HIV-uninfected women in 5 African nations.

FIND OUT MORE AT: www.HVTN.org
Historical Trauma

Historical trauma is an event, or a set of events, that happen to a group of people who share a specific identity. That identity could be based in nationality, tribal affiliation, ethnicity, race and/or religious affiliation. The events are often done with genocidal or ethnical intent, and result in annihilation or disruption of traditional ways of life, culture and/or identity. Each individual event is profoundly traumatic and when you look at events as a whole, they represent a history of sustained cultural disruption and community destruction.

In the United States, African Americans, Native Americans, and Alaska Natives have endured a history of multiple traumas. From the time the first colonists came to shore on what would come to be known as the United States, Native Americans and Alaska Natives have been subjected to:

- colonization;
- epidemic diseases brought from Europe;
- the tradition of extermination and mass homicide;
- forced marches and displacement from their lands;
- peace treaties often signed under coercion and later broken;
- the opening of Indian Boarding schools in response to the “Kill the Indian, Save the Man” policy;
- widespread sexual and physical abuse of children; and
- rates of violence and victimization higher than any other racial group.

African Americans have endured the legacy of:

- being stolen from their native lands;
- enslaved from 1619-1865;
- systematically abused and denied education;
- forced “breeding”;
- widespread sexual assault and rape of Black women;
- the abolition of slavery gave way to indentured servitude;
- “Jim Crow” laws;
- mass lynching;
- mass incarceration; and
- homicide rates higher than any other racial group.

Slavery in the US spanned from 1619-1865. It is estimated that 6 to 7 millions of Africans were imported to the US during the 18th century alone. The status of slave became a caste associated with African ancestry. The rapid expansion of the cotton industry in the late 1700s and early 1800s made Southern Sates dependent on slavery for their economy. Slaves were generally denied the opportunity to learn to read or write and were prohibited from associating in groups (with the exception (in some cases) of religious meetings). Murder of slaves was allowable if the slave was “resisting” or if done “under moderate correction”. Rape and sexual abuse of slave women were common.

Research exploring historical trauma looks at how the trauma of these events is “embodied” or held personally and passed down over generations, such that even family members who have not directly experienced the trauma can feel the effects of the events generations later [Walters et al., 2011]. Individual trauma then becomes collective, as it affects a significant portion of the community and becomes compounded. Multiple
historically traumatic events occur over generations and join an overarching legacy of assaults. The impact of these ongoing traumas has effects on a person’s brain and body, increasing their vulnerability to Post-Traumatic Stress Disorder (PTSD) and other mental health disorders [Walters et al, 2011; Yehuda et al, 1998]. This higher stress vulnerability may impair a person’s ability to cope effectively with current stressors as they arise.

From 1941–1945, Jewish people were systematically murdered in a genocide in Europe by the Nazi regime. Approximately 6 million Jewish people were killed during WWII (and an additional 5-million non-Jewish victims). Initially the German government passed laws to exclude Jewish people from civil society. Beginning in 1939, Jewish people were required to wear a distinctive sign to “mark them as Jews”, either a badge (yellow star of David) or armband (white with blue star of David). By the end of 1942, victims were regularly transported by freight train to extermination camps (United States Holocaust Museum, Learn about the Holocaust, https://www.ushmm.org/learn).

Transmission of trauma across generations was first seen in 1966 by clinicians who were alarmed by the number of children of people who had survived the Nazi Holocaust who were seeking mental health treatment [Trossman, 1968]. The trauma experienced by the Jewish people in the Holocaust was being seen in poor mental and physical health outcomes in their descendant generations. The children of Holocaust survivors were presenting with symptoms of PTSD, survivor guilt, anxiety, anger, grief, symptoms of depression, impaired self-esteem, a preoccupation with death, impaired communication, substance abuse, and exaggerated personal attachments or interdependence [Kellerman, 1999; Yehuda et al, 1998]. Not only does historical trauma influence psychological functioning at the individual level, it also affects family level communication and can appear in stress around parenting [Kellerman, 2001; Last & Klein, 1984). An important point is that the children of Holocaust survivors were NOT more likely than others to have poor mental health. They may have been vulnerable to higher stress, so that when they experienced high levels of stress in their lives, they were more likely to exhibit PTSD or related symptoms than others [Kellerman, 2000].

Since these early studies with the children of Holocaust survivors, scientists have also been gathering evidence showing that historical trauma has an impact at the cellular level. This body of evidence shows the neurological toll of stress on the health of descendant generations. Powerful stressful environmental conditions can leave an imprint or “mark” on the epigenome (cellular material) that can be carried into future generations with devastating consequences [Serpeloni et al, 2017, Ryan et al, 2017]. In studies of pregnant women, we see that psychological and nutritional stress in the mother during pregnancy can lead to biological changes that predispose their children to diabetes, heart disease, high blood pressure, and PTSD as adults. In a study of pregnant women who experienced the stress of the World Trade Center attacks on September 11, 2001, data suggest that effects of maternal PTSD on cortisol (a hormone released in response to stress) can be observed very early in the life of their children. This highlights the importance of effects during pregnancy as factors that contribute to biological risk for PTSD [Yehuda et al, 2005]. In these mothers, the correlation between maternal PTSD and cortisol levels in their infants was remarkably similar to that reported between parental PTSD and cortisol levels in adult
Microaggressions

Stress vulnerability may be especially challenging for racial and ethnic groups who deal with stress daily. Non-White people in the United States often deal with the continuous threat of discrimination and distress due to continuous microaggressions. Microaggressions are the chronic and commonplace verbal, behavioral or environmental indignities and injustices, intentional and unintentional, that communicate hostile, derogatory, demeaning, invalidating, and/or negative (racial, ethnic, homophobic, etc.) slights and insults toward people (of color, homosexual individuals, etc.) [Sue, 2007]. These verbal and non-verbal encounters most often place the burden of addressing them on the recipient of the encounter, creating stress! There are three types of microaggressions – microassaults, microinsults and microinvalidations. Microassaults are characterized by explicit racial derogatory verbal or nonverbal attacks or purposeful discriminatory action. With microassaults the intention is clear and they are most likely to be deliberate (for example, deliberately serving a White patron before a Black patron, displaying a swastika, saying that being gay is a sin, making fun of people with disabilities). Microinsults are behaviors that convey rudeness, insensitivity, reflect unfair treatment, or demean identity or heritage. These are often subtle snubs that the perpetrator may not realize they are doing (for example, when a White teacher fails to call on students of color in the classroom). Microinvalidations are communications that nullify, exclude, or negate the experiences, identity, thoughts and feelings of a person (for example, when Blacks are told that “I don’t see color” or “We are all human beings,” or when gay adolescents are told, “You are just going through a phase.”)

Microaggressions are the chronic and commonplace verbal, behavioral or environmental indignities and injustices, intentional and unintentional, that communicate hostile, derogatory, demeaning, invalidating, and/or negative (racial, ethnic, homophobic, etc.) slights and insults toward people (of color, homosexual individuals, etc.) [Sue, 2007]. There is a great deal of power in microaggressions. Most people see themselves as good, moral and decent, and find it difficult to believe that they have biased attitudes, and that they might engage in discriminatory behaviors. As a result, microaggressions are usually ignored, denied or explained away by seemingly unbiased and valid reasons. Indeed, when other explanations seem reasonable, microaggressions are very difficult to name and identify. This lack of awareness and sensitivity leads to an inability to accept responsibility for behaviors and for changing them. In contrast, 96% of African Americans reported experiencing racial discrimination in a one-year period, including being mistaken for a service worker, being ignored, receiving poor service, being treated rudely, or experiencing strangers who act fearful or intimidated when around them [Sellars & Shelton, 2003]. Experiences of microaggressions have been associated with anger, mistrust, loss of self-esteem, the triggering of old wounds, thinking about and replaying the event (“Did that really happen?”), and triggering feelings of internalized colonization, racism and homophobia, stress, self-doubt, frustration, isolation and shame [Solorzano et al, 2000].

Individually, each encounter creates a great deal of stress. Collectively they result in a tremendous amount of trauma for the individual and the community. Again, this may have a greater impact on racial minorities who have a high stress vulnerability resulting from the historical trauma experienced by their communities.

Trauma and Trauma-Informed Care

“Trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual’s functioning and mental, physical, social, emotional, or spiritual well-being” [U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), 2013]. Trauma occurs throughout a person’s lifetime and is often experienced first in early childhood (or even before birth, during pregnancy, as described above) and there may be subsequent re-traumatizing experiences. Each person experiences trauma differently. Some may have few or no lingering symptoms. People
who experience repeated, chronic or multiple traumas, including historical trauma, are more likely to have more pronounced symptoms and consequences including:

- substance abuse and dependence;
- depression symptoms and disorders;
- anxiety symptoms and disorders;
- impairment in relational/social and other major life areas (including treatment);
- increased risk for mental illness and increases in symptom severity;
- sleep disorders; and
- many health problems, physical disorders and conditions.

In our work, we frequently encounter individuals from marginalized communities, and it is important that we recognize and respond to the effects of historical trauma. They may not even be aware of how this history impacts them! Not only is historical trauma associated with increased stress vulnerability and trauma symptoms, the experience of trauma is a significant risk factor for sexually transmitted infections, depression, alcohol abuse, intravenous drug use, intimate partner violence and attempted suicide [CDC, 2014]. It is crucial that we practice trauma-informed care. SAMHSA (2012) states that, “A program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for healing; recognizes the signs and symptoms of trauma in staff, clients, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, practices, and settings.”

It is really important that we assess how our existing spaces, such as our clinical trial sites, may cause distress [Kamen et al, 2012]. This requires examining the power dynamics of relationships, the impact of a loss or lack of privacy during questioning and/or procedures, and the potential experience of loss when there are changes in staff with little or no notice. Invasive procedures, the removal of clothing, vulnerable physical positions, the gender of a provider, and being asked personal questions by someone who is a stranger may be experienced as traumatizing or re-traumatizing. To reduce the potential negative impact of these factors, we can improve and enhance the things we do to ensure a favorable participant experience by infusing trauma-informed care into our efforts.

A trauma-informed approach builds on understanding the effects of violence and abuse on a person’s life and development [Machttinger et al, 2015; SAMHSA]. It is rooted in a strength-based empowerment model, which fosters growth, and recognizes and promotes strength and resiliency. It is important to be aware of the fact that behaviors have traditionally been viewed through a pathological lens. This means thinking a person is at fault for their reactions or that there is something wrong with them, leading to labelling people as problematic or difficult. In reality, they may just be unsuccessful at coping with a situation that may (or may not) have the outcome that an individual wanted.

To get started on a path toward trauma-informed care, it is important that every member of the clinic team participate in training to learn about the impact of trauma on the health and wellbeing of providers, staff and participants. Training will help clinic staff develop skills to communicate more effectively with participants and with each other. As the clinic team continues down its path to trauma-informed care it will be important to identify clinic champions who will sustain trauma-informed care approaches over time. These individuals would identify and develop partnerships with local trauma and service organizations, and work collaboratively to develop procedures for providing referrals and responding to a participant’s needs [Elliot et al, 2005].

The key steps to a trauma-informed approach are:

1. Create a safe environment.
2. Prevent practices that re-traumatize people who have histories of trauma and are engaging in clinical trial research.
3. Build on the strengths and resilience of the individual in the context of their environments and communities.
4. Endorse trauma-informed principles in the clinic through support, consultation and supervision of staff.
5. Recognize that trauma-related symptoms and behaviors originate from adapting to traumatic experiences.
6. Create collaborative relationships and participation opportunities.
7. Use a strengths-focused perspective: promote resilience.

In our communities, there are many people who not only carry the burden of historical trauma, but must also navigate a disproportionate amount of daily stressors. To improve the health of our collective community, we must strive to make every effort to understand how human beings take in and hold onto trauma and stress so that we can avoid traumatizing and re-traumatizing one another.

*Dr. Michele Andrasik is the Director of Social and Behavioral Science and Community Engagement for the HVTN.*
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27. Library of Congress, Prints & Photographs Division, FSA/OWI Collection, LC-DIG-fsa-8a17057


29. United States Holocaust Memorial Museum, courtesy of Belarusian State Archive of Documentary Film and Photography

30. Library of Congress, Prints & Photographs Division, FSA/OWI Collection, LC-DIG-fsa-8a31160

Dr. Michele Andrasik
We have two major studies in the field to test the concept of whether non-neutralizing antibodies can protect against HIV in the areas of the world most affected by the epidemic. In both instances, the vaccines were made specifically for the epidemic that we are tackling. The 702 vaccine regimen made by the Pox-Protein Public-Private Partnership (P6) is based upon data from RV144, and the strains and the study design are all building on the results from that study.

During the interim years, much has happened in the HIV vaccine field including the sale of the original company that invented the gp120 proteins used in HVTN 702; Novartis was sold to GSK. There has been constancy in the leadership of the ALVAC vector program at Sanofi, which we are happy with.

Success in 702 means an efficacy above what was achieved in RV144, hopefully at least a 50% reduction in new HIV infections over the first two years of the vaccination regimen, and a longer duration of efficacy with the continued booster dose we are giving in 702.

Success means an efficacy above what was achieved in RV144, hopefully at least a 50% reduction in new HIV infections over the first two years of the vaccination regimen, and a longer duration of efficacy with the continued booster dose we are giving in 702.

Success does not mean immediate licensure of the vaccine for widespread use. Success means that we define whether antibodies to the V1V2 region of HIV’s surface proteins are still correlated with reduced HIV infection and/or whether the CD4 T-cell responses are still independently associated with HIV infection. Success leads to continued development of the program. This continued development takes several forms. One is to develop the manufacturing capabilities required to license a vaccine, to move the process of development from a research stage to an industrial stage. This is something necessary for both making the protein as well as the canarypox vector. Success also means increasing the durability of the response (how long it lasts). Should this be done with another adjuvant? GSK has used the AS01B adjuvant in its recently licensed, highly effective varicella zoster (shingles) vaccine, and phase 1 studies using it with the 702 vaccine regimen have begun. If these show greater durability, then bridging studies to replace the MF59 adjuvant with AS01B might be considered.

Lastly, continued development might be to redesign the vaccines to utilize recently discovered strains of clade C that would enhance V2 responses, or even to add the strain from the RV144 trial called A244 to the vaccine regimen. While one could groan at the length of this process, success also means progress. This could include studies to introduce the vaccine to adolescent populations, new regions of the world, or new populations such as Men who have Sex with Men (MSM).

All of these options are available and are under consideration depending upon the degree of protection, the strength of any potential correlate of protection, and the cost and time of bringing a commercially viable vaccine to sub-Saharan Africa. One could say that 702 is just the beginning of the march for the regimen.

Continued on Next Page...
The HVTN 705/HPX2008 study is also in the early stages of the march to potential global efficacy. From the beginning, the construction of the vaccine has been developed to have global coverage. The recent data from HVTN 117 shows that adding the clade C mosaic vaccine and the addition of a clade C gp140 boost enhanced the immune responses in people that were associated with protection shown in the nonhuman primate experiments, as well as enhanced clade C immune responses. Again, the degree of efficacy and any potential human correlate of protection that is associated with efficacy will drive future plans. Will the addition of another protein enhance antibody responses and durability? Can the regimen be compressed more to allow protective immunity to be seen earlier? Can the addition of a novel vector, such as MVA (related to smallpox), enhance immune responses that are associated with reduction of new HIV infections?

One can ask the question: why do these efficacy studies if so much more work is required to bring the vaccine to people? The answer is an easy one. The risk of an HIV vaccine is high, and we need to develop an intermediate step before private and/or public funders can be brought to the table. Funders will need to make a substantial financial investment to meet manufacturing and distribution guidelines for licensure. The HVTN is lucky to have the kind of dedicated partners that will take such risks. We are appreciative of our funders at DAIDS and the Bill and Melinda Gates Foundation, and our pharmaceutical collaborators at Janssen, Sanofi, and GSK.

Experiments to extend the results from women to heterosexual men, MSM, and transgender women and men will also need to be performed.

One can ask the question: why do these efficacy studies if so much more work is required to bring the vaccine to people? The answer is an easy one. The risk of an HIV vaccine is high, and we need to develop an intermediate step before private and/or public funders can be brought to the table. Funders will need to make a substantial financial investment to meet manufacturing and distribution guidelines for licensure. The HVTN is lucky to have the kind of dedicated partners that will take such risks. We are appreciative of our funders at DAIDS and the Bill and Melinda Gates Foundation, and our pharmaceutical collaborators at Janssen, Sanofi, and GSK.

*Dr. Larry Corey is the Principal Investigator for the HVTN.*
HVTN FULL GROUP MEETING
MAY 14-16, 2018
WASHINGTON D.C.
Seen Around the HVTN

PrEP Dance Event with Community Education and Recruitment Leads in Lima, Peru March 2018 (l to r: Hugo Sanchez, UNIDEC; Jose Luis Castro aka Gina, Via Libre; Rosario Leon, IMPACTA)

HVTN Regional Meeting in Cape Town, South Africa February 2018

PrEP Dance Event with Lima Community Education and Recruitment Leads and a site PI in Lima, Peru March 2018 (l to r: Pedro Gonzalez, PI of San Miguel site; Hugo Sanchez, UNIDEC; Jose Luis Castro aka Gina, Via Libre; Rosario Leon, IMPACTA)
Wakefield (HVTN) at NAESM Conference

NAESM Opening Reception: (l to r) Ms. Sophia (NAESM Reception Host), Russell Campbell (HANC), Brian Minalga (HANC), Clare Collins (MTN), and Dr. Michele Andrasik (HVTN)

NAESM Breakfast Plenary: Dr. Hyman Scott (Bridge HIV) giving a talk on the future of preventive HIV vaccine and antibody research

Transgender Session at NAESM Conference: (l to r) Stephaun Wallace (HVTN/KBCAN), Martez Smith (KBCAN/University of Rochester), Jonathan Lykes (KBCAN)
Meet Peru’s HIV Superhero

By finding a better way to prevent HIV, Dr. Jorge Sanchez aims to help end his country’s AIDS epidemic

By Mary Engel / Fred Hutch News Service

The superhero named Vacuman arrived at La Cueva, a strobe-lit, subterranean gay disco in Lima, Peru, at midnight. Dressed in a white body leotard with a plunging neckline to show off his pecs, he danced his way to the stage accompanied by the Impacta Universe Boys, an entourage of buff young men in briefs and go-go boots.

It was quite the entrance, which was the point.

Vacuman is the creation of the Asociación Civil Impacta Salud y Educación, an HIV clinical research site in Lima and part of the global HIV Vaccine Trials Network based at Fred Hutchinson Cancer Research Center in Seattle. Played by an easy-on-the-eyes model, his job is to draw attention to the need for a vaccine against HIV/AIDS. And those disco patrons can help scientists develop one.

Impacta community educators and clinical trial recruiters accompanied the superhero on his monthly tour of Lima discos, bringing buckets of condoms to communities hit hardest by HIV along with information about a possible new path to a long-sought preventive vaccine.

That path is the AMP Study, for antibody mediated protection. HVTN-run clinical trials are underway in the United States, South America, Switzerland and southern Africa to test whether an experimental antibody given by an intravenous “drip,” or infusion, can protect those who receive it from HIV infection.

The Americas portion of the study needs to enroll 2,700 gay men or transgender people who have sex with men — the groups in this region most affected by HIV. Deploying Vacuman, who has a Facebook page, an elaborate backstory and comic-book plots, is a way of cutting through the noise to recruit participants in a sprawling city of 10 million people.

If Impacta is the force behind the Vacuman campaign, the force behind Impacta is a determined leader who is a superhero in his own right. Before co-founding the research clinic in 2000, Dr. Jorge Sanchez rallied his country to fight AIDS, becoming the first openly gay man appointed by the Peruvian Ministry of Health to head its newly expanded AIDS program in 1995.

His battle against the virus had begun almost a decade before that. And decades later, he is fighting still.

“What I am always impressed with by Jorge, beyond what an incredibly good epidemiologist and thinker he is, is how committed he is to his community,” said Dr. Larry Corey, the founder and head of the HVTN. “He built Impacta — this research infrastructure, these buildings, these labs — and trained people and motivated a whole group of physicians. It is remarkably wonderful to see the influence of one man who wanted to change and shape the health of the community.”

‘No one had touched him’

Sanchez’s career is a history of HIV in Peru. For that matter, it is a history of the epidemic worldwide.

Like other infectious disease doctors of his generation, he remembers his first AIDS patient.
It was 1986 — five years after AIDS was first identified in the United States and three years since the first case in Peru. Sanchez, then a young physician, arrived for his Sunday morning hospital shift to find that a patient thought to have AIDS had been admitted on Friday.

“No one touched him for 48 hours,” Sanchez said. “They wouldn’t walk into his room.”

In a recent interview in an Impacta office in Lima’s Barranco district, Sanchez recalled that he had headed straight to the room — and saw that the patient was someone he knew from medical school. Like Sanchez, he was gay, but neither man had been open about it as a student.

The friend was desperately ill and thin from the virus’ wasting effects. With antiretroviral treatment to contain HIV still a decade away, many who were infected delayed seeking care because they feared the very rejection that Sanchez’s friend received.

“At that time, there was much more stigma and discrimination,” Sanchez said. “Even if people knew they were positive, they didn’t go to get care until they were really, really sick at the end of the process because they were afraid of discrimination in hospitals.”

Sanchez couldn’t save his friend’s life. But he could at least offer humane care. Impelled by this encounter, he opened the first practice in Peru for HIV patients. All he could do medically for them at the time was try to treat the infections and cancers that took advantage of their ravaged immune systems and ease their suffering.

“It was so hard,” he said. “Everybody dies. It was really difficult as a physician to just say, ‘I cannot do anything for you.’ The only thing you could provide for your patients is care and love.”

At the time, of course, it meant everything. But his inability to stop or even treat the disease took a deeply personal toll. One day in 1990, he could not go on.

“A new patient came into my office, and even before talking to him, I started crying,” Sanchez said. “I just couldn’t see any more patients.”

‘We were making a difference’

Sanchez left Peru for Seattle to earn a master’s of public health in epidemiology from the University of Washington, where he established relationships with fellow infectious disease researchers that continue to this day. In 1992, he began working as a consultant for the UW Center for AIDS and STD [sexually transmitted disease] Training, traveling to Central America and the Caribbean to provide research training to HIV programs and nongovernmental organizations.

Always when he traveled, he was homesick for Peru but could not find permanent work there, despite being one of the country’s foremost infectious disease experts.

“Basically, I didn’t get a job because the clinics believed that the waiting rooms would be full of gay people, and that would make their general population go away,” he said.

Peru eventually established a small government AIDS program. And as Sanchez’s research in that area became known, he was asked to head it. It took three offers — two of them withdrawn — before Ministry of Health officials accepted that Sanchez had no intention of hiding that he was gay and every intention of promoting condoms for prevention, neither of which went over well with the country’s Catholic hierarchy.

And so five years after leaving his clinic in despair over not being able to do enough, Sanchez was in a position to change how all HIV patients were treated.

As head of an expanded National AIDS and STD Control Program, he put hundreds of HIV prevention educators on the streets.

Cristina Magán was one of them. Now the president of Impacta’s community advisory board, she first met Sanchez when he was finishing his medical residency. She worked at a clinic that served sex workers and was concerned over high rates of HIV. When Sanchez began putting outreach programs in place, Magan volunteered to help.

“Dr. Jorge Sanchez was very proactive. He used to go with us to the field for workshops and to visit the transsexual sex workers,” she said, speaking through a translator after an advisory board meeting in Lima in December. “I most remember Dr. Sanchez doing night work, going to the streets to find the people in the community to get them to be tested and into...
prevention programs. ... With a big budget and a whole team of people, he brought programs to the whole country."

Remembering how his friend had been treated, Sanchez made STD clinics more welcoming to gay men by setting aside waiting rooms decorated with gay-themed posters and training gay men to work as patient advocates.

“It looked like a gay clinic inside of a Ministry of Health clinic, which was revolutionary for that time, 1995,” Sanchez said. “We had what now people call peer navigators. If a gay person was coming for an appointment, this guy accompanied him to pay his receipt, to go the pharmacy, the lab, whatever was needed.”

His staff grew to 25 people, the second largest AIDS program in South America after Brazil.

“Many of the most brilliant professionals were there,” said Maria del Rosario León, who worked for Sanchez then and now heads the Impacta Community Involvement Unit. “We had a special program for female sex workers, a special program for the gay and trans community. We were making a difference.”

AIDS had taken root during a tumultuous period for Peru. The 1980s and early 1990s brought car bombings, political murders and disappearances when the Maoist guerrilla group Sendero Luminoso, or Shining Path, waged an armed battle against the state and the army cracked down harshly in return.

Through all these upheavals, Sanchez worked to contain the AIDS epidemic. In 2000, the continuing political tumult cost him and his staff at the AIDS program their jobs. That did not stop him either.

He had earlier helped found a private, nonprofit AIDS service organization. Now he co-founded Impacta to add research to the mix.

“The to have an answer to this epidemic, it’s important to have research,” said León, who followed him to Impacta. “That is how we are going to make a difference now.”

With help from Seattle colleagues — including Drs. Julie McElrath, now a Fred Hutch senior vice president and director of its Vaccine and Infectious Disease Division, and Connie Celum, a UW global health professor and co-director of its International Clinical Research subunit. Today it is independent and a vital unit of not just the HVTN but of two other global HIV networks, the HIV Prevention Network, which is co-directing the AMP Study, and the AIDS Clinical Trials Group, which focuses on treatments.

Another night, another disco

Last Dec. 1, the Impacta outreach team worked a World AIDS Day event at Plaza Mayor, the palm-treed oasis in the heart of Lima fronting its oldest cathedral (finished in 1622) and its presidential palace. Then they crawled through Lima’s infamous traffic to the Miraflores district. Just before midnight, the second part of their workday began: a private party at the Legendaris nightclub to honor AMP Study participants.

Vacuman was there, along with superheroes representing other HIV studies. An Impacta Universe boy dropped to the floor to do a few pushups before hitting the dance floor to “put happiness in the room,” as León described the go-go boys’ role, and to warm up the audience for the superheroes’ dance show. Luis “Lucho” Castro, a community educator who has been with Impacta almost since its founding, introduced the heroes and thanked the enthusiastic audience.
The HVTN sites in Peru and Brazil are responsible for roughly half the AMP Study’s targeted enrollment. Not only are the numbers challenging — 700 enrollees from Lima alone — but the “ask” is big: participants receive 10 intravenous infusions every other month, each one lasting 30 to 60 minutes.

But the potential payoff is even bigger. If antibodies are found to be protective, scientists can try to reverse-engineer a vaccine to elicit them or engineer other delivery methods to help end one of the largest and deadliest pandemics in history.

“Without volunteers,” Castro said in Spanish, “we wouldn’t have heroes.”

Castro’s cheerful emceeing belies his knowledge of the epidemic’s dark side. Like Sanchez and others who have worked in the field for decades, he has lost loved ones to AIDS. He had just found his calling as a field educator in the 1990s when a beloved friend was diagnosed, well before antiretroviral therapy became available to Peruvians in 2004. His most painful memory is of his friend’s family rejecting their dying son and brother.

Today, Castro passionately believes that information ends stigma. He honors his friend’s memory by helping people understand the need to get tested and treated in the short-term — and to get involved in scientific research to end the epidemic.

“Letting others know about research and studies is very important,” he said, speaking through a translator. “Changes in the epidemic have come about because of results of studies. And Dr. Sanchez is a leader in the scientific community for HIV in Peru.”

The changes that have taken place since the early days of AIDS were unimaginable that day, more than 30 years ago, when Sanchez recognized his old medical school friend in the emaciated face of his new patient. Still, he knows that the work is not finished. The epidemic in Lima, he said, is concentrated in gay men and transgender people who are poor and have little access to education or medical care. Those circumstances — and stigma that lingers beyond a disco’s welcoming circle — mean that people still show up at Lima hospitals as desperately ill as his friend was.

“I know we have made a lot of progress,” he said. “But the epidemic keeps growing. The volume of this epidemic will crush the budget of any country. There is no money to support forever HIV treatment. We need to go back to find the best way to prevent HIV transmission. That is the goal.”

Sanchez, who describes himself as a former partygoer turned homebody, appeared at the party that night to show his appreciation to the trial participants, though with typical modesty, he shook off Castro’s efforts to introduce him.

As Vacuman took the stage, Peru’s real HIV superhero slipped away to go home to his partner of 26 years. He would be back at work the next morning.

Editor’s note: Fred Hutch News Service writer Mary Engel was in Lima and Iquitos, Peru, in December, where this story was reported. This is one of an occasional series of behind-the-scenes stories on the HVTN’s AMP Study.

*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.
Dr. Gregory Wilson is co-principal investigator for the Vanderbilt HIV Vaccine Trials Program in Nashville, Tenn., a unit of the Fred Hutch-based HIV Vaccine Trials Network. The director of the Pediatric and Adolescent HIV Unit at Vanderbilt University Medical Center, he first encountered HIV as a pediatrician in training, treating HIV-infected infants.

My history with HIV goes back to my training in the late 1980s and early ‘90s, when we started seeing infants in middle Tennessee infected through mother-to-child transmission. I was finishing up my residency and had chosen infectious diseases as my specialty, but I did not foresee my role in the HIV epidemic. Viral infections in general and HIV specifically became a specialty for me and a research interest also.

Treatment was just beginning to come out at that time. Adults had access to one or more medicines — first AZT, then other medications in that class. We didn’t yet have a lot of information on the medication’s effects on children.

From 1997 to 2006, we had a Pediatric AIDS Clinical Trials Unit here in collaboration with St. Jude’s Children’s Research Hospital [in Memphis]. That gave us access to medications. And it was a natural transition over to becoming an HIV vaccine trials unit.

You used to only be able to make an HIV diagnosis by following babies to 18 months of age. A baby born of an HIV-positive mother had antibodies for that long. With pediatric trial resources, we were able to make an earlier diagnosis. So we could concentrate our resources on those who needed them.

Mother-to-child transmission was the main route of infection, though children who were hemophiliacs were infected through blood products. By the late ‘90s, we were beginning to see adolescents infected behaviorally. If we had more access to schools and much more frank educational discussion about sex and risk factors, that could play a big role in preventing infection. Some schools do better than others.

As far as mother-to-child-transmission, we’ve really reduced that dramatically. In the U.S., it’s down to less than 1 percent. It’s now very rare.

What we’re seeing now are families who have adopted children from resource-limited areas like sub-Saharan Africa, so we’re seeing another wave of young children in our clinics. Like the infants before them, they go on medication and graduate from our clinics with the virus well controlled. We see waves of children graduating from clinic, going through elementary, middle and high school, going to college.

Some of them come back to see us because they’ve stopped treatment, and we try to get them back into treatment. Some of those children are mothers now with children of their own. We see those children to make sure they’re not infected, and it’s a chance to see that their mothers stay on treatment.

We try to get them into our transition program and into adult care. If they fail, you just try to help them again. That’s the pediatric way.

Editor’s note: Dr. Wilson talked about his early experiences treating HIV pediatric patients during a June 2017 interview for a story on the Vanderbilt unit’s record enrollment in the HVTN AMP study.
Our Seattle CRS CAB would like to take a moment of remembrance in loving memory of Abe Gaston III. We are extremely heartbroken to have recently lost him. For over a decade, he had been a dedicated member of our Seattle CAB as well as an active member of other research groups, including the ACTU (AIDS Clinical Trials Unit), defeatHIV, and CFAR (Center for AIDS Research). Abe was a kind soul, was a warm and welcome presence, contributing his time and energy, and our community is so grateful to have known him. His humor, deep care for others, and passion will be forever missed. Thank you, Abe for all you have taught us in our journey together.

*Victoria Chinnell is a CAB member of the Seattle CRS.*
“For any recruitment process to be successful, instilling the spirit of community ownership amongst the participants is an integral element”, says M’modzi as he prepares for one of his daily errands of engaging potential participants and communities in general. Pearson M’modzi, himself a recruiter, believes community engagement is central to any study. M’modzi has been working with the Lilongwe, Malawi CRS for the past 12 years, primarily focusing on engaging communities and stakeholders, and notes that increasing research literacy in the communities he works with is a passion of his. M’modzi notes that engaging communities should not only be during the time of recruitment – it should be in preparation, throughout the period of study and after.

HVTN is very helpful whenever there is a study; the educational and giveaway materials make his work easier and exciting, especially with so many youth interested in HIV vaccine research in the region.

M’modzi holds a Bachelor of Science in Public Health as well as a Diploma in Community Development, and looks forward to pursuing a Master’s degree. M’modzi first started working with HVTN in 2014 as the site was beginning HVTN 111, and is now involved in the AMP Study and HVTN 705/HPX2008. M’modzi states, “I enjoy doing this work with HVTN, learning so much from the team and my colleagues from the sites all over the world, especially knowing that we are doing all this for a common cause.”
I entered the field of HIV prevention research though a non-conventional route. As Vice President of a for-profit Employees Assistant Program (EAP) and managed care company, I had the unique opportunity to consult with senior executives and Human Resource staff to develop policies and procedures regarding employees infected with HIV. Beginning in 1994, I joined the University of Pennsylvania HIV Prevention Research Division and served as Project Director for HIVNET (HIV Network). I was tasked to focus on injection drug users and women at risk for HIV due to their drug use and sexual practices. We soon became a HPTN site, and as Project Director I oversaw a High Risk Injection Drug User trial, Women Fighting HIV Intervention trial and the HPTN 037 Injection Drug Users Network trial conducted in Philadelphia and Chiang Mai, Thailand. We subsequently became an HVTN site.

Since 2007, it has been my privilege to serve as the Coordinator for Community Engagement: Recruitment & Community Education for the UPenn HIV site. I have worked with our computer programmer to design databases to track recruitment and enrollment, resulting in the development of innovative tools to match recruitment venues to enrollment success in trials (Phase I and efficacy trials).

As a member of the HANC Legacy Project and the Women’s HIV Research Collaborative, the HVTN Efficacy Trials Working Group and the HVTN Social Behavioral Working Group, I am an innovative voice and bridge between the Community Educator and Recruiter Working Group and these committees.

Gail Broder was born and raised in Detroit, Michigan, receiving her Bachelors Degree in Music Therapy at Eastern Michigan University. She subsequently moved to St. Louis, Missouri, where she worked in long-term care settings as a music therapist specializing in Alzheimer’s disease and other dementias. In the 1990’s, Gail began losing friends and a mentor to AIDS, and she made the decision to redirect her career to HIV prevention in order to tackle the epidemic proactively. She received her Master's Degree in Health Science with emphasis in Health Education in 1999 from Washington University in St. Louis. Her thesis work formed the basis for a curriculum in HIV prevention education. Following graduate school, one of Gail’s volunteer affiliations was with the Community Advisory Board (CAB) of the HIV Vaccine Trials Unit which was then located at St. Louis University. After serving for 2½ years as a CAB member, Gail moved to Seattle in 2003 to join the staff of the HVTN's Community Engagement Unit.

Away from the office, Gail has maintained a semi-professional music career. She sang with the Detroit Symphony Orchestra Chorus for two seasons, then with the St. Louis Symphony Orchestra Chorus for 16 seasons, including four performances in New York's Carnegie Hall and three CD recordings. In Seattle, she performs with Seattle Pro Musica and sings in her synagogue's choir.
I first started in HIV work in 2012 when I was volunteering at the Centre for Youth Institute, where I was teaching youth about HIV and other activities. It is in the same year I started my journey with HVTN as a CAB Member and also as a study participant of the Klerksdorp Research Site. HVTN has broadened my knowledge about HIV and vaccines. It is an amazing experience to work with the HVTN. I have learned a lot since I started working with HVTN, and I still am because there are new things coming up every day. I am grateful to be part of HVTN.

I am a South African woman, born in 1989, a Christian, married, and a mother of one daughter. I can speak several of the languages in South Africa. My hobbies are to play tennis, singing and reading. I have a Diploma in Applied Philosophy and Public Ethics, a Higher Certificate in Management, and am busy finishing off my Bachelor’s Degree. I have worked in the health sector since 2012. I strive for nothing but success in whatever I do, and do not settle for less. In 2015, I received the HVTN Octavio Valente Junior Volunteer Service award for my contributions in HIV vaccine prevention research, and in 2017 I was elected to serve as the HVTN Global CAB Co-chair. What people do not know about me is that I have a desire to write a book and I am preparing to fulfil that dream.
### UPCOMING EVENTS/CONFERENCES/MEETINGS

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<td>14-16 MAY 2018</td>
<td>HVTN Full Group Meeting</td>
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<td>18 MAY 2018</td>
<td>HIV Vaccine Awareness Day</td>
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I immigrated to the United States from Kenya with my family in 2001 and did my undergraduate studies at the University of California, Berkeley. In 2016, I earned a Master’s in Public Health (MPH) in Epidemiology from the University of Washington.

As an undergraduate, I was a Minority Health and Health Disparities International Research Training fellow, working in South Africa to examine the potential effects of diseases spreading between wildlife, livestock and people. I also worked as a volunteer for the sex worker outreach program in Nairobi, Kenya, providing health education and medical services to sex workers. As a graduate student, I worked with Dr. Anna Wald at the University of Washington Virology Research Clinic where we designed and conducted a mixed methods study to assess the interest of persons with genital herpes in finding a herpes cure and their willingness to take on the risks associated with experimental therapy to completely clear or inactivate their infection. I also worked with Dr. Michele Andrasik at the HVTN, where I coordinated the development of animated educational videos for the AMP study.

I was a collegiate and post-collegiate track and field athlete (Hammer Throw). I was encouraged to do track and field by a friend I played basketball with in high school. As a post-collegiate athlete, I competed for Kenya at two Commonwealth Games (India and Scotland), 3 African Championships (Kenya, Benin and Morocco), and the World University Games (China). I was voted co-captain of four of these teams. I am currently the Kenyan record holder in the Women’s Hammer.

As a young child in Kenya, my dream was to find the cure for HIV. I imagined myself as a lead scientist of a lab that would discover a cure. Every paper I wrote in middle school, high school and university was in one way or another linked to HIV. Working at the HVTN is a dream come true! I am proud to be a member of an organization that is conducting cutting edge research to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates. I appreciate working in an environment with like-minded people who are collaborative, passionate and committed to working toward an HIV/AIDS-free generation. Thank you for the opportunity to make my small contribution to our mission of finding a safe and effective vaccine for HIV prevention globally.
Khanyisile Khumalo  
Rechner/Counsellor- PHRU, Soweto-Bara CRS, Johannesburg, South Africa

After matriculation at age 18, I joined a community policing forum we call a “youth desk” at the local Moroka Police station. Then we were invited to attend a workshop by PHRU on education about HIV Research. It was in 2007 when we established the first Adolescent CAB for PHRU and that was the start of my passion for HIV research. From then on, we were educated on vaccines and a whole lot of other things about HIV research. That is how I learned about the HVTN and the work that it does and funds. Since then we have been going into our local communities and educating them about the HIV research, and I work as a recruiter for the pre-teen study introducing adolescents and teens to HIV research.

Though I studied for a diploma in journalism, I continued to work with PHRU and was later hired full time as a recruiter for HVTN vaccine studies in 2016. I have been working directly with HVTN since then, and I have to say I have learned a lot. I totally look forward to many more years with HVTN for the work that we do is incredible and very important. Meeting so many different people who teach you new and interesting things has been amazing, and the participants we recruit and build research relationships with has been bliss. Something personal that people may not know about me, is that I am strict and disciplined, and I was raised that way.

Erick Murayari  
CAB Member ACSA Iquitos CRS, Iquitos, Peru

Activist and founder of the Homosexual Community Esperanza Loreto Region (CHERL)

“We CAME OUT OF CLANDESTINITY TO DEFEND THE RIGHTS OF THE LGBT COMMUNITY”

“When I began in 1998, discrimination was very high, and in addition to the HIV/AIDS pandemic that had a great impact on our community, many friends and acquaintances died, abandoned, without treatment. Many of them went to the shelter “Something Beautiful for God” for medical and human service attention, but the needs could not be covered, so this was motivation to help friends and get involved. Erick, affectionately known as “Guada” (Erick goes by he/him or she/her) began to work in different aspects, as a small and visible group within the community.

In 2003, Erick along with others decided to form an alternate organization called, “Homosexual Community Esperanza Region Loreto” (CHERL), and “…during these times, you could not dress as a woman because of discrimination and hatred, including thrown stones and homophobia and stigmatization. It was believed that we (LGBT people) were all carriers of AIDS, before we armed ourselves with courage to defend our rights, defend human rights, and have a political and social impact on our community, says Erick. This commitment led her to volunteer for the research work carried out in Iquitos by the Asociación Civil Selva Amazónica y HVTN. Erick adds, “We won spaces at the cost of effort and courage; some media even invited us to introduce ourselves as weird beings or mock us, but with perseverance and good arguments we won little by little the respect of the community”. The work and perseverance has resulted in progress however, “…now we are invited to universities, we are interviewed, including the Technical School of Police, those who chased us before now invite us to give conferences with the police students. Erick Murayari, with his experience and perseverance, is now a member of the Community Advisory Committee of the ACSA CRS, where his contributions are valued and appreciated, “We follow the efforts into a vaccine for HIV prevention, this is very important. Unfortunately the pandemic is maintained and the face of HIV is getting younger, now the population in general is involved and we will continue in the effort because I am convinced that with the organization and work we will overcome barriers, overcome difficulties and work for a better world and future for all.”
Background

World AIDS Day is an internationally commemorated event. Its purpose is to provide an opportunity for people worldwide to unite in the fight against HIV, to show support for people living with HIV, and to commemorate those who have died from an AIDS-related illness.

The Synexus Stanza clinical research site, as part of the Mamelodi community and working with various non-profit organisations, supported the World AIDS Day 2017 event. The message emphasised at the event was about strengthening HIV education and encouraging the uptake of community HIV testing.

The main objective of collaborating with local organisations and clinics is to strengthen existing working relationships and to expand the Synexus footprint in the community. The World AIDS Day event was organized in collaboration with twenty local organizations; each organization sent a representative to attend weekly meetings to plan for, as well as mobilize attendance for, the event.

The Synexus clinic manager provided an inspirational message of support and the role of the clinic, especially with implementing the Universal Testing and Treatment (UTT) approach by Department of Health. New HIV prevention tools being researched, such as HIV vaccines, were presented by Dr. Sheena Kotze regarding the HIV vaccine study known as Imbokodo or HVTN 705/HPX2008. Refreshments were provided to close the event. The community expressed satisfaction with our hospitality.

Stakeholders Collaboration

The Synexus Stanza clinical research site, as part of the Mamelodi community and working with various non-profit organisations, supported the World AIDS Day 2017 event. The message emphasised at the event was about strengthening HIV education and encouraging the uptake of community HIV testing.

The Brothers for Life and Right to Care provided HIV testing services at the event. Twenty participating stakeholders came from important service providers such as Youth employment agencies, Harambee, Stanza Development, Godisang Skills Development Centre, Health services, Drug and Alcohol Abuse services, Ward Based outreach teams, Computer school, Treatment Action Campaign (TAC), HIV educators, health care workers, CAB, MAMS radio, National Development Agency, and Circle of life.

Structure of Agenda

There were twenty (20) information stalls from various service providers including two HIV testing service providers. At the main gate entrance, all attendees completed a general registration. The programme was divided into two parts. Part A catered to entertainment activities by local artists. This part of the programme was strategically created to allow people to be seated before the start of the Part B formal proceedings. The formal proceedings of the day started with prayer by Prophet Sipho, followed by a hymn performed by the Mamelodi Salvation choir, and then a candle lighting led by Synexus Operational manager Ms. Deidre Traynor. Bobby Mohanoe from TAC gave a talk on the origin and meaning of Candle Lighting. Dr. Vathi Papu-Zamxaka, Head of Patient Engagement, spoke on behalf of Synexus. Other speakers included a motivational talk by a person living with HIV (PLWA), and Reverend Thobejane and Dr. Philemon Mahuma of the Synexus Community Advisory Board (CAB) made presentations on the role of the CAB and the significance of World AIDS Day. The Synexus clinic manager provided an inspirational message of support and the role of the clinic, especially with implementing the Universal Testing and Treatment (UTT) approach by Department of Health. New HIV prevention tools being researched, such as HIV vaccines, were presented by Dr. Sheena Kotze regarding the HIV vaccine study known as Imbokodo or HVTN 705/HPX2008. Refreshments were provided to close the event. The community expressed satisfaction with our hospitality.
Attendance

The event aimed to reach about five hundred community members, with emphasis on youth attendance. According to the registration figures, there were six hundred (600) people reached with a great mix of youth attendees. 55 people registered at the HVTN stall about the Imbokodo study, and two people followed up by attending initial visits at the site the next week. The Global Studies stall registered 63 new people for our database for recruiting future studies.

Media

The event was promoted on weekly broadcasts on MAMS community radio as part of the mobilisation strategy by Synexus doctors focusing on HIV and AIDS topics. On the day of the event, the Daily Sun newspaper and MAMS radio conducted interviews with key Synexus staff and other organisations representatives during the proceedings.

Conclusion

This event was an opportunity for younger and older community members to have first-hand information on HIV prevalence and incidence in South Africa and how each individual can play a role in bringing about much needed change in combating the scourge of HIV. The introduction of HIV vaccine research to the community was an eye opener. A talk by a person living and surviving with HIV caught the attention of the audience. For the people who did not know about Synexus and Harambee activities, it was an opportunity to register for opportunities geared toward youth empowerment such as internships, learnerships, computer literacy, etc. Amongst many activities that were highlighted was the artistic flair exhibited by our Mamelodi youth. The need to support growth of domestic talent was also highlighted. The plenary team agreed to host an evaluation meeting as part of improving our future events. Synexus is honoured by the support and collaboration from our community stakeholders.

*Lucky Molefe is the Clinical Awareness Manager at the Mamelodi CRS in Pretoria, South Africa.

1 This touched so many souls because she reflected on how she got infected with HIV within marriage, and how she got the courage to live her life to the fullest while raising children after her husband passed on.

2 Community Advisory Board (CAB) is an independent group within the clinical research organisation playing an advisory role to the researchers on behalf of the community and research participants.
In order to strengthen the links between participants and researchers of the AMP Study (Antibody Mediated Prevention) by ACSA - Iquitos, a thank-you dinner was held where participants and researchers committed themselves to the achievement of new goals, strengthening trust among allies.

Thus, it was possible to gather the largest number of participants recruited in the study who have fulfilled their visits in the last year, in addition to the presence of all the members of the Community Advisory Committee (CAC).

The special guest of the night was the extraordinary Monique Pardo, a national TV artist who is recognized and identifies with the LGBT community and the equality of all. She highlighted the heroic research work of the Amazon Rain Forest Civil Association and congratulated the participants of the AMP Study for their courage. Monique aired the trans dancer cast “Las Ricuritas del Amazonas” who also delighted the audience with the beat of the music.

This culminated a night of celebration and gratitude for the joint work that continues to achieve the goals of the AMP Study worldwide.

*Carlos Vela is a Community Educator/Recruiter for the ACSA Iquitos in Iquitos, Peru.
**ACROSS**

3 A substance that may be included in a vaccine to improve the body’s ability to fight disease or infection.

4 A research study or experiment in humans (as opposed to animals) that is designed to answer specific questions.

6 A subtype or strain of HIV.

8 The body’s system of many organs and cells that defends the body against infection, disease, and foreign substances.

11 The process of deciding whether or not to join a clinical trial, after learning enough information to make a responsible decision about participating.

12 A test-of-concept trial that is not designed to establish the efficacy of a particular candidate but rather to help researchers decide if a candidate is worth testing in larger Phase III trials.

13 An HIV vaccine created by a computer program to optimally reflect the known circulating strains of HIV from around the world.

14 A common virus that causes colds and sore throats. A defective version that cannot cause infections in humans is sometimes used as a vector in HIV vaccines.

**DOWN**

1 The effectiveness of a vaccine, or how well it works.

2 Assigned to a group by chance, like the toss of a coin.

5 One of the groups that monitors HVTN trials. Each research institution has one. Some sites may know them as Ethics Committees.

7 The process clinicians use to see if a volunteer is eligible to participate in a clinical trial.

9 An inactive substance designed to resemble the vaccine (or treatment) being studied.

10 Infection-fighting proteins that tag, destroy, or neutralize bacteria, viruses, or other harmful toxins.

15 An intermediate clinical trial to learn more about vaccine safety and to see if the vaccine generates an immune response.

16 An early clinical trial designed to study an experimental vaccine in humans. Generally small (less than 100 participants) and designed to see if the product is safe.

17 An independent group that reviews data during a study and can recommend the study be stopped if it appears the volunteers are being placed at risk.
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.

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