INSIDE THIS ISSUE

The NIAID-funded HIV Vaccine Trials Network (HVTN) Responds to COVID-19
Welcome to the latest edition of the HIV Vaccine Trials Network (HVTN) Community Compass.

In this issue, we highlight some of the recent World AIDS Day activities, updates from some of our sites and about some of our studies, dive deeper into upcoming phase 1 broadly neutralizing studies, as well as a very personal interview with our very own Dr. Larry Corey. The novel coronavirus SARS-CoV-2 which can result in COVID-19 disease has also cut short the life of one of our beloved colleagues, Professor Gita Ramjee, who, in addition to having been a renowned scientist and role model to many, also served as Chief Specialist Scientist and Director of the HIV Prevention Research Unit of the South African Medical Research Council in Durban, South Africa.

The COVID-19 pandemic has taken center stage, becoming the topic of conversation in nearly every virtual space that I access. Many cities have some sort of “Stay at Home” order* in place. On social media, I see posts daily from people who express concerns about (or barriers to) getting tested; concerns about themselves, friends, or family members who have possible or actual symptoms of the virus; and have seen just as many posts about people who have died as a result of complications of COVID-19. As I have sat and pondered about what to pen for this letter, I have thought many times about the relationship between this disease and others, including HIV, specifically for people and communities who are more vulnerable to negative health outcomes due to oppressive systems and structures. Similar to HIV and many other diseases, COVID-19 illustrates the very real impacts of bias in healthcare/medical systems, poverty, historical trauma, and other conditions impacting many communities, including communities of color.

I believe we will see this pandemic end, but we cannot achieve this end ethically by leaving anyone behind, or without ensuring that appropriate efforts are focused on those who are most vulnerable. There are many stakeholder mobilization efforts happening in local and national settings around the world with goals of raising awareness about these issues, and ensuring resources and solutions are inclusive of those most impacted and vulnerable. We are a global community; let us work together in response to this pandemic.

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 submission page that offers the ability to submit content and articles for inclusion in future issues. More information about this follows on the “Meet the Community Compass Team” page.

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 for 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, Ph.D.
Editor-in-Chief, HVTN Community Compass

Note: This was true at the time of writing in April 2020. Please follow your institutional guidance regarding any updates on COVID-19 in your location.
| CONTENTS |
|-----------------|-------|
| Meet The Community Compass Team | 4     |
| Hope and a “Queen” | 5     |
| In Harmony - Transgender People and Early Phase HIV Vaccine Trials | 8     |
| Upcoming Events/Conferences/Meetings | 10    |
| Responding to a Four-Decade Old Epidemic While Thwarting the “New Kid on the Block” | 11    |
| Facing Down Pandemics: Dr. Larry Corey on HIV and COVID-19 | 15    |
| The HVTN and HPTN Remember Gita Ramjee | 17    |
| Phase 1 Broadly Neutralizing Antibody Efforts | 18    |
| New SBS-CEU Staff at HVTN Core | 22    |
| Getting the Right Test for HIV | 23    |
| World AIDS Day Commemoration Event Report December 2019 Hosted By Synexus | 25    |
| Setshaba Research Centre World AIDS Day Commemoration 2019 | 28    |
| Updates at Vanderbilt CRS | 30    |
| Mosaico: A Fleeting 72 Hours Inscribed to Memory | 31    |
| Public statement by the HIV Vaccine Trials Network (HVTN) on COVID-19 | 35    |
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. 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”. 

Meet the COMMUNITY COMPASS Team

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Communities, scientists, investigators in the field of HIV prevention, and other stakeholders are likely anticipating the announcement of the preliminary results of two large-scale HIV prevention studies later this year. Notably branded as AMP, antibody mediated prevention, both studies are designed to determine whether a broadly neutralizing antibody called VRC01 can prevent the transmission of HIV in people.

Fittingly, the NIAID-funded HIV Vaccine Trials Network (HVTN), together with its our partners at the HIV Prevention Trials Network (HPTN) and the study funder and sponsor the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), will lead discussions when the preliminary results of the Antibody Mediated Prevention (AMP) studies are shared.

Two interdependent stories will be at the heart of the announcement: the stories of science and the will and hope of communities. These stories will be told through the voices of the 4,625 AMP study participants, consisting of women in sub-Saharan Africa between the ages of 18 – 40 years, and men and transgender people between the ages of 18 – 50 years in the Americas and Switzerland who have sex with men. These stories will color a canvas set against a backdrop of the world’s HIV epicenter in a venue likely to have limited seating and an air of anticipation.

The Story of Science

A preventive vaccine that is safe and globally effective against HIV is to HIV prevention research what a queen represents on a chessboard. On the chessboard the queen is a game changer as it moves any number of squares vertically, horizontally and diagonally. Similarly, a vaccine against HIV will change the game by offering a new long-lasting HIV prevention option, which may mitigate the need for daily medication like PrEP or post-exposure prophylaxis (PEP) for some people; could offer herd immunity that protects individual who get vaccinated and their communities; and could potentially prevent the asymptomatic transmission of HIV from an infected person who is not aware that they are infected to others. In developing countries an HIV vaccine has the potential to alleviate pressure on poor social and health infrastructure that is already under tremendous pressure from other diseases such as Tuberculosis (TB), diabetes and cancer. The socioeconomic benefits to any one society will be tremendous if an HIV vaccine is introduced to scale and made accessible to communities. History reminds us that smallpox was eradicated by a vaccine. In the United States, a long list of diseases such as diphtheria, measles, mumps, rubella, and tetanus near eradication as a result of vaccines.

The Will and Hope of Communities

In early February 2020, the Network stopped all vaccinations in its HVTN 702 vaccine trial. An interim analysis showed that while the
What is a Broadly Neutralizing Antibody (bnAb)?

A bnAb is an antibody that neutralizes many of different strains of HIV that are found around the world. Antibodies are proteins produced by the immune system’s B cells that can neutralize the virus, blocking it from causing infection. Antibodies can also help eliminate the virus from the body. They are shaped like the letter “Y”.

The good news is that antibodies can prevent infection. The even better news is that they have immunological memory. The first time you are infected by a virus you will develop antibodies against that virus. The next time you come in contact with that same virus, you will already have antibodies prepared to fight against that particular virus. This is what preventive vaccines try to mimic.

The Science of bnAbs

Four decades later, the HIV and AIDS pandemic continues to impact lives in spite of significant progress in treatment and prevention. In 2018 UNAIDS estimated there to have been more than 74 million HIV transmissions and 32 million deaths since the epidemic began. The need for a safe and globally effective preventive HIV vaccine cannot be emphasized enough.

In the future, history will remind us of the scientific and people-centered lessons learned from HVTN 702 and the other previous efficacy trials that have shown disappointing outcomes. Equally important to those lessons will be an account of how many study participants, communities, stakeholders, and study teams remain committed to help end the epidemic and its impact the world over.

When the AMP teams’ scientists take to the podium, more than 4 years after the study’s first infusion, their voices will be amplified by the study participants from 11 countries who want to see an end to HIV. Around the world people will witness an account of the dedicated communities from Botswana, Brazil, Kenya, Malawi, Mozambique, Peru, South Africa, Switzerland, Tanzania, the United States, and Zimbabwe who were a part of a global response to end the pandemic.

The HIV prevention field will move forward, regardless of the AMP outcome. We will learn as a global community, and remain steadfast in our commitment to the pursuit for a safe and globally effective preventive HIV vaccine. When audiences step back, hope will be the narrative that conveys the story painted on a canvas at the world’s HIV epicenter.
What is VRC01?

VRC01 is a bnAb against HIV. It stops HIV from binding to human CD4 T-cells by attaching to the virus and preventing it from infecting the T cells. The VRC01 antibody is able to bind onto HIV at the CD4 binding site on the gp120 protein, which is the same spot that HIV would ordinarily use to attach to CD4 T-cells to infect them. In animal studies, VRC01 neutralized HIV and prevented about 90% of the HIV samples that were tested from being able to attach to T-cells and infect them.

Advancing HIV Vaccine and Prevention Efforts

In early HIV vaccine development efforts, attempts were made to induce neutralizing antibodies, but no HIV vaccines tested thus far have produced neutralizing antibodies of significance. Naturally occurring bnAbs in individuals living with HIV arise rarely, and typically take many years to develop. However, most effective licensed vaccines, such as the measles vaccine, induce neutralizing antibody responses, and they provide protection from infection via neutralization. The AMP studies are the first efficacy trials to address the question of whether a broadly neutralizing antibody against HIV could be protective against infection.

The AMP Studies Can:

1. tell us what the best models are for testing candidate HIV vaccines in animals;
2. help determine effective blood antibody levels that could prevent HIV;
3. determine what antibody levels an HIV vaccine may need to elicit to prevent HIV infection; and
4. make future HIV vaccine development more efficient and cost effective.

Aziel Gangerdine is the Director of Communications for the HVTN.
Featured Article

In Harmony - Transgender People and Early Phase HIV Vaccine Trials

By: Aziel Gangerdine, HVTN Core, Seattle, WA, USA

Early phase HIV vaccine clinical trials are designed to assess if an investigational HIV vaccine is safe and well tolerated in study participants. In addition, researchers study if the vaccine will stimulate the body’s immune system to make responses against HIV. Study participants who enroll in the trials must be HIV seronegative and less vulnerable to the transmission of HIV. Knowing this made it necessary for me to meet the first author of a published manuscript titled, “A descriptive analysis of transgender participants in phase 1 -2a trials of the HIV Vaccine Trials Network (HVTN) in the United States and Peru.”

For the layperson, the manuscript can deter you from reading – it contains a range of graphs and scientific terms that necessitate a place for the Oxford dictionary in your office, or google.com on “speed click.” Dr. Michele Andrasik is the Director of Social and Behavioral Sciences and Community Engagement for the NIAID-funded HIV Vaccine Trials Network (HVTN), and we met to talk about the manuscript, the result of a cross-protocol study that analyzed data from 694 participants enrolled in six early phase clinical trials conducted by the HVTN.

Andrasik exudes a pleasant disposition and smiled radiantly in a thought-provoking discussion about the importance of early phase HIV vaccine trials in this cross-protocol analysis. The study measured several variables to determine why 681 (98%) cisgender and 13 (2%) transgender study participants enrolled in the HVTN’s early phase studies conducted between 2009 and 2014. The primary reasons for participation were altruistic for all participants.

Overall, figure 2 confirms that transgender and cisgender people had similar motivations for participating in early phase trials. Participants expressed that the most compelling reasons for participation were to help find an effective HIV vaccine, to help their community, and to be informed about HIV research. Transgender participants were less motivated by financial incentives, naming “knowing someone living with HIV” as a more compelling reason to enroll as a participant.

“It is really clear that the communities most impacted want a resolution to a four-decade old pandemic [HIV/AIDS],” Andrasik pointed out.

Statistics from the 2015 US Transgender Survey (USTS) reported that “one-third (33%) of transgender participants experienced at least one negative health care experience related to being transgender.” Verbal harassment and refusal to provide treatment because of gender identity are two reasons noted by transgender people for why they actively avoid seeking healthcare. And, in Peru structural factors such as legislation that restricts changes

Continued on the next page...

Figure 2: Reasons for enrolling in Phase 1-2a HIV Vaccine Trial Network Trials 2009 – 2014
to gender markers and legal names on official documents” limits access to healthcare for transgender individuals.

In addition, “multilevel social and structural factors such as poverty, discrimination, mental illness, homelessness, abuse, distrust of the health care community, and concerns about disclosing transgender status” make transgender people more vulnerable to the transmission of HIV.

Knowing the lopsided burden that HIV places on transgender communities, and the factors that create barriers for transgender individuals’ participation clinical trials, requires transformation strategies to create an experience where the individual’s interest and willingness to participate in a clinical trial is met by a transgender-affirming healthcare setting.

“We need to continue and enhance our efforts to create clinical trial environments that are equipped to welcome and affirm our diverse communities who are willing to enroll and move science forward,” stated Andrasik.

Creating transgender-affirming environments is no easy undertaking. In 2007, the HVTN took bold steps when it established a Transgender Working Group to “identify and provide input regarding operational and clinical needs related to the inclusion of transgender participants in HVTN trials.” First, the Network adapted its demographics Case Report Forms (CRFs) to collect data on sex assigned at birth and self-identified gender identity – a process known as the two-step method. Secondly, clinical trial staff were trained to be more culturally responsive to transgender participants. Having site staff who were familiar with gender transition and affirmation procedures, specific health concerns, hormone use, and identity documents specifying gender identities or legal names are all factors that impact the retention of transgender people and their experience as study participants.

“The results, after implementing data-driven strategies to create transgender-affirming environments at our clinical trial sites, are noteworthy,” Andrasik beamed.

Furthermore, the study confirmed that “transgender participants reported no negative social impacts due to clinical trial participation, and 93% of transgender participants identified having experienced at least one social benefit of participation.” Additionally, researchers wondered whether it was plausible to enroll transgender study participants in early phase clinical trials. When the population has higher vulnerability, can individuals with low vulnerability be identified, enrolled, and retained?

Data from this cross-protocol study provided evidence that transgender people can not only be eligible for trials enrolling people who are determined to have low vulnerability to the transmission of HIV, but they are also able to remain HIV uninfected over the course of their study participation. The study team suggests that transgender participants in early phase HIV vaccine trials are more likely to be in communities where there is high HIV incidence. This explains why “I know someone with HIV infection” was cited as a reason why transgender participants get involved in preventive HIV vaccine trials. Transgender participants also demonstrated excellent retention, as shown by only three missed visits (2.1%) and no discontinuation of vaccinations across the six protocols included in the analysis.

Andrasik is adamant, “We must conduct clinical trials that are inclusive. In order to do so we must be aware of the factors that make some people in our communities more vulnerable to HIV transmission than others. In many cases these factors also create barriers to participation. Whenever possible, we should be prepared to mitigate these challenges.”

Dr. Michele Andrasik, Director of Social and Behavioral Sciences and Community Engagement, HIV Vaccine Trials Network.

Dr. Michele Andrasik, Director of Social and Behavioral Sciences and Community Engagement, HIV Vaccine Trials Network
UPCOMING EVENTS/CONFERENCES/MEETINGS

HIV VACCINE AWARENESS DAY
May 18, 2020

ADHERENCE 2020
https://www.iapac.org/conferences/adherence-2020/

2020 IMPAACT ANNUAL MEETING
https://impaactnetwork.org/

2020 SAVING OURSELVES SYMPOSIUM
https://sosexperience.org/

2020 ACTG ANNUAL MEETING
https://actgnetwork.org/

23RD INTERNATIONAL AIDS CONFERENCE (AIDS2020)
https://www.aids2020.org/

HIV2020 CONFERENCE
https://actgnetwork.org/

2020 US CONFERENCE ON AIDS
http://usconferenceonaids.org/

2020 AMERICAN PUBLIC HEALTH ASSOCIATION MEETING
https://www.apha.org/events-and-meetings/annual

Editors Note: Many of these meeting dates have changed prior to print, and it is unclear if they will change again. Please use the above links to determine the most accurate dates of the meetings.
Responding to a Four-Decade Old Epidemic While Thwarting the “New Kid on the Block”

By: Aziel Gangerdine, HVTN Core, Seattle, WA, USA

Pulitzer Prize-nominated author James Martin astutely stated that we must “thwart the rapid spread of infectious diseases that could kill millions of people.” In 2007, Martin described “The 17 Greatest Challenges of the Twenty-First Century,” listing conquering disease as number 10 amongst others such as reversing poverty, preventing all-out war, defusing terrorism, and cultivating creativity.

In the US, the state of Washington (where the HVTN’s offices are located) is under a “stay home, stay safe” order, one of several measures underway to prevent the transmission of a contagious viral infection called Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2), known to cause the disease COVID-19. If asked, I’d best describe Seattle, Washington, as a young dame – breathtaking in natural beauty and kind in socio-economic experience. As can be expected, I regularly enjoy brisk walks in my neighborhood where flora meets concrete and wood in the bustling landscape of the city’s South Lake Union neighborhood. It has been two months and the sounds of nature are amplified in a deafening silence.

My recollection of when COVID-19 started to reorganize my daily pattern of life is clouded by my feeling the need for a silver lining every so often, not succumbing to the confinement of my apartment and the sense of suffocation, all as a result of the necessary State order. COVID-19 is testing our definition of freedom amongst other things. In our homes and in the workplace, measures are implemented that redefine our social and economic patterns of life.

It seldom rains, instead it pours

The impact of COVID-19 manifested quickly in the HIV prevention clinical research environment. Known for its pursuit of a safe and globally effective preventive HIV vaccine, the HIV Vaccine Trials Network’s (HVTN) study teams are now facing off with a “new pathogenic kid on the block,” in addition to conducting clinical trials to help end HIV. I suspect that Martin would applaud the Network’s efforts to quell the potential impact of SARS-CoV-2 at the same trial sites where HIV prevention trials are underway.

“Our study teams are dedicated to finding solutions for health problems that have affected our communities in a profound way,” says Dr. Azwi Takalani, one of the HVTN’s Regional Medical Liaisons in Johannesburg, South Africa. Study teams at trial sites were empowered to implement measures, aligned with recommendations from their local public health authorities, to prevent the possible transmission of SARS-CoV-2.

My most recent in-person meeting with Dr. Takalani, fondly known as “Azwi,” was at the 2019 International Conference on AIDS and STIs in Africa (ICASA), held in Kigali, Rwanda. She has a booming laugh and a memorable smile to complement her engaging personality.

“A lot of children in my community were/are being raised by their grandparents or elderly aunts and uncles after losing their parents to HIV/AIDS,” said Azwi, illuminating the context in South Africa. Immediately, I was reminded of the devastation the four-decade old HIV/AIDS epidemic had on families and communities in the country. This impact was replicated in many communities globally.

Although I could not enjoy Azwi’s in-person conversation, it was clearly evident that her responses were saturated with a deep sense of concern as we delved into her thoughts on the circumstances in South Africa.

She started to peel back her thoughts about the ripple effects set in motion by the “new kid.” “The realization that the population group that filled the parenting gap is also probably the most vulnerable to severe COVID-19 illness is an important factor to consider when we re-organize life as a community during and after this pandemic.”
Since it first emerged in late 2019 in China, a significant number of people around the world succumbed to the disease, prompting the World Health Organization to officially declare it a pandemic on March 11, 2020.

“The global picture of the impact of the pandemic is sobering. While a lot of work is ongoing in South Africa toward COVID-19 preparedness, the inherent weaknesses in our health care system and endemic HIV and TB infections are an additional source of concern for South Africa,” Azwi said, summarizing the on-the-ground circumstances and coloring the deep concern I read between the lines of her responses.

The world is mobilized and making every effort to save lives and to prevent the transmission of SARS-CoV-2. On March 23, 2020 the President of the Republic of South Africa ordered a 21-day nationwide lockdown, a period later extended on April 9 for an additional two weeks. The President delivered the executive order altering the lives of all citizens, and the aftermath of the decision started to manifest in communities as the country transitioned to an “essential services only” way of life.

Among these essential services, study staff at the sites are frontline responders who have in their hands the health and safety of study participants enrolled in HIV prevention clinical trials. They have the responsibility to maintain the scientific integrity of each study, and at the same time, protect themselves and the participants from the possible transmission of SARS-CoV-2.

Frontline responders are known to many as heroes. I am in awe of their courage and the bold relentlessness they demonstrate in the face of a new global pandemic, while not losing sight of the charge to respond to a four-decade old epidemic, when both infectious diseases are claiming lives and impacting communities. I cannot help but draw inspiration from their actions. While on duty and in service to their communities and countries, study teams must take every measure necessary to protect the families they go home to at the end of each working day. I cannot pen in these pages the weight of such an emotional and mental burden.

“It is certain that life as we knew it has already changed, and will continue to do so in the near future,” Azwi concluded. Continued on the next page...
Navigating Unchartered Waters to Support our Frontline Responders

COVID-19 drew new battle lines in the sand at each clinical trial site and decisive action was needed to equip study teams with specialized personal protective equipment (PPE) for their daily showdowns with COVID-19. The global demand for PPE, largely produced by the People’s Republic of China, increased significantly as response efforts gained momentum. However, travel and export restrictions set in motion to curb the spread of SARS-CoV-2 led to unintended consequences such as restricted shipment of PPE items globally. In South Africa, sites were having difficulty obtaining the necessary items they needed to appropriately protect their staff members. My university professor used to say that there are three kinds of people: those who watch things happen; those who wait for things to happen; and those who make things happen.

Fittingly, I think of Yunda Huang, PhD, Principal Staff Scientist at the Fred Hutchinson’s Statistical Center for HIV/AIDS Research & Prevention (SCHARP), as the latter of the three personalities. A US citizen, responding from her home in Shanghai, China, she described what it took to equip study teams in South Africa with much-needed personal protective equipment (PPE).

Yunda is the lead statistician on other “normal” HVTN projects, and worked to obtain the PPE while carrying out her research duties. “Procuring PPE in such a political and epidemiological climate was simply a non-existent type of job before this pandemic. Although I felt a tremendous responsibility to help, I severely underestimated the complexity of the mission,” she stated.

According to Yunda, vetting business partners became the most important step in a very complex process involving a “sea of connections.” Navigating the uncharted waters also meant that she would be in direct competition with governments and large medical supply companies, all in need of the same approved PPE, and who, unlike Yunda, demonstrated significant purchasing power.

A series of reports such as the CBS news story on April 13, titled “As world turns to China for PPE, U.S. buyers risk knock-offs and price gouging,” (https://www.cbsnews.com/news/china-ppe-us-buyers-knock-offs-price-gouging/) confirmed the race to locate and procure the coveted PPE, ultimately increasing the demand even more.

Yunda explained that the purchase of N95 masks, for example, is only possible when paying cash up front, and is considered successful only when the item is delivered and in your hands. Sellers readily accept new offers from buyers if the profit margin can be doubled, and the generated revenue would settle the payment of penalties incurred for breach of contract with the first buyer. While your payment could be refunded from a breach of contract, such an incident would delay the shipping timeline, which was scheduled based on the purchase agreement before the seller opted to cancel because of a more lucrative sale.

“Just for one shipment, I had to use a lot of free consultation time from my lawyer friend to help me...
comb through 11 legal agreements to make sure the purchase was legitimate, protected our rights and funds, and ultimately made the delivery of about 10 different types of PPE items possible,” Yunda described, as she reflected on the important details needed to mitigate the potential risks to the HVTN.

All of this was further complicated by international travel restrictions and the ever-changing export policies in China. Every delay to planned shipping schedules inevitably derailed all of the anticipated delivery of the PPE items to the research sites. Eventually, the clouds did part and a silver lining appeared.

"It took only three weeks between the moment the mission was 'assigned' and the moment that first-rate PPE was safely delivered in South Africa from China. If that is not a miracle, what is?“ Yunda said.

**Witnesses to the Extraordinary, and What Motivates Our Heroes**

COVID-19 is the new pathogenic kid on the block, and is proving to be a formidable adversary by forcing the hands of decision makers to exercise what some deem to be draconian measures in order to save lives.

Amidst the uncertainty of the near future and the disheartening circumstances we are faced with at home, in our communities, in the workplace, and in our countries, I think about what it is that gives our heroes at the frontlines like Azwi, and the brave yet often unseen heroes like Yunda, and many other individuals the support they need to do what they are called on to do.

Globally, COVID-19 continues to test more than just the strength of economies, the resilience of healthcare systems, our definition of freedom, and the going concerns of businesses – it is testing our humanity and benevolence. History is being written with these unrelenting efforts to face life threatening adversaries such as HIV/AIDS and COVID-19. We call each adversary by name and we recognize the impact of each. We also recognize what these adversaries do not have – our will and human spirit to overcome, as well as the need to protect future generations who are the spirit behind our struggle and the wind beneath our wings.

_Aziel Gangerdine is the Director of Communications for the HVTN._
When Dr. Larry Corey first heard reports of a respiratory virus spreading rapidly in Wuhan, China, the renowned virologist and former President and Director of Fred Hutchinson Cancer Research Center felt that unsettling sense of déjà vu.

“As you saw the devastation that it was causing in Wuhan, and you understood the transportation patterns and the people flow in China, you started to understand the implications,” said Corey, during a recent interview for HVTN Community Compass.

“In many respects, COVID-19’s a re-living of what happened 39 years ago in HIV, when it was difficult and frustrating,” he said. “The lesson that we learned then is that when the academic, biotech and pharmaceutical communities put their collective scientific assets together, things happen.”

In June 1981, as a University of Washington researcher then working on a treatment for genital herpes, Corey read in the Centers for Disease Control’s weekly newsletter a brief report of five cases of gay men in Los Angeles felled by Pneumocystis carinii, a rare pneumonia previously found in people with compromised immune systems.

It would be another two years before the Pasteur Institute’s Drs. Francoise Barre-Sinoussi and Luc Montagnier isolated the retrovirus later proven to be the cause of it, and still years before the global impact of HIV would be fully comprehended.

Yet that tiny virus quickly transformed the trajectory of Corey’s career. The deep ties he had developed with the community as a researcher in sexually transmitted diseases propelled him into a leadership role in fighting stigma, bigotry and fear. As the world struggled to understand HIV, he rose to become an authoritative voice on how to treat it with antiviral drugs.

As chairman of the AIDS Clinical Trials Group, he shuttled from Seattle to Washington D.C. to oversee critical trials, first proving that AZT could protect newborns of HIV-positive mothers, then launching the trials on combination therapies that have since saved millions of lives. Then his focused shifted to vaccines.

In 1998, at the urging of National Institute of Allergy and Infectious Diseases director Dr. Tony Fauci, Corey co-founded the HIV Vaccine Trials Network, headquartered at Fred Hutch. One of the first people he hired was Steve Wakefield, who today leads HVTN’s global efforts for stakeholder engagement.

“Larry has a deep moral conviction to take care of the world that he’s in with the talents that he has,” Wakefield told Fred Hutch writer Mary Engel. “But he didn’t get any recognition for the sacrifices he’s made to solve this epidemic. Until he had his grandchildren, I never remember him going on vacations. Now, part of his drive to find a vaccine is so his grandchildren will never have to live with HIV.”
Over decades, the tireless quest for an HIV/AIDS vaccine has weathered a string of disappointments. The vaccines tested in carefully designed clinical trials have so far failed, but as the body of knowledge about the immune system continues to expand, Corey remains cautiously, but steadfastly, optimistic.

In early February, he had to deliver the news that the Uhambo trial, HVTN 702, showed no efficacy and was shutting down. The hope had been that this vaccine regimen would improve upon an earlier version found modestly effective in a large trial in Thailand in 2009. Instead, it showed no effectiveness at all.

"You did a damn good job," he told a gathering of staffers at Fred Hutch. "It was a painful answer, but our job is to do these studies, and you did it incredibly well."

Later that month, Corey met with his South African counterparts and the disappointed participants in Cape Town to thank them for their courage and to assure them that the quest will go on.

"One trial of five failed, but we still have four more out in the field," he said in his recent interview. "There is sadness, but science is about resilience. You have to have optimism, resilience and perseverance."

By year-end, Corey anticipates results from the recently completed Antibody Mediated Prevention, or AMP, studies, where over 40,000 infusions of broadly neutralizing antibodies were given to volunteers. One other HVTN trial, Imbokodo, is fully enrolled with ongoing follow-up underway, and a related trial, Mosaico, was just getting underway when COVID-19 struck.

"Altruism and concern about HIV are alive and well, and you certainly see it in the MSM and transgender communities in the U.S. and South America, and among the people of southern Africa," he said.

Yet the impact of COVID-19 was coming quickly, even to South Africa. Corey had to cut his trip short and return to Seattle, where he is coordinating multiple efforts with Fred Hutch, the University of Washington (UW), the Bill & Melinda Gates Foundation, and other community partners to respond to the latest threat.

Cruelly underscoring the interconnectedness of the struggle against pandemic viruses, the HVTN community learned in March that Dr. Gita Ramjee died of COVID-19 in March, soon after returning to Durban, South Africa, from a visit with her sons in London. She was 63.

"It is so sad when you see so many deaths happening. When a colleague passes away prematurely, it's a loss in our family, but also for the world," Corey said.

With a new pandemic underway, he once again stands in the forefront of scientific efforts to stop a global threat. When COVID-19 reached Seattle, its first significant toehold in North America, researchers at Fred Hutch, UW and Public Health-King County & Seattle, responded decisively because of the deep understanding of virology and the infrastructure of laboratories and expertise that Corey had built over four decades of confronting HIV.

"I came to this city that I love 42 years ago as a UW faculty member to start a virology division. I inherited a program in a small lab in the basement of Children's Hospital," he recalled. "And we built it into the largest academically based virology lab in the country. Then of course we set up the Vaccine and Infectious Disease Division at Fred Hutch, and between UW and the Hutch, I believe it's the largest faculty in infectious diseases in the country."

"We trained an enormous number of people in viral disease. So, it is gratifying to see how that infrastructure presented Seattle with the opportunity to handle this new epidemic. It allowed us to do COVID-19 testing at a rate better than essentially any other city, and that has been an incredible factor in our response."

Sabin Russell is a writer and editor for the Fred Hutch News.
Gita Ramjee, PhD, renowned for her extensive work on HIV prevention and a valued colleague to so many in the HIV Vaccine and Prevention Trials Networks (HVTN and HPTN), sadly succumbed to complications associated with SARS-CoV-2 infection.

Gita started her career in science after receiving her PhD at the University of Sunderland in the United Kingdom (UK). Her scientific work centered in South Africa early in the epidemic where she led a project on vaginal microbicides for the prevention of HIV among a group of sex workers working along the trucking route between the port city of Durban and the commercial capital in Johannesburg.

As she noted when she received the European “Outstanding Female Scientist” Award by the European Development Clinical Trials Partnerships for her work on finding new HIV prevention methods.

“I learned about the dire need for women-initiated HIV prevention options and the socio-behavioral and cultural factors that impact women’s lives. I dedicated my time to researching methods of HIV prevention.” – Dr. Gita Ramjee

Gita pursued this mission up to her sudden passing, as a critical investigator for the HVTN and HPTN.

“We are deeply saddened that Dr. Gita Ramjee passed away due to a COVID-19 infection,” said Dr. Larry Corey HVTN principal investigator (PI).

Gita spent the past 18 years of her career as the director and chief specialist scientist of the HIV Prevention Research Unit, South African Medical Research Council (SAMRC). She was also an honorary professor in the Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, and a clinical professor in the Department of Global Health, School of Public Health, University of Washington, Seattle.

“She left a lasting imprint on HIV prevention research and the HVTN through her dedication, critical thinking and lasting commitment to our collaborative group of scientists,” said Dr. Glenda Gray HVTN co-PI and President and CEO of the SAMRC. “She was an incredibly committed colleague to the cause of reducing the impact of HIV on South African society.”

In her leadership role, she trained and mentored numerous cohorts of scientists and clinical trial staff, who now populate the network of trial sites in South Africa and beyond. They will carry her legacy forward for many years.

Gita was a study principal investigator and unit director for many of the National Institutes of Allergy and Infectious Diseases and the Division of AIDS’ HIV prevention networks clinical trials, ranging from early phase studies to late phase efficacy trials. She contributed to our understanding of the role of topical and systemic products in HIV prevention, and more recently, made a notable contribution to the active and passive immunization programs in the HVTN and HPTN.

“She will be sorely missed by generations of HIV prevention scientists,” said Dr. Wafaa El-Sadr, HPTN co-PI and director of ICAP at Columbia University in New York. “Gita’s energy and dynamism were incomparable. Her steadfast commitment to the quest for effective HIV prevention methods and women’s health will continue to motivate all of us who had the opportunity to know her and work with her”.

“Gita was a wonderful colleague and friend who made critical contributions to HIV prevention throughout her long and distinguished career; she will be greatly missed,” said Dr. Myron S. Cohen, HPTN co-PI and director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill.

Our thoughts and prayers go out to her family and all her friends and colleagues who worked with her throughout these years. Her sudden passing will be a significant loss to our organizations and an even larger hole in our hearts.

We carry you in our memories, Gita,

Drs. Larry Corey, Glenda Gray, Myron S. Cohen, Wafaa El-Sadr, and Jim Kublin
Broadly neutralizing antibodies (bnAbs) have the potential to greatly contribute to global HIV prevention, treatment and cure efforts. These antibodies are naturally developed by the immune systems of some people living with HIV, though usually the virus evolves faster than the immune system’s antibody response. When HIV outpaces the development of these special antibodies, they may be unable to prevent, fully suppress, or eradicate the virus in the body of the person who made them. However, scientists can identify these bnAbs and make copies of them in a lab. Sometimes, scientists can also make small changes to these antibodies to improve their potential ability to prevent, treat, or cure HIV.

Antibodies are shaped a little like the letter Y, with two “arms” and a “foot.” Antibodies work to fight HIV in two primary ways. First is neutralization, in which the “fingertips” of the antibody bind to the HIV envelope protein (gp140, or Env) and prevent it from binding to and infecting target cells like healthy T-cells (see Figure 1). Second is through Fc-effector functions, in which the “foot” portion of an antibody recruits other healthy immune cells, like natural killer (NK) cells or macrophages, to help kill or remove HIV from the body (see Figure 2). BnAbs are special because they can do these functions for many of the different strains or types of HIV found around the world, whereas more common antibodies, those that are not broadly neutralizing, usually only recognize some viruses from one or a few strains of HIV. Different bnAbs can bind to several different parts (“epitopes”) of the HIV Env protein, including the CD4 binding site, the V2 loop, the V3 glycan region, the membrane-proximal external region (MPER), and others (see Figures 3-4). They can also work with other immune cells like NK cells or dendritic cells in different ways. This is comparable to how different antiretroviral drugs (ARVs) attack HIV at different places and in different ways.

Since 2014, the HVTN has collaborated with many partners on the development and implementation of a portfolio of studies to evaluate the potential of several different bnAbs against HIV. These studies began with the HVTN 104 and HVTN 116 studies, which evaluated VRC01 and/or the longer-acting VRC01LS bnAbs, demonstrating their safety and providing more information about their pharmacokinetics in blood and in mucosal tissues. Pharmacokinetics (PK for short) describe how the antibodies travel in the body, and how much antibody is in the body over time.

In 2015, using information from the earlier trials, the HVTN, HPTN, Vaccine Research Center (VRC), and DAIDS began collaborating on the world’s first two bnAb HIV prevention efficacy trials—the Antibody Mediated Prevention (AMP) studies (HVTN 704/HPTN 085 and HVTN 703/HPTN 081). The AMP Study results are anticipated in late 2020, and the trials are designed to teach us whether the VRC01 bnAb can prevent HIV infection, and if so, what concentration of VRC01 in the blood is required for that protection.

Continued on the next page...
Since AMP opened in early 2016 to evaluate VRC01, which attaches to the CD4 binding site, we have seen several other bnAbs enter clinical trials, including:

- additional VRC01-class antibodies with changes made to help them last longer in the body (e.g., VRC01LS, VRC07-523LS);
- several antibodies that bind to other HIV Env epitopes including the MPER (e.g., 10E8 and variants), V2 loop (e.g., PGDM1400), and V3 glycan region (e.g., PGT121 and 10-1074);
- and antibodies with multiple specificities, meaning that one antibody can attach to several places (e.g., trispecific bnAbs like SAR441236).

The HVTN and HPTN are collaborating with the National Institute of Allergy and Infectious Disease’s Vaccine Research Center (VRC), Sanofi, Rockefeller, CAPRISA, Beth Israel Deaconess Medical Center (BIDMC) and the International AIDS Vaccine Initiative (IAVI) to advance these bnAb products into DAIDS-sponsored clinical trials, and we have designed these trials to explore many research questions (e.g., dose, administration route, timing between infusions) to inform the next bnAb efficacy trial. We are now primarily looking at combinations of bnAbs to determine the safety of using them together. We think that using combinations of bnAbs that attach to different parts of HIV (see Figure 3-4) could lead to greater efficacy, both for prevention and for treatment, similar to how we need to use combinations of ARVs to effectively prevent and treat HIV infection. These phase 1 trials will also provide lessons crucial for the smooth implementation of the next efficacy trial, as HVTN 104 did for AMP. See Tables 1 & 2 for a summary of the current phase 1 bnAb portfolio.

### Glossary

**Bioavailability** is the proportion of a drug or other substance which enters the circulation when introduced into the body, and so is able to have an active effect.

**Pharmacokinetics (PK)** describe how the antibody moves through the body and tissues, and how the body processes the antibody over time.

The first post-AMP phase 1 trial in the bnAb portfolio, HVTN127/ HPTN 087, explores a range of doses and routes of administration, including the first evaluation of intramuscular (IM) bnAb administration in our field. It tests the potent CD4 binding site antibody, VRC07-523LS, which we think will be an anchor for a next-generation bnAb combination. This trial not only builds a robust safety database for VRC07-523LS,

<table>
<thead>
<tr>
<th>mAb(s) Evaluated</th>
<th>Results Projected</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRC01</td>
<td>Published 2017</td>
</tr>
<tr>
<td>VRC01LS Mucosal</td>
<td>Early data available; later timepoints 2020</td>
</tr>
<tr>
<td>VRC07-523LS</td>
<td>2021</td>
</tr>
<tr>
<td>VRC07-523LS Mucosal</td>
<td>2021</td>
</tr>
<tr>
<td>VRC07-523LS</td>
<td>2021</td>
</tr>
<tr>
<td>VRC07-523LS</td>
<td>2020</td>
</tr>
<tr>
<td>VRC01</td>
<td>2020</td>
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<tr>
<td>VRC01</td>
<td>2020</td>
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</tbody>
</table>

**Table 1. Network bnAb trials fully enrolled.**

<table>
<thead>
<tr>
<th>mAb(s) Evaluated</th>
<th>Projected Opening</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR441236 (VRC01, 10E8, &amp; PGDM1400; with LS modification)</td>
<td>Q1 2021</td>
</tr>
<tr>
<td>10E8VLS</td>
<td>CLOSED (AE in FIH)</td>
</tr>
<tr>
<td>VRC07-523LS</td>
<td>Q2 2020</td>
</tr>
<tr>
<td>PG121.414LS</td>
<td>Q4 2020</td>
</tr>
<tr>
<td>CAP256V2LS</td>
<td>2021</td>
</tr>
<tr>
<td>VRC07-523LS</td>
<td>2021-2</td>
</tr>
<tr>
<td>iMab-10E8v4 bispecific</td>
<td>Feb 2020</td>
</tr>
<tr>
<td>Post-AMP follow-up (VRC01)</td>
<td>Q3 2020</td>
</tr>
</tbody>
</table>

**Table 2. Network bnAb trials enrolling and in development.** Note that timelines are anticipated to shift due to the COVID-19 pandemic. (*AE in FIH means adverse event in first in human study)
but it also allows us to compare bioavailability, neutralization, and PK profiles across IV, SC, and IM administration routes in preparation for future trials.

HVTN 128 supplements HVTN 127/HPTN 087 with data regarding mucosal concentrations of VRC07-523LS. This trial includes vaginal, rectal, and semen sample collections and builds upon the HVTN’s extensive bnAb/mucosal sampling experience in HVTN 104 and HVTN 116.

HVTN 129/HPTN 088 will truly be a vanguard trial, exploring the potential for a single bnAb that binds to three different HIV Env sites or epitopes. This manufactured “trispecific” bnAb from Sanofi includes elements from other bnAbs: binding to V2 from PGDM1400, binding to MPER from 10E8, and binding to the CD4 binding site from VRC01. We think this will provide greater breadth and potency than any single bnAb that has only one epitope specificity. It may also greatly simplify manufacturing, regulatory, operational, and other potential challenges of administration compared to using a combination of separate bnAbs. This trial, together with HVTN 130/HPTN 089, HVTN 136/HPTN 092, and others will explore the potential neutralization effects of bnAb combinations, including whether the combinations might result in the antibodies working against each other, helping each other, or building on each other. As HVTN 129/HPTN 088 builds the first-in-humans safety, PK, and neutralization profile of a multi-specific product for HIV prevention, it will also inform further bi- and trispecific bnAb development work being done by several groups in the HIV bnAb field.

HVTN 130/HPTN 089 and HVTN 136/HPTN 092 are, in many ways, partners to the trispecific trial, as they evaluate triple and dual combinations of bnAbs administered separately. All of the combinations are anchored by VRC07-523LS. The triple combination adds PGDM1400 and the V3-binding bnAb PGT121. One of the 2-bnAb combinations uses the V2-binding bnAb PGDM1400 with VRC07-523LS. The remaining 2-bnAb combinations use different V3 glycan binding bnAbs (10-1074 and PGT121 or its long-acting version, PGT121.414.LS) with VRC07-523LS. This will allow for a comparison of any differences in how the different V3 bnAbs contribute to neutralization when paired with VRC07-523LS. One of the key concepts these trials will explore is whether the site of action (where the bnAb attaches to HIV) influences the neutralization activity in the body, and whether this activity is similar when different combinations or binding sites are used.

HVTN 138/HPTN 098 also evaluates a dual combination of VRC07-523LS with a V2-binding bnAb, CAP256V2LS, that is particularly potent against Clade C HIV. The bnAb on which CAP256V2LS is based

Continued on the next page...
is based was identified from a participant in a trial at the Centre for the AIDS Programme of Research in South Africa (CAPRISA). The bnAb was then developed and manufactured by the VRC. Clade C is the major strain of HIV that causes infection in South Africa, and this study is planned for South Africa, as well as the US.

The identification and optimization of bnAbs against HIV have helped scientists learn more about the structure of HIV and its vulnerabilities, which helps target and expedite efforts to develop an HIV vaccine. The efforts described here are advancing us toward a goal the HVTN has held for two decades—to expand the HIV prevention toolbox and, in particular, to achieve a safe and effective HIV vaccine as efficiently as possible, an effort the bnAb portfolio informs and thus advances.

Yet much work remains. Optimal bnAb combinations—and the effects of combining bnAbs in a multi-specific design or separately—must be further explored. Subcutaneous (SC) administration must be improved, such as making higher concentrations of the antibodies to allow a lower volume to be given, and testing different SC doses and routes, such as SC injection vs. infusion pump, or even wearable SC injectable devices. Changes to the Fc or “foot” portion of the bnAbs may help bnAbs last longer in the body (e.g., the LS modification) or may help bnAbs work better with immune cells to add to neutralization for improved HIV prevention, treatment and possibly cure. Additional mucosal studies may help us better understand how these antibodies get into different mucosal tissues and how they function. And perhaps most importantly, a marker such as antibody concentration in the blood could support more efficient advancement of bnAbs and HIV vaccines for future efficacy testing.

Many of these advances are possible starting with the suite of Network antibody trials described here, and moving forward with the next generations of bnAbs, to bring bnAbs for HIV prevention—and a preventive HIV vaccine—to communities throughout the world.

Editor’s Note: The research described in this article has been published: Karuna, S. T., & Corey, L. (2020). Broadly Neutralizing Antibodies for HIV Prevention. Annual Review of Medicine, 71, 329-346.
New SBS-CEU Staff at HVTN Core

Luciana Kamel joined the HVTN and her first day was December 11th. Luciana is the newest Community Engagement Project Manager who is based in Rio de Janeiro, Brazil. As the newest member of the Social and Behavioral Sciences and Community Engagement Unit, Luciana will be primarily focused on implementing the HVTN Community Engagement program in Argentina and Brazil for the Mosaico Study (HVTN 706/HPX3002).

Luciana joins our team with a wealth of experience in community engagement in clinical research environments and health education. She was previously at the Fiocruz CRS in Rio as the Community Engagement Manager, and has extensive experience engaging MSM and transgender communities in health education and research. She’s earned Bachelor of Arts degrees in psychology and law from Universidade Federal do Rio de Janeiro, Brazil in 2000 and 2013, respectively, and a Master of Arts degree in psychosociology also from Universidade Federal do Rio de Janeiro, Brazil in 2005. She is excited to join the team in this capacity.

Luciana can be reached via email at: lkamel@fredhutch.org.

For more information about the Mosaico Study’s community engagement efforts, please reach out to Stephaun Wallace, PhD, HVTN Social and Behavioral Sciences Junior Investigator Liaison via email at: sewallac@fredhutch.org.
Antibodies help to prevent infection. Most vaccines cause the body to make antibodies. If you get an HIV vaccine, your body may make antibodies to HIV. However, standard HIV tests search for HIV antibodies, a sign of HIV infection for people who have not previously received an HIV vaccine. If you get a standard HIV test after receiving an HIV vaccine, your HIV test results could come back positive even if you are not infected with HIV. This is called a VISP (Vaccine-Induced Seropositive) test result. To avoid this confusion, our study sites use different kinds of HIV tests that look for the virus itself, not antibodies.

**FREQUENTLY ASKED QUESTIONS ABOUT VISP**

**Where can I get the right test for HIV?**
You can get the right HIV test at the study site for free. After you leave the study you can continue to go to your study site to request HIV testing. If you are no longer located near your study site, the HVTN VISP Testing Service can help you get HIV testing in your area. The testing is free.

Getting the right test will prevent an incorrect diagnosis of HIV. Your study site or the VISP Testing Service can provide the right test.

**What is “opt-out” testing for HIV?**
“Opt-out” testing for HIV means that HIV tests may be done routinely unless a patient refuses to have the testing done. For more information on the Center for Disease Control’s (CDC) recommendations for HIV testing in the U.S., please visit: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

For (U.S.) state-specific information, please visit: http://www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws/

For other information about HIV testing guidelines in your country, please visit: http://www.who.int/hiv/pub/national_guidelines/en/

**What does “opt-out” testing mean for me?**
You should tell your healthcare provider about your HIV vaccine study participation and refuse HIV testing. Even if your healthcare provider does not mention the HIV test, be sure to tell them that you do not want an HIV test because you are (or were) an HIV vaccine study participant.

**How can I explain this situation to my healthcare provider?**
No one can force you to have an HIV test for any reason.

- If anyone asks to test you for HIV or to draw your blood, tell them you are in (or have been in) an HIV vaccine study and that you need to get all your HIV tests at the study site.
- Explain that being tested outside of your study site or the HVTN VISP Testing Service could result in an incorrect diagnosis of HIV infection.
- Give the provider your study coordinator’s contact information. Ask the provider to call the study site or the HVTN VISP Testing Service directly (U.S. toll free: 1-800-327-2932).
- If you have to, simply say “no” to the HIV test, and then ask the study site or the HIV Vaccine Trials Network to help. We are happy to work with you to resolve your situation.

**How long does VISP last?**
If you have tested VISP, the antibodies may fade quickly or they may last for several years. In some cases, participants continue to test VISP for more than 20 years.
Can VISP be passed from one person to another?

- In most cases, no. If you have tested VISP you cannot pass the antibodies to another person by kissing or through sexual contact.

- If you are pregnant, we think there may be a chance that you could pass the vaccine antibodies to your baby. Although this has not been shown to happen with HIV study vaccines, we know that this happens with other vaccines, like the tetanus vaccine. Vaccine antibodies that mothers pass to their babies are temporary and go away over time, and they are not harmful to the baby. The HVTN can arrange for you and your baby to have accurate HIV testing for free for as long as it is needed.

- In order to donate blood or organs, the donation site will screen you using an HIV antibody test. If you test positive for HIV antibodies you may be unable to donate an organ. You may also be permanently banned from blood donation even though you are not infected with HIV.

How will a VISP test result affect me?

- If someone believes you are infected with HIV, you could face discrimination and/or other problems. For example, you could have problems with medical or dental care, employment, insurance, a visa for traveling, or entry into the military. You might not be allowed to donate blood or other organs. If you are pregnant, you may have to explain your situation to avoid receiving any HIV treatment during your pregnancy or labor/delivery.

- If you are planning to apply for insurance, employment, or the military, please inform your study site right away. The insurance company, employer, or military agency may not accept HIV test results from the HVTN. However, the HVTN can work with them to ensure the right test is done that will show your true HIV status.

What happens if I move far away from the study site where I participated in an HIV vaccine study?

For U.S. participants, call the HVTN VISP Testing Service at 1-800-327-2932 during business hours, Pacific Time. For participants outside the U.S., call your study site and they can assist you with testing for HIV. If you are unable to reach someone at your study site, send an email to vtn.core.vispcounselor@hvtn.org to request testing.

The HVTN VISP Testing Service provides HIV testing for participants who have received a study HIV vaccine in a National Institutes of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS)-funded HIV preventive vaccine trial and who are no longer able to be tested at their study site.

Will my information be confidential?

Yes. All of your information will be stored in a limited-access, password-protected, secure computer database. Access to your information will be limited to the HVTN VISP counselors. No identifying information concerning the testing will be released to any third party without your written approval, except when required by law.

How long does the HVTN VISP Testing Service take to provide test results?

Approximately 2 weeks.

Am I eligible for the HVTN VISP Testing Service?

YES:

- If you participated in an HIV Vaccine Trials Network (HVTN), AIDS Vaccine Evaluation Group (AVEG), or HIV Network for Prevention Trials (HIVNET) HIV preventive vaccine study, AND

- If you received an HIV vaccine*, AND

- You are willing to provide consent to have your blood drawn and for HIV testing.

NO:

- If you have a confirmed HIV infection, OR

- If you are currently enrolled in an HIV Vaccine Trial,** OR

- As a former study participant, you received a placebo.

* If you are not sure if you received an HIV vaccine, call the HVTN VISP Testing Service (1-800-327-2932).

**If you are currently enrolled in an HIV vaccine trial, your testing is provided by your trial site. If for some reason you are unable to be tested at your site, you can contact your study site or the HVTN VISP Testing Service (US toll free: 1-800-327-2932).

What if I live outside the U.S.?

Will I have access to the HVTN VISP Testing Service?

The HVTN VISP Testing Service is open in the United States. Expansion of the testing service in southern Africa is underway. For locations outside of the U.S., please contact your study site or email vtn.core.vispcounselor@hvtn.org to request testing.

For more information about getting the right test for HIV

Contact your study coordinator at the HIV vaccine study site or the HVTN VISP Testing Service at (US toll free) 1-800-327-2932.
Synexus hosted an annual world AIDS day event on the 6th of December at Stanza Bopape Community clinic in Mamelodi East. World AIDS Day is commemorated on the 1st of December globally to bring awareness to the disease that effects millions of people across the world. We once again pulled together members of the community, young and old, under this year’s theme ‘communities unite against HIV’. The day was divided into two parts: the colour walk, and speeches that included the traditional candle lighting ceremony.

**Part One: 5km Colour Walk**

All registered participants gathered at the starting point for the colour explosion that kicked off with the colour walk through the community of Ext 5. CAB members Lesego and Milton coordinated the proceedings for the walk, and marshals that included young high school students from Loxion Science were placed along the route to distribute water and splash powder paints to those participating in the walk.
Part 2: Speeches

The candle lighting ceremony was led by our CAB chairperson, who is also a TAC representative in Mamelodi, who gave a brief explanation on the significance of lighting the candles, saying that candle lighting is about remembering those who have lost their lives to AIDS and those affected by the scourge of HIV. Before candles were lit, a prayer session commenced and after the lighting of the candles, a moment of silence took place. The community members were advised not to blow out their candle when extinguishing them, but to use their hands in order to feel the pain that HIV is causing in our society. Continued on the next page...

Present at the event was Dr. Sheena Kotze (HVTN Principal Investigator) who gave a talk about the importance of not stigmatizing people living with HIV using the placard “Hate the disease not the diseased.” Dr. Kotze also touched on the role of HIV vaccine research, and emphasis was put on the importance of ongoing research to prevent HIV and finding alternative preventive methods to complement what is currently available. The Community Advisory Board (CAB) chairperson emphasised the importance of research, and appealed to community members to embrace research instead of subscribing to negative statements reported by ill-informed people. Research is important for communities because it improves quality of life. The chairperson encouraged community members to come forth to the CAB or Synexus staff to clarify any information that might be misunderstood.

The motivation by a person living with HIV from Treatment Action Campaign (TAC) really touched community members’ moods in a positive way. The speaker danced to a popular song called Amapiano to demonstrate that people living with HIV are enjoying life like any other person.
There was a message of support from local leaders who encouraged people to support Synexus research programmes, and to come forward with questions for clarity. A follow-up speaker promoted the community projects that support the elderly people in Mamelodi, and encouraged other elderly to join senior citizens clubs in order to access support in times of need. The benefit of joining senior citizens gym clubs include staying healthy and being able to receive professional and peer counselling in resolving personal issues around family matters.

The event was full of entertaining activities from dance, singing, and thoughtful words of wisdom. The Stanza Development centre was able to update and register youth who are looking for skills and jobs opportunities.

There were 197 registered people in attendance. More community members came after registration closed, which means more people were actually present.

The Synexus staff and CAB members were instrumental in making the event a success in various ways from community mobilisation, planning, catering and task allocation. We wish to thank Stanza Development Centre, Lulaway, Loxion Science, the CAB and all the other stakeholders in ensuring that community members attended the event as expected despite the forecast for rain.

Lucky Molefe is the Community Engagement Manager of the Synexus Clinical Research Site.
Setshaba Research Centre
World AIDS Day Commemoration 2019

By: Kagiso Mothwa, Setshaba Clinical Research Site, Pretoria, South Africa

Theme: “Know your Status”

For Setshaba Research Centre’s (SRC) World AIDS Day commemoration event, this year we took a twist on the norm. The event promoted SRC’s visibility to the public and surrounding areas within a 3km radius to the site. A Fun Walk from the surrounding areas to SRC was organized to attract not only the community, but also show communities that we are in this fight together, standing to say “Together We Can.”

Participants of the commemoration included site staff, our CAB, members of the general community, and stakeholders including SAPS volunteers, SANCA, Tshwane Multi-sectoral AIDS Unit, Facility Clinic representatives and other neighboring NGOs. What was even more interesting was that each organization was given a platform to exhibit services they provide to community members.

The purpose of the event was to increase global and local efforts in the prevention of HIV & AIDS by encouraging people to test so that they know their status, and to raise awareness and remind the world that barriers to HIV testing still do exist and that more effort must be given to pulling down these barriers. Lastly, we wanted to promote healthy living and lifestyles amongst our communities.

Continued on the next page...
The walk made so much impact based on the positive feedback received from community members, including an inclusive invite from South African Democratic Teacher’s Union (SADTU) – Tshwane West District, who held a similar event and requested SRC to present a message of awareness and ways we can collaborate toward alleviating this pandemic. For a long time community members within our surrounding area have seen the majority of the staff onsite, but this time it was really a highlight to notice that the walkers included staff reaching out to them. This strengthened our contributions toward combating the HIV/AIDS epidemic, and to also show the affected community that SRC staff members also care.

Dr. Khatija Ahmed (SRC CEO) gave opening remarks during the WAD event programme.

The walk made so much impact based on the positive feedback received from community members, including an inclusive invite from South African Democratic Teacher’s Union (SADTU) – Tshwane West District, who held a similar event and requested SRC to present a message of awareness and ways we can collaborate toward alleviating this pandemic. For a long time community members within our surrounding area have seen the majority of the staff onsite, but this time it was really a highlight to notice that the walkers included staff reaching out to them. This strengthened our contributions toward combating the HIV/AIDS epidemic, and to also show the affected community that SRC staff members also care.

Ross Malamatsho (SRC CLO) presenting the purpose of the day to members present at the event.

Kagiso Mothwa is the Community Liaison Officer for the Soshanguve CRS.

Candle lighting in commemoration of all who are infected and affected by this epidemic.

Our very own CAB member keeping us rejuvenated, pledging support.

We will keep our little lights burning, as part of combating to win the HIV/AIDS battle.

Dr. Mookho Malaheha and SRC staff gave closing remarks on the journey toward combating the HIV epidemic.

A beautiful day was sealed with a good dance from our invited guests and staff.
This year the Rev. Edwin C. Sanders II Service Award was awarded to Dwayne Jenkins, Director of MyHouse Nashville. Thank you, Dwayne, for your outstanding support and contributions in ending the epidemic! We couldn’t have found a more deserving person to honor this year. The award was presented at our World AIDS Day event, which featured Gail Broder as the keynote speaker.

Vanderbilt CRS Welcomes New Team Member

The Vanderbilt HIV Vaccine Program welcomes our new Research Nurse Specialist Amber Massey. Amber is a graduate of the University of Memphis where she earned her Bachelors of Science in Nursing degree in 2015. Since then, she has worked as a Registered Nurse at Vanderbilt University Medical Center for 4 years. Amber transitioned into her new role as Research Nurse Specialist at the beginning of 2020. Her previous experience has been with cardiology, but Amber found a passion to help in HIV vaccine research and we are thrilled to have her a part of the team. Amber has two children and 2 stepchildren with her husband, who is also a VUMC nurse. “I am so excited to be a part of the team, and I feel like the work you guys (and now, I) do is a way to really make a difference.”

 Updates at Vanderbilt CRS

**One of Our Own at Vanderbilt CRS Gets Recognized**

CAB chair Alberta Hardison received the 2019 Brother’s And Sister’s United (BASU) Legacy Award. Alberta has dedicated over 10 years of volunteer service and support to Nashville Black Pride.

“My volunteer work with the Vanderbilt HIV Vaccine program started because I wanted to do something more. I saw a video on my local news station in 1998. I called and started in a trial. I was in the canarypox trial where I received the vaccine, which made me have VISP\(^1\). I often talk to people about how much HIV has changed within the last 20 years in Nashville. When I started volunteering, African Americans were not as willing to be a part of the trials or talk about HIV, especially in the South. This has changed a lot and I have worked hard to be out in the community to help educate and let people know about HIV vaccine research.”

1- VISP is an acronym that stands for Vaccine-Induced SeroPositivity. Antibodies help to prevent infection. Most vaccines cause the body to make antibodies. If you get an HIV vaccine, your body may make antibodies to HIV. However, standard HIV tests search for HIV antibodies, a sign of HIV infection for people who have not previously received an HIV vaccine. If you get a standard HIV test after receiving an HIV vaccine, your HIV test results could come back positive even if you are not infected with HIV. This is called a VISP test result.

**Vanderbilt CRS Welcomes New Team Member**

The Vanderbilt HIV Vaccine Program welcomes our new Research Nurse Specialist Amber Massey. Amber is a graduate of the University of Memphis where she earned her Bachelors of Science in Nursing degree in 2015. Since then, she has worked as a Registered Nurse at Vanderbilt University Medical Center for 4 years. Amber transitioned into her new role as Research Nurse Specialist at the beginning of 2020. Her previous experience has been with cardiology, but Amber found a passion to help in HIV vaccine research and we are thrilled to have her a part of the team. Amber has two children and 2 stepchildren with her husband, who is also a VUMC nurse. “I am so excited to be a part of the team, and I feel like the work you guys (and now, I) do is a way to really make a difference.”

**Updates at Vanderbilt CRS**

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At approximately 8:30 a.m. I stepped into the cool clinic entrance of the Crofoot Research Center, Inc. and was instantly relieved from the city’s humidity, the effects of which had become noticeable by the damp blotches on my dress shirt. I had arrived at one of the more than 50 global clinical trial sites participating in the Mosaico study after my flight from Seattle, Washington landed in Houston, Texas a little shy of 4 hours and 40 minutes. The next 72 hours of invaluable experiences, and what seemed fleeting, were inscribed to my memory.

A milestone, in the phase III HIV vaccine efficacy study announced earlier in July by a consortium of global partners, was scheduled to take place. The study team led by Dr. Gordon Crofoot would inject Mosaico’s first study participant setting in motion the testing of an investigational mosaic-based vaccine regimen with the goal of determining if it is effective in preventing the transmission of HIV infection in men who have sex with men (MSM), and transgender individuals aged 18-60.

During the initial hours of the first 24 I was immersed in facts and the tale of how a legacy was built dating back to 1985 when Dr. Crofoot first started doing research with the initial testing of AZT as a single agent for the treatment of HIV. More than three decades on and the Center is a beacon of hope in the community of Houston offering research and LGBTQ focused healthcare.

In 2017 an estimated 1,133 new HIV diagnoses were documented in the city of Houston of which Black and Hispanic/Latinx communities bear a disproportionate burden, with an estimated 48.2%, 34.8% and 12.9% of new HIV transmissions reported among Black, Hispanic/Latinx, and white communities, respectively1.

"While Houston has some of the leading medical treatment and research facilities in the world, we still bear a disproportionate burden in the amount of persons living with and affected by HIV,” said Maggie White, MPH APRN FNP-BC AAHIVS, study spokesperson for the Crofoot Research Center, Inc. Among transgender communities, 12 transgender men (assigned female at birth) and 252 transgender women (assigned male at birth) were reported to be living with HIV in Houston in 20171.

"We hope that by conducting this study in Houston, we can celebrate and reflect the diversity of our city in HIV prevention research”, concluded White.

Time marched on and 48 hours drew close. I listened to more facts and figures at the dinner table and was indulged by the team’s enthusiastic conversation about working with the community they serve. Since 1985, the Center had conducted more than 130 clinical trials, the majority being interventional HIV, hepatitis C virus (HCV), hepatitis B virus (HBV) and some other indications.

I needed to understand how the team earned the support and involvement of the community on their scientific journey to conduct numerous clinical trials.

"We view community engagement as being the tree trunk which supports HIV research,” said Frankie Garcia, Study Coordinator for the Crofoot Research Center, Inc. “The tree trunk has many roots which..."
reaches out to all the different groups representative of our community”, Garcia explained in a pleasant demeanor and warm smile.

In the early days, according to the team, the Crofoot Research Center, Inc. studies were driven by the community, with advocates being the link between the study team and HIV patients hopeful for any chance of treatment.

“Our networks are strong, and we have been fortunate to have earned the trust of our community over many years of advocacy, love, and mutual respect”, Garcia added.

At approximately 9:30 p.m. (CDT) on Thursday, November 21, 2020 the first study participant enrolled in the Mosaico study was injected at the Crofoot Research Center, Inc. At the time of print, study participants were enrolled across clinical trial sites in the United States, Argentina and Spain. These include Hope Clinic (Atlanta), Fenway (Boston), Orlando (Florida), Philadelphia (Pennsylvania), Rochester (New York), Bridge HIV (San Francisco), Montbau (Barcelona), Buenos Aires (Argentina), Logan Circle (Washington DC), and the Crofoot Research Center, Inc. (Houston).

“For many of us on the team, being part of this endeavor and here for this first injection, is an unimaginable gift,” Charles Sydnor, Project Manager for the Crofoot Research Center, Inc. conveyed as we stood in the clinic hallway having been present for the first study injection. “Whatever the outcome of the study, we all can look back and say we bore witness and were able to contribute to the goals of the study. Being part of this program is one of the highest points in our careers”, Sydnor concluded.

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**Profile of Mosaico (HVTN 706/HPX3002)**

- Study teams aim to enroll 3,800 cisgender men and transgender people who have sex with cisgender men and/or transgender people between the ages of 18-60 years.
- The study will take place at over 50 trial sites in the U.S., Mexico, Brazil, Peru, Argentina, Poland, Italy and Spain.
- Mosaico will evaluate an investigational mosaic-based vaccine regimen with the goal of determining if it is effective in preventing HIV infection in MSM and transgender individuals.
- Initial results from the study may be available by 2024.
- **Public-private partnership making the search for a safe and globally effective preventive HIV vaccine possible**
- Mosaico is supported by a public-private partnership led by Janssen Vaccines & Prevention B.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson; the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health (NIH); and the NIAID-funded HIV Vaccine Trials Network (HVTN). Additional partners providing support include the U.S. Army Medical Research and Development Command (USAMRDC).
A guiding principle of the HVTN is the need for a strong bi-directional partnership between the clinical trial site and the local community to help facilitate innovation and advances in HIV biomedical research, foster trust and an understanding between the site staff and local community, to ensure that research strategies honor and respect the myriad of differences among study participants. This partnership is underscored by the unique community engagement plan that each site develops.

“Every person is unique, and every geographic location where our sites are working to engage local communities is also unique and diverse. Our strategies to reach those persons must also be unique and diverse”, Wallace concluded.

Source: aidsvu.org

Aziel Gangerdine is the Director of Communications for the HVTN based in Seattle, WA.

72 Hours - it was fleeting but I recall the friendly introductions, sincere conversations and the abundance of information enthusiastically shared by the Crofoot Research Center, Inc. study team. I will treasure most the moment of audible silence in the clinic’s hallway as we all waited with bated breath to receive confirmation of the first injection, penning a page in history of a study participant and a committed team who are part of a global endeavor to help end HIV.

Responding to Challenges to Maintain Study Momentum

On March 11, 2020 the World Health Organization declared COVID-19 a global pandemic following the deaths of a significant number of people around the world. The situation rapidly evolved, and countries responded with unprecedented measures to stop the transmission of SARS-CoV-2 the virus that causes COVID-19.

Within days following the declaration of a pandemic, the HIV prevention research enterprise implemented measures to mitigate the impact of COVID-19 on the conduct of clinical trials. Mosaico is one of the many HIV clinical trials, coordinated by the HIV Vaccine Trials Network (HVTN), that is impacted by COVID-19.

At the time of going to print the leadership of the Mosaico Study implemented measures to minimize the impact of COVID-19 on the study and prioritize the safety of study participants and the clinic team. The leadership held weekly updates with the trial sites to inform decision making as the circumstances evolved.

I reached out to Stephaun Wallace, Ph.D., who is the HVTN’s Social and Behavioral Sciences Junior Investigator Liaison, and who directs and manages community engagement for the Mosaico Study globally. It was fitting to get Stephaun’s insights on the value and importance of community engagement strategies to help maintain the momentum of a clinical trial in consideration of the impact of COVID-19 and how to keep communities engaged.

Each clinical trial site, via their community engagement plan and Community Advisory Board, are equipped with the tools and strategies to communicate updates or changes in the conduct of clinical trials when the need arises for any reason, including the recent impact of COVID-19.

“There is no one-size fits all approach to the specific activities to educate communities, and recruit and retain study participants”, said Stephaun Wallace, Ph.D., HVTN Social and Behavioral Sciences Junior Investigator Liaison. “Each clinical trial site develops a unique community engagement plan, which is informed and approved by the local community, so that it represents the voices and social norms of that local community,” Wallace pointed out.

Stephaun Wallace, PhD., HVTN Social and Behavioral Sciences Junior Investigator Liaison
Public statement by the HIV Vaccine Trials Network (HVTN) on COVID-19

April 1, 2020

We acknowledge and thank all members of our communities and organizations who are at the forefront helping in the response to overcome COVID-19. We laud your service and unwavering commitment!

The HVTN continues to monitor the impact of COVID-19 on the conduct of the early and large-scale clinical trials it coordinates globally. We remain committed to the safety and wellbeing of all study participants and study teams.

In a previous statement, www.hvtn.org/en/media-room/news-releases/public-statement-HIV-vaccine-trials-network_HVTN-COVID-19_March-2020.html, we outlined how our study teams are empowered to implement measures necessary to prevent the possible transmission of COVID-19 at each trial site. All measures are aligned with the recommendations and guidance from local public health authorities and Institutional Review Boards (IRBs)/Ethics Committees (ECs). In addition, some trial sites abide by specific requirements if they are part of a larger research organization or health care facility.

The impact of COVID-19 is evolving rapidly and many countries are introducing response measures such as school and business closures and asking people to stay home. All measures aim to stop transmission and save lives.

An update on the status of the large-scale clinical trials coordinated by the HVTN is provided in the accompanying table: Impact of COVID-19 on large-scale antibody-mediated HIV prevention efficacy clinical trials and HIV vaccine efficacy trials

As a general approach all trial sites are implementing the following measures to stop the transmission of COVID-19:

- Schedule telephone or virtual study participant visits
- Require those with a scheduled appointment to contact the site beforehand if they feel unwell
- Encourage physical distancing to minimize potential exposures in the waiting area or while visits are being conducted
- Monitor the temperatures of the clinic staff and participants on entering the clinic
- Frequently clean and disinfect all surfaces
- Frequently hand wash with soap for at least for 20 seconds.

Our mission remains the pursuit of a safe and globally effective preventive HIV vaccine to help end HIV. We appreciate the collaborative efforts at all sites to ensure the safety of participants and staff and preserve the scientific integrity of each clinical trial.

Enquiries:
HVTN Director of Communications
Aziel Gangerdine
Email: azielg@fredhutch.org

Editor’s note: Due to the time between when this statement was developed and publication of HVTN Community Compass, there may have been changes to our measures. For public inquiries about the current operational status of our studies, please contact Aziel Gangerdine at azielg@fredhutch.org.
## Impact of COVID-19 on Large-scale Antibody-Mediated HIV Prevention Efficacy Clinical Trials and HIV Vaccine Efficacy

<table>
<thead>
<tr>
<th>HVTN Clinical Trial</th>
<th>Current Status</th>
<th>What Has Changed</th>
<th>Countries</th>
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<tbody>
<tr>
<td><strong>HVTN 703/HPTN 081</strong>&lt;br&gt;<strong>HVTN 704/HPTN 085</strong>&lt;br&gt;(Antibody Mediated Prevention Studies (AMP))&lt;br&gt;AMP is testing whether a broadly neutralizing antibody (bnAb), called VRC01 can prevent HIV acquisition in people.</td>
<td>Fully enrolled</td>
<td>The leadership of the AMP study has discontinued all further infusions in the interest of staff and participant safety. The data accrued on infusions already administered are sufficient to achieve the study objectives. Participant follow-up continues, utilizing remote or in-person visits, as feasible.</td>
<td>Two studies are underway in 11 countries: Botswana, Brazil, Kenya, Malawi, Mozambique, Peru, South Africa, Switzerland, Tanzania, United States and Zimbabwe.</td>
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<tr>
<td><strong>HVTN 705/HPX2008</strong> (Imbokodo)&lt;br&gt;Imbokodo is testing an investigational <strong>vaccine regimen based on “mosaic” immunogens</strong> – vaccine components comprising elements from multiple HIV variants – <strong>designed to offer protection against a variety of global HIV strains</strong>. The study has enrolled women aged 18-35 with the goal of determining if the vaccine regimen is effective in preventing HIV infection.</td>
<td>Fully enrolled</td>
<td>To ensure the health and safety of study participants and staff, the leadership of the Imbokodo Study has issued guidance that is specific to the particular circumstances of participating countries and study sites. Where appropriate, this guidance may include temporarily pausing vaccinations.</td>
<td>South Africa, Malawi, Mozambique, Zambia, and Zimbabwe.</td>
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<tr>
<td><strong>HVTN 706/HPX3002</strong> (Mosaico)&lt;br&gt;Mosaico is testing an investigational <strong>mosaic-based vaccine regimen that is very similar to the regimen being studied in Imbokodo</strong>, with the goal of determining if it is effective in preventing HIV infection in men who have sex with men (MSM), and transgender individuals aged 18-60.</td>
<td>Enrolling</td>
<td>To ensure the health and safety of study participants and staff, the leadership of the Mosaico Study has temporarily paused all new screening, enrollment, and vaccination visits through May 1, 2020. The pause will be reassessed periodically to determine next steps.</td>
<td>Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain and the United States.</td>
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<td><strong>HVTN 702</strong> (Uhambo)&lt;br&gt;Uhambo tested an experimental vaccine regimen against HIV, that builds on the regimen tested in the RV144 clinical trial conducted in Thailand.</td>
<td>Vaccinations stopped in February 2020, but participant follow-up continues.</td>
<td>The leadership of the Uhambo Study has empowered each participating site to implement measures aligned to guidance from local public health authorities and Ethics Committees. This includes expanding visit windows, delaying visits and/or conducting some visit procedures remotely.</td>
<td>South Africa.</td>
</tr>
</tbody>
</table>
STAND UP TO HIV!
IMBOKODO.ORG.ZA
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 magazine and make this a true community sharing platform.

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