Engaging Transgender Women and Transgender Men in Digital Spaces

Trans Participants in the AMP Study

Fostering Transgender Inclusion in HIV Research
Welcome to the newest edition of the HIV Vaccine Trials Network (HVTN) Community Compass.

In this issue, we dive deeper into some of the considerations, perspectives, and best practices for the engagement of transgender populations in our research. It is my hope that this issue enhances your understanding of the dynamic lives of transgender people, and gives you a glimpse into the topics and concerns that should be considered when engaging transgender persons in HIV prevention research.

In this issue, we offer perspectives from members of the population, overviews of research done with transgender populations, and other information that I hope you find useful.

None of this is a substitute for effective community engagement in your own local communities, and as always, the best way to ensure that the voices of any community or population are heard is to meaningfully engage and include them. When you engage transgender persons and ask for their input and perspective, do so from a place of sincere humility, and be prepared to be responsive to the feedback you receive.

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 page 04 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 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
The Transgender Pride Flag was created by American trans woman Monica Helms in 1999,[1][2] and was first shown at a pride parade in Phoenix, Arizona, United States in 2000.[3]

The flag represents the transgender community and consists of five horizontal stripes: two light blue, two pink, and one white in the center.

Helms describes the meaning of the transgender pride flag as follows:

“The stripes at the top and bottom are light blue, the traditional color for baby boys. The stripes next to them are pink, the traditional color for baby girls. The stripe in the middle is white, for those who are transitioning or consider themselves having a neutral or undefined gender.”[3][4]


[3]“Transgender Flag Flies In San Francisco’s Castro District After Outrage From Activists” by Aaron Sankin, HuffingtonPost, 20 November 2012.

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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”.

Gail Broder, Contributing Editor
Nina Ennis, Production & Distribution
Stephano E. Wallace, Ph.D. Editor-in-Chief
Cody Shipman, Layout & Design
There are approximately 1 million adults in the US who identify as transgender. And while we don’t know the true prevalence and incidence of HIV transmission within the community, we do know that about 2,300 folks who identify as trans were diagnosed with HIV between 2009 and 2014 in the United States. It’s estimated that HIV is 5 times the national average among transgender women and men. Yet transgender people account for a small proportion in HIV prevention research studies, including vaccine research studies. With the growing prevalence of HIV among transgender men and women, it is essential to identify barriers and facilitators for transgender people to participate in HIV vaccine clinical trials.

Studies that are exploring the reasons for underrepresentation of trans people in HIV vaccine trials have pointed out that there is a need to develop recruitment strategies geared specifically toward the transgender community. Some of the barriers to address in such strategies include stigma, being unaware of or misinformed about HIV, mistrust of the scientific community, and concerns about possible vaccine side effects. But before any of these can even be addressed, how are we reaching trans-identified women and men?

Our ever-evolving culture is guiding us into digital spaces where visual advertisements grab the attention of people. It has been estimated that 72% of US adults visit social media websites and 12% of internet users access social media to research health-related issues.

Participants identified the need to be inclusive and have visible transgender representation in an ad. The representation can take place in a variety of ways: visible Trans flag colors, or including specific text that explicitly states the study is recruiting transgender women and men. If using models in a campaign, the consensus was to use people from within the community rather than opting for stock photos that use non-familiar or celebrity-style images.

A variety of messages were discussed that ranged from “Doing Good” by helping end HIV, to messages that were not directly about HIV but spoke to the community such as “Big and Bold. Beyond the Binary.” Participants unanimously agreed that messages such as “Do Good” imply judgment (that if you are not interested in participating or being involved in HIV prevention, you are doing bad). A transman under age 30 in the focus group stated, “People are imperfect, also, their goodness is not determined by their STI status.” On the other hand, some of the younger transwomen in the group...
felt that a tagline like “Big and Bold. Beyond the Binary” targeted them in a good way. They felt that the message is “really clever alliteration” and that “this is meant for me. This is meant for me to be reading right now.”

Animated or cartoon-based campaigns were appreciated among the group. Specifically, the conversation focused on a campaign created for HPTN 077 and HPTN 083, phase 1 and 2b (respectively) injectable PrEP studies that required participants to receive an injection in one of their butt cheeks. This campaign depicts a variety of cartoon butt cheeks in different shapes and sizes with text stating, “Show us yer cheeks!” Participants thought that cartoon-based images were a great way to be inclusive: “I like the butts, because I think they’re universal, and I think that isn’t – it’s not very gendered, and I like that.”

Our take-away at Bridge HIV is to create a customized campaign for the trans community, as opposed to creating one general campaign. While cartoon-based and text-based advertisements are acceptable, we think creating a campaign with members from the transgender community as models would be a great way to show the community that we are listening to their feedback, that we care, and that we want to cultivate our relationship with the community. It would also create a paid opportunity for the models, which is also a facilitator in establishing trust.

Rafael Gonzalez is the Community Program Manager and Bianca Hill is a RAMP Scholar at the Bridge HIV CRS.

References:

On October 5, 2018, the Community Advisory Board (CAB) of the Case Western Reserve University/University Hospitals AIDS Clinical Research Site sponsored a showing of the film “Kings, Queens, & In-Betweens” for the Greater Cleveland community. The film, a documentary filmed in Columbus, Ohio, explores gender, race, sexuality and changing self-identity against the backdrop of a then-thriving local drag performance scene. The event was open to the community free of charge.

Approximately 50 people attended the event which started out with a reception, and included popcorn (of course!). Following the screening, an audience discussion was led by CAB Chair Julie Patterson. One of the stars of the movie, Sile Singleton who performs as Luster dela Virgion and Anita Kwan, owner of Reel Hoot Productions and editor of the film. The discussion was lively and inspirational. Topics covered included the differences between drag performance and gender identity, and the particular ways race and racism impact transgender people and communities.

The CAB brainstormed new ways to continue the critical conversation around gender, justice, and HIV. Several members had previously seen the film at the Cleveland International Film Festival. In addition to being an intelligent and entertaining film, the CAB members thought that having the film set in Ohio would allow a greater connection with our community than if it had been filmed in a larger coastal city, and they were correct.

Julie Patterson summed up the event, “Community members enjoyed the film and found it was a springboard for discussion about gender fluidity, generational differences in identity, and the transformative power of drag. Ohio is full of amazing people - you just have to know where to find them!”

Bob Bucklew is the outreach coordinator with Case Western Reserve University.
From Noun to Verb: Three Parallel Lives of Beauty, Competitiveness, and Empowerment

By: Carolina Arredondo Villar, Lucía Ruíz Escalante, Carlos Vela Vela, Association Civil Selma Amazonica CRS, Iquitos, Peru

The value of stories lies in learning from brave people who share their so-called life lessons and how they have overcome life’s challenges. These three survival stories lead us to understand the urgency of leaving speech behind and taking action, that is, transforming nouns into verbs.

“Some people mistake nudity for sensuality and vulgarity. Stay a mystery!”
- Carolina Herrera

BEAUTY + INTELLIGENCE = POWER

Since 2015, Chris Martínez dreamt about becoming a queen after watching Lady Jeri crowned as Miss Amazonas, but there was a huge obstacle Chris had to overcome: her shyness. She had never participated in any play in high school, nor being a contestant for any beauty pageant. She had actually refused to run for Miss Belén Trans. Then, her mother and sister encouraged her. At that moment, Miss Amazonas 2018 Queen was born, bringing the crown back to Belén after 11 years of absence.

It was difficult for Chris to accept herself, and the process began with a hormone treatment at the age of 17. The following year she began her transformation to become a trans woman. Were there any jokes? Yes there were, and they were indeed as numerous as the love of her family was huge, which was Chris’ source of power to face life. Likewise, Chris has Francesca, her transgender sister who always supports and accompanies her.

The Beauty Academy (a component of the Miss Amazonas pageant) was very difficult for Chris because it demanded her time and sacrifice, which in exchange gave her information and empowerment. It was great. Now Chris wants to follow this method to strengthen herself and help other transgender women by giving motivational speeches on the advantages and disadvantages of hormone treatment. “There is very little known about this topic, but by 2019 I’ll start this path at the Asociación Civil Selva Amazónica,” she said. Chris will also carry out sensitization work about the importance of participating as volunteers in the research for solutions to prevent HIV.

Chris thinks about modeling in Lima, plans she’ll carry out in the future. Chris is convinced that physical beauty is accompanied by intellectual beauty, your education, which she defines as the glamor of women.

Like many others, Chris Martínez considers that Angela Ponce’s participation in the Miss Universe 2018 pageant (representing Spain) has opened a wide door for transgender women. She also thinks that this fact will help to unite the Iquitos trans community, minimizing the fears of coming out and making themselves visible to society. For that purpose, Chris will continue to help empower others through beauty, knowledge, and acceptance of themselves, because it is not only about a face or a body, but also about education, and there is much to learn!

"Some people mistake nudity for sensuality and vulgarity. Stay a mystery!"
- Carolina Herrera

Chris Martínez, Miss Amazonas 2018

Chirs Martínez presentation MA2018

Dragon fantasy costume show

Continued on Next Page...
Cristina Vela, previously runner-up for “Miss Amazonas 2016,” is currently hostess of the Asociación Civil Selva Amazónica. She has worked in many places where she had played a role as a male, but knew herself to be a transgender woman. For Cristina, education is the engine for change in the world.

The first challenge of her life was to accept herself. It was difficult because she didn’t know who she was, she didn’t know what a “trans girl” was, and she was not comfortable with her gender. Nowadays, she knows she is a transgender woman and why she is living day after day. Knowledge was the key to her liberation.

Cristina states that competitiveness has meant improving herself to overcome the difficult circumstances she has faced along her way. Therefore, she faces obstacles and challenges, including within her family, and responds with defiance on a daily basis, because it has been neither easy nor impossible at all.

Cris works at a store in Iquitos where she was required to have a short hairstyle, and when she asked her boss if the company would hire a trans girl as allowed by law, she was told “absolutely not” and that they would take her application but wouldn’t hire her. This affected Cris’ self-esteem, since she had to play a role that was not true to herself. To be a contestant in “Miss Amazonas 2016,” Cris joined the Beauty Academy, empowered herself, acquired knowledge, and changed.

Cris has been working for two years at the Asociación Civil Selva Amazónica as hostess and it’s a great opportunity to empower herself and widen her knowledge. She works in a comfortable environment, because her co-workers treat her as a transgender woman.

Cris says, “The trans community is in the process of strengthening itself and gaining acceptance from society. If they have no rights, they cannot move forward or evolve. Transgender women are often labeled as thieves, “peperas” [women hired to attract men at parties, bars or clubs and then drug and rob them], or sex workers, however there are many trans women who don’t do any of that.”

“We cannot allow others’ limited perceptions to define us.”
- Virginia Satir

“Those who don’t move do not notice their chains.”
- Rosa Luxemburgo

BUILDING IDENTITY TO EMPOWER

Fiorella Jiménez is a spokesperson for Kalpa, and jointly works with CHERL and the Office of the Public Defender in Loreto-Perú on the defense of the community. She doesn’t consider herself as a role model, but she does desire to become a reference for her community.

Fiorella’s at Ayacucho, in Mesa de Kalpa, to share experiences using a methodology guide to implement a comprehensive sexual education program with CHERL and the Office of the Public Defender. She has been working on this since she was 15 years old and in high school. Her life has not been easy, especially regarding her family; she got away for a while, but now they live together once again.

Cristina Vela, hostess at ACSA

Fiorella Jiménez, transgender woman leader
Fiorella has a great concern about the absence of regional ordinances that directly endorse transgender women. There are ordinances about discrimination based on sexual orientation and gender identity that are more focused on the gay community, and the trans communities don’t consider themselves included. In the health sector, for example, many women stop coming to medical facilities because they are badly treated. “Using the bathroom is a small thing but causes great damage,” she stated.

Fiorella shared that an example of a positive response from an authority is that her social name is respected, and she is acknowledged in her study center. On the other hand, she received a negative answer when she tried to talk to the dean of a local university and the members of the university assembly but they refused to receive her because of being transgender.

However, discrimination is not only experienced externally, but also internally because there are those who say they are transgender but do not transition and live openly as transgender people. It is a challenge to build a self-identity that includes the concept of “trans” and to live with the suffering of not knowing who you are. For Fiorella, transgender women may be directed and empowered to know and enforce their rights from this moment on, and then they can dialogue with the authorities to propose changes.

Participating in “Miss Amazonas 2015” contributed to her empowerment. Through the Beauty Academy she had the opportunity to receive support, and since then she has had the opportunity to empower other contestants. In 2019, she plans to develop a personal project with transgender women.

Carolina Arredondo Villar, Communication expert on Community Education, Asociación Civil Selva Amazónica
Lucía Ruíz Escalante, Chief of the Community Education Area, Asociación Civil Selva Amazónica.
Carlos Vela, Recruitment and Retention Coordinator, Asociación Civil Selva Amazónica.
Among the participants enrolled in the AMP Study at the VIA LIBRE research site, about 9% identify as a transwoman (about 24 out of a total of 254 enrolled). Five of the women happily gave us their feedback and testimony regarding a few questions we asked them during one of their scheduled study visits.

How was the process of acceptance of your gender identity?

One of the women, Michel, found that the conception of their identity was a trauma that could be overcome, and sought the assistance of a psychologist for about 8 years: “I received psychological therapy since I was 4 years old, because at school they realized [my true identity]. It was a pleasure, because it was something that could not be hidden.”

Another woman, Zoe, found that the discovery of, initially, a gay identity, gave way to her transgender identity: “In the garden I played with the girls, with the dolls. I felt like I was gay. When I was 12, I felt different. The change started at 15, 16. I let my hair grow and I started taking hormones.”

Jeampi said: “I started to realize that I was gay when I was 5 years old, when I was in the nest. I realized that I liked a child in the classroom. At 8 I had my first kiss with a boy who was from my neighborhood. I think that my taste for being a woman came at 12 years. At 5 [as a boy] he was mannered, he had a taste for makeup, but I still did not see my future like that [as a woman].”

Likewise, the family plays an important support role in this process, or can reject them. Carola shared: “My dad looked at me, gave me a bean on the forehead and said “I cannot do anything.” But my mom did not talk to me for almost a year.”

Problems with trans identity?

For this question, we heard answers ranging from feeling pessimistic about being trans, linked to the difficulty of being recognized in their authentic gender identity to being able to obtain an identification in which their “social” name is used and appreciated. Michel said, “Study something else, not because the society we live in does not accept a transgender person.... It is not easy to get a job because in a job application they look for male or female sex. You go where it says female, but your documentation comes out as a man.”

There is also a difference in the treatment of homosexuals and heterosexuals, especially with trans girls who demand equality. Zoe said, “They need to recognize us as they recognize the heterosexuals, and getting that recognition is in the works. They need to call me by my name if I think about changing it, but that will come later.”

On the other hand, there are those who have a more optimistic outlook and the conviction that they can create changes. Jeampi said, “My dream is to be a journalist and work on a newscast. I want to escape the cliché of gossip journalism and do more serious journalism. A trans girl can also be a professional.” Jeampi also noted that it is important to recognize the difficulties and lack of sexual education that trans women still suffer, which hinders personality development and the affirmation of their identities.
According to a recent statistic, 70% of the trans population is engaged in sex work. This affects those who suffer stigma for being trans. Shirley told us, “Most people discriminate against you, treat you badly, sometimes insult you. I try to lead my life quietly. We are dedicated to our homes, I am a stylist; not all trans women are dedicated to sex work.”

On the other hand, Jeampi hopes the study will obtain beneficial results. “More than any benefit, it is knowing how to inform people. And to know if it works, if it really works and if it can protect many people.”

Four of the women granted us permission to publish their photos. Jeampi’s photo is particularly significant for her, since she published it on social networks for the viral #10YearChallenge, which was shared and generated many comments. Jeampi decided to communicate, with great courage and pride, the change in how she looks now, different from the earlier child that appears in the first part of the photo.

Julio Ortiz is the Recruitment and Retention Coordinator and Diego Torres is a Recruiter at the VIA LIBRE CRS in Lima, Peru.
HIV is very common among transgender women, indicating a special population that would greatly benefit from pre-exposure prophylaxis (PrEP) with oral tenofovir and emtricitabine (sold by the brand name Truvada®). However, transgender women are not well represented in most large PrEP clinical trials and there are very few pharmacokinetic studies (where drug concentrations are measured over time) in transgender women. In addition, many transgender women also benefit from taking estrogens with or without anti-androgens as gender-affirming hormone therapy (GAHT). However, several surveys of transgender women taking GAHT indicate a high degree of unwillingness to take PrEP due to concerns that PrEP may impact their hormone regimens. Given the established benefits from both PrEP and GAHT, their likely use together, and the reluctance of many transgender women to take PrEP, it is essential to understand the potential for interactions between these drugs. Better understanding could provide reassurance to transgender women and clinicians that PrEP and GAHT could be prescribed together without risk of reducing the effectiveness or increasing side effects of either regimen.

Previously, laboratory and animal studies suggested that estrogens might either increase or decrease the concentrations of PrEP drugs, depending on which specific tests were used and in which tissues. Naturally high concentrations of estrogen in pregnant women are associated with reduced concentrations of many drugs that are processed by the kidneys, including PrEP drugs. There is no laboratory or clinical evidence to suggest that PrEP drugs have any effect on estrogen concentrations, but this has not been previously studied directly in clinical trials. Given the concern among transgender women that PrEP might adversely affect GAHT, and conflicting laboratory data that estrogen might affect PrEP drug concentrations, we and others set out to study drug-drug interactions between PrEP and GAHT in transgender women.

We performed a small, open label study of daily oral PrEP drug concentrations in blood and rectal tissue in eight HIV-negative transgender women (TGW) consistently taking GAHT and eight cisgender men. Research participants took daily oral PrEP for one week under direct observation in the research clinic to assure 100% adherence. After the last dose, blood and rectal tissue were collected to measure PrEP drug concentrations. We also measured estrogen and testosterone in the blood. We reported study results at the HIVR4P (HIV Research for Prevention) meeting in Madrid in October 2018.

The two primary outcome measures were differences in PrEP drug concentrations between transgender women and cisgender men, and changes in estrogen concentrations before and after PrEP in transgender women. To assess the impact of GAHT on PrEP, we calculated the total drug concentration in blood over 24 hours, also known as the area under the concentration versus time curve for 24 hours (AUC24), and we measured the drug concentration 24 hours after the last PrEP dose was taken, also known as the trough concentration. After one week of daily PrEP dosing, tenofovir and emtricitabine AUC24 and trough in the blood plasma of TGW were lower by 20% to 27% when compared to cisgender men. The other research team at the Thai Red Cross/HIVNAT also showed a slightly lower 12-18% reduction in tenofovir blood concentrations when an estrogen/cyproterone regimen was added to PrEP alone (presented at the Paris IAS 2019 meeting). Seeking a biologic explanation for these results, we found that kidney function (creatinine clearance and glomerular filtration rate) was substantially higher in the transgender women. These measures were also strongly and inversely correlated with plasma AUC and trough concentrations for both drugs—meaning that the higher the clearance, the lower the PrEP drug concentrations.

To work, both of the medicines included in Truvada® must be activated by enzymes in the body's cells by the addition of phosphates to become tenofovir diphosphate.
and emtricitabine triphosphate. Because we believe the location of drug action for these medicines used as PrEP in transgender women is primarily in the rectal tissue cells, we measured these activated forms of the medicines in rectal tissue as well as blood. The differences in concentration of both active drugs inside certain white blood cells, known as peripheral blood mononuclear cells (PBMC), showed similar lower concentrations like that seen in the blood plasma. Unlike the plasma, however, these were not statistically significant and could have occurred by chance alone. In rectal tissue cells, the differences in active drug concentration were 62% to 68% lower in TGW compared to cisgender men, however, as in the PBMC, these were not statistically significant. Measuring drugs in tissue cells is highly variable and the small differences seen in plasma are hard to detect. Thus, we cannot say with confidence that the differences in activated drug in PBMC and rectal tissue cells are real. However, PBMC concentrations are highly related to blood plasma concentrations based on other studies, and we saw no evidence of changes in the body to explain a loss of this relationship. These facts provide a good reason to do larger studies to determine with confidence whether or not these changes in active PrEP drug concentration truly occur when PrEP is taken together with GAHT.

We saw no effect of Truvada® on estrogen or testosterone in our study. However, not all transgender study participants were on the same GAHT regimen, which introduced a lot of variability, making it harder to pick up small differences. Better evidence to prove there is no effect of PrEP on GAHT comes from the Thai Red Cross/HIVNAT study (mentioned earlier) in which all transgender women were on the same GAHT regimen of estrogen/cyproterone, in which PrEP drugs had no impact on estrogen concentrations. Their rigorous study design allowed the investigators to confidently detect smaller differences in drug concentrations than we could. Taken together, these studies provide good evidence that GAHT is not affected by oral PrEP. Because cyproterone is not available in the US and its specific role in the changes seen in PrEP drug concentrations was not directly assessed, we believe additional studies are needed.

The magnitude of the decreases in the 2 PrEP medicines in transgender women on GAHT are similar to the effects of regularly missing 1-2 doses each week. This decrease probably still provides high concentrations of protection with a daily dosing regimen – even if the rectal tissue cell concentrations are real and consistent with every other day dosing. However, PrEP drug concentrations in combination with GAHT and an on demand oral PrEP regimen, such as the regimen used in the Ipergay trial (the so-called 2-1-1 regimen), may fall below protective concentrations. Therefore, it would be wise to only recommend daily dosing of oral PrEP using Truvada® in transgender women, as in cisgender women, until other studies are completed. More importantly, there is reassurance across these two studies that PrEP drugs do not affect GAHT drug concentrations. Larger and more carefully controlled PrEP-GAHT interaction studies are needed to establish whether the differences in PBMC and rectal tissue are real, so that we could better understand the role of the different anti-androgen drugs such as spironolactone or Lupron in the GAHT regimens, and to provide more definitive guidance to clinicians who prescribe GAHT to transgender women who wish to take Truvada® as PrEP and GAHT together.

Dr. Craig Hendrix is the Wellcome Professor and Director in the Division of Clinical Pharmacology in the Departments of Medicine and Pharmacology and Molecular Sciences at Johns Hopkins University School of Medicine.

Craig W. Hendrix, MD.
UPCOMING EVENTS/CONFERENCES/METINGS

11-14 JUNE 2019
2019 IMPAACT Annual Meeting
Washington, DC, USA
https://impaactnetwork.org/

16-20 JUNE 2019
2019 ACTG Annual Meeting
Washington, DC, USA
https://actgnetwork.org/

14-17 JULY 2019
2019 STI and HIV World Congress
Vancouver, BC, Canada
https://stihiv2019vancouver.com/

21-24 JULY 2019
10th IAS Conference on HIV Science
Mexico City, Mexico
http://www.ias2019.org/

5-8 SEPTEMBER 2019
2019 US Conference on AIDS
Washington, DC, USA
http://2019usca.org/

2-6 NOVEMBER 2019
2019 American Public Health Association Meeting
Philadelphia, PA, USA
https://www.apha.org/events-and-meetings/annual

3-4 DECEMBER 2019
NMAC Biomedical HIV Prevention Summit
Houston, TX, USA
https://www.biomedicalhivsummit.org/
LET'S END HIV TOGETHER!

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Dr. Larry Corey (HVTN PI) being interviewed by the South African Broadcasting Corporation (SABC) during HIVR4P Conference in Madrid, Spain, October 2018

Zoe Moodie (SCHARP) being interviewed by Malawi News during HIVR4P Conference in Madrid, Spain, October 2018

HVTN RAMP Scholar Shay Behrens (Duke University School of Medicine) presenting her poster on bnAb lineage at the HIVR4P Conference in Madrid, Spain, October 2018
UNIDEC Recruitment and Retention Team: Daniel Alva, Hugo Sanchez, Yolanda Vidal, and David Velasquez at UNIDEC Participant Appreciation Dinner, November 2018

Hosts in vintage costume welcoming the attendees at UNIDEC Participant Appreciation Dinner, November 2018

“Doctor Owl and his team”: (l to r) UNIDEC community educator Ruller Soto, Drag Langosta, Hugo Sánchez, Dr. Buho, Juan Carlos Gomez, and Lenin Silva at UNIDEC Participant Appreciation Dinner, November 2018

UNIDEC Counselor Miguel Morales and hostess Ariel in vintage clothes at UNIDEC Participant Appreciation Dinner, November 2018
UNIDEC Patient advocate Jhonatan Zamor (r), event coordinator Cristal del Castillo (center), and UNIDEC volunteer Augusto Vallejos at UNIDEC Participant Appreciation Dinner, November 2018

UNIDEC Retention Coordinator Daniel Alva and even host Benjamin Marin at UNIDEC Participant Appreciation Dinner, November 2018

UNIDEC Principal investigator Dr. Jorge Sanchez (left) and performer Monique Pardo at UNIDEC Participant Appreciation Dinner, November 2018
Ceremonial masters and UNIDEC CER leads Daniel Alva and Hugo Sanchez at UNIDEC Participant Appreciation Dinner, November 2018

Drag Performer Georgia Hart at UNIDEC Participant Appreciation Dinner, November 2018

Drag Performer Georgia Hart at UNIDEC Participant Appreciation Dinner, November 2018
The phase 2b HVTN 505 study (n=2,504) opened in May 2008 and the final participant enrolled in March 2013. The trial assessed the safety and efficacy of a preventive DNA/rAd5 HIV vaccine regimen in MSM and transgender women (TGW) who have sex with men who were at risk for acquiring HIV. It was HVTN’s first trial to specifically include TGW, distinct from MSM. Though by eligibility criteria participants were required to have been assigned male sex at birth, no required gender identity was specified, and 44 participants did not identify as having a male gender identity at study entry. These 44 identified their gender as: transgender female (n=28); female (8); transgender male (2); queer (2), gender queer (1); born male with female hormones (1); not claiming male or female, no sex (1); or decline to state (1). These 44 individuals were included as "transgender" (ie, their sex assigned at birth was discordant from their gender identity) in a comparative analysis of HVTN 505 transgender and cisgender participants. This analysis compared transgender and cisgender participants in HVTN 505. Eight participants were excluded who were found to have been HIV-infected upon enrollment, for a total of 2,496 HVTN 505 participants included in this comparative analysis.

HVTN 505 transgender (TG) participants were more likely than cisgender (CG) participants to have demographic factors associated with HIV incidence, including non-White race (57% TG vs. 24% CG; p<.001) and young age (average 29 vs. 32 years old; p=0.04). Of the TG pts, 14% identified as Hispanic, 43% White, 41% African-American,

11% “other,” and 2% each as Asian or multi-racial. [Editor’s note: a statistic is defined as “significant” when the p value is <.05.]

More transgender participants than cisgender participants missed at least one study visit (34% vs. 21%; p=.01). There was no statistically significant difference in other retention factors such as stopping vaccinations or dropping out of the study. Trans and cis participants did not differ in average number of pre-existing conditions or adverse events (AEs), including serious AEs. There were more deaths among TG pts (n=2 or 5% vs. n=7 or 0.29%; p=.01).

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Table 1 | Baseline Demographics in HVTN 505

Some of these conditions are referable to participants’ TG status (eg, gender dysphoria)
Transgender participants said that “a friend joined” as a reason to enroll more often than cisgender participants, which may prove informative for future transgender engagement & recruitment. Both trans and cis individuals reported participating primarily for altruistic reasons.

There were no differences in numbers of social harms or benefits. 87% of participants reported experiencing social benefits to trial participation. The most common benefit was feeling good about helping others, reported by 75% of TG and 70% of CG participants. Other benefits included: receiving risk reduction counseling (50% TG, 42% CG); receiving medical care (46% TG, 29% CG); and positive impacts on personal relationships (36% TG, 31% CG).

New HIV infections were higher among TG ppts. However, the difference was not statistically significant, although there was limited power to detect a difference because of the small number of transgender participants who were enrolled (3 TG ppts or 4.3/100 person-yrs vs. 84 CG ppts or 2.1/100 p-y; p=0.37).

In conclusion, transgender and cisgender participants at risk of HIV can be successfully recruited and retained, and contribute meaningfully to HIV vaccine clinical trials.

In March 2011 the Institute of Medicine (IOM) published a report of lesbian, gay, bisexual, and transgender health in which it was noted that transgender individuals (TG) in the US have increased risks of adverse health outcomes, generally. With respect to HIV infection, specifically, prevalence and incidence rates are much higher among TG than among cisgender (CG) individuals, with prevalence among black TG approaching 25%. This is largely attributed to complex relationships between known predictors of HIV incidence such as sero-discordant primary partners, unprotected anal intercourse, sex work and drug use, as well as the interaction of interpersonal, social, and structural variables with these predictors.

TG are, thus, among those most in need of an HIV vaccine. Yet, TG experience increased rates of stigma, discrimination, and prejudice and these factors—alongside lower educational attainment and income, employment discrimination risks, and reduced social support—create significant barriers to HIV vaccine trial participation.

Dr. Shelly Karuna is the Director of Clinical Development for the HVTN and the Protocol Team Leader for HVTN 505.
Transgender people face stigma and discrimination in all aspects of society—family, schools, workplace, health care settings, housing, the criminal justice system, and more. The cumulative effects of these traumatic experiences often create fear and distrust among transgender people, and this may directly impact their involvement in HIV research. In order to successfully recruit, enroll, and retain transgender individuals into our clinical trials, it is important for research staff to develop some degree of understanding, knowledge and humility. This is necessary across all the NIH-funded HIV/AIDS clinical trials networks and can help ensure that the mistreatment and discrimination that are already part of the transgender experience are not perpetuated in the clinical research setting. To address these issues, the Division of AIDS (DAIDS) established the Cross-Network Transgender Working Group (CNTWG) in 2015. The group’s goals are to foster coordination, collaboration and an exchange of information related to transgender issues across the networks. The Working Group has members representing each of the networks and DAIDS and meets quarterly.

Data collection was the first issue the CNTWG addressed, recognizing that the research networks were not regularly collecting information about study participants’ gender identity in a unified, systematic, and affirming manner. By failing to collect information about gender identity, we do two things: we compromise the validity of the research, and we perpetuate discrimination against people whose gender does not match the sex they were assigned at birth. Simply asking if someone is male or female fails to capture that person’s identity as a transgender or cisgender person. Furthermore, it completely excludes those who don’t fit into one of the binary boxes of man or woman. Transgender people represent an entirely distinct population and experience unique epidemiological circumstances. We now know that transgender people—particularly transgender women of color—are among the populations most vulnerable to HIV worldwide, and the factors driving this are different from those affecting cisgender women and men of all sexual orientations. To miscategorize transgender people is not only disrespectful and discriminatory, it’s just bad science. Without accurate scientific information about transgender people, it’s difficult to fully assess HIV treatment and prevention interventions for transgender communities.

After reviewing data collection forms across the networks and looking at best practices from organizations such as the Center of Excellence for Transgender Health, the CNTWG recommended the standard use of the two-step method, which as the name implies, asks people to describe themselves in two ways: their gender identity and the sex they were assigned at birth. By separating gender identity from sex assigned at birth, study participants can accurately describe who they are, and researchers can correctly categorize transgender participants who might otherwise be missed (for example, a participant who indicates she is a woman but was assigned male at birth). The two-step method also provides multiple choices for responding, including options such as genderqueer, transgender man, transgender woman, man, woman, and gender non-conforming. We also recommend providing space for someone to write-in how they identify, since there are many terms for gender identity, and they are always evolving. As an example, the 2015 U.S. Transgender Survey of nearly 28,000 individuals included a list of gender identity terms; respondents could check all the terms that they used to describe themselves. In addition to the 26 gender identity terms listed, the respondents wrote in more than 500 unique terms with which they identified. No one identifies as “other,” nor should we ask them to.

1. What is your current gender identity?
   - Genderqueer
   - Gender Variant, Gender Non-conforming
   - Man
   - Transgender Man/Trans Man/FTM
   - Transgender Woman/Tran Woman/MTF
   - Woman
   - Additional Category, please specify ____________________________
   - Decline to answer

2. What was your sex assigned at birth?
   - Female
   - Male
   - Intersex
   - Decline to answer

This is an example of the two-step method with the gender options listed alphabetically to avoid the perception that they’re listed in any form of hierarchy. Intersex was also added to the question about sex assigned at birth. While people are not necessarily assigned intersex at birth, and some intersex conditions aren’t identified until later in life, an additional category is available in some states in the U.S. so that people can change their birth certificate to reflect their intersex or non-binary status.
The HIV Vaccine Trials Network (HVTN) was at the forefront regarding data collection, having revised its Demographic Case Report Forms in 2009 to adopt the two-step method. Using the HVTN form as a model, the DAIDS CNTWG developed a template to share with the other networks and recommended its use for all studies. Given the unique needs of each network, not all the case report forms are identical but overall, the two-step method is now a regular part of the data collection process. However, DAIDS and the networks acknowledge that there may be specific reasons not to ask about gender identity. For instance, in some regions of the world, gender identity disclosure could result in harm to the participant due to significant discrimination, stigma, or criminalization. Therefore, exceptions can and should be made for not asking about gender identity, but there should be a clear rationale as to why this is being done. The two-step method helps acknowledge participants for who they are and helps ensure that the information collected is accurate. In the context of HIV research, this allows us to better understand the impact of HIV vaccines, other prevention strategies, and treatment on transgender communities.

The CNTWG also recognized that in order to foster a welcoming and affirming environment for transgender participants, staff needed more educational tools. While some materials exist, the Working Group felt that they weren’t always applicable to the research setting. The group decided to create a comprehensive transgender training curriculum and identified five of the most important content areas to help build the capacity of all site and network staff. Input and guidance from subject matter experts, including transgender and gender non-conforming people, advocates, researchers, and site staff, were solicited to further identify, design, develop, and review the training content. Their experiences and perspectives were essential to the process and ensured that a variety of key issues were appropriately addressed. The specific content of each module was then pilot tested during training sessions at the annual network meetings of each of the five DAIDS clinical trials networks. The idea was to test the content to make sure that it was relevant and clear before pursuing the costlier development of web-based training tools, which were needed to reach staff throughout the research enterprise.

The five modules that were developed as part of the overall Transgender Training Curriculum for HIV Research include: 1) An Introduction to Transgender Communities; 2) HIV in Transgender Communities; 3) Creating a Gender-Affirming HIV Research Environment; 4) Clinical Considerations and HIV Risk Assessments for Transgender Research Participants; and 5) Trauma-Informed Care for Transgender Research Participants.

To date, each module has been presented at one or more of the annual network meetings. Each one was very well received and generated thoughtful discussion. We found that having at least one transgender presenter was extremely valuable, as their personal stories and experiences helped bring the material to life. Attendees of the training represented a cross-section of our networks and sites, including community advisory board members, clinicians, community educators/recruiters, data managers, study coordinators, laboratory and regulatory staff, as well as staff from DAIDS – all of whom are the intended users of the final training tools. While the training modules were developed with a strong U.S. focus, training attendees from outside of the U.S. felt that the content was relevant, valuable, and globally applicable.
The process used to develop the content, which involved ongoing review and input by a transgender-inclusive and diverse group of subject matter experts, was essential to the success of the final training curriculum. Having the input and experience of the subject matter experts helped ensure the accuracy, sensitivity, and cultural responsiveness described in the curriculum itself. The first two modules are already available as web-based training tools, and the remaining modules should be available in the coming months. It is hoped that they will help reduce the misinformation and lack of understanding that perpetuate the misgendering, stigma, mistreatment, and trauma too often experienced by transgender people. Cultivating awareness, knowledge and understanding of transgender communities is a vital step in providing transgender-affirming care and services, and in supporting transgender inclusion in HIV vaccine, prevention, and treatment research.

Sidebar: Transgender Training Curriculum for HIV Research:

Two of the five training modules – An Introduction to Transgender Communities and HIV in Transgender Communities are currently available to the public on the DAIDS Learning Portal at https://daidslearningportal.niaid.nih.gov/

Anyone affiliated with a site, including community representatives, can get an account by clicking on “request an account” and providing your site number (available from your site) and other relevant information. For people who are not affiliated with a site or network, you can request an account using the link at the bottom of the page (“Contact DAIDS Training Support Team”). Simply note that you are interested in the transgender training modules. In addition to the web-based training tool, you will also have access to the in-person training materials, including a PowerPoint presentation, facilitator’s guide, and any hand-outs such as exercises, answer keys, and a listing of resources and publications.

Sidebar: Selected Definitions

**Sex** is typically considered to be our anatomy as female or male. It includes our internal and external sex organs, chromosomes, and hormones.

**Sex Assigned at Birth** is determined when a health care provider inspects a baby’s genitalia; the infant’s sex is assigned, without the expectation of ambiguity.

**Gender** is the social construct of being a man, woman, neither, or both, and can vary by culture.

**Gender Identity** is a person’s internal sense of their gender. It’s how we identify themselves. We may identify as a man, woman, as neither, or as non-binary – which describes any identity that doesn’t fit neatly into the categories of man or woman.

**Cisgender** describes someone whose gender identity matches the sex they were assigned at birth. This term comes from chemistry, where “cis” means “same.”

**Transgender** or trans describes a person whose gender identity differs from their sex assigned at birth, and it is defined by the person’s present identity. As an example, a transgender woman is someone who currently identifies as a woman but was assigned male at birth. In the US, transgender can also be used as an “umbrella” term to encompass the other gender identities.

**Gender Non-Conforming** refers to a person whose gender expression is not consistent with the societal or cultural norms expected of that gender. People who are gender non-conforming do not follow other peoples’ ideas or stereotypes about how they should look or act based on the female or male sex they were assigned at birth.

**Genderqueer** is used to describe people who don’t identify as a man or a woman; they do not subscribe to conventional gender distinctions. It may also be considered a catch-all term for gender identities other than man and woman, thus outside of the gender binary. It can also be a term that separates someone from the heteronormative majority.
Intersex is a term refers to person born with a combination of male and female biological characteristics, such as chromosomes, hormones, or genitals, that make it difficult to assign their sex as distinctly male or female. For example, person might be born with a vagina, appearing to be female on the outside, but having mostly male-typical anatomy on the inside. There are a number of different conditions that can result in someone being intersex. Intersex is distinct from and generally not connected with being transgender, and most intersex people do not identify as transgender.

Cross-dressing generally refers to people who wear clothing typically associated with the sex different from the one they were assigned at birth. Individuals who regularly engage in cross-dressing may have a more fluid sense of their own gender presentation, and do not necessarily feel limited to presenting themselves strictly in accepted binary (male or female) attire.

Transvestite is a dated term used to refer to someone who cross-dresses; it is no longer commonly used in the U.S. and is considered offensive by many people. Transvestites are commonly used across South America. Peru and Brazil use transexuales to broadly refer to transgender people. Travesti is also often used across South America and shouldn’t be confused with the term transvestite. In some South American cultures, a travesti is a person who was assigned male at birth and who now has a feminine gender identity.

HIV Diagnoses Among Transgender People in the U.S. by Race/Ethnicity, 2009-2014

In the U.S. and globally, there is a high burden of HIV in transgender communities, particularly among transgender women of color. Stigma and discrimination are key factors driving this.
HVTN 705/HPX2008 is an HIV vaccine efficacy trial, designed as a proof of concept for a combination vaccine regimen. It completed enrollment on May 28, 2019, and now continues in follow-up.

The study aims to show the level of efficacy that can be provided by a combination of two different HIV vaccine candidates. An Adenovirus Vector Vaccine, Ad26.Mos4.HIV, is given at two timepoints, followed by two administrations of a combination of Ad26.Mos4.HIV and a protein vaccine called Clade C gp140. The study will enroll 2600 young women at 24 sites in 5 sub-Saharan countries: Malawi, Mozambique, the Republic of South Africa, Zambia, and Zimbabwe. 1300 will receive the combination vaccine regimen, and 1300 will receive placebo. The women enrolled in this study will be healthy, HIV uninfected volunteers at risk of HIV infection.

Several studies have evaluated the different components of this regimen, and pre-specified “Go/No-Go criteria” were met before the study was started. The results are expected to inform the HIV vaccine field and the HIV prevention field at large.

The HVTN 705/HPX2008 study represents an ongoing collaboration between the HIV Vaccine Trials Network (HVTN) and multiple partner organizations. The study is sponsored by Janssen Vaccines and Prevention B.V., part of the Janssen pharmaceutical companies of Johnson & Johnson, with co-funding from two primary partners, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Bill & Melinda Gates Foundation. Other partners providing support include the U.S. Military HIV Research Program at the Walter Reed Army Institute of Research, US Army Medical Materiel Development Activity (USAMMDA), and the Ragon Institute. The development of this study was an extensive, multi-stakeholder effort. The partners are all motivated by the continued impact of the HIV epidemic despite recent advances in HIV prevention and treatment. We are inspired by the potential contribution an effective HIV vaccine could have on the devastating pandemic.

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Table 1. Study schema
The first participant enrolled in this study on 9th November 2017, with participants enrolled at 21 active research sites. Enrolling such a large number of participants requires tremendous work within the communities and as such, community engagement efforts began months before the trial opened, underscoring the HVTN’s commitment to community engagement. These early efforts included trainings and stakeholder engagement meetings, as well as additional local and regional activities designed to engage communities early on in the trial development and implementation phases to ensure community support, and a degree of ownership, of the study. Community engagement activities have remained strong throughout the ongoing conduct of the study. HVTN staff meet with the sites’ community engagement teams regularly to provide support that is focused on working in the communities, concentrating on community education and effective recruitment and retention strategies.

A team of dedicated laboratory, statistical, data management, core operations, and clinical staff based in the participating countries, the US, the Netherlands, Belgium, and beyond are supporting committed community educators, recruiters, CAB members, clinicians, data managers, laboratory technicians, investigators, clinic coordinators, and many others at our fantastic study sites. Together with our inspiring study participants, the HVTN 705/HPX2008 team hopes to find an effective HIV vaccine, moving us all toward an AIDS-free future.

Dr. Philipp Mann is the HVTN Protocol Team Leader and Carrie Sopher is the HVTN Clinical Trial Manager for HVTN 705/HPX2008.
A Community Launch Event for the Imbokodo Study

By: Blossom Makhubalo and Thandiwe Papalagae, Klerksdorp CRS, Klerksdorp, South Africa

The launch event for the Imbokodo study drew 123 young women, and was held at the Knowledge Centre in Kanana on the 29th of January 2019. The area where the event was held is one of our high transmission areas, which is characterised by high rates of unemployment, poverty, gender-based violence and gangsterism.

The purpose of the event was to make the community aware that HVTN 705/HPX2008 Imbokodo Study is being conducted at our trial site, and to get input from the community on questions they may have about the study and how we are conducting it. Our CRS Principal Investigator, Dr. Craig Innes, addressed the community members who attended the event and provided information on the trial.

The community members in attendance felt valued, and not only engaged when there is a need for recruitment. The women and their male partners who accompanied them to the event were empowered as well. It was great to see the men interested in issues that involve women.

We had stakeholders from the Department of Health, The Matlosana Youth Centre, the Crime Prevention Unit from Mahikeng, the local Pastor from Kanana, and the Ward Councillor. The site has maintained good stakeholder relationships, and strengthening of stakeholder relations is an ongoing process. Multi-sectoral stakeholder collaboration is key in how we work with our communities and stakeholders.

Dr. Innes focused his presentation on giving an overview of the trial. The community members showed interest and they were interacting. Dr. Innes addressed all the questions that were raised by community members. Two of our CAB members attended the event and explained the role of the CAB to the community.

Questions that were asked included:

- Why is the study not taking older women?
- How will the researchers know that the vaccine is working?
  Do you have to sleep with a person living with HIV?
- Are people paid for being in the study?
- Can the person who received the vaccine transmit it to partner?

The community members also asked health-related questions about stroke, asthma, cancer and diabetes. Mr. George Mokhutswane, a professional nurse from the Matlosana Youth Centre, addressed these questions raised by the community. We also had entertainment for the attendees with a DJ and dancers.

The take-home message was, “Moving together toward an HIV/AIDS-free South Africa: only by working together can we achieve this.”

Blossom Makhubalo is the Community Engagement Manager and Thandiwe Papalagae is the Recruitment and Retention Team Leader at the Klerksdorp CRS, in Klerksdorp, South Africa.
STAND UP TO HIV!
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South Africans Do Not Have the Luxury to Claim That They Are HIV/AIDS Fatigued

By: Blossom Makhubalo, Klerksdorp CRS, Klerksdorp, South Africa

During one of our community engagements events, we heard a statement from one of the male attendees, "Are we not HIV fatigued? We are always hearing about HIV all the time."

My response (being the social worker that I am): "Until we win the fight against HIV/AIDS we can never have the luxury to claim that we are fatigued."

Not while adolescent girls and young women in South Africa are at the greatest risk of HIV infection. In South Africa, HIV prevalence in women aged 15-24 is nearly four times greater than men of that same age. More than 120,000 women in this age group are thought to become HIV positive every year. Therefore, today more than ever, we can never be fatigued when 2000 young women in South Africa are infected with HIV weekly.

Perhaps we are fatigued by the way HIV prevention awareness is conducted, and more innovative ways of providing HIV education are needed.

The majority of women who are at risk of HIV are disempowered, and a range of socio-economic circumstances contributes to placing them at risk. Now more than ever, we need to escalate our efforts in the fight against HIV/AIDS and ensure that these prevention messages and tools reach our women, and are tailored for women in our communities. It is important to understand the factors that place women at risk in order for us to tailor our prevention strategies to meet their needs.

What places women at risk

Women are more vulnerable than men are to HIV infection through sexual intercourse (Rodin & Ickovics, 1990. Studies have shown that heterosexual transmission from men to women is two to four times more likely than from women to men. Major factors that make women more vulnerable to HIV infection include the larger mucosal surface area in women that can be exposed to the virus (Cheryl De La Rey, et al, 1997: Contemporary issues in Human Development, A South African Focus). Rates of infection are higher among younger women than among older women. One reason for this could be that the immature cervix and relatively low vaginal mucus production in young women presents less protection against HIV (WHO, 1994). One could argue that when it comes to our physiological vulnerability to HIV Infection, all women are created equally.

Where the "playing fields" for women are not equal is our socio-economic circumstances. For many women in South Africa their socio-economic circumstances place them at a greater risk for HIV infection. South Africa remains one of the most unequal societies in the world according to the World Bank. Many South African women have not yet achieved economic freedom, and many women still depend on their male partners for financial support, placing them in a disempowered position. Women still occupy powerless positions in South African society, often dictated culturally. Unequal power dynamics between men and women still exist today, and are exacerbated by patriarchy.

What my 15 years as a practising social worker have shown me is that a powerless woman is likely to be less sexually assertive, and may find it impossible to negotiate condom use even when she knows her partner has many other sexual partners. Men enjoy more power, and their positions are reinforced by gender discrimination and inherent traditional roles. Men are usually the dominant partner in the sexual relationship, and that position is even more amplified if the man is the financial provider. Women are socialised to be "good wives" and never question their partners. When a young woman seeks advice from older females in the family, her unhappiness with the relationship is downplayed and she is told, "Yamazela," meaning to endure.

South Africa is also characterised by high rates of gender-based violence. A woman may be beaten for refusing sexual advances or recommending condom use. According to Statistics SA, one in five women experienced violence at the hands of an intimate partner. The rape of South African women is among the highest in the world.

Women at times feel that they have no option but to stay with their abusive partners. "Where will I go?", lack of family support, and extended families who are facing their own struggles and cannot afford to financially support women, all contribute to women feeling...
trapped and staying in an abusive relationship. When a woman does decide to leave, usually the family encourages her to return to her abusive partner. The longer she remains in an abusive relationship, the greater the risk for HIV.

We cannot win the fight against HIV if we do not understand and address the factors that place women at risk. We should engage with young women when designing HIV prevention strategies. Just providing HIV education and prevention tools to women is not enough. We need to address the structural factors that place women at risk in order for prevention programs to be successful and impactful.

Until we have overcome HIV in our beautiful country, we can never be fatigued.

Blossom Makhubalo is the Community Engagement Manager at the Klerksdorp CRS, in Klerksdorp, South Africa.

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- Cheryl De La Rey, Norman Duncan, Tamara Shefer, Ashley Van Niekerk. (1997). Contemporary issues in Human Development, A South African Focus

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AMP Participant Experiences

Interview With a Study Volunteer

By: Brooke Willis, Case Western Reserve University/AIDS Clinical Trials Unit, Cleveland, OH, USA

Hello! I’m Brooke Willis with the CWRU AIDS Clinical Trials Unit and I’m talking with my friend Robin, a study volunteer.

Robin: Hi! Glad to be here!

BW: I wanted to talk with you about your experiences volunteering for clinical trials, and how that has gone for you and how satisfied you are with the process. Tell us a little about your background.

Robin: Well, it’s been about 6 or 7 years since I heard about the studies. The way I first heard about it, I think was on Craigslist or an employment ad. I did one study that wasn’t working so it was stopped, and I learned I got the placebo. Then I heard about the next study from you and this one has been going a lot better. Honestly, the second study feels safer than the first one. The thing about the first one that was troublesome to me was the idea that there were synthetic pieces copied from HIV in the injections, and even though it was safe, it sounds so scary. I didn’t tell anybody about it, because I didn’t want people to be, like, “What are you doing?” But the experiences at the clinic have been fantastic. The doctors are all very good and the nurses have always been very interested in me and nice and wanting to know how I’m doing.

BW: So, tell us more about your experience in terms of being treated with respect and courtesy, especially as a trans person. How do you feel about the cultural competency of the staff - the doctors, the nurses, even the receptionist? How do you feel about that whole experience?

Robin: The whole experience has been excellent. Everyone referred to me with the correct gender and were interested about what I was going through but didn’t pry. There was one receptionist who said something inappropriate once, but I mentioned it to my nurse and she said something to her and it’s never been an issue since, so out of everyone in the building there was just that one instance, which is a really good track record.

BW: That’s great to hear that because we certainly know that trans people in general are not treated very well by the broader community. We like to think that we’re doing a good job but we want to check in with folks and make sure that’s true. So, is this something that you feel you would recommend to family and friends and colleagues?

Robin: Yeah, I actually have, to people I know, saying hey, you could try this. But you’re always careful with a study, because you never know how people will react, so I’m not vocal about it. Even though I’m not embarrassed to be in a study, I don’t know how that person would react, so I usually keep it to myself.

BW: Do your family and friends know that you’re participating?

Robin: No, I don’t really put that information out there, especially if they don’t need to know. But I remember being at a dinner once and people brought up PrEP and things, and I told them about what HIV research is being done right now, so people know what other avenues were being explored. I was happy to be able to share that information with people. And just from being in this study I learned a ton about PrEP and have been able to tell people about PrEP, which is a nice benefit to be able to spread that information around, because if you’re not in a high-risk community, you just don’t know about it.

BW: So just by interacting with the nurses and doctors, you feel more medically competent about prevention.
Robin: I do; I learned a lot about HIV. You get to learn about the ignorant ways that people still view HIV. I learned some of the science of what the studies are attempting to do, blocking the ways that HIV attaches to immune cells.

BW: Have you met other folks in the clinic who are transgender? Do you know if there are other transgender participants?

Robin: I don’t know that there are. I’ve never seen anyone, and it’s not something I would ask the nurses. But I think it’s important for a trans person to be in the study, because to see that you’re thought of, not forgotten about, so that part is great. And then, a trans person is going to come across with different aspects of life than a gay or lesbian or straight person does, so getting all these people in a study, you get a better study, really, because you have a broader sample of everybody, so I think that’s important.

BW: Well, Robin, we are very grateful for your participation, and we do want people to know that we’re always enrolling transgender people for our studies, with some exclusions depending on the study. We’re trying to be very welcoming of the entire LGBTQ community in our studies and we hope that you will consider volunteering in the future if you are eligible. Thanks again, Robin!

Robin: One more thing: When I first started to go and do the study, honestly I needed money, but as I learned about what it was we were doing, it became a thing where I felt like I was doing something good, where the money wasn’t important after a while. I was like, wow, we’re actually changing people’s lives. It was like that shift, I think, where everything there felt so valid and important, so that’s been nice, too.

BW: People have different reasons, different motivations to join a study, and it doesn’t really matter to us whether it’s the money, the medicine, or altruism and wanting to advance the cause of ending HIV. We just are so grateful for your volunteering, so thank you very much, Robin.

Brooke Willis is the Community Educator/Recruiter for the Case Western Reserve University CRS in Cleveland, Ohio.
Never Give Up

By Felipe Vilcachagua and MaR León, IMPACTA CRSs, Lima, Peru

Stephanie Peña, a participant in the AMP study at the Impacta-Barranco site and an Impacta CAB member, shares with us how she dealt with discrimination and violence for being a transgender woman, and her experience as a clinical trial participant.

Stephanie was born 33 years ago in Quillabamba (in the Cusco province of Peru). From an early age, she broke stereotypes. “When I was a girl, my gender identity was not so marked as relating to women - in a country like Peru - with cooking and dolls. I liked soccer, I liked cars... but I also liked dolls. I cried about playing soccer, but I also liked being very feminine.”

At the age of 6, she knew that she was different. She used to take baths with underwear, so as not to see her sexual organs. Her childhood was peaceful, thanks to the care of her father. However, she knew that being different “was a sin” when she went to the city of Cusco, a cosmopolitan but conservative city. “Homosexuals, transgender women and lesbians will not enter the Kingdom of God”, “Lower your pants. Let’s rape her...” - the previous phrases marked her life. Her eyes redden when she remembers that she suffered severe depression, to the point of trying to commit suicide.

This is me

When she became a legal adult, she came out of the closet with her parents as bisexual so that it would be “less painful for them”. The lack of transgender role models and the little information she found forced her to investigate the transgender world on the internet. This is how two trans YouTubers became her “mothers,” and were the source of inspiration for Stephanie to create her own channel on YouTube. Sometime later, Dr. Javier Salvatierra of the Impacta-San Miguel CRS guided her in the use of hormone therapy as part of her gender transition process.

Stephanie is one of the few transgender women visible in Peru who has a degree in psychology. She worked in a health center and in a public university, where she endured the heteronormativity of her co-workers. She did not give up. Currently, she works as a psychologist in a non-governmental organization aimed at the gay and transgender population, which receives funding through the Global Fund. “I’m helping people who at some point felt lonely like me.”

Since 2016, her YouTube channel “Teffy Lu,” has become her main project, whose videos have exceeded 9000 visits. Through this channel, she shares her personal experiences and knowledge of psychology; explains the transition process of a transgender woman; coming out of the closet; hormone therapy; sexual relations for transgender women; and other topics such as depression.

IMPACTA: I feel at home

She remembers how she started her participation in clinical trials. Almost all her youth, she thought she lived with HIV. But through the TRANS PREP project from IMPACTA, she had her first HIV test, learned she did not have HIV, and learned about HIV prevention strategies. At the end of TRANS PREP, IMPACTA recruiter Lucho Castro talked to her about the AMP Study and that’s how this story begins. She initially accepted so she could have the periodic HIV tests, but through the study she learned more about her sexual health and how to prevent HIV. The attention of all the professionals at the site influenced her personal self-care.

“At IMPACTA I feel at home. From Martin the patient advocate, the doctors, nurses, recruiters and tutors: they all have been very respectful to me. They treat me like a friend, as if we have known each other forever. Now I take the issue of HIV more seriously. I think it’s important to take care of yourself, to love your life.”

With her participation in the AMP Study, Stephanie has shown a lot of responsibility in the fulfillment of her goal to educate others, and she has shared information about the trials at IMPACTA with her friends and peers. This attitude, combined with her professional experience, made her eligible to join the Community Advisory Committee. For her, the CAC is a space for professional growth and an opportunity to contribute to the prevention and control of HIV and TB in different populations. “Through the CAB we can contribute to science, and care for all populations: gay, transgender and cisgender, without distinctions.”

Now Stephanie counts the days to experiencing her new life with a new identification document where her chosen name is recognized. She dreams of being listened to through her channel on YouTube, and she continues to contribute to achieving new HIV prevention strategies in her roles as a trial participant and member of the CAB. “The key is not to surrender: love and take care of oneself.”

Felipe Vilcachagua is the Retention Coordinator, and MaR Leon is the Head of Community Involvement at the IMPACTA Barranco and San Miguel CRSs in Lima, Peru.
Out Role Model: Shawn Reilly

By Shawn Reilly, Community Advisory Board Member, Vanderbilt University, Nashville, TN

When it comes to organizing for social justice, it’s rare to find anyone more motivated and gifted at inspiring others to use their voice for positive change than Shawn Reilly. Shawn was most recently a principal organizer for the Nashville Women’s March, which attracted hundreds of participants despite rainy weather.

“I enjoy putting together events and demonstrations that support transgender people, abortion access, and queer youth,” Shawn explains.

Shawn also serves on the board of GLSEN Tennessee (Gay, Lesbian and Straight Education Network), an organization dedicated to creating safe schools for LGBTQ youth. In that role, Shawn leads high school students across the state in activities that teach self-advocacy skills.

Most recently, Shawn’s students worked to get a proclamation from Nashville Mayor David Briley and a resolution from Metro Nashville’s City Council to declare Jan. 21-25 No Name Calling Week, an event dedicated to end name-calling and bullying in schools.

Shawn has been a vital member of the Vanderbilt community for several years. They have a Bachelor of Science in Human and Organizational Development with a concentration in Health and Human Services. Shawn is now a Masters of Education candidate in Peabody College’s Learning and Design program and will complete that degree in May, 2019.

As if that weren’t enough, Shawn took on an important role this past fall as the coordinator of the Trans Buddy program, an initiative of the Vanderbilt Program for LGBTQ Health.

“Through my position, I help transgender patients navigate the healthcare system. I work with an incredible team of volunteers who answer questions, give referrals, and attend appointments with transgender people who need extra support when trying to access healthcare,” Shawn explains.

Just this past weekend, Shawn organized and facilitated a training for 18 new volunteers, which is the largest enrollment the program has had since its founding more than four years ago.

Shawn’s been recognized widely for their scholarship, as well as for their volunteer contributions. Shawn is a Davis-Putter Foundation Fellow; Peabody Dean’s Scholar; Citizen’s University Civic Seminary Fellow; Posse Scholar; and a Youth+Tech+Health Youth Advisory Board member. They have also received the Peabody Faculty Council Award for Equity, Diversity, and Inclusion; the Lori Groves-White Award for Advocacy and Courage; and the Nashville Pride Rising Star Award.

It’s easy to be inspired by Shawn’s passion for others, yet Shawn credits several role models as their source of inspiration.

“Chris Purcell, Director of Vanderbilt’s Office of LGBTQI Life, has been an incredible possibility model and mentor for me,” Shawn says. “Not only has he worked with me to develop professionally, he has also supported me through personal and academic growth.”

“Beyond that, my young people are the ones who inspire me. It is their courage that gave me the space to come out, because of them I came out, and I am inspired every day by their ability to be their full selves at such a young age.”

Shawn identifies as both queer and genderqueer. They think it’s important to be out professionally “because young people need possibility models for what they can be. By being out at work, I am showing the world that I am not afraid or ashamed, and I am creating space for current and future generations to be their full selves.”

Shawn’s advice for young people seeking careers in healthcare is straightforward. “Look for organizations and resources where you can explore the healthcare industry in an affirming way. Apply to be on youth boards, for fellowships, and for programs. Organizations like Youth+Tech+Health and Advocates for Youth offer incredible opportunities for young people to engage in progressive healthcare work in their own community.”

When Shawn has downtime, which is rare, they enjoy graphic novels and spending time with their cats, Frankenstein and Camus, who they refer to as the queens of their household.

Link for No Name-Calling Week: https://www.glsen.org/no-name-calling-week
Getting the Right Test for HIV

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/

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.

Why don’t standard HIV tests look for actual HIV?
Standard HIV tests that look for antibodies quick, reliable and affordable. Tests that look for the virus are expensive and not commonly used for an initial diagnosis.

Getting the Right Test for HIV

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.
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.
Healthcare Experiences and Being Transgender

By: Jennifer Barnes-Balenciaga and Marquise Vilson

Physicians and other medical staff must ensure that when a transgender person decides to undergo hormone replacement therapy (HRT), that those initial interactions result in the person feeling comfortable, heard, and affirmed. This choice is considered a luxury in our community. Positive and affirming healthcare experiences need to become routinized, and to do that requires staff to be well trained in cultural competence and the nuances of gender identity. Engaging in healthcare is not a traditional practice for many persons of color, let alone transgender persons of color. Medical staff must ensure that the use of proper pronouns and/or preferred names are standard practice among all staff, including those who conduct intake processes, and that medical records and healthcare databases are updated to include this information in a front-facing way as well. Past gender history information should not be accessible to all staff, just those that need to know the information to provide care to people. Routine and regular trainings with medical staff on appropriate interactions with patients and clients, and providing medical staff simple but effective ways to absorb the training and information would be most effective.

At present, there is little healthcare information specific to HIV prevention and/or treatment adherence for trans-masculine bodies. The usage of hormone replacement therapy causes thinning and dryness to the lower region (vaginal mucosa), so having penetrative sex puts trans men at a higher risk for HIV than cis women who engage in the same kinds of sexual practices/behaviors. Medical professionals have to better understand the trans-masculine community, and have more dialogue about not only their bodies but also their sexual practices/behaviors, and their sexual partners.

In my experience as a trans-masculine person of color, it has been rare that medical professionals have spoken to me directly about HIV beyond pre-test counseling before an HIV test. Often times, studies have not involved or included people with trans-masculine bodies, and it is mostly assumed that trans men aren’t at risk. In a recent study from the CDC, 361 trans men were newly diagnosed with having HIV, and of the 361 men 84% of those diagnoses were men of color; 58% were Black (15% were Latino, and 11% were listed as “other” making them ‘non-White’). There’s a huge gap between the HIV medical community, clinical trials and study groups, and the trans-masculine community.

Healthcare Experiences and Being Transgender

Special Feature

By: Stephaun E. Wallace, Ph.D.

An Incomplete Toolbox: We Truly Have More Work to Do

For more than 3 decades, HIV/AIDS has continued to impact individuals, families, and communities in the United States, and around the world. From a socio-ecological lens, the factors that influence HIV incidence are multifactorial. In addition to the behavioral factors that contribute to direct acquisition and transmission, social and structural forces 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 also converge to create the conditions that make acquisition and transmission more likely. From a structural perspective, how individuals, communities, and populations access health services, including the availability of services, costs, methods of access such as insurance, and language considerations also contribute to the direct acquisition and transmission of HIV. Among Black and Latinx populations, and specifically Black and Latinx gay, bisexual, transgender, and queer persons, cultural and systemic implicit and explicit biases about race, sex, sexuality, gender norms, and others permeate throughout the medical industry influencing attitudes and behaviors toward these groups which undermine the quality and accessible care they could, and should, be receiving to maintain optimal health. Direct HIV transmission and acquisition can be addressed, on some level, by the current tools we have in the HIV prevention toolkit; however, we have no tools in the tool kit currently to address the determinants of health that create and influence the conditions in which HIV transmission and acquisition occurs.

For these reasons and many more, I do not believe that we will be able to end the epidemic utilizing the current array of approved HIV prevention options. Merely bringing these technologies to scale does very little to address direct acquisition and transmission of HIV, especially if these activities are not paired with interventions that also address the conditions mentioned earlier that increase their likelihood. Of course, the uncomfortable truth that often goes unspoken is that even if the current approved technologies were scaled up to ensure 100% access and coverage, many people would still neither accept nor take them. There are research products in the pipeline that if, and when, approved, will offer an expanded “buffet of options” to individuals and communities, such as an effective globally-deployed HIV vaccine which is one of our greatest opportunities to end the HIV epidemic. These studies require clinical trial support and participation by diverse communities. We know that there are populations underrepresented in HIV research, and these are also the same populations...
that are disproportionately impacted by HIV and other adverse health outcomes, and the same populations who currently have significant drop-offs on the HIV care continuum, and many of the same populations with lower uptake of PrEP. While the research enterprise deploys countless research studies, and billions are spent to investigate technologies and biomedical prevention strategies to respond to direct acquisition and transmission of HIV, we must also continue to simultaneously ask critical social and behavioral science questions to guide our efforts and our pathway. Some of these questions include:

• How do we arm people with the appropriate and accurate information to make informed decisions about their support of, and possible participation in, these studies (particularly for persons who are not engaged in medical care or prevention services and have less access to accurate HIV and medical information)?

• How do we address historical trauma in communities of color, particularly among Black, Latinx, and Native American persons that have resulted in generations-old mistrust or distrust in the medical establishment, which contributes to adverse health outcomes in these groups?

• How do we have conversations about sex, sexuality, and sexual health that center desire, intimacy, and connectedness, particularly for Black and Latinx gay, bisexual, transgender and queer persons?

• How do we develop studies that pair the implementation of biomedical HIV prevention technologies with metrics to assess how individual-level factors (e.g., attitudes and beliefs about research, HIV, and science) and community-level factors (e.g., the physical environment, stigma, discrimination, healthcare access/utilization) may serve as an implementation facilitators or barriers?

• How do we genuinely center the diverse lived experiences of Black and Latinx persons, including Black and Latinx gay, bisexual, transgender and queer persons, as we develop HIV prevention strategies, messages, and interventions?

Some of these questions have been responded to in the literature, but we must continue to ask these questions if we want to address the HIV epidemic, and the general health and wellness needs, among Black and Latinx populations. In my professional experience, centering communities utilizing a community-based participatory or action model has been at the heart of my work. In research endeavors, my research commitment, inquiry, and interests are situated at the intersection of public health and social justice with an intentional focus on the health of African Americans and LGBTQ persons, as well as HIV prevention and treatment focused on key populations. Part of this ethos rests with the knowledge and belief that individuals and communities have inherent value and assets, by which they derive resiliency, strength, courage, and determination to persevere even in the most oppressive environments. We have come very far in the last 3 decades in reducing new HIV cases and slowing disease progression globally, but many places and communities remain heavily burdened by HIV and by the conditions that facilitate HIV acquisition and transmission, so the work must absolutely continue. We are not at a place where we can, in good conscience, say we have all the tools necessary to end the HIV epidemic, because the epidemic is much more than just the actual virus; it represents the conditions and environments that support its transmission and acquisition. It represents the systems of oppression, classism, racism, misogyny, sexism, patriarchy, colonialism, and subjugation that for decades, centuries, and longer, have permeated societies, cultures, board rooms, and living rooms. Biomedical HIV prevention research has laid a path toward ending the epidemic, and many biomedical advances have supported this journey, but behavioral and social science research must be paired equitably to ensure the data exist to aid in addressing ecological, systems, implementation, and delivery considerations.

Stephaun E. Wallace is the Senior Community Engagement Project Manager at the HIV Vaccine Trials Network (HVTN) and a clinical assistant professor in the Department of Global Health at the University of Washington. He has a Ph.D. in public health with a specialization in epidemiology.

*Disclaimer: The commentary and opinions expressed here are the author’s own, in his professional capacity. The author’s opinion does not represent the official position of the HIV Vaccine Trials Network (HVTN) or the University of Washington. This article was originally published on TheBodyPro (https://www.thebodypro.com/article/ending-the-hiv-epidemic-will-take-more-than-medicine), which informs and supports people whose work intersects with the HIV/AIDS epidemic. We have reprinted it with their permission.
I started working in the lab with the old AIDS Vaccine Evaluation Group in March of 1992 under the leadership of Dr. Barney Graham and Dr. Peter Wright. The AVEG later became the HVTN. Other leadership has included Dr. Paul Spearman, Dr. Spyros Kalams, and Dr. Greg Wilson. My role in the lab was to process specimens from the clinic. Over the years this included extracting PBMCs (white blood cells), processing serum, saliva, semen, and cervical and rectal washes, for example. I was also responsible for shipping specimens to the HVTN Core labs and to the specimen repository, ordering supplies, doing routine maintenance and cleaning of equipment, defrosting freezers, etc. – not fun jobs, but vital to the performance of the lab. Being error-free is vital to the success of the Network.

I felt that I couldn’t expect our participants to be involved if I wasn’t willing too. I had wanted to be a participant in one of the trials. My husband was pretty old-school and didn’t want me to be a study participant – fear born from ignorance! So, I waited until after his death to enroll. I was one of the first two enrollees in HVTN 032*, which lasted for 18 months. It was informative to me to see how the clinic staff conducted “business” – so professional! This particular study involved injections in both arms and at least thirty tubes of blood drawn, which was done as painlessly as possible. I was pampered and was able to get the good juice to drink. The clinic staff have changed over the years, but they always put the participants first. I would have been willing to do another study, but I received the study vaccine, not the placebo, so I wasn’t eligible. What I could do though, was get involved with the CAB. I was interested in the CAB almost from the beginning.

Later, at an HVTN meeting in Seattle, where I was scheduled to give a talk to laboratory personnel about how to conduct error-free shipping, it was suggested that I attend the CAB sessions happening during the meeting. I was so impressed with Mark Hubbard (Vanderbilt CAB member) and the work that was being done that I decided to become a member of our local CAB. So began my 20+ years of serving on the Vanderbilt CAB.

I have learned so much being on the CAB, especially about the stigma that people living with HIV have to deal with on a daily basis, and how having an HIV diagnosis affects their health. In turn, I have been able to interact with my community of friends and answer questions and impart what knowledge I have.

CAB engagement in the community is vital, and trial sites are held accountable by their CABS. This is why it is so important for each of us to read consent forms for new trials. Safety for trial participants is of the upmost importance, and it is our job to do too. Community engagement at events like the AIDS Walk should always have CAB members involved. We have a story to tell and can help identify new study participants to enroll. CAB members and research staff are responsible for the implementation and launch of studies, and the conduct and closure of these studies.

For our CAB, we need to broaden the diversity in our membership, and continue to have a strong commitment to the goals of our CAB. Working together, vaccine advocates and researchers can expand the status quo. An example is advocating for PrEP. We need to be prepared to answer questions from the community such as:

- How are trials conducted?
- What are the eligibility requirements?

We also need to be able to engage the concerns of skeptics. Our goal is to have a success story, laying the foundation for new studies and fewer HIV infections.

*Policies have changed since this study, and employees are no longer allowed to be participants in our studies.
Seventeen years ago there were many cases of HIV in Iquitos, Peru, and very little information on prevention and treatment. Although the HIV incidence has not changed much in Iquitos, there is hope that prevention and research will yield concrete results.

Association Civil Selva Amazónica (ACSA) wanted to contribute to the health of the population of the Loreto region, specifically with infectious diseases and particularly HIV infection control and prevention. For that reason, Dr. Martin Casapía Morales, Principal Investigator of ACSA, developed a local research site to implement studies that contribute information to prevent HIV infection. The site also supports the efforts of Dr. Jorge Sanchez, who leads a research center in Lima.

The first study we conducted was preparatory to assess the incidence of HIV locally, given the high number of cases reported in Iquitos which represented a significant public health problem. In this preparatory study, we demonstrated that we were able to meet people and enroll them in a research study. This was important because Iquitos has the third largest number of new HIV cases in Peru, following Lima and Callao.

With formal training as a specialist in infectious and tropical diseases, Dr. Martin Casapía Morales has held the roles of Investigator of Record and Principal Investigator, and is now the Clinical Research Site Leader. The ACSA site started by conducting basic studies with small numbers of participants, but today it manages studies with 300 to 600 participants in different clinical trials.

Dr. Martin Casapia Morales started working as a general practitioner in Iquitos, initially seeing patients with HIV at the Hospital Cayetano Heredia in Lima. From there, he gained experience in the management of these patients and then ventured into HIV prevention. Dr. Casapia Morales believes, “Patients should not die, because we have the tools to detect and treat HIV early.”

Working with the HVTN is a great experience because it is an organized, systematic way to develop and implement clinical trials. “The Network has given me a number of opportunities to learn a lot in the clinical trial field. In addition, I recognize that we have the opportunity to interact and learn about new research experiences with diverse researchers, including those who direct the Network, and receive permanent contributions from them, which gives us security for good development in our work,” he emphasized.
My decision to join the HVTN was inspired by the need to serve with significance. In my country of birth, South Africa, there is a saying, “umuntu ngumuntu ngabantu”. Translated, this saying means a person is a person through or because of other people, or that you are who you are because of how you relate to others around you. Serving communities with significance, in my opinion, is about making time to see the world through their eyes. In my role at the HVTN, I serve the information needs of global communities and the media about the journey to find a safe and effective HIV vaccine.

My professional journey began as a communication and reputation strategist in corporate South Africa. Teaching media and communication management to undergraduate students was one of my most rewarding experiences. After one year of teaching I joined the second tier of South Africa’s government as a “fixer” and political communication strategist. The opportunity catapulted my career into global communications when I led the communication strategy for shale gas extraction for the Western Cape Government, and served on the FIFA World Cup Crisis Communications team.

My exposure to the field of medical research started in December 2013 when I accepted the responsibility of rebranding South Africa’s premier medical research organization, the South African Medical Research Council (SAMRC). Through the eyes of many leading researchers and investigators, I came to understand the information needs of communities and stakeholders for more than 12 research priority areas such as non-communicable diseases; communicable diseases; gender-based violence; violence, peace, and injuries; health systems; tuberculosis; and stress and anxiety disorders, among others.

I have a consistent observation that every chapter of my career has afforded me the opportunity to serve the information needs of a diverse audience. To me, serving with significance means placing people at the heart of each communication strategy and plan. Being in service to the HVTN is ultimately being in service to each study participant, their communities, and all stakeholders who make the search for a safe and effective HIV vaccine possible.

The HVTN is not only about changing lives, it is a game-changing network. This is a brand that inspires hope!
Jerry Ockfen-Copeland
Conference & Events Manager, HVTN Core, Seattle, WA, USA

My first connection to HVTN was about 19 years ago when I enrolled in a study at the Seattle HVTU.

Seven and a half years ago I was looking for a new job. My partner was Gail Broder's hairdresser and they got to talking about my work experience - the rest is history. A few weeks later I was hired as an HVTN Travel Coordinator. Five years ago, I took on the role of Conference & Events Manager and I love its challenges. I often boast about the teamwork that goes on within our network. I’m proud to support the efforts to find a vaccine for HIV.

Shawn Demmons, MPH
CAG Member, Bridge HIV CRS San Francisco, CA, USA

HVTN Global Community Advisory Board Representative to the Transgender Working Group
Capacity Building and Assistance Provider, UCSF Center of Excellence for Transgender Health

When the HIV/AIDS crisis emerged in the early 1980s, there was little education available about the disease except that death was certain and imminent if you acquired the virus. In the early 1990s, that’s exactly what started happening to the guys in my circle of friends. It really hit home for me when my good friend Emmett, seemingly out of nowhere, died from AIDS-related complications. Stigma and shame prevented Emmett from telling any of us he was sick or letting us support him. A few years after his death, I attended a conference where I learned about HIV treatment. This motivated me to become an HIV treatment advocate. Unfortunately, by then Tweety had died, Kevin and Derrick were very sick, and my other gay friends remained at risk. That was the impetus for my work in HIV treatment and prevention. Throughout my career I’ve worked with people affected by and living with HIV in various capacities.

In 2017, I was recruited to join the Bridge HIV Community Advisory Group (CAG). As a Black trans man and a public health professional, I know the importance of including the voices of marginalized communities in research. Transgender people are grossly underrepresented in research across illnesses, and it’s important to me that this change. Sharing my expertise in trans health and community organizing to inform HVTN research studies is one way toward that end. I believe the first step to inclusion of trans people in research is education. As a CAG member, I’ve had the opportunity to participate on panels, present at community forums, and provide technical assistance to research scientists about the HIV prevention needs of transgender people. But my absolute favorite thing about being a CAG member is being able to share accurate up-to-date information about things like PrEP and U=U (Undetectable = Untransmittable) with ordinary people in everyday situations.
In the decade of the 90’s and the beginning of 2000, my life changed significantly, but I didn’t understand why. Little by little I was losing friends from my very close environment, victims of AIDS. An epidemic had arrived in Peru without warning in 1983.

My life, and those of many of our generation, were dying or in mourning at every moment. We began to schedule constant visits to hospitals, homes, to see friends who were consumed by the terrible evil, which at that time was impossible to think of a treatment that could calm the anguish and pain that invaded us.

I remember clearly the constant meetings of friends, where the issue of AIDS was entering our conversations, but we were unable to do anything. I also remember the unexpected telephone calls announcing the death of a friend or acquaintance. I remember the wakes, funerals, masses and visits to cemeteries. I remember our cries, our helplessness, our anger, our despair, our life planning. I always remember Leo, Ronald, Carlos, Victor, Raiza, Pedro, Paco, Jesús, Juan, and many other friends who died of AIDS complications.

In the face of such impotence, I felt the need to be able to do something that could make me feel good. I inquired, I searched, I asked; and that’s how I came to VIA LIBRE. In 2002 I joined the volunteer program that VIA LIBRE had. I had the opportunity to learn more about AIDS. I participated in various information campaigns. VIA LIBRE became my second home. It was the space from which I could feel relief, and be able to do something in the face of so much misinformation that existed at that time about AIDS.

Later, I was invited to participate in projects of political advocacy, prevention and human rights that VIA LIBRE implemented. I felt good, grateful, and satisfied to work on a topic that impacted me. I felt welcomed, and a feeling of being able to always help friends and the community about the new advances that had been taking place regarding HIV infection.

I went to other institutions also working on HIV. It was the issue I had decided to work on, with no doubt. In 2015, VIA LIBRE summoned me and proposed that I be part of the research center, in the position of Community Educator for the AMP Study. A new challenge came into my life, which I assumed with a lot of commitment. Being in research allows me to have a more comprehensive view of the epidemic. Being involved means I can be a part of new alternatives in the prevention of HIV, I can contribute to science, I can have hope, and in some way, I can repay what I could not do at the time with the friends I lost.

In parallel, in 2014 I formed a community group in my area. Casa Diversa, an organization that brings together volunteers from LGTBI communities, works to make our sexual orientations and identities visible, and works with civil society and state organizations to expand access to social services and integral health care, with a focus on respect, inclusion and human rights.
In 1995, with a degree in biochemistry in my pocket from Trinity College Dublin, I jumped at the opportunity to spread my wings and took up a position in pre-clinical research at one of the ‘big-pharma’ in Switzerland. I quickly realized that (a) there is more to Switzerland than chocolate, watches, and mountains, and (b) life in the lab really was not for me. Soon after I found my first position in clinical operations and can truly say that I found my niche. My first encounter with HIV was circa 1997 when I started working on numerous clinical trials, many of which ultimately gave rise to some of the antiretroviral therapies in use today. Following a period working mainly on oncology trials for a bio-pharmaceutical company, I decided a change was in order and in April 2018, I had the opportunity to come to work at the university hospital in Lausanne (the CHUV) and take up the position of Study Manager at the Vaccine and Immunotherapy Center. This was my first experience working with the HVTN. In terms of HVTN studies, my role is Clinical Site Coordinator and also the Community Educator-Recruiter. Being a relatively recent addition to the Lausanne site, I am progressively getting to know the CAB and gaining a better understanding of my role vis-à-vis the community. The Lausanne CAB is composed of individuals with diverse backgrounds, all deeply committed to the prevention of HIV and who have been instrumental in educating me on the current culture and public opinion in Switzerland and the challenges we face.

From a clinical operations perspective working with the HVTN, I cannot help but be impressed by the commitment to quality and excellence; all the systems, processes and procedures have been shaped and guided by GCP and every operational aspect of a protocol has a corresponding, well thought through practical application.
I was introduced to HIV and the surrounding prevention work at an early age as a peer youth advocate for the MOCHA Center, an organization focused on supporting LGBT youth of color in Rochester, NY. I learned about the devastating impact the disease was having on my community, and how community engagement activities are critical to providing education and tools to those who need it most.

When I first learned of my own HIV diagnosis in 2015, it lit a fire within me. I wanted to turn my diagnosis into something positive. In 2016, I joined the Community Education & Recruitment team at the Rochester Victory Alliance, where it has been my mission to not only recruit new study volunteers but also educate people from all backgrounds about HIV prevention research.

Recently, I played an integral role in the University of Rochester Artist in Residence Project. This project aims to break the cycle of stigma surrounding HIV and to foster awareness through a series of watercolor portraits (of folks within our local HIV community), painted by our Artist in Residence. As part of the project, a short documentary was created about the process entitled, "Don’t Define Me", where I shared my story of being an African American trans woman living with HIV.

Being a part of the HVTN feels like belonging to a big family of superheroes from different walks of life all around the world. From Africa to South America to cities all over the USA, we are all doing the hard work of engaging our communities toward a common goal. I’m proud to be a part of that. In addition to my work with the HVTN, I am also a Community Health Specialist with the MOCHA Center.

Maria del Rosario Leon Rhandomy
Head of Community Involvement, IMPACTA CRSs, Lima, Peru

I have worked in the field of HIV for more than fifteen years. I graduated from Universidad de Lima, where I received a Bachelor of Social Communication degree and later completed a Master in Social Investment from Universidad del Pacifico (Peru). I worked in the National HIV Program of Peru as Head of the Information, Education and Communication unit in the implementation of behavioral interventions. My goal: people should be educated about HIV prevention.

However, it was clear that condom use was not enough and we need to work on new prevention strategies. In 2005, I worked as Community Educator at IMPACTA, on my first HIV vaccine trial, and also served as HVTN CER Co-Chair for the North and South America sites. Since 2007, I was the Community Educator for the Lima sites in the iPrEx trial on pre-exposure prophylaxis, where I designed the branding for the Andean sites, as well as community involvement, recruitment and retention strategies that contributed to the trial achievements. Since 2016, I am working on the AMP study.

One of the things that I appreciate the most about working with the HVTN is the permanent respect about education and community involvement efforts. These include: putting in action the Community Advisory Board recommendations, implementation of new strategies on recruitment of participants, as well as educational materials customization. Now, we continue contributing to the generation of science evidence in health and “the force is with us” (Yes! I am a Star Wars groupie. Alias: MaR Leia or Vader)
Mmathapelo Masala  
CRS Coordinator, Soweto Bara CRS  
Soweto, South Africa

I have more than a decade of nursing experience both in a clinical setting and a research setting. My work in HIV clinical care doing nurse-initiated management of antiretroviral therapy (NIMART) prompted my interest in HIV research, particularly HIV prevention. Treating an ever-increasing population of HIV-infected people highlighted to me that antiretroviral therapy alone could not halt the epidemic in South Africa. I wanted to increase my knowledge and skills in the area of prevention and this led me to apply for the position of research nurse at the HIV Vaccine Trials Network (HVTN) Clinical Research Site (CRS) of the Perinatal HIV Research Unit (PHRU).

Mostly I love that I am part of the team that is working to make HIV history globally. “If you want to make history, you have to do historic things.” (Kobe Bryant). HVTN’s mission is to fully characterize the safety, immunogenicity and efficacy of HIV vaccine candidates with the goal of developing, as rapidly as possible, a safe, effective vaccine for prevention of HIV infection globally. This mission shows that it is evident that innovative and new methodologies are required for prevention of HIV/AIDS epidemic. Working on HVTN studies gave me an opportunity to increase my knowledge and skills in the development of a safe, effective methodology through preventive vaccine trials.

HVTN allows interaction, such as monthly protocol conference calls, clinic coordinators calls, and conferences, and through this interaction you learn and grow. Being part of this supportive team is awesome.

I would be remiss if I did not share that I was one of the primary research nurses on the novel HVTN 915 study that assessed the feasibility of using daily vaginal swabs to identify HIV exposure. These experiences provided me with the opportunity to learn all aspects of clinical trial implementation and it was for this reason that I was chosen to attend a study coordinator training course in August 2015. Thank you to HVTN for giving the Soweto-Bara team this opportunity. HVTN is indeed the vessel of opportunities and learning. This is where you meet the world’s greatest!
I became involved in the END HIV agenda as a result of the frequently heard statement, “MSM populations are difficult to find.” From this, I created a magazine named UrbanSocialites that celebrated Black gay culture. At that time, much of the HIV/STI awareness activities conducted in my area was centered around a heteronormative Rap music publication that didn’t speak about the experiences of Black gay culture, and thus was not reaching a greater population of gay individuals. I began attending Community Advisory Board meetings at the Emory Hope Clinic site to bring awareness about the publication, and with my marketing experience I offered assistance with reaching MSM. Sometime later, I was hired by Mercy Care as their Health Promotion Specialist which began my formal work within public health, and then later I was hired by Emory Hope Clinic. HVTN has a coordinated agenda that helps to establish the best practices to engage the community. We meet regularly to better improve on the strategies and systems we use to educate and recruit populations into HIV prevention research. As part of the HVTN, the CERT of Emory Hope Clinic receives additional capacity building, support, and training for best outcomes. In addition, the Network allows flexibility to use non-traditional methods to engage communities.

Around 2016 when I was working in corporate America doing logistics for a shipping company, I found myself working and living without a purpose. I would go to work and do my 9 to 5 but come home miserable and repeat the same patterns every day. HIV research became an area of interest to me when I attended my first Nashville AIDS Walk and met former Community Educator Vic Sorrell. We had a deep conversation that day about all the work that goes on in the community and throughout the world regarding HIV/AIDS. I became involved the following year and started working for the Vanderbilt HIV Vaccine Program, where I met a wonderful community of CAB members, nurses, physicians, activists, researchers, PLWHA and most importantly our study participants. I knew that my role would be more than just working in an office setting and talking to patients, but getting to know these individuals and their stories. This work is not about me but for the greater good of humanity and finding resources to help end the epidemic. We must start educating and having more uncomfortable conversations with our peers as well as ourselves. What I love about working with the HVTN community is that you get to meet so many people who are willing to sacrifice their time and energy for a noble cause; these participants and community leaders genuinely care about the work and it shows. I truly feel that all of us have a mission while we are here on Earth. This mission can be identified as a charge and responsibility to pull the next generation up behind you.
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.

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

Send Inquiries about this issue of Community Compass to: Stephau E. Wallace, sewallac@fredhutch.org

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