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

In this issue, we highlight some of the critical topics relating to health equity from the HVTN Community, remember three longtime activists and community leaders who recently passed, and provide important updates from our partners. We also provide updates on community engagement activities from some of our sites around the world. We also must celebrate the amazing work that has gone into developing the Red Ribbon Registry for use by our US sites and the marketing campaign that accompanies it (which you can review at www.helpendhiv.org), which will gradually expand to include all of the DAIDS networks, and the amazing work that went into refreshing our HVTN.org website. If you haven’t checked it out lately, I encourage you to do so!

Finding a safe and effective HIV vaccine remains a key priority for the Network and our communities. Over the next couple of years, we will see many early phase studies launch that are focused on testing the safety of HIV vaccine candidates, seeking to better understand the immune responses generated by the vaccines, and exploring other strategies to vaccine development. We are looking forward to seeing results in the near future. This study uses a mosaic-based platform which supports the evaluation of the vaccine across various types of HIV found around the world.

Please help us ensure that this publication is representative of our entire global HVTN community! HVTN members (who have access to the HVTN member’s website) can use our submission page that offers the ability to submit content and articles for inclusion in future issues. More information about this follows on the “Meet the Community Compass Team” section. If you are a member of the general public and have questions or ideas for submission, please reach out to us via our information on the HVTN Community Compass home page: https://www.hvtn.org/community/community-compass.html.

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 a globally effective 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
Stephaun E. Wallace, Ph.D.
Editor-in-Chief, HVTN Community Compass
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** and require at least one photo or graphic 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".

We wanted to take a chance to reintroduce you to the External Relations team at the HVTN. After this issue Louis is going to be temporarily stepping in as Editor-in-Chief for Compass.
UPCOMING MEETINGS/CONFERENCES/AWARENESS DAYS

Coordination of COVID-19 Vaccine Clinical Trials Produces a ‘Treasure Trove’ of Data and a Model for the Future

Harmonized approach and vast database of trial participants could bolster future research well beyond SARS-CoV-2

By: Sandy Van, Fred Hutch

SEATTLE (Monday, January 23, 2023) – The federally funded COVID-19 Prevention Network (CoVPN), headquartered at Fred Hutchinson Cancer Center in Seattle, was instrumental in the rapid development of safe, effective and lifesaving COVID-19 vaccines during earlier phases of the pandemic.

Its vital work to expedite Phase 3 COVID-19 vaccine clinical trials also resulted in a highly collaborative and harmonized approach that can serve as a national and even international model for major research initiatives while also guiding responses to future public health emergencies.

That’s the overarching theme from a new study published Monday, Jan. 23, in JAMA Network Open.

Publication #: JNO22-8432R
DOI: 10.1001/jamanetworkopen.2022.51974

“Our success, which depended entirely on the investments into HIV vaccine research, can be replicated for other important research initiatives and highlights the importance of investments that boost pandemic preparedness for years to come,” explained James G. Kublin, MD, MPH, executive director of CoVPN and senior and corresponding author of the study.

Additionally, he and his colleagues, including Alfredo Mena Lora, MD, assistant professor of medicine at the University of Illinois at Chicago, and co-first author Jessica Long, PhD, MPH, a postdoctoral fellow at the University of Washington Department of Medicine in Seattle, noted that the COVID-19 clinical trials produced a vast database of critical information that could help researchers answer pressing questions about this novel virus moving forward.

“The harmonization of data across trials is a new strategy that will set the standard for collaboration in future clinical trials,” said Mena Lora.

The authors detail how CoVPN was able to help secure authorized vaccines in less than a year by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health as part of Operation Warp Speed. Its mission was, and continues to be, to support the rapid development of vaccines for the U.S. and global populations by coordinating and implementing Phase 3 trials for COVID-19 vaccine candidates.

CoVPN officials were able to leverage existing resources, including clinical and laboratory infrastructure, community partnerships and research expertise, to get clinical sites to quickly pivot to conduct the vaccine trials as soon as investigational products were ready for Phase 3 testing.

“The CoVPN approach drew on years of experience and infrastructure from partnering networks and institutions, which not only allowed for rapid rollout of the trials,
but also contributed to broader representation of trial participants,” said Long.

Overall, CoVPN deployed five Phase 3 clinical trials involving more than 136,000 participants to test the safety and effectiveness of COVID-19 vaccines. While doing so, it implemented several innovative procedures that were essential to its ultimate success. These included:

- Harmonized study designs that were similar in relative size, number of endpoints and time to analysis.

- A model that accelerated vaccine development by allowing phases to occur in parallel rather than sequentially. For example, vaccine manufacturing and scale-up were greenlighted while the trials were ongoing in anticipation of meeting efficacy targets.

- Establishment of a single Data Safety Monitoring Board for review and oversight of all vaccine studies.

- Targeted outreach and enrollment efforts supported by an online screening registry to ensure broad and diverse representation among study participants. Extensive engagement was conducted with communities and community leaders to build and enhance trust in the science to help enroll more Black, Indigenous and people of color (BIPOC) volunteers who are historically underrepresented in clinical trials.

- A cross-platform approach that led to harmonization of data collection across trials and the ability to analyze data from all studies.

“This unique, cross-platform concept allowed for sharing of data from all of the studies and helped bridge gaps in understanding so we could better answer key research questions and guide policy decisions,” explained Kublin, who’s also a principal staff scientist at Fred Hutch.

Larry Corey, MD, an internationally renowned expert in vaccine development, and principal co-investigator of CoVPN, believes the success of COVID-19 clinical trials should be thought of as an important model for developing vaccines for significant infectious diseases globally.

“Harmonizing study design, enrollment, clinical endpoints and methods for follow-up could very well become best practices that shape the future landscape of major research initiatives and pandemic responses,” he said.

Kublin and colleagues regard the vast database from more than 130,000 trial participants, including over 2,500 with documented COVID-19 cases, as a “treasure trove” of data that could help unlock mysteries about the virus. For example, they noted that the pooled data from five trials can help address specific questions such as:

- Are safety, immunogenicity and vaccine efficacy different in special populations, such as people living with HIV?

- What impact do chronic health conditions have on vaccine efficacy or protection duration?

- What are the impacts of variants on both the population at large and within special communities?

Additional CoVPN publications planned for the months ahead will address many of these topics. Researchers who have ideas for further investigation and want to collaborate with CoVPN please email research@covpn.org.
Recent News

Arrested Development:
Discontinuation of the MOSAICO Trial, its Legacy and Expectations for HIV Vaccine Research

By: Dr. Susan Buchbinder, San Francisco Department of Public Health, Richard Jefferys, Treatment Action Group, Ntando Yola, Desmond Tutu HIV Foundation

In the first of the three MBC sessions we heard from Dr. Susan Buchbinder, San Francisco Department of Public Health, who gave an overview of the MOSAICO trial and the reasons for its discontinuation. MOSAICO was stopped after the Data Safety Monitoring Board (DSMB) did their review and found that, whilst the product was safe, it did not meet their predefined criteria for efficacy.

The MOSAICO vaccine was intended to work against globally relevant strains and subtypes of HIV. It used an Ad26 vector (like that of a cold virus), a mosaic insert (including a variety of global HIV strains) and a Clade B and gp140 envelope to prevent HIV infection.

The type of vaccine used in the MOSAICO study provides binding and functional antibodies (not neutralising antibodies), which had proved to give some protection in studies with non-human primates.

Let’s refresh our memory on what the difference is between the types of antibodies:

- Neutralising antibodies work to neutralise and clear the virus,
- Non-neutralising antibodies like binding antibodies bind to the virus,
- Functional antibodies use cells, like T cells, to clear the virus.

The sister study to the MOSAICO trial, the Imbokodo trial, in women in Southern Africa used the same vaccine regimen, with some slight differences. In 2021, non-efficacy was found in this study. However, it was decided to continue the MOSAICO study because of the differences (as they used a Clade C and gp140, they took place in a different population, was protecting against different subtypes and PrEP use was different in the populations involved).

The MOSAICO study population was 18–60-year-old transgender men and men who have sex with men with sites mainly in Latin America. The study, started in November 2019, was recommended to stop on 12 January 2023. Participants were notified and informed of which arm they had been participating in. There were no safety issues with the vaccine.

The main takeaway, as further stated by Richard Jefferys, Community Activist from Treatment Action Group, is that the key question on which antibodies can protect against HIV has been answered. Indeed, the non-efficacy shown in this study suggests that, unlike vaccines that provide non-neutralising antibodies, vaccines that can induce broadly neutralising antibodies can protect against HIV infection.

Richard also drew the attention to the fact that essential lessons were learned in the study in terms of community engagement in HIV vaccine trials. The community were involved at all stages of the process: involvement in the protocol team; reviewing informed consent forms; members of community ethicists; community discussions on how to handle PrEP within the trial; community advisory boards at each site.

With these key lessons learned, there is plenty more discussion to be continued on the next steps of HIV vaccine research.

To watch the recording of the session head over to https://youtu.be/idsozzkEteY

Editor’s Note: This article was first published by the European AIDS Treatment Group, it has been reprinted with their permission. https://tinyurl.com/44fb8vjp
This year, the HVTN External Relations team is adding a new award to the list of honors bestowed by the HVTN. The Wakefield Outstanding Dedication Award honors an individual, group, or organizational community partner for their years of exceptional contributions and extraordinary, committed service to HIV vaccine research. This award is one of a kind in the HVTN since researchers, site staff, and CAB/CAG members are not eligible.

Named in honor of longtime HVTN External Relations Director Steve Wakefield for his decades of exemplary service, this award recognizes the recipient’s steadfast passion for HIV research. The award recipient’s passion is demonstrated through their years of contributing to community and stakeholder engagement, education, research awareness, and facilitating inclusivity and belonging in the research environment. This award acknowledges those stakeholder partners whose tireless efforts help shape HIV vaccine education and research efforts in their local community, at a local research site, nationwide, or globally.

Three Wakefield Outstanding Dedication Award winners will be selected each year. Each awardee will be recognized for their work in one of the regions where the HVTN has a consistent presence: North America, Latin America, and Southern Africa. The North American and Latin American winners will be presented with their awards at the HVTN Full Group Meeting regularly held in Washington, DC. The Southern African awardee will be presented with their award at the annual HVTN Sub-Saharan Africa Regional Meeting. Individual awardees (single persons) will receive a $500 stipend, while group/organizational winners will receive a $5,000 stipend. Additionally, all award winners will be recognized in HVTN Community Compass and on the homepage of the HVTN website.

It brings us immense pride to announce the inaugural 2023 North American Wakefield Outstanding Dedication Award winner is the incomparable Rev. Edwin Sanders of Nashville, TN. We are also proud to announce the inaugural 2023 Latin American Wakefield Outstanding Dedication Award winner is the remarkable Epicentro, a Non-Governmental Organization (NGO) in Lima, Peru. Congratulations to both of our stellar award winners.

Be on the lookout for the announcement of the inaugural 2024 Southern African Wakefield Outstanding Dedication Award winner next year. On behalf of the HVTN External Relations team, thank you to all the community partners, stakeholders, and advocates who champion the HVTN globally. We look forward to utilizing this award to honor you and your work in the future.

Continued on the next page...
Recent News

North American Winner

Rev. Edwin Sanders; Nashville, Tennessee

Reverend Edwin Sanders is the Senior Servant and Founder of Metropolitan Interdenominational Church in Nashville, Tennessee. A staunch advocate for faith communities, health equity, and diversity in clinical trials, Rev. Sanders led the HVTN’s Faith Initiative from its inception to 2022, and the COVID-19 Prevention Network (CoVPN) Faith Initiative from 2020-2021. Rev. Sanders also served as one of the first Chairs of the Legacy Project under the HVTN and the Office of HIV/AIDS Network Coordination (HANC). The HVTN’s consistent prioritization of faith community engagement is the legacy of Rev. Sanders’ decades of tireless work.

Latin American Winner

Epicentro; Lima, Peru

Epicentro is a community-based organization serving the LGBTQIA+ community in Lima, Peru. Led by esteemed community leader Hugo Sanchez (Executive Director), Epicentro works to advance universal healthcare access with an emphasis on improving sexual health, and offers various sexual and mental health services. Since its founding in 2008, Epicentro has supported HVTN trials, educating communities about HIV research and vaccines as prevention tools. Epicentro also plays an active role in HVTN/CoVPN social media engagement in Peru, creating content that empowers and informs Latin communities.

Louis Shackelford is the Acting Director of External Relations with the HVTN.
Because HIV can happen to anyone.

HIV is something anyone can be exposed to, regardless of age, gender, or sexual orientation.

That is why we need all types of people to volunteer for an HIV prevention study.

We’re looking for people who are not living with HIV, 18-55 years old, and in general good health. Participants of these studies will be compensated.

People in the United States can learn more and register to participate in an HIV prevention study to help end HIV sooner. Go to HelpEndHIV.org*
HIV Advocacy and Using Joy as Resistanceing

By: Andrew Ashiofu, Special to the SGN

When I was first diagnosed with AIDS, I was terrified. I felt ashamed. I felt despair. But above all, I felt alone.

I had just been experiencing homelessness, with a rescinded job offer due to the last recession, and without a family or other social support system due to coming out as Gay. As a Black man from a Nigerian background, the pain was compounded when I experienced harassment or even cold indifference to my situation due to racism and oppressive systems.

My life sentence for existing in these intersections of my identity suddenly felt like a death sentence.

It took months, and even years, to come to a place where I could finally feel healthy again. Through the kindness of nonprofit organizations and newfound friends, I was slowly but surely placed on the path to recovery. I started a regimen of antiretroviral drugs that brought me from the brink of death back to just HIV-positive, until finally I was able to get the virus under control to the point where it is no longer transmissible.

I was also able to find steady housing, and employment that could keep me fed, housed, and able to afford lifesaving medical help.

To this day, I still feel guilty that I can access a doctor when I need care. I still wonder if I’m “undeserving” of the nice apartment near the park, after knowing what it felt like to make do on others’ couches or take a risk on the streets. To enjoy a sweet bubble tea — a favorite of mine — is to experience a luxury I once thought beyond me.

I know deep inside that I deserve joy, and that many of the things I continue to second-guess for myself — like safe shelter and adequate food — are human rights I deserve simply because I am alive.

That is where joy as resistance comes in, and where paying it forward is my reconciliation. I am now working full-time in HIV advocacy, as well as serving as a board member of many local LGBTQ+ and HIV+ advocacy organizations.

I am proud of my journey, but it is one that I am taking because I don’t want others to go through what I went through. The tears I shed in those darkest, loneliest moments are ones I wish for nobody.

To that end, I am disheartened that, in a city filled with such wealth, there are so many struggling to make do,
without their basic human rights, such as housing, healthcare, and nutrition. Compounded with the ongoing social stigmas related to HIV status, it becomes even harder for some to seek these services.

As the second annual “HIV Is Not a Crime Day” has come and gone (February 28), I reflect on what this means for a seemingly progressive area such as Seattle. In numerous states across the country, there are overt attacks on people living with HIV and AIDS, including laws that not only further stigmatize people living with the condition but that discourage people from getting testing and seeking resources [https://www.hivisnotacrime-etaf.org/about/].

These laws may not be what we have on the books in cities like Seattle and states like Washington, but much like a lot of our area’s progressive politics, often we see performative gestures taking the place of meaningful action. In short, the absence of criminalized laws does not absolve us from our moral responsibility to do better.

My work and advocacy on HIV and AIDS awareness and resources has continued to inform me of where we need to take more action as a region. Despite our city and greater metropolitan area being home to some of the most ethnically diverse neighborhoods in the nation, our infrastructure for disseminating information about HIV/AIDS is often lacking when it comes to cultural sensitivity, breaking language barriers, and physically meeting people where they are at. Our healthcare in general, especially for lower-income people — predominantly BIPOC neighborhoods and in immigrant communities — is lacking, and especially so when it comes to health conditions that are already greatly stigmatized.

I ask my siblings in the LGBTQ+ community to join me in advocating for those with similar intersections of identity that are often overlooked by our institutions. Talk with your friends and family. Demand that your local policymakers include culturally sensitive HIV information, and that neighborhood clinics prioritize HIV/AIDS treatment.

Just as we are fighting back that it’s “okay to say ‘Gay,’” we must also be willing to shout “HIV/AIDS” and, with that greater presence, demand more direct interventions in our communities. My goal is that in my lifetime, not one more person will have to experience what I went through to get support and treatment. We are a community that looks after each other; let’s continue to stand with each other, especially when confronting stigma, so that more can stand with pride.

Editor’s Note: This article first appeared in Seattle Gay News and is reprinted with their permission. [https://www.sgn.org/story.php?ch=op_ed&sc=&id=323717].
Recent News

Remembering Jorge Beloqui

By: Luciana Kamel, HVTN Core, Rio de Janeiro, Brazil

A pioneering voice in national and international activism, Jorge Beloqui has always dedicated his life to the continuous defense of the rights of people living with HIV and to combat against stigma and discrimination in Brazil. He advocated for unrestricted access to scientific advances in prevention and treatment. His generosity in sharing scientific knowledge and access to new scientific findings in a sensitive way to the community will always be remembered. He was one of the most important activists/leaders in maintaining the Brazilian response to HIV/AIDS. Beloqui, who was born in Argentina, was a Senior Professor at the Institute of Mathematics and Statistics at the University of São Paulo (IME/USP) and he was a researcher at Nepaids (Núcleo de Estudos para a Prevenção da Aids). He was one of the founders of the NGO Pela Vidda and the Movimento Paulistano de Luta Contra AIDS (Mopaids), in São Paulo. He was also a member of the Board of Curators of the Associação Brasileira Interdisciplinar de Aids (ABIA) and director of the Grupo Incentivo a vida (GIV). He served on several committees and working groups nationally and internationally. His many contributions include advocacy for an HIV vaccine, and participation in the Working Group of Intellectual Property (GTPI), which he has been involved with since its foundation in 2003. Beloqui was part of the editorial board of a bulletin about HIV vaccines, Anti HIV Vaccine Bulletin. He was a member of the National Research Ethics Committee (CONEP, acronym in Portuguese), as well as the intersectoral committees on Pharmaceutical Assistance (CICTAF, acronym in Portuguese) and on Health Care for People with Pathologies (CIASPP, acronym in Portuguese). Undoubtedly, he was an important leader and founder of community activism in the fight against AIDS. He was a community voice of constant commitment to ensure equity of access and overcoming inequities. Recently, he served on the NIH-funded COVID-19 Prevention Network (CoVPN) Panel of Latin America Scientific Experts to help the Network prepare to initiate an experimental COVID-19 vaccine study in the Latin America region. His legacy will always be remembered.

Luciana Kamel, is a former Community Engagement Project Manager with the HVTN.
HVTN Statement on the passing of Kirk D. Myers-Hill

By: External Relations Team, HVTN Core, Seattle, WA

The HIV Vaccine Trials Network (HVTN) extends our deepest sympathy and condolences to the family, loved ones, and broader Dallas community on the passing of Kirk Myers-Hill. In addition to being the founder and CEO of Abounding Prosperity, he was a longtime community partner to HVTN through his tireless efforts via Dallas Southern Pride and the House Ball Community. We are appreciative of his unwavering commitment to see the end of health inequities in the communities he intersected, and the diligent and laser-focused work he led to improve the lives of those around him. As we honor his legacy, it is important we also honor the family, friends, mentees, and community Kirk left behind to continue his work.

Donations in memory of Kirk Myers-Hill can be made to Abounding Prosperity, Inc. https://www.aboundingprosperity.org/?page_id=21

Photo credit: Kirk Myers-Hill appeared on the cover of Dallas Voice on June 18, 2021.
Douglas Silva, with his generosity and empathy even in the face of the most difficult challenges, showed us that his tirelessness was unstoppable. For many years, Douglas was part of the National Network of Adolescents and Young People Living with HIV/AIDS and coordinator of the Associação Fênix in Curitiba. He stood out as an activist for human rights, for universal access to treatment, and he always advocated for a full democratic and participatory health system. Douglas’ advocacy went far beyond the fight for health, as he was and always will be an inspiration for young people, especially young gay, black, and poor people in Brazil. In recent years Douglas led the Curitiba site’s Community Engagement team for the Mosaico study. His leadership was a significant factor in communicating about the study with the community, and it helped the site earn recognition with the Marcio Martins award in June 2022. This was an important acknowledgment of the site’s efforts in support of the LGBTQIA+ community. Douglas will always be remembered for having shown us how to work in solidarity, and to uphold critical universal values in the fight for human rights.

By: Luciana Kamel, HVTN Core, Rio de Janeiro, Brazil
The development of a safe and effective HIV vaccine is one of the greatest biomedical research challenges of our time. The HIV Vaccine Trials Network (HVTN) is now accepting applications for Research and Mentorship Program (RAMP) Scholar Awards to attract African American/Black, Hispanic/Latinx, Native American/American Indian, Native Hawaiian, Asian and Pacific Islander medical students who want to make a difference in their communities and contribute to the development of an effective HIV vaccine.

**PROGRAM HIGHLIGHTS:**
- 8 -10 week or 9 -12-month research projects in the areas of clinical, laboratory, or social-behavioral research
- Structured mentorship by HVTN investigator(s)
- Travel to an HIV Vaccine Clinical Research Site in the US or abroad (if COVID has been controlled)
- Attendance at an HVTN Full Group Meeting
- Oral and poster presentations and potential for publication

**PROGRAM RESOURCES:**
- Up to $20,000 for short-term projects (8-10-weeks)
- Up to $70,000 for long-term projects (9-12 months)
- Funding includes salary, materials, and travel
- Career mentoring and access to HIV vaccine research expertise
- Attendance at a maximum of five training webinars through the course of the year, and a professional development workshop at the conclusion of the program.

Please visit [hvtn.org/RAMP](http://hvtn.org/RAMP) or contact: Linda Oseso at loseso@fredhutch.org
The use of illicit drugs and alcohol in young adults from our participant recruitment catchment areas has reached alarming levels, as reported by the Zimbabwe Civil Liberties and Drug Network (ZCLDN). It is estimated that 57% of young adults have experimented with or are involved in illicit substance use, and 40% of those seeking mental health services are young adults. This has not spared our study participants, and the major concern is that this affects their participation, especially adherence to using study products as directed. Most young people abusing drugs acquire HIV within the first 12 months of substance use initiation. Young Women and Adolescent Girls (YWAGs) involved in substance use have an increased likelihood of acquiring HIV.

According to the ZCLDN, commonly used illicit substances are, marijuana, prescription drugs for mental health, crystal methamphetamine, prescription cough syrup, industrial ethanol, and chemicals from boiled diapers and television tubes.

It is important to understand the cases of substance and alcohol use experienced among research participants to determine the challenges and draft a mitigation plan. The outreach team looked at the triggers and clinical outcomes of illicit substance use among participants in an HPTN 084. A history of illicit substance or alcohol use was not reported by all participants. The site inquired about substance use among participants by asking them to voluntarily report this behavior, or by clinically observing them. We investigated the types of illicit substances used by participants and assessed how they were affecting participation. Seven cases (out of 160) were recorded and followed-up, where 6 participants aged 21 – 30 self-reported the use of illicit substances or drugs to get high during the study, and 1 presented symptoms consistent with substance abuse but never admitted this use. The most common illicit substances reported as used by participants were marijuana, crystal methamphetamine (“crystal meth, mutoriro or dombo”) marijuana, and BronCleer Cough Syrup (“Bronco”).

Cough syrup & a tube used to burn Crystal Meth
Peer pressure, dysfunctional families, physical abuse, and rape were the tiggers for use among the participants, with peer pressure the most common. Participants often missed visits and exhibited the following clinical symptoms: psychosis, aggressive behaviour, wandering, schizophrenia, acute liver disease, swollen limbs, swollen legs, and Grade 3 unintentional weight loss. Medical records for all seven participants indicated mental health issues related to substance use. According to their clinical symptoms, participants were counselled and referred to appropriate service providers for professional help. Our interventions had mixed results: 3 participants received treatment, 1 reported successfully dealing with her issues, 1 refused the referral due to fear of hospitalization, 1 absconded referral, and the seventh participant never admitted substance use.

We continue to follow-up to learn more about the effects of substance use on study metrics, especially adherence and retention, and to support participants for effective protocol implementation.

Lydia Samaneka is the Community Educator & Charles Chasakara is the CTU Community Engagement Coordinator of the University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC)/Seke South CRS in Harare, Zimbabwe.

Resources

HIV Resources:

**UNAIDS 2022 Update Report: In Danger**

UNAIDS published a report that highlights some of the pressing issues facing global efforts to end HIV, along with strategies and considerations for refocusing and revitalizing efforts that also factor in the impact of the COVID-19 pandemic.

For more information about the report, or to download and review it, go to: [https://indanger.unaids.org](https://indanger.unaids.org).

**HIV in the USA**

HIV is an epidemic that continues to impact communities around the world, burdening some communities disproportionately, especially during COVID-19. Check out this open-access series of published works by leading experts in community engagement, epidemiology, and healthcare.

[https://tinyurl.com/4dp2hfzx](https://tinyurl.com/4dp2hfzx)

Partner Organization Resources:

**Asian and Pacific Islander American Health Forum Resources**

The Asian and Pacific Islander American Health Forum compiled and produced many resources focused on engaging Asian and Pacific Islander communities. Check out the resources at [https://www.apiahf.org](https://www.apiahf.org).

**Association of Nurses in AIDS Care**

The Association of Nurses in AIDS Care compiled and produced many resources focused on engaging nurses, healthcare providers, and communities. Check out the resources at [https://www.nursesinaidscare.org](https://www.nursesinaidscare.org).

**AVAC**

AVAC has compiled and produced many resources focus on engaging advocates in the HIV response. Check out the resources at [https://www.avac.org](https://www.avac.org).

More Resources can be found on page 27.
Health Inequity Perspectives

Do Research Teams Have a Role to Play in Breaking the Culture of Silence?

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

In South Africa, most of the HIV/TB research studies are conducted with communities where the burden of disease is fueled by structural drivers such as economic, political, cultural, social, and religious factors. Power inequalities do exist between research teams and community stakeholders, and this includes imbalances in research literacy, education, and economic resources (GPP, 2011). These imbalances may result in communities and community stakeholders viewing research teams as superior, and research teams need to possess the skills to manage these imbalances, which can reinforce a culture of silence.

In our work with communities, we are often faced with the culture of silence. We conduct our research with communities who have endured the brunt of an oppressive apartheid regime. The system was oppressive for blacks, coloreds (the South African term for people of mixed-race heritage), and Indians. Apartheid and colonization are conducive to the development of the culture of silence which is passed on from one generation to the next. To understand the culture of silence, we look at the ideas of Paulo Freire, a Brazilian pedagogue who revolutionized ideas about poor and oppressed people (Freire, 1998). His ideas trust people to critically explore and understand their world and seek their own solutions. When people understand their world, people in the community can develop community-based solutions. Understanding the culture of silence enables the facilitation of change that is consistent, ethical, professional, and accountable (Schenk, Nel & Louw, 2010).

Freire is of the view that when people are oppressed, a “culture of silence” develops. Culture is the way people structure their experiences conceptually and may be transmitted as knowledge from person to person and from one generation to the next (Freire, 1998). People base this knowledge on how they view the world around them and how they adjust to this world. It is important to note that culture develops over a long time, through generations. According to Freire, society is made up of two groups of people and these are the oppressors/invaders and those who are oppressed or invaded. The oppressors may emphasize that the oppressed are of an inferior social/educational and economic class and that their status is unchangeable. Over time, the oppressed believe that they are inferior and accept the oppressors’ views of the world, and how they are viewed by the oppressors. Oppression is often reinforced by the technological, financial, and scientific resources available to the oppressors.

The culture of silence may play out in research settings when people in communities see research teams as superior, and accept what research teams say as the only reality because research teams are viewed as possessing scientific knowledge that cannot be challenged. People may depend on research teams to guide the community’s actions in the research process, especially when The community struggles to question research proposals made by researchers. When people rely too heavily on research teams, this can result in dependency. The culture of silence compromises research autonomy. When a person or a “community stakeholder” is autonomous, it is believed that the person can make their own decisions about what to do and what to agree to do. Community stakeholder autonomy is defined as the right of the community stakeholders to support or refuse proposals to conduct research (GPP, 2011). When there is no autonomy, people become dependent and...
community stakeholders are likely to view themselves as having no ownership in the research process.

According to Freire, the culture of silence is broken through a process of “conscientization” which is a process for developing, strengthening, and changing the consciousness of people rather than just educating them. What do we do at the clinical research site to break the culture of silence? We always negotiate our entry into a community. This is negotiated according to the cultural norms and requirements of the community and with respect. When entry is not negotiated, the people of the community feel invaded and view us as invaders or oppressors. We avoid reproducing oppression by being aware of the impact of our actions, and we take deliberate steps to avoid our voices dominating the conversations. We adopt the view that people can think critically about their circumstances and themselves. People don’t have to be “taught” and can learn through self-reflected learning within their frame of references, experiences, realities, values, and culture. We must allow and trust people to take control of their lives, as people are the experts of their own realities. We must allow people to engage in a collective process of conscientization on their circumstances. When we create safe spaces for dialogues, people have the power to assert their voices to transform their reality. We show empathy by listening attentively as people talk, and we listen to understand.

Research teams can play a role in breaking the culture of silence. When we break the culture of silence, we aim for real authentic participation where people and communities share fully and have equal voice in any decision-making and efforts directed toward change. Lastly, the more we know and understand about the realities of people and the communities where we work, we can engage in ways that avoid unintentional oppression.

Blossom is the Community Engagement Manager for the Aurum Institute CRS in Klerksdorp, South Africa.

References:
To expand the conceptual framework for people-centered community practice in our work, we include ideas from Paulo Freire, Robert Chambers, David Korten and Max Neef. This article explores Paulo Freire’s view of people. Paulo Freire was a Brazilian pedagogue who revolutionized ideas about poor and oppressed people. This article provides an overview of the “culture of silence” described by Freire, and how we are applying this in our work to understand communities better. It is important to note that we do not work intuitively, but we utilize theoretical frameworks that assist us to think about and understand a phenomenon that may exist, guiding our actions to be ethical, non-biased and professional.

Why should clinical research sites be concerned about the culture of silence that may exist in our communities? A culture of silence manifests in our settings when communities accept what we say all the time, without questioning things presented by researchers, and when communities feel obliged to always agree with the researchers.

People may also miss asking critical questions during the informed consent process, becoming passive participants in the research process who will look at research sites as owning the research. As a result, communities will feel that they have no ownership in the research process. This defeats our aim for communities to co-own the process.

Our research usually focusses on communities and people who are disproportionately impacted by a disease. For this reason, HIV/TB studies focus on communities who are impacted by HIV/TB. In most cases these communities are also dealing with multi-dimensional poverty and other social issues. A person is considered “multi-dimensional poor” when they are living in households where they are deprived of at least three of the seven dimensions of poverty which are health, housing, nutrition, protection, education, information, water, and sanitation (Stats SA, 2017). The report also revealed that Black women, children, and youth are disproportionally impacted by poverty. Black women, and persons considered multidimensional poor, are also most impacted by long term unemployment (unemployed for 12 months or more) (Stats SA, 2017). Women, children and youth, especially adolescent girls and women, suffer the brunt of many social and economic factors. South Africa is also challenged with Gender Base Violence and Femicide. It is on this background that our engagements with communities should always aim to empower and break the culture of silence.

In South Africa we are recovering from a history of oppression. The apartheid regime (1948-1994) was oppressive for Blacks, Colored and Indians. One may argue that apartheid ended 29 years ago, so why are we still talking about apartheid? Apartheid and colonization are conducive to the development of the culture of silence which is passed on from one generation to the next. 29 years later, these communities are still living in poverty. The legacy left by apartheid is an unequal society. A World Bank Report indicated that South Africa is the most unequal country in the world, with race playing a determining factor, in a society where 10% of the population owns more than 80% of the wealth (World Bank, 2022).

Another reason why breaking the culture of silence is important is due to the principle of autonomy. When a person or a community is autonomous, it is believed that the person can make their own decisions about what to do and what to agree to do. To what extent
are participants or communities exercising their autonomy when a culture of silence exists? When a culture of silence exists, participants may struggle to assert themselves when they are unhappy about the way they are treated at the study site. For example, participants may struggle to raise concerns about long waiting hours, or raising other issues that they are unhappy about. Instead, participants may decide to stop coming for visits, becoming lost to follow-up instead of addressing their concerns. It is for this reason that sites should be intentional about breaking the culture of silence.

Our entry into the community is always negotiated according to the cultural norms and requirements of the community. We don’t enter the community with the aim to teach or to impose our beliefs onto the community. When entry is not negotiated in the correct way the people of the community will feel invaded and view us as invaders. We may also unintentionally reproduce oppression when we invade communities. We thus adopt the view that people can think critically about their situation. People don’t have to be taught and can learn through self-reflected learning and they do this within their frame of references, experiences, realities, values, and culture. Allow people to take control of their lives, to take control of their lives people engage in a collective process of conscientization on their situation. Conscientization is a process for raising the self-reflected awareness of people rather than educating. We create spaces where people have the power to assert their voice to transform their reality. We show empathy by listening attentively as people talk spontaneously. We listen to understand and convey this understanding. When we convey understanding people can see that they have been heard and understood and that they are valued. Use dialogue to discover, through dialogue people develop their capacity to think critically about themselves and their context.

We always strive towards real participation where people and community share fully and have equal voice in any decision making and efforts directed towards change (Schenck, Nel & Louw, 2010). In closing it is important for research sites to be aware of the culture of silence that may exist and not feel that we don’t have a role to play in empowering our communities. During the process of doing this we are building trust and building sustainable relationships with our communities.

Blossom is the Community Engagement Manager for the Aurum Institute CRS in Klerksdorp, South Africa.

References:
Health Space for In-School Young People

By: Stanford Chimutimunzeve, University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC)/Seke South CRS, Harare, Zimbabwe

There are increased cases of drug and illicit substance use among young people that may lead to an increase in HIV incidence in our setting. Creating a supportive environment for youths to benefit from health education efforts will yield dividends in empowering them with essential health information. Young Women and Adolescent Girls (YWAGs) continue to have a high likelihood of acquiring HIV due to biological and social factors, and patriarchy in society, and they often fail to negotiate safer sex successfully.

In view of the above background, in collaboration with the Ministry of Primary and Secondary Education in Zimbabwe, we conducted two Health Expos in a bid to create space for in-school adolescents and young adults to access health information. The Health Expos were conducted on 2 March and 16 March in two districts on the Western side of Harare, Glenview-Mufakose and High Glen respectively, and were attended by approximately 800 students from over 50 schools.

The Health Expos mobilized health-focused governmental and Non-Governmental Organizations including the University of Zimbabwe- Clinical Trials Research Center (UZ-CTRC). The diverse organizations included those working on HIV/AIDS, COVID-19, Gender Based Violence (GBV), Sexual Reproductive Health Rights (SRHR), and research in HIV prevention and treatment. The CAB members played an important role, educating the students as they visited the various exhibitors’ tables. On one exhibition table, students learned about child sexual abuse and how they could report it, and how they could deal with the issue including the available services for gender-based violence. At the UZ-CTRC table, students learned about novel HIV prevention strategies being researched, and those that have been found effective and are now in the regulatory pipeline to be approved for public access. Of interest was information on discrete HIV prevention mechanisms for women that included the Dapivirine Ring and Long Acting Injectable Cabotegravir as PrEP. The students and their teachers were excited to learn that UZ-CTRC was working on clinical trials to find a vaccine for HIV prevention in collaboration with HIV Vaccine Trials Network (HVTN). “The Imbokodo trial results were not pleasing, but they provided a learning platform for upcoming..."
HIV vaccine research,” said Mr. Charles Chasakara, the Community Engagement Coordinator at UZ-CTRC.

The CAB was also instrumental in teaching young people about character building for resilience as a way of empowering them with skills to overcome problems associated with drug and substance use. The students also asked for more opportunities for behavioral research protocols focusing on drug and substance use among young people.

In conclusion, opening such a space for young people to access health information builds a foundation for the healthy future of a nation.

Stanford Chimutimunzeve is a CAB member at the University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC)/Seke South CRS in Harare, Zimbabwe.

Resources

Partner Organization Resources (continued):

Black AIDS Institute Resources

The Black AIDS Institute has compiled and produced many resources focused on engaging Black communities. Check out the resources at https://blackaids.org.

Latino Commission on AIDS COVID-19 Resources

The Latino Commission on AIDS has compiled and produced many resources focused on engaging Hispanic/Latino communities. Check out the resources at https://latinoaids.org.

National Medical Association/W. Cobb Institute

The National Medical Association (NMA) is the largest and oldest U.S.-based organization representing African American/Black physicians and patients. They have compiled and produced many resources focused on engaging Black healthcare providers and communities. Check out the NMA resources at https://www.nmanet.org.

Treatment Action Group COVID-19 Resources

Treatment Action Group has compiled and produced resources focused on engaging diverse communities, including persons living with HIV. Check out the resources at https://www.treatmentactiongroup.org.

Urban Indian Health Institute Resources

The Urban Indian Health Institute produced many resources focused on engaging American Indian and Alaska Native communities. Check out the resources at https://www.uuihi.org.

COVID-19 Prevention Network Virtual Community Sessions

You can watch past recordings of our community education and engagement discussions COVID in Black, PANDEMA, and Imam and COVID-19 on the CoVPN YouTube Page at https://tinyurl.com/54wzuf3w.
HIV vaccine research was a new concept in our communities, and the occurrence of Vaccine Induced Sero-Positivity (VISP) in HVTN 705 (Imbokodo) participants had a negative impact on other prevention studies being done at Clinical Research Sites (CRSs) where Imbokodo was conducted, such as HPTN 084. There were rumours that participants were being infected with HIV. Participants were counseled about VISP when they were enrolled and throughout the study. They were instructed to disclose their participation in an HIV vaccine study to health workers whenever they sought healthcare. Stakeholders and participants from other studies looked with suspicion at the instruction given to Imbokodo participants to only seek HIV testing at HVTN sites, whereas the standard of care at hospitals and clinics is to offer HIV tests to all patients if they fall sick. Failure to disclose that they were in an HIV vaccine study could result in commencement of ARVs.

The CAB, in collaboration with research staff, held 10 meetings with various community groups to give study overviews of all prevention studies at the HVTN- affiliated sites, disseminate the results of HPTN 084 and HVTN 705, and to sensitize stakeholders about HIV vaccine studies with a special focus on VISP. The following groups were targeted to attend: medical and non-medical staff at Chitungwiza Central Hospital and Municipal clinics, health promoters, male-focused groups, and stakeholders such as NGOs, business people, religious leaders, traditional healers, Zimbabwe Republic Police, and the Ministry of Education. Over 200 stakeholders attended the 10 meetings.
Stakeholders appreciated the results from both studies and were curious to know the way forward after the disappointing Imbokodo results. They wanted to know when they should expect to find the Cabotegravir Long Acting injectable on the shelves after the promising results. It was evident that HIV vaccine research literacy is limited among stakeholders, especially in the non-medical staff. Little was also known about VISP, and only a few understood the concept of Pre-Exposure Prophylaxis (PrEP) described in the HPTN 084 study. Conversely, health workers at local clinics where studies are being done were well informed because the studies were running on their premises.

These dialogues taught us that communities should be involved from the onset, and sensitization should continue throughout the study. Research involving new technologies should be carefully and widely explained to gain community buy-in, and to avoid rumours that can potentially harm participants and studies. Updates to key stakeholders should be frequent throughout the study. We should prioritize health workers when engaging stakeholders because they are in touch with members of the communities daily. Implementation of Good Participatory Practices (GPP) principles in research is critical, and there is a strong need to explore other forms of communication, such as using social media, to keep discussing health issues and to distribute new information.

Alexious Zindoga, Audrey Tasaranarwo, Obed Mukuya, and Beauty Nerupfunde are CAB members, and Charles Chasakara is the CTU Community Engagement Coordinator, at the University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC)/Seke South CRS in Harare, Zimbabwe.
Let’s look at two lifelong diseases common in South Africa: HIV (South Africa has the largest number of people living with this infectious disease in the world) and diabetes (a larger share of South Africans have this non-infectious disease than any other African country). You’ll notice in the Table below that all groups of South Africans have some cases of HIV and diabetes. But you’ll also see that the poor (“low socio-economics”) have a larger share of HIV and the rich (“high socio-economics”) have a larger share of diabetes. Women have a larger share of HIV and of diabetes compared to men. A larger share of Black Africans have HIV than other races. Clearly, disease is not equal between groups of South Africans. Countries also have disease patterns different to other countries.

<table>
<thead>
<tr>
<th>Groups of people</th>
<th>Out of 100 South Africans, how many were living with HIV?</th>
<th>Out of 100 South Africans, how many were living with diabetes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low socio-economics</td>
<td>21</td>
<td>12</td>
</tr>
<tr>
<td>Middle socio-economics</td>
<td>16</td>
<td>14 to 16</td>
</tr>
<tr>
<td>High socio-economics</td>
<td>5</td>
<td>23 to 35</td>
</tr>
<tr>
<td>Women</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>Men</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Black</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>Other races</td>
<td>&lt;3</td>
<td>24</td>
</tr>
</tbody>
</table>

*Socio-economics* was measured by living standards, such as infrastructure and housing characteristics (source of drinking water, electricity, main source of energy for cooking, and toilet type) and household ownership of fridge, radio, television, and phones.

HIV data is from 2008. Diabetes data is from 2016 except *socio-economics* from 2012.

References: 1-4
Is it Bad Luck or Choice When Some Diseases Affect Some Groups of People More?

Disease differences seem unfair. More poor people have HIV, but they have the least time and resources to visit clinics because they often have to prioritize survival needs of shelter, safety and food over health. More rich people have diabetes (type 2) even though they could buy healthier food.

Someone once told me his opinion that HIV prevention research is unnecessary because people are “choosing” not to use condoms. Interestingly, he and his partner had never used condoms nor gotten tested, probably because consistent condom use is not only a personal choice: it is shaped by complex forces. Incidentally, condoms prevent HIV by 80% or more, but are not failsafe. Although people make decisions, it might be too simple-minded to think that a person controls everything behind their health. The way today’s societies and economies have been set up helps spread disease, whether it is an infectious disease or not. Power and money affect what groups of people can access. For example, advertisements and shops expose people to products that help spread non-infectious diseases: many cheap unhealthy processed foods and drinks contribute to obesity and related conditions, alcohol and tobacco products can lead to addiction, cancers, and other conditions. We may judge the “personal choices” driving diabetes, but they are rooted in a system of industries that are enriched by selling these products, even though they can damage health.

Preventable Unfairness?

Health stretches beyond clinics managing disease, or research exposing issues behind disease and finding treatments. It is one task to educate each person on better health, but communities also organize to find, advocate for, and apply preventive solutions to issues in the system. Especially when taxing citizens are paying for healthcare systems to care for people who get diseases rooted in unhealthy industries, communities could ask industries to use simple product labels stating how many teaspoons of sugar have been added, could demand more taxes on products that add to disease burden while lifting taxes from products that improve health, or could call to ban harmful and unnecessary chemicals. If some humans created unfair systems that ignore some groups of people, then perhaps communities’ main work for health must be improving those same unequal social, economic, gender, and racial systems.

Dr. Fatima Laher is the Clinical Research Site Leader of the HVTN Soweto-Bara site in South Africa.

References:
Two interventions are giving the world another chance to build better models for equity and impact in HIV, and for public health more broadly.

Following robust, well-run research programs that included essential community and stakeholder engagement components, the monthly dapivirine vaginal ring (DVR) and the every-two-month injectable cabotegravir (CAB) are beginning to enter the global market.

In 2020, two large-scale efficacy trials found that CAB showed a substantial prevention benefit in gay men and other men who have sex with men, transgender women who have sex with men, and cisgender women. ViiV Healthcare, the developer of CAB, received US FDA approval for use as PrEP in late 2021, and Malawi, South Africa and Zimbabwe have also approved CAB for PrEP, with decisions (https://tinyurl.com/mr5umuvt) from close to two dozen other countries expected in 2023 and 2024. WHO has recommended injectable CAB as an additional PrEP option as well.

In 2021, WHO also recommended the DVR as an additional PrEP option, and it is now approved in seven African countries (Kenya, Lesotho, Rwanda, South Africa, Uganda, Zambia and Zimbabwe), and pending in five others. Developed by the International Partnership for Microbicides, which is now part of the Population Council, this monthly option for HIV prevention is a crucial new addition to the prevention toolkit.

But the experiences of the first decade of oral PrEP implementation – and the experiences of the past three years of the inequitable access to COVID-19 vaccines around the world – show the impact of delays in delivery and uneven access to life-saving interventions. The experiences also show what needs to be done differently going forward.

Oral PrEP was first shown to be safe and effective in 2010 and was first approved in 2012, but the field moved too slowly. And now 11 years later, approximately 3.8 million people have initiated use of this option, reaching the 2020 target of 3 million PrEP users two years late, and still representing only a tiny fraction of the estimated number of people who could benefit from it. Too many new HIV infections have occurred in the past 11 years because of the fundamental error underlying the drug’s painfully slow roll-out: the public health
world’s seemingly single-minded focus on developing products and technologies, without similarly focused and funded efforts to make those products accessible, affordable and responsive to user needs.

There are significant questions about how to deliver CAB for PrEP and DVR, but the world cannot afford to squander another decade navigating these questions. Bold actions, global urgency, and coordinated partnerships are needed now.

Conversations are finally underway about accessible pricing, introduction projects, health systems support, and generic production of these new PrEP options, all of which are essential to ensuring that people in low- and middle-income developing countries can access new forms of PrEP simultaneously with wealthy countries. Regulatory approval, normative guidelines, and conversations on pricing will not prevent infections, however. To do that, the entire global health community – funders, planners, health systems, educators and advocates – must apply some critical lessons to ensure that every person who can benefit from these critical scientific advances has real access to them.

If introduced and supported strategically, these two new products, along with oral PrEP, internal and external condoms, and voluntary medical male circumcision could slow annual HIV infections significantly, saving thousands of lives and billions of global health dollars.

In June 2022, AVAC published A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP (https://tinyurl.com/mry7rhyd), in hopes that global stakeholders could collaborate around a shared strategy to translate scientific advance into public health impact. The overarching focus must be to move faster, more strategically, and with more coordination than was seen with oral PrEP or with COVID-19 vaccines, using the following principles as a guide:

- **Lead with equity:** Products don’t end pandemics if principles of equity are not embedded in every decision; COVID vaccine delivery is a stark reminder of this reality. People are keenly aware of whether research and development reflects their priorities, if programs speak to their needs, and if essential health products are being distributed according to need or stockpiled by wealthy countries. The tendency of wealthy nations to hoard and waste critical goods, most recently COVID-19 vaccines, has been fatal to the credibility of many essential health products.

- **Center the community and user:** Centering communities and users in the design and implementation of programs and product delivery is absolutely crucial. We have learned from the Good Participatory Practice Guidelines (https://tinyurl.com/2cwpa7bd) that effective community engagement builds mutually beneficial, sustaining relationships and strengthens programs. Community engagement is essential at every stage of product development, introduction and access. Many health systems need a 180-degree turn-

Around in how they approach their customers. No business succeeds by making it difficult to access their product. Bad service, inconvenient hours and stigmatizing attitudes don’t build interest in anything, including health products.

- **Accelerate scale and speed:** We need to do away with slow, unnecessary waiting games that keep efforts to scale up delivery on hold, while demonstration projects (aka implementation science) tests consumer markets. Part of accelerating scale-up is moving toward a parallel approach where research, implementation science, and rapid scale up of programs are designed, funded and put in place in parallel.

- **Deliver impact:** Align implementation priorities with targets for the next 12 months to deliver significant benefits and measurable impacts on public health. Wildly ambitious coverage targets cannot be supported with small-scale projects, as seen in the oral PrEP experience. Ambitious targets on coverage, before there’s a clear understanding of capacity, can add confusion. Instead, set deadlines for assessments on operational capacity, and tie those assessments to setting coverage targets.

- **Let education and outreach efforts drive product uptake and effective use:** Most marketing efforts for health lack the budget, imagination or insight to engage potential users. While many HIV

Continued on the next page...
prevention efforts use clinical terminology and focus on HIV risk, research shows that uplifting, aspirational conversations about healthy sexuality and relationships are much more likely to generate and sustain demand for HIV prevention tools.

- **Fundamentally reframe HIV prevention products, services and information to emphasize consumer choice.** Science has given us pills, long-acting injections and a vaginal ring for HIV prevention in addition to the tools we already had. Implants, antibodies, vaccines, multi-purpose prevention technologies (MPTs) and other potential options are in development. A comprehensive approach to HIV prevention must embrace and support choice, based on the understanding that different prevention options will be right for different people at different times in their lives and for different reasons. This approach is essential to both increasing prevention uptake and ensuring that products are used for maximal impact.

- **Work with what we know, while continually adding to the evidence-base.** There is still much we don’t know about CAB for PrEP and DVR. But there is also a lot we do know. We have consistently failed at prevention by letting the perfect be the enemy of the good. We can learn from past mistakes and missteps. These two exciting, effective options offer a chance to reorient and re-energize HIV prevention programs.

This is the best chance we’ve ever had, likely in the entire history of the AIDS pandemic, to reimagine prevention and to do it with equity and impact. History will judge us very harshly if in 5 or 10 years we go back to AIDS conferences and report on low uptake, and persistent new infections year in and year out.

And we will be judged even more harshly if we don’t use the opportunity of introducing these new options to build a robust and equity-guided platform to deliver the next generation of prevention options, including, we hope, an HIV vaccine. That’s hard work, and much of it still lies ahead.

*Stacey Hannah is the Director of Research Engagement, and Nandisile Sikwana is a Regional Stakeholder Engagement Manager with AVAC.*
Determining whether a study product works or does not work in a particular population is one of the evaluation objectives of clinical studies. Among other processes, this involves evaluating the interaction of the product and the genetic, biological and environmental factors of the participants because these could influence safety and efficacy. It has been shown that there are differences in the body’s response to a drug or vaccine between people of different ethnic groups, but also due to factors related to health conditions such as HIV, tuberculosis, etc. However, despite efforts to facilitate access to participation in clinical trials, it is still a challenge to achieve equitable participation for all populations.

Added to this situation are other social determinants that cut across the realities of the participants’ lives, including accessibility of the research centers, socioeconomic level, illiteracy, lack of job opportunities, gender violence, and low confidence of community members regarding research. Faced with this, clinical research sites develop community involvement plans with approaches tailored to the various populations and individuals with whom we interact, paying extra attention to populations that are poorly represented in the protocols.

Always Close to You

We start from the idea that we should get closer to people. For this reason, in tuberculosis studies we periodically visit the health centers in the areas with the highest number of reported cases, characterized by low-income families who mostly come from the Andean regions of the country. In partnership with health department personnel, we sensitize and inform people about the importance of timely testing for tuberculosis, and the need for shorter and more effective preventive or curative treatments. To get people’s attention, pre-tested educational materials are developed and adjusted to the characteristics of the populations to whom we are targeting. The information must be simple, clear, and attractive, with which the population can identify.

For HIV prevention studies, we reach out to the communities of trans women and gender non-binary people, who face expulsion by their families because of their identities, causing deterioration in their quality of life, unemployment, dropping out of studies, having little economic income to cover food expenses, precarious housing, and other social problems. Given this, the “Trans Houses” or “Houses of Ball Room” have emerged as self-managed spaces for people to gather, socialize, and access services related to health, identity, and legal issues.
Health Inequity Perspectives

protection, emotional support and development of artistic abilities that allow community members to stand out in Balls or beauty pageants. In this sense, we not only seek to disseminate information about advances in HIV research, but we also contribute to the development of their organizational capacities. Currently, the community involvement team of the Impacta Barranco CRS and Impacta San Miguel CRS provide advice to House XXXX about building a support network with institutions that address mental health, job opportunities, physical health, entrepreneurship, and more.

Meet our Participants

Previous work in community education in the areas of the city at greatest risk for TB facilitates entry into the homes of the most vulnerable families, and allows the identification of social and cultural barriers that could affect adherence to the study product and/or retention. In addition, people with recently diagnosed cases with whom contact is made are identified to inform them about studies, as well as the importance of prevention among their close contacts. A relationship of trust is built with the families, who identify us as leaders in the approach to the disease. Accessibility of the study sites is key, and even more so in the case of family groups affected by the social determinants of health. For this reason, transportation to the site is facilitated and visit schedules that are adjusted to their work commitments are offered. We also provide vouchers to purchase food in a supermarket chain, to supplement the diet of our participants.

For HIV studies, a presence on social networks and dating apps such as Facebook, Instagram, TikTok, Telegram, Grindr, and others has been added to the strategies of visiting places of socialization. This allows us to reach LGBTQIA+ populations of all ages and social strata. In addition, private transportation is facilitated in order to optimize visit times, especially for trans women and participants who have a disability.

Mental Health: The Importance of Listening

HIV prevention studies have allowed us to build the retention strategy called tutoring or case management. With it we seek to ensure continuity in the study, but we also contribute to addressing social determinants such as mental health, lack of job opportunities, violence, or barriers to accessing other health services. We created emotional support services, links to comprehensive health services, and legal advice (in cases of violence), as well as access to a database of job opportunities. Using this strategy, it has been possible to generate an empathetic bond, and our participants recognize our concern for them as people beyond their participation in a study.

All these strategies cannot be implemented by a single actor, but in coordination with state entities, civil society, and communities. We must all aim at the elimination of inequalities. In our case, we must begin by evaluating and reinforcing our work to achieve greater representation of the diversity of populations, which results in finding vaccines and medicines that benefit everyone.
“Sadness made one interesting,” said Susan Sontag in her book “The Illness and Its Metaphors.” And it is even more interesting if you are a student of social sciences, and you work in the writing of a newspaper. In those undergraduate years, melancholy was a part of me, and coughing was not uncommon in a city where smoking was not questioned. I was a secondhand smoker going about my life among heavy smokers in the newsroom. I was a person affected by Tuberculosis.

How did I get it? A series of social determinants appeared simultaneously: irregular eating and working endless schedules; closed spaces with little ventilation and lack of daylight (both in the university classroom and in the newspaper office); exposure to the risk of contagion when volunteering with street children; a weakened immune system (the year before I was diagnosed with juvenile rheumatoid arthritis).

Could I get over it? Of course. My family faced the costs of daily medication and improved nutrition, among others. They also decided to take all care measures for themselves, but stayed by my side. The emotional support of the family is of the utmost importance for a person who must receive daily medication (in my case, for 6 months). The distant support of some university colleagues also strengthened me, sharing class notes and agreeing to let me continue in working groups and contribute to discussions by letter or by phone. More difficult was overcoming my own self-discrimination: the shame of having contracted this disease kept me silent about my diagnosis for many years, as well as the guilt for “allowing it to be transmitted to me.” At that time, I did not know that tuberculosis was an endemic disease with high incidence rates and active transmission that could impact anyone.

After finishing my studies and having taken the path of health communication, I had the opportunity to share about my past diagnosis of TB with a group of health promoters while developing self-training materials on tuberculosis for community agents. The catharsis experienced by sharing our stories and knowing that the lack of information in the general population remained, as well as the difficulties people had with adhering to their treatments, clearly showed me the need to work in this field.

TB was and continues to be a challenge to overcome. It is a challenge for many reasons, including the lack of information or misinformation, the insufficient involvement of local authorities in the development of prevention measures, and due to the resistance of some authorities to incorporate the scientific evidence that clinical trials provide to make decisions regarding changes in schemes, duration of treatments, and the development of new vaccines. The process is long, but the satisfaction will be great when, hand in hand with the affected people, we achieve more informed communities and see access to new treatment options, vaccines, and prevention measures that science can offer us.

MaR León is the Head of Community Involvement at the IMPACTA CTU in Lima, Peru.
Social inclusion and access to quality healthcare continue to be challenges in a middle-income country like Peru, especially in vulnerable populations such as those affected by TB, living with HIV, and LGTBI+, who not only face stigma and discrimination, but also an exclusive social environment. This reality was more noticeable with the arrival of COVID-19. Below is the opinion of the community leaders, belonging to the Impacta Community Advisory Committee:

For people affected by Tuberculosis

César Alva, coordinator of the National Network of Organizations of People Affected by Tuberculosis, reflects: “there was no direct supervision by public service health personnel for people with tuberculosis during the COVID-19 pandemic. Many dropouts to treatment were generated, there was no support. Now the consequences of these abandonments are being seen”.

Mercedes, General Director of the Association of People Affected by Tuberculosis (ASAT), complements what César said, indicating: “tuberculosis is linked to poverty, inequality, overcrowding. In recent years, a biomedical approach has predominated. Addressing it including social factors is still pending”.

Along the same lines, Mercedes highlights the need to have mental health services, and adds: “there is a lack of a comprehensive approach that includes mental health, which includes continuous, higher-quality psychological therapies.”

Mercedes also comments on the need for health personnel in public establishments to show willingness and warmth when doing their work. Recalling his experience, he recounts: “the same day my diagnosis was revealed, they explained everything to me. I don’t remember anything he said. All the information was given immediately. I was completely ignorant when I started the treatment, until I contacted a tuberculosis organization, where I was able to learn”.

For People Living with HIV/AIDS

People living with HIV/AIDS (PLWHA) experienced difficulties in continuing their treatment in the midst of the pandemic. Maria Luz Quispe, a member of the Network of Women Living
Maria Luz adds that a great difficulty in Peru is access to free health insurance that guarantees adequate care for all people. In the case of the Comprehensive Health Insurance (SIS) provided by the Peruvian State, the following barriers are presented: "If you had a refrigerator at home, it was impossible to access the SIS, considering that the person had financial resources. It was not analyzed that as a result of complex diseases such as HIV or Tuberculosis and even COVID, the family group could end up in poverty as a result of this disease", Quispe comments, "the PLHIV community has had to hold many meetings, dialogues with the Ministry of Health and the SIS. Now, thanks to these efforts, if you are a person diagnosed with HIV or Tuberculosis, you have direct access to the SIS".

On the other hand, Maria Luz also demands greater participation of cisgender women in clinical trials of HIV treatment in Latin America: "All the studies are based on how men react, with a few exceptions. There should be studies dedicated to drug reaction in cisgender women."

**For LGBT+ Communities**

In another social aspect, there is still a pending issue, the approval of equal marriage, the mainstreaming of the gender approach, the visibility of trans communities, among others.

Regarding discrimination against the LGBT+ population, Sascha Reinstein, a young man from a non-binary community, believes that LGBT+ communities “face violence and discrimination both in the media and on a daily basis.” However, she notes that not everyone suffers in the same way, due to racism. “The discrimination that a gay, white man who has achieved professionalization and lives in the capital city experiences is not the same as that experienced by a trans-racialized woman who engages in sex work,” concludes Reinstein.

Erika Trejo, a trans woman and President of the Impacta Community Advisory Committee, adds “there is a prejudice among health personnel in public establishments, as well as in Peruvian society in general, regarding trans people. That we are not ‘correct’ people, that we have made a mistake” comments Trejo, “sometimes the health personnel refuse to call us by the name that represents us, they call us by the name that appears on our identity document. It’s intentional, in the form of mockery.”

This situation worsened with the arrival of the pandemic, as reflected by Maria Luz: “they [trans women] could not go out to work, they had no food, no access to work, and even less to health services.

A lot of work had to be done, with organizations and NGOs, so that the compañeras had minimal relief during the years of the COVID pandemic”.

Finally, regarding health research, Erika believes that greater participation of the trans population should be promoted: "trans women are the most vulnerable to HIV/STIs in the country, it is important to promote their participation”.

Felipe Vilcachagua and Cesar Bayona are Community Educators at the Barranco CRS, part of the IMPACT CTU, and Maú León is the Head of Community Involvement in the IMPACTA CTU in Lima, Peru.
In the city of Rosario, the communities speak as well as the walls. Rosario is a region with 1.3 million inhabitants, 300 km from the city of Buenos Aires. It is a place where feminism, sexual diversity and even HIV activism cross.

It is impossible to think about the health of individuals or communities from the mere presence or absence of a disease. The historical view, an approach that recognizes the tensions caused by a multiplicity of problems, shows that demanding policies and interventions by and for health is not a simple task.

Infections like tuberculosis and HIV are indicative of these difficulties. These are public health problems that are unequal among jurisdictions, and handled in unequal ways, with a tendency toward increased incidence in recent years. These infections mostly affect groups of young people, with a concentration in large urban areas. The inequalities are not distributed randomly, but are deeply determined by the social, political, sexual, ethnic and economic structures in which we live.

From the epidemiological point of view, there has been an increase in the incidence of diagnosed and reported cases of tuberculosis in the city of Rosario, as well as the appearance of late or very late diagnoses of HIV, which leads to the person presenting symptoms of AIDS marker diseases accompanied by a very low CD4+ count.

By: Gustavo Osimani CER, Centro CAICI CRS, Rosario, Argentina, Lautaro Martín Maino, CAB member, Centro CAICI CRS, Rosario, Argentina

Inequities in Prevention and Treatment of HIV and TB, and the Influence of Social Determinants on Health in Rosario, Argentina

The Other Face of the State: Inequities in the Face of Right

As community representatives or people involved in primary health care, we believe it is absolutely necessary that the State (national government), with its public policies, analyze and evaluate how the diversity of social determinants have an impact on late diagnosis, on inequities in access to prevention policies, and on difficulties in access to treatment, which often only reach the middle-to-upper sectors of society.

From a rights-based perspective, it is possible to observe an increase in exclusion, inequality, and social fragmentation that have generated a direct impact on the increase of TB cases and late diagnosis of HIV during the last decade and following the COVID pandemic. There is an increase in the number of people accessing primary health care later than in previous years, and it is possible to observe how situations of poverty were aggravated, and how these situations affected key and stigmatized populations. This made class differences more clearly evident, demonstrating the vulnerability of migrant populations (people from bordering countries who come into the public health system with clear symptoms of tuberculosis), and highlighting how inequalities in access to prevention, diagnosis and treatment policies are carried out across racial and gender differences in parts of the LGBTQIA+ community.
Given this context, we see the need to build more comprehensive prevention and support tools that allow key populations to access diagnosis and treatment, while at the same time improving the quality of life of these stigmatized and vulnerable groups.

A combination prevention policy is being implemented currently in Rosario which unfortunately does not reach the most excluded population groups. Community work has much to contribute regarding access to prevention and diagnostic policies, such as dissemination through social networks, significantly increasing testing sites, developing strategies that favor accessing the health system earlier by those who arrive too late to be attended, and participating in the education and training of health personnel in order to make the public health system more culturally responsive.

We believe that policies aimed at a more equitable distribution of income, providing educational opportunities, reducing precarious employment conditions, and drastically reducing the housing deficit, among other policies, would surely attenuate the above-mentioned inequalities.

Although these are broader social objectives that should not be forgotten, there are actions that community advocates can take along the way, and this is our challenge.

**Relationship Between HIV and Tuberculosis**

There is a high prevalence of HIV among people who have tuberculosis, and there is an increasing number of cases of people who seek care in public health systems with symptoms of tuberculosis and who are also found to have HIV as a co-infection. Despite the inconsistencies that exist in the reports provided by different levels of the government and health sub-sectors (reports from the public, private and mixed medical spheres, which report new cases in a partial manner), it is clear that both diseases show no signs of decreasing.

While the ways in which both illnesses exist and are transmitted are clear and have been known for more than 40 years, we still need to work for the eradication of HIV and tuberculosis in our region. With policies that intervene in different ways and with very different intensity in different segments of the community, the incidence has remained stable but is increasingly occurring in young people. What else is necessary to implement to take a greater step forward?

Although it is necessary to think beyond biomedical prevention, broadening the dimensions of the health-disease-care process is a task that must not be abandoned. Understanding the social determinants of health should be a key training requirement for healthcare workers. They must also understand that the configuration of health problems is not the individual’s fault, but the result of a historical process to which societies have been exposed.

Our bodies and our illnesses have stories that still deserve to be told. And with scientific advances, our quality of life is improving every day. But that is only the first step: having laws to protect us and loving bonds to accompany us in living with illness is one of the greatest signs of love.

Living with HIV is a political situation, and so is living with tuberculosis. Understanding the perspectives of groups that demand a cure, including stigma, is a requirement not only for community, health or political groups, but also for the entire population. People living with HIV and TB should not be exposed to late diagnosis, isolation, difficulties in accessing treatment, or the fear of discontinuity due to shortcomings in health services.

Gustavo Osimani and Lautaro Martín Maino work to ensure community members are engaged and meaningfully involved in HIV research conducted at the Centro CAICI Clinical Research Site.
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.

**Why don’t standard HIV tests look for actual HIV?**

Standard HIV tests that look for antibodies are quick, reliable and affordable. Tests that look for the virus are expensive and not commonly used for an initial diagnosis.

**What does “opt-out” testing mean for me?**

You should tell your healthcare provider about your HIV vaccine study participation and refuse HIV testing. Even if your healthcare provider does not mention the HIV test, be sure to tell them that you do not want an HIV test because you are (or were) an HIV vaccine study participant.

**How long does VISP last?**

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

- In most cases, no. If you have tested VISP you cannot pass the antibodies to another person by kissing or through sexual contact.
- If you are pregnant, we think there may be a chance that you could pass the vaccine antibodies to your baby. Although this has not been shown to happen with HIV study vaccines, we know that this happens with other vaccines, like the tetanus vaccine. Vaccine antibodies that mothers pass to their babies are temporary and go away over time, and they are not harmful to the baby. The HVTN can arrange for you and your baby to have accurate HIV testing for free for as long as it is needed.
- In order to donate blood or organs, the donation site will screen you using an HIV antibody test. If you test positive for HIV antibodies you may be unable to donate an organ. You may also be permanently banned from blood donation even though you are not infected with HIV.

How will a VISP test result affect me?

- If someone believes you are infected with HIV, you could face discrimination and/or other problems. For example, you could have problems with medical or dental care, employment, insurance, a visa for traveling, or entry into the military. You might not be allowed to donate blood or other organs. If you are pregnant, you may have to explain your situation to avoid receiving any HIV treatment during your pregnancy or labor/delivery.
- If you are planning to apply for insurance, employment, or the military, please inform your study site right away. The insurance company, employer, or military agency may not accept HIV test results from the HVTN. However, the HVTN can work with them to ensure the right test is done that will show your true HIV status.

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

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

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

Will my information be confidential?

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

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

Approximately 2 weeks.

Am I eligible for the HVTN VISP Testing Service?

YES:
- If you participated in an HIV Vaccine Trials Network (HVTN), AIDS Vaccine Evaluation Group (AVEG), or HIV Network for Prevention Trials (HIVNET) HIV preventive vaccine study, AND
- 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.
My career in HIV began 15 years ago, by accident. Year three of my formal medical training was planned to be a one-year clinical fellowship caring for people with cancer in Buenos Aires, Argentina, but as the old Yiddish proverb goes, “When we plan, God laughs.” I’d spent my entire life planning and preparing for a career dedicated to curing cancer, and until 2008, things were going as planned. Then God laughed.

My plans to care for people with cancer quickly fell apart, and I was left scrambling to salvage a year abroad at a critical point in my training with no time to waste. An alternative opportunity to train with Argentina’s principal HIV foundation, the Fundación Huésped, was presented to me, and although I’d only studied cancer up until this point in my education, I accepted. Little did I know that decision would change not only the trajectory of my career, but my faith formation, and my life. My time in Argentina introduced to me the social determinants of health in a way I had not experienced before. Everyone I cared for presented with an HIV diagnosis that was deeply rooted in complex social circumstances and conditions.

One such person was a woman of trans experience with a history of sex work. She talked openly about life as a trans woman in Latin America. She lamented over the friends she’d lost along the way, mostly from HIV/AIDS but some from violence rooted in transphobia. But what stuck with me the most was her relationship - or lack thereof - with her faith. She talked about being raised Roman Catholic, as more than 90% of Latin America was and continues to be – and I could tell that she had great passion for Christ just from the emotion that she spoke with. So, you could imagine my dismay when she shared that she no longer identified with the Church, because the church didn’t identify with her. The Church condemned her identity as a transgender person living with HIV because the only way she could survive was by putting herself at risk for HIV exposure when selling the sole thing she could offer at the time - her body.

I left Argentina that year really struggling with her story and how Church and society had rejected her in a way that ultimately made her more vulnerable to HIV. I realized that no matter what we did for people seeking care in a clinical setting, we would always have to send them back into a world that makes them sick, and...
faith was a part of the story, for better or worse. I returned to the United States conflicted about my own professional path, but also emboldened to learn how the social determinants of health, and particularly faith, play a role in the HIV epidemic in the U.S., because faith is a social determinant of health.

This is especially true for Black Americans who shoulder the greatest burden of HIV in the U.S. According to Pew Research, Black people are the most religious ethnic group in the country, with almost eight-in-ten Black Americans being affiliated with some religion, and nearly all Black Americans (97%) indicating that they believe in God or a higher power, regardless of their religious affiliation. Likewise, most Black adults say they rely on prayer to help make major decisions, including about health. When considering this in the context of the demographic landscape of the HIV epidemic in the U.S., where the southern region of the country accounts for the largest population of Black people, people who identify as LGBTQIA+, people living with HIV, and people of faith – it’s impossible to ignore faith as a social determinant of health overall, and of HIV specifically.

Rightfully, research is beginning to support the case for more consideration of faith when assessing health outcomes in Black Americans. Another study by the Center for HIV/AIDS Educational Studies and Training (CHEST) at City University of New York reviewed 9 studies with 13 statistical analyses, examining the relationships between individual HIV syndemic-related health conditions, religion, and spirituality in men who have sex with men (MSM). This systematic review identified 5 negative associations and 2 positive associations between religion/spirituality and HIV-related health conditions in MSM, concluding that the need for the inclusion of faith in HIV and health disparities research with MSM is clearly supported, and that scientists and public health policymakers should critically examine how faith can promote positive health outcomes among MSM.

The HVTN Faith Initiative is a prime example of the ways in which institutions committed to biomedical discovery can effectively integrate faith into their research priorities, but you don’t have to be a scientist or clinician to understand the impact faith has on the wellness of communities. Just drive through any urban epicenter in America and note the number of houses of worship present compared to the number of healthcare facilities, grocery stores, or fitness centers. For many people, faith isn’t merely an ideal, but rather a support system that fills the gaps in access to the things that are supposed to keep us healthy.

In the 15 years since I started this journey, I’ve grown into a more complete healthcare provider; not solely because I refined my clinical skills, but mostly because I honed my people skills. Treating people versus treating disease means considering everything that people bring with them when assessing their well-being, including their faith, because faith is a social determinant of health. For better or worse, faith has to be a part of the conversation when addressing health disparities like HIV/AIDS if we expect to make our worst better, and our better, best. Without faith, we’ll still be having conversations around health inequity well into the fifth decade of the HIV epidemic and beyond.

Although the struggle continues... remember to keep the faith!

Dr. Ulysses Burley is the founder of UBtheCURE LLC and Project Director of the HVTN Faith Initiative.

References:
HVTN Updates

HVTN RAMP Scholar Program –

Welcome RAMP Cohort 13!

By: Linda Oseso, RAMP Program Manager, HVTN Core

The HVTN has accepted 17 scholars for the 2023-2024 RAMP Cohort 13 Scholar program! This is the largest cohort in program history; previous cohorts have ranged from 4 to 9 students. We have 14 scholars in the general program and 3 scholars in the alumni program.

The program criteria have expanded to include students who identify as Native American/ American Indian, Native Hawaiian, Asian and Pacific Islander, and individuals granted deferred action for childhood arrivals (DACA) status by the U.S. Citizenship and Immigration Services.

The HIV Vaccine Trials Network, in collaboration with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, is investing in a young generation of HIV prevention researchers by providing them with opportunities to conduct independent research while receiving mentoring, project and salary funding, training, and professional development opportunities. Scholars will be working on their projects with sites in the US: Atlanta, Birmingham, and New York; Malawi: Lilongwe; South Africa: Cape Town and Soshanguve; and Zimbabwe: Harare.

To learn more about our scholars and the projects they will be working on, please visit the RAMP Scholar Profiles on our website: https://www.hvtn.org/scientific-programs/scholar-awards/ramp-scholar-profiles.html

For more information, please visit www.hvtn.org/ramp or contact Linda Oseso, RAMP Program Manager, at loseso@fredhutch.org.
Partner Updates

Party With a Purpose!

By: Kyle Gordon, HVTN External Relations Unit, Seattle, WA

Seated in South Central Los Angeles, the AMADD Institute has become one of the premiere social service organizations in the Greater Los Angeles area. Founded by Dr. Carl Highshaw, Arming Minorities Against Drugs & Disease Institute provides essential and supportive services, community support, resources and referrals aimed at impacting LGBTQ people of color. The organization ended their year with a bang with their event: PARTY WITH A PURPOSE!

What a time was had when A.M.A.D.D. brought community members together to ensure there was access to education, information, and a safe space to dialogue about how the community has been impacted by intersecting pandemics. Co-Sponsored by the HIV Vaccine Trials Network External Relations Unit, PARTY WITH A PURPOSE dropped knowledge with fireside chats on HIV prevention and treatment modalities, the latest information on COVID-19, MPOX (monkeypox), and the importance of mental health and well-being. The night provided access to at-home HIV self-testing kits, COVID testing kits, and COVID vaccinations/boosters. With the help of health professionals like Dr. Leo Moore, Leon Maultsby, and Dr. Steph aun Wallace, the community gained valuable information including various perspectives on the importance of health equity.

This was a phenomenal event that truly brought community together and showed the power of community and grassroots mobilization! In between the panel discussions, dynamic talent graced the stage. The party ended with several hits from the headliner, Dreezy, where she dropped a few tracks that showed her unique style of streetwise lyrics with an R&B flow.

There is no doubt that great things are still on the horizon for the AMAAD Institute as they continue to root their work in communities that may need it the most. As they expand their programmatic footprint, AMADD will continue to create agency in the community, facilitating access to programs and services that foster safe and supportive environments.

Kyle Gordon is an External Relations Project Manager with HVTN.

Dreezy, the American singer, rapper, and artist graces the stage and drops a few of her latest hits to keep the party going!

It is always good to see Donnie Frazier out in the community.

During the fireside chat, Leon Maultsby of Charles Drew University, talks about the importance of engagement in HIV prevention and care services.

Community is all smiles as they prepare for the raffle at PARTY with a Purpose.

AMAAD staff and partygoers come together for a night of education, information, fellowship, and music.
CHEERS TO 30 YEARS!!!

By: Kyle Gordon, HVTN External Relations Unit, Seattle, WA

In 1992 four activists decided to start an organization to respond to the lack of HIV prevention and education services for youth of color. At the time, their main goal was to provide programming that would reduce HIV incidence, but little did they know that after three decades, their scope of work would make them a staple in Los Angeles and around the nation in using performing and creative arts to influence the health of young people. Since their inception, REACH LA has expanded to provide sexual health services, social groups, mental health services, and wraparound linkage to care for youth and young adults.

After years of COVID mitigation restrictions, the community came together to celebrate and support the 30th Anniversary of REACH LA and their awardees. Hosted by an amazing Board of Directors and staff, the central theme of the evening was the organization's four pillars: Health & Wellness, Creative Arts, Personal Development and Social Enterprise. The HIV Vaccine Trials Network External Relations Team served as a platinum sponsor for the gala, and worked to ensure our collaborative partners at clinical research sites and community based organizations in the Greater Los Angeles area were in the building.

The celebration was one you did not want to miss! The evening brought together over 200
community members for a black-tie affair. The event included a cocktail networking hour, a sit-down dinner, live entertainment, and an awards ceremony highlighting some of REACH LA’s most influential stakeholders. The staff and Board of Directors highlighted the impact and investment of 9 individuals and businesses with the presentation of the Founders Awards, Creative Ally Awards, and Community Ally Awards.

Creating agency for community has allowed REACH LA to stand strong in providing services in an ever-evolving social landscape. It is our greatest hope that we can look forward to 30 more years of service and advocacy to ensure the community is engaging and prioritizing the voices of young people as we endeavor to end HIV and improve health outcomes.

Kyle Gordon is an External Relations Project Manager with HVTN.
The Community Advisory Board (CAB), coordinated by the Unit for Clinical Vaccine Trials of the Medical School of the Federal University of Minas Gerais (UPqVac - UFMG), started its activities on May 25, 2006, in Belo Horizonte. Since its formation, the CAB has been actively advising on several studies from different clinical trials networks, taking information to the interested community about the importance of research, and ensuring that all volunteers have their rights guaranteed.

The Community Advisory Board for the Mosaico Study was established in 2019 and is composed of health worker representatives such as nurses, dentists, social workers; and representatives from NGOs such as:

- **Família Positiva**, an organization that welcomes people living with HIV/AIDS
- **TRANVEST**, an organization that offers financial aid, basic education, psychological and medical care, and food baskets for 148 transgender women in Belo Horizonte
- **Horizonte Project**, a research project with educational interventions about prevention of HIV/AIDS
- **Clã das Lobas**, a collective of cis and transgender women sex workers from Belo Horizonte, and representatives from civil society and the LGBTQIA+ community.

Initially our meetings were held in person every month, where the schedules of duties were prepared and discussed. The first challenge we faced was the COVID-19 pandemic, and due to protective health measures, the meetings started to occur remotely. This demanded from us a greater strength to gather people and to carry out the activities.

The CAB has developed partnerships with social movements that work in several areas of comprehensive health care and social welfare. This created a bridge to facilitate activities with an emphasis on potential study participants, as well as youth, women, and the LGBTQIA+ population.
meetings are fundamental for the construction of strategies and for understanding the needs of the populations involved, in addition to guaranteeing the rights of the participants within clinical trials. The CAB plays an important role within the community. Together with the Community Education Program, they have been doing educational work and walking together in the never-ending journey to improve the lives of these populations.

Establishing dialogue with the community was an important step to understanding the need for information about HIV prevention, testing, diagnosis, and treatment that this population experiences. The information was not always accessible and presented in the same way to everyone, so the inclusion of the key populations made it possible to better understand the participants. This brought the team closer to the lived reality of each participant, and provided an effective, safe, friendly, and individual service to each member of the team and the community in general.

The information and knowledge acquired since the CAB began its activities have allowed us to have more contact with the community, and access to a large number of people interested in contributing to science, to one’s fellow human beings, and this effort. Stigma and prejudices are increasingly left behind. The partnership built between the CAB, the participants, and the site further strengthened the dialogue between peers and the community as a whole.

The responsibilities and activities of the CAB remain in place, and the demands raised at CAB

“The best way to build knowledge is through the exchange of experiences and information, considering the uniqueness of each individual.”

Luize Campozzela

Jeferson Fonseca is a Social Worker, Luize Campozzela is a Community Educator/Recruiter, Marcus Vinicius Trigueiro is a Community Educator/Recruiter, and Lucas Brás, Luciana Gravito, Max Nunes and Abio Silva are CAB members for the Belo Horizonte CRS in Belo Horizonte, Brazil.

Outreach for HIV prevention with the local community (Pictured: Marciley Nunes, Jeferson Fonseca, Luciana Gravito and Lucas Brás)
Transphobia is described as discrimination and attitudes based in prejudice toward trans people. It takes various forms and has diverse actors ranging from psycho-emotional and physical violence to social exclusion and denial of public services to trans people (or obstacles to accessing them), or those whose expression of gender does not conform to traditional roles. Transphobia is classified as a hate crime according to the 2020 report from the National Observatory of Crimes of Hate Against LGBT People in Mexico, which states that:

“Hate crimes are sustained, above all, in a dense cultural fabric of discrimination, rejection and contempt. That is to say, they are culturally founded behaviors, systematically and socially extended, of contempt against a person or cluster of people based on a prejudice or stigma related to an undeserved disadvantage, and which has the effect of impairing your fundamental rights and freedoms, whether intentionally or not.”

In Mexico, transphobic violence and discrimination has become generalized and is part of the social fabric, such that transwomen experience it in various spheres of their daily lives. It restricts access to services and prohibits full human development. In the development of clinical studies, Morales (2019) also noticed the problems that generate this discriminatory phenomenon, since trans people are often excluded, or their participation may have a low priority in the inclusion criteria during the recruitment phase. The scientific community continues to postpone the inclusion of the trans population and their experiences and needs, and as a consequence, there is little understanding of how this directly affects the physical and mental health of the population. As a result, it is not always possible to generate solutions to their problems.

On the other hand, when studies have appropriate inclusion criteria, the research can take the trans population into account, and they can be recruited. Now the issue of adherence to the clinical program arises: are the requirements of the study compatible with trans people’s realities? This question has arisen due to the experience we have had with trans women who enrolled in the MOSAICO Study at the Mexico City CRS, where we have witnessed the difficulties that have sometimes limited or made it impossible for them to attend protocol visits. We enrolled 10 trans women who met all the inclusion criteria and chose to join the study. They generally attended their visits in a timely manner and were quite
committed to their participation, despite the fact that most of them invested more than 3 hours in transportation transfers to get to the clinic and back to their homes or workplaces afterward.

First, from the recruitment stage where screening interviews were held to verify if female candidates met the inclusion criteria, the site’s hours of operation were not compatible with the times of day the transwomen were available, because many of them engaged in sex work as their main source of income. The schedules of this job are often nocturnal, but the interviews and study visits were scheduled first thing in the morning. These participants often came to appointments using the time they would otherwise spend resting from their prior evening’s work or take care of personal matters. It was not realistic to think that good adherence to the protocol would be achieved, both because of the scheduling issues, but also because of the participants’ limited economic resources to travel to the site, located on the eastern outskirts of the city. Many of these participants lived on the northern outskirts, requiring an investment of time and money to attend their appointments. Although financial support was offered to cover travel expenses, for many the financial support offered was not enough to cover their actual expenses.

The visits to the site over the duration of the study allowed a trusting relationship to be built with the participants, and they gradually felt comfortable enough to share some aspects of their everyday lives. For example, some of them reported that they did sex work because they did not have opportunities to be employed in the field they had studied, because they were isolated in their jobs, or because they were unable to access services (because of the cost of those services). Some have felt that their gender identity or expression was being dismissed. Their sex work activities generally occur in environments where there is consumption of substances (sometimes illicit). They participate in this dynamic, prolonging their consumption, which affects their everyday activities. Toward the end of the protocol, site staff noticed the effects of this consumption among both trans and MSM participants, some of them coming to their visits under the influence of a substance.

Another situation that caught the attention of the Community and Involvement team was acts of transphobia that participants reported as occurring every day. This put retention in the study at risk and violated the dignity and humanity of the participants. Transgender participants reported being exposed to situations of discrimination in public health services, and they feared that this situation would be repeated with the staff of MOSAICO. Some participants requested that their study visits only be done with female staff members, because they feared discrimination or violence by the male members of the team like they had experienced elsewhere. Fortunately, this was addressed by making sure that participants felt as comfortable as possible, the site staff were responsive to their requests, and the site required frequent training for MOSAICO staff on the topics of sex, gender, and creating safe spaces for the LGBTQIA+ community.

This trusting relationship between the Community and Involvement team and the transwomen in the study allowed us to understand the consequences of transphobia on the mental health of the participants. Some of them reported having periods where they felt depressed or anxious, and on one occasion this made it impossible for study visits to be carried out in a timely manner, requiring them to be rescheduled. While mental health issues in general could be addressed by linking the participants to psychology and psychiatry services, in the case of the trans women only one accessed the services. A frequent reason they gave for not accepting the services was lack of time, while others commented that they would seek remedies on their own.

One of the trans participants was discontinued from the study because she suffered trans-femicide violence and requested political asylum in a foreign country. The HVTN did not have research clinics there, so her participation in the study could not be continued. It is important to note how close trans-femicide violence is, since 2 of the 10 trans participants in the study experienced this type of attack on their integrity and their lives. Another participant was able to finish all her visits, but the last one had to be done outside the visit window because she received death threats and had to flee her place of residence and “disappear” for a while to stay safe. Fortunately, she was able to contact us to let us know about this situation and asked for our understanding and special support for moving from this other location to return for the...
last study visit. When she came to the site, she was calm because she was able to get to safety, however, she said that it is not the first time she had received death threats or been harassed because of gender.

In contrast, we asked participants about any benefits they experienced while participating in the study. They reported that being able to know the clinic was a space where they did not have to worry about being mistreated by the staff was very important. They also valued the linkages to other health services including annual vaccination campaigns, being able to contribute to clinical studies and their analysis, having access to testing for sexually transmitted infections, being able to access PEP and PrEP, and that their visits were compensated with travel allowances.

In conclusion, how can we facilitate the inclusion of trans people in clinical studies? It is evident that the financial support to cover travel expenses to the site was not enough, so it is important to consider how to better address the real needs of potential transgender participants. This unmet need made it impossible to recruit more trans women.

It is also important for clinic staff to educate themselves about how transphobia manifests in different ways in the community, and the impact it can have on the development and implementation of clinical studies. To address this situation, it is not enough to include the trans population within eligibility criteria, and it is not enough to ensure their adherence to the study visit schedule. It is essential that clinical and community personnel who are in contact with the transgender population sensitize themselves to the lived realities that trans participants face, continue to receive training, and be constantly updated about the specific needs of the population, and in particular their need for mental health services. It is recommended that the community teams continue creating spaces for coexistence and building trust; that they remain open and receptive to the experiences of visitors to the clinic; that they seek links to people, programs and services that could positively impact the lives of trans participants; and that they ensure that the clinic is a space for attentive listening.

The scientific community must make room for trans voices to be heard in order for them to be included in clinical trials and for them to have opportunities to lead research when appropriate. It is essential that trans people are included in research teams, contributing to the design, implementation, and analysis of clinical studies. Their participation should not only be as subjects of investigation. It is urgent that trans people have access to clinical studies and the results so that they can synthesize, understand, and communicate what the results mean for their own community.

Diana Angélica Pacheco is the Community Engagement Coordinator for the CDMX CRS in Mexico City, Mexico.

References:
Site Updates

Mosaico Study Community Education

LGBTQIA+ PRIDE MONTH 2022

By: Curitiba CRS, Curitiba, Brazil

During the month of June several community events take place. This is because these dates go back to the history of the LGBTQIA+ movement beginning in 1969 at the Stonewall revolt in New York. In the early morning of the 28th of June, 1969, a group of LGBTQIA+ people decided to confront the police at a pub that was a meeting place for LGBTQIA+ people. In protest, they were confined inside the pub. During this time, the group gained the support of a crowd of gay men and lesbians outside.

The Centro Médico São Francisco site located in Curitiba, Paraná, Brazil held several activities to celebrate the LGBTQIA+ pride month including engaging with the LGBTQIA+ community throughout June/July 2022.

On June 26, 2022, the team held a round of talks with the Capivara Football Club team about a potential HIV vaccine for prevention, PEP/PrEP, combination HIV prevention, VISP (vaccine-induced seropositivity), distribution of condoms and HIV self-test supplies (made available by the Curitiba Health Department), and the Mosaico Kit (bag, glasses, pen, bracelet, and flyers). The gathering was carried out at the Bola de Meia court, in partnership with Curitiba’s Community Advisory Board (CAB).

A similar conversation was also held with the Lycans Volleyball team on June 30, 2022 at the Network Sport Court for Volleyball and Soccer.

CURITIBA PRIDE 2022 was held on June 28th. - Organized by Associação Paranaense da Parada da Diversidade de Curitiba (APPAD), the event had several cultural presentations, presentation of the APPAD team, and the first presentation of the Márcio Marins Award.

MÁRCIO MARINS worked at AtoBá Group in Rio de Janeiro before moving to Curitiba in 2005. He became a member of APPAD. In addition, he founded the Dom da Terra AfroLGBTI, was a member of the Forum of the African Matrixes (religious groups of Curitiba and the surrounding area). He served at Brazilian Association of Lesbian, Gay, Bisexual, Transgender, and Intersex People in addition to being active in the Permanent Council of Human Rights of the State of Paraná. Márcio was also recognized as a carnival celebrity in Curitiba, leading carnival groups and samba schools in the capital.

Our site, Centro Médico São Francisco, was awarded for its work and efforts in support of the LGBTQI+ community.

Continued on the next page...
As we have seen, the marches of the LGBTQIA+ movement are historically related to protests for access to citizenship and rights. We have provided some information to help people understand the importance of the fight against homophobia in Brazil.

A survey conducted in 2017 about the LGBT population by the Getúlio Vargas Foundation (FGV), based on data obtained by Dial 100, found that:

- 73% of LGBT students say they have been victims of verbal violence;
- 36% of LGBT students say they have been victims of physical violence.

Furthermore, the reports made by LGBT people show how the group is still a victim of violence. The reports show the percentages of those who had reported one of the following:

- Psychological violence: 35%.
- Discrimination: 35%.
- Physical violence: 20%.

In 2019, LGBTphobia (homophobia) became a crime in Brazil. Through a vote, the Supreme Court decided (8 votes to 3) that discrimination against homosexuals and transgender people is a crime, with a penalty of 1 to 3 years in prison in addition to a fine.
Scenes from the 5th March For Diversity, “Democracy in All Colors”
The HIV Vaccine Trials Network (HVTN) is an international multi-disciplinary collaboration. Support for the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health, an agency of the U.S. Department of Health and Human Services. The Network and NIAID have a close, cooperative working relationship, with shared attention to intellectual and scientific issues.

**ABOUT COMMUNITY COMPASS**

The Community Compass aims to keep the HVTN community informed about the Network’s research, site activities, and advances in the field of HIV prevention and vaccination. We encourage community members to submit news and event reports to this magazine and make this a true community sharing platform.

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