TOGETHER WE WILL FIND VACCINES FOR COVID-19
Welcome to the latest edition of the HIV Vaccine Trials Network (HVTN) Community Compass.

In this issue, we highlight some of the efforts of our clinical trial sites and updates from the HVTN Leadership and Operations Center (Core), including a special article that describes how and why the Network and other collaborators have pivoted our attention to respond to COVID-19. The COVID-19 Prevention Network (CoVPN) has been organized at the direction of Dr. Anthony Fauci, leveraging the clinical trials, laboratory, community engagement, and statistical/data management expertise of key NIAID clinical trials networks to test vaccines and monoclonal antibodies that are designed to protect people from COVID-19 disease. For more information on the CoVPN and to learn more about the clinical trials, visit www.PreventCOVID.org.

Though we have pivoted our efforts in response to COVID-19, we at the HVTN remain committed to our pursuit to find safe and effective preventive HIV vaccines that have global application.

I believe we will see an end to the COVID-19 pandemic, but we cannot achieve this end ethically by leaving anyone behind, or without ensuring that appropriate efforts are focused on those who are most vulnerable. There are many stakeholder mobilization efforts happening in local and national settings around the world with goals of raising awareness about these issues, and ensuring resources and solutions are inclusive of those most impacted and vulnerable. We are a global community; let us work together in response to this pandemic.

The Mosaico Study, also known as HVTN 706/HPX 3002, was previously paused in response to COVID-19. The study team wanted to ensure the safety and health of participants and study staff. We are in the process of working with regulatory groups and clinical trial sites to ensure a safe restart to the study globally. Our other HIV vaccine and antibody concept proposals and protocols are starting to reopen now.

Change is said to be the only constant in our lives. 2020 has brought about significant change to me personally and professionally, to my colleagues and our community partners, and I am certain to all of you. One of the significant changes that we touch on in this issue is the retirement of our very own Steven Wakefield (who prefers to go by just “Wakefield”) in July 2020. Wakefield was not only one of the initial hires of the HVTN, but has helped to lead and fortify community engagement within the network, and in communities globally.

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

Thank you for your continued support of the HVTN wherever you are in the world, for the work that you do in whatever role you have in the HVTN community, and for the impact we have been able to make in our collective history and communities, together. Though we have come very far in response to the HIV epidemic, we have so much further to go to achieve 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
<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meet The Community Compass Team</td>
<td>4</td>
</tr>
<tr>
<td>Building an Investigative Army in 100 Days</td>
<td>5</td>
</tr>
<tr>
<td>COVID-19 Prevention Network Active Studies Recruiting Volunteers</td>
<td>10</td>
</tr>
<tr>
<td>The CoVPN Faith Initiative</td>
<td>11</td>
</tr>
<tr>
<td>Upcoming Meetings/Conferences/Awareness Days</td>
<td>14</td>
</tr>
<tr>
<td>HIV Prevention Efficacy Trial Designs of the Future</td>
<td>15</td>
</tr>
<tr>
<td>Community Engagement Manuscript Published</td>
<td>16</td>
</tr>
<tr>
<td>After 20 Years, Wakefield Retires from HIV Vaccine Trials Network</td>
<td>18</td>
</tr>
<tr>
<td>Harmonizing Efforts to Conduct Large Scale COVID-19 Vaccine Efficacy Trials</td>
<td>21</td>
</tr>
<tr>
<td>HVTN Responds – No Justice, No Progress</td>
<td>22</td>
</tr>
<tr>
<td>Staffing Updates at HVTN Core</td>
<td>23</td>
</tr>
<tr>
<td>Understanding the Socio-Behavioral Dynamics of the Transgender Population in an Under-Resourced Setting in South Africa</td>
<td>25</td>
</tr>
<tr>
<td>“Banda Mole” is Also Prevention!</td>
<td>30</td>
</tr>
<tr>
<td>CoVPN Profiles</td>
<td>31</td>
</tr>
<tr>
<td>COVID-19 and HIV: What You Need to Know</td>
<td>39</td>
</tr>
<tr>
<td>Keeping Our Eyes on Sexual and Reproductive Health in the Middle of a Pandemic in Zimbabwe</td>
<td>44</td>
</tr>
<tr>
<td>Discovering the Necessity for ‘Meaningful Community Engagement’ in the Face of the COVID-19 Pandemic in Kenya</td>
<td>45</td>
</tr>
</tbody>
</table>
Our vision is an informed HVTN community that is aware of current events and activities relating to the HVTN network and its sites, advances in the field of HIV prevention and vaccination, as well as community priorities. We work to accomplish this by providing relevant information and updates to promote awareness, understanding, and support for HIV prevention and HIV vaccines, reaching global communities invested in the response to the HIV epidemic.

We welcome submissions of articles on any topic for publication that is relevant to the HVTN community. Submissions must be exclusive to us, and not appear in any other publication. Submissions must be 500 words or less to comply with our layout and design requirements. Due to space limitations, we may need to hold publishing your article for a future issue.

To submit articles for Community Compass, please go to the HVTN Members Site homepage, click on “About”, then click “Community Compass”, then click on “Submit to Community Compass”.

Meet the Community Compass Team

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WHY/HOW WAS THE CoVPN DEVELOPED?

The birth of a network

The first week of March 2020 brought several changes to the Seattle area. HVTN workers were ordered by Fred Hutch to work remotely. Conferences, such as the large annual HIV meeting CROI, went virtual. And infectious disease physicians and scientists everywhere started focusing on what they could do about severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2) and the disease it causes, COVID-19. HVTN Principal Investigator Larry Corey’s weekly calendar shifted from meetings about HIV antigens and monoclonal antibodies to how to combat the SARS-CoV-2 epidemic in Seattle and how to develop what he knew was the burgeoning scientific infrastructure and initiative on developing vaccines to the new pathogen. By then, National Institute of Allergy and Infectious Diseases (NIAID) Director Tony Fauci was on television every day as part of the White House Coronavirus Task Force and his conversations with Corey were reminiscent of those 20 years ago when the HVTN began. Mainly, that we (the nation) needed a seamless infrastructure to get these vaccines tested as soon as humanly possible. John Mascola, director of the National Institutes of Health (NIH) Vaccine Research Center (VRC), and Fauci became Corey’s most frequent cell phone and text contacts on the development of an NIH/Biomedical Advanced Research and Development Authority (BARDA) infrastructure, and conversations on how to build a nationwide investigative organization to handle this task were initiated. Confidentiality agreements to allow access to information were signed and the task began in earnest.

When a global catastrophe like the COVID-19 pandemic hit, the HVTN’s infrastructure and experience became priceless. Two decades of developing vaccine and monoclonal antibody clinical trial protocols. Two decades of building relationships with physician-scientists, pharmacists, and clinic staff. Two decades of community engagement programs collaborating with local advocacy groups to reach people most burdened by disease. Two decades of immunology lab assays perfected and Federal Drug Administration (FDA)-approved. Two decades of statistical expertise analyzing large datasets.

“This expertise in HIV needs to and can be leveraged,” Corey said. “Our faculty site investigators are all interested in and affected by this epidemic. There is universal support for doing this.”

The first HVTN COVID-related protocol, which opened May 13, 2020, was HVTN 405/HPTN 1901: characterizing SARS-CoV-2-specific immunity in convalescent
individuals (convalescent means someone who recovered from disease). The time of concept sheet (initial protocol idea) to trial opening (screening participants) was 1 month. The median for HVTN trials has been well over a year. Before the US government’s (USG) Operation Warp Speed was even created, before the Network had even been given the official gracing of a new name, the Network was operating at ‘warp speed.’ It’s a tribute to the staff that they could and did embrace the mantra of quality and speed to this task. This does not mean corners were cut; only that this trial was the priority for everybody – HVTN, HPTN, Division of AIDS, etc. There was no longer a delineation between weekdays and weekends. The HVTN saw early on how the pandemic would cripple the economy and society, much like a World War, and therefore all hands were on deck to end it as quickly as possible.

The new COVID-19 Prevention Network (CoVPN) was born, with Corey and Kathy Neuzil (from the Infectious Diseases Clinical Research Consortium and University of Maryland) as head of the operations center and HPTN’s Mike Cohen and Emory University’s David Stephens leading the monoclonal antibody program. The NIAID oversight team included Emily Erbelding, Carl Dieffenbach, Mary Marovich, and Mascola. “This is not business as usual” became the new mantra around the remote office. “We’re building the plane as we fly it” was another favorite analogy at the time. Trial names would not begin with ‘HVTN,’ but now have ‘CoVPN’ numbers.

Finding an efficacious vaccine wasn’t the only problem. The logistics of manufacturing, packaging, and distributing a vaccine to billions of people is, in a word, complicated. [Read a recent viewpoint in Science Magazine (https://science.sciencemag.org/content/368/6494/948.long) by Corey et al to go into depth.] That is just for one vaccine. Now multiply that by four or five different companies and things get crazy. It was apparent to CoVPN leadership that these efficacy trials, involving as many as 30,000 people each, would need to be harmonized – something pharmaceutical companies haven’t historically worried about. But in order to make sense of results, sample collection, lab assays and statistical analyses would need to be consistent across all trials. The CoVPN is making sure that happens.

**Engaging the nation**

The HVTN/CoVPN Community Engagement Team, led by Michele Andrasik, faced a formidable challenge on participant recruitment. The group couldn’t just repurpose the HVTN’s longstanding HIV materials. A simple ‘find/replace’ for ‘HIV/SARS-CoV-2’ in an informed consent form would not be adequate. Not only are the viruses, and the respective diseases they cause, extremely different, but so are the target audiences for educational materials. Historically, when participants volunteered for an HVTN Phase 1 study, they often commented their participation stemmed from a passion for stopping a disease that affected them or their communities personally. But now, with a global pandemic that has infected 40 million people worldwide and killed more than 1 million in under a year, people who may have never thought twice about infectious disease or public health have become the target demographic. Nursing home residents, grocery store clerks, and bus drivers are examples of populations at risk for COVID-19.

There the challenge lay: a new disease, a new demographic(s). The team consulted with expert panels for recommendations on engaging priority communities, mainly African American/Black, Latinx, Native/Indigenous and older adult populations. The team developed a suite of materials in record time. A website was built (www.PreventCOVID.org). Informational videos were produced. Flyers, posters and brochures received Institutional Review Board approval and hit the streets. In addition, the CoVPN received federal funding to develop and produce a series of public service announcements (PSAs) in both English and Spanish aimed at recruiting Americans for the vaccine trials.

The CoVPN developed a Volunteer Screening Registry, led by HVTN Executive Director Jim Kublin, that allows people interested in volunteering for a trial to sign-up. Within a week of going live on July 7, 2020, more than 91,000 people had signed up. As of late October, the number rose to over 407,000, with now more than 515,000. Many of the CoVPN clinical research sites have used the registry to prioritize those populations that have been disproportionately impacted by the national epidemic. Participants in the registry have also contributed to a public service announcement narrated by Harrison Ford, and the registry will continue to provide participants for all efficacy trials regardless of vaccine or monoclonal antibody developer. 

**Continued on the next page...**
Expanding the reach

The Network (HVTN-now-CoVPN) increased its number of US clinical trials sites from 62 in June 2020 to 151 in September: more than doubling its national footprint in a mere few months (Figure 1). This new cadre of sites included for the first time Veterans Administration Facilities, Historically Black Medical Colleges, and the Indian Health Service. The Site Operations Team, led by Niles Eaton, worked tirelessly to not only onboard new sites in the US and internationally, but also prepare longstanding HVTN sites for the era of COVID. Site preparation visits were restructured to be virtual. Running clinical trials during a pandemic is logistically complex. Sites needed personal protective equipment for safe clinic reopening, educational materials for volunteer recruitment, nasal swabs and PCR machines for testing. At least 29 of these sites, according to Eaton, will most likely employ one or more temporary locations, such as a mobile clinic, trailer, or tent, to reach individuals in remote locations.

WHAT PRODUCTS ARE BEING TESTED, AND WHICH COMPANIES ARE INVOLVED?

The CoVPN is currently involved in five COVID-19 vaccine efficacy trials, which are scheduled to open approximately one per month for the remainder of the year (Figure 2). All these vaccines have advantages and disadvantages with regard to speed of manufacturing, scalability, type of immune response, and target population.

Moderna

The first trial to open, the COVE Study, used a two-dose nucleic acid-based approach developed by the company Moderna (modernatx.com/cove-study). This vaccine uses the relatively novel platform of messenger RNA (mRNA) that encodes for the main surface protein of SARS-CoV-2, the spike protein. Advantages of this vaccine include speed of production, ability to deliver multiple antigens at the same time, and durable antibody

![Figure 1. Rapid site expansion both within the US and internationally.](image1)

![Figure 2. Expected course of Phase 3 clinical trials.](image2)
responses. Although many Phase 1 studies using mRNA vaccines have shown promise, none have reached licensure. The SARS-CoV-2 viral genome sequence was published January 10, 2020 and the COVE Study opened 6 1/2 months later on July 27, 2020. This speed is unparalleled in history. It usually takes decades between deciphering what pathogen causes disease to a vaccine efficacy trial.

**AstraZeneca**

The second CoVPN trial to open was a vaccine developed by Oxford University and subsequently sold to the company AstraZeneca. The vaccine regimen, also two-dose, uses a viral vector from a chimpanzee adenovirus (Ad) that does not cause disease in humans. This vaccine, like the Moderna vaccine, encodes for the SARS-CoV-2 spike protein. The trial began in August 2020 and was subsequently put on hold due to adverse events. The hold was lifted in late September in Europe/Brazil/South Africa, where a parallel trial is being conducted, and the FDA approved restart in the US on October 23, 2020.

**Janssen**

The third trial to begin was another adenovirus vector vaccine, this time using human Ad26 as the backbone delivering the spike protein antigen and developed by Janssen (part of Johnson & Johnson). One aspect of the ENSEMBLE Trial is that the regimen includes one dose, as opposed to two doses for each of the other vaccine trials. A one-dose regimen is advantageous logistically, especially if hundreds of millions of people need to be vaccinated. The Ad26 backbone was recently shown to be safe and stimulate a robust immune response against Ebola and is the platform used in the HIV efficacy trials HVTN 705 (Imbokodo) & 706 (Mosaico). This trial was also temporarily put on safety pause for approximately 10 days in October in response to adverse events. It has since resumed.

**Novavax & Sanofi Pasteur**

Two more trials are in the process of being developed, one by the company Novavax and the other by Sanofi Pasteur, scheduled to open in November and December of this year. Both vaccines will be two-dose and use traditional recombinant protein technology to deliver the spike protein. Protein vaccines are widely used globally and given to people of all ages, something important to consider if COVID vaccination plans in the future include children.

One important point is that these companies would, under normal circumstances, never produce millions of doses of a vaccine before FDA approval and licensure, much less concurrent with the efficacy trial. The reason they are doing so in this case is because the USG has agreed to purchase those doses, regardless of whether they show efficacy, resulting in minimal risk to the company. This is why the field has made such strides so quickly.

*Continued on the next page...*
HOW MANY PEOPLE ARE NEEDED FOR EACH STUDY?

Approximately 30,000 participants are needed for each vaccine trial in order to have what statisticians call “power” to determine whether the vaccine provides any benefit or efficacy against COVID-19 disease. Based on current epidemiological projections and what is known about disease progression, the CoVPN can assume that for each 30,000-person trial, it will take approximately 24 weeks from trial opening to accrue enough “endpoints” to determine efficacy. An endpoint is COVID-19 disease.

Table 1 lists the CoVPN studies and their status as of October 2020. In addition to the five Phase 3 vaccine trials mentioned above, the CoVPN is involved in several monoclonal antibody studies as well as observational studies to learn about disease prevalence and immune responses.

In summary

The HVTN/CoVPN is in the middle of the most important health crisis of the last century. Not since the 1918 influenza pandemic have we seen such rapid morbidity and mortality from an infectious disease. Unlike the 1918 flu, when approximately 1/3 of the world’s population was infected and ~50 million people died, the COVID-19 pandemic is occurring at a time of unparalleled biomedical advances and information technology. Humanity’s ability to join together and overcome this virus will be something never forgotten.

Dr. Mindy Miner is the Science Writer/Editor of the HVTN. Dr. Larry Corey and Dr. Jim Kublin, HVTN Principal Investigator and HVTN Executive Director, respectively, contributed to this article.

Table 1. CoVPN pipeline of studies and status.
Pfizer & BioNTech’s mRNA Vaccine Study

BNT162b2 is an investigational mRNA vaccine being developed by Pfizer and BioNTech to help prevent COVID-19, the disease caused by the SARS-CoV-2 virus. The purpose of the study is to test how well the investigational vaccine works at preventing COVID-19 disease and evaluate whether it is safe for adults and adolescents. BNT162b2 contains a small part of the genetic code for the SARS-CoV-2 spike protein. BNT162b2 does not contain any live virus. It cannot give you SARS-CoV-2 infection, nor will you get COVID-19.

Visit ClinicalTrials.gov - NCT04368728 for additional details.

The ENSEMBLE Study with Janssen’s Ad26.COV2.S Investigational Vaccine

The Ad26.COV2.S investigational vaccine is being developed to prevent or lessen the severity of COVID-19, the disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The Ad26.COV2.S investigational vaccine includes bits of genetic material copied from the spikes of the SARS-CoV-2 virus. The goal is for the body to be immunized against COVID-19. The investigational vaccine does not contain the actual virus and cannot cause COVID-19. The ENSEMBLE study aims to test Janssen’s investigational vaccine in many different populations across the globe.

Visit ClinicalTrials.gov - NCT04505722 for additional details.

AstraZeneca Study of AZD1222

AZD1222 is an investigational vaccine being developed by AstraZeneca to prevent COVID-19, the disease caused by the SARS-CoV-2 virus.

The vaccine is based on a weakened version of a common cold (adenovirus) virus. The adenovirus vaccine has been changed so that it can’t replicate inside your body. It presents part of the COVID-19 spike protein to the body so that an immune response can be made to it. The purpose of the study is to test how well the investigational vaccine works at preventing COVID-19 disease and how safe it is.

Visit ClinicalTrials.gov - NCT04516746 for additional details.

Regeneron’s 10933 and 10987 Antibodies, the REGN-CoV2 Study

REGN-CoV-2 is testing a combination of two antibodies called REGN10933 and REGN10987 to see whether they are able to prevent acquisition of SARS-CoV-2. This study will enroll approximately 2,000 adults in the United States who are living in the same household as a person who has recently tested positive for SARS-CoV-2. This will include about 1,700 participants who test SARS-CoV-2 negative at enrollment and about 300 participants who have a positive SARS-CoV-2 test result but do not have any COVID-19 symptoms.

The REGN10933 and REGN10987 antibodies are designed to bind to SARS-CoV-2 and prevent the virus from entering healthy cells. The antibodies were made in a lab by the pharmaceutical company Regeneron. REGN10933 and REGN10987 cannot give you SARS-CoV-2, nor will they make you sick with COVID-19.

Visit www.regeneron.com/covid19 or ClinicalTrials.gov - NCT04452318 for additional information about the study.

Eli Lilly’s LY3819253 Antibody, the BLAZE-2 Study

BLAZE-2 is testing the LY3819253 antibody. It will be enrolling staff and residents in skilled nursing and assisted living facilities with a high risk of exposure to SARS-CoV-2. The study questions are:

• Does the antibody prevent the acquisition of SARS-CoV-2?
• Does the antibody help to prevent the development of more severe COVID-19, or does it reduce the symptoms?

The study will be conducted in the United States with up to 2,400 participants. LY3819253 is designed to bind to SARS-CoV-2 and prevent the virus from entering healthy cells. LY3819253 was developed in a lab by the pharmaceutical company Eli Lilly. LY3819253 cannot give you SARS-CoV-2, nor will it make you sick with COVID-19.

Visit blaze2study.com or ClinicalTrials.gov - NCT04497987 for additional details. You may also call the BLAZE-2 Call Center at 718-210-9713 from 9 a.m. to 5:30 p.m. Eastern Time Monday through Friday.

With many communities across the U.S. disproportionately impacted by the COVID-19 pandemic, the COVID-19 Prevention Network (CoVPN) is very excited to share that we have launched a new, national faith-based program called the CoVPN Faith Initiative to build trust and engage diverse populations about COVID-19 and CoVPN clinical trials. This initiative is one of many strategies we have deployed to meaningfully engage and include communities in the research process.

Rev. Edwin C. Sanders, II, head of the Metropolitan International Church in Nashville, TN, will lead the CoVPN Faith Initiative and coordinate the work of seven Faith Ambassadors and more than 30 clergy-consultants from Black, Latinx and American Indian/Alaska Native communities throughout the nation.

Charged with implementing a faith-focused COVID-19 and CoVPN education program that supports inclusive engagement of members in key communities, the Faith Ambassadors will expand existing faith networks to conduct educational webinars, community town hall meetings and share information through existing faith gatherings, programs and support groups.

Speakers at the press conference included Rev. Sanders, two Faith Ambassadors: Bambi Gaddist, DrPH, CEO & Founder and Executive Director of the South Carolina HIV Council in Columbia; Ulysses W. Burley III, MD, Founder of UBtheCure, in Chicago, IL; and myself. Here are a couple of stories that have run to date: Scripps Newswire (includes approximately 60 TV stations in 42 markets), www.youtube.com/watch?v=xYlKEuB9jI, and CBS This Morning, www.cbsnews.com/video/covid-19-vaccine-trials-volunteer-demographics-reveal-need-for-greater-racial-diversity/.

CoVPN Faith Ambassadors:

With decades of experience in the fight against HIV/AIDS, Rev. Sanders, each of the seven Faith Ambassadors, and I, will leverage what we have learned to build trust and “engage everyone so that when a COVID-19 vaccine is approved, it is effective for all people,” noted Rev. Sanders. Key efforts will include involving and expanding existing faith networks to help conduct educational webinars, community town hall meetings and share information through existing faith gatherings, programs and support groups.

To date, six Faith Ambassadors have been named, as follows:

- **Khadijah Abdullah**, Executive Director of Reaching All HIV+ Muslims in America (RAHMA), Washington, DC
- **Bishop Oliver Clyde Allen III**, Senior Pastor and Founder of The Vision Cathedral of Atlanta., Atlanta, GA
- **Ulysses W. Burley III**, M.D., Founder of UBtheCure, Chicago, IL.
- **Bambi W. Gaddist**, DrPH, CEO & Founder and Executive Director of the South Carolina HIV Council in Columbia.
- **Rev. Kamal Hassan**, Pastor of Sojourner Truth Presbyterian Church, Richmond, CA
- **Rev. Bertram G. Johnson**, Union Theological Seminary, New York, NY
Call to Action

As stakeholders, our readers play an important role in educating your respective organizations and communities on the vital work of the CoVPN, including the CoVPN Faith Initiative. It’s important that we listen, learn and develop the partnerships that enable us to enhance trust and meaningfully engage key communities.

To assist you in your efforts, we’ve provided helpful information on the COVID-19 Prevention Network’s website (www.PreventCOVID.org), including COVID-19 clinical studies, how people can volunteer, and a detailed “FAQ,” or most frequently asked questions about the studies.

Should you have any questions or need further information about the CoVPN Faith Initiative or other CoVPN stakeholder engagement strategies and programs, please do not hesitate to reach out to me directly.

Stephaun E. Wallace, PhD
Director of External Relations, COVID-19 Prevention Trials Network (CoVPN)/HVTN
Staff Scientist, Vaccine and Infectious Disease Division, Fred Hutch Clinical Assistant Professor, Department of Global Health, University of Washington
Director, Office of Community Engagement, UW/Fred Hutch Center for AIDS Research
ONE SHOT CAN CHANGE THE PANDEMIC

Volunteer for a vaccine study today.

Learn more at PreventCOVID.org

Help end the uncertainty.
UPCOMING MEETINGS/CONFERENCES/AWARENESS DAYS

2021 NATIONAL AFRICAN AMERICAN MSM LEADERSHIP CONFERENCE

2021 HIV RESEARCH FOR PREVENTION (HIVR4P) CONFERENCE

2021 IAS COVID-19 CONFERENCE
Virtual, 2 February, https://covid19.iasociety.org

CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS (CROI)
6-10 March 2021, www.croiconference.org

U.S. NATIONAL BLACK HIV/AIDS AWARENESS DAY
7 February

U.S. NATIONAL WOMEN & GIRLS HIV/AIDS AWARENESS DAY
10 March

U.S. NATIONAL NATIVE HIV/AIDS AWARENESS DAY
21 March

IAPAC FAST TRACK CITIES CONFERENCE 2021
Lisbon, Portugal 22-25 March 2021 www.iapac.org/conferences/fast-track-cities-2021/

U.S. NATIONAL YOUTH HIV/AIDS AWARENESS DAY
10 April

U.S. NATIONAL TRANSGENDER HIV TESTING DAY
18 April

2021 HVTN FULL GROUP MEETING
Washington, DC, USA 5-7 May 2021 www.hvttn.org

HIV VACCINE AWARENESS DAY
18 May

U.S. NATIONAL ASIAN & PACIFIC ISLANDER AMERICAN HIV/AIDS AWARENESS DAY
19 May

HIV LONG TERM SURVIVORS DAY
5 June

U.S. NATIONAL HIV TESTING DAY
27 June

Editors Note: Many of these meeting dates have changed prior to print, and it is unclear if they will change again. Please use the above links to determine the most accurate dates of the meetings, and to determine if they will be in person or virtual.
Special Feature

HIV Prevention Efficacy Trial Designs of the Future

The “HIV Prevention Efficacy Trial Designs of the Future” workshop, organized by the Global HIV Vaccine Enterprise in partnership with the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN) and the Forum for Collaborative Research, is currently in progress. This workshop is a series of live events supported by pre-recorded presentations. These short-pre-recorded presentations (10-15 minutes) will be made available prior to each live event. It will be possible, and we encourage you to do so, to ask questions through our online platform ahead of and during the live events.

These presenters will then join us to answer your questions during the live events as listed below. The full schedule of events is as follow:

<table>
<thead>
<tr>
<th>Dates</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>Friday 16 October</td>
<td>Launch by Email</td>
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<tr>
<td></td>
<td>Pre-recorded presentations for Session 1 will made available online on the Enterprise website (see below)</td>
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<tr>
<td>Tuesday 27 October</td>
<td>Live Session 1 – Panel discussion (60 minutes)</td>
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<tr>
<td>8AM PDT</td>
<td>Current design approaches - challenges &amp; lessons learned</td>
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<tr>
<td>11AM EDT</td>
<td>Session 2 pre-recorded presentations made available online on the Enterprise website</td>
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<tr>
<td>4PM CET</td>
<td>Confirmed presenters: Jared Beaten, Eduard Grebe, Sinead Delany-Moretlwe, David Radley, Mia Moore, Jeff Eaton</td>
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<td>5PM SAST</td>
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<tr>
<td>Friday 06 November</td>
<td>Live session 2A – Panel discussion (60 minutes)</td>
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<tr>
<td>8AM PST</td>
<td>Future design approaches for settings where all study participants are on active HIV prevention – ARV based prevention</td>
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<tr>
<td>11AM EST</td>
<td>Confirmed panelists: Jeremy Sugarman, Sheena McCormack, Mike Robertson, David Glidden, Thamban Valappil, Grace Kumwenda</td>
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<td>5PM CET</td>
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<td>6PM SAST</td>
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<td>Wednesday 18 November</td>
<td>Live session 2B – Panel discussion (60 minutes)</td>
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<tr>
<td>8AM PST</td>
<td>Future design approaches for settings where all study participants are on active HIV prevention – Vaccines</td>
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<tr>
<td>11AM EST</td>
<td>Confirmed panelists: Cathy Slack, Glenda Gray, Hanneke Schuitemaker, Georgia Tomaras, Carol Weiss, Dean Follman, Rob Newells</td>
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<td>5PM CET</td>
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<td>6PM SAST</td>
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<tr>
<td>Wednesday 02 December</td>
<td>Live session 2C – Panel discussion (60 minutes)</td>
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<tr>
<td>(TBC)</td>
<td>Future design approaches for settings where all study participants are on active HIV prevention – Monoclonal antibodies</td>
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<td>January 2021</td>
<td>Live session 3 (60 minutes)</td>
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<td>Panel Discussion 1: A critical investigation into new methodological approaches.</td>
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<td>Panel Discussion 2: Community engagement and involvement in clinical trial design.</td>
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<td>Regulatory Forum organized by the Forum for Collaborative Research</td>
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Additional details and updates are on the Enterprise Website (https://vaccineenterprise.org). We look forward to an exciting series of events, and do not hesitate to share the events with your networks.

On behalf of the Organizing Committee: Roger Tatoud, Holly Janes, Deborah Donnell, Veronica Miller, Stephauin Wallace, and Linda-Gail Bekker
A manuscript in the works for over a year was published in September 2020, entitled “Standardized metrics can reveal region-specific opportunities in community engagement to aid recruitment in HIV prevention trials.” It describes the HPTN’s and HVTN’s commitment to Good Participatory Practice (GPP), how the Networks approached recruitment efforts in the AMP Studies, and what we observed about how these efforts differ in various regions. We had presented initial data about this work at the HIVR4P conference in Madrid in 2018, and this paper now presents the full analysis. The paper can be accessed at the link below. This journal is “open access,” which means that you are welcome to share this information without concern about copyright or confidentiality.

Many of the HVTN’s and HPTN’s community educators and CAB members contributed to this effort by providing us with their sites’ screening and enrollment data, and many are members of the AMP Community Working Groups that provided input into our study parameters. Thank you to all of you for your contributions!

We think that this information may be meaningful to consider as sites are thinking about COVID-19 study recruitment efforts, so we wanted to share the paper with that in mind.

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239276

Gail Broder is a Senior Community Engagement Project Manager with the HVTN.
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- 18 – 60 years old
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After 20 Years, Wakefield Retires from HIV Vaccine Trials Network

‘He created the DNA of our organization’

By: Sabin Russell / Fred Hutch News Service

Fond words and accolades are rolling in for Steven Wakefield, who retired June, 2020 from Fred Hutchinson Cancer Research Center after 20 years of bridge-building between vaccine researchers and underserved communities in Seattle and around the globe.

As external relations director for the HIV Vaccine Trials Network, Wakefield traveled to 32 nations to develop ties between the Hutch-headquartered operator of clinical trials and the communities where volunteers roll up their sleeves to test potential vaccines to stop HIV/AIDS.

“What I can do at the age of 67 is not what I could have done as a younger man,” he said. “My cardiologist has become my interior decorator: My first week of retirement I will get rid of either my sofa or my La-Z-Boy and replace it with an indoor bike.”

It is a change of pace earned from a lifetime of activism.

“He has been, for me, a moral compass, a wise adviser and a close friend,” said former Fred Hutch president and director Dr. Larry Corey, who cofounded the HVTN. When the organization received funding from the National Institute of Allergy and Infectious Diseases in 2000, Wakefield was a key initial hire.

“His values, his voice and his intellect just don’t permeate our culture — he created the DNA of our organization. No one has had more of an impact on how we operate.”

A lifetime of activism

Wakefield, who long ago dropped “Steven” and prefers to be known by the single name “Wakefield,” had been an activist since he was an 8-year-old member of the Rev. Jesse Jackson’s Operation Breadbasket, which later became Operation PUSH, in Chicago.

Continued on the next page...
As a young man he began volunteering in a storefront clinic that provided testing and treatment for gay men with sexually transmitted diseases, and showing that penchant for leadership, he became chair of its board of directors. When HIV emerged a mortal threat to his community, he helped to secure one of the first publicly funded AIDS research grants.

By the time Corey began setting up HVTN as the world’s largest publicly funded collaborative for development of HIV vaccines, Wakefield had already co-founded AVAC, a New York-based global advocacy group for HIV vaccine research. (Wakefield only recently retired from AVAC’s board of directors.)

He had been working in South Africa, helping epidemiologists develop volunteer community advisory boards, before returning to Chicago and learning about Corey’s newly funded HVTN. Soon he began shaping its outreach and communications programs, forging critical ties between vaccine researchers and the people from hard-hit communities they needed to recruit from for clinical trials.

As Corey told Fred Hutch News Service’s Mary Engel (on the occasion of Wakefield being named a grand marshal of the 2018 Seattle Pride Parade), “He understands science, he asks hard questions and pushes back when anything doesn’t seem right or principled.”

Renowned HIV researcher Dr. Glenda Gray, leader of the South African Medical Research Council and co-principal investigator for HVTN, said Wakefield helped to expand clinical trial capacity in her country through his skill in working with both scientists and community advocates. “His vision and passion for Africa resulted in a vibrant and highly successful program. He rejected the concept of Afro-pessimism and helped promote the growth of science in Africa. For that I will always be grateful,” she said.

Wakefield’s retirement is a bittersweet moment for those who have worked closely with him. Kimberly Louis, outreach manager for the Seattle Vaccine Trials Unit, part of HVTN’s web of clinical trials sites for vaccines for HIV (and now COVID-19), called Wakefield “the godfather of the community work for the network.”

“He taught me that outreach was a conversation. Before you can make an ask of recruitment to a vaccine trial, there has to be education. There has to be reciprocity. You can’t go into communities asking them to support us without giving them something back,” she said.

Dr. Michele Andrasik, senior staff scientist in the Hutch’s Vaccine and Infectious Disease Division, said Wakefield was “always making connections, opening doors and ensuring that those doors stay open.”

Dr. George Counts, a retired University of Washington professor of medicine, said working with Wakefield in South Africa and Botswana were among the most memorable moments of his career. “He has extraordinary people skills,” said Counts. “He earned the respect of scientists at the highest level of government, academia and industry.”

After 20 years, Wakefield said it was time for a younger person to take on the grueling hours required for such work, which now encompasses the crash effort to run massive clinical trials of potential COVID-19 vaccines.

Corey has named Dr. Stephaun Wallace to succeed Wakefield as Director of External Relations, a selection Wakefield heartily applauds.

Wallace has more than 25 years of social justice and community mobilization experience. He joined HVTN as a community engagement project manager in 2016 and was affiliated with the network for more than a decade through collaborations with the clinical research site at the University of Rochester in New York.

“He is no stranger to the organization,” Wakefield said. “I believe that he and Larry [Corey] will develop the kind of relationship that ensures the work that I’ve done — the sweat equity, the years of investment — will continue to pay dividends.”

Wallace called Wakefield, whom he has known for nearly ten years, both a mentor and a friend. “He has a very strong sense of self,” Wallace said. “He has a very warm personality, and when he walks into a room, everyone just feels better.”

As Wakefield pondered the two decades of work at Fred Hutch, he said he is pleased by the
recent emphasis on diversity and inclusion at the organization.

“My first week at the Hutch, I remember writing to a friend that said, ‘I am so glad I have a mirror, otherwise I would not have seen another Black man all week,’” Wakefield said. “And just last week, I got to join those hoisting the Black Lives Matter banner at the Hutch.

“I really think that the organization has made a new commitment to transparency, and a new commitment to change and responsiveness. It just makes it that much harder to leave.”

Sabin Russell is a staff writer at Fred Hutchinson Cancer Research Center. For two decades he covered medical science, global health and health care economics for the San Francisco Chronicle, and wrote extensively about infectious diseases, including HIV/AIDS. He was a Knight Science Journalism Fellow at MIT, and a freelance writer for the New York Times and Health Affairs. Reach him at sruiddell@fredhutch.org.

Editors note: This article has been reprinted with permission. The original article was published July 2020 and can be found here: https://www.fredhutch.org/en/news/center-news/2020/07/wakefield-hvtn-hiv-vaccine.html
SEATTLE, JULY 9, 2020 – A clinical trial called CoVPN 5001 will help the newly formed COVID-19 Prevention Network (CoVPN) understand early SARS-CoV-2 infection and the body’s early immune responses to the virus that causes COVID-19 illness. Gathered from diverse populations worldwide, the data obtained through this study will describe viral progression and immunological characteristics of early infection with SARS-CoV-2. Information about the clinical course of SARS-CoV-2 infection, especially during its early stage, is needed to close knowledge gaps and will potentially suggest markers of protection that could be used in evaluating the efficacy of future COVID-19 vaccine candidates.

“The CoVPN 5001 study is the first study conducted under the aegis of the CoVPN, and is designed to develop the clinical and laboratory pipelines for the rapid implementation of future COVID vaccine efficacy trials while conducting groundbreaking scientific investigations,” said Will Hahn, M.D., Protocol Chair for CoVPN 5001 and staff scientist at Fred Hutchinson Cancer Research Center. “The protocol is explicitly designed to be a ‘dry run’ for pivotal trials testing the efficacy of a COVID vaccine,” Hahn concluded.

CoVPN 5001 is designed to follow an estimated 800 study participants aged 18 years or older who have tested positive for SARS-CoV-2 infection. Study participants will be enrolled into one of three groups: those showing no symptoms, those showing mild symptoms, and those showing severe symptoms that require hospitalization. Participants may move between groups if their symptoms worsen over the course of the study.

Six study visits spread over one month will be conducted at either a participating trial site, hospital, or at the place where the study participant resides. Samples to be collected from participants include blood samples, nasal samples, saliva samples, and urine samples. The collection of stool samples will be optional. These sample collections may be done either by clinic staff or the study participant themselves. Blood samples will only be collected by clinic staff. A final study visit to check on the health of study participants will be conducted approximately two months after enrollment.

SARS-CoV-2 is the most infectious of three coronaviruses that have caused recent epidemics resulting in significant morbidity and mortality in humans in the past 20 years. Since declared a pandemic by the World Health Organization on March 11, COVID-19 has claimed a significant number of lives. A safe and effective vaccine [to prevent the acquisition and transmission of SARS-CoV-2] is necessary to reduce morbidity and mortality and aid the global community to return to a thriving social and economic global infrastructure.

“The participants in this study will give us a unique opportunity to understand the natural immune responses in the early stage of infection. Without the community’s support, science can’t move forward,” said Gail Broder, MHS, Community Engagement Lead for CoVPN 5001 and CoVPN Senior Community Engagement Project Manager at Fred Hutch.

The CoVPN will use existing clinic and laboratory infrastructure to capture clinical and immunologic information among persons with acute SARS-CoV-2 infection. CoVPN 5001 will take place across more than 58 participating trial sites in the United States, South America and sub-Saharan Africa.

CoVPN 5001 is sponsored by NIH’s National Institute of Allergy and Infectious Diseases. Interested individuals can email CoVPN.SBS-CEU@fredhutch.org for more information.
HVTN Responds – No Justice, No Progress

A statement by HVTN leadership, June 2020

George Floyd, Gabriella Nevarez, Michelle Cusseaux, Alexia Christian, Breonna Taylor, Trayvon Martin, Michael Brown, Charlena Lyles, Stephon Clark, Terence Crutcher, Alton Sterling, Philando Castile, Che Taylor, Eric Garner, Mi’Chance Dunlap-Gittens, Laquan McDonald...the list of Black/African American people murdered continues to grow. This is unacceptable.

Epidemics and pandemics are magnifying glasses for tragedies. Those of us who have fought to address the biological outcomes of racial injustice work every day in communities where the human cry of “no justice, no peace” is resonating off the walls. It echoes with us as we try to work in a world where structural racism and discrimination consistently highlight difference.

Racism and discrimination against Black/African Americans cannot continue to be normalized. We must shift how institutional policies are created, how policies and laws are enforced, and how we create spaces and environments that are welcoming, inclusive and support equity. This must happen at the community-level, institutional-level, and policy-level. America must be transformed in order for the senseless murders of Black/African Americans to stop. Transformation to truly bring about racial equity and justice must be guided by leaders who believe in human rights, anti-racism, and socio-economic equality for all citizens of this country. We who are involved in bettering humanity from diseases such as HIV must be leaders in achieving racial transformation in American society.

George Floyd’s fate at the hands of police in Minneapolis could be described as just the latest in a series of Black fatalities brought about by overzealous policing or racial profiling. We stand today with those who recognize these are times that call on us to examine our individual responses and corporate responsibilities. It is not possible to list in a brief statement the extent of the injustice. We urge all of us to reflect on what actions we can take to ensure a focus on anti-racism and continue to find a way forward that reverberates with the clarion cry “NO JUSTICE, NO PROGRESS.”

This call to activism about social justice in America was written by S. Wakefield, Michele Andrasik, Stephaun Wallace and Aziel Gangerdine and endorsed by the Executive Management Team of the HIV Vaccine Trials Network
New Hires

**Jasmin Aina,**  
**HVTN & CoVPN Community Engagement Project Coordinator**

Jasmin joined the HVTN & CoVPN in July as a Project Coordinator for the SBS/CEU team. She brings with her a wealth of experience in community engagement in various settings. She started her career in rural emergency health care staffing and recruitment at Acute Care Inc. in Des Moines, IA. In her role as Regional Coordinator for Acute Care Inc., she managed the recruitment of emergency healthcare providers and emergency room staffing for 30 hospitals in her region, continuing education programs, and the establishment of partnerships with key stakeholders and organizations. After moving to Seattle in 2015, Jasmin served as Grade School Director with Quest Church where she worked to provide faith-based education and training to grade school-aged students, their families, volunteers, and community partners. Jasmin earned a Bachelor of Arts degree in Health Sciences from the University of Iowa, and is excited to return to her roots and take on this new challenge in public health with the Community Engagement Unit.

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**Louis Shackelford,**  
**HVTN & CoVPN External Relations Project Manager**

Louis Shackelford joined the HVTN on September 15, 2020. As External Relations Project Manager, Louis is the newest member of the External Relations Unit based in the HVTN Leadership and Operations Center (Core) at Fred Hutchinson Cancer Research Center in Seattle, WA. Louis’ primary focus will be implementing stakeholder engagement strategies domestically and globally. These strategies create opportunities for consultation with key stakeholders and communities to inform the design and implementation of Network studies. Consultations will optimize the inclusion and participation of populations and communities who bear the greatest burden of HIV and COVID-19.

Louis joins the HVTN with a wealth of experience in community and stakeholder engagement in clinical research settings and health education. He spent nearly eight years at the Harlem Prevention Center (HPC) clinical research site, based in Columbia University’s Mailman School of Public Health, where he served in various roles. His most significant role at HPC was Community Education Coordinator, managing outreach and education programs, including establishing partnerships and strategic alliances with key groups, organizations, and stakeholders. Most recently, Louis served as Project Manager with the Office of HIV/AIDS Network Coordination (HANC) Legacy Project, where he worked across all five of the DAIDS-funded clinical trials networks to support increased engagement and enrollment of historically underrepresented populations in HIV clinical research. Always seeking new opportunities to serve others, Louis enlisted in the U.S. Air Force Reserves as a Medic in 2019, and is currently assigned to McChord Air Force Base, Joint Base Lewis-McChord, Washington. Louis earned a Bachelor of Arts degree from Columbia University, and is currently a student at Florida Agricultural and Mechanical University (FAMU), completing his Master’s degree in Public Health. Louis is extremely excited to join the External Relations Unit, and we are thrilled to have him on board.
Promotions

Francisco Rentas, MAT, HVTN & CoVPN Community Engagement Project Manager

Francisco began his work with the HVTN in January 2018 as Program Assistant with the travel team. He joined the SBS/CEU team as a Project Coordinator in June 2019, and we are thrilled to announce his promotion to Project Manager in August 2020. Francisco has been an active part of the Seattle LGBTQ community for the past 13 years, in particular as a theater artist and singer with the Seattle Men’s Chorus. His professional life began as a public school teacher in middle and high school English/Language Arts and Theater Arts classrooms in Texas and Washington. After receiving his Master's degree in Teaching from the University of Washington, a unique opportunity presented itself at Fred Hutch as a cancer educator and tobacco cessation counselor. Meanwhile, his participation as a study participant in the HVTN 505 vaccine trial solidified his interest in the world of research. Francisco had his eye on the HVTN with the goal of eventually working there in some capacity having to do with community engagement, and he feels incredibly humbled to see that goal come to fruition, thanks in large part to his mentors along the way. Francisco was born into a Puerto Rican, US military household in Germany and spent most of his childhood moving around, which he credits as molding him into the confused but culturally-aware person he is today.

Linda Oseso, MPH

HVTN and COVPN Social and Behavioral Sciences Project Manager and Research and Mentorship Program (RAMP) Program Manager

Linda Oseso began her work with the HVTN in September 2015 as a subcontractor focusing on moving the AMP animated video project forward. In just three short months, and during her graduate public health studies at the University of Washington, she was hired as a research assistant to coordinate the expansion of the AMP video project for the sub-Saharan Africa and South American sites. Linda's drive, motivation and commitment to the work were instantly apparent and within six months of joining the Social and Behavioral Sciences Research team, she was promoted to Project Coordinator II. Although Linda's initial responsibilities focused on coordinating the AMP behavioral sub-study and our social behavioral research efforts, she was soon coordinating production of other video projects. In this position she excelled and has become an expert in Community-Based Participatory Research (CBPR) approaches, utilizing them to enhance the HVTN’s community engagement educational materials as well as relationships with stakeholders and community members. Two years after her promotion to Project Coordinator II, Linda was promoted to Project Manager, where she led a research study looking at site level barriers and facilitators to engaging transgender participants in the AMP studies in the USA and Peru. In September 2019, her scope of work was expanded exponentially and she is now managing the Research and Mentorship Program (RAMP), where she works tirelessly to ensure that our Latinx and African American/Black scholars have a meaningful research experience that opens them to considering HIV prevention research as a viable career path. Linda is now actively considering entering into a PhD program. Her goals are to continue contributing to the HVTN’s efforts of finding an HIV vaccine and facilitating opportunities for African/Black and Latinx medical students to gain exposure to the possibilities of careers as physician scientists dedicated to the search for a safe and effective HIV vaccine. She is also excited to be bringing her experience with video projects to the CoVPN’s efforts, and is currently managing the production of 8 animated videos to address frequently asked questions and myths surrounding clinical research.
Understanding the Socio-Behavioral Dynamics of the Transgender Population in an Under-Resourced Setting in South Africa

By: Dr Shapo Annah Pitsi, Neo Buthuma, Kagiso Mothwa, Tercia Makhaphiedza, and Lebogang Mpete of the Setshaba Clinical Research Site, Soshanguve, South Africa

Background
The transgender population experiences many challenges in society when they identify with and express a different gender that is not congruent to social expectations for their sex assigned at birth. The South African transgender population is no exception to these challenges (Sithole, 2015).

In South Africa (SA), where transgender populations are marginalized, there is limited understanding of the community’s behavioral dynamics. Limited access to socio-economic opportunities, psychosocial support, and health care are key issues that impact on the wellbeing of the transgender population. Their vulnerability to infectious diseases such as HIV, set against the backdrop of limited access to healthcare programs, is of particular concern.

The Setshaba Research Centre (SRC), based in the under-resourced community of Soshanguve, Tshwane, South Africa, has been conducting prevention and socio-behavioral studies in this community with a focus on HIV and TB for over 15 years. These studies were primarily amongst cisgender heterosexual participants with limited studies among the marginalized LGBTQI population.

SRC aimed to understand the impact of stigma, increased risk of violence, and economic vulnerability among the transgender population prior to embarking on research studies among this population. As part of community engagement and enhancing researchers’ knowledge of the transgender population, the SRC hosted a participatory consultative workshop in Soshanguve.

Process
In March 2020, a group of seven participants (4 trans women and 3 cisgender homosexual men) were invited by the SRC through a partnership with the OUT organization that provides support to the LGBTQI community. The 4-hour long workshop was facilitated by Dr. Pitsi in English based on the participants’ preferred language. All attendees provided voluntary informed consent to be part of the discussions. Participants narrated their personal experiences, with site staff asking for questions and clarifications. The consultation discussed their responses to questions regarding how they define transgender, safety and disclosure, sexual orientation and behavior, gender transition, healthcare access and utilization, psychosocial support, employment, and interest in clinical trial participation.

Outcomes
1. How participants described the transgender population in the community

Transgender was defined by the participants as identifying as a person of a different gender than the sex assigned at birth. One is either trans woman, trans man or gender fluid. However, the respondents reported that locally, it was easier for them to say that they are gay, as that is the term most people understood and are familiar with in their community rather than the term transgender. The vernacular or slang name used to describe them is ”Isitabane”, which is a local description for gay people. Participants did clarify that being gay is about sexual orientation while transgender is about gender identity and expression irrespective of one’s sexual orientation. They all mentioned that they knew that they were transgender from as early as their preteen years. Most of them received family support in their ‘coming out’, while others struggled to disclose or did not get support after disclosure. One participant reported that her mom realized that as a kid he liked his sister’s clothes and dressed him in women’s clothes from a young age, which made sense later on when the family accidentally found out their son was trans female. Coming out was unplanned for some attendees, as they did not know how to approach family members...
and were unsure of how they would be received. It was mentioned that acceptance is easier with immediate family members than with extended family members. Uncles were reported to be the least accepting.

The community was generally receptive of attendees as trans women, with the exception of a few people who insist on addressing them as men (mfana/buti) which are terms used to describe a young man/brother. Pronouns were very important to the attendees, who expressed a preference for using she/her pronouns.

Bullying was experienced at school from peers and teachers alike. This led to some dropping out of school as they were told that they were not wanted, and they felt forced to wear boys’ uniforms per the school regulations. Such discrimination led to several attendees using recreational drugs as their way of coping with the stigma they experienced with regard to their gender identity. One participant ended up as a street kid for 10 years after being chased out of three schools and the family home.

The attendees have chosen a feminine gender expression. They wear women’s clothes and use make-up. They make use of women’s toilets where they are not frowned upon. Gender-specific protocols are observed in social settings; for example, the 4 trans women are expected to dress in funeral-appropriate attire for women which includes covering the head and shoulders, or else they are not allowed to enter a burial site. Given the cultural significance of a male role in this community, it would be interesting to find out if trans men are limited in their male roles.

2. Safety and Disclosure

There seems to be a generational shift with regard to issues of safety when in public. Safety concerns were more prominent in the older participants based on their experiences, whilst younger participants felt they were generally safe.

Disclosing transgender status provides safety while posing risk of victimization at the same time. Violence can erupt following discovery of trans status by a potential sexual partner. As one participant mentioned, it is very important to be upfront, as she knew of friends who were brutally assaulted and killed for not disclosing their status. She mentioned that she prefers to disclose her gender status where there are other people nearby for her protection, in case an assault arises from the disclosure. In some instances, attendees have had to resort to physical violence to protect themselves. Incidences of "corrective rape," which is when someone who does not conform to gender norms is raped to "cure" them of their homosexuality or transgender identity, were reported. Participants also reported incidences of corrective initiations; where a man is forced to undergo circumcision at a traditional initiation as part of a transitional rite of passage from boyhood to manhood. One trans woman participant reported an incident where she was arrested...
with fellow trans people at a club, and through it all she was paraded in front of everyone at the police station. Some mentioned that they find it difficult to disclose to everyone as they are afraid of people’s reactions. Others choose to confront incidences of trans hate and transphobia as they believe it is an opportunity to educate others, because they believe that silence perpetuates discrimination. They regard themselves as activists for the LGBTQI community.

3. Sexual orientation and behavior

Sexual orientation is diverse amongst transgender people. The four trans women present engaged in sexual activity with males, including men who do not identify as transgender or gay. There are apparently many married men who have an attraction to trans women. They attribute this partly to curiosity, and the so-called “after nines” who are in the closet about their transgender or gay identity. These men live their lives as married straight men during the day, but come out at night to explore their sexuality and gender identity. Anal sex is practiced since none of them have had vaginal construction surgery. There are different sexual preferences, which need to be disclosed to potential partners: top, bottom or verse (versatile), depending on whether they prefer to be on top, bottom, or either top or bottom during sex.

Promiscuity is common until people find someone they feel like settling down with. Attendees were divided as to whether they engage in risky sexual behaviors more than cisgender heterosexual people do. The general feeling was that they are riskier than heterosexuals, while some believed risky behavior is the same in both groups since it is an individual choice.

Transactional sex occurs a lot, which fuels promiscuity. Alcohol was mentioned as a factor driving risky sexual behaviors. Money is needed for maintenance of their lifestyle, which they describe as high maintenance. According to them, they would rather starve than not have make-up or hair weaves. If a man is known to have a lot of money, they will target that man for transactional sex even if they know he has multiple partners.

4. Gender Transition

Participants were aware of only one referral hospital in the province, the Steve Biko Academic Hospital, which offered gender transition services. Most of them expressed the desire for a full transition, i.e. social and physical. One participant reported social transitioning only. She reported that for her it is important to be recognized for her gender identity and did not see the need for physical transition to achieve that. No fears of the hormones, side effects or surgery were reported. One participant was undergoing hormonal transition only, and another two were on hormones and awaiting surgeries. They expressed frustrations with the system with regard to the process. Getting the first appointment at the hospital can take several months. It takes a long time to get approval in the public sector to initiate the transition process, as this involves psychiatric evaluation for a minimum of 6 months prior to appearing before a panel of medical experts (psychiatrist, endocrinologist, plastic surgeon, urologist, gynecologist, and another physician) who assess suitability for transition. Once the process has been initiated, it takes a long time to move from one stage of transition to the next due to long waiting lists, e.g. initiation of hormonal therapy to having surgical procedures done. One participant was in transition for >10 years and ended up being excluded from further transition due to his age and chronic conditions that came with aging.

5. Health care access and utilization

All attendees accessed health care through public health facilities. Healthcare access was described as not challenging. They freely consult anywhere and felt that their needs were being addressed by health care providers. No hostility/discrimination was reported. The usual practice is to disclose that they are transgender to avoid awkwardness during consultations. They were not aware of any private general practitioners who offered hormone therapy for transitioning purposes, and indicated that even if hormone therapy was available through private practitioners, they would not be able to afford these services.

6. Psychosocial support

LGBTQI organizations

Three organizations were reported to be providing support to the transgender community, and it is through these organizations that they are linked to health services including HIV testing, treatment, and prevention; sexual health and STI treatment; and gender transition services. In addition, they organize various events where HIV counselling and testing is always offered by nurses. This is also a platform where they socialize and get introduced to other members of the LGBTQI community. The use of social media platforms for transgender support or services is not common. They generally use social media to find sexual partners.
**Home affairs**

None of the attendees had changed their gender identification with the local Home Affairs Department. They were aware of the availability of the service but report being discouraged by the requirements and long process. Some indicated that they do not feel the need to change identity documents. However, they did note the issue of travelling challenges, with one attendee describing how she was delayed at the airport because the ticket was issued for a woman and her identity document indicated she was man. She was not allowed to board the plane until it was corrected. She remarked that she could not imagine what international travel would be like. They felt privileged to live in a country where their rights are protected. Access to other services, such as church and police services, were reported to be without hassles.

**7. Employment**

Only one of the participants was employed. Reasons for unemployment were reported to be the same as for the general population and not completely related to being transgender. Challenges with getting jobs as a trans person included confusion at interviews, as the identity documents indicate a different gender than their appearance at the interview, amongst others. Some were told at interviews that they could not be offered the job as it required a specific gender due to the type of job, e.g. lifting heavy objects, amongst other reasons. Attendees were financially dependent on their families. Those in stable relationships were financially dependent on their partners. Some engaged in transactional sex for financial support, thus placing themselves at risk of STIs and HIV.

**8. Interest in clinical trial participation**

Some of the participants were familiar with the clinical trials at our research center, with one being a participant in an HIV vaccine trial. They expressed willingness to participate in clinical trials, especially ones that would address their needs. They felt there was greater need for education on transgender issues at schools and in the community. When asked about biological sampling, they indicated that they did not have objections to blood and rectal sampling. No concerns were raised regarding clinical trials and voluntary participation.

**Next steps and Future direction**

Going forward, the site plans to engage the local LGBTQI organizations to foster collaborations, to develop an understanding of their social dynamics, and to get more insight into the role they play in the community. In addition, we aim to obtain input from trans men, trans women and gender fluid individuals to broaden our scope and understanding of these marginalized populations. It is also crucial to include transgender persons in Community Working Groups (CWGs) or Community Advisory Boards (CABs), and to support employment opportunities through networking with NGOs.

The public sector hospitals and social services will be engaged to understand their role in the services offered and processes followed for community members in gender transition. Thus, we will be able to design interventions and conduct studies that will contribute to overcoming some of the community’s challenges and enhance their wellbeing.

**Acknowledgements:**

We would like to acknowledge the transgender women and cisgender men who participated in the workshop for sharing their stories and experiences. A special thank you to contributing co-author Neo Buthuma, a trans female participant in the workshop. We appreciate the site management and staff for organizing and participating in the workshop and to those who contributed to the write-up of the article.

We also acknowledge Dr Athmanundh Dilraj and Neetha Morar for their valuable guidance, input and review of this report.

**References:**


Dr Shapo Annah Pitsi is the Sub-Investigator, Neo Buthuma is a transgender study participant, Kagiso Mothwa is the Community Liaison Officer, Tercia Makhaphiedza is the Pharmacist and Lebogang Mpete is the Participant Engagement Supervisor at the Setshaba CRS.
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“Banda Mole” is Also Prevention!

By: Jeferson Fonseca Carvalho, Luciana Branco Gravito, Lucas Emanuel Braz, Marciley ‘Max’ Nunes de Andrade Ferreira, Belo Horizonte CRS, Brazil

Banda Mole is a traditional carnival parade that takes place in the city of Belo Horizonte, in the state of Minas Gerais, Brazil. The traditional Banda Mole brightened Avenida Afonso Pena, one of the main streets of the city, on February 15, 2020. The theme of the parade was “educação” (education), satirizing the last acts of Minister Abraham Weintraub, the current Minister of Education, and also marking the celebration of the 45th anniversary of the event. Taking advantage of pre-carnival festivities, it was also the ideal time for preventive educational activities about STIs, AIDS, and HIV.

Joining forces with diverse partners such as Família+ and BH de mãos dadas among other groups, together with the support of the City Hall of the City of Belo Horizonte - Prefeitura de Belo Horizonte (PBH), it was possible to promote the distribution of condoms, lubricants and information pamphlets.

A tent was set up in front of the PBH, serving as a shelter for the team of volunteers to assemble kits to facilitate the distribution of condoms among the revelers. In addition to the distribution in front of the tent, the volunteers circulated along the block, approaching the revelers to distribute preventive informational material and also clarifying doubts and myths.

It was a successful festive event, and an appropriate environment for the dissemination of information about healthy practices.

Team of Community Educators of the Mosaico Study, Belo Horizonte, Brazil, working on an educational action for HIV prevention during a pre-carnival event, February 2020. Left to Right: Max Nunes (CER), Jeferson Fonseca (CER), Luciana Gravito (CAB member), and Lucas Emanuel (CER).
# CoVPN Native & Indigenous Expert Panelists

<table>
<thead>
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<tr>
<td>Denise Dillard (Inupiaq Eskimo), PhD</td>
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<td>Karina L. Walters (Co-Chair, Choctaw Nation of Oklahoma), PhD, MSW</td>
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<tr>
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<tr>
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## CoVPN African American & Black Expert Panelists

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<td>Gregorio Millett, MPH</td>
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<td>Rachel Issaka, M.D.</td>
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<td>Vivian Carter (Co-Chair), PhD</td>
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# CoVPN LatinX Expert Panelists

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<td>Robert Valdez, PhD, MHSA</td>
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<td>Efrén Pérez, PhD</td>
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CoVPN Older Adult & VA Expert Panelists

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<td>Marianne Shaughnessy, PhD</td>
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Senior Pastor and Founder of The Vision Cathedral of Atlanta, Georgia

Dr. Bambi W. Gaddist,  
CEO and Founder, Executive Director of the South Carolina HIV Council – Wright Wellness Center in Columbia, SC

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Pastor of Sojourner Truth Presbyterian Church, Richmond, California

Rev. Bertram G. Johnson,  
Union Theological Seminary, New York, New York
Updates from the Field

COVID-19 and HIV: What You Need to Know

People living with HIV are learning how to cope with a new pandemic.

By: Liz Highleyman, for POZ

For many people with HIV, the COVID-19 pandemic seems all too familiar: the fear, the stigma, the loss of loved ones, the disproportionate impact on marginalized communities and a federal government that has failed to adequately respond to the crisis.

“Again, there’s a sense of existential dread—a low-grade panic,” says blogger and activist Mark S. King.

This fear is compounded by uncertainty. People with HIV wonder whether they’re more likely to contract the coronavirus (officially known as SARS-CoV-2) or are at greater risk of becoming seriously ill. Will the crisis affect their ability to access HIV care and services? And how will they deal with the disruption of normal life, the social isolation and the financial fallout of the pandemic?

HIV and COVID-19 Risk

Typically, people with compromised immune systems are more susceptible to a variety of infections. Early reports from China, where the COVID-19 outbreak first emerged late last year, indicated that people with immune suppression were more likely to become seriously ill if they acquired the coronavirus.

What’s more, nearly half of people living with HIV are over 50—the risk of severe COVID-19 rises with age—and many have underlying health conditions associated with worse outcomes, such as diabetes, high blood pressure, chronic lung disease or cardiovascular disease.

But so far, experts agree that people on antiretroviral treatment who have an undetectable HIV viral load and a near-normal CD4 count do not appear to be at higher risk than their HIV-negative counterparts.

“My sense from the accumulating evidence is that incidence rates might be lower than expected,” says Steven Deeks, MD, a professor of medicine at the University of California at San Francisco. “I personally think that’s because people with HIV were well aware of how to protect themselves and educated about the nature of the epidemic, and they responded pretty quickly.”

In one of the first reports about COVID-19 in people with HIV, researchers contacted 1,178 HIV-positive people in Wuhan, China. Eight people with symptoms were found to have COVID-19. Six of them had mild cases, one had severe disease and one died. Among the remaining asymptomatic people, just one of the nine individuals known to have had close contact with COVID-19 patients tested positive for SARS-CoV-2.

In another early report, Spanish researchers found that among the first 543 people admitted to a Barcelona hospital with the new coronavirus, five were HIV positive. Three had mild or moderate disease, and they recovered and were released from the hospital within about a week. One person, who was not on HIV treatment and had a CD4 count of 13, received supplemental oxygen and recovered. The oldest man (age 49) was put on a ventilator and remained hospitalized.

A related study from Italy identified 47 people known or suspected to have the coronavirus out of nearly 6,000 people with HIV followed at a hospital in Milan. They were less likely to have advanced respiratory disease or to be hospitalized than HIV-negative people, and only two died. But the researchers noted that the HIV-positive group was about 10 years younger, on average, than HIV-negative patients with severe COVID-19.

In contrast, a report from Germany described 33 HIV-positive people diagnosed with COVID-19; all of them were on antiretrovirals with

3D print of a SARS-CoV-2 virus particle, the virus that causes COVID-19.
Courtesy of NIH Image Gallery

Steven Deeks, MD
Courtesy of Jan Brittenson

In one of the first reports about COVID-19 in people with HIV, researchers contacted 1,178 HIV-positive people in Wuhan, China. Eight people with symptoms were found to have COVID-19. Six of them had mild cases, one had severe disease and one died. Among the remaining asymptomatic people, just one of the nine individuals known to have had close contact with COVID-19 patients tested positive for SARS-CoV-2.
an undetectable or low HIV viral load. Fourteen were hospitalized, six required intensive care and three died—higher rates than those observed for German COVID-19 patients overall—but ultimately, 91% recovered.

Turning to the United States, researchers identified 43 HIV-positive people (0.8%) among 5,700 patients hospitalized with COVID-19 in New York City—where about 1% of the population is living with HIV—indicating that HIV itself does not appear to be a risk factor. A separate analysis compared 21 HIV-positive and 42 HIV-negative people with COVID-19. Although the HIV group had somewhat higher rates of intensive care admission, use of ventilators and death, these differences were not statistically significant, meaning they could have been due to chance.

“We thought maybe we were going to see it more in people living with HIV because there are these clear risk factors, but we haven’t seen people with HIV coming into the hospital more or having more severe COVID-19 at all,” says Monica Gandhi, MD, MPH, the medical director of Ward 86, the HIV clinic at Zuckerberg San Francisco General Hospital, where most patients have well-controlled virus.

Taken together, these early studies and anecdotal reports suggest that HIV-positive people—at least those on effective antiretroviral therapy—are not a high-risk group based on their HIV status alone. As a result, interim guidance from the Department of Health and Human Services states, “People living with HIV who are diagnosed with COVID-19 have an excellent prognosis, and they should be clinically managed the same as persons in the general population with COVID-19, including when making medical care triage determinations.”

The World Heath Organization (WHO) concurs: “At present, there is no evidence that the risk of infection or complications of COVID-19 is different among people living with HIV who are clinically and immunologically stable on antiretroviral treatment when compared with the general population.”

However, the jury is still out on people with HIV who are not taking antiretrovirals and those who are on treatment but have not experienced good CD4 recovery. Around 40% of diagnosed HIV-positive people in the United States do not have viral suppression, and the 15% of individuals who remain undiagnosed are, of course, not on treatment.

Are People with HIV Protected?

Findings like these actually raise the opposite question: Are people living with well-controlled HIV—and potentially those taking antiretrovirals for pre-exposure prophylaxis (PrEP)—somehow protected against COVID-19?

Preliminary data suggested that some HIV medications might help control the new coronavirus, as certain antiretrovirals have shown activity against SARS-CoV-2 in the laboratory. Tenofovir disoproxil fumarate (one of the drugs in Truvada, used for HIV treatment and PrEP) appears to have both antiviral and immune-modulating effects. And during the 2003 SARS outbreak, caused by a related coronavirus, some patients improved after being treated with the protease inhibitor combination Kaletra (lopinavir/ritonavir).

But so far, studies in humans have not yielded much evidence that this is the case. In fact, most HIV-positive people who have developed severe COVID-19 were on antiretroviral treatment.

One of the first randomized clinical trials of Kaletra for COVID-19 found that it is no more effective than standard supportive care, although it may offer some benefit for those treated early. And the company that manufactures darunavir (Prezista and Prezcobix) cautioned that it is unlikely to have much activity against SARS-CoV-2.

Nonetheless, at least a dozen clinical trials of antiretrovirals for COVID-19 are underway, including WHO’s large Solidarity trial and a Spanish study evaluating whether Truvada might help prevent SARS-CoV-2 infection or lessen disease severity in health care workers.

Until more is known, experts advise against switching antiretrovirals in an effort to prevent or treat COVID-19, and they stress that people living with HIV and those using PrEP should take all the same precautions recommended for the general population to guard against the coronavirus.

Continued on the next page...
COVID-19 and Your Immune System

Another avenue of exploration relates to the fact that COVID-19’s serious lung and other organ damage is largely caused by the immune system’s response rather than by the coronavirus itself. In the most severe cases, an immune overreaction known as a cytokine storm floods the body with chemical messenger proteins that trigger excessive inflammation. If the immune system is causing the damage, some wonder, could modest immune suppression actually be an advantage?

“So far, it looks like anyone who has been exposed probably is going to get antibodies,” says Gandhi, “but it’s possible that in immunosuppressed patients—and even people living with well-controlled HIV—this may take longer.”

Scientists have already made remarkable progress in understanding COVID-19, but much remains to be learned. “We don’t know what kind of antibody response is protective. We don’t know what kind of responses we want to generate with vaccines. We don’t know how long they’ll last. And we don’t know whether or not people with HIV or cancer are going to have a less robust antibody response,” says Deeks. “These are the billion-dollar questions that the world is trying to answer.”

When it comes to treatment, he adds, “The ideal thing would be a benign, orally available drug that has a potent effect on the virus, is safe and is not susceptible to viral resistance and that can be made for pennies and would be easy to distribute widely. We don’t have anything on the shelf like that, so we need to start at the beginning.”

The antiviral drug furthest along in the pipeline, Gilead Sciences’ remdesivir, must be given by IV infusion, though injectable and inhaled formulations are being studied. Hydroxychloroquine, an old drug touted by President Trump, appears to have modest activity at best, and it can cause fatal heart problems. Medications that dampen the immune response can help some people with advanced disease, but it would be better to prevent cytokine storms in the first place.

COVID-19 PrEP also holds potential. “In a prevention setting, you might see a fair amount of benefit with drugs that only have modest activity,” Deeks says. “It may be that for prevention, you don’t really need something super powerful just to block transmission.” Although they would be more difficult and expensive to produce and administer than pills, Deeks thinks long-acting antibodies against SARS-CoV-2 might be “the kind of thing that you’d want to give a health care worker in the middle of a hot zone.”

Don’t Neglect HIV

COVID-19 is currently the hot topic for virologists, immunologists and epidemiologists worldwide. In fact, many of the top names in the HIV field—all the way up to National Institute of Allergy and Infectious Diseases director Anthony Fauci, MD—are applying the lessons they’ve learned from HIV to the latest pandemic.

“The massive investments that the National Institutes of Health has made into HIV research are paying off in amazing ways in terms of our capacity to deal with this new epidemic,” Deeks notes.

But many researchers, public health officials and advocates are concerned about the diversion of resources from the domestic and global HIV/AIDS response to COVID-19.
WHO and the Joint United Nations Programme on HIV and AIDS (UNAIDS) have warned that disruptions in HIV services and access to antiretrovirals could lead to more than half a million extra AIDS-related deaths, an increase in new HIV infections and a steep rise in mother-to-child HIV transmission in sub-Saharan Africa by the end of next year.

“The COVID-19 pandemic must not be an excuse to divert investment from HIV,” says UNAIDS executive director Winnie Byanyima. “There is a risk that the hard-earned gains of the AIDS response will be sacrificed to the fight against COVID-19, but the right to health means that no one disease should be fought at the expense of the other.”

In the United States, in an effort to both protect patients and reduce the demand on health care systems, experts initially urged people with HIV to utilize telemedicine and minimize in-person medical visits—for example, by delaying viral load monitoring. But this is not a viable long-term approach as the COVID-19 pandemic stretches into its sixth month.

“People with HIV went into hiding, but we need to get them back into the clinics. We need to start doing viral load measurement and make sure they have access to treatment. We need a balance between staying out of the health care system and engaging with the health care system,” says Deeks. “I think we’ll be doing a lot more telemedicine in the future, and for a lot of my interactions with my patients, it’s been fine. But I know people who I should be seeing in person much more frequently.”

Numerous efforts are underway to learn more about COVID-19 in people with HIV. For example, Jeff Taylor, a longtime treatment activist and advocate for long-term survivors, is working on a study that aims to follow a cohort of HIV-positive and well-matched HIV-negative people age 50 or older to see who gets the coronavirus, what kind of immune responses they mount and what the course of disease looks like over time.

“An important part of that will be studying the psychosocial impact of COVID-19 to see if this triggers posttraumatic stress disorder from the AIDS pandemic, how well people cope and if there are unique kinds of stigma associated with COVID-19 among people who are more vulnerable and may need to continue to remain socially isolated even after things reopen,” Taylor says.

Gandhi is also worried about the financial impact of the shutdown and the effects of social isolation—especially on older people and those struggling with mental health or substance use issues—as well as the reemergence of the same disparities long familiar to people living with HIV.

“COVID-19 has basically proven again that we haven’t fixed our structural inequities, structural racism, homelessness and all of the other unfair things that happen in society,” she says. “We’ve been shouting this from the rooftops since the beginning of HIV. It’s important for all of us as advocates to change the equation.”

CATCHING A BREAK

Art Jackson’s experience living with HIV has helped him face the challenges of COVID-19.

On the first weekend in March, Art Jackson, 55, lost his sense of taste. He soon started to have intense headaches and chest congestion. But his experience living with HIV for three decades stood him in good stead.

“One of the things about being HIV positive is that we know our bodies. We know when something is wrong,” Jackson says. “I’ve been very proactive about my health. When I started getting congested in my chest, I said, ‘This is not cool.’”

After a friend he had spent time with a week and a half earlier got sick and tested positive for the new coronavirus, he got tested too, with the same result.

“My congestion started getting really bad when the sun was about to go down, and by the time it was dark, it felt like someone was standing on my chest,” he recalls. “My body was hurting from the toes on up.”

Jackson, who has long had undetectable HIV and a high CD4 count, participated in telemicine visits with his doctor via Zoom, but he didn’t want to go to the hospital because “friends who were going in were dying.” Instead, his doctor or a nurse would call to check on his breathing every few hours. He managed his symptoms with over-the-counter medications and breathing in steam from a pot of hot water with lemons.

Continued on the next page...
“Updates from the Field

“A couple nights, I really thought I wasn’t going to make it. It took all my energy just to go into the kitchen,” he says. “The virus wanted me to lie down, so I said I’m going to get up and walk and try to give my lungs a chance. I thought about my grandmama and mama and auntsies and their home remedies, and I did what I knew I had to do.”

Jackson, who lives alone, also knew to call on loved ones for support. “People in my life weren’t going to let me go under,” he says. “I have an amazing family and a network of people who love and care about me. I have some amazing friends who called me in the middle of the night and made me laugh. They knew I needed that connection and needed to hear they cared about me.”

After about seven days, his symptoms started to ease up. But things still are not back to normal. “I still feel a little off-kilter. I still get winded. Even now, I would say I’m at about 80%. It’s a gradual process,” he says.

In addition to his own battle with the coronavirus, Jackson has lost three family members and four friends to COVID-19.

“It’s brought back so much of the trauma of HIV in the ’80s and ’90s—the stigma, the fear, but especially the deaths,” he says. “It’s brought back survivor’s guilt and wondering why I’m still here. For others, this is new, but we’ve dealt with a plague before.”

What’s more, Jackson has faced hurtful attitudes from others about having had COVID-19. “Fear just breeds stigma,” he says. “Now we’ve got to educate people. For some reason, this is something I’ve been charged to do, and I’m OK with that.”

He’s also felt the financial impact of the pandemic. After waiting weeks for unemployment assistance with no relief in sight, Jackson, who recently moved from Indianapolis to Charlotte, North Carolina, landed a new job as an HIV prevention coordinator with the Carolinas CARE Partnership.

“I’m not a religion person, but I believe in faith and grace, and I’m grateful for my blessings,” he says. “Sometimes it seems unfair. I’ve lived with HIV longer than I lived without it, and I wonder, When can I catch a break? But my break was to make it through, because many people didn’t.”

Editors Note: This article, published June 2020, was reprinted with permission from POZ, an award-winning print and online brand for people living with and affected by HIV/AIDS.

www.poz.com/article/covid19-hiv
Keeping our eyes on sexual and reproductive health in the middle of a pandemic in Zimbabwe

By: Munashe Mhaka, sexual reproductive and health rights advocate, Africa free of New HIV infections (AMHi) Youth Cohort

As I got off the call with Spiwe*, my heart sank, and my mind struggled to focus, knowing that my young friend could be in real physical danger and there was not much I could do about it. She had been enduring physical abuse at home for the past three months and had called to tell me she was thinking about ending her life.

Spiwe’s mother had remarried soon after the death of her father and she and her stepfather never saw eye to eye. Most of the time, their paths did not cross much because she was away at boarding school but following the reporting of the first case of COVID-19 in Zimbabwe, the government, like many other governments worldwide, took measures to curb the spread of the disease, including a nationwide lockdown. This meant that, unable to retreat to the refuge of school and without the excuse of going for church youth meetings, Spiwe, like many other victims of domestic abuse, was trapped with her abusers — her stepfather and her mother.

The outbreak of COVID-19 has seen a gigantic shift in the lifestyle of the entire globe. Since the disease is spread through respiratory droplets in the air at close range with an infected person and on surfaces, the World Health Organization (WHO) recommended measures to limit people’s physical interactions. Sadly, the restriction on travel, banning of social gatherings, and lockdowns have resulted in an increase of intimate partner abuse and domestic violence as women, children, and other at-risk persons are locked down with their aggressors. An upsurge of HIV transmission and unplanned pregnancies are expected as vulnerable individuals find it even more difficult to negotiate safe sex. The idle time from being out of schools and colleges is pushing young people deeper into drug abuse and risky sexual encounters, due to anxiety about the pandemic and personal vulnerability.

For my friend Spiwe, physical abuse is not the only trauma she has been enduring. Her stepfather has taken to sexually molesting her every night her mother is away on night duty at the hospital. Her phone call was to let me know that she was considering ending her life because she could not take any more physical and emotional pain. Fortunately, I was able to convince her to call a hotline where she could get counselling and possibly options on how to get to safety.

The attention and resources devoted to the COVID-19 response has shifted community engagement away from conversations and existing initiatives that address other public health issues such as HIV, TB, domestic violence, and sexual and reproductive health. While the world focuses on preventing deaths from the new pandemic, we should not risk losing lives due to lack of appropriate medical, physical, and psychosocial support for conditions we already know exist.

* Name has been changed to protect this individual’s privacy.

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https://www.iavi.org/news-resources/voices-newsletter/issue-6-keeping-all-eyes-on-the-target-to-end-hiv-despite-a-pandemic

Munashe Mhaka, youth advocate from Zimbabwe
Discovering the necessity for ‘meaningful community engagement’ in the face of the COVID-19 pandemic in Kenya

By: Munashe Mhaka, sexual reproductive and health rights advocate, Africa free of New HIV infections (AFNH) Youth Cohort. Co-authors: Jane Ng’ang’a, community liaison officer, KAVI-ICR; Fredrick Oyugi, community advisory board member, Kangemi; Stephen Anguva, community advisory board member, Kangemi

Since the opening of a clinical research site in Kangemi in 2003, the Kenya AIDS Vaccine Initiative – Institute of Clinical Research (KAVI-ICR) team has built a strong relationship of trust with the communities in the surrounding low-income settlements. The nearly two decades long partnership has seen the establishment of a robust Community Advisory Board (CAB), a critical link between researchers and the community, which has enhanced HIV prevention research literacy and the willingness of community members to participate in HIV vaccine clinical trials.

Located on the outskirts of Nairobi, Kangemi, is home to nearly 100,000 people reliant on subsistent wages often earned by travelling long distances across the city to jobs that provide a daily wage. As the COVID-19 pandemic has progressed in Kenya, it is increasingly clear that the already vulnerable communities in Kangemi and other informal settlements are being hard hit by the measures that have been put in place to try to curb the spread of the disease. The countrywide restriction on movement and social gatherings has resulted in loss of income for many households. Many have also had their access to treatment for existing conditions interrupted. The requirement for regular handwashing with soap and usage of face masks in public presents a challenge, as many of the settlements have limited access to running water at home and for them the purchase of extra soap, water, and masks is too expensive.

In keeping with the principle of leaving communities where studies are conducted better off as a result of its research activities, the KAVI-ICR community liaison team was inspired to find innovative ways of helping the community find home-grown solutions to address the new challenges. In partnership with community-based organizations, KAVI-ICR established the Kangemi Family Support (KFS), which identifies and rallies support for the most vulnerable families. Bringing together the Ngao Society, Strings For Life Kenya, Betty Adera Foundation, and several individual well-wishers, KFS has mobilized food support for 45 households, 129 children, and 200 beneficiaries across Kangemi within the first two weeks of its existence.

In addition to supporting the identification of deserving beneficiaries, CAB members have used the food distribution rounds as an opportunity to educate the community on the importance of social distancing and maintaining high standards of hygiene to avoid COVID-19 infection. They have also conducted HIV vaccine research literacy and distributed relevant information, education, and communication (IEC) materials.

While the initiative has proved to be successful and continues to receive in-kind and moral support from friends and well-wishers, the KFS is not without challenges. Owing to the low income of most of the households, the community has largely looked to the team to provide face masks. Another major shortcoming has been the inadequate supply of IEC materials to educate the community on COVID-19. However, on the more hopeful side, the community has indicated a willingness to participate in COVID-19 vaccine trials if and when they do happen. This can only be attributed to the significant investment in time and resources that has been made over the years to develop a truly meaningful engagement with the community.

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The HIV Vaccine Trials Network is an international multi-disciplinary collaboration. Support for the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health, an agency of the U.S. Department of Health and Human Services. The Network and NIAID have a close, cooperative working relationship, with shared attention to intellectual and scientific issues.

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

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