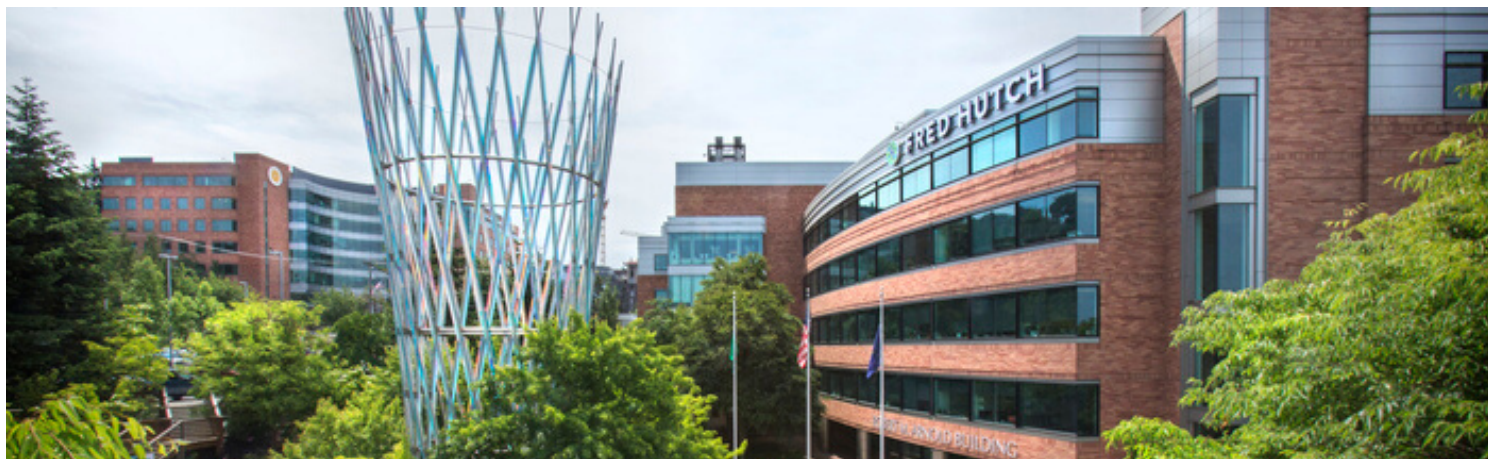


JUNE 2020

# NEWSLETTER

Office of HIV/AIDS Network Coordination



*Pictured: Fred Hutch campus, home of HANC offices and staff in Seattle, WA*

## HANC ANNOUNCEMENTS

*"Ending HIV means that we must also work to end structural racism, transphobia, misogyny, homophobia, and the entire syndemic ecosystem that has sustained the HIV epidemic for nearly four decades."*

Recent events in the U.S. have called profound attention to the persistent injustice, inequality, violence, and death faced by Black people in the country.

To that end, the Women's HIV Research Collaborative has issued a [Statement of Solidarity](#) with the Black community, including a link to resources for getting involved.

The latest [BTG News From the Editor](#) also reflects on the disproportionate burdens borne by indigenous, Black, and Latinx communities, reminding us to strive for justice and never leave anyone behind.

Finally, network voices add to the call for justice and equity. Read full statements from the [ACTG](#), [HPTN](#), [HVTN](#), [IMPAACT](#), and [MTN](#).

### INSIDE THIS ISSUE:

<b>A Message from the HANC Team</b>	<b>2</b>
<b>Network Announcements</b>	<b>3-5</b>
<b>Meeting Calendar</b>	<b>6</b>
<b>Webinars &amp; Training</b>	<b>6</b>
<b>HANC Program Highlights</b>	<b>7-9</b>
<b>Working Group Member Spotlight</b>	<b>10</b>
<b>Resources</b>	<b>11</b>

*Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at [mhvu@fredhutch.org](mailto:mhvu@fredhutch.org)*

## A MESSAGE FROM THE HANC TEAM

I debated as to whether I should write this because my heart is heavy and I'm weary. I'm tired of hearing about and seeing Black and Brown bodies being discounted and killed because of systems and individuals that have determined that we are not worthy of health, happiness or life. As a Black man, I live with the awareness that at any point, through no fault of my own, that my life could end at the hands of the police, or from any individual who feels that my very existence poses a threat.

Last week, in response to hearing me talk about the murders of George Floyd, Ahmaud Arbery, and Breonna Taylor, one of my children started crying and told me that they don't want the police or anyone else to kill me because of the color of my skin. I'm sure that Black and Brown parents around the country are having similar conversations with their young children. While I fear for my children, I don't want them to live in fear. I want them to be vocal and stand up and fight against these systems that perpetuate racism and oppression.

We must all be vocal and take a stand against racism and oppression. HANC leadership and staff will continue to advocate, educate and fight against systems of racism and oppression. As we continue to respond to the reality that HIV/AIDS and now COVID-19 disproportionately impacts Black and Brown bodies, we are committed to working with our many partners not only around addressing factors that influence participation of historically underrepresented communities in HIV clinical research, but in dismantling racism. We will continue to boldly stand with you and beside you and use all available resources to help end disparities related to HIV, health, and race.

In recognition of HIV Long-term Survivors Day, HANC would like to thank you for all that you have given in the fight to end the HIV epidemic.

While some of us may be weary, it is important for us to continue to raise our voices and fight for justice and freedom for all. In the words of Sweet Honey in the Rock, "[We Who Believe in Freedom Cannot Rest Until it Comes](#)". Black Lives Matter!

In solidarity,

Russell Campbell, on behalf of the Office of HIV/AIDS Network Coordination (HANC) Team

# NETWORK ANNOUNCEMENTS



## Designing a Study to Evaluate New Treatments for Pulmonary TB

Given the difficulty in adhering to long courses of treatment for TB, there is a great deal of interest in testing shorter courses of treatment against the standard regimen for pulmonary TB. This paper, published in *Contemporary Clinical Trials*, describes the design of A5349, a phase 3 trial that harnesses the expertise of the ACTG and the CDC TB Trials Consortium to test two shorter course regimens of anti-TB treatment against typical six months of isoniazid, rifampin, ethambutol, and pyrazinamide for two months, followed by isoniazid and rifampin for four months. The study evaluates two four-month regimens: high-dose rifapentine, isoniazid, ethambutol, and pyrazinamide for two months followed by two months of high-dose rifapentine with isoniazid or moxifloxacin, isoniazid, ethambutol, and pyrazinamide for two months followed by two months of high-dose rifapentine, isoniazid, and moxifloxacin.

A5349 will complete follow-up by September 30, 2020 with results available soon thereafter. The study will randomize ~2,500 participants 1:1:1 to each of these regimens, provided seven days a week with directly observed therapy at least five days a week. The primary outcome is tuberculosis disease-free survival at 12 months. Participants with HIV and without HIV are being enrolled. This important trial should provide insights into whether we can shorten the course of therapy for the leading infectious disease killer worldwide.

([Contemporary Clinical Trials](#). 2020 Jun 22; doi: 10.1016/j.cct.2020.105938. [Epub] PubMedID: 31981713; Dorman S, et al)

## Study Update from A5395 Team Leadership

Study A5395 is a clinical trial to evaluate whether the drug combination hydroxychloroquine and azithromycin can prevent hospitalization and death from COVID-19. Please find an abbreviated summary of an update from the A5395 study team leadership sent out on May 27, 2020.

"Recently published data in [The Lancet](#) regarding the safety and efficacy of hydroxychloroquine (HCQ) with and without azithromycin (and the media coverage that accompanied it), have led to concerns about studying this drug for the treatment of COVID-19 illness. Our team, which includes clinicians who manage patients with COVID-19, is very aware of these issues and the amplification of the concerns in the media." We are also aware that [serious concerns](#) have been raised about the data and analysis methods used in the Lancet study. The team met and concluded that there remains strong justification for proceeding with A5395 as:

- There is an urgent need for an oral outpatient treatment of COVID-19
  - There is at present no such agent for outpatient COVID-19
- An antiviral agent is most likely to be effective early in the course of COVID-19

# NETWORK ANNOUNCEMENTS



- While HCQ and azithromycin are oral, available, and have biologically plausible mechanisms of action, thus far they have been incompletely studied for COVID-19 for outpatient disease
  - The currently available data on the safety and efficacy of HCQ with and without azithromycin are mixed, observational (not randomized), primarily evaluated those with severe COVID-19 in the hospital setting
- The [Lancet study](#) stresses that data from randomized controlled trials are needed
- The ACTG is working to mitigate safety concerns in A5395 by:
  - Using a lower dose of HCQ than in prior COVID-19 studies (the same dose as with long-term treatment of rheumatoid arthritis)
  - Excluding those with a higher risk of HCQ + azithromycin toxicity



HPTN researchers [announced](#) on Monday, May 18, results from HPTN 083, a global randomized, controlled, double-blind study that compared the safety and efficacy of long-acting injectable cabotegravir (CAB LA) to daily oral tenofovir/emtricitabine (TDF/FTC) (Truvada) for pre-exposure prophylaxis (PrEP).

The study showed CAB LA lowered HIV incidence among cisgender men and transgender women who have sex with men.



HIV VACCINE  
TRIALS NETWORK

There is no update from the HVTN this month. Visit the HVTN [website](#) and [media room](#) for the latest information.



[IMPAACT P1090](#), a Phase I/II trial to evaluate the safety, tolerability, pharmacokinetics (PK) and antiviral activity of Intelence® (etravirine) in ARV treatment-experienced infants and children living with HIV, has informed the Committee for Medicinal Products for Human Use (CHMP) positive opinion to lower the age limit for the drug in children living with HIV in Europe. This CHMP positive opinion follows the U.S. Food and Drug Administration's (FDA) approval in July 2018 of etravirine for treatment of HIV-1 infection in treatment-experienced patients two years of age and older.

# NETWORK ANNOUNCEMENTS



The IMPAACT Network is also proud to announce six abstracts have been accepted for the AIDS 2020 conference: three as oral presentations and three as poster presentations. Studies to be presented include [P1025](#), [P1093](#), [P1078/TB APPRISE](#), [P1104s](#), and [ACTG5300/IMPAACT 2003 \(PHOENIX\)](#). More information will be available at [impaactnetwork.org/publications/AIDS2020.html](https://impaactnetwork.org/publications/AIDS2020.html) closer to the conference.



The final participant in MTN's EMBRACE study has completed follow-up. An observational study and registry to understand any effects the use of antiretroviral-based HIV prevention products may have on pregnancy and infant outcomes, [EMBRACE \(MTN-016\)](#) enrolled its first participant more than a decade ago. A total of 460 cisgender women and 413 infants have participated in EMBRACE, which has paved the way for a multitude of studies at MTN focused on the need for safe and effective HIV prevention products for all stages of life -- including during pregnancy and breastfeeding.

On May 14, MTN leadership made the decision to lift the blanket pause in study enrollment across network trials, which was instituted on March 18 in response to the COVID-19 pandemic. The decision regarding when study enrollment can begin at individual sites will be governed by the management team for each study, in concert with local and regional guidelines and stay-at-home orders. The MTN looks forward to completing network studies while honoring the continued commitment to the safety of our global network of participants and study teams. As this is an ever-changing situation, MTN has developed a [COVID-19 Response page](#) to keep study participants, staff and teams and community members updated on any new developments.

## MEETING CALENDAR

*In light of the COVID-19 pandemic, numerous events have been postponed or made virtual. Please check each event's website for the latest details.*

### June-Sept 2020

[Saving Ourselves  
Symposium Series](#)  
(Virtual)

### June-Oct 2020

[HIV2020 Online](#)  
(Virtual)

### July 6-10

[AIDS 2020](#)  
(Virtual)

### July 10-11

[IAS COVID-19  
Conference](#)  
(Virtual)

### Aug 9-14

[2020 National Ryan  
White Conference on  
HIV Care &  
Treatment](#)  
(Virtual)

### Oct 21-25

[IDWeek 2020](#)  
(Philadelphia, PA)

### Oct 24-28

[APHA 2020](#)  
(San Francisco, CA)

### Nov 1-4

[Adherence 2020](#)  
(Orlando, FL)

### Jan 17-21 2021

[HIVR4P](#)  
(Cape Town, ZA)

For details and other events, visit the [HANC calendar](#)



## WEBINARS & TRAINING

### Upcoming Webinars

#### COVID-19 and Impact on Latinx Communities

*June 24 @ 10AM PT / 1PM ET*

This webinar will feature Dr. Carlos Rodriguez-Diaz and Dr. Audrey Harkness. Stay tuned for more details, including the official webinar announcement, description, and registration link.

### Training

#### DAIDS Applied Research Training Toolkits

*Available on the DART website*

A new tool kit is available in support of the DAIDS Applied Research Training (DART) event held in Johannesburg, South Africa in September 2019. Please visit the “Resources” tab on the [DART website](#) to access the new tool kit and other resources previously released.

Newly released tool kits:

- Activity 22: Inspection Visits

### HANC Webinar Archives

Missed a webinar you wanted to attend? Visit the [HANC website](#) to view archived recordings of past webinars. Recent webinars of interest include:

- [ART Adherence and the Promise of Long-Acting Injectable HIV Treatment](#) featuring Dr. Michael Stirratt (*aired June 3, 2020*)



## HANC PROGRAM HIGHLIGHTS

Need to contact a HANC staff member? [Click here](#) to go to the About the HANC Staff page.

### HANC Staff Situation Update

In accordance with Fred Hutch policies in response to the novel coronavirus situation in Washington state, HANC staff are out of the office and working remotely until further notice. Work with HANC collaborators will continue with as few disruptions as possible.



#### Behavioral & Social Sciences

*Greg Davis, HANC Project Manager*

The Behavioral Science Consultative Group recently held a webinar titled, "Adherence Support Intervention Approaches used in the NIH HIV/AIDS Clinical Trials Networks - Part 1". The presenters for the webinar were Dr. Steven Safren and Dr. Ivan Balan.

Dr. Rivet Amico moderated the webinar. [Click here](#) to view the webinar. Part 2 is currently being planned and a registration link will be shared with HANC collaborators once details are finalized.

Youth Prevention Research Working Group: The Youth Prevention Research Working Group hosted a webinar on May 26 with Dr. Audrey Pettifor (YPRWG Co-chair) and Dr. Sandra McCoy. The webinar, "Adolescent Girls and Young Women: Self-testing in sub-Saharan Africa" can be [viewed here](#).



#### Community Partners

*Russell Campbell, HANC Deputy Director*

Community Partners will work with the Legacy Project and WHRC to convene and host a community conversation focusing on issues and concerns regarding COVID-19 and HIV Research efforts. The webinar announcement and registration details will be

shared in the near future.



#### Cross-Network Coordination

*Milan Vu, HANC Project Manager*

The Data Management Center Working Group (DMCWG) discussed continued data management center adjustments to COVID-19, protocol deviation reporting, and ongoing work related to safety data reconciliation.

# HANC PROGRAM HIGHLIGHTS

*(Cross-Network Coordination, continued)* Representatives from the Division of AIDS (DAIDS) and PPD joined the most recent Cross-Network Site Coordinators Working Group (SCWG) meeting to discuss a new DAIDS Manual initiative. The DAIDS Manual is a compilation of DAIDS policies, procedures, and processes that incorporates links and references to other DAIDS manuals, such as Protocol Registration, or DAIDS Adverse Event Reporting System (DAERS). The purpose of the manual is to act as a training and reference document to highlight aspects of compliance with DAIDS, regulatory entity, the International Council on Harmonisation/Good Clinical Practice (ICH/GSP), and the U.S. Food and Drug Administration (FDA) requirements.

The Communications Working Group (CWG) met to discuss ongoing impacts of COVID-19 on network HIV studies and network engagements in new COVID-19 studies. The group also discussed coverage of HPTN 083 and communication challenges in the current environment.

The public listing of network CTU/CRSs has been updated and is available [here](#).



## Laboratory Coordination

*Tyler Brown, HANC Project Manager*

The Laboratory Technologists Committee held two conference calls to discuss changes to quality assurance program activities due to COVID-19, resources for labs conducting COVID-19-related work, and the anticipated reopening of lab sites and clinical research sites.

The Laboratory Focus Group (LFG) published a set of high-level guidelines for labs that have experienced workload/workforce reductions and closures due to the COVID-19 pandemic. These guidelines are available on the HANC COVID-19 Laboratory Resources Page or by clicking [here](#). The LFG held a conference call to discuss ongoing disruptions for network labs and lab quality assurance providers, and the soon to be published revised Cross-Network Backup Laboratory Guidelines.

COVID-19 Laboratory Resources Webpage: HANC continues to post lab-focused announcements and resources related to COVID-19 on the HANC Laboratory Resources webpage [here](#).



## The Legacy Project

*Brian Minalga and Louis Shackelford  
HANC Legacy Project Team*

The Women's HIV Research Collaborative has released a [Statement of Solidarity](#) with the Black community and all those affected by the ongoing violence in our country. The statement includes a link to helpful resources for getting involved.

The latest issue of the Be the Generation newsletter is now available, covering recent advancements in HIV prevention research from the HPTN, HVTN, and MTN. View the newsletter in the BTG News section at the bottom of the [BTG website](#).

# HANC PROGRAM HIGHLIGHTS

*(Legacy Project, continued)* The Legacy Project had three (out of three) abstracts accepted to the American Public Health Association annual meeting, taking place October 24-28 in San Francisco, CA, or virtually depending on the COVID-19 pandemic at that time. Two of these abstracts were submitted by the Women's HIV Research Collaborative: "Okay ladies let's get information: Women & biomedical HIV prevention" and "Addressing the intersection of intimate partner violence and HIV in women." The other abstract was submitted on behalf of the DAIDS Cross-Network Transgender Working Group: "Fostering transgender inclusion in HIV research."

Legacy is delighted that the "HIV Prevention for Historically Black Colleges and Universities" abstract submitted on behalf of Legacy was accepted as a 90-minute session at the [2020 National Ryan White Conference on HIV Care & Treatment](#).

Brian Minalga and Rona Siskind will present at the virtual ACTG annual meeting on July 2 at 10 a.m. Pacific, covering information from the [Cross-Network Transgender Working Group's Guidance Document](#) for Gender-Inclusive Practices and the [Women's HIV Research Collaborative's HIV Cure Research training](#). More information to come.

Legacy recognizes National Caribbean American HIV/AIDS Awareness Day on June 8th and National HIV Testing Day on June 27th.

Legacy is planning an upcoming webinar entitled, "COVID-19 and Impact on Latinx Communities" on June 24 at 10AM PT/1 PM ET. The webinar will feature Dr. Carlos Rodriguez-Diaz and Dr. Audrey Harkness. Stay tuned for the webinar announcement and registration link.

## ABOUT COMMUNITY PARTNERS

[Community Partners](#) (CP) is a cross-network body charged by the Network Leadership and the Division of AIDS (DAIDS) with promoting representation of the communities within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research.

## ABOUT THE LEGACY PROJECT

The [Legacy Project](#) works nationally to increase awareness and support for HIV prevention and treatment clinical and behavioral research by addressing factors that influence participation of historically underrepresented communities.

The Legacy Project Work Group (LPWG) is comprised of members from HANC, CP, network operations centers, clinical research sites, community members, and DAIDS. The LPWG works to increase representation and engagement of African-Americans, Latinos and Native Americans in HIV prevention and therapeutic research in the U.S.

# WORKING GROUP MEMBER SPOTLIGHT

In an effort to highlight the work of HANC and members involved in HANC working groups, we would like to introduce you to a few of our members from Community Partners and the Legacy Project Working Group:



### Milton Mathonsi

Milton Mathonsi is a current member of Community Partners (CP) based at the South Africa Johannesburg PHRU Soweto site. Milton serves as the ACTG community representative for the PHRU Soweto site.

### What do you like most about community engagement?

What I like most is working together regardless of differences. I enjoy engaging with my community through workshops, health events and research studies. Individuals need more attention to make sure they don't feel isolated by whatever is taking place in their communities. As a peer educator, I appreciate serving as a bridge between the researchers and my community to share information so that community members feels empowered to ask questions and participate in research.

I'm looking forward to being a part of CP to learn and share ideas to help better engage with community members, especially those who are from poor socio-economic backgrounds, including women who are at risk of contracting HIV and other sexual health diseases, in South Africa.



### Hamilton Richardson

Hamilton Richardson is a longstanding member of HANC's Legacy Project Working Group. Hamilton has served a member of Community Partners and its Executive Committee, as well as the DAIDS Cross-Network Community Advisory Board. Additionally, Hamilton served as community representative to the Strategic Working Group (SWG), the senior scientific

advisory panel under the aegis of the National Institute of Health (NIH) branch of National Institute of Allergy and Infectious Diseases (NIAID) to advise Division of Acquired Immunodeficiency Syndrome (DAIDS) on the undertaking of large, costly and cross cutting clinical trials proposed from within the six DAIDS funded clinical trials networks.

Distinguished for his outstanding leadership and commitment to communities disproportionately impacted by HIV, Hamilton has provided invaluable insight to ensure the voices of the global community are heard.

# RESOURCES

## Newsletters

### Be the Generation Newsletter

The Be the Generation (BTG) project builds scientific literacy and community capacity to engage with biomedical HIV prevention research. *BTG News* is its quarterly newsletter publication on biomedical HIV prevention research, geared for community audiences who are interested in the HIV prevention research field. [Click here](#) to view current and past newsletters. Email [btg@hanc.info](mailto:btg@hanc.info) to subscribe.

### Behavioral Science Interest Group Newsletter

Interested in behavioral science? Join the Behavioral Science Interest Group (BSIG) and subscribe to the BSIG Newsletter. Email Greg Davis at [gpdavis@fredhutch.org](mailto:gpdavis@fredhutch.org) for more details.

## Laboratory

### CNICS Research Network

The CFAR Network of Integrated Clinical Systems (CNICS) provides peer-reviewed-open access to a rapidly evolving clinical research platform that prospectively collects patient data, including validated outcomes, longitudinal resistance data, and detailed PROs with readily available biological specimens. [Click here](#) for more information.

### EQAPOL

The goal of the External Quality Assurance Program Oversight Laboratory (EQAPOL) is to establish a panel of fully characterized viruses from acute/early and chronic HIV infections. Viral Diversity samples are available to NIAID-approved laboratories, and products created for the EQAPOL Viral Diversity Program are available to order. [Click here](#) for more information.

### Specimen Repository

The specimen repository is a collaboration between the ACTG, IMPAACT, and HVTN clinical trial networks to make available to investigators the large body of specimens collected for HIV research. [Click here](#) to visit the site and request specimens.

### Network Publications

Several of the HIV/AIDS clinical trials networks and collaborators publish their own newsletters, covering a range of topics from network-wide news to community level events. Links to various network publications are on the *Newsletters* page of the HANC website. [Click here](#) for more information.

### OCSO MOB Newsletter

Looking for the latest on site monitoring and regulatory compliance? Check out the Monitoring Operations Branch (MOB) Newsletter, produced by the DAIDS Office of Clinical Site Oversight (OCSO). [Click here](#) to find newsletter archives.

## NIH Corner

### C3PNO Virtual Data Repository

The C3PNO Virtual Data Repository facilitates the sharing of HIV, substance use, clinical data, behavioral, and biospecimens collected by the NIDA longitudinal HIV cohorts with outside researchers. [Click here](#) to learn more or email [c3pno.info@fstrf.org](mailto:c3pno.info@fstrf.org) to request data or specimens.

### ClinRegs

ClinRegs is an online database of country-specific clinical research regulatory information designed to assist in planning and implementing international clinical research. [Click here](#) to explore ClinRegs.

### NICHD Data and Specimen Hub (DASH)

NICHD DASH is a centralized resource for researchers to access data and biospecimens from NICHD-funded research studies for secondary analyses. [Click here](#) to explore DASH.

FOLLOW HANC ON



FIND MORE RESOURCES AT  
[WWW.HANC.INFO](http://WWW.HANC.INFO)