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Link to the full article [here](#).

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**LAND, LABOR, AND JUSTICE ACKNOWLEDGEMENTS**

We acknowledge the land we occupy today as the traditional home of the Duwamish, Tulalip, Muckleshoot, and Suquamish tribal nations, the original caretakers of this land who are still here. Without them we would not have access to this working, teaching, and learning environment. We commit to conducting ourselves with dignity and treating this land and all the life it sustains with respect. We ask you to join us in this commitment, wherever you may reside.

We also acknowledge exploited labor and ongoing struggles for justice on this land. We reflect on the ancestors of our various peoples, nations, tribes, and families; ancestors whose struggles, pain, power, privilege, and strivings we hold in our very bodies.

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

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**HANC ANNOUNCEMENTS**

**Address Medical Mistrust to Recruit Minorities to COVID-19 Trials**

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**INSIDE THIS ISSUE:**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Updates</td>
<td>2</td>
</tr>
<tr>
<td>Network Announcements</td>
<td>3-7</td>
</tr>
<tr>
<td>Meeting Calendar</td>
<td>8</td>
</tr>
<tr>
<td>Webinars &amp; Training</td>
<td>8</td>
</tr>
<tr>
<td>HANC Program Highlights</td>
<td>9-10</td>
</tr>
<tr>
<td>Resources</td>
<td>11</td>
</tr>
</tbody>
</table>

Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org

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Please join us in welcoming Hugo Brown-Romero as the newest HANC team member! Tyler Brown, HANC Laboratory Project Manager, and his wife Ilse are the proud parents of Hugo, who arrived earlier this week! Ilse, Tyler and Hugo are doing well. Congratulations to Tyler and Ilse!
Researchers turn to HIV/AIDS clinical trial network for help in building Black Clevelanders’ trust in COVID-19 studies

Featuring HANC collaborators Ray Allmond, Michele Andrasik, and Stephaun Wallace (pictured L to R)

CLEVELAND, Ohio — It took more than a decade of participation on the Community Advisory Board at University Hospitals’ AIDS clinical trial unit for Ray Allmond, who is Black, to understand the vital role he and other people of color can play by having a say in the clinical trial process. It took years of work, he said, to build up trust — through community education, awareness-raising efforts and one-on-one conversations — to reach a point where Black Clevelanders were more willing to participate in trials aimed to treat and prevent HIV and AIDS.

Now, top infectious-disease experts have turned to the HIV/AIDS clinical trial network, including community volunteers such as Allmond, to help combat another virus ravaging the U.S. Black community: the novel coronavirus.

“When you are doing research with communities, it’s a different frame than doing research on communities,” said Wallace, who has guided engagement efforts for the HIV Vaccine Trials Network and is doing the same for the new COVID-19 Prevention Network. The goal also isn’t to persuade or guilt people into participating in research for the good of their communities.

“If individuals and families and communities have the appropriate information and they have access to our clinical research sites, then they are equipped to make their own decisions about how much or how little they want to be involved in these trials and whether or not they want to participate or share the information with their friends and families so that they might participate,” Andrasik said.

Read the full article here.
Landmark Trial Demonstrates Effectiveness of Shortened TB Treatment
The ACTG is pleased to share the primary results of Study 31/A5349, which were presented at the 51st virtual Union World Conference on Lung Health on October 21st, 2020. This important study showed that the four-month regimen of rifapentine, isoniazid, pyrazinamide, and moxifloxacin (RPT-MOX) was non-inferior to the currently recommended six-month regimen of rifampicin, isoniazid, ethambutol, and pyrazinamide for the treatment of drug-susceptible pulmonary TB. RPT-MOX was also safe and well-tolerated by patients. A second four-month regimen of rifapentine, isoniazid, pyrazinamide, and ethambutol failed to meet the non-inferiority margin.

To put this study in historical context, the last time pulmonary TB treatment was successfully shortened for drug-susceptible TB was 48 years ago, when the British Medical Research Council (MRC) published results showing a six-month regimen was as effective as the standard 18-month regimen at that time. Despite many trial attempts to shorten TB therapy since, the standard treatment regimen for drug-susceptible pulmonary TB has remained at six months.

Thirteen countries contributed to Study 31/A5349, a phase 3, open-label, randomized controlled clinical trial, at 34 clinical sites. Approximately 2,500 people aged 12 years and older participated in the study, including 214 people with HIV infection. The study was led by the CDC Tuberculosis Trials Consortium (TBTC) in collaboration with the ACTG. ACTG sites enrolled two-thirds of participants and TBTC sites enrolled one-third.

Participants with HIV infection were enrolled in a staged fashion to allow for drug-drug interaction studies between rifapentine and efavirenz, which is why the number was relatively small. Reassuringly though, the participants did just as well as those without HIV, and the RPT-MOX regimen was also non-inferior and safe in these participants. “Shortening treatment for TB has been front and center in the TB TSG scientific agenda for decades, and this new regimen that reduces treatment by two months will facilitate significant progress in global tuberculosis control,” said Dr. Susan Swindells of the University of Nebraska Medical Center and a co-chair of the study. “This trial demonstrates the value of collaborative efforts between the ACTG and other networks,” added Dr. Richard Chaisson of Johns Hopkins University, another co-chair of the trial.

A5360 Results to be Presented at AASLD
The ACTG is thrilled to announce that the results of A5360 (Monitoring SOF-VEL in Treatment Naive, HCV Participants with Active Infection) will be presented at the Liver Meeting (AASLD) on November 16. A5360 evaluated the safety and efficacy of a minimal monitoring (MINMON) approach to hepatitis C therapy in people who had not received prior treatment and had no evidence of decompensated cirrhosis.
In this study, the MINMON strategy comprised of four elements: no genotyping prior to treatment, all tablets dispensed at entry, no scheduled on-treatment clinic visits or labs, and two remote contacts at weeks four (an adherence assessment) and 22 (scheduling a sustained virologic response – SVR – visit). All participants received a single-tablet, fixed-dose regimen of sofosbuvir/velpatasvir for 12 weeks.

A5360 demonstrated that in a diverse global patient population recruited across four continents, a MINMON approach to HCV treatment delivery was safe and achieved SVR comparable to current standards. Wider adoption of the MINMON strategy, coupled with innovative case-finding strategies, may facilitate the elimination of hepatitis C while minimizing in-person appointments and resource use.

In order to achieve the WHO’s global hepatitis C elimination agenda by 2030, it is estimated that 80 percent of the approximately 71 million people with chronic infection will need to be treated. To accomplish this, treatment delivery and associated laboratory monitoring need to be simplified without compromising efficacy or safety. The COVID-19 pandemic has hampered progress of public health programs including the viral hepatitis program, further highlighting the need for simple and safe models of healthcare delivery that minimize face-to-face patient-provider contact without compromising efficacy.

2020 HPTN Update Webinar Recap
More than 800 participants joined the recent 2020 HPTN Update Webinar to learn about the state of the Network, community engagement successes, the HPTN Scholars program, presentations on placebo counterfactuals for PrEP and laboratory testing for SARS-CoV-2, and a discussion of our future research agenda. Keynote speaker Dr. Anthony S. Fauci kicked off the event with a prerecorded talk on COVID-19 public health and scientific challenges. Watch the recording here.
Thomas Fleming Receives 2020 Ward Cates Spirit Award
Dr. Thomas Fleming received the 2020 Ward Cates Spirit Award during the recent HPTN Update Webinar. He was acknowledged for his admirable dedication, passion, and tireless pursuit of ensuring clinical trials are well designed, properly implemented, and correctly interpreted. Dr. Fleming has generously given his time to develop capacity within the HPTN and elsewhere to understand the issues related to clinical trials through teaching both in U.S. and HPTN trial sites in Africa. The award honors the legacy of Dr. Willard (Ward) Cates Jr., a dedicated steward of the HPTN scientific and research programs, and a respected scientist who contributed to groundbreaking contraceptive and HIV prevention research.

HPTN Network Performance Awards
The HPTN Network Performance Awards, recognizing top performers in community engagement, study participant accrual and estimated retention, laboratory performance, and staff excellence in leadership, were announced during the 2020 HPTN Update Webinar. We congratulate all award recipients for their achievements.

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 follows:

<table>
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<th>DATES</th>
<th>EVENT</th>
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| Friday 16 October| Launch by Email
Pre-recorded presentations for Session 1 will made available online on the Enterprise website (https://vaccineenterprise.org/) |
## NETWORK ANNOUNCEMENTS

<table>
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<tr>
<th>DATES</th>
<th>EVENT</th>
</tr>
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<tr>
<td><strong>Tuesday 27 October</strong></td>
<td>Live Session 1 – Panel discussion (60 minutes)</td>
</tr>
<tr>
<td>8AM PDT</td>
<td>Current design approaches - challenges &amp; lessons learned</td>
</tr>
<tr>
<td>11AM EDT</td>
<td>Session 2 pre-recorded presentations made available online on the Enterprise website</td>
</tr>
<tr>
<td>4PM CET</td>
<td><strong>Confirmed presenters:</strong> Jared Beaten, Eduard Grebe,</td>
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<td></td>
<td>Sinead Delany-Moretlwe, David Radley, Mia Moore, Jeff Eaton</td>
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<td></td>
<td><strong>Confirmed panelists:</strong> Jeremy Sugarman, Sheena McCormack, Mike</td>
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<td></td>
<td>Robertson, David Glidden, Thamban Valappil, Grace Kumwenda</td>
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| Friday 06 November     | Live session 2A – Panel discussion (60 minutes)                      |
| 8AM PST                | Future design approaches for settings where all study participants are |
| 11AM EST               | on active HIV prevention – ARV based prevention                      |
| 5PM CET                | **Confirmed panelists:** Jeremy Sugarman, Sheena McCormack, Mike     |
|                        | Robertson, David Glidden, Thamban Valappil, Grace Kumwenda          |

| Wednesday 18 November  | Live session 2B – Panel discussion (60 minutes)                      |
| 8AM PST                | Future design approaches for settings where all study participants are |
| 11AM EST               | on active HIV prevention – Vaccines                                 |
| 5PM CET                | **Confirmed panelists:** Cathy Slack, Glenda Gray, Hanneke Schuitemaker, Georgia Tomaras, Carol Weiss, Dean Follman, Rob Newells |

| Wednesday 02 December  | Live session 2C – Panel discussion (60 minutes)                      |
| (TBC)                  | Future design approaches for settings where all study participants are |
| 8AM PST                | on active HIV prevention – Monoclonal antibodies                      |

| January 2021           | Live session 3 (60 minutes)                                          |
|                        | Panel Discussion 1: A critical investigation into new methodological |
|                        | approaches                                                           |
|                        | Panel Discussion 2: Community engagement and involvement in clinical |
|                        | trial design                                                         |
|                        | Regulatory Forum organized by the Forum for Collaborative Research   |

Additional details and updates are on the Enterprise Website [https://vaccineenterprise.org](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, Stephaua Wallace, and Linda-Gail Bekker
The IMPAACT Network is pleased to announce that IMPAACT P1026s has closed to follow-up as of 30 September 2020. P1026s was a Phase IV, prospective pharmacokinetic (PK) study of selected ARV drugs, TB drugs and/or postpartum contraceptives currently used in the clinical care of pregnant women and postpartum. Highlights of the study included:

- 1,037 mothers and 541 infants enrolled
- 43 abstracts presented
- 28 manuscripts published

Also, on 30 October 2020 the U.S. FDA approved two supplements for Selzentry (Maraviroc) Tablets and Oral Solution, which expanded the Selzentry label to include dosing for individuals less than two years of age and weighing at least 2 kg, thus providing approved labeling for all age groups receiving non-interacting concomitant medications for this product. The supplements consisted of new pharmacokinetic and safety data from IMPAACT 2007 in neonates (birth to six weeks of age) born to mothers living with HIV-infection as well as modeling and simulation data to bridge the age groups and provide dosing for pediatric patients aged > 6 weeks to < 2 years. The approved indication is “SELZENTRY is a CCR5 co-receptor antagonist indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients weighing at least 2 kg.”

In addition, participants in IMPAACT 2010 completed all Week 50 visits as of 3 October 2020, and IMPAACT P1107 closed to accrual as of 12 October 2020.

Finally, a number of abstracts from IMPAACT have been accepted for the 2020 International Workshop on HIV Pediatrics, rescheduled from July to November 2020. A full listing will be shared prior to the meeting and materials will be posted following the meeting here.

MTN is continuing our “A Look Back…” series, featuring stories about some of the incredible people and participants who have formed the heart of the MTN since 2006. The latest installments, Life Changing Journeys in HIV Prevention and The Mighty Women of MU-JHU, as well as earlier pieces, can be accessed on the MTN A Look Back… page.

MTN is thankful for the many contributions Jared Baeten, network co-PI, has made over the years, and wishes him the best as he transitions to a new position with Gilead Sciences. Read Saying Goodbye to Jared Baeten by MTN leader Sharon Hillier, including a message from Jared.
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.

Nov 2-3
Adherence 2020
(Virtual)

Nov 16-17
International Workshop on HIV Pediatrics
(Virtual)

Nov 16-20
International Conference on Stigma
(Virtual)

Jan 15-16, 2021
NAESM Conference
(Virtual)

Jan 27-28 & Feb 3-4, 2021
HIVR4P
(Virtual)

Feb 2, 2021
IAS COVID-19 Conference: Prevention
(Virtual)

Mar 6-10, 2021
CROI 2021
(Virtual)

For details and other events, visit the HANC calendar

WEBINARS & TRAINING

Upcoming Webinars

NIH Virtual SARS-CoV-2 Antiviral Therapeutics Summit
November 6 from 11AM - 3:30PM ET
NCATS and the National Institute of Allergy and Infectious Diseases (NIAID) are sponsoring this scientific summit to discuss progress and remaining challenges in developing antiviral treatments for COVID-19. The summit opens with remarks from NIH Director Francis S. Collins; NIAID Director Anthony S. Fauci, and NCATS Director Christopher P. Austin.

The meeting can be viewed live or on demand. Registration is not required.
Website | Agenda | Join via NIH VideoCast

Iman & COVID: Reflections from the Muslim Community Series
Hosted by RAHMA and the CoVPN, tune in to the I Am Khadijah Facebook page to watch each episode live.

   November 11  Episode 2: Islam, COVID & Dismantling Racism
                   6PM PT / 9PM ET  Watch on Facebook Live

   November 18  Episode 3: Surviving Marriage, Incarceration, and COVID. Watch on Facebook Live
                   6PM PT / 9PM ET

COVID in Black Series
To watch previous episodes of COVID in Black, please visit the CoVPN YouTube page.

   November 12  Episode 4: Faith and COVID-19: A Pathway Forward
                   4PM PT / 7PM ET  Zoom registration | Watch on Facebook Live

   November 18  Episode 5: Black Health Providers Can Help End the Uncertainty. Watch on Facebook Live
                   4PM PT / 7PM ET

Pandemia Episode 1: Facts, Not Politics: What We're Doing About COVID-19
November 19 @ 11AM PT / 2PM ET
Are you tired of the politics surrounding COVID-19? The CoVPN, Latino Commission on AIDS, and UnidosUS have you covered! Learn just the facts about COVID-19 research with a focus on Latinx communities. Register here.
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 coronavirus situation in Washington state, HANC staff are 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 (BSCG) continues to meet monthly to provide updates on ongoing HIV trials and COVID-19 studies. The BSCG recently completed a paper and have submitted it for publication. Once the paper is accepted and published, it will be shared with the members of the Behavioral Science Interest Group via the BSIG Newsletter.

On October 8, 2020, the Youth Prevention Research Working Group (YPRWG) hosted a webinar with Dr. Lisa Hightow-Weidman and Dr. Travis Sanchez on the Adolescent Trials Network’s (ATN) iTech studies. The webinar, ATN's iTech Studies and COVID-19: Adapting iTech During a Pandemic” can be viewed here.

Community Partners
Russell Campbell, HANC Deputy Director

Community Partners is in the process of finalizing its workplan for 2020. In addition, Community Partners is updating the Recommendations for Community Engagement in HIV/AIDS Research document which will be available in English, Portuguese and Spanish. Finally, a Community Engagement Landing Page is being developed for the DAIDS Learning Management System which will include community resources and trainings.

Cross-Network Coordination
Milan Vu, HANC Project Manager

The Data Management Center Working Group (DMCWG) discussed updates on the safety data reconciliation policy, protocol deviation reporting, and trial master file data transfer. The DMCWG also revised and finalized working group objectives for 2021.
(Cross-Network Coordination, continued) The Cross-Network Site Coordinators Working Group (SCWG) discussed site training needs for new staff along with messaging related to study pauses in the context of COVID-19 trials. The SCWG revised their workplan for 2021 and anticipates releasing an open solicitation for new members following the start of the new grant cycle.

**Laboratory Coordination**

*Tyler Brown, HANC Project Manager*

The Laboratory Technologists Committee (LTC) held two conference calls to discuss process improvement strategies for ACTG protocol A5401, new specimen barcode scanning requirements and LTC new membership solicitations.

The LTC is seeking new applicants for the upcoming membership term that begins 01 March. Committee membership solicitation begins on 21 December with a deadline of 15 January. Please contact Rose Lagattuta (rlagattuta@milabcentral.org) if you or someone from your lab would like to apply.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss current proficiency testing round updates and updates to FSTRF’s AVR/SOP Submission Utility. The call included a webinar presented by Dr. Tim Cressey and Yardpiroon Tawon from Chiang Mai University entitled Estimation of Uncertainty of Measurement for the Quantification of Antiretroviral Drugs by LC-MS/MS assays.

The Virology Quality Assurance Advisory Board (VQAAB) held the first annual VQA Annual Review Meeting. The two-day virtual meeting included presentations from the Duke VQA Program that highlighted past and future PT program milestones, updates to PT program participation requirements and scoring procedures, and VQA SARS-CoV-2 activities, including the SARS-CoV-2 Neutralization Assay Concordance Survey (SNACS).

Frontier Science released a new guidance document that describes LDMS tools for generating reports for inspections and audits. That document can be accessed on the LDMS website or by clicking here.

**The Legacy Project**

*Brian Minalga, HANC Legacy Project Community Engagement Officer*

**November 19:** Submission from the HPTN, HVTN, and MTN are due to Brian Minalga for inclusion in the Be the Generation newsletter.

**November 20:** Legacy recognizes the [Transgender Day of Remembrance](https://www.transdayofremembrance.org/).

Russell Campbell represented HANC/Legacy during an online panel presentation on the Black, Indigenous and other People of Color’s (BIPOC) experience and concerns as part of the Age Friendly Seattle LGBTQ+2S & BIPOC: Vaccinations, Vaccine Trials and YOU forum on October 30th.
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 for more details.

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
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.

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 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 for more details.

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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.

FOLLOW HANC ON
FIND MORE RESOURCES AT WWW.HANC.INFO