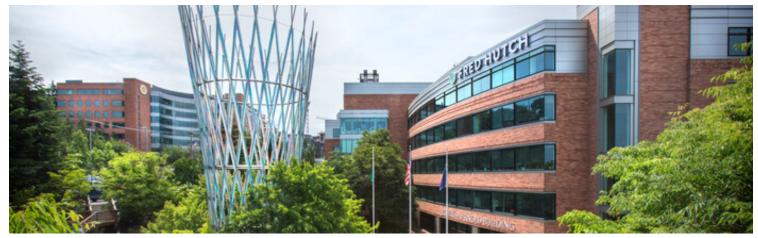
APRIL 2020

NEWSLETTER



Office of HIV/AIDS Network Coordination



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

HANC ANNOUNCEMENTS

NEW COVID-19 Resource Pages

HANC will maintain and frequently update a new <u>COVID-19</u> <u>Resources</u> page on the HANC website for resources and information on the COVID-19 pandemic with a focus on the intersection with the HIV pandemic.

In addition, public network announcements on COVID-19 are also available under Network Announcements on COVID-19. Laboratory-specific guidance is posted the COVID-19: Laboratory Resources page. Links to all three pages are posted on the HANC homepage under Announcements.

Collaborators are welcome to submit any other resources that they find helpful. This page will hopefully serve as a useful source of information to community and research sites.

April Webinars

Four new webinars are scheduled for April. Check out the **Webinars & Training** page for details and registration links.

Recently changed your email address? Let us know by emailing hancadmin@hanc.info to update your mailing list information.

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





The 2020 HPTN Annual Meeting has been postponed due to the COVID-19 pandemic. The meeting is expected to be held in Fall 2020 or later, dependent upon the outcome on the pandemic response. We will share relevant updates via email and the Annual Meeting webpage.



HPTN researchers virtually presented 14 abstracts showcasing <u>HPTN 052</u>, <u>HPTN 071</u>, <u>HPTN 075</u>, <u>HPTN 078</u>, and the HPTN Modelling Center and HPTN Laboratory Center's ongoing work at the 27th annual <u>Conference on Retroviruses and Opportunistic Infections</u> (CROI).

HPTN 052 was a Phase III, two-arm, randomized, controlled, multi-center trial that determined antiretroviral therapy (ART) can prevent the sexual transmission of HIV-1 in HIV-1 serodiscordant couples.

HPTN Scholar Dr. Maganizo Chagomerana's poster <u>Sexually Transmitted</u> <u>Infections Among HIV Serodiscordant Sexual Partners: HPTN 052</u> showed sexually transmitted infection (STI) prevalence at enrollment was slightly higher among study participants living with HIV compared to their HIV-uninfected partners. In addition, STI prevalence at enrollment was higher among females and unmarried participants.



(HPTN 052, continued)

HPTN Laboratory Center's Dr. Yinfeng Zhang presented <u>Use of Phylogenetic Analysis to Infer the Direction of HIV Transmission</u>. The poster showed accurate predictions of transmission direction were obtained using wholegenome and pol next-generation sequencing data. Further research is needed to evaluate the performance of these methods in other settings and cohorts and in cases where both individuals (source and recipient) have long-term infection.

HPTN 071 (PopART) examined the impact of a package of HIV prevention interventions on community-level HIV incidence. Results showed delivery of an HIV prevention strategy that includes offering in-home HIV testing to everyone, with immediate referral to HIV care, and treatment for people living with HIV based on prevailing in-country guidelines, can substantially reduce new HIV infections.

Dr. Tim Skalland's poster <u>HIV Incidence and Viral Burden at the Community</u> <u>Level in HPTN 071 (PopART)</u> demonstrated association between higher HIV incidence and higher viral burden.

Dr. William Probert's poster <u>HIV-1 Dynamics Following Universal Testing-and-Treatment Within HPTN 071 (PopART)</u> showed how continuation of Universal Testing and Treatment (UTT) as delivered in the study through 2030 could dramatically reduce new HIV infections in sub-Saharan Africa, but that targeting of high-risk individuals might be necessary.

In a third study-related poster from the HPTN Laboratory Center, <u>Evaluation of Cross-Sectional HIV Incidence Testing In the HPTN 071 (PopART) Trial</u>, Ethan Klock showed that a widely-used cross-sectional incidence algorithm that included the limiting antigen avidity assay and HIV viral load yielded accurate point estimates of incidence, despite high rates of viral suppression among those with both prevalent and incident infection.

HPTN 075 evaluated the feasibility of HIV prevention research among men who have sex with men (MSM) and transgender women (TGW) in three countries in sub-Saharan Africa. Findings showed participants were at an alarming risk for getting HIV.

HPTN Laboratory Center's Philip Palumbo presented <u>HIV Superinfection</u> <u>Among MSM and TGW in Sub-Saharan Africa: HPTN 075</u>. The poster demonstrated the incidence of HIV superinfection among seroconverters was significantly higher than the rate of primary HIV infection. This finding contrasts with previous studies reporting superinfection rates were equal to or lower than the rate of primary HIV infection.



HPTN 078 was a U.S.-based research study designed to evaluate the effectiveness of a combined HIV prevention strategy, including a peer-to-peer referral method to recruit men who have sex with men (MSM) living with unsuppressed HIV and an intervention to help them achieve and maintain viral suppression.

Dr. Ken Mayer's poster <u>Cascade to Trickle: Reasons for Suboptimal PrEP Use Among at Risk U.S. MSM (HPTN 078)</u> suggests that strategies to increase effective PrEP uptake in U.S. MSM will need to address socioeconomic issues and misinformation about side effects, and should assist MSM in assessing their true HIV acquisition risk.

Two other posters from the HPTN Laboratory Center presented additional findings from this study.

Dr. Jessica Fogel's poster Resistance to Integrase Strand Transfer Inhibitors Among MSM in the U.S.: HPTN 078 documents significant levels of INSTI resistance and highlights the importance of including baseline integrase resistance testing when selecting antiretroviral therapy regimens for MSM in the U.S.

Dr. Risha Irvin's poster <u>HPTN 078: High Incidence of Hepatitis C Virus</u> <u>Infections Among MSM</u> suggests HCV risk counseling should be considered in both people living with HIV and HIV-negative MSM, particularly in those with a high number of lifetime sexual partners and substance use.

HPTN Modelling Center

Dr. Kate Mitchell's poster <u>Using Surveillance Data to Measure Trial HIV</u> <u>Incidence Outcomes: A Modelling Study</u> showed surveillance diagnoses data can only rarely be used to estimate HIV incidence reductions in cluster-randomized controlled trials of HIV interventions.

Dr. Dobromir Dimitrov's poster <u>Achieving 95-95-95 May Not Be Enough to End AIDS Epidemic in South Africa</u> suggests that without HIV prevention, scale-up practically all high-risk people living with HIV may need to be virally suppressed for HIV incidence to fall below AIDS elimination threshold.

Additional posters from the HPTN Laboratory Center

George Mwinnyaa's poster <u>Indeterminate HIV Rapid Test Results: Outcomes</u> <u>and Risk Factors</u> suggests HIV surveillance programs should develop a protocol for reporting individuals with mixed or persistently indeterminate HIV results on multiple follow-up visits.



(Additional posters from the HPTN Laboratory Center, continued)

Wendy Greenawalt's poster <u>HIV Drug Resistance in Female Sex Workers</u> <u>from the Dominican Republic and Tanzania</u> demonstrated high rates of HIV drug resistance among female sex workers in the Dominican Republic and Tanzania, including high rates of multi-class resistance.

Athena Chen's poster <u>Improving Classification for Recent HIV Infection Using Top Scoring Pairs</u> found the approach can be easily applied to other populations and viral subtypes to identify novel peptide signatures for cross-sectional incidence estimation.



The rapidly evolving COVID-19 situation is impacting clinical trials coordinated by the HIV Vaccine Trials Network (HVTN) globally. In response, the leadership of the Network empowered staff at each trial site to implement measures necessary to preserve the safety and wellbeing of study participants and their staff from potential exposure to COVID-19.

The measures implemented at each site are aligned with the guidance from local public health authorities and sites' Institutional Review Board/Ethics Committee. This approach ensures that the clinical trials are conducted with regard for the local context and in the interest of preserving the scientific integrity of the clinical trials.

Network leadership will continue to monitor the situation to help trial sites make informed decisions to mitigate the impact of COVID-19.

Access public statement

Following careful thought and consideration of the impact of COVID-19, the HVTN Full Group Meeting, scheduled to take place in Washington D.C. from May 27th – 29th, is cancelled. Alternative dates will be communicated when available, considering factors such as travel restrictions into the United States and travel notices for other countries.



The IMPAACT Network has released a formal statement about action steps and plans surrounding the COVID-19 pandemic, as well external guidance and resources, on a dedicated webpage at

https://impaactnetwork.org/news_/COVID19Response.html. The Network has also made the difficult decision to cancel the 2020 Annual Meeting that was to be held 8-12 June 2020. Alternative plans are currently in discussion.



(continued) Additionally, recent publications on IMPAACT studies have been released and include the <u>PROMISE Studies in Clinical Trials</u>, <u>IMPAACT P1110 in JAIDS</u>, and <u>IMPAACT P1026s in JAIDS</u>.



Given the profound global impact of the COVID-19 pandemic, MTN leadership has decided to pause screening and enrollment for all studies. Where feasible, those studies still following participants will take extra precautions to help ensure their safe participation in this new environment as well as enable the collection of data vital to study completion. 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.

MTN is happy to report the first births coming out of the **DELIVER study**. Three of four participants being followed by the Wits Reproductive Health and HIV Institute (Wits RHI) Shandukani Research Centre in Johannesburg recently delivered. Moms and babies are doing well. Another participant is due any day. All will continue to be followed by the team to the extent this can be done safely and in accordance with local guidelines for protecting against COVID-19. The study is otherwise paused. DELIVER (MTN-042) is assessing the safety & acceptability of HIV prevention products used during pregnancy – the dapivirine vaginal ring and Truvada as PrEP – in 750 cisgender women in Malawi, South Africa, Uganda and Zimbabwe. Wits RHI is the only site that has been activated to date.

The **DESIRE study (MTN-035)**, a behavioral study of rectal microbicide placebo products, completed enrollment just prior to the closure of study-wide accrual due to the COVID-19 pandemic. The targeted 210 participants were enrolled into the study at sites in Malawi, Peru, South Africa, Thailand and the U.S., with approximately 180 still in study follow-up. To enable study follow-up to safely continue, data collection procedures are being instituted that will not require participants to come to the clinic. Participants will be able to remotely complete follow-up procedures (in-depth interviews and communication through text messaging services) with ongoing guidance and support from site study staff. The study team is hopeful that implementing these necessary changes will allow DESIRE to be completed on time – anticipated at the end of June – and ultimately help answer important questions about preferences for future rectal microbicide products.



There is no update from the ACTG this month. For the latest news, please check the ACTG website at https://actgnetwork.org/.

MEETING CALENDAR

In light of the coronavirus disease (COVID-19) pandemic, numerous events have been postponed or cancelled. Please check each event's website for the latest details.

May 27-29

Postponed

HVTN Full Group Meeting (Washington, DC)

May 30-June 3

Postponed

HPTN Annual
Meeting
(Washington, DC)

June 7-10

Adherence 2020 (Orlando, FL)

June 8-12

Postponed

IMPAACT Annual Meeting (Washington, DC)

June 15-21

Postponed

ACTG Annual Meeting (Washington, DC)

July 5-7

Cancelled

HIV2020

(Mexico City, MX)

July 6-10

Now Virtual

AIDS 2020 (San Francisco & Oakland, CA)

For details and other events, visit the HANC calendar



WEBINARS & TRAINING

Upcoming Webinars

Characterizing Loneliness among YBMSM: Considerations toward Sexual Health and Well-being

April 8 @ 10AM PT / 1PM ET

The Legacy Project invites you to join a webinar highlighting the impact of social disconnection prompted by the results of a study of loneliness among a Chicago cohort of young Black men who have sexual relationships with men (YBMSM). Register here.

TB Vaccine Development Update / HVTN 602

April 20 @ 10AM PT / 1PM ET

Community Partners and the Tuberculosis Trials Consortium invite you to join Dr. Jim Kublin, Executive Director of the HVTN to review the TB vaccine candidate pipeline and discuss the results of HVTN 602/Aeras A-042, a phase 1b randomized study to assess how the immune system responds to vaccination with H4:IC31, H56:IC31, and BCG revaccination in Mtb-uninfected adolescents conducted in South Africa. Register here.

Virtually (Not) Impossible: Novel Approaches Utilizing Online Platforms to Address Disparities in HIV Prevention

April 22 @ 10AM PT / 1PM ET

This webinar will explore novel methods of data collection among sexual minority individuals using mobile technologies, and examine approaches to engage traditionally marginalized MSM via online platforms. Register here.

HANC Webinar Archives

Visit the <u>HANC website</u> to view archived recordings of past webinars. Recent webinars of interest include:

COVID-19 & HIV Update: Impact on Communities and HIV/AIDS Clinical Research

Aired April 2, 2020

As COVID-19 continues to have a devastating impact on individuals, communities and societies globally, the need for accurate, concise and timely updates is critical. Featuring Dr. Carl Dieffenbach, Dr. Sarah Read, Manizhe Payton, and Dr. Jeffrey Schouten. Link to the recording 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 novel coronavirus situation in Washington state, HANC staff are out of the office and working remotely through April 24th or 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) will host a two part webinar series on adherence support approaches used in the NIH HIV/AIDS Clinical Trial Networks this spring. The first webinar will be held on May 19 at 10am PT/1pm ET. Presenters for

the first webinar are Dr. Ivan Balan (MTN, Columbia University) and Dr. Steven Safren (HPTN, University of Miami). The webinars will be moderated by BSCG Representative, Dr. Rivet Amico. A registration link will be available in the near future.

The Youth Prevention Research Working Group (YPRWG) held a call last week. The group discussed its satellite symposium submission for HIVR4P. A proposal is being drafted and will be submitted soon. The YPRWG also discussed its spring webinar on adolescent self-testing. The group is currently searching for a date that will work for both presenters. Once a date is selected, an invite will be sent to all HANC collaborators.



Community Partners

Russell Campbell, HANC Deputy Director

We are excited to announce that Raymond Allmond and Milton Mathonsi are the new ACTG representatives on Community Partners! Community Partners is also planning to submit abstracts to the <u>HIVR4P Conference</u>.

HANC PROGRAM HIGHLIGHTS



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Communications Working Group (CWG) discussed network presentations and major study results emerging from CROI 2020, network plans for AIDS 2020 and HIV 2020, and information dissemination from network annual meetings. In addition, the

group discussed network announcements and plans for messaging around COVID-19.

The Data Management Center Working Group (DMCWG) discussed impacts of COVID-19 on data management center operations, staffing, study-related activity, and data metrics in addition to other DMC priorities and initiatives for the remainder of 2020.

The Site Coordinators Working Group (SCWG) discussed DAIDS and network guidance in response to COVID-19 as well as local impacts of the pandemic on site-level operations.



Laboratory Coordination *Tyler Brown, HANC Project Manager*

The Lab Technologists Committee (LTC) held two conference calls to discuss processing and testing sputum for tuberculosis protocols, shipping standards for gut biopsies, and changes to standard storage and shipping procedures resulting from the

COVID-19 pandemic. The LTC SOP Working Group held four conference calls to continue developing new standard wording guidance materials, and conduct end user testing on the electronic lab processing chart being developed by the ACTG/IMPAACT Lab Center.

The Laboratory Focus Group (LFG) and DAIDS Clinical Laboratory Oversight Team (DCLOT) held a joint conference call to discuss the impact of COVID-19 on network protocols and lab operations. Additional discussions focused on the upcoming publication of the GCLP Manual v4.1, and the development of new tools to improve cross-network communication.

COVID-19 Laboratory Resources: Over the coming months, HANC will be posting 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

Legacy is hosting a webinar on Wednesday, April 8, "Characterizing Loneliness Among Young Black Men who have Sex with Men:

Considerations Toward Sexual Health and Well-Being." Register here.

HANC PROGRAM HIGHLIGHTS

(The Legacy Project, continued)

The Legacy Project commemorated National Native HIV/AIDS Awareness Day on March 20th with a webinar featuring presenters Harlan Pruden and Tyler Adamson. A recording of the live webinar is available here.

Brian Minalga represented HANC/Legacy at a workshop hosted by NIAID, <u>Phylodynamic Monitoring of HIV Transmission Hotspots to End the HIV Epidemic</u>. A recording of the live webcast is not yet available, but please follow the Legacy Project on Facebook to gain access to the recording when it becomes available soon.

The Legacy Project and Women's HIV Research Collaborative (WHRC) supported the development of a new language guide to encourage the use of affirming and non-stigmatizing language among NIAID staff. Access the the guide here.

The WHRC commemorated National Women & Girls HIV/AIDS Awareness Day on March 10th with an <u>infographic</u> featuring the latest advancements in HIV research relevant to cisgender and transgender women. The infographic includes information about studies across all five NIH-funded HIV/AIDS clinical trials networks and has reached nearly 1,000 people on <u>our Facebook page</u>

ABOUT COMMUNITY PARTNERS

Community Partners

(CP) is a crossnetwork 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:



Shonte M. Daniels

Shonte Daniels is a member of Community Partners, representing the IMPAACT network. Shonte is a CAB member at the Los Angeles County + University of Southern California Maternal Child Adolescent Clinic.

What do you like most about community engagement? What I like most is the

engagement aspect of it. I love interacting with an array of individuals from different ethnic backgrounds. I appreciate the diversity and different perspectives. I look upon it as a blessing to engage in activities and advocacy that benefits individuals beyond my immediate scope. It gives my life purpose and I am forever grateful.



Christopher Hucks-Ortiz, MPH

Christopher Hucks-Ortiz is a member of the Legacy Project and serves as the Director of HIV and Clinical Services at the Black AIDS Institute. In this role, he will be integral in expanding BAI's direct service work and ensuring that all clinics and partnerships run efficiently and effectively, and will continue to use his expertise in community-based HIV prevention and treatment

research to support the development of culturally relevant and evidence-based services and protocols.

Mr. Hucks-Ortiz has more than 18 years of experience in the development, implementation, and management of community-based clinical trials targeting those at high risk for HIV acquisition. He has served as a Project Director for the HPTN 061 study and is an active member of the NIH-funded HPTN Black Caucus since its inception and serves as the current Caucus Chair. The role of the Black Caucus is to help to ensure the cultural competence of clinical trials as related to Black Men who have Sex with Men (MSM) and trans-women through the HPTN. Mr. Hucks-Ortiz is also a member of the HPTN Community Working Group Steering Committee and represents the interests of community in the review of new proposed clinical trials. In addition to his own research work, Mr. Hucks-Ortiz counsels other researchers to ensure cultural capacity of community-based research protocols.

A lifelong resident of California, he received a B.S. in Community Health Science from California State University, Los Angeles, and an MPH from the University of California, Los Angeles, School of Public Health.

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.

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 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. <u>Click here</u> to explore DASH.

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