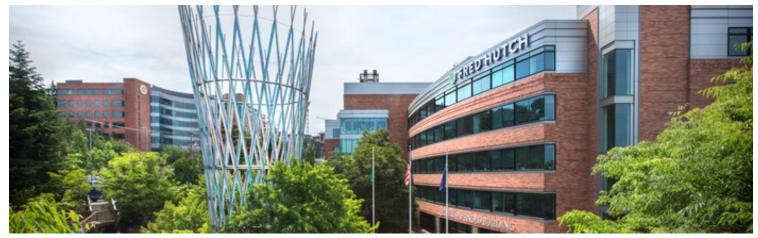
MAY 2020

# NEWSLETTER



Office of HIV/AIDS Network Coordination



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

# HANC ANNOUNCEMENTS

Join us in observing the following upcoming awareness days:



HIV Vaccine Awareness
Day - May 18th

Visit <u>bethegeneration.org</u> for resources on HIV vaccine research for community use!



## **May Webinars**

Three new webinars are scheduled for May. 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.

## **INSIDE THIS ISSUE:**

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

## **NETWORK ANNOUNCEMENTS**



There is no update from the ACTG this month. Please check the <u>ACTG website</u> or the ACTG newsletter for the latest updates from the network.



Congratulations to the **HPTN 091** study team for reaching protocol V1.0.

The Vanguard feasibility and acceptability study is investigating the integration of HIV prevention, gender-affirmative medical care, and peer health navigation to prevent HIV acquisition and transmission for transgender women.





# Delve into another inspiring read of the HVTN's Community Compass, out by June 2020

In the next edition of HVTN Community Compass, Editor in Chief Stephaun Wallace, PhD., and team takes the reader on a journey of hope, determination and the lived experience of clinical trial study teams who are frontline responders in the fight against COVID-19. Dr. Larry Corey, HVTN's Principal Investigator, discussed what it means to simultaneously face down two infectious diseases – HIV/AIDS and COVID-19.

A behind-the-scenes tale is brought to life when the study team in Houston, Texas, recalls the first injection administered to a study participant in the phase 3 vaccine clinical trial called Mosaico, also known as HVTN 706/HPX3002. Anticipation is building as the Editorial team recaps the importance of the Antibody Mediated Prevention (AMP) studies, and looks ahead to the muchanticipated announcement of the preliminary study results.

To receive the next edition, please send your email address to: Stephaun Wallace - sewallac@fredhutch.org

Access previous editions of HVTN Community Compass.

# **NETWORK ANNOUNCEMENTS**



## **HVTN** moves mountains to deliver PPE to study teams on the frontlines

The impact of COVID-19 on the conduct of the HVTN's clinical trials required swift decisive interventions by the Network's leadership and team members around the globe to deliver personal protective equipment (PPE) to study teams in South Africa to safely face the new global pandemic. Delivery of the PPE to the clinical trial sites ensured that study teams could safeguard their health and that of study participants, preventing the possible transmission of SARS-CoV-2 while continuing the pursuit to find a safe and globally effective preventive HIV vaccine.



Pictured: Dr. Nigel Garret (left) of CAPRISA and another study team member pictured with the PPE delivered at the eThekwini clinical trial site in Durban, South Africa. Credit: photo supplied by eThekwini site



Pictured: Michelle Nebergall, PhD, HVTN Clinical Trials Manager, equipped with PPE. Credit: Michelle Nebergall



There is no update from the IMPAACT Network this month. For the latest information, please see the IMPAACT website at <a href="https://impaactnetwork.org/">https://impaactnetwork.org/</a>



The sites from MTN's REACH study are going above and beyond to ensure the health and safety of the young women participants, despite the challenges caused by the COVID-19 pandemic. REACH (Reversing the Epidemic in Africa with Choices in HIV Prevention), or MTN-034, is seeking to understand the HIV prevention needs and preferences of adolescent girls and young women ages 16-21 by evaluating how they use the monthly dapivirine ring and Truvada as daily PrEP and their preferences for each, as well as evaluating the safety of these methods.

# **NETWORK ANNOUNCEMENTS**



(MTN, continued) As with other MTN studies, enrollment has been paused due to the pandemic, but innovation and commitment by site staff have enabled participant follow-up to safely continue. REACH participants have shown similar resolve and resiliency. Read more about how the sites and participants are REACH-ing Beyond Expectations.





Pictured: photos from the Makerere University-Johns Hopkins University (MU-JHU) Research Collaborative in Kampala, Uganda, a REACH study site.

In the interest of safety and public health, MTN has made the difficult decision to cancel the 2020 MTN Regional Meeting this October in Cape Town. The decision was not made lightly as it was to be MTN's last regional meeting as a network. Please read <u>a message about the cancellation</u> from MTN PI and co-PI Drs. Sharon Hillier and Jared Baeten.

## 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.



## \*Postponed\*

HVTN Full Group Meeting (Washington, DC)

May 30-June 3

## \*Postponed\*

HPTN Annual
Meeting
(Washington, DC)

June 8-12

#### \*Postponed\*

IMPAACT Annual
Meeting
(Washington, DC)

June 15-21

### \*Postponed\*

ACTG Annual Meeting (Washington, DC)

June-Oct 2020 HIV2020 Online (Virtual)

July 6-10 AIDS 2020 (Virtual)

Nov 1-4

Adherence 2020 (Orlando, FL)

Jan 17-21 2021 <u>HIVR4P</u> (Cape Town, ZA)

For details and other events, visit the HANC calendar



## **WEBINARS & TRAINING**

## **Upcoming Webinars**

# Finding the Middle Ground: Managing Stress and Anxiety while Providing Clinical Care during the COVID-19 Crisis

May 7 @ 11AM PT / 2PM ET

Providing care for patients during the COVID-19 pandemic is challenging, emotionally draining, anxiety provoking, and stressful. Finding sources of resilience to respond to stress engendered by this crisis can prevent burnout and mitigate its toll on quality of life, relationships, and overall functioning. Drs. Safren and Jones Weiss will discuss self-care strategies to minimize distress and prevent burnout during these difficult times. Register here.

# **Ending the HIV Epidemic American Indian/Alaska Native Engagement Webinar**

May 8 @ 10AM PT / 1PM ET

In collaboration with the HRSA Office of Regional Operations, HANC invites you to participant in a webinar exploring strategies to address HIV/AIDS among the American Indian/Alaska Native (AI/AN) population. A panel of presenters from Native organizations, the Division of AIDS (DAIDS), and HHS will provide an update on the Ending the HIV Epidemic Initiative activities and resources for the AI/AN population. Register here.

# PrEP Adherence Support Intervention Approaches Used in the NIH HIV/AIDS Clinical Trials Networks - Part 1

May 19 @ 10AM PT / 1PM ET

The HANC-facilitated Behavioral Science Consultative Group would like to invite you to a two part webinar series on PrEP adherence support intervention approaches used in the NIH HIV/AIDS Networks moderated by Dr. Rivet Amico. Our first webinar features Dr. Balan, who will focus on fidelity monitoring of adherence counseling interventions in biomedical HIV prevention studies, and Dr. Safren, who will highlight approaches used in HPTN. Register here.

## **HANC Webinar Archives**

Missed a webinar you wanted to attend? Visit the <u>HANC website</u> to view archived recordings of past webinars.



# 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

On May 7 at 11am PT/2pm ET, the Behavioral Science Consultative Group (BSCG) will host a webinar with Dr. Steven Safren and Dr. Deborah Jones Weiss discussing stress management while providing clinical care during the COVID-19 crisis. Providing care for

patients during the COVID-19 pandemic, whether working directly with infected individuals, testing, or in primary care or other medical specialties is challenging, emotionally draining, anxiety provoking, and stressful. Whether your medical setting is gearing up for, in the middle of, or coming down from a surge of infections, it is important for medical providers to employ self-care strategies. Finding sources of resilience to respond to the stress, anxiety, and distress engendered by this crisis can not only prevent burnout, but also mitigate its toll on quality of life, relationships, and overall functioning. Drs. Safren and Jones Weiss will provide an overview and discussion of self-care strategies that minimize distress and prevent burnout during these difficult times. Register here.

On May 19 at 10am PT/1pm ET, the BSCG will host the webinar, "PrEP Adherence Support Intervention Approaches Used in the NIH HIV/AIDS Clinical Trials Networks - Part 1". There are numerous strategies deployed in clinical trials that leverage social behavioral science, communication, education and counseling. These are often included as part of standard procedures for a clinical trial, and, as such, are not the focus of evaluation. There is, however, a growing experiential knowledge base that can be shared. To help disseminate approaches and lessons learned in this area we are holding two webinars showcasing several different PrEP adherence support approaches. We are not focusing on efficacy or effectiveness, but rather on what teams have created and implemented in support of participants engaged in biomedical HIV prevention studies. Dr. Rivet Amico will moderate the webinar and Drs. Steven Safren and Ivan Balan will present. Register here.

The Youth Prevention Research Working Group (YPRWG) is hosting a webinar on adolescent self-testing on May 26 at 11am PT/2pm ET. The webinar is still being planned, but more details will be available soon. A registration link will be shared with HANC collaborators once available.

# HANC PROGRAM HIGHLIGHTS

(Behavioral & Social Science, continued) Adherence 2020 has been rescheduled to Nov. 1-4, 2020. HIVR4P has been rescheduled to Jan. 17-21, 2021.



**Community Partners** 

Russell Campbell, HANC Deputy Director

Community Partners (CP) will convene a group of volunteers to update and revise the <a href="CUREiculum">CUREiculum</a> since there have been some major changes since it was developed five years ago. CP is also delighted to welcome Doreen Kemigisha as the new MTN

representative. Last, CP members have been invited to provide an overview of CP on the upcoming Martin Delaney Collaboratory CAB call as part of collaboration around HIV CURE and ATI community engagement efforts.



**Cross-Network Coordination** 

Milan Vu, HANC Project Manager

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

practices for reporting sexual assault and intimate partner violence.

The Site Coordinators Working Group (SCWG) discussed DAIDS guidance around remote monitoring during COVID-19 and site practices related to electronic or remote consenting.

HANC hosted a webinar session on 20 April 2020 with representatives from DAIDS to address remote monitoring guidance in light of the COVID-19 pandemic. Resources from the DAIDS Remote Monitoring discussion are now available on the HANC website, <u>DAIDS Resources and Announcements</u> page for reference:

- DAIDS Remote Monitoring discussion recording and slides
- A <u>FAQ page</u> capturing the Q&A portion of the session



**Laboratory Coordination** 

Tyler Brown, HANC Project Manager

The Lab Technologists Committee (LTC) held two conference calls to discuss lab site operations for ACTG protocols 5394 and 5395, and changes to the review and sign-off process for ACTG Lab Processing Charts.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss new technical guidance documents, the CPQA Program's new comparative reference document for CLIA, GCLP and GLP requirements, and updates on proficiency testing for new network study compounds, including COVID-19 treatments.

# HANC PROGRAM HIGHLIGHTS

(Laboratory, continued) The CPQA Advisory Board (CPQAAB) held a conference call to discuss CPQA program updates on proficiency testing, CPQA-AB sub-working groups, and the AVR/SOP Peer Review Program. Anthony DeStefano was welcomed as the new CPQA-AB Chair, and Alex Greninger, Scott Letendre and Agnieszka Witkiewicz were introduced as new CPQA-AB members.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to discuss changing VQA proficiency testing frequency, and shipping logistics issues for proficiency testing panels. The VQA Program announced the suspension of all shipments of controls and panels due to the COVID-19 pandemic effective April 24 - Click here for more information.

The Laboratory Focus Group (LFG) and DAIDS Clinical Laboratory Oversight Team (DCLOT) held a joint conference call to discuss developing a cross-network guidance document for re-starting laboratory activities disrupted by the COVID-19 pandemic.

Resuming DAIDS GCLP Laboratory Audits: As DAIDS supported and/or sponsored labs gradually resume DAIDS protocol-related testing activities, audit visits will resume on a limited basis, starting in May. Click here for more information.

During the COVID-19 pandemic the Frontier Science Data Management Center continues to maintain normal operations, including 24/7 support. User Support is accessible by email at user.support@fstrf.org or by phone at (716) 834-0900 x7311.





The Legacy Project
Brian Minalga and Louis Shackelford
HANC Legacy Project Team

Check out Legacy's <u>Hot Article Review</u> video, where Brian Minalga walks us through an article on 4 studies to answer the question,

"Can treatment as prevention end the HIV epidemic?"

**5/8**: The Legacy Project brings you another webinar, "Ending the HIV Epidemic: American Indian / Alaska Native Engagement." Register here.

**5/16**: Brian's 4-year anniversary with HANC/Legacy!

**5/18**: Legacy recognizes HIV Vaccine Awareness Day. Share the Be the Generation information on <u>HIV vaccine research!</u>

5/19: Legacy recognizes National Asian & Pacific Islander American HIV/AIDS Awareness Day.

**5/21**: HPTN, HVTN, and MTN updates for the community are due to Brian Minalga for the Be the Generation newsletter.

## 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:



## **Doreen Kemigisha**

Doreen Kemigisha is a member of Community Partners. She is a Senior Health Visitor/Community Educator at Makerere University Johns Hopkins (MU-JHU) Research Collaboration located in Mulago Hospital Complex in Kampala, Uganda. She is also a Community Working Group representative on the MTN 042/043 Protocol.

What do you like most about community engagement? I love and enjoy educating communities about clinical trials especially in the field of HIV/AIDS prevention. Addressing community rumors and myths about products intended for HIV prevention is also something I enjoy as this helps in informing the subsequent strategies in educating communities and also informs community education material development. My overall happiness and achievement is when I am able to recruit some community members into these clinical trials who also eventually turn out to be advocates for HIV prevention clinical trials.

Communities are a great source of knowledge and information hence the heart of research involving human subjects.



## **D'Vaughn House**

D'Vaughn House is a member of the Legacy Project and a Clinical Research Assistant at the University of Cincinnati Medical Center (UCMC) Division of Infectious Diseases (IDRU) in Cincinnati, OH. He has been a part of this institution for nearly seven years, and he plays a significant role in several federally and privately funded biomedical interventional clinical trials

that aim to prevent and treat threats to public health.

Prior to his work at the IDRU, D'Vaughn worked in the Early Intervention Program at the UCMC Department of Emergency Medicine. He worked on federally funded brief interventions and Linkage-to-HIV Medical Care services that prevented and treated HIV. His published works include several abstracts aimed at finding novel approaches to HIV testing and prevention in a Level 1 trauma hospital setting.

# **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. <u>Click here</u> 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 countryspecific clinical research regulatory information designed to assist in planning and implementing international clinical research. <u>Click here</u> 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.

### **FOLLOW HANC ON**





