MARCH 2019

NEWSLETTER
Office of HIV/AIDS Network Coordination

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

HANC ANNOUNCEMENTS

National Native HIV/AIDS Awareness Day
March 20, 2019 is National Native (Native American, Native Alaskan, and Native Hawaiian) HIV/AIDS Awareness Day. This day is an opportunity to increase awareness of the impact of HIV/AIDS on Native Americans, Native Alaskans, and Native Hawaiians.

In recognition of National Native HIV/AIDS Awareness Day, the Legacy Project invites you to join us for a powerful webinar where Gabrielle Evans and Harlan Pruden will highlight the importance of engaging with Native Americans and Native Alaskans in a way that’s culturally relevant and respectful. Click here to register for the webinar.

Congratulations Milan!
Please join us in congratulating HANC staff member Milan Vu on her acceptances to the University of Washington MPH and Johns Hopkins MPH programs!

Milan is awaiting notification from a third MPH program before she makes her decision on which program she plans to attend.

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Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhu@fredhutch.org
Network Presentations at CROI 2019

Several of the NIH HIV/AIDS networks will have a presence at the annual Conference on Retroviruses and Opportunistic Infections (CROI) held from March 4 to March 7, 2019 at the Washington State Convention Center in Seattle, WA. Links to listings of presentations accepted by network can be found here on the HANC website.

This month, we’d like to highlight a few of the ACTG’s 11 oral and 19 poster presentations at CROI 2019 (Seattle, March 4-7), including following:

**84LB. QT EFFECTS OF BEDAQUILINE, DELAMANID OR BOTH IN MDR-TB PATIENTS: THE DELIBERATE TRIAL** (presented by ACTG investigators Dr. Kelly Dooley and Gary Maartens). Bedaquiline and delaminid, the first two novel medications for MDR-TB to be developed in decades, generated extensive excitement when released. However, there is a lingering concern about overlapping toxicities with the two medications, specifically prolongation of the QT interval. This abstract resolves the debate.

**82. EARLY BACTERICIDAL ACTIVITY OF HIGH-DOSE ISONIAZID AGAINST MULTI DRUG RESISTANT TB** (presented by Dr. Dooley). High-dose isoniazid (INH) 10-15 mg/kg was recently left off of the World Health Organization guidelines for multidrug-resistant TB due to lack of data about bacteriocidal killing against TB with typical patterns of INH resistance. This abstract provides pivotal data that could impact guidelines.

While at CROI (or through the conference webcasts), we also invite you to hear important new data from ACTG studies on the interactions between hormonal contraceptive and HIV-TB medications (abstract 78, Dr. Rosie Mngqibisa); the risk of weight gain with integrase inhibitors (abstract 669, Dr. Jordan Lake); the impact of cardiovascular risk scores on neurocognitive function (abstract 128, Dr. Felicia Chow); the impact of obesity on cognitive function (abstract 129, Dr. Jeremiah Perez); sex differences on 3rd line ART (abstract 518, Dr. Catherine Godfrey); the impact of pharmacogenetics on drug-drug interactions between efavirenz and hormonal contraceptives (abstract 52, Dr. David Haas); and important abstracts on cure including the effects of sirolimus (abstract 131, Dr. Timothy Henrich) and romidepsin (abstract 26, Dr. Deborah McMahon); along with many other ACTG studies.

Finally, we’d like to announce the upcoming publication of the A5279 study (the BRIEF TB study) slated for March 14th in the New England Journal of Medicine. This pivotal phase 3 trial showed that a one-month antibiotic regimen with rifapentine and isoniazid to prevent active tuberculosis (TB) disease was at least as safe and effective as the standard nine-month therapy with isoniazid for people living with HIV. This important trial is likely to change the standard of care for preventative therapy for TB worldwide.
On March 18th, representatives from HVTN Core, SDMC and Laboratory Staff, and CRS Investigators will convene to lead the 2nd HVTN HIV Vaccine Science Workshop in Johannesburg, South Africa. This workshop will coincide with the HVTN Regional Meeting and provide attending site investigators an opportunity to deepen their knowledge of the immunology and vaccinology principles underlying HVTN studies. This year’s workshop will focus on T cell and antibody assays, and provide investigators an opportunity to do hands-on data interpretation from an HVTN trial.

On March 18th, representatives from the CEU and CTM units will convene to lead a Retention Workshop for Efficacy Trials in Johannesburg, South Africa. This workshop will coincide with the HVTN Regional Meeting and provide attending clinical research site staff an opportunity to share and discuss retention challenges, identify targeted retention strategies, and identify effective methods to implement and maintain strategies.

The HVTN Sub-Saharan Africa Regional Meeting which follows on March 19 & 20 will provide research sites, community members and other partners with an update including where we are as an organization and progress on efficacy studies in Africa. Shared operational sessions will ensure participants understand progress in measuring immune responses after vaccination as well as impact of antibodies and T cell function.

The Conference on Retroviruses and Opportunistic Infections (CROI) takes place March 4-7 at the Washington State Convention Center in Seattle. HPTN researchers will present 19 abstracts covering HPTN 071, HPTN 074, HPTN 077, HPTN 078, and HPTN 082.

Richard Hayes, DSc, FMedSci, HPTN 071 protocol chair, will present primary results from the study during an oral session entitled, “Impact of Universal Testing and Treatment in Zambia and South Africa: HPTN 071 (PopART).” Also, from the HPTN 071 protocol team, Mohammed Limbada, BSChB, MBchB, MSc, will lead the themed discussion, “Treat All, Treat Fast.” James Moore, PhD, will discuss, “Estimating HIV Incidence Among Young Women in HPTN 082 Using Baseline HIV Risk Scores,” and Raphael Landovitz, MD, MSc, HPTN 077 and HPTN 083 protocol chair, will deliver a presentation entitled, “CABG is not Associated with Weight Gain in HIV-Negative Individuals: HPTN 077.” CROI 2019 webcasts, abstracts, electronic posters, and other electronic resources will be available online after the conference ends.

For more information on HPTN protocols, click below:

HPTN 071
HPTN 074
HPTN 077
HPTN 078
HPTN 082
The IMPAACT Network is delighted to report that accrual of 643 mother-infant pairs in IMPAACT 2010/VESTED, a study of the virologic efficacy and safety of DTG-containing versus EFV-containing ART regimens in HIV-infected pregnant women and their infants, has been successfully completed as of 8 February 2019. Congratulations to all 22 sites that enrolled participants in Zimbabwe, South Africa, Uganda, Brazil, Botswana, Tanzania, Thailand, India and the United States! To learn more about the study, please see the IMPAACT website.

The Network is also pleased to announce that enrollment into IMPAACT 2015, a study of the HIV reservoir in the central nervous system of perinatally-infected youth with neurocognitive impairment, has begun enrolling as of 6 February 2019. Congratulations to the Jacobi Medical Center NICHD Clinical Research Site in Bronx, NY, for leading the way! To learn more about the study, please see the IMPAACT website.

MTN has launched the REACH study which is evaluating the use of Truvada as oral PrEP and the monthly dapivirine vaginal ring in cisgender young women and teens. REACH (Reversing the Epidemic in Africa with Choices in HIV prevention), or MTN-034, is a Phase IIa study designed to fill important gaps in information about the safety and acceptability of oral PrEP and the dapivirine ring in younger populations. REACH has begun enrolling young women and girls ages 16 to 21 at five clinical research sites in Kenya, South Africa, Uganda and Zimbabwe.

Another vaginal microbicide study that has launched, MTN-038, is evaluating the safety and pharmacokinetics of a 90-day vaginal ring containing the antiretroviral drug tenofovir. The ring being tested is designed to protect cisgender women against both HIV and herpes simplex virus type 2 (HSV-2), and is enrolling 48 participants at sites in Birmingham (Alabama), Pittsburgh and San Francisco.

The MTN has completed enrollment of MTN-037, the first study of a rectal gel developed to prevent HIV, herpes simplex virus (HSV), and human papillomavirus (HPV). The gel (PC-1005) was developed by the Population Council to prevent HIV, HSV and HPV simultaneously.

MTN's 2019 Annual Meeting was held February 10-13. Specific topics covered at the meeting included: microbicides in the prevention landscape; understanding PrEP in pregnant and breastfeeding women; prevention for youth; and moving from options to choices. Presentations from the meeting are available on MTN's website.
WEBINARS & TRAINING

Upcoming Webinars

National Native HIV/AIDS Awareness Day Webinar
March 20, 2019 @ 10AM PST
In recognition of National Native HIV/AIDS Awareness Day, the Legacy Project invites you to join us for a powerful webinar where Gabrielle Evans and Harlan Pruden will highlight the importance of engaging with Native Americans and Native Alaskans in a way that’s culturally relevant and respectful. During this webinar, presenters will discuss how historical trauma impacts culture, traditions, and mental and physical well-being, specifically for Native Americans and Native Alaskans impacted by HIV. Presenters will share what individuals, communities, providers and researchers can do to work towards ensuring that Native Americans and Native Alaskans have healthier futures.
Register here.

Conditional Economic Incentives to Improve HIV Prevention and Treatment Outcomes
March 25, 2019 @ 12PM PST
What are economic incentives? Do conditional economic incentives work? Economic incentives (often money and/or gift cards) are used to motivate behavioral change. They can be powerful tools when conducting research. Please join the Behavioral Science Working Group and Dr. Omar Galarraga on March 25, 2019 for a webinar exploring this topic. Register here.

Without Our Consent: Centering People Living with HIV in HIV Genetic Sequencing (Part 1)
March 27, 2019 @ 1PM PST
HIV genetic sequencing (HGS) is a powerful tool that is helping us to better understand HIV, but it also raises some critical ethical concerns. Join us for part 1 of this four-part webinar series to learn more about HGS and how you can advocate for the meaningful and ethical use of this technology. Register here.

HANC Webinar Archives

HANC Working Groups host webinars throughout the year and post recordings to the HANC website. Click here to view archives of past webinars.
HANC PROGRAM HIGHLIGHTS

Need to contact a HANC staff member? Click here to go to the About the HANC Staff page.

Behavioral & Social Sciences

Greg Davis, HANC Project Manager

The Behavioral Science Working Group (BSWG) will be hosting a webinar with Dr. Omar Galarraga on March 25 at 12pm PT/3pm ET. The webinar is titled, “Conditional Economic Incentives to Improve HIV Prevention and Treatment Outcomes”. During the webinar, Dr. Galarraga will discuss the use, benefits, and the results when applying economic incentives. You can register for the webinar here.

Members of the Behavioral Science Consultative Group (BSCG) will meet for a lunch during CROI on Tuesday, March 5. The BSCG is continuing to put together a webinar that will be held on April 16. More details will be available in the near future.

The Youth Prevention Research Working Group submitted a proposal for a satellite symposium at IAS 2019. The proposal was accepted. The title of the symposium is, “Prevention Solutions for the Next Generation: Highlighting Adolescent Research and Participant Perspectives in the NIH HIV/AIDS Clinical Trials Networks and the Adolescent Trials Network for HIV/AIDS Interventions (ATN)”. The YPRWG will also host a webinar on IMPAACT 2016 on April 26 at 7am PT/10 am ET. More information will be available soon.

Community Partners

Russell Campbell, HANC Deputy Director

Community Partners (CP) has confirmed its annual F2F Meeting dates for October 26-27, 2019.

CP and the National CFAR CAB Coalition are exploring ways to formally collaborate, exchange information, share resources and materials.
HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
Milan Vu, HANC Project Coordinator

The Communications Working Group (CWG) has assembled a webpage for accepted network presentations at CROI 2019. Click here to access the page on the HANC website.

The Data Management Center Working Group (DMCWG) met to review progress on the Safety Data Reconciliation Policy pilots and to discuss protocol deviation reporting.

The Evaluation Working Group (EWG) received a progress update from the HVTN on their use of Tableau for visualization of site metrics. The group also discussed the utility of protocol deviations in site evaluations.

Representatives from the Division of AIDS (DAIDS) joined the most recent Site Coordinators Working Group (SCWG) to review the revised Common Rule and changes to informed consent, IRBs and ethics committees, as well as DAIDS’ approach to compliance. In addition, the group discussed pilots of a new protocol deviation form in two ACTG trials as well as efforts to grant secondary permissions to access electronic investigator brochures.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held a conference call to discuss HIV RNA testing and shipping requirements for international vs. U.S. laboratory sites. The LTC SOP sub-working group held three calls to continue revising the Protocol Participation and Lab Processing Chart Preparation Procedures SOP. The LTC also organized a new working group to review and revise the SOP for PAXgene® Blood RNA Tube collection, processing and storage.

The Clinical Pharmacology Quality Assurance (CPQA) Program’s Bioanalytical Revisions Advisory Group (BRAG) Working Group held a meeting to continue updating the CPQA guidance document for validating bioanalytical methods for use in analyzing samples. The CPQA announced an expanded BRAG Working Group to review the CPQA guidance document specific to ligand binding assays.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new HIV proficiency testing reports from RNA035 and a preliminary analysis of data from HCV RNA validation studies for the HCV proficiency testing program.

The Laboratory Focus Group (LFG) held a conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) and the Patient Safety Monitoring in International Laboratories group (pSMILE) to continue discussing the development and implementation of new procedures related to cross-network laboratory site Action Plans.
HANC PROGRAM HIGHLIGHTS

The latest issue of BTG News is now available! Check out this publication on biomedical HIV prevention research on the Be the Generation website in English and Español.

The Women’s HIV Research Collaborative (WHRC) has a poster featured at the International Workshop on HIV & Women taking place in Seattle, March 2-3. The poster is titled, “We Can Do It! Addressing intimate partner violence in HIV research with women.” Dr. Liz Barr is the presenting author during Poster Viewing Session 1 on March 2 from 5:15 to 6:15 p.m.

The WHRC is also commemorating National Women and Girls HIV/AIDS Awareness Day (March 10th) by releasing a factsheet on the most exciting HIV research and related advancements relevant to cisgender and transgender women. The factsheet will be released via email and social media; check out Legacy’s Facebook page during the week leading up to March 10th.

The Division of AIDS Cross-Network Transgender Working Group (CNTWG) has a poster on display at the CDC’s National HIV Prevention Conference, March 18-21. Rona Siskind is the presenting author for the poster, “First, Do No Harm: Fostering Transgender Inclusion in HIV Research,” during Poster Session B on Wednesday, March 20 from 12:30 to 1:30 p.m. The CNTWG also had an abstract accepted to the Transgender Health Summit taking place in Oakland, CA April 13-14. Brian Minalga is the presenting author for the oral presentation, “Fostering Transgender Awareness and Inclusion in HIV Research.”

The New Investigators Working Group is in the process of planning a webinar scheduled for April 10th featuring participant experience in clinical trials. Stay tuned for details.

The Legacy Project has some upcoming webinars:
- March 27 at 1 p.m. Pacific: “Without Our Consent: Centering People Living with HIV in HIV Genetic Sequencing.” Register here.

Brian Minalga is out of the office until March 14. For any needs related to the Legacy Project / WHRC, please contact Russell Campbell (rcampbel@fredhutch.org).

WWW.HANC.INFO/LEGACY
BE THE GENERATION
FOLLOW THE LEGACY PROJECT ON

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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:

**Steven Mphonda**

Meet Steven, a member of Community Partners who has served as a community educator for the UNC project since 2008.

From Steven: *I have a strong commitment to the prevention, treatment, and control of HIV and as such was elected as the chairman of the Lilongwe City AIDS Coordinating Committee (CACC), which coordinates all HIV/AIDS activities in Lilongwe, Malawi. Since my site is a multi-trial site, I have been involved with HPTN, ACTG and IMPAACT networks. As part of IMPAACT, I have served as an ICAB member and am also serving in the ICAB leadership group.*

I was presented with the Donna Davis Community Achievement Award at the 2012 ACTG annual meeting for my hard work and good relationship with the community. I published a paper in the African Journal of Reproductive Health titled *Assessment of Peer-Based and Structural Strategies for Increasing Male Participation in an Antenatal Setting in Lilongwe, Malawi*. I am a Nurse/Midwife by profession and have a bachelor’s degree in Health Systems Management.

**Reverend Shawn-Patrick Torres, Jr.**

Shawn is a member of the Legacy Project Working Group and works at the Latino Commission on AIDS in NYC as a Capacity Building Assistance Specialist. As a CBA Specialist, Shawn provides training nationwide to AIDS Service Organizations and Community Based Organizations on how to better serve communities. He is working on his second MPH focusing on Epidemiology and recently relocated to Columbia, SC to expand his job’s reach in providing capacity building services to agencies in Southern states.

While attending Benedict College in Columbia, SC, Shawn became a member of First Nazareth Baptist Church where the Pastor is Rev. Dr. Blakely N. Scott. Shawn was licensed to preach in 2010 at First Nazareth and ordained in 2011 under the Midlands Baptist Association. In 2014, Shawn relocated to New York to attend Union Theological Seminary, with a study concentration of Pastoral Ministry & Practical Theology focusing on the intersection of Spirituality and Sexuality. Shawn served as the chair of the FIERCE Caucus, Queer Caucus for Black & People of Color and as Co-chair for Student Senate. In 2017, Shawn graduated with a Master of Divinity.
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.

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 store and access data from NICHD-funded research studies to use for secondary research. Click here to explore DASH.

Protocol Quick Summary
HANC developed the Protocol Quick Summary tool to allow users to search for information pertaining to DAIDS-funded protocols. Study design, status history, protocol documents, and more can be found via this tool. Data displayed on the tool is pulled from the NIAID Clinical Research Management System (CRMS), which is the database of record and should be referred to for real-time protocol information. Click here to explore the tool. Note that a HANC Portal username and password are required for access.

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