April is a full month for learning about HIV genetic sequencing (HGS), social and behavioral science, and other topics related to HIV/AIDS clinical trials. Check out the “Webinars & Training” page for complete details and registration links.

Airman Shackelford

HANC Legacy Project Community Engagement Officer Louis Shackelford and his wife, Nordia, celebrated his graduation from Air Force Reserve Basic Training on March 8, 2019!

Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org
ACTG researchers gave 11 oral and 19 poster presentations at CROI 2019 (Seattle, March 4-7) on topics such as short-course therapy for people with MDR-TB; advances and challenges in HIV cure research; interactions between ARVs and hormonal contraception; cognitive function, obesity and long-term HIV infection; predictors of virologic outcome and failures; and many other research topics. A complete list of ACTG presentations, with a short synopsis, author list, and links to posters or presentation webcasts is available here.

ACTG researchers Katharine Bar, Sara Bares, Judith Currier, Kelly Dooley, Kristine Erlandson, Monica Gandhi, Sara Gianella, Timothy Henrich, Peter Hunt, and Gary Maartens helped to explain the conference research and its implications in more than two-dozen media reports filed from the Seattle meeting, available here.

In other ACTG news, A5279, the BRIEF study, was published March 14 in the New England Journal of Medicine, along with an accompanying editorial, "Ending Tuberculosis Through Prevention." This important trial is likely to have a major impact on global TB control guidelines and the lives of people living with HIV. Congratulations to the study team and to the 3,000 volunteers whose tireless work made this critically important research finding possible.

The 2019 National HIV Prevention Conference was held March 18-21, 2019 at the Hyatt Regency Hotel and the Marriott Marquis Hotel in Atlanta. The theme for this year’s conference was Getting to No New HIV Infections, which highlighted dynamic approaches to HIV prevention, detection and management, and the critical roles that different communities have in achieving this vision. HPTN LOC scientist Dr. Theresa Gamble presented "Creating a Platform for Self-Directed Antiretroviral Medication and Appointment Adherence via Text, Phone and Email Messages for HPTN 078." Her poster illustrated the feasibility to collaboratively develop a system to create, deliver and capture participant-driven messages to support and encourage antiretroviral therapy and appointment adherence, as well as provide a mechanism for participants to request assistance. Separately, Dr. James Moore’s poster “Improving Efficiency by Assignment of Daily vs Non-Daily PrEP Based on Sex Frequency: Lessons from HPTN 067/ADAPT” showed there is a clear trade-off between efficiency and effectiveness when comparing daily and event-driven pre-exposure prophylaxis (PrEP) dosing. Assigning only individuals with frequent sexual activity to daily PrEP, provides substantial effectiveness improvement over event-driven PrEP at the cost of slightly worse efficiency.
The HVTN Sub-Saharan Africa Regional Meeting was held 19 & 20 March 2019 at the Sandton Convention Centre in Johannesburg, South Africa. The meeting provided attendees with an overview of the four ongoing HVTN efficacy studies, insight to the expanding TB vaccine program, infant vaccine developments, and data from other ongoing African studies. There were several sessions which provided insight on scientific advances such as measuring immune responses after vaccination, including both antibodies and T-cell functions.

As with all HVTN network gatherings there were opportunities for robust exchanges to enhance operations through collaboration and building understanding. One such session was a Regulatory/Ethics engagement session. Representatives from regulatory bodies across the region, our clinical trial sites, and DAIDS representatives examined issues/topics that impact the regulatory processes, and how the barriers can be resolved to improve the relationships with all stakeholders. Additional sessions provided opportunities for investigators, community educators, and community advisory group members to look at population-specific dynamics. For example, in one session on persons with different HIV risk vulnerabilities, there was exploration of social structures and the importance of male partner involvement in trials that enroll women.

Investigators with the IMPAACT Network presented findings in 15 abstracts from eleven studies, including P1078/TB APPRISE, PROMISE 1077, P1115, HPTN 046, and P1093, as well as laboratory studies at the Conference on Retroviruses and Opportunistic Infections (CROI 2019) in Seattle, Washington, 4-7 March 2019. The full listing of abstracts as well as the presented materials are available on the IMPAACT website.

The Network is also pleased to announce that IMPAACT 2005, a study to evaluate the pharmacokinetics and safety of delamanid for children with multidrug-resistant tuberculosis, and IMPAACT 2009, a study of oral pre-exposure prophylaxis for primary HIV prevention among pregnant and postpartum adolescents and young women, have begun enrolling. The first enrollment into IMPAACT 2005 occurred on 19 February 2019 at the Byramjee Jeejeebhoy Medical College site in Pune, India; the first enrollment for IMPAACT 2009 occurred on 4 March 2019 at the Seke North site in Harare, Zimbabwe – congratulations to both sites for leading the way on these studies. In addition, IMPAACT 2002, a study of cognitive behavioral therapy and medication management for treatment of depression among youth living with HIV in the United States, successfully completed accrual with 13 participating sites, as of 5 March 2019. To learn more about these studies, please see the IMPAACT website.
In March, the MTN held stakeholder consultations in Johannesburg, South Africa and Blantyre, Malawi on two HIV prevention studies currently being planned – DELIVER (MTN-042), for pregnant women, and B-PROTECTED (MTN-043), for women who are breastfeeding. The meetings provided stakeholders with the opportunity to share their views about the studies before their anticipated start later this year or early 2020. The DELIVER and B-PROTECTED studies plan to evaluate the safety of two HIV prevention methods – the monthly dapivirine vaginal ring and daily use of Truvada as PrEP. Topics addressed during the meetings included regulatory plans, study implementation and community engagement. The meeting in Malawi meeting was co-hosted by AVAC and Maikhanda Trust, an NGO focused on maternal and infant health, in collaboration with the Blantyre Clinical Research Site – Johns Hopkins Research Project. The meeting in Johannesburg was co-hosted by AVAC and Soul City Institute for Social Justice, in collaboration with the Wits Reproductive Health and HIV Institute.

MTN Principal Investigator, Dr. Sharon Hillier, was selected as the 2019 Pittsburgh Women who Rock Award recipient for her work to empower women with agency over their bodies, health and safety. She will be honored at a concert in Pittsburgh on May 30 featuring the performer Shelia E. In an announcement about the award, Dr. Hillier said, “Women and girls need tools and methods that are under their control to stay healthy throughout their lives. Across the globe, women and girls have told us that being able to protect themselves from HIV and other STIs would be empowering, and that having a choice of products that they could use would be especially empowering. As women, we want and deserve to have control of our health, our lives and our destinies.”

Finally, the IMPAACT Network is excited to announce that IMPAACT 2017, a study to evaluate the safety, acceptability, tolerability, and pharmacokinetics of long-acting injectable cabotegravir and rilpivirine in children and adolescents with HIV, opened to accrual on 19 March 2019, with 8 sites currently activated to begin enrollment. To learn more about IMPAACT 2017, please see the IMPAACT website.
WEBINARS & TRAINING

Upcoming Webinars

Understanding Participant Experiences/Ethics/Incentives/Informed Consent in HIV Research
April 10, 2019 @ 10 AM PST
The Legacy Project's New Investigators Working Group invites you to participate in an informative webinar promoting the scholarship programs of the networks, where a group of presenters will share their expertise on various topics around research participant experiences, research ethics, informed consent and payment in research. Register here.

Leveraging Social and Behavioral Science in Network Clinical Trials
April 16, 2019 @ 11AM PST
The HANC-facilitated BSCG invites you to join Dr. Rivet Amico, Dr. Michele Andrasik, and Dr. Jessica Haberer as they explore social and behavioral science topics. Register here.

These Trees Cast No Shade: Understanding HIV Phylogenetics Research (Part 2 - HIV Genetic Sequencing Series)
April 18, 2019 @ 10AM PST
Dr. Carl Dieffenbach will explain phylogenetics, how it is being used in HIV research, and how the communities most impacted by HIV are being prioritized in this research. Venita Ray will then share recommendations for conducting this research ethically. Register here.

Understanding Molecular HIV Surveillance (Part 3 - HIV Genetic Sequencing Series)
April 25, 2019 @ 11AM PST
Dr. Eugene McCray will explain molecular HIV surveillance (MHS) from the perspective of the Centers for Disease Control and Prevention. We will then hear from Naina Khanna (Positive Women’s Network-USA) who will discuss ethical and social justice considerations for MHS. 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

On March 25, the Behavioral Science Working Group (BSWG) hosted a webinar with Dr. Omar Galarraga on behavioral economics. The webinar, “Economic Incentives to Improve HIV Prevention and Treatment Outcomes" can be viewed here.

The Behavioral Science Consultative Group (BSCG) will host a webinar on April 16 at 11am PT/2pm ET. Presenters for the webinar include BSCG representatives Dr. Rivet Amico (University of Michigan), Dr. Michele Andrasik (HVTN, University of Washington), and Dr. Jessica Haberer (Harvard Medical School, Massachusetts General Hospital). The webinar is titled “Leveraging Social and Behavioral Science in Network Clinical Trials”. More information and webinar registration can be found here.

The Youth Prevention Research Working Group (YPRWG) will be hosting a webinar with IMPAACT 2016 Co-chairs Dr. Dorothy Dow and Dr. Geri Donenberg. The webinar will be held on April 26 at 7am PT/10am ET. A registration link will be shared with HANC collaborators in the near future.

The YPRWG will be hosting a satellite symposium at IAS 2019. More information about the symposium will be made available at a later date. IAS 2019 will be held in Mexico City, Mexico from July 21-24, 2019.

Community Partners
Russell Campbell, HANC Deputy Director

Community Partners (CP) members will be presenting at the ATN National Community Advisory Board/Youth Experts and Advocates for Health (ATN-YEAH) Meeting on April 8th.

The CP Participant Bill of Rights and Responsibilities (PBoRR) Working Group is in the process of developing a cross-network PBoRR.

CP and the TB Community Research Advisors Group (CRAG) will be working on developing a joint abstract focusing on TB-HIV co-infection to submit to the 50th Union Work Conference on Lung Health.
Tubes and three calls to continue revising the Protocol Participation and Lab Processing Chart Preparation Procedures SOP.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new proficiency testing reports from RNA036, GEN031, GEN033, GEN034, and a preliminary analysis summarizing HCV validation data. The group also discussed the status of several DAIDS policies in development and communications needs from sponsors to grantees.

The Laboratory Technologists Committee (LTC) held a conference call to discuss harmonizing Lab Processing Chart development and upcoming changes to LDMS. The LTC SOP Sub-working Group held a call to update the SOP for PAXgene® Blood RNA Tubes and three calls to continue revising the Protocol Participation and Lab Processing Chart Preparation Procedures SOP.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new proficiency testing reports from RNA036, GEN031, GEN033, GEN034, and a preliminary analysis summarizing HCV validation data. The group also reviewed a poster presented by Cheryl Jennings at CROI 2019 entitled The Use of External Quality Assurance Data to Compare HIV-1 RNA Assay Performance.

The Laboratory Focus Group (LFG) held a conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) to approve and continue discussing the implementation of new procedures for cross-network laboratory site Action Plans.

The CPQA held an ad-hoc conference call to discuss results from a new pilot study on methods for measuring Tenofovir-diphosphate in dried blood spots. The 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 Advisory Board held a conference call to discuss CPQA program updates on proficiency testing, trends in network research, and the AVR/SOP Peer Review Program.
HANC PROGRAM HIGHLIGHTS

The Legacy Project
Brian Minalga and Kacie Sadorra
HANC Legacy Project Team

April 5: Abstracts are due to the United States Conference on AIDS. The Legacy Project, Women’s HIV Research Collaborative, and Cross-Network Transgender Working Group are submitting a variety of abstracts on topics ranging from long-acting injectables, PrEP and Black MSM in Washington state, the Be the Generation project, engaging historically black colleges and universities, engaging Latinx communities, heterosexual Black men in the HIV workforce, trauma-informed care for transgender people, HIV prevention and cure research with cis and trans women, and screening for intimate partner violence in HIV research with women.


Legacy also recognizes National Youth HIV/AIDS Awareness Day.

April 12-14: Brian Minalga will represent the Legacy Project at the National Transgender Health Summit in Oakland, CA. He will deliver an oral presentation, “Fostering Transgender Awareness and Inclusion in HIV Research” on behalf of the Cross-Network Transgender Working Group.

April 18: The Legacy Project hosts the webinar, “These Trees Cast No Shade: Understanding HIV Phylogenetics Research” featuring speakers Carl Dieffenbach (NIAID) and Venita Ray (Positive Women’s Network-USA). Register here.

This is part 2 of a 4-part webinar series; the recording for part 1 is available here.

April 25: The Legacy Project hosts the webinar, “Understanding Molecular HIV Surveillance: Public Health and Human Rights Implications” featuring speakers Eugene McCray (CDC) and Naina Khanna (Positive Women’s Network-USA). Register here. This is part 3 of a 4-part webinar series.

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

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

ABOUT THE LEGACY PROJECT

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

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

WORKING GROUP MEMBER SPOTLIGHT

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

Ernest M. Moseki

Meet Ernest Moseki, a current member of Community Partners.

Location/role at site: Botswana CTU, sites Gaborone CRS Molepolole CRS 12701 & 12702. I am a Community Engagement Coordinator working across ACTG, HPTN & IMPAACT. I have worked in HIV/AIDS research since 2007. I also work in the regulatory office.

What you like most about community engagement: Community engagement ensures that researchers recognize the autonomy of the community where research is conducted and thus accorded respect. It also ensures that research conducted addresses the health needs of communities and ensures that they are part of the entire research process (doing it with the community for the community) and beyond a given research study.

Any other interesting things about yourself you care to share? I served as a member of the HPTN 075 protocol team and I am a member of the University of Botswana IRB.

Stephaun E. Wallace, PhD

Meet Stephaun Wallace, a member of the Legacy Project Working Group.

Location/role at site: Senior Community Engagement Project Manager, HVTN Core (Leadership and Operations Center).

What you like most about community engagement: I appreciate opportunities to connect with diverse community members and leaders around the world in an effort to understand the barriers and facilitators to engaging in HIV clinical research, and support HVTN sites and communities to effectively engage in the important research that is occurring.

Any other interesting things about yourself you care to share? I served in the US Army, my favorite color is red, and I am a Scorpio.
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 access data and biospecimens from NICHD-funded research studies for secondary analyses. 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