HANC ANNOUNCEMENTS

NEW HIV Cure Research Webinar Series
HANC is pleased to announce an upcoming three-part webinar series exploring HIV cure research. See the Webinars & Training section for more information!

Harlan Pruden selected for NMAC Fellowship
Harlan Pruden, who serves on the Legacy Project Working Group, was announced as a recipient of the Gay Men of Color Fellowship in Biomedical HIV Prevention. The fellowship program trains 20 gay men of color recruited from the targeted 48 counties in the federal plan to end HIV to become educators and advocates for Biomedical HIV prevention in their communities. More information about the fellows is available on the NMAC website.

Harlan is a first Nation Cree and works with and for the Two-Spirit community locally, nationally and internationally. Harlan is a Ph.D student at the University of British Columbia (UBC) and an Educator at the British Columbia (BC) Center for Disease Control’s Chee Mamuk program. Harlan is also the Managing Editor of the TwoSpiritJournal.com.

INSIDE THIS ISSUE:

Network Announcements 2-4
Meeting Calendar 5
Webinars & Training 5
HANC Program Highlights 6-8
Behavioral & Social Sciences 6
Community Partners 6
Cross-Network Coordination 7
Laboratory Coordination 7
The Legacy Project 8
Financial Disclosure 8
WG Member Spotlight 9
Resources 10

Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org
The ACTG annual meeting took place June 17-21 in Arlington, VA and drew more than 850 attendees. Highlights included robust discussions about the ACTG research agenda among international investigators, a workshop introducing new investigators to the ACTG and plenary sessions providing a sneak preview of new ACTG data that will be presented at the 10th IAS Conference on HIV Science, taking place in Mexico City in July.

In addition, our recent publication **ACTG A5308** examined the effect of ART on virologic suppression, the viral reservoir, immune activation and quality of life in a group of elite controllers enrolled in the ACTG, in an attempt to answer the question of whether elite controllers require ART for secondary benefits, including control for low-level viral replication and reduction of inflammation. A5308 study was a prospective, open-label study of rilpivirine, emtricitabine and tenofovir disoproxil fumarate provided to ART-naïve HIV controllers (n=35) defined as having HIV RNA levels of <500 copies/mL off of therapy. The study found that ART was effective in increasing the proportion of individuals with undetectable residual viremia and decreasing the proportion of CD38+HLA-DR+CD8+ T cells (a marker of immune activation). Researchers also identified a modest but statistically significant improvement in self-reported quality of life. A5308 resolves the debate around the value of ART for elite controllers, by demonstrating the clinical benefits of ART in this population. Read more in **Clinical Infectious Diseases** 2019: ciz442 (Li J et. al).

The ACTG HIV Reservoirs Cohort Study (**A5321**) addressed the challenges of persistence in the nervous system. In this study, virally suppressed individuals with HIV taking long-term ART were tested for persistent HIV in their cerebrospinal fluid and underwent neurocognitive assessments, which included tests of memory, learning, motor function, and more. The study revealed that HIV DNA was detected in almost half of participants and was associated with poorer neurological and cognitive function. This persisted even after adjusting for participants’ age and the severity of immune suppression they had experienced in the past. The association between HIV genetic material in cerebrospinal fluid with poorer performance on cognitive tests suggests that there may be a link between HIV persistence in the brain compartment and the neurological complications that some people living with HIV experience. Further studies will help determine strategies to reverse this persistence and improve neurological functioning in patients with long-standing HIV. (Journal of Clinical Investigation 2019, in press; Spudich S, Robertson K, et al.)
The 10th IAS Conference on HIV Science (IAS 2019) will take place 21-24 July at the Centro Citibanamex in Mexico City. More than 6,000 scientists, clinicians, public health experts, and community leaders are expected to attend. The scientific program will focus on advances in HIV treatment and cure research, new research on HIV co-infections, the latest progress in biomedical HIV prevention, and insights on vulnerable populations. HPTN researchers will present 18 abstracts covering HPTN 062, HPTN 065, HPTN 067, HPTN 068, HPTN 071, HPTN 078, HPTN 082, and AMP (HVTN 703/HPTN 081 and HVTN 704/HPTN 085).

On Monday, 22 July, HPTN researchers will participate in a symposia session focused on results and lessons learned from HPTN 071 (PopART). In a second Monday symposia session, Dr. Myron Cohen, HPTN co-principal investigator, and Dr. Nyaradzo Mgodi will discuss new prevention products in the pipeline including long-acting injectables and broadly neutralizing antibodies. Also, Dr. Connie Celum will discuss HPTN 082 during a satellite session on prevention solutions for the next generation. On Tuesday, 23 July, Dr. Wafaa El-Sadr, HPTN co-principal investigator and Dr. Ken Mayer will co-chair an oral abstract session entitled, “Hot off the Press: What’s New in HIV Prevention.”

IAS 2019 webcasts, e-posters and links to abstracts will be available online after their initial presentation at the conference.

**HVTN and collaborators’ four large-scale HIV vaccine and antibody efficacy studies fully enrolled**

With the full enrollment of HVTN 702, the HVTN and our partners have fully enrolled four ongoing large-scale HIV vaccine and antibody efficacy trials! These trials – HVTN 702, HVTN 703/HPTN 081, HVTN 704/HPTN 085, and HVTN 705 – are made possible by 12,559 study participants and the collaborative efforts of our study teams. “Every day, we recognize and appreciate the unwavering commitment of our study participants, communities, scientific teams, funders, and governments who make the research to help end HIV possible,” said Steven Wakefield, Director of External Relations at the HVTN. “These clinical trials underscore the importance of our global public-private partnerships.”

**Read the HVTN press release**

**HVTN at IAS 2019**

At this year’s [IAS 2019 Conference](#) in Mexico City, the HVTN is organizing a satellite session to talk about the Mosaico study, a “sister study” to HVTN 705. This session will provide an overview of the study, summarize ongoing advances in preclinical work, and describe plans to implement the study in Europe, the US and Latin America.
On June 18-19, the MTN held a stakeholder consultation in Kampala, Uganda 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 meeting included 60 stakeholders who shared their thoughts about the studies before the anticipated start later this year/early 2020. The DELIVER and B-PROTECTED studies will evaluate the safety of two HIV prevention methods – the monthly dapivirine vaginal ring and daily use of Truvada as PrEP. Topics addressed during the meeting include regulatory plans, study implementation and ongoing community engagement. The meeting was co-hosted by AVAC, The White Ribbon Alliance Uganda, The International Community of Women Living with HIV Eastern Africa and the Makerere University-Johns Hopkins University (MUJHU) Research Collaboration.

The Network is pleased to announce that IMPAACT 2021, a randomized, placebo-controlled, Phase I/I study to assess safety and immunogenicity of three candidate vaccines among healthy, RSV-seronegative children 6-24 months of age, has begun enrolling. This study is being implemented at IMPAACT and Vaccine and Treatment Evaluation Units (VTEU) sites in the United States. The first enrollment into IMPAACT 2021 occurred on 20 June 2019 at the Lurie Children’s Hospital Chicago site – congratulations to the Lurie Children’s site for leading the way on this study. To learn more about IMPAACT 2021, please see the IMPAACT website.
WEBINARS & TRAINING

Upcoming Webinars

HIV Cure Research Updates (Part 1)
July 9, 2019 @ 10 AM PST
The Office of HIV/AIDS Network Coordination (HANC) invites you to join this three-part webinar series on HIV cure research. The first webinar in the series will focus on the work of the Martin Delaney Collaboratory and their current research focused on HIV cure research. Register here.

Community Perspectives on HIV Cure Research (Part 2)
August 6, 2019 @ 10 AM PST
Part two of the three-part webinar series on HIV cure research centers on perspectives from members of the community and will feature Bré Anne Rivera and Laurie Sylla. Register here.

Training

HIV in Transgender Communities
Available on the DAIDS Learning Portal
The HIV in Transgender Communities training module provides an overview of the extent of HIV in transgender communities in the U.S. and globally, and highlights some of the factors that contribute to the high burden of HIV in transgender communities. The module was developed to help improve understanding and cultural responsiveness in the clinical research setting. All staff are encouraged to complete this module, as well as the other courses within the larger five-part training curriculum as they become available. Access the course here.

To supplement the Web-based course, the in-person training tool for HIV in Transgender Communities is also available for those interested in providing in-person training at sites or in the community. Access the tool 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 Consultation Group (BSCG) met face-to-face on June 20 at the conclusion of IAPAC’s Adherence 2019 conference. The BSCG will resume its regular call schedule in July and continue the discussions from the face-to-face meeting.

The Youth Prevention Research Working Group (YPRWG) is hosting a satellite symposium at IAS 2019. The satellite symposium will take place on July 22, 2019 at 7am. The symposium will include the following presenters and protocols:

- Dr. Connie Celum will present on HPTN 082
- Dr. Lulu Nair will present on MTN 034
- Dr. Nahida Chakhtoura will present on IMPAACT 2009
- Dr. Isa Fernandez will present on ATN adolescent recruitment and enrollment in studies
- HANC Director, Dr. Jeff Schouten, will moderate the symposium

**Community Partners**

*Russell Campbell, HANC Deputy Director*

Community Partners (CP) and the Community Research Advisors Group (CRAG) will submit a joint Community Session abstract to the 50th Union World Conference on Lung Health October 30- November 2nd in Hyderabad, India.

The next CP Participant Bill of Rights and Responsibilities Working Group call to develop a cross-network document is scheduled for July 3rd.

CP is in the process of developing an agenda for its face-to-face meeting scheduled for October 26-27.
HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
Milan Vu, HANC Project Manager

The Evaluation Working Group (EWG) shared updates on the Protocol Deviation Reporting pilot and cross-network effort to harmonize community engagement reports.

The Site Coordinators Working Group (SCWG) and Data Management Center Working Group (DMCWG) did not meet in the month of June due to member attendance at the network annual meetings. Presentation slides from the network meetings can be found on the following network websites:

HPTN Annual Meeting Presentations

IMPAACT Annual Meeting Presentations

Highlights:
- Updates: The Revised Common Rule, Informed Consent Process Policy, Age & Identity Verification Policy, Delegation of Duties Policy, and Clinical Quality Management Plan Policy (presented by DAIDS OPCRO and OCSO staff)
- Good Documentation Practices (presented by Sheryl Zwerski)

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Lab Technologists Committee (LTC) held a conference call to plan and discuss LTC sessions at the upcoming ACTG Annual Network Meeting. The LTC held two sessions at the meeting which focused on Leukopak processing, LDMS end-user validation, and the electronic Lab Processing Chart. The LTC SOP Sub-Working Group held two conference calls to continue updating the Leukopak Collection and PBMC Isolation SOP.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new panel analysis reports from RNA036, RNA035, DNA220RT, DNA220BS, 034g PR/RT and 036g IN.

The Lab Focus Group (LFG) held a conference call to continue reviewing and revising cross-network Backup Lab Guidelines, a guidance document outlining cross-network standards for developing and approving back-up plans for non-US laboratory sites and equipment. The LFG also began developing new standard processes for cross-network communication aimed at quality control.

The CPQA Advisory Board (CPQAAB) held a conference call to discuss CPQA program updates on proficiency testing, CPQAAB sub-working groups, and the AVR/SOP Peer Review Program. The CPQA Program’s Bioanalytical Revisions Advisory Group (BRAG) Working Group held a conference call to finalize the new CPQA guidance document for bioanalytical method validation. The CPQA CNCPL Forum hosted a webinar on the topic of LDMS end-user validation and audit readiness, presented by Howard Gutzman (LDMS Program Director at FSTRF). The CPQA held two sessions at the IMPAACT and ACTG Annual Network Meetings, where they launched the new Clinical Pharmacology Study Conduct Tutorial, which is now available through the DAIDS Learning Management System.
The Legacy Project, in collaboration with the Behavioral Science Consultative Working Group, is hosting a three-part webinar series on HIV cure-related research:

- July 9th at 10 a.m. Pacific: Dr. Karl Salzwedel presents on the work of the Martin Delaney Collaboratory
- August 6th at 10 a.m. Pacific: Bré Anne Rivera and Laurie Sylla present on community perspectives of HIV cure-related research
- TBD: Drs. Karine Dubé and Pablo Tebas present on the AIDS Clinical Trials Group's efforts in the HIV cure research arena

The Legacy Project has been invited to present a workshop at the upcoming 2019 MSM HIV Prevention Institute in Columbia, South Carolina August 22-23. Russell Campbell and Dr. Kenric Ware will present: “Legacy Project-Engaging HBCUs in HIV Prevention Research”.

The WHRC and the Legacy Project are currently planning for the following workshops at the United States Conference on AIDS this Fall:

- Thursday, September 5 from 2 to 4 pm: "The Future is Female: Women of Color Leadership in the HIV Movement" (WHRC)
- Friday, September 6 from 9 to 11 AM: “Native Americans and Alaska Natives, Historical Trauma & Sexually Transmitted Blood Borne Infections/HIV” (Legacy Project)
- Sunday, September 8 from 9 to 11 am: “All About Us: Women & Biomedical HIV Prevention” (WHRC)

The Legacy Project is collecting updates from the HPTN, HVTN, and MTN for inclusion in the next issue of BTG News, our quarterly publication on biomedical HIV prevention research, which will come out at the end of August.

The Legacy Project is nearing completion of a full update of the Be the Generation HIV Prevention Research module. We look forward to releasing the updated version of this training resource soon.

Financial Disclosure

Greg Davis, HANC Project Manager

The Annual Solicitation will take place on September 20, 2019 this year.
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:

**Luciana Kamel**
Meet Luciana, a member of Community Partners.

Luciana Kamel is a community educator and a counselor at LaPClin/Fiocruz in Rio de Janeiro, Brazil. Currently, she is a protocol team member of the HPTN 085/AMP study as a community educator representative. She joined Fiocruz Luciana Kamel Community Advisory Board (CAB) in 2005, and since then has been very involved with community education. She has her Bachelor’s Degree in Psychology and Law from the Rio de Janeiro Federal University and Estácio de Sá University, respectively. In addition, she obtained her Master’s Degree in Psycho-sociology and Community Social Ecology. She has worked for several years at a major HIV/AIDS NGO in Rio de Janeiro, where she gained valuable experience in the fields of national health policies on HIV, sexuality programs, gender rights, youth programs and STI/AIDS prevention program.

From Luciana:
*I’ve been very lucky and grateful for the work I have been doing because it’s a unique opportunity to learn the community needs and make sure that their voice is heard. This experience along the years has helped me gain constructive feedback that significantly enabled me build strong partnership with Community in the prevention of HIV.*

**Clare Collins**
Meet Clare, a member of the Legacy Project Working Group.

**Location/role:** Pittsburgh, PA; Communications and External Relations at the Microbicide Trials Network (MTN)

**What you like most about community engagement:** Community engagement encourages me to “take a seat” and listen to the knowledge shared by people who have entirely different experiences than my own – experiences that are often silenced by our institutionalized systems of oppression. It truly has enriched my life, in addition to making the HIV research we conduct at MTN much more meaningful and just.
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.

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.

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.

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.

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FIND MORE RESOURCES AT WWW.HANC.INFO