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  7
  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

HANC ANNOUNCEMENTS

HANC-facilitated Financial Disclosure Annual Solicitation

The HANC-facilitated Annual Financial Disclosure Solicitation will occur on September 20, 2019.

HANC assists the networks in collection of financial disclosure data from a limited number of investigators, primarily those on executive committees, scientific committees, and in leadership roles on protocol teams. This allows the networks to manage any potential conflicts of interest. HANC is not involved with the financial disclosure process at sites per the FDA collection of financial disclosure information. The HANC-facilitated cross-network system does not collect financial disclosure information on all 1572 Investigators of Record.

For more information about the HANC-facilitated financial disclosure solicitation, and its distinction from grantee institution and FDA reporting requirements, please see the HANC Financial Disclosure Memo.

Review the NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest Guidelines SOP here.
The ACTG would like to highlight two recent publications of important ACTG studies:

The **OPTIONS study (A5421)** looked at whether NRTIs are a necessary component of salvage antiretroviral regimens. The study included more than 350 people with HIV who had received and developed resistance to a variety of medications. The trial, which lasted almost 2 years, showed that clinicians do not need to add NRTIs to salvage regimens, as long as the new regimen has a cumulative activity of 2 or more active medicines from other drug classes. Salvage regimens that did not include NRTIs gave similar rates of durable virologic suppression as those that included NRTIs. This study changes the dogma that NRTIs are necessary in a salvage regimen and has major implications for clinical care. The publication (Gandhi RT et al.) and an accompanying editorial (Hoenig M et al.) can be found in the Journal of Infectious Diseases 2019 May 28.

The **MULTI-OCTAVE study (A5288)** is one of the first studies to look at interventions for medication adherence in lower- and middle-income countries (LMICs) for individuals failing second line therapy. Study participants received and responded to a randomized cell phone-based adherence support intervention, first daily and then tapering down to once a week. The study showed a small (but not significant) benefit of a mobile phone-based intervention for ART adherence on the primary outcome of achieving virological suppression at 48 weeks, and a small (and statistically significant) effect on the outcome of time to virological failure. The authors conclude that adherence behavior is challenging and that, while two-way text messaging might help given the effects on virological failure, more research on this and other adherence support strategies are needed. Read more in *Lancet Digital Health* 2019; 1: e26–34 (Gross R et al.).

More than 700 people attended the 2019 HPTN Annual Meeting in Washington, D.C. from June 1-5. A full agenda covered the latest developments in prevention research, and novel approaches critical to furthering the HPTN research portfolio. Topics discussed included sexually transmitted infections, pregnancy, multipurpose prevention technologies (MPT), substance use, sex work, and trial ethics. The HPTN Community Working Group kicked-off the event with a series of talks covering best practices for community engagement, community advisory board involvement, and study participant recruitment and retention. Regional roundtable discussions and capacity building sessions were also held. In addition, researchers from **HPTN 071 (PopART)** shared some of the study’s findings, best practices, and lessons learned during a general plenary discussion. Special sessions were also organized by the HPTN’s Laboratory Center, Statistical and Data Management Center, and the HPTN Scholars. The 2020 HPTN Annual Meeting will take place May 30 – June 3 at the Grand Hyatt Washington in Washington, D.C.
The HVTN Communications team piloted its media training program at the HVTN Full Group Meeting in Washington, D.C. Potential or current HVTN spokespersons from sites across the globe took part, including investigators, co-investigators, Community Advisory Board members and community managers. Trainees participated in 8 training modules, culminating in mock interviews and a mock press briefing.

On June 11-14, speakers and team members from the HVTN will be attending the 9th SA AIDS Conference in Durban, South Africa. To create an HVTN-focused experience, the HVTN will participate in the following activities:

**Plenary 2: A journey to find a safe and effective HIV prevention response**
June 12, Hall 1
9:30 a.m.: Vaccines with Professor Linda-Gail Bekker
10:00 a.m.: bnAbs with Professor Glenda Gray

**Satellite session: The journey to find a safe & effective HIV vaccine**
June 13, Hall 8 – 12AB | 7:30–8:30 a.m.
This session will focus on the contribution of study participants & communities in clinical trials, HIV risk in women and an update on the HVTN’s large-scale HIV vaccine efficacy clinical trials.

**HVTN community booth** recognizing the commitment of our study participants, communities and Community Advisory Board members who make our clinical trials possible.
June 11–14, Main Exhibition Hall, Booth 32
In June, the MTN is holding 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 will provide 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 to be addressed during the meetings include regulatory plans, study implementation and ongoing community engagement. The meeting will be 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. A similar consultation was held last year in South Africa with stakeholders from all of the DELIVER and B-PROECTED trial site countries -- Malawi, South Africa, Uganda and Zimbabwe.

At a concert in May to benefit research on the health of women and infants, MTN Principal Investigator, Dr. Sharon Hillier, was honored with the 2019 Women who Rock Award. She received the award for her research and advocacy on women's health and HIV prevention. The concert featured "Queen of Percussion" Sheila E. as well as other all female-fronted music acts.

The IMPAACT Network is pleased to announce publication of results from several studies:

- Pharmacokinetic results from P1080 (Hanan et al. Sertraline Pharmacokinetics in HIV-Infected and Uninfected Children, Adolescents, and Young Adults. Front Pediatr. 2019 Feb 6;7:16)

In addition, the IMPAACT Annual Meeting will be held from 10-14 June 2019 in Washington, DC. The final agenda and additional information are available on the network's website.
WEBINARS & TRAINING

Upcoming Webinars

No HANC webinars are scheduled for the month of June.

Recordings of recent webinars, including the Legacy Project’s HIV Genetic Sequencing Series, are available in the HANC webinar archives.

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.

An Introduction to Transgender Communities - In-person Training Tool

Available on the DAIDS Learning Portal

The in-person PowerPoint training materials for An Introduction to Transgender Communities are now available in Spanish and Portuguese. The training tool includes a PowerPoint presentation, facilitators guide, exercises, and list of resources to conduct in-person trainings at research sites or in the community.

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.*

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**Behavioral & Social Sciences**

*Greg Davis, HANC Project Manager*

The Behavioral Science Consultative Group will be meeting in Miami on June 20, 2019 at the conclusion of the *Adherence 2019* conference.

The Behavioral Science Working Group’s (BSWG) June call will be cancelled due to a schedule conflict.

The Youth Prevention Research Working Group (YPRWG) is gearing up for its satellite symposium at *IAS 2019*. The satellite symposium will take place on July 22, 2019 at 7am. The location and confirmed speakers will be announced at a later time. The YPRWG will be discussing the following protocols during the symposium: HPTN 082, MTN 034, IMPAACT 2009, and ATN adolescent recruitment and enrollment in studies.

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**Community Partners**

*Russell Campbell, HANC Deputy Director*

Community Partners is delighted to welcome the following new members: Calvin Mdeba (MTN), Emanueli Msuya (IMPAACT), and Benardo Odhiambo (MTN). More about these new members will be featured in upcoming newsletters.

Community Partners is delighted to share that community engagement materials developed by Community Partners and CRAG for PHOENIx have been approved and posted on the PHOENIx PSWP. The first document is intended as a resource (talking points) to help the *index case/participant* to explain PHOENIx to their household contacts. The other document is intended as a resource (talking points and considerations) for *site staff* when discussing TB, MDR TB, PHOENIx and ways that individuals and families can support each other.

As part of the collaboration between Community Partners and CRAG focused on TB/HIV co-infection, Community Partners members attended and represented Community Partners at the 43rd Semi-Annual Tuberculosis Trials Consortium (TBTC) Meeting in Atlanta May 14th-May 16th.

CP and CRAG will be submitting a joint Community Session abstract to the 50th Union World Conference on Lung Health.
HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
Milan Vu, HANC Project Manager

The Data Management Center Working Group (DMCWG) reviewed progress of the ongoing Safety Data Reconciliation Policy pilot and protocol deviation CRF pilot.

The Communications Working Group (CWG) discussed upcoming network presence at the International AIDS Society (IAS) Conference happening July 21-24, 2019 in Mexico City, Mexico. Several networks will be attending and presenting at the conference, and the HANC-facilitated Youth Prevention Research Working Group (YPRWG) will be hosting a satellite symposium focused on research with youth and adolescent populations.

The Site Coordinators Working Group (SCWG) discussed implications of recent changes to monitoring processes on access to electronic medical records (EMRs) and staff workload, as well as communication timelines around monitoring reports. Sites also exchanged knowledge and experiences around implementing electronic regulatory binders and electronic informed consent.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Lab Technologists Committee held two conference calls to discuss the LTC Open Session at the upcoming ACTG Annual Meeting and changes to PEC reporting. The LTC SOP Sub-Working Group held four conference calls to continue reviewing and updating the Leukopak Collection and PBMC Isolation SOP.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review fifteen new DNA and RNA panel analysis reports.

The Lab Focus Group (LFG) held a conference call to review and continue updating cross-network standard processes and operating procedures focused on quality assurance.

The Data Management Center Working Group (DMCWG) reviewed progress of the ongoing Safety Data Reconciliation Policy pilot and protocol deviation CRF pilot.

The Women’s HIV Research Collaborative is proud to announce that we have had two abstracts accepted as workshops at the 2019 United States Conference on AIDS, taking place in Washington, DC:

- Thursday, September 5th from 2 to 4 p.m. “The Future is Female: Women of Color Leadership in the HIV Movement”
- Sunday, September 8th from 9 to 11 a.m. “All About Us: Women and Biomedical HIV Prevention”

The latest edition of BTG News, our quarterly newsletter on biomedical HIV prevention research, is now available. Check it out on the Be the Generation website in English and Español.
The Legacy Project Working Group is proud to announce that so far we one abstract has been accepted as a workshop at the 2019 United States Conference on AIDS, taking place in Washington, DC:

- Friday, September 6th from 9 to 11 a.m. “Native Americans, Historical Trauma, & Sexually Transmitted Blood Borne Infections/HIV”

Russell Campbell represented the Legacy Project at the HPTN annual meeting, June 1-5.

Brian Minalga will represent the Legacy Project at the ACTG annual meeting, June 17-21.

Legacy also recognizes HIV Long-Term Survivors Day on June 5th, National HIV Testing Day on June 27th, and LGBTQ+ Pride Month!

Financial Disclosure

Greg Davis, HANC Project Manager

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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:

**Busi Buthelezi**
Meet Busi, a current member of Community Partners.

**Location/role:** BARA SITE Johannesburg
Soweto South Africa / CAB Chairperson

**What you like most about community engagement:** I do a lot of community work in Soweto and the inner city Johannesburg and I meet diverse community, some out of the country. I engage with them in issues relating to human rights and this makes me enjoy the community engagement, discovering that though people come from different backgrounds we all have a lot in common, and that all human beings want a healthy long life at the end of the day.

Being exposed to the research community has also made me enjoy my work much more, because I have met people who care most about the challenges people are facing because of the life threatening diseases that affect the communities around the world. That has been my highlight of my little contribution to life.

**Gabrielle Evans, MPH, CHES**
Meet Gabrielle, a member of the Legacy Project Working Group.

**Location/role:** Chapel Hill, NC. Research Assistant

**What you like most about community engagement:** Community engagement gives me the opportunity to not only step outside of the traditional work environment, but to also meet people where they are to provide them with available resources. It also allows me to connect with them on a more personal level.

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.
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 gp.davis@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.

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.

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. [Click here](#) to explore DASH.