HANC ANNOUNCEMENTS

Check out the NEW Member Spotlight!

In an effort to highlight the work of HANC and members involved in HANC working groups, starting this issue we will be introducing you to a few of our members from Community Partners and the Legacy Project Working Group. Check it out on page 8!

Understanding HIV & Aging - Part 3

The third and final webinar of the series is scheduled for February 5th. The webinar will feature Gail Graham and Porchia Dees and cover issues focused on African Americans and women and some of the challenges living and aging with HIV including:

- Experiences of Black women living and aging with HIV
- Loneliness, isolation and/or depression related to HIV and aging
- Resources for African Americans and women living and aging with HIV

Click here to register for Understanding HIV & Aging, Part 3. Further details and links to recordings of past webinars can be found under Webinars & Training.

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

There are no announcements from the ACTG this month.

For news and other updates from the ACTG, visit the ACTG’s web site.

HPTN 083 has enrolled more than 3100 out of a target enrollment of 4500 participants. The study is evaluating long-acting injectable cabotegravir (CAB LA) compared to daily oral pre-exposure prophylaxis (PrEP) in HIV-uninfected men and transgender women who have sex with men (MSM and TGW) in the Americas, Asia and South Africa.

HPTN 084 has enrolled more than 550 participants. The target enrollment is 3200 participants. The study is evaluating long-acting injectable cabotegravir (CAB LA) compared to daily oral pre-exposure prophylaxis (PrEP) in HIV-uninfected women in sub-Saharan Africa.

The National AIDS Education and Services for Minorities (NAESM) conference took place January 17-20 in Arlington, Virginia. During the four day event, representatives from the HPTN and the Black Caucus delivered two presentations. “HPTN Responds to the BGRG Research Agenda: A Multi-Disciplinary Approach” provided an overview of the HPTN’s research, as well as additional research strategies that can be used to inform the development of community programs. “Be The Generation: Empowering Communities to End the HIV/AIDS Epidemic” featured representatives from the Legacy Project, HPTN, HVTN, and MTN discussing the Be the Generation (BTG) project.

The HVTN continues to prioritize development of tools to help trial participants and their providers to understand our science. To that end we will soon provide sites with a new VISP educational video. This will complement our previous work to ensure persons considering study enrollment have an understanding of VISP, and how the HVTN is prepared to assist them in navigating issues that can arise. We have just completed consultations with CAB Members, CERs, Community Stakeholders, and Clinic Coordinators across our US sites. Final editing is underway, and the finished video will be distributed to sites in February 2019.
An NIH news release issued in January highlighted the contributions of IMPAACT P1026s, an ongoing study of how pregnancy affects the body’s processing of drugs for HIV and TB in women being treated for HIV. The study has resulted in one of the world’s largest data sets of its kind and publications on more than 20 of the most commonly used antiretrovirals, as well as many commonly prescribed TB therapies and contraceptives used after giving birth. These data have helped provide a foundation for national and international HIV treatment guidelines for women living with HIV who are pregnant or have recently given birth. The study is being conducted in Botswana, Brazil, South Africa, Thailand, Uganda and the United States. A follow-on study to include evaluation of additional HIV and TB therapies and contraceptives in this population is in development (IMPAACT 2026).

The Microbicide Trials Network (MTN) presented an update on microbicide research at a Be the Generation Bridge session on Empowering Communities to End the HIV/AIDS Epidemic at the 2019 National African American MSM Leadership Conference on Health Disparities and Social Justice. The meeting was held January 17-20 at the Renaissance Arlington Capital View Hotel in Arlington, Va., and also included updates the HPTN and HVTN. MTN presented on vaginal ring studies in development that are focused on key populations, including pregnant and breastfeeding women and young women and adolescent girls. An update on rectal microbicide studies underway and being planned was also included.

An upcoming webinar on the CHARISMA study will present new data from interventions with cisgender women to address HIV prevention, relationship dynamics and intimate partner violence. The CHARISMA study is nested within MTN’s HIV Open Label Prevention Extension (HOPE) study of the dapivirine ring study, and includes HOPE participants enrolled at the Wits RHI Hillbrow site in Johannesburg, South Africa. The webinar, Love, Power and PrEP: Addressing relationship dynamics and intimate partner violence to promote successful prevention for women and girls, will be held 9-10:30 a.m. EST, Tuesday, February 5. Click here to register.

MTN’s 2019 Annual Meeting will be held, February 10-13 at the Crystal Gateway Marriott in Arlington, Va. Topics covered at the meeting will include: microbicides in the prevention landscape; understanding PrEP in pregnant and breastfeeding women; prevention for youth; and moving from options to choices. The meeting agenda is available on MTN’s web site.
WEBINARS & TRAINING

Upcoming Webinars

Historical Trauma & HIV
February 7, 2019 @ 9AM PST
As part of National Black HIV/AIDS Awareness Day on February 7, 2019, the Legacy Project invites you to register and participate in this informative webinar featuring Dr. Michele Andrasik. Register here.

Part 3: Experiences of Black Women Living and Aging with HIV
February 5, 2019 @ 12PM PST
Community Partners and the Legacy Project have assembled a diverse group of experts working in community advocacy, biomedical research, and geriatrics to guide us through a three-part webinar series focused on the connections between HIV and aging and the impact of age-related factors on older adults with HIV. Register here.

Part 3 of the series will feature Gail Graham and Porchia Dees and focus on the following:
- Experiences of Black women living and aging with HIV
- Loneliness, isolation and/or depression related to HIV and aging
- Resources for African Americans and women living and aging with HIV

Save the date!
April 18, 2019 (National Transgender HIV Testing Day)
A webinar on HIV phylogenetics research featuring Dr. Carl Dieffenbach (NIH, Division of AIDS) and Venita Ray (Positive Women’s Network).

April 25, 2019
A webinar on molecular HIV surveillance featuring Dr. Eugene McCray (CDC) and Naina Khanna (Positive Women’s Network).

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.

For details and other events, visit the HANC calendar.
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 is hosting a webinar with Dr. Omar Galarraga on March 25 at 12pm PT/3pm ET. Dr. Galarraga will be discussing behavioral economics on the webinar.

On April 16, at 11am PT/2pm ET, the Behavioral Science Consultative Group will host a webinar on the AMP Study and the PHOENIx Study. Dr. Rivet Amico will host the webinar and presentations will be given by Dr. Michele Andrasik and Dr. Jessica Harberer. Once registration links are available, they will be shared with HANC collaborators.

The Youth Prevention Research Working Group (YPRWG) will host a webinar on April 26 at 7am PT/10am ET on IMPAACT 2016. Dr. Geri Donenberg and Dr. Dorothy Dow will present on the webinar. A registration link will be made available in the near future.

The YPRWG will be submitting a proposal for a satellite symposium at IAS 2019 in Mexico City, Mexico. The proposal is currently being reviewed by the YPRWG co-chairs.

**Community Partners**
*Russell Campbell, HANC Deputy Director*

Community Partners (CP) is working on developing a harmonized, cross-network Participant Bill of Rights and Responsibilities (PBoRR) document. While modeled after a Patient Bill of Rights for health care, the PBoRR provides clarity about the rights and responsibilities of participants in HIV clinical trials including the following:

- Rights given to participants as indicated by universal ethical research protections
- Responsibilities of a participant when committing to join a trial
- Shared responsibilities of the Networks, investigators and site staff to participants

The CP PBoRR WG has been tasked with developing this document which sites will have to option to utilize.

CP is preparing to present at the upcoming ATN YEAH F2F Meeting in Washington DC in April and is in the process of seeking input from the networks around potential training topics to present at upcoming Network annual meetings.
Bioanalytical Chromatographic Method Development, Validation and Application v1.0). The first conference call was held in January and calls are scheduled to continue twice per month through April 2019.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new proficiency testing reports from RNA035, DNA209PE and DNA211PE. The group discussed testing requirements for the VQA Program's new HCV RNA Proficiency Testing Program. VQAAB leadership announced that Bill Meyer has been re-elected as Chair of the VQAAB.

The Laboratory Technologists Committee (LTC) held a conference call to discuss changes to the cost and logistics for aliquot storage and pass-through shipments handled by the Biomedical Research Institute. The LTC organized and held a sub-working group call to review and revise the Protocol Participation and Lab Processing Chart Preparation Procedures SOP, and began organizing additional sub-working groups to update other LTC SOPs and standard wording documents.

The Laboratory Focus Group (LFG) held a joint conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) and the Patient Safety Monitoring in International Laboratories group (pSMILE) to discuss the implementation of new cross-network terminology standards for laboratory site action plans.

The Data Management Center Working Group (DMCWG) discussed continued progress along the Safety Data Reconciliation Policy pilots and efforts to improve automation of manual reconciliation processes.

The Site Coordinators Working Group (SCWG) reviewed draft DAIDS policies out for public comment and followed up on site concerns related to implementation of revised informed consent forms, electronic distribution of investigator brochures, and electronic storage of source documents.

Cross-Network Coordination

Milan Vu, HANC Project Coordinator

The Communications Working Group (CWG) met to discuss communications priorities and activities for 2019 and network representation at upcoming conferences, including the annual Conference on Retroviruses and Opportunistic Infections (CROI). The group also discussed participation in the Legacy Project Conference Engagement Working Group as an opportunity to highlight and coordinate network activities at major conferences.

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Laboratory Coordination

Tyler Brown, HANC Project Manager

The Clinical Pharmacology Quality Assurance (CPQA) Program re-started the BRAG Sub-working Group with the goal of updating the CPQA guidance document for validating bioanalytical methods for use in analyzing samples (CPQA Guidelines for Bioanalytical Chromatographic Method Development, Validation and Application v1.0). The first conference call was held in January and calls are scheduled to continue twice per month through April 2019.

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HANC PROGRAM HIGHLIGHTS

The Legacy Project
Brian Minalga and Louis Shackelford
HANC Legacy Project Community Engagement Officers

Upcoming dates on the Legacy Project calendar for the month of February:


February 11-12: Brian Minalga will represent HANC and the Legacy Project at the MTN annual meeting.

February 25: The latest edition of BTG News, Legacy’s quarterly newsletter on biomedical HIV prevention research, will be released here. Submissions from the HPTN, HVTN, and MTN are due to Brian Minalga no later than 2/8.

February 27 – March 13: Brian Minalga will be out of the office. For any needs related to the Legacy Project / Women’s HIV Research Collaborative, please contact Russell Campbell (rcampbel@fredhutch.org).

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

Facebook  Twitter  Instagram
WORKING GROUP MEMBER SPOTLIGHT

In an effort to highlight the work of HANC and members involved in HANC working groups, starting this issue we will be introducing you to a few of our members from Community Partners and the Legacy Project Working Group:

Marie Theunissen

Meet Marie Theunissen, one of the Community Partners Co-Chairs who works at the Family Clinical Research Unit (FAM-CRU) CRS in Cape Town, South Africa.

From Marie: *What I like about community engagement is that it enables me to grow from sharing and learning with and from my peers. It is also a platform where I can express myself freely and an opportunity where I can make scientists aware that community matters. I believe in empowering people and am very passionate about adolescents and vulnerable populations. I am actively involved in my community and, in an endeavor to minimize crime and gang violence in my surrounding areas, I offer free extra curriculum classes in various subjects to pupils who are struggling with learning. I am a second year Law student at UNISA.*

I FIRMLY BELIEVE IN THE RIGHTS OF ALL POPULATION GROUPS!!!
More so those who are not able to speak or fend for themselves. I am a great animal lover and love the outdoors. My favorite sport and hobby is swimming and tennis.

Dr. Jose Bauermeister

Meet Dr. Jose Bauermeister, one of the new Legacy Project Working Group members who represents the Microbicide Trials Network (MTN).

Dr. Bauermeister is a Penn Presidential Professor & Penn Fellow at the University of Pennsylvania, where he directs the Technology to Address HIV Disparities Scientific Working Group for the Penn Center for AIDS Research. He holds a Bachelors in Psychology from the University of Puerto Rico, and a joint MPH/PhD in Public Health from the University of Michigan. Dr. Bauermeister's research focuses on developing innovative biobehavioral HIV prevention interventions for racial/ethnic and sexual minority youth using interdisciplinary, technology-assisted approaches. His technology-based work includes the development and testing of several behavioral HIV prevention apps, and efficacy of next generation Pre-Exposure Prophylaxis (PrEP) modalities as a biomedical strategy for HIV prevention.
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.

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

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.