HIV and Aging Webinar Series

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. Special attention will be given to marginalized communities disproportionately impacted by HIV and AIDS, specifically African Americans and women. The first webinar of the series is scheduled for November 8th featuring Dr. Jeffrey Schouten.

Dr. Schouten will provide an overview of HIV and aging, current research focused on HIV and aging with an emphasis on the following topics:
- CDC Data on HIV & Aging
- Research exploring HIV & Aging
- Cardiovascular Issues
- Oncology
- Neurocognitive Issues

Click here to register for Part 1, Understanding HIV & Aging. Further details on the series can be found under Webinars & Training.
This month the AIDS Clinical Trials Group (ACTG) launched enrollment for a long-awaited study, specifically A5360: A Single-arm Study to Evaluate the Feasibility and Efficacy of a Minimal Monitoring Strategy to Deliver Pan-genotypic Ribavirin-free HCV Therapy to HCV Infected Populations who are HCV Treatment Naïve with Evidence of Active HCV Infection or The MINMON Study. Globally, nearly 71 million people have chronic HCV, of whom an estimated 4-5 million also have HIV. In this context, there is an urgent need for advances in treatment delivery. In some parts of the world, the healthcare system itself - through requiring frequent visits and laboratory monitoring during HCV treatment - can lead to barriers to HCV treatment with the new easy-to-take once a day treatments for HCV cure. The basic premise of the study is to eradicate all of these healthcare system barriers. In A5360, patients (n=400) will be provided HCV treatment with sofosbuvir/velpatasvir (Epclusa) for 12 weeks without any traditional laboratory or clinical monitoring or planned visits. Enrolling sites will be based in Africa, Brazil, India, Thailand and the United States, with two-thirds of participants being enrolled at international sites. Following HCV treatment, participants will be followed for an additional 72 weeks to assess the long-term outcomes related to HCV and liver disease, including the incidence of HCV reinfection. Study investigators hypothesize that this “minimal monitoring” for HCV treatment outcomes will result in more cost-efficient and effective paradigms in HCV treatment management, expanding the number of people who can achieve HCV cure worldwide.

The ACTG is also pleased to announce that the Tuberculosis Trials Consortium (TBTC) Study 31/ ACTG A5349 study completed participant enrollment in October. This important study will examine the efficacy of a shorter 4-month course of treating pulmonary tuberculosis (TB) with a rifapentine-containing regimen compared to the traditional 6-month course of TB therapy.

During the recent HIV Research for Prevention (HIVR4P) meeting, HPTN researchers presented 18 abstracts – seven oral presentations and 11 poster presentations. HPTN data was also featured in four satellite sessions and Raphael Landovitz, MD, MSc, HPTN 077 and HPTN 083 protocol chair, delivered a talk on PrEP during a plenary session.

In addition, HPTN researchers announced results from HPTN 075. The study evaluated the feasibility of HIV prevention research among men who have sex with men (MSM) and transgender women (TGW) in three countries in sub-Saharan Africa. Findings from the study showed participants were at an alarming risk for getting HIV. The incidence among study participants was substantially higher than the estimated incidence among heterosexual men and women in the general population in the same countries. A total of 401 MSM and TGW, regardless of HIV infection status, were enrolled at four sites in Kenya, Malawi and South Africa. Each participant was followed for 12 months, during which five study visits were conducted. (continued on next page)
These visits included interviewing participants about behaviors that may put them at risk for HIV infection, medical examinations and collection of blood samples. Of the 401 enrolled, 329 were HIV-negative at the time of enrollment. By the end of the study, 21 of them had become infected with HIV. This translates to an overall incidence rate of 6.96 per 100 person-years. Incidence rates differed substantially by study site: Malawi: 1.3; Kenya: 3.75; Soweto, South Africa: 8.97; and Cape Town, South Africa: 14.44. HPTN 075 is funded by the National Institute of Allergy and Infectious Diseases (NIAID) and National Institute of Mental Health (NIMH), both part of the U.S. National Institutes of Health (NIH).

Last week, HVTN researchers gathered in Madrid, Spain for the HIV Research for Prevention Conference (HIVR4P). Among the science presented were 11 general and 12 late breaker abstracts from HVTN, as well as two satellite sessions — State of the Art of HIV bNAbS for Prevention of HIV Infection, presented by Larry Corey and Myron Cohen, and A Treasure Trove of Clinical Specimens and Data: Mining Research Opportunities with the HVTN, presented by Jim Kublin and Ashley Clayton.

Click here for a dedicated program of HVTN-related coverage at HIVR4P. For slides and audio from HIVR4P presentations, visit this page.

Members of the IMPAACT Tuberculosis (TB) Scientific Committee and representatives of several IMPAACT study teams chaired sessions and presented important outcomes, updates and proposals for future TB research at the 49th Union World Conference on Lung Health in The Hague, the Netherlands, on 24-27 October 2018. More details on the network’s contributions at the conference are available on the IMPAACT website here.

MTN researchers presented on a range of topics at the recent 2018 HIV Research or Prevention (HIVR4P) meeting in Madrid, Spain. More than 25 presentations and sessions focusing on MTN-related research were presented at the meeting, with the findings from two MTN studies selected as part of the meeting’s official press program.

MTN-related HIVR4P press releases can be accessed in the News Room of the MTN website.

Be sure to also visit MTN’s Facebook page for photos from the meeting.

MTN is excited to announce that MTN-033 has completed enrollment. The Phase 1 study was designed to evaluate and compare the pharmacokinetics of dapivirine gel administered rectally by two methods — an applicator and a coital simulation device. The study included 16 participants at a site in Pittsburgh, Pennsylvania. The study results are anticipated in mid-2019.
WEBINARS & TRAINING

Upcoming Webinars

Part 1: Understanding HIV & Aging

*Thursday, November 8, 2018 @ 10AM 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. Special attention will be given to marginalized communities disproportionately impacted by HIV and AIDS, specifically African Americans and women. [Click here to register.](#)

Part 2: Multimorbidity & Polypharmacy/Lack of HIV expertise in Geriatrics

*Wednesday, December 5, 2018*

Registration link forthcoming.

Part 3: Experiences of Black Women Living and Aging with HIV

*Date TBD*

Training

*An Introduction to Transgender Communities*

*Available on the DAIDS Learning Management System*

This is the first of the five-module Transgender Training Curriculum for HIV Research series developed by the DAIDS Cross-Network Transgender Working Group. The remaining modules will be rolled out as they become available. The course requires a DAIDS Learning Portal account, which can be created by clicking on “Request Account”. [Start the course by clicking 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.
Community Partners held their annual face-to-face meeting on October 13-14 at the Hyatt Regency Crystal City in Arlington, VA. Thank you to those who were able to attend and for making this a positive and productive meeting.

The Behavioral Science Working Group (BSWG) is in the early stages of planning a webinar on economic incentives/behavioral economics with Dr. Omar Galarraga. Once the webinar is calendared, an invite with a webinar description will be emailed to all Behavioral & Social Sciences HANC collaborators.

The Behavioral Science Consultative Group (BSCG) continues to plan a webinar showcasing the work that BSCG members have provided on network protocols. Confirmed speakers for the webinar include Dr. Jessica Haberer who will present on the PHOENIx study and Dr. Michele Andrasik who will present on the AMP study. Originally, the webinar was going to be held in November, but due to scheduling conflicts, it will most likely be held in early 2019. Once the webinar is calendared, an invite will be emailed to all HANC collaborators.

The Youth Prevention Research Working Group (YPRWG) hosted a webinar on October 31, 2018. A recording of the webinar, “Adolescent Research Update: An Overview of ACTG A5359 and the DREAMS Partnership” can be found here. Presenters for the webinar were Dr. Aadia Rana, co-chair of ACTG A5359 and Dr. Sanyukta Mathur, the Project Director of the DREAMS Implementation Science Research portfolio at The Population Council.

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

HANC PROGRAM HIGHLIGHTS

Behavioral & Social Sciences
Greg Davis, HANC Project Manager

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Community Partners
Russell Campbell, HANC Deputy Director

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HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
Milan Vu, HANC Project Coordinator

The Data Management Center Working Group (DMCWG) continued to discuss efforts to unify data management evaluation metrics across the five networks, resolving to periodically review and track changes to data management metrics and standards moving forward.

The Evaluation Working Group (EWG) discussed harmonization of the Community Indicator Surveys, including network philosophies regarding the survey, scope of questions, and survey recipients.

The Site Coordinators Working Group (SCWG) reviewed progress along several site-relevant topics and initiatives, including the DMCWG’s effort to harmonize data management metrics, the Age and Identity Verification and Co-enrollment Prevention Policy, electronic Trial Master File system, and cross-network protocol deviation reporting CRF. The SCWG also held the first of two start-up calls orienting new members both to the SCWG and HANC. The second start-up call is scheduled for Wednesday, November 7, 2018 @ 8AM PT.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Clinical Pharmacology Quality Assurance group held a limited ad-hoc call to discuss results from the third pilot on intracellular measures of tenofovir-diphosphate and emtricitabine-triphosphate in peripheral blood mononuclear cells using one source for quality control preparations.

The Clinical Pharmacology Quality Assurance Monoclonal Antibodies and Small Molecule Tissue Pharmacology Working Group hosted a webinar presentation by Dr. Mark Marzinke from Johns Hopkins University School of Medicine on the considerations for small molecule drug quantification in tissue.

The Clinical Pharmacology Laboratories Forum hosted a webinar presentation by Kevin Ryan, Laboratory Manager at University of Alabama at Birmingham. The presentation focused on lessons learned from a recent FDA audit, providing information about GLP, FDA compliance, industry standards, regulatory management, and audit preparedness. If you would like a copy of the presentation, please contact HANC Laboratory Manger, Tyler Brown, at tdbrown3@fredhutch.org.

The Laboratory Technologists Committee (LTC) held a conference call with voting protocol support members to review committee nominations for the upcoming term. Eleven vacancies are to be filled for the new term, which begins December 1, 2018.

Virology Quality Assurance Advisory Board held a conference call to review new proficiency testing reports from RNA035, GEN034 and GEN035.

The Laboratory Focus Group (LFG) held a call to discuss their ongoing work with the DAIDS Clinical Laboratory Oversight Team to develop cross-network standards for how terminology is used on laboratory audit action plans.
The Legacy Project
Brian Minalga and Louis Shackelford
HANC Legacy Project Community Engagement Officers

The Legacy Project Working Group is currently soliciting nominations for co-chairs. The Legacy Project Working Group co-chairs may serve up to two terms of two years each. For more information about the co-chair nomination process and responsibilities, contact Russell Campbell at rcampbel@fredhutch.org.

**November 8-10:** Brian Minalga will represent the Legacy Project at the National Trans Health Conference in Atlanta, GA. Along with Tori Cooper and Rona Siskind, Brian will present, “First, Do No Harm: Fostering Transgender Awareness and Inclusion in HIV Research.” This 90-minute workshop will describe the process undertaken by the DAIDS Cross-Network Transgender Working Group to create a training curriculum for HIV researchers and research staff working with transgender research participants. It will also describe some of the recent advancements and ongoing studies in HIV biomedical research that are most relevant to transgender communities.

**November 14:** Submissions to BTG News, the quarterly newsletter on biomedical HIV prevention research, are due from the HPTN, HVTN, and MTN to Brian Minalga.

**November 20:** Transgender Day of Remembrance.

**November 28:** The Women’s HIV Research Collaborative opens nominations for co-chairs. WHRC co-chairs may serve for up to two terms of two years each. For more information about the responsibilities of co-chairs, contact Brian Minalga or the current WHRC co-chairs, Clare Collins and Liz Barr.

**November 30:** Abstracts due to the Pre-CROI Workshop on HIV and Women. The WHRC plans to submit one abstract on screening for intimate partner violence in HIV research settings.

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**Financial Disclosure**
Greg Davis, HANC Project Manager

The annual solicitation period ended on October 21, 2018. HANC would like to thank the Financial Disclosure Working Group for all of their efforts to ensure a successful solicitation period.
RESOURCES

Newsletters

**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.

**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.

**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 and IMPAACT clinical trial networks to make the large body of specimens collected for HIV research available to investigators. [Click here](#) to visit the site and request specimens.

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