NEW Webinar: You Want a Sample of My What? Clinical and Community Perspectives on the Use of Hair Samples in HIV Research

Join us on August 14 for a webinar about the use of hair samples in HIV research. This session will explore questions like why hair samples are such a powerful tool for monitoring HIV treatment and PrEP adherence, how lessons from historical research abuses can help researchers understand barriers and facilitators to research participation, and how donating a hair sample can present greater participant burden among certain cultures and religious groups.

Featuring Dr. Monica Gandhi, Moréniike Giwa Onaiwu, and Charles Z. Chasakara, this excellent group of presenters will give updates and answer questions on this emerging area of HIV research. Register here.
Different vaccine strategies called mRNA-1273 and AZD1222 tested against COVID-19 take center stage in two separate phase 3 studies

The first of several promising study vaccines will be administered to study participants enrolled across approximately 100 clinical trial sites in the US. The COVE study is led by Moderna as the regulatory sponsor and is providing the study vaccine called mRNA-1273. Study participants will receive two doses of mRNA-1273 or placebo administered 28 days apart. The primary scientific question of the COVE study is to evaluate the safety of mRNA-1273 and whether the study vaccine can prevent symptomatic COVID-19 after two doses.

A second phase 3 randomized, double blind, placebo-controlled trial, set to get underway in mid-August will test whether a different study vaccine called AZD1222 is safe, tolerable and prevents symptomatic COVID infection. AstraZeneca is the regulatory sponsor for the study and will provide the study vaccine. Study participants will be randomized to receive either the study vaccine or an injection of sterile saline solution. The injections will be administered to study participants four weeks apart, at days one and twenty-nine.

Study teams at participating trial sites will seek to enroll an estimated 30,000 study participants for each study. The Moderna study will take place in the US only. AstraZeneca will involve clinical trial sites globally.

The promising study vaccines are being tested under Operation Warp Speed, a multi-agency collaboration led by the Department of Human and Health Services that aims to accelerate the development, manufacturing and distribution of medical countermeasures for COVID-19. The COVID-19 Prevention Network (CoVPN) relies on the knowledge and expertise of infectious disease experts and its existing research networks to help coordinate the trials.

The studies are completely voluntary and interested individuals from diverse racial/ethnic, geographic, and age groups who are aged 18 years and older can visit http://www.coronaviruspreventionnetwork.org for more information.

CoVPN community webinars

As part of the CoVPN external relations team, HANC Legacy Project staff are organizing webinars with collaborators across the country to help inform underrepresented populations and address questions about COVID-19 vaccine and antibody research. Upcoming events include:

Our Bones Remember: Uniting to End COVID-19
Tuesday, August 11 from 10AM-11AM PT | Register here
Native communities in particular are dealing with a disproportionate impact of COVID-19. Urban Indian Health Institute is working with the CoVPN to bring you the latest information.
Building upon a strong foundation developed through HIV and TB research, AVAC, TAG, and ITPC are partnering with health advocates, civil society representatives and impacted individuals around the world to launch a COVID Advocates Advisory Board (CAAB). The CAAB builds on the experience of community advisory structures such as AfroCAB, Global TB CAB, World CAB, Coalition to Accelerate and Support Prevention Research (CASPR), ATAC, EATG/ECAB, NIH DAIDS Community Partners, and HIV Prevention Trial Design Academy, and was developed to bring civil society and community expertise to the COVID R&D enterprise. Robust community engagement and consultation is essential to support the ethical, efficient advancement of COVID R&D; build understanding and support for research studies in the communities in which they occur; and ensure equitable, global access to urgently needed interventions.

The CAAB’s work includes:

- Lobbying for formal engagement with all four pillars of WHO’s ACT-Accelerator (ACT-A) and the US government’s Operation Warp Speed, ACTIV and CoVPN programs, in order to ensure civil society input into research and access planning, development, implementation, and dissemination of results;
- Expanding research literacy to support civil society input into COVID-19 research at community, national, regional and global levels;
- Adapting and disseminating an approach to applying Good Participatory Practice Guidelines to COVID research;
- Facilitating meaningful dialogue among research teams and communities to include stakeholders' perspectives in the design, planning, and implementation of clinical trials and ensure open communication about research goals, processes, and results;
- Advocating for equitable access to products developed through COVID-19 R&D to all people in need.

The CAAB has been designed as a ready platform to facilitate meaningful dialogue among research teams and communities. For more information visit the CAAB website or contact us at avac@avac.org.
Examining the Role of Women in HIV Cure-Related Research

Women bear a significant burden of the HIV epidemic, yet they remain underrepresented in HIV research. Led by Dr. Eileen Scully of John Hopkins University, ACTG 5366 study is the first HIV cure-related clinical trial conducted entirely in women living with HIV. ACTG 5366 enrolled 31 postmenopausal women living with HIV, the majority of whom were women of color, at locations across the United States.

This paper highlights findings from two online surveys that were administered to participants, one at the beginning and the other at the end of the ACTG 5366 study, to gauge their thoughts and feelings about the trial. ACTG 5366 demonstrated that HIV cure-related research can recruit and retain women. It also showed the relevance and feasibility of incorporating patient-centered outcomes into biomedical research. Increasing the representation of women in HIV cure-related research is important to ensure that future treatments are safe and effective for everyone. Understanding how both the biological and social differences between men and women affect HIV is critical to achieving equity and justice in the treatment of HIV. The results of the ACTG 5366 study underscore the need for multidisciplinary collaborations that integrate participant values, perceptions, and lived experiences in HIV cure research.


Is Isoniazid Essential for Early Bactericidal Activity (EBA) in TB?

It has long been thought that isoniazid (INH) does most of its bacterial killing in the first two days of therapy. ACTG 5307 is a Phase 2a study evaluating four treatment arms:

- The standard regimen of INH+rifampin+ pyrazinamide+ethambutol for 14 days
- Rifampin+ pyrazinamide+ethambutol for 14 days
- INH+rifampin+ pyrazinamide for two days, followed by rifampin+ pyrazinamide+ethambutol for 12 days
- INH+rifampin+ pyrazinamide+ethambutol for two days, followed by moxifloxacin+ rifampin+pyrazinamide+ethambutol for 12 days

The authors found that all four regimens provided good early bactericidal activity that was not statistically significantly different across arms.

This study casts doubt on the long-held belief that isoniazid is essential for early killing of Mycobacterium tuberculosis during standard therapy. (continued on next page)
Genomic studies have shown that in most cases of multidrug-resistant tuberculosis, resistance to isoniazid precedes rifampicin resistance, and human studies have shown that the three-drug combination therapy of rifampin+ pyrazinamide+ethambutol for six months is effective. These observations, along with high rates of isoniazid mono-resistance, implicate isoniazid as the weak link in preventing the ongoing emergence of multidrug-resistant tuberculosis.

(The Lancet Microbe 2020 Jun; 1(2):e84–e92. doi: 10.1016/S2666-5247(20)30011-2; Diacon A et al)

Working to Uncover the Causes of Neurocognitive Impairment in People Living with HIV

Many people living with HIV experience deficits in memory, attention, and other aspects of brain function despite being undetectable on effective antiretroviral therapy (ART). For some individuals, this neurocognitive impairment is worse than seen in the general population and can interfere with quality of life, work, and other activities of daily living. The exact cause of this neurocognitive impairment is not known and doctors do not have good ways of treating it. To shed light on this issue, the ACTG 5303 investigators examined whether level of inflammation, or the degree of activation of immune cells in blood, was tied to presence and/or severity of neurocognitive impairment in people living with HIV. The study was designed this way because it is well known that inflammation and immune activation often remain elevated in people living with HIV despite effective ART and because elevated levels of these markers have been linked to other chronic diseases.

The participants in ACTG 5303 received ART for 48 weeks. Participants with high levels of interleukin-6, a marker of inflammation, were more likely to have neurocognitive impairment before ART was started. Having higher blood levels of proteins that indicate activation of lymphocytes was also linked to an increased likelihood of having neurocognitive impairment before ART initiation. However, the results after 48 weeks of ART were different. Specifically, presence of neurocognitive impairment after 48 weeks of ART was linked to evidence of activation of a different kind of monocytes. These findings suggest that the factors driving impairment before ART is started and those driving impairment while on ART may be quite different. Notably, no associations were found between neurocognitive impairment and the majority of the markers of inflammation and immune activation looked at in this study. Further, the associations found were modest. Taken together, these results mean we still have a lot to learn about the cause(s) of neurocognitive impairment in people living with HIV.

The HIV Prevention Trials Network (HPTN) has launched its first study enrolling exclusively adolescents under the age of 18. HPTN 083-01 is evaluating whether a pre-exposure prophylaxis (PrEP) regimen containing long-acting injectable cabotegravir (CAB LA) is safe and acceptable for adolescents assigned male at birth. Twenty-one percent (21%) of new HIV acquisitions in the United States occur among young people. Most of these infections occur due to sexual activity and about half of the youth who are living with HIV don’t know it. Read More.

There is no update from the HVTN this month. For the latest news, visit the HVTN website at www.hvtn.org.

The IMPAACT Network will soon be enrolling participants in IMPAACT 2032, a Phase I pharmacokinetic (PK) study of remdesivir in pregnant and non-pregnant women of childbearing potential for treatment of COVID-19. Women hospitalized for COVID-19 and receiving remdesivir as part of their clinical care (i.e., outside of the study) will be enrolled at 17 study sites located in the United States.

Learn more at https://impaactnetwork.org/studies/impaact2032.asp
On Friday, July 24, the European Medicines Agency issued a positive opinion of the monthly dapivirine vaginal ring to reduce HIV risk. This opinion moves the ring closer to approval in African countries for use by cisgender women. The ring’s developer, International Partnership for Microbicides, now plans to submit applications to national medical regulatory authorities in east and southern Africa, in collaboration with the WHO, and to the U.S. FDA later this year. In addition to MTN’s press release, the opinion was the topic of several other press releases from NIAID, International Partnership for Microbicides, UNAIDS and AVAC, as well as a joint statement issued by the International Community of Women Living with HIV (ICWEA), Advocates for the Prevention of HIV in Africa (APHA) and Emthonjeni.

The DESIRE, MTN-035, study has been completed. This global study evaluated three placebo methods (douche, insert and suppository) for the delivery of a rectal microbicide. An incredible effort by DESIRE study leadership, teams, sites and participants enabled the safe and timely completion of the study in the midst of the COVID-19 pandemic. Results are anticipated in 2021.
WEBINARS & TRAINING

Upcoming Webinars

Our Bones Remember: Uniting to End COVID-19  
*August 11 @ 10AM PT / 1PM ET*  
Native communities in particular are dealing with a disproportionate impact of COVID-19. The urgency of this pandemic calls upon all of us to unite and protect each other from this new virus. Urban Indian Health Institute is working with the COVID-19 Prevention Network (CoVPN) to bring you the latest information. [Register here](#).

Clinical and Community Perspectives on the Use of Hair Samples in HIV Research  
*August 14 @ 7AM PT / 10AM ET*  
Join us for a webinar to explore why hair samples are such a powerful tool for monitoring HIV treatment and PrEP adherence, how lessons from historical research abuses can help researchers understand barriers and facilitators to research participation, and how donating a hair sample can present greater participant burden among certain cultures and religious groups. [Register here](#).

Past Webinars of Interest

Understanding the EMA Opinion: Next Steps for Dapivirine Vaginal Ring  
*Aired July 29, 2020*  
AVAC held a webinar Understanding the EMA Opinion: Next Steps for Dapivirine Vaginal Ring for advocates to learn about next steps on the regulatory process and implications for rollout from advocates, International Partnership for Microbicides (IPM) and the WHO. [Watch the recording here](#).

HPTN 083 Community Webinar  
*Aired July 16, 2020*  
Researchers from the HPTN announced the HPTN 083 clinical trial showed that a pre-exposure prophylaxis (PrEP) regimen containing long-acting cabotegravir (CAB LA) injected once every 8 weeks was superior to daily oral tenofovir/emtricitabine (TDF/FTC) for HIV prevention among cisgender men and transgender women who have sex with men. [Watch the recording here](#).
**HANC PROGRAM HIGHLIGHTS**

*Need to contact a HANC staff member? [Click here](#) to go to the About the HANC Staff page.*

**HANC Staff Situation Update**

In accordance with Fred Hutch policies in response to the coronavirus situation in Washington state, HANC staff are working remotely until further notice. Work with HANC collaborators will continue with as few disruptions as possible.

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**Behavioral & Social Sciences**

*Greg Davis, HANC Project Manager*

The Behavioral Science Consultative Group (BSCG) will begin planning Part 2 of its webinar series, “Adherence Support Intervention Approaches Used in the NIH HIV/AIDS Clinical Trials Networks”. The BSCG had planned to host it in early summer, but it was postponed.

The Youth Prevention Research Working Group (YPRWG) is starting to plan for the fall webinar. The fall webinar will focus on the Adolescent Trials Network’s iTech trials. The ATN has added COVID-19 measures to the trials. Presenters include YPRWG member, Dr. Lisa Hightow-Weidman and Dr. Travis Sanchez. The YPRWG also recently submitted a proposal for a satellite session at HIVR4P. More information will be made available if the proposal is accepted.

The annual financial disclosure solicitation will occur on September 21, 2020. The Financial Disclosure Working Group recently updated the SOP. [The updated SOP can be viewed here.](#)

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**Community Partners**

*Russell Campbell, HANC Deputy Director*

Community Partners is in the process of updating the *Research Ethics Informed Consent Module* and the *Community Advisory Boards and Clinical Research and the Clinical Research Process* materials on the DAIDS Learning Portal. The Research Ethics Informed Consent module explores how research is ethically conducted and what the informed consent process involves. The other modules are intended for new CAB members and staff who are working to help orient CABs and provide a better clinical research process to help them be more effective.
HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
Milan Vu, HANC Project Manager

The Data Management Center Working Group (DMCWG) met to discuss experiences with Medidata electronic clinical outcome assessment (eCOA), updates on COVID-19 studies, and activation of Medidata Imaging Solutions for remote monitoring. The group continues to discuss ongoing work on protocol deviation reporting and safety data reconciliation.

The Cross-Network Communications Working Group (CWG) debriefed on major highlights from the AIDS 2020: Virtual Conference and reflections on moving major conferences to a virtual format. The group also discussed communication efforts from the Coronavirus Prevention Network (CoVPN), including the communications structure for the network, priorities, and lessons learned from working with various partners in the COVID-19 research space.

The DAIDS Office of Clinical Site Oversight (OCSO) joined the HANC-facilitated Cross-Network Site Coordinators Working Group (SCWG) meeting in July to present on the DAIDS Remote Monitoring Strategy for Source Document Review. A memo from DAIDS addressing the implementation of remote source document verification (rSDV) was issued on July 23, 2020 to network leadership and operations centers, CTUs, CRSs, and the data management centers. The memo is posted on the HANC website, under the DAIDS Resources and Announcements page. Link directly to the memo here.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held two conference calls to discuss lab site operations and logistics for ongoing and upcoming COVID-19 therapeutic and vaccine protocols, and the resumption of laboratory activities, including specimen testing at Quest Diagnostics Baltimore and specimen storage at the Biomedical Research Institute Repository.

The CPQA Advisory Board (CPQA-AB) held a conference call to discuss updates on the CPQA AVR/SOP Peer Review Program, CPQA-AB sub-working groups, and the CPQA Proficiency Testing Program, including the resumption of Round 45 shipments. The group also discussed updates from the ACTG COVID-19 Clinical Pharmacology WG and other COVID-19 related quality assurance activities.

The Lab Focus Group (LFG) held a conference call with members of the DAIDS Clinical Laboratory Oversight Team (DCLOT) and the Patient Safety Monitoring in International Laboratories group (pSMILE) to discuss DCLOT and SMILE-related program updates, ongoing operational challenges imposed by COVID-19, and planned changes to the current laboratory site monitoring process.
HANC PROGRAM HIGHLIGHTS

The Legacy Project
Brian Minalga and Louis Shackelford
HANC Legacy Project Team

Team Legacy is planning a number of sessions for the USCHA virtual meeting taking place in October.

Brian and the Women's HIV Research Collaborative are preparing for the APHA virtual conference taking place in October, where they will be presenting two sessions: "Addressing the intersection of intimate partner violence and HIV in women" and "Okay ladies let's get information: Women and biomedical HIV prevention." Brian will also be presenting a session on behalf of the DAIDS Cross-Network Transgender Working Group: "Fostering transgender inclusion in HIV research."

Legacy has been working with researchers in the Carolinas focused on establishing partnerships to address HIV disparities on HBCU campuses through the promotion of the HPR Module. As part of that on-going partnership, Legacy and HBCU researchers Drs. Lance Okeke and Kenric Ware will be presenting the workshop HIV Prevention for HBCUs on 8/14 from 11:00 AM-12:30 PM at the virtual Ryan White Conference.
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:

Leslie Raneri

Leslie Raneri is based in Houston, Texas, USA. She is a member of Community Partners and chair of the IMPAACT Community Advisory Board and the Texas Children's Hospital/ Baylor College of Medicine Community Advisory Board.

What do you like most about community engagement? I love making sure community voices are heard early and often in research development and implementation. Particularly in research with children, adolescents, and pregnant women, realities for families living with HIV must be included when developing research priorities, study designs, and processes for the research to be relevant and valid. Children and teens don't pop up at the research site by themselves; they come with parents/caregivers and other family members. As a family, we have been involved in research at our site and have different perspectives than research and medical staff. Frequently we see attempts to combine maternal, adolescent, and pediatric research with adult research, and see our priorities and perspectives overlooked and minimized. Since research has historically left out women, especially pregnant women, children, and adolescents, I believe our voices are essential in the research that will affect us, our families, and future generations.

Aside from my work with the IMPAACT ICAB and CP, I'm a mom to 2 daughters (17 and 19) and a hospital emergency room social worker. I love reading and learning new things and spending time with friends and family.

Morénike Giwa Onaiwu

Morénike Giwa Onaiwu, MA is a global advocate and educator who has been involved in HIV clinical trials community work for over a decade as part of the ACTG, IMPAACT, and the HPTN. A proud mother of five in a neurodiverse, serodifferent family, Morénike currently co-chairs two HANC working groups: Community Partners and the Women's HIV Research Collaborative.

She is also a member of the HANC Legacy Project Working Group. Previously, Morénike chaired the ACTG Global Community Advisory Board and served on the protocol teams of HIV/HPV study A5282; early COVID-19 trial A5395, the HPTN 065 Test & Link to Care Advisory Group, and the joint ACTG/IMPAACT maternal/pediatric study PROMISE (1077HS).

Morénike is passionate about meaningful community involvement and leadership, dismantling stigma, and empowering others.
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.

Behavioral Science Interest Group Newsletter
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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.