HANC ANNOUNCEMENTS

Join us in observing World AIDS Day this December 1st. The theme for the 2019 observance is "Ending the HIV/AIDS Epidemic: Community by Community".

Blood, Hair, Saliva: Addressing Mistrust in Medical Research and Demystifying How HIV Lab Researchers Use and Store Samples

The Office of HIV/AIDS Network Coordination (HANC) invites you to join a webinar that brings together a unique group of presenters to discuss the ongoing mistrust in research, and demystify one of the key components of clinical research: lab samples. Read more about the webinar under the Webinars & Training section, and register here!

DAIDS Applied Research Training (DART) Toolkits

New toolkits are available on the DAIDS Applied Research Training (DART) website. Read more about it under the Webinars & Training section on page 5!
This month, the ACTG is highlighting two important studies:

**NWCS 399: CT as Non-Invasive Assessment of Fat Quality**

Fat quality or function contributes to risk for diseases such as heart disease, fatty liver disease, and diabetes, and may be as important as fat quantity when assessing the risk of poor health outcomes. In the past, fat quality could only be determined by performing fat biopsies and measuring fat cell size under the microscope. However, measuring fat cell density on a CT scan may also measure fat quality (lower density=poorer quality/more poorly functioning fat cells). NWCS 399 compared data from abdominal subcutaneous fat biopsy specimens with fat density data from CT scans in the ACTG A5224s study (a substudy of A5202, which randomized adults living with HIV to abacavir/lamivudine (ABC/3TC) or tenofovir/emtricitabine (TDF/FTC) with open-label efavirenz (EFV) or atazanavir/ritonavir (ATV/r)).

Subcutaneous abdominal fat density was on the CT scans in Hounsfield Units (HU). Subcutaneous fat biopsy specimens were digitally scanned for calculation of mean fat cell area. All participants who had fat biopsy and CT data at baseline (n=54), undetectable viral loads on ART, and biopsy or CT data at week 96 (n=30) were included. At study entry (prior to starting ART), median age was 40 years, CD4+ T lymphocyte count was 219 cells/mm3, and BMI was 26.0 kg/m2; 89% of participants were male and 67% self-identified as Caucasian. Median subcutaneous abdominal fat quantity and density were 199 cm2 and -100 HU. Over 96 weeks of ART, fat quantity increased (+18%) and fat density decreased (-3%). Mean fat cell area correlated with fat density measured on CT scan both before and after ART and after adjusting for fat quantity, age, race, sex, CD4+ T lymphocyte count, and HIV-1 RNA. Therefore, subcutaneous fat density measured by CT scan served as an accurate representation of subcutaneous fat cell size in adults with HIV on and off ART, suggesting that CT is a useful tool for non-invasive assessment of fat quality. Further study of the use of CT-measured fat quality on health outcomes is indicated.


**1077HS/4: Predictors of Viremia in Postpartum Women on Antiretroviral Therapy**

Undetectable viral load is associated with optimal health outcomes for people living with HIV. However, among women living with HIV who have recently given birth and are on ART, there are high rates of viremia, which typically occurs because women are struggling to take their medication every day. 1077HS/4 sought to better understand the characteristics of post-partum women with viremia in order to understand how best to support their adherence. *(continued on next page)*
Congratulations to the HPTN 083-01 and HPTN 084-01 study teams for reaching protocol V1.0. Both are sub-studies of HPTN 083 and HPTN 084, investigating safety, tolerability, and acceptability of the long-acting cabotegravir (CAB LA) injection in adolescent populations in the U.S. and sub-Saharan Africa. Screening and enrollment are set to begin in December 2019 for HPTN 083-01 and April 2020 for HPTN 084-01.

The study enrolled a subset of women who were part of the PROMISE study. PROMISE was originally designed during the era when women living with HIV were instructed to take ART during pregnancy and then stop after delivery, if they had strong immune systems. PROMISE enrolled postpartum women with good immune function (CD4 counts > 400 cells/mm3) from 56 sites in Argentina, Botswana, Brazil, China, Haiti, Peru, Thailand, and the U.S. between December 2011 and November 2014. Women were randomly assigned to continue their ART (828 women) or discontinue it (825 women) under their providers’ supervision. When deemed medically necessary, women who discontinued treatment were put back on ART. 1077HS/4 looked at a subset of PROMISE women who were on ART during study follow-up: those in the group asked to continue ART (802 women) and those who discontinued ART but later restarted for a medical reason (137 women). Over 144 weeks of follow-up, researchers evaluated the frequency with which women experienced viremia (>1000 copies/mL), their ART adherence (self-reported missed doses), and their self-reported health.

The study found that viremia was common among all women who had recently given birth who were continuing on ART (~20%) and that most viremia was due to difficulty taking medication rather than drug resistance (only 12% had viremia due to resistance). Younger women, women who started ART later in pregnancy, and women enrolled from the South American/Caribbean region had the highest rates of viremia during follow-up. Women in the group who discontinued ART and restarted later had very similar rates of viremia compared to women who continued ART after delivery. Among women with viremia, many never returned to an undetectable viral load during the follow-up period. Information from this study and others like it can be used to design programs to support the adherence of postpartum women on ART and tailor these adherence interventions to women’s unique needs.

The Mosaico Study (HVTN 706/HPX3002) has officially opened as of October 31, 2019! The first site to open is the Crofoot Research Center in Houston, Texas, and the first participant enrolled has completed their first injection visit. We are excited about this news and look forward to the remaining sites in the United States opening soon. The other countries conducting this study are expected to open throughout the first quarter of 2020.

Stephaun Wallace, Ph.D., Social and Behavioral Sciences Junior Investigator Liaison at the HVTN and Staff Scientist in the Vaccine and Infectious Diseases Division at Fred Hutch, will give a talk at the upcoming NMAC Biomedical HIV Prevention Summit in Houston on Mosaico. During this talk Dr. Wallace will explore how the Mosaico study, and preventive HIV vaccines generally, fit into the context of the shifting landscape of HIV prevention. Dr. Wallace will be joined by the HPTN’s Dr. Sheldon Fields for a breakfast plenary entitled, Long-Acting Injectables and the Mosaico Vaccine Study: The New Paradigm on Biomedical HIV Prevention. This plenary will take place Wednesday, December 4th, 2019 from 8:30am-10:00am in the Houston Ballroom Salon 4, Level 3 of the Houston Marriott Marquis.

On Tuesday, December 10th from 8am-9am Pacific Time, Dr. Michele Andrasik will join other presenters on a HANC webinar entitled, Blood, Hair, Saliva: Addressing Mistrust in Medical Research and Demystifying How HIV Lab Researchers Use and Store Samples. During this webinar, the presenters will describe and discuss historical abuses and misinformation that continue to foster mistrust and fear related to research participation, and share reliable information about the use of human samples in the conduct of HIV research. To register for the webinar please [click here](http://www.hvtn.org/ramp).

The HVTN RAMP Scholars Program has released its latest request for applications, which are due January 6, 2020. This program is focused on African American/Black and Latinx medical students interested in HIV vaccine research. The HIV Vaccine Trials Network, in collaboration with the National Institute of Mental Health, the National Institute of Allergy and Infectious Diseases, and the Bill & Melinda Gates Foundation, is investing in a young generation of HIV prevention researchers by providing African-American and Latinx medical students with opportunities to conduct independent research while receiving mentoring, project and salary funding, training, and professional development opportunities. Complete information and the Request for Applications can be found at [http://www.hvtn.org/ramp](http://www.hvtn.org/ramp).
The MTN will be holding its final in-country stakeholder meeting for the planned **DELIVER (MTN-042)** and **B-PROTECTED (MTN-043)** studies that will be evaluating the safety of the dapivirine vaginal ring and Truvada as oral PrEP in pregnant and breastfeeding women, respectively. The two-day meeting will be taking place in Harare, Zimbabwe, January 28-29, 2020. Similar meetings have already been conducted in Malawi, South Africa and Uganda. As with previous meetings, the MTN is partnering with AVAC as well as local civil society and NGO partners. These include the Pangea Zimbabwe AIDS Trust and the Organization for Public Health Interventions and Development, working closely with the Zengeza Clinical Research Site of the University of Zimbabwe College of Health Sciences – Clinical Trials Research Centre.
WEBINARS & TRAINING

Upcoming Webinars

Blood, Hair, Saliva: Addressing Mistrust in Medical Research and Demystifying How HIV Lab Researchers Use and Store Samples
December 10, 2019 @ 8 AM PST
This webinar will address the historical abuses and misinformation that continue to foster mistrust and fear related to research participation, and share reliable information about the use of human samples in the conduct of HIV research. How are samples handled and utilized by researchers? What safeguards are in place to protect sample integrity? Join us as we discuss these questions, dispel common myths about what can happen to a sample after it's donated, and explore unique sample types, such as hair, that can present greater challenges and participant burden among certain cultures and religious groups. Register here.

Training

Good Clinical Practice (GCP) and International Council for Harmonization (ICH) Compliance Toolkits
Available on the DART website
The DAIDS Applied Research Training pilot this fall kicked off a new style of training for the Division of AIDS. Since then attendees have requested information about how to implement this style of training at their site. To assist with this need, DAIDS created a series of toolkits with instructions on implementing activity-based training locally for your staff.

The toolkits focus on different elements of Good Clinical Practice (GCP) and International Council for Harmonization (ICH) compliance at clinical research sites. Each kit is a stand-alone training element that can be used by sites to educate on a particular topic, but they also build upon each other to give a wider understanding of these topics. To start using the toolkits today visit the DART website. DAIDS strongly encourages you to share this information with your staff and check out the site to see if any of the tool kits can be used for your training needs.

Any questions regarding the DART website can be sent to DARTsupportteam@niaid.nih.gov.
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 Consultative Group (BSCG) will meet via conference call again on December 18. The group will begin discussing plans for the BSCG’s 2020 face-to-face meeting. In the past, the BSCG has met before or after IAPAC’s Adherence Conference (June 7-10). The BSCG will continue discuss webinar topics for 2020. More details will be available in the near future.

The Youth Prevention Research Working Group (YPRWG) will have its next call on December 5. The YPRWG will discuss whether or not it will submit an abstract to host a satellite symposium at AIDS 2020 (July 6-10). Other notable discussion that the YPRWG will have on the call are webinar topics for 2020 and having community representation on the YPRWG.

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

Community Partners is delighted to have Morénike Giwa-Onaiwu as our new ACTG representative! In addition, Community Partners is in the process of selecting new co-chairs for the group.

**Cross-Network Coordination**
*Milan Vu, HANC Project Manager*

The Cross-Network Site Coordinators Working Group (SCWG) met in November to discuss new ideas for the working group to focus on in 2020. Members identified several topics to explore in the upcoming year, including clinical trial management systems for sites, investigator of record (IOR) training and additional data to improve site performance and quality.

The ad-hoc Pregnancy Outcomes Data Working Group (PODWG) will meet on December 11th to finalize the working group charter and identify steps to move forward with improving standards for collecting data related to pregnancy outcomes and data sharing between the data management centers.
The Lab Technologists Committee (LTC) held two conference calls to discuss new LDMS compliance standards, SOP updates for leukopak shipping, and the implementation of modified process and training requirements reflected in the new DAIDS Good Clinical Laboratory Practice (GCLP) Manual. The LTC SOP Working Group held four conference calls to continue developing new Lab Processing Chart Standard Wording Documents.

The Laboratory Focus Group (LFG) held a joint conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) to discuss quality assurance improvements and the rollout of changes included in the GCLP Manual v4.0.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to introduce Duke VQA team members, new VQA and VQAAB standards under Duke, and review seven DNA and RNA Summary Reports.

Other Cross-Network Lab Announcements and Updates:

- The Special Studies Department at Quest Diagnostics Baltimore will not be staffed on Saturdays until 4 January 2020. Until then, please do not ship specimens for Saturday delivery. Anything received on Saturday will be maintained at the temperature it was received until the following Monday. Please contact Larry Hirsch at Larry.A.Hirsch@questdiagnostics.com with any questions.

- A new DAIDS training module, "Preparation for Regulatory Inspections at Laboratories," is now available on the DAIDS Learning Portal. This module is intended for staff at laboratories that are participating in DAIDS-supported and/or sponsored clinical trials so that they may prepare themselves and their laboratories for potential regulatory inspections. Click here to visit the course page and get started.

- The Clinical Pharmacology Quality Assurance Program (CPQA) has issued a new online Clinical Pharmacology Study Conduct Tutorial designed to educate clinic and laboratory research staff on the collection, handling and processing of samples at sites that conduct clinical trials with one or more pharmacology objectives. Click here to access the tutorial on DAIDS Learning Management System.

**Biomedical HIV Prevention for Women:** a comprehensive training on biomedical HIV prevention (present and future) specifically for cisgender and transgender women. This training includes slides, speaker notes, and a facilitator's guide for those who would like to present it in their communities.

**Women & HIV Cure-Related Research:** a comprehensive training on the state of HIV cure-related research and the meaningful involvement of cisgender and transgender women in this research. Slides and speaker notes are available to download. See also the video interview Brian Minalga did for Contagion News to learn more about this issue.
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:

**Rona Siskind, M.H.S.**
Rona Siskind is a current member of Community Partners. She is a Health Specialist at the Division of AIDS, located in Bethesda, Maryland.

*From Rona:*
*What I like most about community engagement are the community members who are involved with our research networks reflect the diverse communities in which we conduct our research, and help us to better understand community needs and concerns, and to address critical issues and challenges. When communities are well-informed and given a voice, the research is better designed and more successful. Personally, I consider it a privilege to work in support of community engagement and as a part of Community Partners. I learn from all the different perspectives and admire everyone’s dedication, sincerity, and passion. It’s a constant source of inspiration.*

*In my spare time, I love to draw and paint, practice yoga, and go for a hike!*

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**Tyler Adamson**
Tyler is currently a Congressional Fellow working on Health and Addiction Policy. He has Bachelor of Science and Arts in Molecular Biology and Anthropology from Johns Hopkins University, as well as a Masters of Public Health from Johns Hopkins University.

*From Tyler:*
*My background is in biomedical and diagnostic device development but I have since pursued further education in public health, epidemiology, policy and human rights. I joined the Legacy Project Working Group almost two years ago, and have been honored to support further efforts to engage and collaborate with Indigenous and other underrepresented communities around the United States.*

*Community engagement is a constant reminder that we are not the experts in this realm, we go to these communities for their expertise and knowledge, and are but a conduit towards the knowledge and outcomes they already know and see for themselves. Our role is to partner with the work already being done and empower community leaders to continue to lead this work.*
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

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.

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