CAB Conference Call
February 25, 2016
12:00 EST
Meeting Minutes

Participants:

Alexandria	FSTRF
Andrea	Jacobi Medical Center
Carrie	University of Colorado, Denver
Claire	Harvard University
Delia	University of Miami
Exzavia	Children's Diagnostic and Treatment Center
Jeanie	University of Southern California
Joel	University of Puerto Rico
Juanita	Tulane University
Julie	Harvard University
Julie	Westat
Kimberly	Rutgers New Jersey Medical School
Kimbrae	Texas Children's Hospital
Kylie	Texas Children's Hospital
Lesley	Texas Children's Hospital
Megan	Westat
Michael	University of Florida, Jacksonville
Raiko	University of Colorado, Denver
Stephanie	University of California, San Diego
Stephanie	University of Miami
Tatania	Tulane University
Theresa	Texas Children's Hospital
Trenise	Tulane University

• APPROVAL OF MINUTES

The minutes from the January 26, 2016 call were approved with no changes.

• SMARTT VERSION 5

Julie from Harvard talked about the Surveillance Monitoring for ART Toxicities Study (SMARTT), Version 5. SMARTT looks at uninfected children born to mothers with HIV. The goal of SMARTT is to study the long-term safety of HIV-medications for babies who were exposed to them in the womb or after birth. There are many changes in SMARTT Version 5. SMARTT participants were scheduled to come off the study at age 18. SMARTT Version 5 will include a Young Adult (YA) Cohort. There will also be changes to the SMARTT Dynamic and Static Cohorts.

The SMARTT YA Cohort will include participants ages 18-24. As SMARTT participants get older they may not be able to come into the clinic for visits. Participants who were in the SMARTT study will be able to join the SMARTT YA Cohort. Participants must have reached "the age of majority" to join. The age of majority is 18 in most states. In some states and Puerto Rico, that age of majority may be older than 18. Participants must be aware that their mom had HIV while she was pregnant with them. This is because they will have to agree to participate in the study as adults. They will sign their own informed consent form. Participants with legal guardians may also be in the study. In those cases, participants and their legal guardians must sign the informed consent forms.

Before potential SMARTT YA Cohort participants are told about the study, they must know about their biological mom's HIV status. Starting at the Year 13 SMARTT visit, study staff will talk to caregivers

about disclosure. The disclosure surveys will be given to caregivers privately. This is so there is no accidental disclosure without the caregiver's permission. The surveys will take place during the Year 13, 15, and 17 visits (if needed). This means there will be plenty of time for site staff and caregivers to work together to make sure that no participants are approached who shouldn't be approached due to non-disclosure.

The first study visit for the SMARTT YA Cohort is the Entry Visit. The entry visit can take place in the clinic. Participants will be asked to answer questions in an online survey during each visit. There will also be a chart abstraction at the entry visit. Chart abstraction is when the site staff looks up information about a participant through their medical records. Other assessments will include physical assessments like blood pressure, height, weight, and a blood draw for the repository. The repository is a place where blood and/or other specimens are stored. There is a repository in SMARTT so that researchers can look at blood samples in the future. This is because there may be more advanced tests in the future. There may also be new research questions that are formed after the researchers learn more about HIV. Finally, there will be a survey about depression at the entry visit called, the Center for Epidemiologic Studies Depression Scale (CES-D10). Only the chart abstraction and online surveys will be done if the participant is not able to come to the clinic.

There are many topics in the online survey. Topics include demographics, general health information, and healthcare. There will also be questions about diagnoses and medications. The reason for asking questions about diagnoses and medications is because chart abstraction will not be done on everyone. If a participant reports a medication or a diagnosis that is particularly important, it will alert the site staff to do a chart abstraction. If this happens, the site will get a basic email that tells them to do a chart abstraction. The email will not show any specific information that the participant answered on the survey. This is to protect the participant's privacy. Finally, there will also be questions on the online survey about sexual behaviors, substance abuse, and stigma.

Follow-up visits in the SMARTT YA Cohort will include yearly online assessments. Follow-up visits may also include chart abstraction, if needed. If a participant is not able to do the online surveys, site staff may try to do a phone interview. The study team put together instructions for participants that show them how to protect their privacy when completing the online surveys.

SMARTT Version 5 will also include changes to the Static and Dynamic cohorts in SMARTT. If a participant meets a neurodevelopmental trigger he/she will no longer need to do a neurology consultation. This is to help make visits less time consuming. There will no longer be POC lactate test checking for lactate levels. Lactate levels used to be measured using a finger stick. The machine that measured lactate levels is no longer being made. The study team decided that they have enough data from the previous POC lactate measures and no longer need to measure them. In previous versions of SMARTT, if a participant's POC lactate was a certain level, then he/she would need to have a venous lactate or pyruvate test. These samples are taken from a participant's arm. In Version 5, venous lactate or pyruvate will only be measured if a growth or neurology trigger is met. There will again be clinic visits during Years 13, 15, and 17. The visits will include chart abstraction and some physical assessments. There will be blood tests at age 15. Caregivers will also take disclosure and stigma surveys during the Years 13, 15, and 17 visits. Finally, participants will complete the Audio Computer Assisted Survey Instrument (ACASI) during these visits.

• PHACS CAB EVALUATION SURVEY

Megan talked about the survey. There were 7 responses. Topics suggested through the survey included:

- Dementia and HIV;
- Recruitment;
- Opportunities for community input;
- Nutrition and HIV;

- HAART update; and
- AMP Up.

Megan and **Claire** will talk about study visits during the March CAB call.

• SPOTLIGHT ON PHACS CAB MEMBER SKILLS

Michael talked about skills in advocacy. It can help to pay attention to participants who are happy with their care. Encourage participants to get involved. Peer advocacy can help reach troubled participants because peers understand what a participant may be going through since they may have gone through it themselves. If participants are not involved in their own care, they may leave treatment. This can result in a participant not taking his/her medications. It is best to find a way to keep in contact with participants. It can help to create a network of peer advocates so that everyone can advocate for each other's care.

• PHACS CAB NEWSLETTER, JANUARY 2016 EDITION

Megan talked about the PHACS CAB Newsletter, January 2016 Edition. The newsletter was sent out to all PHACS members. Megan thanked the CAB for submitting articles to the newsletter. The Spanish version is in progress. All CAB newsletters may be found on the PHACS website: https://my.phacsstudy.org/cab/CAB-Semi-Annual-Newsletter.

NOTE: The next CAB call will be on Thursday, March 24, 2016 at 12:00 pm EST.