

**CAB Conference Call  
September 28, 2017  
12:00 EST  
Meeting Minutes**

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**Participants:**

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<b>Claire</b>	Harvard University
<b>Delia</b>	University of Miami
<b>Ellen</b>	Ann & Robert Lurie Children's Hospital of Chicago
<b>Exzavia</b>	Children's Diagnostic and Treatment Center
<b>George</b>	Harvard University
<b>Gena</b>	University of Miami
<b>Jennifer</b>	University of Colorado, Denver
<b>Juanita</b>	Tulane University
<b>Julie</b>	University of Alabama, Birmingham
<b>Julie</b>	Westat
<b>Kimberly</b>	Rutgers New Jersey Medical School
<b>Kimbrae</b>	Texas Children's Hospital
<b>Kylie</b>	Texas Children's Hospital
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<b>Marilyn</b>	Bronx-Lebanon Hospital Center
<b>Megan</b>	Westat
<b>Raiko</b>	University of Colorado, Denver
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<b>Russ</b>	Tulane University
<b>Shannon</b>	University of Alabama, Birmingham
<b>Stephanie</b>	University of California, San Diego
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<b>Veronica</b>	University of California, San Diego
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• **APPROVAL OF MINUTES**

The minutes from the August 24, 2017 call were approved with no changes.

• **PHACS FALL 2017 NETWORK MEETING AND CAB RETREAT – Q & A**

**Drs. Ellen Chadwick, George Seage, and Russ Van Dyke** reviewed the CAB's questions from the PHACS Fall 2017 Network Meeting and CAB Retreat. Questions and answers included the following:

- **Has the team considered looking into other aspects of women's reproductive systems such as fibroids, cysts, and/or early menopause?**

The study team will collect any medical history in the medical records for women participating in the Women's Cohort. The first year of the Women's Cohort will focus on mothers with children in SMARTT. Specifically, the cohort will enroll women with children in SMARTT who are 4 years and under. This is because the Women's Cohort was funded as a substudy of SMARTT. The team may consider researching early menopause in the future. The team may also collect more detailed gynecological history in the future.

- **What is the ARV registry?**

The ARV registry is a database. It is a collaborative database used by the CDC, the FDA, and the NIH. The purpose of the ARV registry is to have a database of medications used in pregnancy to monitor any poor outcomes. Doctors enter their pregnant patient's information in the database. Information includes medication, gestation, and any adverse events. PHACS is currently working to input data from the SMARTT Dynamic Cohort into the ARV registry.

- **Can women who have not yet had children participate in the Women's Cohort?**

Currently, only women with children participating in SMARTT will be eligible to participate in the Women's Cohort.

- **Why is it important to study women with repeat pregnancies?**

It is not uncommon for women to fall out of care after their first pregnancy. The team is looking to study if women fall out of care after their first pregnancy. If they have fallen out of care, the team wants to look at if there is any difference in health status from one pregnancy to the next.

- **Is the team considering exploring adherence and its relation to medication side effects? For example, are some women reporting lowering adherence rates due to high rates of adverse effects of their medications?**

The team will be studying adherence. Lower adherence rates may be due to medications that are hard to tolerate.

- **Will the Women's Cohort be looking into heart failure in women after they've given birth?**

The team will study any complications in the health of women between pregnancies. This would include heart health.

- **Will you be studying plaque buildup in arteries?**

Data on plaque build up in arteries may possibly be looked at in the future. This could require more data to be collected on women. Right now, the team is looking at data that has already been collected.

- **Are you looking at recruiting women earlier in their pregnancy? How will you go about doing that?**

Women will be enrolled during their first trimester. Site staff is working with birthing hospitals. This is so when a women comes to a birthing hospital to start prenatal care, they can connect her with PHACS staff. This will hopefully help engage women early in their pregnancy. This is something that will help researchers understand women's health during pregnancy.

- **Have they found a significant amount of memory loss in HIV-exposed but uninfected children (HEUs) and perinatally HIV-infected children (PHIVs)?**

PHACS has found subtle outcomes in cognitive measures, including memory. In most cases, the outcomes have been the same between the HEUs and PHIVs. Overall, scores on neurological tests have been slightly lower than average. However, they have been similar between the two groups. That being said, PHIV Children with advanced disease tend to have lower scores.

- **Has any DNA research been done/started yet? What are some of the questions you might be looking at?**

The DNA research will be getting started soon. PHACS has loaded all results into their database. All DNA analysis is complete. The team is going to start addressing some of the research

questions soon. Research questions will center around complications. This includes neurocognitive changes, changes in growth, and metabolic problems. All of these complications could have genetic factors. Some people are more predisposed to certain conditions than others. Additionally, some people might be more vulnerable to side effects of ARVs because of genetics. Studying DNA will help PHACS learn more about how much genetics plays a role.

- **It was noted that youth who had been very sick in the past had more trouble remembering to do things when they were supposed to. Does this suggest that it's the virus causing more memory issues than the medications?**

PHIV children with more advanced disease may have greater problems with memory. This may be due to the virus and the degree of viral infection. It may also be due to the inflammatory markers associated with viral infection. The team is particularly interested in studying PHIV children, who had more advanced disease when they were very young. Researchers want to study whether these children have more poor health outcomes later in life.

- **Does the way a person feel about a medication affect their motivations to take it? Does emotional regulation play a role in prospective memory and adherence?**

Adherence can be very complicated. How a person feels about their medication can influence whether they take their medications. Memory and poor neurological outcomes can make an important impact on someone's ability to take their medications.

- **Are you looking into social factors that may impact memory and adherence?**

PHACS is looking into social factors that may impact memory and adherence. Specifically, the team is looking at social circumstances, family status, and socioeconomics. The team is also looking at education levels and resources. All these factors can contribute to a variety of outcomes. Outcomes may include memory, adherence, and other neurocognitive outcomes.

- **Can environment or other factors change DNA?**

Epigenetics is the study of biological changes that switch genes on and off. PHACS is looking to identify specific genes and genetic make-up. DNA can be changed by the environment. In these cases, the DNA is modified by chemical changes to the DNA. Some genes that are normally expressed may be less frequently or more frequently expressed due to epigenetic changes. Measuring epigenetic changes can be challenging.

- **How is data protected in the DNA studies? Can government or law enforcement agencies gain access to someone's DNA data?**

There are legal provisions that protect research data. This includes the PHACS Certificate of Confidentiality. This certificate protects PHACS in the case of a court-ordered subpoena. While research data is highly protected, anything is possible. PHACS uses many measures to make sure data is protected. All of this is disclosed in the informed consent form, so that participants can make an informed decision about whether to participate in DNA studies.

- **As the children grow up in PHACS, do researchers continue data abstraction every year?**

Researchers continue to use chart abstraction. Chart abstraction is the major way PHACS researchers can follow children into adulthood. It allows researchers to monitor how a participant is doing without having them come into the clinic in person.

- **Are participants notified when they have missing data? What if they could retrieve their medical records, but didn't know that the doctors needed them?**

Missing data is primarily a site issue. Participants are not primarily responsible. Missing data can often be due to having problems finding a participant's medical record.

- **Has PHACS employed any of the strategies for missing data yet that Sean Brummel reviewed during his presentation? If not, is there a plan in place?**

PHACS is using some of the techniques used to create some of the missing data. These techniques can help to fill in gaps in missing data. However, site staff members are still encouraged to collect as much data as possible to avoid missing data.

- **Did the research team look into whether passing out information to people potentially affected by Zika would lower the infection rates?**

Research has not yet been done to look into whether passing out information regarding Zika would lower infection rates.

- **Regarding the “placenta protocol,” during a C-section, how do they capture the placenta?**

During a C-section the placenta is captured very similarly to a vaginal delivery. It is not difficult to obtain the placenta during a C-section.

- **Has there been any study into the severity of adverse effects (such as microcephaly) in babies who got Zika from mothers who acquired it themselves vs. mothers who acquired Zika by sexual contact?**

No research has been done yet. There are very few transmissions by sexual contact. The team is looking into the timing of infection. Researchers will study timing in relation to the impact on the fetus.

- **What findings are you seeing for low white blood cell count among PHACS HEU youth?**

There are no significant findings.

- **Has there been any correlation in low white blood cell count and CMV?**

Children born with CMV have low white blood cell counts. There have not been many children born with CMV. Because there are few cases, there are not enough participants to correlate a relation between low white blood cell count and CMV.

- **Will WIN data also be collected in the SMARTT YA Cohort?**

WIN data will not be collected in the SMARTT YA Cohort.

- **Are researchers monitoring HEUs with genetic links to skin cancer and early skin cancer?**

Some genomic sequencing has been done in the PHIV cohorts. In these cohorts, researchers are looking to associate genetic DNA changes with cancers and other outcomes. DNA testing has not yet been done in the HEU cohorts.

- **Is bone health continuing to be studied in SMARTT?**

Bone health is continuing to be studied in SMARTT. PHACS is looking at bone fractures. Fractures can be the best way to study abnormal bone health. Fractures can potentially identify decreased bone health and decreased bone density. Researchers want to look at how fractures occurred and the cause of the fractures.

- **Is there any data regarding the use of vitamin D supplements in PHACS participants?**

PHACS researchers continue to study vitamin D. There is an analysis being done regarding vitamin D and supplementation as it relates to bone health.

- **Have any recommendations for vitamin D supplements come out of PHACS?**

Between PHACS and other studies, it is becoming increasingly recognized that vitamin D deficiency is very common among PHIV children. It is suggested that PHIV children should be screened for vitamin D deficiency. If vitamin D levels are low, it is suggested that children get supplements to raise levels. Some recommendations regarding vitamin D have come out of PHACS and other studies.

- **It was noted that use of combination ARVs after birth for infants of women living with HIV is increasing in the US. But some clinics still seem reluctant to use it. Was any research done as to why some clinics still seem reluctant to use it?**

The PHACS team is continuing to research this question.

- **Is there a plan to continue to study brain imaging following the pilot study that occurred? What about in AMP Up?**

PHACS hopes to continue to study brain imaging. Data from brain imaging can tell us how the brain is developed and how it is functioning.

- **How will you collect the cervical wash? Is this something young women can do themselves or do they need to go into a clinic and have it done?**

Participants will not be able to collect cervical wash themselves. Cervical wash will be obtained during a pelvic exam. The doctor squirts a saline solution over the cervix. The doctor then collects the saline solution that washes off the cervix.

- **Will the HPV study visits be combined with Pap exams? What about combined with other PHACS visits?**

The HPV study visits will be combined with the regular PHACS visits. They pelvic exam will be done by an obstetrician/gynecologist or trained study coordinator.

- **Is there any data on caregiver (non-biological parent) disclosure to HEUs?**

PHACS collects disclosure data starting at 10 years of age in SMARTT. Disclosure information is also collected from the non-biological parent.

- **Has PHACS done any research on stress-related pulmonary issues in PHIV/PHEU?**

PHACS has collected some stress data. However, this data has not been correlated to pulmonary issues.

- **Has arrhythmia been studied in relation to specific ARVs?**

Arrhythmia means abnormal heart rate. This is not yet been studied in PHACS.

**NOTE: The next CAB call will be on Thursday, October 26, 2017 at 12:00 pm EST.**