CAB Conference Call
July 22, 2021
12:00 ET
Meeting Minutes

Participants:

Carol	Bronx-Lebanon Hospital Center
Carrie	University of Colorado, Denver
Claire	Harvard T.H. Chan School of Public Health
Eduardo	Harvard T.H. Chan School of Public Health
Falon	University of Colorado, Denver
Haleigh	FSTRF
Joel	University of Puerto Rico
Karim	Westat
Kimbrae	Texas Children's Hospital
Kylie	Texas Children's Hospital
Mandy	Harvard T.H. Chan School of Public Health
Lela	Ann & Robert H. Lurie Children's Hospital of Chicago
Lesley	Texas Children's Hospital
Megan	Westat
Paige	Harvard T.H. Chan School of Public Health
Raiko	University of Colorado, Denver
Shary	University of Southern California
Tracy	Westat

• APPROVAL OF MINUTES

The minutes from the June 24, 2021 call were approved with no changes.

• DISCUSSING THE SMARTT PROTOCOL WITH PHACS MPI, DR. PAIGE WILLIAMS

Megan introduced **Paige Williams**. **Paige** talked about changes to the SMARTT protocol. The changes are part of Version 6.0.

The goal of SMARTT is to evaluate health outcomes in children. The children were not born with HIV, but were exposed to antiretroviral (ART) medications in utero. The research question is to examine whether exposure to maternal ART will impact children. Impact could vary by type and timing of ART use while the mothers were pregnant. The study purpose is to make sure that medications are safe for the mother and the child. The study is looking to detect any problems with the medications. The study is going to enroll 200 mother and baby pairs per year.

Paige described the SMARTT study. She explained that there will be two main cohorts:

1. Intensive Cohort:
    - 200 mother-baby pairs will be enrolled each year
    - Follow-up study visits are scheduled from birth to age 5
    - The goal is to evaluate the health impact of the following:
        - potential adverse birth outcomes
        - changes in different areas such as the following:

- growth,
- neurodevelopment,
- cardio-metabolic,
- maternal, and
- oral health.

- In addition to the follow-up study visits, there will be detailed visits a birth, age 1, age 3, and age 5

2. Extended Cohort
    - Participants in this cohort will participate in long-term follow-up to age 17.
    - The goal is to evaluate the following:
        - continuing or resolved adverse events
        - Profiles of health (only in a sub-group of participants)
    - Study visits at age 7, 9, 11, 13, 15, and 17
        - Detailed study visits at age 9 and 15. These visits will include:
            - Growth and Physical Exam
            - Labs
            - Neurodevelopmental / behavioral
            - Mental health - anxiety and depression
    - Total number of participants (~1400-1500) include:
        - Random sample: Approximately 40% of all enrolled participants in each site.
        - Cases (~600). **Paige** explained that a "case" will be chosen by the following:
            - Participants will start at the Intensive Cohort. If the child is identified as a "case," then they will move into the Extended Cohort after they complete the Intensive Cohort. Participants not identified as cases will go off study after they complete the Intensive Cohort.
            - To identify cases, the study team will analyze different triggers in the following areas:
                - Metabolic
                - Growth
                - Language
                - Neurodevelopment
                - Neurologic
    - The research team will let the sites know which participants are selected for the Extended Cohort at the following time points:
        - Participants age 5 or over selected to the Extended Cohort (cases and random sample) - before Version 6.0 opens
        - Participants under age 5 selected to the Extended Cohort (cases and random sample) – at age 5 visit
        - Participants under 5 not selected – sites will be notified after age 5 visit and before age 7 visit

Kim thanked **Paige** for presenting the SMARTT protocol. CAB members had the following questions:

- **Kim** asked if the study will look at children who had problems at birth. **Paige** answered that the study will look at problems at birth.
- **Raiko** asked if the study will examine children who develop triggers after age 5. **Paige** answered that they will not because researchers previously found in SMARTT that the majority of children had triggers before age 5.
- **Kim** asked if surveys that will be used in the study are available in other languages (other than English). **Paige** answered that the surveys will be available in Spanish and English. She explained that they hope to be able to offer more language options in the future.
- **Raiko** wondered if there will be check-ins between visits. She asked about health issues that could happen between visits that will not be addressed in the surveys. **Raiko** suggested to create an email or call line were participants could leave a message if they have any issues. **Paige** recognized that they could miss health issues including mental health concerns between visits. However, the sites should contact participants between visits. In addition, she mentioned that there is a comment report that Site Coordinators can use to give feedback about the study visit. The report could be used to indicate issues between visits. **Paige** will recommend that sites consider creative ways to ask participants and caregivers about health outcomes in between visits.
- The HECC is working ideas for retention. **Kim** suggested that sites do birthday check-ins. **Paige** mentioned that other retention ideas included newsletters, birthday cards, and coloring books.

Paige talked about the next steps for the SMARTT protocol. She explained that FSTRF will register participants for the Extended Cohort. No new consent is required. **Paige** noted that there may be times where siblings or twins are randomly selected for the Extended Cohort. This could mean that one sibling or twin is accepted and the other is not. In these cases, sites can request enrollment of twins and siblings. Caregivers might prefer that all siblings be in the study. Additionally the HECC and Site Coordinators will work on designing a letter thanking participants and families who are not continuing in Extended Cohort.

Paige talked about other SMARTT evaluations including the following:

- Mothers can enroll prior to delivery (ideally by 26 weeks gestation). Children can be enrolled up to 14 days after birth.
- There will be some laboratory evaluations. This includes a fasting metabolic panel at ages 5, 9, and 15. Some lab evaluations will be abstracted from the participants' medical records if they already had them done recently. A stool sample for the repository will be collected at age 1. Researchers want to study stool to look at the different bacteria. Some research has shown that diversity of bacteria can predict health outcomes.
- There will be some brand new assessments for participants and caregivers including the following:
    - Oral health questionnaire and collection of 1-3 baby teeth
        - **Paige** explained that the researchers understand that some caregivers may not be comfortable with giving their children's baby teeth.
    - Mental health assessments for children
        - These assessments will be given to children ages 11-15
        - These assessments will be done in an interview format to allow site staff identify issues
    - Maternal questionnaires on stress, experiences of racism and discrimination, food insecurity, HIV stigma, and disclosure of HIV status.

    - **Paige** noted that there will be an audio option for caregivers who prefer to hear the questions instead of read them.

CAB members had the following additional questions:

- **Kate** asked if the team will provide site staff with mental health resources for children. **Paige** explained that sites will receive a sheet with links to support resources. Additionally, sites will be asked to include their local/site resources.
- **Shary** expressed the importance of including stress questions in the mental assessments. **Paige** mentioned that there is a grant to evaluate how stress in people's lives affect their ability to care for their child. The grant could be funded in the future. **Paige** will talk with **Claire** and **Megan** about possibly reviewing the stress questions on a future CAB call.
- **Kim** asked if the SMARTT team can share results from the stool microbiome analysis to the adults participating in the study. **Paige** explained that to the research team will not be analyzing the stool sample. The samples will go to the repository for possible future testing.

NOTE: The next CAB call will be on Thursday, August 26, 2021 at 12:00 pm ET.