CAB Conference Call April 26, 2012 12:00 EST Meeting Minutes

Participants:

Andrew Jacobi Medical Center Carlos San Juan Hospital

DeAngelo University of Florida – Jacksonville

DeliaUniversity of MiamiJenniferUniversity of ColoradoJuanUniversity of Puerto Rico

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Mariana University of California – San Diego

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Megan Westat

Melanie UMD – New Jersey Medical School

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APPROVAL OF MINUTES

The minutes from the March 22, 2012 call were approved with no changes.

SPRING 2012 MEETING DISCUSSION

Jennifer talked about the Spring 2012 Meeting. There were sessions for each Working Group (WG). The WGs talked about retention. They also talked about ways to help participants to stay on study as they transition into adulthood. The group talked about the possibility of collecting data using the internet or cellphones. When a participant turns 18, they can consent for themselves. The consent form has information about HIV. If a mother has not disclosed to her HIV-exposed but uninfected child, the child may not understand why the consent has information about HIV. The PHACS leadership is still talking about this issue.

Each group talked about their capsules, concept sheets, and manuscripts. Manuscripts are created through a process. The group first looks at data and develop it into a capsule. The capsule is developed into a concept. The concept sheet is reviewed by the Executive Committee (EC). After it is approved by the EC, it can be developed into a manuscript to be published.

The Adolescent WG talked about birth control use and pregnancies in AMP. They also looked at clinical and behavioral predictors of STIs in acquired and perinatally HIV-exposed adolescents.

The Metabolic WG talked about the effect of HIV infection and antiretroviral (ARV) medications on the start of puberty. The group also talked about the effect of the HIV and ARV medications on obesity in the HIV uninfected but exposed group.

The Maternal Exposures WG talked about growth and ARV exposure.

The Complications WG talked about HIV-infected children potentially having less immunity to measles, mumps, and rubella (MMR) even if the children had gotten the MMR vaccine.

The ND/Neurology WG talked about the Memory Substudy. They also talked about mental health problems in mothers living with HIV. They found that the numbers of mothers suffering from mental health problems were close to the national averages. Depression and anxiety were the highest. Few mothers received treatment for their conditions.

There was a Clinical Investigators Group (CIG) business meeting. The group talked about reimbursement for study participants. They also talked about the retention strategies from the CAB and Study Coordinators (SC).

The Oral Health Substudy team wanted to thank CAB member, Rosetta Fortune, for her participation on the Oral Health Substudy calls. Rosetta was the CAB representative on the Oral Health Substudy protocol team.

Julie reminded the CAB that presentations from all PHACS meetings can be found on the PHACS website.

NEW ARV MEDICATIONS – DR. ANDREW WIZNIA

Dr. Andrew Wiznia continued his talk about new ARV medications. Medications are absorbed differently in different age groups. There are guidelines for pediatric HIV treatment.

Combination pills combine several drugs into one pill. Atripla is a combination pill of Emtricitabine, Tenofovir, and Efavirenz. The single pills in this combination can only be used by adults. The combination pill can be used for children.

Dr. Wiznia talked about the replication cycle of the virus. The virus can use a cell's machinery to replicate its viral DNA. The goal of some medications is to stop the virus from reproducing. The drugs can work by messing up this process. For example, if the virus is trying to spell a word in order to replicate, the drug would misspell the word to stop the virus from replicating. Other drugs work like putting gum in a lock. If there is gum in a lock, then the key will not work to open the door.

The virus has to get into a cell in order to reproduce. It first binds to the cell. ARV medications called CCR5 co-receptor antagonists stop the virus from binding to the cell.

The viral DNA has to get into the cell's nucleus to reproduce. Drugs called integrase inhibitors stop this process. Raltegravir is an integrase inhibitor. The virus reproduces by making very long proteins. The long proteins need to be cut into smaller proteins to make them more flexible to make more copies of virus. ARV medications called protease inhibitors can stop the protease enzyme from cutting the large proteins. This stops the virus from making more copies of virus.

ARV medications are broken down by the liver. There are medications that can boost the drug levels of other medications. This can help the medication stay in the body longer. Ritonavir can boost the drug levels of other ARV medications. It blocks the steps that that break down the drug.

ARV medications are developed for children through clinical trials like the IMPAACT study. IMPAACT protocol P1066 studied Raltegravir use in HIV-1 infected children and adolescents. Study participants were put into two groups. One group took a placebo for 96 weeks. The other group took Raltegravir for 96 weeks. The data showed that 28% of the participants taking the placebo had undetectable viral loads. It also showed that 62% of the participants taking Raltegravir had undetectable viral loads. There were limitations to this study. The participants were in a small targeted population. There was a small amount of information about the drug and drug interaction.

IMPAACT protocol P1058A studies the interaction of Tenofovir and Raltegravir. IMPAACT protocol P1093 is a study of the drug Dolutegravir in children from six weeks to 19 years of age. IMPAACT protocol P1090 is a study of the drug Etravirine in HIV infected children from two months to six years of age. IMPAACT protocol P1070 is a study of Efavirenz in HIV-infected children from three months to

three years of age. IMPAACT protocol P1101 is studying treating children who have Tuberculosis and HIV.

Dr. Wiznia talked about treatment failure. Treatment failure can happen because of the potency of the drug, resistance of the drug, food restrictions with the drug, and toxicity. Failure can also happen because of mental health, adolescence, and adherence.

NEWSLETTER, JUNE 2012 EDITION

Megan asked the CAB to consider submitting articles to the June 2012 edition of the PHACS CAB Newsletter. The theme for the newsletter is Living Healthy with HIV. Please consider submitting an anonymous (your name will not be included) testimonial to the newsletter about living healthy with HIV. This can also be about children living with HIV. The deadline to submit personal testimonials is June 8, 2012.

The newsletter will also include a section for "My Favorite Think about Summer" by CAB kids. CAB kids can submit anything having to do with their favorite thing about summer including (but not limited to):

- pictures,
- drawings,
- descriptions of 1-3 sentences,
- poems, and
- recipes.

The deadline for CAB kids submissions is also June 8, 2012.

CAB VICE CHAIR NOMINATIONS

Megan talked about the PHACS CAB Vice-Chair nominations. Delia has been serving as Vice-Chair for 2 years. Delia is now the incoming CAB Chair effective June 2012. Therefore, the Vice-Chair position is open. We will be taking nominations by email or through the PHACS CAB evaluation survey. The CAB Vice-Chair position is a two-year commitment. The Vice-Chair attends the monthly CAB calls and helps to set the agenda for those calls. The Vice-Chair also attends the PHACS Network meetings in the spring and fall each year. PHACS pays for all travel, room and board during those meetings. The Vice-Chair participates as a non-voting member on the monthly EC call.

Action Item: Please nominate yourself or another CAB member for the Vice-Chair position. To nominate someone, submit a brief summary why you or your nominee would be a good candidate. Once names have been collected, a list of the nominees and the brief summaries will be sent to the CAB for a vote.

FUTURE CALL – HELPING CHILDREN AND TEENS COPE WITH LOSS

Megan talked about a future call with the PHACS neuropsychologists. The PHACS CAB leadership has been working with the PHACS neuropsychologists on the topic of helping children and teens cope with the loss of a parent. The PHACS neuropsychologists are professionals who specialize in mental health. Megan sent out articles that highlight the main issues. Megan asked the CAB to look over the articles and share them with their local CABs. If you are interested in participating in a discussion with the PHACS neuropsychologists regarding this topic, please let us know. We are planning to hold a separate conference call with them in the next couple months to talk about this topic. This call will be voluntary.

• JUNE PHACS CAB CONFERENCE CALL

The PHACS CAB conference call in June has been rescheduled for June 21, 2012 at 12:00 pm EST.

NOTE: The next CAB call will be on Thursday, May 24, 2012 at 12:00 pm EST.