

PH/ACS *In focus*

June 2010
Volume 2, Issue 1



FROM THE CAB

Jennifer, Rosia, and Samantha at the Network Meeting!



This year's PHACS Spring Network meeting was held in Bethesda, Maryland on April 22-23, 2010. It was a very relaxed and more casual atmosphere than the larger Fall Meeting for PHACS, yet it seemed extremely productive. It is amazing to see so many different groups come together to work on such interesting and diverse research. The ability to share relevant findings in each area of study helps to answer questions, and it raises new questions for further research.

The format for the Spring Meeting was similar to the Fall Meeting last November. There were large group presentations, and then there were smaller working group meetings each day. In addition to the research findings, economic and financial factors were discussed at the conference due to budget cuts that the PHACS research is facing. The PHACS project is learning how to do more with less money.

My own personal experience at the meeting was one of familiarity and unfamiliarity, just as there were familiar faces from those I had met at the meeting in November, and there were new faces too. I felt more at ease with the terms and acronyms, like "CAB," which I now know means "Community Advisory Board." Many acronyms were used in the discussions.

The topics relevant to CAB members that were addressed were participant willingness to schedule and keep appointments. In addition, the topic of participant retention on the studies was discussed. At one point in a large group discussion, a researcher wondered what participants would think if more testing was added to the study visits. Samantha and I were in the room, and Samantha readily spoke up to give her opinion on the matter. Even in the small working group meetings, Samantha was often called upon for her input on what participants might think about when adding different types of testing to the protocol study visits. At this Spring Meeting in particular, I really felt that the researchers looked for CAB member input, and although there were only two of us at the meeting, Samantha and I, the Chair and Co-Chair for CAB, essentially represented the entire population that the researchers care so much about. CAB may be small, yet it has a noticeable presence, and is not missed or overlooked by the researchers.

I was Vice Chair under Samantha, the CAB Chair, since October 2009, so it has not even been a whole year that I was Vice Chair. It was a brief overlap but one for which I am very grateful. Meeting Samantha this spring and listening to her sage advice on when, where, and how to comment on something was invaluable! In addition, although I do not have nearly her experience or expertise, I look forward to contributing in any way that I can. As Vice – Chair, I was really just becoming comfortable with the idea of being on the CAB, and what it was all about and why the CAB is so necessary. As Chair, I look forward to continuing to learn, as well as contributing on a national and local level. Best wishes to you and thank you, Samantha, for everything!

Jennifer, Incoming PHACS CAB Chair

Please send all questions, comments, and suggestions for the CAB newsletter to RosiaWarner@westat.com

INSIDE THIS ISSUE

From the CAB	1
PHACS Member Profile	2
DOC Updates	2
Publications in the News	3
Online Resources	4
Upcoming Events	4
HIV QUIZ	4
Just for You	5
CAB Glossary	6
Quiz Key	6

PHACS MEMBER PROFILE

Hello! My name is Julie Davidson and I am the Westat Project Manager for PHACS.

I was born in New Jersey and grew up in the southwestern tier of New York state and central Vermont. In 1977, my parents, my three siblings, and I relocated to the Northern Virginia suburbs of Washington, DC, where I graduated from high school. I completed my Bachelors Degree in Nursing at Radford University in Radford, Virginia. Shortly thereafter, I realized that I had SO much more to learn, so I went on to complete a Master's Degree in Nursing at the University of Virginia in Charlottesville, VA. During my time in Charlottesville, I worked as a behavioral health care nurse at a local hospital.

In 1990, my son Ryan was born and, six months later, we moved back to the Northern Virginia area where I worked for a behavioral healthcare company, which provided healthcare services to employees of both large and small companies. I was initially hired as a case manager but I went on to pursue supervisory and management roles in clinical operations, quality assurance, and business reporting. After surviving a string of lay-offs during my 12 years with the company, it was finally my turn in 2003.

Things do happen for a reason. Being laid off actually turned out to be a very positive experience for me as it gave me the opportunity to re-evaluate my career goals. I began searching the internet for new opportunities and was absolutely fascinated by my discovery of this field called "clinical research" of which I had been mostly unaware. I decided to enroll in a clinical research course to determine if this pursuit was a good fit for me. I absolutely loved it!!

Upon completion of the course, I began my job search and Westat hired me as a protocol specialist on the Adolescent Trials Network (ATN) project. In addition to this assignment, I also worked on a project sponsored by the Centers for Disease Control and Prevention entitled "Longitudinal Epidemiologic Study to Gain Insight into HIV and AIDS in Children and Youth (LEGACY)" as the Westat Clinical Operations Manager. In February of this year, I was offered the opportunity to join the PHACS team. It has been so gratifying to be just a small part of this very important work and I truly admire the commitment and dedication of all the people I have encountered who are involved in HIV/AIDS research.



Outside of work, I love to cook and try new recipes from my cooking magazines - so much so that my husband rarely eats the same dish twice. He is SO sweet to say he likes everything I make!! I also enjoy opportunities to travel to new places, camping on the Shenandoah River, get-togethers with family and friends, and I am an avid fan of Washington Redskins football and my son's West Virginia University Mountaineers sports teams!

DOC UPDATES

Last fall, the PHACS Data and Operations Center (DOC) at Harvard University and the Coordinating Center (CC) at Tulane University submitted applications for additional funding. The National Institutes of Health (NIH), the agency that funds PHACS, just finished their review of the applications. Both applications received outstanding scores. The applications were scored on a scale from 10-90, with 10 being the best. The DOC scored 13 and the CC scored 18. These scores show the strong support PHACS has at the NIH. We also just received official word that the NIH will fund PHACS for five more years! The PHACS leadership is currently hard at work, planning for the next five years.

As the study continues, it has become more important to focus on keeping participants in PHACS. The research term for this is "retention." It is important for both the care of the children and the quality of the research that participants stay in the study. PHACS researchers have been astonished by the positive retention numbers. In SMARTT, 98% of the static cohort children and 99% of the dynamic cohort children are still on study. In AMP, 98% of the infected children and 97% of the uninfected children are still on study. These numbers are an incredible testament to the dedication of PHACS caregivers and the children and to the hard-working staff at our clinical sites. PHACS researchers are thankful for your continued participation!

Please feel free to contact the PHACS DOC Project Director, Julie Alperen, if you have questions. She can be reached at 617-432-6762 or jalperen@sdac.harvard.edu.

PUBLICATIONS IN THE NEWS

Since the publication of the last PHACS CAB Newsletter in December 2009, the PHACS team has had two manuscripts accepted for scientific journal publication and five abstracts presented at scientific conferences. A Participant Summary is also included in this newsletter so that you can learn about the findings from one of the PHACS studies.

Publications:

“The Relationship between Immune Activation and Neurocognitive and Neurobehavioral Outcomes in Children and Adolescents with Perinatal HIV Infection.” This manuscript will be published in the journal *AIDS*. Suad Kapetanovic, MD, lead author, is an Assistant Professor of Clinical Psychiatry at the University of Southern California, Keck School of Medicine and a member of the PHACS Neurodevelopmental and Neurological Disease Working Group.

“Disclosure of Maternal Substance Use During Pregnancy By HIV-Infected Women.” This manuscript will be published in the journal *AIDS and Behavior*. Katherine Tassiopoulos, MPH, DSc, lead author, is a Research Scientist in the Department of Epidemiology at the Harvard School of Public Health and a member of the PHACS Adolescent, Risk behaviors, HPV and other STDs and the Neurodevelopmental and Neurological Disease Working Groups.

Abstracts

These abstracts were presented at the 17th Conference on Retroviruses and Opportunistic Infections. The first two abstracts listed are from AMP. The third abstract is from SMARTT.

“Association of Vascular Biomarkers with Neurodevelopmental Outcomes in Children with Perinatally Acquired HIV Infection.”

“Differences in Body Fat Distribution in HIV-infected versus HIV-uninfected Children.”

“Prenatal exposure to antiretrovirals among HIV-exposed but uninfected children: Surveillance Monitoring for ART Toxicities (SMARTT) Study.”

“The long-term impact of HIV disease severity on cognitive and adaptive functioning during childhood and adolescence.” This AMP abstract was presented at the 2010 Pediatric Academic Societies' Annual Meeting.

“Association of cardiac structure and function within utero antiretroviral exposure among uninfected children born to HIV-infected mothers in the Surveillance Monitoring of ART Toxicities (SMARTT) Study.” This SMARTT abstract was presented at the 2010 HIV Observational Databases Workshop.

Participant Summary

Title: A Trigger-Based Design for Evaluating the Safety of *in utero* Antiretroviral Exposure in Uninfected Children Born to HIV-infected Mothers

Authors: Paige L. Williams, Russell Van Dyke, George R. Seage, Ray Griner, Denise Jacobson, Susan Brogly, Katherine Tassiopoulos, Yanling Huo, Rohan Hazra, George Siberry, Jennifer Read, Lynne Mofenson and Kenneth Rich for the PHACS Team.

Study Description: Treating women who are HIV infected with antiretroviral drugs has helped lower the number of babies born with HIV infection. However, we still need to see if HIV medicines taken by pregnant women cause problems in their children as they grow up. We designed a large study in the United States to look at how safe these HIV medicines are for the babies born to mothers with HIV infection. The study is called SMARTT, which stands for **S**urveillance **M**onitoring for **A**ntiretroviral **T**herapy **T**oxicities. The children are seen once each year. We first look at some measures that are easy to collect. This helps make the visits shorter and less expensive. We do blood tests, and collect height and weight measurements. We also test for learning, hearing, or language problems. If any of these tests are not normal, we call this “meeting a trigger.” If a child meets a trigger, we do other follow-up tests to learn more about the problems.

Study Population: The SMARTT study started in March 2007. As of January 2009, 1459 babies and children had enrolled in the study, and 1284 had their first study visit. The children were all born to mothers with HIV infection. They were aged 0 to 12 years at enrollment.

Results: Of the 1284 babies and children who had a study visit, 354 (28%) met at least one trigger. Over half of the 354 children who met a trigger had a high body mass index (BMI). This means they weighed a lot, given how tall they were. One third of the 354 who met a trigger had problems with language or hearing. The children who met the BMI trigger had blood tests done to see if there were more serious problems with their metabolism (the way their bodies use energy). Of the children with blood tests, one fourth had high cholesterol or other metabolic problems. We want to know what percent of all of the children in SMARTT have metabolic problems. Based on past studies, we assumed that 90% with metabolic

problems also have high BMI. We then estimate that 6.4% of all SMARTT children had these types of metabolic problems. This estimate is more precise than if we had just picked the same number of children at random to look for metabolic problems.

Conclusions: The trigger design of the SMARTT study helps keep the study visits shorter and makes the study less expensive. It also makes it easier to find children who might have serious problems. We found that problems with metabolism and with language or hearing were common among young children born to mothers with HIV infection. Almost all (98%) of the children have stayed on the study so far. It is important to keep studying these children as they grow up.

Support: This study was supported by NICHD with co-funding from NHLBI, NIAID, NIDA, NIMH, and NIDCD.

Participant Summaries with information on these study findings are posted on the PHACS website. You can also get a copy from Rosia Warner, PHACS Community Advisory Board Liaison, at RosiaWarner@westat.com.

ONLINE RESOURCES

HIV Testing

HIVtest.org

AIDS Resources

<http://aids.gov/>

HIV Fact Sheets

<http://www.cdc.gov/hiv/resources/factsheets/>

UPCOMING EVENTS

June 27	National HIV Testing Day
July 10-11	Chicago Ride for AIDS
July 24	Memphis AIDS Walk
August 14	AIDS Walk Colorado
September 25	Harbor to the Bay AIDS Ride/Boston to Provincetown

HIV QUIZ

1. In what year was AIDS first reported in the United States?
 - A. 1975
 - B. 1981
 - C. 1986
2. If someone with HIV has a CD4 count of 200 or less, what does this mean?
 - A. Their immune system is very healthy
 - B. They no longer have HIV
 - C. They should probably start antiretroviral therapy
3. Which of these drugs is most commonly used on its own to reduce mother-to-child HIV transmission?
 - A. Aspirin
 - B. Tenofovir
 - C. Paracetamol
 - D. Nevirapine
4. In 2007, what percentage of people needing HIV treatment in lower- and middle-income countries received it?
 - A. 31%
 - B. 51%
 - C. 71%



JUST FOR YOU

Simple Summer Smoothie



Ingredients

- 1 banana
- 1 Cup frozen strawberries
- 1 Cup frozen blueberries
- 1 Cup frozen cherries
- 4 ice cubes
- 1/2 Cup orange juice
- 3/4 Cup vanilla yogurt
- 1/2 teaspoon honey (optional)

Directions: Place the banana, strawberries, blueberries, cherries, and ice cubes into a blender. Pour in the orange juice, vanilla yogurt, and honey. Puree until smooth. Enjoy!

Who Are You? Written by S.D.

My smile shows no viral load.

My laughter contains no CD4 count.

The joy in my soul doesn't remember my missed doses.

My vision in the mirror doesn't reflect a compromised immune system.

But what I see is a beautiful woman, full of grace, strong, and intelligent.

In control of who she is and who she is going to be.

I have decided to Hold on to my Inspiration and keep positive Visions about my future.

I know who I am.

Who Are You?

CAB GLOSSARY

Cohort - A subgroup of research participants who share a common characteristic.

Community Advisory Board (CAB) - A group comprised of nonscientific community members, who provide input and act as liaisons between researchers and the local community where they live and work.

Good Clinical Practice (GCP) - A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

Site Monitor - The person who reviews study records to determine that a study is being conducted in accordance with the protocol, network policies, and government regulations.

Working Group - Within PHACS, a group of individuals who review the data, monitor triggers, and develop conference and publication materials related to a particular domain.

QUIZ KEY

1. **B.** AIDS was first identified in the U.S. in 1981 after several gay males became ill with a rare form of cancer. The term "AIDS" was first used the following year.
2. **C.** The more CD4 cells there are in a person's blood, the stronger the immune system. A CD4 cell count below 200 indicates that the person has a very weak immune system and requires antiretroviral therapy.
3. **D.** A single dose of Nevirapine given to the mother at the onset of labor and to the baby after delivery roughly halves the rate of HIV transmission.
4. **B.** In 2007, antiretroviral therapy coverage in less wealthy areas of the world was very low. Far greater investment and political will is needed to achieve universal access.

Source: AVERT.org