

PHACCS

December 2010
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In focus



FROM OUR CAB CHAIR



*Delia, Rosia, and Jennifer
at the Network Meeting!*

This year's PHACS Fall Network meeting was held in Baltimore, Maryland on September 30 – October 1, 2010. The format for the Fall Meeting was similar to last Fall's Meeting. There were large group presentations, and then there were smaller Working Group meetings each day. Meeting attendees were especially pleased that Working Group sessions were not overlapping. In addition to the research findings, there was an ACASI training held for the Study Coordinators.

I am pleased to report that in 2010, we have had a consistently high number of participants on the CAB calls. We have had wonderful discussions and several guest speakers who have been very interesting and provided an abundance of information. In 2010, we also wrote the following Mission Statement for the PHACS CAB: ***The Mission of the PHACS CAB is to serve as an intermediary between researchers and community members to improve and optimize clinical research studies for children/families who are participants and who are most affected by them.***

As we enter 2011, we are looking forward to increased CAB participation. In addition to the positions of CAB Chair & Vice-Chair, we would like to see other members take on more active roles and duties. Some possible roles we are considering right now are secretary and newsletter editor. If you can think of any other roles, please let me know!

As mentioned on the December Executive Committee call, additional funding will be available in the 2011 budget for more than just the CAB Chair & Vice-Chair to attend PHACS Network Meetings. This is a great opportunity to meet each other face-to-face and to feel invested in our work, and to better understand the PHACS research! I will keep you informed about that decision.

Jennifer, PHACS CAB Chair



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

PHACS MEMBER PROFILE



Hello! My name is Delia, and I am the CAB Vice-Chair for the PHACS project. I am from a small island in the Caribbean called St. Lucia. When I was 20 years old, I lived in Belgium for about a year, before moving to Canada. In 1990, I returned to St. Lucia. In October 2002, I moved to Miami to save my daughter's life. She was only two years old at the time.

The University of Miami's pediatric doctors, nurses, staff, and social workers saved my little girl's life. It was a miracle! Now, I look at my daughter and continue to be amazed by the wonderful care and attention given to her. Even now, my daughter continues to be one of many children who attend this clinic.

In 2003, an inspirational woman who mentored me about the local CAB at the University of Miami introduced me to the local PHACS CAB. Before my mentor's death, she made it clear to me that she wanted me to become more involved in the CAB. I have made it my mission to continue with my CAB involvement and make her proud of me, wherever she is.

The local CAB at the University of Miami is like a family. We are there for each other and help in every way we can, in sickness and in health. I guess that is why we are such a strong group. I want to give back to my community. I want to help as much as I can. If it were not for the University of Miami Pediatrics and people like my mentor, I would be alone and angry.

I am very excited to be working with the CAB and being involved with such a prestigious group of people. I will do my best to do what is expected of me, and then some. Since I am new in the position of Vice-Chair, I would gladly appreciate any advice or criticism that would help me with this role. It is an honor and a true privilege to represent "our children."

DOC UPDATES

The last few months have been busy at the PHACS Data and Operations Center (DOC) at Harvard! We announced in the last CAB newsletter that the National Institutes of Health (NIH) funded PHACS for five more years. We now have these funds and are working hard with your sites to put them to good use.

Updated SMARTT and AMP protocols were released in August 2010. Most PHACS sites have received IRB approval to use these updated protocols.

The DOC received funds from NIH to do a substudy in SMARTT. This study looks at the possible effects of Tenofovir on newborns exposed to this ART in utero. (The study is described in detail in this newsletter.) We are working with SMARTT sites to start up the study in the next few months.

The DOC received funds from NIH to collect extra data in AMP. These funds are given to the clinical sites to collect CD4 levels, HIV viral loads, and information on bone fractures and AST levels. This information was always collected in AMP. But, we found we needed more details to address important questions about HIV in adolescence.

The DOC is especially excited to announce a few important PHACS milestones. In November the 1,000th infant was enrolled in the SMARTT Dynamic Cohort. In September, we passed 500 echocardiograms (echoes) in AMP. Echoes are tests that take images of the heart. PHACS researchers are studying these images to see if HIV affects the heart in adolescents. In November, we were 30 echoes away from our target of 400 in SMARTT.

We look forward to reaching new milestones in PHACS. As always, the DOC and PHACS researchers thank you for your participation. Please feel free to contact 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 June 2010, the PHACS team has had four abstracts presented at scientific conferences. A participant summary is also included in this newsletter, which presents the findings from one of the PHACS studies.

Abstracts

These first three abstracts were presented at the XVIII International AIDS Conference held in Vienna, Austria on July 18 – 23, 2010. The first two abstracts listed are from AMP. The third abstract is from SMARTT.

“Risk Behavior in Perinatally HIV-infected Youth: Co-Morbidity of Mental Health Problems, Sexual and Drug Use Behavior, and Non-Adherence to Antiretroviral Therapy.”

“Language Impairment in Perinatally HIV-Infected Children and Adolescents as Compared to Uninfected HIV-Exposed Children in the Pediatric HIV/AIDS Cohort Study (PHACS).”

“Safety of Tenofovir Use During Pregnancy: Associations with Low Birth Weight and Early Growth in HIV-Exposed Uninfected Infants.”

The following SMARTT abstract was presented at the American Heart Association Scientific Sessions 2010 held in Chicago, Illinois on November 13-17, 2010.

“Association of Cardiac Structure and Function with In Utero Antiretroviral Exposure among Uninfected Children Born to HIV-Infected Mothers in the Pediatric HIV/AIDS Cohort Study.”

Participant Summary

The following summarizes the SMARTT abstract presented at the International AIDS Conference. The Tenofovir study described in this newsletter will give us a more detailed look at this subject.

Title: Safety of Tenofovir Use During Pregnancy: Associations with Low Birth Weight and Early Growth in HIV-Exposed Uninfected Infants

Authors: G. Siberry, P. Williams, H. Mendez, G. Seage III, D. Jacobson, R. Hazra, K. Rich, R. Griner, K. Tassiopoulos, D. Kacanek, L. Mofenson, D.H. Watts, for the Pediatric HIV/AIDS Cohort Study

Study Description: Tenofovir (Viread or TDF) is a medicine used by many adults with HIV infection. TDF is also used more and more by pregnant women to treat their own HIV or to make sure their babies will not get HIV. Because so many pregnant women with HIV are beginning to use TDF, we want to make sure it is safe for their babies. Studies in animals show TDF may affect how babies grow. We conducted this study to see if growth differed between babies whose mothers took TDF and those whose mothers did not.

Study Population: We used data from babies who joined the SMARTT study through February 2010. We looked at 1,855 babies, to see how much they weighed when they were born. Our study focused on babies born at low weight (less than 2.5kg, or about 5½ lbs). We also looked at body size for 470 babies when they were one years old.

Results: Overall, 20% of mothers in our study used TDF when pregnant. 15% used TDF in 2003 compared to 38% in 2009. The percent of babies with low birth weight did not differ between mothers who used TDF and mothers who did not (21% vs. 20%). Even after we took into account other factors, like mother’s cigarette smoking, there was no difference in low birth weight. However, at age 1, babies whose mothers used TDF when pregnant were more likely to be shorter and to weigh less. Babies whose mothers used TDF early in pregnancy were also more likely to have a smaller head size at one years old.

Conclusions: Over time, we found that more and more mothers of SMARTT babies used TDF when pregnant. There was no relationship between TDF and low birth weight. However, babies whose mothers took TDF while pregnant tended to be smaller on average when they were one years old. More studies are needed to look at this possible effect of TDF on growth in the first year.

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

Participant Summaries are posted on the PHACS website. You can also get copies from Rosia Warner, PHACS Community Advisory Board Liaison, at RosiaWarner@westat.com.

SUBSTUDY FOCUS

SMARTT Tenofovir Substudy. PHACS received funds to enroll a group of SMARTT participants in a related study (a substudy). The funds come from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. In SMARTT. We are studying children born to mothers with HIV who are not infected themselves. We want to understand the possible effects of their mothers' HIV infection and HIV medications on their child's health. In this substudy, we are looking for effects on infants of a specific drug called Tenofovir. This drug is often taken by women with HIV during pregnancy.

Tenofovir is safe and effective. It is widely used for treatment of HIV in adults. It is sold under the name "Viread." Tenofovir is one of the drugs in the combination pills Truvada and Atripla. Many women with HIV are already taking Tenofovir for their own treatment when they get pregnant. Others start it in pregnancy because of its good record in treating HIV in adults. In fact, about 40% of women in SMARTT were taking Tenofovir in pregnancy in 2009.

However, Tenofovir has not yet been studied carefully in pregnant women. There are some studies in adults and children with HIV. These studies link Tenofovir to weaker bones and occasional kidney problems. But most studies show no serious effects. Some studies in animals show Tenofovir during pregnancy can cause slow growth and poor bone development. Even though there is concern that using Tenofovir in pregnancy could affect an infant's growth, bone development, and kidney function, it is not clear if such effects do occur. None of these problems has been reported in infants whose mothers used Tenofovir during pregnancy.

This substudy will enroll 150 SMARTT Dynamic infants. One group will include 75 infants whose mothers used Tenofovir for at least 8 weeks in the second half of pregnancy. The other group will be 75 infants whose mothers did not use any Tenofovir during pregnancy. A DXA scan (an x-ray that measures bone strength) will be used to see if there is a difference in bone strength between the two groups of infants. The study will also see if there are differences in body size and kidney function between the groups. These measurements should allow us to see if there are even small differences in infant growth, bone strength, or kidney function that is related to Tenofovir use in pregnancy.

This article was written by Dr. George Siberry, Medical Officer for PHACS at the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

ONLINE RESOURCES

HIV/AIDS Health Education Tutorial

<http://www.nlm.nih.gov/medlineplus/tutorials/aids/hp249102.pdf>

AIDS Resources

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

<http://www.kidstalkaids.org/program/index.html>

HIV/AIDS Diet & Disease Resources

http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=2&tax_subject=278&topic_id=1380

UPCOMING EVENTS

December 1 **World AIDS Day**

February 7 **National Black HIV/AIDS Awareness Day**

March 10 **National Women and Girls HIV/AIDS Awareness Day**

March 20 **National Native HIV/AIDS Awareness Day**

May 18 **HIV Vaccine Awareness Day**



CAB SPOTLIGHT



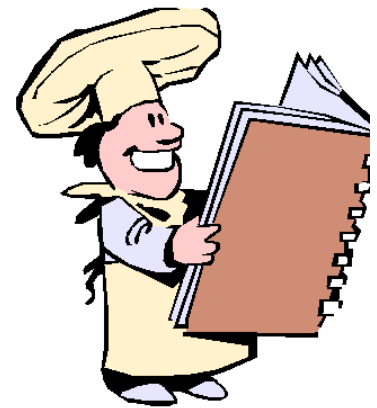
Marilyn, a member of the Bronx-Lebanon CAB, contributed these recipes for our newsletter!

Tuna Salad

Prepare Elbow noodles according to package instructions.
Finely cut green and red peppers and onions and add them to the cooked noodles.
Add A little bit of mayo.
Add A little bit of olive oil.
Finish by adding the tuna.

Spanish Rice

To cook Carolina rice, add Pigeon peas, Red or Pink beans
Add a little bit olive oil
Add Fresh Olives
Add Fresh peppers and onions.
Add one tablespoon of *Sofrito* (blend of sweet peppers, onions peppers, cilantro-- ground up and mixed together)
Finish by adding Saffron to the mixture



Chicken Wings

Marinate wings in *Sofrito*, vinegar, and a touch of lemon.
After marinating, put in oven with cut onions on top of the chicken.
Toward the end of cooking, add honey-mustard barbecue sauce on top of the chicken.

CAB PERSONAL STORIES

The following was written by a CAB member talking about her experience with HIV/AIDS.

My story begins when IMPAACT was PACTG. In the early 90s, I gave birth to a boy. That was a happy day for me.

Within a few months, I noticed that my son developed a cold, which I could not break. At that time, I was a pediatric nurse. After numerous attempts, I decided to take him to see the doctor at Jackson Memorial Hospital. After the doctor examined him, he asked if I could consent to a HIV test, I agreed. The head doctor of pediatrics asked if anyone had spoken with me. She then took me to a private room where I was diagnosed HIV positive, and so was my son.

My life as I knew it was over. The doctor assured me they would do all they could for him. I was then asked to allow him to participate in a research. I have been an active participant of research and to this day, I am now Chair of my local CAB (University of Miami Pediatrics) and ICAB member.

A PHACS team member who wanted to share her experience with HIV/AIDS wrote the following:



This drawing is used to counsel children in Africa who have HIV, as a reminder to take their ARVs.

A TRIBUTE TO A FRIEND by Victoria Kioko, PHACS Protocol Specialist

We all attended the same primary school, her husband a year or two ahead of us. Her husband was a distant relative and a neighbor in my village. When my family relocated to the USA, we would receive updates on events taking place in the village. I knew they had gotten married and were parents of a baby boy. He joined the Kenyan Military and later transferred to the military barracks. Then one day, the shocking news that her husband had passed reached us. He had been so young and his wife had just given birth to another baby boy. I met up with my friend on one of my visits back home and she updated me on the events leading up to his death. My friend told me that she had gone to visit her husband to deliver their second son when her husband became ill. My friend was informed that her husband had contracted meningitis and, devastatingly, he was dead within a week's time. My friend however, believed that her mother-in-law had bewitched her husband! I tried to convince her

otherwise, but her beliefs were too strong! My friend buried her husband and suddenly found herself a single mother with two young boys. Since her husband was the sole breadwinner, my friend was left to fend for herself and her two sons with the help of her in-laws.

I saw my friend once again when I went to bury my grandmother about four years ago. I remember that my friend looked sickly and tired, but she told me that she was fine. A few months after I returning to the USA, I received the news that she too, had passed on. My friend had died of AIDS. Her two sons were now orphans and under the care of their elderly grandparents. I later learned the truth that her husband had also died of AIDS. I wondered whether my friend knew that she was HIV positive or if she was in denial. I wondered whether ARVs would have made a difference in their lives; I wondered whether I could have made a difference if I had known that she was HIV positive; I also wondered whether either of the children were also HIV positive (I have since learned that her second son passed away last month and was HIV positive).

This story is too common in Kenya where it is "customary" for husbands to live away from their families while working. This often results in men engaging in sexual activity with other women while they are away. Sometimes, the women left behind in the villages also engage in sexual activity with other men in the village. This has resulted in a high rate of HIV/AIDS in the country. Every other homestead in my village has orphans whose parents have died of AIDS and who are now being raised by their elderly grandparents. There are a few projects that assist grandparents but most of the time, they just are not adequate. I knew that there had to be so much I could do from here, and really was not sure where to start, but PHACS seemed to be the right place for me. As a Protocol Specialist, I am grateful that I can dedicate my time working for a cause that I believe in, and that has had such an impact on my life. Although I miss my friends, I have been fortunate to be a part of a great team that continues in their commitment to fight this battle.



World AIDS Day was on December 1, 2010. Here are some of the PHACS CAB Members' experiences on that day:

This is a poem written by Gloria, a PHACS CAB Member from the University of Florida in Jacksonville. Gloria read this moving poem during the University of Florida World AIDS Day Kick-Off Event and she received a standing ovation!

Who Am I? Am I...

**ASHAMED
STIGMA
CAGED
SOLITUDE
SILENCE
SECRETIVE
POISONOUS
LONELY
DEPRESSED
ANGRY
HATRED
SELF-PITY
I SAY NO!!**

**When learning all these things I named above is a part of some of our lives,
When we find out we'll have to live with HIV for the rest of our lives,
I see these things as a MASK.**

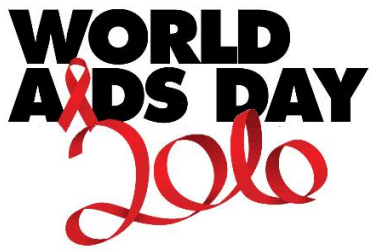
Some people have worn this mask all the way to their death, but I've learned it don't have to be that way.

**It's education out here about HIV,
It's also treatment out here for HIV,
All we have to do is go out and get it.**

I have learned that I have HIV, HIV don't have me, so I can do something about it. I can still live a happy and normal life.

**I'm
STRONG
BEAUTIFUL
I'M FREE
I'M BETTER
I'M A BOLSTER
FOR ME AND OTHERS
POSITIVE
MOTIVATED
AND
DEDICATED**

**In this fight for my life and others, so will you join me and take off your mask?
And with or without your mask, will you join me in the fight to help prevent HIV & AIDS?**



World AIDS Day Continued...

In celebration of World AIDS Day, Delia, PHACS CAB Vice-Chair, joined other University of Miami PHACS CAB Members at a luncheon held at the Miami Site.



Delia, Yuri and Stephanie, World AIDS Day 2010



Delia and Yuri, World AIDS Day 2010



Stephanie (University of Miami CAB Chair), Yuri (University of Miami CAB Liaison), and Delia (PHACS CAB Vice-Chair), World AIDS Day 2010



CAB KIDS

A 10-year-old CAB member, contributed these recipes!

"Bananza" Smoothie

Ingredients:

- 3 bananas
- ½ Cup white sugar
- 1-Cup milk (evaporated or 2%)
- ½ tsp vanilla essence
- Ice, as needed

Directions Combine all ingredients in a blender, and serve.



Curry Rice

Ingredients

- | | | | |
|--------------|----------------|---------------|-----------------|
| 2 cups rice | ½ tsp salt | 1 whole onion | 2 garlic cloves |
| Black pepper | Seasoning salt | 3 tbsp curry | 3 tbsp butter |

Directions

In a saucepan, combine, onions, garlic, black pepper, seasoning salt, and curry with butter and sauté until the curry looks a little burnt. Add rice and water, and then transfer all ingredients to a rice cooker. Add more water to the rice cooker until nearly full. Cook according to rice cooker instructions and serve with your favorite dish.

Children of the Denver CAB created artwork that was later sold at a benefit for the Denver Children's Hospital Immunodeficiency Program (CHIP). These are photos of some of the children and their artwork.



HIV QUIZ

1. **After taking a rapid HIV antibody test, how long must the patient wait for a result?**
 - A. 1 minute
 - B. 30 minutes
 - C. 24 hours
2. **What does the standard HIV test identify?**
 - A. RNA Strands
 - B. T-Cell Counts
 - C. Antibodies
3. **What does PEP stand for in the context of HIV prevention?**
 - A. Prevention of Excessive Production
 - B. Prohibitively Exorbitant Prescription
 - C. Post Exposure Prophylaxis



CAB GLOSSARY

Antiretroviral Therapy (ART) - A treatment developed to suppress a retrovirus, such as Human immunodeficiency virus (HIV).

Closed to Accrual - A protocol is closed to accrual when the last subject has been enrolled.

Protocol Concept Sheets (PCS) - An elongated summary of a proposed study or substudy, which must be approved prior to protocol development.

Sponsor - The entity that initiates a clinical investigation, but does not actually conduct the investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.

HIV QUIZ KEY

1. **B.** Results from a rapid test are usually available in approximately 30 minutes. Rapid tests are single-use and do not require laboratory facilities or highly trained staff. This makes rapid tests very suitable for use in resource-limited countries.
2. **C.** When HIV enters the body, special proteins are produced called antibodies, which are the body's response to an infection. The standard HIV test looks for antibodies in a person's blood, as this will mean they have been infected with HIV.
3. **C.** Post Exposure Prophylaxis involves taking antiretroviral drugs after HIV exposure in order to prevent infection. PEP should be the prevention method of last resort, be started no later than 72 hours after exposure, and is not guaranteed to work.

Source: AVERT.org