

**Cincinnati Pediatric Research Group**  
**Minutes of the Meeting**  
**January 10, 2006**

**IN ATTENDANCE:** Lea Alaei  
Jeralyn Bernier, MD, MPH  
Chris Bolling, MD  
Debbie Boyd, MD  
Mark Dies, MD  
Lisa Green, MD  
Elena Huang, MD  
Bob Siegel, MD

Guest attendees:

Mike Spigarelli, MD, PhD – Clinical Trials Office  
Jane Houry – General & Community Pediatrics' biostatistician  
Matt Turner – medical student from Dr. Siegel's office  
Eva Schaff, MD – University of Indianapolis  
Steve Downs, MD – University of Indianapolis  
Nancy Swigonski, MD, MPH – University of Indianapolis  
Cathy Luthman, MD – University of Indianapolis

**1. ADMINISTRATIVE**

- Clinical Trials Office – Dr. Spigarelli, associate medical director of the CTO, talked about the services and experience the CTO can offer to the CPRG and its membership, ranging from full-scale study development and execution to a la carte services including study lab space, clinical coordinator assistance, protocol development, IRB submission assistance, etc. They can also help us recruit for studies or can provide studies that the CPRG membership might be interested in.

One particular study Dr. Spigarelli thought would be a good fit for the CPRG is a community acquired pneumonia study they have received from a pharmaceutical company. It is a multi-center drug study for children. The CTO could be the PI for the study, or they could completely turn it over the CPRG. Dr. Bolling will further discuss this with Dr. Spigarelli.

Enhancing communication between the CTO and CPRG was discussed, and we will add a link from the CPRG website to the CTO website to that members can find other studies being conducted that might be of interest to their patients.

- Website Updates – The [cprg.org](http://cprg.org) website has been updated to include the maternal depression resources. In a few months, we will be moving the website from the pediatric

bioinformatics server to a marketing server. This will make the CPRG website part of the entire [cincinnatichildrens.org](http://cincinnatichildrens.org) website, although we have been assured we can keep [www.cprg.org](http://www.cprg.org) – it will automatically redirect to the new site location. Making this change will allow CPRG staff to easily update information on the website without paying fees to bioinformatics. The Surveillance data entry will remain on the bioinformatics server, but still be accessible through the cprg website. We'll let you know more information as this change happens.

- Growing CPRG – Dr. Bolling asked the group whether membership should be extended to the entire community medical staff as an “associate member” level of membership. This would be an information-only membership level that individuals could opt-out of. Full membership would be reserved for those members that are active.

There was discussion about how information would be shared with this larger group, what “active” means, and whether having a larger number of members with a small percentage of active participation is better than a smaller number of member with a larger percentage of active participation.

Dr. Bernier suggested that since community physicians are not seeing patients as much in the hospital anymore, that the Medical Staff has been looking at other ways to define “active status” at the hospital, and perhaps active participation in the CPRG (participating in a study, attending meetings, etc.) could be a qualifying factor.

Dr. Bolling will speak with Dr. Kevin Reidy, incoming president of the Medical Staff, to seek his blessing to make all community medical staff members of CPRG and to investigate the possibility of having active CPRG participation count toward active status.

- IECRN Best Practice Network – NIH began an Roadmap Initiative to determine how research is being done in Clinical Research Networks (PBRNs) across the country. They profiled networks funded at some time by AHRQ via questionnaires and interviews and will make a statement in May about the state of clinical practice.

They also asked for nominations and self-nominations of “best practice sites”, and the CPRG is a finalist! Dr. Bernier has been involved in additional interviews on a variety of topics and the interviewers will want to speak to 10 or so members to get their input also.

Kudos to Drs. Bernier and DeWitt for their work toward this exciting honor!

- University of Indianapolis – Four guests from UI joined our meeting because they are interested in starting a pediatric PBRN in their area and wanted to see how we work. UI bought or went into partnership with the various health departments in the city, and as a result, they have a large number of pediatric practices, many of whom are research oriented. While there is an infrastructure on the adult side for research, there is nothing for pediatrics, and they would like to grow and support investigative ideas of practitioners and clinicians.

- PAS Abstracts – PAS is April 29-May 2 in San Francisco. We have submitted two abstracts on ADD (Dr. Manny Doyne) and the Atkins study (Dr. Siegel). We have not yet heard about acceptance.

## 2. STUDIES UNDERWAY

- Atkins Low-Carbohydrate Diet Study – 33 patients have completed 6 months so far. 56 have lost (average of 11 lbs) with a high loss of 68 lbs in one year! Eight have gained or stayed the same.

The Atkins Foundation is very interested in a continuation study and the IRB is allowing us to submit as a revision to the current study. It would extend enrollment, for those patients who are interested, to a total of 36 months in the study. Patients would see the dietician at 3-month intervals in years 2 and 3, and would see their physicians at months 24 and 36. We will be submitting the revision to the IRB this week and should hear from the Atkins Foundation regarding funding within a few weeks.

- Surveillance – Dr. Bev Connolly sent an email last week that everything has arrived in the Cincinnati area. This is the third winter season for the surveillance project, and we have an average of 12 members that provide data. Our data closely matches and corroborates what has been seen in the hospital and sometime precedes it by a week.

Dr. Bernier is talking with the Cincinnati Health Department regarding an automatic signal detection system that would link our data to the CDC database so that our data can become even more useful.

- Obesity Prevention Toolkit – We have piloted a demonstration version of our cards (adapted from WIC Help Me Grow cards) in the CCHMC Pediatric Primary Care waiting room and are currently analyzing the results to determine what modification should be made. Dr. Bolling thinks the cards will be a great adjunct to either Dr. Debra Krummel's study or his own study as a control tool.

## 3. NEW & UPCOMING STUDIES

- POINT Study (Preventing Obesity in Newborns and Toddlers) – Dr. Krummel should receive an answer regarding approval by June.

## 4. PROPOSED STUDIES

- Night Terrors and Iron – Dr. Dies is interested in studying the effects of a multivitamin with iron on children with night terrors. He read an article that iron was effectively used to halt breath holding behavior in children and then mistakenly applied this to a patient with night terrors. The patient tested iron deficient and a multivitamin stopped the terrors within two weeks. Almost all kids he has seen since then with night terrors have been iron deficient and, after starting a multivitamin with iron, have had the night terrors stop.

He has found there is no research and nothing written about the effect of iron on night terrors and thinks it would be a great study. There was discussion about controlling for the effect of iron versus other components of the multivitamin, and about what the control group would be. Drs. Seigel and Bolling will work with Dr. Dies to develop a study design and funding opportunities. It was suggested that a company that produces a children's vitamin might be interested in funding the study. The University of Indianapolis also thought this would be a fantastic first study to kick off their new research group.

- Tailored Nutritional Therapy (TNT) – Dr. Siegel is interested in a study that would apply nutrition to a shared decision making model. The literature continues to show that it doesn't really matter what diet you are on as long as you stick with it and are losing weight – low carb, low fat, low glycemic, low calorie all work.

He would like to divide patients, overweight/obese 6 yrs old and up, into 2 groups: One group (control) would get randomized into one of four diets (low fat, low GI, low carb, paleodiet) with no choice. The second group (TNT group) would meet with a counselor who reviews the family situation and the dieting options with the family and customizes/recommends a diet for the patient. They would then re-evaluate after a month and could change diets if warranted.

Dr. Green noted that she is already doing a form of this with her patients – she discusses the different dieting options and allows the family to decide based on their situation and interest.

There were questions from the group regarding what the research question is (does selection of diet lead to greater success? are parents more compliant with a diet they have chosen?) and what the control would be. There was also discussion that in Shelly Kirk's study they are finding that some patients are dropping out if they don't get randomized into the diet they wanted.

Dr. Downs and Mrs. Khoury noted that randomization would be difficult as you would have to statically weight the diets and that would get extremely complicated.

**Next Meeting: TBD, early March**