

CINCINNATI PEDIATRIC RESEARCH GROUP
Minutes of the Meeting
March 31, 2004

IN ATTENDANCE: Jeanie Bailey, CCRP
 Richard Berger, MD
 Jeralyn Bernier, MD, MPH
 Jim Davis, MD
 Camille Graham, MD
 Evie Joseph, MD
 Willie Ng, MD
 Robert Siegel, MD

I. ADMINISTRATIVE

1. Members attending the Pediatric Academic Society (PAS) annual meeting include Drs. Bernier, Siegel, Davis, Doyne, and possibly Dr. Joseph.
2. Dr. Bernier received an email on the APA listserv regarding a workshop for performing research in community practice. She is going to send a reminder that there is a PBRN special interest group for interested parties.
3. The Advisory Board exists because it is required by the AHRQ grant. We need a community member to sit on the board. Everyone should consider if they have a parent who might be interested in discussing research in practice and would be available for noon meetings four times a year..
4. A link to the NIH online research compliance training "Human Participant Protections Education for Research Teams" has been added to the CPRG website. It can also be found at <http://cme.cancer.gov/c01/>. This is not a required training, but is recommended by the CPRG and provides CME credit.
5. The new CPRG brochures are in. If you would like a small supply, please call Lea at (513) 636-4183 or email at lea.alae@cchmc.org

II. STUDIES UNDERWAY

1. CHIRP Study
We still need participants who are 7-15 year old asthmatics. If they complete the three visit study, the provider also receives a monetary incentive payment. Call Jeanie at 636-4946 to refer patients.
2. Obesity Study
The obesity management survey is complete with more than 50% returns. The summary report is

almost finished and will be shared with CPRG members before being distributed to the community.

3. Surveillance

There will be user meetings and an upgrade to the system completed by May or June. Suggestions were made by meeting participants to make data entry quicker and more user-friendly, such as checkboxes for common as well as unusual complexes and adding symptoms for conjunctivitis. Questions will be added to help capture symptoms that are managed via phone and not with office visits.

There was also discussion about the bulletin feature, and an effort will be made to work with the Health Department to update bulletins regularly and make it more interesting.

III. NEW STUDIES

1. Atkins Study

General: The Atkins Foundation has funded this program. It is a low-carbohydrate intervention for 70 participants ages 12 and up who have failed with a conventional low fat/low calorie diet. Any patient who has not tried a conventional diet in the past will be placed into Group 1 and given a conventional diet to follow for 2 months. Those who have a history of failure on a conventional diet will be immediately entered into Group 2. After 2 months, failures in Group 1 will crossover to Group 2. Under the protocol, failure is defined as weight gain after 2 months; however, after discussion, failure may be redefined as weight gain or no weight loss, allowing patients who have not lost under a conventional plan to crossover into the Atkins plan.

Nutritional Protocols: The nutritional protocols will be developed by a nutritionist, who will meet with the study participants at regular intervals to assess their progress. The nutritionist is paid by the study and will ideally meet with participants at the physician's office so that the physician can also check in with the patient.

Follow-Up Visits: The extent of the physician's visit with the participant during the follow-ups and the timing of the follow-ups was the topic of much discussion, and will be more specified in the study sheet.

Lab Tests: There was also much discussion regarding the lab tests called for in the protocol, and the group decided to modify the protocol to add an 8-9 hour fasting lipid profile, renal profile, and thyroid (TSH only) to rule out metabolic syndrome. These tests will be required upon entry into Group 2 and recommended at entry into Group 1. Testing and office visits will be billed through insurance, however there is a fund to cover self-pays and claims rejected by insurance.

Activity: Original protocol called for participants to wear an activity bracelet, but this will be changed to a pedometer due to the cost of the activity bracelets (\$1200 each). An activity log will also be kept by the participants.

Enrollment/Timeframe: 70 total participants will be enrolled with an assumption that 36-38 will finish the study. Exclusionary criteria include any condition or medication that causes weight gain or obesity and concurrent involvement in another obesity study. Dr. Siegel wants to make the parents call the nutritionist to make an appointment to enroll instead of having the physician enroll the patients. The physician will only give the patient a pamphlet with the study information and the nutritionist's phone number. The timeframe is flexible, and can begin

anytime. Summer was agreed to be a good time because kids are coming for physician visits, it is easier for them to keep their appointments, and activity level will be higher, which may increase success.

III. PROPOSED STUDIES

1. Otitis Media

Dr. Berger heard that Lynn Olsen of the AAP suggested that the CPRG join with North Carolina for a study of observation management of otitis media. Dr. Bernier will check with Lynn regarding this during a CHIRP conference call next week.

2. Further Obesity Research

Dr. DeWitt still wants to pursue additional obesity funding for a broader study, and Dr. Bernier is looking for an opportunity to submit an application in the fall.