



Dear Colleague,

I am writing to make you aware of an important clinical trial supported by the National Institutes of Health (NIH) that we are conducting at Children's Hospital of Pittsburgh of UPMC (Oakland), and at affiliated PittNet practices. The study evaluates duration of treatment for young children with acute otitis media (AOM), 5 versus 10 days, and its impact on antimicrobial resistance.

We invite you to actively participate in this research program by referring parents whose children have AOM for which they have not received treatment. We will keep you updated about the enrollment and progress of your patients participating in our study. Our purpose is not to assume the care of your patients, but only to carefully follow this group of children in order to document the treatment and course of this episode of AOM.

A "watchful waiting" approach has been advocated in the AAP/AAFP joint management guidelines, based on review of clinical trials that were characterized by numerous and serious methodological limitations. We conducted a carefully designed NIH-funded clinical trial between 2006 and 2009 of amoxicillin-clavulanate versus placebo for children 6-24 months of age with AOM, and found that children who received antibiotics had a more rapid resolution of clinical symptoms and a lower clinical failure rate at the end of therapy (N Engl J Med. 2011 Jan 13;364:105-15). In our current study, we will determine whether 5 days versus 10 days of amoxicillin-clavulanate are equally effective. With the shorter course of antibiotics we hope to demonstrate less side effects and lower antibiotic resistance.

The U.S. Food and Drug Administration and the NIH have again approved and funded our study, respectively. The study will enroll a total of 600 children with AOM during the next 4 years. Children will be randomized to receive amoxicillin-clavulanate for 5 or 10 days and will be seen for this AOM episode and every 6 weeks thereafter during the respiratory season. You can find information about this study on Children's Hospital's Web site at www.chp.edu/ears.

As always, thank you for your support of our research program. If you have any questions, please do not hesitate to contact me at 412-999-EARS (3277) or hoberman@chp.edu.

Very truly yours,

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