



March 7, 2007

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 and at Children's Community Pediatrics in Kittanning, Pa. The study is titled "Efficacy of Antimicrobials in Young Children With Acute Otitis Media."

We invite you to actively participate in this research program by referring parents and their children who currently have acute otitis media (AOM) and 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.

As you know, AOM remains the most frequently occurring clinical condition for which antibiotics are prescribed. Three interrelated factors have grown increasingly important in the management of children with AOM:

- 1) The increasing development of antimicrobial resistance and, in particular, the rapidly increasing prevalence worldwide of drug-resistant *Streptococcus pneumoniae*
- 2) The fact that antimicrobial usage contributes significantly to the development of antimicrobial resistance, and, accordingly, less antibiotic use will help decrease the spread of resistance
- 3) The substantial decrease in invasive pneumococcal disease that resulted from universal routine immunization with pneumococcal conjugate vaccine

However, at the same time, a "watchful waiting" approach has generated interest, in part, related to its inclusion as an option in the AAP/AAFP joint management guidelines, based on review of clinical trials that were characterized by numerous and serious methodological limitations. Accordingly, we believe that conducting a carefully designed clinical trial in children 6–24 months of age will address an issue of particular concern that has not been satisfactorily addressed in previous studies — whether antimicrobial treatment, along with analgesic treatment, offers young children with AOM an earlier and more complete overall clinical improvement than analgesic treatment alone.

The U.S. Food and Drug Administration and the NIH have endorsed our study, which will enroll a total of 268 children with AOM during this and next year's respiratory seasons. Children will be randomized to receive Augmentin ES-600 or placebo and will be seen four times during a one-month period. If not improving, they will be seen almost immediately.

You can find information about this study on Children's Hospital's Web site at www.chp.edu/ears, as well as other educational opportunities (with optional CME) for practitioners. Two Web-based, interactive, multi-modal, self-study modules are available on the Diagnosis of Otitis Media with Effusion (OME) and Diagnosis of AOM. Each module includes tympanic membrane photographs, videos of tympanic membrane mobility, clinical tips and an interactive practice session. For diagnostic practice and feedback, check out the DxEar: Standardization of AOM Diagnosis self-assessment exercise. Fifty tympanic membrane videos offer the opportunity to distinguish AOM, OME and a normal middle ear status.

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 alejandro.hoberman@chp.edu.

Very truly yours,

Alejandro Hoberman, MD
Chief, Division of General Academic Pediatrics