## Antibiotics for Acute Otitis Media Get a Boost

#### BY SHERRY BOSCHERT

EXPERT ANALYSIS FROM THE ANNUAL MEETING OF THE AMERICAN ACADEMY OF PEDIATRICS

SAN FRANCISCO – Antibiotic therapy for acute otitis media may be more effective than some physicians think, a study has shown.

Some new data add to controversy that has been stirring since 2004 clinical

## Parental AOM Diagnoses Held To Be Unreliable

EXPERT ANALYSIS FROM THE ANNUAL MEETING OF THE AMERICAN ACADEMY OF PEDIATRICS

SAN FRANCISCO – Parents may think they know when their child has an acute ear infection, but they don't.

That's the implication of a study of children aged 6-35 months that showed parents' reasons for suspecting acute otitis media (AOM), symptoms, and symptom scores could not differentiate 237 children with AOM from 232 who had respiratory tract infection without AOM. Only when tympanic-membrane examination was added to these clues could the diagnosis be made (Pediatrics 2010;125: e1154-61).

"For me, this study has quite a lot of meaning," Dr. Ellen R. Wald said at the meeting. "Parental diagnosis of acute otitis media" is not reliable. "We shouldn't let the presence of those historical items persuade us" to accept a presumed diagnosis.

The diagnosis of AOM relies heavily on accurate otoscopy, said Dr. Wald, professor and chair of pediatrics at the University of Wisconsin, Madison.

She did not participate in the Finnish study, in which parents completed structured questionnaires on the occurrence, duration, and severity of symptoms before otoscopic examination of the child.

The reasons that parents thought a child might have an ear infection did not differ significantly between groups. In children with and without AOM, respectively, parental suspicion was raised by restless sleep in 28% and 29%, ear pain in 13% and 9%, ear rubbing in 10% and 18%, severe or prolonged rhinitis or cough in 9% and 7%, and irritability in 17% and 19%.

Fever also did not differentiate between the two groups.

Otoscopy also is essential to differentiate AOM from OM with effusion, Dr. Wald added. AOM results from a bacterial infection, and antibiotic therapy may help. OM with effusion is a sterile, nonbacterial inflammatory state that resolves spontaneously, and antibiotic therapy is neither appropriate nor beneficial. OM with effusion causes hearing loss, which is a confounder for AOM, she said.

Dr. Wald said she has no relevant conflicts of interest.

practice guidelines from the American Academy of Pediatrics and the American Academy of Family Physicians included the option of watchful waiting in some children with uncomplicated acute otitis media (Pediatrics 2004;113:1451-65).

Support for management by observation came primarily from the desire to avoid escalation of antibiotic resistance and from the results of several metaanalyses suggesting that antibiotics are only modestly beneficial in treating acute otitis media, compared with placebo.

"Many of the meta-analyses had substantial flaws," and included studies that used weak definitions of acute otitis media and so classified some children who had otitis media with effusion as having acute otitis media, Dr. Ellen R. Wald said at the meeting. Because antibiotic therapy does not help otitis media with effusion, it's no wonder that antibiotics barely outperformed placebo in these studies, said Dr. Wald, professor and chair of pediatrics at the University of Wisconsin, Madison.

She described a new study led Dr. Alejandro Hoberman, chief of pediatrics at Children's Hospital, Philadelphia, that found significantly lower rates of treatment failure in children treated with amoxicillin-clavulanate, compared with placebo, she added. The results have

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#### been submitted for publication.

The study randomized 291 children aged 6-23 months with confirmed acute otitis media to treatment with the antibiotics or placebo for 10 days, with follow-up on days 4/5, days 10/12, and days 21/25. Patients with clinical failure to first-round therapy received amoxicillin and cefixime.

The amoxicillin-clavulanate treatment failed at or before days 4/5 in 4% of patients, compared with a 23% clinical failure rate in the placebo group (P less than .001). Clinical failure rates at or before days 10-12 were 16% in the amoxi-

cillin-clavulanate group and 51% in the placebo group (P less than .001).



These differences are 'more dramatic than in previously reported trials.'

DR. WALD

These differences are "more dramatic than in previously reported trials," Dr. Wald said. For children aged 6-23 months who have acute otitis media, treatment with amoxicillin-clavulanate for 10 days provides measurable short-term benefit, she said.

In a separate study by other investigators, surveys completed by 1,114 physicians found no significant increase in the proportion who managed acute otitis media without antibiotics after the guidelines (16%), compared with before the guidelines (11%), she added (Pediatrics 2010 [doi:10.1542/peds.2009-1115]).

Dr. Wald said she had no relevant conflicts of interest.



INFECTIOUS DISEASES

Source: Kantar Media, Focus® Medical/Surgical June 2010 Readership Summary; Pediatrics Section, Table 139 Projected Average Issue Readers

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References: 1. Pentacel vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2009. 2. Decker MD, Edwards KM, Bradley R, Palmer P. Comparative trial in infants of four conjugate Haemophilus influenzae type b vaccines. J Pediatr. 1992;120:184-189. 3. Granoff DM, Anderson EL, Osterholm MT, et al. Differences in the immunogenicity of three Haemophilus influenzae type b conjugate vaccines in infants. J Pediatr. 1992;121:187-194. 4. Greenberg DP, Differences in the immunogenicity of three Haemophilus influenzae type b conjugate vaccines in infants. J Pediatr. 1992;121:187-194. 4. Greenberg DP, Lieberman JM, Marcy SM, et al. Enhanced antibody responses in infants given different sequences of heterogeneous Haemophilus influenzae type b conjugate vaccines. J Pediatr. 1995;126:206-211. 5. Centers for Disease Control and Prevention (CDC). Estimated vaccination coverage with individual vaccines and selected vaccination series before 24 months of age by state and local area US, National Immunization Survey, 2008. http://www2a.cdc.gov/nip/coverage/nis/ nis\_iap2.asp?fmt=v&rpt=tab09\_24mo\_iap&atr=@1/2008-Q4/2008. Accessed October 12, 2010. 6. CDC. Recommended immunization schedules for persons aged 0 through 18 years—United States, 2010. MMWR. 2010;58(51&52):1-4. 7. American Academy of Pediatrics. Combination vaccines for childhood immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). Pediatrics. 1999;103:1064-1077. 8. Food and Drug Administration. Pentacel®; DTaP-IPV/Hib Combined (diptheria and tetanus two ids and acellular pertursis adsorbed incretived policyius and Haemonhilus in

toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus* b conjugate [tetanus toxoid conjugate] vaccine combined). VRBPAC Briefing Document. http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4275B1-01.pdf. Accessed October 12, 2010.

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