

treatment of TB, which remains a major cause of morbidity and mortality worldwide.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107LLLL

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Burden of Seasonal Influenza Hospitalization in Children, United States, 2003 to 2008

Dawood FS, Fiore A, Kamimoto L, et al; Emerging Infections Program Network. *J Pediatr.* 2010;157(5): 808–814

PURPOSE OF THE STUDY. To estimate the rates of hospitalization with seasonal influenza in children younger than 18 years from a large, diverse surveillance area during 2003–2008.

STUDY POPULATION. A case-subject was defined as a child younger than 18 years residing in the surveillance area who was hospitalized with laboratory-confirmed influenza virus infection from the 2003–2004 and 2007–2008 influenza seasons. Surveillance was conducted through the Centers for Disease Control and Prevention Emerging Infections Program Network, which included up to 10 different states and 5.3 million children.

METHODS. Hospitalized children were identified retrospectively; clinicians made influenza-testing decisions. Data collected from the hospital record included demographics, medical history, and clinical course. Incidence rates were calculated with census data.

RESULTS. The highest hospitalization rates occurred in children younger than 6 months (seasonal range: 9–30 per 10 000 children), and the lowest rates occurred in children aged 5 to 17 years (0.3–0.8 per 10 000). Overall, 4015 children were hospitalized, 58% of whom were identified with rapid diagnostic tests alone. Forty percent of the children who were hospitalized had underlying medical conditions; asthma (18%), prematurity (15% of children younger than 2 years), and developmental delay (7%) were the most common. Severe outcomes included ICU admission (12%), respiratory failure (5%), bacterial coinfection (2%), and death (0.5%).

CONCLUSIONS. Influenza-associated hospitalization rates varied according to season and age and likely underestimated true rates, because many hospitalized children are not tested for influenza. The proportion of children with severe outcomes was substantial across seasons. Quantifying the incidence of influenza hospitalization and severe outcomes is critical to defining disease burden.

REVIEWER COMMENTS. Children younger than 6 months had the highest rates of hospitalization across all seasons.

Because these children cannot receive the influenza vaccine, immunization of household contacts, out-of-home caregivers of children in this age group, and pregnant women and women who are or will become pregnant during influenza season remains the primary way to reduce the risk of influenza in infants younger than 6 months. The data from this investigation should provide an even stronger argument for recommending the influenza vaccine for appropriate patients.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107MMMM

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A Placebo-Controlled Trial of Antimicrobial Treatment for Acute Otitis Media

Tähtinen PA, Laine MK, Huovinen P, Jalava J, Ruuskanen O, Ruohola A. *N Engl J Med.* 2011;364(2): 116–126

PURPOSE OF THE STUDY. To examine the efficacy of treatment of acute otitis media (AOM) with amoxicillin-clavulanate.

STUDY POPULATION. The study included a total of 319 children aged 6 to 35 months with AOM.

METHODS. The diagnosis of AOM was made with strict criteria, including signs on physical examination and typical symptoms. The subjects were randomly assigned to receive amoxicillin-clavulanate or placebo for 7 days. The primary outcome was the time to treatment failure from the first dose until the end of treatment on visit day 8. Treatment failure was based on the overall condition of the subjects (including adverse events) and otoscopic examination.

RESULTS. Among the subjects who received amoxicillin-clavulanate, treatment failure occurred 18.6% of the time compared with a rate of 44.9% for the subjects who received placebo ($P < .001$). This difference was already apparent at the first scheduled visit at day 3, at which time 13.7% of the subjects who received amoxicillin-clavulanate, compared with 25.3% of subjects who received placebo, had treatment failure. Amoxicillin-clavulanate reduced the progression to treatment failure by 62% ($P < .001$) and the need for rescue treatment by 81% ($P < .001$). Adverse events (primarily diarrhea) were significantly more common in the amoxicillin-clavulanate group than in the placebo group.

CONCLUSIONS. Children with AOM (aged 6–35 months) treated for 7 days with amoxicillin-clavulanate had a much lower rate of treatment failure and much lower need for rescue treatment than children treated with placebo. However, the children treated with amoxicillin-clavulanate had more adverse effects.

REVIEWER COMMENTS. This article challenges us to rethink an approach to therapy. Some of the reasons for the differences between these results and other studies that have been performed in past years (which have not shown as pronounced an effect of treatment versus placebo) might include the strict criteria for diagnosing AOM, the decision to include all subjects in the trial with AOM irrespective of the severity, and the use of a potent antibiotic. The authors pointed out that, because the treatment group showed improvement as early as day 3, additional investigation might be needed to examine the practice of “watchful waiting.” Another article

in the same issue of the journal (Hoberman A, Paradise JL, Rockette HE, et al. *N Engl J Med.* 2011;364[2]:105–115) reported that among children younger than 2 years with AOM, treatment with amoxicillin-clavulanate for 10 days, relative to placebo, tended to reduce the time to resolution of symptoms and reduced both the overall burden of symptoms and the rate of clinical failure of treatment.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107NNNN

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A Placebo-Controlled Trial of Antimicrobial Treatment for Acute Otitis Media

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Pediatrics 2011;128;S146

DOI: 10.1542/peds.2011-2107NNNN

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