## Pneumococcal Vaccine Also Works vs. H. influenzae

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hildren receiving an investigational conjugate pneumococcal vaccine that uses a carrier protein derived from *Haemophilus influenzae* experience a one-third reduction in acute otitis media episodes compared with controls, said Dr. Roman Prymula and associates of the University of Defense, Hradec Králové, Czech Republic.

The vaccine, GlaxoSmithKline Inc.'s Streptorix, combines the seven strains of *Streptococcus pneumoniae* that are currently included in Wyeth's Prevnar (4, 6B, 9V, 14, 18C, 19F, and 23F) with four additional strains (1, 3, 5, and 7F). And in contrast to Prevnar, in which the seven strains are conjugated to a nontoxic mutant of diphtheria toxin (CRM 197), the 11 pneumococcal serotypes of this investigational vaccine—hereafter called the protein D conjugate vaccine—are conjugated to a

carrier protein derived from *H. influenzae*, thereby providing protection against disease caused by that organism as well, the investigators said (Lancet 2006;367:740-8).

A total of 4,968 infants were randomized to receive doses of the protein D conjugate vaccine, or hepatitis A vaccine as a control, at 3, 4, 5, and 12-15 months of age.

During follow-up through 24-27 months of age, clinical episodes of acute otitis media (AOM) occurred in 366 protein D conjugate vaccine recipients and 553 controls,

of which 333 and 499, respectively, were recorded in the per-protocol analysis. The overall incidence of AOM was 83.3 cases per 1,000 person-years with the protein D conjugate vaccine, compared with 125.2 per 1,000 person-years for the controls.

Efficacy of the protein D conjugate vaccine against the first episode of AOM caused by vaccine pneumococcal serotypes was 52.6% in both the per-protocol and intention-to-treat groups; efficacy against the first episode of AOM caused by nontypable H. influenzae was above 30% for both cohorts, but only significant for the intent-to-treat analysis (32.7%). Overall protective efficacy against clinical AOM episodes was 33.6%, reported Dr. Prymula, a consultant to Glaxo-SmithKline, and associates. Safety data after the primary series—available for 2,489 infants in the protein D conjugate vaccine group and 2,479 controls who received hepatitis A vaccine—showed no significant differences in the number of unsolicited adverse events reported within 31 days after vaccination (48% vs. 50%), or in the number of events judged to be casually related to the vaccine (2.5% vs. 3.0%).

Total adverse event rates after the booster and rates of serious adverse events also did not differ significantly between the two groups in this study, which was supported by GlaxoSmithKline Biologicals, Rixensart, Belgium.

### HIV Infection Adds to Spread Of Hepatitis C

The risk of transmission of hepatitis C from mother to infant is increased by concomitant HIV infection.

The study turned up the surprising result that girl babies are at twice the risk of vertical transmission as are boys (J. Infect. Dis. 2005;192:1872-9). The study, by the European Paediatric Hepatitis C Virus Network, involved 1,479 pregnant women with confirmed hepatitis C infections from 33 sites across Europe. They and their babies were followed prospectively over at least 24 months.

Infants were counted as being infected only if they tested positive (by an RNA polymerase chain reaction test and/or by the presence of anti-hepatitis C antibodies) after the age of 18 months. This is the age by which passively acquired maternal antibodies have almost always disappeared.

The overall hepatitis C vertical transmission rate was 6.2%. Among mothers who were coinfected with HIV, the transmission rate was 8.7%, significantly higher than the 5.5% rate seen among mothers who were infected only with hepatitis C.

After adjusting for maternal HIV infection status, mode of delivery, prematurity, and infant feeding type, the study showed that female infants had 2.07 times the risk of vertical transmission as males, a statistically significant increase.

—Robert Finn



# 70,000 HOSPITALIZATIONS

EVERY YEAR.

**AN ESTIMATED** 

#### AN UNAVOIDABLE DISEASE...2

- The most common cause of severe gastroenteritis in infants and young children in the United States<sup>2</sup>
  - Greatest risk for severe disease occurs primarily in young children between 6 and 24 months of age.<sup>3</sup>

### WITH UNPREDICTABLE CONSEQUENCES<sup>2,4</sup>

- No way to predict which infants will suffer severe disease4
- Potential for rapid deterioration in cases in which severe vomiting occurs<sup>5</sup>
- Responsible for an estimated 500,000 physician visits,<sup>1</sup>
   70,000 hospitalizations,<sup>1</sup> and 160,000 ER visits<sup>6</sup> among children
   5 years of age every year in the United States<sup>1,6</sup>
- Responsible for an estimated 100 deaths per year among children <5 years of age in the United States—an average of nearly 2 deaths per week<sup>7</sup>

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