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Telephone 503/731-4024
Emergencies 503/731-4030
Fax 503/731-4798
cd.summary@state.or.us
www.oshd.org/cdpe/

CENTER FOR DISEASE PREVENTION & EPIDEMIOLOGY • OREGON HEALTH DIVISION

PNEUMOCOCCAL CONJUGATE VACCINE

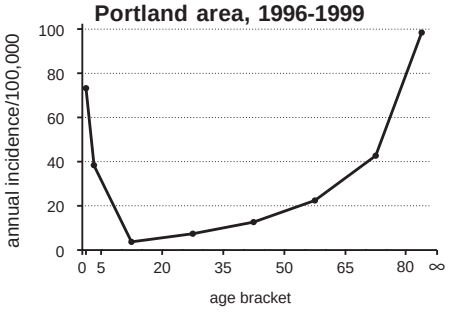
Last June, the Advisory Committee on Immunization Practices voted to recommend the new pneumococcal conjugate vaccine for routine use in infants and as a catch-up vaccination for children 2–5 years of age. The new vaccine should be considered for all children through 59 months of age, including those at high and moderate risk. This issue of the *CD Summary* summarizes these recommendations, including vaccine schedules, and reviews national and Oregon data about pneumococcal disease.

THE PNEUMOCOCCUS

Streptococcus pneumoniae is a Gram-positive diplococcus that comes in 90 flavors, called serotypes, which reflect varying capsular polysaccharides. The pneumococcus causes an estimated 106,000–175,000 cases of pneumonia, 2,600–6,200 cases of meningitis, and 7,000–12,000 deaths annually in the U.S.[2, 3]

Special surveillance for "invasive" pneumococcal disease (defined as isolation of the bacterium from a normally sterile site) has been conducted in Clackamas, Multnomah, and Washington counties since 1995. The overall incidence has been 19 cases per 100,000 residents per year; but the rates are consistently much higher in young children and the elderly (see graph). Data from several states, including Oregon, show a peak incidence at 6–11 months of age (235/100,000). Most of this is bacteremia in the absence of an obvious focus of infection.

Invasive Pneumococcal Disease in the Portland area, 1996-1999



Several ethnic groups have been found to be at significantly elevated risk for invasive pneumococcal disease. Navajo and Apache children 1–2 years of age who live on reservations in the southwestern U.S. have had rates of 557–2,396/100,000. Alaskan Native children have rates about 4 times that of non-Alaskan Native children, and black kids are at 2–3 times the risk of their white peers.[1]

Beneath this peak of invasive disease lies acute otitis media, which is probably the most common pneumococcal infection. By 12 months of age, 62% of children have had at least one episode of acute otitis media, and the costs of this affliction (including >500,000+ tympanostomy tubes placed annually) were estimated at $3.5 billion/year in the U.S. in 1989.[4] The pneumococcus has been found in 28%–55% of acute otitis media cases wherein diagnostic tympanocentesis was performed. Acute otitis media is the leading reason for the prescription of antibiotics for children, and hence contributes substantially to increased antimicrobial resistance.

THE OLD VACCINE

The 23-valent pneumococcal polysaccharide vaccine has been the mainstay of our efforts to prevent pneumococcal disease. The vaccine is 56% to 81% effective in preventing invasive pneumococcal disease and is recommended for all persons ⩾65 years of age, as well as persons ⩾2 years of age with chronic cardiovascular, pulmonary, metabolic, or hepatic illnesses, or those with immune compromise.[5] As is the case for other polysaccharide vaccines, however, it has little effectiveness in the very young. And it has no appreciable effect on nasopharyngeal carriage of the pneumococcus.

THE NEW VACCINE

The conjugate vaccine consists of polysaccharide antigens of *S. pneumoniae* linked to a nontoxic variant of diphtheria toxin. For some reason, the serotype profile of pneumococci causing disease in children differs from that of pneumococci that infect adults. Serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F are the seven most commonly isolated from children with invasive disease, and were therefore chosen for inclusion in the pneumococcal conjugate vaccine (PCV7); these serotypes account for 83% of invasive disease among children <5 years old in Oregon.

EFFICACY

In a prospective, double-blind trial at a California Kaiser HMO, 37,868 healthy children were randomized 1:1 to receive either PCV7 or a control vaccine. Vaccinations were administered at 2, 4, 6, and 12–15 months of age. Cases of invasive pneumococcal disease were identified through active surveillance. Efficacy analysis was performed in April 1999. As of that point, 40 cases of invasive pneumococcal disease had occurred in children who had received 4 doses of the vaccine to which they'd been randomized (either PCV7 or the control); 39 of these had occurred in recipients of the control vaccine—which meant that PCV7 was 97% protective (95% C.I. 83%–100%). In an intent-to-treat analysis, PCV7 proved 94% (95% C.I. 80%–98%) protective. Reassuringly, recipients of PCV7 showed no increase in disease caused by non-vaccine serotypes. Moreover, PCV7 vaccinees had 7% fewer episodes of acute otitis media, and were 20% less likely to get tympanostomy tubes.[6] More good news: vaccination of infants with PCV reduces nasopharyngeal carriage of those serotypes contained in the vaccine.[7]

SAFETY

In the Kaiser trial, immunizations were administered along with other vaccines, such as diphtheria-tetanus-pertussis (DTP) vaccine. Safety was assessed by calling a subset of parents at 48–72 hours and again at 14 days post-vaccination, and comparing reactions to those experienced by recipients of DTP. The usual local side effects occur with PCV7 shots:

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erythema in 10%–14%, induration in 10–12%, and tenderness in 15–23%. These figures were somewhat lower than seen with whole-cell pertussis vaccine but higher than seen with acellular pertussis vaccine. Fever >38°C occurred within 48 hours in 15–24%; 1–2.5% reported fever >39°C. Febrile seizures within 3 days occurred at a rate of 1 per 7,000 doses of PCV7—less than historic rates following vaccination with whole-cell pertussis vaccine.

RECOMMENDATIONS

All children <2 years of age and those 24–59 months of age with high risk for invasive pneumococcal disease should be immunized. High risk includes sickle cell disease, asplenia or splenic dysfunction; congenital immunodeficiency; HIV infection; cancer; renal failure or nephrotic syndrome; chemotherapy or long-term systemic corticosteriod therapy; solid organ transplantation; chronic cardiac disease; chronic pulmonary disease except asthma; chronic CSF leak; or diabetes mellitus.

Consider PCV7 for *all* children 24–59 months old, with priority for kids 24–35 months; those of African-American, Alaska Native, or American Indian descent; and those who attend group day care. The recommended schedule is provided in table below. Children ⩾2 years of age with high risk for invasive pneumococcal disease should also receive the 23-valent pneumococcal polysaccharide vaccine (PPV23) to provide additional serotype coverage[5]; see reference 1 for specifics.

Prevnar™ contains no preservatives. Hypersensitivity to any vaccine component is a contraindication to its use. Mild URI with or without fever is not a contraindication. Moderate or severe illness may merit postponement. Possible adverse events should be reported to the FDA's VAERS hotline (800/822-7967). Concurrent vaccination with PCV7 and PPV23 has not been studied and is not recommended.

IS THIS FREE OR WHAT?

What. This vaccine is not cheap: current estimates are $58/dose. Vaccine For Children (VFC) funds are available for both PCV7 and PPV23. For the VFC-eligible child <6 years old, no questions will be asked regarding compliance with the recommendation/consideration criteria. For non-VFC-eligible children, coverage varies by health plan. Check with the insurer.

Recommended Vaccination Schedules

Age at first dose (mos)	Primary series	Additional dose
2 – 6	3 doses, 2 mos apart *	1 dose at 12 – 15 mos **
7 – 11	2 doses, 2 mos apart *	1 dose at 12 – 15 mos **
12 – 23	2 doses, 2 mos apart *	–
24 – 59		
Healthy children	1 dose	–
At-risk children	2 doses, 2 mos apart ***	–

* For children vaccinated at age < 1 year, minimum interval between doses is 4 weeks.
** The additional dose should be administered ⩾ 8 weeks after the primary series has been completed
*** Minimum interval between doses is 8 weeks

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Influenza Reemerges

FIVE CULTURE-CONFIRMED cases of influenza type B have been reported by the Oregon State Public Health Laboratory. Four adult patients resided in Lane County and one in Benton County. All experienced onset of symptoms in the latter half of November.

Nationally, 86% of isolates tested this season by the Centers for Disease Control and Prevention were found to be type A, of which 92% were A(H1N1) and the remainder A(H3N2). A and B isolates studied thus far were antigenically similar to the current vaccine strains.