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Updated Recommendations on the Use of Pneumococcal Conjugate Vaccine: Suspension of Recommendation for Third and Fourth Dose

On February 13, 2004, CDC recommended that health-care providers temporarily suspend routine use of the fourth dose of 7-valent pneumococcal conjugate vaccine (PCV7) when vaccinating healthy children (*1*). This action was taken to conserve vaccine and minimize the likelihood of shortages until Wyeth Vaccines, the only U.S. supplier of PCV7 (marketed as Prevnar®), restores sufficient production capacity to meet the national need. Since that recommendation, PCV7 production has been much less than expected because of continuing problems with the PCV7 vial-filling production line. Shipments have been delayed, resulting in spot shortages that might continue beyond summer 2004 and become widespread. Effective immediately, to further conserve vaccine, CDC recommends that all health-care providers temporarily suspend routine administration of both the third and fourth doses to healthy children.

Approximately 1.3 million doses of PCV7 are needed each month to provide every infant in the United States with the full, 4-dose vaccination series. For January–April 2004, total shipments are estimated to be ≤55% of the amount needed. Limiting healthy children to 2 doses of PCV7 will conserve vaccine and permit more children to receive at least 2 doses. More vaccine is expected to become available for distribution in May and June, but availability cannot be guaranteed. CDC will continue to update health-care providers on the status of vaccine supplies while the shortage persists.

PCV7 is highly effective. The routinely recommended 4-dose series has been 97% (95% confidence interval [CI] = 76%–100%) effective against invasive disease caused by serotypes represented in the vaccine; effectiveness in children who received 3 doses before age 1 year has been 87% (95% CI = 71%–94%), and effectiveness in children who received 2 doses has been 94% (95% CI = 84%–98%) (CDC, unpublished data, 2004). Efficacy data from a randomized, controlled trial suggest that 1–2 doses of pneumococcal conjugate vaccine are protective during the 2-month interval before the next dose, with 86% effectiveness (but a 95% CI that includes zero) (*2*). Although limited data support a 2-dose schedule among infants, this regimen is preferable to vaccinating certain children with 3 doses and not vaccinating others. Because PCV7 is a new vaccine, no long-term data on vaccine effectiveness are available. However, the incidence of invasive pneumococcal disease declines rapidly after age 2 years, even in unvaccinated children. In 1998, before PCV7 was licensed, the incidence of invasive disease was 203 per 100,000 infants aged 1 year and 63 per 100,000 children aged 2 years (*3*).

To ensure that every child is protected against pneumococcal disease despite the PCV7 shortage, CDC, in consultation with the American Academy of Family Physicians, the American Academy of Pediatrics, and the Advisory Committee on Immunization Practices, recommends that all health-care providers temporarily discontinue administering the third and fourth dose of PCV7 to healthy children. Health-care providers should continue to administer the routine 4-dose series to children at increased risk for severe disease*. Unvaccinated, healthy children aged 12–23 months should receive a single dose of PCV7. For children aged ≥2 years, PCV7 is not recommended routinely.

This recommendation reflects CDC's assessment of the existing national PCV7 supply and will be changed if the supply changes. Updated information about the national PCV7 supply is available from CDC at http://www.cdc.gov/nip/news/shortages/default.htm.

Health-care providers should maintain lists of children for whom conjugate vaccine has been deferred so it can be administered when the supply allows. The highest priority for vaccination among children who have been deferred is children vaccinated with ≤2 doses who are aged <1 year.

* Including children with sickle cell disease and other hemoglobinopathies, anatomic asplenia, chronic diseases (e.g., chronic cardiac and pulmonary disease and diabetes), cerebrospinal fluid leak, human immunodeficiency virus infection and other immunocompromising conditions, immunosuppressive chemotherapy or long-term systemic corticosteroid use; children who have undergone solid organ transplantation, and children who either have received or will receive cochlear implants (*4*). All these children have been identified as being at either "high risk" or "presumed high risk" for severe invasive pneumoccocal disease (*5*).

Because data on the long-term efficacy of 3-dose or 2-dose vaccine regimens are limited, health-care providers should consider the diagnosis of invasive pneumococcal disease in incompletely vaccinated children and are encouraged to report invasive pneumococcal disease after any regimen of pneumococcal conjugate vaccine to CDC through state health departments. If a pneumococcal isolate is available from a vaccinated child, CDC will perform serotyping to determine whether the type is included in the vaccine. Additional information is available from CDC at http://www.cdc.gov/nip/home-hcp.htm and by telephone, 404-639-2215 or fax, 404-639-3970.

References

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5. American Academy of Pediatrics. Table 3.43. In: Pickering LK, ed. 2003 Red Book: Report of the Committee on Infectious Diseases, 26th ed. Elk Grove Village, Illinois: American Academy of Pediatrics, 2003.