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Notice to Readers: Limited Supply of Pneumococcal Conjugate Vaccine: Suspension of Recommendation for Fourth Dose

In December 2003, CDC reported that Wyeth Vaccines, the only U.S. supplier of 7-valent pneumococcal conjugate vaccine (PCV7, marketed as Prevnar[®]), was experiencing production constraints that could cause delays in shipments and was implementing an allocation plan to ensure the equitable distribution of available vaccine (*1*). In February 2004, Wyeth advised CDC that production constraints had not been resolved and that supplies will remain limited at least through July 2004. Until full production capacity is resumed, local shortages might occur. Effective immediately, CDC recommends that health-care providers temporarily suspend routine use of the fourth dose of PCV7 to conserve vaccine and minimize the likelihood of shortages.

PCV7 is a highly effective vaccine. In October 2000, a primary series of three PCV7 injections and one booster was recommended for all children (*2*). In 2001, the incidence of invasive pneumococcal disease among children aged <2 years was 69% less than during 1998--1999, before the recommendation (*3*). Preliminary data from CDC's Active Bacterial Core Surveillance program indicate that effectiveness, at least for the short term, is not compromised by delaying administration of the fourth dose. A case-control study comparing the effectiveness of a 3-dose series with a 4-dose series found that 3 doses were 90% effective (95% confidence interval [CI] = 74%--96%) against invasive disease caused by serotypes represented in the vaccine, whereas 4 doses were 96% effective (95% CI = 68%--100%); this difference was not statistically significant.

Because precise allocation of PCV7 is difficult, spot shortages are inevitable when supplies are limited. To ensure that every child can be protected against pneumococcal disease despite the limited supply, and on the basis of the short-term effectiveness of the 3-dose primary series of PCV7 at ages 2, 4, and 6 months, 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, regardless of the amount of PCV7 in their inventories, help conserve the national PCV7 supply by temporarily discontinuing administration of the fourth

dose of PCV7 for healthy children. Health-care providers should continue to administer the fourth dose to children at increased risk for severe disease*. Children whose booster dose is deferred should receive PCV7 on their first visit after supplies are restored. If all health-care providers comply with this temporary recommendation, >1 million doses will be conserved by July 2004, making widespread or prolonged disruptions in vaccination services less likely.

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

References

1. CDC. Limited supply of pneumococcal conjugate vaccine. MMWR 2003;52:1234.
2. CDC. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000;49(No. RR-9).
3. Whitney CG, Farley MM, Hadler J, et al. Decline in invasive pneumococcal disease after the introduction of protein-polysaccharide conjugate vaccine. *N Engl J Med* 2003;348:1737--46.
4. CDC. Pneumococcal vaccination for cochlear implant candidates and recipients: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2003;52:739--40.
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.

* Includes 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 (2); 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 pneumococcal disease (5).

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