



Complete Summary

GUIDELINE TITLE

Updated recommendations for use of pneumococcal conjugate vaccine: reinstatement of the third dose.

BIBLIOGRAPHIC SOURCE(S)

Updated recommendations for use of pneumococcal conjugate vaccine: reinstatement of the third dose [published erratum appears in MMWR 2004, Jul 16; 53(27):616]. MMWR Morb Mortal Wkly Rep 2004 Jul 9; 53(26):589-90.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Pneumococcal disease (Streptococcus pneumoniae)

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide updated recommendations on the use of 7-valent pneumococcal conjugate vaccine (PCV7)
- To ensure that every child is protected against pneumococcal disease

TARGET POPULATION

- Unvaccinated, healthy children aged 2 to 23 months seen in primary care settings
- Children identified as being at "high risk" for severe invasive pneumococcal disease, including children with sickle cell disease, asplenia, chronic heart or lung disease, diabetes, cerebrospinal fluid leak, cochlear implant, human immunodeficiency virus infection or another immunocompromising condition, and Alaska Native or American Indian children in areas with demonstrated risk for invasive pneumococcal disease more than twice the national average (i.e., Alaska, Arizona, New Mexico, and Navajo populations in Colorado and Utah)

INTERVENTIONS AND PRACTICES CONSIDERED

Revised vaccination schedule for 7-valent pneumococcal conjugate vaccine (PCV7)

MAJOR OUTCOMES CONSIDERED

- Effectiveness of 7-valent pneumococcal conjugate vaccine (PCV7) at 3 doses and 4 doses
- Incidence of invasive pneumococcal disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Notice from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (CDC, ACIP): In February 2004, production of the 7-valent pneumococcal conjugate vaccine (PCV7), marketed as Prevnar® and manufactured by Wyeth Vaccines (Collegeville, Pennsylvania), failed to meet

demand, resulting in shortages. To conserve the limited supply, CDC recommended that the fourth dose of PCV7 be withheld from healthy children. In March, because evidence indicated that production would be curtailed for several months, CDC recommended that the third dose also be withheld. Production problems now appear to have been resolved. As a result, deliveries are projected during the near term to permit the recommendation that every child receive 3 doses. Some providers might have short-term difficulties obtaining vaccine because of distribution delays; however, every effort will be made to provide sufficient vaccine to all providers.

July 2004 Recommendations

- Effective immediately, CDC, in consultation with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians, and the American Academy of Pediatrics, recommends that providers administer 3 doses of PCV7.
- The fourth dose should still be deferred for healthy children until further production and supply data demonstrate that a 4-dose schedule can be sustained.
- The full, 4-dose series should continue to be administered to children at increased risk for pneumococcal disease because of certain immunocompromising or chronic conditions (e.g., sickle cell disease, anatomic asplenia, chronic heart or lung disease, diabetes, cerebrospinal fluid leak, and cochlear implant).
- Alaska Native children and American Indian children who live in Alaska, Arizona, or New Mexico, and Navajo children who live in Colorado and Utah have a risk for invasive pneumococcal disease more than twice the national average. These children should receive the standard 4-dose PCV7 series despite the shortage.

An interim catch-up schedule is provided for children who are incompletely vaccinated ([Table](#)). The highest priority for catch-up vaccination is to ensure that children aged <5 years at high risk for invasive pneumococcal disease are fully vaccinated. Second priorities include vaccination of healthy children aged <24 months who have not received any doses of PCV7 and vaccination of healthy children aged <12 months who have not yet received 3 doses.

Because of the frequency of health-care provider visits by children during their first 18 months, catch-up vaccination might occur at regularly scheduled visits for most children who receive vaccines from their primary-care providers. Programs that provide vaccinations but do not see children routinely for other reasons should consider a notification process to contact undervaccinated children.

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>.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effectiveness of Vaccine

Four doses of the 7-valent pneumococcal conjugate vaccine (PCV7) provide the best protection, but children who have received three doses should also have a very high level of protection. PCV is a highly effective vaccine. In 2003, the incidence of invasive pneumococcal disease among children less than two years of age was 69 percent lower than it was during 1998–99, before universal recommendation for the vaccine. There is evidence of high, short-term effectiveness of the 3-dose primary series of the PCV7 administered at 2, 4, and 6 months. Preliminary data from the Center for Disease Control and Prevention's Active Bacterial Core Surveillance program indicate that effectiveness, at least for the short term, is not greatly compromised by delaying administration of the fourth dose in healthy children.

Vaccine Supply

Limiting healthy children to 3 doses of PCV7 will conserve vaccine and permit more children to receive at least 3 doses.

Subgroups Most Likely to Benefit

Children identified as being at "high risk" for severe invasive pneumococcal disease, including children with sickle cell disease, asplenia, chronic heart or lung disease, diabetes, cerebrospinal fluid leak, cochlear implant, human immunodeficiency virus infection or another immunocompromising condition, and Alaska Native or American Indian children in areas with demonstrated risk for invasive pneumococcal disease more than twice the national average (i.e., Alaska, Arizona, New Mexico, and Navajo populations in Colorado and Utah)

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

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Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Wyeth Vaccines is allocating nonpublic-purchased doses of Prevnar® directly to all physicians on the basis of previous purchasing patterns or practice birth cohort. Wyeth does not currently ship products to either wholesalers or distributors. Providers with questions about their allocation or about obtaining Prevnar® should contact Wyeth's customer service department, telephone 800-666-7248. For problems not resolved by the customer service department, providers can contact Wyeth directly, telephone 866-447-8888, extension 37932. For public-purchased vaccine, including Vaccines for Children Program vaccine, providers should contact their state/grantee immunization projects to obtain vaccine. These projects should contact their project officers at the National Immunization Program at CDC for information regarding vaccine supply.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Updated recommendations for use of pneumococcal conjugate vaccine: reinstatement of the third dose [published erratum appears in MMWR 2004, Jul 16; 53(27):616]. MMWR Morb Mortal Wkly Rep 2004 Jul 9; 53(26):589-90.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Mar (revised 2004 Jul 9)

GUIDELINE DEVELOPER(S)

American Academy of Family Physicians - Medical Specialty Society
American Academy of Pediatrics - Medical Specialty Society
Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

Centers for Disease Control and Prevention

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Updated recommendations on the use of pneumococcal conjugate vaccine: suspension of recommendation for third and fourth dose. MMWR Morb Mortal Wkly Rep 2004 Mar 5; 53(8): 177-8.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#).

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- PCV7 (Prevnar®) shortages and reinstatement of the 3rd dose in PCV7. Recommendation. Q&A. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2004 Jul.

Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 23, 2004.

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