



# PHYSICIANS' BULLETIN

## Change In Pediatric PCV Recommendation and Other Updates

### Health Groups Recommend Suspension Of 3rd and 4th Pediatric Pneumococcal Conjugate Vaccine Doses

*(Note: The following was adapted from a CDC Health Advisory sent out on March 2, 2004).*

The Centers for Disease Control and Prevention (CDC) has recommended that all health-care providers should temporarily suspend routine use of both the third and fourth doses of pneumococcal conjugate vaccine (PCV7). Children at increased risk of severe disease should continue to receive the full, routine four-dose series.

CDC acted in consultation with the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP), to most effectively use the limited available doses of the vaccine until the manufacturer can restore full production. Wyeth Vaccines, the sole manufacturer in the U.S., markets PCV7 under the trade name Prevnar®.

CDC had previously recommended that health care providers temporarily suspend routine use of the fourth dose. Since that recommendation was issued, PCV7 production has been much less than had been expected and shipments have been further delayed, resulting in vaccine shortages. Widespread shortages may

now continue beyond this summer.

According to the CDC, while four PCV7 doses provide the best protection, children who have received three doses should also have a very high level of protection. In addition, children who have had two doses should also have some protection, but the exact level is unknown.

Children whose third and fourth doses are delayed should receive the missed doses on their first visit to a health care provider after supplies return to normal. Health care providers should keep track of children who are not able to get all of the recommended doses of the vaccine and then contact those patients when the providers receive adequate supplies of the vaccine.

Children with certain health conditions, such as sickle cell anemia or immune system disorders, are at increased risk of severe disease and should continue to receive the full, routine four-dose series.

The vaccine is normally recommended for young children in a four-dose schedule: one dose at two months, four months, and at 6 months, and one dose between 12 and 15 months. This recommendation suspends the third and fourth doses usually administered at 6 months and between 12 to 15 months for healthy children. PCV7 is not routinely recommended for children 2 years of age or older.

The vaccine can help prevent serious pneumococcal diseases, such as meningitis and blood infections. Pneumococcal infection can cause serious illness and even death. Invasive pneumococcal disease is the leading cause of bacterial meningitis in the U.S. Children under two years of age are at highest risk. Before a vaccine was available, each year pneumococcal infection caused more than 700 cases of meningitis, 13,000 blood infections and about 5 million ear infections.

### Physicians' Bulletins Available Online at EMAN website

Physicians' Bulletins are available at the County Health and Human Services Agency's Emergency Medical Alert Network (EMAN) website ([www.emansandiego.com](http://www.emansandiego.com)). To access them, simply go to the site and click on the Physicians' Bulletin button.

EMAN is a network dedicated to facilitating bi-directional confidential communication between San Diego County's medical community and public health and safety agencies in order to ensure rapid identification of and response to unusual disease events or public health emergencies.

### Request for Reporting of Influenza-Related Deaths in Children

*(Note: The following text was excerpted from recent issues of the the Centers for Disease Control*

*(continued)*

*and Prevention [CDC]Morbidity and Mortality Weekly Report [MMWR].)*

During the 2003-04 influenza season, CDC is requesting that all influenza-associated deaths (and hospitalizations; see next page) among children aged <18 years be reported to CDC through state and local health departments. To report the influenza-associated death of a child aged less than 18 years in San Diego County, please call the Division of Community Epidemiology at 619-515-6620 or fax the attached form to 619-515-6644.

The increased surveillance of flu-related deaths in children is part of its effort to determine whether there is a pattern of rare flu complications in some children.

Since October 2003, a total of 93 influenza-associated deaths among children aged <18 years have been reported to CDC. All patients had evidence of influenza virus infection detected by rapid antigen testing or other laboratory tests.

The date of death was reported for 92 of the 93 cases. The median age of the 93 children was 4 years (range: 4 weeks-17 years), with 55 (59%) children aged <5 years and 24 (26%) aged 6-23 months. Among the 92 children whose sex was reported, 41 (45%) were male. A total of 35 (38%) of the 93 children were reported to have had underlying chronic medical conditions, and 41 (44%) were reported to have had no underlying conditions; the medical history was unknown for 17(18%) children. Of the 55 children for whom the location of death was reported, 15 (27%) died at home, 12 (22%) died in emergency departments, 25 (45%) died as inpatients, and three (5%) died in transport to hospitals.

Pneumonia was a reported complication in 25 of the 93 children. Invasive bacterial co-infections were reported in 15 children, including methicillin-resistant *Staphylococcus aureus*,

*Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus sp.*, *Haemophilus influenzae* (type b and non-typable), *Neisseria meningitidis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Serratia marcescens*.

Of the 45 children whose influenza vaccination status was reported, one child had evidence of adequate vaccination, whereas 33 (73%) were not vaccinated, and six children were partially vaccinated (i.e., they had received 1 of 2 doses); five children were reported as vaccinated, but the interval between vaccination and onset of illness was not documented.

Influenza A viruses were isolated from respiratory specimens collected from 28 patients. A total of 55 children had influenza virus infection confirmed by rapid antigen testing and direct fluorescent antibody staining of respiratory specimens. Four additional children had influenza virus infection confirmed solely by reverse transcriptase polymerase chain reaction (RT-PCR) of respiratory specimens.

A total of 16 children with evidence of influenza virus infection by culture, rapid antigen detection test, or RT-PCR also had autopsy specimens tested at CDC by immunohistochemical (IHC) staining. Of these, 11 had influenza A viral antigen detected by IHC staining in respiratory epithelium of airway tissue specimens. In addition, autopsy tissue specimens from four of 11 pediatric deaths without previous laboratory confirmation of influenza virus infection were positive by IHC staining for influenza A viral antigen.

CDC Editorial Note:

During October 11, 2003-January 6, 2004, a total of 93 influenza-associated deaths among children aged <18 years were reported to CDC. Of the 51 deaths that were not reported previously, 26 occurred before publication of the previous report.

Because laboratory-confirmed influenza illnesses and deaths among children are not nationally reportable conditions, the numbers of deaths reported this season cannot be compared directly with previous influenza seasons, and the proportion of illnesses associated with death cannot be estimated. Heightened awareness of severe complications and deaths associated with influenza among children this season and increased testing might be contributing to identification of more pediatric fatalities related to influenza than in previous seasons.

These reports underscore the need to further characterize the impact of influenza among children. In addition to initiating voluntary reporting of influenza-associated deaths, CDC is developing studies in collaboration with health departments (including San Diego County; see below) and other partners to estimate the rates of influenza-associated hospitalization and serious complications and to

*(continued on next page)*

The *Physicians' Bulletin* is published on an as-needed basis by the County of San Diego Health and Human Services Agency to provide updated information on health issues of concern to San Diego County's medical community.

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identify risk factors for severe illness and complications during the current season. Additional studies are planned to assess the relative severity of this season by comparing influenza-associated hospitalizations and mortality among children with those in previous seasons. Such information might be helpful in evaluating current pediatric influenza vaccination recommendations.

Clinicians should consider influenza testing in children who have severe febrile illness, when influenza viruses are circulating in their local community. Clinicians should recognize that secondary conditions such as bacterial infection can complicate some cases of influenza. Susceptibility testing of bacterial isolates is important to guide appropriate antibiotic therapy. Guidelines for antiviral treatment of influenza are available at:

<http://www.cdc.gov/flu/professionals/treatment/index.htm>.

**CDC Requests Information About Acute Encephalopathy Associated With Influenza Virus Infection in U.S. Children**

Since the mid-1990s, several hundred cases of acute encephalopathy have been reported in Japanese children with influenza virus infection. These cases have been characterized by fever and rapid onset of encephalopathy, resulting in a high frequency of neurologic sequelae and mortality. The majority of the children have had laboratory-confirmed evidence of influenza.

Reports of influenza-associated encephalopathy have been uncommon in the U.S. To determine if a similar pattern is occurring in the U.S., CDC is requesting information on any case meeting certain criteria. The criteria include a person aged less than 18 years with altered mental status or personality change lasting more than 24 hours and occurring within 5 days of onset of an acute febrile

respiratory illness, laboratory or rapid diagnostic test evidence of acute influenza virus infection associated with the respiratory illness, and diagnosis of the condition in the U.S. Cases meeting these criteria should be reported to CDC by telephone at 404-639-0277 or 404-639-2893; by fax at 404-639-3866, or by e-mail at [tmu0@cdc.gov](mailto:tmu0@cdc.gov) or [nib9@cdc.gov](mailto:nib9@cdc.gov). To report a case to the County of San Diego Health and Human Services Agency, please call the Division of Community Epidemiology at 619-515-6620.

**Information About Varicella-Related Deaths and Hospitalizations Needed**

To help in evaluating the effectiveness of varicella immunization in preventing varicella disease and in cooperation with the California Department of Health Services, County Health and Human Services Agency is requesting that local health care providers report all cases of varicella-related deaths and hospitalizations. (Please note that this request does not include cases of hospitalized herpes zoster [shingles]). To report a case, please call the Division of Community Epidemiology at 619-515-6620.

**ACIP Publishes New Recommended Childhood and Adolescent Immunization Schedule**

The CDC's Advisory Committee on Immunization Practices (ACIP) has released the "Recommended Childhood and Adolescent Immunization Schedule--United States, January-June 2004."

Changes from the prior schedule include:

- 1) A change in the minimum age for the last dose of hepatitis B vaccine--the minimum age is now 24 weeks (previously 6 months);
- 2) Clarification of the age for the final doses of DTaP, Hib and PCV7--final doses of the Hib and PCV7 series should be at age  $\geq 12$  months

and for DTaP series, the final dose should be at age  $\geq 4$  years;

- 3) Emphasizing preference for Td dose--the adolescent Td dose should be given at ages 11-12 years, with ages 13-18 years serving as a catch-up interval; and,
- 4) The influenza vaccine schedule for the remaining half year *encourages* healthy children aged 6-23 months to receive flu vaccine when feasible during the flu season--however, July-December 2004 schedule will reflect change recommending that children of this age *receive annual flu vaccine*.

For a copy of the ACIP January-June 2004 schedule and catch-up schedule, go to <http://www.cdc.gov/nip/recs/child-schedule.htm#Printable> and select the format you want.

To access the AAP policy statement, go to <http://pediatrics.aappublications.org/cgi/content/full/113/1/142>.

To access the AAFP practice guidelines, which includes a link to the 2004 schedule, go to <http://www.aafp.org/afp/20040101/practice.html>.

**Strengthening Supply of Routinely Recommended Vaccines in the U.S.**

The December 17th issue of JAMA contains recommendations from the National Vaccine Advisory Committee (NVAC) on strengthening the supply of routinely recommended vaccines. The report was prepared in response to shortages of vaccines against 8 of 11 preventable diseases in children between late 2000 and the spring of 2003 in the U.S. NVAC appointed a Working Group to identify potential causes of vaccine shortages, develop strategies to alleviate or prevent shortages and enlist stakeholders to consider the applicability and feasibility of these strategies. It was concluded that the supply disruptions are likely to continue to occur. Strategies to be implemented include: expansion of vaccine stockpiles,

increased support for regulatory agencies, maintenance and strengthening of liability protections, improved communication among stakeholders, increased availability of public information and a campaign to emphasize the benefits of vaccination.

To access this article online, go to <http://jama.ama-assn.org/cgi/content/abstract/290/23/3122>

**2003-2004 Influenza Vaccination Pocket Information Guide Available at IAC Website**

The Influenza Pocket Information Guide, developed by the Immunization Action Coalition and a host of professional organizations, is available for download from IAC's website at <http://www.immunize.org>.

For a color (black, orange and white) version of the guide, go to <http://www.immunize.org/influenza/pocketguide.pdf>.

For a black-and-white version, go to <http://www.immunize.org/influenza/pocketguidebw.pdf>.

To read more about the guide, go to <http://www.immunize.org/influenza/pocketguide.htm>.

**Influenza and Pneumococcal Immunization Sample Standing Orders**

The Medicare Quality Improvement Community Web site provides links to various sample forms for collecting information on influenza and pneumococcal immunization status as well as sample standing orders for administering the vaccines to hospitalized patients. The standing orders are provided in a variety of formats in order to provide hospitals with several options for implementing a system that fits their workplace needs and culture.

To access the sample forms, go to <http://www.medquic.org/content/CommonItems/InterventionTools/TK69.jsp?topicID=445>

**Pertussis Trends Among Infants in the U.S., 1980-1999**

A study published in the December 10th issue of the Journal of the American Medical Association (JAMA) describes the trends and characteristics of reported cases of pertussis among infants younger than 12 months in the U.S. from 1980-1999 as reported to the National Notifiable Disease Surveillance System during this period and the Supplementary Pertussis Surveillance System. The incidence of reported cases of pertussis among infants increased 49 percent in the 1990s compared with incidence in the 1980s. Increases in the incidence of cases and the number of deaths among infants during the 1990s primarily were among those aged four months or younger. Because of the limited age group affected, the increased rate of bacteriologic confirmation and the unchanged severity of illness, it was concluded that the increase in infant pertussis has occurred apart from any change in reporting. The authors suggest that strategies are needed to prevent the morbidity and mortality from pertussis among infants too young to be fully vaccinated according to the current recommended vaccination schedule.

To access this article online, go to <http://jama.ama-assn.org/cgi/content/abstract/290/22/2968>

**Addressing Parents' Concerns About Vaccine Preservatives, Adjuvants, Additives and Residuals**

The December issue of Pediatrics addresses parents' concerns raised by stories in the media or on the Web about substances in vaccines. The article reviews data on thimerosal (a mercury-containing preservative), aluminum, gelatin, human serum albumin, formaldehyde, antibiotics, egg proteins and yeast proteins. The

authors found that both gelatin and egg proteins are contained in vaccines in sufficient quantities to induce rare instances of severe, immediate type hyper-sensitivity reactions. Mercury, aluminum, formaldehyde, antibiotics, human serum albumin and yeast proteins in vaccines have not been found to be harmful in humans or experimental animals.

To access this article online, go to <http://pediatrics.aappublications.org/cgi/content/full/112/6/1394>.

**Important Prescribing Information for FluMist™**

Wyeth and MedImmune have released new prescribing information concerning their FluMist™ live, intranasal influenza vaccine.

MedImmune and Wyeth have obtained FDA approval for a modification of the storage requirements for doses of FIuMist shipped between December 31, 2003 and March 31, 2004 to enable wider distribution of FIuMist™ and to expand the number of vaccine providers. Effective immediately, FIuMist received **after** December 31, 2003, may be stored in its packaging in a frost-free freezer without the use of a FIuMist™ FreezeBox until March 31, 2004. This storage change does not apply to vaccine shipped previously in the Freeze Box.

FluMist CANNOT be stored in dorm-style refrigerator/freezer units (i.e., a refrigerator not having a separate isolated freezer section).

MedImmune will provide additional data to the FDA in order to determine storage requirements for FIuMist for the 2004-2005 influenza season.

Questions regarding this information, should be directed to FluMist representatives at 1-800-411-0086. To order FIuMist, call 1-800-FLU-7443.

Visit the San Diego County Immunization Initiative (I-3) website at [www.immunization-sd.org](http://www.immunization-sd.org).

**CDC Adds Extensive New Information To Its Influenza Web Site**

The CDC has added significant new information to its influenza web page (<http://www.cdc.gov/flu>). Titles and URLs of the new information are listed below:

“Respiratory Hygiene/Cough Etiquette in Healthcare Settings” (posted 12/17)

To access the ready-to-copy (PDF) version, go to: <http://www.cdc.gov/flu/professionals/pdf/resphygiene.pdf>

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm>

“Laboratory Diagnostic Procedures for Influenza” (updated 12/17)

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>

“Staph Infection and the Flu” (updated 12/17)

To access the ready-to-copy (PDF) version, go to: <http://www.cdc.gov/flu/protect/pdf/staphflu.pdf>

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/protect/staphflu.htm>

“Questions & Answers for Health Care Professionals” (posted 12/19; Q&As for the public and professionals will be updated as needed)

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/about/qa/fluseason.htm#hcp>

“Influenza Antiviral Medications: Interim Chemoprophylaxis and Treatment Guidelines” (posted 12/17)

To access the ready-to-copy (PDF) version, go to: <http://www.cdc.gov/flu/professionals/pdf/antiviralguid.pdf>

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/professionals/antiviralguid.htm>

“Antiviral Agents for Influenza: Background Information for Clinicians” (posted 12/16)

To access the ready-to-copy (PDF) version, go to: <http://www.cdc.gov/flu/professionals/pdf/antiviralsbackground.pdf>

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/professionals/antiviralback.htm>

“When to Use Antiviral Drugs for the Flu” (posted 12/19)

To access the ready-to-copy (PDF) version, go to: <http://www.cdc.gov/flu/protect/antiviral/pdf/antiviralwhentouse.pdf>

To access the web-text (HTML) version, go to: <http://www.cdc.gov/flu/protect/antiviral/index.htm>.

**HHS Issues Rule For Smallpox Vaccine Injury Compensation Program**

The federal Department of Health and Human Services has issued a rule to identify and compensate people injured as a result of receiving a smallpox vaccine. The interim rule for the new Smallpox Vaccine Injury Compensation Program describes eligibility criteria, the process for requesting benefits and receiving payments, and other necessary procedures. The program provides financial and medical benefits to eligible members of an HHS-approved smallpox emergency response plan who sustain certain medical injuries caused by smallpox vaccine.

Those who wish to file a claim will find forms and information at [www.hrsa.gov/smallpoxinjury](http://www.hrsa.gov/smallpoxinjury).

