FDA Approves Two Vaccines to Boost Pertussis Immunity

On May 3, 2005, the U.S. Food and Drug Administration (FDA) approved the first combination vaccine that provides a booster immunization against pertussis (whooping cough) in combination with tetanus and diphtheria for adolescents. This vaccine will be marketed as Boostrix by GlaxoSmithKline (GSK) in Philadelphia, Pa. On June 10th, a second tetanus (T), diphtheria (d), Pertussis (ap) vaccine was approved for use in adolescents and adults. This vaccine will be marketed as Adacel manufactured by Sanofi Aventis.

Pertussis is a highly communicable disease of the respiratory tract that can be especially serious for infants less than one year old, and may even be fatal. Pertussis can cause spells of coughing and choking that make breathing difficult. The disease is generally less severe in adolescents, but it is thought that they might transmit the disease to susceptible infants and other family members. In the last 20 years, rates of pertussis infection have been increasing in very young infants who have not received all their immunizations and in adolescents and adults.

Although booster vaccines containing tetanus and diphtheria are currently licensed and marketed for use in adolescents and adults, none contained a pertussis component. Boostrix is indicated for use as a single booster dose to adolescents 10-18 years of age. Adacel is indicated as a single booster dose to adolescents and adults 11-64 years of age.

Complete the 4-Dose Series of Prevnar at the 1-Year Visit

Although the ACIP recommends administering the fourth dose of Prevnar at 12-15 months of age, data shows that earlier is better than later. Giving the fourth dose of Prevnar at 12 months, rather than 15 months, affords infants maximum protection against pneumococcal disease by boosting antibody response at a peak incidence. Vaccinating against invasive pneumococcal disease at the child’s one-year visit is strongly encouraged, as national averages indicate a sharp drop off, 60%, in pediatric visits following year one. Children in daycare also benefit immensely from receipt of this immunization at 12 months. Children who attend daycare are at approximately 3x greater risk of invasive pneumococcal disease. Though no minimum serum antibody concentration necessary for protection against invasive pneumococcal disease has been determined, a significant increase in antibody concentrations was observed following the 4th dose.
**Meningococcal Conjugate Vaccine**

On January 17, 2005, the Food and Drug Administration (FDA) approved the licensure of a new meningococcal conjugate vaccine (MCV4), brand name Menactra, manufactured by Sanofi Pasteur. In February, the Advisory Committee on Immunization Practices (ACIP) recommended this vaccine for inclusion as part of the Vaccine For Children’s (VFC) Program. The vaccine is licensed for use for vaccination of adolescents and adults aged 11-55 years and protects against four serogroups of Neisseria meningitidis (A, C, Y, W-135), the bacterium that causes meningococcal infection. Full ACIP recommendations can be found at: http://www.cdc.gov/nip/vaccine/meningitis/mcv4/mcv4_acip.htm

MCV4 is similar to the polysaccharide meningococcal vaccine (Menomune, Sanofi Pasteur) that has been licensed since the early 1970s in that it covers the same four serogroups and is expected to produce at least 90% protection initially. However, it differs in that the duration of protection is expected to be much longer than the approximately 3 years that the polysaccharide vaccine provides, allowing it to be considered for long-term instead of situational protection.

**Availability of MCV4 through the VFC Program**

Effective June 1st, providers will be able to order Menactra for VFC-eligible children in the following age cohorts.

- **Adolescents aged 11-12 years old at their preadolescent assessment visit**
- **Adolescents at high school entry (~15 years old) who were not vaccinated at the preadolescent visit**
- **College freshmen who live in dormitories**

New Vaccine Order Forms (VOFs) have been mailed to all providers. Providers should upon receiving the new VOFs, discard any old versions. MCV 4 comes packaged in single dose vials or in a box of five single dose vials. The vaccine does not need to be reconstituted before administration and needs to be kept refrigerated at between 35-46 degrees Fahrenheit. The new Vaccine Information Statement (VIS) is dated April 4, 2005. As a reminder, the VIS must be given to the parent or legal guardian before administration of the vaccine.

**Potential Limits on MCV4 Supply**

The initial national supplies of MCV4 are expected to be sufficient to completely vaccinate one but not all age cohorts for whom MCV4 is now recommended. Depending on demand, it is possible that supplies could become limited and that there could be substantial delays in filling orders. Currently, the only requirement in Connecticut for vaccination against meningococcal disease is for students entering college who live in dormitories. If MCV4 vaccine supplies become temporarily exhausted, the polysaccharide vaccine (Menomune) can be used.

**Influenza**

For the influenza vaccination season of 2005-2006, it is anticipated that there will be three suppliers of inactivated flu vaccine and one of live attenuated vaccine.

- **Sanofi Pasteur** (the old Aventis Pasteur) is anticipating a supply of 50-55 million doses. New this season, their .5 cc pre filled syringes are thimerosal-free. They will also be supplying 25cc pre-filled syringes with no thimerosal. The multiple dose vials will still contain Thimerosal. The vaccine is approved for anyone >6 months of age.
- **Chiron** has been given permission to manufacture inactivated influenza vaccine. The manufacturing takes place in Britain. They will still need to have the vaccine licensed in the U.S. They are anticipating 18-26 million doses. The vaccine is indicated for those >3 years of age.
- **Glaxo SmithKline** has applied to the FDA for approval to sell their inactivated influenza vaccine in the U.S. If they secure approval, they anticipate supplying 10-15 million doses.
- **MedImmune** is the manufacturer of the live attenuated influenza vaccine (nasal spray). They anticipate providing

(Continued on page 3)

**Reporting Diseases to the State**

The Immunization Program would like to remind providers that cases of pertussis and varicella, as well as all other reportable diseases, must be reported at the time of recognition or suspicion of disease. This includes all types of varicella cases may they be wild-type, breakthrough, or a result of vaccine failure (very rare). Please DO NOT wait for laboratory confirmation to report. With pertussis, a nasopharangeal culture is essential for confirmation. A positive pertussis-specific PCR test is also considered to be confirmatory. If you are unsure of what diseases need to be reported, you may call the Immunization Program at 860-509-7929 or the Epidemiology Program at 860-509-7994 and request a supply of the "Reportable Disease Confidential Case Report Form" (PD-23). For those reporting cases of varicella disease, please use the "Varicella Case Report Form", available from the Immunization Program.

If you already have this form but it does not include space for reporting MMR vaccine history, please request the updated form. As a reminder, varicella vaccine is required for all children born in 1997 or later who attend day care, pre-school, and school and for all 7th through 12th grade students.
Flu vaccine, Continued from page 2

3 million doses. The vaccine is indicated for health individuals between 5 and 49 years of age.

The recommendations for who should be vaccinated for the upcoming season have not been announced, as of this writing. They are generally released in an MMWR (Morbidity and Mortality Weekly Report). The link to the MMWR website is: www.cdc.gov/mmwr/. Click on Recommendations and Reports. CDC also has an influenza website: www.cdc.gov/flu/. The American Lung Association of Connecticut is anticipating the flu hotline to begin on October 1, 2005. The number is 1-888-NO-TO-FLU (1-888-668-6358). The hours of operation are M-F 9am to 3pm. Their website will also have a find a flu shot online at their website: www.alact.org. There is 24/7 access to the information on the clinics at that website.

HIB

The State Immunization Program will soon be switching from ActHIB®, to PedvaxHIB® manufactured by Merck.

A memo will be sent to all users of state vaccine regarding the official date of the switch as well as specific indications for use of Pedvax-HIB.

Increase in Administration Fee

The State Immunization Program has increased the maximum allowable administration fee for vaccine supplied by the state from $16 to $21 per dose.

Providers may bill an insurance company for vaccine administration fees in excess of the $21 fee cap up to the maximum allowed by the company’s policy.

As a reminder providers cannot impose a charge for the cost of the vaccine supplied by the State.
HELP STOP VACCINE WASTE

Accidents happen and sometimes vaccine gets wasted. But vaccines should never expire while sitting in someone’s refrigerator or freezer.

The VFC program expects our providers to make every attempt to find someone in their immediate area to use the vaccines before they reach the expiration date. If you can’t find anyone, please call us (860-509-7929) and we will work with you to find a home for the vaccine.

SUGGESTIONS:

ievaccine to

 rotating stock: Put new vaccines in the back and move older vaccines to the front.

Look at your expiration dates: If vaccines will expire in two or three months, consider transferring them to another provider in your area. In the comments box on your next Vaccine Order Form list the name of the provider, their PIN #, types of vaccine, and quantity transferred.

Remember...NEVER throw away vaccines! If for any reason vaccines are wasted, the vaccines should be returned to the State Immunization Program along with a Vaccine Wastage Form.

DEPARTMENT OF PUBLIC HEALTH IMMUNIZATION PROGRAM
MORBIDITY REPORT

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“National Infant Immunization Week” Celebrated

Kate Baker, RN, a Public Health Nurse and Immunization Action Plan Coordinator for the Meriden Health Department distributed over 100 free Health Promotion Kits to Meriden children and their parents, recognizing National Infant Immunization Week (April 25 – April 29, 2005).

This family is shown accepting the kits at the Meriden Health Department Clinic.