

DEPARTMENT OF HEALTH

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Please distribute to immediately to all Emergency Departments, Infection Control Departments, Employee Health Services, Infectious Disease Departments, Pediatrics, Director of Nursing, Medical Director, Pharmacy, Laboratory Director and all acute and primary patient care areas.

Summary

The New York State Department of Health (NYSDOH) would like to provide you with important updates on the following immunization topics:

- 1. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants (5/30/08);
- 2. Meningococcal conjugate vaccine (MCV4) recommendations for children aged 2 to 10 years (5/2/08);
- 3. Syncope after vaccination (5/2/08);
- 4. Pneumococcal conjugate vaccine (PCV7) recommendations for 24 to 59 month-old children (4/4/08);
- 5. Provisional recommendations for 2008-09 influenza vaccine (3/25/08);
- 6. Modifications to current Advisory Committee on Immunization Practices (ACIP) recommendations for human papillomavirus (HPV) vaccine and the combination measles, mumps, rubella, and varicella vaccine (MMRV);
- 7. Vaccine shortages, delays and recalls; and
- 8. Recommendation to refrain from using vaccines obtained through offsite pharmacies.

<u>Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants</u>

In 2005, two Tdap vaccines were licensed and recommended for use in adults and adolescents in the United States. Both Tdap vaccines are licensed for single-dose use to add protection against pertussis and to replace the next dose of tetanus and diphtheria toxoids vaccine (Td).

Available evidence does not address the safety of Tdap for pregnant women, their fetuses, or pregnancy outcomes sufficiently. Available data also do not indicate whether Tdap-induced transplacental maternal antibodies provide early protection against pertussis to infants or interfere with an infant's immune responses to routinely administered pediatric vaccines. Until additional information is available, ACIP recommends that pregnant women who were not vaccinated previously with Tdap:

- 1. Receive Tdap in the immediate postpartum period before discharge from the hospital or birthing center. An interval as short as 2 years since the most recent Td vaccine may be used.
- 2. Receive Td during pregnancy for tetanus and diphtheria protection when indicated, or defer the Td vaccine indicated during pregnancy to substitute Tdap vaccine in the immediate postpartum period, if the woman is likely to have sufficient protection against tetanus and diphtheria. This criterion is defined in the MMWR.

Although pregnancy is not a contraindication for receiving Tdap vaccine, healthcare providers should weigh the theoretical risks and benefits before choosing to administer Tdap vaccine to a pregnant woman.

The complete article published 5/30/08 may be viewed at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5704a1.htm

MCV4 for children aged 2 to 10 years

At its February 2008 meeting, ACIP decided not to recommend routine vaccination against meningococcal disease for all children aged 2 to 10 years. This decision was based on reviews of safety and immunogenicity data, the epidemiology of meningococcal disease, a cost-effectiveness analysis and programmatic considerations.

- 1. ACIP continues to recommend vaccination for children aged 2 to 10 years at increased risk for meningococcal disease. These children include travelers to or residents of countries in which meningococcal disease is hyper-endemic or epidemic, children who have terminal complement deficiencies and children who have anatomic or functional asplenia.
- 2. Health care providers may elect to vaccinate children aged 2 to 10 years who are infected with human immunodeficiency virus (HIV).
- 3. MCV4 is preferred for children aged 2 to 10 years in those groups at increased risk and for the control of meningococcal disease outbreaks.
- 4. If health care providers or parents elect to provide meningococcal vaccination to other children in this age group, MCV4 is preferred.

The complete article published 5/2/08 may be viewed at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a4.htm.

Syncope after vaccination

Syncope (fainting) can be triggered by various stimuli, including medical procedures. Syncope has been documented to occur after vaccination, most commonly among adolescents, and can result in hospitalization for a medical evaluation or because of injury.

During 2005 and 2006, ACIP recommended the use of three newly licensed vaccines for adolescents: HPV vaccine; MCV4; and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap).

To describe trends in occurrence of post-vaccination syncope, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) analyzed data from the Vaccine Adverse Event Reporting System (VAERS) for January 1, 2005, through July 31, 2007. The results were then compared with VAERS reports received during January 1, 2002, through December 31, 2004.

The findings indicate that, since 2005, reports to VAERS regarding post-vaccination syncope have increased, primarily among females aged 11 to 18 years, and rarely, subsequent serious injuries have occurred. During 2005 to 2007, syncope was associated with at least one of the recently approved and recommended adolescent vaccines: MCV4, Tdap, and HPV. To prevent syncope-related injuries:

- 1. All providers administering vaccinations should be aware of the potential for syncope after vaccination and should take appropriate measures to prevent potential injuries.
- 2. In accordance with ACIP recommendations, providers should strongly consider observing patients for 15 minutes after they are vaccinated.
- 3. If syncope develops, patients should be observed until symptoms resolve.

The complete article published 5/2/08 may be viewed at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm

PCV7 for 24 to 59 month-old children

The ACIP Pneumococcal Vaccines Work Group reviewed data on the safety and immunogenicity of PCV7 in children aged 24 to 59 months, current rates of PCV7-type invasive disease, vaccination coverage rates and post-licensure vaccine effectiveness. In October 2007, on the basis of that review, ACIP approved the following revised recommendations for use of PCV7 in children aged 24 to 59 months:

- 1. For all healthy children aged 24 to 59 months who have received 0 to 3 doses of PCV7 before 24 months of age, administer 1 dose of PCV7.
- 2. For all children aged 24 to 59 months with underlying medical conditions who have received 3 doses of PCV7 before 24 months of age, administer 1 additional dose of PCV7.
- 3. For all children aged 24 to 59 months with underlying medical conditions who have received fewer than 3 doses of PCV7 before 24 months of age, administer 2 additional doses of PCV7 at least 8 weeks apart.

No changes were made to previously published recommendations regarding 1) the use of PCV7 in children aged 2 to 23 months, 2) the list of underlying medical or immunocompromising conditions or 3) the use of 23-valent pneumococcal polysaccharide vaccine in children aged >2 years who have previously received PCV7.

Previous ACIP recommendations regarding PCV7 in 24 to 59 month-old children were more restrictive and were based on concern about vaccine supply and higher vaccine cost. The supply of PCV7 is no longer a concern. Therefore, ACIP has issued these revised recommendations.

The complete article published 4/4/08 is available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5713a4.htm

Provisional recommendations for 2008-09 influenza vaccine

On February 27, 2008, ACIP made new recommendations for the use of influenza vaccine during the 2008-2009 influenza season:

- 1. Annual vaccination of all children aged 6 months through 18 years is recommended. If feasible, annual vaccination of all children should begin in the 2008-2009 influenza season but no later than the 2009-2010 influenza season.
- 2. Effective July 1, 2008, the Vaccines for Children (VFC) program will add coverage for influenza vaccine to meet the expanded age recommendations for the routine use of influenza vaccine in children ages 6 months through 18 years. More information published 3/25/08 is available at: http://www.cdc.gov/vaccines/recs/provisional/downloads/flu-3-21-08-508.pdf

Other current recommendations on influenza include:

- 1. Children aged 6 months through 8 years should receive 2 doses of influenza vaccine, separated by 4 or more weeks, if they have not been vaccinated previously at any time with at least 2 doses within an influenza season of either live attenuated influenza vaccine (LAIV) or trivalent inactivated influenza vaccine (TIV). For example, if a child aged 6 months through 8 years of age received only 1 influenza vaccine during the 2007-2008 influenza season, he or she should receive 2 doses during the 2008-2009 influenza season. If more than 1 year elapses after the first vaccination season, then only 1 dose should be administered during the next influenza vaccination season and then annually.
- 2. Persons at higher risk of influenza complications because of underlying medical conditions, children aged 6 to 23 months, and persons aged >49 years should receive TIV. Either TIV or LAIV should be used when vaccinating persons aged 2 through 49 years who do not have medical conditions that put them at higher risk for influenza complications.
- 3. When considering use of LAIV for children aged 2 through 4 years, clinicians and immunization program staff should screen for reactive airway disease. Avoid use of LAIV in children with asthma or a recent wheezing episode. The ACIP has previously provided recommendations on screening for possible reactive airway disease in children aged 2 through 4 years which can be found at:
 - http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5646a4.htm.

- 4. Recommendations for annual vaccination of persons in other age or risk groups have not changed and can be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5606a1.htm.
- 5. The 2008–2009 trivalent vaccine virus strains are A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like and B/Florida/4/2006-like antigens. All three strains are different from the 2007-2008 Northern Hemisphere influenza vaccine.

The antiviral medications recommended for chemoprophylaxis or treatment of influenza (oseltamivir or zanamivir) have not changed for the 2008-2009 influenza season and can be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5606a1.htm.

Modifications to current ACIP recommendations for HPV vaccine and MMRV vaccine

HPV vaccine

On March 5, 2008, a revised child and adolescent immunization catch-up schedule was published that added a 24 week interval between HPV vaccine doses 1 and 3. This recommendation was added because of the lack of data to support vaccine efficacy when doses 1 and 3 are administered without the appropriate spacing interval between them.

The corrected catch-up schedule can be viewed at:

http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2008/08_catch-up_schedule_pr.pdf.

MMRV vaccine

On February 27, 2008, new information was presented to ACIP regarding the risk for febrile seizures among children aged 12 to 23 months after administration of the MMRV vaccine (ProQuad). The Vaccine Safety Work Group summarized current knowledge regarding the risk for febrile seizures after MMRV vaccination and presented updated ACIP recommendations that were voted on and accepted after presentation of the new information.

Due to a possible increased risk of febrile seizures after receiving MMRV vaccine, the updated recommendations remove the previous ACIP preference for administering combination MMRV vaccine over separate injections of measles, mumps, and rubella (MMR) vaccine and varicella vaccine. Combination MMRV vaccine continues to be approved for use among healthy children aged 12 months to 12 years and is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella. The Vaccine Safety Workgroup will continue to conduct in-depth evaluation of the findings regarding the increased risk for febrile seizures after the first dose of MMRV vaccine to present for consideration of future policy options. The CDC, FDA, and ACIP will communicate updates and implement further necessary actions based on these evaluations.

The complete summary may be viewed at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5710a3.htm.

Vaccine shortages, delays and recalls

On Monday May 19, 2008, Sanofi Pasteur announced that, effective immediately, they will no longer allow purchase of IMOVAX Rabies (human rabies vaccine) for use in primary and booster pre-exposure prophylactic immunization. A letter from the manufacturer explaining this change was released to clinicians on May 19, 2008. Sanofi Pasteur is taking this action to maintain sufficient supply of rabies vaccines in the US market for use in postexposure prophylaxis.

The complete summary may be viewed at:

https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080521_0.pdf.

Additional information on national vaccine shortages and supply is available at: http://www.cdc.gov/vaccines/vac-gen/shortages.

Recommendation to refrain from using vaccines obtained through offsite pharmacies

The NYSDOH Immunization Program continues to receive many reports of providers giving prescriptions to their patients to obtain vaccine or vaccines from a pharmacy in the community. Patients will then bring the vaccine back to the provider for administration. **This practice is to be discouraged.** Transporting of vaccine without the proper handling and storage specifications in place cannot guarantee that the vaccine will be safe or efficacious when administered to a patient. It is acknowledged that certain vaccines are problematic for providers to obtain due to the cost of stocking expensive vaccines. However, patient transport of vaccines is not a viable solution.

For more information

For more information on immunization, please contact the Erie County Department of Health Immunization Action Plan at (716) 961-6839 or the NYSDOH Immunization Program at (518) 473-4437.

If you have questions regarding influenza control, please contact the Erie County Department of Health Bureau of Disease Control at (716) 858-7698; facility infection control personnel should contact their NYSDOH Regional Epidemiology office at the number listed below.

Buffalo Western Regional Office: (716) 847-4503

Health Category Definitions:

Health Alert FLASH: conveys the highest level of importance due to a large-scale, catastrophic public health emergency; warrants immediate action or attention

Health Alert Priority: conveys the highest level of importance; warrants immediate action or attention to a health problem or situation

Health Advisory: provides important information for a specific incident or situation; may not require immediate action

Health Update: provides updated information regarding an incident or situation; no immediate action necessary