

Immunize NY!

Bureau of Immunization

Welcome to *Immunize NY!*

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Frequently Used Abbreviations:

- ✓ **AAP:** American Academy of Pediatrics
- ✓ **ACIP:** Advisory Committee on Immunization Practices
- ✓ **CDC:** Centers for Disease Control and Prevention
- ✓ **FDA:** Food and Drug Administration
- ✓ **MMWR:** Morbidity and Mortality Weekly Report
- ✓ **NYSDOH:** New York State Department of Health
- ✓ **NYSIIS:** New York State Immunization Information System

Why ACIP Recommendations Do Not Always Agree with Vaccine Package Inserts

Vaccine package inserts and ACIP statements are usually in very close agreement. The FDA must approve each package insert and requires documentation for all claims and recommendations made in the insert. Occasionally, ACIP may use different data to formulate its recommendations, or try to add flexibility to its recommendations. This may result in wording different than what is included on the package insert.

ACIP also makes recommendations based on expert opinion and public health considerations. Published recommendations of ACIP should be considered equally authoritative as those in the package insert.

FDA Revises its Recommendations for Rotavirus Vaccine: Clinicians Can Resume Use of Rotarix and Continue Use of RotaTeq

The FDA is updating its recommendations on both Rotarix and RotaTeq vaccines for the prevention of rotavirus disease in infants. On March 22, 2010, the FDA recommended suspending the use of Rotarix vaccine due to the presence of DNA from porcine circovirus type 1 (PCV1). Based on careful evaluation of a variety of scientific information, the FDA has determined it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq.

The FDA considered the following information in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of recipients.
- There is no evidence that either PCV1 or type 2 (PCV2) poses a safety risk in humans. Neither is known to cause infection or illness in humans.

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The benefits of rotavirus vaccines are substantial. In the United States, rotavirus vaccine has prevented hospitalizations for severe rotavirus disease. In other parts of the world it has prevented death. The benefits of the vaccines far outweigh any theoretical risk.

The FDA also recommends that clinicians and public health professionals inform parents:

- of the findings of PCV DNA or PCV in rotavirus vaccines.
- that there is no evidence these findings pose a safety risk in humans.

Both the prescribing information and patient labeling will be revised to include this information.

FDA will keep the public and clinical community updated through its website and other communications.

To review the revised recommendations, visit the FDA website:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm212140.htm>

Corrected Guidance for the Use of MenACWY-CRM (Menveo)

ACIP recommends quadrivalent meningococcal conjugate vaccine for all persons aged 11 through 18 years and for persons aged 2 through 55 years who are at increased risk for meningococcal disease.

Menveo is licensed by the FDA as a single dose for use in persons aged 11 through 55 years.

Persons aged 2 through 10 years, who are recommended to receive a meningococcal vaccine, should receive MCV4 (Menactra). Menactra is the only meningococcal vaccine licensed for vaccinating children ages 2 through 10 years.

Both Menveo and Menactra are preferred to quadrivalent meningococcal polysaccharide vaccine (MPSV4).

Joint Commission Clarifies Requirements Regarding Multi-dose Vial Vaccines

On July 20, 2010, the Joint Commission **clarified its requirements for the use of multi-dose vials and their expiration dates**. This was based on a statement published in June 2010. In that statement, the commission required a 28 day expiration date for multi-dose vials from the date of opening or puncture, unless the manufacturer specifies otherwise.

In a new *Frequently Asked Questions* (FAQ) sheet, the **Joint Commission exempts all vaccines from the 28 day rule and states**: "The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization programs or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to ensure integrity of the vaccine."

The complete FAQ can be viewed at the following link: http://www.jointcommission.org/accreditationprograms/longtermcare/standards/09_FAQs/mm/multi-dose_vials.htm

Updated Guidance for the Use of HPV2 (Cervarix) and HPV4 (Gardasil)

On October 16, 2009, the FDA licensed bivalent human papillomavirus vaccine (HPV2--Cervarix, GlaxoSmithKline) for use in females aged 10 through 25 years. Cervarix is the second human papillomavirus (HPV) vaccine licensed for use in females in the United States. Quadrivalent HPV vaccine (HPV4--Gardasil, Merck & Co, Inc.) was licensed in 2006 for use in females aged 9 through 26 years. ACIP recommended routine HPV4 vaccination of females aged 11 or 12 years, and catch-up vaccination for females aged 13 through 26 years.

ACIP now recommends routine vaccination of females aged 11 or 12 years with 3 doses of either HPV2 or HPV4. The vaccination series can be started beginning at age 9 years.

Vaccination is recommended for females aged 13 through 26 years who have not been vaccinated previously or who have not completed the 3-dose series. If a female reaches age 26 years before the vaccination series is complete, remaining doses can be administered after age 26 years. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

ACIP recommends vaccination with HPV2 or HPV4 for prevention of cervical cancers and precancers. Both vaccines might provide protection against some other HPV-related cancers in addition to cervical cancer, although there are currently only data sufficient to recommend HPV4 for protection against vulvar and vaginal cancers and precancers. HPV4 is recommended also for prevention of genital warts.

On October 21, 2009, ACIP stated that HPV4 may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. ACIP does not recommend HPV4 for routine use among males. HPV4 would be most effective when given before exposure to HPV through sexual contact.

To read the MMWR article *FDA Licensure of Bivalent Human Papillomavirus Vaccine (HPV2, Cervarix) for Use in Females and Updated HPV Vaccination Recommendations from the Advisory Committee on Immunization Practices (ACIP)* go to:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a4.htm?s_cid=mm5920a4_e

To read the MMWR article *FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)* go to: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm?s_cid=mm5920a5_e

New York State Insurance Coverage Requirements for HPV Vaccine in Males

At this time, New York State is unable to provide Vaccines for Children HPV vaccine for boys who have insurance that doesn't cover this particular vaccine. NYSDOH is waiting for further information on insurance coverage requirements from the New York State Insurance Department. We apologize for the delay and hope to have clarification of the situation shortly.

It's Time for Tdap!

Currently, New York State is reporting an increase in pertussis. Adults and older children can spread pertussis to infants too young to be fully vaccinated. Providers should recommend and administer Tdap to health care personnel, older children and adults, including grandparents and babysitters, and anyone else who will have close contact with a new infant.

For more information visit the CDC website:

<http://www.cdc.gov/features/pertussis>

CDC publishes "Preliminary Results: Surveillance for Guillain-Barré Syndrome (GBS) after Receipt of Influenza A (H1N1) 2009 Monovalent Vaccine--United States, 2009-2010"

GBS is an uncommon peripheral neuropathy causing paralysis and, in severe cases, respiratory failure and death. GBS often follows an antecedent gastrointestinal or upper respiratory illness but, in extremely rare cases, can follow vaccination.

To monitor influenza A (H1N1) 2009 monovalent vaccine safety, several federal surveillance systems, including CDC's Emerging Infections Program (EIP), are being used. In October 2009, EIP began active surveillance to assess the risk for GBS after 2009 H1N1 vaccination. Preliminary results from an analysis by the EIP comparing GBS patients hospitalized through March 31, 2010, who did and did not receive 2009 H1N1 vaccination, showed an estimated age-adjusted rate ratio of 1.77 (GBS incidence of 1.92 per 100,000 person-years among vaccinated persons and 1.21 per 100,000 person-years among unvaccinated persons). If the final surveillance analysis confirms this finding, this would correspond to 0.8 excess cases of GBS per 1 million vaccinations, similar to that found in seasonal influenza vaccines. No other federal system to date has detected a statistically significant association between GBS and 2009 H1N1 vaccination. Surveillance and further analyses are ongoing.

The 2009 H1N1 vaccine safety profile is similar to that for seasonal influenza vaccines, which have an excellent safety record. Vaccination remains the most effective method to prevent serious illness and death from 2009 H1N1 influenza infection. Illness from the 2009 H1N1 influenza virus has been associated with a hospitalization rate of 222 per 1 million and a death rate of 9.7 per 1 million population. The 2009 H1N1 vaccine will be in the seasonal trivalent influenza vaccine this fall.

To access the full article visit the CDC website:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm59e0602a1.htm?s_cid=mm59e0602a1_e

New Format for the Fall 2010 NYSIIS User Group Meetings

NYSIIS user group meetings will now include a new segment entitled "NYSIIS at Work." This segment will highlight and demonstrate how a health care organization in each region has successfully incorporated NYSIIS into their everyday business practices. In addition, three concurrent breakout sessions will be conducted specifically for local health department users, data exchange users and health care providers who data enter directly into NYSIIS.

Save The Date!

Below is a list of the regional user group meeting locations and dates. Details will be emailed to all current users in the coming weeks.

Upcoming User Group Dates:

Albany	Tuesday, October 5 at 9:00AM
Tarrytown	Wednesday, October 6 at 1:00PM
Plainview	Thursday, October 7 at 9:00AM
Syracuse	Tuesday, October 26 at 1:00PM
Buffalo	Wednesday, October 27 at 9:00AM
Rochester	Thursday, October 28 at 9:00AM

Did you know?

All significant health events that may have been related to a dose of vaccine, particularly those that lead to hospitalization, disability, or death, should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Healthcare providers do not need to be certain the event was vaccine related in order to report it. It is not necessary to report minor adverse reactions, such as local reactions or low-grade fever.

For more information about VAERS visit <http://vaers.hhs.gov> or call (800) 822-7967.

Alternate Vaccination Schedules Lead to Delays in Vaccine Protection

Alternate vaccination schedules create delays in immunizations and, therefore, less or no protection against vaccine preventable diseases.

Spreading out the schedule:

- Keeps individuals unprotected against disease for longer periods of time.
- Leads to unimmunized populations that are at risk for outbreaks of disease.
- Increases the number of doctor visits needed to complete the vaccine series.

There is no valid research indicating the delay of vaccinations is the best route. Parents who are considering delaying their child's immunizations need to be made aware that they are putting their child at risk.

For more information visit the following websites:

Medscape: <http://www.medscape.com/viewarticle/724562>

Children's Hospital of Philadelphia: <http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/too-many-vaccines.pdf>

CDC'S Immunization 2010 Webcasts now Available On-line

The CDC's *Adult Immunization 2010* self-study course is now available for viewing. This webcast includes the latest recommendations for vaccines that protect against influenza; pneumococcal; tetanus, diphtheria, and pertussis; HPV; and zoster. Case studies and a discussion of frequently asked questions provide the learner with the opportunity to apply course information to real-life scenarios.

For additional information, and to view the webcast, visit the CDC website at:

<http://www.cdc.gov/vaccines/ed/adultimupdate>

The CDC's *Immunization Update 2010* is an annual presentation that highlights current and late-breaking immunization issues.

For additional information, and to view the webcast, visit the CDC website at:

<http://www.cdc.gov/vaccines/ed/imzupdate/default.htm>

Vaccine Shortages, Delays and Recalls

Information on national vaccine shortages and supply is available at the CDC website:
<http://www.cdc.gov/vaccines/vac-gen/shortages>.

Vaccine recall information will be provided as it is necessary through the NYSDOH Health Commerce System (HCS) and through this newsletter.

General information on recalled vaccines is available at the CDC website:
<http://www.cdc.gov/vaccines/recs/recalls/default.htm>

Did you know?

Federal law requires that a copy of the appropriate Vaccine Information Statement (VIS) be given to the adult recipient or to a child's parent/legal representative prior to vaccination.

Visit the Immunization Action Coalition's website to view "It's Federal Law" which details those VISs required by law and those recommended.

<http://www.immunize.org/catg.d/p2027.pdf>

A CDC Commentary Video on Medscape Can Help You Reassure Your Patients about the Safety of HPV Vaccine

On June 14, 2010, Medscape posted a 6-minute video titled "*CDC Commentary: New Safety Data on the HPV Vaccine--Reassure Your Patients.*" In it, Dr. Claudia Vellozzi, deputy director of CDC's Immunization Safety Office, discusses important safety data on the Gardasil brand of HPV vaccine. Dr. Vellozzi also provides clinicians with sound guidance on communicating HPV vaccine safety to patients.

The video is a collaboration between CDC and Medscape. It is one in a series of commentaries designed to deliver CDC's authoritative guidance directly to healthcare professionals.

To view Dr. Vellozzi's discussion visit Medscape:
<http://www.medscape.com/viewarticle/722555>

To view other topics available, including H1N1 and seasonal influenza, infection control, travel medicine, visit Medscape:
<http://www.medscape.com/partners/cdc/public/cdc-commentary>

Note: to access the videos, you must register with Medscape. There is no charge for this service. Medscape, a free resource for clinicians and other healthcare professionals, provides timely and relevant clinical information.

Vaccine Safety Resources

CDC: *Provider Resources for Vaccine Conversations with Parents*
<http://www.cdc.gov/vaccines/spec-grps/hcp/conversations.htm>

Click on "Get Email Updates" on the CDC link above to receive emails every time information on the *Provider Resources for Vaccine Conversations with Parents* page is updated!

Immunization Action Coalition (IAC): *Need Help Responding to Vaccine-hesitant Parents?*
<http://www.immunize.org/catg.d/p2070.pdf>

NYSDOH: http://www.nyhealth.gov/prevention/immunization/vaccine_safety.htm

CDC: <http://www.cdc.gov/vaccinesafety/>

IAC: <http://www.immunize.org/concerns/>

Every Child By Two: <http://www.vaccinateyourbaby.com>

FDA: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm>

AAP: <http://www.aap.org/immunization/>

Children's Hospital of Philadelphia, Vaccine Education Center:
<http://www.chop.edu/consumer/jsp/division/generic.jsp?id=75697>

Important Contact Information

NYSDOH Bureau of Immunization: 518-473-4437
www.nyhealth.gov/prevention/immunization/

For more information, please contact your local health department or your regional NYSDOH Bureau of Immunization office:

Western Regional Office
Buffalo: 716-847-4385
Rochester: 585-423-8014

Central New York Regional Office
Syracuse: 315-477-8164

Capital District Regional Office
Troy: 518-408-5278
Oneonta: 607-432-2890

Metropolitan Area Regional Office
New Rochelle: 914-654-7149
Central Islip: 631-851-3096

Providers and facilities in New York City should contact:
New York City Department of Health and Mental Hygiene, 212-676-2323.

Email the NYSDOH Bureau of Immunization
to receive this e-newsletter directly if you did not.
immunize@health.state.ny.us