The VacScene
Immunization News & Information

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Public Health
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Immunization Program
401 5th Ave, Suite 900
Seattle, WA 98104

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In this issue:

Gardasil Safety Information from FDA and CDC

Questions regarding the safety of the human papillomavirus (HPV) vaccine, Gardasil, have received abundant media attention recently. Vaccine safety, including post-marketing surveillance, is a priority for the Federal Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), and currently Gardasil and other vaccines are monitored more closely than has been possible in the past.

To date, the manufacturer, Merck and Co., has distributed over 16 million doses of Gardasil in the United States, so it is expected that, by chance alone, serious adverse events and some deaths will be reported among vaccine recipients after vaccination.

As of June 30, 2008, there have been 9,749 VAERS reports of adverse events following Gardasil vaccination. VAERS reports may or may not be related to the vaccine that was administered before the event being reported and, for that reason, are investigated further. Of these, 6% were considered serious (which is about half the number seen with other vaccines) and 94% were classified as non-serious events (including fainting, pain at the injection site, headache, nausea, and fever).

Fainting is common after injections, especially in adolescents. A fall after fainting may cause serious injuries, such as head injuries, and can be prevented with simple steps such as keeping the vaccinated person seated for up to 15 minutes after vaccination.

Six percent were classified as serious events (including Guillain-Barré Syndrome (GBS), blood clots, and death.)

GBS is a rare neurological disorder causing muscle weakness and has been associated with a variety of specific infections. FDA and CDC have reviewed the reports of GBS submitted to VAERS and, to date, have concluded that the rates of GBS are not increased after vaccination with Gardasil.

Thromboembolic disorders (blood clots) have been reported to VAERS in people who have received Gardasil. Most of these individuals had known risk factors such as use of oral contraceptives. The CDC's Vaccine Safety Datalink system is designed to detect rare and unanticipated adverse events rapidly, and is evaluating potential associations with thromboembolic events and other conditions reported through VAERS. MERCK is also conducting a large post-marketing study to further assess the vaccine's safety.

Twenty deaths were reported to VAERS, but an association with vaccine was not apparent. Where autopsy, death certificate, and medical records were available, the cause of death was explained by other factors.

Based on review of available information, FDA and CDC have concluded that Gardasil is safe and effective, and its benefits continue to outweigh its risks. CDC has not changed current recommendations for use of Gardasil, and FDA has not made any changes to the prescribing information or to the vaccine's precautions. In addition, FDA has not identified any issues affecting the safety, purity, and potency of Gardasil. Gardasil vaccine safety monitoring activities and findings are online at www.cdc.gov/vaccinesafety/vaers/FDA_and_CDC_Statement.htm

ACIP 2008 Influenza Vaccine Recommendations

The CDC Advisory Committee on Immunization Practices' (ACIP) 2008 Recommendations for Prevention and Control of Influenza were published in *MMWR* on July 17. Recommendations include:

- **(NEW)** annual vaccination of **all children aged 5–18 years**, beginning in the 2008–09 influenza season, if feasible, but no later than the 2009–10 influenza season
- **(NEW)** either trivalent inactivated influenza vaccine or live, attenuated influenza vaccine (LAIV) can be used when vaccinating healthy persons aged 2 through 49 years (the previous recommendation was to administer LAIV to persons aged 5–49 years)
- Continued emphasis on annual vaccination of all children aged 6 months through 4 years because these children are at higher risk for influenza complications compared with older children
- Use of 3 new strains for the 2008–09 trivalent vaccine: A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Florida/4/2006-like antigens.

The recommendations also include new information on antiviral resistance in the United States and a summary of safety data for U.S. licensed influenza vaccines. The recommendations, subsequent updates, and other resources are available at CDC's influenza website (www.cdc.gov/flu).

The 2008-09 Influenza Vaccine Information Statements (VIS) for both injectable (TIV) and intranasal (LAIV) influenza vaccines are available online at www.immunize.org/vis/

Vaccines For Children

Program News and Alerts

FAULTY EQUIPMENT CAN MEAN REVACCINATION FOR PATIENTS

Using quality thermometers is just as important as using reliable refrigerators. Following is an article that describes one potential consequence of faulty equipment. Use thermometers that have been certified and calibrated; look for "NIST," "NSF," or "ASTM" on the thermometer or its packaging. Here's an example of the consequences of improper vaccine storage:

> **Hundreds of Staten Island Kids to Be Revaccinated** *(from WCBS-TV in New York)* A health care provider in New York State is notifying many parents that their children should be revaccinated. Shots received by 528 children between January 2, 2008, and June 4 could be less potent because the vaccines were stored in a refrigerator at temperatures of 30 to 32 degrees, instead of the required 35 to 46 degrees. The provider's storage refrigerator had a faulty thermometer. More information and a video clip can be found at http://wcbstv.com/seenon/vaccines.vaccinations.children.2.771352.html.

THE VFC PROGRAM and FLU VACCINE

The 2008-09 flu season is fast approaching. Sometime in early September, you will be receiving the 2008-09 Influenza Vaccine Request form. Flu vaccine will be ordered and shipped separately this year. Along with the request form, you will receive guidance on approved usage of state-supplied flu vaccine.

CHECKLIST FOR SAFE VACCINE HANDLING AND STORAGE

We have included a copy of a new "Checklist for Safe Vaccine Handling and Storage" to help you evaluate how vaccines are stored in your practice. This checklist is available online at: www.immunize.org/catg.d/p3035.pdf

Did you know…

…About vaccines that contain tetanus, diphtheria, and pertussis?

DTaP: Contains diphtheria, tetanus and acellular pertussis
- *For ages* 6 weeks through 6 years (up to 7th birthday)
- *5 doses* recommended

DT, pediatric: Contains diphtheria and tetanus
- *For ages* 6 weeks through 6 years (up to 7th birthday)
- *5 doses* recommended
- Given instead of DTaP when pertussis component is contraindicated or parent declines it

Td, adult: Contains tetanus and diphtheria
- *For ages* 7 years through adulthood
- *3 doses* in primary series if the patient has not already received DT, DTP or DTaP
- *Routine booster* every 10 years. *Booster* after 5 years if tetanus prophylaxis for a wound is needed
- One time administration of Tdap (see below) instead of a Td booster is recommended for adolescents and adults who have not yet received it

Tdap: Contains tetanus, diphtheria and acellular pertussis
- *For ages* 10 through 18 years (Boostrix) or 11 through 64 years (Adacel)
- *Single dose* only, given instead of Td
- Although a 2 year minimum interval between Td and Tdap is specified in the package insert, Tdap can be given at any time after Td to prevent infant exposure to pertussis.

New ACIP Provisional Recommendations for Rotavirus Vaccine

Two different rotavirus vaccine products are now licensed for use in the United States: RotaTeq® (Merck) (RV5), and Rotarix® (licensed in April 2008 by GlaxoSmithKline Biologicals) (RV1). The products differ in composition and schedule of administration. On June 25, 2008, the ACIP voted on new recommendations for the use of these rotavirus vaccines for the prevention of rotavirus gastroenteritis among infants and children.

NOTE: Washington's VFC program provides only RotaTeq, but the new maximum age recommendations still apply.

Routine Administration: RV5 is given orally in a 3-dose series at ages 2, 4, and 6 months. RV1 is given orally in a 2-dose series at ages 2 and 4 months.

- The first dose of rotavirus vaccine should be administered from age 6 weeks through age 14 weeks 6 days (**the maximum age for the first dose is 14 weeks 6 days**). Vaccination should not be initiated for infants of age 15 weeks 0 days or older.
- The minimum interval between doses of rotavirus vaccine is 4 weeks.
- **All doses should be administered by age 8 months 0 days.**
- There are no maximum intervals, only maximum ages.

Interchangeability of Rotavirus Vaccines: ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is not available or is unknown. In this situation, the provider should continue or complete the series with the product available. **If any dose in the series was RV5 or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given.**

Contraindications: Rotavirus vaccine should not be administered to infants who have a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. Latex rubber is contained in the RV1 oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive RV1. The RV5 dosing tube is latex-free.

The ACIP provisional recommendations for rotavirus vaccine can be found on the CDC website at: www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf

The VIS for rotavirus vaccine has not yet been updated with these changes.

Public Health—Seattle & King County
Communicable Disease Epidemiology & Immunization Section
401 Fifth Avenue, Suite 900, Seattle WA 98104
www.kingcounty.gov/health/
(206)296-4774 Fax (206) 296-4803 TTY Relay: 711

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Publication Staff
Betsy Hubbard, Editor
Email: Betsy.Hubbard@kingcounty.gov
Contributors:
Darren Robertson, Yolanda Stetson, Lauren Greenfield, Marilyn Silkworth

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