Immunization Update

The Iowa Immunization Program Newsletter

September 2006

This newsletter is a quarterly publication and contains important updates and immunization information. Please share this newsletter with your coworkers.

Iowa’s Immunization Registry Information System (IRIS)
Enroll Today!

Call the IRIS Help Desk at 1-800-374-3958 for Enrollment Details or IRIS Questions.

Help Us Help You!
Is this newsletter helpful to you? What articles would you like to see? Please contact Bridget Konz at bkonz@idph.state.ia.us or 1-800-831-6293 ext. 7.

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Do It For Their Health!

“What is required?” This is a common question in vaccines. As more and more vaccines are recommended by ACIP, CDC, and AAP it is important for us to remember that vaccines required by state law (IAC 641.7) are the minimum requirements to protect the public’s health. As healthcare professionals it is incumbent upon us to provide care that is best for the health of the patient. This often means providing vaccines that are not required by law but are recommended as a standard of care.

This year ACIP has recommended several new vaccines including rotavirus, Human Papillomavirus (HPV), and Zoster. (Please see our article on page 5 about HPV vaccine.) Additionally, there have been updated recommendations for the following vaccines related to doses administered:

- Hepatitis B birth dose
- Hepatitis A recommendation for all children ages 12-23 months
- Second dose of varicella vaccine

The Immunization Program supports the administration of all vaccines recommended by ACIP. The current harmonized schedule does not reflect all the changes the ACIP has recommended since the last publication in December 2005. There will be a new schedule published early in 2007, but until that time please log on to http://www.cdc.gov/nip/reec/child-schedule.htm#Printable. At the bottom of the page there is a brief update that shows all the approved changes. For the changes related to rotavirus, HPV and second dose of Varicella please see http://www.cdc.gov/nip/default.htm#schedulers

Are They Certified?

Immunization certificates are an essential part of the back to school routine. In Iowa, there are three valid certificates children may present for entry into school and licensed child care centers: Certificate of Immunization, Certificate of Immunization Exemption (Medical/Religious), and Provisional Certificate of Immunization.

Certificate of Immunization is required to demonstrate proof of immunization to attend childcare and school. The certificate is a detailed listing of what vaccines the child has received and when they were given. A Certificate of Immunization is only valid if it is signed by one of the following health care providers: a physician, PA, nurse, or a CMA. A faxed copy, photocopy, or electronic copy of the valid certificate is acceptable for school entry. Clinics that utilize Iowa’s Immunization Registry Information System (IRIS) are able to print these certificates for patients on demand. Continued on page 2.

Questions regarding the latest recommended vaccines? Please contact IDPH Immunization Program at 1-800-831-6293.
Certificate of Immunization Exemption may be issued for two reasons: the child has a genuine medical need that precludes immunization; or the parents have a religious objection to immunizations. Iowa law does not permit a child to be exempt from immunizations for philosophical, scientific, or personal reasons.

A medical exemption may be granted when, in the opinion of a physician, nurse practitioner, or physician assistant, the required immunizations would be injurious to the health and well-being of the applicant or any member of the applicant’s family or household. The exemption certificate may cover a single vaccine, multiple vaccines, or all required immunizations. The certificate is valid only when signed by a physician, nurse practitioner, or physician assistant. RNs and CMAs are not eligible to sign a medical exemption certificate. Physicians signing the medical exemption must be licensed in the State of Iowa for the certificate to be valid.

An expiration date shall be recorded on the certificate if, in the opinion of the medical provider issuing the medical exemption, the exemption should be terminated or reviewed at a future date. This is important to remember as there may be time sensitive issues as to why a child should not be immunized, but the opportunity for vaccination in the future should not be lost. If an expiration date is not recorded, the exemption is valid for the duration the individual is enrolled in the school or child care.

A religious exemption may be granted to an applicant if immunizations conflict with a genuine and sincere religious belief, and is not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations. To be valid the certificate must be signed by the applicant or, if the applicant is a minor, by the parent or guardian. Additionally, the certificate must be notarized. It is important to remind parents that this type of certificate has the possibility of becoming null and void during times of emergency as determined by the State Board of Health and declared by the Director of Public Health.

Provisional Certificate of Immunization may be granted when a child needs to enter school or licensed child care and has begun but not completed the required vaccinations for their age. This certificate may be used for any student entering a new school or childcare program. The child must have received at least one dose of each of the required vaccines prior to entry into school or childcare. Provisional enrollment may not exceed 60 calendar days and all vaccinations should be completed as soon as medically feasible. The 60 day period begins on the date the certificate is signed. A Provisional Certificate is only valid if it is signed by one of the following health care providers: a physician, PA, nurse, or a CMA. The expiration date must be included on the certificate.

If the child has not completed the required vaccinations due to minimum interval requirements, the Provisional Certificate may be extended by submitting a new Provisional Certificate. If, at the end of the 60 day window period the child has not received the next dose of required vaccine the school admitting official shall exclude the child from school and associated activities.

If you have any questions regarding immunization certificates please see Iowa Administrative Code, Chapter 7 or contact the Iowa Immunization Program at 1-800-831-6293.

Fall is fast approaching and it is time to think about scheduling flu clinics. As in the past IDPH will be distributing flu vaccine as it is produced and approved by the FDA. Due to these circumstances you may be receiving several shipments of vaccine in September, October and November. FluMist is distributed directly from the manufacturer and will be sent to you as soon as it is available.

Reminder: The Advisory Committee on Immunization Practices voted to expand the VFC influenza vaccine recommendation to include all VFC eligible children 6 months through 18 years of age.
On March 20, 2006, an MMWR was published titled “Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine.” This issue of the MMWR provides scenarios and guidelines for patient care in the event of a Tdap or DTaP administration error. Additionally, we have included a cut-out chart of action in the case of an administration error on page 4 of this newsletter.

The following is an excerpt from the March 20, 2006, MMWR: “To help prevent inadvertent administration of Tdap when pediatric DTaP is indicated or pediatric DTaP when Tdap is indicated, vaccine providers should review product labels before administering these vaccines; the packaging might appear similar.

**Tdap is not indicated for children aged <10 years.** Tdap contains lower amounts of diphtheria toxoid and lower amounts of some pertussis antigens compared with pediatric DTaP. Studies of the immune responses to Tdap among infants have not been conducted.

**Pediatric DTaP is not indicated for persons aged ≥7 years;** the increased diphtheria toxoid content is associated with higher rates of adverse reactions in older persons.

Guidance on the best approach to vaccination following inadvertent administration of Tdap or pediatric DTaP is based primarily on expert opinion. The family should be informed of any inadvertent vaccine administration. Adverse events associated with inadvertent vaccine administration can be reported to VAERS.

If Tdap is inadvertently administered instead of pediatric DTaP to a child aged <7 years as any one of the first three doses of the tetanus-diphtheria-pertussis vaccination series, the Tdap dose should not be counted as valid, and a replacement dose of pediatric DTaP should be administered.

If the inadvertent administration is discovered while the child is in the office, the pediatric DTaP can be administered during the same visit. If the child has left the office, some experts suggest administering the replacement dose of pediatric DTaP within approximately 72 hours, or administering it 4 weeks later to optimize the child's immune response to the antigens in pediatric DTaP.

This practice helps ensure that the child stays on the primary series schedule and has adequate protection against diphtheria and pertussis. However, the replacement dose of pediatric DTaP can be administered as soon as feasible at any interval after the inadvertent Tdap dose. The remaining doses of the pediatric DTaP series should be administered on the routine schedule, with at least a 4 week interval between the replacement dose of pediatric DTaP and the next dose of pediatric DTaP.

For example, if an 8-week-old infant inadvertently received a dose of Tdap instead of the first dose of pediatric DTaP and does not receive a replacement dose of pediatric DTaP within about 72 hours, a replacement dose of pediatric DTaP can be administered 4 weeks after the inadvertent Tdap dose (age 12 weeks).

The routine schedule of pediatric DTaP can then be resumed 4 weeks after the pediatric DTaP replacement dose (age 16 weeks). With the other recommended vaccines. **Continued on page 4**
If Tdap is inadvertently administered as the fourth or the fifth dose in the tetanus-diphtheria-pertussis vaccination series to a child age <7 years, the Tdap dose should be counted as valid and does not need to be repeated; the child who received Tdap as a fourth dose should complete the pediatric DTaP schedule. The routine adolescent Tdap vaccination recommendations would apply when this child becomes an adolescent. For example, a child who inadvertently receives Tdap at age 5 years instead of the fifth dose of pediatric DTaP should receive a second dose of Tdap at age 11-12 years.

If Tdap or pediatric DTaP is inadvertently administered to a child aged 7-9 years instead of Td as part of catch-up vaccination or for wound management, this dose can be counted as the adolescent Tdap dose, or the child can later receive an adolescent booster dose of Tdap according to the interval guidance used for Td to Tdap. In either case, the child should receive a dose of vaccine containing tetanus and diphtheria toxoids no longer than 10 years after the inadvertent Tdap or pediatric DTaP dose or according to the guidance for catch-up vaccination.

If pediatric DTaP is inadvertently administered to an adolescent age 11-18 years, the dose should be counted as the adolescent Tdap booster. The adolescent should receive the next dose of a vaccine containing tetanus and diphtheria toxoids 10 years after the inadvertent pediatric DTaP dose or according to the guidance for catch-up vaccination.

You can view this issue of the MMWR (March 24, 2006/Vol.55/No. RR-3) in its entirety at http://www.cdc.gov/nip/vaccine/tdap/tdap_child_summary.htm

**Tdap/DTaP Inadverant Administration Flow Chart**

### Child Less Than 7 Years of Age

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<tr>
<th>Doses 1-2-3</th>
<th>Doses 4-5</th>
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</thead>
<tbody>
<tr>
<td>Tdap given inadvertently</td>
<td>Tdap given inadvertently</td>
</tr>
<tr>
<td><strong>Action:</strong> Repeat ASAP with DTaP</td>
<td><strong>Action:</strong> Count as a valid dose. Do not need to repeat using DTaP.</td>
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**Tdap vaccination recommendation would apply when the child becomes an adolescent.**

### Child 7-9 Years of Age

- Tdap given inadvertently
- **Action:** Count the Tdap as a valid/protective dose. This dose counts as the single adolescent Tdap dose.
- Future doses should be Td: every 5-10 years.

### Adult

- DTaP given inadvertently
- **Action:** Count DTaP as a valid/protective dose. This dose should be counted as the single Tdap booster.
- Future doses should be Td: every 5-10 years.

**STORAGE REMINDER!**

![ProQuad](image)

ProQuad is a live attenuated vaccine for Measles, Mumps, Rubella, and Varicella approved for children 12 months through 12 years. The ProQuad vaccine must be stored in the **FREEZER ONLY**.

Unlike single antigen Varicella vaccine, ProQuad can not be stored in the refrigerator for any reason. If you have questions regarding storage and handling, please contact us at 1-800-831-6293.
Human Papillomavirus (HPV) Vaccine

HPV infection is the most common sexually transmitted infection (STI) in the United States with approximately 20 million Americans currently infected. Each year, an additional 6.2 million people become newly infected. As many as half of those infected with HPV are adolescents and young adults, ages 15-24 years.

HPV is the name of a group of viruses that includes more than 100 different strains or types. More than 30 of these viruses are sexually transmitted, and they can infect the genital area including the skin of the penis, vulva, or anus, and the linings of the vagina, cervix, or rectum.

Most people who become infected with HPV will not have any symptoms and will clear the infection on their own.

While most HPV infections are asymptomatic and transient, HPV is of clinical and public health importance because persistent infection with certain oncogenic types can lead to cervical cancer. Cervical cancer is one of the most common cancers in women worldwide. Certain oncogenic types also have been associated with other, less common anogenital cancers. Moreover, non-oncogenic HPV types can cause genital warts and, rarely, respiratory tract warts in children.

On June 8, 2006, an HPV vaccine was licensed by the Food and Drug Administration (FDA) and on June 29, 2006, it was approved to be included by the Advisory Committee on Immunization Practices (ACIP). On the same day it was added to the Vaccines for Children (VFC) Program. Continued on page 6.
Human Papillomavirus (HPV) Vaccine, continued

VFC will cover the HPV vaccine for females age 9-18 who are VFC eligible. IDPH estimates this vaccine will be available in 2006.

According to ACIP’s recommendation, three doses of the new vaccine should be routinely given to girls when they are 11 or 12 years old. The advisory committee, however, noted that the vaccination series can be started as early as nine years old at the discretion of the physician or health care provider. The recommendation also includes girls and women 13-26 years old because they will benefit from getting the vaccine. The vaccine should be administered before onset of sexual activity (i.e., before women are exposed to the viruses), but females who are sexually active should still be vaccinated.

“This vaccine represents an important medical breakthrough,” said Dr. Anne Schuchat, director of CDC’s National Center for Immunization and Respiratory Disease “As a result, these vaccine recommendations address a major health problem for women and represent a significant advance in women’s health. It has been tested in thousands of women around the world and has been found to be safe and effective in providing protection against the two types of HPV that cause most cervical cancers.”

HPV Vaccine Information

• Quadrivalent HPV vaccine (manufactured by Merck) has been licensed by the (FDA) for females, ages 9-26 years. The vaccine protects against four types of HPV (6,11,16,18), including two that cause 70% of cervical cancers and two that cause 90% of genital warts. The vaccine has been tested in over 11,000 females (ages 9-26 years).

• This vaccine is prophylactic and made from non-infectious HPV-like particles (VLP), composed of the L1 major capsid protein. There is no thimerosal or mercury contained in the vaccine.

• The vaccine should be delivered through a series of three intra-muscular injections over a six-month period (at 0, 2, and 6 months. Minimum interval between dose 1 and 2 is 1 month, and between dose 2 and 3 is 3 months).

• Clinical trials in females (ages 16-26 years) have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types. The vaccine has also been found to be almost 100% effective in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types. The vaccine has no therapeutic effect on HPV-related disease; it does not protect from disease due to HPV types already acquired.

• There are no serious side effects. Adverse reactions are mainly injection site pain. This reaction is common but mild.

• The duration of protection is unclear. Current studies indicate the vaccine is effective for five years. There is no evidence of waning immunity during that time period. This information will be updated as additional data regarding immunity become available.

• Ideally, the vaccine would be administered before onset of sexual activity. However, females who are sexually active may also benefit from vaccination. Those who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Those who have already been infected with one or more HPV type would still get protection from the vaccine types they have not yet acquired.

• While it is possible that vaccination of males with the quadrivalent vaccine may offer direct health benefits to males and indirect health benefits to females (through herd immunity), there are not yet data to confirm this. The retail price of the vaccine is $120 per dose ($360 for a full series).

• Although an effective HPV vaccine is a major advance in approaches to the prevention of genital HPV and associated diseases, it will not replace other prevention strategies since vaccines will not work for all genital HPV types.

• Vaccinated women will still need regular cervical cancer screening since the vaccine will NOT provide protection against all types of HPV that cause cervical cancer, and since some women may not receive the full vaccine series (or they may not receive them at appropriate intervals).

• Vaccinated women should still practice protective sexual behaviors which is associated with lower rates of genital warts and cervical cancer), since the vaccine will not prevent all HPV types—nor will it prevent other STIs.

News You Can Use—Useful Websites for Immunization Providers

Centers for Disease Control and Prevention / National Immunization Program  www.cdc.gov/nip
The Immunization Action Coalition  www.immunize.org  Children’s Hospital of Philadelphia  www.vaccine.chop.edu
American Academy of Pediatrics  www.aap.org  Iowa Immunization Program www.idph.state.ia.us/adper/immunization.asp