

Immunization Update

The Iowa Immunization Program

Chester J. Culver, Governor • Thomas Newton, Director, IDPH

July 2009

Don Callaghan, Chief Bureau of Immunization and TB

> • Mary Jo<u>nes, Director</u>

Division of Acute Disease Prevention and Emergency Response



Call the IRIS Help Desk at I-800-374-3958 for Enrollment Details or

 The Immunization Update is available on the Web Click

 HERE

 Inside This Issue

 HIB Booster Reinstated

 Reminder of VFC Dorm Refrigerator Phase Out

 H1N1 Information

 Change in VIS Guidance

 2009 Conference was a Success!

Training Announcements and Ask the Experts

Limited Supply of Hepatitis B Vaccine

Since February 2009, there has been limited supply of pediatric monovalent hepatitis B vaccine nationally. **Despite these supply constraints, CDC has determined there is sufficient pediatric hepatitis B vaccine available to continue the current hepatitis B recommendations for the remainder of 2009.** However, providers will need to order hepatitis B containing vaccine judiciously to ensure there is sufficient product available for all providers.

At this time, providers should continue to administer pediatric hepatitis B vaccine according to the ACIP/AAP/AAFP 2009 childhood immunization schedule, including giving the hepatitis B birth dose. Given the current situation with the supply of pediatric hepatitis B vaccine, providers should <u>not</u> combine two pediatric doses of hepatitis B (Merck, Recombivax HB allows this practice) to vaccinate an adult patient (>19 years old), doing so will diminish doses that are available for patients 19 and younger, especially high-risk infants born to HBsAg-positive mothers.

Vaccines for Children (VFC) Program providers should order pediatric hepatitis B vaccine monthly and only order enough vaccine to cover their needs for a 30-day period. In order to assure equitable vaccine distribution throughout the VFC Program, the CDC has set monthly allocation limits for the number of Hep B vaccine doses each state will receive. Similar limitations are being put in place for private sector orders.

CDC has worked with both Merck and GSK, the two manufacturers of pediatric monovalent hepatitis B vaccine, to determine how much vaccine will be available for the remainder of 2009. Merck expects to have a very limited supply and GSK plans to provide additional vaccine by September or October 2009. Vaccine supply is anticipated to be very tight during the summer months.

Questions regarding the VFC hepatitis B vaccine supply should be directed to Janean Iddings or Tina Patterson at 800-831-6293 ext 5 and 4, respectively. Contact Bridget Konz, at 800-831-6293 ext. 7 with questions regarding the hepatitis B birth dose.

A chart showing how to protect infants against hepatitis B virus infection when using Pentacel vaccine during the Hib vaccine shortage, can be found at the following CDC Web site:

http://www.cdc.gov/vaccines/vacgen/shortages/downloads/eo-hib-hepbcov.pdf

The Pink Book is Now Available: The 11th Edition of the Epidemiology and

Prevention of Vaccine-Preventable Diseases, (The Pink Book) published by the National Immunization Program, Centers for Disease Control and Prevention, is now available. The Pink Book provides physicians, nurses, nurse practitioners, physician assistants, pharmacists, and others with the most comprehensive information on vaccine-preventable diseases. For more information on how to order a Pink Book, or to view chapters and index online, go to:

Presentant Vectors Presentante Discover

http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm

HIB Booster Dose Reinstated

On December 13, 2007, certain lots of Haemophilus influenzae type b (Hib) vaccine marketed as PedvaxHIB (monovalent Hib vaccine) and Comvax (Hib-HepB vaccine) manufactured by Merck, were recalled voluntarily, and the company temporarily suspended production of these vaccines. To conserve the limited supply of Hib-containing vaccines, CDC, in consultation with the ACIP, AAFP, and AAP, on December 18, 2007, recommended that vaccination providers temporarily defer the routine Hib vaccine booster dose administered to most healthy children at age 12 through 15 months.

Production of Merck Hib vaccine products is still suspended. However, two other Hib-containing vaccines manufactured by Sanofi Pasteur monovalent Hib vaccine (ActHIB) and DTaP-IPV/Hib (Pentacel) - have been available for use in the United States during this shortage. Beginning in July 2009, Sanofi will increase the number of doses of these two products available for use in the United States, which will result in the supply being sufficient to reinstate the Hib vaccine booster dose.

Effective immediately, CDC, in consultation with ACIP, AAFP, and AAP, is recommending reinstatement of the booster dose of Hib vaccine for children aged 12 through 15 months who have completed the primary 3dose series.

Infants should continue to receive the primary Hib vaccine series at ages 2, 4 and 6 months. Children age 12 through 15 months should receive the booster dose on time.

Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter. Although supply is sufficient to reinstate the booster

dose and begin catch-up

vaccination, supply is not yet ample enough to support a mass notification process to contact all children with deferred Hib booster doses.

Sufficient vaccine will be available to administer the primary series at ages 2, 4 and 6 months and a booster dose on time to children age 12 through 15 months. As part of delivering the booster dose to those children for whom it was deferred to the next routinely scheduled appointment or medical encounter, practices should discuss with parents the reasons for the change in recommendation and might consider 1) reviewing electronic or paper medical records or immunization information system records to identify children in need of a booster dose before physician encounters, 2) evaluating children's vaccination status during their scheduled visit, and 3) sharing immunization schedules with parents to make them aware of this plan.



During the Hib shortage, children received protection from certain vaccine preventable diseases in their primary vaccination series through combination vaccines (e.g., DTaP-IPV/Hib [Pentacel] and DTaP-IPV-HepB [Pediarix]) and monovalent vaccines (e.g., ActHib, HepB, and IPV). Therefore, a mismatch might exist between patient vaccination needs and the available stock of different vaccine formulations (e.g., combination products versus single-antigen vaccines) in local provider offices. This situation presents a challenge for providers to administer vaccines to ensure appropriate coverage while minimizing extra doses of unneeded vaccine.

For example, if a provider is using DTaP-IPV/Hib (Pentacel) vaccine to protect infants against Hib disease, the provider should ensure that adequate stock of monovalent HepB vaccine is available to complete the HepB vaccine series.* Children who need the Hib booster and who already have received four doses of DTaP should receive monovalent Hib vaccine (ActHIB) as their Hib booster dose. However, if DTaP-IPV/Hib is the only Hib-containing vaccine available, this combination product can be used to complete the series of Hib vaccination, even if the child already has received all the necessary doses of DTaP and IPV.

Vaccination providers with questions about their supplies of monovalent Hib vaccine (ActHIB) or DTaP-IPV/Hib (Pentacel) purchased with nonpublic funds should contact Sanofi Pasteur's customer service department at 800-822-2463. Sanofi Pasteur will work directly with physicians to increase allotments of Hib-containing vaccines on the basis of previous purchasing patterns or practice birth cohort and estimates of additional vaccine doses needed. For VFC vaccine supply, providers should contact the Immunization Program at 800-831-6293.

The Immunization Program is currently reviewing the Hib waiver for licensed child care centers and is planning to extend the waiver until recommendations and vaccine supply is adequate to vaccinate all children with a deferred Hib booster dose.

This recommendation reflects CDC's assessment of the existing national Hib vaccine supply and will be updated if the supply changes. Updated information about the national Hib vaccine supply is available at:

http://www.cdc.gov/vaccines/vacgen/shortages/default.htm.

Continued on page 3

HIB Booster Dose Reinstated, continued

Detailed Vaccination Schedule for Haemophilus <i>influenzae</i> type b Conjugate Vaccines			
Vaccine	Age at 1 st Dose (Months)	Primary Series	Booster
ActHib (Sanofi)	2-6	3 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12.14	1.4	2 months later

(Sanon)	12-14	1 dose	2 months later
	15-59	1 dose	
PedvaxHib (Merck)	2-6	2 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12-14	1 dose	2 months later
	15-59	1 dose	

*At least 2 months after previous dose

The number of doses in the primary series depends on the type of vaccine used. A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series. Any brand can be used for the booster dose. If brands are changed during the primary series, a 3 does primary series is required (2, 4, 6 months of age) with a booster (12-15 months of age).

Details about the routine Hib schedule are available at:

http://www.cdc.gov/vaccines/recs/schedule s/default.htm#child.

Adverse events following receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) at: http://vaers.hhs.gov.

This article is printed directly from the CDC MMWR June 26, 2009 / 58(24);673-674 and can be found at the following address: http://www.cdc.gov/mmwr/preview/mmwrh tml/mm5824a5.htm?s_cid=mm5824a15e

* Additional information available at http://www.cdc.gov/vaccines/vacgen/shortages/downloads/eo-hib-hepbcov.pdf.

Reminder from January 26, 2009 VFC Memo



The CDC released new VFC Program requirements to eliminate the use of dorm-style refrigerators as permanent (overnight) vaccine storage units for vaccine. Guidelines indicate dorm-style units should only be used to store a single-day supply of refrigerated vaccines as long as the unit temperatures are monitored and documented twice a day on temperature log specifically for that unit and vaccine is returned to the recommended storage unit at the end of the clinic day.

Dormitory-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures. A dormitory-style unit should never be used for storing Varicella-containing vaccines.

A dorm-style refrigerator is defined as a small combination refrigerator/freezer unit that has one external door and an ice-maker/freezer compartment within the refrigerator.

CDC requires all VFC providers who permanently store (overnight) vaccine in a dorm-style refrigerator to replace it with a recommended storage unit by December 31, 2009.

The Immunization Program will be working with VFC Program providers throughout the upcoming year to comply with this new requirement. If you have questions regarding this issue or the VFC Program, please contact Tina Patterson at 1-800-831-6293, ext. 4.

H1N1 Influenza Information

As we near closer to our typical influenza season and the world learns more about H1N1 there are two sources of information that are reliable and easy to access. The CDC H1N1 Web page is full of resources for providers and patients with easy downloads and plenty of guidance. The Web page is found at: http://www.cdc.gov/h1n1flu/.

The Iowa Department of Public Health's H1N1 Web page and contains Iowa specific information is found at: http://www.idph.state.ia.us/h1n1/default .asp

The FDA is warning consumers regarding products related to the 2009 H1N1 flu virus offered on the Internet. The products involved are those that are promoted and marketed to diagnose, mitigate, prevent, treat or cure the 2009 H1N1 flu virus but are not approved, cleared or authorized by the FDA. To view the full press release:

http://www.fda.gov/NewsEvents/Newsroo m/PressAnnouncements/ucm166801.htm

On June 17, 2009, the CDC updated the requirements for Vaccine Information Statements (VIS). While providers are still required to provide

VIS by federal law, there are innovative ways to comply with the VIS law while conserving paper.

The legal mandate, as stated in the National Childhood Vaccine Injury Act, is that providers must give the appropriate VIS to the recipient or to the recipient's parent or legal representative with each dose of vaccine; give it



Providers must give the appropriate VIS to the recipient or to the recipient's parent or legal representative with each dose of vaccine

prior to administration of the vaccine; give it each time the vaccine is given (not just with the first dose), and record certain information in the patient's permanent medical record.

Within the context of this mandate, there are a variety of ways a VIS can now be offered. The following list of options for providing VIS offers several ways clinics can meet the legal 3. requirements. Any one or combination of the following is acceptable:

 Always offer the patient or parent a copy of the appropriate VIS to read during the immunization visit and a copy (either paper or electronic) to take home. Always offer the patient an opportunity to ask guestions. [*Note: When a*

> combination vaccine is administered for which there is not a consolidated VIS, give the patient the individual VIS for each component.]

2. It is acceptable to make a VIS available to be read before the immunization visit (e.g., by giving the

patient or parent a copy to take home during a prior visit or telling them how to download or view a copy from the internet). We encourage this when possible. These patients must still be offered a copy to read during the immunization visit, as a reminder, and a copy to take home.

The patient may be offered a permanent (e.g., laminated) copy of the VIS to read during the immunization visit (instead of their own paper copy), or may be directed to the appropriate VIS on an office computer. *[Note: Check the CDC's VIS Web site* periodically to ensure that the office copies you are using are the current editions.]

4. Always encourage the patient to take a copy of each appropriate VIS home when they leave the office. This is because some information (e.g., the routine schedule, or how to recognize or report an adverse event) can be useful later. Offer the patient a paper copy, or if they prefer to download the VIS onto a mobile device, direct them to CDC's patient download Web page during the visit.

http://www.cdc.gov/vaccines/pub s/vis/vis-downloads.htm

As needed, supplement VIS orally, with videotapes, with additional printed material, or in any other way that will help recipients understand the disease and vaccine. Record the following required information on the patient's medical record or on a permanent office log (the record should be both permanent and accessible):

- The edition date of the VIS (found on the back in either the left or right bottom corner). [Note: When multiple VIS are given for a combination vaccine, record the individual edition dates.]
- 2. The date the VIS is provided (i.e., the date of the visit when the vaccine is administered).

Continued on page 6

New IRIS List Serve

Subscribe to the *new* IRIS list serve! This service will provide you with timely information regarding changes, maintenance or new information about IRIS. To subscribe, send a blank email message to <u>join-IRISUSERS@lists.ia.gov</u>.

Please share this new resource with your colleagues and fellow IRIS users who may wish to receive up to date information about IRIS. For questions about the IRIS list serve, please call the IRIS Help Desk at 800-374-3958. The IRIS Program looks forward to serving you through this new process!



More than 600 hundred public health leaders, health care providers and immunization experts gathered in Des Moines on Wednesday and Thursday, June 10 and 11, 2009, for the Statewide Iowa Immunization Conference.

Held every two years, the conference provides an opportunity for immunization professionals to hear from experts in the field and honor excellence among their peers. For the first time, an awards ceremony was held the evening before the conference and featured recognition of six recipients of Immunization Awards of Excellence for their commitment to immunizations and the health of Iowans. The honorees are as follows:



Towncrest Pharmacy - The pharmacists at Towncrest Pharmacy in Iowa City use unique strategies to promote immunizations. Most notably, the pharmacists work with several community living organizations that care for adults and children with disabilities. Physical constraints prevent many of them from visiting the pharmacy or other health care providers for vaccinations. In response, the pharmacy developed a vaccination

service in which staff go to the individual's home to provide immunizations. Towncrest Pharmacy has provided vaccines to over 7,500 individuals over the last five years.



Hancock County Public Health Department As part of a required bio-emergency preparedness exercise, Hancock County conducted a mass vaccination clinic. Student immunization records were reviewed and qualifying teens were transported from local schools to receive the meningitis vaccine. The clinic provided information about how long a mass vaccination clinic would last in a realworld situation, and students received needed immunizations.



Linda Manders – A nurse at Davenport Public Schools, Linda was able to successfully implement a school-based vaccination clinic. Using student ambassadors and peer educators, Linda was able to build enthusiasm among the students for the clinic. Linda was instrumental in spreading the message that adolescent immunizations should be a priority.

Brooke Grundman - Brooke is



employed by Alegent Mercy Hospital in Corning, as the infection control nurse. One of her most successful campaigns was to increase the number of staff members at her hospital to receive the influenza vaccine. Brooke increased the percentage of employees receiving the flu vaccine from 75 percent in the fall of 2007, to 86 percent in 2008.

McFarland Clinic Pediatric



Department - The staff at McFarland Pediatrics in Ames developed a cooperative staffing plan, offering flu vaccinations for patients before and after normal business hours without requiring additional staff time. More than 9,000 doses of flu vaccine were administered in the 2008-2009 season. Many of the vaccinations were given in these before and after hour clinics.



- Vaccine Education Center at the Children's Hospital of Philadelphia www.chop.edu/consumer/your_child/index.jsp
- Autism's False Prophets, by Dr. Paul Offit- <u>http://www.amazon.com/Autisms-False-Prophets-Science-Medicine/dp/0231146361</u>

Change in VIS Guidelines, continued

- 3. The name, address (office address) and title of the person who administers the vaccine.
- 4. The date the vaccine is administered.
- 5. The vaccine manufacturer and lot number.

Providers May Also add a practice's name, address, or phone number to an existing VIS. If the publication date is cut off during downloading, add the date. Have a recipient or their parent or legal representative sign a separate "informed consent" form if it is required by your agency. There is no federal requirement for written informed consent for vaccinations, and VIS are not considered informed consent forms, nor dose lowa have such requirements.

Providers Should Not change a VIS or make your own VIS. The law requires providers to use those developed by CDC.

Providers can still offer VIS the traditional way, with a provider giving the patient or parent a paper copy to read prior to the vaccination, and then encouraging them to take the same copy home with them. Or one of several options above can be exercised. As long as the patient/parent is 1) given the appropriate VIS to read prior to vaccination and 2) offered a copy, either paper or electronic, to take home, the federal legal requirements are satisfied.

VIS will continue to be available at no cost through the Iowa Health Protection Clearinghouse and can be ordered directly from the Immunization Program Web page at <u>http://www.idph.state.ia.us/adper/imm</u> <u>unization_products.asp</u> For further information, visit the CDC Web site <u>http://www.cdc.gov/vaccines/pubs/vis/</u> <u>vis-facts.htm</u> or contact Bridget Konz or Terri Thornton at 800-831-6293 ext. 7 and 2, respectively.

Training Announcements

Immunization Update 2009 Mark your calendars for the July 30, 2009 Live Satellite Broadcast and Webcast from CDC's National Center for Immunization and Respiratory Diseases (NCIRD).

The event will take place from 9:00 AM – 11:30 AM and noon – 2:30 PM EST. More information about this broadcast will soon be available at the <u>CDC Vaccine Education and</u> <u>Training Web page.</u>

Epidemiology & Prevention of Vaccine-Preventable Diseases is a comprehensive overview of the principles of vaccination, general recommendations, immunization strategies for providers, and specific information about vaccine-preventable



diseases and the vaccines that prevent them. This program can be watched via the web or ordered on DVD. It is a 12 hour course with four 3-hour sessions. For more information on go to the following CDC Web site: http://www.cdc.gov/vaccines/ed/epivac/default.htm

Ask the Experts



Question: I accidentally gave Zostavax IM instead of SC. What do I need to do?

Answer: You can count the dose as valid. ACIP recommends that vaccines given by the wrong route be counted as valid with one exception: hepatitis B administered by any route other than intramuscular should not be counted as valid and should be repeated. Vaccines should always be given by the route recommended by the manufacturer, but errors do occur. Your practice should put procedures in place to ensure that you give vaccines by the recommended route.

Avoid such errors by using the following resources: How to Administer Intramuscular (IM) and Subcutaneous (SC) Injections

http://www.immunize.org/catg.d/p2 020.pdf

How to Administer IM and SC Injections to Adults http://www.immunize.org/catg.d/p2

<u>020a.pdf</u>

Administering Vaccines to Adults: Dose, Route, Site, Needle Size, and Preparation

http://www.immunize.org/catg.d/p3 084.pdf

Administering Vaccines: Dose, Route, Site, and Needle Size (includes all vaccines) http://www.immunize.org/catg.d/p3 085.pdf

This question/answer is re-printed from the Immunization Action Coalition "Ask the Experts" site. <u>http://www.immunize.org/askexpert</u> <u>s/</u>