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Immunization E-Letter

Indiana State Department of Health

Issue #307

June 19, 2009

Immunization Program

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When vaccine shortages occur, the ACIP may recommend certain provisions to allow a limited vaccine supply to vaccinate the most children at need.

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[Click here for full story.](#)

FDA Makes Change To Gardasil® Label

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) revised the label for Gardasil®, a vaccine to protect against cervical, vulvar and vaginal cancers caused by Human Papillomavirus (HPV) types 16 and 18 and genital warts caused by HPV types 6 and 11.

[Click here for full story.](#)

Setting and Stabilizing the Temperature

Only the primary or backup vaccine coordinator should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately.

[Click here for full story.](#)

Upcoming Events [Click here list of events.](#)

Program Announcements

Help Us Improve the E-Letter!

Please take the Immunization E-Letter survey at http://www.surveymonkey.com/s.aspxsm=IMx9ApK5v6rwPGTu1o7cHA_3d_3d. Your feedback will help us continue to improve the quality and content of the Immunization E-Letter.

New Field Staff Phone Numbers!

All Immunization field staff have received new phone numbers! Please see the attached phone list for the new phone numbers.

Vaccine to Expire Reminder!

Please notify your AFIX field representative at least a 60-90 days prior to expiration of vaccine in order to transfer it to another facility. This will allow enough time for the vaccine to be transferred and utilized by the other facility before expiration.

Twinrix® Initiative

ISDH is encouraging all Local Health Departments to participate in the Twinrix® Initiative, to provide the combination HepA & HepB vaccine to high risk adults. Also, if you are current participating in the initiative and have had a tremendous response or would like to plan a clinic day to provide Twinrix®, please contact the ISDH Immunization Program first in order to plan for the increase in vaccine orders. Also, please allow ample time prior to the clinic for the order to be processed and the vaccine delivered.

Pediatric Diphtheria & Tetanus (DT) Vaccine Now Available

DT will be furnished in 10 packs of 1 dose vials. There is a limit of 10 doses each time you order, however, you may order less than 10 and the warehouse will split the package. The CDC does not carry DT any longer. As a courtesy, ISDH continues to purchase DT, which is why we ask you to use it for patients whose primary physicians do not want the child to have pertussis vaccine, or for whom pertussis vaccine is contraindicated.

Order Form Reminder

Please remember to only use the current VFC order form, which has 4 columns of Current month and previous Month. Fill out all columns even if you are not ordering a particular vaccine to account for how much you have on hand, have administered or wasted. If in the previous month you wasted more than 5 doses at any one time, you must then fill out an incident report in addition to a return form. Fax the incident report and a copy of the return form included with the vaccine return to McKesson to Alex ThurdeKoos at (317) 233-3719.

Delegation Of Authority Update

We now have 67 Indiana counties with signed DOA to vaccinate underinsured children! Thank you to the LHDs, RHCs, and FQHCs who have allowed us to expand coverage to our underinsured children. If you are a LHD without DOA and you would like more information, please call your ISDH representative, or Joan Duwve, MD, MPH, ISDH Medical Director at (317) 233-7164.

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Vaccine Deferrals & Limitations Update

When vaccine shortages occur, the ACIP may recommend certain provisions to allow a limited vaccine supply to vaccinate the most children at need. Current vaccine deferrals include:

Hib: Defer 4th Hib dose (Booster)

Children at increased risk for Hib disease should continue to receive the primary series and the booster dose. This includes children with asplenia, sickle cell disease, and human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms. In addition, American Indian/Alaska Native (AI/AN) children should also continue to receive the primary series and the booster dose.

Pediatric Hepatitis B: Do not use 2 pediatric doses for adults

Since February 2009, there have been intermittent pediatric hepatitis B vaccine supply constraints in the United States, with some local areas experiencing delays in shipments. Despite these supply constraints, current analysis indicates that during the remainder of 2009, sufficient pediatric hepatitis B vaccine will be available to meet demand, if providers continue to order vaccine judiciously. To ensure a sufficient amount of pediatric hepatitis B vaccine is available for children, use of two pediatric hepatitis B doses for adults is strongly discouraged.

All Other Vaccines

All other ISDH provided vaccines should be given based on the current ACIP recommendations. Previous limitations for use of some vaccines, such as Varicella and Hepatitis A, have been lifted by CDC.

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New Resources Available

CDC Vaccine Information Statements Update

As of June 10, 2009, patients who receive VISs statements during vaccination visits may opt to download them onto a mobile device (e.g., iPhone, BlackBerry) in lieu of receiving paper copies. A new web page (www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm) has been created to give patients easy access to the VISs. A link from the main VIS page (www.cdc.gov/vaccines/pubs/vis/default.htm) goes to this new page. For more information, see the note on the VIS-News page (www.cdc.gov/vaccines/pubs/vis/vis-news.htm). Also see the note on VIS-News about the elimination of separate "text only" VIS files. These are no longer needed because PDF files can now be made Section-508 compliant (i.e., accessible by screen-reader software) for the visually impaired.

Parents of Kids with Infectious Diseases (PKIDS) "Travel in Health" Web Page

To help families stay healthy and safe this travel season, Parents of Kids with Infectious Diseases (PKIDS) has posted a "Travel in Health" Web page. The page includes tips on rest, vaccinations, first aid kits, bugs, and common travel illnesses. To view the page, visit http://www.pkids.org/fam_travelhealth.php.

An Updated and Redesigned "After the Shots. . . What to Do if Your Child Has Discomfort" from IAC

An updated version of IAC's parent-focused piece, "After the shots. . . What to do if your child has discomfort" is now available. Topics covered include medicines and dosages for reducing pain and fever. To access the updated piece, go to <http://www.immunize.org/catg.d/p4015.pdf>.

The Vaccine Education Center Offers a New Resource on Aluminum in Vaccines

The Vaccine Education Center has developed new tear pads for parents titled "Aluminum in Vaccines: What you should know." This tear sheet addresses common questions from parents including: "Why is aluminum in vaccines?," "How much aluminum is in vaccines?," "What happens to aluminum after it enters the body?," "Does aluminum accumulate in the body?," "Is the amount of aluminum in vaccines safe?," "What is the harm in spacing out vaccines that contain aluminum?." To download the tear pad, click here: <http://www.chop.edu/consumer/jsp/division/generic.jsp?id=81901>.

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FDA Makes Change To Gardasil® label

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) revised the label for Gardasil®, a vaccine to protect against cervical, vulvar and vaginal cancers caused by Human Papillomavirus (HPV) types 16 and 18 and genital warts caused by HPV types 6 and 11. The revised label includes new information in the Warnings and Precautions section noting that individuals who faint sometimes have tonic-clonic (jerking) movements and seizure-like activity.

Information on syncope has been in Gardasil®'s labeling for both healthcare providers and patients since 2007. However, FDA and CDC continue to receive reports of traumatic injuries in individuals who have fainted and fallen after receiving Gardasil®. The addition of this information to the Warnings and Precautions section is intended to remind healthcare providers that Gardasil® recipients should be observed closely for 15 minutes after vaccination. Vaccine recipients should be encouraged to remain seated or lying down for this length of time and be alert for signs and symptoms that can occur before fainting, such as paleness, sweating, nausea, dizziness and ringing in ears or vision changes.

Syncope has been reported after administration of other adolescent and adult vaccines, so it is not unique to Gardasil® or even vaccines. Syncope can also occur with certain medications, after blood donation or in response to pain. Jerking movements, loss of bladder control, and other signs that resemble seizures may occur, but these do NOT mean that the person is having a seizure. Syncope and its associated signs and symptoms usually last only a short time (seconds to minutes) and resolve when the patient is placed in a position, such as lying down, to restore adequate blood flow to the brain.

Information about this change may be found on FDA's web site at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm165145.htm>. Additional information regarding syncope following vaccination may be found in the May 2, 2008, issue of the Morbidity and Mortality Weekly Report at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm>.

The revised package insert, patient information, and background on the labeling revision can be found at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094042.htm>.

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Setting and Stabilizing the Temperature of Vaccine Storage Units

Who Should Adjust the Temperature?

Only the primary or backup vaccine coordinator should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. If the thermostat requires adjustment, alert the vaccine coordinator or immediate supervisor. A warning sign should be posted on the storage unit that says, "Do not adjust refrigerator or freezer temperature controls. Notify (insert name) if adjustments are necessary."

Thermostats

Refrigerator and freezer thermostats are marked in various ways, depending on the brand. There are a variety of ways to indicate the temperature setting. For example, some have a series of numbers or letters on the control knob. Others may have "MIN," "MED," and "MAX" marked on the knob or a dial ranging from "cold" to "coldest." In general, thermostats do not show temperatures, but rather the levels of coldness. The only way to know the temperature inside the unit is to measure it with a thermometer. In combination refrigerator-freezer units, the thermostat actually controls the volume of cold freezer-temperature air that goes into the refrigerator. Consult the manual that came with the refrigerator for instructions on how to operate the thermostat.

How to Adjust the Temperature

To adjust the temperature, first be sure the unit is plugged into a power source, then check the temperatures inside the refrigerator and freezer compartments. Next, turn the knob slightly toward a warmer or colder setting as necessary. Adjust the thermostat slowly so as not to exceed the recommended temperature range. Allow the temperature inside the unit to stabilize for 30 minutes then recheck the temperature. Adjust the thermostat again as necessary. Aim to stabilize the refrigerator temperature around 40°F (5°C). Make sure the temperature does not fall below the lower limit or rise above the upper limit of the recommended refrigerator temperature range of 35° to 46°F (2° to 8°C). Aim to stabilize the freezer temperature at 5°F (-15°C) or colder. If you are using a combined refrigerator-freezer unit, be careful not to lower the freezer temperature so much that the refrigerator temperature falls below the recommended temperature range. Combined refrigerator-freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment. This type of unit has two thermostat controls: one controls the freezer temperature and the other controls the volume of freezing air that enters the main refrigerator cabinet. Therefore, use care when adjusting the freezer temperature because this will affect the temperature of the air venting into the refrigerator compartment. Without careful and frequent temperature monitoring inside the refrigerator compartment there is a danger of inappropriately freezing the refrigerated vaccines.

Frequent temperature monitoring of both the freezer and refrigerator compartments throughout the day as well as at the beginning and end of the work day is required whenever thermostats are adjusted. The temperature in a newly installed or newly repaired refrigerator may take 2 to 7 days to stabilize within the recommended range or 35° to 46°F (2° to 8°C). The temperature in a newly installed or newly repaired freezer unit may take 2 to 3 days to stabilize within the recommended range of 5°F (-15°C) or colder. CDC recommends that you allow 1 week of twice daily refrigerator and freezer temperature recordings before using a newly installed or newly repaired refrigeration unit to store vaccines.

To maintain the cold chain during any period when the refrigerator or freezer is out of service, vaccines should be temporarily stored in an alternate vaccine storage unit until the temperature in the original unit can be stabilized within the recommended range. The alternate unit should be functioning properly and should have sufficient space to properly store the vaccines. Another option is to store the vaccines in an appropriately packed cooler if the storage unit will be out of service for a short time. However, if the refrigerator or freezer cannot be repaired in time to maintain the temperature in the cooler within the recommended range, move the vaccines to an alternate vaccine storage unit. Contact the state health department immunization program for policies regarding vaccine packing and procedures for maintaining the cold chain while the vaccine storage unit is not functioning properly or turned off.

When to Adjust the Temperature

The refrigerator temperature should be adjusted if it is outside the recommended range or if, over time, the temperature appears to be moving toward the upper or lower temperature limit. It is best to set the temperature mid-range to achieve an average of about 40°F (5°C). This temperature setting will provide the best safety margin.

The freezer temperature should be adjusted if it is outside the recommended range or if, over time, the temperature appears to be moving toward the upper temperature limit of 5°F (-15°C).

In some situations, the thermostat may need to be reset in summer and winter, depending on the room temperature. If so, post instructions about this procedure on the vaccine storage unit door and include this information in the [Routine Vaccine Storage and Handling Plan](#).

Stabilizing the Temperature with Water Bottles and Frozen Packs

You can help stabilize the temperature in the refrigerator by keeping at least two or three large containers of water inside. Store the water bottles against the inside walls and in the door racks. You can help stabilize the temperature in the freezer by keeping frozen packs or ice trays inside. Store the frozen packs along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. Not only will water bottles and frozen packs help maintain an even temperature in the compartments with frequent opening and closing of the doors, they will also help keep the temperatures stable in the event of a power failure.

Opening the Door

Limit the number of times the vaccine storage unit doors are opened and avoid letting the doors stand open unnecessarily. Not only does this affect the temperature in the unit, it also exposes the vaccines to light (which can affect the potency of HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines). Routinely check the doors throughout the day and at the end of the day to ensure they are tightly closed.

Vegetable Bins

Consider removing the vegetable bins from the refrigerator. Removing the bins not only provides extra space for storing containers of water, but it also removes the temptation to use the bins for storage of food, beverages, or vaccines. Food and beverages should never be stored in a vaccine storage unit. Vaccines should never be stored near the floor of the refrigerator in the vegetable bins because the temperature in this area is different from that in the body of the refrigerator.

Temperature Variations

Temperatures can vary in a vaccine storage unit based on the contents, how often the door is opened, and power interruptions. The only way to be sure the temperature in the storage unit has remained within the recommended range is to frequently monitor and record the temperature using a thermometer.

Please refer to the ISDH Immunization Program Refrigerator/Freezer for Vaccine Storage policy at https://chirp.in.gov/chirp_files/docs/II-02%20Refrigerator-Freezer%20Policy%20Final%202-18-09%20Rev.pdf and the Vaccine Cold Chain Failure policy at https://chirp.in.gov/chirp_files/docs/II-09%20Cold%20Chain%20Failure%20Policy%20Final%202-18-09%20Rev.pdf

Excerpt from the CDC Vaccine Storage & Handling Toolkit. Full S&H Toolkit can be downloaded at http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_equipment.htm.

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Upcoming Events

June 26, 2009; 8:30am - 12:00pm (EST); Immunizations from A to Z
Good Samaritan Hospital, Vincennes, IN [Click here for registration form](#).

July 17, 2009; 9:30am - 11:30am; CHIRP User Group Meeting
Hendricks Regional Health, Danville, IN

July 17, 2009; 1:30pm - 3:00pm; Introduction to CHIRP Training
Hendricks Regional Health, Danville, IN

August 25-26, 2009
Epidemiology & Vaccine Preventable Disease Training Course
Presented by the Centers for Disease Control & Prevention
Renaissance Hotel, Carmel, IN
Registration information coming soon!

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Categories of Immunization Messages:

E-Alert conveys the highest level of importance; warrants immediate action or attention.

E-Advisory provides important information for a specific incident or situation; may not require immediate action.

E-Update provides updated information regarding an incident or situation; unlikely to require immediate action.

E-Letter traditional newsletter; distributed every other week with new information and educational articles.
