IOWA DEPARTMENT OF PUBLIC HEALTH • BUREAU OF DISEASE PREVENTION AND IMMUNIZATION

IOWA Immunization Program

Immunization Update

The Iowa Immunization Program Newsletter

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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!

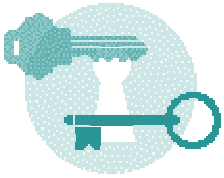
Is this newsletter helpful to you? What articles would you like to see? Please contact Bridget Konz at bkonz@idph.state.ia.us or 1-800-831-6293 ext. 7.

Inside This Issue

Vaccine Storage and Handling

The Right Temperature is Key

Storing vaccine at temperatures either too hot or too cold, can have a devastating effect on product efficacy. Additionally, it is impossible to tell if vaccine has been exposed to temperatures outside the intended range just by looking at it. Temperature monitoring is a key component to safely storing vaccine.



Temperatures should be monitored twice a day, even if alarm monitors and continuous graphing thermometers are used. Some of the most common mistakes in vaccine storage include not recording temperatures twice daily, not taking action if the temperature falls outside the allowable range, and not designating more than one person in each office to monitor temperatures.

Refrigerator temperatures must be between 35° and 46° F (2° - 8° C). Refrigerator temperatures naturally fluctuate, so aim for an average daily temperature of 40° F. Freezer temperatures must be maintained at 5° F or less (-15° C or less).

Recording temperatures twice daily is the standard protocol for vaccine storage and is the best way to identify when a unit is not maintaining proper temperature ranges. The Immunization Program has temperature charts available on our Web page or at the Health Protection Clearing House at 1-888-398-9696 (see page 3 for Web address).

Temperature logs should be kept for at least 3 years (some facilities may require logs be kept longer) to identify on-going problems or when a unit may need to be replaced. *Continued on page 3.*

It's Not to Late to Vaccinate Against Influenza

Influenza is a serious disease that attacks people of every stage of life. In the United States, even in an average year, influenza causes 36,000 deaths (mostly among those aged 65 years or older) and more than 200,000 hospitalizations. The "flu season" in Iowa generally peaks in February each year. An annual influenza vaccine (either the flu shot or the nasal-spray flu vaccine) is the best way to reduce the chances of getting and spreading the virus.

Vaccinating against influenza after the month of November will still benefit patients, even if flu is present in the community. Vaccine should continue to be offered to unvaccinated people throughout the "flu season" (through March) as long as vaccine remains available. Once vaccinated, it takes only about two weeks to make protective antibodies against the influenza virus.

When determining influenza vaccine dosing consider the following:

- **Age of the recipient.** Dose of vaccine is dependent on the recipient's age, a child 6 months through 35 months should receive 0.25 ml, persons 36 months (3 year old) and older should receive 0.5 ml.
- **Previously unvaccinated children.** Children 6 months through 8 years of age, should receive 2 doses of vaccine (inactivated one month apart, live-attenuated 6 weeks apart).
- **Vaccine manufacturer.** Brands are licensed for specific ages (refer to the chart on page 4).

Influenza vaccine contains three virus strains: two type A viruses and one type B virus. The exact vaccine composition changes year to year. Inactivated influenza vaccine, "the flu shot," contains killed viruses. In contrast, the nasal spray contains live attenuated viruses. See page 4 for a table describing the approved influenza vaccines for different age groups.

Hepatitis B and the Health Care Worker

In this article the CDC answers commonly asked questions regarding hepatitis B and Health Care Workers (HCW). This is re-printed, in part, from the Immunization Action Coalition. You can view and print the entire article at the following Web page: http://www.immunize.org/catg.d/2109hcw.htm

If a HCW had one dose only of hepatitis B vaccine 4 months ago, should the series be restarted?
No. The hepatitis B vaccine series should not be restarted when doses are delayed; rather, the series should be continued from where it stopped. The HCW should receive the second dose of vaccine now and the third dose at least 8 weeks later. There needs to be at least 16 weeks between the first and the third doses and at least 8 weeks between the second and third doses of vaccine.

Which HCWs need serologic testing after receiving 3 doses of hepatitis B vaccine?
All HCWs who have a reasonable risk of exposure to blood or body fluids containing blood (e.g., HCWs with direct patient contact, HCWs who have the risk of needlestick or sharps injury, laboratory workers who draw or test blood) should have postvaccination testing for antibody to hepatitis B surface antigen (anti-HBs). Postvaccination testing should be done 1–2 months after the last dose of vaccine.

What should be done if a HCW's postvaccination anti-HBs test is negative 1-2 months after the last dose of vaccine?
Repeat the 3-dose series and test for anti-HBs 1–2 months after the last dose of vaccine. If the HCW is still negative after a second vaccine series, the HCW is considered a non-responder to hepatitis B vaccination. HCWs who do not respond to vaccination should be tested for HBsAg to determine if they have chronic HBV infection. If the HBsAg test is positive, the person should receive appropriate counseling and medical management. Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain hepatitis B immune globulin (HBIG) prophylaxis for any known or likely exposure to HBsAg-positive blood.

How often should I test HCWs after they've received the hepatitis B vaccine series to make sure they're protected?
For immune competent HCWs, periodic testing or periodic boosting is not needed. Postvaccination testing (anti-HBs) should be done 1–2 months after the last dose of hepatitis B vaccine. If adequate anti-HBs (at least 10 mIU/mL) is present, nothing more needs to be done. If postvaccination testing is less than 10 mIU/mL, the vaccine series should be repeated and anti-HBs testing done, 1-2 months after the last dose of the second series. This information should be recorded in the HCW's employee health record.

Should a HCW who performs invasive procedures and who once had a positive anti-HBs result be revaccinated if the anti-HBs titer is rechecked and is less than 10 mIU/mL?
No. Immune competent persons known to have responded to hepatitis B vaccination do not require additional passive or active immunization. Postvaccination testing should be done 1–2 months after the original vaccine series is completed. In this scenario, the initial postvaccination testing showed that the HCW was protected. Substantial evidence suggests that adults who respond to hepatitis B vaccination (anti-HBs of at least 10 mIU/mL) are protected from chronic HBV infection for as long as 23 years, even if there is no detectable anti-HBs currently. Only immunocompromised persons (e.g., hemodialysis patients, some HIV-positive persons) need to have anti-HBs testing and booster doses of vaccine to maintain their protective anti-HBs concentrations of at least 10 mIU/mL.

If HCWs received hepatitis B vaccination in the past and were not tested for immunity, should they be tested now?
No. In this scenario, a HCW does not need to be tested unless she/he has an exposure. If an exposure occurs, refer to the postexposure guidelines in Table 1 on page 6.

How should a vaccinated HCW with an unknown anti-HBs response be managed if they have a percutaneous or mucosal exposure to blood or body fluids from an HBsAg-positive source?
This person should be tested for anti-HBs as soon as possible after exposure. If the anti-HBs concentration is at least 10 mIU/mL, no further treatment is needed. If the anti-HBs concentration is less than 10 mIU/mL, HBIG and one dose of hepatitis B vaccine should be administered. Prior to administering the HBIG and vaccine, blood should be drawn for a baseline HBsAg test. Subsequently, in 3–6 months, an additional anti-HBs and an HBsAg test should be performed. If the HBsAg is positive, the person is infected and should be referred for medical evaluation. If the anti-HBs result is at least 10 mIU/mL, the person is seroprotected. It is necessary to do postvaccination testing later than the usual recommended time frame because anti-HBs from HBIG might be detected if testing is done any earlier. The postvaccination test result should be recorded in the person's health record.

Several physicians in our group have no documentation showing they received hepatitis B vaccine. They are relatively sure, however, that they received the doses many years ago. What do we do now?
Because there is no documentation of vaccination, the 3-dose vaccination series should be administered and postvaccination testing should be performed 1–2 months after the third dose of vaccine. There is no harm in receiving extra doses of vaccine.
Continued on page 6

Vaccine Storage and Handling, *continued*

It is important to have a designated plan in the event of improper vaccine storage and handling. The Immunization Program has an Emergency Response Plan Worksheet to assist in developing action plans in the event of an out of range temperature. The document is available on the Immunization Program Web page at: http://www.idph.state.ia.us/adper/immunization.asp.

If improper vaccine storage and handling is identified the following action steps should be implemented.

1. Immediately notify a supervisor, mark the vaccine that is compromised, do not allow it to be administered, and store it in another unit at the appropriate temperature.
2. Call the manufacture to determine what should be done with the effected vaccine.
3. Check the condition of the refrigerator/freezer for problems. Are the seals tight? Is there excessive lint or dust on the coils?
4. After you have made the necessary adjustments or a trained technician has identified and fixed the problem, document the date, time, temperature, what the problem was, the action you took, and the results of this action. Do not replace vaccine in the unit until it consistently maintains the appropriate vaccine temperatures.

If improperly stored vaccines were administered to patients, revaccination may be necessary. "If mishandled or expired vaccines are administered inadvertently, they should not be counted as valid doses and should be repeated, unless serologic testing indicates a response to the vaccine." (MMWR Vol. 51/RR-2, February 8, 2002) Please contact the Immunization Program (below) for guidelines and resources regarding revaccination efforts.

It is important to train all staff regarding vaccine storage and handling. Staff should be familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and what to do in case of an equipment problem or power outage. A back up person should be designated to review the temperature logs weekly.

Recommendations for handling and storage of selected biologics are summarized in several areas: Epidemiology of Vaccine Preventable Diseases (Pink Book) Appendix C, package inserts for each product, Centers for Disease Control and Prevention publication titled *Vaccine Management*, and a Web-based toolkit available at http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html

Health care providers are encouraged to review temperature monitoring procedures and review and exercise emergency vaccine recovery plans. Contact Don Callaghan, Immunization Program manager, with questions at 1-800-831-6293, ext. 1.

Top 10 Storage and Handling Errors

1. Designating only one person in the office to be responsible for storage and handling of vaccines, instead of a minimum of two.
2. Recording temperatures only once per day and recording temperatures for only the refrigerator or freezer.
3. Documenting out-of-range temperatures on vaccine temperature logs and not taking action.
4. Throwing away temperature logs at the end of every month.
5. Storing vaccine in the refrigerator in a manner that may inappropriately affect its temperature.
6. Storing frozen vaccines in a dorm-style refrigerator.
7. Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.
8. Discarding multi-dose vials 30 days after they are opened.
9. Not having emergency plans for a power outage or natural disaster.
10. Storing food and drinks in the vaccine refrigerator.

VFC Vaccine Ordering ProQuad or MMR and Varicella

In June 2006, the Advisory Committee on Immunization Practices recommended two doses of varicella vaccine for children, adolescents, and adults who previously had only one dose. The second dose is designed to more closely mirror natural disease and to further improve protection from varicella disease.

It is recommended that health care providers use the MMR/varicella combination vaccine (ProQuad) when applicable. The Iowa Vaccines for Children Program is requesting providers assess their inventory of MMR and varicella vaccine and assure an appropriate vaccine inventory level is maintained before placing an order for ProQuad. With the increased cost of vaccines and the addition of new vaccines, it is imperative that vaccine is not wasted.

Iowa Immunization Conference

SAVE THE DATE

The 2007 Immunization Conference will be held June 7, 2007, at the Hy-Vee Conference Center in West Des Moines.

This is the statewide immunization conference sponsored by the Iowa Department of Public Health. Speakers include Dr. William Atkinson from CDC, Dr. Paul Offit from the Children's Hospital of Philadelphia, and Patricia Stinchfield, RN, MS, CPNP from the Children's Hospitals & Clinics, St. Paul, Minnesota. More information to come - mark your calendars for June 7, 2007!

It's Not to Late to Vaccinate Against Influenza, *continued*

Approved Influenza Vaccines for Different Age Groups – United States, 2006-2007 season
Source: MMWR, June 28, 2006/ Vol.55

Vaccine*	Trade name	Manufacturer	Dose/Presentation	Thimerosal mercury content (mcg Hg/0.5-mL dose)	Age Group	No. of Doses	Route
Inactivated							
Trivalent Inactivated Vaccine (TIV)	Fluzone	sanofipastuer	0.25-mL prefilled syringe	0	6-35 mos	1 or 2†	IM§
			0.5-mL prefilled syringe	0	36 months or greater	1 or 2†	IM§
			0.5-mL Vial	0	36 months or greater	1 or 2†	IM§
			5.0-mL multi-dose vial	25	6 months or greater	1 or 2†	IM§
TIV	Fluvirin	Novartis Vaccine	0.5-mL prefilled syringe	<1.0	4 yrs or greater	1 or 2†	IM§
			5.0-mL multi-dose vial	24.5	4 yrs or greater	1 or 2†	IM§
TIV	FLUARIX	GlaxoSmithKline	0.5-mL prefilled syringe	<1.0	18 yrs or greater	1	IM§
Live, Attenuated							
LAIV	FluMist	MedImmue	0.5-mL Sprayer	0	5-49 yrs	1 or 2¶	Intranasal**

* A 0.5-mL dose contains 15 mcg each of A/New Caledonia/20/1999 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like, and B/Malaysia/2506/2004-like antigens. For the A/Wisconsin/67/2005 (H3N2)-like antigen, manufactures may use the antigenically equivalent A/Hiroshima/52/2005 virus, and for the B/Malaysia/2506/2004-like antigen, manufactures may use the antigenically equivalent B/Ohio/1/2005 virus.

† Two doses administered at least 1 month apart are recommended for children aged 6 months through 8 years of age who are receiving influenza vaccine for the first time.

§ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

¶ Two doses administered at least 6 weeks apart are recommended for children ages 5 through 8 years of age who are receiving influenza vaccine for the first time.

Health Care Worker Influenza Vaccination

Influenza outbreaks occur throughout the general population as well as in health care settings. Health care providers can reduce the transmission of influenza by receiving annual influenza vaccine. The Healthcare Infection Control Practices Advisory Committee and the Advisory Committee on Immunization Practices recommends all health care workers, including those in acute care hospitals, nursing homes, skilled nursing facilities, physician's offices, urgent care centers, and outpatient clinics, and persons who provide home health care and emergency medical services be vaccinated annually against influenza. Influenza vaccination benefits health care workers, family members, coworkers and their patients. The Immunization Program has posters and paycheck stuffers available to promote influenza vaccination among health care workers. These products are available online at http://www.idph.state.ia.us/adper/flu_healthcare_provide.asp or by contacting the Health Protection Clearinghouse at 1-888-398-9696. Get your influenza vaccine today, everyone is counting on you!

News You Can Use:

Useful Web Sites 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

Hib – Who Needs a Booster?

In the United States, two single antigen Haemophilus influenza type B (Hib) vaccines are available, ActHib and PedvaxHib. These two vaccines have different requirements that may create confusion.

ActHib, manufactured by Sanofi, 3 dose primary series (2, 4, & 6 months of age) with a booster at 12-15 months.

PedvaxHib, manufactured by Merck, (PedvaxHib is in the combination Comvax-PedvaxHib/Hepatitis B), 2 dose primary series (2 & 4 months of age) with a booster at 12-15 months.

The number of doses in the primary series varies depending upon the type/brand of vaccine used. If brands are changed during the vaccine series, a 3 dose primary series is required. A booster dose is recommended at 12-15 months of age regardless of which vaccine is used for the primary series.

Children starting vaccination late may not need the entire 3 or 4 dose series of vaccine. The number of doses of vaccine recommended for the child depends on their current age and the age when they received the last dose of vaccine. All children 15-59 months of age should receive at least 1 dose. Children 15-59 months of age who have an incomplete Hib vaccination history, including those who are unvaccinated, should receive a single dose of any Hib vaccine. Hib vaccine is not routinely recommended for persons 5 years of age or older unless there are underlying conditions such as sickle cell disease, anatomic asplenia, and immunosuppression from chemotherapy or HIV (see page 120 of the 9th edition of Epidemiology of Vaccine Preventable Diseases "Pink Book").

There are 2 combination Hib vaccines. TriHibit manufactured by Sanofi (ActHib reconstituted with Tripedia DTaP) is licensed for the 4th dose of the DTaP & Hib series only. It may be used as the booster dose of Hib after 12 months of age following any Hib series. TriHibit should not be used if the child has received no prior Hib doses.

Comvax manufactured by Merck (Pedvax Hib & Hepatitis B combination) used after 6 weeks of age when both antigens are indicated. Usually given at 2 and 4 months with a booster at 12-15 months of age.

If you have questions regarding spacing of Hib vaccine or booster doses, please contact Terri in the Immunization Program at 1-800-831-6293, ext. 1.

Hib Vaccine Q and A:

Q: If an infant received one dose of Hib at 5 months and another at 15 months, does he/she need any more doses?

A: No. If a child receives a dose of Hib vaccine at 15 months of age or older, he or she does not need any further doses regardless of the number of doses received before 15 months of age.

Q: Since the booster dose of Hib can be given at 12-15 months, is it still necessary to "boost" two months later if the first dose was given at 12-14 months?

A: If the child received a primary series (2 or 3 doses) of Hib vaccine in the first year of life, then the final (booster) dose of the series may be given as early as 12 months, provided at least 2 months have passed since the last dose. An unvaccinated 12-14 month old child should receive one dose as a primary series, and a booster dose 2 months later. Unvaccinated children 15-59 months of age need only a single dose of any licensed Hib vaccine.

Q: A 4-year old received dose #3 of Hib at 6 months of age. Does the child need dose #4?

A: Yes. All children less than 5 years old need at least one dose of Hib vaccine on or after the first birthday. The last dose should be separated from the previous dose by at least 2 months.

ATTENTION

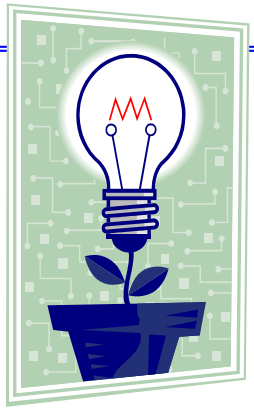
HOLIDAY VACCINE

During the holiday season, the Immunization Program will NOT ship vaccine from December 21st through January 5th.

In addition, vaccine orders will NOT be distributed during periods of extreme cold and snow. It is of the utmost importance that vaccine wastage is minimized and vaccine remains efficacious and viable.

Pay close attention to your vaccine inventory throughout the winter. Please remember to return coolers upon receipt of vaccine, using the enclosed postage paid label.

We Want Your Bright Ideas!



We are looking for creative ideas that you use in practice to assure proper storage and handling of vaccine.

We would like you to send ideas that have worked well for your clinic or agency or ideas of techniques, products, or support the Immunization Program may provide to assist with appropriate vaccine storage and handling.

Please send comments and ideas to Bridget Konz at bkonz@idph.state.ia.us or fax them to 1-800-831-6292.

We hope to learn from you. Ideas will be shared in future issues of the newsletter. Don't be shy, we want your bright ideas!

Hepatitis B and the Health Care Worker, *continued*

Care should always be taken to document vaccine lot, date, manufacturer, route, and vaccine dosages. Postvaccination testing results should also be documented, including the date testing was performed. All organizations (e.g., hospitals, clinics) should develop policies or guidelines to assure valid hepatitis B immunization.

A healthcare worker (HCW) thinks she had 3 doses of hepatitis B vaccine in the past but has no documentation of receiving those doses. Before reading the recommendations to revaccinate her, we obtained an anti-HBs titer and the result was greater than 10 mIU/mL. With this lab result, can't we assume she is immune?

A positive anti-HBs indicates that the vaccinated person is immune at the time the HCW was tested, but does not necessarily assure that the HCW has long-term immunity. Long-term immunity has been shown only for persons attaining an adequate anti-HBs result of at least 10 mIU/mL after a 3-dose vaccination series. The most direct way to deal with this is to vaccinate the HCW with the 3-dose series of hepatitis B vaccine; test for anti-HBs in 1–2 months and document the result in the HCW's employee health record. An adequate anti-HBs result from a documented 3-dose vaccine series would assure not only seroprotection, but long-term protection, as well.

Of course, it is possible that the HCW has an anti-HBs result of greater than 10 mIU/mL because of an HBV infection in the past. If this is of concern, a total anti-HBc test could be performed to discern this (a positive result indicates a history of HBV infection at some undefined period in time).

I'm a nurse who received the hepatitis B vaccine series more than 10 years ago and had a positive follow-up titer (at least 10 mIU/mL). At present, my titer is negative (less than 10 mIU/mL). What should I do now?

Nothing. Data show that vaccine-induced anti-HBs levels might decline over time; however, immune memory (anamnestic anti-HBs response) remains intact indefinitely following immunization. Persons with anti-HBs concentrations that decline to less than 10 mIU/mL are still protected against HBV infection. For HCWs with normal immune status who have demonstrated adequate anti-HBs (at least 10 mIU/mL) following vaccination, booster doses of vaccine or periodic anti-HBs testing is not recommended.

Table 1: Recommendations of post-exposure prophylaxis after percutaneous or mucosal exposure to HBV in an occupational setting

Vaccination and antibody response status of exposed persons[1]	Treatment			
	Source is HBsAg positive	Source HBsAg negative	Source is unknown or not tested	
			High risk	Low risk
Unvaccinated	HBIG[2] (1 dose) and begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series
Known responder[3]	No treatment	No treatment	No treatment	No treatment
Nonresponder[3]				
Not revaccinated[4]	HBIG (1 dose) and begin a revaccination series	Begin a revaccination series	HBIG (1 dose) and begin a revaccination series	Begin a revaccination series
After revaccination[4]	HBIG (2 doses)[5]	No treatment	HBIG (2 doses)[5]	No treatment
Antibody response unknown	Test for anti-HBs[6] If adequate,[3] no treatment If inadequate, HBIG x 1 and vaccine booster	No treatment	Test for anti-HBs[6] If adequate,[3] no treatment If inadequate, give vaccine booster and check anti-HBs in 1–2 months	

1. Persons known to have had HBV infection in the past or who are chronically infected do not require HBIG or vaccine.
2. Hepatitis B immune globulin (0.06 mL/kg) administered IM.
3. Adequate response is anti-HBs of at least 10 mIU/mL after vaccination.
4. Revaccination = additional 3-dose series of hepatitis B vaccine administered after the primary series.
5. First dose as soon as possible after exposure and the second dose 1 month later.
6. Testing should be done as soon as possible after exposure.