

Reinstatement of the *Haemophilus influenzae* type B (Hib) Booster Dose

Since December 2007, Merck production of Hib vaccine products has been suspended. To conserve the limited supply of Hib-containing vaccines, the Centers for Disease Control and Prevention (CDC) recommended that providers defer the routine Hib vaccine booster dose administered to most healthy children at age 12 to 15 months.

Effective July 1, CDC is recommending reinstatement of the booster dose of Hib vaccine for children ages 12 to 15 months who have completed the primary three-dose series. Infants should continue to receive the primary Hib vaccine series at ages 2, 4 and 6 months. Children ages 12 to 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.** Currently, supply of Hib-containing vaccine is adequate to reinstate the booster dose and begin catch-up vaccination. **However, supply is not yet sufficient enough to support a mass notification process to contact all children with deferred Hib booster doses.**

During the Hib shortage, many children received combination vaccines (Pentacel[®] or Pediarix[®]) for protection from vaccine-preventable diseases. Therefore, a mismatch may exist in provider offices between vaccination needs and available stock of different vaccine formulations (combination products versus single-antigen vaccines). Children who need the Hib booster and who

already have received four doses of DTaP should receive monovalent Hib vaccine (ActHIB[®]) as the booster dose. However, if Pentacel[®] (DTaP/IPV-Hib) is the only Hib-containing vaccine available, this combination product can be used to complete the Hib series, even if the child has received all necessary doses of DTaP and IPV.

Because Merck Hib vaccine production is still suspended, CDC continues to provide the North Dakota Department of Health (NDDoH) with an allocation of PedvaxHIB[®] for its Native American population. Providers may order state-supplied PedvaxHIB[®] for Native American children only. Orders will be reviewed by NDDoH staff and compared to the North Dakota Immunization Information System (NDIIS) doses administered data for Native American children. PedvaxHIB[®] is recommended to be administered at 2, 4, and 12 to 15 months of age.



The NDDoH will continue to supply Pentacel[®] for routine administration at 2, 4, 6, and 15 to 18 months of age (may be administered as young as 12 months of age). North Dakota providers should order enough Pentacel[®] from the NDDoH to

routinely vaccinate all Vaccines For Children (VFC) eligible children at 2, 4, 6, and 15 to 18 months of age. As a general rule, providers should order the same amount of Pentacel[®] as pneumococcal conjugate vaccine (Prevnar[®]), since both vaccines are four-dose series at similar ages.

The NDDoH has been allocated only a limited supply of ActHIB[®]. Providers should order limited supplies of ActHIB[®] to have on hand as older VFC-eligible children present for medical visits. **DO NOT order supplies of ActHIB[®] for mass catch-up vaccination.** Please keep this in mind when ordering vaccines for your practice.

For more information about the reinstatement of the booster Hib dose at ages 12 to 15 months, visit www.cdc.gov/mmwr/preview/mmwrhtml/m5824a5.htm.



Revised 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 about syncope has been in Gardasil[®]'s labeling for both health-care 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 health-care 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 the FDA's website at 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

www.cdc.gov/mmwr/preview/mmwrhtml/m5717a2.htm.

Tdap for Uninsured and Underinsured Adults

Prevention Partnership Providers may now use NDDoH-supplied tetanus, diphtheria and pertussis vaccine (Tdap) for uninsured and underinsured (has health insurance, but it does not cover a particular vaccine) North Dakota adults. This program was implemented during the response to flooding in North Dakota and will continue.

State-supplied Tdap vaccine also may be used for:

- VFC-eligible children ages 10 to 18.
- All (including those with health insurance) North Dakotans who have or who anticipate having close contact with an infant aged younger than 12 months:
 - Parents/guardians of infants younger than 12 months
 - Childcare providers, regardless of the age of children attending childcare
 - Expecting fathers

The NDDoH currently supplies both Boostrix[®] and Adacel[®]. Boostrix[®] is approved for use in people ages 10 to 64. Adacel[®] is approved for use in people ages 11 to 64.



New VFC Coordinator

Tatia Hardy started as the new VFC coordinator in June. She will be reviewing

provider orders, inventories, doses administered and temperature logs. Tatia will be administering the vaccine loss and fraud and abuse policies. She also will be conducting immunization presentations and taking calls from the public and providers about immunizations.

Tatia grew up in Rolla, N.D., and graduated from the University of Mary with a bachelor's degree in biology. She is currently working at Medcenter One in the Neonatal Intensive Care Unit, and previously had been an autopsy assistant with the North Dakota Medical Examiner's Office.

Tatia loves traveling, meeting new people and birthdays. She dreams of running victoriously up the front steps of the Capitol in a gray sweatsuit, just like Rocky.

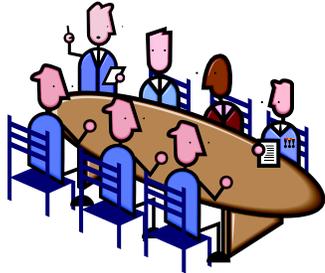
United States Vaccine-Preventable Disease Update (Week Ending 06/20/2009)

Since Sept. 28, 2008, CDC has received reports of 84 pediatric deaths related to influenza. Of these, 10 were related to influenza A H1N1. The average age was 8.1/7.8 years, with a range of 15 days to 17 years. Test results showed that 29 of the deaths were due to influenza A (8 H1, 17 novel H1N1, 2 H3, 1 unknown subtype) and 27 were due to influenza B. Of the 36 children who had specimens collected for bacterial culture, 38.9 percent were positive. Of the 54 children older than 6 months for whom vaccination status was known, only 13 had been fully vaccinated.

In 2009, CDC has received reports of 45 measles cases. The majority of the cases (78 percent) have been associated with importation from other countries. Of the 45

cases, 89 percent were not vaccinated or had an undocumented vaccination status, 11 percent had received one dose of MMR vaccine and 3 percent had received two doses. Of the 27 unvaccinated U.S. residents, 19 percent were younger than 12 months of age and 4 percent were born prior to 1957. Of the remaining 21 unvaccinated cases, 67 percent exempted due to personal or religious beliefs and 24 percent were intentionally delayed.

In 2009, a total of 167 cases of mumps have been reported to CDC. Only one case of rubella has been reported this year. Thirteen cases of Hib in children younger than 5 have been reported. Pertussis cases in the U.S. have increased compared with last year. So far in 2009, 5,037 cases have been reported, compared with 2,827 cases in 2008.



June ACIP Meeting

The Advisory Committee on Immunization Practices (ACIP) met in June.

The ACIP voted to change the recommendations for post-exposure prophylaxis for rabies. The new recommendations still include administration of rabies immunoglobulin (RIG) on day zero for those not previously vaccinated. However, four doses of vaccine are now being recommended instead of five. The vaccine schedule calls for doses to be administered on days zero, three, seven and 14. The recommendation was made based on data showing that no rabies cases

occurred after people who were exposed received only four doses.

The minimum interval between doses three and four of polio vaccine was changed to six months. Because of incomplete data on the duration of immunity into adulthood with the last dose of polio vaccine being administered at 15 to 18 months and the existence of polio in certain parts of the world, a dose may be required after age four in the future. The existing ACIP recommendations should be followed until then, which is that a fifth dose of polio is not needed if four doses are administered prior to four years of age.

A booster dose of meningococcal conjugate vaccine (MCV4) is now recommended for certain groups. People ages 7 to 55 who remain at increased risk for meningococcal disease five years after vaccination with MCV4 should be revaccinated with MCV4. Children who received their first MCV4 at ages 2 to 6 and remain at increased risk should be vaccinated with an additional dose of MCV4 three years after their first dose of MCV4. People at increased risk for meningococcal disease include:

- People with persistent complement component deficiencies.
- People with anatomic or functional asplenia.
- Microbiologists who are routinely exposed to isolates of *Neisseria meningitides*.
- Frequent travelers to or people living in areas with high rates of meningococcal disease.

At this time, college freshman living in dormitories who were previously vaccinated with MCV4 at ages 11 to 18 are not recommended to be revaccinated with MCV4.

The ACIP generally prefers combination vaccines over single antigen vaccines; however, the committee previously voted to make no preference for MMRV due to an increased risk of febrile seizures in infants. At the June meeting, the ACIP made the following recommendations for MMRV:

- For the first dose of measles, mumps, rubella and varicella vaccines at ages 12 to 15 months either MMRV or separate MMR and varicella vaccines can be used. The benefits and risks of both vaccination options should be discussed with the parents or caregivers.
- For the second dose at ages 4 to 6, the use of MMRV is preferred over separate injections of its equivalent component vaccines. Consideration should include patient preference, provider assessment and the potential for adverse events.

The ACIP voted to recommend Japanese encephalitis vaccine (JEV) for travelers who plan to spend a month or longer in endemic areas during the JE transmission season. JEV should be considered for short-term travelers to endemic areas during JE transmission season. JEV is not recommended for short-term travelers whose visit will be restricted to urban areas or times outside of a well-defined JE transmission season. JEV is recommended for all laboratory workers with a potential for exposure to infectious JE.

The ACIP updated recommendations for evidence of immunity for MMR vaccine for health-care workers. Acceptable evidence of immunity to measles, mumps and rubella for people who work in health-care facilities are as follows:

- Documented administration of two doses of live measles virus vaccine, one of live rubella vaccine, and two doses of live mumps or

- Laboratory evidence of immunity or laboratory confirmation of disease or
- Born before 1957:
 - For routine circumstances: health-care facilities should consider vaccinating with two doses of MMR (for measles and mumps) and one dose of MMR (for rubella), respectively.
 - For outbreaks: health-care facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella.



Federal Stimulus Funding Update

The NDDoH will be receiving \$310,296 in non-competitive immunization operations funding. The funding will be used to purchase a forecaster and reminder/recall for the NDIIS, continue a statewide television and radio campaign, conduct a statewide immunization conference in 2010 and provide grants to select local public health units to create or enhance local immunization coalitions.

The NDDoH applied for three other competitive grants, also. The first grant is to conduct varicella surveillance in schools to assess the effectiveness of the two-dose varicella recommendations. Another is to enhance data quality and functionality in the NDIIS by tracking children who have

moved or gone elsewhere (MOGE), vaccine-level de-duplication, updating compliance survey reports and creating school roster reports. The NDDoH also applied for a grant to develop “best practices” for assessing school immunization rates and exemptions.

The NDDoH also will be receiving \$345,221 in vaccine. The Immunization Advisory Committee will determine which vaccines to offer with this funding.

Greater Grand Forks Immunization Coalition Conference

The Greater Grand Forks Immunization Coalition Conference, *Vaccination Expedition 2009*, held in May was a success! Many immunization providers from across the state and Minnesota attended. Topics covered at the conference included childhood and adult immunization recommendations, influenza vaccination of health-care workers, vaccine storage and handling, vaccine-preventable diseases, NDIIS, and many others.

The NDDoH handed out awards to providers who achieved high or improved immunization rates. Providers’ Choice Awards also were given to the following individuals/organizations for their extraordinary contributions to immunizations in North Dakota:

- Minne Tohe Health Center applied for a grant and was awarded funding for an HPV education and vaccination campaign in middle and high schools. As of early May 2009, 69 doses of HPV4 vaccine were administered in schools located on Three Affiliated Tribes Ft. Berthold Reservation. After students receive the third dose of HPV4 vaccine, they are eligible for a drawing for various prizes.

- Dr. Aaron Garman, Coal Country Community Health Center, spearheaded the effort of delegating authority to local public health units and private providers so all North Dakota clinics can provide VFC vaccine to underinsured North Dakota children.
- Deb Solem, Altru Pediatrics, organized a “flu shot blitz” clinic in October 2008, in which more than 500 people were immunized for influenza in three evenings. She was also instrumental in vaccinating new parents/caregivers for Tdap at first well-baby visit.
- Barbara Andrist, Upper Missouri District Health Unit, serves as model local public health unit by working very closely with public and private providers in her region to ensure and encourage the highest possible immunization rates. She distributes NDIIS reports to providers, educates those with low rates and identifies children who are behind on immunizations.
- Blue Cross Blue Shield of North Dakota greatly assisted the NDDoH and private and public immunization providers in the transition to VFC-only. They developed a billing system for local public health units so they could continue to vaccinate insured children. They also strive to cover all childhood and adult immunizations at the first dollar.



Thank you to the Greater Grand Forks Immunization Coalition for making the conference such a success.



Novel Influenza A H1N1 Vaccine

Reference strains for novel influenza A (H1N1) were sent by CDC to manufacturers. Manufacturers are creating master seed strains to prepare for pilot lots. Clinical trials of pilot lots will occur this summer for both adjuvanted and non-adjuvanted vaccines. Decision to manufacture H1N1 vaccine remains separate from decision to distribute, which will be made later in the summer based on the southern hemisphere influenza season experience. The majority of H1N1 vaccine will be in multi-dose vials, with some nasal spray and pre-filled syringes.

The NDIIS pandemic influenza module will be used to track doses administered of H1N1 vaccine, as the NDDoH is required to report weekly to the CDC as to doses administered by high-risk group.



NDIIS update

The parental consent indicator in the NDIIS has been updated. Previously, parental consent for hepatitis B and HPV vaccine defaulted to no for adolescents ages 14 to 17. When parental consent is no, the dose will not print on the client immunization

record. Many people were leaving consent at no, even though there was parental consent. The parental consent will no longer default to no, forcing providers to choose either yes or no. If yes is chosen, then the dose will print on the client immunization record.

In North Dakota, providers may administer hepatitis B and HPV vaccines without parental consent.

The demographics page in NDIIS has been updated with newly required fields. The following fields are now required:

- Middle Name
- Race
- Ethnicity
- Birth State/Country
- Gender
- Mother's first, last and maiden name

The zip code is now validated for North Dakota cities.

The NDDoH Vaccine Administration Record (VAR) has been updated and printed to reflect the required fields.

The NDIIS pandemic influenza module has been completed. The module includes a list of high-risk groups for vaccination. It also includes electronic vaccine adverse events reporting. This module should be used only when entering doses of pandemic influenza vaccine.



9th National Conference on Immunization and Health Coalitions

The 9th National Conference on Immunization and Health Coalitions will be hosted by the Chicago Area Immunization Campaign May 26 through 28, 2010. For more information, visit www.ilmaternal.org/ncihc2010.htm.

McKesson Update

In June, McKesson began shipping vaccine orders in a new box. This new box has been thoroughly tested in laboratory conditions as well as real-world shipping conditions and meets with approval from the CDC. McKesson collaborated with an independent firm with cold chain technology expertise to conduct this testing.

The biggest change is that you will no longer return shipping boxes to McKesson for recycling/reuse. Therefore the boxes no longer have pre-printed return address labels.

McKesson recommends providers keep one or two boxes for any expired or non-viable vaccine returns to McKesson. If providers need to return expired or non-viable product to McKesson, you should contact Customer Service at 877.822.7746, and a representative will schedule a pick-up and send out a return label.

As of July 1, 2009, North Dakota's McKesson vaccine distribution center will no longer be in Memphis. **Vaccine for North Dakota will be shipped from the Sacramento distribution center.** This should be a smooth transition and providers should see no significant changes on your end.



VTrckS

A critical component of the Vaccine Management Business Improvement Project (VMBIP) is the development and introduction of a new vaccine management technology system, the Vaccine Tracking System (VTrckS). VTrckS is an enterprise system that will replace several legacy systems used at CDC and by state and local grantees. VTrckS will serve three levels of users:

- CDC
- 64 immunization program grantees
- More than 44,000 vaccine provider locations

At the CDC level, VTrckS will provide capabilities to allow the CDC to manage more than \$3 billion of vaccines associated with the VFC and Section 317 grantee funded programs. As a single, integrated system, VTrckS will provide the CDC constant visibility to the vaccine inventories held at the distributor locations and at provider locations. It also will allow CDC personnel to understand how dollars associated with these programs are being spent nationally.

At the grantee level, VTrckS will provide capabilities for the grantees to manage the providers who participate in these programs. Some of this support includes:

- Setting up and managing providers.
- Performing a needs assessment for each provider.

- Creating and monitoring spend plans.
- Submitting orders on behalf of providers.
- Facilitating receipt of data from providers (e.g., temperature monitoring reports or doses administered data).



One of the primary goals of VTrckS is to allow grantees to independently and uniquely manage their providers.

At the provider level, VTrckS provides vaccine ordering and order status capabilities.

Interim Guidance for the Use of Pneumococcal Polysaccharide Vaccine (PPSV23) During a Novel H1N1 Outbreak

Influenza predisposes people to bacterial community-acquired pneumonia. During the 20th century influenza pandemics, secondary bacterial pneumonia was an important cause of illness and death and *Streptococcus pneumoniae* (pneumococcus) was reported as the most common etiology. Severe pneumococcal pneumonia associated with inter-pandemic influenza also has been reported, and *S. pneumoniae* remains a leading cause of vaccine-preventable illness and death in the United States. The current novel influenza A (H1N1) outbreak is evolving rapidly, and CDC continues to compile key information regarding risk of influenza, severity of illness and attack rate of secondary bacterial pneumonia among influenza patients. At this time, however, the role of pneumococcal infections among severe cases of novel influenza A (H1N1), such as those requiring hospitalization, is unclear.

During influenza outbreaks, pneumococcal vaccines may be useful in preventing secondary pneumococcal infections and reducing illness and death. Currently, two vaccines are available for prevention of pneumococcal disease, a 23-valent pneumococcal polysaccharide vaccine (PPSV23) and a 7-valent pneumococcal conjugate vaccine (PCV7).

The ACIP recommends a single dose of PPSV23 for all people 65 and older and for people ages 2 to 64 with certain high-risk conditions, such as:

- Chronic cardiovascular disease (congestive heart failure and cardiomyopathies).
- Chronic pulmonary disease including chronic obstructive pulmonary disease and emphysema.
- Diabetes mellitus.
- Alcoholism.
- Chronic liver disease, including cirrhosis.
- Cerebrospinal fluid leaks.
- Functional or anatomic asplenia including sickle cell disease and splenectomy.
- Immunocompromising conditions including HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant.

People in these groups are at increased risk of pneumococcal disease as well as serious complications from influenza. A single revaccination at least five years after initial vaccination is recommended for people 65 years and older who were first vaccinated before age 65 as well as for people at highest risk, such as those who have no spleen and those who have HIV infection, AIDS or malignancy.

PPSV23 vaccination also is recommended for adults, ages 19 to 64, who smoke or have asthma.

All people who have existing indications for PPSV23 should continue to be vaccinated according to current ACIP recommendations during the outbreak of novel influenza A (H1N1). Emphasis should be placed on vaccinating people younger than 65 who have established high-risk conditions because PPSV23 coverage among this group is low and because people in this group appear to be overrepresented among severe cases of novel influenza A (H1N1) infection, based on currently available data.

Use of PPSV23 among people without current indications for vaccination is not recommended at this time. This recommendation may be revised as the epidemiology and clinical presentation of novel influenza A (H1N1) virus infection, as well as the frequency and severity of secondary pneumococcal infections, are better understood.

PCV7 is recommended for all children younger than 5. Immunization rates for PCV7 in children are high. While maintaining this high coverage is important, expanding the use of PCV7 to people ages 5 and older is not indicated because circulation of the seven serotypes included in the vaccine has declined substantially and

disease caused by these serotypes is now uncommon.

Status of Licensure of New Vaccines

The American Academy of Pediatrics, Red Book[®] Online, has a website showing the status of licensure of new vaccines or changes in licensure of current vaccines. To view this website, visit aapredbook.aappublications.org/news/vaccstatus.dtl.



Immunization Update 2009

Save the date for CDC's Immunization Update 2009. The webcast and satellite broadcast will air July 30 at 8 a.m. and 11 a.m. (Central Standard Time). This is an annual update that will highlight current and late-breaking immunization issues. Continuing educational credits are available for the broadcast. For more information or to register, visit www2a.cdc.gov/phtn/immupdate2009/default.asp.



Questions and Answers

1. Are “dorm-style” refrigerators acceptable storage units for vaccine?

- A. No. As of Jan. 1, 2010, “dorm-style” refrigerators no longer may be used to store federally funded vaccines. Dormitory-style refrigerators should be used only to store a clinic’s single-day supply of **refrigerated** vaccines, and these vaccines should be returned to the main refrigerator storage unit at the end of each clinic day. Dormitory-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures. Storage of vaccine in refrigerators that are designed for use in small household spaces such as dorm rooms ***are never acceptable for permanent storage of*** vaccines. Permanent storage is defined as the vaccine supply is maintained in the unit 24 hours a day/seven days a week. “Dorm-style” refrigerators are acceptable for short-term storage of select vaccines under **very limited conditions**, which are listed below:
- i. The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient.
 - ii. **The unit is never used for storing frozen vaccines (i.e., varicella, shingles or MMRV).**
 - iii. Only small amounts of inactivated vaccines can be maintained in these units. The amount of inactivated

vaccines stored in the unit must never exceed the amount used in the clinic in one day.

- iv. The vaccine is returned to the main storage unit at the end of each clinic business day, and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
- v. Each unit has a dedicated certified thermometer in place.
- vi. **Temperatures are monitored and documented twice a day on a temperature log specifically for that unit.** Appropriate action is taken immediately when the temperatures are outside the appropriate range.
- vii. These units must be included and examined during the VFC compliance visit, and corrective actions taken and documented by the grantee if any of the above conditions are not met.

2. For what ages is Boostrix[®] licensed?

- A. Boostrix[®] is licensed for ages 10 to 64. It was previously licensed for adolescents ages 10 to 18. Current supplies of Boostrix[®] may be used for ages 10 to 64, regardless of what is stated on the package insert.



Upcoming Events

- North Dakota Immunization Advisory Committee Conference call: July 16 at 8 a.m. (CST)
- CDC Immunization Update 2009: July 30 at 8 a.m. (CST) and 11 a.m. (CST)
- CDC Adult Immunization Update Webcast: July 31
- ACIP Meeting in Atlanta, Ga.: October 21 – 22.
- Got Your Shots Immunization Conference in Brooklyn Park, Minn.: October 16



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