



## Immunization Program Update



Due to the increase in the number of recommended childhood vaccines and the lack of corresponding increase in federal funding, North Dakota's Immunization Program has begun transitioning to supplying only Vaccines For Children (VFC) vaccine.

VFC vaccine can continue to be ordered at no charge through the NDDoH for VFC-eligible children. VFC-eligible children include those 18 and younger who are Medicaid-eligible, Native American, Alaskan Native, uninsured and underinsured (have health insurance but it does not cover a particular vaccine). Underinsured children can receive VFC vaccine only at federally qualified health-care centers (FQHC), rural health-care centers (RHC), or from a provider who has signed a delegation of authority with an FQHC or RHC.

North Dakota providers will now have to purchase private vaccines for administration to insured children, with the exception of the hepatitis B birth dose in hospitals. **The hepatitis B birth dose will continue to be supplied to hospitals by the NDDoH for VFC and insured children. The NDDoH will also continue supplying MMR vaccine for college students born in or after 1957 and enrolled in a North Dakota college or university who do not have a record of two MMRs.**

VFC and private vaccine must be stored separately in refrigerators. VFC and private

doses administered must be entered into the North Dakota Immunization Information System (NDIIS). VFC vaccine shipments will be entered into the NDIIS provider inventories by the NDDoH. Private shipments must be entered into NDIIS provider inventories by the provider.

Effective Jan. 1, 2008, private providers need to purchase vaccines and bill insurance companies for vaccines provided to children who are not eligible for VFC vaccine.

Due to issues with contracts and billing, the local public health units (LPHU) will not be transitioning to VFC only until March 2008.

The NDDoH encourages private providers to continue to vaccinate their patients and not refer them to LPHUs, as this will create confusion and take children out of their medical home.

To view information specific to private providers and LPHUs, including Question and Answer documents, visit [www.ndhealth.gov/immunize/](http://www.ndhealth.gov/immunize/).

To view educational materials for parents, schools and employers, visit [www.ndhealth.gov/Immunize/PROtectNDKids.htm](http://www.ndhealth.gov/Immunize/PROtectNDKids.htm).

Please contact the Immunization Program at 800.472.2180 or 701.328.3386 with any questions regarding the Immunization Program's transition to VFC only.



## Merck PedvaxHIB Vaccine Recall

On Dec. 13, 2007, Merck & Co. Inc. announced a voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB® and Comvax® (Hib/hepatitis B vaccine). Some state-supplied PedvaxHIB® was included in this recall. Providers also may have private doses of recalled vaccine. The affected doses were distributed beginning in April 2007. Additional information regarding the affected lots is available online from the Food and Drug Administration (FDA) at [www.fda.gov/consumer/updates/hib121307.html](http://www.fda.gov/consumer/updates/hib121307.html)

No potency concerns have been identified for these recalled vaccine lots. Individuals who received vaccine from these lots should complete their immunization series with a Hib-containing vaccine not affected by this recall, but **do not need to be revaccinated** to replace a dose they received from a recalled lot.

Information about how to return recalled lots of Merck Hib vaccine is being sent to providers by Stericycle. Providers who are not contacted may call Stericycle directly at 800.643.0240 to coordinate the return of recalled Hib vaccines, or visit [www.merckvaccines.com/PCHRecall.pdf](http://www.merckvaccines.com/PCHRecall.pdf).

### Hib vaccine shortage:

**Merck has suspended production of its Hib conjugate vaccines and does not expect to resume distribution of these vaccines until the fourth quarter of 2008. The recall of PedvaxHIB and Comvax, along with the suspension of production, is expected to result in short-term disruption to the Hib vaccine supply in the United States.**

Two other Hib conjugate vaccines manufactured by sanofi Pasteur, ActHIB®

and TriHIBit® (DTaP/Hib vaccine), are currently licensed and available for use in the United States. However, due to an expected increase in demand, sanofi Pasteur will likely not be able to immediately provide adequate Hib vaccine to fully vaccinate all children for whom the vaccine is recommended.

Because of the short-term reduction in available doses of Hib-containing vaccines, CDC recommends that **providers temporarily defer administering the routine Hib vaccine booster dose administered at age 12 to 15 months, except to children in specific groups at high risk.** Providers with TriHIBit® on hand may also administer the booster dose. Providers should register and track children for whom the booster dose is deferred to facilitate recalling them for vaccination when supply improves.

### **Children at high-risk include those with:**

- **Asplenia.**
- **Sickle cell disease.**
- **Human immunodeficiency virus infection and certain other immunodeficiency syndromes.**
- **Malignant neoplasms.**

CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to the routinely recommended schedules, including the 12 to 15 month booster dose. PedvaxHIB® (if available) and ActHIB® may be used for the booster doses for these children during this shortage.

**American Indian/Alaska Native (AI/AN) children are also at increased risk for Hib disease, particularly in the first 6 months of life.** Compared with sanofi Pasteur Hib

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vaccines, the administration of Merck Hib vaccines leads to a more rapid seroconversion to protective antibody concentrations within the first 6 months of life. **CDC recommends that providers who currently use PedvaxHIB® and/or Comvax® to serve predominantly AI/AN children in AI/AN communities continue to stock and use only Merck Hib vaccines (not affected by the recall) and vaccinate according to the routinely recommended schedules, including the 12 to 15 month booster dose.**

**CDC has provided the North Dakota Department of Health (NDDoH) with an allocation of PedvaxHIB® for its Native American population. Until further notice, 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.

If a Native American child presents for Hib vaccination and Merck Hib vaccine is unavailable, that child should preferably be referred to a clinic with Merck Hib vaccine on hand (i.e., IHS). If this is not possible, the child should be vaccinated with sanofi Pasteur Hib vaccine.

**The NDDoH will be supplying sanofi Pasteur ActHIB® vaccine until further notice for vaccination of all other North Dakota children. TriHIBit® will be available for order until the limited supply at the CDC is gone.** The NDDoH will notify providers when this occurs.

**REMINDER: As of Jan. 1, 2008, private providers must have private supplies of vaccine to vaccinate insured children, as**

**the NDDoH will supply vaccine only for Vaccines For Children (VFC) eligible children.** Providers must order private Hib vaccine from sanofi Pasteur. Private vaccine may be ordered by calling sanofi Pasteur at 800-VACCINE. If VFC vaccine is unavailable, private Hib vaccine may be given to Medicaid children and Medicaid can then be billed. Due to the nature of their current system, Medicaid claims may initially be denied. For any questions about the Medicaid billing process, please contact Barb Koch at 701.328.1044.

#### **Hib vaccine information:**

PedvaxHIB® is a three-dose series at 2, 4, and 12 to 15 months of age. ActHIB® is a four-dose series at 2, 4, 6, and 12 to 15 months of age. TriHIBit® may only be used for the booster dose of the Hib series at 12 to 15 months of age. **TriHIBit® can be used if the child is 12 months of age or older and has received at least one prior dose of Hib vaccine two or more months earlier and TriHIBit® will be the last dose in the Hib series.** TriHIBit® is not approved for use as the primary series at 2, 4, or 6 months of age. If TriHIBit® is used for one of the doses of the primary series, the Hib doses should be considered invalid, and the child should be revaccinated as age-appropriate for Hib.

#### **Hib disease information:**

A Hib fact sheet is available at [www.ndhealth.gov/Immunize/Disease/](http://www.ndhealth.gov/Immunize/Disease/).

For more information about the shortage, view the Morbidity and Mortality Weekly Report at: [www.cdc.gov/mmwr/preview/mmwrhtml/m56d1219a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/m56d1219a1.htm).

As always, please feel free to contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or 800.472.2180.

## **MMRV Update**

Earlier this year, Merck's combination varicella/MMR vaccine, MMRV (ProQuad®), became unavailable. Recent communications from Merck have indicated that they do not expect MMRV to become available until early first quarter 2009. Therefore, providers will need to continue to order and administer the varicella and MMR vaccines separately.

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you have any questions.

## **Gardasil Vaccine and Vaccine Adverse Event Reporting System (VAERS) Reports**

Since being licensed in 2006, more than 9 million doses of Gardasil have been distributed. As of Sept. 30, 2007, a total of 4,037 VAERS reports were received after Gardasil vaccination in the U.S. Nearly 95 percent of these have been classified as non-serious. The number of serious adverse events reported has been less than 6 percent, which is less than half of the overall average of 10 percent to 15 percent for all vaccines.

Nine deaths have been reported after Gardasil vaccination, and only three of these could be verified. None of these three deaths appear to have been caused by the vaccine. One death was the result of influenza B viral sepsis with contributing staphylococcal secondary infection. Another death was the result of aortic and mitral valve insufficiency of unknown etiology. A third death was the result of pulmonary embolism in an oral contraceptive user.

To summarize, few adverse events have been reported following Gardasil

vaccination, and the number of serious adverse events also has been small compared to the number of doses distributed.

For more information, visit [www.cdc.gov/vaccines/vpd-vac/hpv/downloads/vac-faqs-vacsafe-efficacy.pdf](http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/vac-faqs-vacsafe-efficacy.pdf).



## **Menactra® Approved for Use in Children Ages 2 through 10**

On Oct. 17, 2007, the Food and Drug Administration (FDA) approved the meningococcal conjugate vaccine (MCV4), Menactra®, for use in children ages 2 through 10. Prior approval was for use in those ages 11 to 55.

The meningococcal vaccine workgroup of the Advisory Committee on Immunization Practices (ACIP) proposed recommendations for the use of MCV4 among children ages 2 through 10 who are at increased risk for meningococcal disease. These recommendations were approved by ACIP at its Oct. 24, 2007, meeting. *Routine administration of MCV4 to this age group was not recommended.*

Children ages 2 through 10 who are considered to be at high risk include those traveling to, or who are residents of, countries in which meningococcal disease is hyperendemic or epidemic, children who have terminal complement component deficiencies and children who have anatomic or functional asplenia. MCV4 is also preferred for use in this age group for control of meningococcal disease outbreaks.

The ACIP meningococcal vaccine workgroup is considering options for general use of MCV4 among children ages 2 to 11 and will present recommendations at a future ACIP meeting.





## Transporting Varicella

Just a reminder that varicella must be kept frozen when being transported. This means providers must use either dry ice or a portable freezer that is able to maintain temperatures at or below 5° F (-15° C). Regular ice packs and a cooler will not maintain appropriate temperatures and should not be used. If varicella is transported in this manner, the vaccine would be considered to have been stored at refrigerator temperatures. Once transported, the varicella would then need to be refrigerated, and all doses used within 72 hours. Any doses not used within 72 hours would have to be discarded and could not be refrozen. Providers would be liable for the wasted doses.

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you have any questions.

### **Reminder**

Just a reminder that after Jan. 1, 2008, providers must continue to submit doses-administered reports and temperature logs to the NDDoH. However, the doses-administered reports should reflect the number of doses of state-supplied vaccine given to VFC eligible children only, and not doses administered to insured children with privately purchased vaccine. Doses-administered reports generated from NDIIS can separate the VFC and non-VFC doses given. Orders submitted to the NDDoH for state-supplied VFC vaccine will be filled based on the number of VFC doses given.

## National Influenza Vaccination Week Kickoff Held in Fargo

The second annual National Influenza Vaccination Week (NIVW) was held Nov. 26 through Dec. 2, 2007. The purpose of this week is to encourage influenza vaccination after Thanksgiving and into the winter months.

The North Dakota Department of Health (NDDoH) and the Centers for Disease Control and Prevention (CDC) held a news conference Monday, Nov. 26, 2007, to kick off NIVW. Dr. Jeanne Santoli from the CDC immunization services division spoke at the news conference, and was joined by Dr. Terry Dwelle, NDDoH state health officer, and Dr. John Baird, health officer with Fargo Cass Public Health. In addition, the NDDoH hosted an educational seminar on influenza immunizations that evening with Dr. Santoli as the keynote speaker. Television and radio public service announcements were aired during the month of November to promote influenza vaccination.

To view these public service announcements, visit [www.ndflu.com/News/NewsReleases.aspx](http://www.ndflu.com/News/NewsReleases.aspx).



### **Did You Know?**

The *Immunization Newsletter* can be viewed on the NDDoH Immunization website. Visit [www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize) and click on the “Newsletter” tab to read current and past issues.



## **It Is Winter...and the Flu Season!**

Flu season is here and influenza activity in North Dakota is beginning to increase. As of Jan. 22, 2008, 126 influenza cases have been reported to the NDDoH. The majority of the reported cases (104) have been influenza type A. The number of flu cases currently in the state is typical for this time of the year, and peak influenza season usually occurs in January or later.

Because influenza activity is starting to rise and record amounts of vaccine are available this season, providers should vaccinate anyone who wants to be protected from the flu. There is plenty of time to vaccinate and protect individuals who have not yet received their flu shot. Remember: It is never too late to get the flu shot!

Educating patients about influenza is important. The NDDoH has a wide range of influenza educational materials available free-of-charge. Brochures, posters, bookmarks, vaccine guides and bandaids are stocked and ready to be shipped directly to your facility. Ordering is easy. Visit [www.ndflu.com](http://www.ndflu.com) and click on the “educational materials” link located in the frequently requested box on the right-hand side of your screen.

Please remember that viable influenza vaccine cannot be returned to McKesson or sent to the NDDoH. Providers who have extra vaccine should contact other area providers to transfer the vaccine. Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you need assistance or have any questions.

For more information about influenza and current activity in North Dakota, visit [www.ndflu.com/.](http://www.ndflu.com/)

## **A Few Facts About Live Vaccines**

Immunization program staff often receive calls about administering live vaccines to children with immunocompromised or pregnant household contacts. It is very important that these children be vaccinated in order to reduce the chances of exposure of the household contacts to the wild viruses.

Measles and mumps vaccine viruses produce a noncommunicable infection and are not transmitted to household contacts. Transmission of zoster vaccine virus has not been reported. Transmission of varicella vaccine virus is rare. The suspected secondary transmission cases that have been reported appeared to have occurred only if the vaccine recipient developed a varicella rash. If this occurs, it is recommended that close contact with persons with no evidence of varicella immunity or immunocompromised persons be avoided until the rash has resolved. Live attenuated influenza vaccine may be administered to contacts of immunocompromised persons, unless the contact is severely immunocompromised (i.e., in protective isolation because of immunosuppression).

Another frequently asked question involves live virus vaccines and intervals. The four-day grace period can be applied to the interval between two doses of the same live vaccine (i.e., the first and second MMR doses or first and second varicella doses). However, it does not apply to the interval between doses of two different live vaccines (i.e., MMR and varicella), which should be separated by 28 days.

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you have questions.



## **Administrative Rule Changes** **Approved**

In December 2007, the Legislative Council approved proposed changes to the administrative rules, including day-care and school immunization requirements and an increase in the vaccine administration fee.

Effective Jan. 1, 2008, children attending early childhood facilities will be required to be age-appropriately immunized against hepatitis A, pneumococcal disease, and rotavirus, in addition to the previously required immunizations. Early childhood facility providers have a grace period until April 1, 2008, to have all of the children's records updated.

Effective with the 2008 – 2009 school year, children attending North Dakota schools must receive a second dose of varicella (chickenpox) vaccine before being admitted into kindergarten (or first grade if the student's school does not have a kindergarten). Each subsequent school year, the next higher grade will be included in the second dose varicella (chickenpox) immunization requirement so those students transferring into North Dakota schools are added to the second dose varicella (chickenpox) immunization cohort. Also effective with the 2008-2009 school year, a student must receive meningococcal and tetanus, diphtheria, and pertussis (Tdap) vaccine before being admitted into any middle school, sixth or seventh grade, depending on the school. These new requirements are in addition to the previously required immunizations.

A parent or guardian may sign a *Certificate of Immunization* indicating a history of disease for varicella (chickenpox) or a moral, religious or philosophical exemption. A physician's signature is required for medical exemptions.

Effective Jan. 1, 2008, the vaccine administration fee for vaccines received at no charge from the state is \$13.90, the Medicaid regional fee cap. For vaccines purchased privately by providers, no vaccine administration fee was set. Providers should bill insurance for what it costs them to administer vaccines.

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you have questions.

### **Welcome New Providers!**

The NDDoH would like to welcome these new VFC providers:

- MeritCare Clinic – Enderlin



### **Stacy Lovelace Takes New Position**

Stacy Lovelace has left the Immunization Program but has stayed within Disease Control and taken the field epidemiologist position in Fargo. We will miss her but wish her the best of luck!

Until Stacy's position has been filled, Molly Sander and Darcey Tysver will be taking over her duties.



## **Congratulations to the 2007 AFIX Award Winners!**

The following providers have been recognized as “Immunization Leaders” by achieving immunization rates above 85 percent for the 4:3:1:3:3:1 (4 DTaP:3 HepB:1 MMR:3 Hib:3 IPV:1 varicella) series in 2007:

### **Private Health**

- Q&R Family Practice – Bismarck
- Altru Health Clinic Pediatrics – Grand Forks
- Altru Health Clinic Family Medicine – Grand Forks
- Hettinger Clinic
- Innovis Clinic Wahpeton (formerly Dakota Clinic)
- St. Alexius Missouri Slope Clinic – Beulah
- Innovis Clinic South University (formerly Dakota Clinic) – Fargo
- Trinity Community Clinic – Williston
- Clinicare – Cavalier

### **Public Health**

- Lake Region District Health Unit Benson County – Minnewaukan
- Lake Region District Health Unit Eddy County – New Rockford
- IHS Belcourt



New in 2007 is the “Most Improved Immunization Rates” award. The following clinics increased their rates by 10 percent or greater since their last documented AFIX visit:

### **Private Health**

- Innovis Clinic Wahpeton (formerly Dakota Clinic)
- Family Medical Center North – Bismarck
- MeritCare Island Park – Fargo
- Wishek Clinic

### **Public Health**

- Lake Region District Health Unit Eddy County – New Rockford
- Grand Forks Public Health Unit
- Sargent County District Health Unit – Forman

Also new in 2007 is the “Immunizations: Tradition of Excellence” award. The following providers have achieved rates of 85 percent or greater in 3 out of the last 5 years:

### **Private Providers**

- Medcenter One Health Systems – Dickinson
- Medcenter One Q&R Pediatrics – Bismarck
- Altru Health Clinic Pediatrics – Grand Forks
- Altru Health Clinic Family Medicine – Grand Forks
- MeritCare Medical Group – Fargo

**\*Not all providers are assessed each year. The above providers were assessed in 2007. The overall average for North Dakota for the 4:3:1:3:3:1 series in 2006 was 80.1 percent.**

Keep up the great work!



## Upcoming Events

- Private providers go VFC-only: **Jan. 1, 2008**
- ACIP meeting in Atlanta, Ga.: **Feb. 27 – 28, 2008**
- LPHUs go VFC-only: **March 2008**
- National Immunization Conference in Atlanta, Ga.: **Mar. 17 – 20, 2008**



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