

The Immunization Program has moved! Our new address is:
2635 E. Main Ave.
P.O. Box 5520
Bismarck, N.D.
58506-5520

Our phone and fax numbers are the same.

PHONE
701.328.3386
TOLL-FREE
800.472.2180
FAX
701.328.2499

INSIDE THIS ISSUE:

Hib Booster Dose	2
Influenza Update	2
New HPV Vaccine Info	3
ND Rates Decline	3
Vaccine-Preventable Disease Update	4
Merck News	4
H1N1 Q&A	5
SCHIP Info	6
Coming Soon: Prevnar 13	6
VAERS in NDIIS	7
Antipyretics in the News	7

Immunization Newsletter



NORTH DAKOTA
 DEPARTMENT of HEALTH

DIVISION OF DISEASE CONTROL FALL 2009

H1N1 Vaccine in North Dakota

In response to the H1N1 pandemic that began in April of this year, the federal government funded the manufacturing of the Food and Drug Administration-approved monovalent 2009 H1N1 influenza vaccine. The vaccine is now available in both the live attenuated and inactivated formulations.

The Advisory Committee on Immunization Practices (ACIP) defined five initial target groups for vaccination:

- Pregnant women
- Health-care workers and emergency medical services personnel
- Children ages 6 months through 24 years
- Adults ages 25 through 64 years with chronic medical conditions
- People who live with or provide care for infants younger than 6 months (parents, siblings, day-care providers)

Children ages 6 months through 9 years are recommended to receive two doses of the vaccine separated by four weeks.



Since October, many immunization providers in North Dakota have been receiving and administering H1N1 influenza vaccine. This is in addition to all of the other immunizations that are currently recommended for children, adolescents, and adults. Providers are encouraged to vaccinate as soon as H1N1 vaccine is available and while public demand for the vaccine remains high.

If supply at your practice allows, vaccine now can be given to anyone recommended by the ACIP to receive the vaccine.

The North Dakota Department of Health opened the vaccination effort to the general public on Dec. 7, 2009.

Need To Return Nonviable Vaccine?

McKesson has made some changes in its procedure for returning nonviable vaccine. Empty boxes should no longer be sent back to McKesson. Preprinted return labels are not included in the shipments. If you need to return nonviable vaccine to McKesson, call the NDDoH at 701.328.3386 or toll-free at 800.472.2180. NDDoH will coordinate the return. If your facility does not have a regular pickup, McKesson will schedule a pickup for you, and UPS will bring a label. If your facility has a regularly scheduled pickup, McKesson will mail a return label to you and the box can then be sent with UPS.

Remember that some things must **never** be returned to McKesson: used syringes with or without the needles; broken vials; multidose vials from which vaccine has been withdrawn; wasted products such as a syringe that was drawn up or not used; expired diluent; and IG, HBIG or PPD.

Hib Booster Dose Reinstated



Hib-containing Vaccines
 ActHIB®
 Hiberix®
 Pentacel®
 PedvaxHIB®

Effective immediately, the Centers for Disease Control and Prevention (CDC) recommends that children ages 12 months through 4 years (before the fifth birthday) who did not receive a booster dose because of the recent shortage of Hib vaccine should receive a booster at the earliest opportunity. A complete series of Hib is either three or four doses, depending on the type used.

Providers should continue to use Pentacel® for routine vaccination. Hiberix® may be ordered in addition to ActHIB® and Pentacel®. PedvaxHIB®

production remains suspended and will be available for order only by IHS and other facilities with a significant American Indian population.

Hiberix®, a *Haemophilus influenzae* type B (Hib) conjugate vaccine, has been licensed for use as the booster (final) dose in the Hib series. To facilitate timely booster vaccination, Hiberix® and other Hib conjugate vaccines can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization.

Hiberix® is not licensed for the primary Hib

vaccination series. If Hiberix® is administered inadvertently during the primary series, the dose should be counted as valid. It does not need to be repeated if it was administered according to schedule. If this happens, a total of four doses will complete the series.

Immunization providers should review medical records to identify and recall children in need of a booster dose. The NDIIS (registry) can be used to run a Client Immunization Record report. This will help to determine which children are still in need of a Hib booster dose.

Influenza Update



For the week ending Dec. 4, 2009, there have been 3,203 lab-identified influenza cases reported to the NDDoH from multiple North Dakota counties. Five cases were reported last year at this time in North Dakota. Five hundred and seven of the cases have been identified as type A novel H1N1, one case type A H3, 2,663 are type A unspecified (no further testing was done to determine subtype), 22 are type B and 10 cases are unknown type. Seventy

percent (2,236) of the cases have been in children ages 19 and younger. Nationally, most states are reporting widespread influenza activity. With the addition of the novel H1N1 influenza strain to the seasonal influenza virus, providers in the state have been extremely busy, both providing care for the sick and facilitating timely vaccination efforts. To assist with providing

information, the NDDoH has established a flu hotline and website for the public. The hotline is available Monday through Friday, 8 a.m. to 5 p.m. North Dakota Flu Hotline: 1.866.207.2880 www.ndflu.com The website contains useful information about influenza for both providers and the public, including a flu clinic locator.

Overwhelmed by this year's influenza season? You are not alone!

Human Papillomavirus Vaccines in the News

Gardasil®, the quadrivalent human papillomavirus (HPV) vaccine manufactured by Merck, has been approved by the Food and Drug Administration (FDA) for use in males ages 9 through 26. Vaccination of males was approved to be added to the Vaccines for Children (VFC) program, so state-supplied Gardasil® may be administered to males through the VFC program. Children who are 18 and younger and either American Indian or Alaska Native, Medicaid-eligible, uninsured or underinsured (have insurance, but it does not cover a particular vaccine) are eligible for VFC vaccine. Providers may begin ordering Gardasil® to vaccinate males.

The ACIP did not make a formal recommendation to routinely vaccinate all males. The male indication will be added to the North Dakota immunization schedule and vaccine coverage table. The NDDoH will be receiving information from Blue Cross Blue Shield and Medicaid regarding coverage for males. It is likely that males ages 19 through 26, if not covered by Medicaid or private insurance, will be eligible for state-supplied vaccine through 317 funding.

GlaxoSmithKline has received approval from the FDA for its new vaccine protecting females against human papillomavirus (HPV). Cervarix® provides protection from two high-risk strains of HPV: 16 and 18. Together, these two strains account for about 70 percent of cervical cancers. The three-dose vaccine series is licensed for females ages 10 through 25. A harmonized schedule is expected. The second dose should be given one to two months after the first dose, and the third dose should be given six months after the first dose.

The ACIP recommends routine HPV vaccination with either Gardasil® or Cervarix® for all females ages 11 and 12. Vaccination also is recommended for females 13 through 26 who haven't been vaccinated previously or who have not completed the complete series. The vaccine series may be started as early as age 9. The ACIP did not express a preference for either Gardasil® or Cervarix®.

The ACIP's provisional recommendations for HPV vaccination are now available and can be found at www.cdc.gov/vaccines/recs/provisional/downloads/hpv-vac-dec2009-508.pdf.

At the North Dakota Advisory Committee meeting in November, the committee made the decision to offer only Gardasil®. Cervarix® will not be offered through the NDDoH.

North Dakota Immunization Rates Decline

The results of the 2008 National Immunization Survey (NIS) were published in the August 28 issue of Morbidity and Mortality Weekly Report. The NIS is an ongoing, random-digit-dialed survey of households with children ages 19 through 35 months at the time of interview, followed by a mail survey of the children's vaccination providers to collect vaccination information. The survey is done to estimate vaccination coverage among children ages 19 through 35 months.

North Dakota's estimated coverage in 2008 for the 4:3:1:3:3:1 series (four or more doses DTaP, three or more doses polio, one or more doses of MMR, three or more doses of Hib, three or more doses of hepatitis B, one or more doses of varicella) was 69.8 percent. This is a significant decline from 77.2 percent in 2007 and is below the national average of 76.1 percent.

Seasonal Influenza Vaccine Available

The NDDoH has seasonal influenza vaccine available for VFC-eligible children. All providers who prebooked for seasonal influenza vaccine have received their requested amount. The vaccine is available in two presentations: Fluzone® 0.25mL preservative-free prefilled syringes and FluMist® for healthy children ages 2 through 18. The 0.25mL pediatric dose may be used for children ages 6 months and older. Children ages 3 and older need a 0.5mL dose, so if your facility's supply for older children is insufficient, two doses of 0.25mL will be needed for these children (to equal one 0.5mL dose).

Please let Tatia Hardy know how many doses your facility needs. Also include your provider number in the e-mail. Tatia's e-mail address is tahardy@nd.gov.



U.S. Vaccine-Preventable Disease Update



Since Aug. 30, 2009, CDC has received 189 reports of influenza-associated pediatric deaths that occurred during the current influenza season (34 deaths in children younger than 2, 20 deaths in children ages 2 to 4, 71 deaths in children 5 through 11, and 64 deaths in children 12 to 17). One hundred fifty-two (80%) of the 189 deaths were due to 2009 influenza A (H1N1) virus infections, and the remaining 37 were associated with influenza A virus for which the subtype is undetermined. A total of 210 deaths in children associated with 2009 influenza A

(H1N1) virus infection have been reported to CDC. In 2009, CDC has received reports of 69 measles cases. The majority of the cases (84%) have been associated with importation from other countries. Of the 69 cases, 88 percent were not vaccinated or had an undocumented vaccination status, 10 percent had received one dose of MMR vaccine, and 2 percent had received two doses. Of the 54 unvaccinated U.S. residents, 21 percent were younger than 12 months, 2 percent were born before 1957, and 2 percent had a medical exemption. Of the

remaining 32 unvaccinated cases, 59 percent exempted due to personal or religious beliefs and 31 percent were intentionally delayed.

In 2009, a total of 630 cases of mumps have been reported to CDC, compared with 353 cases for the same time period last year. Four cases of rubella have been reported this year. Hib has been reported in 24 children younger than 5. Pertussis cases in the U.S. have increased dramatically compared with last year. So far in 2009, 12,345 cases have been reported, compared with 9,593 cases at this time in 2008.

Reminder:

School surveys

were due

December 4.

Please complete

and submit

ASAP!

Use of CSL's 2009 H1N1 Vaccine

On Nov. 11, 2009, the FDA expanded the approved use of CSL's seasonal and 2009 H1N1 monovalent influenza vaccines to include children 6 months and older. Both vaccines had previously been approved only for use in adults 18 and older. The immediate effect on the national H1N1 flu vaccination program is that CSL's pre-filled syringe and multi-dose vial formulations now can be used in a substantially broader range of ages.

The CDC recommends both the CSL H1N1 prefilled syringe and multi-dose vial vaccine formulations be reserved for individuals ages 3 and older if alternative products are available.

Merck Discontinues Production of Three Vaccines

In 2008, Merck halted production of its monovalent vaccines for measles, mumps and rubella due to manufacturing constraints. They had previously announced plans to resume production only if sufficient manufacturing resources were available to do so without compromising the production

of MMR-II®, the combination vaccine. Merck has decided not to resume production of Attenuvax® (measles vaccine), Mumpsavax® (mumps vaccine), and MeruvaxII® (rubella vaccine).

Children who started the monovalent series of

measles, mumps or rubella vaccine will have to complete the series with combination MMR. This may mean that some children will receive extra doses of some of the antigens. There are no safety concerns with children receiving an extra dose of some of the antigens.

H1N1 Vaccine Q&A

Q: How many doses of H1N1 vaccine do children need?

A: Children ages 6 months through 9 years should receive two doses of H1N1 influenza vaccine separated by four weeks. Children 10 and older need only one dose of H1N1 vaccine.

Q: Can the seasonal inactivated vaccine and the 2009 H1N1 inactivated vaccine be given at the same visit?

A: Yes.

Q: If seasonal live attenuated intranasal vaccine (LAIV) and 2009 H1N1 LAIV are inadvertently given at the same visit, do either or both doses need to be repeated, and if so, when?

A: If both types are inadvertently administered at the same visit, neither vaccine needs to be repeated.

Q: What is the minimum interval between doses of seasonal LAIV and H1N1 LAIV?

A: The ACIP recommends a minimum interval of four weeks.

Q: If seasonal LAIV and H1N1 LAIV are not administered on the same day but are separated by fewer than 14 days, do either or both doses need to be repeated, and if so, when?

A: If the vaccines are given one to 13 days apart, the second dose should be repeated 28 days from the invalid (second) dose.

Q: Can LAIV be given at the same visit as an inactivated vaccine?

A: Yes.

Is your facility's storage unit in compliance with the VFC program's requirements?

Reminder: Jan. 1, 2010, Is Near!

As of Jan. 1, 2010, the CDC will no longer allow VFC or federally supplied vaccine to be stored in dorm-style refrigerators. The CDC defines a dorm-style refrigerator as a small combination unit that is outfitted with one external door and an evaporator plate, and is void of a temperature alarm device.

Dorm-style refrigerators are not adequate for long-term or permanent storage of vaccine because they do not maintain proper temperatures and pose a high risk of freezing vaccine. As of Jan. 1, 2010, the only acceptable use of dorm-style refrigerators will be to store a clinic's single-day supply of refrigerated (never frozen) vaccine, and these vaccines must be returned to the main refrigerator storage unit **at the end of each day**. Temperatures still must be monitored and recorded twice daily for any dorm-style

refrigerators used for storing single-day supplies of vaccine. These logs must be submitted to the NDDoH monthly, along with the main storage unit's logs. As a reminder, the freezer compartment of a dorm-style refrigerator is never acceptable for storing frozen vaccine for any period of time.

Providers currently using dorm-style refrigerators for permanent VFC or federally-supplied vaccine storage will need to have acceptable storage units in use by Jan. 1, 2010, in order to be compliant with the requirements of the VFC Program.

Please feel free to contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.

Healthy Steps & VFC Eligibility: Important Information

The state's Children's Health Insurance Program (SCHIP) is administered by the Department of Human Services. The program is available for children younger than 18 who:

- ◇ Do not have health insurance coverage.
- ◇ Do not qualify for North Dakota Medicaid.
- ◇ Live in families with qualifying incomes.

This program in North Dakota is called Healthy Steps. Among other health services, Healthy Steps covers routine preventive services, including recommended childhood immunizations.

Children who are covered by Healthy Steps in North Dakota are not considered VFC-eligible. Private vaccine should be used for these children and their insurance billed. Coverage is provided by Noridian Mutual Insurance Company through BCBS of North Dakota.

For more information about the Healthy Steps program, please visit the website:

www.nd.gov/dhs/services/medicalserv/chip/



Update on:

Havrix®

Kinrix®

Boostrix®

Rotarix®

Vaccine Supply Update

GlaxoSmithKline (GSK) is experiencing a supply constraint issue. This issue affects only federally-funded vaccines, so providers should not have problems ordering vaccine on the private market. The following vaccines are affected: Havrix® vials, Kinrix® syringes, Boostrix® vials, and Rotarix®. **GSK has transitioned Havrix® from a five-pack of syringes to a 10-pack of syringes.** Providers may continue to order according to their preferences, but if the vaccine is not available, the alternate products will be ordered on their behalf.

Prevnar 13® To Replace Prevnar®

Prevnar® (PCV7) is currently the only pneumococcal conjugate vaccine available in the United States. In late December, the FDA is expected to approve and license Prevnar 13® (PCV13), a new 13-valent pneumococcal conjugate vaccine. PCV13 will replace PCV7 in the childhood vaccine schedule. The anticipated indication is for the prevention of invasive pneumococcal disease and otitis media. Routine immunization of infants will likely consist of a four-dose schedule with doses at 2, 4, 6 and 12 to 15 months of age, the same schedule that is currently recommended for PCV7. A single dose of Prevnar 13® may be indicated for children ages 12 to 59 months who have already completed an age-appropriate series of PCV7. While no official recommendations have been made, the CDC is preparing states for the upcoming switch from PCV7 to PCV13.

At this time, providers are asked to place small orders for PCV7. This will be done to deplete the supply of PCV7 and make the transition between vaccines smooth. More guidance will be given as formal recommendations are made.





VAERS Reporting Functionality in the NDIIS

Vaccine Adverse Events Reporting System (VAERS) reports now can be completed in the North Dakota Immunization Information System (NDIIS). The VAERS report is found in the “Immunizations” tab for individual clients.

To submit a report, make sure the

vaccine that the adverse event followed is the one highlighted. Click on the VAERS button on the bottom; an electronic VAERS form will open with most of the demographic information already filled in. Once the report is complete, it will give the option to save and submit to NDDoH. The report will be sent on to the CDC by NDDoH Immunization Program

staff.

Completing VAERS reports in the NDIIS will be convenient for providers and eliminate the need to send forms to both the CDC and NDDoH.

If you have questions about how to use this important tool, please contact the NDDoH Immunization Program at 701.328.3386 or toll-free at 800.472.2180.

Vaccine Financing Information

The December 2009 issue of *Pediatrics*, a publication of the American Academy of Pediatrics (AAP), has a supplement on vaccine financing. All of the articles are important resources for immunization providers. The articles can be accessed on the AAP’s website at http://pediatrics.aappublications.org/content/vol124/Supplement_5/. There are numerous articles, including introductory commentaries, original studies that provide the supportive evidence that NVAC considered in making recommendations, recommendations from the Advisory Committee on Immunization Practices, stakeholder commentaries, and an article on vaccine finance resources for physicians.



Kim Weis Resigns From NDDoH

Kim Weis has resigned from her position as AFIX coordinator for the Immunization Program. Kim had been involved with the Division of Disease Control since September of 2004. She will be missed, as she was a tremendous asset to the immunization program. Tatia Hardy will be taking over Kim’s AFIX duties.

Fever-Reducing Medicines in the News

A recent study published in the *Lancet* assessed the effect of administering prophylactic paracetamol, or acetaminophen, at vaccination on infant febrile reactions and vaccine responses. The study concluded that although febrile reactions decreased significantly, prophylactic administration of antipyretic drugs at the time of vaccination should not be recommended routinely since antibody responses to several vaccine antigens were reduced.

The study also states that the clinical significance of the findings is unknown and requires further assessment. The Centers for Disease Control and Prevention (CDC) published an editorial addressing the conclusions of the study, conceding that the study presented a compelling

case, but stating that more research needed to be done before recommendations are made.

Many parents give fever-reducing medications to their children before and/or after receiving vaccines for various reasons, including decreasing pain from the actual injection and preventing post-vaccination fever. Parents who may have heard about this study will undoubtedly have concerns about administering prophylactic antipyretics.

At this time, the ACIP has not made any new recommendations. It is the decision of the clinician whether or not to recommend administration of antipyretic drugs.



NORTH DAKOTA
DEPARTMENT of HEALTH

Division of Disease Control
Immunization Program

2635 E. Main Ave.

P.O. Box 5520

Bismarck, N.D. 58506-5520

Phone: 701.328.3386

Toll-Free: 800.472.2180

Fax: 701.328.2499

www.ndhealth.gov/Immunize

Upcoming Events

- National Immunization Conference in Atlanta, Ga.: April 19-22, 2010
- National Conference on Immunization and Health Coalitions in Chicago, Ill.: May 26-28, 2010
- ACIP Meeting: February 24-25, 2010
- State Immunization Conference: TBD

The *Immunization Newsletter* is a quarterly production distributed to Prevention Partnership Providers.

Molly Sander, MPH
Immunization Program Manager
msander@nd.gov

Abbi Pierce, MPH
Immunization Surveillance Coordinator
apierce@nd.gov

Tatia Hardy
Vaccines for Children/AFIX Coordinator
tahardy@nd.gov

Keith LoMurray
NDIIS Sentinel Site Coordinator
klomurray@nd.gov

Kristin Hertz, RN
AFIX Coordinator
krhertz@custerhealth.com

Charlotte Morgan, MSN, RN
AFIX Coordinator
cmorgan@cityoffargo.com

Teri Arso
Administrative Assistant
tarso@nd.gov

Prevention Partnership 2010

Every year, all providers currently enrolled in the Prevention Partnership Program are required to renew their enrollment in this important program. Copies of the Provider Enrollment and Provider Profile forms, as well as the updated version of the Vaccine Management Plan, will be mailed to providers in early 2010. Updated copies

of forms developed by the North Dakota Immunization Program also will be distributed with this mailing.

As part of an ongoing effort to increase immunizations in North Dakota and recruit more providers to the Prevention Partnership Program, memos were sent to OB/GYN and emergency department providers

statewide. These important health-care providers have opportunities to vaccinate individuals.

If you know of any providers interested in learning more about North Dakota's Prevention Partnership Program, please encourage them to contact the Immunization Program at 701.328.3386 or 800.472.2180.

Terry Dwelle, MD, MPHTM
State Health Officer

Craig Lambrecht, MD, MPH
Chief, Medical Services Section

Kirby Kruger
Director, Disease Control

Molly Sander, MPH
Immunization Program Manager

Published by the North Dakota Department of Health Division of Disease Control, 2365 E. Main Ave., P.O. Box 5520, Bismarck, N.D. 58506-5520

Publication is available in alternative forms; for more information, contact Tatia Hardy, editor, *Immunization Newsletter*.

EQUAL OPPORTUNITY EMPLOYER