

Immunization Newsletter

North Dakota Department of Health

Division of Disease Control

Summer 2006

HPV Vaccine

On June 8, 2006, the Food and Drug Administration (FDA) approved Gardasil™, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. Types 16 and 18 cause about 70 percent of cervical cancers and types 6 and 11 cause about 90 percent of genital warts. Merck is the manufacturer of Gardasil™. The vaccine was approved for use in females, ages 9 through 26. The catalog price for Gardasil™ is \$120 per dose.

The vaccine must be stored in the refrigerator at 35 to 46 degrees Fahrenheit.

Gardasil™ contains no live virus and is to be given as three injections over a six-month period. The vaccine should be administered intramuscularly as three separate 0.5 mL doses according to the following schedule:

- First dose: elected date
- Second dose: two months after first
- Third dose: six months after first

The minimum interval between doses of HPV vaccine is four weeks between dose one and two and 12 weeks between dose two and dose three.

Studies showed that Gardasil™ was nearly 100 percent effective in preventing

precancerous cervical lesions, precancerous vaginal and vulvar lesions and genital warts caused by the types of HPV covered by the vaccine.

HPV is the most common sexually transmitted infection in the United States. The Centers for Disease Control and Prevention (CDC) estimates that about 6.2 million Americans become infected with genital HPV each year, and more than half of all sexually active men and women become infected at some time in their lives. On average, there are 9,710 new cases of cervical cancer and 3,700 deaths attributed to HPV in the United States each year.

The Advisory Committee on Immunization Practices (ACIP) met June 29, 2006, to develop recommendations for the use of HPV vaccine. ACIP recommends that HPV vaccine be given routinely to females when they are age 11 to 12. The recommendation also allows for administration of HPV vaccine as early as age 9 at the discretion of the physician or health-care provider. Females ages 13 to 26 are also recommended to receive the vaccine.



The vaccine works best if given prior to the onset of sexual activity, but girls who are sexually active also should be vaccinated. Pap testing, screening for HPV DNA or HPV antibody are not recommended prior to vaccination. The ACIP also recommends that women with genital warts and an abnormal Pap test or a positive HPV DNA test be vaccinated. HPV vaccine would provide protection against infection with HPV types not previously acquired.

Gardasil™ will be provided by the North Dakota Department of Health (NDDoH) Immunization Program for Vaccines For Children (VFC) eligible children only. VFC eligible children must be age 18 and younger and must meet one of the following criteria:

- Medicaid eligible
- American Indian or Alaskan Native
- Uninsured (no insurance)
- Underinsured (insurance does not cover vaccination): underinsured children must be vaccinated at a rural health clinic or federally qualified health center.

Providers should order private supplies of HPV vaccine to cover their children who have insurance. Parents and patients should check with their insurance company about coverage. **HPV vaccine for VFC-eligible children most likely will not be available for order until fall 2006.**

ACIP Recommends Routine Two-Dose Varicella Vaccination Schedule

On June 29, 2006, the ACIP voted to recommend a second dose of varicella vaccine to be given at ages 4 to 6. The first dose is still recommended to be given at 12 to 15 months. The ACIP also recommended that children, adolescents and adults who

previously received one dose should receive a second.

This recommendation was made because 20 percent of children who have received one dose of the vaccine are not fully protected and may develop chickenpox after being exposed. Also, one dose may not provide protection into adulthood, when chickenpox disease is most severe.

Providers should not start routinely administering two doses of state-supplied varicella vaccine until notified by the NDDoH. MMRV is approved for a two-dose series for children ages 12 and younger and can be used if children need both varicella and MMR vaccine at 12 to 15 months or 4 to 6 years.

Minimum Intervals for MMR and Varicella Second Doses

Age at First Dose	Minimum Interval
MMR	
All ages	4 weeks
Varicella	
< 13 years	3 months
≥ 13 years	4 weeks

For combination vaccines, such as MMRV, the minimum interval between doses is equal to the greatest interval of any of the individual components. Therefore, the minimum interval between doses of MMRV is three months.

Infectious Disease Fact Sheet Website

Disease Control is in the process of updating all of the fact sheets about infectious diseases, including vaccine-preventable diseases. The updated facts are available on the Disease Control website at www.ndhealth.gov/Disease/faq/Faqs.aspx.

New fact sheets will continue to be added as they are updated.

FDA Approves Shingles Vaccine

The FDA licensed Zostavax™ on May 25, 2006. Zostavax™, from Merck, is a new vaccine to reduce the risk of shingles (herpes zoster) for people age 60 and older.

Shingles is caused by the varicella-zoster virus, the same virus that causes chickenpox. After having chickenpox, the virus lies dormant in certain nerve tissue. As people age, it is possible for the virus to reappear in the form of shingles. It is estimated that shingles affects two in every 10 people in their lifetime. It is characterized by clusters of blisters that develop on one side of the body and can cause severe pain lasting for weeks, months or years after the virus reappears.

In clinical trials, the vaccine reduced the occurrence of shingles in people 60 and older by 50 percent. For people ages 60 to 69, it reduced the incidence by 64 percent. The duration of pain following the onset of shingles also was reduced.

Zostavax™ is a live virus vaccine. It boosts immunity to varicella-zoster virus, which in turn protects against shingles and its complications. It is licensed for a single dose for people 60 and older. **Zostavax™ must be stored in the freezer at temperatures less than or equal to five degrees Fahrenheit.** Pediatric providers are used to storing vaccines in the freezer, but fewer internists are familiar with freezer storage.

Zostavax™ is priced at \$150 and should be covered by the Medicare Part D prescription program for people 65 and older, but coverage may vary depending on each patient's drug plan. Merck will provide the

vaccine at no cost to low-income adults through a patient assistance program. The NDDoH will not supply shingles vaccine, since it is an adult vaccine.

The ACIP discussed shingles vaccine at its June meeting. ACIP recommendations for shingles vaccine are expected at its October meeting.

Influenza Vaccine Update

Orders for state-supplied influenza vaccine were due by June 30, 2006. Providers who have not submitted an order should do so as soon as possible to ensure they will receive influenza vaccine this upcoming season.

2005-2006 influenza vaccine expired on June 30, 2006. **Expired influenza vaccine should not be discarded.** Expired vaccine should be returned to the NDDoH. The NDDoH receives an excise tax credit for all expired vaccine.

It is expected that there will be 110 to 120 million doses of influenza vaccine for the 2006-2007 season. GlaxoSmithKline is awaiting approval of FluLaval®, which accounts for possibly 9 million of the doses next season.

More information about state-supplied influenza vaccine shipments will be available in the near future.



Menactra® Shortage

In January 2005, the ACIP recommended routine administration of Menactra® for people ages 11 to 12 years, adolescents at high school entry and college freshman living in dormitories. Immunization also was recommended for other people at high-risk for meningococcal disease, such as certain travelers, laboratory personnel, etc.

Sanofi Pasteur expects that demand for Menactra® will outpace supply at least through the summer of 2006. In May 2006, CDC, in consultation with the ACIP, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College Health Association and the Society for Adolescent Medicine recommended that the dose at age 11 to 12 be deferred. Providers should continue to vaccinate adolescents at high school entry and college freshman living in dormitories. Other people at high-risk for meningococcal disease also should be vaccinated.

The NDDoH supplies Menactra® for VFC-eligible children only.

Updated ACIP Recommendations for the Prevention of Mumps

On May 17, 2006, the ACIP updated criteria for mumps immunity and vaccination recommendations. Previously, documentation of mumps immunity through vaccination has consisted of only one dose of mumps-containing vaccine, including for health-care workers. The majority of people have received two doses of mumps-containing vaccine, since mumps vaccine is included along with measles and rubella in the MMR vaccine. This year's outbreak of mumps, with many cases in vaccinated individuals, caused the ACIP to change the recommendations.

The following recommendations were made in May:

1. Acceptable evidence of immunity: documentation of adequate vaccination, laboratory evidence of immunity, birth before 1957 or documentation of physician-diagnosed mumps. Adequate vaccination now is defined as one dose for preschool children and two doses for school-age children and adults at highrisk (i.e., health-care workers, international travelers, and college students).
2. Routine vaccination of health-care workers: everyone who works in health-care facilities should be immune to mumps. Adequate vaccination for health-care workers born during or after 1957 consists of two doses of live mumps vaccine. Health-care workers with no history of mumps vaccination and no other evidence of immunity should receive two doses (at least 28 days apart). Health-care workers who have received only one dose previously should receive a second. Birth before 1957 is only presumptive immunity; health-care facilities should consider recommending one dose of mumps vaccine for unvaccinated workers born before 1957 who do not have a history of physician-diagnosed mumps or laboratory evidence of mumps immunity.
3. Mumps outbreak control: Depending on the outbreak, a second dose of mumps-containing vaccine should be considered for children ages 1 to 4 and adults who have received only one dose. Health-care facilities should strongly consider two doses of mumps vaccine for all unvaccinated workers born before

1957 who do not have evidence of immunity.

North Dakota Vaccine Loss Policy

Providers will be receiving a North Dakota Vaccine Loss Policy in the mail. The policy should be read and the addendum to the Prevention Partnership Enrollment should be signed and returned by **Sept. 1, 2006**.

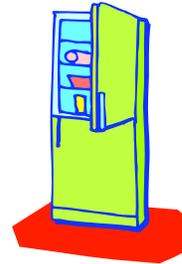
Current state and federal vaccine contracts stipulate that spoiled or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by the NDDoH budget. Since the Prevention Partnership Program is so important to the health and well-being of North Dakota children, it is essential that all of us work together to ensure that every dose of vaccine is used to provide protection against disease in susceptible children. Providers responsible for state-supplied vaccine should continually monitor vaccine storage and handling practices. Please notify the North Dakota Immunization Program if you or your staff would like to receive an educational visit regarding vaccine storage and handling.

Prevention Partnership Providers are required to report all wasted, expired, spoiled or lost vaccine to the North Dakota Immunization Program. The policy serves as NDDoH Immunization Program's policy for management of incidents that result in loss of state-supplied vaccine. Reimbursement for state-supplied vaccine will be requested if wastage was due to the provider's failure to properly store, handle or rotate vaccine inventory.

Some examples of situations that would require reimbursement of vaccine would be storing refrigerated vaccine in the freezer or vice versa, leaving the refrigerator/freezer

door open, spoiled vaccine resulting from not checking refrigerator/freezer temperatures, expired vaccine totaling more than \$500, etc. The policy specifically outlines all of the situations that would require reimbursement.

An invoice will be sent to the provider totaling the amount of wasted vaccine, based on CDC contract prices and minus the excise tax credit. Providers will be required to reimburse the NDDoH for the vaccine within 30 days, or they may no longer be able to receive state-supplied vaccine.



For more information regarding proper vaccine storage and handling, visit www2.a.cdc.gov/nip/isd/shtoolkit/splash.html.



Thanks to the Greater Grand Forks Immunization Coalition

The Greater Grand Forks Immunization Coalition held an immunization conference in May. The conference was a huge success, thanks to the efforts of the Greater Grand Forks Immunization Coalition. The conference featured many speakers, including Dr. William Atkinson and Dr. Paul Offit. Also, thank you to all of the providers from around the state who attended the conference.

North Dakota Mumps Update

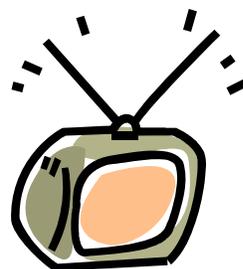
Mumps cases are continuing to occur in North Dakota. So far in 2006, 12 cases of mumps have been reported. Eight of the cases are lab-confirmed and four are probable. Seven of the cases have a history of two MMRs, two have a history of 1 MMR, one has a history of no MMRs and two have an unknown vaccination status. The cases range from ages 1 to 48. So far, none of the cases have been hospitalized. Counties reporting mumps cases in 2006 included Barnes, Burleigh, Dickey, Emmons, Morton, Mountrail, Richland, Rolette and Williams. None of the cases reported in North Dakota were found to be linked to Iowa.

Last year in North Dakota, five cases of mumps were reported. Please report all suspect and confirmed cases of mumps to the NDDoH at 701.328.3386 or toll-free at 800.472.2180.

CDC Immunization Netconferences

A Current Issues in Immunization Netconference was held Friday, July 7. The netconference covered information about HPV, cervical cancer, and HPV vaccine and recommendations. The one-hour session is archived on the National Immunization Program (NIP) website at www.cdc.gov/nip/ed/ciinc/hpv.htm.

Another Current Issues in Immunization Netconference will be held Thursday, July 20, at 11 a.m. CT. The netconference will cover information about vaccine administration (safe and accurate preparation and delivery) and 2006 influenza recommendations. For more information or to register, visit www.cdc.gov/nip/ed/ciinc/default.htm.



Immunization Update 2006

A satellite broadcast and webcast will be held Aug. 10, 2006 from 8 a.m. to 10:30 a.m. CT and repeated from 11 a.m. to 1:30 p.m. CT. Anticipated topics include influenza vaccine, pertussis vaccination of adolescents and adults, revised recommendations for hepatitis A vaccination and new recommendations for rotavirus, human papilloma virus and herpes zoster vaccine. Both broadcasts feature a live question-and-answer session. Site registration began June 22. Individual registration began July 1. Continuing education credits are available. For more information or to register, visit www.phppo.cdc.gov/phtn/immup-2006/default.asp.

Tdap vs. DTaP

Pay attention to which vaccine you are administering. The NDDoH has been receiving many reports of providers administering DTaP instead of Tdap or vice versa. This is a medical error. DTaP is licensed only for children younger than 7. Tdap, depending on brand, is licensed only for children 10 or 11 and older.

If Tdap is administered for one of the first three doses of the DTaP series, the dose should be considered invalid and DTaP should be administered. If Tdap is administered for the fourth or fifth dose of the DTaP series, the dose does not need to be repeated. If DTaP is administered instead

of Tdap, the dose does not need to be repeated. The NDDoH does not get reimbursed for these invalid doses from Blue Cross Blue Shield (BCBS), so please double-check which vaccine you are administering prior to vaccinating. A cheat sheet is available from the California Department of Health Services to assist your staff with determining if the vial is Tdap, DTaP or Td. The *Check Your Vials* poster is available at

www.dhs.ca.gov/ps/dcdc/izgroup/pdf/IMM-508.pdf.



NDIIS Forecaster

The North Dakota Immunization Information System (NDIIS) immunization forecaster became available June 21, 2006. A forecaster is an automated function that determines needed routine childhood immunizations in compliance with current ACIP recommendations, given an individual's immunization history to date. The forecaster shows a list of vaccines and whether or not the client is up-to-date, due now, or past due on those immunizations. The forecaster shows the minimum valid date and the recommended dates for the various vaccinations. The forecaster is an excellent tool for increasing immunization rates in your practice by helping providers avoid missed opportunities and avoid giving invalid vaccinations.

The forecaster button is located on the bottom of the client immunization record screen. You simply click on the forecaster button and another screen will pop up showing the client's forecast.

Reminder/Recall will be available sometime in July. Reminder/Recall is an automated function that produces a list of individuals who, as of a given date, are due or late for immunizations according to forecasting. The output from this function gives the ability to produce reminder or recall notices (produce mailing labels or postcards).

NDIIS trainings will be set up once Reminder/Recall is available so that providers can be trained on both forecasting and Reminder/Recall at the same time.

If you have any questions in the interim, contact the NDDoH Immunization Program. Also, please notify the Immunization Program if you see any issues or if you think there are any inaccuracies in the forecasting of vaccines.

Kari Wahlen Leaves NDDoH

Kari Wahlen is no longer with the NDDoH as an AFIX Coordinator. Kari moved to Rochester, Minn. with her family. Kari was with the NDDoH for four years. The NDDoH appreciates all of her hard work and wishes her well on her future endeavors. Stacy Lovelace will be taking over her duties as an AFIX Coordinator, along with Kristen Hertz.

New Tdap and Influenza Vaccine VISs

A new Tdap vaccine information statement (VIS) became available May 31, 2006. The new VIS has more information about adult vaccination than the prior VIS.

The new influenza VISs are also available as of June 30, 2006. Separate VISs are available for live attenuated and inactivated influenza vaccines.

The most current VIS always should be used. VISs are available for order from the NDDoH by completing the forms order form. VISs also are available at www.cdc.gov/nip/publications/VIS/default.htm. VISs should be given to the patient or parent/guardian for every vaccine at every immunization encounter.



Seventh National Conference on Immunization Coalitions

The Seventh National Conference on Immunization Coalitions will be held in Denver, Colo., Wednesday, Aug. 9 through Friday, Aug. 11, 2006. The conference will provide data and validation for participants of coalitions to use as justification for implementing new projects and programs. The conference supplies participants with examples of successful field-tested programs that can be implemented within their own communities, in addition to the valuable opportunity to develop professional contacts with those who designed and implemented these programs. For more information, an agenda or to register for the conference, visit www.seeuthere.com/rsvp/invitation/invitation.asp?id=/m2c666-455170415278.

New North Dakota Lifetime Immunization Record

A new lifetime immunization record will soon be available for order from the NDDoH. The folded record has the ability to track a person's immunizations throughout his/her lifetime. New vaccines, such as HPV, rotavirus and Tdap are included on the

record. Providers will be notified when the record is available.

Are You Receiving E-Mails From the NDDoH Immunization Program?

The NDDoH Immunization Program sends immunization information to providers via e-mail on a regular basis. If you haven't been receiving e-mails or would like to be added to the list, please contact Molly Sander at 701.328.4556 or toll-free at 800.472.2180.

Updated Vaccine Administration Records

The North Dakota Vaccine Administration Record (VAR) has been updated. The VAR now has updated VIS dates, as well as, newly licensed vaccines. The VAR is no longer on 11 X 17 paper. It is again on regularly sized paper. To order new VARS, just complete a forms request form and fax or mail it to the NDDoH Immunization Program.

Measles Alert for World Cup

The CDC is warning that the World Cup could be a breeding ground for measles given the close proximity of fans from around the world and is urging Americans traveling to Germany to make sure they are fully immunized and on return to see a doctor if symptoms are detected. Three of the cities hosting matches are in a region of Germany where about 1,200 cases of measles have been reported this year. Vaccination within three days of exposure, or immune globulin given up to six days after exposure, can prevent illness.



Questions and Answers

1. **Should rotavirus vaccine be stored in the refrigerator or the freezer?**
 - A. Rotavirus vaccine must be stored in the refrigerator at 35 to 46 degrees Fahrenheit.

2. **If a patient has a history of rotavirus illness and is younger than 12 weeks, should that patient still be vaccinated?**
 - A. Yes. A history of rotavirus illness is not a contraindication to vaccination. There are different types of rotaviruses, and vaccination will still protect against the other types.

3. **Should Prevnar® ever be administered to children 5 and older?**
 - A. No. Prevnar® is not routinely recommended for children 5 and older. If the child is not up-to-date on Prevnar® vaccination by age 5, it is too late to vaccinate. BCBS will not reimburse the NDDoH for doses of Prevnar® administered to children 5 and older.

4. **Can two doses of pediatric Engerix-B® be used to vaccinate adults?**
 - A. No. Both the pediatric and adult formulations of Recombivax HB® are approved for use in any age group. For example, the adult formulation of Recombivax HB® may be used in children (0.5 mL) and adolescents (0.5 mL). However, **pediatric Engerix-B® is approved for use only in children and adolescents younger than 20.** The adult formulation of Engerix-B® is not approved for use in infants and children but may be used in both adolescents (ages 11 to 19) and adults.

5. **Should varicella vaccine be administered to infants younger than 12 months?**
 - A. The NIP does not recommend administration of varicella vaccine to infants younger than 12 months in any setting, including outbreaks and international travel. Varicella vaccine is not approved for this use. Most infants younger than 12 months will have residual maternal antibody. Infants who receive varicella vaccine prior to 12 months of age should be revaccinated.

6. **Should Tdap be used instead of Td for wound management in emergency departments?**
 - A. Yes. Adults ages 19 to 64 who require a Td vaccine as part of wound management should receive Tdap instead of Td if they previously have not received Tdap. If Tdap is not available or was administered previously, Td should be administered. Adults who have never received Td vaccine should receive a series of three vaccinations. The preferred schedule is a dose of Tdap, followed by a dose of Td more than four weeks later, and a second dose of Td six to 12 months later. Tdap can substitute for Td for any one of the three doses in the series. Tdap is not licensed for use among adults 65 and older. All adults, including adults 65 and older, should receive a dose of Td vaccine every 10 years and as indicated for wound management.

Upcoming Events:



- CDC/NIP Current Issues in Immunization Netconference: **July 20, 11 a.m. – 12 p.m.**
- Seventh National Conference on Immunization Coalitions in Denver: **August 9 – 11**
- “Immunization Update 2006” satellite broadcast: **August 10, 8 a.m. – 10:30 a.m. or 11 a.m. – 1:30 a.m.**
- National Adult Immunization Awareness Week: **September 24 – 30**
- ACIP Meeting in Atlanta: **October 25 – 26**

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