

Immunization Newsletter



Summer 2016

June ACIP Update

The Advisory Committee on Immunization Practices (ACIP) met June 22 and 23, in Atlanta, GA. The following is a brief summary of what was presented at the meeting and recommendations that were made. Recommendations will be published in future in Morbidity and Mortality Weekly Reports (MMWR). For more information about the ACIP, please visit www.cdc.gov/vaccines/acip/.

Cholera Vaccine:

On June 10, 2016, the Food and Drug Administration (FDA) approved Vaxchora™, the only vaccine available to prevent cholera caused by serogroup 01, the predominant serotype around the world (99 percent).

Cholera, a watery, diarrheal disease caused by the *Vibrio cholera* bacteria, is rare in the United States, but common in parts of the world where water and sewage treatment programs are inadequate. Approved for adults ages 18 to 64 years, the vaccine is a single oral dose given at least ten days before travel. There is very limited information on the duration of protection beyond three to six months for this vaccine.

The ACIP recommended the use of the vaccine in patients who are traveling to areas of active toxigenic *V. cholera* transmission. Vaccination is especially important for patients who would have poor clinical outcomes if infected. These include

travelers who are unable to follow safe food and water measures, health care workers who may be exposed while treating patients, travelers without access to rapid medical care, those with low gastric acidity, people with type “O” blood, and travelers with chronic medical conditions who would tolerate dehydration poorly.

Meningococcal ACYW-135 Vaccine:

People with HIV are at increased risk of meningococcal disease. The ACIP voted to recommend meningococcal conjugate vaccine (MCV4) for people ages two months and older who have HIV. A primary series should be given, followed by booster doses, every five years for the rest of their life.

Meningococcal B Vaccine:

The FDA approved a change to the meningococcal group B (MenB; Trumenba®) label on April 14, 2016. A two-dose schedule (0 and 6 months) was approved. The ACIP was presented data on the two-dose schedule, but did not take a vote. Until ACIP recommends the two-dose schedule, health care providers should continue to use the three-dose schedule (0, 1-2, and 6 months). The ACIP will further discuss MenB vaccine at the October 2016 meeting.



RSV Vaccine:

Respiratory Syncytial Virus (RSV) is a major cause of lower respiratory tract disease in infants and children, with studies showing that almost all children have been infected by age two. People older than age 60 are also regularly

infected with RSV, accounting for approximately 180,000 hospitalizations per year. A new subunit vaccine targeting patients ages 60 and older is in Phase III trials. A new ACIP workgroup was formed to discuss RSV and to develop recommendations for use of RSV vaccine in the future.

ACIP Votes Against the Use of Flumist® During the 2016-2017 Influenza Season

On June 22, 2016, the Centers for Disease Control and Prevention's (CDC) ACIP voted that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine or Flumist®, should **not** be used during the 2016-2017 flu season. The ACIP continues to recommend annual flu vaccination with either the inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) for everyone six months and older.



The ACIP is a panel of immunization experts that advises the CDC. This ACIP vote is based on data showing poor or relatively low effectiveness of LAIV from 2013 through 2016. During the last flu season, LAIV showed no protective benefit in vaccine effectiveness studies.

Since LAIV should not be used next season, the North Dakota Department of Health (NDDoH) recommends that all North Dakota health care providers cancel pre-booked orders for LAIV with the manufacturer or distributor. Providers should order IIV to replace doses of LAIV. The Influenza Vaccine Availability Tracking System (www.izsummitpartners.org/ivats/) will be updated as to manufacturer and distributor influenza vaccine availability. Providers may not be able to obtain preferred brands or presentations of IIV.

For providers who pre-booked LAIV with the Vaccines for Children (VFC) Program, the NDDoH Immunization Program will be replacing LAIV doses with IIV doses. Providers do not need to contact the NDDoH to cancel pre-booked VFC LAIV. The VFC Program supplies vaccines for children who are American Indian, Medicaid-eligible, uninsured, or underinsured.

For more information about this ACIP action, please see the NDDoH Health Advisory at www.ndhealth.gov/Immunize/default.htm.

Local Public Health Units (LPHU) Transition to Vaccines for Children (VFC)-Only Supply Policy

Starting July 1, 2016, all LPHUs are now VFC-only. This means that state-supplied vaccine can only be used for VFC-eligible patients 18 years and younger who are either Medicaid enrolled or eligible, American Indian, uninsured, or underinsured. Private vaccine must now be administered to insured individuals. Previously, all vaccines for pediatric patients seen at local public health units were supplied by the NDDoH.

Note: the vaccine supply policy has not changed for non-LPHU providers.

If there are any questions, please contact the immunization program at 701.328.3386 or toll-free 800.472.2180.

Number of HPV-associated cancers in the US on the rise, CDC says

On its website, [NBC News](#) (7/7, Gussone) reports that “the number of human papillomavirus (HPV)-associated cancers in the” US “has increased by 17 percent, to nearly 39,000 cases a year, according a report from the CDC.”

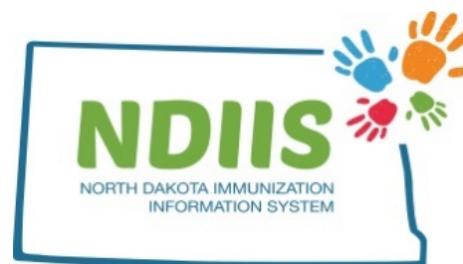
Institute’s Surveillance, Epidemiology, and End Results program.” This “number is up from 33,369 cases between 2004 and 2008.”

[US News & World Report](#) (7/7, Oliver) reports that “between 2008 and 2012, an average of 38,793 HPV-associated cancers were diagnosed annually, according [to] the report,” which “was based on an analysis of data from the CDC’s National Program of Cancer Registries and the National Cancer

On its website, [CBS News](#) (7/7, Welch) reports that the data indicated that “whites had higher rates of oral and throat cancers than blacks and Hispanics,” but “rates of cervical cancer were higher among blacks and Hispanics.” The [findings](#) were published in the MMWR.

NDC Codes – NDIIS required field and 10-digit conversions

When entering vaccine lot numbers into your vaccine inventory in the North Dakota Immunization Information System (NDIIS), there is now a required field for entry of the National Drug Code (NDC) from the vaccine packaging. This field requires the use of the correct 11-digit code in a standard format (99999-9999-99). The-11 digit code is also required for proper billing of the vaccine. However, many NDC codes displayed on the vaccine packaging are in a 10-digit format that will require a strategically placed zero to convert into the correct 11-digit format.



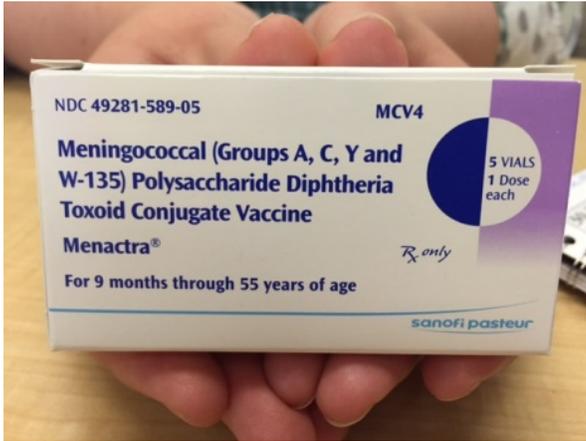
The table below shows the correct placement of the added digit (zero) for the different 10 digit formats for NDC codes:

10-Digit Format on Packaging	10-Digit Format Example	11-Digit Format	11-Digit Format Example	Actual 10-Digit NDC Example	11-Digit Conversion of Example
4-4-2	9999-9999-99	5-4-2	<u>0</u> 9999-9999-99	0002-7597-01	<u>0</u> 0002-7597-01
5-3-2	99999-999-99	5-4-2	99999- <u>0</u> 9999-99	50242-040-62	50242- <u>0</u> 040-62
5-4-1	99999-9999-9	5-4-2	99999-9999- <u>0</u> 9	60575-4112-1	60575-4112- <u>0</u> 1

Lot Number Variations between Unit of Sale and Unit of Use

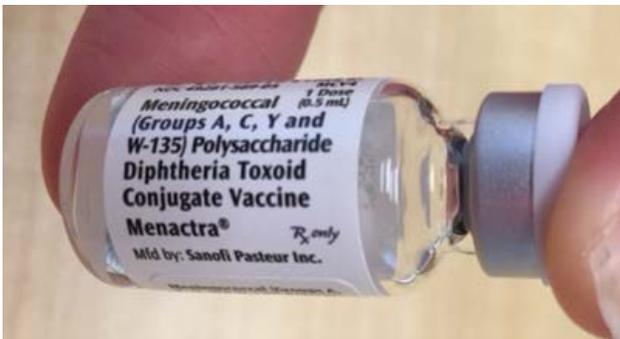
What is Unit of Sale?

The Unit of Sale (UoS) is the exterior packaging or carton that the vaccine is shipped in.



What is the Unit of Use?

The Unit of Use (UoU) is the vaccine vial or pre-filled syringe found within the UoS.



Why is this important?

There are a few vaccine manufacturers that will have a different lot number on the UoS and UoU for the same vaccine. This makes documenting the administration of the vaccine a challenge when trying to figure out which lot number you should record. The UoS is generally the lot number used for inventory management and it is the lot number that the NDDoH Immunization Program receives from the CDC shipping logs and enters into the NDIIS vaccine inventory. Some North Dakota providers and health systems are starting to implement the use of 2D barcode scanning for more accurate documentation of vaccine administration information. However, when using the 2D barcode, many practices want to use the lot number on the

UoU which will not match the lot number in the NDIIS inventory.

What does this mean?

When doses are added to an NDIIS client record, the lot number is a required field. The lot numbers available during dose data entry are only those currently in the provider's NDIIS inventory, which are from the UoS. When the correct lot number is selected during dose entry, the dose will be decremented from the provider's inventory and will be tracked as either a public or private dose administered. When a dose is added to a provider's electronic health record (EHR) system and sent to the NDIIS electronically, the lot number must find an exact match on both the lot number and funding source. If the lot number entered into the EHR is from the UoU and not the UoS, a matching lot number cannot be found in the NDIIS and the vaccine abbreviation (dummy dose) will be added to the client immunization record in place of the actual administered lot number. Without a matching lot number found in the NDIIS and added to the record, the dose cannot be decremented from the provider's inventory and will not be correctly tracked as either a public or private dose administered. This means that providers enrolled in the VFC Program will not have an accurate inventory count of doses on hand or doses administered in the NDIIS. Both of these are used to determine if you are able to order more publicly funded vaccine from the VFC Program. When providers have a high number of doses on hand and a low number of doses administered due to incorrect data entry, the Immunization Program will not allow the provider to order additional vaccine, because it will appear as if the provider is not using their VFC vaccine.

What can we do about it?

When documenting the administration of a vaccine, it is recommended that you record the lot number from the UoS, not the UoU. This will ensure that the inventory management and doses administered date will stay in sync.

The table below shows the vaccines, available for order through the VFC program, that have a different lot number on the UoS and UoU. The table shows the patterns for the different lot numbers for the six VFC vaccines this difference impacts.

Vaccines manufactured by MedImmune (AstraZeneca), Pfizer, Merck and Bio CSL have the same lot number on their UoS and UoU so this issue does not have an impact on any of their vaccines.

Brand Name	Manufacturer	NDIIS Vaccine Abbreviation	Lot Number*	
			Unit of Sale [¥]	Unit of Use
ACTHib	Sanofi Pasteur	HIB (PRP-T) ACTHib	AA###AA <u>A</u>	AA###AA
IPOL	Sanofi Pasteur	IPV	A####-#	A####
Pentacel (antigen – Hib) †	Sanofi Pasteur	DTaP-Hib-IPV (Pentacel)	###AA <u>A</u>	###AA
Pentacel (diluent – DTaP/IPV) †	Sanofi Pasteur	DTaP-Hib-IPV (Pentacel)	<u>###AA<u>A</u></u>	###AA
Menveo††	GSK	MCV4 Menveo	<u>A</u> ####	<u>B</u> ####
Rotarix‡	GSK	ROTAVIRUS (2 dose)	A## <u>A</u> ###A	A## <u>C</u> A###A (antigen) A## <u>D</u> A###A (diluent)
MenHibrix‡‡	GSK	MEN C/Y-HIB	A##AA###A	A##AA###A (antigen) <u>A</u> A##A### <u>A</u> (diluent)

* The **A** and **B** in the lot number patterns represent an alphabetical character. The lots may contain any alphabetical character and are not limited to just the letters **A** and **B**. The # sign indicates a numerical character in the lot number pattern.

¥ The UoS lot number is the one that should be documented during vaccine administration.

† The diluent and antigen for Pentacel® comes in the same UoS packaging so there is one lot number to document that allows for tracking of both components in the event of a recall. The antigen and diluent will each have their own lot number on the UoU that are both different than the UoS but will follow the same pattern.

†† The Menveo® antigen and diluent lot numbers follow the same pattern for UoS and UoU.

‡ The Rotarix® UoU antigen lot number has the letter “C” in the fourth position and the diluent lot number has a “D” in the fourth position.

‡‡ The MenHibrix® UoU antigen lot number is the same as the UoS lot number. The diluent lot number has an additional alpha character at the beginning and the end of the lot number and removes the alpha character that was in the fifth position of the UoS and UoU antigen lot number.

Have you heard “You’re not done if you give just one”?

The Immunization Action Coalition (IAC) and Sanofi Pasteur Inc. want providers, parents, and young adults to know that two doses of MCV4 are needed to protect individuals against meningococcal disease. The first dose should be given at 11-12 years of age, and the



second dose at 16 years of age. This recommendation is not new; the ACIP began its recommendation of one dose at 11-12 years in 2005, and added the recommendation for the second dose at age 16 in 2010. However, rates for the second dose of MCV4 lag behind other adolescent immunization rates.

Meningococcal disease is unpredictable and has a sudden onset. Symptoms (fever, headache, nausea, vomiting and/or loss of appetite) mimic common viral illnesses. Most cases occur randomly. The illness progresses quickly and can lead to shock, coma, and death with 24 hours. The death rate is 10-15%, even with proper treatment.

This disease affects all ages, but the highest risk is in individuals ages 16-21 among people older than one year of age. Antibody studies indicate that the level of protective antibody declines 3-5 years after a single MCV4 dose. A second dose of MCV4 at 16-18 years of age boosts the antibody level to increase immunity and protect an individual from disease.

The mode of transmission for meningococcal disease helps explain why 16-21 year olds are at risk —coughing, sneezing, kissing, and sharing eating utensils or water bottles can spread the bacteria. Crowded settings such as college dorms, night clubs, and bars also increase the risk of transmission.

According to CDC, in 2014, 79% of children aged 13-17 had at least one dose of MCV4. During that same time frame, only 29% of this age group had received the second dose of vaccine by the age of 17.

A health care provider’s recommendation to vaccinate is a motivator for patients to get their children immunized. Creating an environment that is pro-vaccine with employees who are committed to fully vaccinating all eligible adolescents’ increases immunization rates. Staff who vaccinate should receive education on meningococcal disease, be knowledgeable on ACIP recommendations, and be up to date on their own vaccinations.

Evaluate patients’ vaccination status at every clinic visit. To avoid missed opportunities, evaluate patients at wellness visits, acute care visits, sports and camp physicals, routine visits for chronic illnesses, and when patients come to your office to receive their influenza vaccine.

Finally, make education about vaccines visible, easily accessible, and plentiful. Have posters, pamphlets, and handouts in waiting areas as well as clinic exam rooms. Allow parents to ask questions, and educate staff so they are comfortable answering them.

Online ordering of vaccine-related resource materials is available through the Immunization Program’s webpage at www.ndhealth.gov/immunize/order/.

NDDoH Presents at CSTE Conference!

Epidemiologists with the NDDoH Division of Disease control were able to participate this year in the Council of State and Territorial Epidemiologists' (CSTE) annual conference. During this conference, Lexi Barber, immunization surveillance coordinator, gave two presentations regarding surveillance practices in North Dakota. The presentations were authored by:

- Alicia Lepp
- Molly Howell
- Mary Woinarowicz
- Mike Benz
- Tracy Miller
- Stephanie Melquist (2015 Student Intern)
- Amy Schwartz (previous employee)

The first was a poster presentation explaining NDDoH's active chickenpox surveillance in 2015. It was suspected that chickenpox cases in North Dakota were being underreported. Two hospitals were contacted to participate in the project. A line list of patients with ICD9 codes related to chickenpox and diagnosed from Jan. 1, 2014, through June 30, 2015, were requested. In total, there were 115 records with ICD9 codes related to chickenpox. Of these, 83 met the case definition for chickenpox. Eleven of these cases were out of jurisdiction, and another six were previously reported to the NDDoH. This left a total of 66

chickenpox cases that were unreported to the NDDoH. In addition, the study also found that out of all diagnosed chickenpox cases, only four were confirmed by laboratory testing. It is recommended that all suspected chickenpox infections be laboratory confirmed, as fewer physicians have direct experience with breakthrough infections and diagnosing chickenpox. The lack of reporting and laboratory testing emphasizes the need for increased provider education at the facility level. This project will be repeated at these facilities in coming years, as well as at additional facilities throughout the state.

The second presentation at the conference explained the interoperability between the NDDoH's disease surveillance system (MAVEN) and the NDIIS. Previously, NDIIS and MAVEN were not interoperable, meaning epidemiologists had to log into NDIIS and search for the client and then manually enter the vaccine information into MAVEN. This was a time consuming process that allowed for human error in the data entry process. In December 2015, however, MAVEN and NDIIS became interoperable. Now, a message is sent from MAVEN to NDIIS containing the vaccine preventable disease case's first and last names and date of birth. If there is a match in NDIIS to the case information entered, vaccine information will be sent back to MAVEN. Only vaccines that are



relevant to the disease investigation are sent to MAVEN.

The NDIIS query is available for all vaccine preventable diseases in MAVEN. Future steps include expanding the query to other diseases including STDs, HIV, and Hepatitis C, as well as working with MAVEN's ability to know if a case is up-to-date on immunizations. Right now, vaccinations need to be manually reviewed to determine if a case is up-to-date; however, NDIIS does send immunization forecast data in the response message, so a future enhancement to MAVEN could allow MAVEN to display this information automatically.

Interoperability between MAVEN and NDIIS has improved data quality by reducing both human data entry error and the time spent gathering and manually entering immunization data.

School Immunization Requirements in North Dakota

School is just around the corner, and it is time to make sure students are up to date on their immunizations!
 In the state of North Dakota, the following vaccinations are required for students to enter school:

Kindergarten Entry	7 th Grade Entry	College Entry
<ul style="list-style-type: none"> ✓ 5 doses of DTaP <i>(last dose must be given on or after 4th birthday)</i> ✓ 4 doses of polio <i>(last dose must be given on or after 4th birthday)</i> ✓ 3 doses of hepatitis B ✓ 2 doses of MMR ✓ 2 doses of Chickenpox <i>(child is exempt if he/she has history of chickenpox disease)</i> 	<ul style="list-style-type: none"> ✓ 5 Doses of DTaP ✓ 4 doses of polio ✓ 3 doses Hepatitis B ✓ 2 doses MMR ✓ 2 doses of chickenpox <i>(2 doses required for kindergarten to 8th grade. 1 dose required for 9th to 12th grade, unless otherwise exempt)</i> ✓ 1 dose Tdap ✓ 1 dose Meningococcal Vaccine (MCV4) 	<ul style="list-style-type: none"> ✓ 2 doses of MMR ✓ 2 doses of Meningococcal Vaccine (MCV4)

Students who are not up-to-date on vaccinations thirty days after school has started, must be excluded from school until they have received all required vaccines.

For more information, visit: <http://www.ndhealth.gov/Immunize/Schools-ChildCare/> or contact the North Dakota Department of Health immunization program at 701.328.3386.





2016 North Dakota State Immunization Conference

The immunization program has been busy planning the upcoming 2016 North Dakota State Immunization Conference scheduled for Wednesday, August 3, and Thursday, August 4,, 2016. Any and all who work with immunizations are welcome to attend. Staff that should consider attending include, but are not limited to, clinic administration, nurses, physicians, and pharmacists.

The following speakers will be presenting at the immunization conference with many others:

- Dr. Gary Marshall (University of Louisville School of Medicine) – Vaccine Hesitancy
- Dr. Terry Dwelle (NDDOH) – ACIP Update
- Kylie Hall (NDSU) – Immunization and Exemption Policies and Practices in North Dakota
- Dr. LJ Tan (Immunization Action Coalition) – Improving Adult Immunizations and a break-out session on using standing orders to improve access to immunizations
- Dr. John Lee (Sanford Sioux Falls) – Therapeutic and Prophylactic HPV Vaccination
- Dr. Lon Kightlinger (South Dakota Department of Health) – Reviewing recent SD measles outbreak
- Christine Baze (Yellow Umbrella Project) – Cervical cancer survivor and motivational speaker

For more information or to register please go to

und.edu/academics/extended-learning/conference-services/immunization/.

We hope to see everyone there!

Increase in Human Papillomavirus (HPV) Vaccination Rates in North Dakota

According to the NDIIS, as of the end of the second quarter of 2016, adolescent rates for the HPV vaccine three-dose series completion for females and males have increased, in comparison to the previous quarter. The figures below show that rates for females ages 13-15 years are at 39.1%, and at 47.2% for ages 16-18 years. Rates for males ages 13-15 years in North Dakota stand at 32.5%, and for ages 16-18 years, completion rates are 34%. While HPV vaccination rates have been increasing steadily for all adolescents between 2012 and 2016, the rates for males continue to lag behind females, as well as rates for other routinely recommended adolescent vaccines (MCV4 and Tdap). Rates for partial completion of the series are similar for both males and females.



Figure 1: NDIIS HPV Vaccination Rates in North Dakota as of the end of the 2nd quarter of 2016 for both males and females ages 13-15 years.

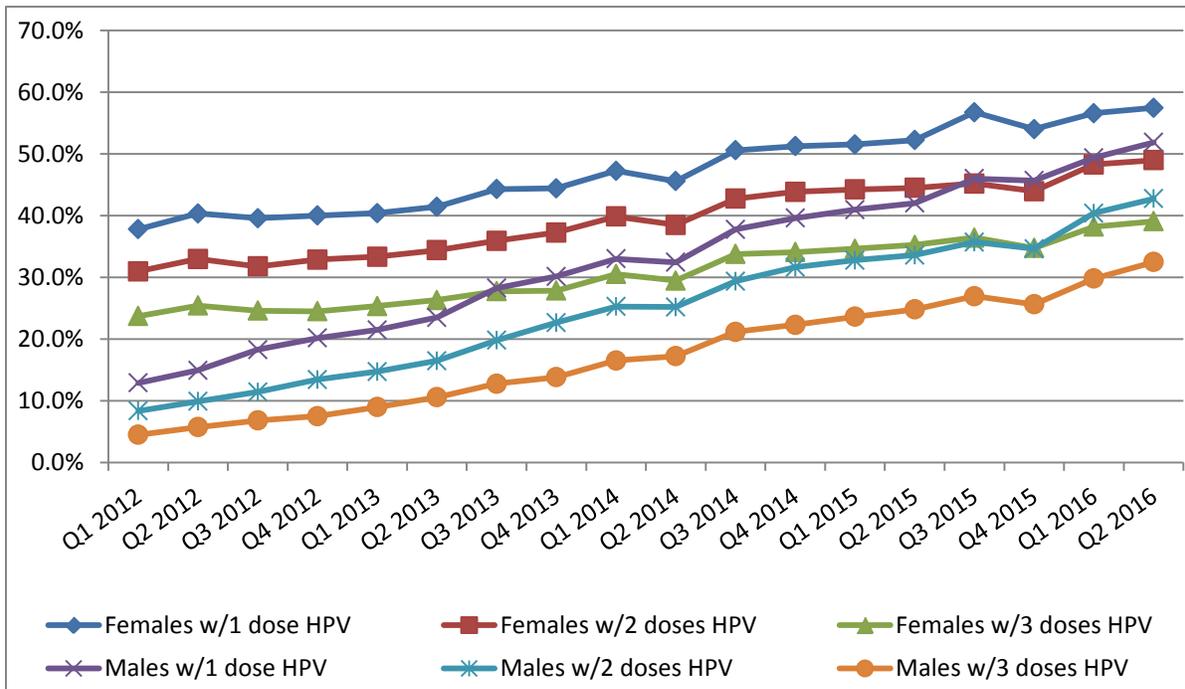
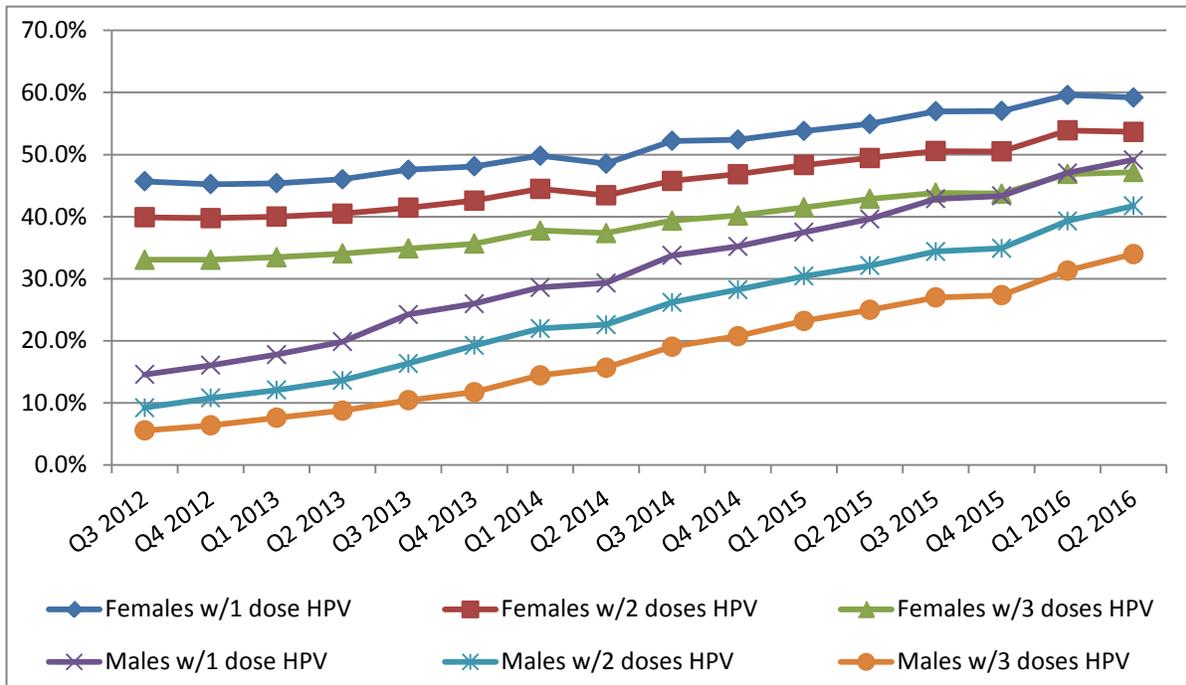


Figure 2: NDIIS HPV Vaccination Rates in North Dakota as of the end of the 2nd quarter of 2016 for both males and females ages 16-18 years.



Updated Storage and Handling Toolkit Now Available!

In June, the CDC released an updated Storage and Handling Toolkit. This toolkit has updated the Fahrenheit temperature monitoring change, which takes effect immediately. Refrigerators should now maintain temperatures between 36° to 46°F (2° to 8°C). The Celsius temperatures have remained unchanged. The change in the Fahrenheit temperature is more consistent with the conversion from Fahrenheit to Celsius in temperature monitoring. Providers do not need to follow up on any alarms at 35°F until Jan. 1, 2017, as this is the transition period for the new guideline. As long as vaccines are stored within the temperature range defined in the manufacturer's package insert, the vaccine is not at risk for a temperature excursion.

All of the temperature monitoring guides have been updated on our website at www.ndhealth.gov/Immunize/Providers/Forms.htm.

The updated Storage and Handling Toolkit can be found on the CDC website at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

If you have any questions, please contact the Immunization Program at 701-328-3386 or toll free at 800-472-2180.



Safe Summer Vaccine Storage and Transport Tips

As summer is here, please keep in mind that warmer weather also brings about storms and construction season. Be prepared for these events when it comes to your vaccines. In the event of a power outage, there are a few important things to keep in mind: If there is a power outage, and it seems unlikely the power will return for some time, and in the event that your facility does not have a backup generator, be prepared to transfer your vaccine to a backup facility. A qualified transport cooler or pack-out with a data logger should be used to transport your vaccine. If you cannot get vaccine to your alternate vaccine storage facility with a backup generator within a reasonable distance or cannot reach the facility, you can use the qualified containers and pack-outs to store vaccine temporarily and safely at your facility. Once the power has been restored and the temperatures have stabilized in your units, you can then transport your vaccines back to your facility. The CDC's Emergency Vaccine Transport Guide can be found online at <https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>. If you have any questions, please contact the Immunization Program at 701-328-3386 or toll free at 800-472-2180.

Calendar of Events



August

National Immunization Awareness Month

3rd & 4th – North Dakota Immunization Conference
Bismarck, ND

September

8th-9th – Got Your Shots Conference
Minneapolis, MN

13th-15th – National Immunization Conference
Atlanta, Georgia

14th – NDDoH Immunization Lunch & Learn

October

12th – NDDoH Immunization Lunch & Learn

22nd-25th - ACIP Meeting
Atlanta, GA

November

4th-6th – NFID Fall 2016 Clinic Vaccinology Course
Philadelphia, PA

9th – NDDoH Immunization Lunch & Learn



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Immunization Program

Molly Howell, MPH
Immunization Program Manager
mahowell@nd.gov

Abbi Berg, MPH
Vaccines for Children Manager
alberg@nd.gov

Lexie Barber, MPH
Immunization Surveillance Coordinator
abarber@nd.gov

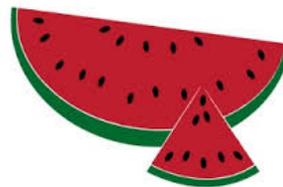
Mary Woinarowicz, MA
NDIIS Sentinel Site Coordinator
mary.woinarowicz@nd.gov

Miranda Baumgartner, MBA
VFC/AFIX Coordinator (West)
mlbaumgartner@nd.gov

Sherrie Meixner
VFC/AFIX Coordinator (East)
smeixner@nd.gov

Dominick Fitzsimmons
NDIIS Coordinator
dfitzsimmons@nd.gov

Kelsie Howes
Administrative Assistant
khowes@nd.gov



Terry Dwelle, MD, MPHTM
Molly Howell

State Health Officer

Kirby

Chief Medical Services Section
Director, Disease Control

Kruger

State Epidemiologist

Tracy Miller

Immunization Program Manager
Assistant Director, Disease Control

Published by the North Dakota Department of Health Division of Disease Control,
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