NORTH DAKOTA DEPARTMENT of HEALTH

Immunization Newsletter

Winter 2017

2017 VFC Compliance Site Visit Results

In 2017, 93 enrolled providers received a Vaccines for Children (VFC) compliance site visit, and nine providers received an unannounced storage and handling visit.

Here is a list of the most common corrective actions issued during these visits:

- Incomplete screening documentation - this includes the patient's date of birth, date of the immunization, and that the correct VFC eligibility is documented and matches the insurance the patient has on file the day of the visit
- Incomplete or missing Vaccine Management Plan
- Not having the up-to-date Vaccine Information Statements (VIS) or not knowing how to report adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Borrowing vaccine since the last VFC site visit, not having all doses documented and replaced
- Borrowing occurring as a routine practice
- Offering all ACIP recommended vaccines, including routine and non-routine vaccines (Men B and PPSV23)

Since the 2018 VFC season is now upon us, we will be contacting providers to schedule visits. If you have any questions either prior to your visit or after your visit, contact the North Dakota Department of Health (NDDoH) Immunization Program at 701.328.3386 or toll-free at 800.472.2180.

VIS Dates

Offering a VIS for each vaccine at all immunization visits, including mass clinics, is a federal requirement. A VIS can be printed and laminated for each room as long as they are sterilized between patients, or paper copies can be provided. The VIS must be offered prior to immunizations, not after. Check your VIS stock against this list. If you have outdated VIS forms, obtain the current version www.cdc.gov/vaccines/hcp/vis/current-vis.html.

Vaccine	VIS Date	Vaccine	VIS Date
Adenovirus	06/11/2014	MMRV	02/12/2018
Anthrax	03/10/2010	Multi-Vaccine	11/05/2015
Chickenpox	02/12/2018	PCV13	11/5/2015
DTaP	05/17/2007	PPSV	04/24/2015
Hib	04/02/2015	Polio	07/20/2016
Hepatitis A	07/20/2016	Rabies	10/06/2009
Hepatitis B	07/20/2016	Rotavirus	04/15/2015
HPV	12/02/2016	Td	04/11/2017
Influenza (inactivated)	08/07/2015	Tdap	02/24/2015
J. enceph.	01/24/2014	Typhoid	05/29/2012
MenACWY/ MPSV4	03/31/2016	Yellow fever	03/30/2011
MenB	08/09/2016	Zoster (Live)	02/12/2018
MMR	02/12/2018	Zoster (Recombinant)	02/12/2018

Temperature Excursion Reporting

Reporting of temperature excursions is a VFC requirement. A temperature excursion is defined as an out-of-range temperature that results in an alarm. An alarm should occur after 15 minutes below 2°C (36°F) and after one hour above 8°C (46°F). The NDDoH immunization program now has an online reporting form at www.ndhealth.gov/Immunize/Providers/ that can be used to report all temperature excursions. If you have any questions, please contact the Immunization Program at 701.328.3386 or toll-free at 800.472.2180.

2018 VFC Enrollment to Start in February

Be on the lookout! The 2018 annual VFC enrollment cycle will begin very soon! Enrollment information should be sent out to providers in mid-February, due back in March. As a reminder, all providers must enroll annually to receive VFC vaccines. When enrollment is ready, all providers will receive an email and a mailed 2018 enrollment packet. With any questions, please contact the NDDoH Immunization Program at 701.328.3386 or toll-free 800.472.2180.

Vaccine Adverse Event Reporting System

What is it?

VAERS is part of a national vaccine safety program that collects adverse events that happen after vaccination. Analysis of the events is ongoing and reports identify events that need further study by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA).

Is it required to report? What is required to be reported?

Anyone who gives a vaccine or receives a vaccine can report any significant health condition that occurs after a vaccination to VAERS. The Reportable Events Table (https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) lists conditions believed to be caused by vaccines. Health care workers are required to report any condition listed on this table to VAERS. You will need to know the vaccine type, when the vaccination was given, when the adverse event started, current illnesses and medication, history of adverse events following vaccination and patient demographics.

How do I report an adverse event?

There are two ways to report a vaccine adverse event. Go to http://vaers.hhs.gov/. You can submit the report online or download a writable PDF form and submit the form when you have it completed. You must do the reporting in one sitting. You cannot save the form online and continue the process later.

What are the strengths of this program?

- National data (from all US states and territories) is collected
- Anyone can report an adverse event
- Data collected includes vaccine information, patient information and the adverse event
- Data is publicly available
- This system can be used to detect rare adverse events
- Patient health records can be obtained when necessary

Are there limitations to this system?

- It may not be possible to determine if the vaccine caused the adverse event
- Reports submitted often lack details and contain errors
- Serious adverse events are more likely to be reported than mild side effects
- The rate of reports may increase due to media attention
- It is not possible to use this data to calculate how often the adverse event occurs in a population

Pediatric Flu Recall Letters

On January 10, the Immunization Program sent out recall letters to parents of children who are recommended to receive a second dose of influenza vaccine during the current influenza season. According to routine Advisory Committee on Immunization Practices (ACIP) recommendations, some children require two doses of influenza vaccine to be fully protected against the flu. This includes children ages six months through eight years getting vaccinated for the first time, and those who previously received only one dose of vaccine. Children who previously received two valid doses of vaccine before July 1, 2017 only need one dose of influenza vaccine this season. Below is the algorithm used to decide if a child needs one or two doses of vaccine this season.

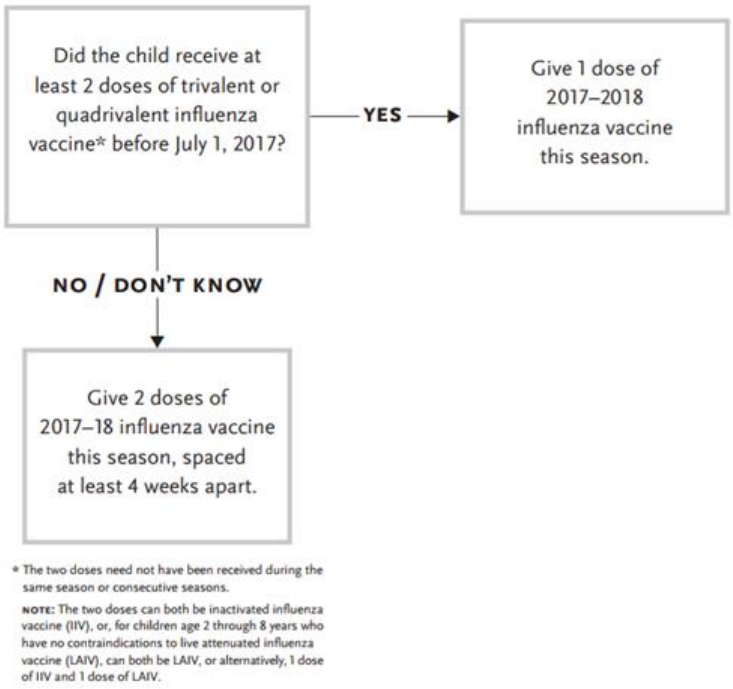


Figure 1: Adapted from Immunization Action Coalition. "Guide for Determining the Number of Doses of Influenza Vaccine to Give to Children Age 6 Months Through 8 Years During the 2017-2018 Influenza Season". http://www.immunize.org/catg.d/p3093.pdf

It is important to be aware that influenza activity is already widespread across North Dakota and children attending childcares and schools are at increased risk of picking up and spreading influenza viruses. Children ages five years and younger, those too young to be immunized, and those who cannot be vaccinated benefit from a high level of vaccination in their community for protection from serious illness. To identify children in need of immunization against influenza or in need of other vaccines, the Immunization Program strongly encourages you to run the North Dakota Immunization Information System (NDIIS) forecaster in the client record during each visit with children at your facility to check which vaccines are recommended. For more information on the reminder-recall mailings sent from the Immunization Program, including the schedule, letter and postcard formats, please refer to the Immunization Program website www.ndhealth.gov/Immunize/NDIIS/AdolescentRR.aspx.

Sentinel Site Evaluation Project - HPV Coverage

The NDIIS has recently completed an analysis of the geographic distribution of Human Papillomavirus (HPV) vaccine coverage among North Dakota adolescents ages 13-17 years. Vaccination coverage at the county and zip code level was analyzed to compare rural and urban areas, oil-producing counties and American Indian reservations.

An additional goal of this project was to compare published National Immunization Survey-Teen (NIS-Teen) coverage rates to those derived from the NDIIS. The NIS-Teen publishes yearly coverage rates for adolescents by state, and may include data stratified by race, ethnicity and other demographic factors, including for American Indian populations. The American Indian population proportion in North Dakota is one of the highest

in the United States, however, owing to our small total population size, the NIS-Teen has not previously produced information on HPV coverage among American Indians.

The results of the NDIIS study show a comparatively lower rate of HPV coverage in western, southern and southwestern counties, and higher coverage within American Indian reservation boundaries. Eastern counties and those closer to more highly populated areas also tended to have better coverage rates. Areas of particularly low and high coverage can be found on the map below:

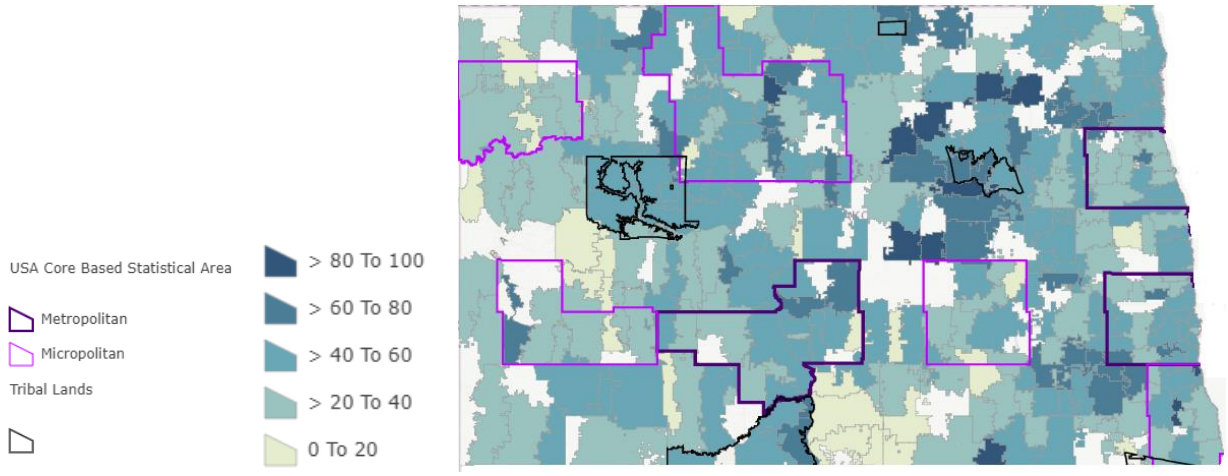
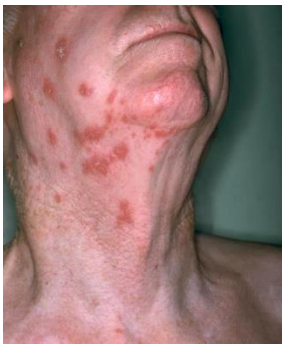


Figure 2: 2015 Female adolescent HPV three dose coverage by zip code. Zip codes with adolescent denominator <= 5 persons have been excluded from display.

Prior to this study, analysis of county-level or statewide coverage rates had not revealed the extent of geographic variability of HPV vaccination coverage within North Dakota. In conclusion, this study validates the usefulness of using NDIIS data to compare to NIS-Teen estimates, and identifies areas of potential geographic and demographic vaccination coverage disparity within our state.

October ACIP Update

The ACIP met October 25 and 26, 2017. They discussed many immunization-related issues and made some new immunization recommendations.



Herpes Zoster Vaccine:

The new Herpes Zoster subunit (HZ/su) inactivated vaccine is a recombinant, adjuvanted vaccine for the prevention of herpes zoster (shingles). It was developed by GlaxoSmithKline (GSK). On October 20, 2017, the FDA licensed this new shingles vaccine, called Shingrix®, for adults 50 years and older in the United States. Two doses of Shingrix® are to be given two months apart. The vaccine is administered intramuscularly.

Approximate cost for Shingrix® is $280 for both shots.

In clinical trials, the new shingles vaccine provided high levels of protection in all age groups against shingles and post herpetic neuralgia (PHN), the most common complication from shingles. The vaccine showed:

- 97% protection against shingles in adults 50-69 years old
- 91% protection against shingles in adults 70 years and older

- 91% protection against PHN in adults 50 years and older
- Protection of 85% or above was maintained for four years after vaccination.

In clinical trials, the most common side effect was mild to moderate pain where the shot was given. Other side effects included pain, redness or swelling where the shot was given, muscle pain, fatigue, fever, nausea, vomiting, diarrhea, headache, or shivering. The side effects generally lasted 1-2 days. Although no serious adverse events were observed, about 17 percent of people who received the vaccine did have a reaction that interfered with their activities. Providers should communicate this to patients, so they are aware that these reactions are normal. As with all vaccines, CDC and FDA will continue to monitor the news shingles vaccine for potential safety concerns.

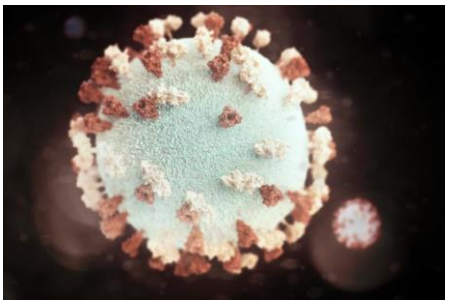
The ACIP voted that HZ/su vaccine is:

- Recommended for the prevention of herpes zoster and related complications for immunocompetent* adults aged 50 years and older
- Recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live**
- Preferred over Zoster Vaccine Live (ZVL/Zostavax®) for the prevention of herpes zoster and related complications.

**Being immunocompromised is not a contraindication or precaution to HZ/su vaccination. The ACIP will discuss formal recommendations for specific high-risk groups, including immunocompromised at an upcoming meeting.*

***CDC guidance will state an 8-week minimum interval between HZ/su and ZVL.*

Official recommendations for HZ/su will be published in early 2018 in Morbidity and Mortality Weekly Report (MMWR).



Mumps Vaccine:

Mumps is a highly contagious, vaccine-preventable disease caused by infection with a virus. Infection with the mumps virus results in tenderness and swelling of the salivary glands in the cheeks and neck. Complications from mumps include swelling of testes, swelling of ovaries, meningitis, deafness, and miscarriage. Forty-two cases of mumps were reported in North Dakota in 2017.

In the United States, mumps outbreaks have been occurring, with 50 percent of outbreaks in colleges and universities. In 2016, 6,366 cases of mumps occurred in the United States. So far in 2017, 4,677 cases have been reported. Most cases are occurring in vaccinated individuals. The median two-dose mumps vaccine effectiveness is 88 percent. Studies have shown an increased risk for mumps and decreased vaccine effectiveness with longer time since vaccination. Risk for mumps complications is lower among people who have received two doses of mumps vaccine compared with those who are unvaccinated.

In October, the ACIP made the following recommendation regarding a third dose of mumps-containing vaccine:

- Persons previously vaccinated with two doses of MMR vaccine who are identified by public health as at risk for mumps because of an outbreak should receive a third dose of MMR vaccine to improve protection against mumps disease and related complications.

Mumps is a mandatory reportable condition in North Dakota. In an outbreak situation, the NDDoH will make recommendations as to who should receive a third dose of MMR vaccine.

Official recommendations for mumps vaccine were published in Morbidity and Mortality Weekly Report (MMWR) at **www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm.**

Other Vaccines:

Other issues discussed at the October ACIP meeting include a new, adjuvanted hepatitis B vaccine, HEPLISAV-B, that will be available in the near future. HEPLISAV-B is a two-dose series, with doses only one month apart. The ACIP is expected to discuss recommendations for this new hepatitis B vaccine at the February 2018 meeting.

The ACIP also heard information about hepatitis A outbreaks currently occurring in California and Michigan. In the future, ACIP will potentially discuss hepatitis A vaccine recommendations for:

- Catch-up hepatitis A vaccination of children ages 3 – 18
- Use of hepatitis A vaccine for post exposure prophylaxis of cases older than 40
- Routine recommendation for homeless
- Vaccination of pregnant women
- Vaccination of people with chronic liver disease
- Vaccination of people with developmental disabilities who live in institutions
- Vaccination of HIV and immunocompromised individuals

The ACIP also received updates about live attenuated influenza vaccine (Flumist®), pneumococcal conjugate vaccine and its impact on those 65 and older, shoulder injuries related to vaccine administration, anthrax vaccines, Japanese encephalitis vaccine, and an RSV vaccine that is in phase II clinical trials.

For more information about the ACIP meeting, please visit www.cdc.gov/vaccines/acip/index.html.

Changes to Mandatory Reportable Conditions

The newest reportable conditions list can be found at www.ndhealth.gov/disease/Disease%20Reporting/Default.aspx. The NDDoH Division of Disease Control continually monitors the reportable conditions list in an effort to stay current with changing/emerging diseases and to remove diseases which have provided minimal value to public health improvement. As of January 1, 2018, the following changes have been made to North Dakota Administrative Rule 33-06-01.

1. Campylobacteriosis continues to be reportable, but isolates no longer need to be sent to the NDDoH Division of Microbiology.
2. Coccidioidomycosis continues to be reportable, but isolates no longer need to be sent to the NDDoH Division of Microbiology.
3. Enterococcus, vancomycin resistant (VRE) is no longer a mandatory reportable condition.
4. Hepatitis A, B, C, D, and E are all mandatory reportable conditions. For hepatitis C, nucleic acid test results (detectable or nondetectable) are reportable. Hepatitis C genotype results are also reportable.
5. HIV infection continues to be reportable. Any positive HIV test result, including gene sequencing and drug resistant patterns, is reportable. HIV nucleic acid test results (including nondetectable) are also reportable.

6. All lead blood level results are reportable. Previously, only results greater than or equal to 10 µg/dl were reportable.
7. Novel severe acute respiratory illnesses are reportable.
8. Organisms resistant to a carbapenem or with emerging antimicrobial resistance are reportable. Previously, the rules stated organisms with reduced susceptibility to a carbapenem are reportable.
9. Pertussis continues to be reportable, but isolates no longer need to be sent to the NDDoH Division of Microbiology.
10. Psittacosis is no longer a mandatory reportable condition.
11. *Staphylococcus aureus*, methicillin resistant (MRSA) is no longer a mandatory reportable condition.
12. *Streptococcus pneumoniae* (invasive) continues to be a mandatory reportable condition, but streptococcus group A and B are no longer reportable.
13. Toxic shock syndrome is no longer a mandatory reportable condition.
14. Tuberculosis infection continues to be reportable, but clarifying language was added to ensure that both tuberculosis disease and infection are reportable.
15. Unexplained and emerging critical illness and death are mandatory reportable conditions.

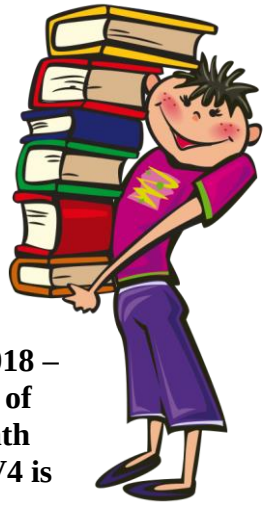
To report a mandatory reportable condition to Disease Control, go to www.ndhealth.gov/disease/reportcard/. Reports can also be made by phone by calling 701.328.2378 or 800.472.2180 (toll free) or by confidential fax at 701.328.0355. Electronic laboratory reporting is also available.

To order additional reportable conditions lists or disease report forms, log onto www.ndhealth.gov/Disease/Disease%20Reporting/. For telephone orders or for more information, please contact 701.328.2378 or 800.472.2180.

Changes to Child Care and School Immunization Requirements

As of January 1, 2018, the following changes have been made to North Dakota Administrative Rule 33-06-05, regarding child care and school immunization requirements.

- **Hepatitis B vaccine is now required for child care entry.** It was previously only required for school entry.
- Tetanus, diphtheria, and acellular pertussis vaccine (Tdap) has been required for school since the 2008 – 2009 school year, however, it has only been required for entry into seventh grade. To ensure catch-up vaccination of children moving into the state or who missed the seventh-grade requirement, additional grades were added. **Starting with the 2018 – 2019 school year, a dose of Tdap is required for eighth through twelfth grade, if missed at seventh grade.**
- Meningococcal conjugate vaccine (MCV4) has been required for school since the 2008 – 2009 school year, however, it has only been required for entry into seventh grade. To ensure catch-up vaccination of children moving into the state or who missed the seventh-grade requirement, additional grades were added. **Starting with the 2018 – 2019 school year, one dose of MCV4 is required for eighth through tenth grade. MCV4 is a two-dose series, with the second dose recommended at age 16, therefore, with the change, children are required to receive a second dose of MCV4 before being admitted to eleventh and twelfth grades.**



- **History of disease exemptions were added for all diseases that could potentially have an applicable history of disease, including**

hepatitis A, hepatitis B, measles, mumps, or rubella. Previously, history of disease exemptions were only allowed for varicella (chickenpox). **A physician signature is required for a history of disease exemption.** Previously, a parent could provide a signature for a history of disease exemption.

- **The time period for when schools are required to exclude children who are not up-to-date or who haven't submitted a record was changed from 30 days after enrollment to October 1st or 30 days after enrollment if enrolling after October 1st.**

The 2018 child care immunization requirements and 2018 – 2019 school immunization requirements can be found at http://www.ndhealth.gov/Immunize/Schools-ChildCare/.

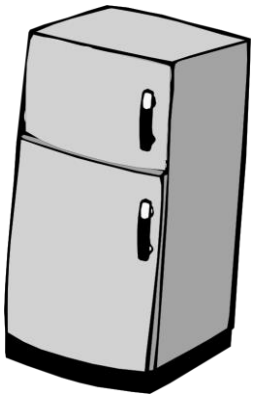
Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 (toll-free) with any questions regarding childcare and school immunization requirements.

Storage and Handling Updates

The CDC has recently released an updated Storage and Handling Toolkit. The updated toolkit can be found at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

The changes highlighted in the toolkit are:

- The CDC requires that digital data loggers are used to continuously monitor temperatures in all VFC units, vaccine transport and at mass vaccination clinics.
- Providers are required to assess and record minimum and maximum temperatures at the start of each clinic day.
- Providers are required to have a digital data logger backup thermometer in the event that the main thermometer fails.



If you have any questions please contact the immunization program at 701.328.3386 or toll-free 800.472.2180.

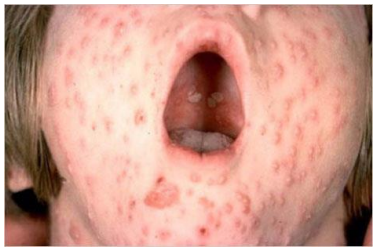
Williams County Chickenpox Outbreak

Last fall, Williams County experienced an outbreak of chickenpox disease. Although chickenpox is usually not a serious illness, it can often be more serious in adults, infants, adolescents, pregnant women, and others with weakened immune systems. During the months of October and November 2017, 28 cases of chickenpox were reported out of Williams County. All of the cases reported were younger than 18. Twenty-two cases had not been vaccinated, three cases had received two doses, and three cases had received one dose.

Although cases were clinically diagnosed by health care providers, none of the cases in the outbreak were laboratory confirmed. The NDDoH recommends that providers collect a specimen for PCR testing if a provider is suspecting varicella.

Vaccination has made the classical presentation of varicella less common, and the disease more difficult to diagnose. Breakthrough varicella rash may look similar to other disease such as hand, foot, and mouth disease (HFMD). Additionally, the vaccination has made the disease less common in general, making it more difficult to diagnose, as health care providers do not see it on a regular basis. For these reasons, laboratory testing is important.

Additionally, cases of varicella must be reported to the NDDoH by the health care provider. This is especially important if laboratory testing is not done. With the Williams County outbreak, an outbreak was already occurring before the NDDoH was made aware of any cases and these cases were reported by a child's school, not by the child's health care provider. Prompt reporting of all cases allows the NDDoH to follow up to ensure cases are excluded from activities during their infectious period and that their contacts are vaccinated. This helps to control the number of cases and prevents outbreak form occurring.



Patients infected with varicella are infectious from two days before onset of rash until all lesions have crusted over, usually 5-6 days after rash onset. Patients should be excluded from school, child care, work, or any other activities during this time. It is important to ensure all your patients are up to date on their varicella vaccinations. Children 12 to 18 months of age should be vaccinated with one dose of chickenpox (varicella) vaccine. A second dose is recommended at 4 to 6 years of age.

ND Immunization Conference Registration Now Available

The 2018 North Dakota State Immunization Conference will be held on July 17 – 18, 2018 in Bismarck. **Conference registration is now officially open** on the Immunization Program's website at www.ndhealth.gov/immunize/. Nursing contact hours will be available at the conference. Conference planners also plan to apply for physician assistant credits (AAPA Category I CME). Blocks of rooms have been reserved at the Radisson and Ramkota Hotels. Participants and vendors can find more information on the registration website.

Topics include: Childhood, adolescent and adult immunization updates, techniques for communicating with vaccine hesitant families, vaccine recommendations for travelers and immunocompromised patients, changes to school and childcare immunizations and much, much more! The agenda will be updated as speakers are added. If you are interested in speaking or have a suggestion for a break-out session, please email Abbi Berg at alberg@nd.gov.

Perinatal Hepatitis B Prevention Program

The number of births to Hepatitis B Surface Antigen (HBsAg) positive women reported to the NDDoH has continued to increase over the years. In 2010, only nine births to hepatitis B positive women were reported to the NDDoH. In 2017, that number reached 47. Hepatitis B is underreported in the state, and the number of births to hepatitis B positive women in North Dakota is likely higher than what is reported to the NDDoH. As this number continues to increase, it is important for all health care providers to become familiar with the protocols for infants born to hepatitis B positive women in North Dakota.

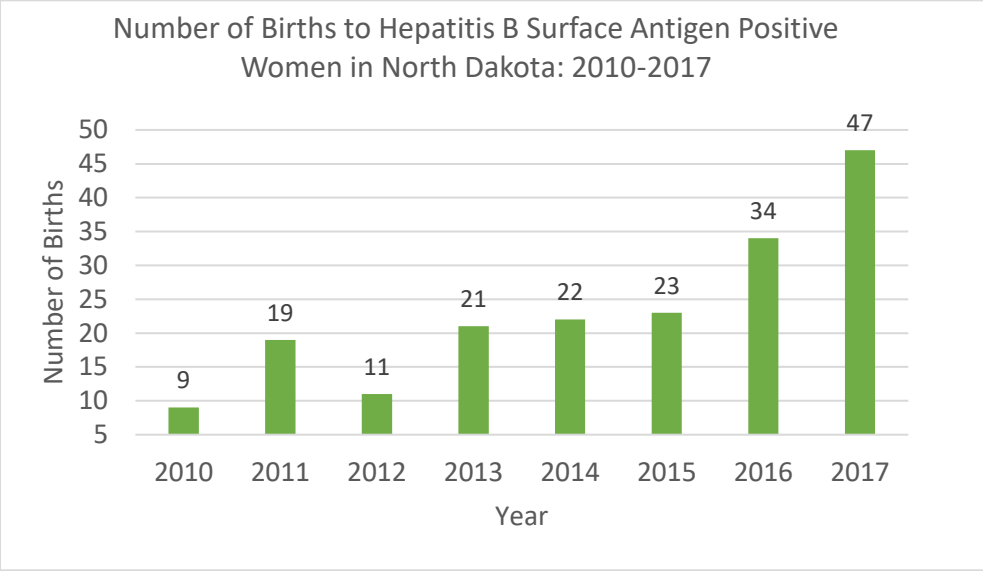


Figure 3. Number of births to hepatitis B positive women in North Dakota (MAVEN).

Perinatal Provider Responsibilities:

- All pregnant women should be screened for hepatitis B surface antigen during every pregnancy.
- Hepatitis B positive women should be reported to the NDDoH by the health care provider using the Health Care Provider Report Form (completed and faxed to 701.328.0355).

Hospital Responsibilities:

- The mother's hepatitis B surface antigen laboratory results should be reviewed upon admission to the delivery hospital. If these are not available, the woman should be tested as soon as possible.
- *After delivery, the infant should receive the hepatitis B vaccine birth dose and hepatitis B immune globulin (HBIG) within 12 hours of birth, regardless of the infant's weight.*
- The Hospital Report Form should be completed and faxed to the NDDoH (701.328.0355).

Pediatric Provider Responsibilities:

- The infant must receive the remaining two doses of hepatitis B vaccine on time. If the infant was less than 2kg at birth, the infant will need to receive three additional doses rather than two. The infants primary care provider should report all hepatitis B doses to the NDDoH using the Provider Checklist (faxed to 701.328.0355) each time the child receives a dose of hepatitis B vaccine.
- One to two months after the last hepatitis B vaccine dose, and when the child is at least nine months old, post-vaccination serological testing (PVST) should be done to ensure the child has not developed hepatitis B infection(HBsAg) and has developed adequate antibody to hepatitis B surface antigen (anti-HBs). This ensures the child is protected from the virus. The Provider Checklist should also be used to report the results of these two blood tests.
- If the infant has not developed adequate immunity (anti-HBs > 10 IU/mL), ACIP recommends one additional dose, followed by PVST (anti-HBs) to ensure the infant has seroconverted. If the infant has not, two additional doses should be given followed by another PVST. Providers may also choose to give the full series again and then test for seroconversion.

More information on the NDDoH Perinatal Hepatitis B Prevention Program, as well report forms is available on the NDDoH immunization website: http://www.ndhealth.gov/Immunize/Providers/PerinatalHepB.aspx.

NHSN Seasonal Influenza

CDC's National Healthcare Safety Network is the nation's most widely used healthcare-associated infection (HAI) tracking system. NHSN provides facilities, states, and regions with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

While ensuring data security, integrity, and confidentiality, NHSN gives healthcare facilities the ability to see their data in real-time and share that information with clinicians and facility leadership, as well as with other facilities and partners such as health departments or quality improvement organizations.

In 2018, the North Dakota Immunization Program will begin utilizing NHSN data as a strategy to increase immunization rates and evaluate health care immunization policy in North Dakota. North Dakota's 2016 - 2017 NHSN seasonal influenza immunization rates are 91% for employee vaccinations, 77% for licensed independent practitioners, and 91% for students, trainees, and volunteers, at reporting facilities. Site specific NHSN influenza immunization rates vary greatly with facilities reporting influenza immunization rates ranging from 46% – 100% and declination rates ranging from 0% – 50%, a total of 1,082 health care worker declinations in North Dakota's NHSN reporting facilities.

North Dakota Immunization Program will begin providing best practices and health care personnel immunization training for facilities with low immunization rates or high employee declination rates. For more information regarding health care worker immunization training, contact Andy Noble at anoble@nd.gov.

Tdap and Influenza Vaccination Rates in Pregnant Women in North Dakota

On October 24, 2012, the ACIP voted to recommend that providers of prenatal care implement a Tdap immunization program for all pregnant women. A dose of Tdap should be administered during each pregnancy, regardless of the woman's prior history of receiving Tdap, in order to maximize the transfer of pertussis antibodies from mom to baby. Studies have shown that maternal antibodies transferred to baby during pregnancy provide protection against pertussis for infants who are too young to begin the DTaP vaccination series. Additionally, all pregnant women are recommended to receive influenza vaccine during pregnancy for any flu season they may be pregnant.

Data from the NDIIS was analyzed to evaluate Tdap and influenza vaccination rates for pregnant women in North Dakota. Data for all North Dakota infants born during calendar years 2013-2016 was evaluated for records with mother's first and last name complete to get the population of pregnant women for the total four-year period. These records were matched to NDIIS female records in order to find Tdap doses administered and time between dose administration and baby's birthdate. Optimal timing for the administration of Tdap vaccine during pregnancy is between 27 and 36 weeks gestation. If Tdap is not administered during pregnancy, a dose should be administered immediately postpartum. The analysis assumes that babies are born at 40 weeks

gestation and looked for Tdap doses administered 13 weeks prior to baby's birthdate to one week after baby's birthdate. For 2013-2016, there were 48,778 newborn records in the NDIIS. Eighty-six percent of those newborn records had mother's first and last name complete. Of those records with mother's information complete, 26,547 (54.4 percent) had a matching NDIIS record for the mother. (Table 1)

	2013	2014	2015	2016	Total
Newborn records including mother's information	91.3%	91.3%	82.8%	78.5%	86.0%
Newborn records matched to mother's record	54.6%	57.4%	53.8%	51.9%	54.4%

Table 1. The percent of North Dakota newborn records in the NDIIS with mother's first and last name complete and matched to an NDIIS record for mom.

The percent of mothers who received Tdap during pregnancy increased from 31.5 percent in 2013 to 51.9 percent in 2016. There was no change in the overall Tdap in pregnancy rate from 2015 to 2016, however the percent of women receiving the vaccine during the recommended interval of 27-36 weeks gestation has continued to increase from 71.4 percent in 2013 to 93 percent in 2016. (Table 2)

	2013	2014	2015	2016	Total
% of mothers with dose of Tdap during pregnancy	31.5%	45.3%	51.9%	51.9%	42.7%
of mothers who received a dose of Tdap during pregnancy					
% of mothers with a dose at 27-36 weeks	71.4%	84.0%	89.7%	93.0%	83.0%
% of mothers with a dose at 37-41 weeks	22.3%	13.6%	8.4%	7.2%	13.8%

Table 2. The percent of mothers of North Dakota newborns with a dose of Tdap vaccine administered during their pregnancy according to the NDIIS.

The number of Tdap doses administered during pregnancy by type of healthcare provider was also compared, focusing primarily on family practice providers and obstetrician/gynecologists (OB/GYN) as the primary providers of prenatal care to pregnant women. When comparing doses of Tdap administered during pregnancy by the different types of providers, family practice and OB/GYN providers administered 33.8 percent and 38.9 percent of doses in 2013 respectively. The percent of doses administered by family practice providers decreased to 18.3 percent in 2016, while the percent administered by OB/GYN providers increased to 68.8 percent in 2016. (Figure 4)

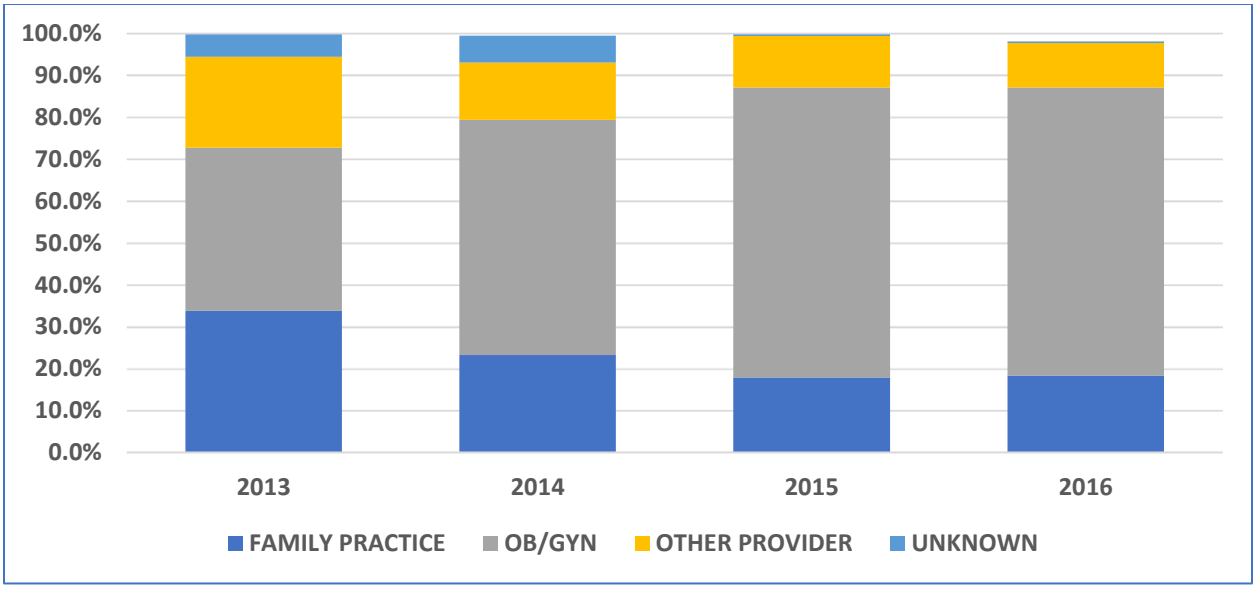


Figure 4. The percent of Tdap doses administered during pregnancy by provider type (NDIIS).

To evaluate influenza vaccination rates in pregnant women data for all North Dakota infants born during each influenza season between 2013 and 2016 was evaluated for records with mother's first and last name complete to get the population of pregnant women. These records were matched to NDIIS female records in order to find influenza vaccine doses administered. The analysis assumes that babies are born at 40 weeks gestation and looked for influenza doses administered 40 weeks prior to baby's birthdate to two weeks after baby's birthdate. For 2013-2016, there were 64,607 newborn records in the NDIIS. Eighty-two percent of those newborn records had mother's first and last name complete. Of those records with mother's information complete, 34,719 (53.7 percent) had a matching NDIIS record for the mother. (Table 3)

	2013	**2014**	**2015**	**2016**	**Total**
Newborn records including mother's information	90.0%	84.4%	77.3%	75.0%	81.9%
Newborn records matched to mother's record	57.6%	55.5%	50.6%	50.8%	53.7%

Table 3. The percent of North Dakota newborn records in the NDIIS with mother's first and last name complete and matched to an NDIIS record for mom for each flu season.

The percent of mothers who received flu vaccine during pregnancy has steadily increased from 23.4% during the 2013-2014 flu season to 30.1% during the 2016-2017 flu season. (Table 4)

	2013	**2014**	**2015**	**2016**	**Total**
% of mothers with dose of flu vaccine during pregnancy	31.5%	45.3%	51.9%	51.9%	42.7%

Table 4. The percent of mothers of North Dakota newborns with a dose of flu vaccine administered during their pregnancy according to the NDIIS.

With such high adult participation and data completeness, the NDIIS is an effective tool for looking at trends in immunization data. Using data from the NDIIS, we can see that North Dakota health care providers have responded positively to the recommendation of the ACIP to administer Tdap vaccination during each

pregnancy. Although we did see a significant increase in the administration of Tdap vaccine during pregnancy and we have seen increases in influenza vaccination rates during pregnancy, these rates should be much higher. To better protect infants from preventable diseases, more efforts are needed to educate pregnant women and healthcare providers about the importance of vaccination during pregnancy.

Flu Vaccination Rates

According to the North Dakota Immunization Information System (NDIIS), influenza vaccination rates for the current flu season are slightly higher for all age groups when compared to the same time last year. Flu vaccination rates for adults 65 years of age and older and for kids 6 months through 4 years of age continue to be higher than other age groups. Rates for adults 19 through 49 years and teens 13 through 18 years continue to be lower than other age groups.

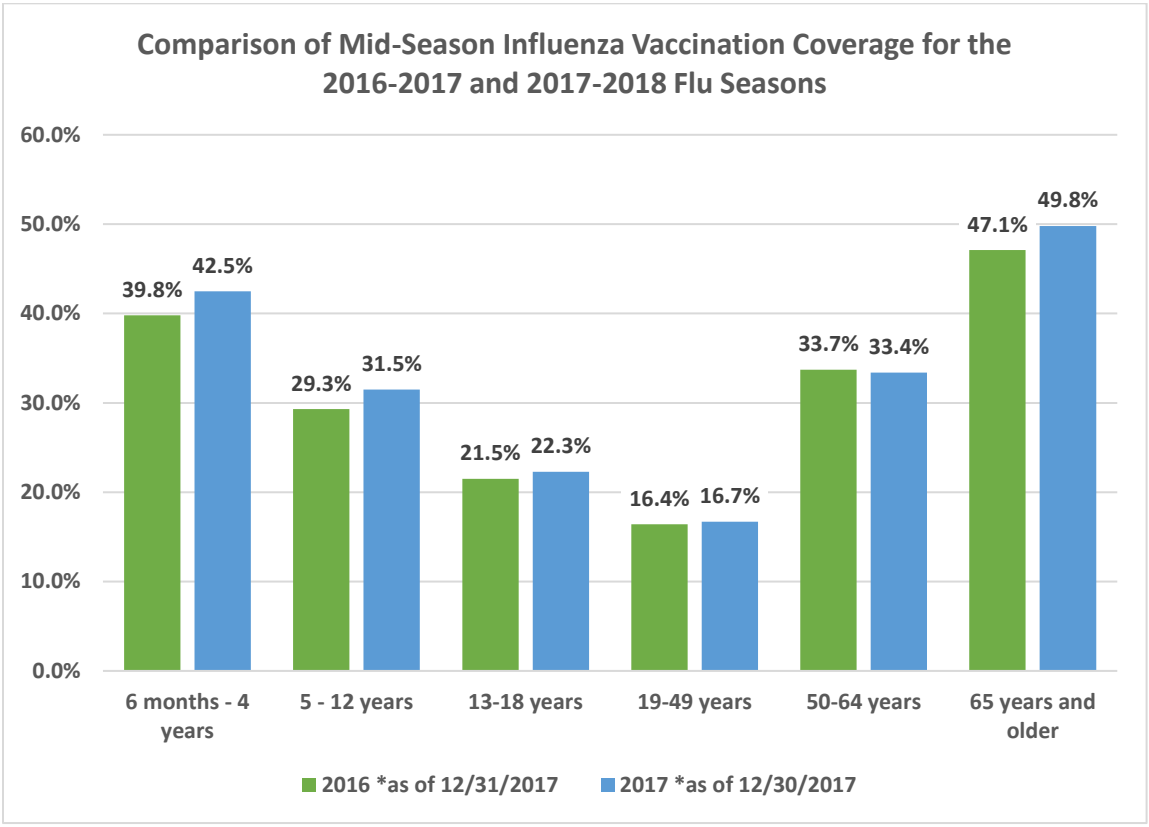


Figure 5. Percent of North Dakota residents with at least one dose of flu vaccine administered during the 2017-2018 flu season compared to the 2016-2017 flu season (NDIIS).

Flu Doses Administered

According to the NDIIS, 246,445 doses of flu vaccine have been administered to North Dakota residents so for this flu season. That is an increase from 238,535 doses for the same time period last season. The highest number of doses are administered the end of September through the beginning of November with almost 70% of flu doses administered during that 6-week time period.

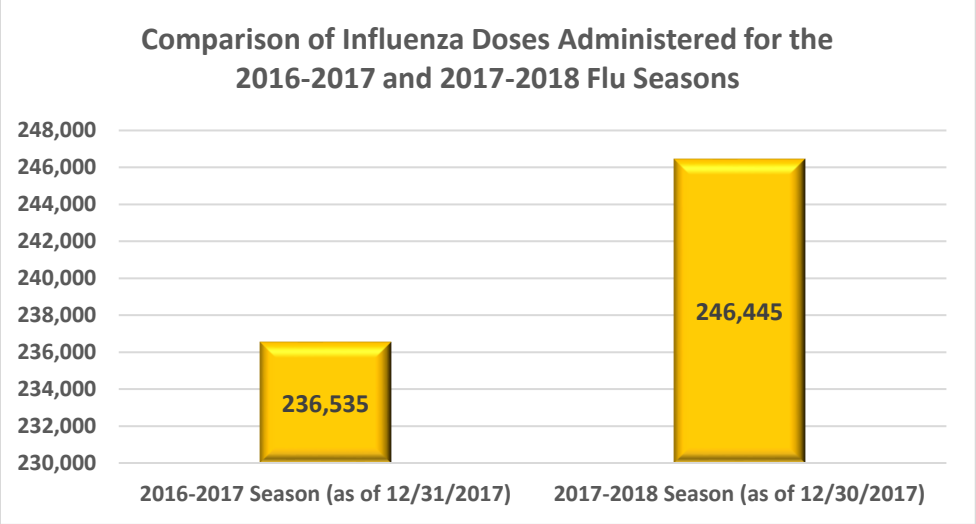


Figure 6. Total number of doses administered during the 2017-2018 flu season compared to the 2016-2017 flu season (NDIIS).

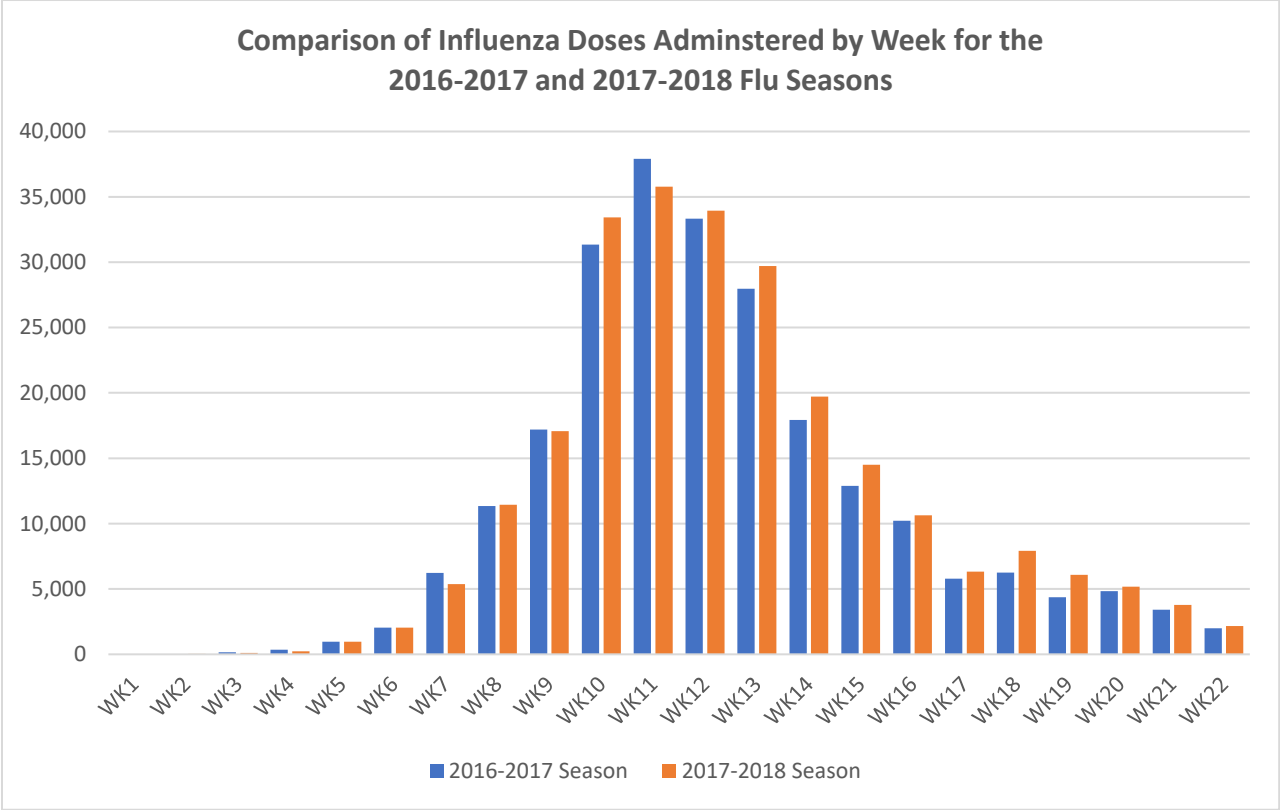


Figure 7. Influenza doses administered by week during the 2017-2018 flu season compared to the 2016-2017 flu season (NDIIS).

FDA Expanded Age Indication for Fluarix®

On January 11, the FDA Center for Biologics Evaluation and Research expanded the indication for Fluarix Quadrivalent (GSK) influenza vaccine to include use in people six months and older. Prior to this, the vaccine was only approved for use in people ages three years and older. The FDA approval letter can be found at www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM592451.pdf.

Blue Cross Blue Shield Health of America Report: Early Childhood Vaccination Trends in America

On January 18, 2018, the Blue Cross Blue Shield Association released results from a study looking at childhood immunization rates amongst children commercially insured by BCBS across the United States. The report can be found at https://www.bcbs.com/the-health-of-america/reports/early-childhood-vaccination-trends-america.

Childhood vaccination rates climbed 12 percent among BCBS young commercially insured members from 2010 through 2016. For children who are not completely vaccinated, missed well-child visits were the largest reason for under vaccination, accounting for 62 percent of under-vaccinated cases for children born in 2013. The study also found that:

- For children born in 2013, variation by state ranges from 86 percent in North Dakota to 63 percent in Nevada. Variation by metropolitan statistical area ranges from a high of 92 percent in Fargo, N.D., to a low 56 percent in Albany, N.Y.
- Medical claims coded with a parental vaccine refusal climbed from 2.5 percent for children born in 2010 to 4.2 percent for children born in 2013. Refusal rates were highest in the states of New York at 8.4 percent, Washington at 7.0 percent, Oregon at 6.8 percent, New Jersey at 6.5 percent and Arizona at 6.4 percent.
- The three metropolitan statistical areas with the highest refusal rates are all in New York. They include Nassau-Suffolk at 14.2 percent, Dutchess County at 10.3 percent and New York-Newark at 10.1 percent. The county with the highest refusal rate was Richmond County (Staten Island) in New York at 25.6 percent.

EXHIBIT 3: PERCENTAGE OF CHILDREN COMPLETING THE CDC-RECOMMENDED SEVEN-VACCINE SERIES BY STATE FOR CHILDREN BORN IN 2013 (AND COMPLETING VACCINES BY 2016)

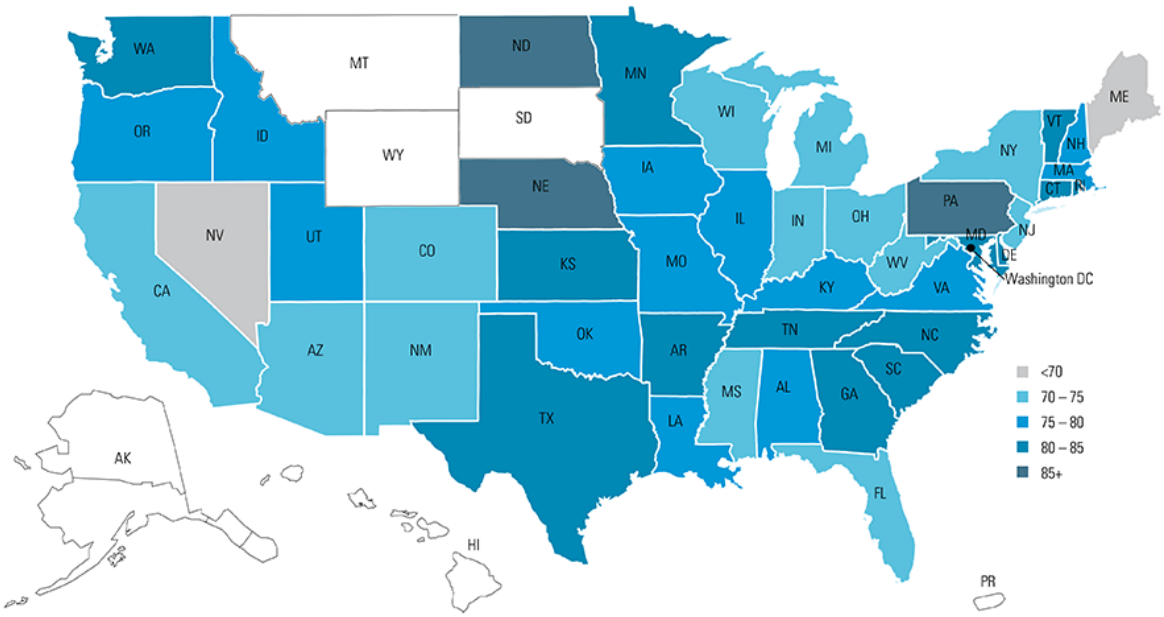


Figure 7. From the BCBS Health of America Report.

Calendar of Events

Immunization Program Lunch & Learn February 14, 2018
http://www.ndhealth.gov/Immunize/

ACIP Meeting in Atlanta, Georgia
February 21 and 22, 2018
www.cdc.gov/vaccines/acip/index.html

Immunization Program Lunch & Learn
March 14, 2018
http://www.ndhealth.gov/Immunize/

Current Issue in Immunization
Net Conference
March 21, 2018
www.cdc.gov/vaccines/ed/ciinc/index.html

Current Issues in Vaccine Webinar
March 28, 2108
www.chop.edu/centers-programs/vaccine-update/vaccine-webinar-series

Immunization Program Lunch & Learn April 11, 2018
http://www.ndhealth.gov/Immunize/

National Immunization Conference, May 15 – 17, 2018 in Atlanta, GA,
www.cdc.gov/vaccines/events/nic/index.html

National Adult and Influenza Summit, May 17 – 18, 2018 in Atlanta, GA
www.izsummitpartners.org/summit/2018-naiis/

North Dakota Immunization Conference, July 17 and 18, 2018 in Bismarck, ND https://und.edu/academics/extended-learning/conference-services/immunization

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