

# Immunization Newsletter

## FDA Approves Varicella Zoster Immune Globulin

On December 21, 2012, the Food and Drug Administration (FDA) released approval for Varizig™. Varizig™ is an Immune Globulin preparation that can reduce the severity of Varicella zoster virus (VZV) infections in high-risk individuals when it is given within four days after exposure. VZV usually causes chickenpox in children and shingles in adults.

Varizig™ is the only FDA-approved immune globulin for VZV post exposure that is available in the United States. Most people living in the U.S. have immunity to VZV from vaccination or from having had chickenpox as a child. Those who do not have immunity to VZV and are exposed to the virus may experience severe infections that can sometimes be fatal.

People that are most at risk include children or adults with weakened

immune systems, pregnant women and infants that are exposed during pregnancy or after birth.

Varizig™ is an antibody preparation manufactured from the plasma of healthy donors with high anti-VZV antibody levels. Varizig™ is administered in two or more injections depending on the weight of the recipient. It must be administered within 96 hours of exposure to lower the risk of severe or fatal infection.

The FDA has approved Varizig™ for use in immune-compromised children and adults, newborns, pregnant women, premature infants, children younger than a year old, and adults with no immunity to VZV.



## 2013 Changes to the VFC Program

The Centers for Disease Control and Prevention (CDC) has made changes to the Vaccines for Children (VFC) Program beginning January 1, 2013. An important change is the requirement for the Department of Health to conduct unannounced storage and handling compliance visits. This change was prompted by a national study showing that many facilities were not complying with storage and handling requirements. The purpose of this visit is to gauge compliance with VFC Program requirements on a daily basis. These visits will be in addition to VFC and AFIX site visits that will be scheduled. The focus of the visits will be on storage and handling related practices.

Further details will be available as part of the enrollment packets coming soon!

### Inside this issue:

National Cervical Cancer Month	2
2012 Vaccine Preventable Diseases Report	3
FDA Approves New Flu Vaccine	3
2012-2013 Influenza Update	4
Children's National Immunization	5
New Storage and Handling Recommendations	5
New Pertussis Study from California	6
Mandating Influenza Vaccine for Health-care	7
Quadrivalent FluMist	8
New Immunization Schedules	8
Lunch & Learn Schedule	9
New Tdap Recommendations	9
Save the Date	9
New Employee	10

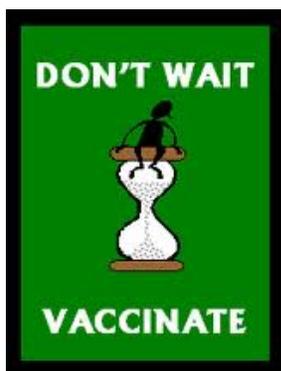
# January was National Cervical Cancer Awareness

January was National Cervical Cancer Awareness Month and the North Dakota Department of Health (NDDoH) Immunization Program continues to encourage the prevention of Human Papilloma Virus (HPV) through increased immunization. HPV causes several cancers in men and women including cervical, vulvar, vaginal, penile, anal and oropharyngeal cancer. HPV vaccine is a three-dose series that ideally should be started between 11 to 12 years of age. Regardless of sexual activity, it should be recommended to all men and women between the ages of 11 and 26 years. It is recommended to be started before the onset of sexual activity to be most effective. Once the series is started, it does not need to be restarted, regardless of the length of time between doses.

HPV vaccines HPV-2 and HPV-4 are available from the NDDoH Vaccines for Children (VFC) Program for adolescents who meet the qualifications for the VFC Program (uninsured, underinsured, Medicaid eligible, or American Indian) and for all adults ages 26 and younger who are uninsured or underinsured. Adults enrolled in Medicaid between ages 19 to 21, should be vaccinated with private vaccine and Medicaid should be billed. If the adult is between ages 22 to 26 and is enrolled in Medicaid, that person may be given state supplied vaccine because he or she is considered underinsured. HPV4 is the only HPV vaccine that is licensed for use in males because it protects against types 6, 11, 16 and 18, while HPV2 only protects against types 16 and 18 and is only licensed for use in females. There is no correlation between being vaccinated and an increase in risky sexual behavior. HPV vaccine does not protect against other STDs or pregnancy.

HPV vaccination rates in North Dakota continue to be low, with only 55 percent of girls ages 13 through 17 completing the series, well below the national average of 71 percent. In 2011, cervical cancer in North Dakota was the third most common cancer with late-stage diagnosis. In North Dakota, children 14 years and older can receive HPV vaccine without parental consent. If the child is insured but does not have parental consent, they can only be vaccinated at family planning clinics with VFC vaccine. VFC vaccine can be administered so the dose remains confidential. The vaccine, if given without parental consent, will not appear on printed immunization records.

To increase immunization rates for HPV, early conversations with parents and continued education with children and adolescents will help to boost rates in North Dakota. Practitioners across the state can encourage and recommend the vaccine to males and females and answer questions parents may have. Increasing immunization rates for HPV will protect future generations from the cancer causing HPV strains.



## Ideas to help increase immunization rates

Using the forecaster in NDIIS at all appointments, reminder recall for all second and third doses of HPV, consistent recommendations among all provider office staff, and scheduling the next appointment for immunization at the time of the first and second visits are all ways to increase rates of immunization with HPV.

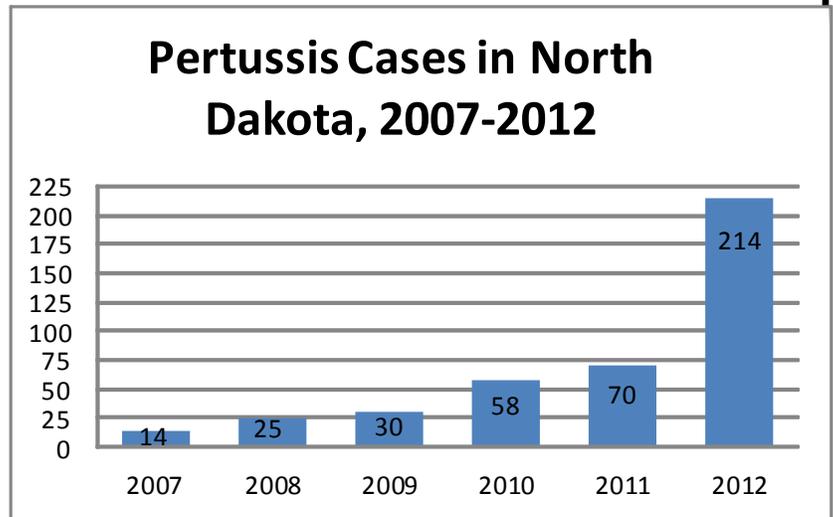
# 2012 Vaccine Preventable Diseases Report

Preliminary data indicates that 214 cases of pertussis were reported from 27 North Dakota counties in 2012. Ten of the cases were hospitalized, and 153 cases were in children and adolescents younger than 18. Pertussis cases in 2012 vastly increased in comparison to 2011 when only 70 cases were reported.

In 2012, two suspected cases of mumps were reported. The cases were from different counties and were not linked. Seven cases of mumps were reported in 2011, 4 confirmed and 3 suspect. Three cases of suspect mumps were reported in 2010.

In 2012, a confirmed case of meningococcal disease (serogroup B) was reported in North Dakota, compared to two confirmed cases (serogroup Y) in 2011 and 1 probable case in 2010. The serogroup was not able to be confirmed in the probable case.

\*No cases of rubella, diphtheria or tetanus were reported.



## FDA Approves First Seasonal Influenza Vaccine Manufactured Using Cell Culture Technology

The FDA announced January 16, 2013, the approval of Flucelvax®, the first seasonal influenza vaccine licensed in the United States produced using cultured animal cells, instead of fertilized chicken eggs. Flucelvax® is approved to prevent seasonal influenza in people ages 18 years and older. The manufacturing process for Flucelvax® is similar to the egg-based production method, but

a significant difference is that the virus strains included in the vaccine are grown in animal cells of mammalian origin instead of in eggs. Cell culture technology has already been in use for several decades to produce other U.S. licensed vaccines.

Cell culture technology is a manufacturing alternative to conventional egg-based influenza vaccine production.

Advantages of cell culture technology include the ability to maintain an adequate supply of readily available, previously tested and characterized cells for use in vaccine production and the potential for a faster start-up of the vaccine manufacturing process in the event of a pandemic.



# 2012-2013 Influenza Update

## 1. Who needs a flu vaccine?

- a) You
- b) You
- c) You
- d) All of the above

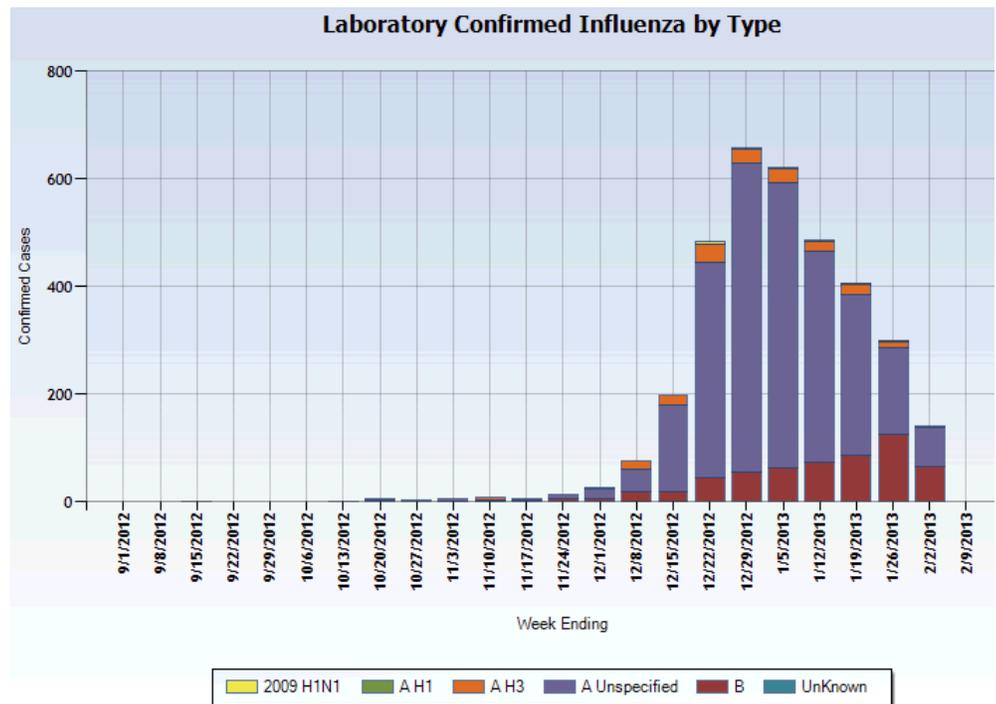
For the 2012-2013 Influenza season, there have been more cases reported nationally and in North Dakota at this time compared to last year. Typically, North Dakota sees its flu cases peak at the end of January or beginning of February. As of February 13, 2013, North Dakota has 3,434 cases of flu reported. Eight of these flu cases resulted in deaths, all of whom were older than 60. Thirty-one outbreaks have been reported in long term care facilities. Thirty of

the outbreaks have been found to be cause by Influenza A and one caused by Influenza B. The majority of all flu cases reported in North Dakota have been in children younger than 10.

If a provider begins treatment for influenza or influenza like illness in an unvaccinated patient, they should encourage the patient to be vaccinated for prevention against the other strains of flu in the vaccine. Even if the patient is currently taking antibiotics, the flu vaccine may be given.

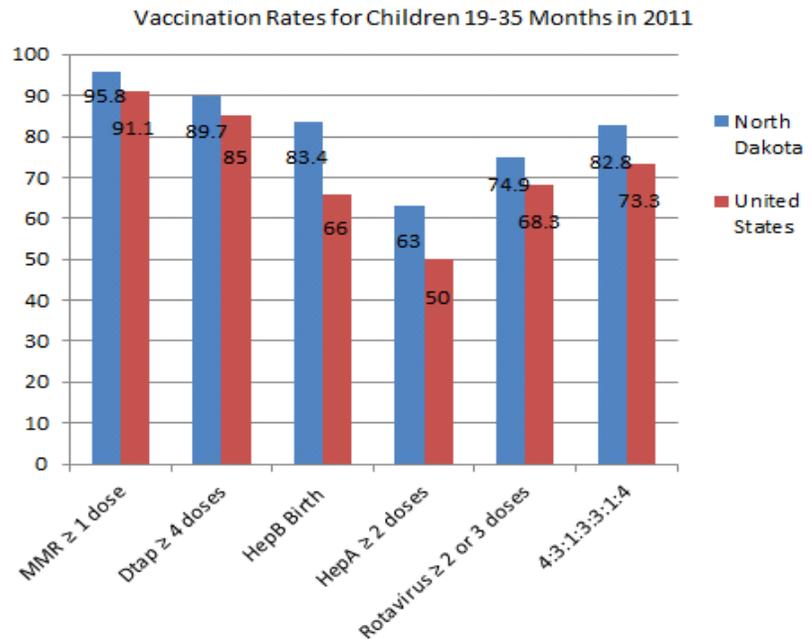
Pre-booking for VFC influenza vaccine for the next influenza season will begin shortly. To ensure adequate supply for patients, providers should evaluate their needs for their VFC eligible children that are seen in their practice.

Providers should begin recommending the flu vaccine as soon as it is available. There is a lack of evidence regarding waning vaccine effectiveness from one month to the next during flu season. A patient vaccinated in the very early fall should have similar antibody responses during the peak of flu season as a patient who has more recently received vaccine, according to a 2008 influenza vaccine effectiveness study from the *Journal of Infectious Diseases*. Vaccinating early will also prevent the expiration of FluMist® and reduce wastage of expired vaccine!



# Children's National Immunization Survey, 2011

The National Immunization Survey uses both landline and cellular phone for a random-digit dial survey to find households with children between 19 and 35 months. A mail survey was sent to identified households to collect vaccination information and the data was weighed to reflect the population of the assessed age group in each state. This information was published in the September 7, 2012, Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR).



## Updated Storage and Handling Recommendations

The North Dakota Department of Health (NDDoH) will be sending a bound copy of the CDC Storage and Handling Tool-kit with all VFC/Prevention Partnership Providers Program enrollment packets. Inside there are many new recommendations, as well as requirements for storage and handling.

A new requirement is that the use of dorm-style refrigerators is prohibited for any kind of storage or transport of VFC vaccine. Extensive testing by the CDC has shown that the temperature is unstable in dorm-style units. Any provider that has a dorm-style refrigerator at this point is required to replace it with a new storage unit. The second requirement is the guidance offered on the lowest allowable temperature for frozen vaccine, which is  $-58^{\circ}\text{F}$  or  $-50^{\circ}\text{C}$ .

The tool-kit has many recommendations for the vaccine management and emergency relocation plans to ensure that anyone working with VFC vaccine knows where the plan is and how to handle temperature excursions and relocation processes. The duties of the primary and back-up vaccine coordinators are clearly outlined and a recommendation to check stock and rotate vaccine to ensure that short dated vaccines are used and expired vaccine are removed have been changed to once weekly rather than monthly.

For facilities in the process of purchasing new equipment, the NDDoH Immunization Program strongly encourages using the recommended guidelines in the tool-kit as they could possibly become requirements in the future.



# New Pertussis Study Indicates Decreasing Protection of Last Dose of DTaP

A look at California children during the state's pertussis outbreak in 2010 revealed that protection from the DTaP vaccine wanes after 5 years, which could be fueling outbreaks.

The findings come after a warning earlier this summer from the CDC. The agency, along with state health department partners, found an unusual illness spike in Washington state 13- and 14-year-olds, which also raised the possibility of waning pertussis vaccine protection. The size of California's pertussis outbreak allowed researchers at Kaiser Permanente Vaccine Study Center (KPVSC) to examine the relationship between the time since pertussis vaccination and how likely children were to test positive for the disease.

The researchers analyzed the risk of pertussis in California children from 2006 to 2011 in relation to the time since their last dose of DTaP vaccine, finding that protection wanes 42 percent each year after the fifth dose. The amount of protection that remained after 5 years depended on the initial effectiveness of the vaccine, according to the study. For example, if the initial effectiveness was 90 percent, it would drop to 42 percent after 5 years.

Pertussis incidence was highest in kids ages 8 to 11 years, suggesting that the drop-off in efficacy after the fifth dose in school children played a role in fueling and sustaining California's pertussis outbreak. Investigators wrote that this observation was surprising, because teenagers are typically considered a pertussis reservoir and have been disproportionately affected in previous outbreaks. Nicola Klein, MD, PhD, who led the study and co-directs the KPVSC, said in a Kaiser Permanente press release that the findings suggest that pertussis control measures may need to be reconsidered.

**"Prevention of future outbreaks may be best achieved by developing new pertussis-containing vaccines or reformulating current vaccines to provide long-lasting immunity."  
-Klein**

The provisional counts of pertussis from the surveillance system indicate more than 40,000 cases of pertussis reported nationwide in 2012 and has surpassed the final number of 27,550 reported for 2010, making 2012 the hardest-hit year in decades, Clark said. Two states—Washington and Colorado—declared epidemics. Twenty-one states reported incidence rates higher than the national average of 11.6/100,000 persons. In the meanwhile, pertussis vaccination is still the best way to fight the disease and is still a very important tool, especially since there is a lot of ongoing pertussis activity, he said.



# Mandated Flu Immunization in Health-Care Workers



The 2012-2013 influenza season has brought many new flu issues into the forefront of health care. One of the most important is how to prevent people seeking health care during flu season from contracting influenza from

health-care personnel they come in contact with. Promotion of cocooning patients with community-wide immunity is an important initiative in educating personnel and patients alike about the necessity of being vaccinated.

“It becomes apparent each year that when influenza cases start to rise dramatically, usually when we don’t expect them to, that getting vaccinated for influenza early is the best way to ensure protection against getting exposed. Once influenza is in your facility, it is usually too late to implement measures that ensure that staff are not exposed and potentially spreading the virus to other patients,” said Lindsey Vanderbusch, Influenza Surveillance and Syndromic Surveillance coordinator.

The Immunization Action Coalition (IAC) encourages health-care facilities to enact “First do no harm,” from the Hippocratic Oath in regards to vaccinating employees for seasonal influenza as well as Tdap. IAC keeps a nationwide Honor Roll to recognize prime examples of influenza vaccination mandates in health-care settings. Three North Dakota facilities have been on the list since 2009, as models for implementing mandatory immunization for employees.

This year’s intense flu season has led to “a nationwide crackdown on hospital employees who have refused to be vaccinated against the flu,” according to the Grand Forks Herald. Many of the unvaccinated health-care workers have said it is an injustice to be required to put something in their body; however, others argue that the obligation to protect patients outweighs their individual rights because they can be causing harm to those they care for.

Facilities in North Dakota that joined the IAC Honor Roll include Altru Health Systems, which made it policy in 2009 that flu vaccination is a condition of employment. The only exemptions permitted are those that include severe allergy to a vaccine component, religious beliefs that forbid vaccination, or if the employee has a condition that is a contraindication for the vaccine. Other North Dakota providers that have made the IAC Honor Roll for influenza vaccination include St. Joseph’s Hospital and Health Care Center in Dickinson and Family HealthCare Center in Fargo.

Providers can apply to join the IAC Honor Roll by going to [www.preventinfluenza.org](http://www.preventinfluenza.org).

*“Encourage institutional, employer, and public health policy to require influenza vaccination of all health workers as a precondition of employment and thereafter on an annual basis, unless a medical contraindication recognized in national guidelines is documented in the worker’s health record.” - American Public Health Association*

# What's New In Immunizations?

## Quadrivalent Influenza Vaccine

MedImmune announced that for the 2013-2014 flu season, FluMist® will be a quadrivalent influenza vaccine for eligible children and adults ages 2 to 49. It is similar to the FluMist® Trivalent formula, but will now include two influenza B strains that circulate rather than only the one. FluMist® Quadrivalent is approved for the same age groups as the previous seasons of FluMist® Trivalent. It is also contraindicated for the same groups as previous years including pregnant women; immunosuppressed individuals; children younger than 2 years or adults older than 49. Contraindications also include children younger than 5 years with a history of wheezing; anyone who has had Guillain-Barre syndrome; has a weakened immune system or is living with someone with a severely weakened immune system; has problems with their heart, kidneys or lungs; diabetics; is pregnant or nursing; or currently taking influenza antivirals.

Antiviral drugs that are active against influenza A and/or B viruses may reduce the effectiveness of FluMist® when administered within 48 hours before vaccination or within two weeks following vaccination. Children and adolescents should also not be given aspirin for four weeks after getting FluMist® Quadrivalent unless directed by their health-care provider. The common side effects are runny or stuffy nose, sore throat, and fevers over 100°F.

FluMist® Quadrivalent will be available for prebooking with the VFC Program for all VFC eligible children (American Indian, Medicaid eligible, un/underinsured) at any enrolled providers, as well as insured children receiving the vaccine at universal local public health units.

---

## New Immunization Schedules Available

The Centers for Disease Control and Prevention (CDC) has released new immunization schedules that are available to be ordered for free from the CDC beginning in early March. There is a new combined immunization schedule for people ages birth through 18 and replaces the previous 0 through 6 years and 7 through 18 years schedules. These schedules reflect all changes in recommendations from 2012, new vaccine licenses, updated flu vaccine abbreviations, and the Pneumococcal Polysaccharide vaccine has been added. The CDC encourages providers to use the schedules in conjunction with the footnotes and not as stand alone references. The footnotes are helpful for identifying exceptions, contraindications, and explaining new recommendations for the administration of routine vaccines.

For providers that would like to display the schedules in an online format on their own websites, there is syndication method that allows you to copy the code for the schedules one time and they will automatically update to match the newest versions available. Visit this website for the codes: [www.cdc.gov/vaccines/schedules/syndicate.html](http://www.cdc.gov/vaccines/schedules/syndicate.html).

## Lunch and Learn Schedule 2013

In 2013, the NDDoH Immunization Program will continue to provide monthly Lunch and Learn presentations for nursing credit. Lunch and Learns will be on the second Wednesday of every month. Please look for our e-mail invitation on the first Monday and second Monday of each month to register. All Lunch and Learns will be from 12 p.m.-1 p.m. on the second Wednesday and the post-test for nursing credit will be available until the following Wednesday at 5 p.m.

March 13, 2013	August 14, 2013
April 10, 2013	September 11, 2013
May 8, 2013	October 9, 2013
June 12, 2013	November 13, 2013
July 10, 2013	December 11, 2013

### Save the Date!!!

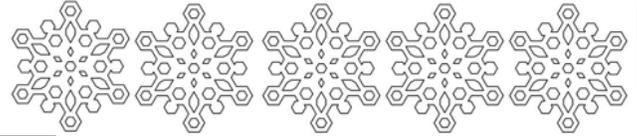
**National Adult & Influenza Vaccine Summit**  
**May 14-16, 2013, in Atlanta , Georgia**

**Vaccine Bootcamp**  
**May 21-23, 2013, in Seattle, Washington**

**Rural Health Conference**  
**June 5-7, 2013, in Mandan, North Dakota**

**North Dakota Immunization Conference**  
**June 17-18, 2014**

***\*The National Immunization Conference has  
been postponed until 2014\****



## New Recommendations for Tdap

In October 2012, the Advisory Committee on Immunization Practices (ACIP) released new recommendations for the use of Tdap during each pregnancy. Tdap should be given during each pregnancy regardless of previous Tdap vaccinations. This is to maximize the maternal antibody response and passive antibody transfer to the infant. The optimal timing of a dose during pregnancy is between 27 and 36 weeks gestation, but can be given any time. If Tdap is not administered during pregnancy, then a dose should be administered immediately postpartum only if the mother was previously unvaccinated with Tdap. Breastfeeding is not a contraindication to receiving Tdap and can allow the mother to pass antibodies to their infants if the vaccine is administered postpartum.

There is no evidence of increased adverse reactions in women receiving Tdap multiple

times. This new recommendation only applies to women who receive the Tdap while pregnant, not if they choose to receive the Tdap postpartum.

This new practice is the best way to protect infants that are not yet eligible for the DTaP vaccine. In addition to vaccinating the mother, all people that will be in close contact with the infant should also be vaccinated with Tdap if they have not yet been. This practice is known as cocooning and has been recommended by the ACIP since 2005 to provide protection to infants.

Tdap is available for uninsured and underinsured adults from the VFC Program. All enrolled providers can order Tdap for their patients that meet these parameters and are encouraged to screen expecting parents and household members for Tdap vaccination during pregnancy and before the infant leaves the hospital.



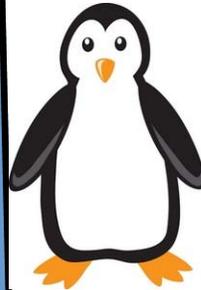
**NORTH DAKOTA**  
DEPARTMENT of HEALTH

Division of Disease Control  
Immunization Program

2635 E. Main Ave.  
P.O. Box 5520  
Bismarck, N.D. 58506-5520

Phone: 701.328.3386  
Toll-Free: 800.472.2180  
Fax: 701.328.2499

[www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize)



**REMEMBER!!!**

**Enrollment packets will be distributed in early March. Make sure to return them by the deadline to ensure the ability to order vaccine from the Immunization Program.**

## Welcome New Employee!

My name is Rahel Gemmeda. I am from Ethiopia, East Africa. I am the new Quality Assurance coordinator in the Immunization Program. I earned my Bachelor and Master's Degree in Public Health in Ethiopia. I did my second Master's degree in Infectious Disease Management at North Dakota State University. I am so excited about my new job at the North Dakota Department of Health. I have two beautiful boys, Oli and Rebir, that keep me busy. I enjoy the time I spend with them.

Molly Howell, MPH  
Immunization Program Manager  
[mahowell@nd.gov](mailto:mahowell@nd.gov)

Abbi Pierce, MPH  
Vaccines for Children Manager  
[apierce@nd.gov](mailto:apierce@nd.gov)

Amy Schwartz, MPH  
Immunization Surveillance Coordinator  
[amschwartz@nd.gov](mailto:amschwartz@nd.gov)

Mary Woinarowicz, MA  
NDIIS Sentinel Site Coordinator  
[mary.woinarowicz@nd.gov](mailto:mary.woinarowicz@nd.gov)

Janna Pastir, MPH  
VFC/AFIX Coordinator (West)  
[jpastir@nd.gov](mailto:jpastir@nd.gov)

Stacy Lovelace  
VFC/AFIX Coordinator (East)  
[slovelace@nd.gov](mailto:slovelace@nd.gov)

Rahel Gemmeda, MPH  
Quality Assurance Coordinator  
[rgemmeda@nd.gov](mailto:rgemmeda@nd.gov)

Teri Arso  
Administrative Assistant  
[tarso@nd.gov](mailto:tarso@nd.gov)

**Terry Dwelle, MD, MPHTM**

State Health Officer

**Kirby Kruger**

Chief, Medical Services Section  
Director, Disease Control

**Tracy Miller, MPH**

State Epidemiologist

**Molly Howell, MPH**

Immunization Program Manager

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

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

**EQUAL OPPORTUNITY EMPLOYER**