

**THE PRESENTATION WILL BEGIN SHORTLY. THERE WILL BE NO AUDIO UNTIL THEN.**



 NORTH DAKOTA DEPARTMENT OF HEALTH

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## **OCTOBER 2016 ACIP UPDATE**

*11/09/2016 LUNCH AND LEARN WEBINAR*

**MOLLY HOWELL, MPH**  
**IMMUNIZATION PROGRAM MANAGER**

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## **ACIP**

• **ACIP: Advisory Committee on Immunization Practices**

- The committee comprises medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States.
- The ACIP includes 15 voting members responsible for making vaccine recommendations.
- Fourteen of the members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine; one member is a consumer representative who provides perspectives on the social and community aspects of vaccination.
- In addition to the 15 voting members, ACIP includes 8 ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 non-voting representatives of liaison organizations that bring related immunization expertise.

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## ACIP

- The information that ACIP reviews for each vaccine always includes the following:
  - The safety and effectiveness of the vaccine when given at specific ages. Only vaccines licensed by the FDA are recommended, and vaccine manufacturers must conduct rigorous studies to show that a vaccine is safe and effective at specific ages.
  - The severity of the disease. Vaccines recommended for children prevent diseases that can be serious for them, potentially causing long-term health problems or death.
  - The number of children who get the disease if there is no vaccine. Vaccines that do not provide benefit to many children may not be recommended for all children.
  - How well a vaccine works for children of different ages. The immune response from a vaccine can vary depending on the age when the vaccine is given.




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## OCTOBER ACIP MEETING

- The ACIP met October 19 and 20, 2016 in Atlanta, GA.
- Agenda:
  - Hepatitis vaccines
  - Pertussis vaccines
  - HPV vaccines
  - Meningococcal vaccines
  - Herpes zoster vaccines
  - Yellow Fever vaccine
  - Zika Virus
  - Childhood/Adolescent schedule
  - Adult schedule
  - Pneumococcal vaccine
  - Influenza
  - RSV vaccine




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## HEPATITIS B VACCINE

- ACIP changed the hepatitis B birth dose recommendation by voting that the birth dose should be given within 24 hours of birth to medically stable infants weighing  $\geq 2000$  grams and born to HBsAg-negative mothers.
  - Removal of permissive language to delay the hepatitis B birth dose for HBsAg-negative mothers
  - Infants born to HBsAg-positive mothers should receive the hepatitis B birth dose and HBIG within 12 hours of birth.
  - Infants born to HBsAg-unknown mothers should receive the hepatitis B birth dose within 12 hours of birth. The mother should be tested immediately to determine status.
- Approved revised statement – consolidated all published recommendations into one




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### PERTUSSIS VACCINE

- Approved the updated statement, "Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the ACIP" – consolidated all published recommendations into one
- The new recommendations also clarify that persons 7–10 years of age who receive Tdap as part of a catch-up series may be given an additional Tdap for the routinely recommended adolescent dose at 11–12 years of age.




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### PERTUSSIS VACCINE

- **Tdap and Pregnancy:**
  - Data presented showed Tdap to be safe during pregnancy.
  - Data presented also showed Tdap vaccination during pregnancy is effective at preventing pertussis in infant.
  - Increased immunogenicity when vaccine administered earlier in pregnancy (27 – 32 weeks)
    - ACIP voted to keep the recommendation at 27 – 36 weeks, but clinicians may want to try vaccinating earlier based on data.
  - The recommendation still calls for administering Tdap vaccine immediately postpartum in women not previously vaccinated with Tdap during pregnancy.




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### HPV VACCINE

- **2-dose schedule for boys and girls initiating HPV vaccination series at 9 to 14 years (0, 6-12 months)**
  - Minimum interval: 5 months
  - FDA approval of 2-dose schedule: [http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM524629.pdf?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM524629.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery)
- **3-dose schedule for persons initiating HPV vaccination series at older ages (0, 1-2, 6-12 months)**
- **3-dose schedule for immunocompromised persons of any age**
- **The NDHIS forecaster and NDDoH educational materials will be changed to reflect the new recommendations.**




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### HPV VACCINE

- The new 2-dose recommendation applies to all HPV vaccine products.
- The new 2-dose recommendation is retroactive, meaning that if a patient started the HPV vaccine series prior to the age of 15 before the new recommendation, then they only need two doses, at least 5 months apart.
- Adolescents ages 9 through 14 years who have already received two doses of HPV vaccine less than 5 months apart, will require a third dose.
- There is not a maximum interval between doses of HPV vaccine.




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### HPV VACCINE

- HPV vaccine continues to be routinely recommended for all adolescents at ages 11 – 12.
- Routine catch-up vaccination is at ages 13 – 26 for females and 13 – 21 for males.
  - High-risk males should be vaccinated at ages 22 – 26.
- Providers should give a strong, bundled recommendation for HPV vaccine:
  - *"Today your child needs vaccines to protect them against tetanus, diphtheria, pertussis, HPV, and meningitis."*




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### MENINGOCOCCAL GROUP B VACCINE

- ACIP provided guidance on the updated dosing schedules for one serogroup B meningococcal vaccine, MenB-FHbp (Trumenba®).
  - For persons at increased risk for meningococcal disease and during serogroup B outbreaks, three doses of MenB-FHbp administered at 0, 1-2, and 6 months
  - When given to healthy adolescents not at increased risk for meningococcal disease, two doses of MenB-FHbp at 0 and 6 months
  - In April 2016, the FDA approved the 2-dose schedule for Trumenba®: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM496391.pdf>




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## MENINGOCOCCAL GROUP B VACCINE

- In 2015, ACIP recommended routine meningococcal serogroup B (MenB) vaccination for persons 10 years of age or older who were at increased risk of meningococcal infection (asplenia, complement component deficiencies, microbiologists).
- The committee also previously recommended the vaccine may be provided to healthy adolescents and young adults 16 through 23 years of age.
- ACIP did not express a preference for use of MenB-4C (Bexsero®, GlaxoSmithKline) or MenB-FHbp (Trumenba®, Pfizer), although the same product must be used for the entire series.
- Bexero® has previously been recommended for use with a 2-dose schedule for high-risk individuals and in outbreak settings, and may be administered to healthy individuals 16 – 23 years of age.




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## MENINGOCOCCAL GROUP B VACCINE

- Data presented at the ACIP meeting showed no impact on carriage of meningococcal serogroup B, meaning during an outbreak, high rates of vaccination are required.
  - A study was recently performed to determine meningococcal B carriage in an outbreak at a college in Rhode Island.
  - It is known that meningococcal serogroup C and A vaccines reduce carriage, but serogroup B vaccination reduction of carriage is not known.
  - Trumenba® was administered during a meningococcal B outbreak, and pre- and postvaccination oropharyngeal swabs were obtained.
  - Results demonstrated that 20% to 24% of participants (n = 622–878, depending on number of doses received) carried meningococcal bacteria, with 4% carrying serogroup type B.
  - Despite high carriage, only one carrier of outbreak strain was found.
  - Vaccination did not appear to affect carriage.
  - Also, persistence studies showed that while there is a decrease in titers over time, titers persist for at least 4 years.




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## HERPES ZOSTER VACCINE

- ACIP was presented data on a new zoster vaccine.
- GlaxoSmithKline Herpes Zoster vaccine (Shingrix™) submitted to the FDA on October 24, 2016.
  - Ages 50 and older
  - Inactivated
  - Adjuvant
  - 2-dose schedule
- Shingrix™ showed 90% efficacy in adults aged 70 years and older that is maintained for at least four years.
  - Cunningham et al., *N Engl J Med* 2016; 375: 1019-32. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older.




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## **YELLOW FEVER VACCINE**

- Stockpiles of yellow fever vaccine have been depleted because of outbreaks in Africa.
  - This is expected to continue through 2016.



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## **ZIKA VIRUS VACCINE**

- Updates on Zika Virus vaccine trials anticipated at February 2017 ACIP meeting.



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## **CHILDHOOD AND ADOLESCENT SCHEDULE**

- ACIP annually approves the childhood and adolescent immunization schedule.
- One of the significant formatting changes in the schedule was made to the age columns.
  - The vaccine recommendations for adolescents 16 years of age have been emphasized by placing them in a separate column from the recommendations for persons 17 – 18 years of age.
  - In making this distinction, ACIP is highlighting the importance of the 16-year-old visit to administer the recommended meningococcal conjugate (Men-ACWY) booster dose, as well as to provide the opportunity to deliver MenB vaccine and catch-up on other recommended adolescent vaccines such as HPV and Tdap.
  - Previously there was one column for ages 16 – 18 years.



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## ADULT SCHEDULE

- ACIP annually approves the adult immunization schedule.
- In addition to multiple revisions being made to improve the readability and clarity of the schedule, a significant change to the table format is that the ages 27 – 59 years will be shown as one age group in a single column.
  - Previously the age groups were in two columns, one for 27 – 49 years, and the other for 50 – 59 years.



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## PNEUMOCOCCAL VACCINE

- In 2014, ACIP voted to add PCV13 for all adults aged 65 years and older with the caveat that this recommendation should be reevaluated in 2018 and revised as needed.
- Current evaluation has shown a significant drop in invasive pneumococcal disease in children as well as adults since the introduction of PCV13 in children.
  - There has been no change in non-PCV13 serotypes.
  - From 2010 to 2015, it is estimated that PCV13 use in children has prevented 280,000 invasive pneumococcal disease cases and 20,000 deaths in all ages.
    - This is a result of both direct vaccination effects and the indirect effects of herd immunity.
  - There has been no evidence of serotype replacement at this time either.
  - It appears that most of the remaining burden of invasive pneumococcal disease in adults is due to non-PCV13 serotypes.



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## INFLUENZA

- Currently, there is little influenza activity in the northern hemisphere.
  - The few viruses circulating are a match to the current vaccine.
  - The predominant virus circulating is A(H3N2), but too few viruses are available to predict what will circulate this year.
  - The A(H1N1)pdm09 virus circulating drifted slightly in the southern hemisphere this year for the first time since 2009.



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## RSV VACCINE

- ACIP was presented data on a RSV vaccine for elderly population.
- RSV is a major cause of community-acquired lower respiratory tract disease in infants and children.
- People older than age 60 years are also regularly infected with RSV, with rates slightly lower than influenza and *Streptococcus pneumoniae* and approximately 180,000 hospitalizations per year.
- Most often, RSV causes respiratory infections that are more severe than the common cold.
- The infection is upper respiratory for the first few days but rapidly becomes a lower respiratory tract infection, making cultures difficult to obtain.
- Diagnosis of RSV in children is fairly easy based on symptoms, but it is more difficult in adults because of lack of distinctive symptoms, lower fever, worsening of chronic diseases, and lower nasal shedding.
- Novavax has completed a Phase III trial of its vaccine in adults. (Phase 3 trial did not meet pre-specified efficacy objectives )
- Studies are continuing for maternal and pediatric immunization.




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## IMMUNIZATION COVERAGE RATE UPDATE




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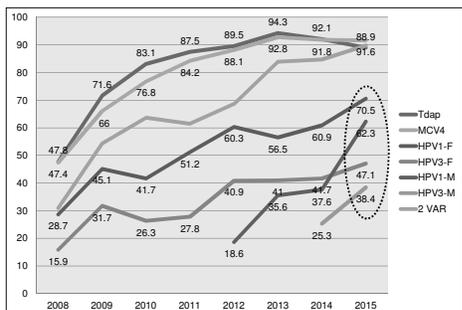
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### NORTH DAKOTA ADOLESCENT (13-17) IMMUNIZATION RATES (NIS)




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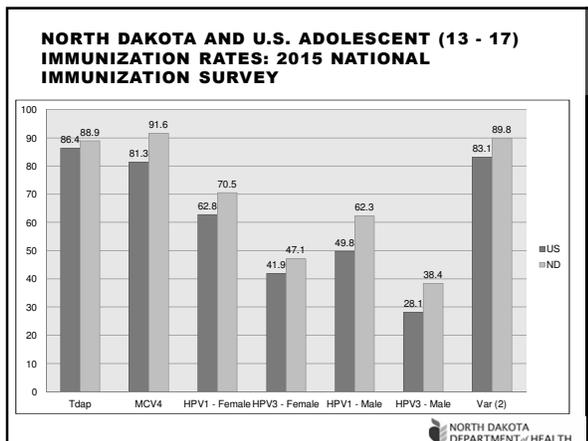
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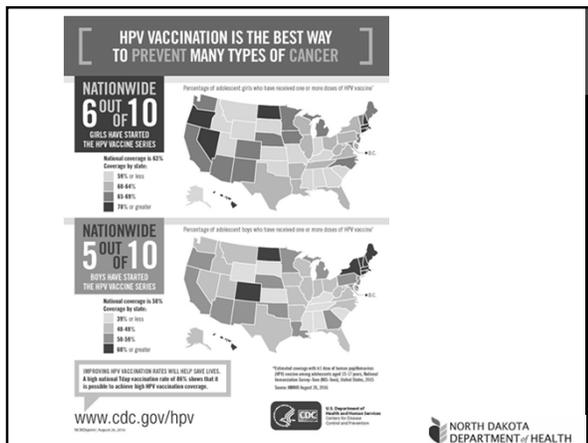
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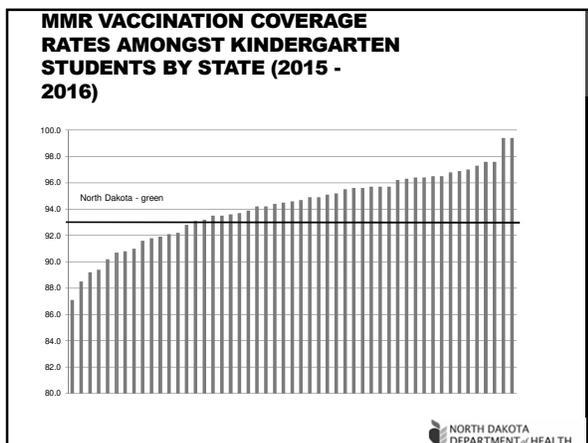
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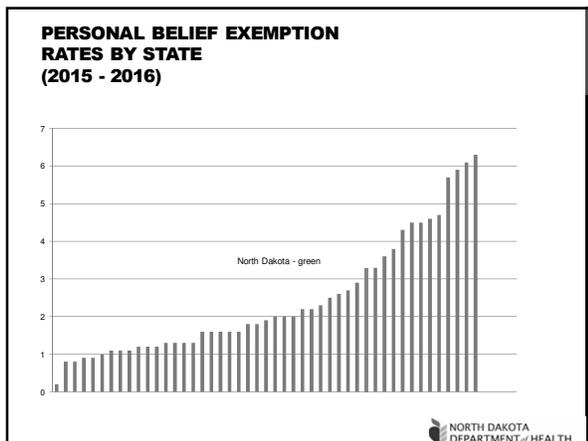
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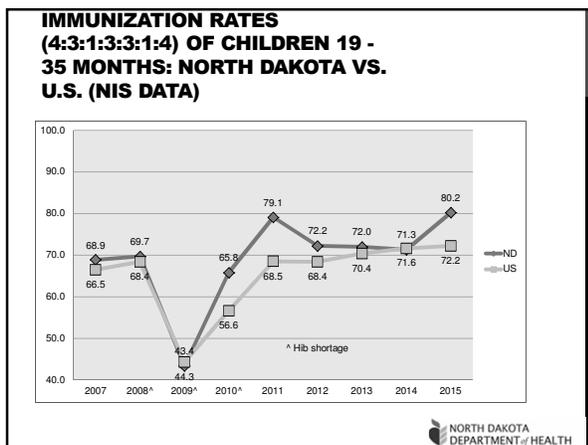
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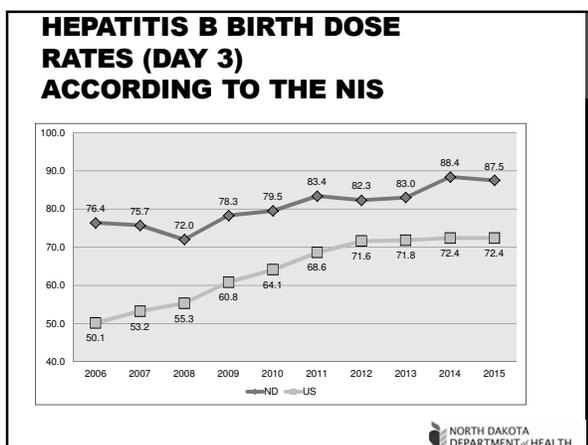
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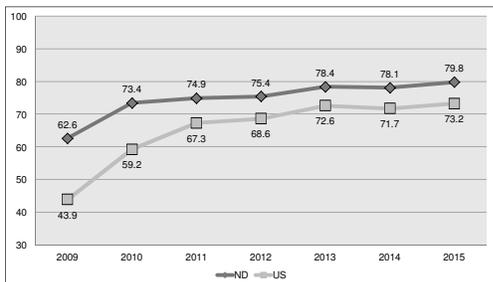
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**ROTAVIRUS UP-TO-DATE RATES FOR CHILDREN 19 - 35 MONTHS ACCORDING TO NIS**



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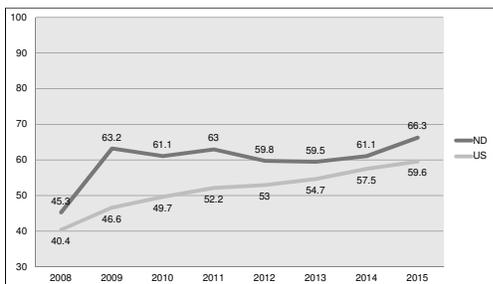
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**2 HEPATITIS A IMMUNIZATION RATE FOR CHILDREN 19 - 35 MONTHS ACCORDING TO THE NATIONAL IMMUNIZATION SURVEY**



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**NDIIS UPDATE**

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### NDIIS FORECASTER

- The new forecaster rules were implemented into the NDIIS on Wednesday October 5<sup>th</sup> at 6 pm.
- The immunization forecaster is a program that evaluates a client's immunization history and determines which vaccines they are due for, the recommended administration date and the earliest date the vaccine can be given and still be considered valid (i.e. minimum valid date) based on the recommendations of the ACIP.
- The NDIIS forecaster can be viewed from the client's immunization record page and is sent to electronic health record (EHR) systems that are connected to the NDIIS.
- The changes implemented better align the NDIIS forecaster with the CDC's clinical decision support for immunization (CDSI).
- The new rules will fix a number of currently outstanding issues with the NDIIS forecaster that providers have reported.




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### NDIIS FORECASTER

- As a result of the forecaster changes, the names of some of the vaccines on the forecaster have the letters "NOS" behind them.
  - This stands for "not otherwise specified" and should be ignored.
  - The NDIIS technical team is working to update the names of the vaccines being displayed on the forecaster and hope to have this resolved soon.
- Other errors have been identified with the forecaster and are being corrected:
  - Hepatitis B and Pediarix®
  - Polio before 2005
  - MCV4 doses before age 16




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### NDIIS EXEMPTIONS

- Previously, moral and philosophical exemptions were listed as separate vaccine exemption reasons.
- The immunization program had received feedback that it was difficult for providers and parents to differentiate between the two options and know which one to select/enter.
- As a result of this feedback and in an effort to reduce this confusion, NDDoH combined the two options into one.
- All of the other exemption reasons (medical, religious and history of disease) did not change.
- Additionally, any records with a moral or philosophical exemption entered in the NDIIS were updated to reflect this change.




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**TYPE YOUR QUESTION IN THE CHAT WINDOW TO THE RIGHT**

After the presentation, your questions may be sent to:

Molly Howell	mahowell@nd.gov
Abbi Berg	aberg@nd.gov
Mary Woinarowicz	mary.woinarowicz@nd.gov
Lexie Barber	abarber@nd.gov
Miranda Baumgartner	mibaumgartner@nd.gov
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Dominick Fitzsimmons	dfitzsimmons@nd.gov
Andy Noble	anoble@nd.gov

**Immunization Program :**  
**701.328.3386 or toll-free**  
**800.472.2180**




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**POST-TEST**

- **Post-test**
- Nurses interested in continuing education credit, visit <http://www.ndhealth.gov/disease/post/default.aspx?PostID=135>
- Successfully complete the five-question post-test to receive your certificate
- **Credit for this session available until December 9, 2016**
- **This presentation will be posted to our website:** [www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize)




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**THANKS.**

**QUESTIONS?**




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