



The presentation will begin shortly. There will be no audio until then.

Vaccines Believe It or Not: Fact and Fiction

Outline

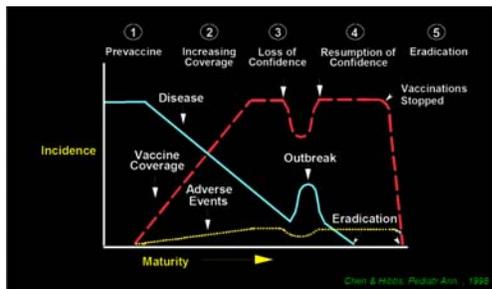
- History of vaccine safety
- Safety monitoring
- Adjuvants
- Vaccine ingredients and allergies
- Vaccines and medical complications
- Frequent administration errors
- Storage
- Handling

Why is this Important?

- Routine vaccination has led to all time low cases of preventable disease. As a result the public are disinterested in the consequences of preventable diseases and are instead focused on the risks associated with vaccines.
- While some reactions may be caused by the vaccine, many adverse events are caused by unrelated events that occur after vaccination by coincidence.



Evolution of Vaccine Program and Prominence of Vaccine Safety



National Childhood Vaccine Injury Act (NCVIA)

- Vaccine safety became a prominent topic in the mid 1970s due to an increase in lawsuits related to the DPT vaccine.
- Legal decisions were made and damages paid despite a lack of scientific evidence supporting correlation between the injury and receipt of DPT.
- As a result, prices increased, manufacturers halted production, and a vaccine shortage ensued.
- Congress passed the National Childhood Vaccine Injury Act in 1986.

National Childhood Vaccine Injury Act cont.

- The National Vaccine Program Office coordinates immunization-related activities between all Dept. of Health and Human Services agencies including the CDC, FDA, NIH, and HRSA
- Requires the distribution of VIS's when administering all routine childhood immunizations to the recipient or guardian at each visit .



National Childhood Vaccine Injury Act cont.

- Requires health care providers to report adverse events that occur after vaccination to VAERS (Vaccine Adverse Event Reporting System.)
- Created the National Vaccine Injury Compensation Program to compensate those injured by vaccine on a "no fault" basis.
- Established a committee from the Institute of Medicine (IOM) to review literature on vaccine side effects and find limitations to our knowledge of risks associated with vaccines.

Safety Monitoring

Safety Monitoring

- Vaccine safety is measured by the number of adverse events that are reported.
- Adverse Event- a medical incident that takes place after an immunization and is believed to be caused by the immunization
 - True reactions to the vaccine
 - Events that would have occurred even if the person had not yet been vaccinated
 - Reactions related to mistakes in preparation, handling or administration
 - Events that cannot be related directly to the vaccine (unknown cause)

Pre-licensing Safety Studies

- Before a vaccine is licensed by the FDA they are tested extensively, some longer than 10 years, first tested with animals and then approved for human testing
- There is a standard of a 3 phase clinical trial with human subjects
 - 20-100 volunteers lasting for only a few months to identify basic safety and very common side effects
 - Several hundred volunteers for several months- 2years to determine composition, number of necessary doses, and create a profile of common side effects
 - Several hundred to several thousand volunteers for several years to compare the vaccinated group to unvaccinated people and identify true side effects
- Only after all phases have been completed successfully and the FDA is satisfied with the safety can a vaccine be licensed for use.

Post-licensing Safety Monitoring

- The FDA requires manufacturers to submit samples from all vaccine lots prior to their release and must include their test results for vaccine safety, potency, and purity.
- Each lot is tested due to the sensitivity to environmental factors like temperature and production related contamination.
- VAERS is also used to determine any connection between the lot of vaccine and the reaction that may be subject to further study.
- In the last 10 years only 3 vaccine lots have been recalled
 - One was mislabeled, one contaminated during production, and one after potential manufacturing problems were discovered at one plant.

Reasons for Safety Monitoring

- **Rare Reactions-** Although vaccines are tested extensively before they are licensed for use in the United States, not enough people are included in the tests to detect reactions that happen only rarely. If serious reactions are found when the vaccine is in widespread use, the vaccine may be withdrawn.
- **Higher Risk Groups-** Vaccine safety monitoring also makes sure new vaccines are safe for groups such as the elderly, those with chronic medical conditions, and pregnant women. Vaccine trials may deliberately exclude members of these groups.
- **Public Confidence-** Monitoring vaccine safety also helps to maintain public confidence needed to keep enough people vaccinated to prevent disease outbreaks.

Result of Long Term Safety Monitoring

- After a purified acellular pertussis combination vaccine (DTaP) was licensed for use in place of the older whole cell pertussis, several studies have confirmed that DTaP is effective at preventing disease and mild/serious side effects are reported less frequently.
- The ACIP changed polio vaccine recommendations to a sequential series of IPV and OPV in 1997 to produce high levels of protection and reduce by 50-70% vaccine associated paralytic polio.
 - Since 2000, only IPV is recommended
 - There have been no polio cases in the U.S. since 1999

Vaccine Adverse Event Reporting System: VAERS

- When a reaction to a vaccination or what is believed to be due to a vaccine, it is to be recorded in VAERS.
 - Does not prove causality
 - Can report if a patient breaks a leg walking out of the clinic.
- Highly sensitive and can detect new, unusual or rare vaccine adverse events
- If it is indicated that the reaction led to hospitalization, life-threatening illness, disability, or death the events are classified as serious and will often be subject to further study
- The program collects data to reflect any increase in reactions to certain vaccines or vaccines from specific manufacturers for analysis



Vaccine Ingredients

Adjuvants

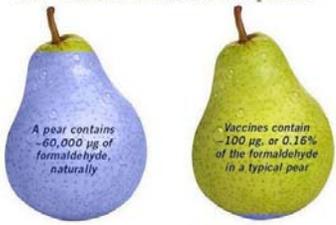
- Adjuvants are substances added to vaccine to increase the body's immune response to the vaccine
- Aluminum gels and salts are the only adjuvants licensed in the U.S. now.
 - Small amounts of aluminum are added to help stimulate better responses to vaccine.
 - Aluminum is one of the most common metals found in nature in air, food, and water
- Adjuvants are used in Hep A, Hep B, DTaP, Tdap, Hib, HPV, and pneumococcal vaccines



Vaccine Additives

- Antibiotics
 - Prevents growth of bacteria during production and storage of the vaccine (no vaccine produced in U.S. contains penicillin.)
- Egg protein
 - Used in some influenza and yellow fever vaccines, from chicken eggs.
- Formaldehyde
 - Used to inactivate bacterial products for toxoid vaccines, kills unwanted viruses and bacteria that might contaminate the vaccine during production. Most is removed from the vaccine prior to packaging.
- Monosodium glutamate (MSG)
 - And 2-phenoxy-ethanol are used as stabilizers in a few vaccines to help the vaccine remain unchanged when the vaccine is exposed to heat, light, acidity, or humidity.
- Thimerosal
 - A mercury containing preservative that is added to vials of vaccine that contain more than one dose to prevent contamination and growth of potentially harmful bacteria.
 - With the exception of some flu vaccines, it has not been used in childhood vaccines since 2001.

Concerned about formaldehyde in vaccines? Consider the pear...



A pear contains ~60,000 µg of formaldehyde, naturally

Vaccines contain ~100 µg, or 0.16% of the formaldehyde in a typical pear

The amount of formaldehyde in a vaccine is so tiny that it doesn't even affect the naturally occurring levels of formaldehyde in a child's blood.

Refutations to Anti-Vaccine Memes

Allergies

- People that have a life-threatening allergic reaction to any vaccine components should not receive the vaccine.
- Anyone with known life-threatening allergy to the following vaccine ingredients:
 - Egg for some influenza and yellow fever vaccines 
 - Yeast for Hep B vaccine, HPV vaccine and Menveo
 - Neomycin in MMR
 - Neomycin or gelatin in MMRV, Varicella and Herpes Zoster
 - Neomycin, streptomycin, or polymyxin B in IPV 

Vaccines and Medical Complications

Pregnancy and Influenza Vaccine

- Pregnant women are contraindicated for receipt of the Live Attenuated Influenza Vaccine but inactivated flu vaccine has been subject to much research
 - Influenza vaccination during pregnancy allows passive immunity to the baby in the form of flu antibodies. Protection from these antibodies has been shown to protect infants for several months.
 - Research has shown no association between receiving flu vaccine during pregnancy and miscarrying. Studies of women receiving flu vaccine during the first trimester indicated that they were no more likely to miscarry than their unvaccinated peers.

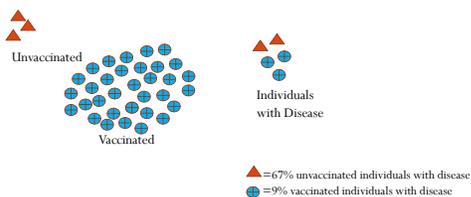
Risk of Disease Vs. Risk of Vaccine

DISEASE	VACCINES
Measles <ul style="list-style-type: none"> • Pneumonia: 6 in 100 • Encephalitis: 1 in 1,000 • Death: 2 in 1,000 	MMR <ul style="list-style-type: none"> • Encephalitis or severe allergic reaction: 1 in 1,000,000
Rubella <ul style="list-style-type: none"> • Congenital Rubella Syndrome: 1 in 4 	DTaP <ul style="list-style-type: none"> • Continuous crying, then full recovery: 1 in 1000 • Convulsions or shock, then full recovery: 1 in 14,000 • Acute encephalopathy: 0-10.5 in 1,000,000 • Death: None proven
Diphtheria <ul style="list-style-type: none"> • Death: 1 in 20 	
Tetanus <ul style="list-style-type: none"> • Death: 2 in 10 	
Pertussis <ul style="list-style-type: none"> • Pneumonia: 1 in 8 • Encephalitis: 1 in 20 • Death: 1 in 1,500 	

Why do people who are vaccinated still get the disease?

- This occurs because...
 - Almost everyone is vaccinated.
 - No vaccine is 100% effective.
 - In an outbreak, the NUMBER of vaccinated people who get a disease will be greater than the number of unvaccinated people simply because the percentage of unvaccinated people is so small. However, the PERCENTAGE of vaccinated people getting the disease will be tiny, whereas the percentage of unvaccinated people getting the disease will be close to 100%
- Most childhood vaccines are very effective when properly administered and all doses are received according to the recommended schedule (80-100%, depending on the vaccine)

Vaccinated vs. Unvaccinated



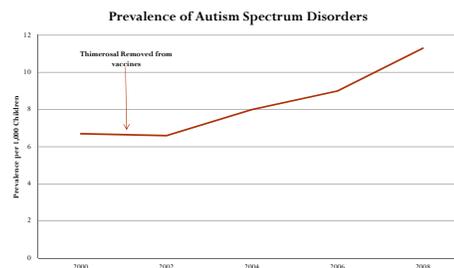
Vaccines and the Immune System

- Many parents are concerned with overwhelming a child's immune system when administering several vaccines in one appointment.
- There is no evidence that giving all recommended childhood vaccines can overload the immune system. From the moment of birth, people are exposed to numerous bacteria and viruses daily.
- A child with a cold is exposed to 4-10 antigens and strep throat is 25-50 antigens.

Thimerosal and Autism Spectrum Disorder (ASD)

- A rise in ASD diagnosis in the early 2000's caused the public to question a connection between ASD and thimerosal-containing vaccines. The CDC was aware of concerns from when thimerosal was used as a preservative in other vaccines that children may have received and the misconception that these vaccines were related to autism.
- Since 2001, with the exception of multi-dose vials of flu vaccine, thimerosal is not used as a preservative in routinely recommended childhood vaccines.
- Only associated with minor reactions like redness or swelling at the injection site and rare allergic reactions.
- Several studies conducted by the CDC, IOM and independent study groups found that children with ASD conditions and children without ASD conditions had similar ethyl mercury exposures between gestation and 20 months of age
- Thimerosal containing vaccine did not increase the risk of any of the ASD outcomes in any of the conducted studies

Autism Spectrum Disorder and Thimerosal



ASD and Vaccines

- Many parents worry about "too many vaccines too soon"
- A study released in March 2013 addresses this concern.
 - Comprehensive review by the Institute of Medicine
 - Found no causal relationship between certain vaccine types and autism
 - Examined the amount of antigens received on one day of vaccination and the amount in total during the first two years of life
 - Found no connection to ASD.
 - Total amount of antigens from vaccines received was the same between children with ASD and those that did not have ASD.
 - The number of vaccine antigens has decreased in recent years .
 - In 2013 the maximum number of antigens a child would be exposed to is 315.
 - In the late 1990s a child was exposed to several thousand antigens.

Too many too soon?

Worrying if the infant vaccine schedule will overwhelm your baby's immune system is like worrying about a few drops of water getting you wet when you are swimming in the ocean.



HPV Vaccine Safety

- Approximately 56 million doses of HPV4 were distributed in the US between 2009-2013
- 21,194 adverse events were reported after receiving HPV4
 - 92.1% of these were classified as non-serious.
 - Most frequently reported symptoms have been fainting, dizziness, nausea, headache, fever, hives and localized pain, redness and swelling at the injection site.
 - 7.9% of reports were classified as serious
 - Headache, nausea, vomiting, fatigue, dizziness, syncope, and generalized weakness were the most common symptoms reported.
- Additionally, three population based published studies of HPV4 vaccine have been done in the U.S.
 - One study found an increased risk for syncope. There have been no serious safety concerns in these large post licensure observational studies.

Chiropractors

- A number of chiropractors are proponents of the anti-vaccine movement.
- The chiropractic profession was founded by Daniel David Palmer, a magnetic healer in the 1890s.
 - The basis of chiropractic philosophy considers 95% of disease to be a result of spinal nerve dysfunction caused by misplaced vertebrae.
 - Once a person's body is properly aligned it can self-heal
- Early dogma refuted the germ theory and was anti-vaccine
- A subset of chiropractors continue to be anti-vaccine.
 - The official position of both the American Chiropractic Association (ACA) and the International Chiropractors Association (ICA) is that they support each individual's freedom of choice when it comes to vaccinating,

Pope Response to the Issue of Fetal Tissues in Vaccine Development

- The Vatican condemned the methods used to manufacture some vaccines.
 - Certain vaccines are produced using cells which were derived from aborted fetal tissue.
- Letter released addressing original statement.
 - Stated that Catholics have a moral responsibility to use alternative vaccines if available
 - However, for those without alternative means of vaccinating, **should continue to use vaccines in order to avoid a serious risk not only for one's own children but also, and perhaps more specifically, for the health conditions of the population as a whole - especially for pregnant women**
 - Catholics should continue to advocate for vaccines made without fetal tissue but are morally justified as an *extrema ratio* due to the necessity to provide for the good of one's children and of the people who come in contact with the children (pregnant women).

Vaccine Administration Errors

Tdap instead of DTaP

- This is an administration error.
 - It cannot be counted as valid for the 1st, 2nd, or 3rd doses of DTaP and should be repeated with DTaP.
 - It may be counted as valid if used for the 4th or 5th dose of DTaP.
 - The DTaP is given to a patient age 7 or older can be counted as valid for the one-time Tdap dose.

Kinrix before 4th birthday

- Use of Kinrix in a child that is not yet 4 years old is off label use and is not recommended.
- Kinrix should be used for the last doses of IPV and DTaP for children 4-6 years only
 - The minimum age for the final dose of IPV is 4 years as is the minimum age for the 5th dose of DTaP.
 - If the dose is given to a younger child but meets the minimum intervals for both components at the time the dose is given then the dose can be counted as valid.
 - Precautions should be taken to prevent this error. This vaccine should not be routinely used in the off label age groups.

Pneumovax(PPSV23) instead of Pevnar(PCV13)

- PPSV23 is not effective in children less than 24 months of age. If given between 0 and 24 months the dose should not be considered part of the pneumococcal vaccination series.
 - PCV13 should be administered as soon as the error is discovered and the patient should be notified of the mistake.
- PCV13 may be used in adults with certain high risk conditions but should not be administered at the same time as PPSV23.
- Patients that need both and who have received neither should receive PCV13 first, followed by a dose of PPSV23 at least 8 weeks later.

Zostavax instead of Varicella

- This is a serious administration error and should be documented.
 - Zoster vaccine contains about 14 times as much varicella vaccine virus as varicella vaccine.
 - If this is the child's first dose of varicella-containing vaccine they will still need the second dose of varicella-containing vaccine on schedule.
- If an adult 50 years or older receives varicella instead of zoster vaccine they would not be sufficiently immunized and should receive a dose of zoster immediately if the error is discovered at the same visit. If not discovered until later, the zoster should be given no sooner than 28 days after the varicella was given.

7 Patient Rights

What is a Vaccine Administration Error?

- Vaccine Error
 - Any preventable vaccine administration that is considered an inappropriate use of a vaccine or may cause patient harm.
- Vaccine Adverse Health Event
 - Health effects that occur after immunization that may or may not be causally related to the vaccine.

Reduce Administration Errors

- The "Rights of Medication Administration" should be applied to each encounter when vaccines are administered. These rights include:
 - the right patient;
 - the right vaccine or diluent;
 - the right time*;
 - the right dosage;
 - the right route, needle length, and technique;
 - the right site; and,
 - the right documentation.
- *(includes administering at the correct age, the appropriate interval, and before vaccine or diluent expires)

Right Patient

- Right name? Has the patient received immunizations under another name?
- Date of birth?
- Has the patient been screened for precautions and contraindications?
- Do you have a current copy of the immunization record or NDIS Forecaster?

The Right Vaccine

- Check the label at least 3 times.
 - Before you draw up
 - After you prepare
 - Before you administer
- Check that you have the correct diluent.



The Right Time

- Use the vaccine schedule
 - Right age
 - Right minimum interval
 - NDHS Forecaster
 - www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/age-interval-table.pdf
- 4-day grace period
- Before the expiration date of the vaccine



Vaccine and dose number	Recommended and Minimum Ages and Intervals Between Doses			
	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Measles II (MgII) ^{1,2}	15m	12m	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3	6-18 months	24 weeks
Diphtheria tetanus acellular pertussis (DTaP) ^{3,4}	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months ^{5,6}	6 months ^{7,8}
DTaP-4	15-18 months	12 months	7 years	6 months ⁹
DTaP-5	4-6 years	4 years
Tetanus toxoid reduced antigen type 6 (TT) ^{10,11}	2 months	6 weeks	2 months	4 weeks
TT-2	4 months	10 weeks	2 months	4 weeks
TT-3	6 months	14 weeks	6-8 months	6 weeks
TT-4	12-15 months	12 months

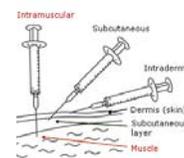
The Right Dosage

- Pediatric versus adult vaccines
 - DTaP/DT v. Tdap/Td
 - PCV13 v. PPSV23
 - Varicella v. zoster
- Flu vaccines
 - Fluzone (Sanofi Pasteur): available for ages 6 months-35 months
 - Fluzone (Sanofi Pasteur): available for ages 3 years and older
 - Fluarix (GSK): available for ages 3 years and older
 - Fluvirin (Novartis): available for ages 4 and older
 - Afluria (CSL): available for ages 9 and older
 - FluMist (Medimmune): available for ages 2- 49 years
- Multidose vials of Fluzone can be used for 6 months and older



The Right Route

- Oral
- Intranasal
- Subcutaneous (SC)
- Intramuscular (IM)
 - Needle length



The Right Site

- Immunization site maps are available from the CDC
- infants 0 to 12 months
 - IM injections are given in the infant's thigh
 - SC injections may be given in the arm or thigh
- 12 months and older
 - Anterolateral thigh is the preferred site for multiple IM injections and for all toddlers aged 12 months-2 years
 - Deltoid is an IM option for children aged 12 months-2 years with adequate muscle mass.
 - Deltoid is the preferred site for age 3 years and older
- Preteens, adolescents and adults
 - Deltoid is preferred; anterolateral thigh may be used. No buttocks!



The Right Site cont.

- During appointments with multiple injections separate the sites by 1-2 inches
- Using combination vaccines will decrease the number of injections.
 - IM needle lengths = 1 inch
 - SC needle lengths = 5/8 inch
 - May consider using a 5/8 inch needle for IM injections **only** in newborns less than age 4 weeks.

The Right Documentation

- To ensure that the correct number of doses are given
- Limit vaccine waste
- Prevent adverse events
- All state supplied vaccine is required by law to be documented by lot number
- The patient name, date of birth, date vaccine is administered, VIS date, lot number and manufacturer, person administering vaccine, name and address of the facility, funding source (state or private vaccine) and VFC eligibility are required to be recorded for every dose.
- Updating patient demographics should be done at every encounter.

VACCINE ADMINISTRATION RECORD
NORTH DAKOTA DEPARTMENT OF HEALTH
SDH 10305 (12-2011)

Information collected on this form will be used to document authorization for receipt of vaccine(s). Information may be shared through the North Dakota Immunization Information System (NDIIS) with other entities in accordance with North Dakota Century Code 23-01-05.3.

Provider ID: _____

Patient's name: (Last, First, Middle) _____

Race: (Check box)
 American Indian or Alaskan Native
 Asian
 Black or African American
 Native Hawaiian or other Pacific Islander
 White

Hispenc or Latino: (Circle) Yes No Date of birth: _____ Age: _____ Gender (Circle): Male Female

Address: (Street or P.O. box) _____ City: _____ State: _____ Zip code: _____ County: _____ Birth state or birth country (if not U.S.): _____

Primary telephone number: _____ Work telephone number: _____ E-mail address: _____

Mother's name (if patient is 18 years or younger): Last, First, Middle _____ Mother's maiden name (if patient is 18 years or younger): _____

A copy of the appropriate Centers for Disease Control and Prevention Vaccine Information Statement(s) has been provided. I have read, or have had explained, the information about the disease(s) and the vaccine(s) listed below. There was an opportunity to ask questions and all questions were answered satisfactorily. I believe that I understand the benefits and risks of the vaccine(s) listed, and ask that the vaccine(s) listed below be given to me or to the person named above (for whom I am authorized to make this request).

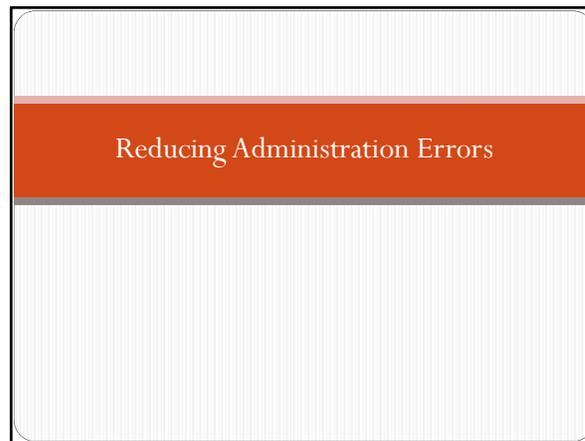
Signature - Person to receive vaccine or person authorized to sign on the patient's behalf: _____ Date: _____

VFC eligibility status: (Check all that apply) THIS SECTION MUST BE COMPLETED FOR ALL CHILDREN YOUNGER THAN 19.
 American Indian Medicaid-eligible No insurance Underinsured (vaccines not covered by health insurance)
 Not eligible (vaccines covered by health insurance) Other state eligible

✓	Vaccine(s) to be given	Route ¹	VIS date ²	Manufacturer ³	Lot number	SP ⁴	Admin. site ⁵	Person admin. ⁶
	DTaP	IM		GSK SP				
	DTaP-HepB-IPV (Pediarix [®])	IM		GSK				
	DTaP-IPV/Hib (Pentacel [®])	IM		SP				
	DTaP-IPV (Kinrix [®])	IM		GSK				
	Hepatitis A	IM		GSK MSD				
	Hepatitis B	IM		GSK MSD				
	Hep A+Hep B (Twinrix [®])	IM		GSK				
	Hib (w/ influenzae type B)	IM		GSK MSD SP				
	IPV	IM		GSK MSD				
	Influenza	ID/IM/IN						
	IPV	IM/SQ		SP				
	MMR	SQ		MSD				
	MMRV	SQ		MSD				
	Meningococcal Conjugate	IM		NOV SP				
	Pneumococcal Conjugate	IM		PFZ				
	Pneumococcal Polysaccharide	IM/SQ		MSD				
	Rotavirus	PO		GSK MSD				
	Td	IM		MBL SP				
	Tdap	IM		GSK SP				
	Shingles	SQ		MSD				
	Varicella	SQ		MSD				

Exemption or contraindication: _____ Date of exemption or contraindication: _____

Signature and title of person administering vaccine: _____ Date vaccine administered: _____



Made an Error, Now What?

- Document the error that occurred.
- Contact the patient or parent to inform them of the error.
- Check the patient's status.
- Explain what the next steps will be.
 - Revaccination
 - No need to repeat the dose

Addressing Errors

- Determine how and why the error occurred.
 - Lack of training
 - Improper storage
 - No clear procedure for immunization appointments.
- Develop a strategy for preventing errors by modifying education or immunization processes.
- Document all errors and all stages of the correction/addressing process.
- Report to VAERS if necessary.

Reduce Administration Errors

- Use the 7 Rights of Medication Administration listed earlier.
- Staff training and education for all personnel who administer vaccines.
 - Comprehensive competency based trainings before administering vaccines.
 - Providers need to validate staff's knowledge and skills using a standard list of requirements.
 - Include training as part of new staff orientation
 - Annual education requirements that can be met with educational opportunities provided by the immunization program or required for VFC program enrollment.

Provider Strategies to Prevent Errors

- Only used standardized ACIP vaccine abbreviations for all documentation
- Keep current reference materials available for staff
- Rotate vaccines to use the shortest outdates first and check frequently.
- Do not store sound-alike and look-alike vaccines next to each other.
- Store private and state supply vaccines separately.
- Separate adult and child vaccines or use a color coding system.

Type your question in the chat window to the right

This presentation will be posted to our website: www.ndhealth.gov/immunize

- After the presentation, questions may be sent to:
 - Molly Howell mahowell@nd.gov
 - Abbi Pierce apierce@nd.gov
 - Mary Woinarowicz mary.woinarowicz@nd.gov
 - Amy Schwartz amschwartz@nd.gov
 - Stacy Lovelace slovelace@nd.gov
 - Rahel Gemmeda rgemmeda@nd.gov

• For any immunization questions, call 701-328-2378 for the Immunization Program



Post-test

- Post-test
 - Nurses interested in continuing education credit, visit www.ndhealth.gov/immunize/posttest/
 - Successfully complete the five-question post-test to receive your certificate
- Credit for this session available until Wednesday, March 26th.

