

# Preventing Vaccine Errors in the Real World: Providing Better Protection to Prevent Vaccine Preventable Diseases

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# Outline

- Prevention measures
- Vaccine Storage and Handling
- Administration
- Scheduling
- Documentation

# Staff Training

- ▶ Never assume
- ▶ Provide a new employee training session for everyone
  - ▶ Professional staff: nurses, MDs, NPs, PAs
  - ▶ Support staff: office managers, clerical
- ▶ Provide ongoing training
  - ▶ Immunization Action Coalition (IAC) e-mail newsletter
  - ▶ NYS immunization Newsletters

# Clinic Resources

- ▶ CDC Education and Training for Health Professionals: <http://www.cdc.gov/VACCINES/ed/default.htm>
- ▶ IAC: <http://www.immunize.org/>
  - ▶ <http://www.immunize.org/dvd/>
- ▶ EZIZ <http://eziz.org/resources/vaccine-admin-job-aids/>
- ▶ Patient Education: <http://www.cdc.gov/VACCINES/ed/patient-ed.htm>
- ▶ Vaccine Safety: <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm>

# Rotavirus Vaccine Administration Errors

- ▶ Jan 31, 2014 MMWR “Rotavirus administration Errors- US 2006-2013”
  - ▶ 39 reports of administration by injection
  - ▶ 6 reports of RV1 vaccine given incorrectly ly by one nurse not properly trained and had not read the package insert
  - ▶ 19 of 39 documented adverse events including irritability and injection site redness
  - ▶ Why?:
    - ▶ **Inadequate training** and not reading package insert
    - ▶ Misinterpreted package insert instructions
    - ▶ Confused RV1 oral applicator with a syringe for injection
    - ▶ Confused RV1 vial with a vial used for injectable vaccine

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# Vaccine Storage and Handling

- Vaccines are fragile and must be kept at recommended temperatures at all times
- Vaccines are expensive
- It is better to not vaccinate than to administer a dose of vaccine that is ineffective

# Avoid Storage and Handling Problems

- Assign a vaccine coordinator and back up
- Store all vaccines appropriately
- Monitor and record refrigerator and freezer temperatures twice daily
  - Use only certified calibrated thermometers
  - Maintain temperature logs for three years
- Establish and test a vaccine emergency protocol
  - Use protocol in the event of an emergency
- Take immediate action for out-of-range temperatures
- Do NOT store food/beverages in refrigerator or freezer with vaccines

# Vaccine Handling Basics

- Open only one vial at a time
- Store vaccine vials separately from other medications or biologics
- Keep light sensitive vaccines in their box until they are ready to be used
- Rotate vaccine stock, using the vaccine with the shortest expiration date first
- Do NOT store vaccines in the door or crisper drawers of the refrigerator or on door of the freezer

# Prefilling Syringes

- ▶ Prefilling syringes is strongly discouraged by CDC
  - ▶ May result in vaccine administration errors and waste
    - ▶ May consider in situations of heavy use of a single vaccine
  - ▶ Consider using manufacturer-supplied prefilled syringes
  - ▶ Syringes other than those filled by the manufacturer should be discarded at the end of the clinic day
    - ▶ Manufactured pre-filled syringes that have had the caps removed and a needle attached to the syringe should be discarded at the end of the day

# Improper Storage and VPD Outbreaks

- ▶ Clinical Microbiology Reviews 1995: Measles Outbreaks 1989 – 1991
  - ▶ Improper cold storage has been associated with vaccine failure
  - ▶ Improper handling practices may be more common than was previously thought
  - ▶ Majority of private pediatricians practiced many improper vaccine storage techniques, such as having refrigerators at temperatures higher than recommended for vaccine integrity or leaving temperature-sensitive vaccine out at room temperature for hours at a time
- ▶ AAP News 2011: findings suggest Improper vaccine storage may have led to pertussis outbreaks

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# Correct Vaccine Administration

- ▶ Provide staff with training opportunities and resources on most current vaccine administration practices
- ▶ Adhere to Occupational Safety & Health Administration (OSHA) guidelines for employee safety

# Administration Errors

- Wrong vaccine or diluent
- Wrong dosage
- Expired vaccine
- Incorrect route/site /needle size

# Administration Error: Similar Packaging?

## Check the vials 3 TIMES

- PPD (tuberculin skin test)
- DT
- Td



**Check the vial 3 TIMES!!!!**

**Check the vial 3 TIMES!!!!**

**Check the vial 3 TIMES!!!!**

# Administration Error: Tdap, DTaP or Td?

California Department  
of Public Health,  
Immunization Branch

<http://www.cdph.ca.gov/programs/immunize/documents/imm-508.pdf>

**Check Your Vials: is it Tdap, DTaP or Td?**

**Tdap: Tetanus, Reduced Diphtheria, Acellular Pertussis** **Preteens - Adults**

- ADACEL™ (small pertussis)** Ages 11-14 years
- Boostrix™ (small pertussis)** Ages 10-64 years

**DTaP: Diphtheria, Tetanus, Acellular Pertussis** **Infants - Young Children**

- ADAPICEL™ (small pertussis)** Ages 6 weeks up to 7 years
- Infanrix™ (small pertussis)** Ages 6 weeks up to 7 years
- DTaP-IPV™ (small pertussis)** Ages 6 weeks up to 7 years
- Pediaris™ (small pertussis)** Ages 6 weeks up to 7 years
- Pentacel™ (small pertussis)** Ages 6 weeks up to 7 years

**Td: Tetanus, Diphtheria**

- Td (small pertussis)** Ages 7 years and older
- Boostrix™ (small pertussis)** Ages 6 years through 6 years

Age restrictions for use of products in the IMZ program may differ from age indications on the package or in the package insert. Not all formulations are available from the IMZ program. **Questions: Toll-free: 877-246-8631 (877-246-IMZ)**

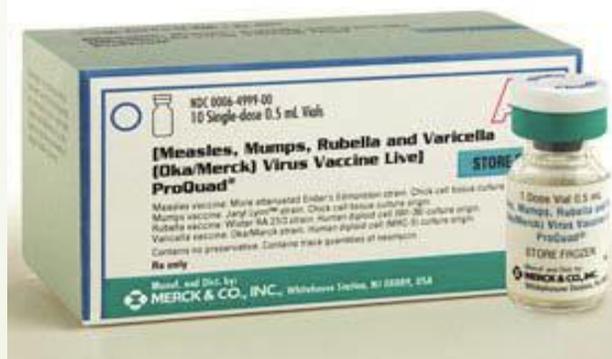
# Pertussis Vaccine Errors

- ▶ DTaP vaccine administered to adult
  - ▶ More diphtheria and pertussis antigen than is recommended
  - ▶ Count as dose, but prevent error in future
- ▶ Tdap given to an infant instead of DTaP
  - ▶ If dose 1, 2 or 3, it should not be counted, vaccinate according to schedule with DTaP
  - ▶ If dose 4 or 5, can be counted as valid
  - ▶ Check the vial 3 times before administering
- ▶ Tdap vaccine administered to an 8 year old
  - ▶ ACIP “off label” recommendation
  - ▶ *Not an error* if child has less than 3 doses of pertussis containing vaccine

# Administration Error: Varicella-Containing Vaccines



**Varivax**  
(12 mos of age and older)



**ProQuad MMRV**  
(12 months through 12 years)



**Zostavax**  
(60 years of age and older)

# Varicella Vaccine Errors

- ▶ An 8 month old erroneously given varicella vaccine
  - ▶ Is likely to have residual passive varicella antibody from his or her mother
    - ▶ The vaccine probably will have no effect, and no action is necessary
  - ▶ The dose should not be counted, and the child should be revaccinated at 12 through 15 months of age
- ▶ A child inadvertently receives zoster vaccine rather than varicella vaccine
  - ▶ Serious vaccine error – contains 14x the antigen
  - ▶ Can be counted as one dose of varicella vaccine
  - ▶ If first dose, child should receive the 2<sup>nd</sup> dose of varicella vaccine
- ▶ Zoster vaccine is administered to adult HCW instead of varicella vaccine
  - ▶ Not acceptable as proof of varicella immunity
  - ▶ If no evidence of prior immunity, count as dose #1 of the 2 dose series

# Administration Error: Giving the Wrong Vaccine

Can lead to:

- More vigorous local reactions to additional doses
- Additional cost
- Inconvenience to patient /parent
- Loss of faith in provider or staff

# Administration Error: Giving the Wrong Vaccine (cont.)

## ➤ Scenario 1:

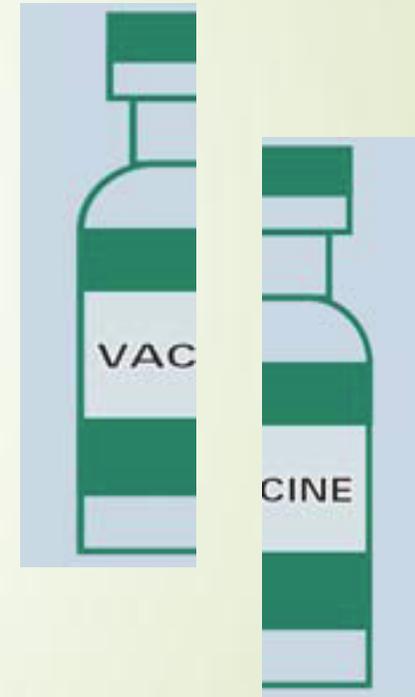
- If an adult patient got a child's dose of hepatitis B vaccine, should the patient be given an adult dose? If so, how soon?
  - If given less than a full age appropriate dose, dose is *invalid* and should be revaccinated as soon as feasible
  - Exception: If a patient sneezes after nasal spray vaccine or if an infant regurgitates, spits, or vomits during or after receiving oral rotavirus vaccine

## ➤ Scenario 2:

- A 5-year-old presented for "catch up immunizations" but was given an adult dose of hepatitis A. What are the side effects or other possible issues?
  - If you give more than an age-appropriate dose of a vaccine, count the dose as *valid* and notify the patient/parent about the error
  - Using larger than recommended dosages can be hazardous because of excessive local or systemic concentrations of antigens or other vaccine constituents

# Administration Error: Split or Partial Doses

- Split or partial (incomplete) doses are NOT valid doses
- This includes situations where the patient moves before the injection is completed
- Exceptions to partial doses:
  - Live attenuated influenza vaccine (LAIV) if person sneezes.
  - Rotavirus if infant regurgitates, spits out, or vomits.

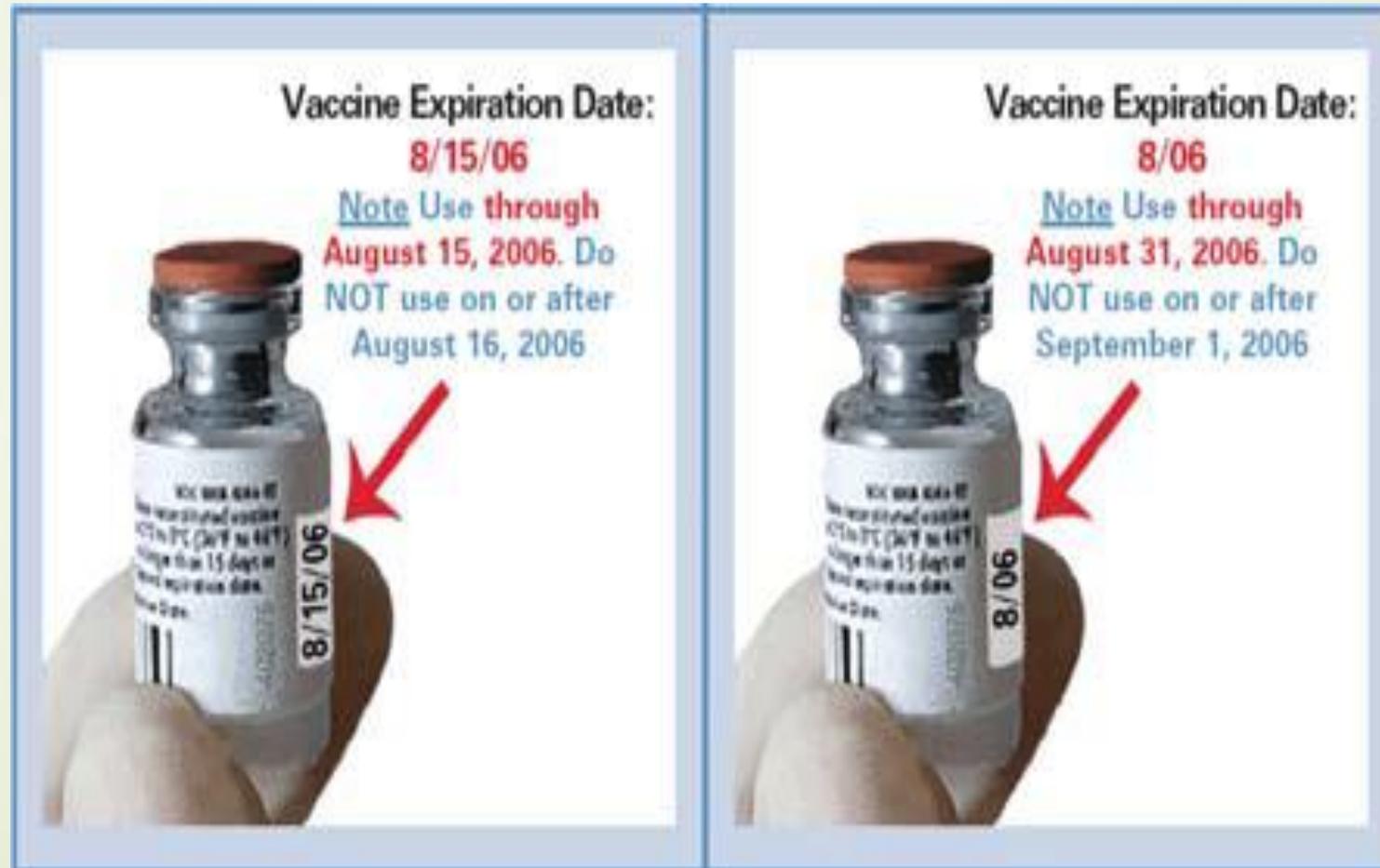


# Administration Error: Combining Vaccines

- ▶ Vaccines should NEVER be combined in the same syringe unless U.S. Food and Drug Administration (FDA) approved for this purpose and combined by manufacturer

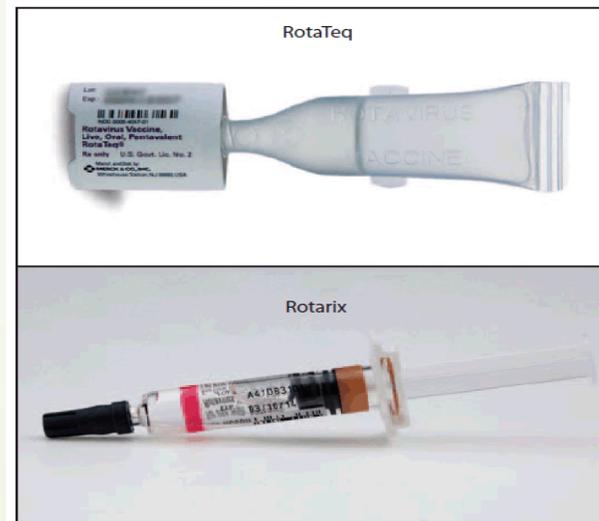


# Administration Error: Using Expired Vaccine



# Expired Vaccine Errors

- ▶ Numerous calls April and May 2014 of expired rotavirus vaccine being administered



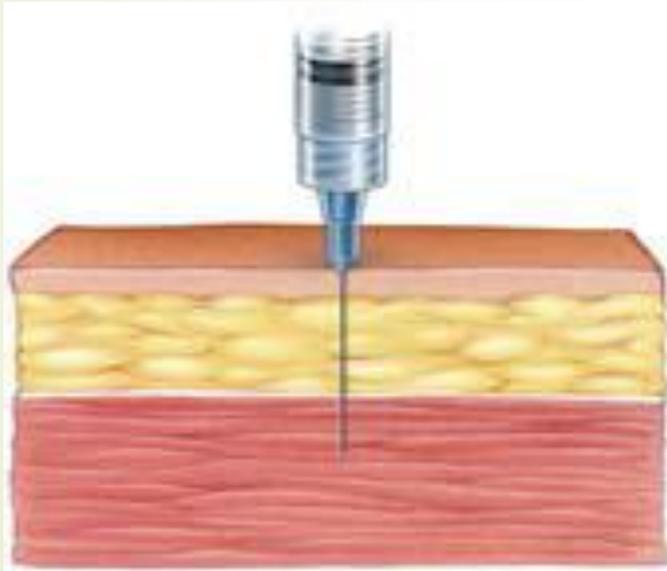
- ▶ Expired Meningitis vaccine administered after refrigerator “cleanup”
- ▶ Single vial put in box with vaccine expiring at a later date



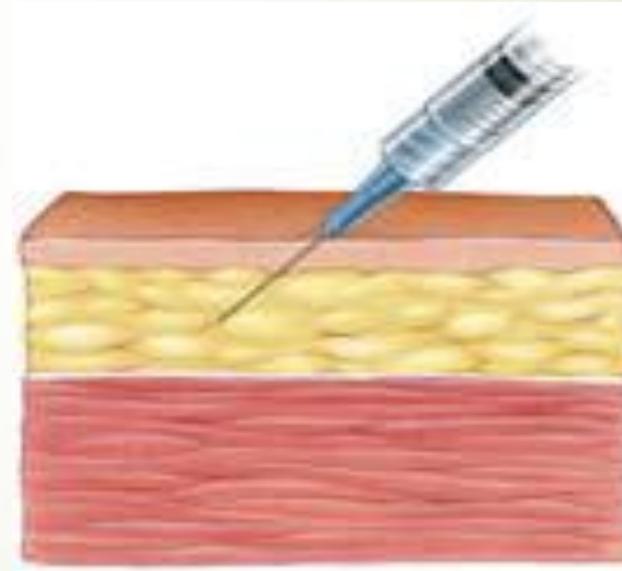
Consult with local health department and vaccine manufacturer  
Doses of expired vaccines that are administered inadvertently generally should not be counted as valid and should be repeated.

# Administration Error: Incorrect Route, Site, or Needle Size

Intramuscular (IM)



Subcutaneous (SC)



# Administering Vaccines: Site and Needle Size

## Injection Sites and Needle Size

### Intramuscular (IM) injection

Use a 22–25 gauge needle. Choose the injection site and needle length appropriate to the person's age and body mass.

<u>Age</u>	<u>Needle Length</u>	<u>Injection Site</u>
Newborns (1 <sup>st</sup> 28 days)	5/8"	Anterolateral thigh muscle
Infants (1-12 mos)	1"	Anterolateral thigh muscle
Toddlers (1-2 yrs)	1-1 1/4" 5/8-1" *	Anterolateral thigh muscle or deltoid muscle of arm
Children & teens (3-18 years)	5/8-1" * 1-1 1/4"	deltoid muscle of arm or Anterolateral thigh muscle
Adults 19 yrs or older		
Male or female less than 130 lbs	5/8-1" *	deltoid muscle of arm
Females 130-200 lbs Males 130-260 lbs	1 - 1 1/2"	deltoid muscle of arm
Females 200+ lbs Males 260+ lbs	1 1/2"	deltoid muscle of arm

\*A 5/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

## Injection Sites and Needle Size

### Subcutaneous (SC) injection

Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person's age and body mass.

<u>Age</u>	<u>Needle Length</u>	<u>Injection Site</u>
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

Reference: Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book), Appendix D

# Administration Errors

- ▶ Zostavax given IM instead of SC
  - ▶ Vaccine administered by the wrong route can be counted as valid
  - ▶ Exceptions: Hepatitis B or Rabies vaccine given by an route other than IM ( and in deltoid or anterolateral thigh muscle) should *not be counted as valid and should be repeated*

REMEMBER ROTAVIRUS VACCINE STORY

# Vaccination Errors and How to Prevent

- Prevention Measures
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# Important Dosage Resource

- CDC Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink book), Appendix A:

“Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines”

[www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf)

Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines <sup>a</sup>				
Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Hepatitis B (HepB)-1 <sup>b</sup>	Birth	Birth	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3 <sup>c</sup>	6-18 months	24 weeks	—	—
Diphtheria tetanus acellular pertussis (DTaP)-1 <sup>b</sup>	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 <sup>d</sup>	6 months <sup>e</sup>
DTaP-4	15-18 months	12 months	3 years	6 months <sup>f</sup>
DTaP-5	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1 <sup>b</sup>	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3 <sup>c</sup>	6 months	14 weeks	6-9 months <sup>d</sup>	8 weeks
Hib-4	12-15 months	12 months	—	—
Inactivated poliovirus (IPV)-1 <sup>b</sup>	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	6 months
IPV-4	4-6 years	4 years	—	—
Pneumococcal conjugate (PCV)-1 <sup>b</sup>	2 months	6 weeks	2 months	4 weeks
PCV-2	4 months	10 weeks	2 months	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	—	—
Mumps-rubella-tetanus (MRT)-1 <sup>b</sup>	12-15 months	12 months	3-5 years	4 weeks
MRT-2 <sup>c</sup>	4-6 years	13 months	—	—
Varicella (Var)-1 <sup>b</sup>	12-15 months	12 months	3-5 years	12 weeks <sup>f</sup>
Var-2 <sup>c</sup>	4-6 years	15 months	—	—
Hepatitis A (HepA)-1 <sup>b</sup>	12-23 months	12 months	6-18 months <sup>d</sup>	6 months <sup>e</sup>
HepA-2	18-41 months	18 months	—	—
Influenza, inactivated (IIV)-1 <sup>b</sup>	6-59 months	6 months <sup>d</sup>	1 month	4 weeks
Influenza, Live attenuated (LAIV)-1 <sup>b</sup>	—	2 years	1 month	4 weeks
Meningococcal Conjugate (MCV)-1 <sup>b</sup>	11-12 years	2 years	—	—
Meningococcal Polysaccharide (MPSV)-1	—	2 years	5 years <sup>g</sup>	5 years <sup>h</sup>
MPSV-2 <sup>i</sup>	—	7 years	—	—
Tetanus-diphtheria (Td)	11-12 years	7 years	10 years	5 years
Tetanus-diphtheria-acellular pertussis (Tdap) <sup>j</sup>	≥11 years	10 years	—	—
Pneumococcal polysaccharide (PPSV)-1	—	2 years	5 years	5 years
PPSV-2 <sup>k</sup>	—	7 years	—	—

# Scheduling errors

- ▶ Giving doses at too young an age
- ▶ Giving doses without minimum spacing
  - ▶ Giving live vaccines not administered at the same visit less than 4 weeks apart

# Reminder

- Vaccine doses should not be administered at intervals less than the recommended minimal intervals or earlier than the minimal ages
- There is no maximum interval (Except for oral typhoid vaccine in some circumstances)
- Refer to schedule for appropriate age and interval recommendations
- Re-starting a vaccine series because of a longer-than recommended interval is **not necessary**

# ACTIVELY USING NYSIIS WILL AVOID SCHEDULING ERRORS

TRAIN ALL STAFF

# Vaccination Errors and How to Prevent

- Prevention Measures
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# Documentation Errors

- ▶ Not providing a Vaccine Information Statement (VIS) every time a vaccine is given
- ▶ Not using the most current VIS
- ▶ Not recording all needed information in patient's chart

# VIS Immunization Provider Responsibilities

- ▶ Federal law requires that providers give patients (or parents/legal representatives) the most current VIS for each vaccine before it is administered
- ▶ Ensure that patients have the opportunity to read the VIS or have it read to them and ask questions prior to administration of the vaccine
- ▶ Provide supplementary educational information (oral or written) as appropriate
- ▶ Offer patients a copy of the appropriate VIS(s) to take home with them

# Required Vaccination Information to Document

- Type of vaccine e.g., MMR or Hib, NOT brand name
- Date given
- Site given (RA, LA, RT, LT, IN, PO)
- Vaccine lot #
- Manufacturer
- Date of the VIS
- Date the VIS was given
- Vaccinator name, address and title

# Resources

- ▶ CDC Storage and Handling web page:  
<http://www.cdc.gov/VACCINES/RECS/storage/default.htm>
- ▶ *Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)* - National Center for Immunization and Respiratory Diseases, CDC:  
<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
- ▶ Advisory Committee for Immunization Practices Recommendations:  
<http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>
- ▶ CDC, Vaccines and Immunization website:  
<http://www.cdc.gov/vaccines/>

# Resources (cont.)

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- Immunization Action Coalition: <http://www.immunize.org/>
- NYSDOH Vaccine Program:  
[https://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children.htm](https://www.health.ny.gov/prevention/immunization/vaccines_for_children.htm)
- NYSIIS:  
[http://www.health.ny.gov/prevention/immunization/information\\_system/](http://www.health.ny.gov/prevention/immunization/information_system/)
- NYSDOH Bureau of Immunization website:  
<http://www.health.ny.gov/prevention/immunization/>
- Institute for Safe Medication Practices, Vaccine Error Reporting Program (ISMP VERP)  
<https://www.ismp.org/orderforms/reporterrortoismp.asp>



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# QUESTIONS AND DISCUSSION

THANK YOU

