

Disclosures

- JoEllen Wolicki is a federal government employee with no financial interest or conflict with the manufacturer of any product named in the following presentations
- The off-label use of any vaccines will not be discussed
- Vaccines not currently licensed by the FDA will not be discussed

Take Out Your Cell Phone



- You will have the opportunity to text answers to clinical questions
- And we will see the group response
 - □ Total numbers- no individual answers ◎
- Please note: message and data rates may apply

What Do You Think?

A co-worker tells you that she reconstituted MMRV with ActHIB diluent **AFTER** she administered the vaccine. You...

- Tell her to repeat the dose Text JW001 to 22333
- Count the dose and counsel her on vaccine preparation - Text JW002 to 22333
- Sneak out the back door and go home Text JW003 to 22333

Note: Message and data rates may apply

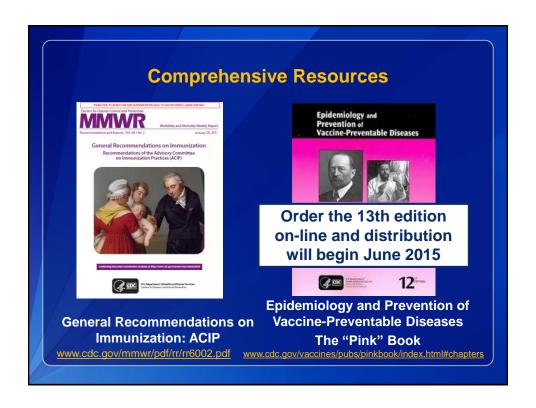
Poll Results

What We Know...

- Appropriate vaccine administration is an essential component of safety and efficacy of vaccines
 - Manufacturers recommend the route of administration that limits vaccine adverse reactions and optimizes the immune response
- Vaccine administration practices are based on clinical trials that determine the dose, route and schedule for each vaccine

Vaccine Administration Activities

- Review the immunization history
- Assess for needed vaccines
- Screen for contraindications and precautions
- Educate the patient and/or family members
- Prepare the vaccine(s)
- Administer the vaccine(s)
- Document the administered vaccine(s)





Rotavirus (RV) Vaccine Administration Errors, United States, 2006-2013

- 66 reports of RV vaccine administration errors to Vaccine Adverse Event Reporting System (VAERS)
 - 39 reports of injecting RV vaccine (RV1: 33; RV5: 6)
 - 19 of 39 reports (49%) documented an adverse event
 - Irritability (7) and injection site redness (5) most common
 - 27 reports of eye splashes
 - 21 cases: infants coughed, sneezed, or spit vaccine into the eyes of vaccination providers (17), parents (1) or themselves (3)
 - 21/27 reported non-serious adverse events-minor eye irritation

MMWR 2014; 63(04);81 www.cdc.gov/mmwr/preview/mmwrhtml/mm6304a4.htm?s_cid=mm6304a4_w

Vaccine Adverse Event Reporting System (VAERS)

- Authorized by National Childhood Vaccine Injury Act of 1986
- Jointly administered CDC and FDA
- National, post-marketing, passive reporting system for adverse events occurring after receipt of US-licensed vaccines
- Began receiving reports in 1990
- Receives average ~36,000* reports/year (2009-2013)
- Data available to the public at http://wonder.cdc.gov/vaers.html
 and https://wonder.cdc.gov/vaers.html

*Numbers include both US and foreign reports, primary and non-primary

Vaccine Adverse Event Reporting System (VAERS) (co-managed CDC and FDA)*

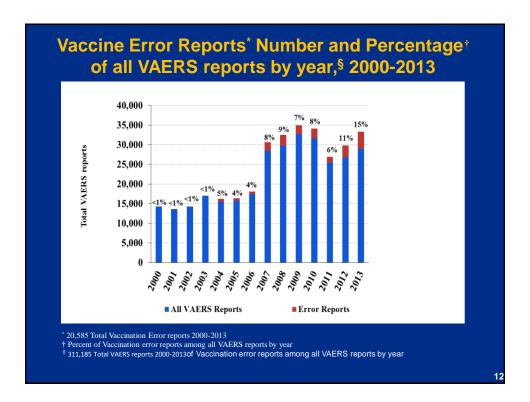
Strengths

- National data; accepts reports from anyone
- Rapid signal detection; rare adverse events (AE)
- Collects information about vaccine, characteristics of vaccinee, adverse event
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Generally cannot assess if vaccine or error, caused an adverse health event
- VAERS coding practices can affect types and numbers of errors reported

* VAERS website: http://vaers.hhs.gov



Methods

- VAERS database search strategy
 - All VAERS U.S. primary reports with a vaccination error code
 - Using Medical Dictionary for Regulatory Activities (MedDRA): 39 MedDRA codes describing vaccination errors
 - Patient vaccinated Jan 1, 2000 Dec 31, 2011
- Investigators assigned the 39 error codes to one of 11 categories describing an error group
- Reviewed and characterized selected categories of reports
 - Most common error groups
 - Errors groups most likely to also report an adverse event

Groupings of Vaccine Error Codes (N=11)

Accidental

- Accidental exposure
- Accidental needle stick

Administration errors

- Drug administered at inappropriate site
- **Drug administration error**
- · Incorrect drug dosage form administered,
- Incorrect drug administration duration
- Incorrect route of drug administration
- Wrong technique in drug usage process

Contraindication

- · Contraindication to vaccination
- · Labeled drug-drug interaction medication error

Equipment

- Injury associated with device
- Medical device complication

General

- **Medication error**
- Vaccination error

Inappropriate schedule

- · Inappropriate schedule of drug administration
- · Drug administered to patient of inappropriate age

Incorrect dose

- Accidental overdose
- Drug dose omission
- Incorrect dose administered
- Under-dose
- OverdoseMultiple drug overdose

Product quality

- · Product contamination,
- · Product contamination physical,
- · Product quality issue,

Product labeling/packaging

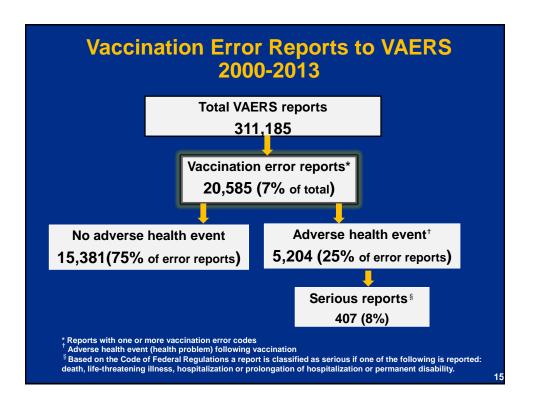
- · Drug name confusion
- Product label confusion
- · Product name confusion
- · Product container issue,
- · Product label issue,
- · Product label on wrong product,
- · Product outer packaging issue,
- · Product packaging issue,

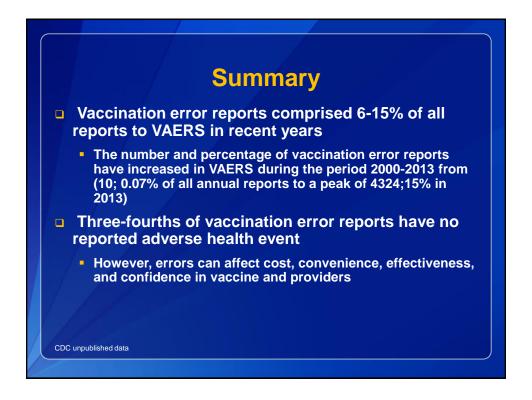
Storage and dispensing

- Drug dispensing error
- Expired drug administered · Incorrect product storage
- Incorrect storage of drug
- Poor quality drug administered

Wrong drug

· Wrong drug administered







Best Practice Strategies

- Educate staff about vaccines and proper administration practices
 - Integrate vaccine administration education into staff education policies/procedures
 - Annually for all staff
 - Orientation for new staff
 - As needed whenever recommendations are updated and new vaccines are added to inventory
 - Don't forget temporary staff

| Skills Checklist for Immunization | State | Skills Checklist for Immunization | Skills | Sk



www.cdc.gov/vaccines/ed/default.htm

Help Staff Use Proper Administration Practices

- Standing orders authorize nurses, pharmacists, and other appropriately trained healthcare personnel, where allowed by state law:
 - to assess a patient's immunization status and

Storage and Handling Toolkit

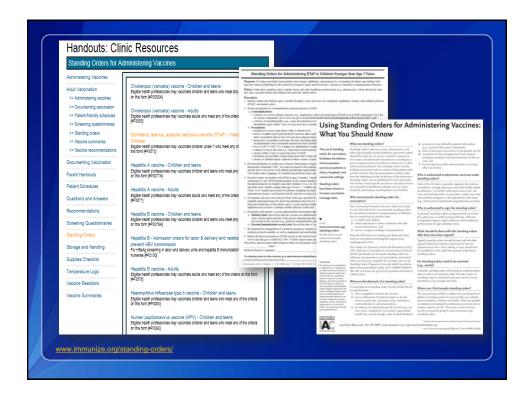
Continuing education credits available

- administer vaccinations according to an approved protocol
- Standing orders enable assessment and vaccination without the need for clinician examination or direct order from the attending provider at the time of the interaction

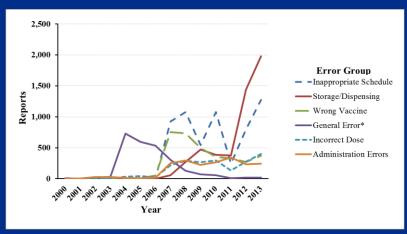
Guide to Community Preventive Services. Increasing appropriate vaccination: standing orders. www.thecommunityguide.org/vaccines/universally/standingorders.html

Standing Orders

- Establish standard orders or protocols, which include:
 - The full generic name, brand name (if applicable), and standard abbreviation
 - Schedule- ages and intervals between doses in a series
 - Criteria for screening patients to determine the need for vaccination, indications, contraindications, and precautions
 - Directions for administering the vaccine, including the route and any special procedures required to enhance safety
 - Information regarding any required follow-up doses
 - Details regarding what (e.g., lot number, expiration date) and where (e.g., vaccination record, immunization registries) to document vaccine administration
 - An emergency protocol to follow if the patient develops an adverse reaction







*In 2007 VAERS transitioned from using Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) to MedDRA coding and updated COSTART terms for years prior to 2007. MedDRA has many more options for vaccination error terms. This change likely resulted in a decrease in use of the "General Error" coding term.

Top 3 Vaccine Administration Errors

- Inappropriate schedule errors (wrong age, timing between doses) (5,947; 27%)
 - Most common vaccines involved
 - Quadrivalent human papillomavirus HPV4 (1,516)
 - Rotavirus vaccine (880)
- 2. Storage errors (4,983, 23%)
 - Expired vaccine administered (2,746)
 - Seasonal live attenuated influenza (LAIV) (978; 36%)
 - Incorrect storage of vaccine (2,202)
 - Vaccines kept outside of proper storage temp, (too cold)

CDC unpublished data

Top Three Vaccination Errors

3. Wrong vaccine administered (3,372; 15%)

Common Wrong Vaccine Mix-ups*				
Varicella	with	Herpes zoster		
Diphtheria, tetanus and pertussis (DTaP)	with	Tetanus, diphtheria and pertussis (Tdap)		
Trivalent inactivated influenza vaccines (IIV3)	with	Another IIV3 of different age indications		
Pneumococcal conjugate	with	Pneumococcal polysaccharide		
Hepatitis A	with	Hepatitis B		

Vaccine mix ups can be either combination (e.g. varicella vaccine instead of herpes zoster vaccine or herpes zoster vaccine instead of varicella vaccine)

CDC unpublished data

What Do You Think?



Increasing the interval between doses of a multidose vaccine does not diminish the effectiveness of the vaccine.

Decreasing the interval between doses of a multidose vaccine may interfere with antibody response and protection

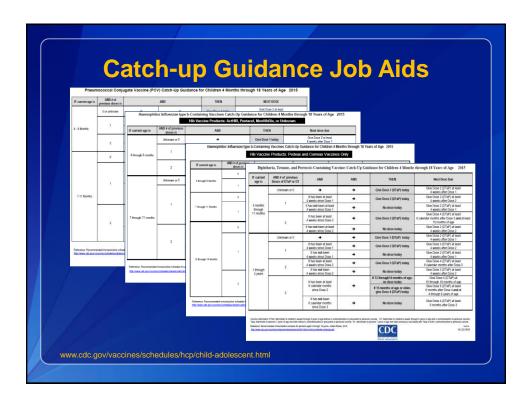
- True Text 135644 to 22333
- False Text 135651 to 22333

Note: Message and data rates may apply

Poll Results

Best Practice Strategies 1. Inappropriate Schedule Errors

- Use the current immunization schedule to determine needed doses
 - Immunization schedule apps are available for smart phones and tablets
 - Minimum ages and intervals can be found in:
 - · Childhood schedule catch-up table
 - Adult schedule footnotes
 - Table 1 in General Recommendations on Immunization Practices
- Immunization Information Systems (IIS) may help
 - Check before administering vaccines for any additional doses
 - Assessment is based on the IIS history- Enter any missing doses



Best Practice Strategies 2. Storage and Handling Errors

- Follow CDC vaccine storage and handling recommendations
 - Take immediate corrective action for vaccines exposed to inappropriate temperatures or handled improperly
- Use the diluent supplied by the manufacturer to reconstitute vaccines
 - Label diluents clearly
 - If possible store diluent and lyophilized component together
 - Do NOT freeze diluent
- Check expiration dates weekly
 - Remove expired vaccine from the unit

Administration of Expired Live Attenuated Influenza Vaccine (LAIV)*

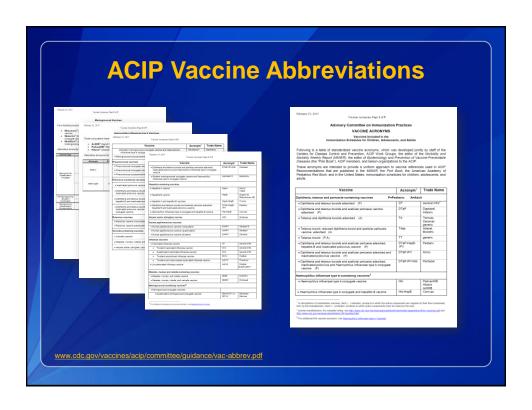
- Reports of administration of expired LAIV flu vaccine 866(18.4% of all LAIV reports to VAERS) July 1, 2007, through June 30, 2014 to VAERS
 - LAIV generally has an 18 week shelf life, Inactivated influenza vaccine generally lasts until the end of flu season (June 30th)
- No adverse health event documented in 98% of the reports
- In 95% of expired LAIV reports the vaccination occurred after the first week in November which is approximately 18 weeks from July 1st

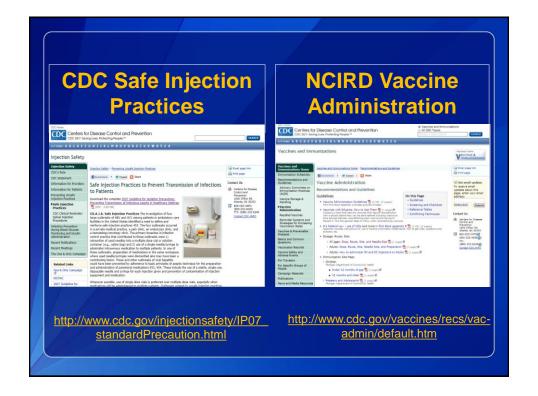
* Haber P, Schembri CP, Lewis P, Hibbs B, Shimabukuro T. Notes from the Field: Reports of Expired Live Attenuated Influenza Vaccine Being Administered -United States, 2007–2014. MMWR Morb Mortal Wkly Rep. 2014; 63(35):773.



Best Practice Strategies 3. Wrong Vaccine Administered Errors

- Make the right thing to do the easy thing to do!
 - Store look-alike or sound-alike vaccines and pediatric and adult formulations in different locations in the vaccine storage unit
 - Clearly label vaccines and diluents
 - Post administration job aids for staff
- Document vaccines correctly in the
 - Medical record
 - Immunization Information System if possible
 - Patient's personal record
- Use standard abbreviations to document vaccines
 - Prohibit the use of coined or informal names for vaccines





What Do You Think?



A healthcare provider administered Pediarix and PCV13 near the hamstring of a 6 month old. He would like information on the safety concerns since they were given in an alternative site and will the vaccines work?

- Yes Text JW011 to 22333
- No Text JW012 to 22333
- I don't know Text JW013 to 22333

Note: Message and data rates may apply

Poll Results

Vaccines

- Vaccines most frequently associated with errors include:
 - Influenza
- HepA

Hib

- HepB
- DTaP-IPV
- HPV

Tdap

Zoster

DTaP

MMRV

ISMP Medication Safety Alert March 19, 2014 Vol. 10 Issue 5

Make the Easy Thing To Do, the Right Thing To Do

- Implement proven medication safety practices to prevent VAEs, including:
 - Reducing reliance on memory
 - Standardization
 - Protocols and checklists
 - Differentiating among products to eliminate look- and soundalike products
 - Monitoring error frequencies and correcting system problems associated with errors
- Create an environment that encourages individuals to report mistakes so precursors to errors can be better understood in order to fix the system issues

Preventing Medication Errors: Quality Chasm Series Institute of Medicine To Err is Human: Building a Safer Health System

A Vaccine Administration Error Was Inadvertently Made- Now What?

- Vaccine administration error recommendations can vary based on the type of error and vaccine
- Not all vaccine administration errors require revaccination
- Seek advice
 - State or local immunization programs OR
 - Manufacturers OR
 - CDC: nipinfo@cdc.gov

Vaccine Administration Error Examples

Wrong vaccine

 DTaP administered to an adult which meets minimum interval dose not need to be repeated

Minimum age and intervals errors

- Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid
- Doses administered 5 days or earlier than the minimum interval or age should not be counted and should be repeated as age appropriate

Wrong route

- Vaccines which should be administered by subcutaneous injection (subcut) given by intramuscularly
 - Do not repeat
- IM vaccines given by subcut injection
 - Repeat if hepatitis B, HPV, or rabies
- Oral or intranasal vaccines (RV, LAIV) given IM or Subcut!!!!
 - Always repeat

MMWR 2011;60(No. RR-2)

Reporting Vaccination Errors to VAERS

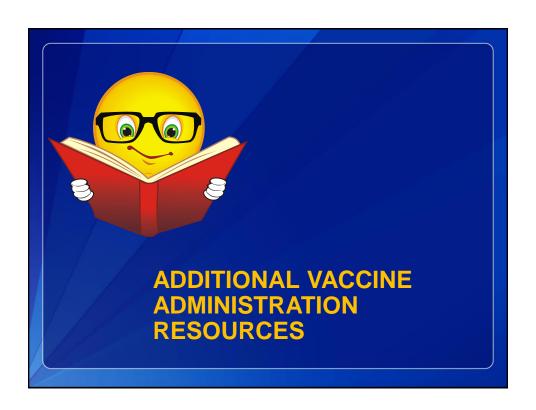
- Healthcare professionals should use clinical judgment in deciding whether or not to report a medical error
- A provider may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the medical error may pose a safety risk (e.g. administering a vaccine when contraindicated)
- VAERS staff are currently conducting studies to better understand the types of vaccination errors that are reported to VAERS. We are also exploring ways to better capture information about vaccination errors and analyze these reports

National Organizations that Accept Reports of Vaccine Administration Errors

- Vaccine Adverse Event Reporting System (VAERS)
 - Accepts reports about adverse events following immunization www.vaers.hhs.gov
- MedWatch
 - Accepts reports about products regulated by the FDA, including drugs and medical devices www.fda.gov/medwatch/how.htm
- Institute for Safe Medication Practices (ISMP) and California Department of Public Health (CDPH)
 - Vaccination Error Reporting Program (VERP) accepts reports related to vaccination errors www.verp.ismp.org
- MEDMARX
 - Limited to hospitals that are part of their medication error program

Conclusions

- Vaccine administration errors are an important area in vaccine safety research and surveillance
- Continued study will be key in understanding risk factors and developing prevention strategies
- Focus of continued study in VAERS:
 - Vaccination errors that occur frequently
 - Errors that may be associated with an adverse health outcome
 - Prevention of vaccination errors





CDC Vaccines and Immunization Resources

Questions? Email CDC

Providers

nipinfo@cdc.gov

Parents and patients

ww.cdc.gov/cdcinfo

Website

ww.cdc.gov/vaccines

Influenza

www.cdc.gov/flu

Vaccine Safety

ww.cdc.gov/vaccinesafety

Other Immunization Resources

- State and local immunization programs
- □ American Pharmacist Association www

www.apha.org

Medical Assistants Resources and Training on Immunizations www.marti-us.org

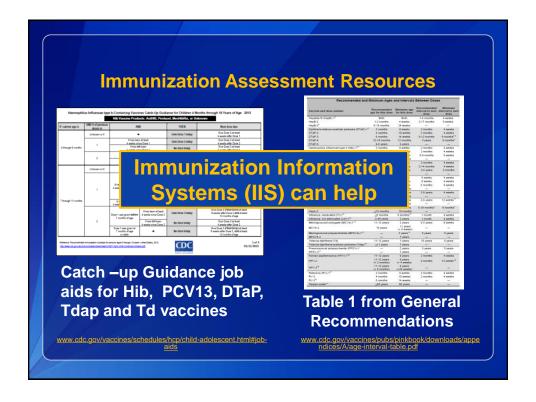
Immunization Action Coalition

www.immunize.org





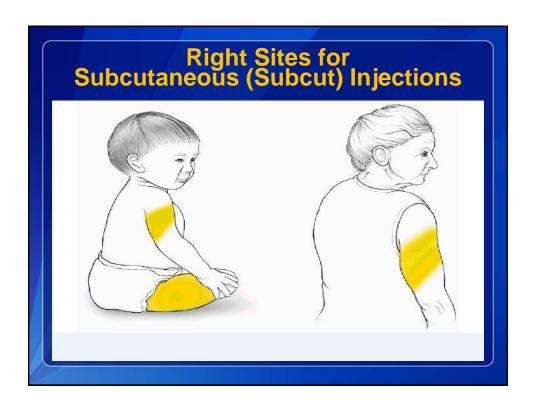
Vaccines	Route	Site
Rotavirus: RV1, RV5	Oral (PO)	Mouth
LAIV	Intranasal NAS	Nostrils
DTaP, Tdap, Td, HepA, HepB, Hib, 2vHPV, 4vHPV, 9vHPV, IPV**, IIV3*, IIV4, RIV3, ccIIV3, MCV4, PCV13, PPSV23** Combinations: DTaP-HepB- IPV, DTaP-IPV,DTaP-IPV/Hib, HepB- Hib, HepA-HepB, Hib-MenCY	Intramuscular injection IM	Less than 12 months: Anterior lateral thigh 1 to 2 years: Anterior lateral thigh or deltoid 3 years and older: Deltoid
MMR, MMRV, MPSV4, Var, HZV IPV*, PPSV23*	Subcutaneous injection Subcut or SC	Less than 12 months: Anterior lateral thigh 1 and older: upper outer triceps



Subcutaneous Injections

- Subcutaneous injections are administered at a 45-degree angle, usually into the thigh for infants aged less than 12 months and in the upper-outer triceps area of persons aged 12 months or older
 - Subcut injections may be administered into the upper-outer triceps area of an infant if necessary
- A %-inch, 23- to 25-gauge needle should be inserted into the subcutaneous tissue

General Recommendations on Immunization MMWR / January 28, 2011 / Vol. 60 / No. 2 15 www.cdc.gov/mmwr/pdf/rr/rr6002.pdf



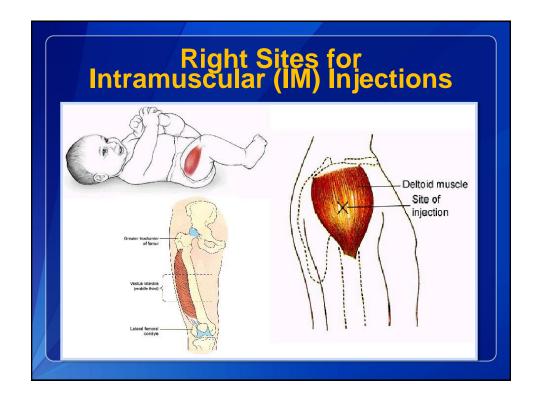
Intramuscular Injections

■ Insert the needle at a 90-degree angle to the skin

Age	Site
Birth through 11 months	Anterolateral thigh
1 year through 2 years	Anterolateral thigh Deltoid*
3 through 18 years	Deltoid
19 years and older	Deltoid

The anterolateral thigh may be used for older children, adolescents and adults if needed

*If the muscle mass is adequate
General Recommendations on Immunization MMWR / January 28, 2011 / Vol. 60 / No. 2 15 www.cdc.gov/mmwr/pdl/rr/rr6002.pdl



IM Injections and Needle Length

Children Birth through 18 Years of Age			
Age	Needle Length		
Newborns (1st 28 days)	5/8 inch*		
1–11 months	1inch		
1–2 years	1 inch		
3–18 years	1–11/4"		
Adults 19 Years of Age and Older			
Weight	Needle Length		
Male or female < 130 lbs	5/8–1"*		
Female 130–200 lbs	1–11/2"		
Male 130–260 lbs	1–11/2"		
Female 200+ lbs	11/2"		
Dependent on muscle mass, site and injection technique			

Document What You Have Done

General Recommendations on Immunization MMWR / January 28, 2011 / Vol. 60 / No. 2 15 www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

- Document vaccines in :
 - Medical record
 - IIS- IRIS
 - Patient's personal vaccination record
- Federal documentation requirements include:
 - Date of administration
 - Vaccine manufacturer
 - Vaccine lot number
 - Name and title of who administered the vaccine
 - Facility address where permanent record is kept
 - Vaccine Information Statement (VIS)
 - Date printed on the back of the VIS
 - Date VIS given to patient or parent/guardian



- Additional information to include:
 - Route
 - Site
 - Expiration date
- Use standardized abbreviations
 - ACIP list of vaccine abbreviations
 - Do not use brand names only
- Accurate documentation can help prevent administration errors

Parliamo (1) 2015

Advisory Committee on Immunistration Practices
VACADE ACCOMMEN

VACADE ACCOMMEN

VACADE ACCOMMEN

VACADE ACCOMMEN

Following is a bollo of electrication accommendment of the Accommend of the Accommendation of the A

http://www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.pd