

The General Recommendations on Immunization

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The General Recommendations Working Group

- Publishes an MMWR ~ 5 year interval
- Addresses immunization issues relevant to all vaccines
- Addresses topics ad hoc that cannot be attributed to a single vaccine

The General Recommendations Working Group

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General Recommendations on Immunization

- Directed to providers that are giving many different vaccines every day
- Providers come from variable background (i.e. physicians, nurse-practitioners, nurses, pharmacists, medical assistants)
- Text accompanied by tables (for quick reference)

General Recommendations - Revision

- Preliminary Results
 - New Outline
 - Revised draft of (roughly) first half of document

General Recommendations - Revision

- Introduction
- Timing and spacing of immunobiologics
- Contraindications and precautions
- Preventing and Managing Adverse Reactions
 - Benefit and Risk Communication
- Reporting adverse events after vaccination
- The National Vaccine Injury Compensation Program
- Vaccine administration
- Storage and handling of immunobiologics
- Altered immunocompetence
- Special situations
- Vaccination records
- Vaccination programs (Adolescent and Adult Vaccination Topics)
- Vaccine information sources

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- Vaccine information sources

General Recommendations Revisions

- Benefit-risk communication placed earlier in the document (moved to Contraindications and Precautions)
- Managing and Preventing Adverse Reactions, Reporting Adverse Events also placed earlier

General Recommendations Revisions

- In 2006 version...
- Table 5 in “Contraindications and Precautions” lists both conditions from vaccine-specific statements AND common misconceptions

TABLE 5. Contraindications and precautions* to commonly used vaccines

Vaccine	True contraindications and precautions*	Untrue (vaccines can be administered)
General for all routine vaccines, including diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP); pediatric diphtheria-tetanus toxoid (DT); adult tetanus-diphtheria toxoid (Td); tetanus-reduced-diphtheria toxoid and acellular pertussis vaccine (Tdap), inactivated poliovirus vaccine (IPV); measles-mumps-rubella vaccine (MMR); <i>Haemophilus influenzae</i> type b vaccine (Hib); hepatitis A vaccine; hepatitis B vaccine; varicella vaccine; Rotavirus vaccine, pneumococcal conjugate vaccine (PCV); inactivated influenza vaccine (TIV); live-attenuated influenza vaccine (LAIV) pneumococcal polysaccharide vaccine (PPV); meningococcal conjugate vaccine (MCV4); meningococcal polysaccharide vaccine (MPSV); human papillomavirus vaccine (HPV); and herpes zoster vaccine (HZ)	<p>Contraindications Severe allergic reaction (e.g., anaphylaxis) after a previous vaccine dose or to a vaccine component</p> <p>Precautions Moderate or severe acute illness with or without fever</p>	<p>Mild acute illness with or without fever</p> <p>Mild-to-moderate local reaction (i.e., swelling, redness, and soreness); low-grade or moderate fever after previous dose</p> <p>Lack of previous physical examination in well-appearing person</p> <p>Current antimicrobial therapy[†]</p> <p>Convalescent phase of illness</p> <p>Preterm birth (hepatitis B vaccine is an exception in certain circumstances)[§]</p> <p>Recent exposure to an infectious disease</p> <p>History of penicillin allergy, other nonvaccine allergies, relatives with allergies, receiving allergen extract immunotherapy</p> <p>Breast feeding</p>
DTaP	<p>Contraindications Severe allergic reaction (e.g., anaphylaxis) after a previous vaccine dose or to a vaccine component</p> <p>Encephalopathy (e.g., coma, decreased level of consciousness; prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP</p> <p>Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy, or other DTP-related</p>	<p>Temperature of $\leq 104^{\circ}\text{F}$ ($<40.5^{\circ}\text{C}$), fussiness, or mild drowsiness after a previous dose of diphtheria toxoid-tetanus toxoid-pertussis vaccine (DTP/DTaP)</p> <p>Family history of seizures[¶]</p> <p>Family history of sudden infant death syndrome</p> <p>Family history of an adverse event after DTP or DTaP administration</p> <p>Stable neurologic conditions (e.g., cerebral palsy, well-controlled seizure disorder)</p>

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General Recommendations Revisions

- Syncope statistics/language updated
(Page 19, Line 16)
- Increase in syncope probably reflects vaccines given to adolescents
- Adolescents at higher risk of syncope-related head injury (VAERS data)
- “Adolescents and adults should be seated during vaccination and the observation period to decrease the risk of injury should they faint”

General Recommendations - Revision

- Feb. 2009 presentation of 2nd half of document
 - Combination Vaccines
 - Storage and Handling
 - Programmatic Issues
 - Adolescent Vaccination
 - Adult Vaccination
 - Final Vote (?)
- Clearance
- Publication – Dec. 2009

POLICY QUESTION: Intramuscular Needle Length

- Discussed in “Vaccine Administration section”
- Choice of needle length dependent on:
 - Technique (Bunching vs Flattening)
 - Site
 - Age
 - Adults Only (weight, gender)

Entire Table

Adapted from Minnesota Department of Health

TABLE 7. Needle length and injection site of intramuscular injections

Birth–18 years		
Age	Needle length	Injection site
Newborn*	5/8" (16mm) [†]	Anterolateral thigh
Infant 1–12 months	1" (25mm)	Anterolateral thigh
Toddler 1 – 2 years	1"–1 1/4" (25–32 mm) 5/8" [†] –1" (16–25 mm)	Anterolateral thigh [§] Deltoid muscle of the arm
Child/adolescent 3–18 years	5/8" [†] –1" (16–25 mm) 1"–1 1/4" (25–32 mm)	Deltoid muscle of the arm [§] Anterolateral thigh
Aged ≥19 Years		
Sex/weight	Needle length	Injection site
Male and female <60 kg (130 lbs)	1" (25mm) [¶]	Deltoid muscle of the arm
Female 60–90 kg (130–200 lbs)	1"–1½" (25–38 mm)	
Male 60–118 kg (130–260 lbs)		
Female >90 kg (200 lbs)	1½" (38 mm)	
Male >118 kg (260 lbs)		

* Newborn = first 28 days of life.

[†] If skin stretched tight, subcutaneous tissues not bunched.

[§] Preferred site.

[¶] Certain experts recommend a 5/8" (16 mm) needle for males and females who weigh <60 kg (130 lbs).

Adapted from: Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277: 1709–11.

Intramuscular Needle Length

- If IM vaccines are administered into the subcutaneous space, the risk for local reactions is higher
- Risk of injection into subcutaneous space is increased if the needle is too short
- Thought to be due to vaccine components (adjuvant)

Intramuscular Needle Length

- Studies of infants using 5/8 vs 1 inch needles clearly indicate that risk for tenderness or swelling higher than with 1 inch needles
 - Vaccines used include DTP, Hib, Group C meningococcal conjugate vaccines
-
- Diggle J, Deeks J, 2000
 - Diggle, L, Deeks JJ, Pollard A. BMJ 2006

Intramuscular Needle Length

- Toddlers and young children: use of shorter needles 5/8 vs 1 inch also associated with increased risk of erythema, swelling and pain
 - Vaccines: DTaP, DTP, Polio
-
- Ipp MM, et. Al. Pediatrics 2003
 - Jackson LA, et. Al. Pediatrics 2008

Intramuscular Needle Length

- Ipp MM article looked at 18 month olds, found that increased risk of pain in thigh when compared to arm ($p < .001$)
- Used 5/8 inch needle
- CDC recommends deltoid for children older than 2 years

Intramuscular Needle Length

- In adults there is evidence of reduced immunogenicity when Hepatitis B vaccine is injected into the gluteus as opposed to the deltoid (Shaw FE Jr., et Al. Vaccine 1989)
- Likely related to superficial placement of vaccine

Intramuscular Needle Length

- New study (Lippert W, Wall EJ) suggests that needle lengths recommended by CDC risk overpenetration and striking of bone and periosteum
- Suggestion that following needle lengths be used:

Younger than 6 y	7/8 – 1 inch (thigh)
Male ≤ 70 kg	½ inch (deltoid)
Female ≤ 75 kg	½ inch
Female 70 – 115 kg	5/8 inch
Male 70 – 140 kg	5/8 inch
Female ≥ 115 kg	7/8 – 1 inch
Male ≥ 140 kg	7/8 – 1 inch

Intramuscular Needle Length – Lippert study

Strengths

- Study recommends flexibility to the providers
- Demonstrates with CT scan/MRI that in patients 3 – 18 years of age 74/137 would reach the measured level of bone using a 1 inch needle
- There is concern regarding hitting of underlying structures (sciatic nerve in some situations)

Intramuscular Needle Length – Lippert Study

Limitations

- Unlike previous studies mentioned, method does not involve actual administration – technique important
- Risk is also reduced with careful site selection

For children younger than 3 years, 6/38 would hit level of subcutaneous fat with 5/8 inch needle

POLICY OPTIONS

Entire Table

Adapted from Minnesota Department of Health

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Child/adolescent 3–18 years	5/8" [†] –1" (16–25 mm) 1"–1 1/4" (25–32 mm)	Deltoid muscle of the arm [§] Anterolateral thigh
Aged ≥19 Years		
Sex/weight	Needle length	Injection site
Male and female <60 kg (130 lbs)	1" (25mm) [¶]	Deltoid muscle of the arm
Female 60–90 kg (130–200 lbs)	1"–1½" (25–38 mm)	
Male 60–118 kg (130–260 lbs)		
Female >90 kg (200 lbs)	1½" (38 mm)	
Male >118 kg (260 lbs)		

* Newborn = first 28 days of life.

[†] If skin stretched tight, subcutaneous tissues not bunched.

[§] Preferred site.

[¶] Certain experts recommend a 5/8" (16 mm) needle for males and females who weigh <60 kg (130 lbs).

Adapted from: Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277: 1709–11.

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Child/adolescent 3–18 years	5/8" [†] –1" (16–25 mm) 1"–1 1/4" (25–32 mm)	Deltoid muscle of the arm [§] Anterolateral thigh

Aged ≥19 Years

Sex/weight	Needle length	Injection site
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Option 1

Birth–18 years		
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Infant 1–12 months	1" (25mm)	Anterolateral thigh
Toddler 1 – 2 years	1"–1 1/4" (25-32mm)	Anterolateral thigh§
	5/8"†–1" (16-25mm)	Deltoid muscle of the arm
Children 3–18 years	5/8"†–1" (16-25mm)	Deltoid muscle of the arm§
	1"–1 1/4" (25-32mm)	Anterolateral thigh

- *Newborn = First 28 days of life.
- †If skin stretched tight, subcutaneous tissues not bunched.
- §Preferred site.

Option 1

Pro's

- Current recommendation
- Reduces local reactions caused by IM injections being given SubQ
- Emphasizes age, site as important parameters
- Simple – children birth through eighteen listed as one cluster
- Accounts for needle-size availability

Con's

- Doesn't emphasize technique (text does)

Option 2

Birth–18 years		
Age	Needle length	Injection site
Newborn*	5/8" (16mm)†	Anterolateral thigh
Infant 1–12 months	1" (25mm)	Anterolateral thigh
Toddler 1 – 2 years	1"–1 1/4" (25-32mm)	Anterolateral thigh§
	5/8"†–1" (16-25mm)	Deltoid muscle of the arm
Children 3–18 years	5/8"¶–1" (16-25mm)	Deltoid muscle of the arm§
	1"–1 1/4" (25-32mm)	Anterolateral thigh

- *Newborn = First 28 days of life.
- †If skin stretched tight, subcutaneous tissues not bunched.
- §Preferred site.
- ¶ assumes needle is fully inserted
- **Some experts recommend a needle shorter than 1 inch (25 mm) for children/adolescents 3 years through 18 years who weigh less than 140 kg (males) or less than 115 kg (females)

Option 2

Pro's

Emphasizes age, site as important parameters

Emphasizes technique with additional footnote about insertion of the needle

Includes weight-based criteria in the footnote (Lippert study)

Accounts for needle-size availability

Con's

Partial adoption of new data

Weight cutoffs don't harmonize with previous adult based cutoffs (this data in the same table)

Option 3

Birth–18 years		
Age	Needle length	Injection site
Newborn*	5/8" (16mm)†	Anterolateral thigh
Child ≤ 6 years	7/8" - 1" (25mm)	Anterolateral thigh
Children 7 – 18 years		
Female ≤ 70 kg Male ≤ 75 kg	1/2 "	Deltoid muscle
Female 70 – 115 kg Male 75 – 140 kg	5/8 "	Deltoid muscle
Female ≥ 115 kg Male ≥ 140 kg	7/8" – 1"	Deltoid muscle

*Newborn = First 28 days of life.

†If skin stretched tight, subcutaneous tissues not bunched.

Option 3

Pro's

Complete adoption of new data from Lippert study

Con's

Increased risk of local adverse reactions due to IM injections into SubQ

Reduced flexibility as to site choice

Not harmonized with published adult data about weight cutoffs

Needle lengths recommended might not be available

Option 4: Entire Table

Adapted from Minnesota Department of Health

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Child/adolescent 3–18 years	5/8" [†] –1" (16–25 mm) 1"–1 1/4" (25–32 mm)	Deltoid muscle of the arm [§] Anterolateral thigh

Aged ≥19 Years

Sex/weight	Needle length	Injection site
Male and female <60 kg (130 lbs)	1" (25mm) [¶]	Deltoid muscle of the arm
Female 60–90 kg (130–200 lbs)	1"–1½" (25–38 mm)	
Male 60–118 kg (130–260 lbs)		
Female >90 kg (200 lbs)	1½" (38 mm)	
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[†] If skin stretched tight, subcutaneous tissues not bunched.

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[¶] Certain experts recommend a 5/8" (16 mm) needle for males and females who weigh <60 kg (130 lbs).

Adapted from: Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277: 1709–11.

Option 4: Entire Table

Adapted from Minnesota Department of Health

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Child/adolescent 3–18 years	5/8" [†] –1" (16–25 mm) 1"–1 1/4" (25–32 mm)	Deltoid muscle of the arm [§] Anterolateral thigh

Aged ≥ 19 Years

Sex/weight	Needle length	Injection site
Male and female <60 kg (130 lbs)	1" (25mm) [¶]	Deltoid muscle of the arm
Female 60–90 kg (130–200 lbs)	1"–1½" (25–38 mm)	
Male 60–118 kg (130–260 lbs)		
Female >90 kg (200 lbs)	1½" (38 mm)	
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* Newborn = first 28 days of life.

[†] If skin stretched tight, subcutaneous tissues not bunched.

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[¶] Certain experts recommend a 5/8" (16 mm) needle for males and females who weigh <60 kg (130 lbs).

Adapted from: Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277: 1709–11.

Current Table

19 Years and Older		
Sex/Weight	Needle Length	Injection Site
Male and female <60 kg (130 lbs)	1" (25mm)***	Deltoid muscle of the arm
Male and female 60–70 kg (130–152 lbs)	1" (25mm)	
Male 70–118 kg (152–260 lbs)	1"-1½"(25-38 mm)	
Female 70 -90 kg (152 – 200 lbs)		
Male > 118 kg (260 lbs)	1½(38 mm)	
Female > 90 kg (200 lbs)		

- ¶Assumes needle is fully inserted. *** Some experts recommend a 5/8 inch needle for adult males and females who well less than 60 kg. Adapted from: Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277: 1709–11, and CDC.General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. MMWR 2002;51(No. RR-2).

Option 4

19 Years and Older	1-1 1/4" (25-32mm)	Deltoid muscle of the arm
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Option 4

Pros

Equalizes (and somewhat diminishes) emphasis on weight for children, adolescents and adults

Cons

Removes current weight parameters for adults (discontinuity from previous recommendations)