

# Vaccinations in practice

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## DZIENNIK URZĘDOWY MINISTRA ZDROWIA

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Warszawa, dnia 16 października 2019 r.

Poz. 87

Elektronicznie podpisany przez:  
Marcin Ciężki  
Data: 16.10.2019 14:34:49



### KOMUNIKAT GŁÓWNEGO INSPEKTORA SANITARNEGO

z dnia 16 października 2019 r.

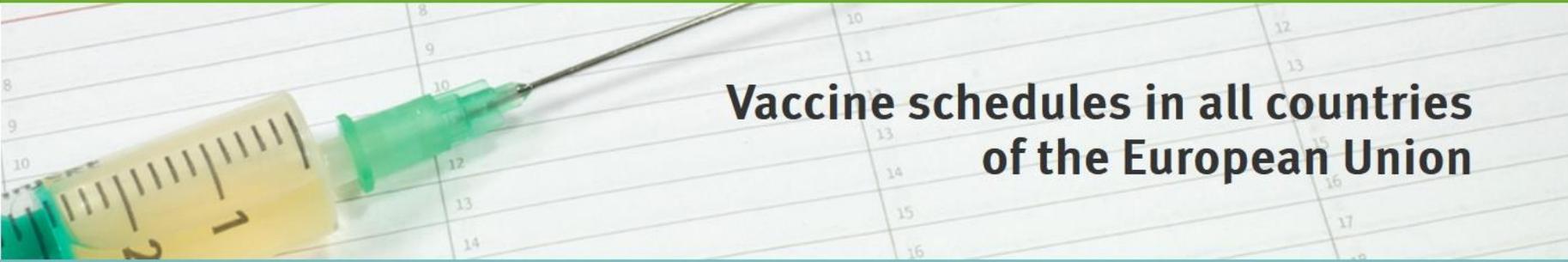
**w sprawie Programu Szczepień Ochronnych na rok 2020**

Na podstawie art. 17 ust. 11 ustawy z dnia 5 grudnia 2008 r. o zapobieganiu oraz zwalczaniu zakażeń i chorób zakaźnych u ludzi (Dz. U. z 2019 r. poz. 1239 i 1495) ogłasza się Program Szczepień Ochronnych na rok 2020, który stanowi załącznik do niniejszego komunikatu.

Główny Inspektor Sanitarny

**Jarosław Pinkas**

# EU - ECDC



## Vaccine schedules in all countries of the European Union

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Adult

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#### Immunisation schedules by target disease

Disease

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In

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# European Medicines Agency



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# European Medicines Agency - EPAR

- EMA publishes detailed information on the medicines assessed by the Committee for Medicinal Products for Human Use ([CHMP](#)) and Committee for Medicinal Products for Veterinary Use ([CVMP](#))
- The main vehicle for this information is known as a European public assessment report

# Summary of product characteristics

## **Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe**

Summary of Product Characteristics Updated 15-May-2020 | GlaxoSmithKline UK

### **1. Name of the medicinal product**

Bexsero suspension for injection in pre-filled syringe

Meningococcal group B Vaccine (rDNA, component, adsorbed)

### **2. Qualitative and quantitative composition**

One dose (0.5 ml) contains:

Recombinant <i>Neisseria meningitidis</i> group B NHBA fusion protein <sup>1, 2, 3</sup>	50 micrograms
Recombinant <i>Neisseria meningitidis</i> group B NadA protein <sup>1, 2, 3</sup>	50 micrograms
Recombinant <i>Neisseria meningitidis</i> group B fHbp fusion protein <sup>1, 2, 3</sup>	50 micrograms
Outer membrane vesicles (OMV) from <i>Neisseria meningitidis</i> group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 <sup>2</sup>	25 micrograms

<sup>1</sup> produced in *E. coli* cells by recombinant DNA technology

<sup>2</sup> adsorbed on aluminium hydroxide (0.5 mg Al<sup>3+</sup>)

<sup>3</sup> NHBA (Neisserial Heparin Binding Antigen), NadA (*Neisseria* adhesin A), fHbp (factor H binding protein)

For the full list of excipients, see section 6.1.

### **3. Pharmaceutical form**

Suspension for injection.

White opalescent liquid suspension.

### **4. Clinical particulars**

# EPAR – check for changes!



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## Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe

GlaxoSmithKline UK

[contact details](#)

Active ingredient

meningococcal group-B vaccine (rDNA, component, adsorbed)

Legal Category

POM: Prescription only medicine

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This information is intended for use by health professionals

### 1. Name of the medicinal product

Bexsero suspension for injection in pre-filled syringe

Meningococcal group B Vaccine (rDNA, component, adsorbed)

Last updated on emc:

15 May 2020

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# Vaccination schedule

## Poland



**General recommendation**



Recommendation for specific groups only



Catch-up (e.g. if previous doses missed)

Vaccination not funded by the National Health system

Mandatory vaccination

# One visit – one vaccination? Check!

## **4.5 Interaction with other medicinal products and other forms of interaction**

### Use with other vaccines

Bexsero can be given concomitantly with any of the following vaccine antigens, either as monovalent or as combination vaccines: diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, heptavalent pneumococcal conjugate, measles, mumps, rubella, varicella, and meningococcal groups A, C, W, Y conjugate.

Clinical studies demonstrated that the immune responses of the co-administered routine vaccines were unaffected by concomitant administration of Bexsero, based on non-inferior antibody response rates to the routine vaccines given alone. Inconsistent results were seen across studies for responses to inactivated poliovirus type 2 and pneumococcal conjugate serotype 6B and lower antibody titers to the pertussis pertactin antigen were also noted, but these data do not suggest clinically significant interference.

Due to an increased risk of fever, tenderness at the injection site, change in eating habits and irritability when Bexsero was co-administered with the above vaccines, separate vaccinations can be considered when possible. Prophylactic use of paracetamol reduces the incidence and severity of fever without affecting the immunogenicity of either Bexsero or routine vaccines. The effect of antipyretics other than paracetamol on the immune response has not been studied.

Concomitant administration of Bexsero with vaccines other than those mentioned above has not been studied.

When given concomitantly with other vaccines Bexsero must be administered at separate injection sites (see section 4.2).



Nowa aktywność Sortuj

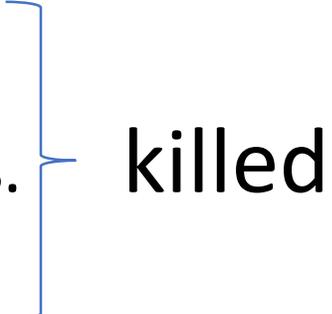
1 godz. •

Proszę o rozszyfrowanie przeciw czemu jest to wpisane w ukraińską książeczkę szczepienie...

Тип щепл.	Препарат Vaccine	Дата Date	Серія Lot #	Підпис, печатка лікаря (All Signature and stamp)
		24.VIII	14/300029	
		12.VI/18	3E0003/18	
		23.08.19	3.00014/18	
P. Mairry				

Komentarze: 17

# Types of vaccines:

- Live-attenuated **vaccines**.
  - Inactivated **vaccines**.
  - Subunit, recombinant, polysaccharide, and conjugate **vaccines**.
  - Toxoid **vaccines**.
- 
- killed

# Intervals between different vaccines

- attenuated  $\leftrightarrow$  attenuated
  - On the same day or >28 days
  - If two live **vaccines** are not given on the same day and are given less than four weeks apart, the second **vaccine** should be repeated
- attenuated  $\leftrightarrow$  killed – no interval required
- Killed  $\leftrightarrow$  killed - no interval required

# Intervals between vaccine doses



vaccines interval



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Okolo 11 000 000 wyników (0,42 s)

TABLE 3-1. Recommended and minimum ages and intervals between vaccine doses (a),(b),(c),(d)

<b>Vaccine and dose number</b>	<b>Recommended age for this dose</b>	<b>Recommended interval to next dose</b>
Influenza, inactivated <sup>(o)</sup>	≥6 months	4 weeks
IPV-1 <sup>(e)</sup>	2 months	8 weeks
IPV-2	4 months	8 weeks-14 months
IPV-3	6-18 months	3-5 years

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[ACIP Timing and Spacing Guidelines for Immunization - CDC](#)

# Intervals between vaccine doses

- Doses of any vaccine administered  $\geq 5$  days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval
- For example, if the first and second doses of *Haemophilus influenzae* type b (Hib) were administered only 14 days apart, the second dose would be invalid and need to be repeated because the minimum interval from dose 1 to dose 2 is 4 weeks. The repeat dose should be administered  $\geq 4$  weeks after the invalid dose (in this case, the second). The repeat dose is counted as the valid second dose.

# Dea



Odstępy  
czasowe między  
kolejnymi  
dawkami tej  
samej  
szczepionki



# Odstępy czasowe między kolejnymi dawkami tej samej szczepionki

**Tabela 1. Zalecany optymalny i minimalny wiek oraz zalecane i minimalne odstępy czasu pomiędzy kolejnymi dawkami rutynowo stosowanych szczepionek<sup>a-c</sup>**

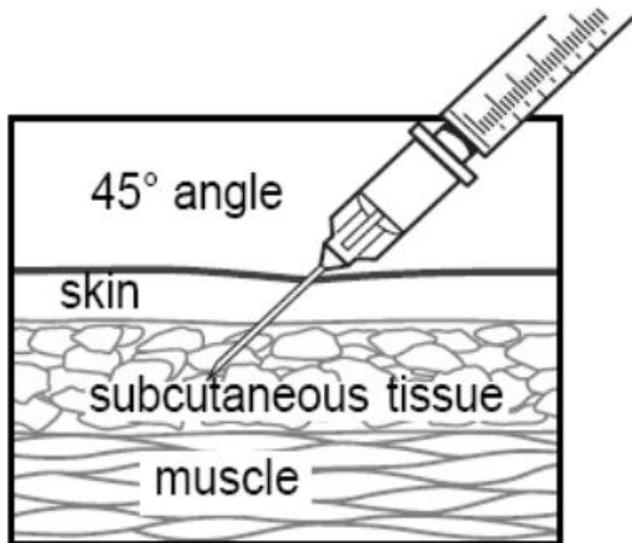
Szczepionka i numer dawki	Zalecany wiek dla podania tej dawki	Minimalny wiek dla podania tej dawki	Zalecany odstęp do podania kolejnej dawki	Minimalny odstęp do podania kolejnej dawki
HepB-1 <sup>c</sup>	w ciągu 24 h po urodzeniu	w ciągu 24 h po urodzeniu	1–4 miesiące	4 tygodnie
HepB-2	1–2 miesiące	4 tygodnie	2–17 miesięcy	8 tygodni
HepB-3 <sup>d</sup>	6–18 miesięcy	24 tygodnie	–	–
(DTPa, DTPw)-1 <sup>c</sup>	2 miesiące	6 tygodni	2 miesiące	4 tygodnie
(DTPa, DTPw)-2	4 miesiące	10 tygodni	2 miesiące	4 tygodnie
(DTPa, DTPw)-3	6 miesięcy	14 tygodni	6–12 miesięcy <sup>e</sup>	6 miesięcy <sup>e,f</sup>
(DTPa, DTPw)-4	15–18 miesięcy	12 miesięcy	3–4 lata	6 miesięcy <sup>e</sup>
DTPa-5	4–6 lat	4 lata	–	–
Hib-1 <sup>c,g</sup>	2 miesiące	6 tygodni	2 miesiące	4 tygodnie
Hib-2	4 miesiące	10 tygodni	2 miesiące	4 tygodnie
Hib-3h	6 miesięcy	14 tygodni	6–9 miesięcy <sup>e</sup>	8 tygodni
Hib-4	12–18 miesięcy	12 miesięcy	–	–
IPV-1 <sup>c</sup>	3–4 miesiące	6 tygodni	2 miesiące	4 tygodnie
IPV-2	5–6 miesięcy	10 tygodni	2–14 miesięcy	4 tygodnie
IPV-3	16–18 miesięcy	14 tygodni	3–5 lat	4 tygodnie
IPV-4	4–6 lat	18 tygodni	–	–

**TABLE 6–1. Dose and route of administration for selected vaccines**

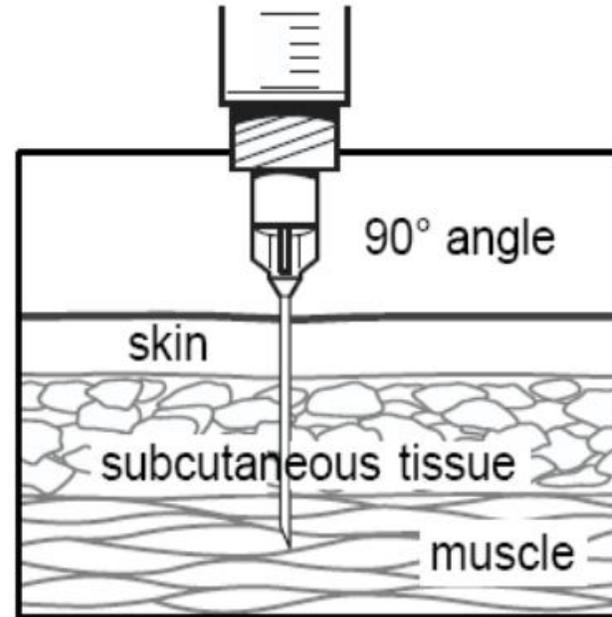
Vaccine	Dose	Route
DTaP, DT, Td, Tdap	0.5 mL	IM
DTaP-HepB-IPV	0.5 mL	IM
DTaP/Hib	0.5 mL	IM
DTaP-IPV/Hib	0.5 mL	IM
DTaP-IPV	0.5 mL	IM
Hib	0.5 mL	IM
Hib-MenCY	0.5 mL	IM
HepA	≤18 years: 0.5 mL ≥19 years: 1.0 mL	IM
HepB	≤19 years: 0.5 mL <sup>(a)</sup> ≥20 years: 1.0 mL	IM
HepA-HepB	≥18 years: 1.0 mL	IM
LAIV	0.2 mL divided dose between nares	Intranasal spray

# Injection types

**Subcutaneous (SC) injection**

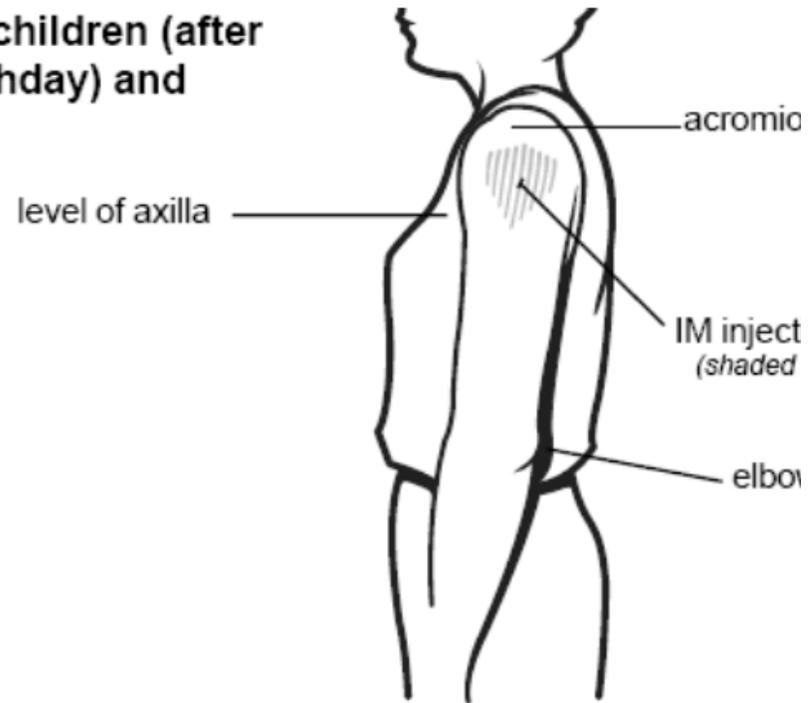


**Intramuscular (IM) injection**



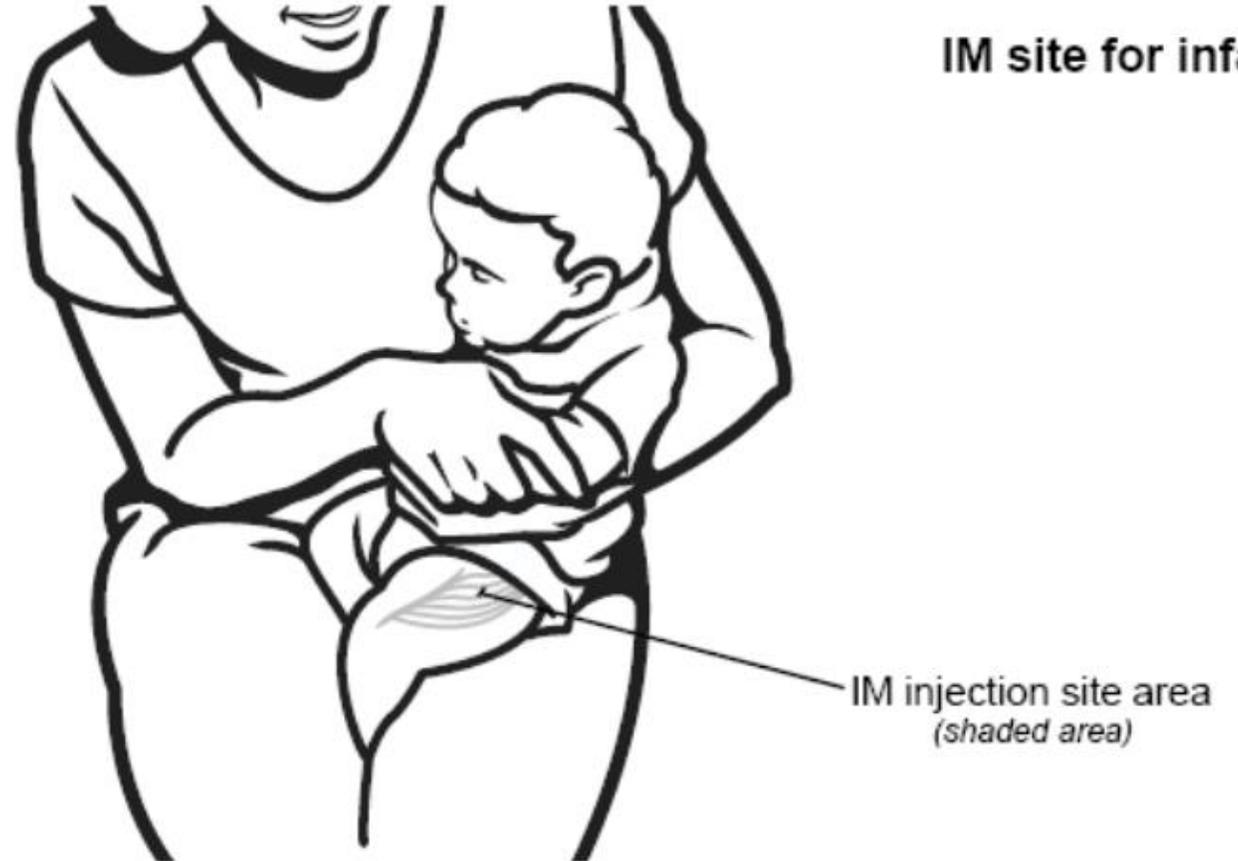
# Intramuscular injection

IM site for children (after the 1st birthday) and adults



Insert needle at a 90° angle into thickest portion of deltoid muscle—a the level of the axilla and below the acromion.

IM site for infants



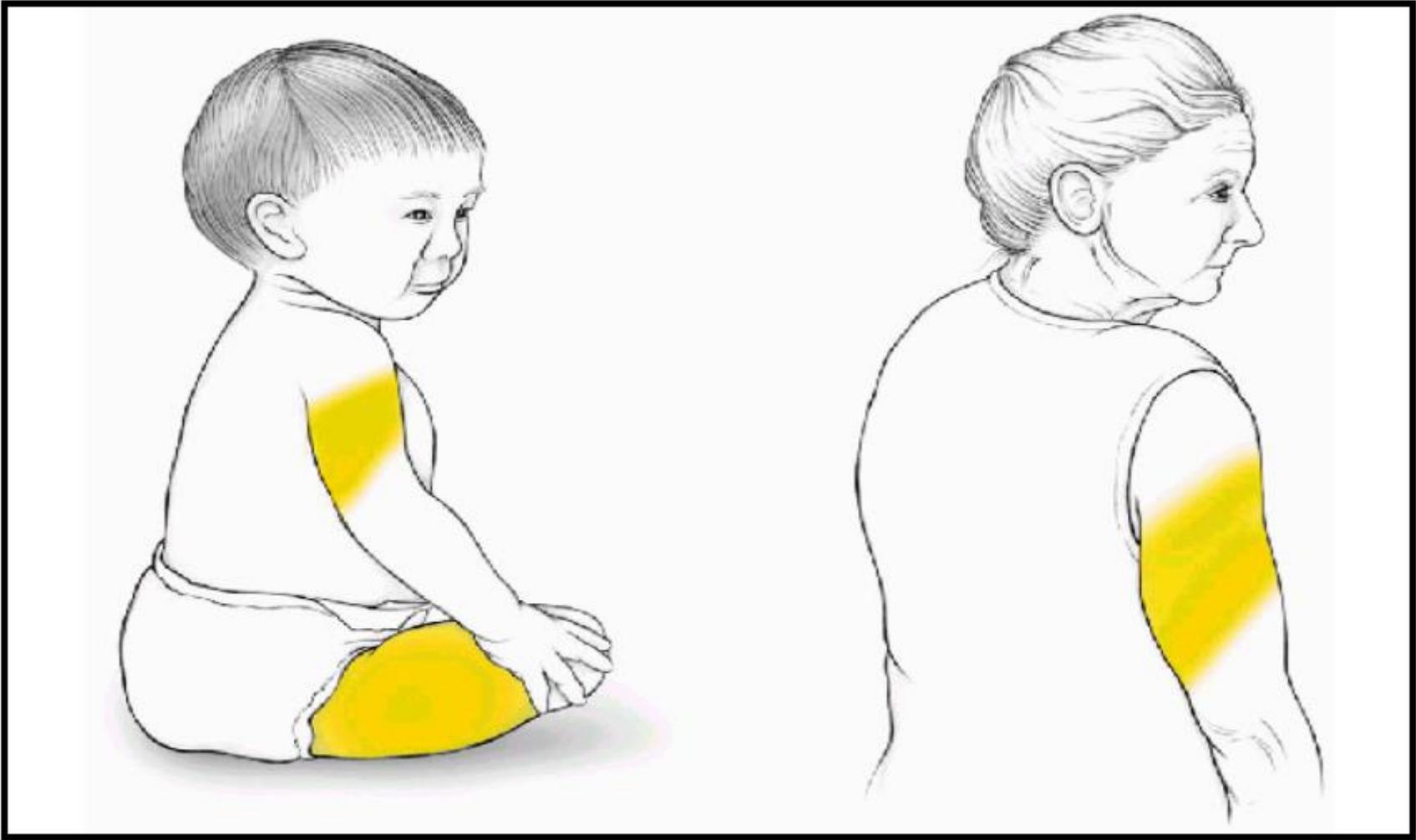
Insert needle at a 90° angle into the anterolateral thigh muscle.

# Intramuscular injection

TABLE 6-2. Needle length and injection site of IM injections for children aged  $\leq 18$  years (by age) and adults aged  $\geq 19$  years (by sex and weight)

Age group	Needle length	Injection site
<b>Children (birth-18 years)</b>		
Neonates <sup>(a)</sup>	5/8 inch (16 mm) <sup>(b)</sup>	Anterolateral thigh
Infants, 1-12 months	1 inch (25 mm)	Anterolateral thigh
Toddlers, 1-2 years	1-1.25 inch (25-32 mm)	Anterolateral thigh <sup>(c)</sup>
	5/8 <sup>(b)</sup> -1 inch (16-25 mm)	Deltoid muscle of arm
Children, 3-10 years	5/8 <sup>(b)</sup> -1 inch (16-25 mm)	Deltoid muscle of arm <sup>(c)</sup>
	1-1.25 inches (25-32 mm)	Anterolateral thigh
Children, 11-18 years	5/8 <sup>(b)</sup> -1 inch (16-25 mm)	Deltoid muscle of arm <sup>(c)</sup>
	1-1.5 inches (25-38 mm)	Anterolateral thigh

# Subcutaneous injection



# Multiple injections?

- DTP
- menB
- menACWY
- PCV13
- hepB

?

## Giving All the Doses $\geq 12$ months

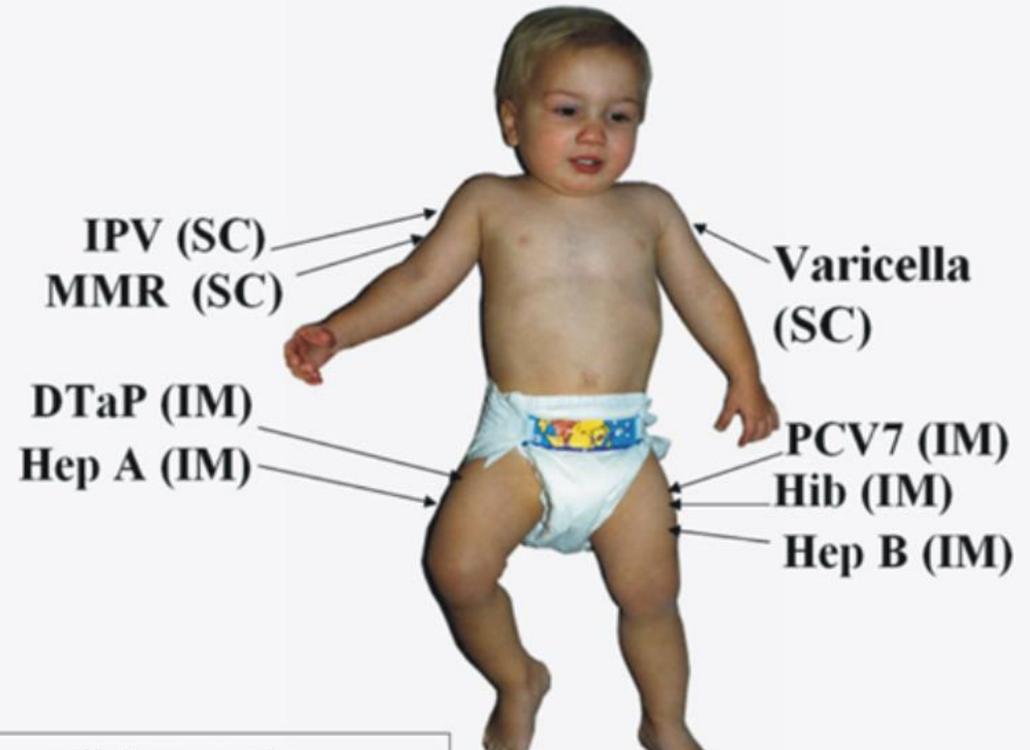
One way to give 8 doses at one visit

- Needle Lengths  
IM=1 inch to 1.5 inches  
SC=5/8 inch

- Separate injection sites by 1-2 inches

- Anterolateral thigh is the **preferred** site for multiple IM injections

- Deltoid (upper arm) is an option for IM in children  $\geq 18$  mo with adequate muscle mass





Time to  
practice!