Immunization 101

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Presenter Disclosure Information

I, Katie Reilly, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations. I have no relationships to disclose.

I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration

- But in accordance with ACIP recommendations

Outline

- Herd Immunity
- Types of vaccines
- 2018 Adult Immunization Schedule
- Screening prior to vaccination
- Contraindications and precautions to vaccination
- Vaccine Safety
- Vaccine Information Statements (VIS)
- Vaccine administration documentation requirements
- Vaccine adverse events and medical error reporting
- Use of Model Standing Orders

Herd Immunity/Community Immunity

"A situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community."

Retrieved from: https://www.cdc.gov/vaccines/terms/glossary.html#commimmunity

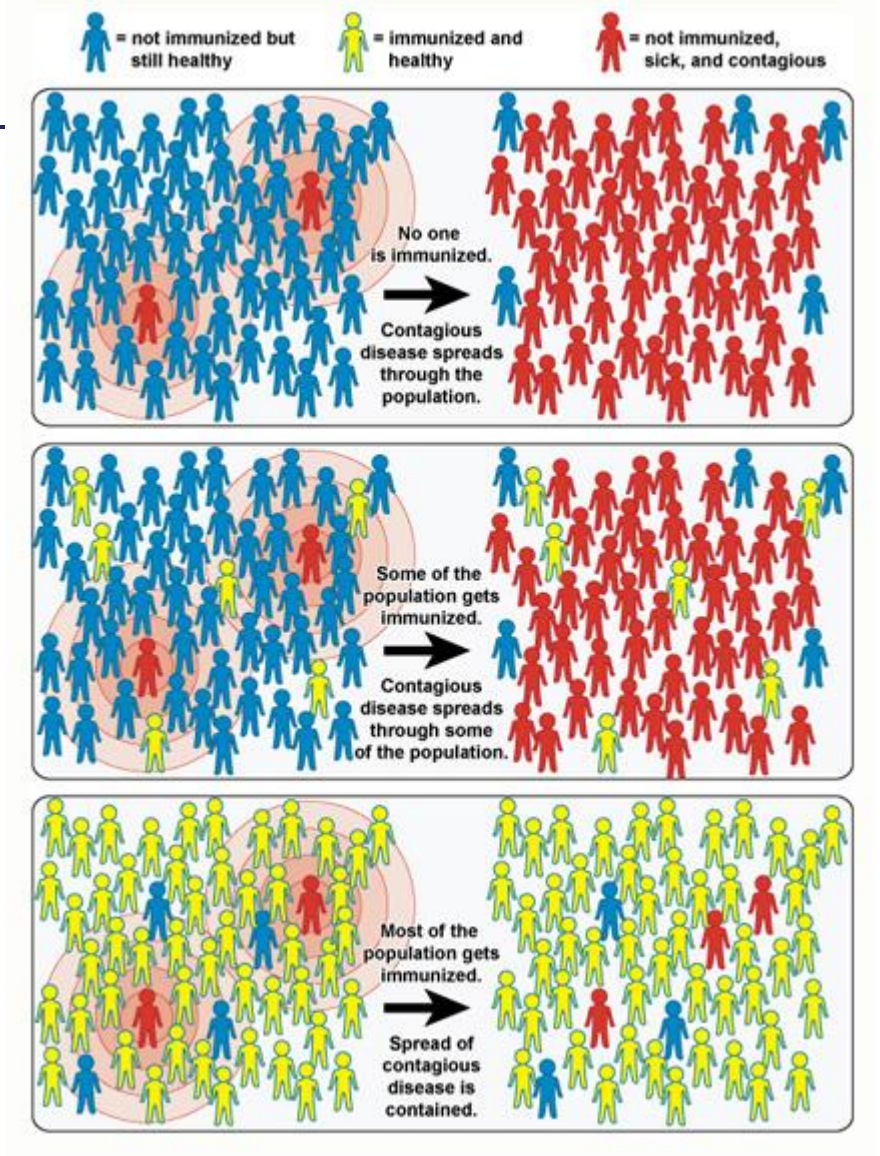


Photo credit: Courtesy: The National Institute of Allergy and Infectious Disease (NIAID)

Live Attenuated Vaccines

- Attenuated (weakened) form of the "wild" virus or bacterium
- Must replicate to produce an immune response
- Immune response virtually identical to natural infection
- Usually produce immunity with one dose (except those administered orally)
- Interference from circulating antibody
- Fragile: must be stored and handled carefully

- Viral: measles, mumps, rubella, vaccinia, varicella, zoster, yellow fever, rotavirus, intranasal influenza, oral polio*
- Bacterial: BCG*, oral typhoid

*not available in the USA

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/prinvac.pdf

Inactivated Vaccines

- Cannot replicate, and therefore cannot cause infection
- Less affected by circulating antibody than live vaccine
- Require multiple doses
- Immune response mostly humoral
- Antibody titer diminish with time
- May require periodic supplemental booster doses

- Whole cell vaccines:
  - Viral: polio, hepatitis A, rabies, influenza*
  - Bacterial: pertussis*, typhoid*, cholera, plague*
- Fractional vaccines
  - Subunits: hepatitis B, influenza, acellular pertussis, HPV, anthrax
  - Toxoids: diphtheria, tetanus

*not available in the USA

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/prinvac.pdf

2018 Adult Immunization Schedule

MMWR 2018:67(5):158-160

Available at:

- https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6705e3-H.pdf
- https://www.cdc.gov/vaccines/schedules/index.html

Updates - 2018 Adult Immunization Schedule

- Recommended use of recombinant zoster vaccine
- Recommended use of MMR in mumps outbreak setting
- Footnotes updated/simplified

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza[1]	1 dose annually				
Tdap[2] or Td[2]	1 dose Tdap, then Td booster every 10 yrs				
MMR[3]	1 or 2 doses depending on indication (if born in 1957 or later)				
VAR[4]	2 doses				
RZV[5] (preferred)				2 doses RZV (preferred)	
or				or	
ZVL[5]					1 dose ZVL
HPV–Female[6]	2 or 3 doses depending on age at series initiation				
HPV–Male[6]	2 or 3 doses depending on age at series initiation				
PCV13[7]	1 dose				
PPSV23[7]	1 or 2 doses depending on indication				1 dose
HepA[8]	2 or 3 doses depending on vaccine				
HepB[9]	3 doses				
MenACWY[10]	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
MenB[10]	2 or 3 doses depending on vaccine				
Hib[11]	1 or 3 doses depending on indication				

Added RZV row

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with other indications

No recommendation

Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	Pregnancy[1-6]	Immuno-compromised (excluding HIV infection)[3-7,11]	HIV infection CD4+ count (cells/μL)[3-7,9-10]		Asplenia, complement deficiencies[7,10,11]	End-stage renal disease, on hemodialysis[7,9]	Heart or lung disease, alcoholism[7]	Chronic liver disease[7-9]	Diabetes[7,9]	Health care personnel[3,4,9]	Men who have sex with men[6,8,9]
			<200	≥200							
Influenza[1]	1 dose annually										
Tdap[2] or Td[2]	1 dose Tdap each pregnancy	r every 10 yrs									
MMR[3]	contraindicated			on indication							
VAR[4]	contraindicated	2 doses									
RZV[5] (preferred)					2 doses RZV at age ≥50 yrs (preferred)						
or					or						
ZVL[5]	contraindicated				1 dose ZVL at age ≥60 yrs						
HPV–Female[6]		3 doses through age 26 yrs			2 or 3 doses through age 26 yrs						
HPV–Male[6]		3 doses through age 26 yrs			2 or 3 doses through age 21 yrs						2 or 3 doses through age 26 yrs
PCV13[7]		1 dose									
PPSV23[7]		1, 2, or 3 doses depending on indication									
HepA[8]	2 or 3 doses depending on vaccine										
HepB[9]	3 doses										
MenACWY[10]	1 or 2 doses depending on indication , then booster every 5 yrs if risk remains										
MenB[10]	2 or 3 doses depending on vaccine										
Hib[11]	3 doses HSCT recipients only	1 dose									

RZV row added

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with other indications

Contraindicated

No recommendation

Hepatitis B MMWR

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices

https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf

Strategy to eliminate HBV transmission in the United States

- Screening of all pregnant women for HBsAg
  - HBV DNA testing for HBsAg-positive pregnant women, with suggestion of maternal antiviral therapy to reduce perinatal transmission when HBV DNA is >200,000 IU/mL
  - Prophylaxis (HepB vaccine and HBIG) for infants born to HBsAg-positive women
- Universal vaccination of all infants beginning at birth, as a safeguard for infants born to HBV-infected mothers not identified prenatally
- Routine vaccination of previously unvaccinated children aged <19 years
- Vaccination of adults at risk for HBV infection, including those requesting protection from HBV without acknowledgment of a specific risk factor

Retrieved from Box 2 in https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf

ACIP Updates Hepatitis B Prevention

- **Relevant for adults**
  - Vaccinate persons with chronic liver disease (hepatitis C virus [HCV] infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- **New or updated ACIP recommendations for children**
  - Universal HepB within 24 hrs of birth for medically stable infants weighing ≥2,000 g
  - Test HBsAg(+) pregnant women for hepatitis B virus deoxyribonucleic acid (HBV DNA)
  - Test postvaccination serology for infants whose mother's HBsAg status unknown indefinitely (e.g., when a parent or person with lawful custody surrenders an infant confidentially shortly after birth)
  - Single-dose revaccination for infants born to HBsAg(+) women when not respond to initial vaccine series
  - Removal of permissive language for delaying birth dose after hospital discharge

Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31

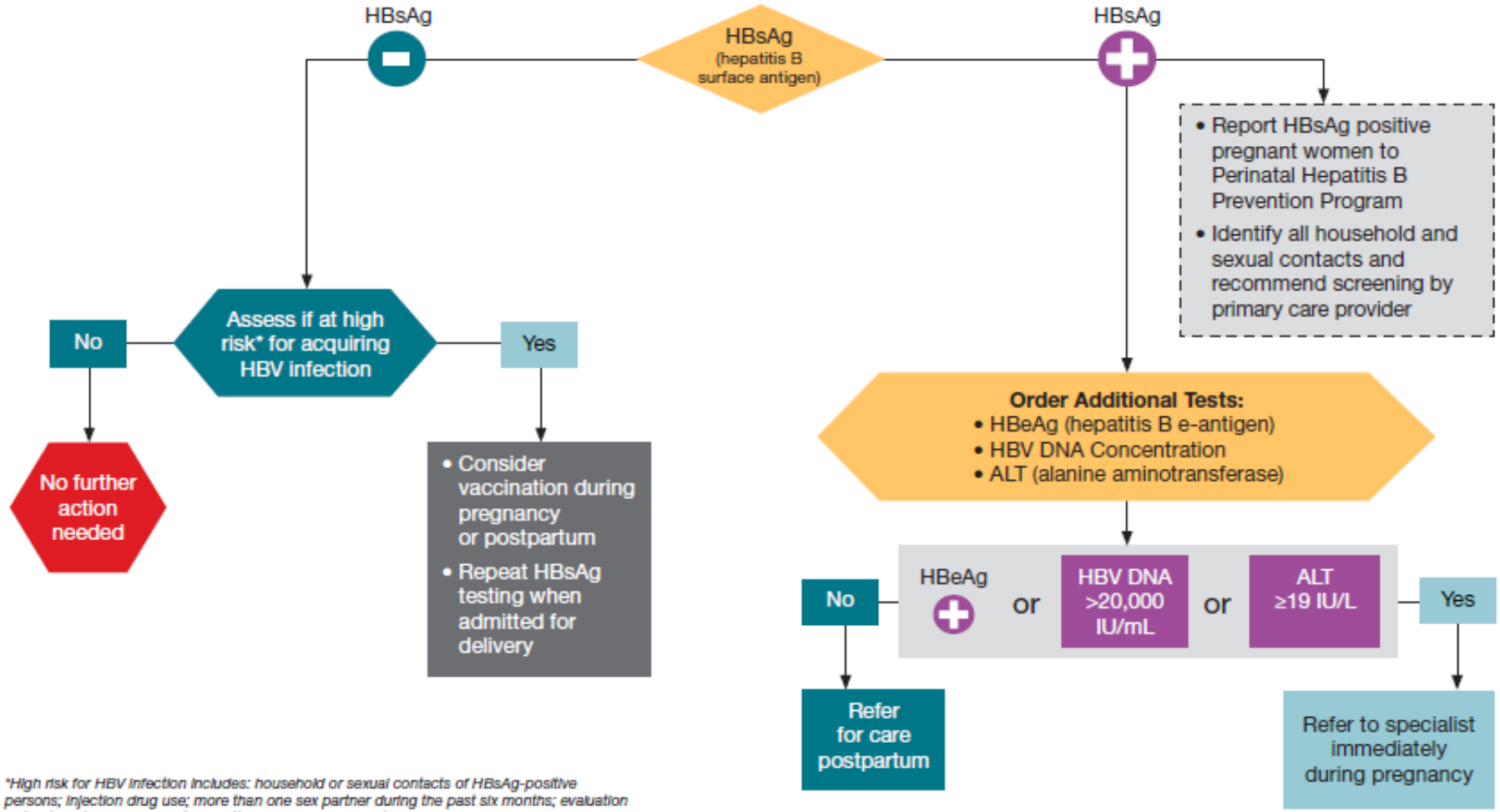
Screening for Risk Factors & Referrals for Perinatal HBV Infection

- Despite post exposure prophylaxis, mother to child transmission occurs in approximately 1% of infants born to HBsAg positive mothers.
- Risk factors for transmission include*:
  - Hepatitis B e-antigen (HBeAg positive)
  - High HBV DNA concentration (DNA >20,000 IU/mL)
  - Elevated alanine aminotransferase (ALT) ($\geq$19 IU/L)
- Emerging evidence suggests that HBV treatment of pregnant women with antiviral agents in the 3rd trimester is safe and reduces rates of transmission
  - AASLD suggests maternal antiviral therapy when the maternal HBV DNA is >200,000 IU/mL
- CDC and ACOG have developed a *Screening and Referral Algorithm for HBV Infection among Pregnant Women*

* Another risk factor is low birth weight (<2,000 grams) who receive the 1st dose of hepB vaccine before 1 month of age.

http://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf

Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women



*High risk for HBV infection includes: household or sexual contacts of HBsAg-positive persons; injection drug use; more than one sex partner during the past six months; evaluation or treatment for a sexually transmitted disease; HIV infection, chronic liver disease, or end-stage renal disease; and international travel to regions with HBsAg prevalence of ≥2%.

Adapted with permission from the Hepatitis B Foundation. Original publication: Apuzzio J, Block J, Cullison S, et al. Chronic Hepatitis B in pregnancy: A workshop consensus statement on screening, evaluation, and management, part 2. The Female Patient. 2012; 37(5):30-34

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

www.cdc.gov/hepatitis

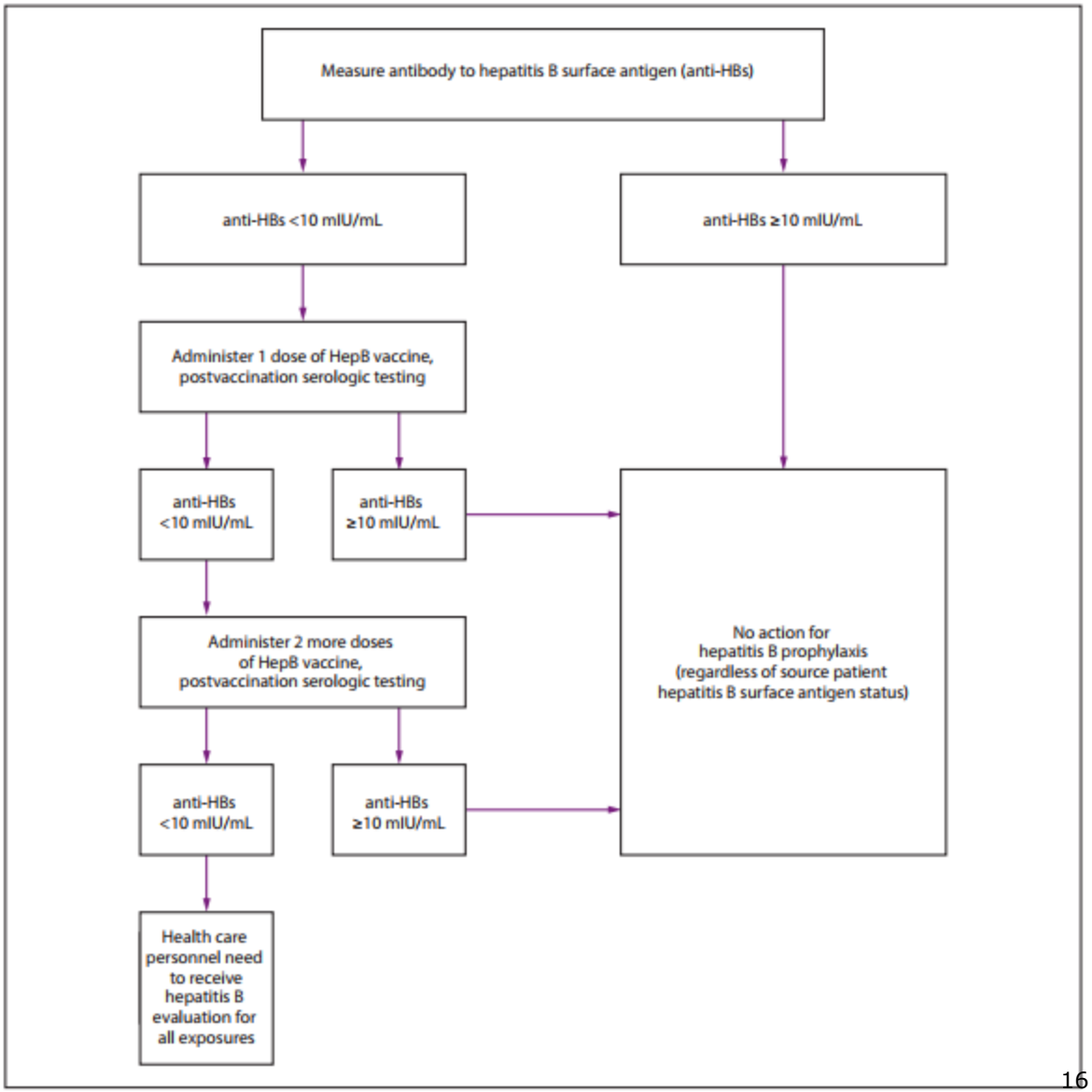
March 2015

Hepatitis B and Healthcare Personnel

- Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices

https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF
(page 22)

FIGURE 3. Pre-exposure evaluation for health care personnel previously vaccinated with complete, ≥3-dose HepB vaccine series who have not had postvaccination serologic testing*



Screening

- Is key to preventing serious adverse reactions
- Specific questions intended to identify contraindications or precautions to vaccination
- Screening must occur at every immunization encounter (not just before the first dose)
- Use of a standardized form will facilitate effective screening

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

Immunization Act Coalition (IAC) Screening Forms

- Child and Teen Immunizations
- Adult Immunizations
- Seasonal Influenza

http://www.immunize.org/handouts/screening-vaccines.asp

Screening Checklist for Contraindications to Vaccines for Adults

PATIENT NAME _____

DATE OF BIRTH ____ /____ /____
month day year

For patients: The following questions will help us determine which vaccines you may be given today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Are you sick today?	☐	☐	☐
2. Do you have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines for Adults

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the end.

1. Are you sick today? *[all vaccines]*

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events.[1] However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections or diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see reference 2; for an extensive list of vaccine components, see reference 3.

People with egg allergy of any severity can receive any recommended influenza vaccine (i.e., any IIV or RIV) that is otherwise appropriate for the patient's age. For people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office. Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.[4]

3. Have you ever had a serious reaction after receiving a vaccination? *[all vaccines]*

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses.[1] Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder? *[MMR, LAIV]*

A history of thrombocytopenia or thrombcytompenic purpura is a precaution to MMR vaccine. The safety of intranasal live attenuated influenza vaccine (LAIV) in people with these conditions has not been established. These conditions, includ-

NOTE: Live attenuated influenza vaccine (LAIV4; FluMist), is not recommended by CDC's Advisory Committee on Immunization Practices for use in the U.S. during the 2017–18 influenza season.

7. Have you had a seizure or a brain or other nervous system problem? *[influenza, Td/Tdap]*

Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (IIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccinate with IIV if at increased risk for severe influenza complications.

8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? *[LAIV, MMR, VAR, ZOS]*

Certain live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.[1]

9. For women: Are you pregnant or is there a chance you could become pregnant during the next month? *[HPV, IPV, MMR, LAIV, VAR, ZOS]*

Live virus vaccines (e.g., MMR, VAR, ZOS, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of exposure is imminent and immediate protection is needed (e.g., travel to endemic areas). Inactivated influenza vaccine and Tdap are both recommended during pregnancy. Both vaccines may be given at any time during pregnancy but the preferred time for Tdap administration is at 27–36 weeks' gestation. HPV vaccine is not recommended during pregnancy.[1,4,5,6,8,9]

Contraindication and Precautions

Contraindication

- A condition that increases the likelihood of a serious adverse reaction to a vaccine for a patient with that condition.
- In general, vaccine should not be administered when a contraindication condition is present.

Precaution

- A condition in a recipient that might increase the chance or severity of a serious adverse reaction, or that might compromise the ability of the vaccine to produce immunity.
- In general, vaccines are deferred with a precaution condition is present. However, situations may arise when the benefit of the protection from the vaccine outweighs the risk of an adverse reaction, and the provider may decide to give the vaccine.

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

Contraindications & Precautions In Adults

- Summary Table Published Annually by CDC with Adult Schedule https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf#page=6
- Immunization Action Coalition: http://www.immunize.org/catg.d/p3072.pdf

Table. Contraindications and precautions for vaccines recommended for adults aged 19 years or older*

The Advisory Committee on Immunization Practices (ACIP) recommendations and package inserts for vaccines provide information on contraindications and precautions related to vaccines. Contraindications are conditions that increase chances of a serious adverse reaction in vaccine recipients and the vaccine should not be recipients.

Contraindications and precautions for vaccines routinely recommended for adults

Vaccine(s)	Contraindications
All vaccines routinely recommended for adults	• Severe reaction, e.g., anaphylaxis, after a previous dose or to a vaccine c

Additional contraindications and precautions for vaccines routinely recommended for a

Vaccine(s)	Additional Contraindications
IIV[1]	
RIV[1]	
Tdap, Td	• For pertussis-containing vaccines: encephalopathy, e.g., coma, decrease or prolonged seizures, not attributable to another identifiable cause wit administration of a previous dose of a vaccine containing tetanus or dip pertussis
MMR[2]	• Severe immunodeficiency, e.g., hematologic and solid tumors, chemoth immunodeficiency or long-term immunosuppressive therapy[3], human i (HIV) infection with severe immunocompromise • Pregnancy
VAR[2]	• Severe immunodeficiency, e.g., hematologic and solid tumors, chemoth immunodeficiency or long-term immunosuppressive therapy[3], HIV infec immunocompromise • Pregnancy
ZVL[2]	• Severe immunodeficiency, e.g., hematologic and solid tumors, chemoth immunodeficiency or long-term immunosuppressive therapy[3], HIV infec immunocompromise • Pregnancy
HPV vaccine	
PCV13	• Severe allergic reaction to any vaccine containing diphtheria toxoid

1. For additional information on use of influenza vaccines among persons with egg allergy, see: CDC. Practices—United States, 2016–17 influenza season. MMWR. 2016;65(RR-5):1–54. Available at www
2. MMR may be administered together with VAR or ZVL on the same day. If not administered on the s
3. Immunosuppressive steroid dose is considered to be daily receipt of 20 mg or more prednisone or immunosuppressive steroid therapy. Providers should consult ACIP recommendations for complet suppression because of other reasons.
4. Vaccine should be deferred for the appropriate interval if replacement immune globulin products a

Guide to Contraindications and Precautions to Commonly Used Vaccines in Adults[1],*

Vaccine	Contraindications[1]	Precautions[1]
Influenza, inactivated (IIV)[2,3] Influenza, recombinant (RIV)[2,3]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • History of Guillain-Barré Syndrome (GBS) within 6 weeks of previous influenza vaccination • For IIV vaccine only: Egg allergy other than hives (e.g., angioedema, respiratory distress, lightheadedness, or recurrent emesis); or required epinephrine or another emergency medical intervention (IIV may be administered in a medical setting, under the supervision of a healthcare provider who is able to recognize and manage severe allergic conditions)
Tetanus, diphtheria, pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For pertussis-containing vaccines: encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of a vaccine containing tetanus or diphtheria toxoid or acellular pertussis.	• Moderate or severe acute illness with or without fever • GBS within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • For Tdap only: progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy; defer until a treatment regimen has been established and the condition has stabilized
Varicella (Var)[3]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy[4]), or persons with human	• Moderate or severe acute illness with or without fever • Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)[5]

Contraindications & Precautions in Adults & Children

Guide to Contraindications and Precautions to Commonly Used Vaccines[1,*]

Vaccine	Contraindications	Precautions
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Hypersensitivity to yeast	• Moderate or severe acute illness with or without fever • Infant weighing less than 2000 grams (4 lbs, 6.4 oz)[2]
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception	• Moderate or severe acute illness with or without fever • Altered immunocompetence other than SCID • Chronic gastrointestinal disease[3] • Spina bifida or bladder exstrophy[3]
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria, pertussis (Tdap) Tetanus, diphtheria (DT, Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For pertussis-containing vaccines: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of DTP or DTaP (for DTaP); or of previous dose of DTP, DTaP, or Tdap (for Tdap)	• Moderate or severe acute illness with or without fever • Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria- or tetanus-toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine • For DTaP and Tdap only: Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy; defer until a treatment regimen has been established and the condition has stabilized For DTaP only:

http://www.immunize.org/catg.d/p3072a.pdf

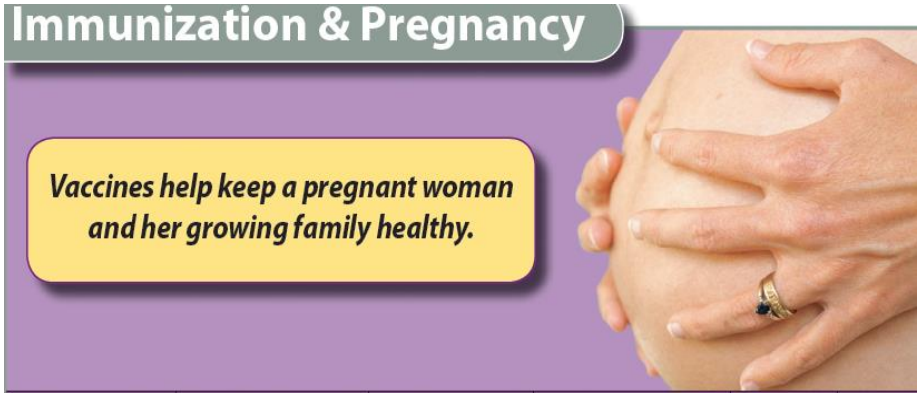
Vaccination of Pregnant Women

- Live vaccines should not be administered to women known to be pregnant
- In general, inactivated vaccines may be administered to pregnant women for whom they are indicated
- HPV vaccine should be deferred during pregnancy

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

CDC Guidelines for Vaccinating Pregnant Women

- Guidelines for vaccination
- Travel and other vaccines
- Breastfeeding and vaccination
- Prenatal screening



http://www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html

Immunizations and Pregnancy

Vaccine	Before pregnancy	During pregnancy	After pregnancy	Type of vaccine
Influenza	Yes	Yes, during flu season	Yes	Inactivated
Tdap	May be recommended; it is better to vaccinate during pregnancy when possible	Yes, during **each** pregnancy	Yes, immediately postpartum, if Tdap never received in lifetime; it is better to vaccinate during pregnancy	Toxoid/ Inactivated
Td	May be recommended	May be recommended, but Tdap is preferred	May be recommended	Toxoid
Hepatitis A	May be recommended	May be recommended	May be recommended	Inactivated
Hepatitis B	May be recommended	May be recommended	May be recommended	Inactivated
Meningococcal	May be recommended	Base decision on risk vs. benefit; inadequate data for specific recommendation	May be recommended	Inactivated
Pneumococcal	May be recommended	Base decision on risk vs. benefit; inadequate data for specific recommendation	May be recommended	Inactivated
HPV	May be recommended (through 26 years of age)	No	May be recommended (through 26 years of age)	Inactivated
MMR	May be recommended; once received, avoid conception for 4 weeks	No	May be recommended	Live
Varicella	May be recommended; once received, avoid conception for 4 weeks	No	May be recommended	Live

http://www.cdc.gov/vaccines/pregnancy/downloads/immunizations-preg-chart.pdf

Importance of Vaccine Safety

Decreases in disease risks and increased attention on vaccine risks

Public confidence in vaccine safety critical

- Higher standard of safety is expected of vaccines
- Vaccinees generally healthy (vs. ill for drugs)
- Lower risk tolerance = need to search for rare reactions
- Vaccination universally recommended and mandated

http://www.cdc.gov/vaccines/pubs/pinkbook/safety.html

US Post-licensure Vaccine Safety System

System	Collaboration	Description
Vaccine Adverse Event Reporting System (VAERS)	CDC and FDA	Frontline spontaneous reporting system to detect potential vaccine safety issues
Vaccine Safety Datalink (VSD)	CDC and 9 Integrated Health Care Systems	Large linked database system used for active surveillance and research ~9.4 million members (~3% of US pop.) -Conducts monitoring & evaluation
Clinical Immunization Safety Assessment (CISA) Project	CDC and 7 Academic Centers	Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research
Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)	FDA and 4 partner organizations	Large distributed database system used for active surveillance and research ~170 million individuals

Source: HPV Safety Presentation by Julianne Gee, MPH Immunization Safety Office
Centers for Disease Control and Prevention (CDC) August 4, 2016

The Provider's Role

Immunization providers can help to ensure the safety and efficacy of vaccines through proper:

- Vaccine storage and administration
- Timing and spacing of vaccine doses
- Observation of contraindications and precautions
- Management of adverse reactions
- Reporting to VAERS
- Benefit and risk communication

http://www.cdc.gov/vaccines/pubs/pinkbook/safety.html

Seven Rights of Vaccine Administration

- Right Patient
- Right Time
- Right Vaccine (and Diluent)
- Right Dosage
- Right Route, Needle, Technique
- Right Injection Site
- Right Documentation

http://www.immunize.org/technically-speaking/20141101.asp

Influenza Vaccine Products for the 2017–2018 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Group	Vaccine Product Billing Code[2]	
					CPT	Medicare
GlaxoSmithKline	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older	90686	90686
ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older	90686	90686
		5.0 mL (multi-dose vial)	<25	6 months & older	90688	90688
MedImmune	FluMist[3] (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	90672	90672
Protein Sciences Corp.	Flublok (RIV3)	0.5 mL (single-dose vial)	0	18 years & older	90673	90673
	Flublok (RIV4)	0.5 mL (single-dose syringe)	0	18 years & older	90682	90682
Sanofi Pasteur, Inc.	Fluzone (IIV4)	0.25 mL (single-dose syringe)	0	6 through 35 months	90685	90685
		0.5 mL (single-dose syringe)	0	3 years & older	90686	90686
		0.5 mL (single-dose vial)	0	3 years & older	90686	90686
		5.0 mL (multi-dose vial)	25	6 through 35 months	90687	90687
		5.0 mL (multi-dose vial)	25	3 years & older	90688	90688
	Fluzone High-Dose (IIV3-HD)	0.5 mL (single-dose syringe)	0	65 years & older	90662	90662
	Fluzone Intradermal (IIV4-ID)	0.1 mL (single-dose microinjection system)	0	18 through 64 years	90630	90630
Seqirus	Afluria (IIV3)	0.5 mL (single-dose syringe)	0	5 years & older[4]	90656	90656
		5.0 mL (multi-dose vial)	24.5		90658	Q2035
	Afluria (IIV4)	0.5 mL (single-dose syringe)	0	5 years & older[4]	90686	90686
		5.0 mL (multi-dose vial)	24.5		90688	90688
	Fluad (aIIV3)	0.5 mL (single-dose syringe)	0	65 years & older	90653	90653
	Fluvirin (IIV3)	0.5 mL (single-dose syringe)	≤1	4 years & older	90656	90656
		5.0 mL (multi-dose vial)	25		90658	Q2037
	Flucelvax (ccIIV4)	0.5 mL (single-dose syringe)	0	4 years & older	90674	90674
		5.0 mL (multi-dose vial)	25		90749/90756[5]	Q2039/90756[6]

http://www.immunize.org/catg.d/p4072.pdf

Administering Vaccines to Adults: Dose, Route, Site, and Needle Size

VACCINE	DOSE
Hepatitis A (HepA)	≤18 yrs: 0.5 ≥19 yrs: 1.0
Hepatitis B (HepB)	≤19 yrs: 0.5 ≥20 yrs: 1.0
HepA-HepB (Twinrix)	≥18 yrs: 1.0
Human papillomavirus (HPV)	0.5 mL
Influenza, live attenuated (LAIV)	0.2 mL (0.1 n each nost
Influenza, inactivated (IIV) **and recombinant** (RIV)	0.5 mL
Influenza (IIV) **Fluzone Intradermal, for ages 18 through 64 years**	0.1 mL
Measles, Mumps, Rubella (MMR)	0.5 mL
Meningococcal conjugate (MenACWY)	0.5 mL
Meningococcal protein (MenB)	0.5 mL
Meningococcal serogroup B (MenB)	0.5 mL
Meningococcal polysaccharide (MPSV)	0.5 mL
Pneumococcal conjugate (PCV13)	0.5 mL
Pneumococcal polysaccharide (PPSV)	0.5 mL
Tetanus, Diphtheria (Td) **with Pertussis** (Tdap)	0.5 mL
Varicella (VAR)	0.5 mL

http://www.immunize.org/catg.d/p3084.pdf

Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert*	Diluent storage environment
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB_{HDCV})	Sanofi Pasteur	Rabies virus	Sterile water	Immediately†	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menveo (MenACWY)	GlaxoSmithKline	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB_{PCECV})	GlaxoSmithKline	Rabies virus	Sterile water	Immediately†	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GlaxoSmithKline	RZV	$AS01_B$§ adjuvant suspension	6 hours	Refrigerator
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	Sanofi Pasteur	YF	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (LZV)	Merck	LZV	Sterile water	30 min	Refrigerator or room temp

http://www.immunize.org/catg.d/p3040.pdf

Vaccine Information Statements (VISs)

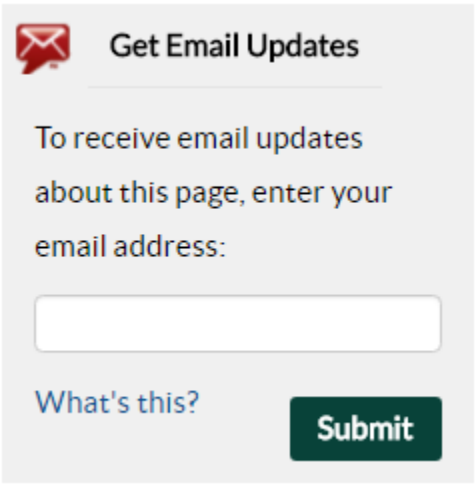
Healthcare provider requirements

- Public and private providers
- Give VISs **before** vaccine is administered
- Applies to **every dose** of a vaccine series not just the first dose
- Opportunities for questions should be provided before each vaccination
- Offer a copy of the VISs to take away
- Available in multiple languages

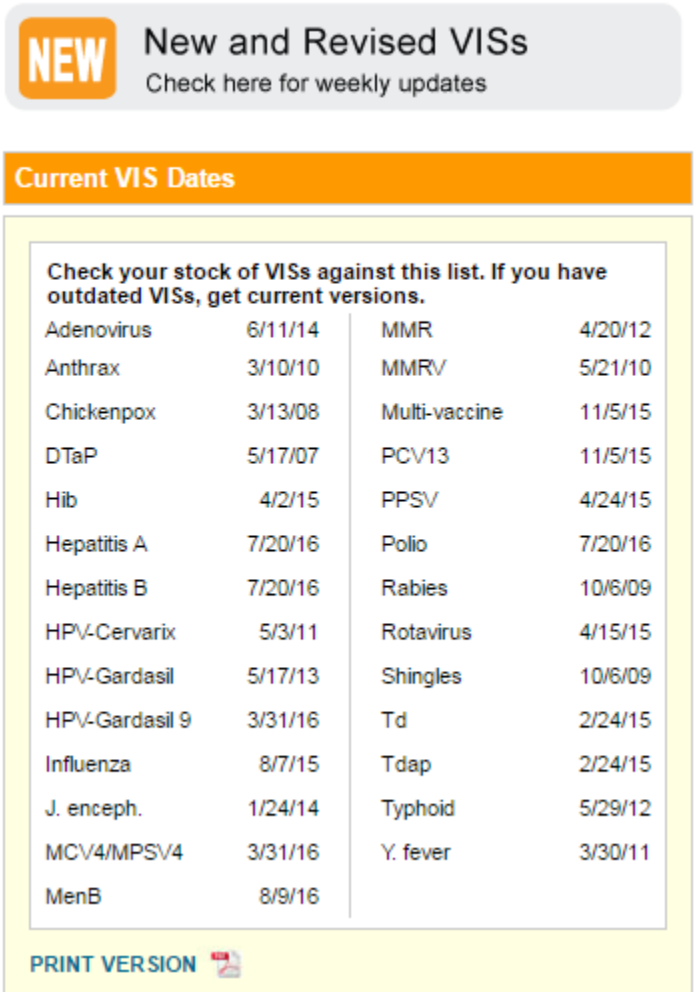
http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html#give

Your Sources for VISs

http://www.cdc.gov/vaccines/hcp/vis/index.html



http://www.immunize.org/vis/



Healthcare Provider Documentation Requirements

Providers must ensure that the recipient's permanent medical record (whether paper-based or electronic) contains all of the required vaccine administration documentation, which shall consist of the following:

- Date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name and title of person administering the vaccine
- Address of clinic where vaccine was given
- The address of the facility where the permanent record will reside (if appropriate)
- Edition date printed on the appropriate VIS
- Date the VIS was given to the vaccine recipient, or the parents/legal representative

- We also recommend that the vaccine type, dose, site, route of administration, and vaccine expiration date be documented, and any vaccine refusal (if appropriate).

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-admin.pdf

MDPH Vaccine Administration Record

Vaccine Administration Record – All Ages

Record No. / Insurance No.: _____

Patient Name: _____

Address: _____

Birth Date: _____ Male _____ Female _____

Clinic Name and Address:

Use Reverse Side for Names and Initials of Vaccine Administrators

Vaccine administrator: Provide the patient, parent or legal representative with the most recent copy of the Vaccine Information Statement (VIS), which explains risks and benefits of vaccine, for **each** dose of vaccine given.

Type of Vaccine: Record the generic abbreviation for the type of vaccine given (e.g., DTaP), not the trade name. For combination vaccines, indicate the type (e.g.,DTaP-Hib) and all other information for each individual antigen (e.g., in the DTP and Hib sections) comprising the combination. Document all lot numbers for each component.

Vaccine	Type of Vaccine	Date Given M/D/Y	Dose	Route (PO, SC, IM, ID, IN, MP)	Site (RA,LA, RT, LT)	Vaccine		Vaccine Information Statement		Vaccine Admin Initials
						lot #	mfr.	Date on VIS	Date Given	
Hepatitis B (e.g., HepB, HepB-Hib, DTaP-HepB-IPV, HepA-HepB)				IM						
				IM						
				IM						
				IM						
Diphtheria, Tetanus, Pertussis (e.g., DTP, DTaP, DT, DTaP-Hib, DTaP-IPV/Hib, DTaP-HepB-IPV, DTaP-IPV, Td, Tdap)				IM						
				IM						
				IM						
				IM						
				IM						
				IM						
***Haemophilus influenzae* type b** (e.g., Hib, HepB-Hib, DTaP-Hib, DTaP-IPV/Hib, Hib-MenCY)				IM						
				IM						
				IM						
				IM						

http://www.mass.gov/eohhs/docs/dph/cdc/immunization/record-vaccine-admin-clinic.pdf

MIIS Reporting Requirements

Legislation passed in June 2010, charging MDPH to establish an immunization registry (M.G.L. c. 111, s.24M)

- **Mandatory reporting of all immunizations administered in MA**

Regulations were promulgated January 2015

- outline information on system access, confidentiality, and requirements for data elements to be reported
- describe a provider's duty to inform patients, and a patient's right to object to data sharing across providers

See MIIS table or **www.contactmiis.info** for more information

Vaccine Adverse Reactions

Adverse reaction

- Extraneous effect caused by vaccine
- Side effect

Adverse event

- Any medical event following vaccination
- May be true adverse reaction
- May be only coincidental

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

Vaccine Adverse Reactions

Local

- Pain, swelling, redness at site of injection
- Occur within a few hours of injection
- Usually mild and self-limited

Systemic

- Fever, malaise, headache
- Nonspecific
- May be unrelated to vaccine

Severe Allergic (anaphylaxis)

- Due to vaccine or vaccine component
- Rare
- Risk minimized by screening

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

Reporting of Vaccine Errors and Adverse Events

VAERS: Vaccine Adverse Event Reporting System

- Report all vaccine adverse events to VAERS at vaers.hhs.gov or (800) 822-7967. Report directly online or upload PDF.

ISMP: Institute for Safe Medication Practice

- Report vaccine administration errors (e.g., wrong route, wrong dose, and wrong age) to the (ISMP) via the Vaccine Error Reporting Program (VERP) website http://ismp.org.
- Vaccine administration errors should also be reported to VAERS (as described above), and MUST be reported if they resulted in an adverse event.

Vaccine Injury Compensation Program (VICP)

- Established by National Childhood Vaccine Injury Act (1986)
- "No fault" program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table
  - Lists conditions associated with each vaccine
  - http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf

http://www.cdc.gov/vaccines/pubs/pinkbook/safety.html

Tips to Increase Immunization Rates

- Assess immunization status of all patients in every clinical encounter
  - Avoid missed opportunities
- Strongly recommend vaccines that patients need
  - Speak from personal experience
- Administer needed vaccines or refer to a vaccinating provider and confirm receipt
  - Utilize standing orders
  - Offer vaccine only visits
- Reminder recall
- Provide information in foreign languages
- Document vaccines received by patients, including entering immunization into immunization registry (MIIS)

Benefits of Standing Orders

- Overcome administrative barriers and save time
- Shown to be **effective** in both adults and children[1]
  - For children, use of standing orders is associated with a median increase in vaccination coverage of 28%
  - Most effective evidence-based method
- **REDUCES MISSED OPPORTUNITIES**
- Consider implementing standing orders for vaccination, particularly for the adolescent immunization 'bundle'
- 'Presumptive' recommendation in action

IAC model standing orders available at:
http://www.immunize.org/standing-orders/
MDPH model standing orders available at:
http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunization/model-standing-orders.html

RESOURCES

General Best Practice Guidelines for Immunization

Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

Kroger AT, Duchin J, Vázquez M

1. Introduction

The Centers for Disease Control and Prevention (CDC) recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults. This report provides information for clinicians and other health care providers about concerns that commonly arise when vaccinating persons of various ages.

ACIP Best Practice Guidelines for Immunization

- Replaces *General Recommendations on Immunization* in MMWR last updated in 2011
- Describes recommendations and guidelines on vaccination practice
- Updates on vaccination record policy, impact of ACA, characterization and protocol for anaphylaxis, definition of precaution; new information on simultaneous vaccination and febrile seizures

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

Minimum Interval Table

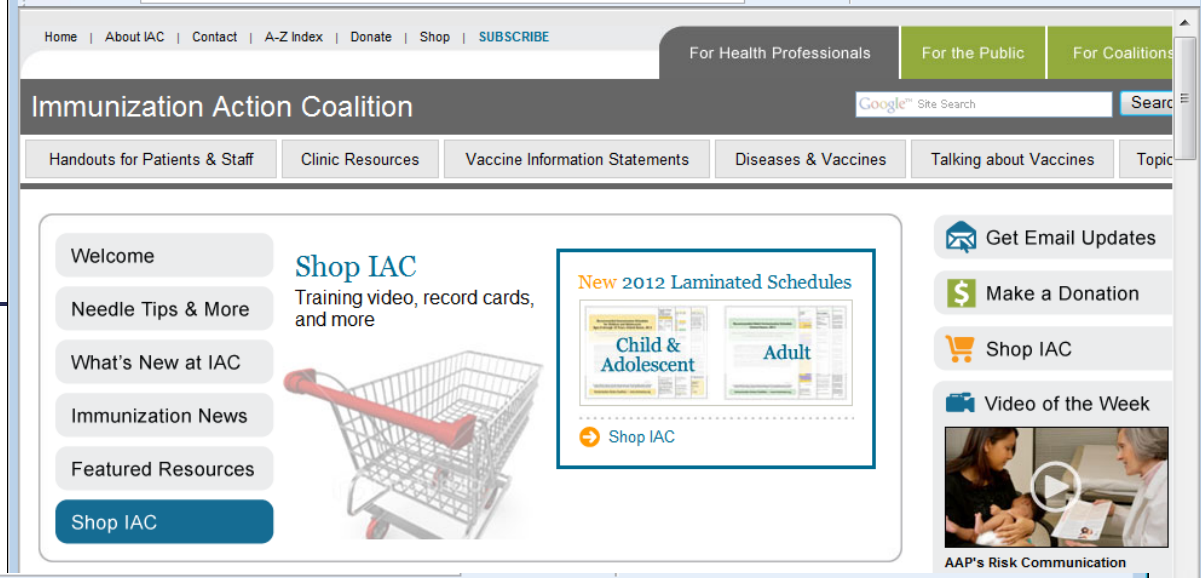
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf

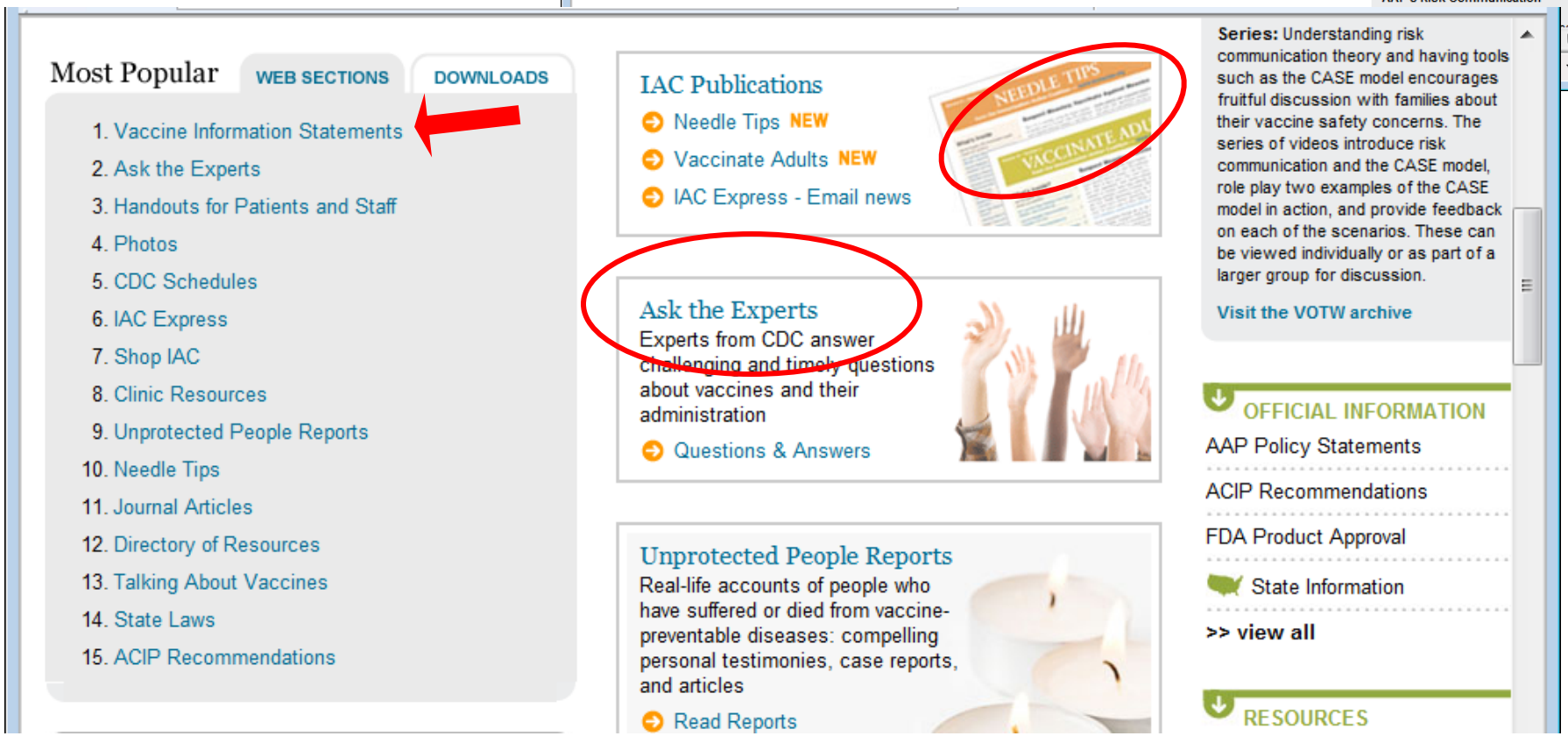
Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines[1,2,3,4]

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Diphtheria-tetanus-acellular pertussis (DTaP)-1[5]	2 months	6 weeks	8 weeks	4 weeks
DTaP-2	4 months	10 weeks	8 weeks	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months[6]
DTaP-4[6]	15-18 months	12 months[6]	3 years	6 months
DTaP-5	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1[5,7]	2 months	6 weeks	8 weeks	4 weeks
Hib-2	4 months	10 weeks	8 weeks	4 weeks
Hib-3[8]	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
Hepatitis A (HepA)-1[5]	12-23 months	12 months	6-18 months	6 months
HepA-2	≥18 months	18 months	—	—
Hepatitis B (HepB)-1[5]	Birth	Birth	4 weeks-4 months	4 weeks
HepB-2	1-2 months	4 weeks	8 weeks-17 months	8 weeks
HepB-3[9]	6-18 months	24 weeks	—	—

Immunization Action Coalition

www.immunize.org





Immunization Action Coalition

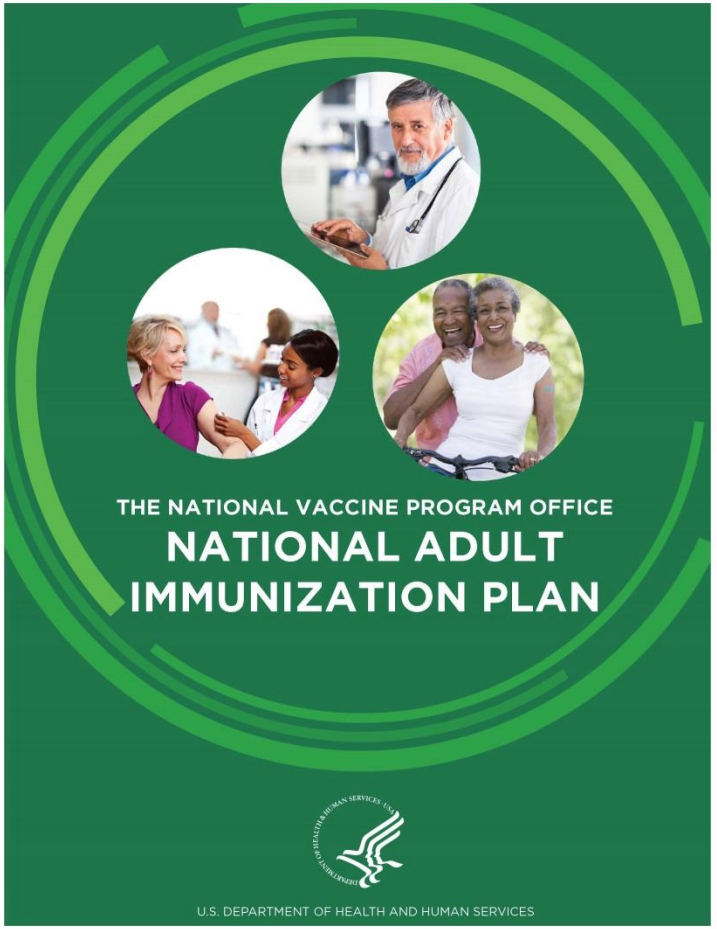
Vaccinating Adults:

A Step-by-Step Guide

http://www.immunize.org/guide/

National Adult Immunization Plan

- Goal 1: Strengthen the adult immunization infrastructure
- Goal 2: Improve access to adult vaccines
- Goal 3: Increase community demand for adult immunizations
- Goal 4: Foster innovation in adult vaccine development and vaccination-related techniques



Learn more at http://www.hhs.gov/nvpo/national-adult-immunization-plan/index.html

MA Adult Immunization Coalition(MAIC)

- MAIC is a collaborative partnership dedicated to increasing adult immunization through education, networking, and sharing innovative and best practices.
- There are currently over 200 members representing:
  - Local and state public health organizations
  - Community health centers
  - Health insurance plans
  - Pharmacies
  - Physicians
  - Vaccine manufacturers
  - Long-term-care and senior service organizations
  - Consumer advocacy groups
  - Hospitals
  - Home health
  - College health services

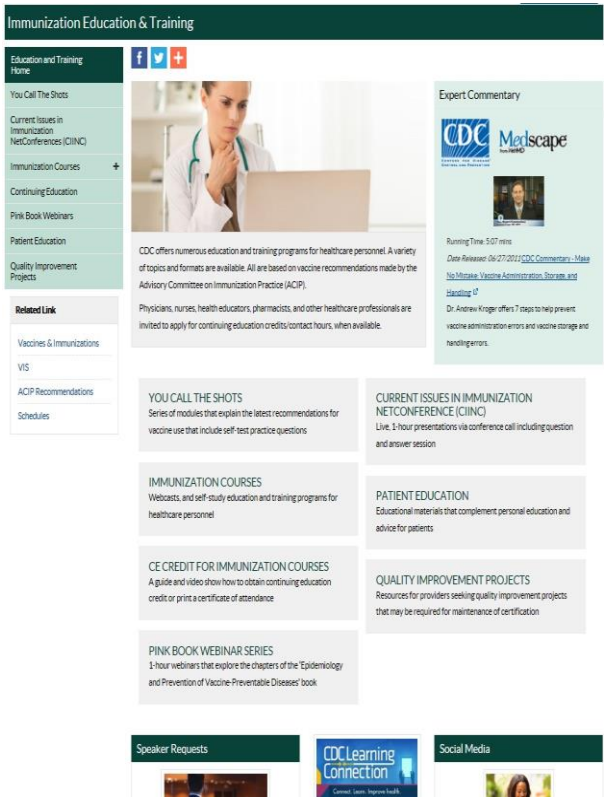
Learn more at
http://maic.jsi.com/

CDC's Toolkit for Prenatal Providers

https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/index.html

CDC Resources for Staff Education

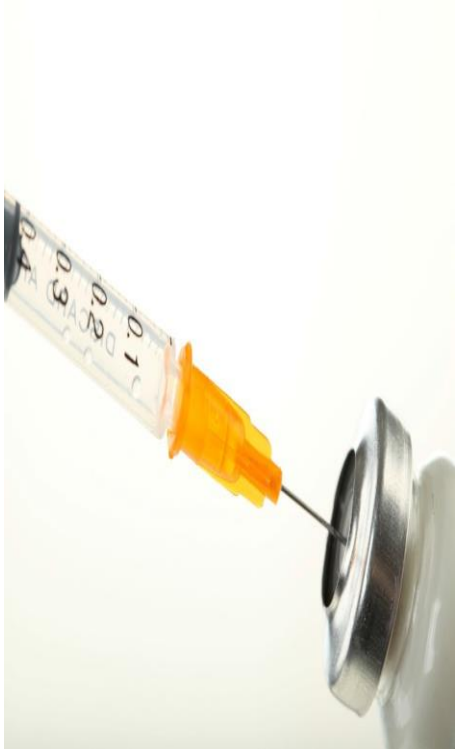
- Competency-based education for staff is critical
- Multiple education products available free through the CDC website:
  - Immunization courses
  - "You Call the Shots" self-study modules
  - Netconferences
- Continuing education is available



http://www.cdc.gov/vaccines/ed/index.html

Vaccine Administration e-Learn

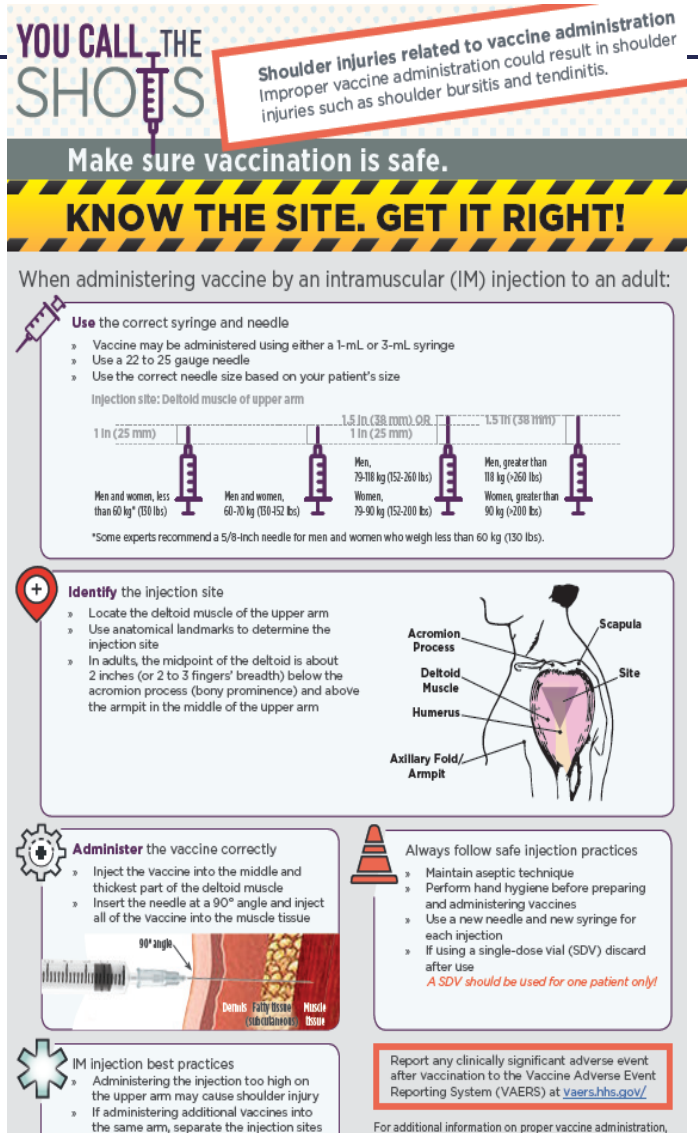
- The e-Learn is a free, interactive, online educational program that serves as a useful introductory course or a great refresher on vaccine administration
- Continuing education available for nurses, physicians, pharmacists, and other health care personnel
- It is available on the Continuing Education web page at: https://www.cdc.gov/vaccines/ed/courses.html#elearn-vaccadmin



Clinical Resources for Shoulder Injury Related to Vaccine Administration

- CDC Vaccine administration webpage for information and materials for health care personnel including
  - IM demonstration video
  - Job aids and infographics

https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html



www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html
www.cdc.gov/vaccines/hcp/infographics/call-the-shots.pdf

Regional Immunization Nurses

- **Denise Dillon** – Northeast 978-851-7261
  denise.dillon@state.ma.us
- **Linda Jacobs** – Southeast 508-441-3980
  linda.jacobs@state.ma.us
- **VACANT** – Metro Boston & Central Region 617-983-6811
- **Theodora Wohler** – Metro West & Western Region 617-983-6837
  theodora.wohler@state.ma.us
- **Katie Reilly**, Nurse Manager 617-983-6833(T/Th) 508-441-3982(M/W/F)
  catherine.reilly@state.ma.us

MDPH Immunization Program Contact Information

Immunization Program Main Number

For questions about immunization recommendations, disease reporting, etc.
Phone: 617-983-6800
Fax: 617-983-6840
Website: www.mass.gov/dph/imm

MIIS Help Desk

Phone: 617-983-4335
Fax: 617-983-4301
Email: miishelpdesk@state.ma.us
Website: www.contactmiis.info|www.mass.gov/dph/miis

MDPH Vaccine Unit

Phone: 617-983-6828
Fax: 617-983-6924
Email: dph-vaccine-management@state.ma.us
Website: www.mass.gov/dph/imm

THANK YOU!