What You Should Know about the 2018 Adult Immunization Schedule & New Recommendations

Adult Immunization Conference
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23 YEARS OF ADULT IMMUNIZATION CONFERENCES

Thank you for all that you do to protect Massachusetts from vaccine preventable diseases!

Presenter Disclosure Information

- I, Susan Lett, 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 our presentations.
    - I have no relationships to disclose.

- I may/will 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

- 2018 Adult Immunization Schedule Changes
- Advisory Committee on Immunization Practices (ACIP) Updates
  - Live Attenuated Influenza Vaccine (LAIV) Recommendations
  - New Hepatitis B Vaccine (HEPLISAV-B)
- New Zoster Vaccine
  - Shingrix
- Shoulder Injury After Vaccination (SIRVA)

2018 Adult Immunization Schedule

MMWR 2018;67:158.

Annals of Internal Medicine 2018;168:210.

Available at:
https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6705e3-H.pdf
https://www.cdc.gov/vaccines/schedules/
http://annals.org/aim/fullarticle/2671913

Updates in 2018 Adult Immunization Schedule

- The schedule and footnotes are presented in a new simplified format.
- Recommended use of recombinant zoster vaccine (RZV), Shingrix.
- Recommended use of third dose of MMR in mumps outbreak.
- Meningococcal Polysaccharide (MPSV4) removed (as no longer available in the U.S.).

CDC. MMWR 2018;67:158

Updates NOT in 2018 Adult Immunization Schedule*

- Reinstituted use of LAIV for the 2018–2019 season

- Recommended use of Cytosine-phosphate-Guanine-adjuvanted hepatitis B vaccine (HepB-CpG), HEPLISAV-B

*** Based on deliberations and votes at the ACIP meeting, February 2018: publication pending**

Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018

In February 2018, the *Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018* became effective, as recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC). The adult immunization schedule was also approved by the American College of Physicians, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Nurse-Midwives.

CDC announced the availability of the 2018 adult immunization schedule in the *Morbidity and Mortality Weekly Report (MMWR)*.[1] The schedule is published in its entirety in the *Annals of Internal Medicine*.[2]

The adult immunization schedule consists of figures that summarize routinely recommended vaccines for adults by age groups and medical conditions and other indications, footnotes for the figures, and a table of vaccine contraindications and precautions. Note the following when reviewing the adult immunization schedule:

- The figures in the adult immunization schedule should be reviewed with the accompanying footnotes.
- The figures and footnotes display indications for which vaccines, if not previously administered, should be administered unless noted otherwise.
- The table of contraindications
- vaccines should not be used o
- When indicated, administer re
- incomplete or unknown.
- Increased interval between do
- effectiveness; it is not necessar
- an extended interval between
- Combination vaccines may be
- when the other components of the combinat
- The use of trade names in the adult immuniz
- identification purposes only and
- does not imply endorsement by the ACIP or

Special populations that need additional conside
lude:

- Pregnant women. Pregnant women shoul
- eive the tetanus, diphtheria, and acellular pertussis vaccine (Tdap) during pregnancy and the
- luenza vaccine during or before pregnancy. Live vaccines (e.g., measles, mumps, and rubella vaccine [MMR]) are contraindicated.
- Asplenia. Adults with asplenia have specific vaccination recommendations because of their increased risk for infection by encapsulated bacteria. Anatomical or functional asplenia includes congenital or acquired asplenia, splenic dysfunction, sickle cell disease and other hemoglobinopathies, and splenectomy.
- Immunocompromising conditions. Adults with immunosuppression should generally avoid live vaccines. Inactivated vaccines (e.g., pneumococcal vaccines) are generally acceptable. High-level immunosuppression includes HIV infection with a CD4 cell count <200 cells/μL, receipt of daily corticosteroid therapy with ≥20 mg of prednisone or equivalent for ≥14 days, primary immunodeficiency disorder (e.g., severe combined immunodeficiency or complement component deficiency), and receipt of cancer chemotherapy. Other immunocompromising conditions and immunosuppressive medications to consider when vaccinating adults can be found in *IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host*.[3] Additional information on vaccinating immunocompromised adults is in *General Best Practice Guidelines for Immunization*.[4]

Special populations that need additional considerations…

Additional resources for health care providers include:

- Details on vaccines recommended for adults and complete ACIP statements at www.cdc.gov/vaccines/hcp/acip-recs/index.html
- Vaccine Information Statements that explain benefits and risks of vaccines at www.cdc.gov/vaccines/hcp/vis/index.html
- Information and resources on vaccinating pregnant women at www.cdc.gov/vaccines/adults/rec-vac/pregnant.html
- Information on travel vaccine requirements and recommendations at www.cdc.gov/travel/destinations/list
- CDC Vaccine Schedules App for immunization service providers to download at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html
- Adult Vaccination Quiz for self-assessment of vaccination needs based on age, health conditions, and other indications at www2.cdc.gov/nip/adultimmsched/default.asp
- *Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger* at www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Report suspected cases of reportable vaccine-preventable diseases to the local or state health department, and report all clinically significant postvaccination events to the Vaccine Adverse Event
www.vaers.hhs.gov or by telephone, 800-822-7967. All vaccines included in the
schedule except 23-valent pneumococcal polysaccharide and zoster vaccines are
ne Injury Compensation Program. Information on how to file a vaccine injury claim
rsa.gov/vaccinecompensation or by telephone, 800-338-2382. Submit questions
DC through www.cdc.gov/cdc-info or by telephone, 800-CDC-INFO (800-232-
Spanish, 8:00am–8:00pm ET, Monday–Friday, excluding holidays.

viations are used for vaccines in the adult immunization schedule (in the order of
their appearance):

IIV	inactivated influenza vaccine
RIV	recombinant influenza vaccine
Tdap	tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine
Td	tetanus and diphtheria toxoids
MMR	measles, mumps, and rubella vaccine
VAR	varicella vaccine
RZV	recombinant zoster vaccine
ZVL	zoster vaccine live
HPV vaccine	human papillomavirus vaccine
PCV13	13-valent pneumococcal conjugate vaccine
PPSV23	23-valent pneumococcal polysaccharide vaccine
HepA	hepatitis A vaccine
HepA-HepB	hepatitis A vaccine and hepatitis B vaccine
HepB	hepatitis B vaccine
MenACWY	serogroups A, C, W, and Y meningococcal vaccine
MenB	serogroup B meningococcal vaccine
Hib	*Haemophilus influenzae* type b vaccine

1. MMWR Morb Mortal Wkly Rep. 2018;66(5). Available at www.cdc.gov/mmwr/volumes/67/wr/mm6705e3.htm.
2. Ann Intern Med. 2018;168:210–220. Available at annals.org/aim/article/doi/10.7326/M17-3439.
3. Clin Infect Dis. 2014;58:e44-100. Available at www.idsociety.org/Templates/Contents.aspx?id=32212256011.
4. ACIP. Available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

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

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				
Td/Tdap[2]	1 dose Tdap, then Td booster every 10 yrs				
MMR[3]	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]					
PPSV23[7]	1 or 2 do				
HepA[8]	2 or 3 doses depending o				
HepB[9]	3 doses				
MenACWY[10]	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
MenB[10]	g on vaccine				
Hib[11]	g on indication				

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

Added new row for RZV with dashed line

Next year will say 2 or 3 doses

Removed MPSV4

MDPH 2018

Same changes as Figure 1

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)[2-7,11]	HIV infection CD4+ count (cells/μL)[2-7,9-10] <200	HIV infection CD4+ count (cells/μL)[2-7,9-10] ≥200	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]
Influenza[1]	1 dose annually										
Tdap[2] or Td[2]	1 dose Tdap each pregnancy	1 dose Tdap, then Td booster every 10 yrs									
MMR[3]	contraindicated	1 or 2 doses depending 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									

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

3rd Dose of MMR

Adults who previously received ≤2 doses of mumps-containing vaccine and are identified by public health authority to be at increased risk for mumps in an outbreak: Administer 1 dose of MMR.

LAIV

ACIP recently voted on changes in recommendation for LAIV for the 2018-2019 season which will appear in the 2019 adult immunization schedule.

Footnotes. Recommended immunization schedule for adults aged 19 years or ol

1. Influenza vaccination

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

General Inf ation

- Administ dose of age-appropriate inactivated influenza vaccine r recombinant influenza vaccine (RIV) annually
- Live att d influenza vaccine (LAIV) is not recommended for the 18 influenza season
- A list o available influenza vaccines is available at www /protect/vaccine/vaccines.htm

Specia s

- Adm propriate IIV or RIV to:
  - P n
  - A -only egg allergy
  - llergy other than hives (e.g., spiratory distress): Administer IIV or RIV under supervision of a health care cognize and manage severe allergic

2. T d pertussis vaccination

Special populations

- **Pregnant women:** Administer 1 dose of Tdap during each pregnancy, preferably in the early part of gestational weeks 27–36

3. Measles, mumps, and rubella vaccination

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html

General Information

- Administer 1 dose of measles, mumps, and rubella vaccine (MMR) to adults with no evidence of immunity to measles, mumps, or rubella
- Evidence of immunity is:
  - Born before 1957 (except for health care personnel, see below)
  - Documentation of receipt of MMR
  - Laboratory evidence of immunity or disease
- Documentation of a health care provider-diagnosed disease without laboratory confirmation is not considered evidence of immunity

Special populations

- **Pregnant women and nonpregnant women of childbearing age** with no evidence of immunity to rubella: Administer 1 dose of MMR (if pregnant, administer MMR after pregnancy and before discharge from health care facility)
- **HIV infection and CD4 cell cou 6 months** and no evidence of im or rubella: Administer 2 doses of
- **Students in postsecondary edu international travelers**, and **ho immunocompromised person** MMR at least 28 days apart (or 1 administered 1 dose of MMR)
- **Health care personnel born in** evidence of immunity: Administ 28 days apart for measles or mumps, or 1 dose of MMR for rubella (if born before 1957, consider MMR vaccination)
- Adults who **previously received ≤2 doses of mumps-containing vaccine and are identified by public health authority to be at increased risk for mumps in an outbreak**: Administer 1 dose of MMR
- MMR is contraindicated for pregnant women and adults with severe immunodeficiency

4. Varicella vaccination

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html

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vaccine (if
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er the first dose)

t women and

ricella or
ks apart
cella or herpes zoster by a health care provider
- Laboratory evidence of immunity or disease

Special populations

- Administer 2 doses of VAR 4–8 weeks apart if previously received no varicella-containing vaccine (if previously received 1 dose of varicella-containing vaccine, administer 1 dose of VAR at least 4 weeks after the first dose) to:
  - **Pregnant women without evidence of immunity**: Administer the first of the 2 doses or the second dose after pregnancy and before discharge from health care facility
  - **Health care personnel without evidence of immunity**
- Adults with **HIV infection and CD4 cell count ≥200 cells/µL**: May administer, based on individual clinical decision, 2 doses of VAR 3 months apart
- VAR is contraindicated for pregnant women and adults with severe immunodeficiency

5. Zoster vaccination

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/shingles.html

General Information

- Administer 2 doses of recombinant zoster vaccine (RZV) 2–6 months apart to adults aged 50 years or older regardless of past episode of herpes zoster or receipt of zoster vaccine live (ZVL)
- Administer human papillomavirus (HPV) vaccine to **females through age 26 years** and **males through age 21 years** (males aged 22 through 26 years may be vaccinated based on individual clinical decision)
- The number of doses of HPV vaccine to be administered depends on age at initial HPV vaccination
  - **No previous dose of HPV vaccine**: Administer 3-dose series at 0, 1–2, and 6 months (minimum intervals: 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 5 months between doses 1 and 3; repeat doses if given too soon)
  - **Aged 9–14 years at HPV vaccine series initiation and received 1 dose or 2 doses less than 5 months apart**: Administer 1 dose
  - **Aged 9–14 years at HPV vaccine series initiation and received 2 doses at least 5 months apart**: No additional dose is needed

Special populations

- Adults with **immunocompromising conditions (including HIV infection)** through age 26 years: Administer 3-dose series at 0, 1–2, and 6 months
- **Men who have sex with men** through age 26 years: Administer 2- or 3-dose series depending on age at initial vaccination (see above); if no history of HPV vaccine, administer 3-dose series at 0, 1–2, and 6 months
- **Pregnant women** through age 26 years: HPV vaccination is not recommended during pregnancy, but there is no evidence that the vaccine is harmful and no intervention needed for women who inadvertently receive HPV vaccine while pregnant; delay remaining doses until after pregnancy; pregnancy testing is not needed before vaccination

7. Pneumococcal vaccination

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html

General Information

- Administer to immunocompetent adults aged 65 years or older 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13), if not previously administered, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) at least 1 year after PCV13; if PPSV23 was previously administered but not PCV13, administer PCV13 at least 1 year after PPSV23
- When both PCV13 and PPSV23 are indicated, administer PCV13 first (PCV13 and PPSV23 should not be administered during the same visit); additional information on vaccine timing is available at www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Footnotes. Recommended immunization schedule for adults aged 19 years or older, United States, 2018

1. Influenza vaccination
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

General Information
- Administer 1 dose of age-appropriate inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) annually
- Live attenuated influenza vaccine (LAIV) is not recommended for the 2017–2018 influenza season
- A list of currently available influenza vaccines is available at www.cdc.gov/flu/protect/vaccine/vaccines.htm

Special populations
- Administer age-appropriate IIV or RIV to:
  - **Pregnant women**
  - Adults with **hives-only egg allergy**
  - Adults with **egg allergy other than hives** (e.g., angioedema or respiratory distress): Administer IIV or RIV in a medical setting under supervision of a health care provider who can recognize and manage severe allergic conditions

2. Tetanus, diphtheria, and pertussis vaccination
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/tdap-td.html

General Information
- Administer to adults who pr… of tetanus toxoid, reduced d… pertussis vaccine (Tdap) as a… recommended at age 11–12… by a dose of tetanus and dip… every 10 years
- Information on the use of Td… in wound management is av… www.cdc.gov/mmwr/previe…

Special populations
- **Pregnant women:** Administ… pregnancy, preferably in the… 27–36

3. Measles, mumps, and rub…
www.cdc.gov/vaccines/hcp/ac…

General Information
- Administer 1 dose of measles, mumps, and rubella vaccine (MMR) to adults with no evidence of immunity to measles, mumps, or rubella
- Evidence of immunity is:
  - Born before 1957 (except for health care personnel, see below)
  - Documentation of receipt of MMR
  - Laboratory evidence of immunity or disease
- Documentation of a health care provider-diagnosed disease without laboratory confirmation is not considered evidence of immunity

Special populations
- **Pregnant women and nonpregnant women of childbearing age** with no evidence of immunity to rubella: Administer 1 dose of MMR (if pregnant, administer MMR after pregnancy and before discharge from health care facility)
- **HIV infection and CD4 cell count ≥200 cells/µL for at least 6 months** and no evidence of immunity to measles, mumps, or rubella: Administer 2 doses of MMR at least 28 days apart
- **Students in postsecondary educational institutions, international travelers,** and **household contacts of immunocompromised persons:** Administer 2 doses of MMR at least 28 days apart (or 1 dose of MMR if previously administered 1 dose of MMR)
- **Health care personnel born in 1957 or later** with no evidence of immunity: Administer 2 doses of MMR at least 28 days apart for measles or mumps, or 1 dose of MMR for rubella (if born before 1957, consider MMR vaccination)
- Adults who **previously received ≤2 doses of mumps-containing vaccine and are identified by public health authority to be at increased risk for mumps in an outbreak:** Administer 1 dose of MMR
- MMR is contraindicated for pregnant women and adults with severe immunodeficiency

4. Varicella vaccination
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html

General Information
- Administer to adults without evidence of immunity to…

…received 1 dose of varicella-containing vaccine, administer 1 dose of VAR at least 4 weeks after the first dose) to:
  - **Pregnant women without evidence of immunity:** Administer the first of the 2 doses or the second dose after pregnancy and before discharge from health care facility
  - **Health care personnel without evidence of immunity**
- Adults with **HIV infection and CD4 cell count ≥200 cells/µL:** May administer, based on individual clinical decision, 2 doses of VAR 3 months apart
- VAR is contraindicated for pregnant women and adults with severe immunodeficiency

5. Zoster vaccination
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/shingles.html

General Information
- Administer 2 doses of recombinant zoster vaccine (RZV) 2–6 months apart to adults aged 50 years or older regardless of past episode of herpes zoster or receipt of zoster vaccine live (ZVL)
- Administer 2 doses of RZV 2–6 months apart to adults who previously received ZVL at least 2 months after ZVL
- For adults aged 60 years or older, administer either RZV or ZVL (RZV is preferred)

Special populations
- ZVL is contraindicated for pregnant women and adults with severe immunodeficiency

6. Human papillomavirus vaccination
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html

General Information
- Administer human papillomavirus (HPV) vaccine to **females through age 26 years** and **males through age 21 years** (males aged 22 through 26 years may be vaccinated based on individual clinical decision)
- The number of doses of HPV vaccine to be administered depends on age at initial HPV vaccination
  - **No previous dose of HPV vaccine:** Administer 3-dose series at 0, 1–2, and 6 months (minimum intervals: 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 5 months between doses 1 and 3; repeat doses if given too soon)

…ful and no intervention
…advertently receive HPV vaccine
…remaining doses until after pregnancy;
…g is not needed before vaccination

…occal vaccination
…dc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html

General Information
- Administer to immunocompetent adults aged 65 years or older 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13), if not previously administered, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) at least 1 year after PCV13; if PPSV23 was previously administered but not PCV13, administer PCV13 at least 1 year after PPSV23
- When both PCV13 and PPSV23 are indicated, administer PCV13 first (PCV13 and PPSV23 should not be administered during the same visit); additional information on vaccine timing is available at www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Recombinant Zoster Vaccine (Shingrix)

Administer 2 doses of recombinant zoster vaccine (RZV) 2–6 months apart to adults aged 50 years or older regardless of past episode of zoster or receipt of zoster vaccine live (ZVL)

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

RZV added to IAC 'Guide'

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:** • Temperature of 105° F or higher (40.5° C or higher) within 48 hours after vaccination with a previous dose of DTP/DTaP • Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP • Seizure within 3 days after receiving a previous dose of DTP/DTaP
Recombinant zoster vaccine (RZV) **Zoster vaccine live (ZVL)[4]**	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component • For ZVL only: Severe cellular immunodeficiency (e.g., hematologic and solid tumors, chemotherapy, or long-term immunosuppressive therapy[5]) or persons with HIV infection who are severely immunocompromised. • For ZVL only: Pregnancy	• Moderate or severe acute illness with or without fever • For ZVL only: Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination. • For RZV only: Pregnancy and lactation.

IAC Guide to Contraindications and Precautions at:
http://www.immunize.org/catg.d/p3072a.pdf

Question 1

You are orienting a new clinician in your office.

Which of the following are new about the 2018 Adult Immunization Schedule?

a) A row has been added for recombinant zoster vaccine (RZV)

b) RZV is the preferred zoster vaccine formulation and is recommended for those ≥50 years

c) The MMR footnote was revised to include guidance about the use of a 3rd dose of MMR for individuals at increased risk in certain outbreaks identified by public health authorities to improve protection against mumps and its complications

d) All of the above

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d) All of the above

Updates from the ACIP Meeting

Deliberations and Votes at the ACIP Meeting, February 2018: Publication Pending

Updates from the ACIP Meeting
February 2018: Publication Pending

- **LAIV Recommendations**
- **New Hepatitis B Vaccine (Heplisav-B)**

LAIV VOTE

- For the 2018-19 season, immunization providers may choose to administer any licensed, age-appropriate influenza vaccine (including IIV, RIV, LAIV). LAIV4 is an **option** for influenza vaccination for persons for whom it is otherwise appropriate.
- Influenza burden of disease is significant

Need every tool in the prevention toolbox

Courtesy of CDC / Bill Atkinson

LAIV

Stay tuned for more information about use of LAIV for the 2018-2019 influenza season.

Courtesy of CDC / Bill Atkinson

HEPLISAV-B VOTE

- HEPLISAV-B is a Hepatitis B vaccine that **may** be used to vaccinate persons aged 18 years and older against infection caused by all known subtypes of HBV.
- Non-preferential vote

Heplisav-B Vaccine

- Licensed by FDA on November 9, 2017 for use in persons ≥18 years
- Series of 2 doses, IM separated by 1 month (minimum interval = 4 weeks)
- Available in single-dose 0.5 mL vials. Each dose contains:
  - 20 micrograms HBsAg
  - 3,000 micrograms 1018 adjuvant (immunostimulatory cytidine-phosphate-guanosine [CpG] motifs), which binds Toll-like receptor 9 to stimulate directed immune response to hepatitis B surface antigen (HBsAg)

HEPLISAV-B Immunogenicity

- Studies demonstrate high rates of seroprotection:
  - 90%-100% of subjects receiving HEPLISAV-B vs. 70.5%-90.2% of subjects in the comparison group
    - Type 2 diabetes mellitus: 90.0% (HEPLISAV-B) vs. 65.1% (comparator)
    - Chronic kidney disease: 89.9% (HEPLISAV-B, 3 doses) vs. 81.1% (comparator, 4 double doses)

Halperin et al., Vaccine 2006;24:20-26.
Halperin et al., Vaccine 2012;30:2556-2563.
Heyward et al., Vaccine 2013; 31:53005305.
Jackson et al., Vaccine 2018;36:668-674.
Janssen et al. Vaccine 2013;31:5306-5313.
HEPLISAV-B package insert 11/2017

HEPLISAV-B Safety & Reactogenicity

- Mild and serious adverse events similar*
  - Mild: 45.6% (HEPLISAV-B) vs. 45.7% (comparator)
  - Serious: 5.4% (HEPLISAV-B) vs. 6.3% (comparator)
- Cardiovascular events: 0.27% (HEPLISAV-B) vs. 0.14% (comparator)
- Potentially immune-mediated adverse events**
  - 0.1%-0.2% (HEPLISAV-B) vs. 0.0%-0.7% (comparator)
- Safety to be further assessed through post-marketing studies

*Herpes zoster: 0.68% (HEPLISAV-B) vs. 0.32% (comparator) (RR=2.1, 95% CI=1.0-4.0)
**e.g., granulomatosis with polyangiitis, Tolosa-Hunt Syndrome, autoimmune thyroiditis, vitiligo

Halperin et al., Vaccine 2006;24:20-26.
Halperin et al., Vaccine 2012;30:2556-2563.
Heyward et al., Vaccine 2013; 31:53005305.
Jackson et al., Vaccine 2018;36:668-674.
Janssen et al. Vaccine 2013;31:5306-5313.
HEPLISAV-B package insert 11/2017
U.S. FDA, HEPLISAV-B (https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm584752.htm)

HEPLISAV- B Summary

- HEPLISAV-B likely to **improve** hepatitis B vaccine series **completion** and result in **earlier protection** (2 doses over 1 month)
  - Especially beneficial in persons with anticipated low adherence (e.g., injection drug users)
- Improved immunogenicity in populations with typically poor vaccine response.
  - e.g., elderly, diabetes, dialysis
- Most safety outcomes similar between Heplisav-B and Engerix
  - Acute MI was reported to be higher in Heplisav-B group; safety will be monitored in post-marketing studies
- Future economic analyses may inform cost-effectiveness considerations of HEPLISAV-B, including its use among persons at an increased risk for vaccine non-response

ACIP Recommendations for the Use of Herpes Zoster Vaccine

Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. MMWR 2018;67:103–108.

https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.htm?s_cid=mm6703a5_w

Herpes Zoster Vaccine Outline

- ACIP Recommendations & CDC Policy Note for Herpes Zoster Vaccines
- Herpes Zoster Disease and Epidemiology
- Rationale for ACIP Recommendations
- Clinical Guidance for Shingrix

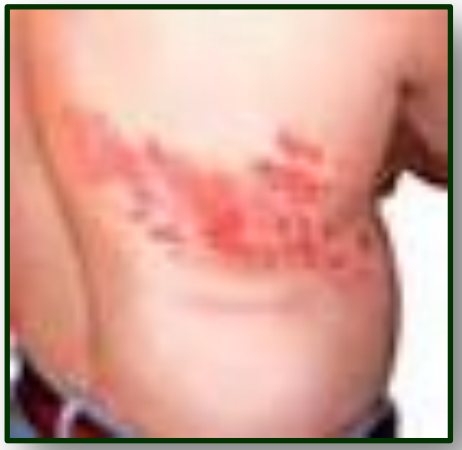
ACIP Recommendations for Zoster Vaccine

1) Recombinant zoster vaccine (RZV, [Shingrix]) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years.
2) RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL [Zostavax]).
3) RZV is **preferred** over ZVL for the prevention of herpes zoster and related complications.

CDC 2018 Herpes Zoster Policy Note recommendations serve as a supplement to the existing recommendations for the use of ZVL in immunocompetent adults aged ≥60 years.

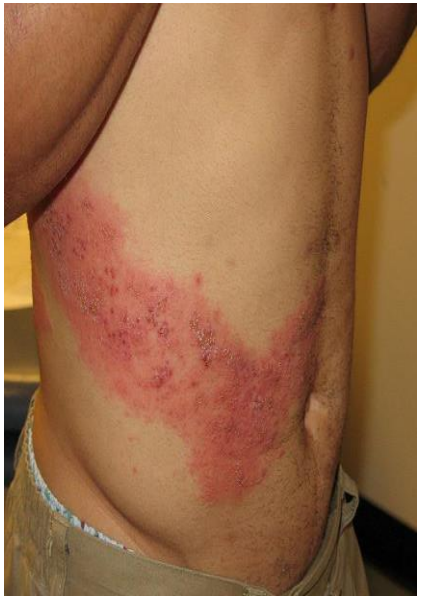
CDC. MMWR 2018;67:103.

Herpes Zoster Disease and Epidemiology

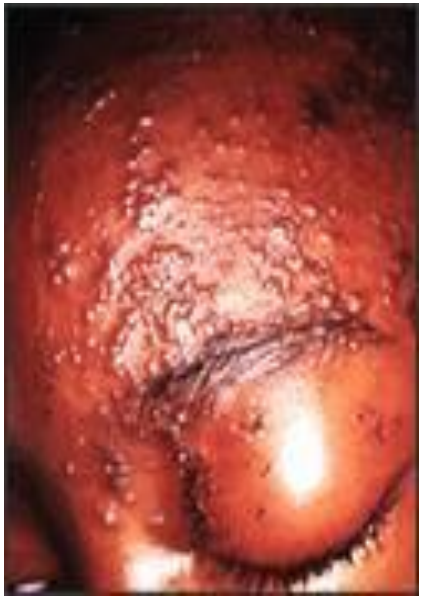


Source: Medline

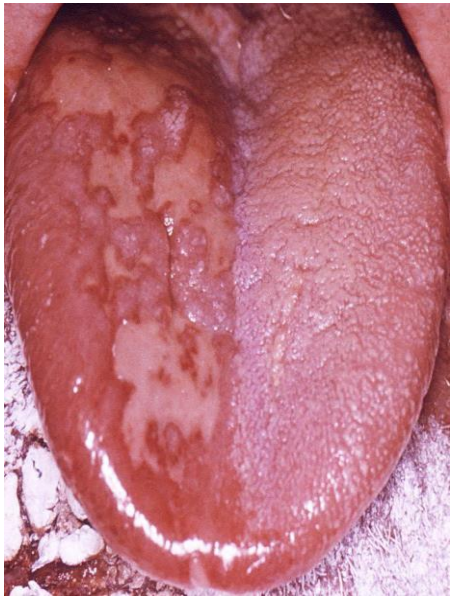
Herpes Zoster (HZ): Clinical Manifestations



Courtesy of NIAID



Courtesy of CDC



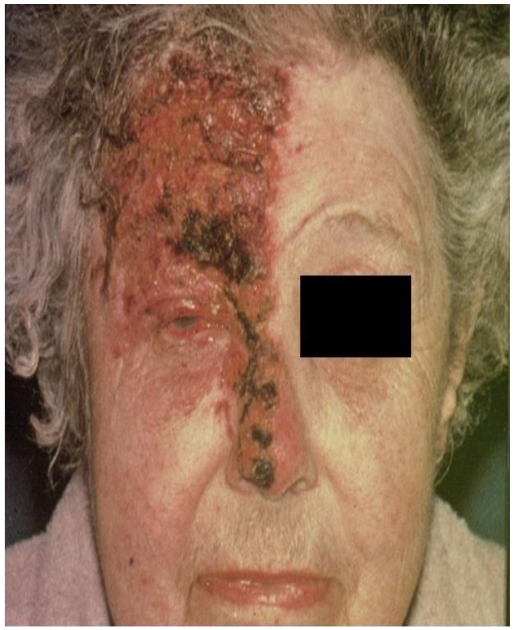
Courtesy of CDC/Robert Sumpter

Herpes Zoster & Postherpetic Neuralgia (PHN): Clinical Manifestations

Herpes Zoster

- About 90% of HZ episodes associated with pain
- Treatment: antivirals reduce duration of rash and pain[1]

- PHN
- Pain at least 90 days following resolution of rash
- Treatment: minimal or no efficacy. Side effects, especially in elderly[2]



Courtesy of M. Oxman

"My PHN is worse than my cancer and chemotherapy… [it] has made me depressed and suicidal in the past"

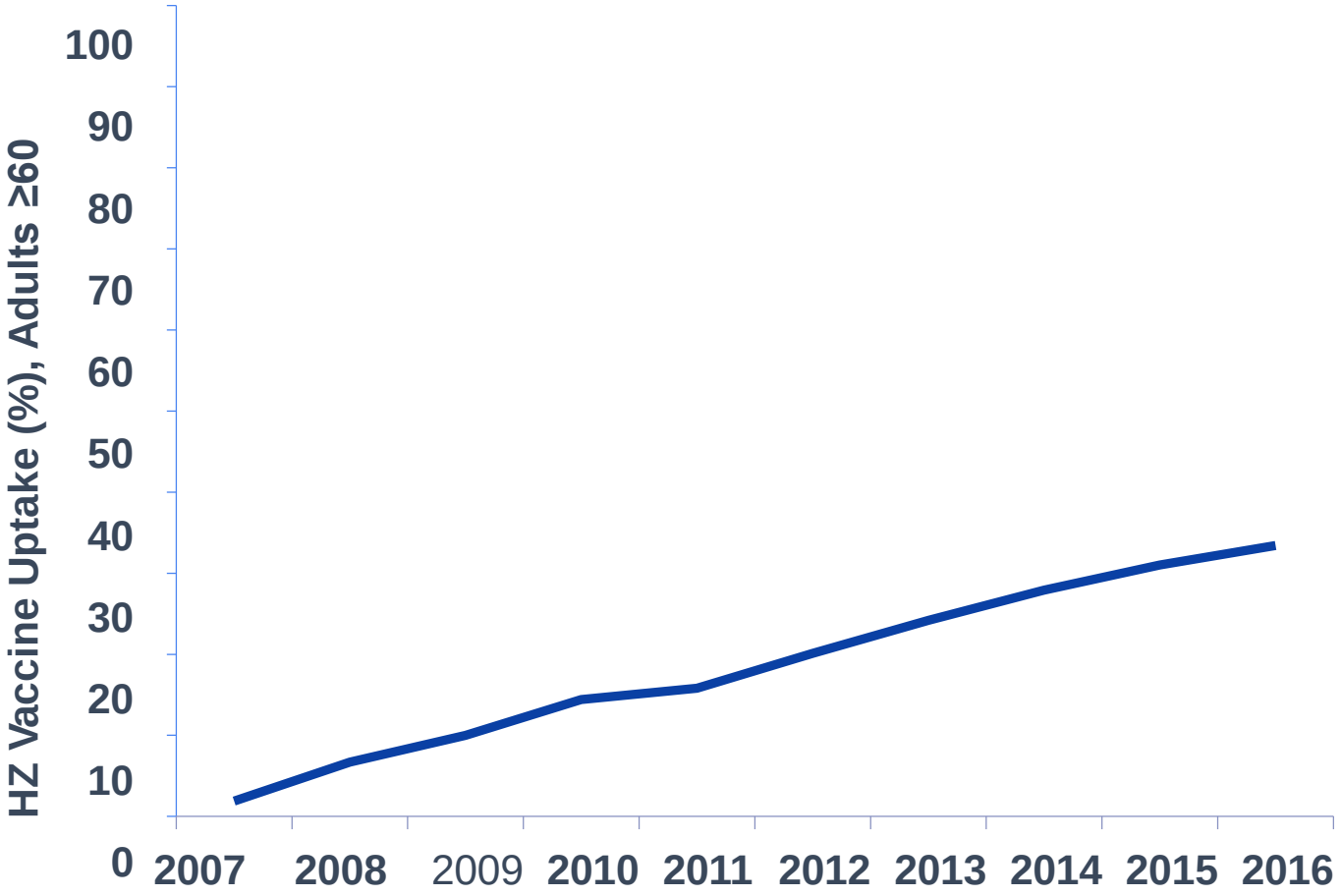
1. Cohen et al, NEJM 2013, 2. Johnson et al, NEJM 2014

Herpes Zoster (HZ) and Postherpetic Neuralgia (PHN) Epidemiology, U.S.

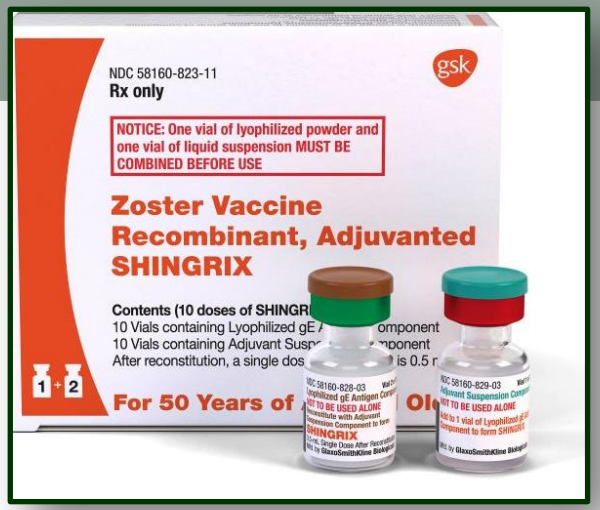
- ~1 million cases annually[1,2]
- Incidence increases with age, ranging from <1 case/1000 children to >15 cases/1000 population 80 years and older[2,3,4]
- For adults 50 years and older with HZ, 10-18% will go on to develop PHN. Similar to HZ, the incidence increases with age[3]
- Zoster Vaccine Live (ZVL) has been licensed in the U.S. since 2006-- 33% of individuals 60 years and older report receipt[5]

1. Jumaan et al., JID, 2005, 191:2002-7
2. Yawn, et al., Mayo Clin Proc. 2007; 82:1341-9
3. Insinga et al., J Gen Intern Med. 2005, 20:748-53
4. Harpaz et al, IDWeek 2015
5. CDC, provisional unpublished data from NHIS

Vaccination Coverage of Zoster Vaccine Live, among Adults ≥60 yrs, U.S., 2007-2016



* 2007: National immunization Survey (Lu et al, Vaccine 27:882-7); 2008-13: NHIS (Am J Prev Med 40:e1-6 & MMWR February 5, 2016 / 65(1);1–36), 2016 CDC, unpublished data.



SHINGRIX
RECOMBINANT ZOSTER VACCINE (RZV)

- Rationale for ACIP Recommendations
- Clinical Guidance for Shingrix

Shingrix- Recombinant Zoster Vaccine (RZV)

- **An adjuvanted recombinant protein subunit vaccine (previously referred to as HZ/su), licensed 10-20-17**
- **2 components**
  - Glycoprotein E (gE): Lyophilized component
    It is the most abundant glycoprotein expressed by varicella zoster virus (VZV)-infected cells; and induces both humoral and cellular immune responses
  - Adjuvant $ASO1_B$: Liquid Component
    $ASO1_B$ is a liposome which contains:
    - Lipopolysaccharide: Monophosphoryl Lipid A from *Salmonella minnesota*
    - Saponin – *Quillaja saponaria* extract
- **Requires Reconstitution**
  - The vaccine is the pellet/powder and the adjuvant is the diluent

https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm581491.htm

1) RZV is recommended for immunocompetent adults aged ≥50 years

Benefits:

- High vaccine efficacy against HZ
  - **97%** (50-69 yrs)
  - **91%** (≥70 yrs)
- High vaccine efficacy against PHN (**91%** for ≥50 year olds)
- Maintained efficacy ≥ **85%** for 4 years following vaccination in ≥ 70 year olds

Harms:

- No differences detected between vaccinated and comparison populations for serious adverse events
- Grade 3 reactions more commonly reported in vaccinated groups (17%) compared to placebo (3%)

CDC. MMWR 2018;67:103.

1) RZV is recommended for immunocompetent adults aged ≥50 years, cont.

- Immunogenicity maintained, including in the oldest age groups

- Number needed to vaccinate to prevent 1 case:
  - HZ: 11-17
  - PHN: 70-187

- Cost-effectiveness:
  - **$31,000/QALY (average ≥50 yrs)**
  - $9,700/QALY (80-89 yo) - $47,000/QALY (50-59 yo)

CDC. MMWR 2018;67:103.

2) RZV is recommended for immunocompetent adults who previously received zoster vaccine live (ZVL)

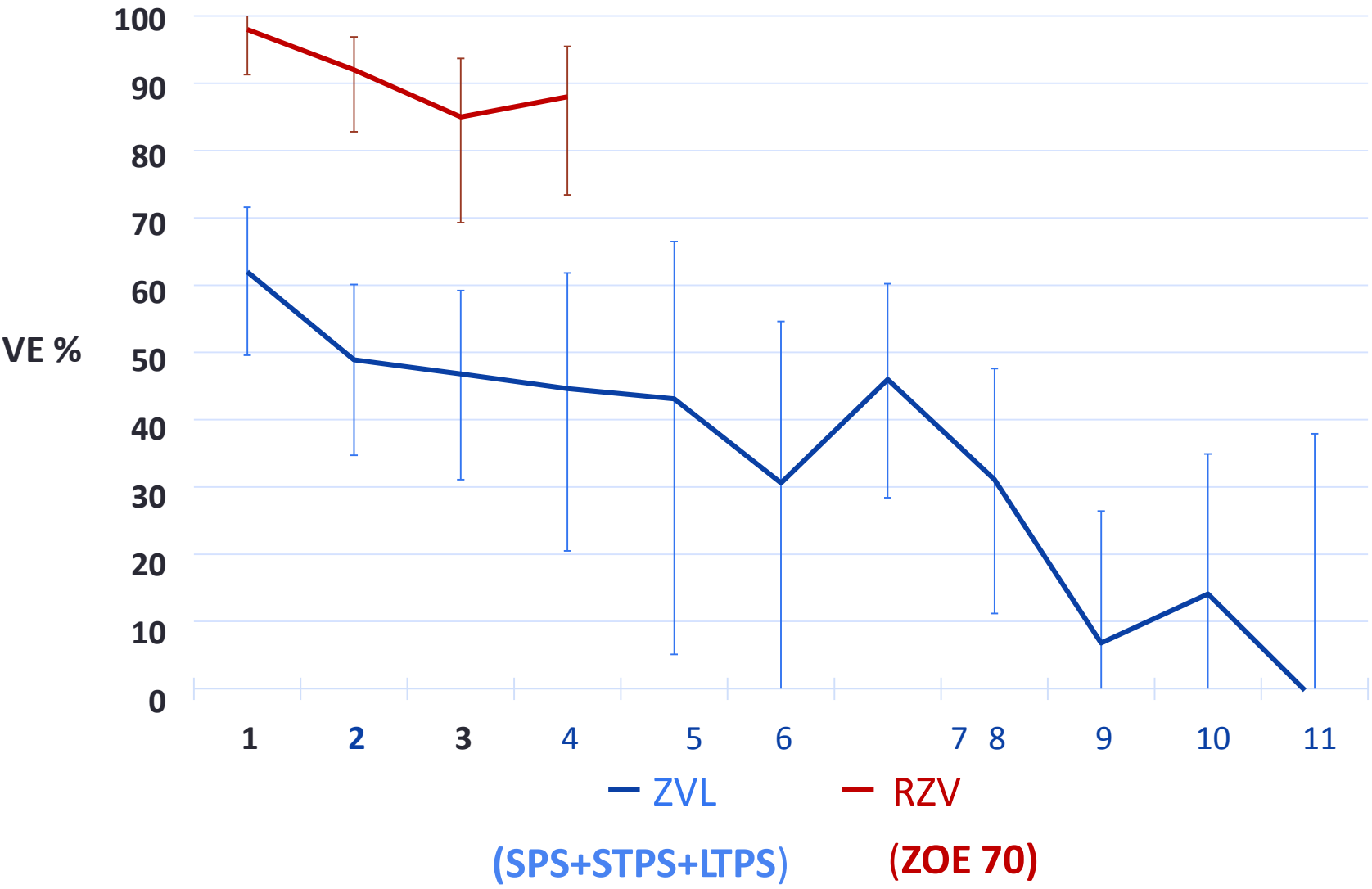
- Experimental and observational studies indicate significant waning of protection from ZVL:
  - VE drops the first year after receipt (15-25%)
  - By 6 yrs post vaccination, VE <35%
  - Negligible protection by 10 years

- RZV is more efficacious than ZVL in all age categories; differences are larger at older ages

- ~20 million people have been vaccinated with ZVL are potentially eligible for RZV and will benefit from it

CDC. MMWR 2018;67:103.

Vaccine efficacy against HZ for ZVL and RZV, by year following vaccination



Note: The Shingles Prevention Study, Short-term Persistence Study, and Long-term Persistence Study followed the same study population over time.

3) RZV is preferred over ZVL.

Efficacy

- RZV estimates of efficacy are significantly higher than ZVL estimates across all age groups:
  - 60-69 years: 97% vs 64%
  - 70-79 years: 91% vs 41%
  - ≥80 years 91% vs 18%
- RZV appears to wane at a slower rate than ZVL over the first 4 yrs
- The expected cases of HZ and PHN averted are far greater with RZV compared to ZVL

Adverse Effects

- Neither vaccine is associated with serious adverse events in immunocompetent persons
- RZV is more reactogenic than ZVL

Economics

- RZV leads to more disease prevention and decreased overall costs (vaccine + expected disease costs)

Note: These vaccines have not been studied in a head to head efficacy trial

CDC. MMWR 2018;67:103.

Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance:

Administration:

- **Store in the refrigerator**, requires reconstitution prior to administration
  - lyophilized gE protein must be reconstituted with the liquid adjuvant ($ASO1_B$)
  - After reconstitution, administer RZV immediately or store between 2-8°C (max=6hrs)
- 2 doses at 0 & 2-6 months (minimum interval 4 weeks)
- Administer **IM**
- Give irrespective of prior receipt of varicella vaccine, ZVL, or herpes zoster episode
- HZ vaccines do not require screening for a history of chickenpox (verbally or laboratory screening)

CDC. MMWR 2018;67:103.

Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance:

Administration, cont:

- RZV may be co-administered with other vaccines
  - CDC's general best practices advise recombinant and adjuvanted vaccines can be administered concomitantly, but at different sites
    - RZV+ QIV (Fluarix) --no interference or safety problems
    - RZV+ PPSV23 (Pneumovax23) or Tdap (Boostrix)– studies ongoing
    - RZV+ Fluad– have not been studied

CDC. MMWR 2018;67:103.

Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance

For adults who previously received ZVL:

- No interference or safety problems when RZV vaccination administered ≥5 years after ZVL
- Consider a shorter interval if individual is ≥70yrs-- protection from ZVL is 38% over ~3yrs
- Minimal interval of 8 weeks (expert opinion)

CDC. MMWR 2018;67:103.

Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance

RZV Recommended Populations:

- Adults with chronic medical conditions (e.g., chronic renal failure, DM, RA, chronic pulmonary disease, etc)
- Adults taking low-dose immunosuppressive therapy*, anticipating or have recovered from immunosuppression

  *e.g. <20 mg/day of prednisone or equivalent; short-term (<14 days of corticosteroids) immunosuppressive therapy; or using inhaled or topical steroids

Note: Immunocompromised persons were excluded from Phase III efficacy studies. ACIP has not made recommendations regarding the use of RZV in these patients. This topic is will be discussed at ACIP meetings as additional data become available.

CDC. MMWR 2018;67:103.

Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance

CONTRAINDICATION*:

- Allergy: RZV should not be administered to persons with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine

PRECAUTIONS:

- Current herpes zoster infection
- Pregnancy and breastfeeding

**** Immunocompromised persons were excluded from Phase III efficacy studies, thus, ACIP has not made recommendations regarding the use of RZV in these patients. This topic is will be discussed at ACIP meetings as additional data become available.***

CDC. MMWR 2018;67:103.

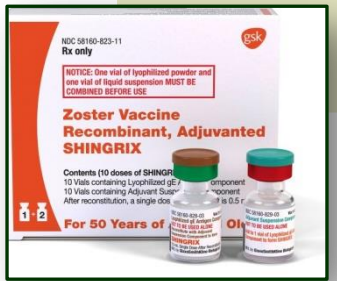
Shingrix- Recombinant Zoster Vaccine (RZV) Clinical Guidance

Counseling for Reactogenicity:

- Before vaccination, counsel about expected systemic and local reactogenicity
  - pain (78%)
  - myalgia (45%)
  - fatigue (45%)
- 1 in 6 patients may experience reactogenicity that prevented regular activities
- Symptoms resolve within 2-3 days
- Reactions to the first dose did not strongly predict reactions to the second dose
- Vaccine recipients should be encouraged to complete the series even if they experienced a grade 1–3 reaction to the first dose

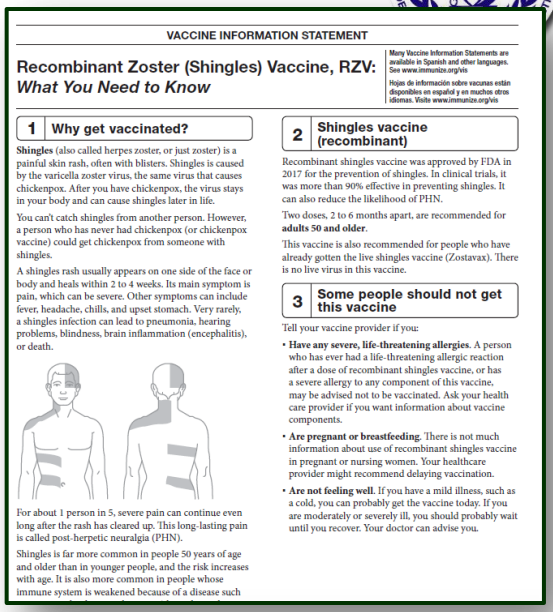
Take Care NOT to Confuse the Two Different Zoster Vaccine Formulations

RZV (Shingrix)	ZVL (Zostavax)
• **Stored in the refrigerator**	• **Stored in the freezer**
• Requires reconstitution with liquid adjuvant supplied by the manufacturer	• Requires reconstitution with liquid diluent supplied by the manufacturer
• Administered **IM as a 2 dose series**	• Administered **SC as a single dose**
• **Recommended for those ≥ 50 years.**	• **Recommended for those ≥ 60 years.**



Resources

- CDC Shingrix website:
  https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html
- Vaccine Information Statement (VIS)
  https://www.cdc.gov/vaccines/hcp/vis/vis-statements/shingles-recombinant.pdf
- IAC Ask the Experts
  http://www.immunize.org/askexperts/experts_zos.asp
- American Pharmacists Association. Zoster Vaccines – Key Points to Be Aware of Regarding Differences
  http://www.pharmacist.com/sites/default/files/files/2018ZosterVaccinesChartv9Final.pdf



VACCINE INFORMATION STATEMENT

Recombinant Zoster (Shingles) Vaccine, RZV:
What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, often with blisters. Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life.

You can't catch shingles from another person. However, a person who has never had chickenpox (or chickenpox vaccine) could get chickenpox from someone with shingles.

A shingles rash usually appears on one side of the face or body and heals within 2 to 4 weeks. Its main symptom is pain, which can be severe. Other symptoms can include fever, headache, chills, and upset stomach. Very rarely, a shingles infection can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.

For about 1 person in 5, severe pain can continue even long after the rash has cleared up. This long-lasting pain is called post-herpetic neuralgia (PHN).

Shingles is far more common in people 50 years of age and older than in younger people, and the risk increases with age. It is also more common in people whose immune system is weakened because of a disease such

2 Shingles vaccine (recombinant)

Recombinant shingles vaccine was approved by FDA in 2017 for the prevention of shingles. In clinical trials, it was more than 90% effective in preventing shingles. It can also reduce the likelihood of PHN.

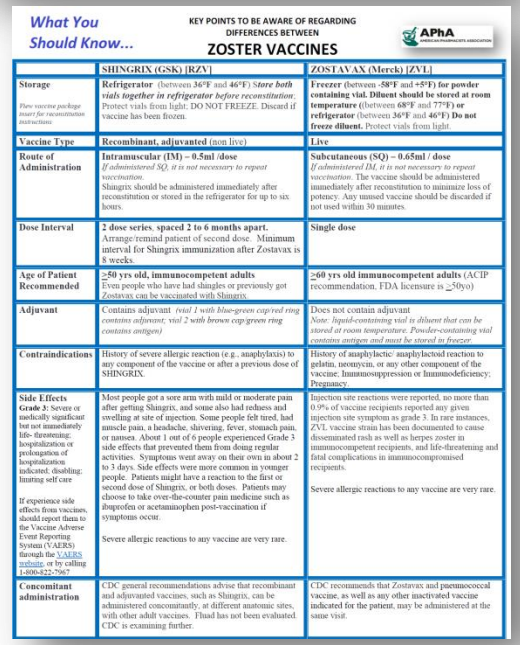
Two doses, 2 to 6 months apart, are recommended for **adults 50 and older**.

This vaccine is also recommended for people who have already gotten the live shingles vaccine (Zostavax). There is no live virus in this vaccine.

3 Some people should not get this vaccine

Tell your vaccine provider if you:

- **Have any severe, life-threatening allergies**. A person who has ever had a life-threatening allergic reaction after a dose of recombinant shingles vaccine, or has a severe allergy to any component of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Are pregnant or breastfeeding**. There is not much information about use of recombinant shingles vaccine in pregnant or nursing women. Your healthcare provider might recommend delaying vaccination.
- **Are not feeling well**. If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



What You Should Know...

KEY POINTS TO BE AWARE OF REGARDING DIFFERENCES BETWEEN

ZOSTER VACCINES

APhA

	SHINGRIX (GSK) [RZV]	ZOSTAVAX (Merck) [ZVL]
Storage *View vaccine package insert for reconstitution instructions*	**Refrigerator** (between 36°F and 46°F) ***Store both vials together in refrigerator before reconstitution.*** Protect vials from light; DO NOT FREEZE. Discard if vaccine has been frozen.	**Freezer** (between -58°F and +5°F) **for powder containing vial. Diluent should be stored at room temperature** ((between 68°F and 77°F) **or refrigerator** (between 36°F and 46°F) **Do not freeze diluent.** Protect vials from light
Vaccine Type	**Recombinant, adjuvanted** (non live)	**Live**
Route of Administration	**Intramuscular (IM) – 0.5ml /dose** *If administered SQ, it is not necessary to repeat vaccination.* Shingrix should be administered immediately after reconstitution or stored in the refrigerator for up to six hours.	**Subcutaneous (SQ) – 0.65ml / dose** *If administered IM, it is not necessary to repeat vaccination.* The vaccine should be administered immediately after reconstitution to minimize loss of potency. Any unused vaccine should be discarded if not used within 30 minutes.
Dose Interval	**2 dose series, spaced 2 to 6 months apart.** Arrange/remind patient of second dose. Minimum interval for Shingrix immunization after Zostavax is 8 weeks.	**Single dose**
Age of Patient Recommended	**≥50 yrs old, immunocompetent adults** Even people who have had shingles or previously got Zostavax can be vaccinated with Shingrix.	**≥60 yrs old immunocompetent adults** (ACIP recommendation, FDA licensure is ≥50yo)
Adjuvant	Contains adjuvant *(vial 1 with blue-green cap/red ring contains adjuvant; vial 2 with brown cap/green ring contains antigen)*	Does not contain adjuvant *Note: liquid-containing vial is diluent that can be stored at room temperature. Powder-containing vial contains antigen and must be stored in freezer.*
Contraindications	History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX.	History of anaphylactic/ anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; Immunosuppression or Immunodeficiency; Pregnancy.
Side Effects **Grade 3:** Severe or medically significant but not immediately life- threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care If experience side effects from vaccines, should report them to the Vaccine Adverse Event Reporting System (VAERS) through the VAERS website, or by calling 1-800-822-7967.	Most people got a sore arm with mild or moderate pain after getting Shingrix, and some also had redness and swelling at site of injection. Some people felt tired, had muscle pain, a headache, shivering, fever, stomach pain, or nausea. About 1 out of 6 people experienced Grade 3 side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger people. Patients might have a reaction to the first or second dose of Shingrix, or both doses. Patients may choose to take over-the-counter pain medicine such as ibuprofen or acetaminophen post-vaccination if symptoms occur. Severe allergic reactions to any vaccine are very rare.	Injection site reactions were reported, no more than 0.9% of vaccine recipients reported any given injection site symptom as grade 3. In rare instances, ZVL vaccine strain has been documented to cause disseminated rash as well as herpes zoster in immunocompetent recipients, and life-threatening and fatal complications in immunocompromised recipients. Severe allergic reactions to any vaccine are very rare.
Concomitant administration	CDC general recommendations advise that recombinant and adjuvanted vaccines, such as Shingrix, can be administered concomitantly, at different anatomic sites, with other adult vaccines. Thad has not been evaluated. CDC is examining further.	CDC recommends that Zostavax and pneumococcal vaccine, as well as any other inactivated vaccine indicated for the patient, may be administered at the same visit.

Question 2

Your office is just getting ready to use Shingrix and your team is meeting.
Which of the following are true about Shingrix?

a) Shingrix is recommended for:
- immunocompetent adults aged ≥50 years; and
- immunocompetent adults ≥50 years who previously received ZVL

b) RZV is preferred over ZVL for the prevention of herpes zoster and related complications.

c) It is administered IM as a 2-dose series at 0 and 2-6 month schedule

d) Counsel the patient about the type of local and systemic reactions they may experience

e) It is important to know the patient's history of varicella, zoster or receipt of ZVL

f) a, b, c and d

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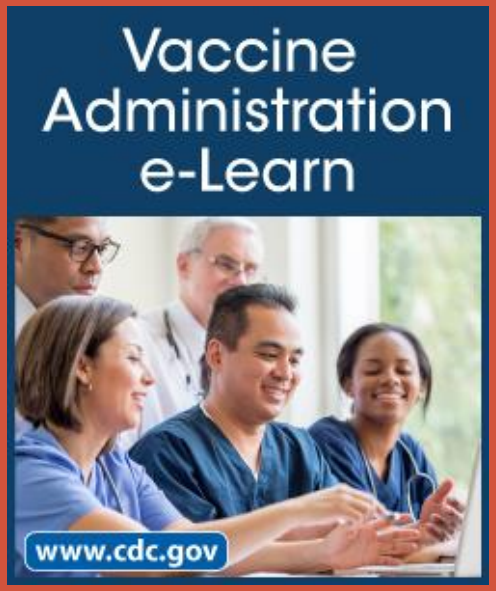
f) a, b, c and d

Shoulder Injury Related to Vaccination Administration (SIRVA)



Shoulder Injury Following Vaccination[1]

- Shoulder injury related to vaccine administration (SIRVA) manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm
- These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction
- **[By definition] SIRVA is caused by an injury to the musculoskeletal structures of the shoulder** (e.g. tendons, ligaments, bursae, etc.)
- **SIRVA is not a neurological injury** and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known)

[1]Reference: Vaccine Injury Table (https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf)

Presented by Dr. Tom Shimabukuro ACIP Meeting 10-25-17

SIRVA Summary

- Reports to VAERS of shoulder dysfunction following IIV ranged from **128-223** (**2% of the 130 million doses per year**) during the six influenza seasons from 2010-2011 to 2015-2016
  - Shoulder injury is **rare** and not increasing
- Most (70%) reports were in the age group 19-59 years; few were in individuals 0-18 years (<1%)
  - More common in females
- The most common location of vaccination documented in reports was in pharmacies/drug stores and doctor's offices/hospitals
- When possible contributing factors were described, vaccination given too high on the arm was most commonly reported
- **Proper administration technique is important**

Anatomy of the Upper Arm

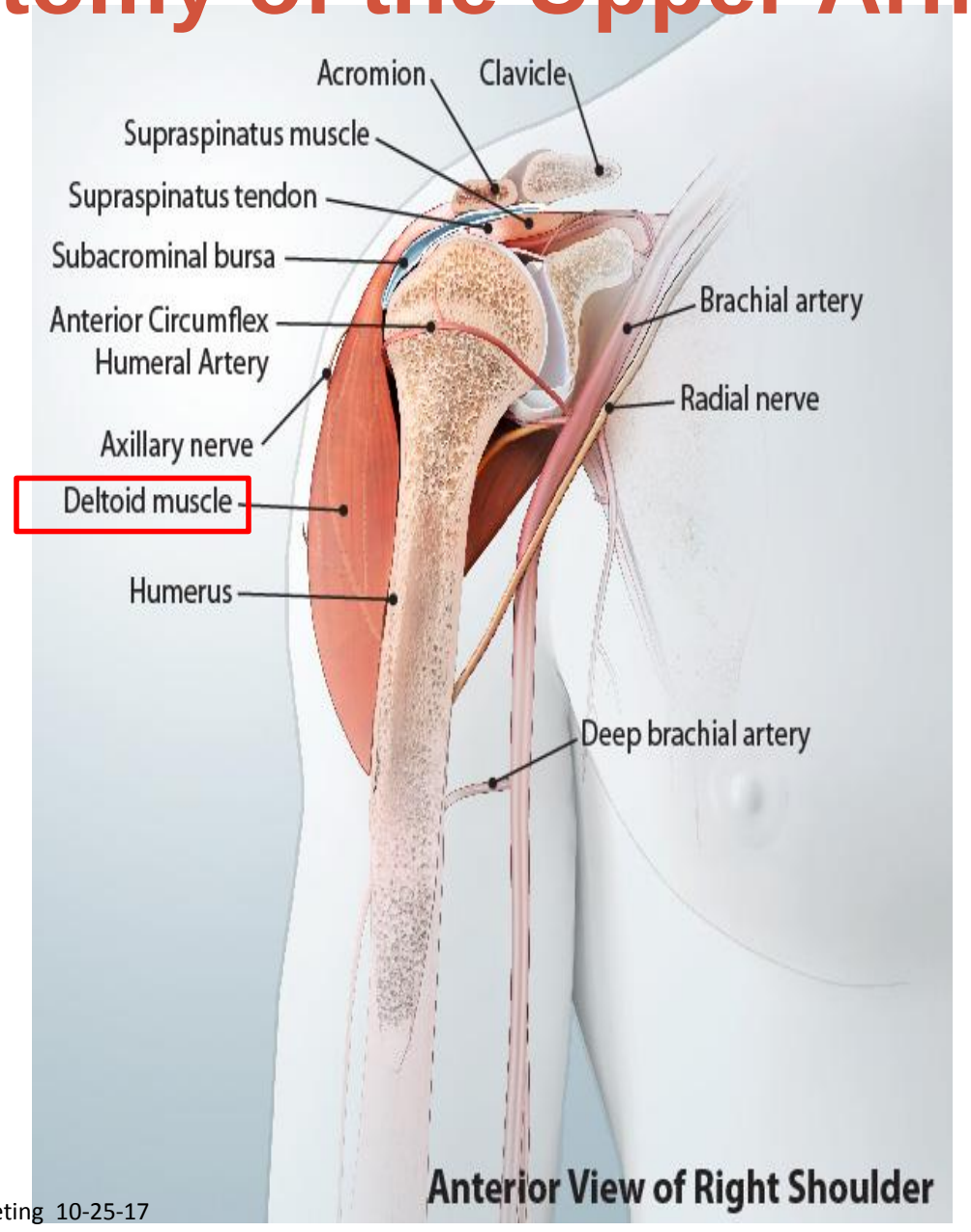
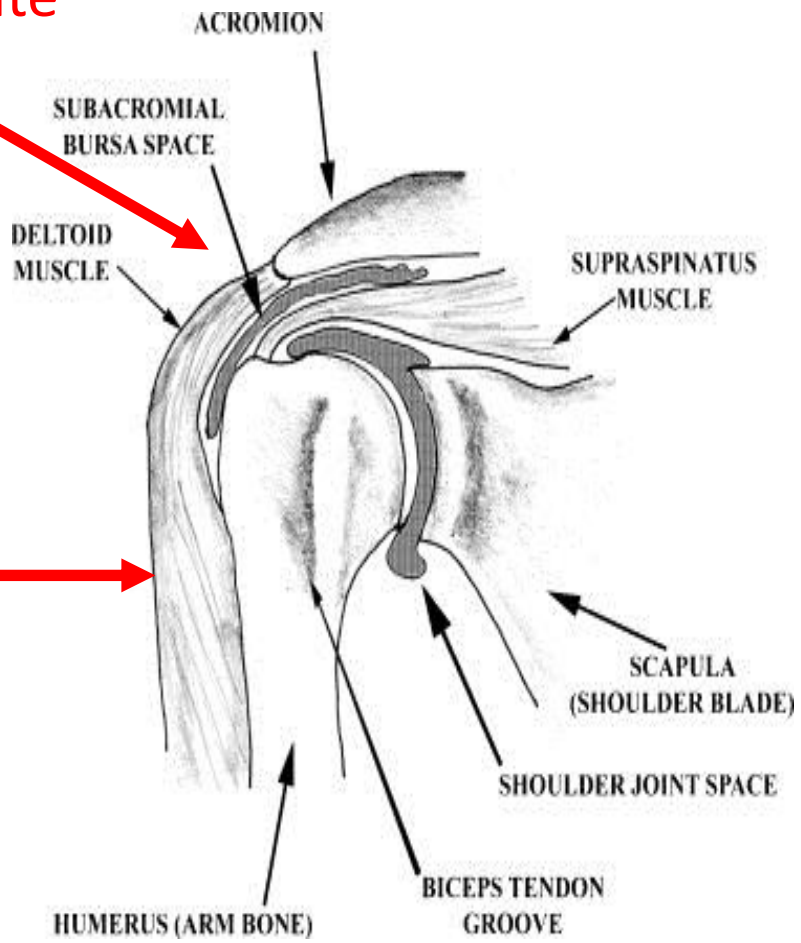


Image by Alissa Eckert, CDC Division of Communication Services

Shoulder Anatomy Related to SIRVA

Incorrect IM Administration Site

Correct IM Administration Site

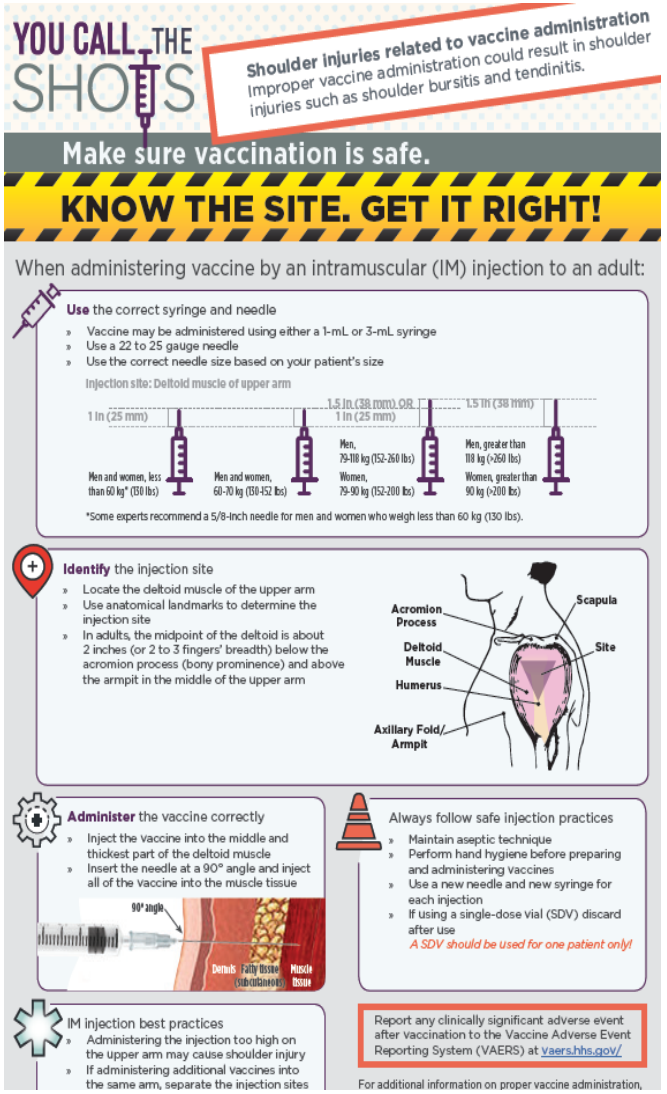


CDC Centers for Disease Control and Prevention

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

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



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

Contact Information

MDPH Immunization Program

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

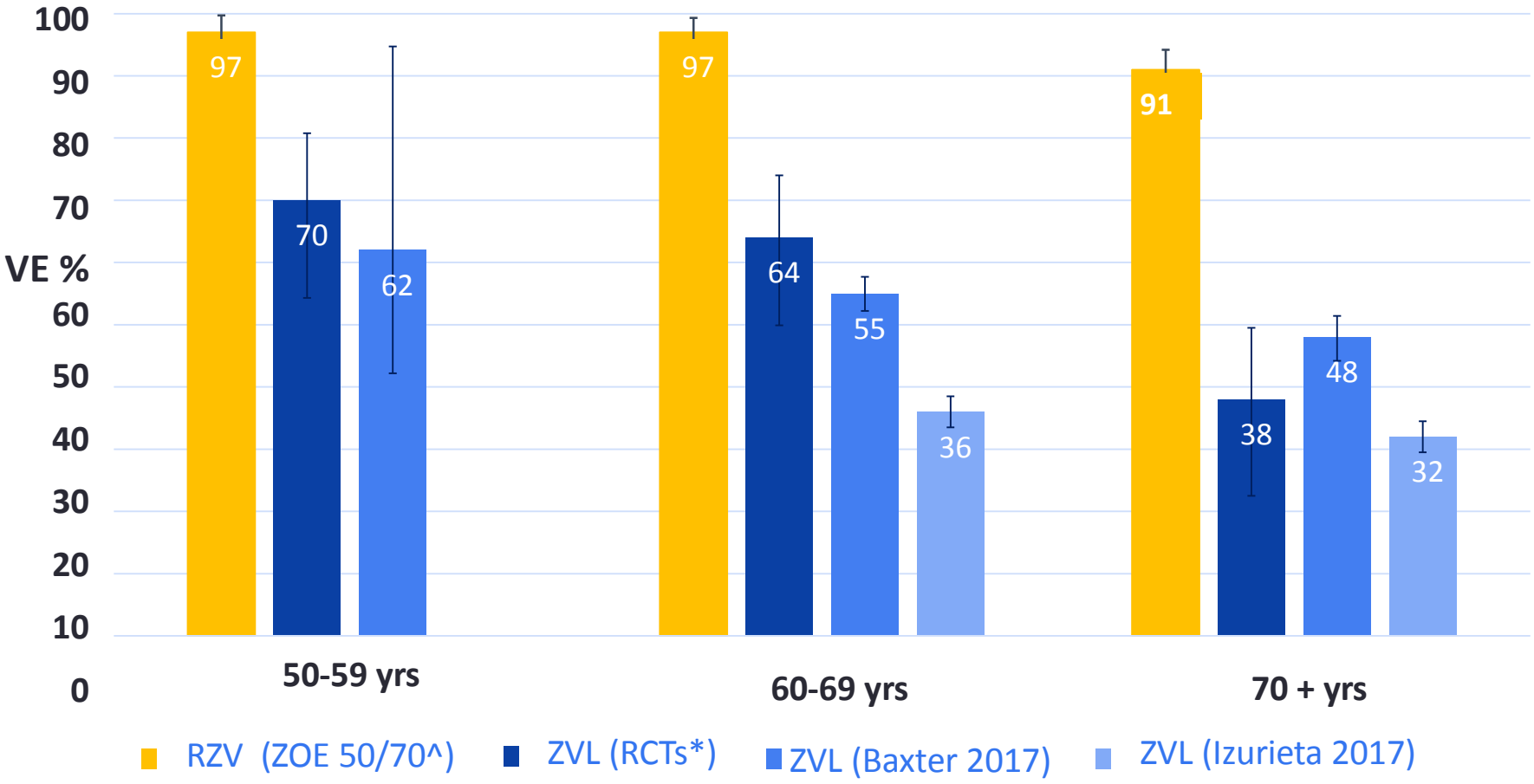
- **Phone:** 617-983-4335
- **Fax:** 617-983-4301
- **Email:** miishelpdesk@state.ma.us
- **Websites:** www.contactmiis.info | www.mass.gov/dph/miis

MDPH Vaccine Unit

- **Phone:** 617-983-6828
- **Fax:** 617-983-6924
- **Email:** dph-vaccine-management@state.ma.us
- **Website:** www.mass.gov/dph/imm (click on Vaccine Management)

EXTRAS

Vaccine efficacy and effectiveness against HZ for RZV and ZVL, by age group, during the first 4‡ years following vaccination

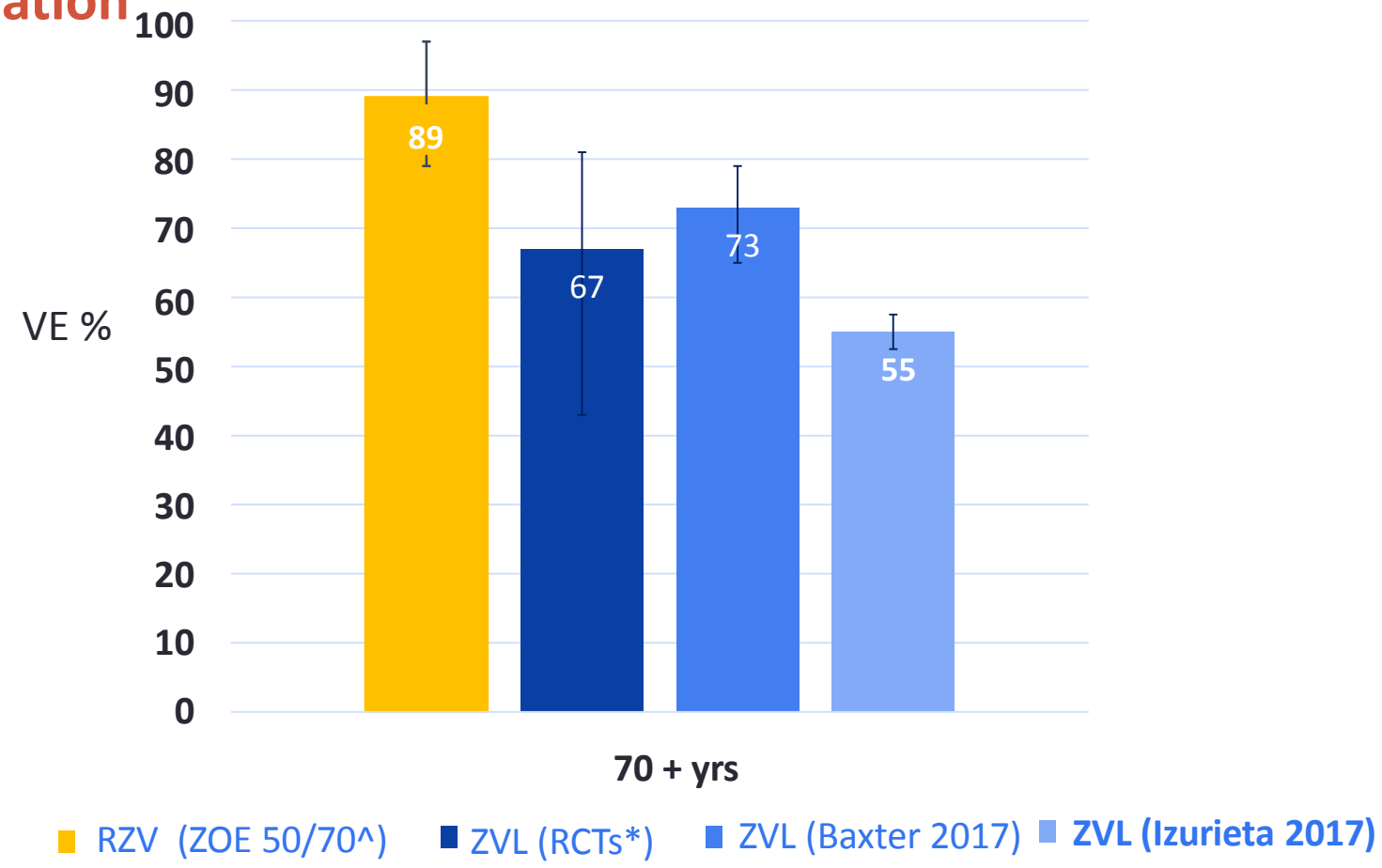


‡ Median follow up may be less than 3 yrs: Schmader 2012= 1.3 yrs

^ ZOE 50/70= 50-59 & 60-69yr: Lal 2015, 70+yrs: Cunningham 2016

* RCTs= 50-59 yrs: Schmader 2012, 60-69 and 70+ yrs: Oxman 2005,

Vaccine efficacy and effectiveness against PHN for RZV and ZVL, in adults 70 years and older during the first 4 years following vaccination



^ Pooled ZOE 50/70: Cunningham 2016

* Shingles Prevention Study: Oxman 2005,