Update on Immunizations for Older Adults

2019-2020 Season

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Speaker Disclosures

Dr. Nace has no conflicts of interest related to this presentation.

Objectives

After this presentation, you will be able to:

- Identify current **recommendations** for routine vaccination of older adults.
- Discuss **approaches to common clinical vaccine scenarios** in older adults.

Case 1 – Kathryn

- Kathryn is an 89-year old female with a history of HTN, AF, Stage 3 CKD, and type II diabetes mellitus. She presents to your office in November 2019 to establish primary care.
- She is widowed, lives in the country, and is an active gardener
- She last received a flu shot in Feb 2019.
- She received the pneumococcal polysaccharide vaccine (PPS23) when diagnosed with diabetes at age 67.
- She has not had a shingles vaccine.
- Her last tetanus shot (Td) was 10 years ago.

Case 1 – In Addition to Influenza Vaccine, What Other Vaccines Should You Recommend for Kathryn?

A. Pneumococcal Vaccination
B. Shingles
C. Lyme Disease
D. Hepatitis B
E. Tdap
F. Coronavirus

Common Immunizations to Consider in Older Adults

- Influenza
- Pneumococcal
- Hepatitis B
- Herpes Zoster (Shingles)
- Tdap

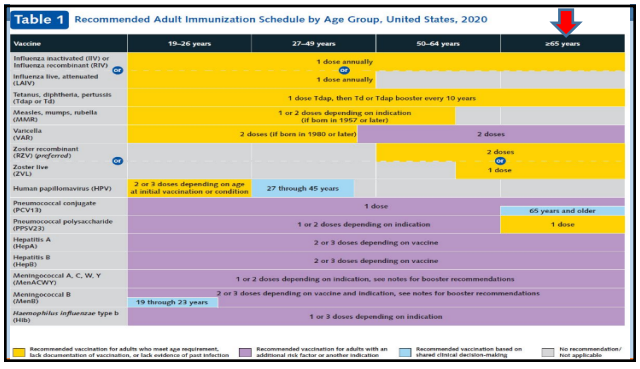
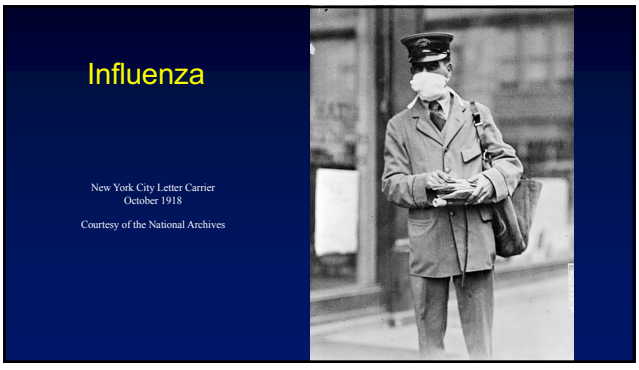
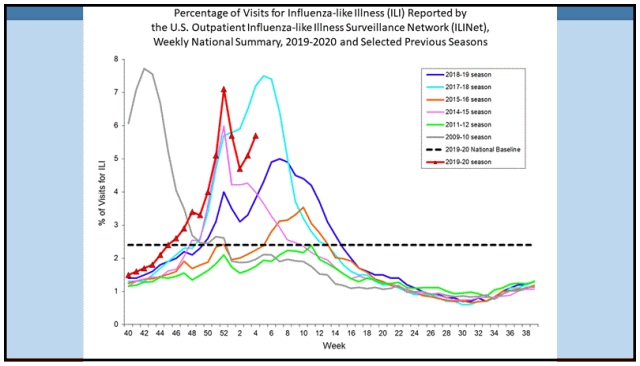


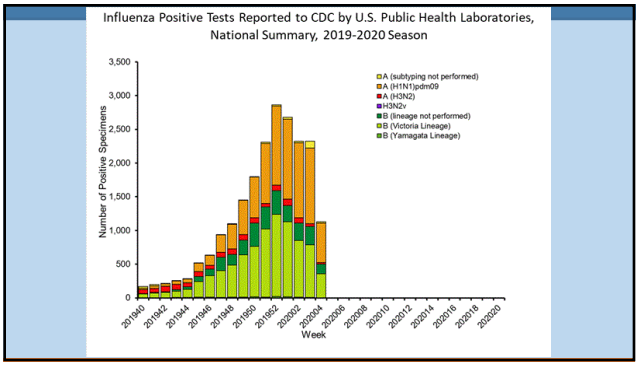
Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2020

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV)	1 dose annually			
Influenza live, attenuated (LAIV)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV) (preferred)			2 doses	
Zoster live (ZVL)			1 dose	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal conjugate (PCV13)	1 dose			65 years and older
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication			1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			
Hepatitis B (HepB)	2 or 3 doses depending on vaccine			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
Haemophilus influenzae type b (Hib)	19 through 23 years	1 or 3 doses depending on indication		

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection | Recommended vaccination for adults with an additional risk factor or another indication | Recommended vaccination based on shared clinical decision-making | No recommendation/ Not applicable







Case 2 – Judy

- Judy is an 85-year old female with HFpEF, HTN, obesity, and major depression.
- She presents to your office in October for her annual flu shot.

Case 2 – Which Flu Vaccine Is Recommended by the ACIP for Judy?

A. Standard dose quadrivalent vaccine (IIV4)
B. High dose trivalent vaccine (HD-IIV3)
C. Adjuvanted trivalent vaccine (aIIV3)
D. Recombinant quadrivalent vaccine (RIV4)
E. Live attenuated vaccine (LAIV)
F. I have no bloody idea (IHNBI)

Influenza Vaccines Approved for Older Adults
2019-2020

Vaccine	Brands	Abbreviation	HA Dose uG	Adjuvant	Technology
High Dose Trivalent	Fluzone HD	HD-IIV3	60	No	Egg
Standard Dose Quadrivalent	Afluria; Fluarix; Flulaval; Fluzone	IIV4	15	No	Egg
Standard Dose Quadrivalent – Cell	Flucelvax	ccIIV4	15	No	Cell
Adjuvanted Trivalent	Fluad	aIIV3	15	Yes (MF59)	Egg
Recombinant Quadrivalent	Flublok	RIV4	45	No	Recombinant

Hi Dose vs Standard Dose Trivalent Egg-Based
Community Dwelling

- RCT, double blind
- 2011-2013
- 31,989 subjects
- 126 sites (US, CA)
- Hi Dose vs Standard Dose Trivalent
- Followed to ~ May 15

Clinical Disease	Relative Efficacy	95% CI
Any Influenza	24.2	9.7-36.5
Influenza A	24.0	7.8-37.4
Influenza A /H3N2	23.3	6.0-37.5

Titers (GMT) – Year 1	HD	SD
A/H1N1	481.8	271.8
A/H3N2	685.5	349.8
B	138.1	97.6

DiazGranados CA, et al. N Eng J Med 2014;371:635-645.

Hi Dose vs Standard Dose Trivalent Egg-Based
Nursing Home

- Single blind RCT
- 2011-2013
- 205 subjects
- Hi vs standard dose trivalent
- Titers 0, 30, 180 days
- Frail population
  - *Mean Gait Speed = 0.7 m/sec*

30 Day Titers (GMT)	SD	HD	p Value
2011-2012			
A/California/07/2009 H1	27.4 (17-44.3)	78.2 (45.1-135.7)	.005
A/Victoria/201/2009 H3	10.2 (7.0–14.8)	26.2 (17.1–40.0)	.001
B/Brisbane/60/2008	14.3 (11.1–18.4)	25.6 (18.7–34.9)	.004
2012-2013			
A/California/07/2009H1N1	50.0 (37.4–67)	45.6 (32.9–63.2)	.672
A/Victoria/361/2011 H3N2	14.2 (11.0–18.4)	23.4 (17.6–31)	.011
B/Texas/6/2011	17.4 (13.9–21.9)	26.0 (21.2–31.9)	.010

Nace DA, Lin CJ, Ross TM, et al. J Infect Dis 2015;211:1915-1924.

Hi Dose vs Standard Dose Trivalent Egg-Based
Nursing Home

- Single blind pragmatic cRT
- 2013-2014
- 823 NF
- 92,269 (75,917 65+) residents
- Hi vs standard dose trivalent
- Hospitalizations for pulmonary and ILI (claims data)

	Adjusted Relative Risk	P Value
Hospitalizations for Respiratory Illness	0·873 (0·776–0·982)	.023
Hospitalizations for Pneumonia	0·791 (0·267–0·953)	.013
All-Cause Hospitalizatins	0·915 (0·863–0·970)	.0028

Gravenstein S, Davidson HE, Taljaard M, et al. Lancet Respir Med 2017;5(9)"738-746.

Other Influenza Vaccines

- Recombinant Vaccine (45 ug)[1]
  - 9003 participants 50 years +
  - PT-PCR confirmed influenza reduced 30% RIV4 vs IIV4 (95% CI 10-47)
- Adjuvanted Vaccine (MF59-adjuvanted)[2]
  - Reduced hospitalizations -pneumonia/influenza
  - Reduced hospitalizations – acute coronary syndrome/cerebrovascular events
  - Reduced ILI among LTC residents

[1]Dunkle LM, et al. N Engl J Med 2017;376:2427-2436.
[2]Domnich A, Arata L, amicizia D, et al. Vaccine 2017;35(4):513-520.

No head to head trials of newer influenza vaccines

Other Considerations?

Egg Based Vaccines

- **Role of egg adaptations** –
  - mutations to virus occur during egg incubation
  - creates mismatch between circulating strain and vaccine strain
  - May account for reduced vaccine effectiveness in some years
- Cell and recombinant vaccines not be impacted by egg adaptations

- Dunkle LM, et al. N Engl J Med 2017;376:2427-2436.
- Yang L, et al. Biosafety and Health 2019;1(1):41-45.

Influenza Vaccine Summary

- The CDC does not recommend one specific flu vaccine over another for use in older adults.
- High dose vaccine appears to protect better standard dose vaccine against the flu.
- Recombinant vaccine appears to offer improved protection over standard dose vaccine
- Adjuvanted vaccine appears to offer improved protection over standard dose vaccine
- No head to head trials of all vaccines.

UPMC Influenza Vaccine Policies Timeline

- 2014 – High dose influenza vaccine recommended for ≥ 65 yrs
- 2015 – Mandatory influenza vaccination for HCP
- 2018 – Elimination of egg-based vaccines ages ≥ 4 years
  - < 4 years – **Fluzone** (standard dose)
  - 4-18 years – **Flucelvax** (ccIIV4)
  - 18 + years – **Flublok** (RIV4)

Timing of Vaccination

- Does vaccine protection last throughout the season?
  - Only data is from observational studies and post-hoc analyses
  - Waning effects not consistently found
  - Numerous confounders
- Risks of delaying influenza vaccination
  - Early flu seasons *(25% of flu seasons have peaks before January)*
  - Missed vaccination opportunities
- Current recommendation
  - No optimal timing
  - At least by end of October
  - Continue to vaccinate until influenza is no longer circulating or vaccine supply exhausted

Grohskopf LA, et al. MMWR Recommendations and Reports 2018;67(3):1-20.

Just remember, Amelia Earhart did not get the flu vaccine. Make sure you get yours.

Pneumococcal Disease

Pneumococcal Disease

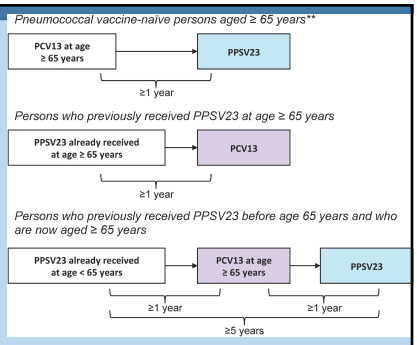
- 20-60% of community acquired pneumonia
- 900,000 cases in U.S. annually
  - 5-7% case fatality rate among those hospitalized
- 90% of invasive pneumococcal disease are in adults
- 40% of older adults not vaccinated

CDC https://www.cdc.gov/pneumococcal/about/facts.html

Nace DA, Archbald-Pannone LR, Ashraf MS, et al. Pneumococcal vaccination guidance for nursing home residents: Recommendations from AMDA's Infection Advisory Committee. J Am Med Dir Assoc 2017;18(2):99-104.

ACIP Recommendations

- **2012 PCV13** recommended for ≥ 65 yr
  - Immunosuppression
  - cochlear implants
  - CSF leak
- **2014 PCV13** recommended for all adults ≥ 65 yr
- **2019 PCV13**
  - well maybe?



2014 recommendations - Kobayashi et al. *MMWR* 2015;64:944–947

Case 3a - Jane

- Jane is a 67-year old active female who bikes 5 miles three times a week.
- She presents to establish primary care.
- She reports never having had a pneumonia shot.
- She is healthy with no medical issues.

What Do You Recommend Regarding Pneumococcal Vaccination?

Shared Decision Making and Likely PPS23 Only

Case 3b - Jane

- Jane is a 68-year old female who is establishing primary care.
- She has never had a pneumococcal vaccination.
- She has Stage 3a kidney disease and HTN.

What Do You Recommend Regarding Pneumococcal Vaccination?

PCV13 followed by PPS23

Case 3c - Jane

- Jane is an 85-year old female residing in a nursing home.
- She has a history of only Alzheimer's Disease.
- She received the PPS23 vaccine at age 65.

Should She Receive PCV13?

Yes

Pneumococcal Vaccination Recommendations
Older Adults 2019

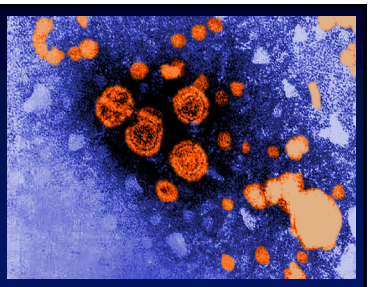
	Category		Vaccine Decision	Frequency
PPS23	All Adults ≥ 65 years		Pneumococcal Polysaccharide (PPS23)	Once at/past age 65
	Category		**Vaccine Decision**	**Frequency**
PCV13	A	All Adults ≥ 65 years with • Immunocompromising condition[1] • Cochlear implant • CSF leak	Pneumococcal Conjugate (PCV13) if not previously received	Once in lifetime
	B	All Adults ≥ 65 years with • Alcoholism • Chronic liver, lung, heart disease • Diabetes mellitus • Cigarette use	Based on shared clinical decision-making (Higher Risk)	Once in lifetime
	C	All Adults ≥ 65 years not covered in A or B[2]	Based upon shared clinical decision-making (Lower Risk)	Once in lifetime

[1]PCV13 - Immunocompromising Conditions	
Chronic Renal Failure	Iatrogenic Immunosuppression (Steroids, XRT, Chemo)
Asplenia (Congenital or Acquired)	Leukemia
Sickle Cell Disease/Hemoglobinopathies	Lymphoma
Immunodeficiencies (Congenital or Acquired)	Multiple Myeloma
Malignancy	Nephrotic Syndrome
HIV Infection	Solid Organ Transplant
Hodgkin Disease	

[2]Additional Risk Considerations
Residents of nursing homes or other long-term care facilities
Persons residing in settings where there is no/low pediatric PCV13 uptake

Timing between PCV13 and PPS23 = generally 12 months

Hepatitis B



Hepatitis B

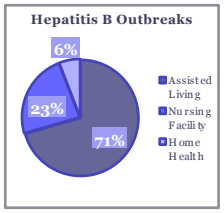
- Diabetic patients have ↑ risk of hepatitis B
  - 23-59 years OR = 2.1 and ≥60 years OR = 1.5
- Many LTC Outbreaks associated with ambulatory blood glucose monitoring devices
  - 25 of 29 outbreaks from 1996-2011 involved adults with diabetes
- 2011 ACIP Hepatitis B Immunization of Adults with Diabetes
  - Recommended 19-59 years
  - Consider ≥ 60 years

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm

University of Pittsburgh — Division of Geriatric Medicine

U.S. Hepatitis B Outbreaks 2008-2014

- 23 total outbreaks
- 175 cases
- 10,700 notified for screening
- 17 (74%) occurred in LTC facilities



http://www.cdc.gov/hepatitis/Outbreaks/HealthcareHepOutbreakTable.htm

FDA Warning
Use of All Point of Care Devices

Recommendations and FDA Action

The FDA and the CDC recommend that health care professionals and patients take the following immediate precautions:

- Never use fingerstick devices for more than one person.
- Use auto-disabling, single-use fingerstick devices for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. These are sometimes called "safety" lancets.
- Whenever possible, use POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, for one patient only. If dedicating POC blood testing devices to a single patient is no possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.
- Change gloves between patients, even when using patient-dedicated POC blood testing devices and single-use, auto-disabling fingerstick devices.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS — CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 10-28-NH

DATE: August 27, 2010

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Point of Care Devices and Infection Control in Nursing Homes

Memorandum Summary

Infection Control Standards for Nursing Homes at §483.65 - F441 –Determining Compliance: The following practices are deficiencies in infection control:

- Reusing fingerstick devices (e.g., pen-like devices) for more than one resident;
- Using a blood glucose meter (or other point-of-care device) for more than one resident without cleaning and disinfecting it after use.

If a surveyor observes a facility doing either of the above, the surveyor should follow the interpretive guidelines, investigative protocol, and severity determination information at F441 to determine the severity of the deficiency.

Scope & Severity: CMS is revising the example in Appendix PP to make a distinction between (a) reuse of fingerstick devices for more than one resident (immediate jeopardy) and (b) use of a blood glucose meter for more than one resident without proper cleaning and disinfection, so that scope and severity can be correctly assessed.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter10_28.pdf

Hepatitis B Vaccination

- Hepatitis B vaccination of all unvaccinated adults with **diabetes mellitus** who are **19-59 years of age**
- Consider hepatitis B vaccination of unvaccinated adults with diabetes 60 years of age and older, based upon:
  - **Likelihood of acquiring HBV**
  - **Likelihood of residing in LTC facilities and requiring blood glucose monitoring**
  - **Risk of sequelae**
  - **Declining immunologic response associated with frailty**
- Vaccine at minimum of 0, 1, & 6 month intervals
- No need to obtain titers one month after vaccination

Herpes Zoster

Case 4 – Ned

- Ned is an 85 year old male who presents to your office for routine follow up. He has a history of HTN and significant COPD for which he has had several intermittent courses of prednisone therapy over the past 10 years. He had an episode of shingles 7 years ago.
- You note he received the live attenuated herpes zoster vaccine (ZVL) 24 months ago. He asks about the new shingles vaccine.

Case 4 – Ned

Which of the following do you recommend?

A. No vaccination is necessary as he was recently vaccinated.
B. No vaccination at this time, but obtain inactivated recombinant zoster vaccine (RZV) in 5 years.
C. Vaccinate with one dose of inactivated recombinant herpes zoster vaccine (RZV).
D. Vaccinate with two doses of inactivated recombinant zoster vaccine (RZV).
E. Phone a friend.

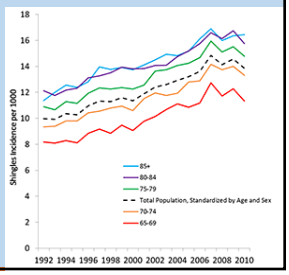
Zoster Incidence

- Despite vaccination of children with varicella (chicken pox) vaccine, the incidence of shingles has increasing.
- Varicella vaccine has been linked to latent infection of sensory neurons and subsequent herpes zoster.

http://annals.org/article.aspx?articleid=1784289

Schmader K. Herpes Zoster. Ann Intern Med 2018;169(3):ITC17-ITC32.

Shingles Rates in People > 65 Years, U.S. 1992-2010

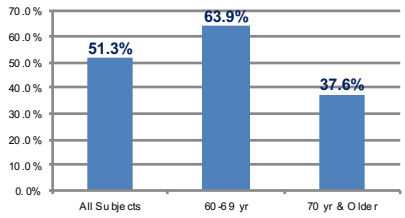


Zoster Vaccines

- Two current vaccines licensed
  - Live attenuated zoster vaccine (ZVL)
    - Single dose
    - ACIP Recommendation adults ≥ 60 years.
  - Inactivated recombinant zoster vaccine (RZV)
    - Two dose series
    - Second dose given 2-6 months later (do not repeat series if second dose missed, simply give second dose)
    - ACIP Recommendation adults ≥ 50 years.

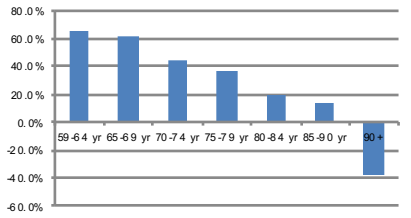
- Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster. MMWR 2018;67(3):103-108.
- Schmader K. Herpes Zoster. Ann Intern Med 2018;169(3):ITC17-ITC32.

Vaccine Efficacy for Incident Herpes Zoster
Live attenuated zoster vaccine (ZVL)



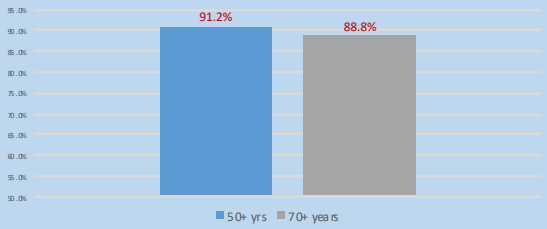
Oxman, et al. J Infect Dis 2008;197:Suppl2:S228-36

Vaccine Efficacy for Incident Herpes Zoster
Live attenuated zoster vaccine (ZVL)



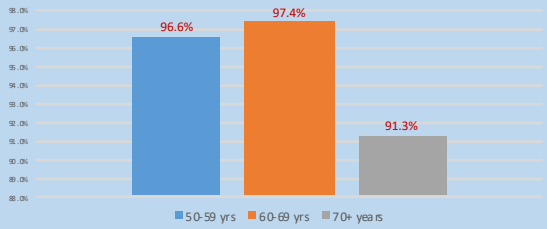
Merck & Co. FDA Clinical Briefing Document. Dec 15, 2005

RZV Efficacy for Prevention of Zoster



Dooling KL, Guo A, Patel M, et al. MMWR 2018;67(3):103-108.

RZV Efficacy for Prevention of PHN



Dooling KL, Guo A, Patel M, et al. MMWR 2018;67(3):103-108.

2018 ACIP Recommendations Zoster Vaccine

- **Recombinant zoster vaccine (RZV)** is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged **≥ 50 years. (IM injection)**
- RZV is recommended for prevention of herpes zoster and related complications for immunocompetent adults previously vaccinated with live attenuated zoster vaccine (ZVL).
- RZV is preferred over ZVL.
- ZVL is indicated in immunocompetent adults ≥ 60 years who have a contraindication to RZV. **(SQ injection)**

Practical Considerations for Prioritizing Patients During Vaccine Shortage

CDC has not established a prioritization strategy for administration of RZV

CDC Information on RZV

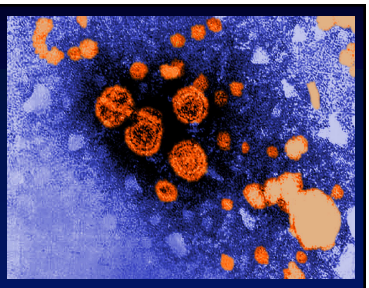
https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/faqs.html

- Risk for immunosuppression
- Frail individuals at increased risk of complications
- Persons needing second vaccine

- Vaccine Recall & Reminder Systems
- Refer to other sources for f/u doses
- Use Vaccine Finder (vaccinefinder.org)

Tdap

Tetanus, Diptheria, acellular Pertussis



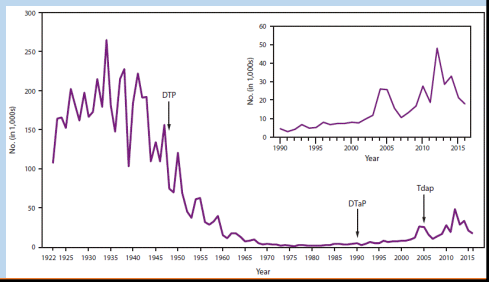
Pertussis

- Pertussis cases declined from the 1940s to the 1990s.
  - 1990s switch from whole vaccine to acelluar vaccine in children
- Pertussis cases increased from the 1990s to present
- Vaccine effectiveness decreases over time
- Numerous outbreaks among healthcare personnel
- Epidemiology in older adults is not well studied.
- Older adults present with milder/atypical symptoms

Liang JL, Tiwari T, Moro P, et al. MMWR Recommendations and Reports 2018;67(2):1-44.

Reported Cases Pertussis, U.S. 1992-2016

https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm



Tdap

- ACIP recommends ALL adults 18 years and older **receive at least 1 dose of Tdap.**
- May be given at any point. Does not have to fall into the 10 year Td schedule.
- **Either Tdap or Td may now be used for 10 year booster doses, post-exposure, or when completing the tetanus series.**
- Not associated with encephalitis, myelopathy, Bell's Palsy, Guillain-Barre Syndrome
- Cost effectiveness analyses support this recommendation

Havers FP, et al. Use of tetanus toxoid, reduced diphtheria toxoid, an dacellular pertussis vaccines: Updated recommendations of the Advisory committee on Immunization Practices - United States, 2019. MMWR 2020;69(3):77-83

Tdap

- Single dose vaccine
- Two Tdap vaccines available
  - Boostrix (10 years and older)
  - Adacel (10 to 64 years)
- While Boostrix is preferred, Adacel is acceptable to be used per CDC 2018 recommendations (no need to stock two versions)
  - Immunogenicity studies support use of both vaccines

Questions?

Thank You!

Contact Information

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