UTAH SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Off-season Just Flu By: Influenza Updates for the 2019-20 Season and Pneumococcal Vaccine Refresher

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Disclosure

No conflicts of interest to disclose

Off-label uses discussed:

- Oseltamivir in severe influenza
- Baloxavir in severe influenza and in combination with oseltamivir
- Peramivir in severe influenza in hospitalized patients unable to absorb or tolerate oseltamivir

Learning Objectives

Technician objectives

Influenza

- Outline the vaccination-based recommendations for the 2019-20 influenza season
- Compare baloxavir marboxil, peramivir, and oseltamivir as they relate to pharmacy logistics

Pneumococcal

- Explain the difference between PPSV23 and PCV13

Learning Objectives

Pharmacist objectives

Influenza

- Outline the vaccination-based recommendations for the 2019-20 influenza season
- Differentiate between eligibility of special populations for influenza vaccine
- Evaluate influenza treatment options and how they fit into current guideline recommendations

Pneumococcal

- Explain the difference between PPSV23 and PCV13
- Assess a patient's eligibility for pneumonia vaccines and create an appropriate pneumococcal vaccination schedule

Abbreviations

ACIP = Advisory Committee on Immunization Practices

IIV = Inactivated influenza vaccine
- aIIV3 = Inactivated influenza vaccine, adjuvanted
- ccIIV = Inactivated influenza vaccine, grown in cell culture

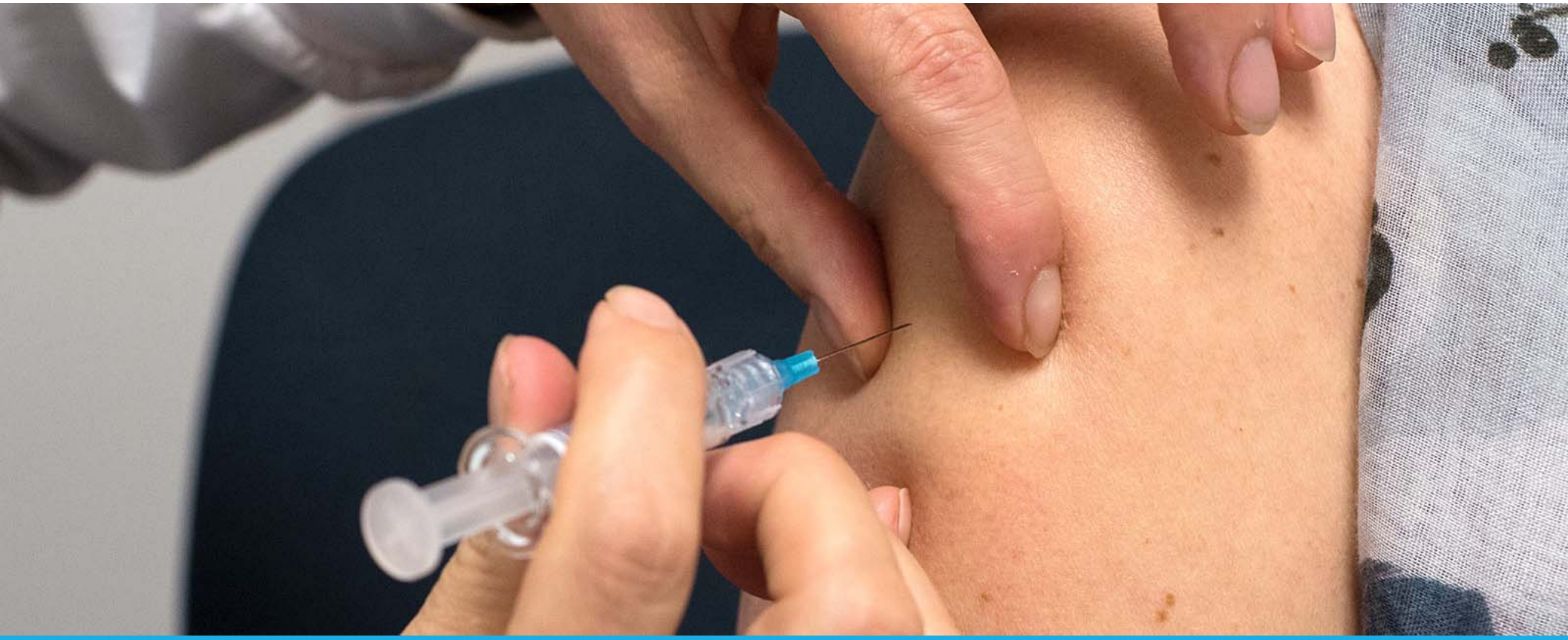
LAIV = Live attenuated influenza vaccine

RIV = Recombinant hemagglutinin influenza vaccine

GBS = Guillain-Barre Syndrome

PCV13 = Pneumococcal conjugate vaccine (13 valent)

PPSV23 = Pneumococcal polysaccharide vaccine (23 valent)



Government of Prince Edward Island. Administering Flu Vaccine [photograph]. In:Flickr, 2017.

Influenza 2019-20 Season Updates

Advisory Committee on Immunization Practices

Formed in 1964

- Federal advisory committee

Responsible for annual update of vaccine schedules

- Childhood and adolescent immunization schedules
- Adult immunization schedule

Liaison Organizations

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- American Medical Association
- American Pharmacists Association

Prevention and Control of Seasonal Influenza with Vaccines

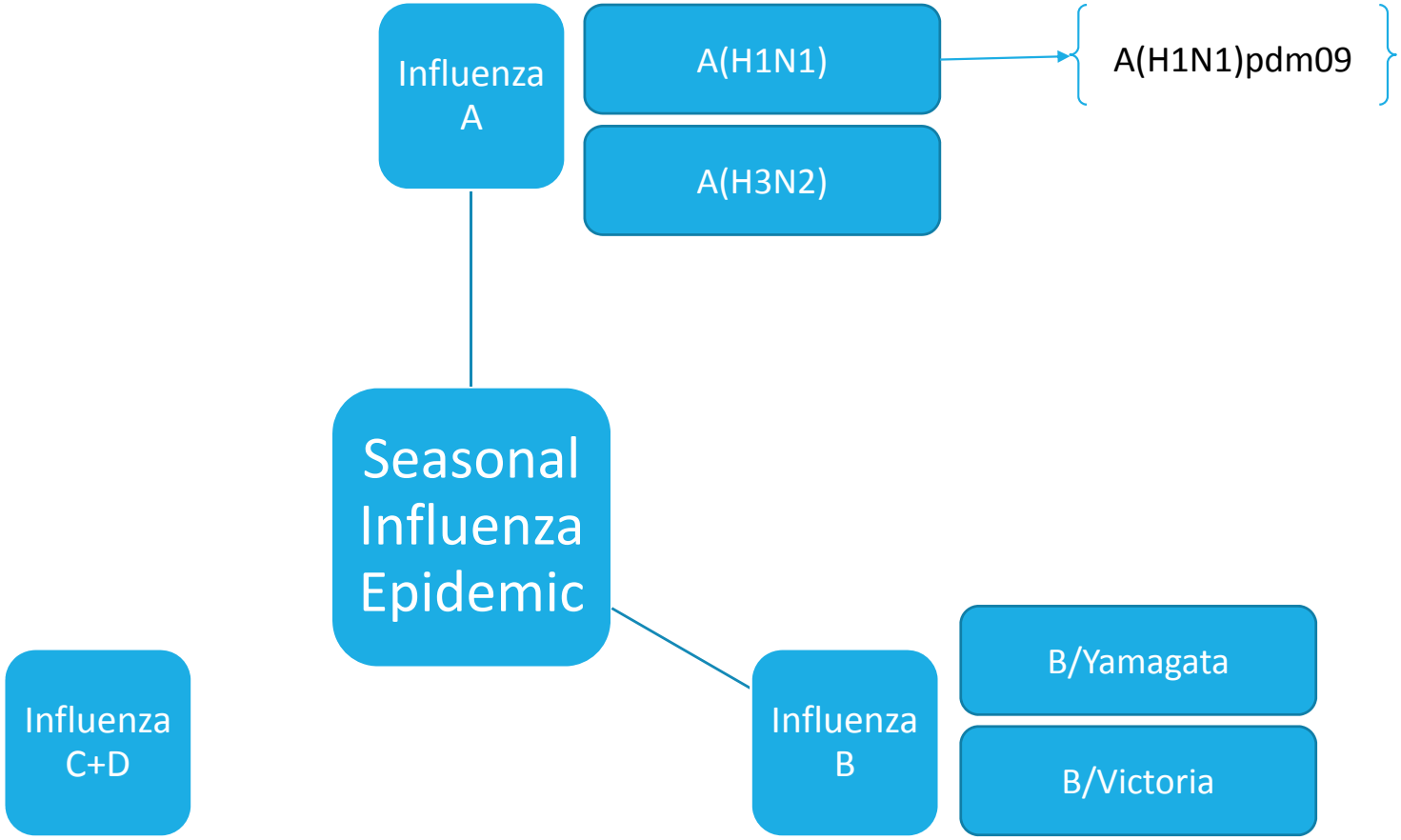
Published yearly in late summer issue of Morbidity and Mortality Weekly Report

- Based off of the early summer ACIP meeting

Sections

- General background/Epidemiology/Strain Selection
- Influenza vaccine subtype descriptions, efficacy
- Recommendations for influenza vaccination
- Guidance for vaccine use in specific populations
- Use of antiviral medications
- Additional resources

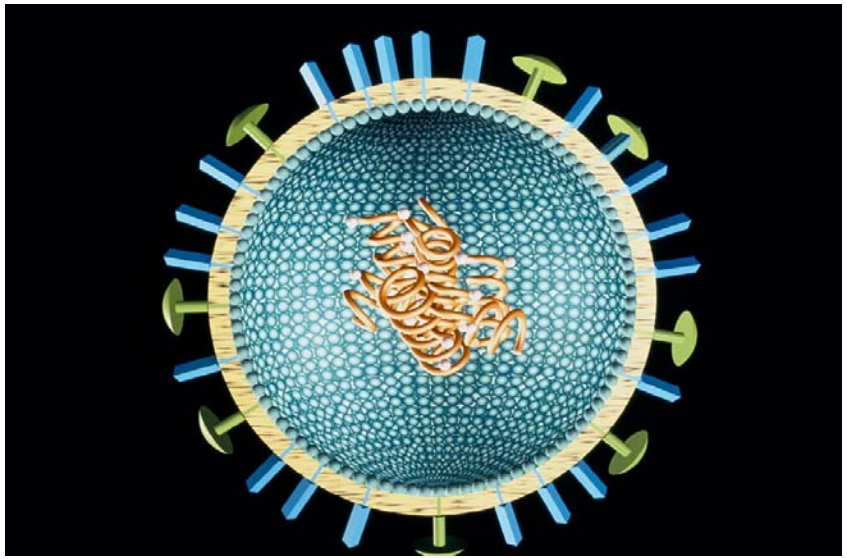
Influenza Virus Subtypes



Prevention and Control of Seasonal Influenza with Vaccines

Influenza Season 2018-2019

- Influenza A predominated
  - 74% A(H1N1)pdm09 strains
  - 26% A(H3N2) strains
- Vaccine Effectiveness
  - 61% against all flu subtypes
    - 62% against A(H1N1)
    - 44% against A(H3N2)



Sanofi Pasteur. Influenza Virus. [photograph] In: Flickr; 2010.

Prevention and Control of Seasonal Influenza with Vaccines

Strain Selection for 2019-20

- Occurred in in March 2019
- Trivalent Vaccine
  - A/Brisbane/02/2018 (H1N1)pdm09-like
  - A/Kansas/14/2017 (H3N2)-like
  - B/Colorado/06/2017-like (Victoria lineage)
- Quadrivalent
  - Above + B/Phuket/3073/2013-like (Yamagata lineage)

Strain Selection for 2018-19

- Occurred in in February 2018
- Trivalent Vaccine
  - A/Michigan/45/2015 (H1N1)pdm09-like
  - A/Singapore/INFIMH-19-0019/2016 (H3N2)-like
  - B/Colorado/06/2017-like (Victoria lineage)
- Quadrivalent
  - Above + B/Phuket/3073/2013-like (Yamagata lineage)

Vaccine Subtypes and Products

IIV

- Afluria®
- Fluarix®
- FluLaval®
- Flucelvax®*
- Fluzone®
- Fluad®
- Fluzone® HD

*Flucelvax is grown in cell culture (ccIIV)

LAIV

Flumist®

RIV

Flublok®

Prevention and Control of Seasonal Influenza with Vaccines

Core Vaccine Recommendations for 2019-20

- Annual influenza vaccination recommended for all patients aged 6 months and older without contraindications
- New products approved for patients 6 months old to 35 months old
  - Afluria Quadrivalent
  - Fluzone Quadrivalent

Contraindications to vaccination

- History of severe allergic reaction after flu vaccine or vaccine components
- LAIV = children 2-4 with asthma, children requiring aspirin, pregnancy, immunosuppression, flu antiviral use within 48 hours

Prevention and Control of Seasonal Influenza with Vaccines

Minor Vaccine Recommendation Changes for 2019-20

- Early vaccination in July and August is associated with suboptimal immunity before the end of the flu season, especially among older adults.
  - Children requiring 2 doses of flu vaccine should still get the first dose as early as possible
- Children requiring 2 doses of flu vaccine should still receive the 2nd dose even if they turn 9 years old between dose 1 and dose 2
- If a patient is getting a noninfluenza adjuvanted vaccine, a provider can consider a nonadjuvanted influenza vaccine, but vaccination shouldn't be delayed based on availability

Prevention and Control of Seasonal Influenza with Vaccines

Special Populations

- Populations at higher risk for medical complications from severe influenza
  - Caretakers
- Patients with a history of Guillain-Barre Syndrome following vaccination
- Patients with a history of egg allergy

Prevention and Control of Seasonal Influenza with Vaccines

Special Populations

- Populations at higher risk for medical complications from severe influenza
  - Adolescents and children (6 months – 18 years) who take salicylate-containing medications or are at high risk for Reye syndrome
  - Adults aged 50 years and older
  - American Indians or Alaska Natives
  - Children 6 through 59 months
  - Immunocompromised patients (due to any cause)
  - Patients with pulmonary, cardiovascular, renal, hepatic, neurologic, hematologic, or metabolic disorders
  - Residents of long-term care facilities
  - Women who are or will become pregnant during the flu season

Prevention and Control of Seasonal Influenza with Vaccines

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Prevention and Control of Seasonal Influenza with Vaccines

Pediatric Flu Recommendations

- Patients aged 6 – 35 months may receive any approved IIV
- Children aged 2 years and older may receive LAIV
- Children aged 6 months through 8 years
  - 1st season of vaccination = 2 doses of vaccine
    - Interval of at least 4 weeks between doses
    - What if the patient received 1 dose the following flu season and is still in this age range?
      - 2 doses separated by 4 weeks
    - What if the patient turns 9 after receiving their first dose of vaccine?
      - Still give the 2nd dose as long as it is 4 weeks apart

Prevention and Control of Seasonal Influenza with Vaccines

Adults aged 50 and older

- Better efficacy in studies against standard dose IIV
  - High dose IIV (Fluzone HD)
  - Adjuvanted IIV (Fluad)
  - RIV
- No head-to-head trials between any of these 3 vaccines
- ACIP has no preference for vaccine type in this population
- Do not delay vaccination

Prevention and Control of Seasonal Influenza with Vaccines

All immunocompromised patients

- VACCINATE!
  - Exception = Patients who are unlikely to respond
- No LAIV
  - Same for caretakers of severely immunocompromised
- IIV or RIV 2 weeks prior to planned immunosuppression

Prevention and Control of Seasonal Influenza with Vaccines

Patients with a history of Guillain-Barre syndrome

- After previous influenza vaccination (≤6 weeks)
  - Not high risk for severe complications = NO VACCINATION
  - High risk for severe complications = benefits v risk
- NOT after previous vaccination
  - No recommendation
  - Patients with a history of GBS are at increased risk for experiencing it again
  - Increased risk of GBS after vaccination is 1 additional case/100,000 vaccinated
    - May be as low as 1 additional case/1,000,000 vaccinated

Prevention and Control of Seasonal Influenza with Vaccines

Patients with a history of egg allergy

- Patients should receive flu vaccine
  - Any licensed vaccine recommended
- RIV is the only egg-free vaccine
- ccIIV is not produced in eggs

Test Questions

What are the major ACIP recommendations/updates for flu season 2019-20?

A. Vaccinate patients 6 months and older who are without contraindications

B. 2 new flu products for pediatric patients were approved, bringing the overall number of available vaccines for pediatric patients as young as 6 months to 4

C. The strains in the quadrivalent vaccine this year include the following:
   - A/Brisbane/02/2018 (H1N1)pdm09-like
   - A/Kansas/14/2017 (H3N2)-like
   - B/Colorado/06/2017-like (Victoria lineage)
   - Above + B/Phuket/3073/2013-like (Yamagata lineage)

D. All of the above

Test Questions

A 6-year-old patient presents to clinic and his guardian asks you about the flu vaccine. He got the flu last year and his guardian wants to do anything possible to prevent illness this year. He is in for a check up and has no health conditions. What is the appropriate flu vaccine schedule for this patient?

A. Fluzone quadrivalent 0.25 mL IM today and 4 weeks from now

B. Afluria quadrivalent 0.25 mL IM today

C. Fluad 0.5 mL IM today and 4 weeks from now

D. Flublok 0.5 mL IM today and 4 weeks from now

Test Questions

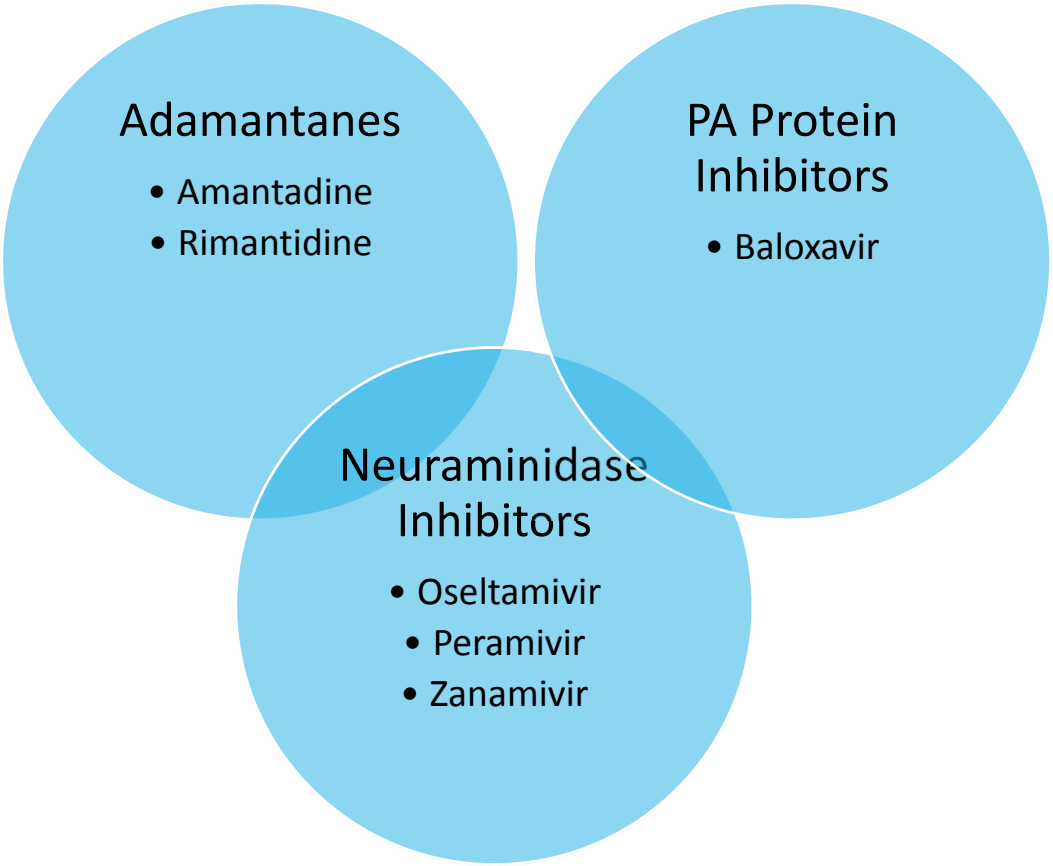
True or false?

The same 6-year-old patient will need 2 vaccinations again in the flu season of 2020-21 IF he misses his second vaccination this flu season.

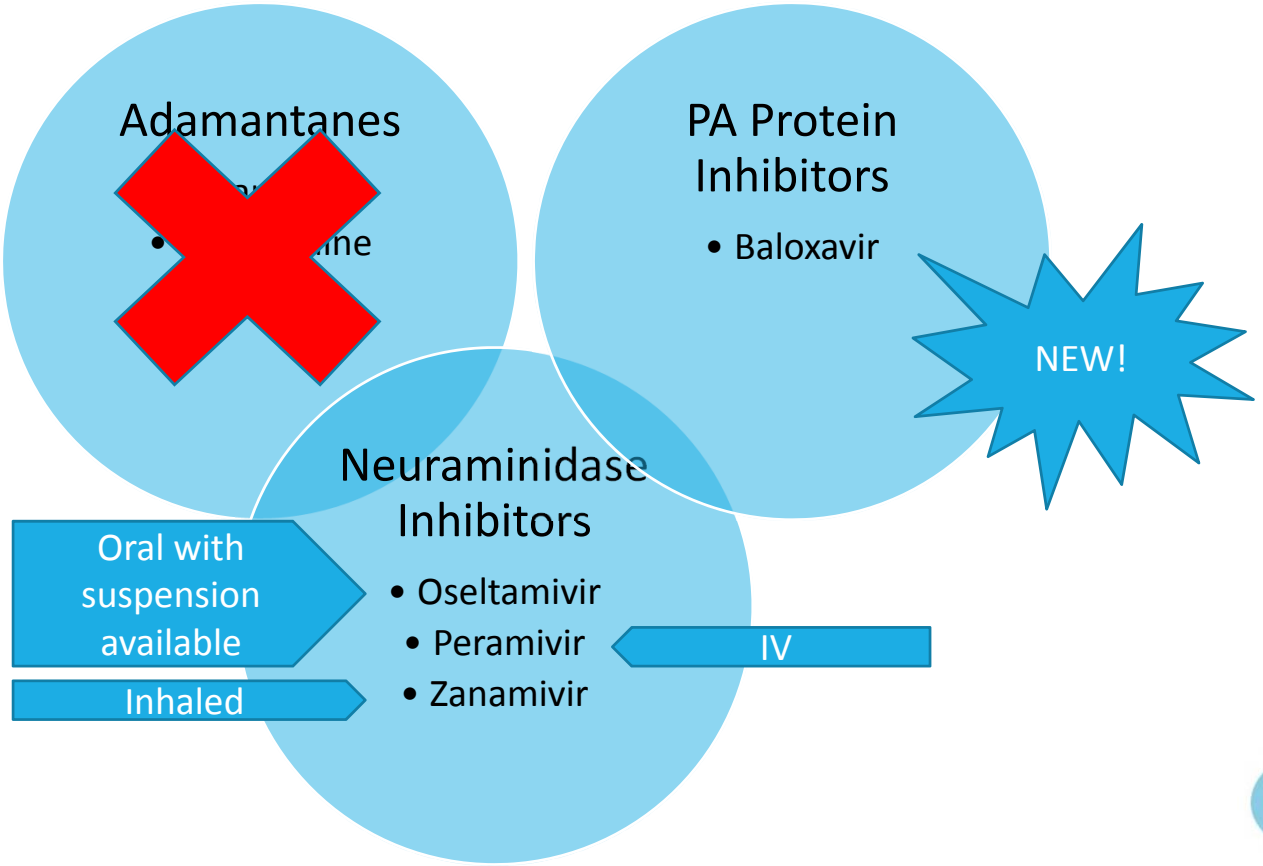
Kakub1n / Sako. Oseltamivir [photograph]. In:Flickr, 2011.

Influenza Treatment Options

Influenza Treatment Options



Influenza Treatment Options



Influenza Treatment Options

Baloxavir marboxil

- First PA protein inhibitor approved
- Approved for adults and adolescents aged 12 and older
  - Approved for acute uncomplicated influenza
- Oral, weight-based regimen
  - Single dose!

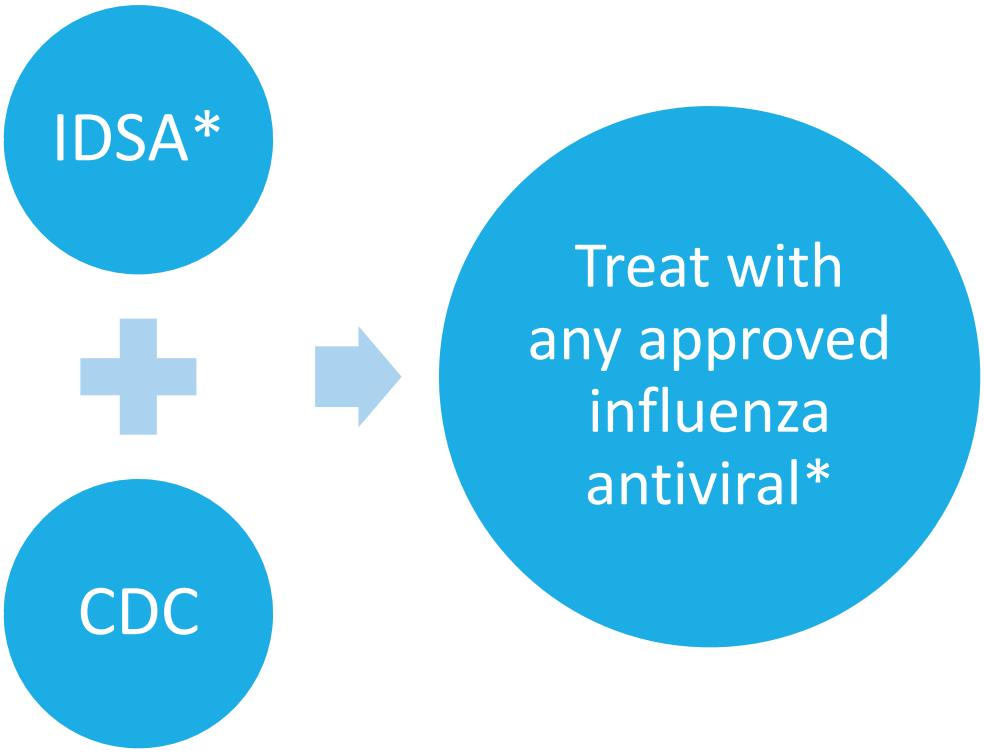
Influenza Treatment Options

Baloxavir marboxil

- Pivotal trial = CAPSTONE-1
  - Randomized, double blind, placebo- and active- controlled
  - Baloxavir weight-based single dose vs placebo or oseltamivir for 5 days
  - Primary outcome = placebo comparison
  - Median time to alleviation of symptoms similar to oseltamivir
- Upcoming trials
  - Pediatric patients (NCT03653364 & NCT03629184)
  - Reduction of Onward Transmission (NCT0396212)
  - With oseltamivir in hospitalized patients with severe influenza (NCT03684044)

Influenza Treatment Options

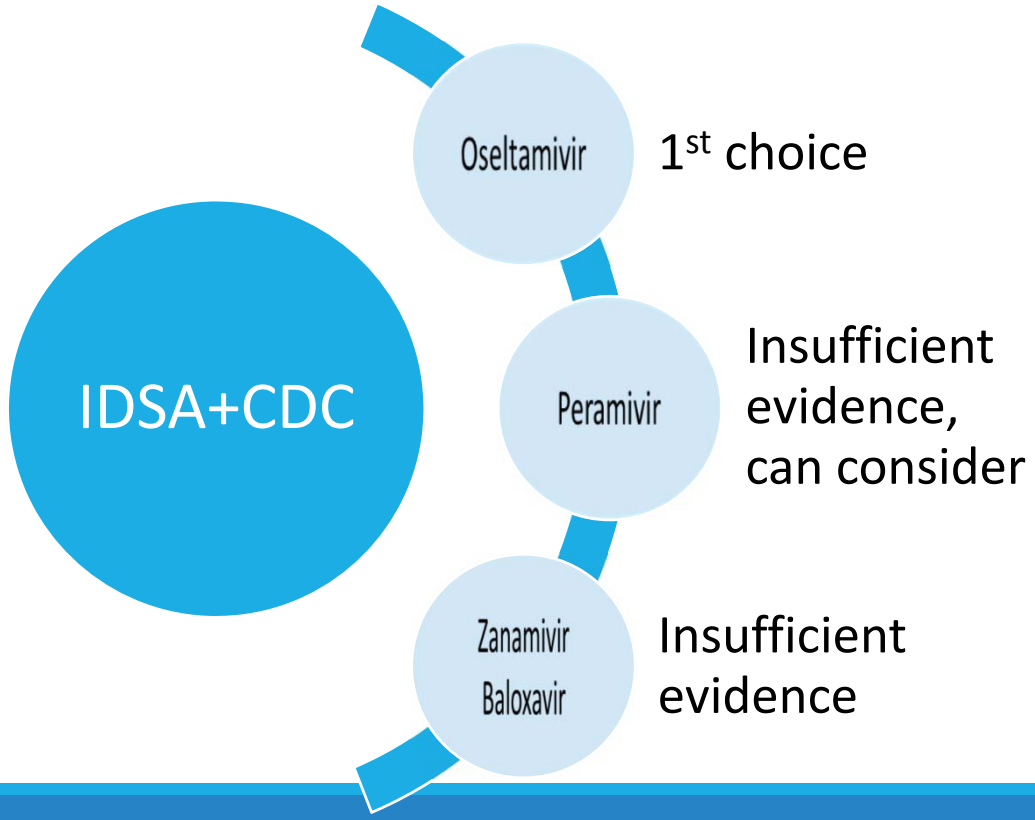
Acute, uncomplicated influenza treatment



*Baloxavir was approved after IDSA guideline finalization and they do not make a recommendation for use

Influenza Treatment Options

Severe influenza treatment (critical illness)



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Test Questions

Which influenza antiviral is available as an option for adult patients who can't swallow pills?

A. Oseltamivir
B. Peramivir
C. Zanamivir
D. Baloxavir
E. All of the above
F. All except D

Test Questions

A 48 year old patient is admitted to your floor with a diagnosis of severe influenza. She reports that she started feeling achy 4 days ago and her symptoms swiftly turned into severe myalgias, with difficulty breathing, and malaise. She has no other comorbidities. What do you recommend for influenza treatment, based on the CDC and IDSA guidelines?

A. Supportive therapy with fluids and breathing treatments

B. Peramivir 600 mg IV once

C. Oseltamivir 75 mg orally twice daily for 5 days

D. Oseltamivir 75 mg orally twice daily for 5 days and baloxavir 80 mg orally once

E. None of the above

Test Questions

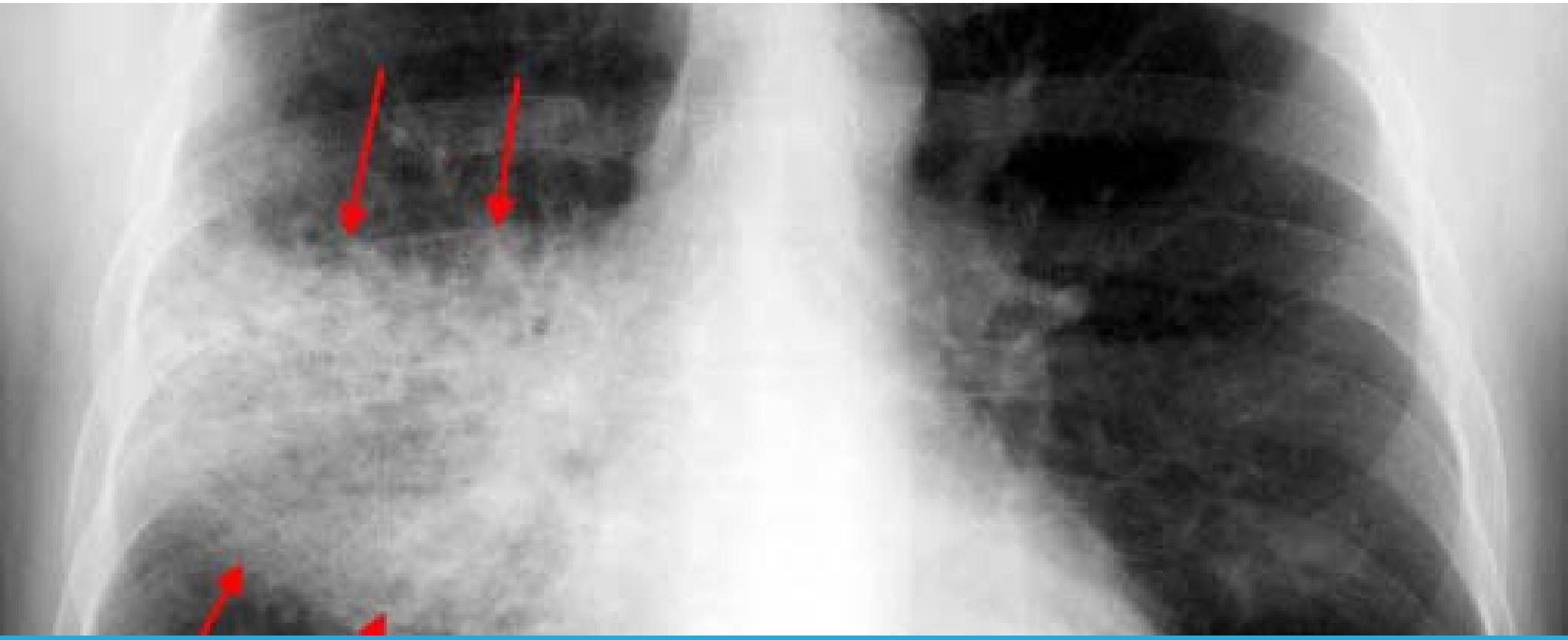
Which statement accurately reflects guideline recommendations regarding peramivir in both critically-ill patients and uncomplicated outpatients?

A. Peramivir is a recommended option for all patients, uncomplicated or critically-ill

B. Peramivir is a recommended option for all uncomplicated outpatients; there is insufficient evidence to recommend it in critically-ill patients but it can be considered if the patient can't absorb oseltamivir

C. Peramivir is ONLY an option for critically-ill patients due to the mode of administration and cost

D. There is insufficient evidence to recommend peramivir to any patient



Cristina M. pneumonia :((((. [photograph]. In:Flickr, 2010.

Pneumococcal Vaccination Refresh

Pneumococcal Vaccines

Pneumococcal bacteria cause a wide range of infections

- Much of the adult population are chronic carriers
- Causative organism in 50% of meningitis cases

PPSV14 = first licensed pneumococcal vaccine for adults

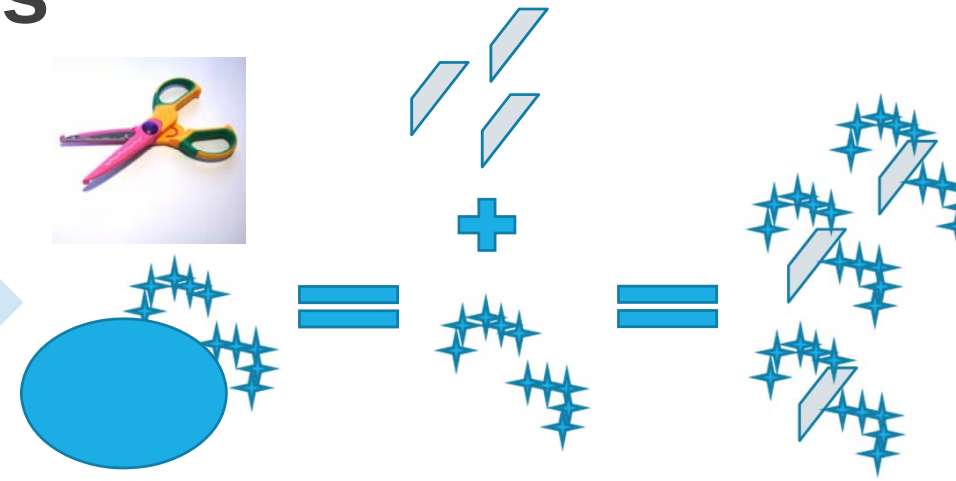
PCV7 = first licensed pneumococcal vaccine for children

- Invasive pneumococcal disease reduced by 80%

Pneumococcal Vaccines

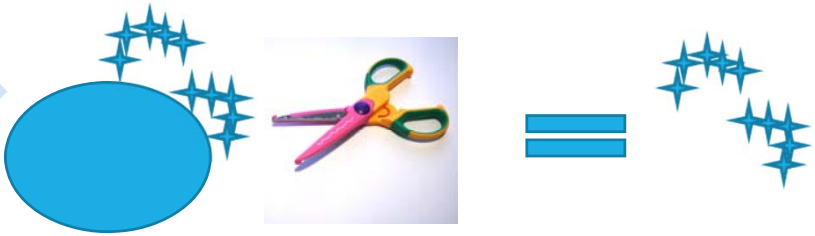
PCV13

- Conjugate vaccine
- Children and some adults with comorbidities



PPSV23

- Polysaccharide vaccine
- Adults with comorbidities and some children



Pneumococcal Vaccines

PCV13

- Conjugate vaccine
- Children and some adults with comorbidities

Storage: 2 to 8 degrees Celsius
Product is stable after excursions up to 77 degrees Farenheit that do not exceed 4 days

PPSV23

- Polysaccharide vaccine
- Adults with comorbidities and some children

Storage: 2 to 8 degrees Celsius
Room temperature stability???
Call Merck 800-672-6372

USHP

Pneumococcal Vaccines Pediatric Schedule

Birth to 15 Months

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Hepatitis B (HepB)	1st dose	2nd dose			←3rd dose→			
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1st dose	2nd dose	See notes			
Diphtheria, tetanus, & acellular pertussis (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			←4th dose→
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See notes		←3rd or 4th dose, See notes→	
Pneumococcal conjugate (PCV13)			1st dose	2nd dose	3rd dose		←4th dose→	

USHP

Pneumococcal Vaccines Pediatric Schedule

PPSV23

- Pediatric patients with chronic heart disease, chronic lung disease, and diabetes mellitus
- Pediatric patients with cerebrospinal fluid lead or cochlear implant
- Pedatric patients with sickle cell disease of anyother hemoglobinopathy, asplenia, immunodeficiency, HIV infection, chronic renal failure, nephrotic syndrome, malignancy associated with immunosuppressive drugs or radiation
- Pediatric patients with chronic liver disease (or alcoholism)

Pneumococcal Vaccines Adult Schedule

Vaccine	19-21 years	22-26 years	27-49 years	50-64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV)	1 dose annually				
or Influenza live attenuated (LAIV)			or 1 dose annually		
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td booster every 10 yrs				
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)				
Zoster recombinant (RZV) (preferred)				2 doses	
or Zoster live (ZVL)					or 1 dose
Human papillomavirus (HPV) Female	2 or 3 doses depending on age at initial vaccination				
Human papillomavirus (HPV) Male	2 or 3 doses depending	on age at initial vaccination			
Pneumococcal conjugate (PCV13)	1 dose				
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication				1 dose

Cited with permission from Centers for Disease Control and Prevention. Table 1. Recommended Adult Immunization Schedule for ages 19 years or older, United States. 2019.

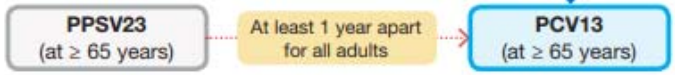
Pneumococcal Vaccines Adult Schedule

Pneumococcal vaccine timing for adults 65 years or older

For those who have not received any pneumococcal vaccines, or those with unknown vaccination history

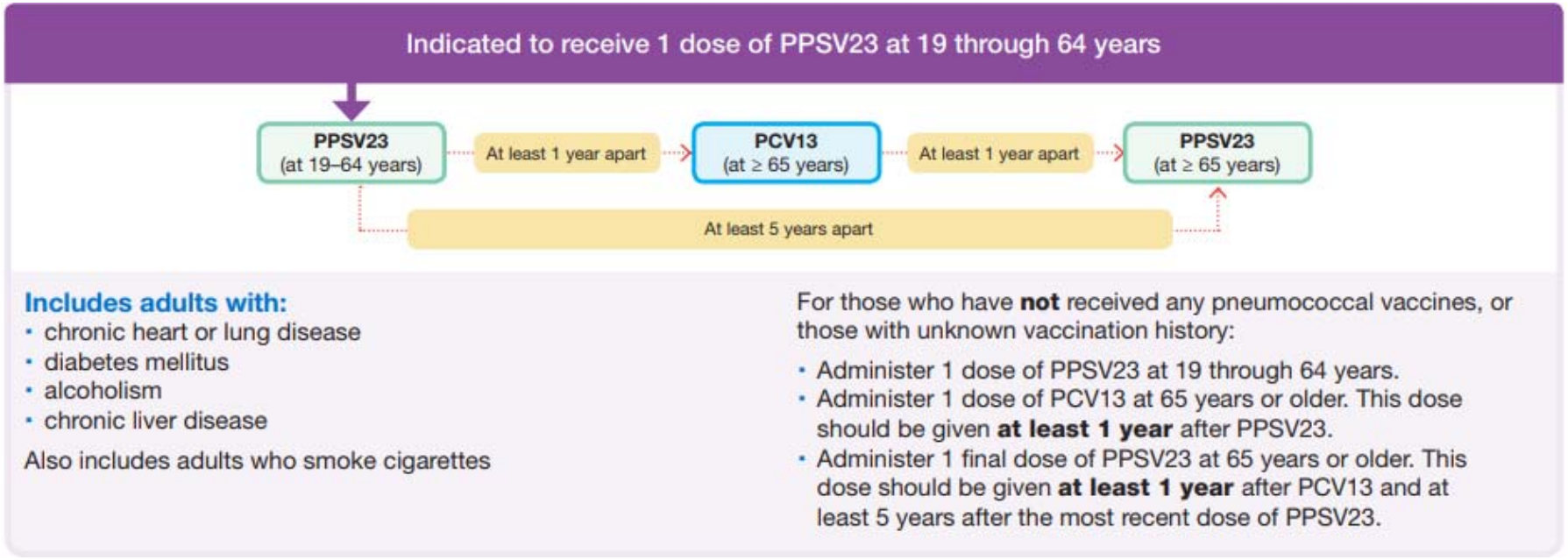
- Administer 1 dose of PCV13.
- Administer 1 dose of PPSV23 **at least 1 year** later for most immuno*competent* adults or **at least 8 weeks** later for adults with immuno*compromising* conditions, cerebrospinal fluid leaks, or cochlear implants. *See Table 1 for specific guidance.*

For those who have previously received 1 dose of PPSV23 at ≥ 65 years and no doses of PCV13



- Administer 1 dose of PCV13 **at least 1 year** after the dose of PPSV23 for all adults, regardless of medical conditions.

Pneumococcal Vaccines Adult Schedule



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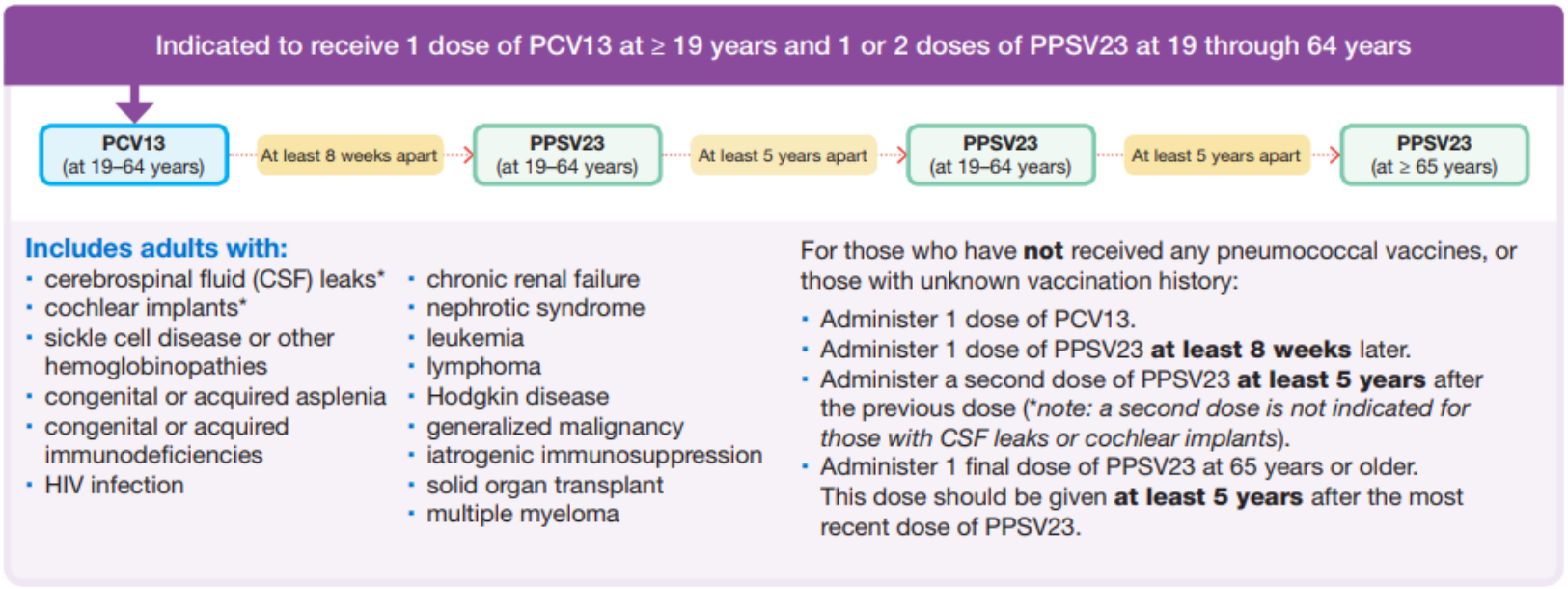
Pneumococcal Vaccines Adult Schedule



USHP

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Pneumococcal Vaccines Adult Schedule

June 2019 Update from ACIP

Age 65 years and older (not immunocompromised*)

- PPSV23 recommendations stand as is
- PCV13 = shared clinical decision making with your healthcare provider

* Immunocompromise = Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV, Hodgkin disease, leukemia, lymphoma, multiple myeloma, SOT, cochlear implant, CSF leak, asplenia, sickle cell disease or other hemoglobinopaties

Cited with permission from Centers for Disease Control and Prevention. Table 1. Recommended Adult Immunization Schedule for ages 19 years or older, United States. 2019.

Table 1. Medical conditions or other indications for administration of PCV13 and PPSV23 for adults

Medical indication	Underlying medical condition	PCV13 for ≥ 19 years	PPSV23* for 19 through 64 years		PCV13 at ≥ 65 years	PPSV23 at ≥ 65 years
		Recommended	Recommended	Revaccination	Recommended	Recommended
None	None of the below				✓	✓ ≥ 1 year after PCV13
Immunocompetent persons	Alcoholism		✓		✓	✓ ≥ 1 year after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	Chronic heart disease†					
	Chronic liver disease					
	Chronic lung disease§					
	Cigarette smoking					
	Diabetes mellitus					
	Cochlear implants	✓	✓ ≥ 8 weeks after PCV13		✓ If no previous PCV13 vaccination	✓ ≥ 8 weeks after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	CSF leaks					
Persons with functional or anatomic asplenia	Congenital or acquired asplenia	✓	✓ ≥ 8 weeks after PCV13	✓ ≥ 5 years after first dose PPSV23	✓ If no previous PCV13 vaccination	✓ ≥ 8 weeks after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	Sickle cell disease/other hemoglobinopathies					
Immunocompromised persons	Chronic renal failure	✓	✓ ≥ 8 weeks after PCV13	✓ ≥ 5 years after first dose PPSV23	✓ If no previous PCV13 vaccination	✓ ≥ 8 weeks after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	Congenital or acquired immunodeficiencies¶					
	Generalized malignancy					
	HIV infection					
	Hodgkin disease					
	Iatrogenic immunosuppression‡					
	Leukemia					
	Lymphoma					
	Multiple myeloma					
	Nephrotic syndrome					
	Solid organ transplant					

*This PPSV23 column only refers to adults 19 through 64 years of age. All adults 65 years of age or older should receive one dose of PPSV23 5 or more years after any prior dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine. No additional doses of PPSV23 should be administered following the dose administered at 65 years of age or older.

†Including congestive heart failure and cardiomyopathies

§Including chronic obstructive pulmonary disease, emphysema, and asthma

¶Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

‡Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

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	CSF leaks					
Persons with functional or anatomic asplenia	Congenital or acquired asplenia	✓	✓ ≥ 8 weeks after PCV13	✓ ≥ 5 years after first dose PPSV23	✓ If no previous PCV13 vaccination	✓ ≥ 8 weeks after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	Sickle cell disease/other hemoglobinopathies					
Immunocompromised persons	Chronic renal failure	✓	✓ ≥ 8 weeks after PCV13	✓ ≥ 5 years after first dose PPSV23	✓ If no previous PCV13 vaccination	✓ ≥ 8 weeks after PCV13 ≥ 5 years after any PPSV23 at < 65 years
	Congenital or acquired immunodeficiencies¶					
	Generalized malignancy					
	HIV infection					
	Hodgkin disease					
	Iatrogenic immunosuppression‡					
	Leukemia					
	Lymphoma					
	Multiple myeloma					
	Nephrotic syndrome					
	Solid organ transplant					

Shared clinical decision instead of blanket recommendation

*This PPSV23 column only refers to adults 19 through 64 years of age. All adults 65 years of age or older should receive one dose of PPSV23 5 or more years after any prior dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine. No additional doses of PPSV23 should be administered following the dose administered at 65 years of age or older.

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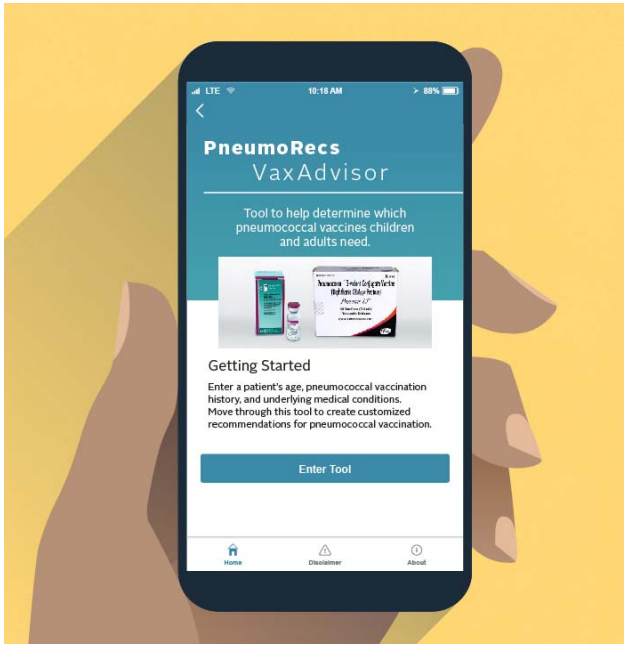
Pneumococcal Vaccines Adult Schedule

Is this all still confusing or hard to remember?

- PneumoRecs VaxAdvisor for iOS and Android
- Mobile app that allows you to enter a patient's age, underlying conditions and pneumococcal vaccination history
- Patient specific recommendations
- Currently undergoing updates to reflect changed recommendations around PCV13 in adults 65 and older without immunocompromise



Test Questions

True or false?

PPSV23 (Pneumovax®) is made by taking bacterial polysaccharide and linking it to proteins

Test Questions

True or false?

PCV13 (Prevnar®) should be stored under refrigeration, however the product can still be used after an excursion up to 77 degrees Farenheit if it was less than 4 days

Test Questions

A 67-year-old patient is establishing care at your clinic. The patient came from rural Wyoming and has no history of pneumococcal vaccine. He has a history of COPD and is on dialysis. What is his recommended pneumococcal vaccination schedule?

A. PCV13 if his provider and him decide that benefits outweigh risks

B. PCV13 followed by PPSV23 after 8 weeks

C. PPSV23 only

D. He is outside of the recommended age range of benefit for pneumococcal vaccination

Test Questions

A 67-year-old patient is establishing care at your clinic. The patient came from rural Wyoming and has no history of pneumococcal vaccine. He has a history of COPD and is on dialysis. What is his medical indication for the prescribed schedule?

A. Age 65 or older

B. Immunocompromising condition – COPD

C. Immunocompromising condition – Chronic renal failure

D. No history of pneumococcal vaccination

Learning Objectives

Pharmacist objectives

Influenza

- Outline the vaccination-based recommendations for the 2019-20 influenza season
- Differentiate between eligibility of special populations for influenza vaccine
- Evaluate influenza treatment options and how they fit into current guideline recommendations

Pneumococcal

- Explain the difference between PPSV23 and PCV13
- Assess a patient's eligibility for pneumonia vaccines and create an appropriate pneumococcal vaccination schedule

Technician objectives

Influenza

- Outline the vaccination-based recommendations for the 2019-20 influenza season
- Compare baloxavir marboxil, peramivir, and oseltamivir as they relate to pharmacy logistics

Pneumococcal

- Explain the difference between PPSV23 and PCV13

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