



 **pshp** ANNUAL ASSEMBLY

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Calling the Shots: 2022 Vaccine Updates with a Focus on Pneumococcal Vaccines

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Disclosures

- I have no actual or potential financial conflicts of interest to disclose for this presentation.

Learning Objectives

- Differentiate among the pneumococcal vaccines available in the US.
- Recommend the appropriate pneumococcal vaccine for a patient based on the latest Centers for Disease Control and Prevention vaccine schedules.

Which pneumococcal conjugate vaccine is preferred for unvaccinated adults aged 65 and older?

- A. Prevnar13® (PCV13)
- B. Vaxneuvance™ (PCV15)
- C. Prevnar20™ (PCV20)
- D. Pneumovax®23 (PPSV23)

Which disease states are indications for pneumococcal vaccination in adults?

Select all that apply.

- A. Diabetes
- B. Influenza infection
- C. Asthma
- D. COVID-19
- E. Cerebrospinal fluid leak

Pneumococcal Vaccines

PNEUMOVAX[®]23

(Pneumococcal Vaccine Polyvalent)

PPSV23

Prevnar[™]20

Pneumococcal 20-valent
Conjugate Vaccine

PCV20

Prevnar[®]13

Pneumococcal 13-valent Conjugate Vaccine
(Diphtheria CRM₁₉₇ Protein)

PCV13

Vaxneuvance[™]

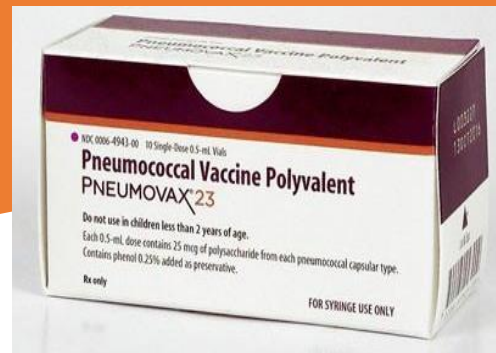
Pneumococcal 15-valent
Conjugate Vaccine

PCV15

Polysaccharide vs. Conjugate Vaccines¹

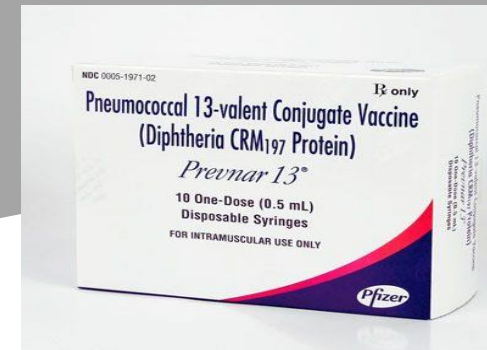
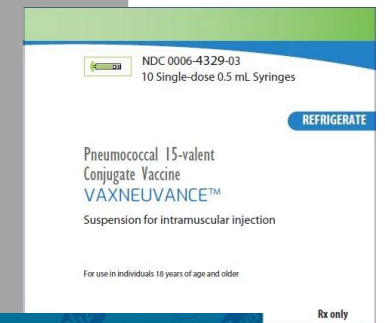
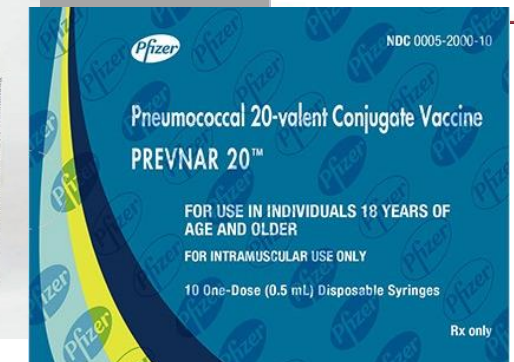
Polysaccharide

- Long chains of sugar molecules
- No memory B-cell production
- T-cell independent
- May require multiple doses


PPSV23 = Pneumovax[®]23

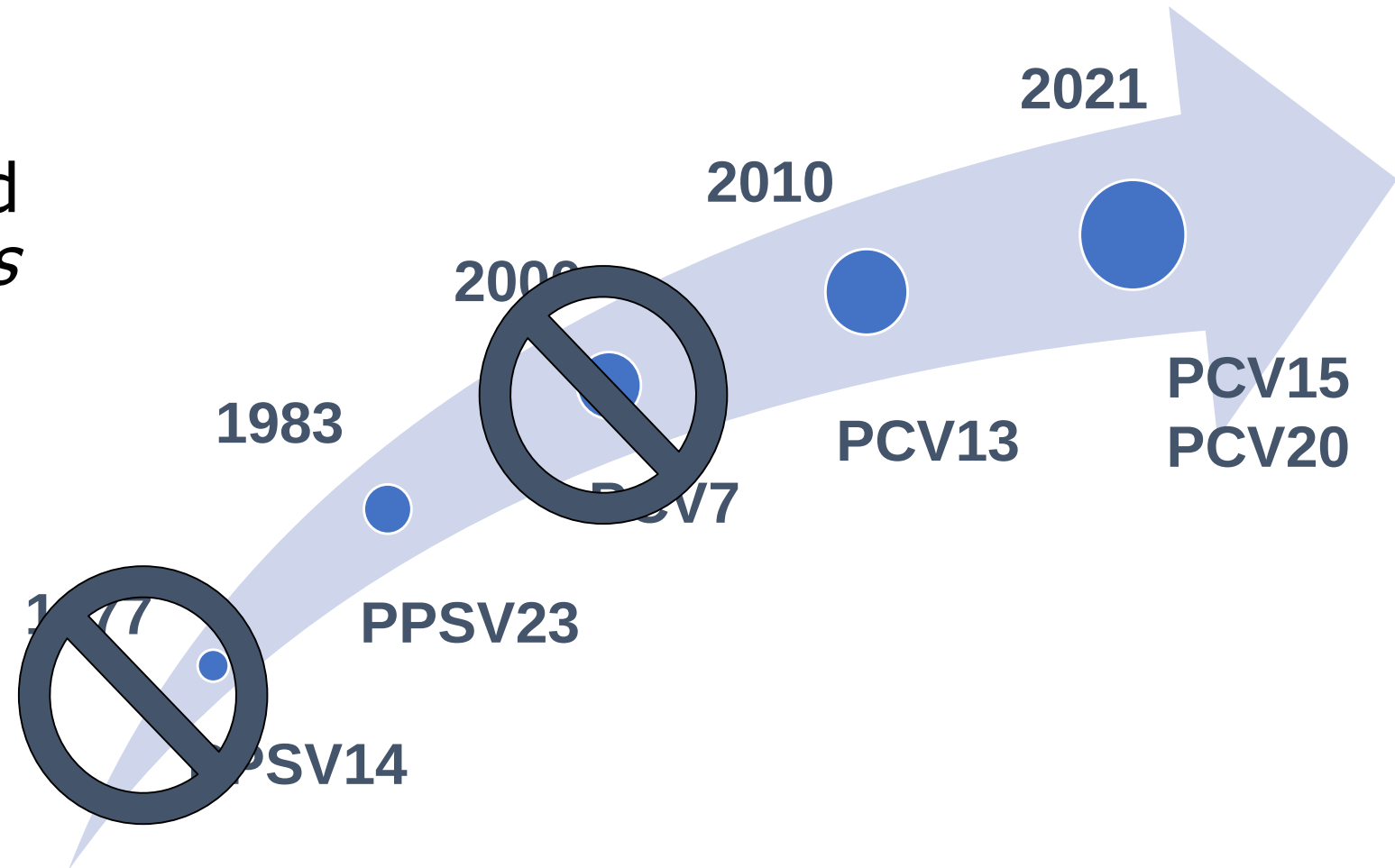
Conjugate

- Polysaccharide attached to a CRM₁₉₇ carrier protein
- B-cell memory production
- T-cell dependent
- Typically only need 1 dose


PCV13 = Prevnar13[®]

PCV15 = Vaxneuvance[™]

PCV20 = Prevnar20[™]

Pneumococcal Vaccine History^{2,3}

- Prevents infections caused by *Streptococcus pneumoniae*
- One-hundred serotypes identified



Invasive vs. Non-invasive Pneumococcal Disease¹

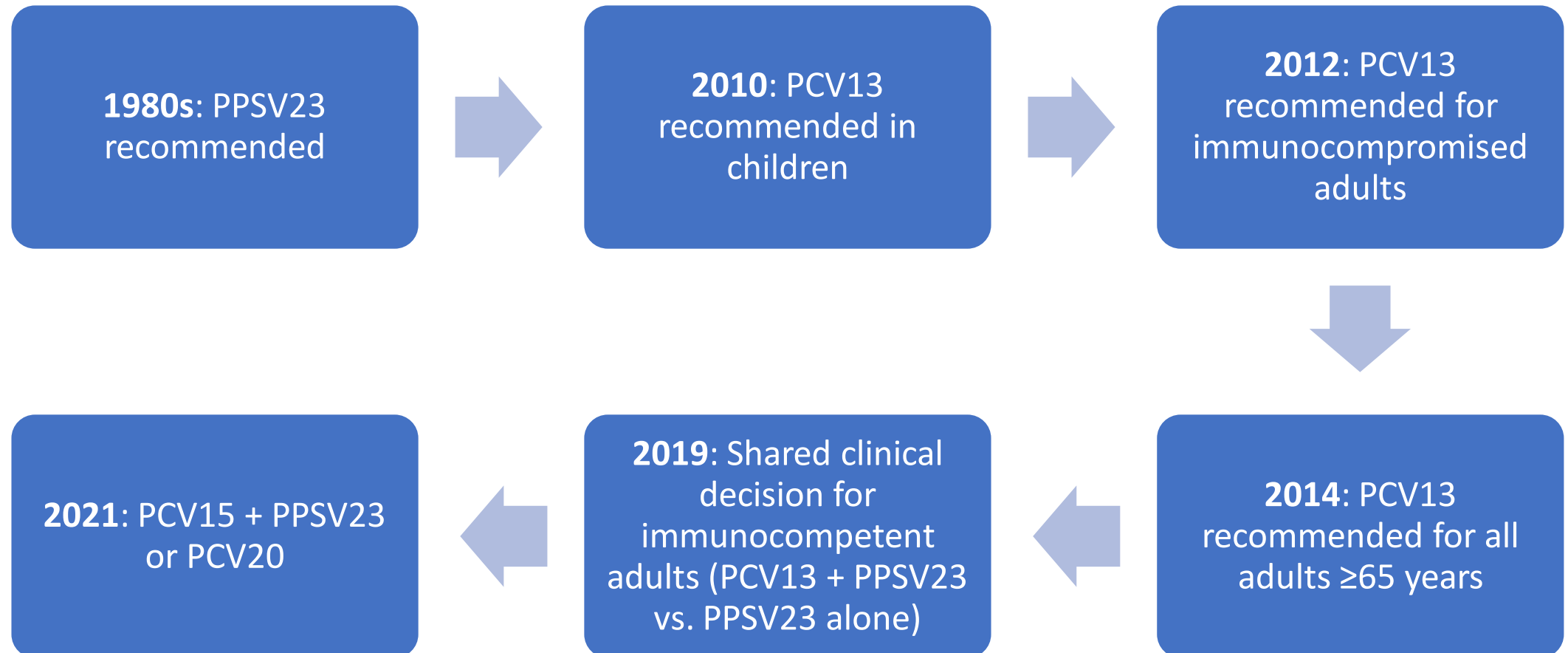
Invasive pneumococcal disease

- Meningitis
- Sepsis/bacteremia without focus
- Bacteremic pneumonia

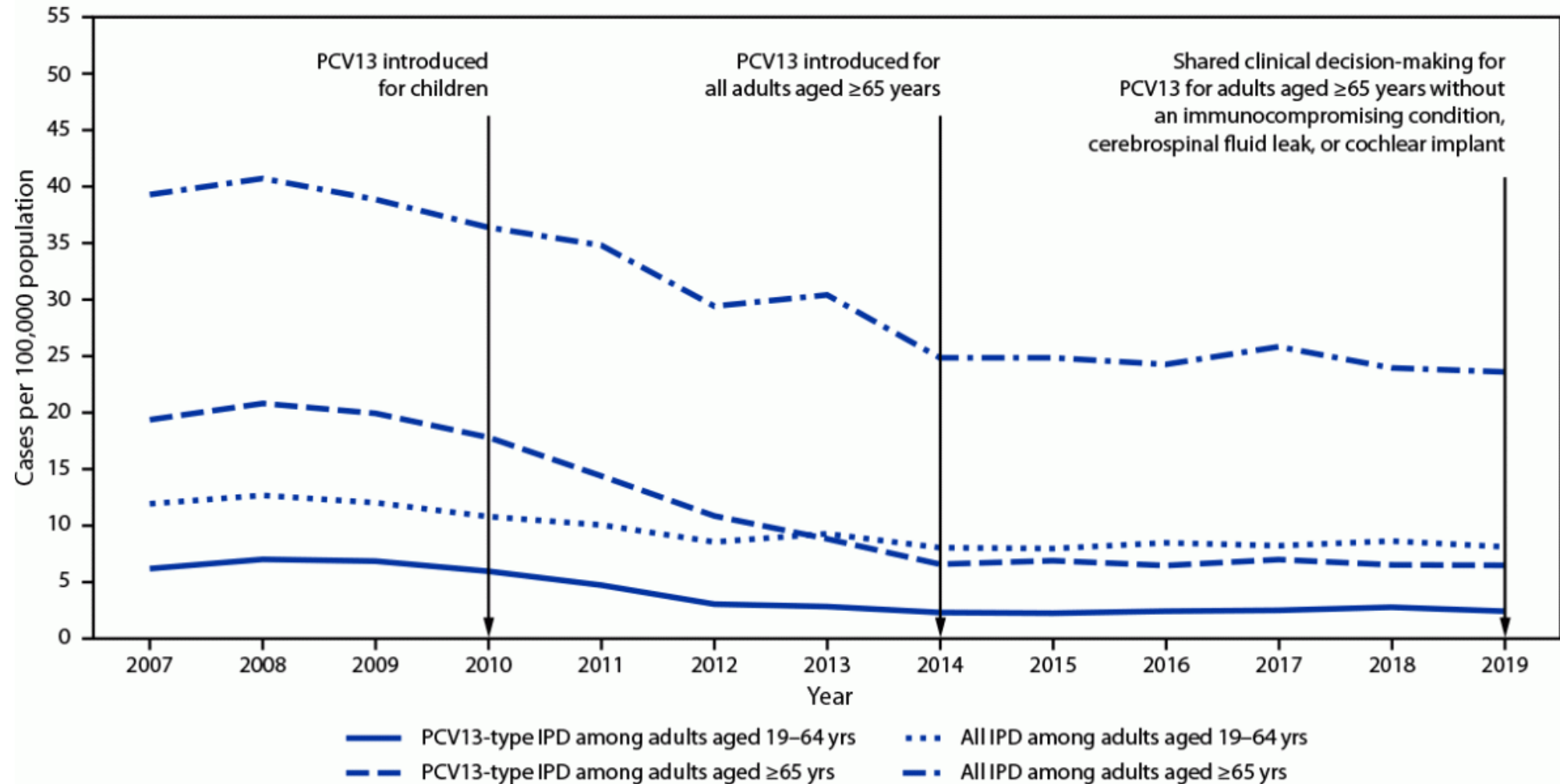
Non-invasive pneumococcal disease

- Sinusitis
- Otitis media
- Nonbacteremic pneumonia

History of Advisory Committee on Immunization Practices (ACIP) Pneumococcal Vaccine Recommendation Changes^{2,3}



Incidence of all invasive pneumococcal disease and 13-valent pneumococcal conjugate vaccine-type* invasive pneumococcal disease among adults aged ≥ 19 years, by invasive pneumococcal disease type and age group — United States, 2007–2019³



Abbreviations: IPD = invasive pneumococcal disease; PCV13 = 13-valent pneumococcal conjugate vaccine.

* Includes serotype 6C, which shows cross-protection from 6A antigen in PCV13 and was grouped with PCV13 serotypes for IPD incidence

Pneumococcal Vaccine Comparison⁴⁻⁷

	PPSV23	PCV13	PCV15	PCV20
Brand Name	Pneumovax [®] 23	Prevnar13 [®]	Vaxneuvance [™]	Prevnar20 [™]
Number of Strains	23	13	15	20
FDA Approval Date	1983	February 2010	July 2021	June 2021
FDA Approved Ages	≥2 years old	≥6 weeks old	≥6 weeks old	≥18 years old
Dose	0.5 ml IM/subQ	0.5 ml IM	0.5 ml IM	0.5 ml IM
Adjuvant	None	Aluminum phosphate	Aluminum phosphate	Aluminum phosphate
Conjugate	None	CRM ₁₉₇	CRM ₁₉₇	CRM ₁₉₇

Looking at the Serotypes⁴⁻⁷



	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20
PCV13	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓											
PCV15	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓									
PCV20	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
PPSV23	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Contraindications^{1,4-7}

- Do not administer a pneumococcal conjugate vaccine to:
 - A person who has ever had a severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV7, PCV13, PCV15, or PCV20, or to any vaccine containing diphtheria toxoid
 - A person with a severe allergy to any component of these vaccines
- Do not administer PPSV23 to:
 - A person who has ever had a severe allergic reaction (e.g., anaphylaxis) after a previous dose
 - A person with a severe allergy to any component of this vaccine



Vaccine Side Effects^{1,4-7}

PCV

- Injection site reactions
- Fever
- Loss of appetite
- Irritability
- Tiredness
- Headache
- Muscle aches/joint pain
- Chills

PPSV

- Injection site reactions
- Tiredness
- Fever
- Muscle aches

PCV15 in Infants and Children



Platt HL, Greenberg D, Tapiero B, et al. A Phase II Trial of Safety, Tolerability and Immunogenicity of V114, a 15-Valent Pneumococcal Conjugate Vaccine, Compared With 13-Valent Pneumococcal Conjugate Vaccine in Healthy Infants. *Ped Infect Dis J* 2020;39:763–70.

Study Design	Randomized, multisite, double-blind phase II study Sites in US, Canada, Finland, Spain, Israel, Demark
Patient Population	Healthy infants 6-12 weeks old
Intervention	V114 (PCV15) (Lots 1 and 2) vs. PCV13
Primary Endpoint	Non-inferiority of V114 Lot 1 and V114 Lot 2 vs. PCV13 measured by proportion of infants achieving serotype-specific IgG concentration ≥ 35 mcg/mL for shared serotypes at 1 month post-dose 3

Baseline characteristics and safety endpoints were similar across groups.⁸

Baseline Characteristics				
Characteristic	PCV15 Lot 1 N=351	PCV15 Lot 2 N=350	PCV13 N=350	Total N=1051
Female, n (%)	164 (46.7)	186 (53.1)	173 (49.4)	523 (49.8)
Age, mean, weeks	8.8	8.8	8.7	8.7
Race, white, n (%)	290 (82.6)	296 (84.6)	289 (82.6)	875 (83.3)

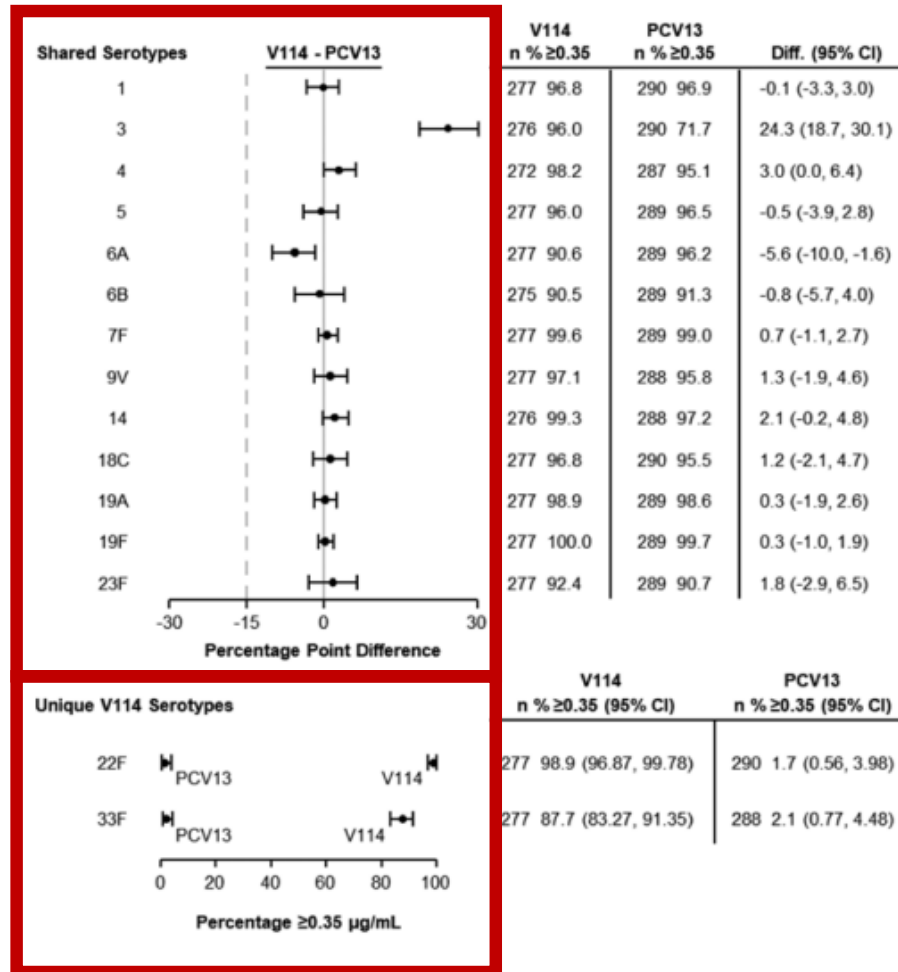
87.6%
completed

Most discontinuations were due to withdrawal of consent or meeting rescue criteria

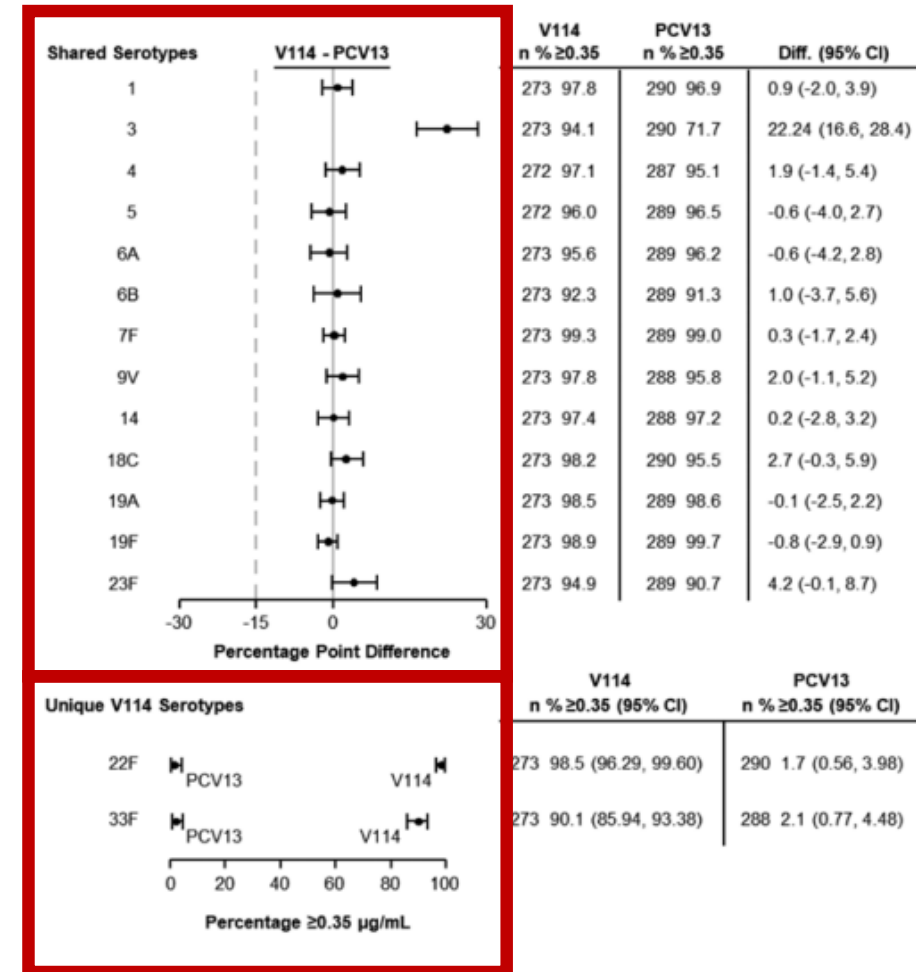
Safety Endpoint			
	PCV15 Lot 1 n (%)	PCV15 Lot 2 n (%)	PCV13 n (%)
Any adverse effect (AE)	335 (95.7)	339 (97.7)	332 (95.7)
Serious vaccine-related AE	0	2 (0.6)	0

PCV15 was non-inferior to PCV13 for shared serotypes and had higher response rates for serotypes unique to PCV15.⁸

V114 Lot 1 vs PCV13



V114 Lot 2 vs PCV13



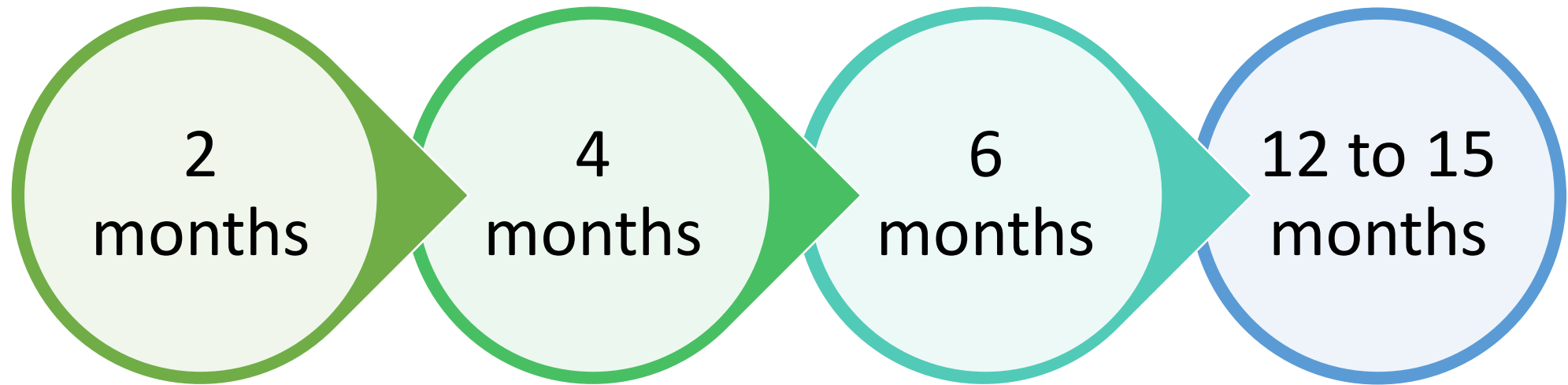
IgG antibody response rates 1-month post-dose 3 PCV15 (V114) vs. PCV13

Recommendations for Pediatric Pneumococcal Vaccines



Infants & Children under 2 Years Old

– 4-dose Series with PCV13 or PCV 15¹⁰



Catch-up guidance is available on the CDC website for late administration up through age 4:

<https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/pneumococcal.pdf>

What about Older Children?^{9,10}

Healthy children aged 2-4 years old

- Give one dose of PCV13 or PCV15

Older Children Aged 2-5 Years with Medical Conditions^{9,10}

Cerebrospinal fluid (CSF) leak, chronic heart or lung disease, cochlear implant, or diabetes Chronic renal failure or nephrotic syndrome, congenital immunodeficiency, asplenia or splenic dysfunction, diseases associated with treatment of immunosuppressive drugs or radiation therapy, HIV infection, sickle cell disease or other hemoglobinopathies	
Unvaccinated or < 3 PCV doses before 24 months: PCV13 or PCV15 x2 doses ≥8 weeks apart	
Received 3 PCV doses before 12 months (missed 4th dose): PCV13 or PCV15 x1 dose	
Give PPSV23 x1 dose ≥8 weeks after completing PCV series	Give PPSV23 x2 doses after completing PCV series. First PPSV dose ≥8 weeks after completing PCV series, then give the second dose of PPSV23 at least 5 years after the first PPSV23 dose

Older Children Aged 6-18 Years Old with Medical Conditions^{9,10}

Cerebrospinal fluid (CSF) leak or cochlear implant

- Unvaccinated: PCV13 or PCV15 x1 dose
- Give PPSV23 x1 dose ≥8 weeks after completing PCV series

Chronic renal failure or nephrotic syndrome, congenital immunodeficiency, asplenia or splenic dysfunction, diseases associated with treatment of immunosuppressive drugs or radiation therapy, HIV infection, sickle cell disease or other hemoglobinopathies

- Unvaccinated: PCV13 or PCV15 x1 dose
- Give PPSV23 x2 doses after completing PCV series. First PPSV dose ≥8 weeks after completing PCV series, then give the second dose of PPSV23 at least 5 years after the first PPSV23 dose

Chronic heart or lung disease, diabetes

- Give PPSV23 x1 dose if not given previously

Infants and Children – Summary^{9,10}

Infants and toddlers 0 to 2 years old

- PCV13 or PCV15 4-dose series at 2 months, 4 months, 6 months, 12-15 months

Catching up – 2 months to 4 years old

- [2021 Pneumococcal Conjugate Vaccine \(PCV\)-Catch-up Guidance for Healthy Children 4 months through 4 years of Age \(cdc.gov\)](#)

Children with underlying conditions

- See the vaccine schedule here: [Vaccines Indicated for Persons Aged 0 through 18 years Based on Medical Indications | CDC](#)

A parent brings their two healthy children, ND and DD, in for their 15-month check up. ND and DD have received three doses of PCV13, and are due for dose #4. Today in clinic the only available pneumococcal vaccines are PCV15, PCV20, and PPSV23. What do you do?

- A. Wait until their next office visit to vaccinate
- B. Give PCV15 to complete the series
- C. Give PCV20 to complete the series
- D. Give PPSV23 followed by PCV13 in 8 weeks

ACIP* recommends **15-valent pneumococcal conjugate vaccine (PCV15)**
as an option for pneumococcal conjugate vaccination of children**

- PCV13 and PCV15:
 - can be used interchangeably
 - are recommended for all children aged 2–59 months and some others based on risk factors
 - can be administered at the same time as other routine vaccines, including COVID-19, using different syringes and vaccine sites
- PCV15 can be used according to currently recommended PCV13 dosing and schedules



**Make sure your patients are up to date
with their pneumococcal vaccinations**



* ACIP (Advisory Committee on Immunization Practices)

** Risk-based recommendations on use of PPSV23 for people aged 2–18 years with certain underlying medical conditions that increase the risk for pneumococcal disease have not changed.

bit.ly/mm7137a3

SEPTEMBER 22, 2022

MMWR

Selected PCV15 and PCV20 Clinical Trials in Adults



Essink B, Sabharwah C, Cannon K, et al. Pivotal phase 3 randomized clinical trial of the safety, tolerability, and immunogenicity of 20-valent pneumococcal conjugate vaccine in adults aged ≥ 18 years. *Clin Infect Dis* 2022 Aug 31;75(3):390-398.

Study Design	Phase III, randomized, active-controlled, double-blind multicenter study Sites: United States and Sweden
Patient Population	Vaccine naïve, immunocompetent adults ≥ 18 years old in 3 cohorts based on age (≥ 60 , 50-59, 18-49)
Intervention	Adults ≥ 60 : PCV20 vs. PCV13 + PPSV23 Adults 18-59: PCV20 vs. PCV13
Primary Endpoint	Safety: local and systemic reactions after PCV20, serious AEs, newly diagnosed conditions within 6 months of PCV20 Efficacy: noninferiority of PCV20 by serotype at 1 month

PCV20 was noninferior to PCV13 for 13 matched serotypes in those aged ≥ 60 years.¹¹

Baseline Characteristics						
Characteristic	≥ 60 Years PCV20/Saline N=1507	≥ 60 Years PCV13/PPSV23 N=1490	50-59 Years PCV20 N=334	50-59 Years PCV13 N=111	18-49 Years PCV20 N=335	18-49 Years PCV13 N=112
Female, n (%)	897 (59.5)	879 (59.0)	195 (58.4)	69 (62.2)	214 (63.9)	77 (68.8)
White race, n (%)	1295 (85.9)	1237 (83.0)	278 (83.2)	90 (81.1)	274 (81.8)	101 (90.2)
Age at vaccination, y, mean $\pm$ SD	64.6 $\pm$ 4.8	64.6 $\pm$ 4.8	54.9 $\pm$ 2.8	55.0 $\pm$ 3.1	34.0 $\pm$ 8.8	33.9 $\pm$ 8

94.2%
completion

Primary endpoint – Noninferiority for ≥ 60 Years

Noninferiority was met for 13 matched serotypes for PCV20 vs. PCV13
Noninferiority was met for 6 of 7 additional serotypes for PCV20 vs. PPSV23

The frequency and severity of local reactions within 10 days after PCV20 or PCV13 were similar within each cohort.¹¹

Across all cohorts 8.1-15.2% of participants experienced any adverse event

Newly diagnosed chronic conditions occurred in 2.3% of participants ≥60 years in both cohorts

Most common local reactions: pain at injection site, redness, swelling

Most common systemic reactions: muscle pain, joint pain, headache, fatigue

Platt HL, Cardona JF, Haranaka M, et al. A phase 3 trial of safety, tolerability, and immunogenicity of V114, 15-valent pneumococcal conjugate vaccine, compared with 13-valent pneumococcal conjugate vaccine in adults 50 years of age and older (PNEU-AGE). *Vaccine* 2022; 40: 162-172.

Study Design	Phase III, multicenter, randomized, double-blind, active comparator-controlled study Sites: US, Japan, Spain, Canada, Taiwan
Patient Population	Pneumococcal-vaccine naïve, healthy adults ≥50 years Three cohorts: 50-64 years, 65-74 years, ≥75 years
Intervention	PCV15 x1 dose vs. PCV13 x1 dose
Primary Endpoint	Efficacy: Noninferiority of PCV15 vs. PCV13 for common serotypes at post-vaccination day 30 Superiority of PCV15 vs. PCV13 for unique serotypes at post-vaccination day 30 Safety: post-vaccination adverse events

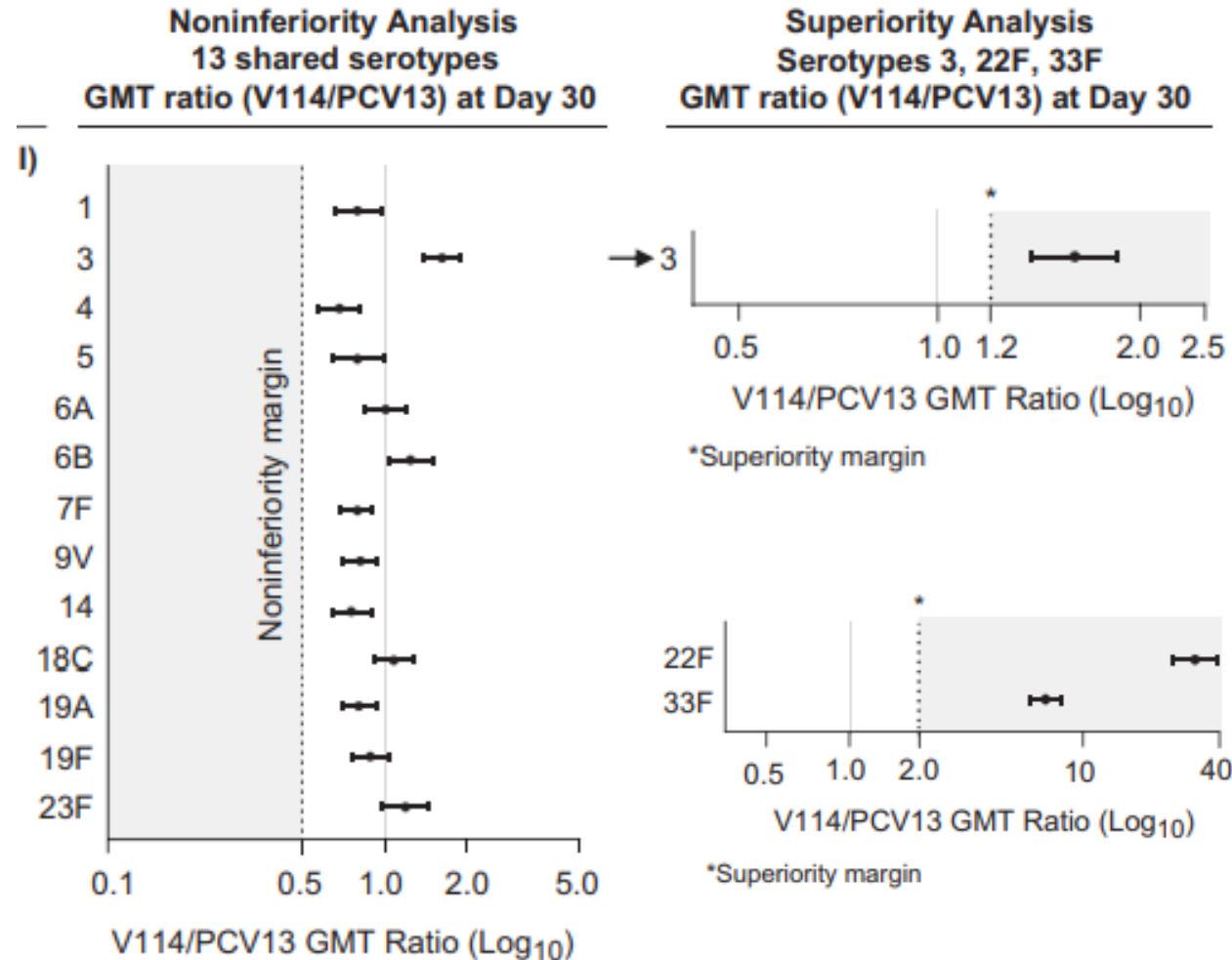
PCV15 had a higher incidence of pain compared with PCV13, but most cases were mild.¹²

Baseline Characteristics			
Characteristic	PCV15 (N=602)	PCV13 (N=600)	Total (N=1202)
Female, n (%)	358 (59.5)	351 (55.2)	689 (57.2)
Age (years), n (%)			
50 to 64	186 (30.9)	186 (31.0)	372 (30.9)
65 to 74	346 (57.5)	346 (57.7)	392 (57.6)
≥ 75	70 (11.6)	68 (11.3)	138 (11.5)

	Injection site reactions*			Systemic reactions*			
	Pain**	Swelling	Erythema	Fatigue	Myalgia	Headache	Arthralgia
PCV15	54	12.5	9	17.4	15.4	11.6	5.3
PCV13	42.3	11.2	11.3	17.3	12.0	13.0	5.5

*Reported as percentages of participants. **statistically significant

PCV15 met noninferiority criteria for all 13 shared serotypes vs. PCV13. Superiority was met for PCV15 unique serotypes.¹²



Hammitt LL, Quinn D, Janczewska E, et al. Immunogenicity, safety, and tolerability of V114, a 15-valent pneumococcal conjugate vaccine, in immunocompetent adults aged 18-49 years with or without risk factors for pneumococcal disease: a randomized phase 3 trial (PNEU-DAY). *OFID* 2022 Mar; 9(3): ofab605.

Study Design	Phase III, multicenter, randomized, double-blind, active comparator-controlled study
Patient Population	Adults aged 18-49 years with or without risk factors for pneumococcal disease
Intervention	PCV15 or PCV13 on day 1, followed by PPSV23 x1 dose at six months
Primary Endpoint	Descriptive results for safety, tolerability, immunogenicity of PCV15

More than half of the participants had at least one risk factor for pneumococcal disease.¹³

Baseline Characteristics			
	PCV15 (N=1133)	PCV13 (N=379)	Total (N=1512)
Female, n (%)	581 (51.3)	200 (52.8)	781 (51.7)
Race, n (%)			
White	580 (51.2)	191 (50.4)	771 (51.0)
American Indian/ Alaska native	445 (39.3)	148 (39.1)	593 (39.2)
Risk factors, n (%)			
No risk factors	285 (25.2)	96 (25.3)	381 (25.2)
1 risk factor	620 (54.7)	207 (54.6)	827 (54.7)

Most common individual risk factors in patients with a single risk factor were tobacco use (14.6%), chronic lung disease (14.3%), and diabetes mellitus (13.8%).

Results¹³

Safety

- 80% of participants experienced an adverse event
- Most common were injection site reactions

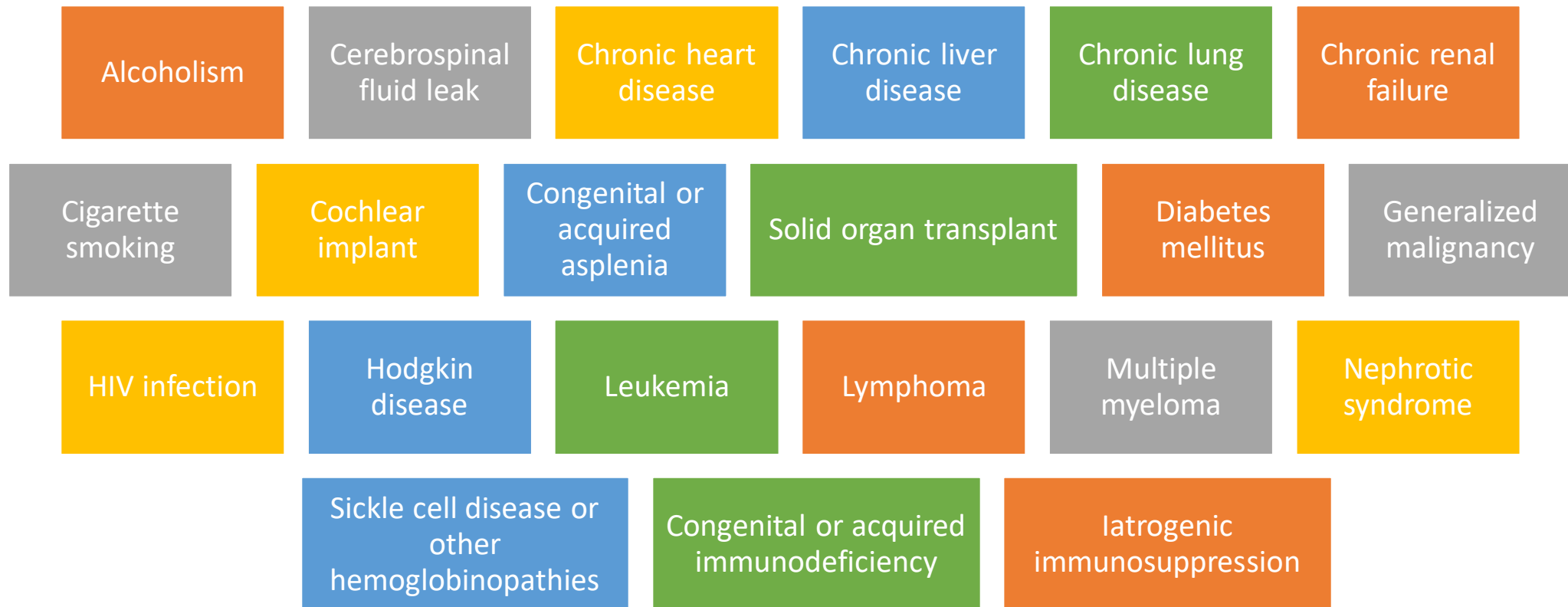
Immunogenicity

- Similar for PCV13 and PCV15 for shared serotypes at post-vaccination day 30
- Higher for serotypes 22F and 33F with PCV15 compared to PCV13

Adult Pneumococcal Vaccine Recommendations



Adults 19 to 64 Years – Indications for Pneumococcal Vaccination^{3,14,15}



Adults 19-64 Years with Health Conditions – Who Gets What?^{3,14,15}

No previous pneumococcal vaccine

- PCV20, **OR**
- PCV15 followed by PPSV23 $\geq$ 1 year later (minimum interval 8 weeks for higher risk patients i.e. immunocompromised, cochlear implant, CSF leak)

History of PPSV23

- PCV15 or PCV20 $\geq$ 1 year after PPSV23

History of PCV13 with or without PPSV23

- Give PPSV23
 - If PPSV23 not available, may give PCV20 x1

Vaccine Naïve Adults ≥ 65 Years – Who Gets What?^{3,14,15}

No previous pneumococcal vaccine

- PCV20, **OR**
- PCV15 followed by PPSV23 ≥ 1 year later (minimum interval 8 weeks for higher risk patients i.e. immunocompromised, cochlear implant, CSF leak)

History of PPSV23

- PCV15 or PCV20 ≥ 1 year after PPSV23

History of PCV13 with or without PPSV23

- Give PPSV23
 - If PPSV23 not available, may give PCV20 x1

One More Thing...^{17,18}

- ACIP met on October 19-20, 2022
 - Adults 19-64 years old with an immunocompromising condition recommended to receive PCV20 5 years after PCV13 + PPSV23
 - Adults 65+ who received PCV13 + PPSV23 - "shared clinical decision making" for PCV20 5 years later
 - PCV20 approval for pediatric use is expected in 2023
- Please note that recommendations from ACIP are not considered final until they are published in the Morbidity and Mortality Weekly Report

Pneumococcal Vaccines in Development¹⁸

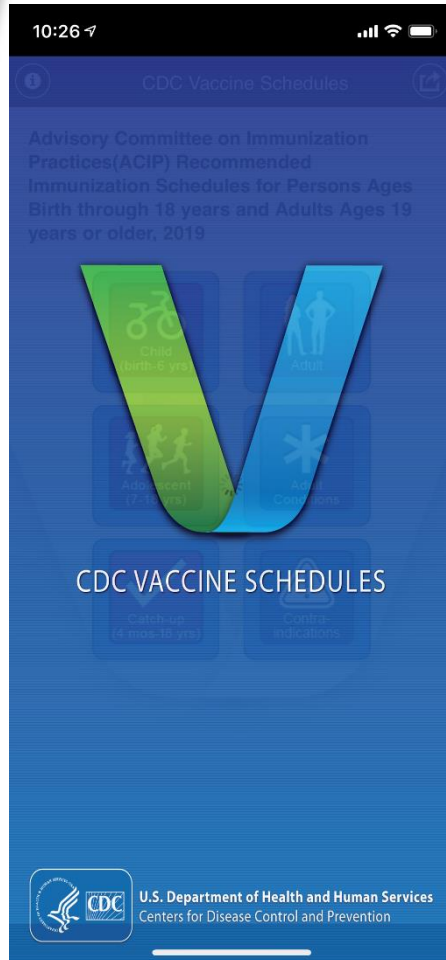
- AFX3772 (GSK)
 - 24 valent vaccine, completed phase I/II in adults
- V116 (Merck)
 - 21 valent conjugate vaccine, phase I/II studies in adults completed, ongoing phase III studies

	1	3	4	5	6 A	6 B	7 F	9 V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9 N	17 F	20	20 B	15 A	15 C	16 F	23 A	23 B	24 F	31	35 B
PCV13	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓																				
PCV15	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓																		
PCV20	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓													
PSPV23	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓									
AFX3772	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓								
V116		✓			✓		✓				✓			✓	✓	✓	✓	✓	✓			✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓

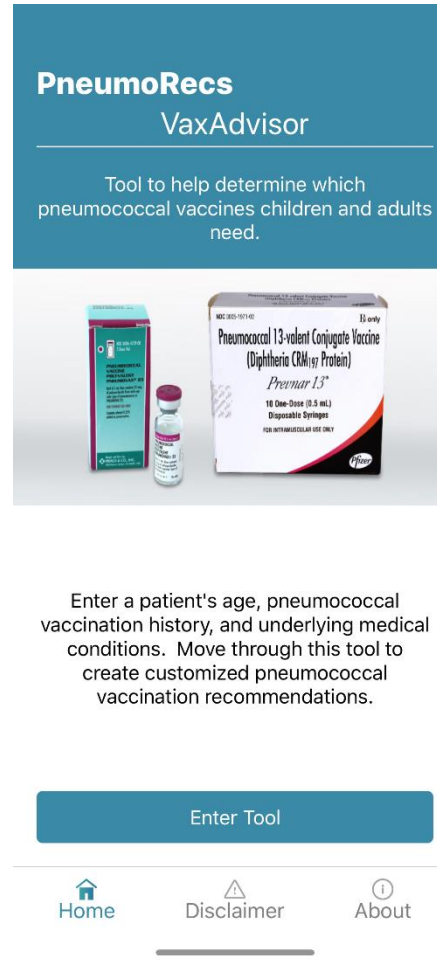
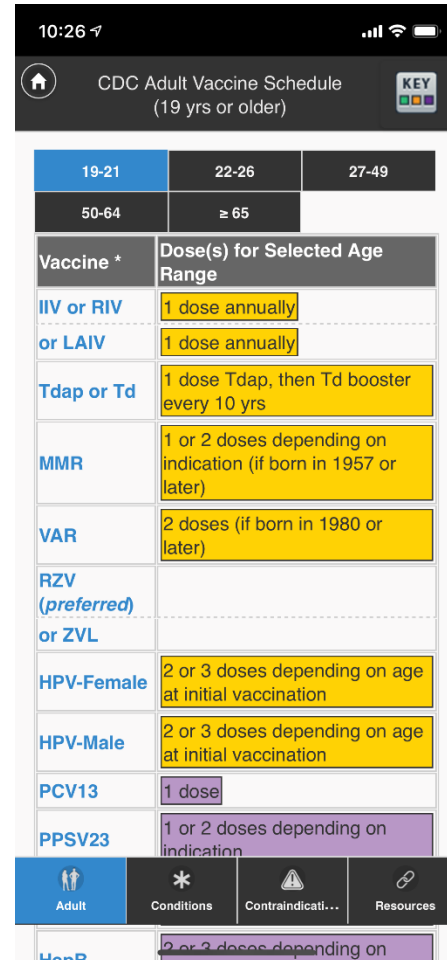
SP is a 35-year-old man with no past medical history except for asthma. He has been working on losing weight and being healthier and wants to know if he needs one of the pneumonia shots he saw on TV. He has not received any PCV in the past. What do you recommend?

- A. Vaccines hurt, and since he is young and fairly healthy, he does not need any vaccines today
- B. PPSV23 x2 doses
- C. PCV20 x1 dose followed by PPSV23
- D. PCV20 x1 dose

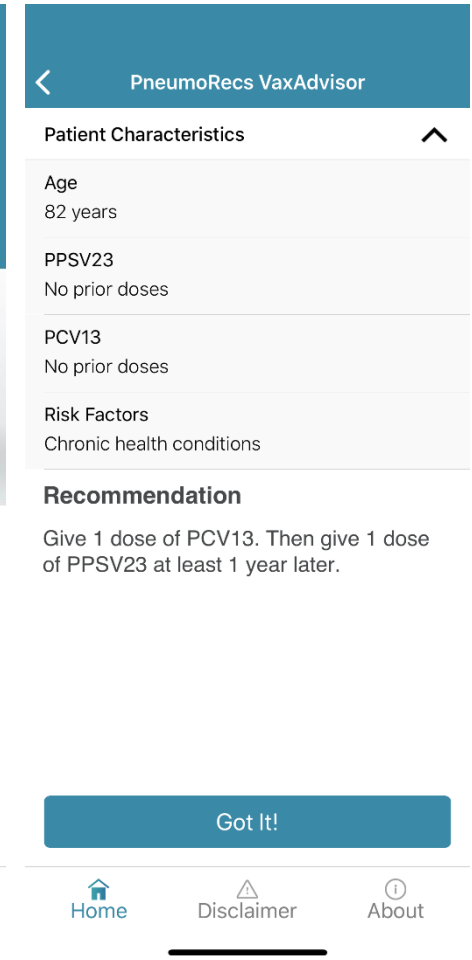
There's an App for That



CDC Vaccine Schedules



PneumoRecs VaxAdvisor



Other Vaccine Updates



Hepatitis B Vaccine Series¹⁹

Now universally recommended for adults aged 19 through 59 years

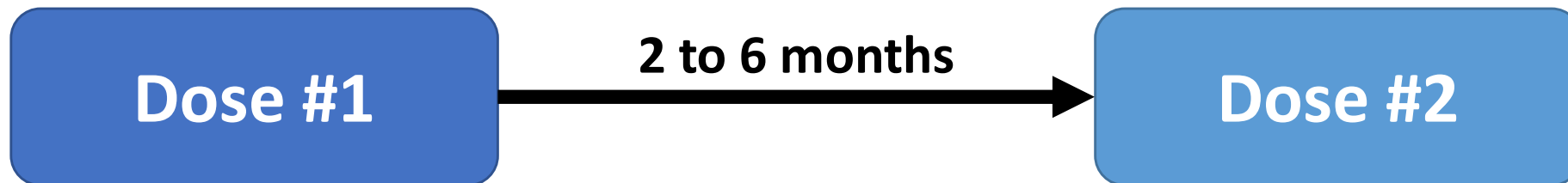
Recommended for adults aged 60+ and at risk for Hepatitis B infection

- Chronic liver disease
- HIV infection
- Sexual exposure risk
- Current or recent injection drug use
- Percutaneous or mucosal risk for exposure to blood Incarcerated persons
- Travel in countries with high or intermediate endemic hepatitis B

If aged 60+ but do not meet risk-based recommendation, may still receive vaccine

Recombinant Zoster Vaccine²⁰

- “RZV is recommended for use in persons aged 19 years and older who are (or will be) immunodeficient or immunosuppressed because of disease or therapy”
- No changes to recommendations for immunocompetent adults aged ≥50 years



COVID-19 Bivalent Booster Vaccine²¹

Contains component of original COVID vaccine plus coverage for omicron variant

Moderna: 6 years and older as a single booster

Pfizer: 5 years and older as a single booster

Clinical Pearls

- Pneumococcal vaccine schedules have been simplified but may get more complicated again
- PCV20 and PCV15 have been shown to be well tolerated and effective in preventing pneumococcal disease
- For now, most unvaccinated adults will receive PCV20 x1 dose

Which pneumococcal conjugate vaccine is preferred for unvaccinated adults aged 65 and older?

- A. Prevnar13® (PCV13)
- B. Vaxneuvance™ (PCV15)
- C. Prevnar20™ (PCV20)
- D. Pneumovax®23 (PPSV23)

Which disease states are indications for pneumococcal vaccination in adults?

Select all that apply.

- A. Diabetes
- B. Influenza infection
- C. Asthma
- D. COVID-19
- E. Cerebrospinal fluid leak

Questions?



References

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