Pneumococcal Vaccines Updates - Fresh from the CDC ACIP

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Company	Role	Details
CDC advisory committee on immunization practice (ACIP)	Voting member	
Yellow Book, travel medicine, CDC	author	Vaccines for Immunocompromised, focus on travel
UpToDate	author	Vaccines for Immunocompromised, various sections

I have been asked to disclose any relevant financial relationships with ACCME-defined commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation.

Other than above, I have no relevant financial relationships to disclose. I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration, but in accordance with ACIP recommendations.





- 1. Understand the clinical importance of pneumococcal vaccination.
- 2. Incorporate vaccine recommendations into routine medical care.
- 3. Understand differences between various pneumococcal vaccines.

Pneumococcal Vaccines

Pneumococcal 13-valent conjugate vaccine PCV13 Prevnar 13 Pneumococcal 15-valent conjugate vaccine PCV15 Vaxneuvance™ Pneumococcal 20-valent conjugate vaccine PCV20 Prevnar 20™ (conjugated to diphtheria carrier protein)

Pneumococcal 23-valent polysaccharide vaccine PPSV23 Pneumovax 23®



Risk Factors for Invasive Pneumococcal Disease

●Age <2 or ≥65 years

•Certain racial/ethnic groups, including people of African descent, Alaskan Natives, and American Indians

• Male sex

•Chronic cardiovascular disease (eg, heart failure, cardiomyopathy)

•Chronic pulmonary disease (eg, chronic obstructive pulmonary disease, emphysema, asthma)

•Chronic liver disease (eg, cirrhosis)

•Chronic renal failure or nephrotic syndrome

• Diabetes mellitus

Alcohol abuse, smoking, opioid/crack cocaine use

•Functional or anatomic asplenia (eg, sickle cell disease, splenectomy)

•Immunosuppressive conditions (eg, HIV infection, congenital immunodeficiency, malignancy, B cell defects, multiple myeloma)

•Solid organ or hematopoietic cell transplantation

•Treatment with alkylating agents, antimetabolites, or systemic glucocorticoids

•Cerebrospinal fluid leaks

Cochlear implants

•Inflammatory bowel disease

From UpToDate

Active Bacterial Core Surveillance (ABCs) Report Emerging Infections Program Network Streptococcus pneumoniae, 2019

- ABCs Population: The surveillance areas represent **34,627,924** persons
- ABCs Areas: California (3 county San Francisco Bay area); Colorado (5 county Denver area); Connecticut; Georgia (20 county Atlanta area); Maryland (6 county Baltimore area); Minnesota; New Mexico; New York (15 county Rochester and Albany areas and children
- ABCs Case Definition: <u>Invasive disease</u> is defined as isolation of *S. pneumoniae* from a normally sterile site or detection of pathogen-specific nucleic acid in a specimen obtained from a normally sterile body site



Deaths Deaths (Preliminary) Survivals Survivals (Preliminary)



* 7-valent pneumococcal conjugate vaccine (PCV7) serotypes: 4, 6B, 9V, 14, 18C, 19F, 23F

** 13-valent pneumococcal conjugate vaccine (PCV13) serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F



23-valent pneumococcal polysaccharide vaccine (PPSV23) serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F.

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** 13-valent pneumococcal conjugate vaccine (PCV13) serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F



23-valent pneumococcal polysaccharide vaccine (PPSV23) serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F.

* 7-valent pneumococcal conjugate vaccine (PCV7) serotypes: 4, 6B, 9V, 14, 18C, 19F, 23F

** 13-valent pneumococcal conjugate vaccine (PCV13) serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F

Estimated Proportion of Adults aged 19–64 years with CMC/IC who

Ever Received Pneumococcal Vaccination, NHIS 2018

	Sample size	%	(95% CI)
Overall	5,851	23.3%	(22.0, 24.6)
White	4,048	23.6%	(22.1, 25.2)
Black	696	25.7%	(21.8, 30.0)
Hispanic	656	18.5%	(15.2 <i>,</i> 22.4) [*]
Asian	192	25.0%	(17.3, 34.5)
Other	259	25.8%	(19.3, 33.5)

National Health Interview Survey, 2018; CMC: chronic medical conditions; IC: immunocompromising conditions *p<0.05 for comparisons with white as the reference.

From ACIP meeting 20 October 2021

Current and New Pneumococcal Vaccines: PCVs vs. PPSV23

	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	80	10 A	11 A	12 F	15 B	2	9N	17 F	20
PCV13																								
PCV15																								
PCV20																								
PPSV23																								

	PCV	PPSV23
Basic Vaccine Composition	Capsular polysaccharides conjugated to CRM197 Carrier Protein	Capsular polysaccharide antigens
Mechanism of action	T-cell dependent	T-cell independent
Memory B cell production	Yes	Νο

PCV: pneumococcal conjugate vaccine, PPSV23v22ent pneumococcal polysaccharide vaccine From ACIP meeting 20 October 2021

Proportion of IPD by Serotype Groups in Adults aged 19–64 Years with Risk-based Indications



ABCs 2017-2018

PCV15 non-PCV13 serotypes: 22F, 33F PCV20 non-PCV15 serotypes: 8, 10A, 11A, 12F, 15B/C PPSV23 non-PCV20 serotype: 2, 9N, 17F, 20

CMC: chronic medical conditions IC: immunocompromising conditions

From ACIP meeting 20 October 2021

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2022										
Vaccine	19-26 years	≥65 years								
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually									
Influenza live, attenuated (LAIV4)	Or 1 dose annually									
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes) 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									
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes) 2 doses									
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	2 or 3 doses depending on age at initial vaccination or condition 27 through 45 years								
Pneumococcal (PCV15, PCV20, PPSV23)		1 dose PCV15 followed by PPSV23 OR 1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes) 1 dose PCV20								
Hepatitis A (HepA)		2 or 3 dos	es deper	nding on vaccine						
Hepatitis B (HepB)		2, 3, or 4 doses de	pending	g on vaccine or condition						
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 19 through 23 years									
Haemophilus influenzae type b (Hib)	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 No recommended vaccination for adults with an additional risk factor or another indication										

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Current Pneumococcal Vaccine Recommendations

Routine vaccination: Age 65 years or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown:

OR

Special situations: Age 19–64 years with certain underlying medical conditions or other risk factors** who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown:

1 dose PCV15 or 1 dose PCV20.

If PCV15 is used, this should be followed by a dose of PPSV23 given <u>at least 1 year</u> after the PCV15 dose.

<u>A minimum interval of 8 weeks</u> between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.

Certain Underlying Medical Conditions/Other Risk Factors:

- Alcoholism
- chronic heart, liver, or lung disease
- chronic renal failure or nephrotic syndrome
- cigarette smoking
- cochlear implant
- congenital or acquired asplenia
- cerebrospinal fluid leak
- diabetes mellitus
- generalized malignancy
- HIV
- Immunodeficiency
- latrogenic immunosuppression
- leukemia, lymphoma, Hodgkin disease, or multiple myeloma
- solid organ transplant
- sickle cell disease or other hemoglobinopathies

Patients who have already received a previous dose of PCV13 and/or PPSV23

• Adults with previous PPSV23 only.

- Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose.
- When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

• Adults with previous PCV13.

- The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated.
- These adults should complete the previously recommended PPSV23 series.

www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm

Why not revaccinate if remote pneumococcal vaccine?

Currently, CDC not recommending revaccination for the following reasons:

- Limited data on duration of protection of currently available higher-valent PCVs
- Anticipated licensure of PCV15/PCV20 for use in children in the near future, and the unknown impact of indirect effects on adult disease
- Potential availability of the higher-valent pneumococcal vaccines that are currently under development
 - Merck's 21-valent: <u>https://www.merck.com/news/merck-announces-u-s-fda-has-granted-breakthrough-therapy-designation-for-v116-the-companys-investigational-21-valent-pneumococcal-conjugate-vaccine-for-the-prevention-of-invasive-pneumococ/</u>
 - Affinivax's 24-valent: https://affinivax.com/pipeline/overview/

CDC will continue to monitor disease trends and revisit the recommendations

Insurance coverage: new pneumococcal vaccines

- PCV15 and 20 are covered by private insurance
- PCV15 and 20 are covered by Medicare part B
- MassHealth has not updated the CPT codes in their manuals to include PCV15 and 20, but it is on their radar to do this.
 - There is no proposed date this will be completed by however, MassHealth told the MDPH immunization division that providers will be able to be reimbursed retroactively from 1/1/2022; not clear if providers actually know about this.

"What is the insurance coverage for PCV 15 and PCV 20? & Is coverage for PCV20 universal? & With the current approval of Prevnar 20, the CPT linked to this vaccine is still not listed under the MassHealth reimbursable codes for community health center administration. When will this be updated?"

CDC Vaccine Schedules App for Healthcare Providers

Download "CDC Vaccine Schedules" free for iOS and Android devices.



Product Specs

Version: 9.0.1

Requirements: Requires iOS 11.0 or later and Android 5.1 or later; optimized for tablets and useful on smartphones.

Updates: Changes in the app are released through app updates.

Download app free for iOS



Download app free for Android



PneumoRecs VaxAdvisor

Customized pneumococcal vaccination recommendations at your fingertips. I LTE 🖘 10:18 AM > 88% PneumoRecs VaxAdvisor Tool to help determine which pneumococcal vaccines children and adults need. Getting Started Enter a patient's age, pneumococcal vaccination history, and underlying medical conditions. Move through this tool to create customized recommendations for pneumococcal vaccination. Enter Tool A T Home Disolalmer About

Questions

- If a patient received PCV13 and PPSV23 are they fully covered? **YES**
- Our facility does not yet carry PCV20 or PCV15, we are still administering PCV13 to adults. Could it be that facilities are using up supply first? & How strong is the recommendation of 15 and 20 over 13 the other if it is subject to availability? YES, many are using up stock; switch to PCV15/20 when possible
- Can a patient only get PCV15 or PCV20 if they haven't had PCV13? **YES**
- If you are unsure if your patient has received a pneumonia vaccine. Would you give PCV 20? YES
- Is the new Prevnar 20 taking the place of Prevnar 13? YES
- The PCP I work for typically gives his 65 y/o older pts Prevnar 13 then 1 year later Pneumovax 23. If these pts - 65 y/o - get the Prevnar 15 or 20 - they no longer need the Pneumovax 23? ONLY IF THEY GET PCV20 (if PCV15 then they need PPSV23)

Clinical case: vaccinate after stem cell transplant? (*CAR-T cell treatment)

- "Sequential administration of 3 doses of pneumococcal conjugate vaccine (*implied PCV13*) is recommended, beginning 3-6 months after the transplant, followed by a dose of PPSV23
 - Some sources state a 4-week interval between these doses as reasonable with the dose of PPSV23 being replaced by a dose of PCV13 in the context of graft-versus-host disease
 - Others sources support 3 doses of PCV13 at 8-week intervals, with a dose of PPSV23 recommended 8 weeks after the last dose of PCV13 and 12 months after the stem cell transplant"

Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022, MMWR, Jan 2022, <u>https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm</u>

ACIP adult immunization schedule 2022, https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

PneumoRecs VaxAdvisor app https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

"Pneumococcal Vaccine Timing for Adults" (with nice graphics): https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf





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