

Pneumococcal Vaccines

Katherine A. Poehling, MD, MPH

Pneumococcal Vaccines Work Group Chair Advisory Committee on Immunization Practices June 22, 2023

Pneumococcal Vaccines Work Group

ACIP Members

- Katherine Poehling (Chair)
- Sarah Long

Ex Officio Members

- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Uzo Chukwuma (IHS)
- Mamodikoe Makhene (NIH)

CDC Lead

Miwako Kobayashi (NCIRD)

Liaison Representatives and Consultants

- Lynn Fisher (AAFP)
- Mark Sawyer (AAP/COID)
- Jason Goldman (ACP)
- David Nace (AGS/AMDA)
- Cora Hoover (AIM)
- Aleksandra Wierzbowski (NACI)
- James McAuley (IDSA)
- William Schaffner (NFID)
- Virginia Caine (NMA)
- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Richard Zimmerman (U. of Pittsburgh)

Pneumococcal Vaccines Work Group

CDC Contributors

Adam Cohen (Respiratory Diseases Branch)

Ryan Gierke (Respiratory Diseases Branch)

• Jennifer Farrar (Respiratory Diseases Branch)

• Diepreye Ayabina (Division of Bacterial Diseases)

Pedro Moro (Immunization Safety Office)

Andrew Leidner (Immunization Services Division)

Liz Velazquez (Immunization Services Division)

Marc Fischer (Arctic Investigations Program)

Noele Nelson (Division of Bacterial Diseases)

GRADE/EtR consultants

- Doug Campos-Outcalt
- Rebecca Morgan

Serotypes contained in pneumococcal vaccines

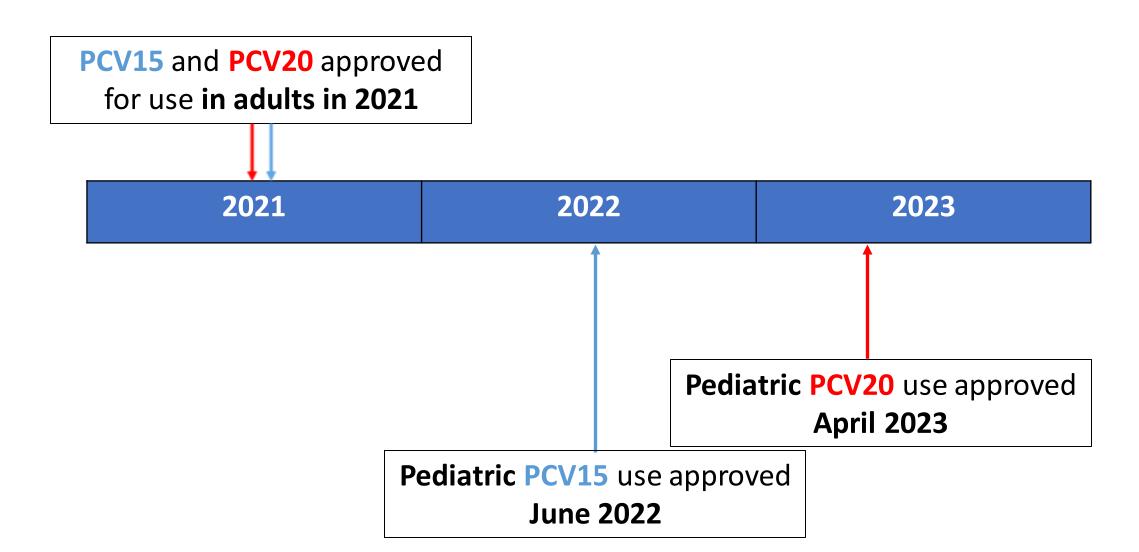
	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20
PCV13																								
PCV15																								
PCV20																								
PPSV23																								

Pneumococcal conjugate vaccines (PCVs): PCV13, PCV15, PCV20

Pneumococcal polysaccharide vaccine (PPSV): PPSV23

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

Extended indication for PCV20 use among children approved on April 27, 2023



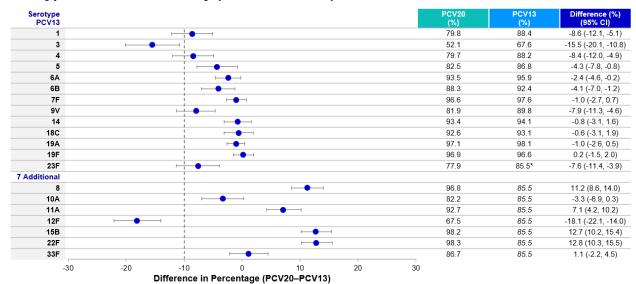
Both PCV15 and PCV20 were approved based on safety and immunogenicity data compared with PCV13

- No direct PCV15 vs PCV20 comparison
- Unknown clinical implications:
 - Numerically lower antibody responses vs PCV13
 - Numerically higher antibody response against serotype 3 in PCV15 vs PCV13

PD3: V114 is **noninferior** to PCV13 for all 13 **shared** serotypes based on the proportion of **responders** ($lgG \ge 0.35 \mu g/mL$)



Post Dose 3: Percentage with Predefined IgG Concentrations 14 Serotypes Met Noninferiority (Difference in %)

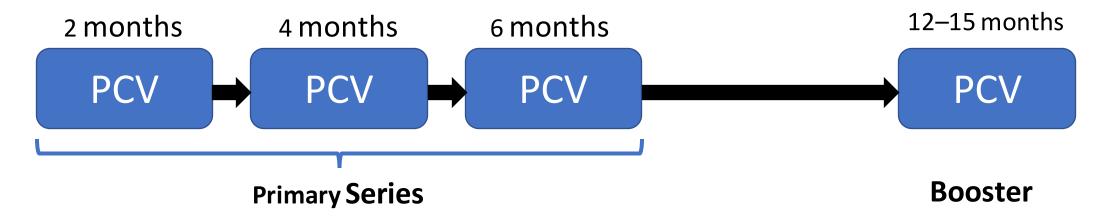


*The 7 additional serotypes are compared to the percentage for serotype 23F after Dose 3 (lowest in PCV13 group, excluding serotype 3). Predefined IgG concentration $- \ge 0.35$ µg/mL for all serotypes except ≥ 0.23 µg/mL, ≥ 0.10 µg/mL and ≥ 0.12 µg/mL for serotypes 5, 6B and 19A respectively

rror bars indicate 95% Cls; CI=confidence interval, IgG=immunoglobulin G

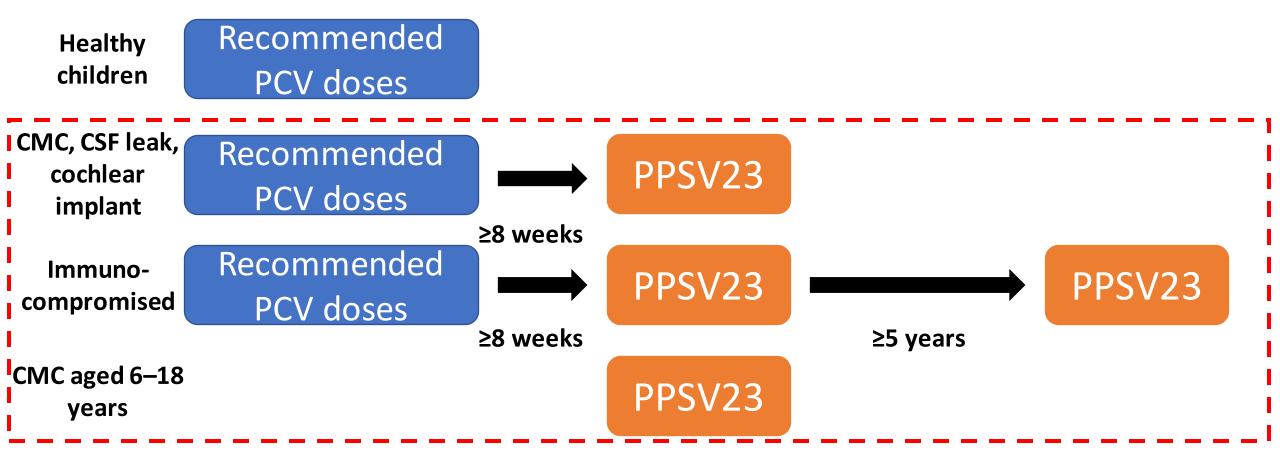
All children under age 2 years have the same pneumococcal vaccine recommendations

• 3 primary series and a booster="3+1" schedule



Currently, either PCV13 or PCV15 can be used

Children with certain underlying conditions are recommended to receive PPSV23 in addition to the recommended PCV doses



Note: Excludes catch-up vaccination schedules.

CMC=chronic medical conditions, including chronic heart disease, chronic lung disease, diabetes mellitus CSF=cerebrospinal fluid

<u>Use of 15-Valent Pneumococcal Conjugate Vaccine Among U.S. Children: Updated Recommendations of the Advisory Committee on Immunization</u>
Practices — United States, 2022 | MMWR (cdc.gov)

Current Risk-Based Pneumococcal Vaccine Recommendations

	Children	Adults			
Alcoholism					
Chronic heart disease					
Chronic lung disease					
Chronic liver disease					
Cigarette smoking					
Diabetes mellitus					
Cerebrospinal fluid leak					
Cochlear implant					
Chronic renal failure or nephrotic syndrome					
Congenital or acquired asplenia, or splenic dysfunction					
Congenital or acquired immunodeficiency					
Diseases and conditions treated with immunosuppressive drugs or radiation therapy	• Children: Including asthma if treated with high-dose oral corticosteroid therapy.				
HIV infection	 Adults: Includes chronic obstructive pulmonary disease, 				
Sickle cell disease or other hemoglobinopathies	emphysema, and asthma.				
Solid organ transplant	→ Should we expand the indication for asthma in children?				

Current Risk-Based Pneumococcal Vaccine Recommendations

	Children	Adults		
Alcoholism				
Chronic heart disease		_		
Chronic lung disease				
Chronic liver disease				
Cigarette smoking				
Diabetes mellitus				
Cerebrospinal fluid leak				
Cochlear implant				
Chronic renal failure or nephrotic syndrome				
Congenital or acquired asplenia, or splenic dysfunction				
Congenital or acquired immunodeficiency				
Diseases and conditions treated with immunosuppressive drugs or radiation therapy				
HIV infection				
Sickle cell disease or other hemoglobinopathies	Should we add "chronic liver disease" as part of pediatric			
Solid organ transplant	risk-based recommendation?	?		

Current Risk-Based Pneumococcal Vaccine Recommendations

	Children	Adults
Alcoholism		
Chronic heart disease		
Chronic lung disease		
Chronic liver disease		
Cigarette smoking		
Diabetes mellitus		
Cerebrospinal fluid leak		
Cochlear implant		
Chronic renal failure or nephrotic		
syndrome		
Congenital or acquired asplenia, or splenic dysfunction		
Congenital or acquired immunodeficiency		
Diseases and conditions treated with immunosuppressive drugs or radiation therapy		
HIV infection	Should we expand the indica	tion to those with stage 2-5
Sickle cell disease or other hemoglobinopathies	chronic kidney disease?	tion to those with stage 2 3
Solid organ transplant		

Policy questions considered by the Work Group

 Should PCV20 be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules, for U.S. children aged <2 years?

 Should PCV20 without PPSV23 be recommended as an option for pneumococcal vaccination for U.S. children aged 2–18 years with underlying medical conditions that increase the risk of pneumococcal disease?

Today's Pneumococcal Vaccines session outline

Introduction

Economic analysis and public health impact of PCV20

use in children

Comparison of cost-effectiveness analyses on PCV20

use in children

Summary of WG interpretation of EtR and policy

options

VFC resolution

Dr. Katherine Poehling

(ACIP, WG Chair)

Dr. Charles Stoecker

(Tulane University)

Dr. Ayabina Diepreye

(CDC/NCIRD)

Dr. Miwako Kobayashi

(CDC/NCIRD)

Dr. Jeanne Santoli

(CDC/NCIRD)