

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases



Pneumococcal Vaccines Work Group

October 2023, ACIP meeting

October 26, 2023

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Work Group Purpose

- The Pneumococcal Vaccines Work Group:
 - Reviews current data on pneumococcal disease burden, and on the efficacy, effectiveness, immunogenicity, and cost-effectiveness of pneumococcal vaccines and assesses the strength of the evidence;
 - Reviews current pneumococcal vaccine recommendations considering up-to-date evidence; and
 - Develops revised or updated policy options for pneumococcal vaccines as needed.

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)

Liaison Representatives

- Lynn Fisher (AAFP)
- Mark Sawyer (AAP/COID)
- Jason Goldman (ACP)

- David Nace (AGS/AMDA)
- Cora Hoover (AIM)
- Risa Claytor (HRSA)
- James McAuley (IDSA)
- Aleksandra Wierzbowski (NACI)
- Robert Hopkins (NFID)
- Virginia Caine (NMA)

Consultants

- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
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- Rebecca Morgan



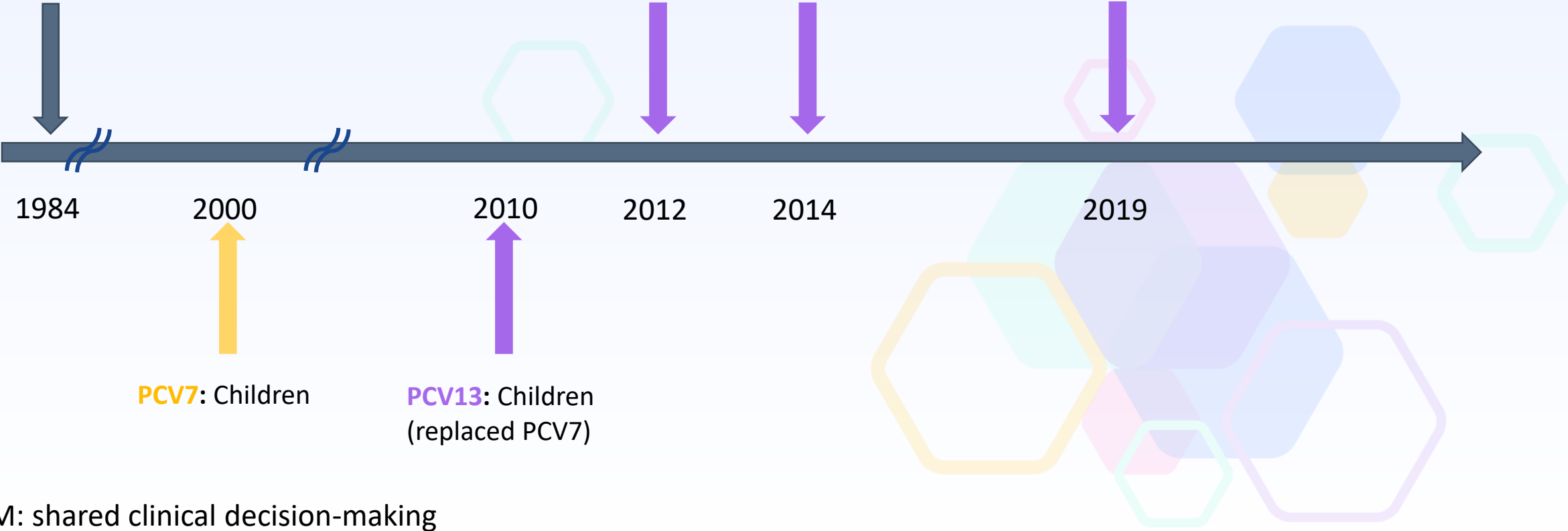
History of ACIP Pneumococcal Vaccine Recommendations through 2019

PPSV23: Adults aged ≥ 65 years and individuals with underlying conditions

PCV13: Adults with immunocompromising conditions in addition to PPSV23

PCV13: All adults aged ≥ 65 years in addition to PPSV23

PCV13: based on SCDM for adults aged ≥ 65 years; routine **PPSV23** recommendation

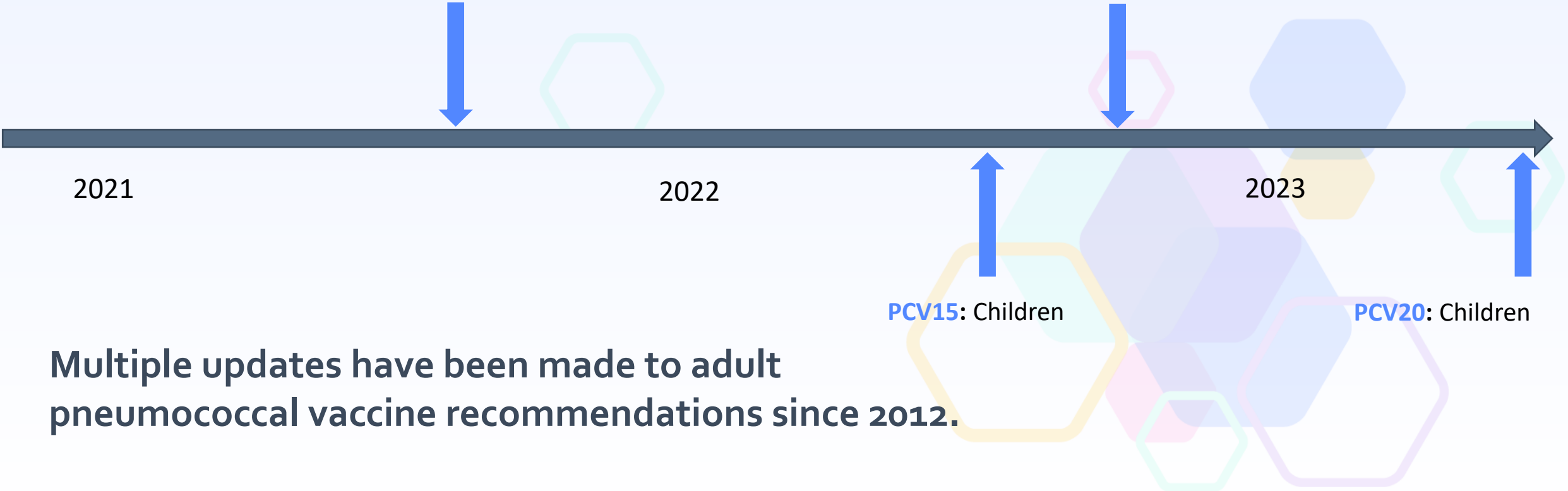


SCDM: shared clinical decision-making

Recent ACIP Pneumococcal Vaccine Recommendations, 2021–2023

PCV15 and PCV20:
Adults who have not received PCV or whose vaccination history is unknown

PCV20: Expanded indication for adults who previously received **PCV13**



PCV15: Children

PCV20: Children

Multiple updates have been made to adult pneumococcal vaccine recommendations since 2012.

Pneumococcal Disease Burden among U.S. Adults

- Prior to the COVID-19 pandemic, estimated to have caused every year¹:
 - **≥100,000** non-invasive pneumococcal pneumonia hospitalizations
 - **≥30,000** invasive pneumococcal disease (IPD) cases (e.g., bacteremic pneumonia, pneumococcal bacteremia, meningitis)
 - **3,000** IPD deaths
- Preliminary data show increase in IPD cases in late 2022²
 - Increase in other invasive bacterial infections reported in children^{3,4}

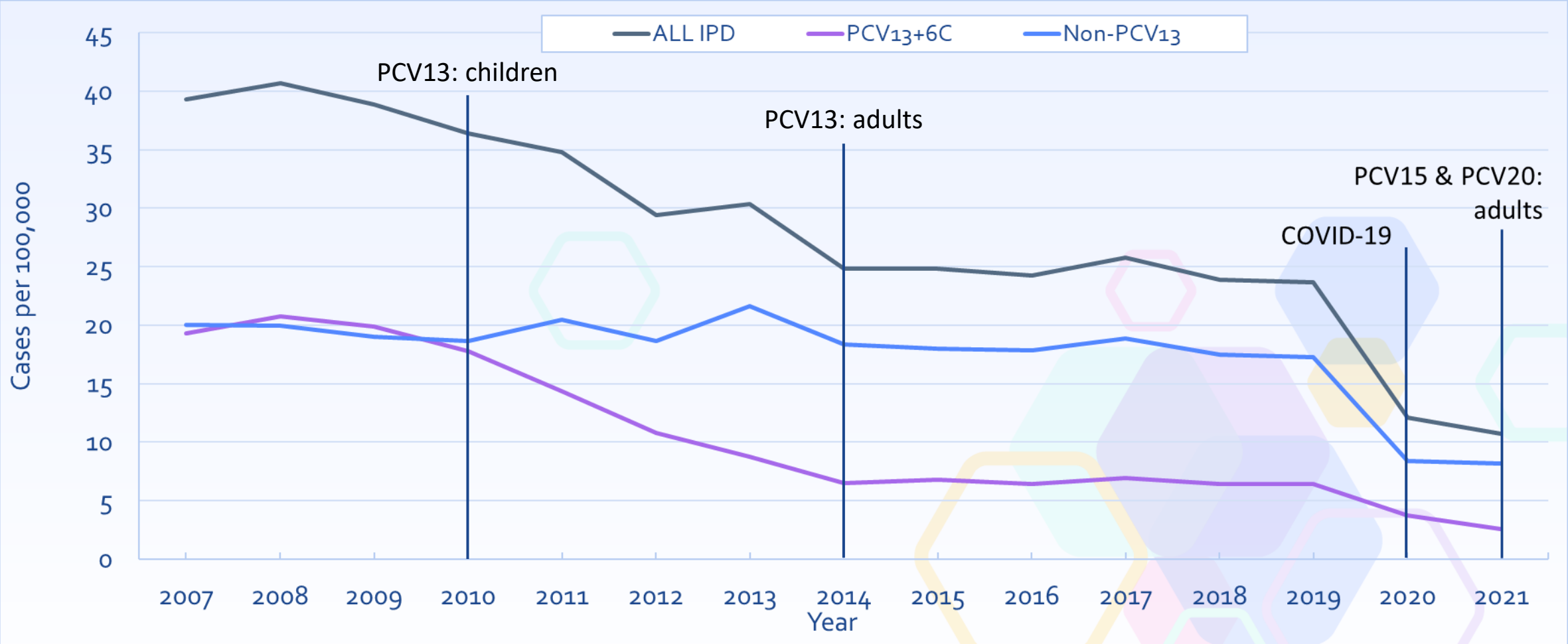
1. Kobayashi M. October 20, 2021 ACIP Meeting Presentation. Considerations for Age-Based and Risk-Based Use of PCV15 and PCV20 among U.S. Adults and Proposed Policy Options.

2. CDC Active Bacterial Core surveillance unpublished data

3. [Notes from the Field: Update on Pediatric Intracranial Infections — 19 States and the District of Columbia, January 2016–March 2023 | MMWR \(cdc.gov\)](#)

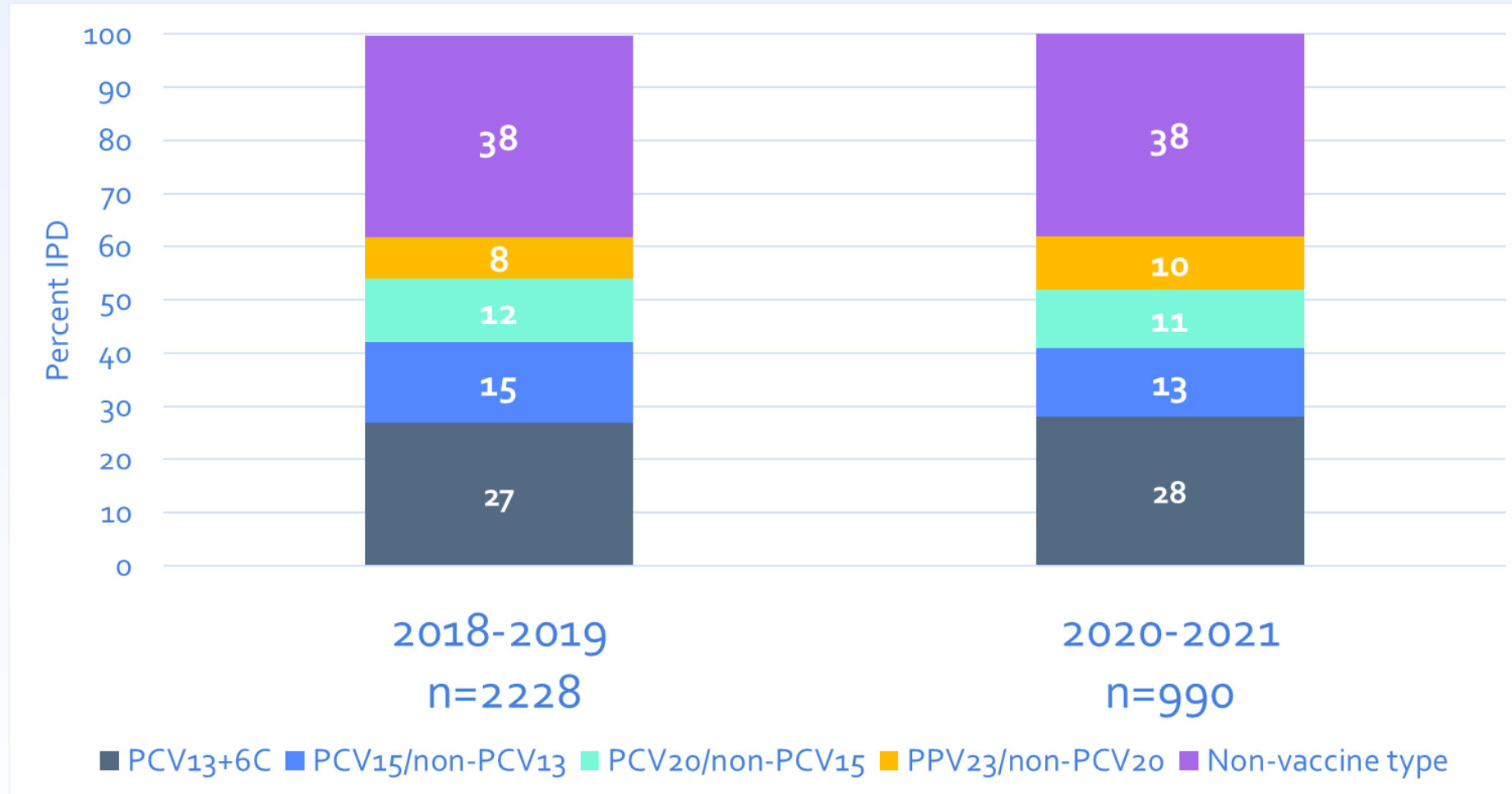
4. [Notes from the Field: Increase in Pediatric Invasive Group A Streptococcus Infections — Colorado and Minnesota, October–December 2022 | MMWR \(cdc.gov\)](#)

Invasive pneumococcal disease incidence among adults aged ≥ 65 years reached a historically low level early in the COVID-19 pandemic



IPD=invasive pneumococcal disease
CDC Active Bacterial Core surveillance

Approximately 40% of IPD cases in adults aged ≥ 65 years were caused by serotypes not contained in currently recommended vaccines



New Adult Pneumococcal Vaccines in Advanced Stages of Development

	1	3	4	5	6 A	6 B	7 F	9 V	1 4	1 8 C	1 9 A	1 9 F	2 3 F	2 2 F	3 3 F	8	1 0 A	1 1 A	1 2 F	1 5 B	2	9 N	1 7 F	2 0	1 5 A	1 5 C	1 6 F	2 3 A	2 3 B	2 4 F	3 1	3 5 B			
PCV15																																			
PCV20																																			
PPSV23																																			
Pn- MAPS24v																								20 B											
VAX-24																								20 B											
V116																								20 A											

24-valent pneumococcal vaccines

- Completed phase 1/2 study for adults¹
- Completed phase 1/2 studies for adults, undergoing phase 2 studies in infants²

21-valent pneumococcal conjugate vaccine

- Completed phase 1/2 study for adults³
- Phase 3 studies in adults are currently ongoing

Pn-MAPS24v, GSK

VAX-24, Vaxcyte

V116, Merck

Next Steps for Pneumococcal Vaccines Work Group

- Review evidence on use of **21-valent pneumococcal conjugate vaccine (V116)** for adults
 - Biologics License Application for V116 to the FDA is anticipated in Q₄ of 2023, with an anticipated FDA approval in the first half of 2024



Data to be Reviewed by Work Group

- Evidence to support EtR domains including,
 - Epidemiology of pneumococcal disease among U.S. adults
 - Assessment of pneumococcal disease caused by serotypes not included in V116 (but included in existing vaccines)
 - Phase 2/3 clinical trial data on V116 among adults
 - Feasibility and resource use involved in V116 use among adults
 - Health equity considerations
- Aim to have an ACIP vote on policy options shortly after FDA approval of V116



Thank you!

For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

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