

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



Pneumococcal Vaccines

February 2024, ACIP Meeting

February 29, 2024

Pneumococcal Vaccine Work Group Chair

James Loehr, MD, FAAFP

Pneumococcal Vaccines Work Group

ACIP Members

- Jamie Loehr (Chair, acting)
- Sarah Long

Ex Officio Members

- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Uzo Chukwuma (IHS)
- Mamodikoe Makhene (NIH, primary)
- Meenu Upadhyay (NIH, alternate)

Liaison Representatives

- Lynn Fisher (AAFP)
- James Campbell (AAP/COID)
- Jason Goldman (ACP)
- David Nace (AGS/AMDA)
- Cora Hoover (AIM, primary)

- Risa Claytor (HRSA)
- James McAuley (IDSA)
- Eva Wong (NACI)
- Robert Hopkins (NFID, primary)
- William Schaffner (NFID, alternate)
- Virginia Caine (NMA)

Consultants

- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Kathy Poehling (Wake Forest)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Richard Zimmerman (U. of Pittsburgh)

CDC Contributors and Consultants

Division of Bacterial Diseases

- Diepreye Ayabina
- Adam Cohen
- Ryan Gierke
- Jennifer Farrar
- Noele Nelson

Immunization Safety Office

- Pedro Moro

Immunization Services Division

- Janelle King
- Andrew Leidner
- Liz Velazquez

Arctic Investigations Program

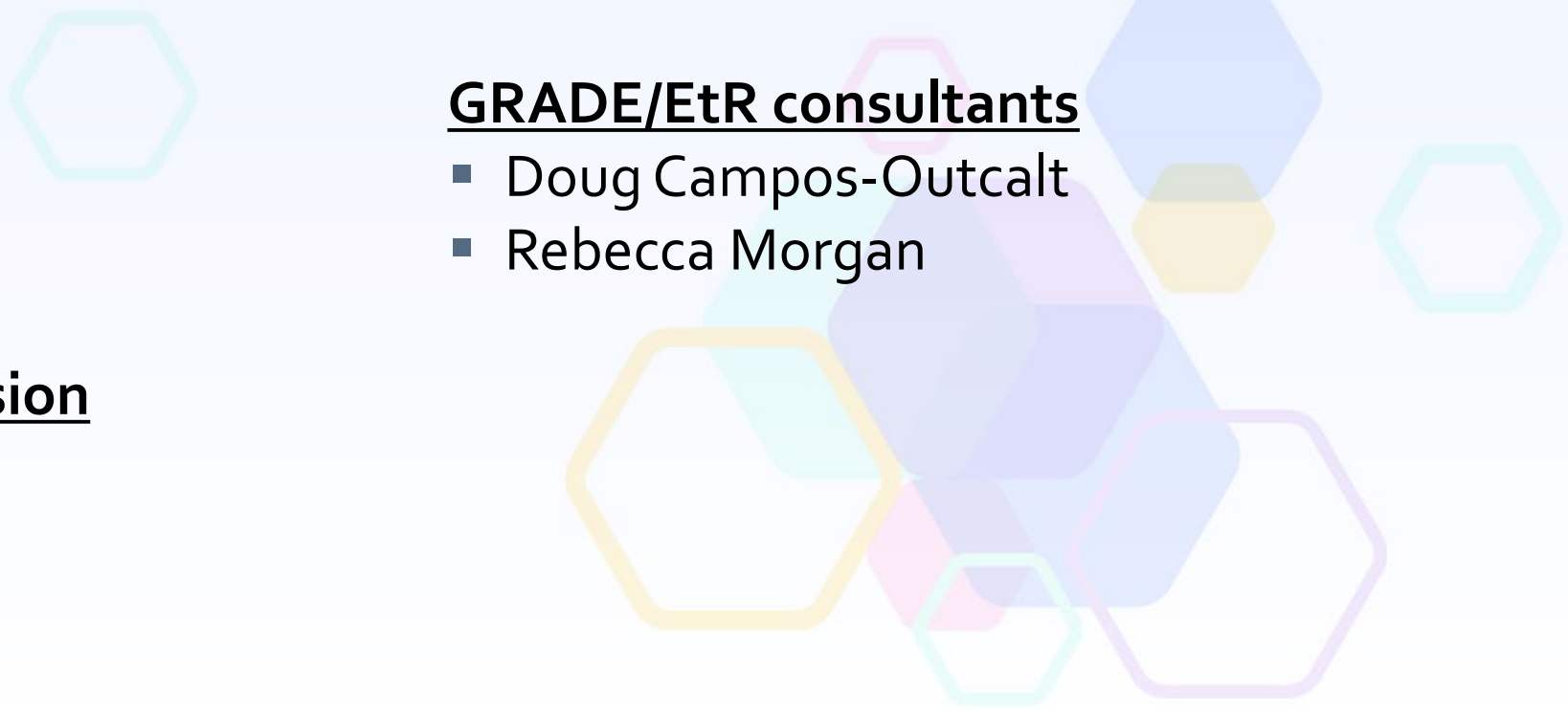
- Marc Fischer

CDC Lead

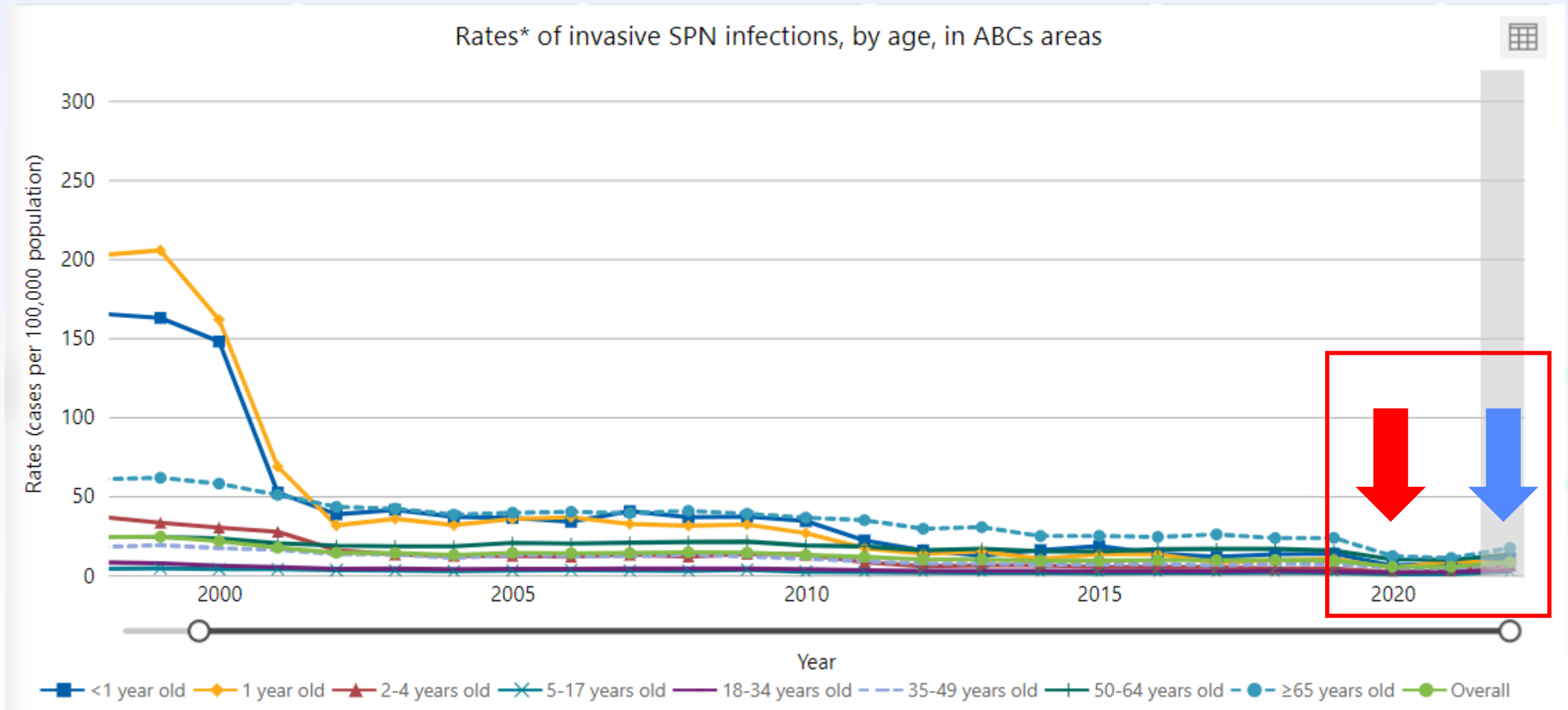
- Miwako Kobayashi

GRADE/EtR consultants

- Doug Campos-Outcalt
- Rebecca Morgan



Invasive pneumococcal disease incidence reached a **historically low level** early in the COVID-19 pandemic but is **returning toward pre-COVID levels**



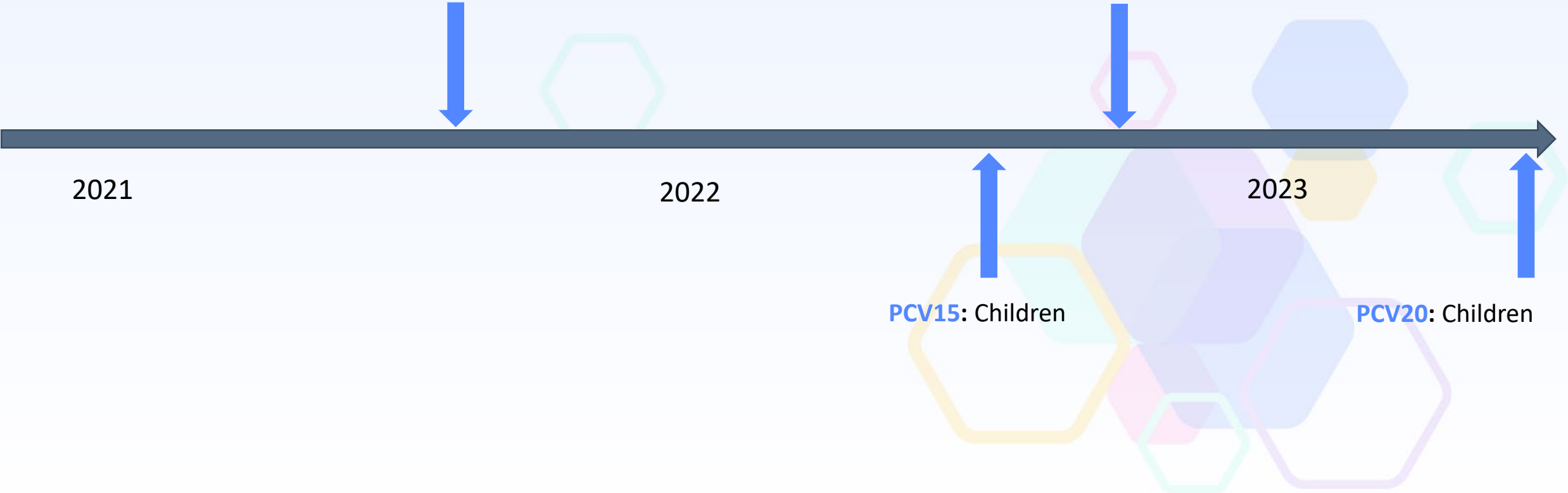
IPD=invasive pneumococcal disease; 2022 data in gray are preliminary

[ABCs Bact Facts Interactive Data Dashboard | CDC](#)

Around the same time, pneumococcal conjugate vaccines **PCV15** and **PCV20** were recommended for both adults and children

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

Additional 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:

- **Pn-MAPS24v (GSK):** Completed phase 1/2 study for adults; Breakthrough Therapy Designation granted and Phase 3 study in preparation; undergoing phase 2 studies in infants¹
- **VAX-24 (Vaxcyte):** Completed phase 1/2 studies for adults, undergoing phase 2 studies in infants²

21-valent pneumococcal conjugate vaccine (V116, Merck):

- **BLA accepted by the FDA for priority review³**

1. Chichili et al. Vaccine 2022; [GSK Pipeline assets and clinical trials appendix Q4 2023](#) 2. Wassil et al. Lancet ID 2023, ClinicalTrials.gov ID: NCT05297578, and NCT05844423; 3. [FDA Grants Priority Review to Merck's New Biologics License Application for V116, an Investigational, 21-valent Pneumococcal Conjugate Vaccine Specifically Designed to Protect Adults - Merck.com](#).

Additional Pneumococcal Vaccines Under Development

- **25-valent** pneumococcal vaccine candidate (IVT PCV-25, Iventprise)
 - Completed Phase 2 dose ranging study in young adults¹
- **31-valent** pneumococcal conjugate vaccine candidate (VAX-31, Vaxcyte)
 - Completed enrollment of Phase 1/2 study in adults aged ≥ 50 years²



1. [Iventprise Completes Vaccination of Participants in a Phase 2 Dose Ranging Study of its 25 Valent Pneumococcal Vaccine Candidate – Iventprise](#)

2. [Vaxcyte Completes Enrollment of Phase 1/2 Study Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease \(IPD\) in Adults Aged 50 and Older - Vaxcyte, Inc.](#)

Current Pneumococcal Vaccine Recommendations for Adults and Vaccine Coverage

- The following groups are currently recommended to receive a dose of pneumococcal conjugate vaccine (PCV):
 - Adults aged ≥ 65 years who have not received a PCV¹
 - Adults aged 19–64 years with certain underlying conditions or risk factors² who have not received a PCV¹
 - Certain adults who have received PCV₁₃ but have not received PCV₂₀³

1. Excludes PCV7

2. alcoholism; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; CSF leak; diabetes mellitus; generalized malignancy; HIV infection; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; or sickle cell disease or other hemoglobinopathies

3. Adults who have not completed the recommended vaccine series, or shared clinical decision-making for adults aged ≥ 65 years who have completed the recommended vaccine series

Adults with risk-based vaccine recommendations have lower vaccine coverage compared with those with age-based recommendations

- Coverage of ≥ 1 dose of any pneumococcal vaccine
 - Adults aged 19–64 years with risk-based indication: **22.2%**
 - Adults aged ≥ 65 years: **65.8%**



Policy Questions Being Considered by the Work Group

1. Should **PCV21** be recommended for U.S. adults aged ≥ 19 years who currently have a recommendation to receive a PCV*?

*Includes,

- Adults aged ≥ 65 years who have never received a PCV
- U.S. adults aged 19–64 years with a risk condition, who have never received a PCV
- U.S. adults aged ≥ 19 year who have received a PCV (i.e., PCV7, PCV13, or PCV15), but have not completed the recommended series

2. Should **PCV21** be recommended for U.S. adults aged 50–64 years who currently do not have a risk-based pneumococcal vaccine indication?

3. Should **PCV21** be recommended for U.S. adults aged 19–49 years who currently do not have a risk-based pneumococcal vaccine indication?

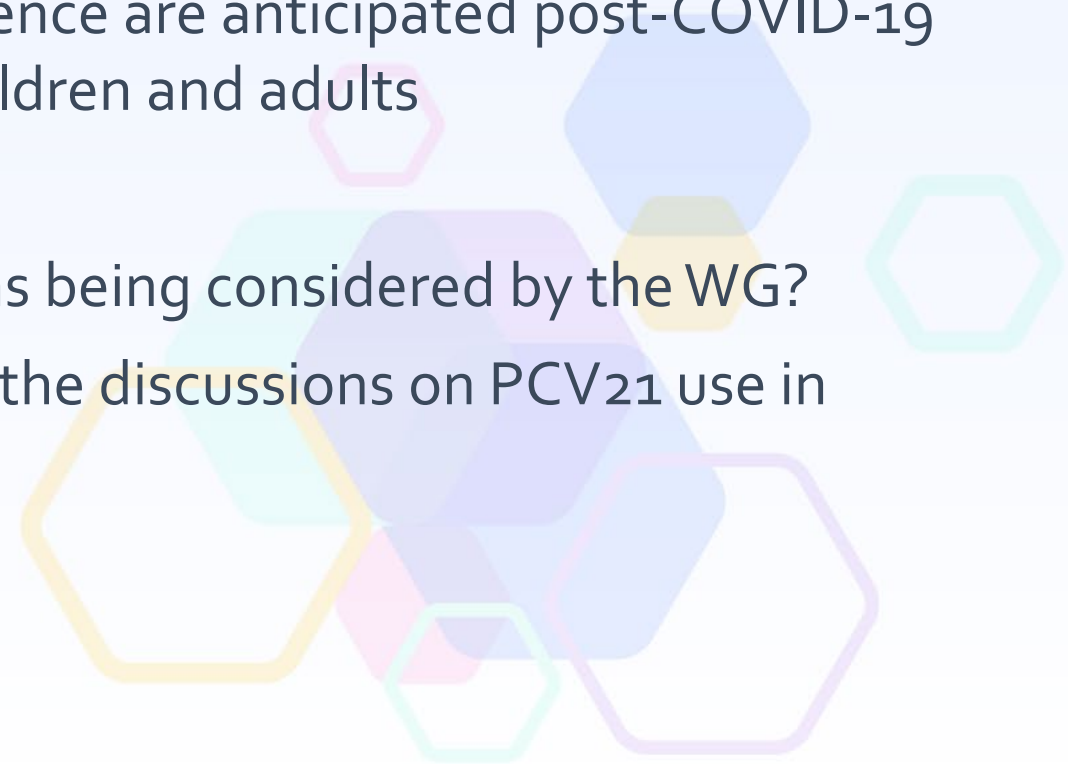
- Questions 2 and 3 would result in a new age-based recommendation for these groups.

Questions for the Committee

Considering:

- Additional pneumococcal vaccines for adults are currently under investigation and may be approved in the near future, and
- Dynamic changes in pneumococcal disease incidence are anticipated post-COVID-19 and with increased uptake in PCV15/PCV20 in children and adults

1. Do you have any feedback on the policy questions being considered by the WG?
2. What additional data would be helpful to inform the discussions on PCV21 use in adults?



Today's Session

Introduction

Current epidemiology of invasive pneumococcal disease among adults in the United States

Interim results from the Pneumococcal pNeumonia Epidemiology, Urine serotyping, and Mental Outcomes (PNEUMO) US study

Phase 3 clinical trial data of PCV₂₁

Post-licensure PCV₂₀ safety data

Preliminary WG interpretations of EtR and Next Steps

Dr. Jamie Loehr (ACIP, WG Chair)

Mr. Ryan Gierke (CDC, NCIRD)

Dr. Wesley Self (Vanderbilt University Medical Center)

Dr. Heather Platt

Dr. Pedro Moro (CDC/NCEZID)

Dr. Richard Forshee (FDA)

Dr. Miwako Kobayashi (CDC, NCIRD)