

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



# Pneumococcal Vaccines

**June 2024, ACIP Meeting**

June 27, 2024

Pneumococcal Vaccine Work Group Chair

James Loehr, MD, FAAFP

# Pneumococcal Vaccines Work Group

## ACIP Members

- Jamie Loehr (Chair)
- Sarah Long
- Robert Schechter

## Ex Officio Members

- 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)
- George Kuchel (UConn)
- Kathy Poehling (Wake Forest)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Richard Zimmerman (U. of Pittsburgh)

# CDC Contributors and Consultants

## Division of Bacterial Diseases

- Adam Cohen
- Ryan Gierke
- Noele Nelson

## Immunization Safety Office

- Pedro Moro

## Immunization Services Division

- Andrew Leidner
- Liz Velazquez

## Arctic Investigations Program

- Marc Fischer

## CDC Lead

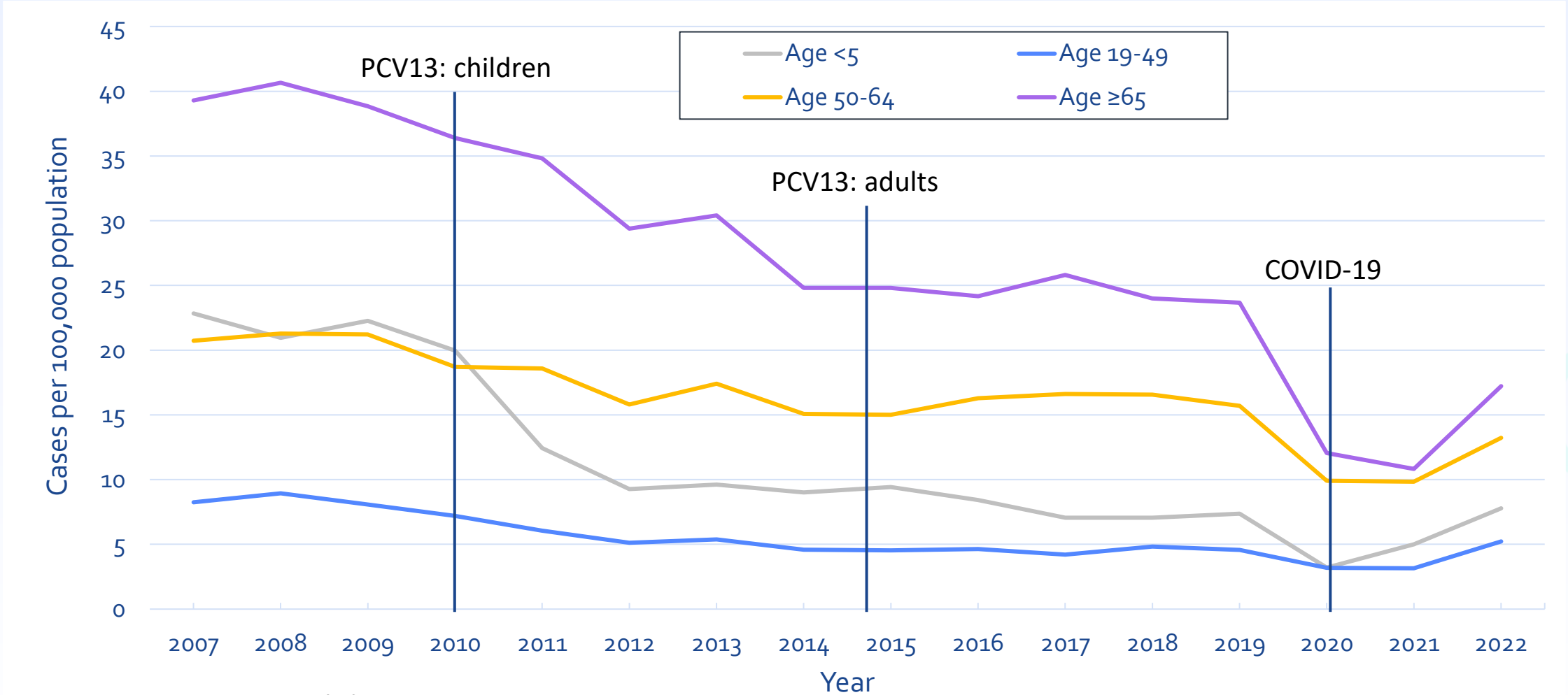
- Miwako Kobayashi

## GRADE/EtR consultants

- Doug Campos-Outcalt
- Rebecca Morgan



# In 2020 during the COVID-19 pandemic, IPD rates reached a historically low level in all age groups



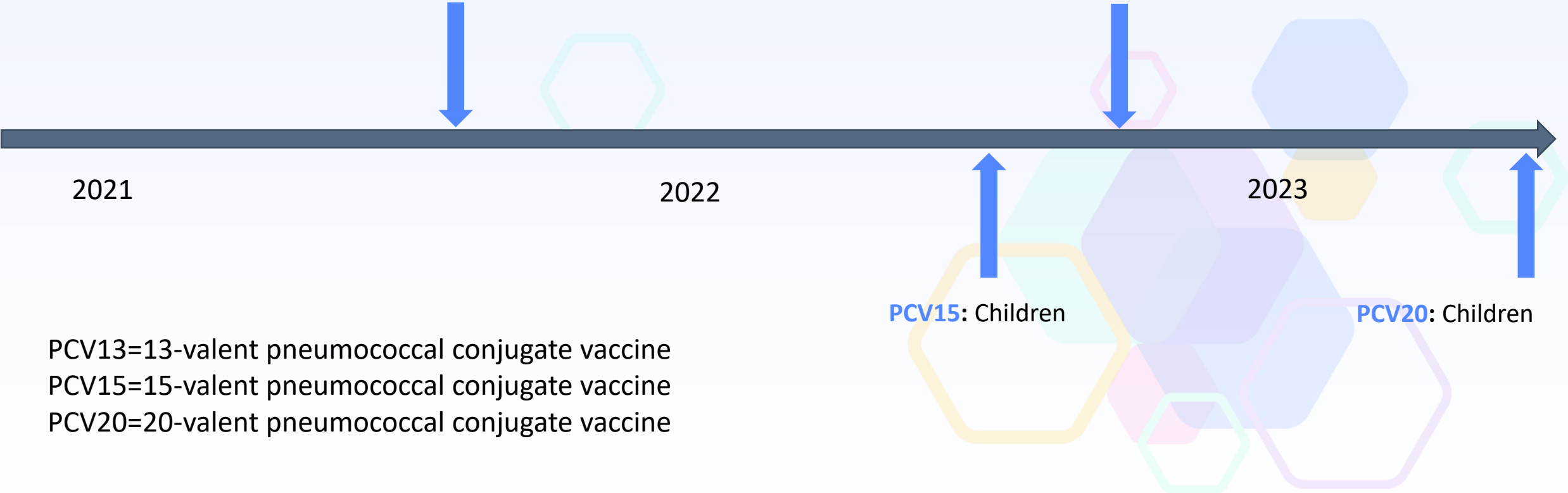
IPD=invasive pneumococcal disease

[Adapted from Gierke February 2024 ACIP meeting presentation](#)

# During 2021–2023, new 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**



PCV13=13-valent pneumococcal conjugate vaccine  
PCV15=15-valent pneumococcal conjugate vaccine  
PCV20=20-valent pneumococcal conjugate vaccine

# Adult Pneumococcal Vaccines

	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			
PCV <sub>15</sub>																																			
PCV <sub>20</sub>																																			
PPSV <sub>23</sub>																																			
PCV <sub>21</sub>																																			

## 21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck):

- Approved by the FDA for adults aged ≥18 years on June 17, 2024<sup>1</sup>

PCV13=13-valent pneumococcal conjugate vaccine

PCV15=15-valent pneumococcal conjugate vaccine

PCV20=20-valent pneumococcal conjugate vaccine

PPSV23=23-valent pneumococcal polysaccharide vaccine

1. U.S. FDA Approves CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults - Merck.com

# 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	1 6 F	7 C			
PCV15																																					
PCV20																																					
PPSV23																																					
PCV21																																					
Pn- MAPS24v																																					
VAX-24																																					
VAX-31																																					

## 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 infants<sup>1</sup>
- **VAX-24 (Vaxcyte):** Completed phase 1/2 studies for adults, completed enrollment for phase 2 studies in infants<sup>2</sup>

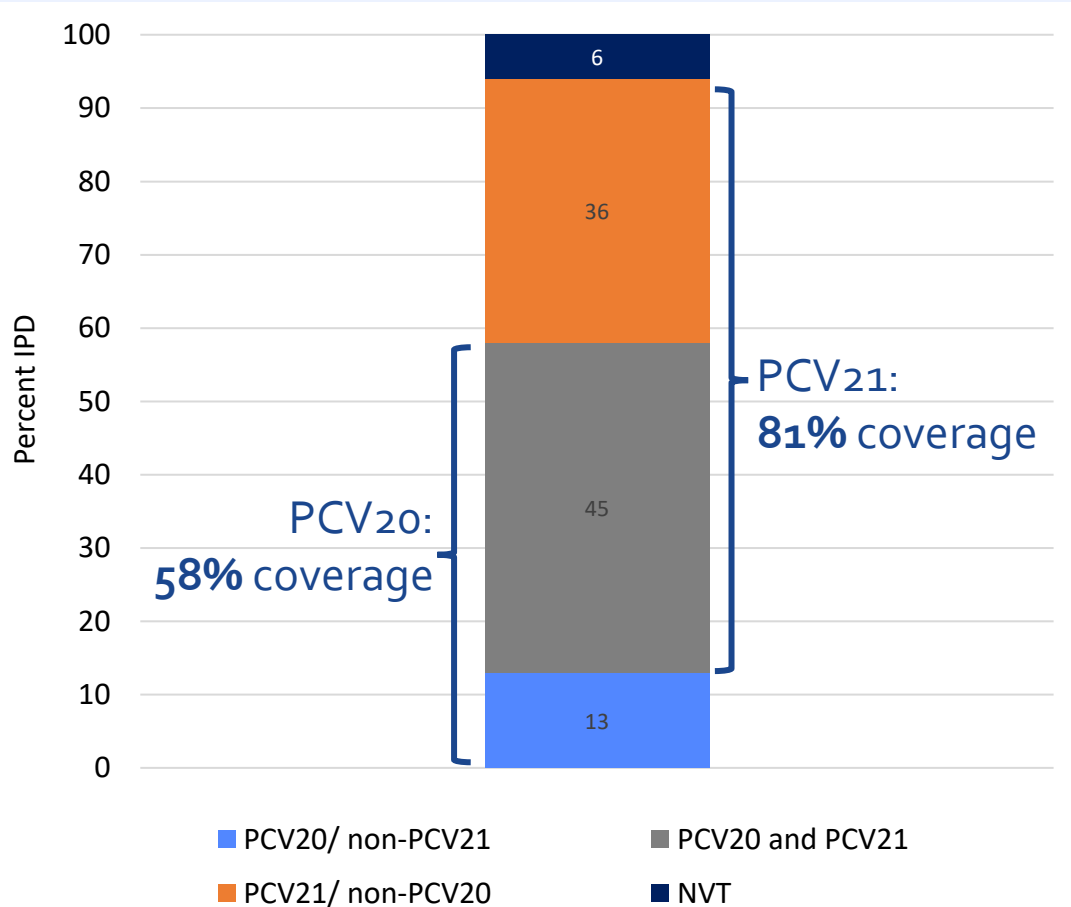
## 31-valent pneumococcal vaccine (VAX-31, Vaxcyte):

- Completed enrollment of phase 1/2 study in adults aged ≥50 years<sup>3</sup>

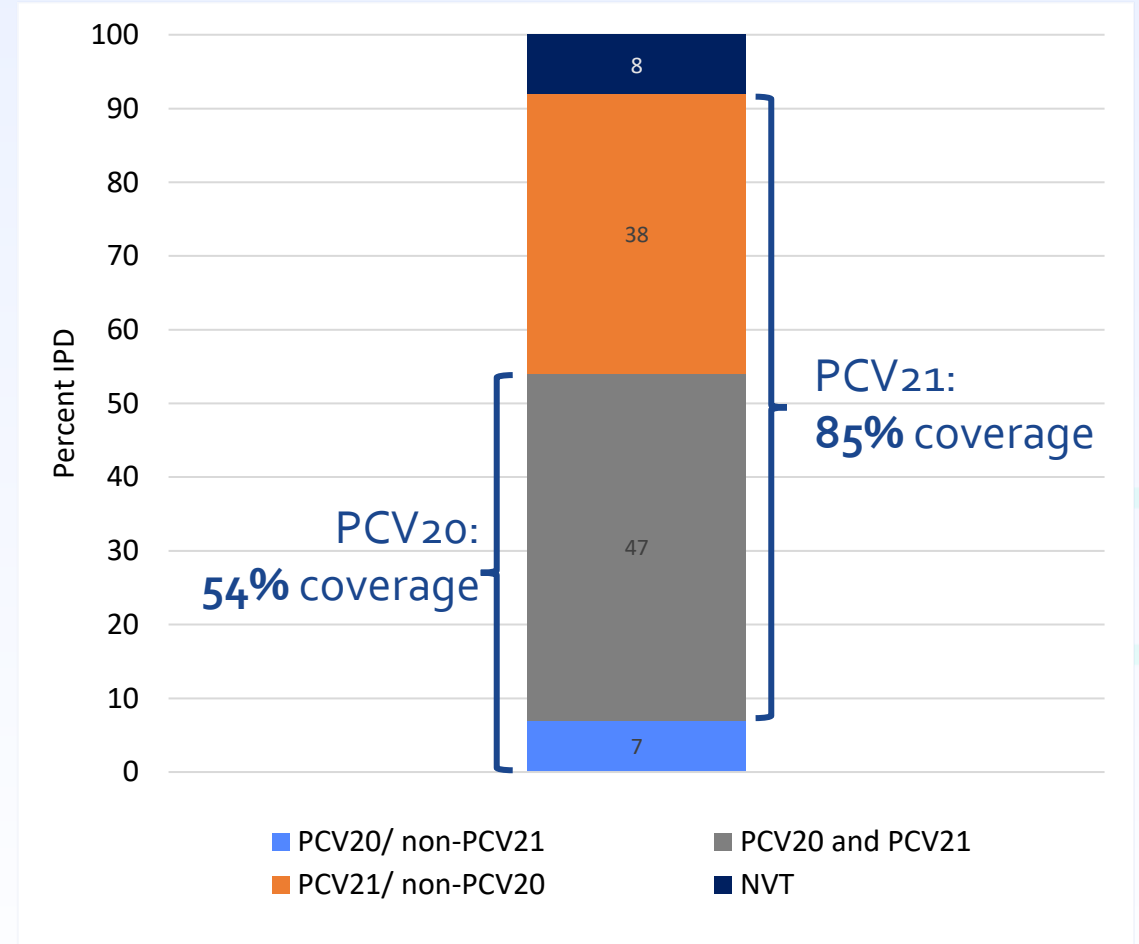
1. Chichili et al. Vaccine 2022; 2. Vaxcyte Completes Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease (IPD) in Infants - Vaxcyte, Inc.; 3. Vaxcyte Doses First Participants in Phase 1/2 Clinical Study Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease in Adults - Vaxcyte, Inc.; Investor Overview (vaxcyte.com), May 8 2024

# Proportion of IPD by vaccine-type among adults with a pneumococcal vaccine indication, 2018–2022

19-64 years old (with a risk-based indication)



≥65 years old



PCV20/ non-PCV21 serotype: 1, 4, 5, 6B, 9V, 14, 18C, 19F, 23F, 15B  
 PCV20/ in-PCV21 serotypes: 3, 6A, 7F, 19A, 22F, 33F, 8, 10A, 11A, 12F, +6C  
 PCV21/ non-PCV20 serotypes: 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31, 35B



# Increase in serotype 4 (included in currently available vaccines, not in PCV21) IPD reported in certain subpopulations

- Adults experiencing homelessness (especially Western United States)
  - **100–300 times higher** serotype 4 IPD incidence reported in people experiencing homelessness (PEH) vs. non-PEH in the Western United States<sup>1</sup>
- Adults in Alaska (especially Alaska Native adults)
  - **88-fold increase** in serotype 4 IPD incidence reported in adults in Alaska, 2011–2018 vs. 2019–2020<sup>2</sup>

[Kobayashi February 2024 ACIP meeting presentation](#)

[1. Upsurge of Conjugate Vaccine Serotype 4 Invasive Pneumococcal Disease Clusters Among Adults Experiencing Homelessness in California, Colorado, and New Mexico | The Journal of Infectious Diseases | Oxford Academic \(oup.com\)](#)

[2. Invasive Pneumococcal Disease and Potential Impact of Pneumococcal Conjugate Vaccines Among Adults, Including Persons Experiencing Homelessness—Alaska, 2011–2020 | Clinical Infectious Diseases | Oxford Academic \(oup.com\)](#)

# 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  $\geq 65$  years** who have not received a PCV<sup>1</sup>
  - **Adults aged 19–64 years** with certain underlying conditions or risk factors<sup>2</sup> who have not received a PCV<sup>1</sup>
  - **Certain adults who have received PCV13** but have not received PCV20<sup>3</sup>

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



# Policy Questions Being Considered by the Work Group

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

\*Includes:

- Adults aged  $\geq 65$  years who have never received a PCV
- Adults aged 19–64 years with a risk condition, who have never received a PCV
- Adults aged  $\geq 19$  year who have received a PCV (i.e., PCV7 or PCV13), but have not completed the recommended series
- PCV20 use based on shared clinical decision-making for adults  $\geq 65$  years who have completed the recommended series with PCV13 and PPSV23

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.

# Proposed Voting Language

ACIP recommends PCV<sub>21</sub> as an option for adults aged  $\geq 19$  years who currently have a recommendation to receive a dose of PCV.



# Today's Session

Introduction

Economic analysis and public health impact of PCV21 use in adults

Comparison of economic analysis of PCV21 use in adults

Summary of WG interpretation of EtR and policy options on PCV21 use in adults

Clinical considerations for PCV21 use in adults

Dr. Jamie Loehr (ACIP, WG Chair)

Dr. Charles Stoecker (Tulane)

Dr. Andrew Leidner (CDC/NCIRD)

Dr. Miwako Kobayashi (CDC/NCIRD)

Dr. Miwako Kobayashi (CDC/NCIRD)

