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

Summary of Work Group Interpretations of EtR and Policy Option on PCV21 Use in Adults

June 2024, ACIP Meeting

June 27, 2024

Miwako Kobayashi, MD, MPH, FACP, FIDSA

NCIRD

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*? (Group 1)**

Comparison (current recommendations):

- PCV-naïve adults aged ≥19 years

PCV20 **OR** **PCV15** **PLUS** **PPSV23†**

† If adults previously received PPSV23 before receiving a dose of PCV15, it need not be followed by another dose of PPSV23

- PCV-experienced adults aged ≥19 years who have **not completed the recommended series**

PCV20 **OR** **1≥ dose of PPSV23**

*Includes:

- Adults aged ≥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 ≥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 ≥65 years who have completed the recommended series with PCV13 and PPSV23

NCIRD

Policy Questions Being Considered by the Work Group

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

(Group 2)

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

(Group 3)

- Questions 2 and 3 imply a **new age-based recommendation** for these age groups.

<u>Comparison (current recommendation):</u>

- No vaccine

NCIRD

Evidence to Recommendations (EtR) framework

EtR Domain	Question
Public Health Problem	• Is the problem of public health importance?
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects? • What is the overall certainty of this evidence for the critical outcomes?
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcomes?
Acceptability	• Is the intervention acceptable to key stakeholders?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?
Feasibility	• Is the intervention feasible to implement?
Equity	• What would be the impact of the intervention on health equity?

NCIRD

Summary of Work Group Interpretation of the EtR Domains for EtR Domains Public Health Problem, Benefits and Harms, and Equity

EtR Domains	Group 1. Adults with current PCV recommendations	Group 2. Adults aged 50–64 years, no risk-based indication	Group 3. Adults aged 19–49 years, no risk-based indication
Public Health Problem	Yes	Probably Yes	No/Probably No
Benefits and Harms			
a. Benefits	Moderate/Large	Small/Moderate	Minimal/Small
b. Harms		Minimal	
c. Benefit>Harm?		Favors PCV21 use	Favors PCV21/Favors no vaccine (split)
d. Overall certainty: effectiveness		Moderate	
e. Overall certainty: safety		Moderate	
Equity		Probably increased	

[Kobayashi February 2024 ACIP meeting presentation]

Evidence to Recommendations (EtR) framework

EtR Domain	Question
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcomes?
Acceptability	• Is the intervention acceptable to key stakeholders?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?
Feasibility	• Is the intervention feasible to implement?

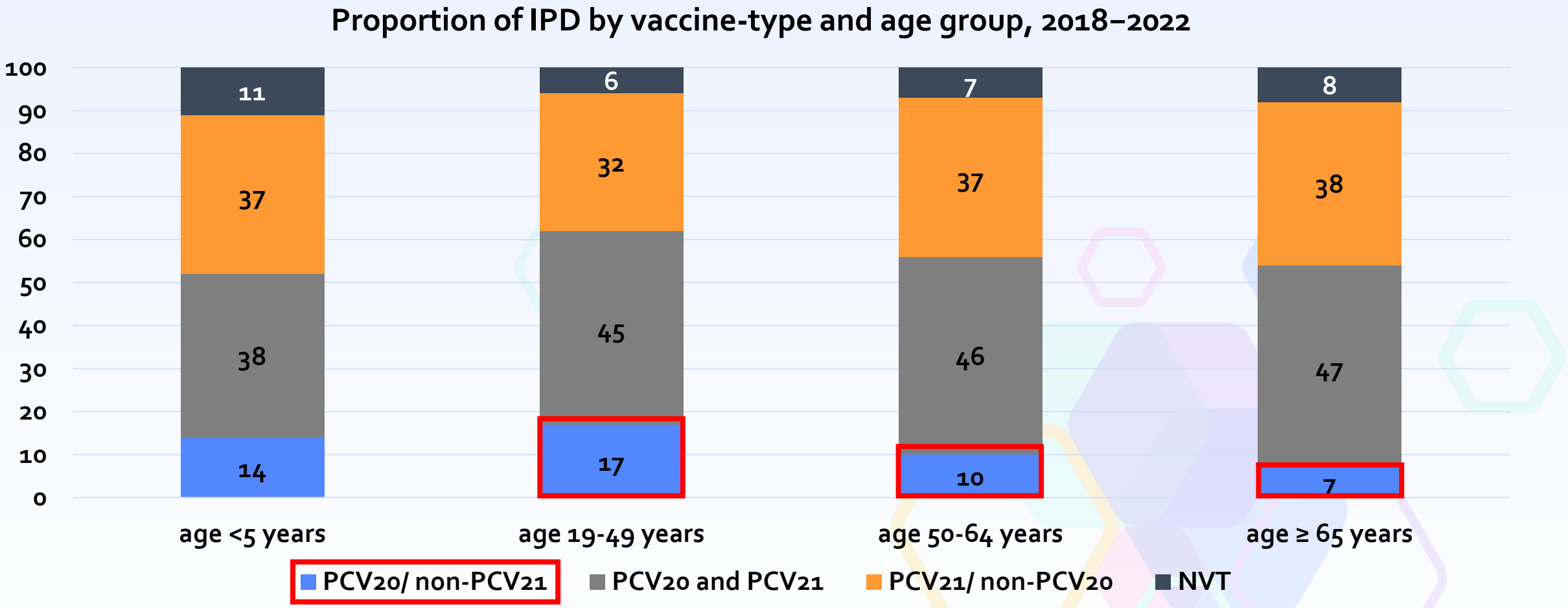
EtR Values and Preferences

- Does the population feel that the **desirable** effects are large relative to **undesirable** effects?
- Is there important uncertainty about or variability in how much people value the main outcomes*?

Outcomes
= Vaccine-type (VT) invasive pneumococcal disease (IPD), VT-non-bacteremic pneumococcal pneumonia, VT-pneumococcal deaths, serious adverse events (SAEs)

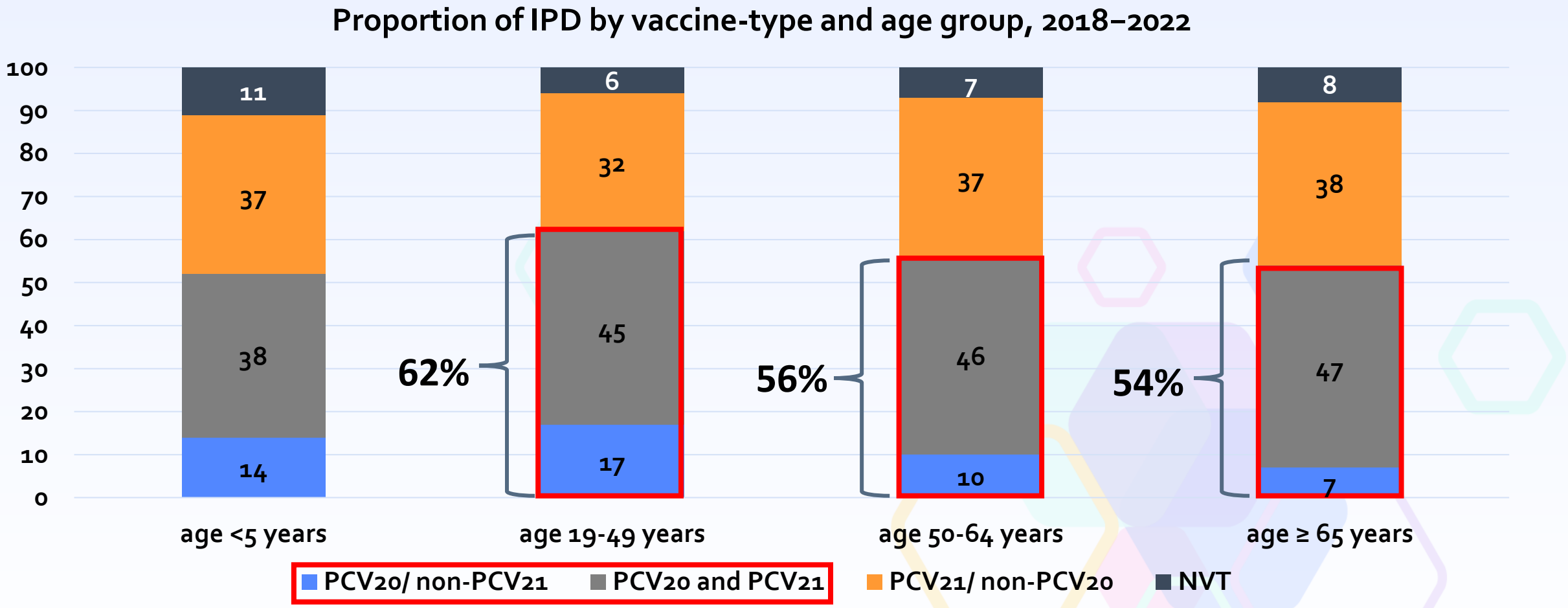
NCIRD

The proportion of IPD cases due to PCV20/non-PCV21 serotypes is relatively lower in older vs younger adults



CDCsActive Bacterial Core surveillance

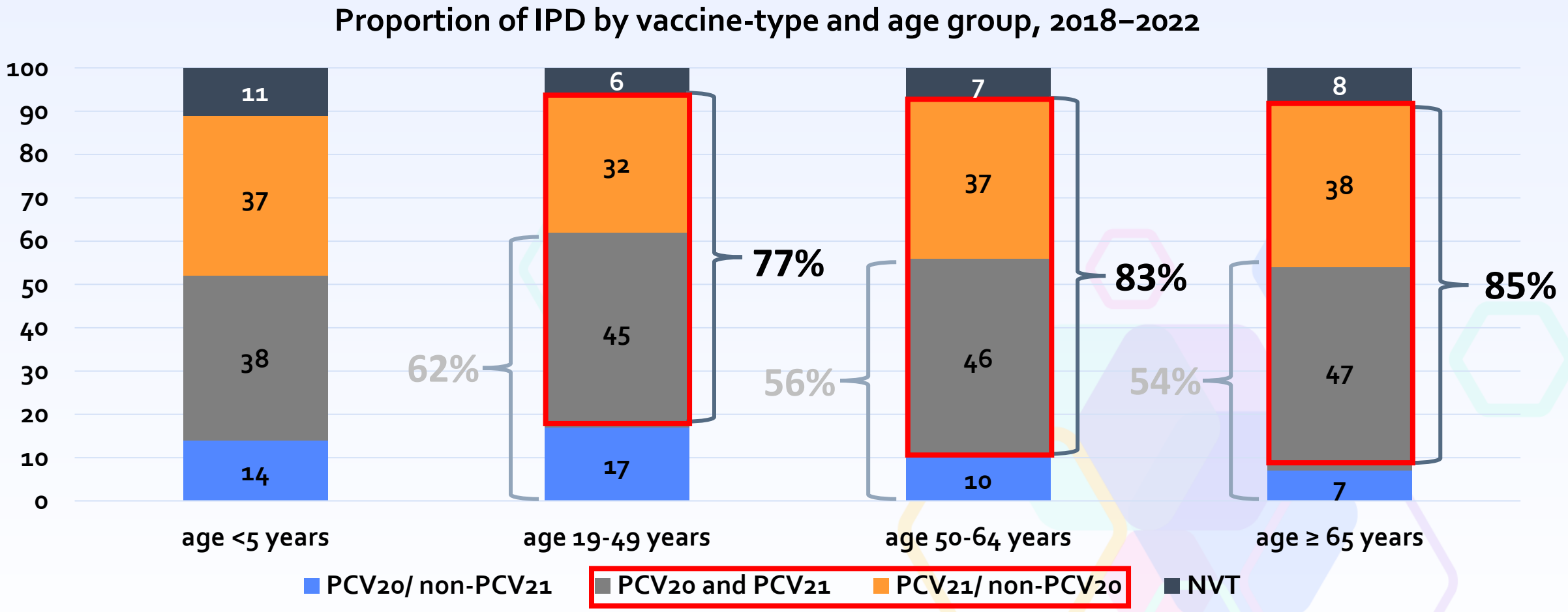
54–62 % of IPD cases in adults were due to PCV20 serotypes



CDCsActive Bacterial Core surveillance

NCIRD

77–85% of IPD cases in adults were due to PCV21 serotypes



CDCsActive Bacterial Core surveillance

NCIRD

GRADE Summary of Findings Table
1: Adults currently recommended to receive PCV

Effect		Certainty	Importance
Relative (95% CI)	Absolute (95% CI)		
• PCV21 **met non-inferiority criteria**[b] for 9/9 shared and **superiority criteria**[c] for 12/12 unique serotypes vs. PPSV23 • PCV21 met **non-inferiority criteria**[d] for 10/10 shared and **superiority criteria**[e] 10/11 unique serotypes vs. PCV20 • PCV21 had numerically higher immune responses for 1-4/6 shared and all unique serotypes vs. PCV15		Moderate	Critical

a. These are all immunogenicity studies and there are no correlates of protection for some critical outcomes considered.
b. Noninferiority for GMT ratio was defined as the lower bound of the 95% CI of the estimated OPA GMT ratio ({PCV21:PPSV23} to be > 0.33.
c. Superiority for GMT ratio was defined as the lower bound of the 95% CI of the estimated OPA GMT ratio [PCV21:PPSV23] to be > 1.0.
d. Noninferiority for GMT ratio was defined as the lower bound of the 2 sided 95% CI of the OPA GMT ratio [PCV21 / PCV20] to be >0.5.
e. Superiority for GMT ratio was defined as the lower bound of the 2 sided 95% CI of the OPA GMT ratio [PCV21 / PCV20] to be >2.0.

Kobayashi February 2024 ACIP meeting presentation

NCIRD

GRADE Summary of Findings Table
1: Adults currently recommended to receive PCV

№ of patients		Effect		Certainty	Importance
PCV21	comparison	Relative (95% CI)	Absolute (95% CI)		
57/4445 (1.3%)	63/2962 (2.1%)	Absolute % difference for SAEs across studies is -0.8%; two SAEs deemed vaccine-related[g] in the V116 group reported		Moderate	Critical

f. few vaccine-related serious adverse events reported.
g. Bronchospasm (V116-005): 50-year-old female in the sequential group with bronchospasm within 30 minutes after the 2ndvaccination (V116); duration 23 hours; resolved; Injection site cellulitis (V116-006): 67-year-old female in Cohort 1 (prior PPSV23) with injection site cellulitis on Day 6; duration 1.57 weeks; resolved (Merck, unpublished).

Kobayashi February 2024 ACIP meeting presentation

Recommendation by a healthcare provider was among the top reasons influencing the likelihood of receiving a pneumococcal vaccine

- **Recommendation by a healthcare provider** was one of the top factors influencing the likelihood of receiving a pneumococcal vaccine[1, 2]
- Among adults aged **19–64 years with risk-based indications**, the top reasons for **not** getting a pneumococcal vaccine were[2]:
  - Not knowing a pneumococcal vaccine was needed (32%)
  - Never receiving a recommendation by a healthcare provider (28%)

1. Online survey conducted in February 2024, funded by Merck. The survey targeted 250 adults aged ≥65 years who previously received a pneumococcal vaccine as an adult and 250 adults aged 50–64 years (healthy & CMC) who have not previously received a pneumococcal vaccine as an adult. Participants were being "in favor" or "neutral" toward adult vaccinations
2. Online survey conducted in January 2024, by HaPPI Survey Collaborative. The survey Targeted adults aged 19–64 years with underlying conditions (self-reported) with indications for risk-based pneumococcal vaccine indications

Does the population feel that the desirable effects are large relative to undesirable effects?

- The Work Group found it challenging to interpret this EtR domain due to limited data

1. Adults currently recommended to receive PCV

- No
- Probably no
- **Probably yes**
- Yes
- Varies
- Don't know

2. Adults aged 50–64 years with no risk-based indication

- □ No
- □ Probably no
- **□ Probably yes**
- □ Yes
- □ Varies
- **□ Don't know**

3. Adults aged 19–49 years with no risk-based indication

- □ No
- □ Probably no
- □ Probably yes
- □ Yes
- **□ Varies**
- □ Don't know

Minority opinion

Is there important uncertainty about or variability in how much people value the main outcomes*?

1. Adults currently recommended to receive PCV

- □ Important uncertainty or variability
- □ Probably important uncertainty or variability
- □ Probably not important uncertainty or variability
- □ No important uncertainty or variability
- □ No known undesirable outcomes

* Vaccine-type (VT) IPD, VT-non-bacteremic pneumococcal pneumonia, VT-pneumococcal deaths, serious adverse events

NCIRD

Is there important uncertainty about or variability in how much people value the main outcomes*?

2. Adults aged 50–64 years with no risk-based indication

- □ Important uncertainty or variability
- □ Probably important uncertainty or variability
- □ Probably not important uncertainty or variability
- □ No important uncertainty or variability
- □ No known undesirable outcomes

*Vaccine-type (VT) IPD, VT-non-bacteremic pneumococcal pneumonia, VT-pneumococcal deaths, serious adverse events

NCIRD

Is there important uncertainty about or variability in how much people value the main outcomes*?

3. Adults aged 19–49 years with no risk-based indication

- ☐ Important uncertainty or variability
- ☐ Probably important uncertainty or variability
- ☐ Probably not important uncertainty or variability
- ☐ No important uncertainty or variability
- ☐ No known undesirable outcomes

* Vaccine-type (VT) IPD, VT-non-bacteremic pneumococcal pneumonia, VT-pneumococcal deaths, serious adverse events

NCIRD

EtR Acceptability

- Is the intervention acceptable to key stakeholders*?

Key Stakeholders
= healthcare providers, healthcare delivery systems, the public

Online surveys among healthcare providers to understand vaccine preference

- Expressed more challenges in identifying patients eligible for pneumococcal vaccination based on **risk factors** vs age[1]
  - **Focus during visit is on other priorities during the visit (e.g., other vaccinations, treatment, counseling)**
    - Most commonly identified challenge among **physicians and NP/PAs**
  - Unknown pneumococcal vaccination history of the patient
  - **Unknown underlying health condition of patient**
    - Most commonly identified challenge among **pharmacists**
- Providers reported they were **slightly likely (32%), likely (39%), or extremely likely (19%)** to support ACIP lowering the age-based recommendation for pneumococcal vaccines from adults aged ≥65 years to ≥50 years[2]

1. Online survey conducted in February 2024 by ZS, funded by Merck. 502 HCPs (physicians, NP/PAs, pharmacists who vaccinate) participated; majority (70%) physicians
2. Online survey conducted from March–May 2024 by OPEN Health, funded by Merck. Included a total of 340 HCPs consisting of physicians, nurse practitioners, physician assistants, and pharmacists

Is the intervention acceptable to key stakeholders?

1. Adults currently recommended to receive PCV

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

2. Adults aged 50–64 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

3. Adults aged 19–49 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

Minority opinion

NCIRD

EtR Resource Use

- Is PCV21 use a reasonable and efficient allocation of resources for adults?

Summary of findings from economic analysis

Policy question populations	Strategy details	Summary across available models
1. Currently recommended adults	Age-based PCV21	Cost-saving to $58,000 per QALY gained
	Risk-based PCV21	Cost-saving in all three models
2. Ages 50–64 years	PCV21	$3,000 to $270,000 per QALY gained
	PCV20	$37,000 to $630,000 per QALY gained
3. Ages 19–49 years	PCV21	$650,000 per QALY gained to "Dominated"
Supplemental dose	Supplemental dose with PCV21	$210,000 to $510,000 per QALY gained

Summary of findings from economic analysis

Policy question populations	Strategy details	Summary across available models
1. Currently recommended adults	Age-based PCV21	Cost-saving to $58,000 per QALY gained
	Risk-based PCV21	Cost-saving in all three models
2. Ages 50–64 years	PCV21	$3,000 to $270,000 per QALY gained
	PCV20	$37,000 to $630,000 per QALY gained
3. Ages 19–49 years	PCV21	$650,000 per QALY gained to "Dominated"
Supplemental dose	Revaccination with PCV21	$210,000 to $510,000 per QALY gained

Summary of findings from economic analysis

Policy question populations	Strategy details	Summary across available models
1. Currently recommended adults	Age-based PCV21	Cost-saving to $58,000 per QALY gained
	Risk-based PCV21	Cost-saving in all three models
2. Ages 50–64 years	PCV21	$3,000 to $270,000 per QALY gained
	PCV20	$37,000 to $630,000 per QALY gained
3. Ages 19–49 years	PCV21	$650,000 per QALY gained to "Dominated"
Supplemental dose	Revaccination with PCV21	$210,000 to $510,000 per QALY gained

Is PCV21 use a reasonable and efficient allocation of resources for adults?

1. Adults currently recommended to receive PCV

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

2. Adults aged 50–64 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

3. Adults aged 19–49 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don’t know

Minority opinion

NCIRD

EtR Feasibility

- Is PCV21 use feasible to implement?

Considerations:
Financial barriers, simplicity and integration, access

Is PCV21 feasible to implement?

- WG interpretation of feasibility generally mirrors interpretation for resource use.
- Some expressed the interpretation of group 2 may depend on whether there are different age-based recommendations for PCV21 and other PCVs

1. Adults currently recommended to receive PCV

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don't know

2. Adults aged 50–64 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don't know

3. Adults aged 19–49 years with no risk-based indication

- ☐ No
- ☐ Probably no
- ☐ Probably yes
- ☐ Yes
- ☐ Varies
- ☐ Don't know

NCIRD

Summary of Work Group Interpretation of the EtR Domains

EtR Domains	Group 1. Adults with current PCV recommendations	Group 2. Adults aged 50–64 years, no risk-based indication	Group 3. Adults aged 19–49 years, no risk-based indication
Public Health Problem	Yes	Probably Yes	No/Probably No
Benefits and Harms			
a. Benefits	Moderate/Large	Small/Moderate	Minimal/Small
b. Harms		Minimal	
c. Benefit>Harm?	Favors PCV21 use		Favors PCV21/Favors no vaccine (split)
d. Overall certainty: effectiveness		Moderate	
e. Overall certainty: safety		Moderate	
Values and Preferences			
a. Desirable>Undesirable?	**Probably Yes**	**Probably Yes**	**Varies**
b. Uncertainty?	**Probably important/not important uncertainty**	**Probably important uncertainty**	**Important/Probably important uncertainty**
Acceptability	**Yes**	**Probably Yes**	**Probably No/No**
Resource Use	**Yes**	**Yes/Probably Yes**	**No**
Feasibility	**Yes**	**Yes/Probably Yes**	**Probably No/No**
Equity			

Summary: Work Group Interpretation

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
- Adults aged 19–64 years with a risk condition, who have never received a PCV
- Adults aged ≥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 ≥65 years who have completed the recommended series with PCV13 and PPSV23

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably* outweigh undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Summary: Work Group Interpretation

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

- "**Desirable consequences probably outweigh undesirable consequences in most settings**" was selected the most, but did not reach the majority
- Some selected "**Desirable consequences clearly outweigh undesirable consequences**" and "**The balance between desirable and undesirable consequences is closely balanced or uncertain**", but few believed that undesirable consequences outweighed desirable consequences.

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably* outweigh undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Summary: Work Group Interpretation

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

*this implies a new age-based recommendation for adults aged ≥19 years

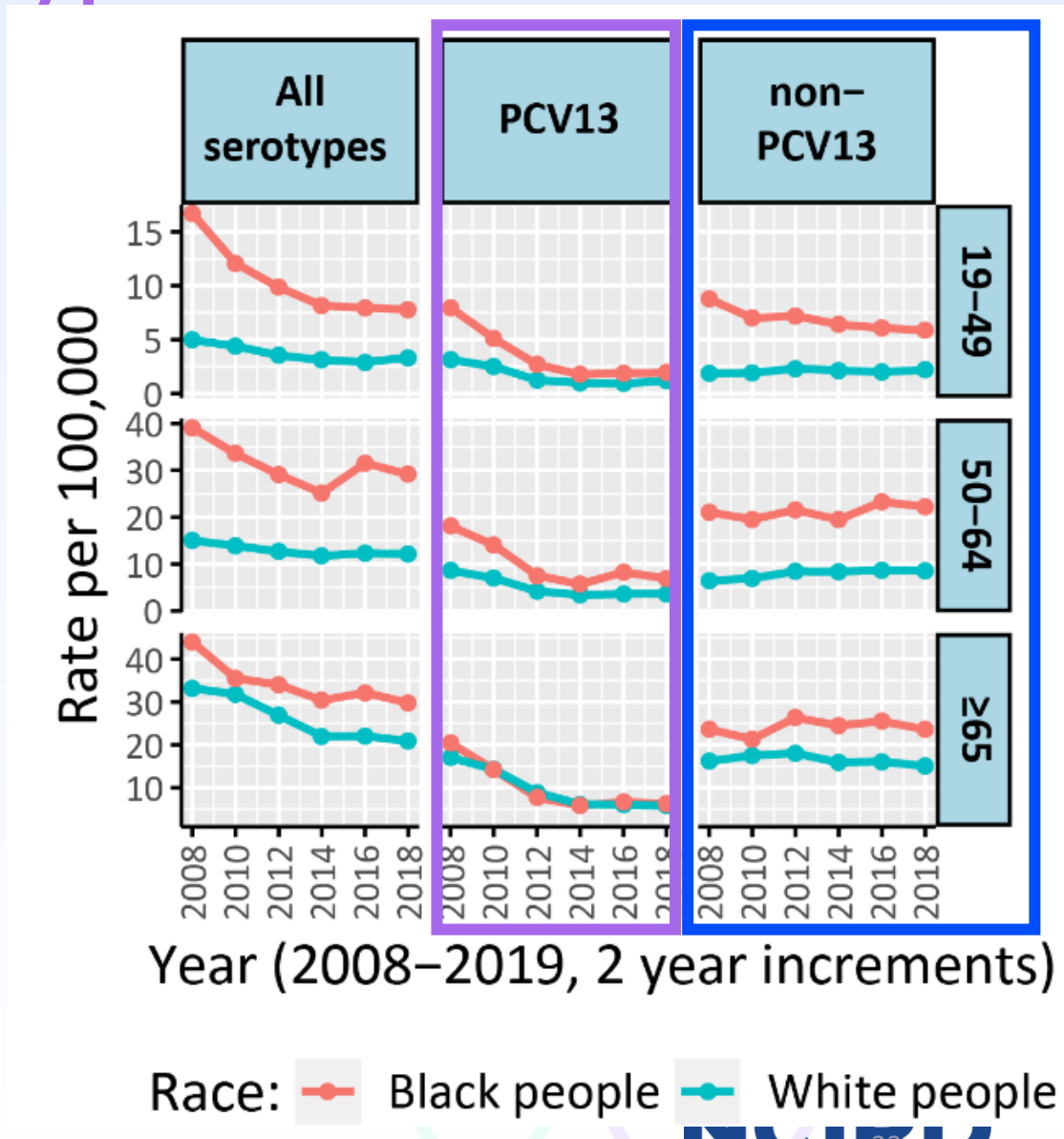
Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably* outweigh undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Additional considerations

What would be the impact of recommending PCV21 use for **all adults aged 50–64 years** on **health equity?**

Racial disparities due to PCV13-type IPD decreased after pediatric PCV13 use

- Racial disparities in IPD incidence exist
- Remaining disparities in IPD incidence are primarily due to **non-PCV13-type** disease



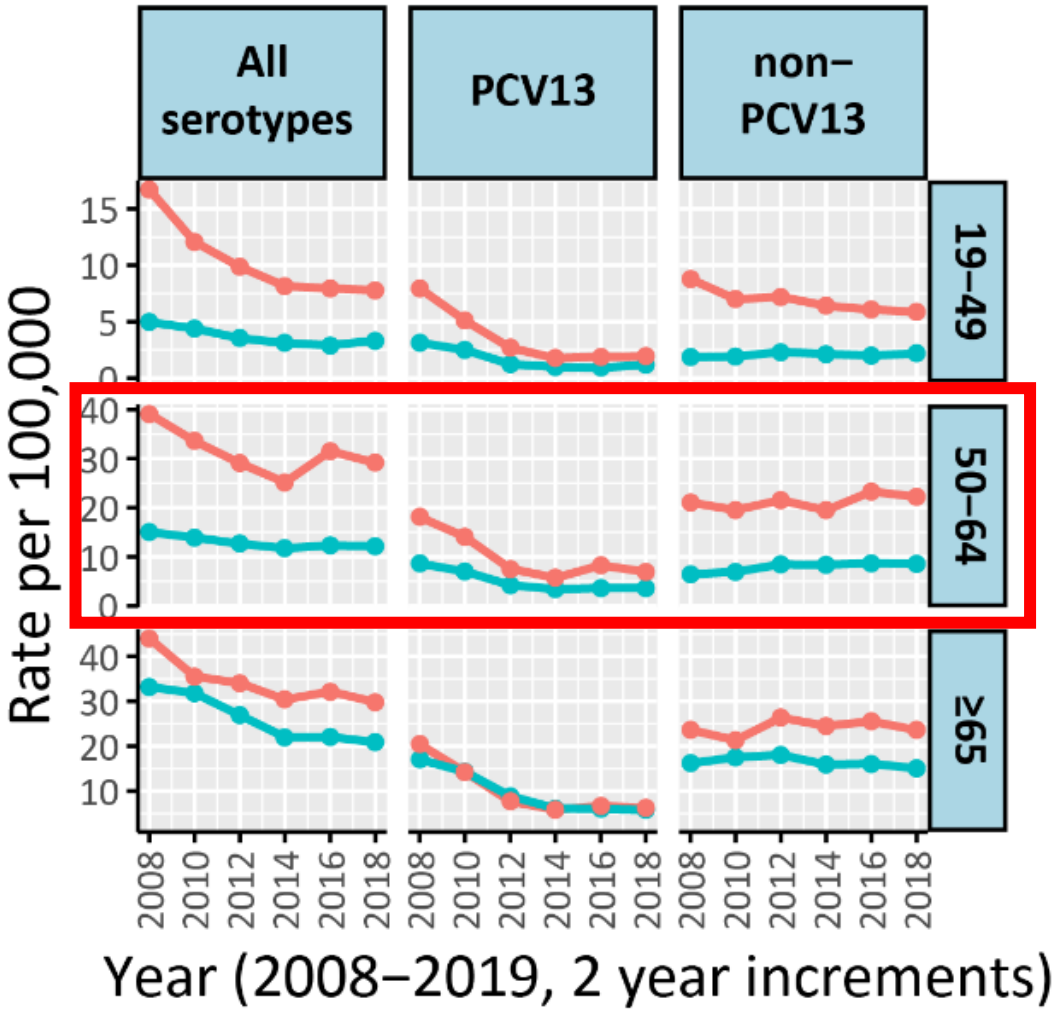
[Adapted from Kobayashi February 2024 ACIP meeting presentation]

Figure: ABCs unpublished data

1. [Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021 | CDC]

Racial disparities due to PCV13-type IPD decreased after pediatric PCV13 use

- Racial disparities in IPD incidence exist
- Remaining disparities in IPD incidence are primarily due to **non-PCV13-type** disease

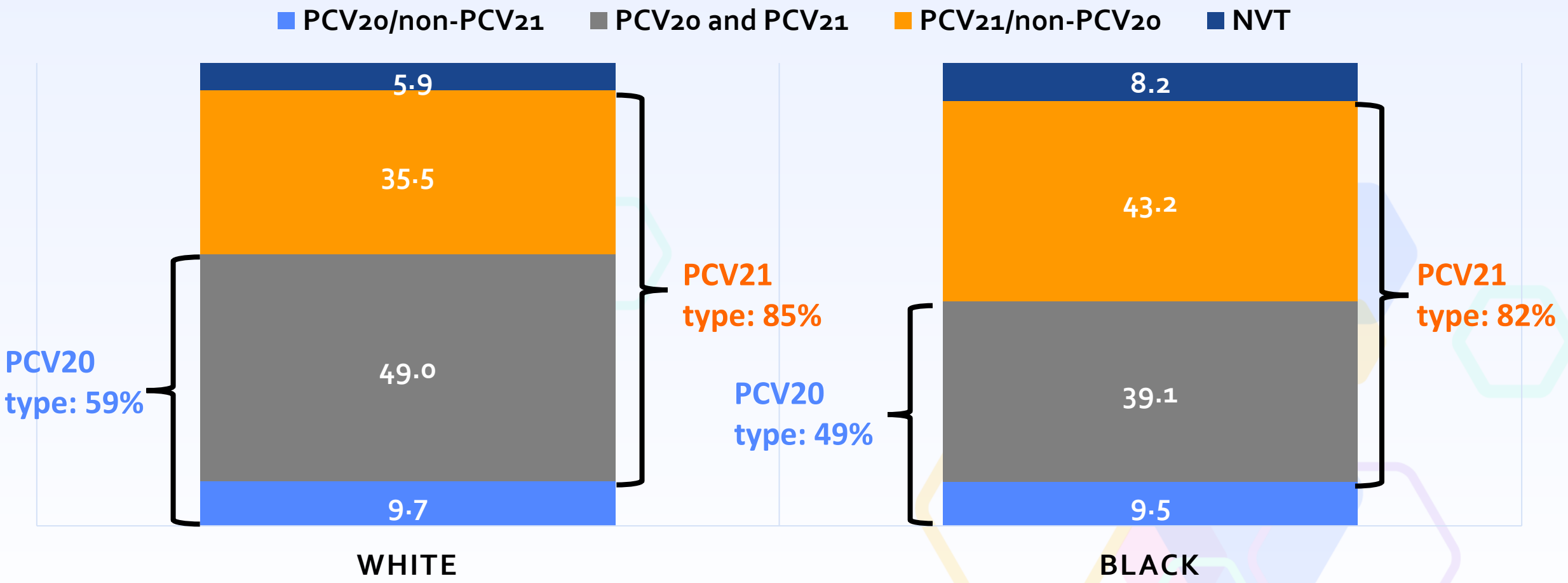


Adapted from Kobayashi February 2024 ACIP meeting presentation

Figure: ABCs unpublished data

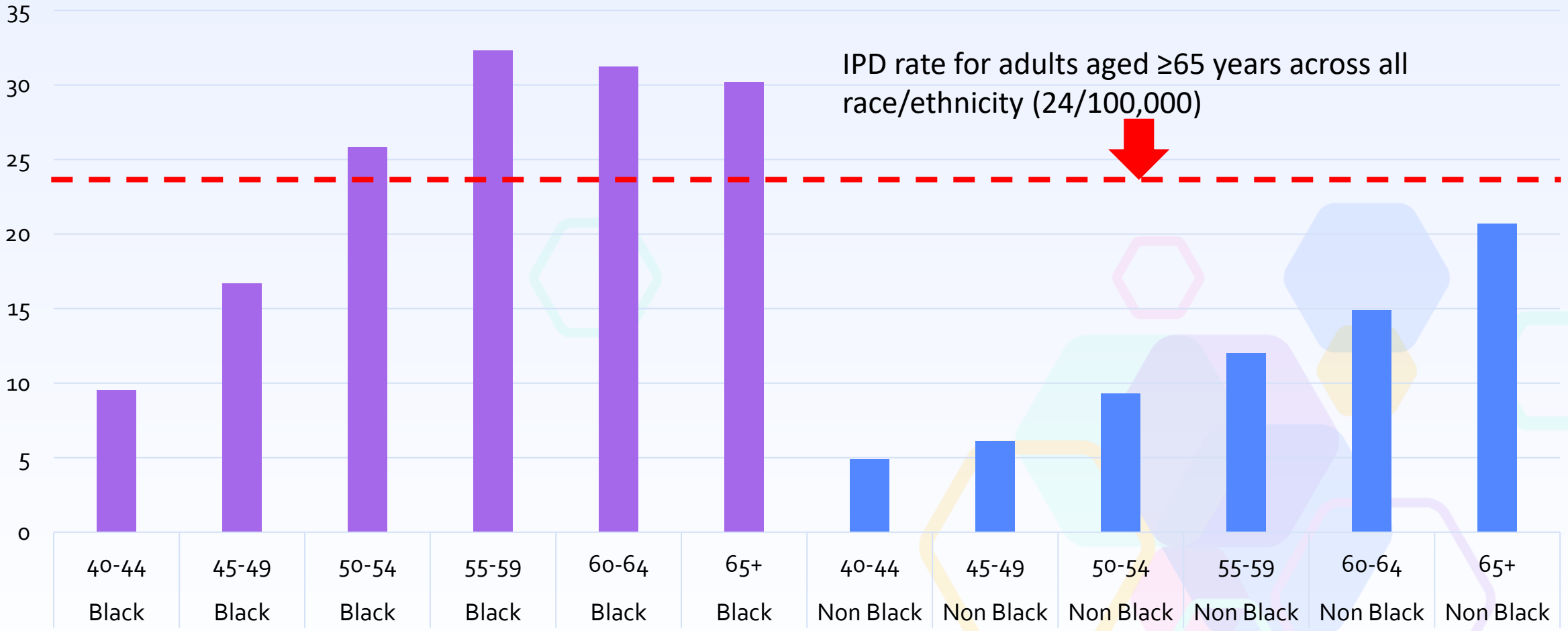
1. Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021 | CDC

PCV21 serotypes caused >80% of IPD cases in both Black and White adults 50–64 years; there was a larger difference in % of IPD cases caused by PCV20 serotypes between Black and White adults 50–64 years



ABCs 2018–2022 unpublished data

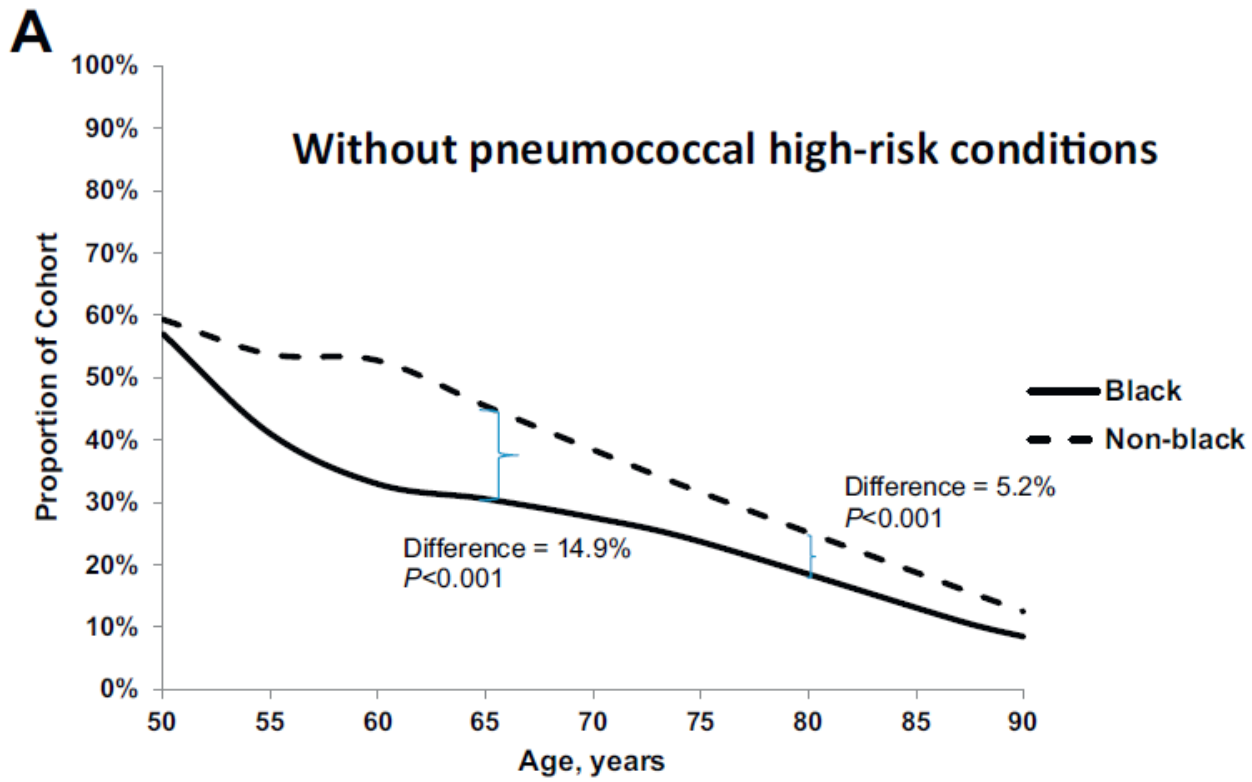
IPD rates in Black adults peak at a younger age compared with Non-Black adults

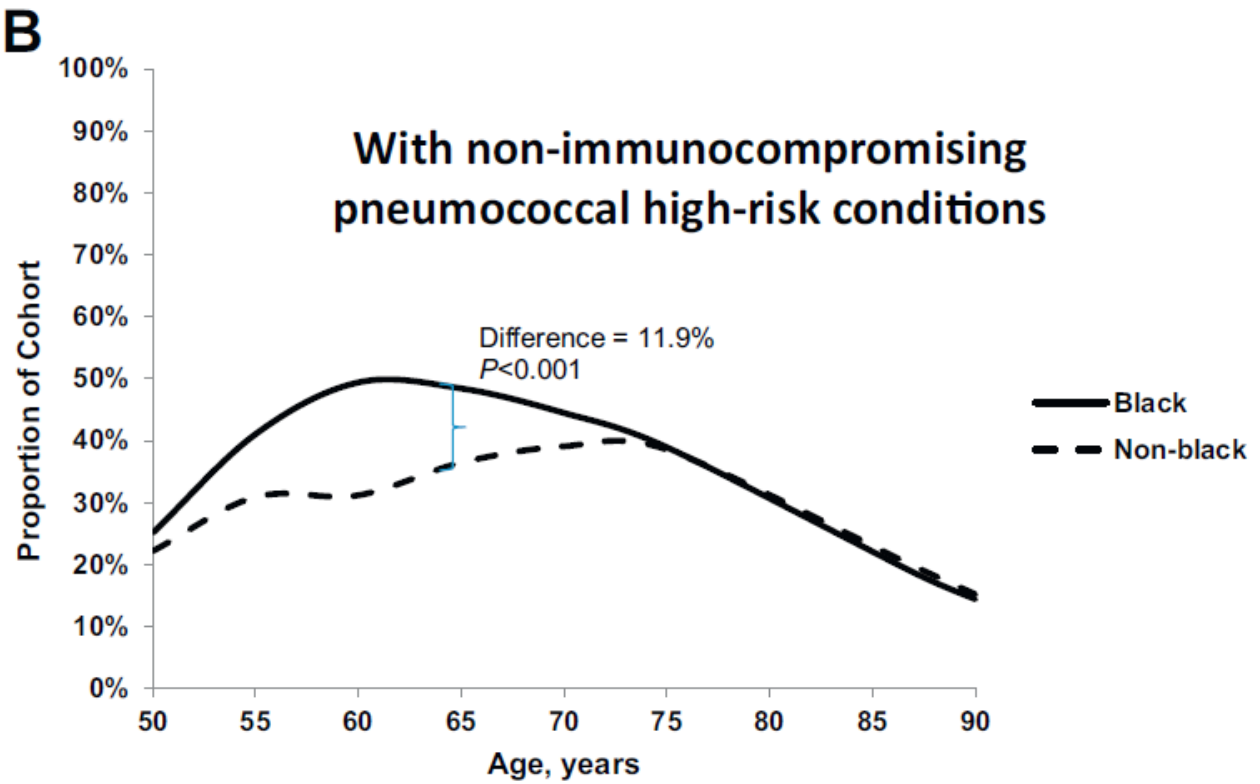


ABCs 2018 –2019 unpublished data

Differences in prevalence of risk conditions among Black vs Non-Black adults may be contributing

Figure 1. A, B and C. Proportion of black and non-black populations who had (A) no pneumococcal high-risk conditions, (B) non-immunocompromising high-risk conditions; and (C) died, by age.





- The proportion of **immunocompromised** individuals was similar for both racial groups at age 50 years and throughout the lifespan

[Racial Disparities in Adult Pneumococcal Vaccination Indications and Pneumococcal Hospitalizations in the U.S - PubMed (nih.gov)]

Adults with risk-based vaccine indications 19–64 years had lower vaccine coverage compared with adults ≥65 years; differences in vaccine coverage by race/ethnicity existed

Age group	%	(95% CI)
Overall (≥65 years)	**65.8**	**(64.4-67.2)**
White	70.1	(68.8-71.4)
Black	54.8	(50.6-59.0)*
Hispanic	46.2	(40.9-51.6)*
Asian	55.8	(48.7-62.7)*
Other	62.5	(53.1-71.1)
Overall (19–64years *with risk-based indication*)	**22.2**	**(21.0-23.5)**

Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021 | CDC

*p<0.05 for comparisons with White as the reference

Increase in serotype 4 IPD cases has been reported in certain adult populations in recent years

- Serotype 4 is contained in existing pneumococcal vaccines but not PCV21
- Serotype 4 IPD cases had nearly been eliminated after PCV7 use in children but IPD clusters have been reported in certain populations (e.g., people experiencing homelessness)[1,2,3]
- In certain areas, increase in serotype 4 IPD cases observed in routine surveillance in recent years, especially post-2020, after near elimination
  - Increase reported in Western United States (Alaska[4], Navajo Nation[5], ABCs CO/NM/OR sites[6])
- Appears to primarily affect adults aged <65 years with risk-based pneumococcal vaccine indications

1. Callaway et al. MMWR 2023; 2. McKee et al. CCDP 2018; 3. Beall et al. JID 2021; 4. Orell et al. ISPPD 2024; 5. Johns Hopkins Center for Indigenous Health and Navajo Epidemiology Center 2024; 6. CDC Active Bacterial Core surveillance unpublished data

Summary of Work Group discussions on lowering the age-based recommendation for PCV21 to age ≥50 years

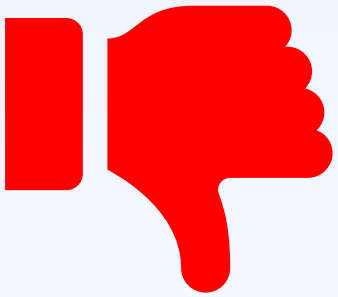
Pros and Cons of lowering the age-based recommendation for PCV21 from ≥65 years to ≥50 years

Pros:

- Potential to improve vaccine coverage in adults aged 50–64 years who currently have risk-based vaccine indications
- Potential to prevent more disease from broad pneumococcal serotype coverage with PCV21
- Potential to reduce racial disparities in pneumococcal disease burden given the differences in when pneumococcal disease rates peak and prevalence of conditions that increase the risk of pneumococcal disease

NCIRD

Pros and Cons of lowering the age-based recommendation for PCV21 from ≥65 years to ≥50 years



Cons:

- Lack of data on duration of protection from vaccination
- Potential unintended consequences of worsening health equity by improving access to those who already have good access to healthcare
- Higher Cost/QALY gained (~270K/QALY gained) reported in some economic models
- Uncertainties with serotype 4 (serotype contained in existing vaccines but not PCV21) disease trends
- Implementation challenges of having different recommendations by product (i.e, 1 PCV option for adults 50–64 years without a risk condition; 3 PCV options for adults with a risk condition)

Summary of WG discussion

- The WG agreed that available evidence supports PCV21 use for adults currently recommended to receive a PCV
- The WG could not reach a consensus on whether the age-based recommendation for PCV21 should be lowered from ≥65 years to ≥50 years
- The WG did not support lowering the age-based recommendation for PCV21 to age 19 years
- The majority of WG members believed there was insufficient evidence to support lowering the age-based recommendation for currently recommended vaccines

Proposed Voting Language

Proposed Voting Language

ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

Clinical Guidance for Implementation

Proposed Language

PCV-naïve adults (or adults with unknown history)

A single dose of PCV21 is recommended as an option for all adults aged ≥65 years and for adults aged 19–64 years with certain underlying conditions or risk factors* who have not received a PCV or whose vaccination history is unknown.

Rationale:

- PCV21 is added as an option to the current recommendation to use either PCV20 alone or PCV15 in series with PPSV23 (if PPSV23 not given previously) for these adults; barrier to implementation is likely low.
- PCV21 exhibited comparable safety and immunogenicity findings to comparator vaccines in clinical trials.
- Economic evaluations were consistently favorable (cost-saving to 58,000 USD/QALY gained).

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

PCV-naïve adults (or adults with unknown history)

Underlying conditions	Previous vaccination history	Age 19–64 years	Age ≥65 years
None	None	No vaccine recommendation	PCV21 OR PCV20 OR PCV15 → ≥1yr → PPSV23*
Chronic medical conditions	None	PCV21 OR PCV20 OR PCV15 → ≥8wks† → PPSV23*; PCV15 → ≥1yr → PPSV23*	
CSF leak, cochlear implant	None		
Immuno-compromised	None		

*If adults previously received PPSV23 before receiving a dose of PCV15, it need not be followed by another dose of PPSV23
†A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak

NCIRD

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

PCV-experienced adults who completed the recommended vaccine series

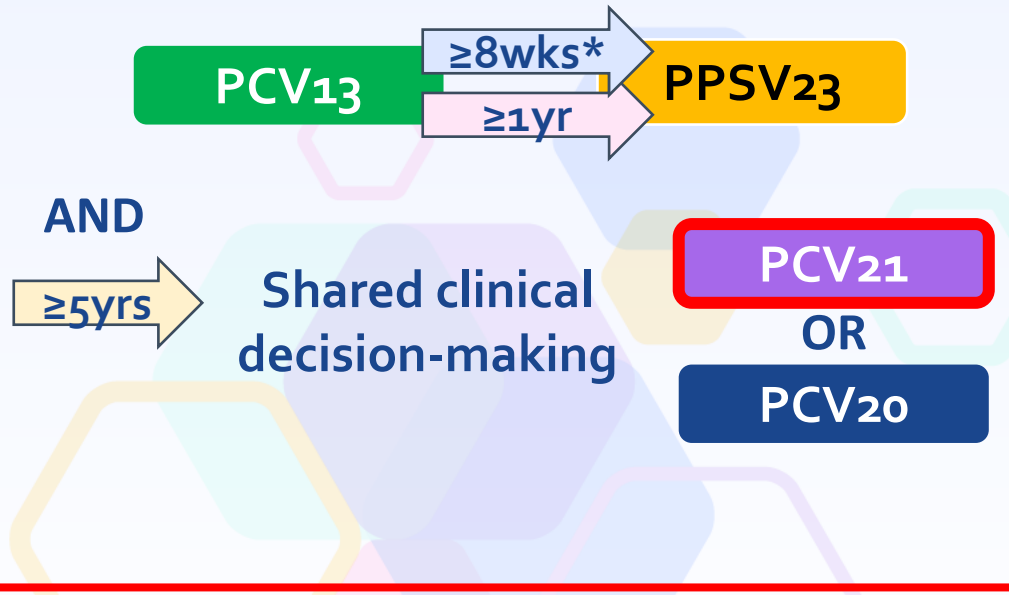
Shared clinical decision-making is recommended regarding use of a supplemental PCV20 or PCV21 dose for adults aged ≥65 years who have completed their recommended vaccine series with both PCV13 and PPSV23.

Rationale:

- This adds PCV21 as an option to the current shared clinical decision-making recommendation for PCV20 among adults aged ≥65 years who completed the recommended vaccine series with PCV13+PPSV23.
- Some WG members were in favor of expanding this indication to adults who received all recommended vaccine doses with a single dose of PCV20 or PCV15+PPSV23 (especially for adults with risk conditions) but others felt that there was insufficient evidence to support that.
- A phase 3 clinical trial on PCV21 use among PCV-experienced children with risk conditions is underway[1]; proposal to discuss PCV21 use in children and adults with risk conditions who completed recommended vaccine series together.

1. NCT06177912

PCV-experienced adults who completed the recommended vaccine series

Underlying conditions	Age 19–64 years	Age ≥65 years
None	No vaccine recommendation	
Chronic medical conditions		
CSF leak, cochlear implant		
Immuno-compromised		

NCIRD

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

PCV-experienced adults who have not completed the recommended vaccine series

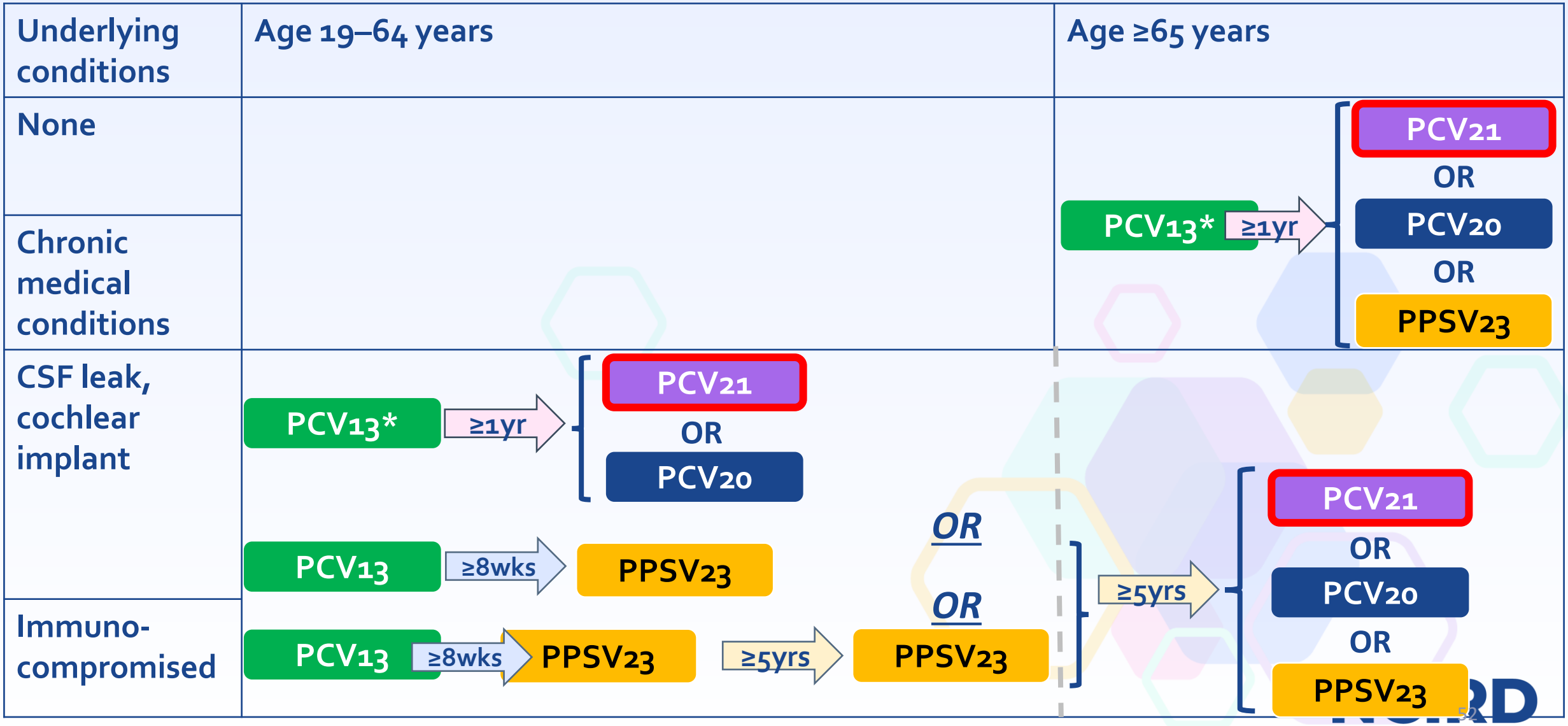
A single dose of PCV21 is recommended as an option for adults aged ≥19 years who have started their pneumococcal vaccine series with PCV13 but have not received all recommended PPSV23 doses.

Rationale:

- This adds PCV21 as an option to the current recommendation to complete the vaccine series with either a dose of PCV20 or ≥1 dose of PPSV23.
- In addition to those who started the series with PCV13, adults who received PCV15 but have not completed the series with PPSV23 will have an option to complete the series with either a dose of PCV21 or PCV20 if they no longer have access to PPSV23.

NCIRD

PCV-experienced adults who have not completed the recommended vaccine series



*includes adults who received PCV15 if PPSV23 not available

Populations at increased risk of serotype 4 disease (draft language)

In certain communities where there are high proportions (i.e., ≥30%) of disease due to serotypes unique to currently recommended vaccines (e.g., serotype 4), those vaccines may provide more protection against locally circulating strains compared to PCV21. Those who may be at increased risk of disease due to serotype 4 include adults aged <65 years in the Western United States with certain underlying conditions or risk factors* that increase the risk of pneumococcal disease.

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

Acknowledgments

- ACIP and the Pneumococcal Vaccines Work Group
- Active Bacterial Core surveillance sites and program
- Charles Stoecker, Yin Wang (Tulane University)
- Laura Hammitt, Catherine Sutcliffe, Tori Sergent (Johns Hopkins Center for Indigenous Health)
- CDC contributors and consultants: Ryan Gierke, Jennifer Farrar, Andrew Leidner, Kristin Andrejko, Lindsay Zielinski, Emma Accorsi, Wei Xing, Adam Cohen, Alison Albert, Angela Jiles, Noele Nelson, Kimberly Fox, Pedro Moro, Bo-Hyun Cho, Elizabeth Velazquez, Janelle King, Fangjun Zhou, Marc Fischer, Laurie Orell, Cheryl Ward, Rebecca Morgan, Doug Campos-Outcalt

NCIRD

Thank you

For more information, contact CDC
1 800 CDC INFO (232 4636)
TTY: 1 888 232 6348 www.cdc.gov