



Pneumococcal Vaccines

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Pneumococcal Vaccines Work Group Chair

Advisory Committee on Immunization Practices

September 29, 2021

Pneumococcal Vaccines Work Group

- **ACIP Members**

- Katherine Poehling (Chair)
- Keipp Talbot
- Sarah Long

- **Ex Officio Members**

- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Thomas Weiser (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)
- Emily Messerli (AIM)
- Elissa Abrams (NACI)
- Carol Baker (IDSA)
- William Schaffner (NFID)
- Virginia Caine (NMA)
- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Cynthia Whitney (Emory)
- Richard Zimmerman (U. of Pittsburgh)

Pneumococcal Vaccines Work Group

- **CDC Contributors**

- Tamara Pilishvili (Respiratory Diseases Branch)
- Ryan Gierke (Respiratory Diseases Branch)
- Jennifer Farrar (Respiratory Diseases Branch)
- Penina Haber (Immunization Safety Office)
- Pedro Moro (Immunization Safety Office)
- Sarah Schillie (Immunization Services Division)
- Marc Fischer (Arctic Investigations Program)
- Jessica MacNeil (ACIP Secretariat)

- **GRADE/EtR consultants**

- Doug Campos-Outcalt
- Rebecca Morgan

Current and New Pneumococcal Vaccines

- Current
 - 23-valent pneumococcal polysaccharide vaccine (PPSV23), Merck
 - 13-valent pneumococcal conjugate vaccine (PCV13), Pfizer
- New
 - **20-valent pneumococcal conjugate vaccine (PCV20), Pfizer**
 - Licensed for use in adults aged ≥ 18 years on June 8th¹
 - **15-valent pneumococcal conjugate vaccine (PCV15), Merck**
 - Licensed for use in adults aged ≥ 18 years on July 16th²

Policy options for PCV15 and PCV20 use are being evaluated separately

1. <https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-prevnar-20tm-pfizers-pneumococcal-20-valent>

2. <https://www.merck.com/news/merck-announces-u-s-fda-approval-of-vaxneuvance-pneumococcal-15-valent-conjugate-vaccine-for-the-prevention-of-invasive-pneumococcal-disease-in-adults-18-years-and-older-caused-by-15-serot/>

Current Adult Pneumococcal Vaccine Recommendations

	19–64 years	≥65 years
None of the conditions listed below	No recommendation	PCV13* based on shared clinical decision making, PPSV23 for all
Chronic medical conditions† (CMC)	PPSV23	
Cochlear implant, CSF leak	PCV13* and PPSV23 in series	PCV13* and PPSV23 in series
Immunocompromising conditions	PCV13* and PPSV23 in series, repeat PPSV23 after 5 years	

PCV13: 13-valent pneumococcal conjugate vaccine

PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking

<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

Simplified risk- and age-based recommendations being considered for each vaccine.

	19–64 years	≥65 years
	19–49 years	≥50 years
None of the conditions listed below	No recommendation	Age-Based Recommendation
Chronic medical conditions† (CMC)	Risk-Based Recommendation	
Cochlear implant, CSF leak		
Immunocompromising conditions		

†Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

The target age group for the age-base recommendation will determine the target population for the risk-based recommendation.

	19–64 years	≥65 years
	19–49 years	≥50 years
None of the conditions listed below	No recommendation	Age-Based Recommendation
Chronic medical conditions† (CMC)	Risk-Based Recommendation	
Cochlear implant, CSF leak		
Immunocompromising conditions		

†Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

Proposed Timeline of ACIP Presentations

June '21
ACIP



Sept '21
ACIP



October
'21 ACIP

Presentation on:

- **Cost-effectiveness analysis and public health impact**
- **GRADE/EtR for use of PCV15/20 in older adults**

Presentation on:

- Comparison of cost-effectiveness analyses
- GRADE/EtR for use of PCV15/20 in adults with underlying conditions

Vote on
recommendations
for both newly
licensed vaccines

Work Group Updates from the June ACIP Meeting

- Updated cost-effectiveness analysis (CEA) based on feedback
 - Added models with 50- and 65-yo cohorts (vs. 19-yo cohort only)
 - Updated key inputs for base-case
 - E.g., waning of PCV, VE assumptions, vaccine costs
 - Performed additional one-way sensitivity analysis
 - E.g., lower VE for PCV20, higher vaccine coverage for PCV only use
- Discussed risk-based use of PCV15 and PCV20
- Reviewed new CEA findings and revisited policy options

Policy Options Initially Considered for Cost-Effectiveness Analysis

PCV20 strategies

Adults with CMC/IC (risk-based)		All adults (age-based)	
Vaccine(s)	Ages	Vaccine(s)	Ages
PCV20	19–49 years	PCV20	≥50 years
PCV20+PPSV23		PCV20+PPSV23	
PCV20	19–64 years	PCV20	≥65 years
PCV20+PPSV23		PCV20+PPSV23	

PCV15 strategies

Adults with CMC/IC (risk-based)		All adults (age-based)	
Vaccine(s)	Ages	Vaccine(s)	Ages
PCV15	19–49 years	PCV15	≥50 years
PCV15+PPSV23		PCV15+PPSV23	
PCV15	19–64 years	PCV15	≥65 years
PCV15+PPSV23		PCV15+PPSV23	

PCV15 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations
≥50 years	PCV15	<ul style="list-style-type: none"> • Worse health outcome vs. current recommendation in most scenarios (both CDC and Merck models)
	PCV15+PPSV23	<ul style="list-style-type: none"> • Worse health outcome vs. current in CDC model • Improved health & increased cost in Merck model
≥65 years	PCV15	<ul style="list-style-type: none"> • Worse health outcome vs. current in CDC model • Cost-saving* in Merck model
	PCV15+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck model

***Cost-saving** indicates an intervention strategy yielded higher health outcomes and lower cost vs. current recommendations

WG selected an option that consistently yielded improved health outcomes compared to the current recommendation.

PCV20 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations
≥50 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* to worse health & lower cost vs. current (CDC models) • Improved health & increased cost in Merck and Pfizer models
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving in CDC model • Improved health & increased cost in Merck and Pfizer models
≥65 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* in CDC and Pfizer models • Cost-saving* to improved health & increased cost in Merck model
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck and Pfizer models

***Cost-saving** indicates an intervention strategy yielded higher health outcomes and lower cost vs. current recommendations

- **PCV20 use at age ≥65 years was cost-saving in most models.**
- **PCV20 use at age ≥50 years improved health outcomes in most scenarios; and was cost-saving in some CDC scenarios.**

PCV20 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations
≥50 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* to worse health & lower cost vs. current (CDC models) • Improved health & increased cost in Merck and Pfizer models
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck and Pfizer models
≥65 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* in CDC and Pfizer models • Cost-saving* to improved health & increased cost in Merck model
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck and Pfizer models

***Cost-saving** indicates an intervention strategy yielded higher health outcomes and lower cost vs. current recommendations

Adding PPSV23 yielded better health outcomes than PCV20 use alone, but with increased cost; economically less efficient

PCV20 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations
≥50 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* to worse health & lower cost vs. current (CDC models) • Improved health & increased cost in Merck and Pfizer models
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck and Pfizer models
≥65 years	PCV20	<ul style="list-style-type: none"> • Cost-saving* in CDC and Pfizer models • Cost-saving* to improved health & increased cost in Merck model
	PCV20+PPSV23	<ul style="list-style-type: none"> • Cost-saving* in CDC model • Improved health & increased cost in Merck and Pfizer models

***Cost-saving** indicates an intervention strategy yielded higher health outcomes and lower cost vs. current recommendations

WG selected the two options for PCV20 use alone since PCV20 use alone yielded better health compared to the current recommendations in most scenarios

Policy Options Under Consideration for October ACIP

PCV15 Age-based:

- Should **PCV15** be routinely recommended to US adults **≥65 years in series with PPSV23**?

PCV15 Risk-based:

- Should **PCV15 in series with PPSV23** be recommended for U.S. adults aged **19–64 years** with chronic medical conditions* or immunocompromising conditions**?

If age-based PCV20 recommendation at age ≥50 years:

- Should **PCV20** be routinely recommended to US adults aged **≥50 years**?
- Should **PCV20** be recommended for U.S. adults aged **19–49 years** with chronic medical conditions* or immunocompromising conditions**?

If age-based PCV20 recommendation at age ≥65 years:

- Should **PCV20** be routinely recommended to US adults aged **≥65 years**?
- Should **PCV20** be recommended for U.S. adults aged **19–64 years** with chronic medical conditions* or immunocompromising conditions**?

*Alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking

**Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies, CSF leak, or cochlear implant

Policy Options Under Consideration for October ACIP

PCV15 Age-based:

- Should **PCV15** be routinely recommended to US adults **≥65 years in series with PPSV23**?

PCV15 Risk-based:

- Should **PCV15 in series with PPSV23** be recommended for U.S. adults aged **19–64 years** with chronic medical conditions* or immunocompromising conditions**?

If age-based PCV20 recommendation at age ≥50 years:

- Should **PCV20** be routinely recommended to US adults aged **≥50 years**?
- Should **PCV20** be recommended for U.S. adults aged **19–49 years** with chronic medical conditions* or immunocompromising conditions**?

If age-based PCV20 recommendation at age ≥65 years:

- Should **PCV20** be routinely recommended to US adults aged **≥65 years**?
- Should **PCV20** be recommended for U.S. adults aged **19–64 years** with chronic medical conditions* or immunocompromising conditions**?

The target populations for the **age-based recommendation** will determine the target populations for the **risk-based recommendation**

Today's Pneumococcal Vaccines Session Outline

Introduction

Dr. Katherine Poehling
(ACIP, WG Chair)

Summary of economic models assessing pneumococcal vaccines in the U.S.

Dr. Andrew Leidner
(CDC/ISD)

EtR summary of risk-based PCV15 and PCV 20 use in U.S. adults

Dr. Miwako Kobayashi
(CDC/NCIRD)

Considerations for use of PCV15 and PCV20 in adults and next steps

Dr. Miwako Kobayashi
(CDC/NCIRD)