National Center for Immunization & Respiratory Diseases



Pneumococcal Vaccines

Katherine A. Poehling, MD, MPH

Pneumococcal Vaccines Work Group Chair Advisory Committee on Immunization Practices September 29, 2021

Pneumococcal Vaccines Work Group

ACIP Members

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- Keipp Talbot
- Sarah Long

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- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Thomas Weiser (IHS)
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- 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)

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- Keith Klugman (BMGF)

- Arthur Reingold (UC Berkley)

- Lorry Rubin (CCMC)

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- Richard Zimmerman (U. of Pittsburgh)

Pneumococcal Vaccines Work Group

CDC Contributors

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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 8^{th1}
 - 15-valent pneumococcal conjugate vaccine (PCV15), Merck
 - Licensed for use in adults aged ≥18 years on July 16^{th2}

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		
Immunocompromising conditions	PCV13* and PPSV23 in series, repeat PPSV23 after 5 years	PCV13* and PPSV23 in series	

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	
Chronic medical conditions† (CMC)		Age-Based Recommendation
Cochlear implant, CSF leak	Risk-Based Recommendation	
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	
Chronic medical conditions† (CMC)		Age-Based Recommendation
Cochlear implant, CSF leak	Risk-Based Recommendation	
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 costeffectiveness 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	10 10	PCV20	- ≥50 years
PCV20+PPSV23	- 19–49 years	PCV20+PPSV23	
PCV20	19–64 years	PCV20	>CE voore
PCV20+PPSV23		PCV20+PPSV23	≥65 years

PCV15 strategies

Adults with CMC/IC (risk-based)		All adults (age-based)	
Vaccine(s)	Ages	Vaccine(s)	Ages
PCV15	10 40 years	PCV15	>FO years
PCV15+PPSV23	19–49 years	PCV15+PPSV23	≥50 years
PCV15	19–64 years	PCV15	>CE voors
PCV15+PPSV23		PCV15+PPSV23	≥65 years

PCV15 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations		
>E0 years	PCV15	 Worse health outcome vs. current recommendation in most scenarios (both CDC and Merck models) 		
≥50 years	PCV15+PPSV23 • Worse health outcome vs. current in CDC model • Improved health & increased cost in Merck model			
>6E years	PCV15 • Worse health outcome vs. current in CDC model • Cost-saving* in Merck model			
≥65 years	PCV15+PPSV23	 Cost-saving* in CDC model Improved health & increased cost in Merck model 		

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

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

PCV20 Options Considered for Cost-Effectiveness Analysis

Ages	Vaccine(s)	Health outcomes and cost compared to the current recommendations	
>E0 years	PCV20	 Cost-saving* to worse health & lower cost vs. current (CDC models) Improved health & increased cost in Merck and Pfizer models 	
≥50 years	PCV20+PPSV23	 Cost-saving in CDC model Improved health & increased cost in Merck and Pfizer models 	
>65 years	PCV20	 Cost-saving* in CDC and Pfizer models Cost-saving* to improved health & increased cost in Merck model 	
≥65 years	PCV20+PPSV23	 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	
>E0 years	PCV20	 Cost-saving* to worse health & lower cost vs. current (CDC models) Improved health & increased cost in Merck and Pfizer models 	
 ≥50 years PCV20+PPSV23 Cost-saving* in CDC model Improved health & increased cost in Merck and Pfizer model 		 Cost-saving* in CDC model Improved health & increased cost in Merck and Pfizer models 	
• Cost-saving		 Cost-saving* in CDC and Pfizer models Cost-saving* to improved health & increased cost in Merck model 	
≥65 years	PCV20+PPSV23	 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	
>E0 years	PCV20	 Cost-saving* to worse health & lower cost vs. current (CDC models) Improved health & increased cost in Merck and Pfizer models 	
≥50 years PCV20+PPSV23		 Cost-saving* in CDC model Improved health & increased cost in Merck and Pfizer models 	
• Cost-saving* to improved		 Cost-saving* in CDC and Pfizer models Cost-saving* to improved health & increased cost in Merck model 	
≥65 years	PCV20+PPSV23	 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 Dr. Andrew Leidner in the U.S. (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 Dr. Miwako Kobayashi steps (CDC/NCIRD)