Evidence to Recommendations and GRADE for PCV13 Use Among Immunocompetent Adults ≥65 Years Old

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Current Adult Pneumococcal Vaccine Recommendations

- In 2012 ACIP recommended PCV13 in series with PPSV23 for adults ≥19 years old with immunocompromising conditions
  - Not currently being re-evaluated
- In 2014 ACIP recommended PCV13 in series with PPSV23 for all PCV13-naïve adults ≥65 years old with the following considerations:
  - Short term use warranted because of the remaining PCV13-type disease burden
  - Long term utility may be limited due to anticipated indirect effects from pediatric PCV13 use

Policy Question

- Should PCV13 be administered routinely to all immunocompetent adults aged ≥65 years in the context of indirect effects from pediatric PCV use experienced to date?
  - Population: Immunocompetent adults ≥65 years old, with and without chronic medical conditions
  - Intervention: PCV13 at ≥65 years old in series with PPSV23, in the context of indirect effects
  - Comparison(s): PPSV23 alone at ≥65 years old, in the context of indirect effects
  - Outcomes: invasive pneumococcal disease (IPD), pneumonia, mortality, and PCV13 safety

ACIP Evidence to Recommendation (EtR) Framework

- Statement of problem
  - Public health priority
  - Burden of disease
- Benefits and harms
  - Balance of desirable and undesirable effects
  - Certainty in evidence
- Values and preferences of target population
- Acceptability to stakeholders
- Resource use
  - Health economic analyses
- Feasibility
  - Implementation considerations

Evidence to Recommendations

- **Statement of problem**
- Benefits and harms with GRADE
- Values and preferences of target population
- Acceptability to stakeholders
- Resource use
- Feasibility

Context: Indirect Effects from Pediatric PCV Use Experienced Among Adults ≥65 Years Old

- Nine-fold reduction in vaccine-type invasive pneumococcal disease (IPD) in the US since pediatric PCV (PCV7 and PCV13 combined) introduction[1]
  - Indirect effects from PCV13 alone led to a 3 fold reduction (2010–2014)
  - Plateau in incidence since 2014 (combined direct and indirect effects)
- Similar reductions seen in IPD in Europe since pediatric PCV13 introduction[2]
  - Decline 77% in PCV7-type and 38% PCV13non7-type IPD (2009–2015)

[1]Active Bacterial Core Surveillance, https://www.cdc.gov/abcs/reports-findings/surv-reports.html, comparing 2000 to 2014
[2]Hanquet et al. 2018

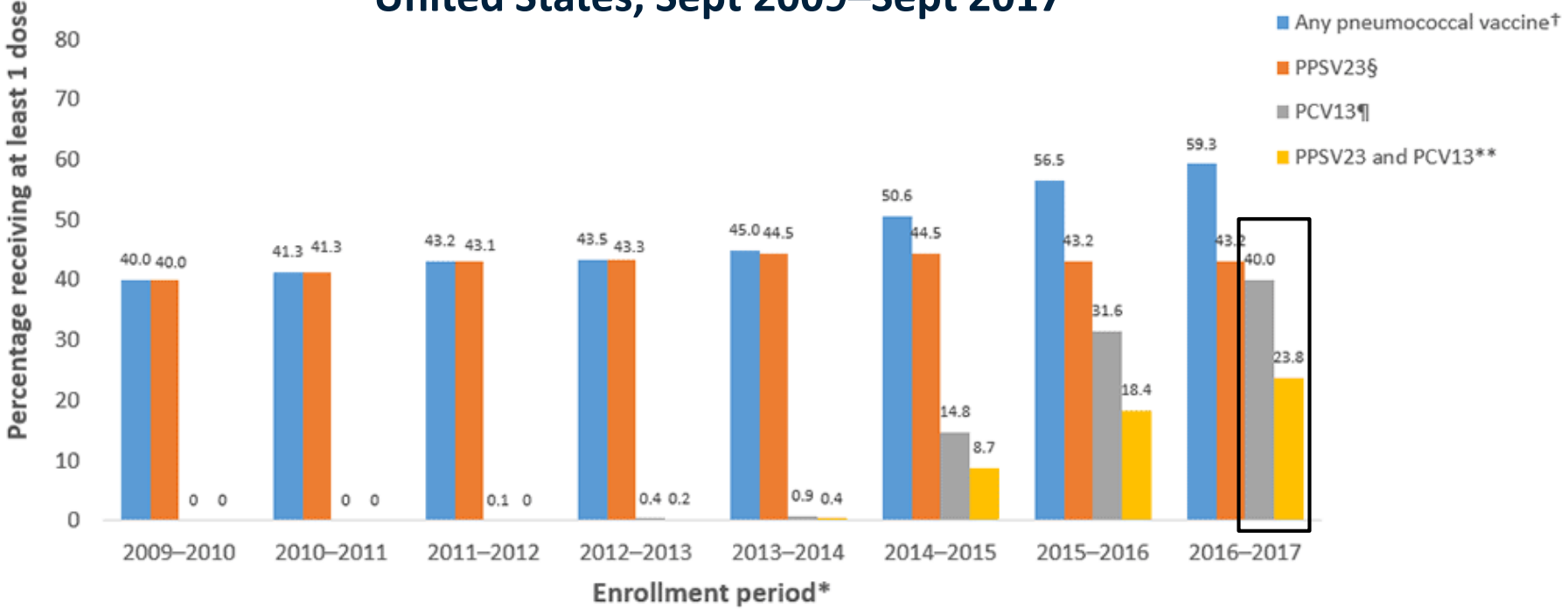
Context: Indirect Effects from Pediatric PCV Use Experienced Among Adults ≥65 Years Old

- Most studies demonstrate a reduction in all-cause pneumonia since introduction of PCVs for children in 2000[1]
  - In the U.K. PCV7-type pneumonia declined by 88% and PCV13non7-type pneumonia declined by 30% (2008–2013)[2]
  - In the U.S. since pediatric PCV13 introduction, pneumococcal pneumonia hospitalizations have declined (2010–2014)[3]

Pneumococcal Pneumonia Among Adults[3]

[1]Tsaban et al. 2017
[2]Rodrigo et al. 2015
[3]Lessa ACIP October 2018

Vaccine Coverage: Percentage of Medicare beneficiaries aged ≥65 years with claims submitted for pneumococcal vaccination — United States, Sept 2009–Sept 2017*



Each enrollment period extends from September 19 of the first year through September 18 of the subsequent year, with the exception of the 2011-12 period, which ends on October 12, 2012, corresponding to the date of publication of the first recommendation for the use of 13-valent pneumococcal conjugate vaccine (PCV13) in series with 23-valent pneumococcal polysaccharide vaccine (PPSV23) in adults with certain immunocompromising conditions; denominators include all beneficiaries continuously enrolled in Medicare Parts A and B for the duration of the enrollment period.

https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/pcv13-medicare-beneficiaries.html

Summary: Vaccine-Preventable Disease Burden (PCV13)

- PCV13-type IPD incidence among adults ≥65 years in 2015–2017
  - Incidence plateaued at 5/100,000
  - PCV13 serotypes account for 20% of all IPD plus an addition 3% including 6C
  - Common PCV13 serotypes (% of PCV13-types): 3 (66%), 19A (13%), 7F (13%), 19F (12%)
- PCV13-type pneumonia incidence among adults ≥65 years in 2015–2016
  - Incidence estimates range across studies 17[+] to 76/100,000
  - PCV13 serotypes account 3.7% of all-cause pneumonia
  - Common PCV13 serotypes (% of PCV13-types): 3 (37%), 19A (28%), 6A (12%), 5 (9%), 7F (7%)

[+]Estimated by applying the %PCV13-type IPD to the non-invasive pneumococcal pneumonia (NIPP) incidence estimate from the Surveillance for Non-invasive Pneumococcal Pneumonia (SNiPP)

Remaining PCV13-type Disease Burden Compared to Other Vaccine-Preventable Diseases

Disease	Outcome	Incidence per 100,000	Adult Vaccine Recommendation
Pneumococcal	Invasive and non-invasive PCV13-type pneumonia hospitalization among ≥65 years old	76	≥65 years old
Herpes zoster	Herpes zoster cases among 50 year olds (incidence increases with age)	530	≥50 years old
Influenza	Laboratory confirmed influenza hospitalization among ≥65 years old in the 2017-2018 season	437	Universal, all adults
Meningococcal	Serogroup B meningococcal meningitis among 16–23 year olds	0.14	Individual clinical decision for healthy 16–23 year olds

Evidence to Recommendations

- **Statement of problem—Work Group Perspective**
- Benefits and harms with GRADE
- Values and preferences of target population
- Acceptability to stakeholders
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Burden of Disease

- PCV13-type disease reduced through indirect effects but burden still remains in older adults
- Uncertainty about the burden of PCV13-type pneumococcal pneumonia
- Since 2014 recommendation, at the population level, no further reductions in IPD, and inconsistent results from pneumonia impact studies
- Question: Is the PCV13-type disease burden still of public health importance?
- Judgement:

No	*Probably no*	*Uncertain*	*Probably yes*	*Yes*

ACIP EtR Framework Elements

- Statement of problem
- **Benefits and harms with GRADE**
- Values and preferences of target population
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Policy Question

- Should PCV13 be administered routinely to all immunocompetent adults aged ≥65 years in the context of indirect effects from pediatric PCV use experienced to date?
  - Population: Immunocompetent adults ≥65 years old, with and without chronic medical conditions
  - Intervention: PCV13 at ≥65 years old in series with PPSV23, in the context of indirect effects
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Outcomes of Interest

Type	Outcomes	Importance
Benefits	PCV13-type IPD	Critical
	PCV13-type non-bacteremic pneumococcal pneumonia (NIPP)	Critical
	PCV13-type disease mortality	Critical
Harms	Serious adverse events associated with PCV13	Critical

Measures of Effect Evaluated:

- Efficacy/effectiveness: individual-level effects associated with PCV13 use (PCV13 direct effects)
- Impact: population level changes in disease outcomes associated with PCV13 use (PCV13 direct and indirect effects)

Evidence Retrieval

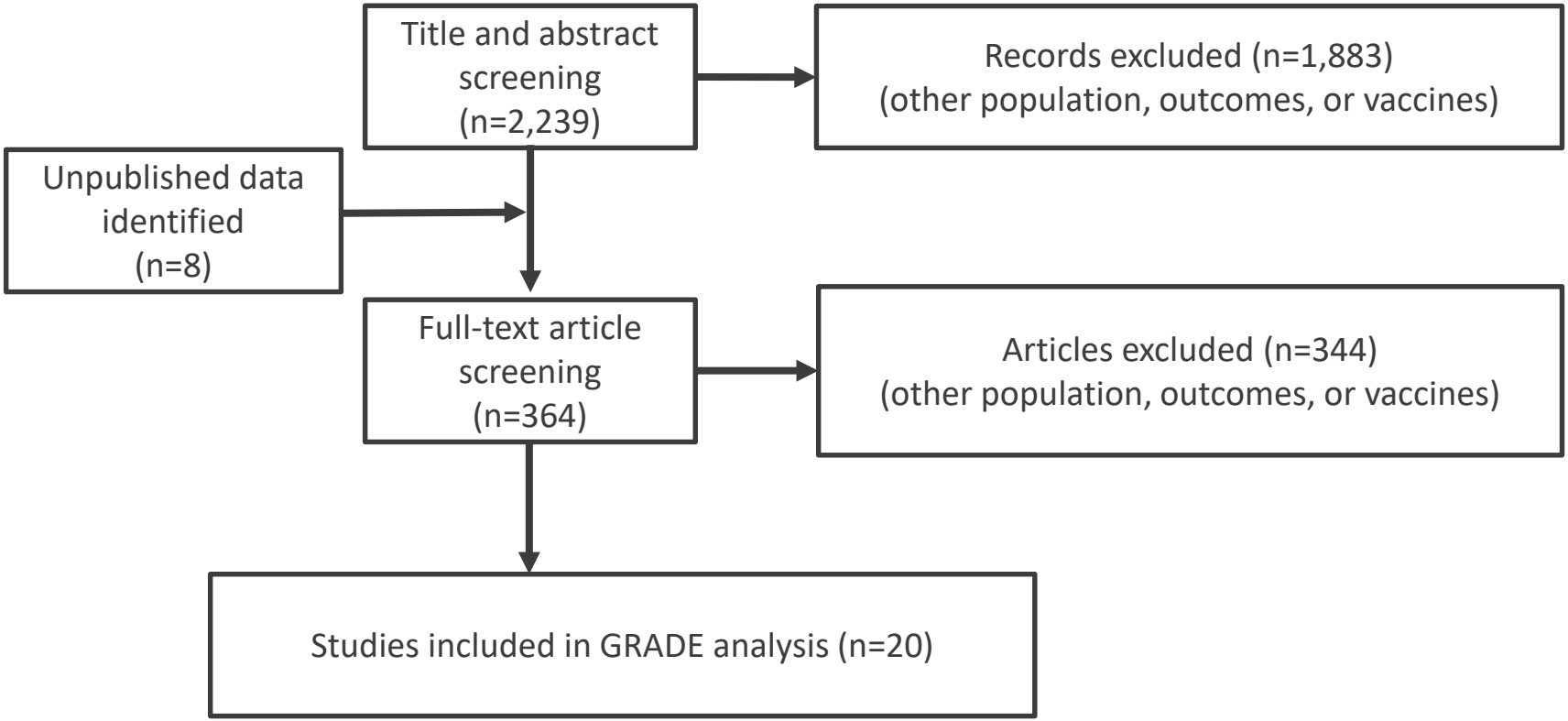
- Systematic review of studies from Medline, Embase, CINAHL, Cochrane, and clinicalstrials.gov databases using search string:
  - (Pneumococcal Vaccin*) OR (pneumococcus vaccin*) OR (pneumonia* vaccin*) OR PCV13 OR pneumovax OR PPSV23 OR prevnar* OR pnu-immune AND senior* OR aged OR older adult* OR elderly OR (over 65) OR (older 65) OR >=65 OR =>65
- Dates January 1, 2014 to July 3, 2018
- Efforts made to obtain unpublished or other relevant data
  - Presentations to the work group from industry and independent researchers

Exclusion Criteria

- Observational studies
  - Low (<20%) PCV13 coverage in the population studied
  - Not applicable to the U.S. population (i.e. low pediatric vaccine coverage, no pediatric PCV13 program, low income country)
- Safety studies
  - PCV13 co-administered with other vaccines*
  - Randomized control trials (RCTs) with comparison groups other than PPSV23 or placebo

*included in the initial review process, but because SAEs could not be attributed to a single vaccine when vaccines were co-administered we excluded these studies from GRADE

Review Process



PCV13 Efficacy, Effectiveness, and Impact on PCV13-type IPD

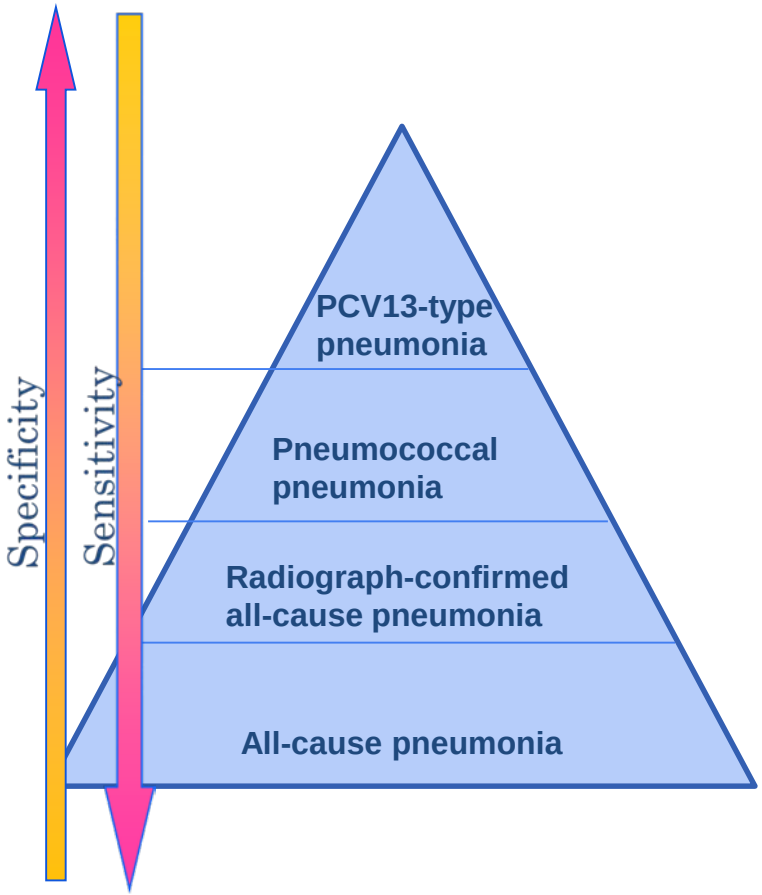
Study	Population	Method	VE	(95%CI)
Bonten [1]*	Dutch adults ≥65 years old	Community Acquired Pneumonia Immunization Trial in Adults (CAPiTA) RCT (PCV13 vs placebo) (n=84,496)	75%	(41, 91)
Gessner [2]*	Dutch adults ≥65 years old	CAPiTA RCT (PCV13 vs placebo) (n=84,496) [+]	76%	(48, 89)[+]
Pilishvili [3]	US adults ≥65 years old	Case-control; Active Bacterial Core Surveillance (ABCs) IPD cases and age- and zip code matched population-based controls (n=1,530)	59%	(11, 81)
Pilishvili [4]	US adults ≥65 years old	Case-control; ABCs IPD cases enrolled in Medicare part B matched to controls on age group, census tract, and length of enrollment in part B (n=10,851)	47%	(4, 71)
			% change	**(95%CI)**
Unpublished ABCs data [5]	US adults ≥65 years old	Pre-post analysis comparing incidence in 2013-14 vs 2016-17 (n=4,700,000)	-13%	(-26, 2)

[+]All episodes of PCV13-type IPD using modified intent-to-treat (mITT)

*Pfizer funded studies

Pneumonia Outcomes Included

- PCV13-type pneumonia – most specific outcome
  - Studies using Pfizer serotype specific urine antigen test (not commercially available)
  - Not able to detect the serotype for cases caused by non-invasive non-PCV13 types
- All-cause pneumonia – most sensitive, but least specific outcome
  - Expected measure of effect small due to smaller proportion of vaccine preventable disease
  - Replacement with non-PCV13-types can obscure impact on PCV13-type disease



PCV13 Effectiveness and Impact on Pneumonia
— PCV13-type Pneumonia Including IPD

Study	Population	Method	VE	(95%CI)
Bonten [1]*	Dutch adults ≥65 years old	CAPiTA RCT (PCV13 vs placebo) (n=84,496)	45%	(14, 65)
McLaughlin [7]*	U.S. adults ≥65 years old	Louisville cohort study [8] nested test negative design case-control; non-PCV13-type pneumonia as controls (n=2,034)	71%	(6, 91) [i]
Prato [9]*	Italian adults ≥65 years old	Test-negative design case-control; non-PCV13-type pneumonia as controls (n=186)	38%	(-131, 89) [ii]
			% change	**(95%CI)**
Swerdlow [10]*	U.S. adults ≥65 years old	Louisville cohort study [8] pre-post analysis comparing incidence in Jun2014-May2015 vs Jun2015-May2016 (n=587,499)	-32%	(-8, -49)

[i] In the primary analysis, reported here, the controls were defined as all non-PCV13-type pneumonia. In a sensitivity analysis, where controls were defined as non-PCV13-type pneumococcal pneumonia, the VE was 69% (-47, 93).

[ii] *S. pneumoniae* confirmed in nasopharyngeal, sputum, bronchoalveolar-lavage, or sterile site on polymerase chain reaction (PCR) or culture

*Pfizer funded study

PCV13 Effectiveness against Pneumonia
— PCV13-type NIPP Exclusively

Study	Population	Method	VE	(95%CI)
Webber [6]*	Dutch adults ≥65 years old	CAPiTA RCT (PCV13 vs placebo) (n=84,496)	43%	(12, 63)
McLaughlin [7]*	U.S. adults ≥65 years old	Louisville cohort study [8] nested test negative design case-control; non-PCV13-type pneumonia as controls (n=2,034)	68%	(-6, 90)

*Pfizer funded study

PCV13 Impact on Pneumonia — NIPP

Study	Population	Method	% Change	(95%CI)
Gierke [11]	US adults ≥65 years old	Pre-post analysis comparing incidence in 2013-14 vs 2015-16 (n=1,948,275)	-35%	(-14, -49) [i]

[i] No change observed from 2014–2016 (most recent year of data), p=0.5.

PCV13 Effectiveness against Pneumonia
— All-Cause Pneumonia

Study	Population	Method	VE (95%CI)
Gessner [2]*	Dutch adults ≥65 years old	CAPiTA RCT (PCV13 vs placebo) (n=84,496) [+]	8% (1, 15) [+]
Lessa [13]	U.S. adults ≥65 years old enrolled in Medicare part A/B	Cohort; discrete time survival model stratified by influenza vaccine receipt and influenza season (n=24,121,625)	6–11% (4, 14)

[+]All episodes of clinical pneumonia using modified intent-to- treat (mITT) and exact method

*Pfizer funded studies

PCV13 Efficacy and Impact on Mortality
— PCV13-type Disease Mortality

Study	Population	Method	Outcome	VE	(95%CI)
Bonten [1]*	Dutch adults ≥65 years old	RCT (PCV13 vs placebo) (n=84,496)	PCV13-type disease mortality	0%	(-1280, 93)
			All-cause mortality	-0.03%	(-5, 5)
				% change	**(95%CI)**
Unpublished ABCs data [3]	US adults ≥65 years old	Pre-post analysis comparing incidence in 2013-14 vs 2016-17 (n=4,700,000)	PCV13-type IPD mortality	2%	(-30, 49)

*Pfizer funded studies

Annual Number Needed to Vaccinate (NNV) among Adults ≥65 Years Old*

Outcome	Incidence per 100,000	Vaccine Effectiveness (VE)	(95%CI)	NNV	(95%CI)
PCV13-type IPD	5[a]	76%[b]	(48, 89)	26,300	(22,500, 41,700)
PCV13-type pneumonia, inpatient	17[c]–76[d]	43%[e]	(12, 63)	3,000–14,000	(2,100, 50,200)
PCV13-type pneumonia, outpatient	88[f]	43%[e]	(12, 63)	2,600	(1,800, 9,500)

***Calculation: NNV= 1/(incidence rate*VE)**

[a] Unpublished ABCs data [3]
[b] Bonten [1]*
[c] Gierke [11], estimated by applying the %PCV13-type IPD to the NIPP incidence estimate
[d] Swerdlow [10]*
[e] Webber [6]*
[f] Nelson et al. 2008, estimated as 5.1% of all-cause outpatient pneumonia is PCV13-type

Serious Adverse Events (SAEs) from RCTs
— PCV13 Safety Critical Outcome

Study	Population	Study Design	Observation period	% SAE among PCV13 vaccinated	PCV13 (N)	% SAE among controls	Control (N)
Bonten [1]*	Dutch adults ≥65 years old	RCT (PCV13 vs placebo)	1 month	0.8%	42,237	0.7%	42,255
Jackson [14]	US adults 55-74 years old	RCT (PCV13 with and without prior PPSV23)	6 months	2.3%	883	NA	NA
Juergens [15]*	South African adults ≥65 years old	RCT (PCV13 vs PPSV23)	43 days	0.6%	309	0.3%	301
Shiramoto [16]*	Japanese adults ≥65 years old	RCT (PCV13 vs PPSV23)	43 days	0.3%	382	0%	382

*Pfizer funded studies

Serious Adverse Events (SAEs) from Observational Studies — PCV13 Safety Critical Outcome

Study	Population	Study Design	Observation period	% SAE among PCV13 vaccinated	PCV13 (N)	% SAE among controls	Control (N)
Durando [18]*	Italian adults ≥70 years old	Cohort study	6 months	0.1%	871	NA	NA
Haber [19]	US adults ≥65 years old	Cohort study (Vaccine Adverse Events Reporting System [VAERS])	--	<0.01%	~9,269,000	NA	NA
Shiramoto [20]*	Japanese adults ≥50 years old	Cohort study	1 month	0%	271	NA	NA
Tinoco [21]*	Mexican adults ≥65 years old	Cohort study	1 month	1.2%	161	NA	NA
Tseng [22]	US adults ≥65 years old	Cohort study (PCV13 vs PPSV23)	6 months	1.2%-5.8%	5,055	2.4%-5.5%	1,124

*Pfizer funded studies

GRADE Summary

Outcome	Design	# studies [references]	Initial Evidence Type	Risk of Bias	Inconsistency	Indirectness	Imprecision	Evidence Type
Benefits								
PCV13-type invasive pneumococcal disease (IPD)		1 — [1, 2]	1	Not serious	N/A	Serious	Not serious	2
PCV13-type pneumonia	RCT	1 —[1, 2, 6]	1	Not serious	N/A	Not serious	Not serious	1
Mortality from PCV13-type disease		1 — [1]	1	Not serious	N/A	Not serious	Very serious	2
PCV13-type IPD		4 — [3-5]	3	Serious	Not serious	Serious	Not serious	4
PCV13-type pneumonia	Observational	5 — [7, 9-12]	3	Very serious	Very serious	Serious	Very serious	4
Mortality from PCV13-type disease		1 — [5]	3	Serious	N/A	Serious	Very serious	4
Harms								
Serious adverse events	RCT	4 — [1, 13-15]	1	Serious	Not Serious	Serious	N/A	2
	Observational	5 — [16-20]	3	Serious	Not Serious	Not Serious	N/A	2

Summary: PCV13 Effects Among Adults ≥65 Years Old

- PCV13 is effective/efficacious in preventing:
  - PCV13-type IPD
  - PCV13-type NIPP, but the effectiveness data inconsistent across studies
- At the population level, no impact on IPD and inconsistent data across studies for impact on pneumonia observed since 2014
- No impact on mortality demonstrated
- No concerning safety signals detected

ACIP EtR Framework Elements

- Statement of problem
- **Benefits and harms with GRADE — Work Group Perspective**
- Values and preferences of target population
- Acceptability to stakeholders
- Resource use
- Feasibility

Anticipated Desirable Effects

- Summary: PCV13 effective in preventing disease among older adults, but the remaining disease burden low and predominated by serotype 3

- Question: How substantial are the desirable anticipated effects?
- Judgement: *Minimal* | *Small* | *Moderate* | *Large* | *Don't know* | *Varies*

- Question: What is the overall certainty of this evidence for the critical outcomes?
- Judgement: *No included studies* | *4 Very low* | **3 Low** | *2 Moderate* | *1 High*

Anticipated Undesirable Effects

- Summary: No concerning safety signals have been detected

- Question: How substantial are the undesirable anticipated effects?
- Judgement: *Minimal* | *Small* | *Moderate* | *Large* | *Don't know* | *Varies*

- Question: What is the overall certainty of this evidence for the critical safety outcomes?
- Judgement: *No included studies* | *4 Very low* | *3 Low* | *2 Moderate* | *1 High*

Balance of Benefits and Harms of PCV13 Use Among Adults ≥65 Years Old

- Summary: Benefits of continued PCV13 use relatively small, but outweighed the risks, which are also small
- Question: Do the desirable effects outweigh the undesirable effects before considering values, acceptability, recourses used and feasibility?
- Judgement: *Favors intervention* | *Favors comparison* | *Favors both* | *Favors neither* | *Unclear*

ACIP EtR Framework Elements

- Statement of problem
- Benefits and harms with GRADE
- **Values and preferences of target population**
- Acceptability to stakeholders
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Values and Preferences of Older Adults

- Evidence: very limited data available
  - Very few studies focus on older adult perceptions of PCV13 specifically
    - Pneumonia perceived as severe (more so than influenza), sometimes fatal illness[1-3]
    - Low perceived personal susceptibility of pneumonia[1-2]
- Work group perspective: Potential protection against pneumonia likely outweighs the side effects of PCV13 for older adults

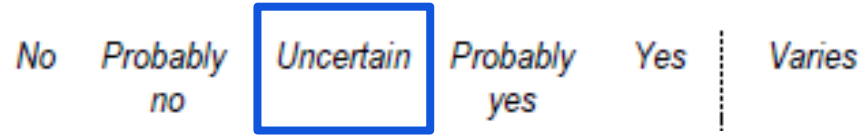
[1] Doshi et al. 2016
[2] Brown et al. 2017 (PPSV23 only)
[3] Kaljee et al. 2017

ACIP EtR Framework Elements

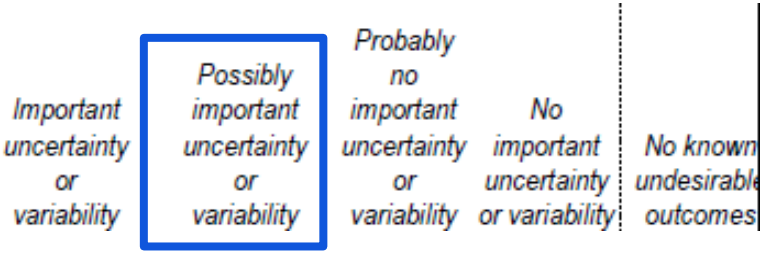
- Statement of problem
- Benefits and harms with GRADE
- **Values and preferences of target population — Work Group Perspective**
- Acceptability to stakeholders
- Resource use
- Feasibility

Values and Preferences of Older Adults

- Question: Do adults ≥65 years old feel that the desirable effects are large relative to the undesirable effects?
- Judgement:



- Question: Is there important uncertainty about or variability in how much adults ≥65 years old value the main outcomes?
- Judgement:



ACIP EtR Framework Elements

- Statement of problem
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- Values and preferences of target population
- **Acceptability to stakeholders**
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Acceptability Evidence

- Limited studies assessing acceptability among stakeholders
- Three studies reviewed by the workgroup found:
  - Current recommendations are confusing for providers[1]
  - Providers recommended continuing with current recommendation[2]
  - Keeping the current recommendations maybe best programmatically if new conjugate vaccines available soon[3]
  - Reimbursement for vaccine is still a programmatic issue[3]

[1] Hurley et al. 2018
[2] Pfizer sponsored provider survey, unpublished, 2018
[3] Association of Immunization Managers (AIM) survey, unpublished, 2018

ACIP EtR Framework Elements

- Statement of problem
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- **Acceptability to stakeholders — Work Group Perspective**
- Resource use
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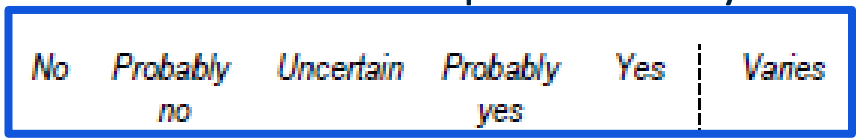
Deliberations on the Acceptability of Continued PCV13 Use Among Adults ≥65 Years Old

- Considerations for discontinuing PCV13: overall impact on PCV13-type disease from vaccinating older adults is minimal in the context of indirect effects from pediatric PCV use
- Considerations for continuing PCV13
  - PCV13 can provide individual-level protection against remaining burden of disease
  - Frequent changes in recommendations may negatively impact the perceived importance of future adult vaccine recommendations and may present implementation challenges

Assessment Acceptability of Continued PCV13 Use Among Adults ≥65 Years Old

- Question: Is the intervention acceptable to key stakeholders?
- Judgement:



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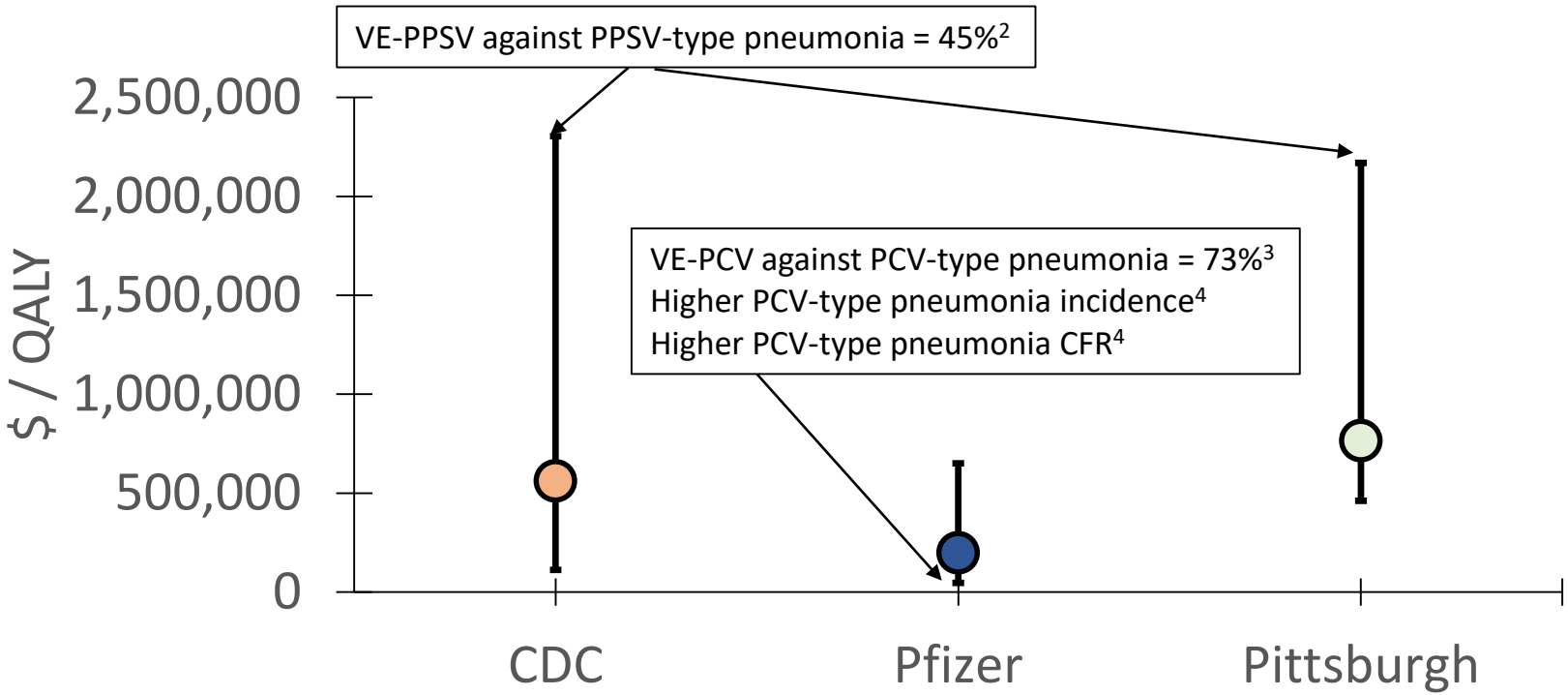
Cost-effectiveness results

Ranges from one-way and multi-way sensitivity analyses[1]



Note: Axis has changed from previous graphs of CERs to accommodate wider range in estimated CERs.

[1]These do not include results from probabilistic sensitivity analyses. [2]Schiffner-Rohe (2016), Falkenhorst (2017), Tin Tin Htar (2017).[3]McLaughlin (2018). [4]Ramirez (2017) and Pfizer Inc. internal data

Resources Used: Comparison of 2013 vs 2019

		2013 Model Projection for 2013 (2017$)	2013 Model Projection for 2019 (2017$)	2018 Model Projection for 2019 (2017$) (PCV13 VE for ST3 IPD and ST3 pneumonia 0%)	2018 Model Projection for 2019 (2017$) (PCV13 VE for ST3 IPD 26% and ST3 pneumonia 45%)
Health Outcomes	IPD Cases	-226	-163	-76	-84
	Hospitalized Pneumonia Cases	-4,961	-1,858	-2,047	-5,262
	Non-hospitalized Pneumonia Cases	-7,252	-2,715	-2,205	-5,611
	Deaths due to IPD	-33	-24	-10	-11
	Deaths due to Pneumonia	-332	-124	-79	-207
	QALYs	3,053	990	709	1,624
	Life-years	4,627	1,587	1,101	2,611
Costs (million $)	Total Cost	$199	$284	$398	$361
	Medical Costs	-$139	-$54	-$25	-$63
	Vaccine Costs	$338	$338	$423	$423
Cost Ratios ($)	Cost/QALY	$65,306	$286,855	$561,417	$222,132
	Cost/Life-year	$43,087	$178,848	$361,367	$138,122

ACIP EtR Framework Elements

- Statement of problem
- Benefits and harms with GRADE
- Values and preferences of target population
- Acceptability to stakeholders
- **Resource use — Work Group Perspective**
- Feasibility

Resources Used

- Summary: Estimated resources used higher now than in 2014
- Question: Is the intervention a reasonable and efficient use of resources?
- Judgment:

No	*Probably no*	*Uncertain*	*Probably yes*	*Yes*	*Varies*

ACIP EtR Framework Elements

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- Acceptability to stakeholders
- Resource use
- **Feasibility — Work Group Perspective**

Feasibility Considerations

- Current recommendations are complex, but have been integrated into many health care and public health systems
- Universal age-based recommendations are easier to implement than risk-based recommendations
- Medicare covers pneumococcal vaccination series (PCV13 and PPSV23) for adults ≥65 years old
  - If a change is made CMS will review the new recommendation and the supporting evidence
- Some state regulations that allow public health nurses and pharmacists to provide PCV13 are tied to ACIP recommendations
- Effective communication strategies will be needed if policy changes are considered

Feasibility

- Question: Is the current intervention feasible to continue?
- Judgement: *No* | *Probably no* | *Uncertain* | **[*Probably yes*]** | *Yes* | *Varies*

ACIP EtR Framework Elements

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Type of Recommendation

- Options for consideration
  A. We do not recommend the intervention (PCV13 in series with PPSV23 no longer recommended for immunocompetent adults ≥65 years old)
  B. We recommend the intervention for individuals based on clinical decision-making (PCV13 in series with PPSV23 would be given to immunocompetent adults ≥65 years based on patient-provider judgement)
  C. We recommend the intervention (continue PCV13 in series with PPSV23 for immunocompetent adults ≥65 years old)

Summary of Key Issues

Reasons Raised in Favor of Continuing Routine PCV13 Use	Reasons Raised in Favor of Discontinuing Routine PCV13 Use
• **PCV13 effective in preventing PCV13-type pneumococcal disease** • PCV13-type disease has been reduced through indirect effects, but not eliminated • Easier to adhere to universal prevention strategies than to risk-based ones • Frequent changes in recommendations may negatively impact the perceived importance of future adult vaccine recommendations and may present implementation challenges	• **Overall impact on PCV13-type disease from vaccinating older adults is minimal in the context of indirect effects from pediatric PCV use** • Low remaining burden of PCV13-type disease limits the potential benefit from direct effects • Lack of clear population-level impact on disease since 2014 • Judicious use of resources • Simplification of the recommendations

Next Steps — June 2019

- Provide updated summary of the Evidence to Recommendations framework to ACIP including on studies being finalized:
  - Direct effects:
    1. Mathematical model estimating PCV13 direct and indirect effects against IPD using data from Active Bacterial Core Surveillance updated
    2. Case-control studies estimating PCV13 VE against IPD updated
  - Trends by serotype: Native American Adult Pneumonia Etiology Study updated
  - Acceptability and Feasibility: Adult and Child Consortium for Health Outcomes Research and Delivery Science, primary care provider survey
- Expected ACIP vote

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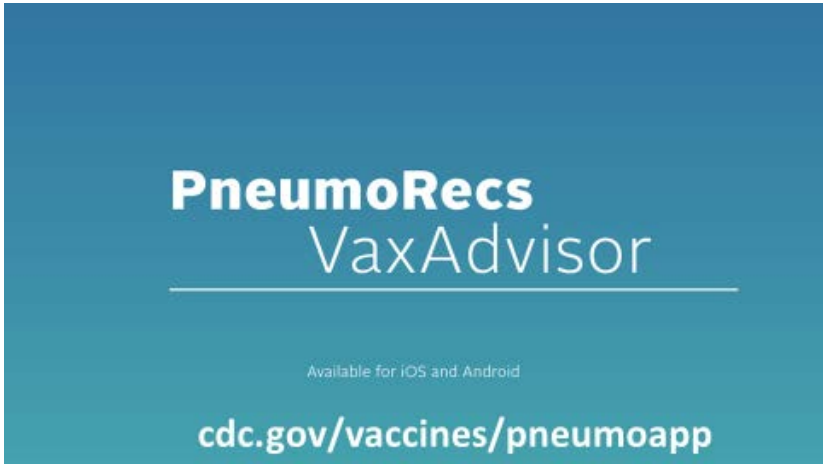
Thank you!



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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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