

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**Advisory Committee on
Immunization Practices (ACIP)**



**Summary Report
August 13, 2014
Atlanta, Georgia**

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Final – July 28, 2014

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Additional Meeting on Use of Pneumococcal Vaccines in Adults

Centers for Disease Control and Prevention
 1600 Clifton Road, NE, Atlanta, Georgia 30333
 Roybal Building 24 Room 1103A
 August 13, 2014
 2:00-4:00 p.m. Eastern Daylight Time (EDT)

This meeting will be conducted via Webinar and telephone:

URL: <https://www.mymeetings.com/nc/join/>

Conference number: PW7936898

Audience passcode: 5994905

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<u>AGENDA ITEM</u>	<u>PURPOSE</u>	<u>PRESIDER/PRESENTER(S)</u>
Wednesday, August 13 2:00 Welcome & Opening Remarks		Dr Jonathan Temte (Chair, ACIP) Dr Larry Pickering (Executive Secretary, ACIP, CDC)
2:10 Use of Pneumococcal Vaccines in Adults <ul style="list-style-type: none"> • Introduction • Routine PCV13 use among adults >65 years old: summary of evidence, cost-effectiveness, and GRADE conclusions • Considerations for PCV13 use among adults and policy options • Recommendations for PCV13 use among adults • Public comment 	Information & Discussion	Dr Nancy Bennett (ACIP, WG Chair) Ms Tamara Pilishvili (CDC/NCIRD) Ms Tamara Pilishvili (CDC/NCIRD)
Vote	Vote	Ms Tamara Pilishvili (CDC/NCIRD)
4:00 Adjourn		

Acronyms

AA	Accelerated Approval (FDA)
AAFP	American Academy of Family Physicians
ACIP	Advisory Committee on Immunization Practices
AHIP	America's Health Insurance Plans
AIM	Association of Immunization Managers
CAP	Community-Acquired Pneumonia
CAPiTA	Community-Acquired Pneumonia Immunization Trial in Adults
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
COI	Conflict of Interest
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
DVA	Department of Veterans Affairs
FDA	Food and Drug Administration
GRADE	Grading of Recommendation Assessment, Development and Evaluation
GSK	GlaxoSmithKline
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IPD	Invasive Pneumococcal Disease
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
NBP	Non-Bacteremic Pneumonia cases
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
PCV	Pneumococcal Conjugate Vaccine
QALY	Quality Adjusted Life Years
RCT	Randomized Controlled Trial
SSUAD	Serotype-Specific Urinary Antigen Detection
VE	Vaccine Effectiveness
WG	Work Group

Welcome and Introductions

Welcome

Dr. Jonathan Temte
Chair, ACIP / CDC

Dr. Larry Pickering
Executive Secretary, ACIP / CDC

Dr. Temte officially called the interim meeting of the Advisory Committee on Immunization Practices (ACIP) to order. He welcomed everyone to the teleconference, explained the process, and reviewed the agenda.

Dr. Pickering welcomed everyone to the interim meeting of ACIP, the purpose of which was to address the use of 13-valent pneumococcal conjugate vaccine (PCV13) and 23-valent polysaccharide pneumococcal vaccine (PCSD23). He indicated that the proceedings of this meeting would be accessible only by phone and web, and that following the presentations there would be time for public comment before ACIP voting members took a vote. Slides presented during this meeting will be posted on the ACIP website approximately two weeks after the meeting concludes, and the meeting minutes will be available on the website within 90 days following the meeting. Meeting minutes generally are posted on the ACIP website within 90 days of the meeting. Members of the press interested in conducting interviews with ACIP members were instructed to contact Alison Albert for assistance in arranging these interviews. Ms. Albert can be reached at 404-428-6620 or through the Internet at apalbert@cdc.gov.

Dr. Pickering indicated that the telephone operator managing this meeting would leave telephone lines open throughout the entire meeting for the 15 voting ACIP members and representatives from the Centers for Medicare and Medicaid Services (CMS), as well as for the presenters in the CDC conference room. ACIP members were instructed to mute their phones. All others on the call, including ACIP *ex officio* members, liaison representatives, and members of the general audience, were placed in listen-only mode by the operator until Dr. Temte called for discussion and public comment. Those wishing to speak were instructed to identify themselves before speaking. Dr. Pickering indicated that Dr. Temte would take questions in the following order: Voting ACIP members, followed by *ex officio* members and liaison representatives, followed by general audience and members of the public. *Ex officio* members, liaison representatives, and general audience members wishing to speak during the discussion period were instructed to signal the operator by pressing *1 on the telephone keypad to be placed in the queue.

To summarize conflict of interest provisions applicable to ACIP as noted in the ACIP Policies and Procedures manual, Dr. Pickering indicated that members of the ACIP agree to forego participation in certain activities related to vaccines during their tenure on the committee. For certain other interests that potentially enhance a member's expertise while serving on the committee, limited conflict of interest waivers are issued. Members who conduct vaccine clinical trials or who serve on data safety monitoring boards (DSMBs) may present to the committee on matters related to those specific vaccines. However, they are prohibited from participating in committee votes on issues related to those specific vaccines. Regarding other vaccines of the concerned company, a member may participate in a discussion with the *proviso* that he or she

abstains on all votes related to the vaccines of that company. It is important to note that in each meeting, ACIP members declare any conflicts of interest. Dr. Pickering called upon Dr. Temte to proceed with the roll call and the request for disclosures of any conflicts of interest from the voting ACIP members.

Dr. Temte pointed out that it was relatively unusual to have an interim ACIP meeting such as this. ACIP provides advice to the Director of CDC on matters pertaining to use of Food and Drug Administration (FDA)-licensed vaccines in the civilian population for control of vaccine-preventable diseases. ACIP is sometimes called to an interim meeting when there is new information or pressing issues, which is well within the ACIP charter. He expressed appreciation for the incredible efforts of Dr. Pickering, Dr. Jean Smith, Stephanie Thomas, and a number of others at CDC who worked diligently during the two previous weeks to plan this teleconference. Pertaining to conflict of interest and the roll call, Dr. Temte pointed out that when there are votes, it is preferable to reserve abstentions for conflicts of interest. He then called the roll, and requested that any conflicts of interest be declared:

ACIP Member	Conflicts of Interest
Dr. Belongia	Receives research funding from MedImmune
Dr. Bennett	No conflicts
Dr. Bocchini	No conflicts
Dr. Campos-Outcalt	No conflicts
Dr. Harriman	No conflicts
Dr. Harrison	No conflicts
Dr. Karron	No conflicts
Dr. Kempe	No conflicts
Ms. Pellegrini	No conflicts
Dr. Reingold	No conflicts
Dr. Riley	No conflicts
Dr. Romero	His institution receives funding from Pfizer and GlaxoSmithKline (GSK) for research
Dr. Rubin	No conflicts
Dr. Temte	No conflicts
Dr. Vázquez	No conflicts

The following *ex officio* members were also confirmed to be present on this teleconference:

Ex Officio Member	Affiliation
Drs. Hance and Chin	Centers for Medicare and Medicaid (CMS)
Dr. Geibe	Department of Defense (DoD)
Dr. Sun	Food and Drug Administration (FDA)
Dr. Houston	Health Resources and Services Administration (HRSA)
Ms. Groom	Indian Health Service (IHS)
Dr. Kinsinger	Department of Veteran's Affairs (DVA)
Dr. Gorman	National Institutes of Health (NIH)
Dr. Gellin	National Vaccine Program Office (NVPO)

Dr. Temte confirmed that a quorum was present, noting that this was the first meeting for Drs. Belongia, Riley, and Romero and that further introductions for these new members would be made during the October 2014 ACIP meeting.

Use of Pneumococcal Vaccines in Adults

Introduction

Nancy M. Bennett, MD, MS
Pneumococcal Vaccines Work Group Chair
Advisory Committee on Immunization Practices

Dr. Bennett indicated that the focus of this interim meeting was directed toward recommendations regarding 13-valent pneumococcal conjugate vaccine. She thanked the members of the Pneumococcal Vaccines Work Group (WG) who had been working very hard since the June 2014 ACIP meeting to engage in two additional meetings and many long and complicated discussions. In addition, she expressed gratitude to Ms. Tamara Pilishvili for her dedication and hard work since June to support the WG in being able to bring these recommendations forward during this interim meeting.

She reminded everyone that the terms of reference for the Pneumococcal Vaccines WG are to:

- Review current data on efficacy, effectiveness, immunogenicity, and cost-effectiveness of pneumococcal vaccines
- Review current recommendations considering up-to-date evidence, including epidemiological studies conducted post-licensure, and assess strength of the evidence
- Revise or update recommendations for pneumococcal vaccine use, as needed

The specific focus of this interim session was to address routine immunization with PCV13 for adults 65 years of age and older and to propose language for a vote.

As a reminder, PCV13 was licensed for use among adults 50 years of age and older on December 30, 2012. The FDA approved this use under the Accelerated Approval (AA) pathway based on non-inferior immunogenicity compared to PPSV23. The indications are for prevention of pneumococcal disease, including pneumonia and invasive disease, in adults 50 years of age and older; and prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. A post-approval condition of licensure included the conduct of a randomized controlled trial (RCT) of PCV13 against pneumococcal pneumonia among adults ≥ 65 years old in the Netherlands, which is known as the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA).

To summarize the discussions from the June 2014 ACIP meeting, evidence was reviewed that included the CAPiTA study results; indirect (herd) effects of PCV13 use in children; and cost-effectiveness and public health impact of different adult pneumococcal vaccination strategies. During that meeting, the WG received recommendations from the committee to consider various factors pertaining to selecting the optimal strategy; the decreasing utility in a setting of increasing herd effects; and a variety of inputs in the sensitivity analysis of the cost-effectiveness model presented in June 2014. The WG completed all of this work since June 2014 and eventually narrowed down to one strategy, which was that PCV13 be used in combination with PPSV23. Thus, the objectives for this interim meeting were to present a specific policy option and to ask the committee to vote.

Given that this has been a matter of concern for the WG as well as other ACIP members for quite some time, Dr. Bennett reviewed the reasons the WG felt that an accelerated timeline was appropriate. One reason decision-making about recommendations was deferred in 2012 was to await results of the CAPiTA study, the results of which are now available, and also to have the most current information on herd effects. Another reason is that the WG is interested in providing the benefits of PCV13 to older adults and recognizes that these benefits are likely to be greatest in the short-term. It has been almost three years since vaccine licensure, so the WG felt that it was important to move quickly toward making a recommendation now that the results of CAPiTA are available, and no additional evidence is anticipated in the near future that would affect ACIP's decision. Thus, there was no reason to extend the timeline to await additional data. The WG also viewed this as an opportunity to afford the greatest population benefit of an optimal vaccination strategy against pneumococcal disease that would include PCV13 and PPSV23. Finally, it is not likely that the process of full implementation will occur until ACIP makes the recommendation. Therefore, the WG felt that it was important to move forward as expeditiously as possible toward ACIP making a recommendation.

The proposed recommendation the WG presented during this session included the following language:

Adults >65 years of age with no previous pneumococcal vaccine (PCV13 or PPSV23)

Proposed language:

Adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first followed by a dose of PPSV23

PCV13-naïve adults >65 years of age previously vaccinated with PPSV23

Proposed language:

Adults 65 years of age or older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13.

Potential time-limited utility of routine PCV13 use among adults >65 years

Proposed language:

The recommendations for routine PCV13 use among adults >65 years old* should be re-evaluated in 2018 and revised as needed.

*if recommended by ACIP and approved by CDC Director

Dr. Bennett pointed out that the WG was proposing this simple language for the recommendation with the expectation that recommendations about intervals will appear in the guidance that accompanies these recommendations.

Routine PCV13 Use among Adults Aged >65 Years Old: Summary of Evidence, Cost Effectiveness, and GRADE Conclusions

**Tamara Pilishvili, MPH
Respiratory Diseases Branch,
National Center for Immunizations and Respiratory Diseases
Centers for Disease Control and Prevention**

Ms. Pilishvili thanked Dr. Bennett for leading the WG through these very complex discussions over the past year or so. During this session, Ms. Pilishvili reviewed a summary of evidence supporting routine PCV13 use among adults >65 years of age and Grading of Recommendation Assessment, Development and Evaluation (GRADE) conclusions. These data have been presented extensively to the committee over the past couple of years when the vaccine was licensed and again during the June 2014 ACIP meeting. The GRADE review and conclusions were also revised and presented to the committee, and the details of evidence reviewed through GRADE were in the background materials shared with the committee prior to this interim meeting. Therefore, only a brief summary was presented during this session. Ms. Pilishvili also summarized the discussion the WG had on sequential use of PCV13 and PPSV23 in terms of intervals and rationale for selecting those intervals. In addition, she reiterated the issues pertaining to the indirect effects and long-term utility of routine PCV13 use among adults and presented the proposed language for a vote.

To summarize the evidence the WG has reviewed supporting PCV13 use among adults ≥ 65 years of age, the results of the long-awaited CAPiTA trial were presented to ACIP during the June 2014 meeting. The results of the trial showed that PCV13 prevents IPD and non-bacteremic pneumonia among adults¹. This trial demonstrated efficacy of 75% against vaccine-type invasive pneumococcal disease (IPD), as well as a 45% reduction in vaccine type non-bacteremic pneumonia. In addition, the WG reviewed a large body of evidence through immunogenicity studies that showed that the immune response is non-inferior or improved for some serotypes for PCV13 or PCV7 versus PPSV23^{2,3}. The safety of PCV13 was demonstrated in clinical trials, and results show that the vaccine is safe for use among adults. The WG presented the GRADE evaluation and conclusion to the committee that demonstrated that a type 2 quality of evidence supports the use of this vaccine among adults 65 years of age or older [¹CAPiTA, June 2014 ACIP; ²Phase III trials, Pfizer, ACIP 2011, 2012; ³DeRoux et al. CID 2008, Goldblatt et al 2009].

Recent data demonstrate that vaccine-preventable disease burden remains among adults 65 years of age and older. In 2013, an estimated 2600 vaccine-type cases of IPD occurred.¹ In one year, an estimated 50,000 cases of vaccine-type inpatient community-acquired pneumonia (CAP) occurred.² In the short-term, PCV13 likely provides adequate coverage of disease causing serotypes. Approximately 20% to 25% of IPD is caused by PCV13 types¹ based on 2013 data, and approximately 10% of all CAP cases may be caused by PCV13 types.² The last estimate is based on studies using a serotype-specific urinary antigen detection (SSUAD) test, which is the same test that was applied in the CAPiTA Trial [¹Active Bacterial Core Surveillance, 2013; ² Estimate based on studies using serotype-specific urine antigen test, Pfizer].

The WG considered various strategies for PCV13 use among adults, including vaccination at ages 50, 60, and 65 years; using PCV13 instead of PPSV23; and using PCV13 in sequence with PPSV23. Consideration was given to the expected public health impact and cost-effectiveness of these various strategies. After the two meetings, the WG concluded that adding PCV13 at age 65 years to existing PPSV23 recommendations is likely to be the optimal strategy. This is based on the expected health benefits for all outcomes assessed, as well as cost-effectiveness that is comparable to other adult interventions accepted as cost-effective under the base case assumption.

The results of the analysis assessing expected public health impact of adding PCV13 at age 65 to existing polysaccharide vaccine recommendations are shown in the following table:

Health Outcomes	Change in Outcome Compared to Existing PPSV23 Recommendation
IPD	-226
Inpatient NBP	-4,961
Outpatient NBP	-7,252
Deaths (IPD)	-33
Deaths (NBP)	-332
QALYs	3,053
Life-years	4,627

This base case analysis was shared with the committee during the June 2014 meeting. Ms. Pilishvili reiterated that she was not presenting the methodology again. Briefly, this model estimates the public health impact for one cohort of 65 year olds who were followed through their lifetime and compares the new strategy of adding PCV13 at age 65 to existing PPSV recommendations, which was the comparison used for all of the analyses presented. According to the results presented in June 2014 pertaining to this base case assumption, health benefits are expected for all of the outcomes evaluated. For example, over 200 cases of IPD, around 5000 cases of in-patient NBP cases (NBP), and over 7000 cases of outpatient NBP cases are expected to be averted.

In terms of the cost-effectiveness of adding a dose of PCV13 at age 65 years to PPSV23 for the same model, for the base case assumptions, it was estimated that the cost per quality adjusted life years (QALY) gained for this strategy is approximately \$62,000 and over \$40,000 per life-year gained. These estimates fall within the range of the interventions that are accepted as cost-effective [Stoecker, ACIP June 2014].

Following the June 2014 meeting, the WG received several suggestions on the inputs for the cost-effectiveness and public health impact analyses for the model that was presented. Sensitivity analyses were conducted for some of these inputs, including shorter duration of protection for PCV13 against IPD and NBP, PPSV23 efficacy against NBP, and CMS price for vaccine doses.

For the sensitivity analysis varying the input of the waning of PCV13 protection against IPD and NBP, the assumption was no change in the efficacy during the 5 years post-vaccination based on the results of the CAPiTA trial that showed no measurable decline in efficacy for the duration of the trial. Following that a linear decline to 0% efficacy over a period of 20 years was assumed. The results of the sensitivity analysis varying the input for waning of PCV13 protection are presented in the following table:

Sensitivity analysis: waning of PCV13 protection		
Strategy: Adding PCV13 to the current schedule at age 65 vs. current strategy	June 2014 (base case)	PCV13 waning to VE 0% over 20 years
Change in Health Outcomes		
IPD	-226	-173
Hospitalized non-bacteremic pneumonia	-4,961	-4,687
Non-hospitalized non-bacteremic pneumonia	-7,252	-6,850
Deaths due to IPD	-33	-25
Deaths due to non-bacteremic pneumonia	-332	-314
Discounted QALYs	3,053	3,014
Discounted Life-years	4,627	4,526
Total Cost (Millions)		
Medical	-\$132	-\$123
Vaccine total cost	\$321	\$321
Cost Ratios		
Cost/QALY gained	62,065	65,681
Cost/Life-year gained	40,949	43,736

When the input for the waning for PCV13 was varied, the number of cases averted for all of the outcomes was reduced, but a large change was not observed for all of the outcomes. The costs per QALY gained increased from \$62,000 for base case to over \$65,000, and cost per life-year gained increased from \$40,000 to over \$43,000. However, no qualitative changes were observed in the results by varying these inputs.

An additional sensitivity analysis was performed for the input of efficacy of PPSV23 against NBP. To reiterate, zero efficacy against NBP was used for the base case analysis. The WG reviewed the available literature and published studies showing the efficacy of this vaccine against NBP. In particular, this was focused on the meta-analysis that was conducted in 2008 that showed a 73% efficacy against of PPSV¹ against NBP. However, four of the five studies that were used for that endpoint were conducted with a previous formulation of the polysaccharide vaccine, and only one of the five studies utilized the current formulation of the 23-valent vaccine. That particular study showed no efficacy against NBP². In addition, the later

meta-analysis conducted also showed no efficacy against NBP³. A recent study reported 64% efficacy against NBP in an RCT conducted among long-term care residents⁴, and another reported 48% efficacy in a large cohort study⁵. [1 Moberly et al 2008; 2 Ortquist et al; 3 Huss et al 2009; 4 Muruyama et al 2010; 5 Ochoa-Gondar et al 2014]

The WG reviewed both of these studies, and there were questions about the limited generalizability of the findings of the study in long-term care residents, methodological concerns related to the proportion of disease that was bacteremic from the cases that were used as the endpoint for the analysis for both studies, and questions about the analytic methods. Therefore, the WG decided not to alter the base case assumptions for this input. However, they did conduct a sensitivity analysis evaluating 45% efficacy for PPSV23 against NBP, equivalent to the efficacy input for the conjugate vaccine. The results of this sensitivity analysis are presented in the following table:

Strategy: Adding PCV13 to the current schedule at age 65 vs. current strategy	June 2014 (base case)	PPSV23 VE against NBP = 45%
Change in Health Outcomes		
IPD	-226	-226
Hospitalized non-bacteremic pneumonia	-4,961	-1,547
Non-hospitalized non-bacteremic pneumonia	-7,252	-2,261
Deaths due to IPD	-33	-33
Deaths due to non-bacteremic pneumonia	-332	-104
Discounted QALYs	3,053	892
Discounted Life-years	4,627	1,449
Total Cost (Millions)		
Medical	-\$132	-\$46
Vaccine total cost	\$321	\$321
Cost Ratios		
Cost/QALY gained	62,065	309,211
Cost/Life-year gained	40,949	190,286

As expected, there was a reduction in the number of pneumonia cases expected to be averted assuming an efficacy of 45%, which is equivalent to the efficacy of PCV13. The cost per QALY gained increased from over \$62,000 to over \$300,000 and the cost of life-year gained increased from over \$40,000 to over \$190,000.

In addition, the WG considered using a different source for cost of vaccine dose as recommended. Given that the population of adults 65 years of age and older are Medicare-eligible, the WG used the CMS prices instead of CDC contract prices in the sensitivity analysis. The prices per dose by source are shown on the following table:

Vaccine	CDC Cost/ Dose	CMS price (95%AWP)**
PPSV23	\$44.50	\$ 78.00
PCV13	\$89.75	\$154.00

The CMS prices represent 95% of the average wholesale price. These are the prices that are annually reported and are being set as a maximum reimbursement price for each vaccine by CMS. The inputs in the last column were used in the sensitivity analysis. In consultation with the CDC's lead Health Economist, the decision was made to use CMS price for the sensitivity

analysis only: because the analysis was done from the societal perspective, costs were intended to reflect the value of resources used to produce intervention; whereas, the CMS figure represents reimbursements, which are not likely the resource value. The results of this sensitivity analysis are presented in the following table:

	CDC Cost/ Dose (base case)	CMS price (95%AWP)** (sensitivity analysis)
Cost/QALY	62,065	110,284
Cost/Life-year saved	40,949	72,763

In this analysis, the cost per QALY changed from over \$62,000 to over \$110,000 and the cost per life-year saved change from over \$40,000 to over \$72,000.

To summarize the evidence that the WG reviewed pertaining to the sequence and intervals for PCV13 and PPSV23, the studies reviewed showed that immune response is improved when PCV13 given as the first dose^{1,2}. No studies were designed to evaluate the length of an optimal interval between PCV13 and PPSV23. Various intervals have been utilized in studies including 2, 6, or 12 months and 3-4 years^{1,2,3,4}. These individual intervals were assessed in separate studies. The conclusion that the WG drew from this evidence was that there is an improved immune response compared to baseline for the various intervals evaluated. Comparing the sequence of PCV13 followed by polysaccharide vaccine to the baseline, there was an improved response seen for all intervals. In addition, there was a non-inferior response following administration of PCV followed by PPSV23 versus PCV alone observed for all intervals. However, it is difficult to make comparisons across all studies since each used only one interval. There was one study with direct comparison of the 2-month interval in a series of PCV followed by PPSV versus a 6-month interval, which found that the immune response was equivalent between the 2-month and 6-month interval groups. However, the study did reveal increased reactogenicity with a 2-month interval⁴ [Phase III studies (004, 3005, 3010), February 2011 ACIP; ²DeRoux et al. CID 2008; ³Goldblatt et al. CID 2009; ⁴Myernik et al. CID 2008].

The WG's considerations for selection of intervals included immune response and safety. In addition, as the WG discussed intervals for PCV followed by PPSV, they were mindful of the fact that by extending this interval, the risk window for the serotypes unique to the polysaccharide vaccine might also be increased. Therefore, for that interval there will be no protection provided by the additional serotypes that are included only in the polysaccharide vaccine. The WG also took into consideration practical aspects such as timing for the next visit, and programmatic considerations such as quality measures and immunization systems.

The WG concluded that PCV13 should be given first when possible. In terms of the interval between PCV13 followed by PPSV23, the WG felt that 6 to 12 months would be appropriate. The interval for PCV13 when given post-PPSV23 for adults who previously received a polysaccharide vaccine for either an age-based or risk-based indication should be one year or longer. In addition, the WG felt that it is important to include flexibility in the guidance to providers if doses cannot be administered within the recommended window. For example, language could be included in the guidance to state that, "If a second dose cannot be given during this time-window, a dose can be given later during the next visit."

Indirect effects and the long-term utility of PCV13 have been the subject of a lot of WG discussion. The WG has presented several times to this committee on the indirect effects of PCV7 introduction in the pediatric population on PCV7-type IPD and pneumonia among adults of all age groups, showing that dramatic effects have been observed among adults of all age groups. In addition, the WG shared the most recent data with ACIP on indirect impact provided by 3 years of PCV13 use among children. PCV13 indirect effects have further reduced the proportion of adult IPD caused by PCV13 types and the pneumonia disease burden. If the impact post-PCV13 is similar to what was observed after introduction of the 7-valent vaccine, additional reductions in vaccine-type disease burden among adults are likely in the next 3 to 5 years. However, given the fact that PCV13 uptake was much more rapid than for PCV7, because of PCV7 shortages observed soon after licensing, the largest impact post-PCV13 may have already been observed due to this rapid PCV13 uptake. Nevertheless, the key point is that the expected benefits of PCV13 use among adults will likely decline over time with continued use of PCV13 among children.

The WG estimated cases potentially preventable annually among adults 65 years of age and older, which is reflected in the following table:

Outcome (PCV13 type)	2015	2019
	<ul style="list-style-type: none"> • 20% reduction due to herd effects* • PCV13 direct effects** • Coverage 10% (5%-30%) 	<ul style="list-style-type: none"> • 86% reduction due to herd effects* • PCV13 direct effects** • Coverage 30% (20%-60%)
IPD	160 (80-480)	80 (50-170)
Inpatient CAP	2,030 (1,020-6,090)	1,070 (700-2,130)
Outpatient CAP	2,970 (1,480-8,900)	1,560 (1,040-3,120)
Total CAP	5,000 (2,500-14,990)	2,630 (1,740-5,250)

*Based on post-PCV7 reductions observed between 2003 and 2009
 **Assume PCV13 VE =75% (IPD) and 45% (CAP)

Ms. Pilishvili reiterated that this table does not present the cumulative impact anticipated over the timeframe presented here, but rather shows cases potentially preventable for each year presented. It was estimated that in 2015, if a 20% additional reduction due to herd effect and coverage of 10% (with a range of 5% to 30%) were presumed, the estimated 160 IPD cases are vaccine preventable, and over 2000 cases of inpatient CAP, and nearly 3000 cases of outpatient CAP. Moving to 2019, based on the post-PCV7 experience, an 86% reduction due to herd effects occurred between 2003 and 2009. From 2013 to 2019, if the same 86% reduction due to herd effects is observed, and coverage improves to 30%, the number of preventable cases would be lower in 2019.

To summarize the WG conclusion on PCV13 use for adults 65 years of age and older, in the short-term, a recommendation for universal PCV13 use is warranted. In the long-term, continued herd effects may limit the utility of a universal recommendation. The magnitude of indirect effects is unknown, and there is uncertainty around the burden of vaccine preventable non-bacteremic pneumonia. There is an opportunity to prevent disease during the 2014-2015 respiratory disease season.

Considerations for PCV13 Use among Adults and Policy Options

Tamara Pilishvili, MPH
Respiratory Diseases Branch,
National Center for Immunizations and Respiratory Diseases
Centers for Disease Control and Prevention

Ms. Pilishvili highlighted the categories of adults under consideration for PCV13 use, as well as policy options. A recommendation is already in place for adults with immunocompromising conditions. For this discussion and the recommendation language, adults who previously received PCV13 for one of the indications based on the 2012 ACIP recommendations were not considered. The discussion and language shared with ACIP focused on adults who have not received PCV13 previously. Within this group are adults who are naïve to polysaccharide vaccine, as well as those who would have received a dose or more of the polysaccharide vaccine for an age-based or risk-based indication.

The proposed recommendation the WG presented during this session included the following language:

Adults >65 years of age with no previous pneumococcal vaccine (PCV13 or PPSV23)

Proposed language:

Adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first followed by a dose of PPSV23

Adults >65 years of age with no previous pneumococcal vaccine (PCV13 or PPSV23)

Proposed guidance on intervals for sequential use:

A dose of PPSV23 should be given 6 to 12 months following a dose of PCV13. If PPSV23 cannot be given during this time window, a dose of PPSV23 should be given during the next visit. The two vaccines should not be co-administered.

PCV13 (@ 65 years or later) + PPSV23

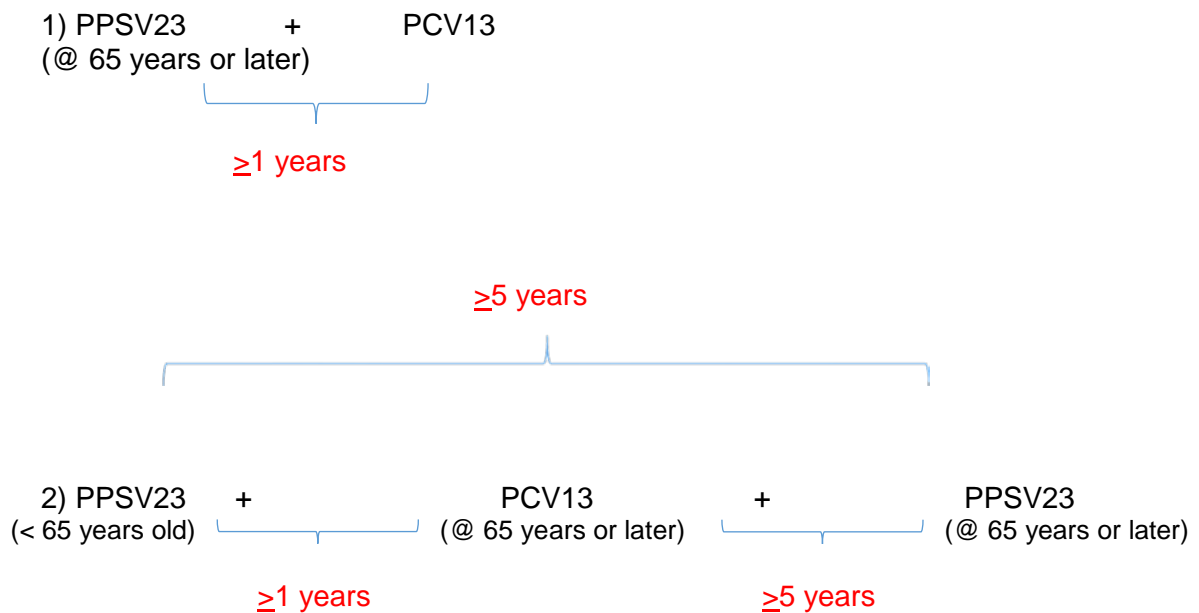

6-12 months

PCV13-naïve adults >65 years of age previously vaccinated with PPSV23**Proposed language:**

Adults 65 years of age or older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13.

PCV13-naïve adults >65 years of age previously vaccinated with PPSV23**Proposed guidance on intervals for sequential use:**

A dose of PCV13 should be given at least 1 year after the receipt of the most recent PPSV23 dose. For those for whom an additional dose of PPSV23 is indicated, such dose should be given 6 to 12 months after PCV13 and at least 5 years since the most recent dose of PPSV23.

Potential time-limited utility of routine PCV13 use among adults >65 years**Proposed language:**

The recommendations for routine PCV13 use among adults >65 years old* should be re-evaluated in 2018 and revised as needed.

*if recommended by ACIP and approved by CDC Director

The WG felt that it would be important to continue to monitor the impact of the new recommendation in the target population of adults ≥ 65 years in terms of vaccine uptake of PCV13 and PPSV23, PCV13-type IPD burden and serotype distribution for IPD cases, and PCV13-type and all CAP burden. Continued monitoring of disease trends among PCV13-naïve adults is needed to evaluate the impact of herd effects and the long-term utility of routine PCV13 use among adults in terms of PCV13-type IPD burden and serotype distribution for IPD cases among unvaccinated, and changes in PCV13-type CAP burden among individuals younger than 65 years. ACIP should be routinely updated on the changes in the vaccine-preventable disease burden among adults due to PCV13 direct and indirect effects during the next 3 years. These data should inform revisions as needed to the proposed adult PCV13 recommendations in 2018. Declining burden of PCV13-type disease among adults <65 years old due to indirect effect of vaccinating children may signal that PCV13 is no longer needed. Revised cost-effectiveness evaluation incorporating changes in disease burden, uptake, and the cost of the vaccines will help align this recommendation with other adult vaccines in use.

Discussion Points

Dr. Harrison recalled that one of the issues discussed during the last ACIP meeting focused on whether both vaccines would be covered by Medicare, but some of the background materials implied that they would not be covered until 2016. He wondered how that might impact implementation of the program.

Ms. Pilishvili asked the CMS liaisons to respond to this question.

Dr. Chin (CMS) envisioned two situations where this potentially could be influenced from a Medicare standpoint. In the short-term, there would probably be less of an impact for those who are recommended to receive a vaccine but have not previously received one under Medicare. Mostly this will impact those who have received a prior vaccination, which is likely to be the 23-valent vaccine. Currently, the CMS coverage policy is that one vaccination is permitted for all adults under Medicare. There are instances in which some individuals who are at the highest risk may receive a second vaccine under Medicare. That is specifically defined in the CMS regulations, but is not a general practice. In the immediate timeframe, it would be unlikely for those who have received a prior vaccine to receive a second vaccine. This would mainly apply to this coming season. In order for CMS to modify the coverage policy, any recommended changes from ACIP and the supporting evidence would have to be reviewed. There are policy mechanisms available if CMS decides to proceed with a change in coverage to allow a 2-vaccine regimen. However, Dr. Chin was not certain which mechanism would be the most appropriate for this type of change. There will have to be a discussion with CMS's General Council. Based on past experience, when there is a substantial change in a recommendation or coverage policy, CMS's typical approach is to use a mechanism that allows for public comment. This is typically in the form of a rule or regulation through Rulemaking. Typically, Rulemaking is entered into at the beginning of the year with a Proposed Rule usually by the summer and a Final Rule in November, which would be effective the following January. If CMS were to undergo a change, it would likely be a year before a second dose would be available for those who have been previously vaccinated. Approval of the recommendation in the fall would probably be the best timeframe in order to overlap the doses in the next cycle. That would be a year and a half for those individuals who would want a second vaccine. Depending upon the

recommendation from the committee, there is a mechanism and an opportunity for CMS to modify the coverage policy.

Dr. Harrison wondered about implications for someone who receives the first vaccine at age 65 but is turned down for the second vaccine.

Dr. Chin (CMS) responded that there is no mechanism for that scenario if such an individual wanted to get the second vaccine this year. If there is a change in ACIP's recommendation, they can address this during the next cycle. Some people will be able to get the vaccine immediately, but they could possibly get the following year if CMS makes changes.

Dr. Temte requested clarification regarding whether this meant that coverage of the cost of the vaccine and the administration fee would be denied for a Medicare recipient.

Dr. Chin (CMS) replied that currently, if an individual has received a vaccine under Medicare Part B, the second vaccine and administration fee would not typically be covered unless the individual is in the highest-risk group.

Dr. Campos-Outcalt inquired as to whether there was any chance that this vaccine could be made a Part D vaccine rather than Part B.

Dr. Chin (CMS) indicated that many vaccines that are not covered under Part B are perhaps covered under Part D. However, since CMS has a very specific section that covers pneumococcal vaccine under Part B, that is where the benefit is currently and it is unlikely to cross two programs.

Dr. Kempe said she is not concerned that someone would be denied for a year. However, she is concerned about the risk window for the PPSV23-only serotypes if this is a prolonged process. She asked about the chance that this could be a three-year process, or perhaps not occur at all.

Dr. Chin (CMS) replied that this would be based on the evidence and the recommendation. From the initial review, evidence supported by an RCT is very strong and CMS would like to see a publication from that. In addition to evidence supported by an RCT, a change in the recommendation would also be helpful. In that sense, if benefit is clearly demonstrated for the Medicare population, that benefit would drive CMS's decisions and would be a major factor in CMS making changes in the policy to improve the health of the population. From a preliminary read, this would meet those criteria. It would be unlikely that no change would be made, based on the evidence. In terms of how long it would take, the optimal timeframe would be the typical 12-month timeframe.

Ms. Pellegrini thought this was an incredibly important question, not because it should affect the actual science of the recommendation, but because it is going to have tremendous bearing on implementation from a practical perspective in terms of uptake and whether people are going to be able to afford to have this vaccine. She was troubled that as a group, ACIP was feeling a great deal of urgency to the extent of having an interim meeting, but it did not seem that CMS shared that sense of urgency based on a minimum of a one-year lag. She realized the challenge since this vaccine is in the statute and is under a different standard, but she asked the

CMS representatives whether the agency might consider issuing an interim Final Rule in January, February, or March that would allow the recommendation to go into effect and coverage to begin but still have public comment and later refinement of the Rule.

Dr. Chin (CMS) said that while it was a good suggestion, he could not immediately respond. However, he said he would present it to their director to determine the feasibility of an interim Final Rule.

Dr. Reingold said that he did not quite understand the financial aspect in terms of whether Congressional approval would be required for the extra expenditure.

Dr. Chin (CMS) responded that typically with coverage decisions, the costs for most services are not directly calculated in the manner mentioned. In rare instances, costs enter the equation, but not specifically for immunization. Those services are basically always described in statutes. This is not one of them.

Dr. Temte said he thought that of the 44 million Americans 65 years of age and older, roughly 65% have already received PPSV23, and that about 2 million Americans enter Medicare per year, which is approximately 170,000 to 180,000 per month.

Dr. Chin (CMS) confirmed this to be correct, noting that the Medicare population also includes the disabled, which adds about 8 million. The total number is roughly 50 million in the Medicare population, with roughly 42% to 44% being older adults. Enrollment is usually 1.5 to 2 million, but the “Baby Boomers” are starting to age into the population. Looking at the demographics, the peak will be up to 4 million individuals each year.

Dr. Campos-Outcalt requested clarification that if this recommendation is made sometime this fall, it is likely not to be implemented until January 2016. People were saying about a year from now, but that really would not be the case. It would be closer to 15 to 16 months. He clarified that he asked the question about Part D instead of Part B because he was not familiar with the statute on pneumococcal vaccine in terms of whether it is specific to a particular vaccine, or if it is general to disease or a bacteria. In the past, some vaccines have been put into Part D rather than Part B because of consideration of this formula that calculates the payment reduction to physicians when costs exceed a certain amount—not that it has ever been implemented. There has been an attempt to fix this, but in the past, the cost of vaccines has been a consideration. That does not count when they go into Part D.

Dr. Chin (CMS) confirmed that with CMS’s typical mechanism to make changes, that assumption would be correct. If they proceed rapidly in drafting the Rule and Regulation, it would be effective in January 2016. In terms of Part D versus Part B, Dr. Chin said he was not familiar with the way Part D prices are decided. There is a mechanism for Part D policies as well. The statute for pneumococcal vaccine is Part B and is not specific. It basically is for a pneumococcal vaccination, and does not specify any particular formulation. When a vaccine is in a program, it usually stays in that program.

Dr. Schuchat indicated that usually when ACIP makes a recommendation, there is a lag before insurance coverage picks it up regardless of whether it is public or private insurance. It turns out that the pneumococcal conjugate 13-valent vaccine would immediately be covered for Medicare beneficiaries under Part B for those who have not had a previous vaccine or who have unknown prior vaccine status. Unlike the usual recommendations that are not required by private insurance until the calendar year following publication in the *Morbidity and Mortality Weekly Report (MMWR)*, Medicare Part B uptake of a first dose of the 13-valent conjugate vaccine could be taken up immediately. The timing of the Medicare process is unclear. It could take a few different paths to implement a second dose regardless of whether it was a polysaccharide following a conjugate or vice versa. The WG suggested an interval that could be 6 to 12 months in terms of the guidance with some flexibility. To clarify the road that ACIP would be taking with some sense of urgency about what could happen this fall, a first dose of conjugate vaccine for unvaccinated people or those with unknown status would have no delay in Medicare Part B uptake because of how the statute is written. Following an ACIP vote, Medicare authorities can review the evidence, look at the process, and sort out how quickly or slowly the sequential subsequent dose language could catch up with ACIP so that there is no delay for the first dose. That was why ACIP was being convened for a vote during this interim meeting, given the 5000 cases of CAP that might be prevented if there is 10% uptake of a vaccine this year.

Dr. Temte added that basically it would apply to 15 million Americans over 65 years of age receiving Medicare benefits who have not yet received a pneumococcal vaccination. Unfortunately, many of those are either people who refuse, who are in situations where the vaccine has not been offered, or who have problems with access to care. Still, there remains a large group of individuals to whom this could apply immediately. The last figure he saw for "Baby Boomers" reaching age 65 was about 170,000 per month.

Dr. Harriman thought that CMS must know, based on their own records, whether someone has been vaccinated previously. In theory, someone with an unknown history could be rejected for vaccine coverage.

Dr. Chin (CMS) responded that it would be difficult to say how many would be rejected, if any at all, in that situation. The recommendation was written based on a clinical recommendation, so he did not know what was in place regarding the coding system.

Dr. Harriman requested clarification for the rationale for not using the CMS price for the vaccine in the analysis, and whether this is what is done when costing other vaccines in similar analyses.

Ms. Pilishvili requested that Dr. Stoecker respond as one of the Health Economists who was consulted about how the analysis should be done.

Dr. Stoecker (Tulane University) did not want to use CMS reimbursement rates as the cost, because these are reimbursements and do not necessarily reflect the resources expended to produce the vaccine. Some of this is a possible transfer payment to other parties. When taking a societal perspective, it is important to talk about the production costs of the vaccine. This is what is done with other vaccines. In general, they do not want to use transfer payments, which are payments made from one party to another that do not necessarily reflect a creation of value.

Dr. Reingold thought that for the polysaccharide, the recommendation was that people should receive a second dose 5 years after the first dose, or that at least some individuals should get a second dose. It was not clear whether that was covered under Part B or was relevant, but it seemed to him that at this point, CMS already covers some second doses of the pneumococcal vaccine. Regarding monitoring the impact of introducing the conjugate vaccine into the over 65 population, he was in favor of what was laid out on slide 27. It was not clear to him how they would disentangle the data about the indirect effects of vaccinating children versus the direct effects of vaccination the older population. He cautioned against implying with this slide that at some time in the future they would be able to disentangle that, unless someone could explain to him how that would be done.

Dr. Chin (CMS) replied that basically the revaccination in Medicare is for the group of highest risk patients. Those who are immunocompromised can get a second vaccination after 5 years. That is a small group.

Ms. Pilishvili added that the WG discussed, and everyone agreed, that it will be challenging to disentangle direct and indirect effects, and what was presented on slide 27 was just a general approach to monitor impact of age-based recommendation focused on adults 65 years of age and older. There will not be routine use of PCV13 in younger adults. Monitoring for disease among younger adults will offer some indication of the contribution of herd effects. She agreed that this would not be a clear-cut understanding of the contribution of direct versus indirect effects. They did not mean this slide to be a final proposal for a defined study that would allow for the disentanglement of herd effects from direct effects. She agreed with Dr. Reingold's comment that it will be challenging to disentangle those two effects.

Dr. Bennett agreed that this will be very complicated, but there is potential to assess the rates of disease in vaccinated people versus unvaccinated people, particularly in the EIP sites. It will not be easy, but if they can collect vaccination rates and good data on the cases that occur for IPD and NBP, they may be able to make inferences.

An inquiry was posed regarding whether the issue related to the indirect effect of vaccinating older people with PCV13 and figuring out that contribution versus the indirect effects of children receiving PCV13. Large differences in vaccine coverage during the first couple of years may help, but the issue concerns whether there will be large differences.

Dr. Bennett did not think there was a good answer for that.

Dr. Karron inquired about the timeline for reassessment and the choice of 2018 as the time to do that. This is the most expensive vaccine in the armamentarium, and it should be used as long as necessary to provide protection, but it probably should not be used beyond that time period if the benefits are found to have decreased significantly. She wondered whether some assessments should be done earlier than that, recognizing that they are difficult. Regarding the interval between PCV and PPSV, she understood that they were not being asked to vote on recommendations related to that interval and that it would be in the guidance, but it seemed from the data presented that there is not a lot of data on exactly what that interval should be. Given some of the programmatic considerations, she wondered whether there might be some

thought given to specifying a minimum interval and then allowing beyond that. For example, not less than two months or whatever that might be, rather than 6 to 12 months.

Ms. Pilishvili replied that 2018 was the date that the WG projected based on expected herd effects post-PCV7 in terms of when maximum herd effect would be expected to be observed. Potentially, that is a good time to re-evaluate the recommendation. She agreed with Dr. Karron that some studies should monitor the trends over this period of time. This should not be a one-time assessment and it can be done on a continuous basis. The WG did propose that the ACIP continuously be updated on the direct and indirect impact of the new recommendations. Regarding the 6 to 12 month interval, the WG did not have perfect evidence to allow them to say that one interval is better than another. Therefore, the practical consideration was weighted toward that 6 to 12 month interval based on comments received from healthcare providers on the WG who felt that a practical time when a patient would present for a second visit would be within that window of 6 to 12 months. At the same time, everyone on the WG felt that it would be important to allow flexibility so that providers do not interpret the 6 to 12 month interval as the only possibility for giving a subsequent dose. The WG started approaching the guidance in terms of minimum intervals similar to what is recommended for immunocompromised adults, which is worded as "8 weeks or greater." However, there was concern among the WG that this approach does not provide good guidance to providers, so they wanted a more defined interval than "8 weeks or longer." From a programmatic and provider perspective for immunization services and quality measures, the WG members felt that it would be useful to provide a more defined interval in the primary language.

Dr. Belongia noted that he was somewhat hesitant to speak up, since he is new to ACIP and does not have all of the history that other members have. He said he had reviewed the videos of the meeting, gone over the slides, and read a lot of the original references. He expressed concern that this analysis may be rushed and may not be sufficiently robust to support a change in national policy. The WG did a tremendous job given their timeframe, but due to the complexity of the issue, it seemed impossible to fully understand all of the implications in less than two months. Three issues in particular concerned him in terms of the impact on burden of illness and cost analysis versus the CAPiTA study itself. The entire analysis essentially hinges on the assumption that 10% of all CAP is due to vaccine-type pneumococcal disease. That assumption is based on 4 studies, 3 of which are unpublished and all of which use the proprietary Pfizer diagnostic urine test to identify vaccine-type cases of pneumococcal disease. Second, the results from those studies, which are using highly validated cases of confirmed pneumonia, are extrapolated to incidence rates that are based merely on ICD codes, which Dr. Belongia was positive have a substantially lower predictive value compared to a research-based case definition for pneumonia. Third, the assumption in the base case of vaccine efficacy of PPSV23 against pneumococcal pneumonia was zero. He acknowledged that the sensitivity analyses were conducted using 45%, but in that analysis everything else was held at the base level. Some lessons were learned from the influenza vaccine in terms of the dangers of relying on non-specific outcomes to estimate the impact of an intervention, but it seemed that this analysis was doing that. At this point, he did not feel that there was enough evidence to make that judgment.

Dr. Bennett agreed that there are a lot of questions about moving forward with this. The weaknesses that Dr. Belongia pointed out in the data are not likely to be resolved in a timely manner. These are profound issues with respect to the knowledge of pneumonia, and they have been issues with pneumococcal vaccine for the last 25 to 30 years. She agreed that the data are not perfect, and the analysis is therefore not perfect. However, in the context of the last 25 to 30 years, they are moving toward better knowledge, but it will not be immediate. The WG concluded that the longer they wait, the less they afford people over the age of 65 protection from pneumococcal disease. It is not clear when these questions will be answered in a satisfactory way, and the WG feels that there will not be helpful information forthcoming.

Dr. Belongia appreciated these comments, noting that data were also reported for hospitalized NBP, which should be a much more specific type of outcome than taking all-cause pneumonia. Similarly in the outpatient setting, it is a wild guess as to what proportion of ICD-coded pneumonia actually represents pneumococcal pneumonia. He thought it would be possible to perform additional analyses to assess some inputs like IPD and hospitalized NBP and then use some sensitivity analyses assuming different vaccine-type proportions to determine whether these findings are robust, and whether this is the best intervention compared to all of the possible interventions that the WG considered, but with a range of scenarios.

Referring to slide 3 from the CAPiTA trial showing 45% efficacy of PCV13 in prevention of NBP, Dr. Temte noted that the study was conducted in the Netherlands, where he did not believe they use a PPSV23 or equivalent vaccine in the elderly, and the patients recruited for the study were all pneumococcal-vaccine naïve. He thought that this approach maximized the benefit. He wondered whether this was considered by the WG or in the cost-effectiveness analysis.

Ms. Pilishvili confirmed that PPSV is not routinely recommended in the Netherlands and is not being used. This was a placebo-controlled trial in adults who were naïve to the polysaccharide vaccine. This was accounted for in the GRADE review of the evidence. The comparison of interest for the GRADE review was comparing PCV to the current standard of care, polysaccharide vaccine; whereas, the trial compared it to placebo. Therefore, the evidence was downgraded for not having the correct comparison group when extrapolating CAPiTA results. The overall conclusion was that there is still strong type 2 evidence.

Dr. Campos-Outcalt thought the 4th bullet in slide 3 was worded incorrectly, as type 2 or level 2 evidence is moderate, not strong. He was not sure where the term “strong” came from and he did not believe it was in the methodology. The categories are: High, Moderate, Low, and Very Low. Level 2 is “moderate,” and he thought the slide needed to be corrected. He wondered what was known about this vaccine and co-administration in this age group, particularly regarding adverse reactions and the benefits of this vaccine and others that might be co-administered (e.g., zoster vaccine, Tdap, and influenza). In childhood vaccines, this is one of the things that is tested.

Dr. Temte inquired as to what extent doses of pneumococcal vaccine are coupled with influenza vaccination for those 65 years of age and older in this country. A lot of clinics, his included, will have standing orders for both pneumococcal and influenza vaccine during the season when influenza immunization is administered. Standing orders tend to work very well.

Dr. Schuchat responded that the number was not readily available, but they can get it in the future. As a reminder, in the CAPiTA study, many of the individuals in the placebo and pneumococcal conjugate arm received influenza vaccine with their investigational vaccine. Quite a bit of adult immunization occurs in conjunction with influenza vaccination, so it is not unlikely that a lot of polysaccharide doses given to people 65 and over would be given with annual influenza vaccine.

Dr. Bennett emphasized that one of the reasons the WG is eager to move forward with this recommendation is the hope that PCV13 will be given as the first dose with influenza vaccine. She indicated that many of the people in CAPiTA received both vaccines.

Dr. Campos-Outcalt emphasized that this was entirely different from actually studying the efficacy question, so the effect of co-administration of influenza and pneumococcal vaccine on either is not known.

Dr. Bennett said that she did not believe that the efficacy of influenza vaccine was studied at the same time.

Dr. Schuchat reminded everyone that for those 65 years and older, the Tdap recommendation is based on fairly indirect information. The 13-valent vaccine is now being considered based on a randomized placebo-controlled trial in 85,000 people. Much of the vaccine is being co-administered with influenza vaccine, so it is likely to mimic the performance of the vaccine when given with influenza. CDC can check with the company about the data they have developed, if there are data, about immunogenicity results for PCV13 given at the same time as other adult vaccines. She said she was not personally familiar with the literature on PPSV23 co-administered with other vaccines, so CDC can look into this. Again, the CAPiTA results would be mimicking influenza and PCV13 co-administration with clinical protection data.

Dr. Campos-Outcalt said it seemed like they should be providing some guidance on this question, and it stood out that they were not saying anything about this even though they do for most other vaccines.

Ms. Pilishvili replied that they could review more details of the data and include it in the guidance for the language of co-administration of this vaccine with other vaccines. She reminded everyone that when the immunogenicity data were presented to ACIP initially, data on co-administration with influenza vaccination were also shared. The bottom line conclusions were that non-inferiority was demonstrated by applying the statistical tests when PCV was co-administered with influenza vaccine versus separately. But, a lower response was observed for some serotypes. However, she cautioned that the WG did not recommend this vaccine based on immunogenicity data before the CAPiTA trial results were available because the correlate of protection among adults was not understood. In other words, when more antibody response was seen for some serotypes with co-administration with the influenza vaccine, there was no way of translating that into clinical protection.

Given the perceived urgency and the fact that the CAPiTA findings are very important, Dr. Belongia wondered whether anyone had considered the possibility of issuing an interim guidance that PCV13 may be used in lieu of PPSV23 in people over 65, and that ACIP will issue more comprehensive recommendations in 2015 regarding the use of those two vaccines. That approach would buy some more time to carefully consider the issues.

Dr. Bennett responded that the WG briefly discussed an interim recommendation, but they were not confident that they would have a pathway to a more firm recommendation than is already available. Also, there was concern about implementation. As discussed earlier, Medicare moving forward with coverage for two pneumococcal vaccines depends upon ACIP making a recommendation, and the WG felt that it was important to move forward.

Regarding the spacing of PCV13 after PPSV23, Dr. Campos-Outcalt wondered what was known about the optimal interval and what it was based on. Two-thirds of people over 65 have had PPSV23 and now are recommended to receive a PCV13, although they probably will not receive it for a year to a year and a half.

As with the interval of PCV13 followed by PPSV23, Ms. Pilishvili indicated that no studies have assessed the optimal waiting interval for adults who have previously received polysaccharide vaccine to receive the conjugate vaccine. The interval was based on all studies that are available in terms of intervals that have been evaluated. She reminded the committee that this evidence was reviewed previously, and a similar recommendation was made for immunocompromised adults stating that waiting one year or longer was optimal for following the polysaccharide vaccine with the conjugate vaccine. Again, the data are also limited for that interval.

Referring to slide 23 regarding the optimal sequence of 6 to 12 months following a dose of PCV13, Dr. Campos-Outcalt wondered if less than 6 months would be acceptable. That is, is there a minimum time that has to pass?

Ms. Pilishvili reiterated that minimum time was incorporated in the initial language. However, the WG did not like the open-ended “8 weeks or later,” but certainly a minimum interval could be indicated for providers in the guidance language. Intervals as short as 8 weeks have been evaluated with an adequate immune response. The study she shared that assessed a 2-month versus 6-month interval showed that immunogenicity was somewhat higher with the 2-month or 8-week interval.

Dr. Campos-Outcalt suggested revising the language to say “no earlier than 2 months,” because stating the minimal interval is important.

Ms. Pilishvili emphasized that the WG discussed this and felt that including the interval in the recommendation wording might be problematic. The way minimum intervals are usually interpreted, if a vaccine is given at an interval sooner than 8 weeks, the adult dose is invalidated and repeat vaccination is recommended. There are no data to show that if the vaccine is given 2 days before the 8-week minimum interval that it should be repeated, or that there is any value or potential harm in repeating that dose. Therefore, the WG tried to avoid having the 8-week minimum interval defined in the guidance. That was one of the reasons the WG preferred not to include a minimum interval in the language.

Dr. Kempe said her impression was that the 2-month interval was not optimal because of increased reactogenicity.

Ms. Pilishvili confirmed that the WG discarded a 2-month or 8-week interval because of the one study that showed increased reactogenicity. However, specifying anything other than 8 weeks as a minimum was avoided for the reasons outlined earlier.

Dr. Bennett referred to slide 15 showing considerations for the selection of intervals. One of the reasons the WG elected to include the intervals in the guidance rather than the recommendation was in order to refine the language about the intervals.

Dr. Doskey (AHIP) inquired as to whether CDC had ensured vaccine supply from the manufacturer if the recommendation was extended as proposed.

Ms. Pilishvili called upon the manufacturers to comment. She reminded everyone that the manufacturers commented on this during the June 2014 ACIP meeting, when they indicated that they anticipated that a sufficient supply is available if this recommendation is made. Dr. Schuchat confirmed that Pfizer publicly commented during the June meeting that they anticipate supply in all projections, and that this should not be a constraint.

Dr. Temte asked Dr. Doskey if he had any idea how many people over the age of 65 have co-insurance through which vaccine would be covered. In his practice, those are the people who easily get zoster coverage.

Dr. Doskey (AHIP) said that while he did not readily have the information, he could find out.

Dr. Loehr (AAFP) indicated that there are already people who will be handled under the normal policy of PPSV23 who would have protection. He expressed concern as a practicing family physician, as he has a 67-year old in his office who already had PPSV23 two years ago, and he cannot tell this individual whether Medicare will pay for PCV13. The vaccine costs \$135/dose, which is a sizeable concern, and this patient probably will not get the vaccine because of the cost. He was pleased that the Pneumococcal WG included a sunset evaluation. Based on other vaccine recommendations, the implication is that 6 to 12 months will be interpreted as a minimum interval even if there are indications elsewhere in the guidance.

Dr. Moore (AIM) expressed her desire to determine how the immunization program can best support clinicians implementing this recommendation for the Medicare population. Her concern is that implementation will be extremely limited because of the hesitation to administer something for which they might not be reimbursed. She thought that PCV13 was already covered under Medicare Part B, because CMS pays for a single dose of pneumococcal vaccine regardless of the formulation. The vote during this session would make explicit ACIP's recommendation that the one dose should be PCV13 for those who have zero or unknown doses administered since enrolling in Medicare, which is 1 in 3 Medicare patients. The ACIP-recommended second dose would be administered if and when CMS changes its regulations to permit reimbursement for a second dose, and the earliest estimated date for that would be January 2016. If this is needed to make this happen, she supported moving forward so that the CMS process could get underway. She inquired as to whether there was any estimate of the

risk that the CMS change would not happen, or that the second dose coverage effective date could be delayed well beyond early January 2016, and whether this would pose any risk for those who received the PCV13 vaccine first and then had an open-ended time for getting the second dose.

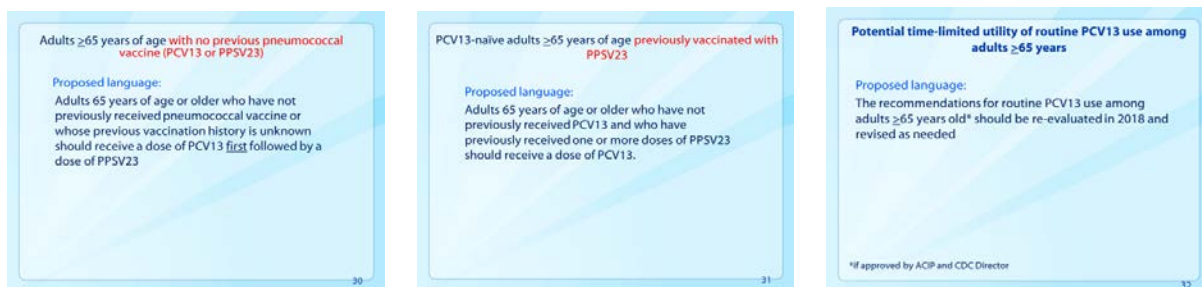
Dr. Schuchat confirmed that Dr. Moore's understanding of the Medicare coverage already in effect was correct. She invited Medicare experts to comment on the probability of delays; however, she did not believe they would be able to predict what would unfold over the years ahead. There is a Medicare process to update the guidance based on recommendations.

Dr. Kempe reminded everyone that Dr. Chin did comment on this earlier, and indicated that while he could not guarantee it, he thought that the January 2016 date could be assumed. She was also concerned with whether there was a reasonable chance this would occur, but she felt reassured by Dr. Chin's response.

Dr. Temte noted that the meeting was nearing the end of its allotted timeframe, and he inquired as to whether anyone was willing to make a motion.

Dr. Bennett made a motion that ACIP vote to recommend PCV13 for adults over the age of 65, and that the WG anticipated a vote on the combined package.

Dr. Temte requested that the slides with the proposed language be shown again (slides 30, 31, 32), and reminded everyone that no direct comments would be made on the intervals in the recommendation, but would be included in the guidance based on discussions during a number of ACIP meetings and review by the WG.



Dr. Reingold suggested inserting a comma after word "first" on slide 30.

Dr. Rubin seconded the motion.

Dr. Temte called for any additional and/or public comments.

Regarding the language of the proposed recommendation, Dr. Jodar (Pfizer) indicated that Pfizer is concerned about the specific mention of a date of 2018. Evaluating the effectiveness of the vaccine and the herd protective effects on a regular basis is warranted; however, stating a specific date is problematic considering the low immunization rate and the difficulty of increasing uptake. He wondered whether the WG was concerned that healthcare professionals might wait until 2018. It would be unprecedented for ACIP to specify a date, especially since constant evaluation of effectiveness and herd protection is being done on regular basis.

Bob Blancato (NANASP) indicated that he was present during the June 2014 ACIP, and he wanted to repeat some points. The National Association of Nutrition and Aging Service Programs (NANASP) serves older people daily with meals in homes and community centers and strongly associates themselves with comments on use of pneumococcal vaccines, especially older adults. NANASP is concerned that too few people are taking advantage of this vaccine, and is sensitive to the issue about Medicare and hopes that ACIP's vote will expedite activity on the part of Medicare for expanding coverage. NANASP's concern is very basic. If someone comes to their program and has influenza, it can spread rapidly and create major problems in NANASP's daily operations. On behalf of older people served on a daily basis, NANASP applauds ACIP's efforts and hopes the vote comes out in a way that supports broader use of this vaccine.

Virginia Ladd (AARDA) reiterated her comments from earlier in the summer on behalf of the American Autoimmune Related Diseases Association (AARDA), which represents 50 million Americans with autoimmune disease, many of whom have been compromised either by therapy or by disease. She emphasized that herd immunity is an important factor for this population because they are compromised or are taking immunocompromising therapy.

Alice Knapp (Pasco County Health Department) indicated that she did not have a question, but requested that Slide 30 be shown again.

Dr. Mel Kohn (Merck) ensured that the committee was aware that there may be some limitations on manufacturers' ability to discuss this kind of sequential vaccination. These intervals are not aligned with what is on the label for either vaccine and might represent an off-label recommendation. He wondered if FDA might want to comment on that. Many issues around implementation were raised during this meeting, and he expressed personal concern about them. They should assess the completion of series of vaccines outside of the pediatric population. Unfortunately, the track record as a nation was not encouraging in that regard. Therefore, he was concerned that people would get one vaccine and not the other. He wanted to make sure that point was clearly called out for ACIP to consider.

Dr. Sun (FDA) said that the labels make no reference to the other vaccine, so he did not think this would necessarily preclude an ACIP recommendation for sequential use of the two products. Further, because no claims are made within labels about other competitors' vaccines, he did not see this as a problem.

Dr. Temte read slides 30, 31, and 32 reflecting the full recommendation for which the motion was made to ensure that everyone was clear about the motion.

Dr. Campos-Outcalt requested further clarifications about Dr. Temte's earlier comments regarding abstentions, as he was unaware of any particular rules that would prevent this. Dr. Temte replied that there are no rules for abstentions; however, traditionally there has been an effort to minimize abstentions and make "yes" or "no" votes. Abstentions are typically used in situations where there is a conflict of interest. Based on the ACIP charter and other rules of order, there are no direct limitations.

Vote: Use of Pneumococcal Vaccines in Adults 65 Years of Age and Older

Dr. Bennett made a motion to accept the three components of the recommendation for use of pneumococcal vaccines in adults ≥ 65 years of age as a package as proposed. Dr. Rubin seconded the motion. The motion carried with 13 affirmative votes, 2 negative votes, and 0 abstentions. The disposition of the vote was as follows:

13 Favored: Bennett, Bocchini, Harriman, Harrison, Karron, Kempe, Pellegrini, Romero, Reingold, Riley, Rubin, Temte, and Vazquez
2 Opposed: Belongia and Campos-Outcalt
0 Abstained: N/A

Dr. Bennett thanked everyone, acknowledging that this was a huge amount to ask from CDC staff and ACIP members. The WG is very grateful for everyone's hard work, and for allowing this meeting to occur.

Dr. Temte expressed appreciation for all of the efforts from CDC staff and Dr. Pickering for helping to organize and operationalize a meeting, which is difficult over the phone and through web mediums with over 500 people attending. He also expressed appreciation for the liaisons and ACIP members who took a large amount of time out of the day for this.

Dr. Pickering reported that ultimately, 1142 participants were on the teleconference. This vote was very important and interesting for everyone, and he expressed his hope that the majority of people would be happy. He thanked everyone, emphasizing that this was a combined effort by a lot of high quality people.

In conclusion, Dr. Temte said he still felt very strongly that this is a large problem in terms of a vaccine-preventable disease, especially the older adult population. Regardless of the vaccine being used, this vaccine is still greatly underutilized not only for adults over 65 years of age, but also for younger adults with ongoing medical indications. This at least provides a signal that ACIP takes seriously the issue of health care and prevention in older adults, and at least strives to do the best they can for this population. He thanked everyone for their time and attention and wished them a very good rest of the day.



Certification

Upon reviewing the foregoing version of the August 13, 2014 ACIP meeting minutes, Dr. Jonathan Temte, ACIP Chair, certified that to the best of his knowledge, they are accurate and complete. His original, signed certification is on file with the Management Analysis and Services Office (MASO) of CDC.

A 3D-style header bar with a blue gradient and a white border, containing the text "ACIP Membership Roster" in white, bold, sans-serif font.

ACIP Membership Roster

CHAIR

TEMTE, Jonathan L., MD, PhD
Professor of Family Medicine
University of Wisconsin School of Medicine and Public Health
Madison, WI
Term: 07/01/2011-06/30/2015

EXECUTIVE SECRETARY

PICKERING, Larry K., MD
Senior Advisor to the Director
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases
Atlanta, GA

MEMBERS

BENNETT, Nancy, MD, MS
Professor of Medicine and Community and Preventive Medicine
University of Rochester School of Medicine and Dentistry
Rochester, NY
Term: 07/01/2011-06/30/2015

BELONGIA, Edward, MD
Director
Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Foundation
Marshfield, WI
Term: 07/01/2014-06/30/2018

BOCCHINI, Joseph A., Jr., MD
Professor and Chairman
Department of Pediatrics
Louisiana State University Health Sciences Center
Shreveport, LA
Term: 07/01/2011-06/30/2015

CAMPOS-OUTCALT, Douglas, MD, MPA
Chair
Department of Family, Community and Preventive Medicine
University of Arizona College of Medicine - Phoenix
Phoenix, AZ
Term: 07/01/2011-06/30/2015

HARRIMAN, Kathleen, PhD, MPH, RN
Chief, Vaccine Preventable Disease Epidemiology Section
Immunization Branch
California Department of Public Health
Richmond, CA
Term: 07/01/2012 – 06/30/2016

HARRISON, Lee H., MD
Professor of Medicine and Epidemiology
Infectious Diseases Epidemiology Research Unit
University of Pittsburgh
Pittsburgh, PA
Term: 07/01/2012 – 06/30/2016

KARRON, Ruth A., MD
Professor and Director
Center for Immunization Research
Department of International Health
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD
Term: 07/01/2012 – 06/30/2016

KEMPE, Allison, MD, MPH
Professor of Pediatrics
Director of Primary Care Fellowship
University of Colorado School of Medicine
Director of Research
Division of General Academic Pediatrics
Director of Children's Outcomes Research Program
The Children's Hospital of Denver
Denver, CO
Term: 07/01/2013 - 06/30/2017

PELLEGRINI, Cynthia
Senior Vice President
Public Policy and Government Affairs
March of Dimes
Washington, DC
Term: 07/01/2013-06/30/2017

REINGOLD, Arthur L., MD
Professor of Epidemiology
Edward Penhoet Distinguished for Global Health and Infectious Disease
Associate Dean for Research
School of Public Health
University of California
Berkeley, CA
Term: 07/01/2013-06/30/2017

RILEY, Laura E., MD
Associate Professor, Obstetrics, Gynecology and Reproductive Medicine
Harvard Medical School
Maternal Fetal Medicine
Massachusetts General Hospital
Boston, MA
Term: 07/01/2014-06/30/2018

ROMERO, José R., MD, FAAP
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section University of Arkansas for Medical
Sciences and Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Hospital Research Institute
Little Rock, AR
Term: 07/01/2014-06/30/2018

RUBIN, Lorry, MD
Director
Pediatric Infectious Diseases
Steven and Alexandra Cohen Children's Medical Center of New York
North Shore-Long Island Jewish Health System
New Hyde Park, NY
Professor of Pediatrics, Hofstra-North Shore LIJ School of Medicine
Hempstead, NY
Term: 07/01/2012 – 06/30/2016

VÁZQUEZ, Marietta, MD
Associate Professor of Pediatrics
Department of Pediatrics
Yale University School of Medicine
New Haven, CT
Term: 07/01/2011-06/30/2015

EX OFFICIO MEMBERS

Centers for Medicare and Medicaid Services (CMS)

HANCE, Mary Beth
Senior Policy Advisor
Division of Quality, Evaluations and Health Outcomes
Children and Adults Health Programs Group
Center for Medicaid, CHIP and Survey & Certification
Centers for Medicare and Medicaid Services
Baltimore, MD

Department of Defense (DoD)

GEIBE, Jesse, MD, MPH, MBA
CDR, Medical Corps
Defense Department Liaison Officer
Centers for Disease Control and Prevention
Atlanta, GA

Department of Veterans Affairs (DVA)

KINSINGER, Linda S., MD, MPH
Chief Consultant for Preventive Medicine
Office of Patient Care Services
National Center for Health Promotion and Disease Prevention
Durham, North Carolina

Food and Drug Administration (FDA)

SUN, Wellington, MD
Director, Division of Vaccines and Related Product Applications
Office of Vaccines Research and Review
Food and Drug Administration
Rockville, MD

Health Resources and Services Administration (HRSA)

HOUSTON, A. Melissa, MD, MPH, FAAP
Chief Medical Officer
Division of Vaccine Injury Compensation
Health Resources and Services Administration
Rockville, MD

Indian Health Service (IHS)

GROOM, Amy, MPH
Immunization Program Manager
Indian Health Service
Albuquerque, NM

National Vaccine Program Office (NVPO)

GELLIN, Bruce, MD, MPH
Director
National Vaccine Program Office
Department of HHS, Public Health and Science
Washington, DC

National Institutes of Health (NIH)

GORMAN, Richard L., MD
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases/NIAID
National Institute of Health
Bethesda, MD

LIAISON REPRESENTATIVES

American Academy of Family Physicians (AAFP)

LOEHR, Jamie, MD, FAAFP
Cayuga Family Medicine (Owner)
Ithaca, NY

American Academy of Pediatrics (AAP)

BYINGTON, Carrie L., MD
H.A. and Edna Benning Presidential Professor of Pediatrics
Associate Vice President for Faculty and Academic Affairs
University of Utah Health Sciences Center
Salt Lake City, UT

American Academy of Pediatrics (AAP)

Red Book Editor
KIMBERLIN, David, MD
Professor of Pediatrics
Division of Pediatric Infectious Diseases
The University of Alabama at Birmingham School of Medicine
Birmingham, AL

American Academy of Physician Assistants (AAPA)

LÉGER, Marie-Michèle, MPH, PA-C
Senior Director, Clinical and Health Affairs
American Academy of Physician Assistants
Alexandria, VA

American College Health Association (ACHA)

EVEN, Susan, MD
Executive Director
Student Health Center
University of Missouri
Columbia, MO

American College of Obstetricians and Gynecologists (ACOG)

AULT, Kevin A., MD
Professor and Division Director, General Obstetrics and Gynecology
Department of Obstetrics and Gynecology
Kansas City, KS

American College of Physicians (ACP)

FRYHOFER, Sandra Adamson., MD, MACP
Adjunct Associate Professor of Medicine
Emory University School of Medicine
Atlanta, GA

American College of Physicians (ACP) (alternate)

POLAND, Gregory A., MD
Mary Lowell Professor of Medicine and Infectious Diseases
Mayo Clinic
Rochester, MN

American Geriatrics Society (AGS)

SCHMADER, Kenneth, MD
Professor of Medicine-Geriatrics
Geriatrics Division Chief
Duke University and Durham VA Medical Centers
Durham, NC

America's Health Insurance Plans (AHIP)

NETOSKIE, Mark J., MD, MBA, FAAP
Market Medical Executive, CIGNA
Houston, TX

American Medical Association (AMA)

FRYHOFER, Sandra Adamson., MD, MACP
Adjunct Associate Professor of Medicine
Emory University School of Medicine
Atlanta, GA

American Nurses Association (ANA)

BREWER, Katie, MSN, RN
Assistant Director
Patient Care Services
Fairfax County Government
Fairfax, VA

American Nurses Association (ANA) (alternate)

HAYES, Carol E., CNM, MN, MPH
Advanced Practice Nurse
American Nurses Association
American College of Nurse Midwives
DeKalb Board of Health
Decatur, GA

American Osteopathic Association (AOA)

GROGG, Stanley E., DO, FACOP
Associate Dean/Professor of Pediatrics
Oklahoma State University-Center for Health Sciences
Tulsa, OK

American Pharmacists Association (APhA)

FOSTER, Stephan L., PharMD, FAPhA
Professor and Vice Chair, Department of Clinical Pharmacy
University of Tennessee Health Sciences Center, College of Pharmacy
Memphis, TN

Association of Immunization Managers (AIM)

MOORE, Kelly, MD, MPH
Medical Director, State Immunization Program
Tennessee Department of Health
Nashville, TN

Association for Prevention Teaching and Research (APTR)

McKINNEY, W. Paul, MD
Professor and Associate Dean
University of Louisville School of Public Health and Information Sciences
Louisville, KY

Association of State and Territorial Health Officials (ASTHO)

DWELLE, Terry L, MD, MPHTM, FAAP, CPH
State Health Officer
North Dakota Department of Health
Bismarck, ND

Biotechnology Industry Organization (BIO)

LEWIN, Clement, PhD, MBA
Head, Medical Affairs and Immunization Policy
Novartis Vaccines and Diagnostics
Cambridge, MA

Council of State and Territorial Epidemiologists (CSTE)

HAHN, Christine, MD
State Epidemiologist
Office of Epidemiology, Food Protection and Immunization
Idaho Department of Health and Welfare
Boise, ID

Canadian National Advisory Committee on Immunization (NACI)

GEMMILL, Ian MacDonald, MD, CCFP, FCFP, FRCP(C)
Medical Officer of Health
Kingston, Frontenac and Lennox & Addington Public Health
Kingston, Ontario, Canada

Healthcare Infection Control Practices Advisory Committee (HICPAC)

Vacant

Infectious Diseases Society of America (IDSA)

NEUZIL, Kathleen M., MD, MPH, FIDSA
Vaccine Development Global Program (PATH)
Clinical Professor
Departments of Medicine and Global Health
University of Washington School of Medicine
Seattle, WA

Infectious Diseases Society of America (IDSA) (alternate)

BAKER, Carol J., MD
Professor of Pediatrics
Molecular Virology and Microbiology
Baylor College of Medicine
Houston, TX

National Association of County and City Health Officials (NACCHO)

ZAHN, Matthew, MD
Medical Director, Epidemiology
Orange County Health Care Agency
Santa Ana, CA

National Association of Pediatric Nurse Practitioners (NAPNAP)

STINCHFIELD, Patricia A., RN, MS, CPNP
Director
Infectious Disease/Immunology/Infection Control
Children's Hospitals and Clinics of Minnesota
St. Paul, MN

National Foundation for Infectious Diseases (NFID)

SCHAFFNER, William, MD
Chairman, Department of Preventive Medicine
Vanderbilt University School of Medicine
Nashville, TN

National Immunization Council and Child Health Program, Mexico

VILLASEÑOR RUIZ, Ignacio
Directora del Programa de Atención a la Salud de la Infancia y la Adolescencia / Director
General, Child and Adolescent Health
Centro Nacional Para la Salud de la Infancia Y La Adolescencia / National Center for Child and
Adolescent Health
Ministry of Health / Secretaría de Salud
Mexico

National Medical Association (NMA)

WHITLEY-WILLIAMS, Patricia, MD
Professor and Chair
University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School
New Brunswick, NJ

National Vaccine Advisory Committee (NVAC)

ORENSTEIN, Walt, MD
Chair, NVAC
Associate Director, Emory Vaccine Center
Emory University
Atlanta, GA

Pediatric Infectious Diseases Society (PIDS)

SAWYER, Mark H, MD
Professor of Clinical Pediatrics
University of California, San Diego School of Medicine
San Diego, CA

Pediatric Infectious Diseases Society (PIDS) (alternate)

ENGLUND, Janet A., MD
Professor, Department of Pediatrics
Seattle Children's Hospital
University of Washington
Seattle, WA

Pharmaceutical Research and Manufacturers of America (PhRMA)

BRAGA, Damian A.
President, Sanofi Pasteur
Swiftwater, PA

Society for Adolescent Health and Medicine (SAHM)

MIDDLEMAN, Amy B., MD, MEd, MPH
Professor of Pediatrics
Chief, Section of Adolescent Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, OK

Society for Healthcare Epidemiology of America (SHEA)

WEBER, David, MD, MPH
Professor of Medicine, Pediatrics, and Epidemiology
University of North Carolina Schools of Medicine and Public Health
Medical Director, Hospital Epidemiology and Occupational Health, UNC Health Care
University of North Carolina
Chapel Hill, NC