

# ACIP Meeting: Pneumococcal, Zoster, and Influenza Vaccines

October 20, 2021

*Disclaimer: These notes were taken by AIM staff who observed the meeting. These are not official notes provided by CDC or ACIP.*

## SUMMARY EMAIL

**PNEUMOCOCCAL AGE BASED RECOMMENDATION:**“Adults 65 years of age and older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23

**VOTE: 15-0 Recommendation passes.**

**PNEUMOCOCCAL RISK BASED RECOMMENDATION:** Two doses of recombinant zoster vaccine are recommended for the prevention of herpes zoster and its complications in adults aged 19 years and older who are or will be immunodeficient or immunosuppressed due to disease therapy.

**VOTE: 15-0 Recommendation passes.**

**ZOSTER RECOMMENDATION:** Two doses of recombinant zoster vaccine are recommended for the prevention of herpes zoster and its complications in adults aged 19 years and older who are or will be immunodeficient or immunosuppressed due to disease therapy.

**VOTE: 15-0 Recommendation passes.**

## Introduction and Agency Updates

- **Purpose of this section:** The ACIP introduced voting members and liaisons. Agency updates, including updates from the CDC and FDA were provided.
- **Key Points:** The FDA provided a summary of the discussion, votes, and data from the VRBPAC meetings on 10/14 and 10/15. FDA is wrapping up their review of the data presented last week, and is expecting a final authorization (Moderna/J&J boosters) today 10/20/21.

## Pneumococcal Vaccines DATA SLIDES UPDATED POLICY/VOTING QUESTIONS

- **Purpose of this section:** Updated policy questions regarding pneumococcal vaccines were presented. These have been simplified since the September 2021 meeting. Workgroup considerations and data were presented for use of PCV20 alone or PCV15 and PPSV23 in series (65+ or 19-64 with underlying conditions).
- **Updated Policy Questions for Consideration from Sept. 2021 ACIP Meeting:**
  - Should PCV20 alone OR PCV15 in series with PPSV23 be routinely recommended for US adults aged ≥65 years?

- Should PCV20 alone **OR** PCV15 in series with PPSV23 be recommended for U.S. adults aged 19–64 years with certain underlying medical conditions or other risk factors\*?
- **Proposed Recommendation (to be voted on):**
  - Age Based: Adults **65 years of age** or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
  - Ages Based with AMENDMENT: Adults **50 years of age** or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
  - Risk Based: Adults aged 19 years of age or older with certain underlying medical conditions or other risk factors\* who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
- **Key Points:**
  - The workgroup presented a very complicated and convoluted policy question during the September 2021 ACIP meeting ([slides](#)). This included a potential age based recommendation for 50+, 65+, 19-49 with underlying conditions, as well as risk based recommendations. The ACIP committee felt that this language needed to be simplified before voting on a recommendation during this meeting in Oct. 2021.
    - Different age based recommendations would be more confusing for implementation and public acceptance. The committee felt that a simplification of the policy question was necessary to increase vaccine coverage.
  - The workgroup considered the following guiding principles when simplifying the policy question:
    - Decisions on policy options should be supported by best-available evidence
    - Simplifying existing pneumococcal vaccine recommendations could help improve vaccine coverage among adults
    - Disparities in pneumococcal disease burden and vaccine coverage should be reduced
    - Timely recommendations for each new vaccine should be made after FDA licensure
  - The rationale for harmonizing the age based recommendation to age ≥65 years is as follows:
    - Due to potential waning of immunity, vaccination later in life (65+) may be favorable when risk of disease may be higher

- Consistently cost-saving (lower cost and better health outcome compared to current recommendations) in cost-effectiveness analyses
- Proposed risk-based and age-based options still provide an opportunity for higher PCV coverage, which may prevent more disease compared with current recommendations and may address some health equity concerns

**Summary of WG Considerations: Age-Based at Age 50 vs. 65 years**

| In favor of age-based at age 50 years   | In favor of age-based at age 65 years   |
|---|---|
| <ul style="list-style-type: none"> <li>• May reduce disparity in disease burden in adults aged 50–64 years</li> <li>• May provide more opportunities to vaccinate adults before they develop underlying conditions</li> </ul> | <ul style="list-style-type: none"> <li>• Potential for waning immunity makes it favorable to vaccinate later in life when risk of disease is higher</li> <li>• Consistently cost-saving* in cost-effectiveness analyses</li> <li>• Still provides an opportunity for higher PCV coverage in adults vs. current recommendations</li> </ul> |

**Summary of WG Considerations: PCV20 Use Alone OR PCV15+PPSV23**

| Advantages of PCV20 Use Alone  | Disadvantages of PCV20 Use Alone  |
|--|---|
| <ul style="list-style-type: none"> <li>• Acceptable and feasible to implement a single vaccine option</li> <li>• Cost-saving* in cost-effectiveness analyses</li> <li>• Expected to provide better protection for the serotypes covered by PPSV23 alone</li> </ul> | <ul style="list-style-type: none"> <li>• Clinical significance of lower immunogenicity vs. PCV13 unknown</li> <li>• No data in immunocompromised adults</li> <li>• Losing protection against PPSV23, non-PCV20 serotypes</li> </ul>   |
| Advantages of PCV15+PPSV23   | Disadvantages of PCV15+PPSV23   |
| <ul style="list-style-type: none"> <li>• Provides broad serotype coverage</li> <li>• Age-based use at age 65 was cost-saving* according to CDC’s cost-effectiveness analysis</li> </ul>  | <ul style="list-style-type: none"> <li>• Logistically more challenging to administer PCV15-PPSV23 vaccine series</li> <li>• Need to know vaccination history to correctly complete series</li> <li>• Can result in lower serotype coverage if series not completed</li> </ul> |

- **Vote on Amendment to Age Based Recommendation:**
  - **Voting Question:** Adults 50 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
  - **Vote: 4 YES - 11 NO Amendment does not pass.**
- **Committee Discussion:**
  - Many committee members felt that pneumococcal vaccines should be recommended for 50+, rather than 65+, would be more encompassing and increase vaccine coverage/reduce rates of pneumococcal disease.

- Liaison and committee members expressed concern that an age based recommendation for 65+ may miss at risk individuals 50-65 years and may cause equity issues. Liaison and committee members felt that a simple recommendation for 50+ would increase access and reduce barriers. However, voting members noted that since immunity declines between 50-65, it may be more valuable to recommend the pneumo. vaccines for 65+ to achieve highest immunity in older age (highest risk group).
  - Overall, the workgroup felt that the simplification of policy/discussion questions is essential and necessary for ease of implementation.
  - There is no data on using PCV20 for immunocompromised individuals. Many committee members felt that this is a limiting factor when considering current policy questions.
  - According to data presented, some committee members felt that PCV20 used alone would provide higher protection than PCV15 in series with PPSV23.
  - Some committee members felt that underlying conditions included in the risk based considerations (19-64 underlying conditions) are not all encompassing.
- **Outcome:** The committee will continue discussion on the pneumococcal vaccines later in the day and vote on the aforementioned proposed recommendations.

### Zoster Vaccines [DATA SLIDES](#) [INTRO/VOTING QUESTIONS](#)

- **Purpose of this section:** Review EtR framework for recommending the Zoster vaccine for adults 19 and older with immunocompromising conditions and inform ACIP members of work group findings regarding RZV vaccination in immunocompromised individuals 19 years and older.
- **Policy Question:** Should adults aged  $\geq 19$  years who are or will be immunodeficient or immunosuppressed due to disease or therapy be recommended to receive two doses of recombinant zoster vaccine for the prevention of herpes zoster and its complications? Including but not limited to:
  - Hematopoietic stem cell transplant (HSCT) recipients
  - Patients with hematologic malignancies (HM)
  - Renal or other solid organ transplant (SOT) recipients
  - Patients with solid tumor malignancies (STM)
  - People living with HIV
  - Patients with primary immunodeficiencies, autoimmune and inflammatory conditions, and taking immunosuppressive medications/therapies
- **Key Points:**
  - Since the last ACIP meeting, the comment has considered and reviewed the EtR framework presented during the September 2021 ACIP meeting.
  - The EtR framework was presented during the meeting. Overall, benefits outweigh the risks, there are no safety concerns for the Zoster vaccine, and many physicians

are already recommending the Zoster vaccine for adults 19 years and older with immunocompromised individuals. The vaccine is feasible to implement for this younger population, and there are cost benefits related to recommending this vaccine for a younger population.

- **Discussion:**
  - Work group findings state that desirable consequences clearly outweigh undesirable consequences in most settings.
  - Work group recommends the intervention.
  - Committee members seemed supportive and in favor of the recommendations.

## **Influenza Vaccines FLU COADMINISTRATION CHANGE IN AGE FLUCELVAX**

- **Purpose of this section:**
  - The committee reviewed phase II safety and immunogenicity study of the coadministration of Fluzone® High-Dose Quadrivalent Influenza Vaccine and a third dose of mRNA-1273 COVID-19 vaccine (Moderna).
  - The committee also heard and update regarding change in age indication for Flucelvax Quadrivalent and a review of recent influenza activity from the Southern and Northern Hemisphere.
- **Key Points/Discussion:**
  - Results from the phase II safety and immunogenicity study of the coadministration of Fluzone® High-Dose Quadrivalent Influenza Vaccine and a third dose of mRNA-1273 COVID-19 vaccine (Moderna) demonstrate that that QIV-HD and mRNA-1273 vaccine (100µg) can be administered safely together without evidence of immunogenicity interference, supporting existing co-administration recommendations of COVID-19 and influenza vaccines.
  - There was a question from a member regarding the study and any bias introduced in regards to the open label study design (e.g: subjective reporting of symptoms). The presenter acknowledged that these concerns are well received and that there is potential for bias with this type of study. Additionally a question was raised since the study participants received the vaccines in different arms, if there was any attempt to study if they were given at the same site – if the reactogenicity and immunogenicity would differ? The presenter responded that this was outside of the scope of the protocol for this study.
  - There was other discussion regarding the study inclusion and exclusion criteria (were participants excluded if they had COVID-19? Were they only included if they received the Moderna vaccine?). The presenter provided that data on if a participant themselves had COVID-19 was not collected and yes, they had to have received two doses of the Moderna vaccine at least 5 months prior to the study.
  - Studies such as these are important to be able to answer important public health questions and boost trust and confidence about the co-administration of COVID-19 and Influenza vaccine.

- Regarding the presentation on change in age indication for Flucelvax Quadrivalent there was no discussion.
- Lastly, data was presented on flu activity in the Northern and Southern Hemispheres. Data shows that in the Southern Hemisphere activity was overall well below the epidemic threshold; and although early, we are seeing the same pattern in the Northern Hemisphere. However, flu activity has not peaked in the Northern Hemisphere yet, too early to tell which strain(s) are predominant and can't make a call on what kind of flu season it is going to be.
- **Outcomes:**
  - The QHD00028 study results demonstrate that QIV-HD and mRNA-1273 vaccine (100µg) can be administered safely together without evidence of immunogenicity interference, supporting existing co-administration recommendations of COVID-19 and influenza vaccines.
  - Change in Age Indication for Flucelvax Quadrivalent; Age indication changed from ≥4 years to ≥2 years (approved by FDA in March, 2021). On October 14, 2021, FDA approved for ages ≥6 months. For Flucelvax: Will be reflected in [online version](#) of Table of available vaccines for 2021-22 → Will be including a brief summary of ACIP recommendations

## Final Discussion and VOTES

- **PNEUMOCOCCAL AGE BASED RECOMMENDATION:**“Adults 65 years of age and older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23
  - **VOTE: 15-0 Recommendation passes.**
- **PNEUMOCOCCAL RISK BASED RECOMMENDATION:** Two doses of recombinant zoster vaccine are recommended for the prevention of herpes zoster and its complications in adults aged 19 years and older who are or will be immunodeficient or immunosuppressed due to disease therapy.
  - **VOTE: 15-0 Recommendation passes.**
- **ZOSTER RECOMMENDATION:** Two doses of recombinant zoster vaccine are recommended for the prevention of herpes zoster and its complications in adults aged 19 years and older who are or will be immunodeficient or immunosuppressed due to disease therapy.
  - **VOTE: 15-0 Recommendation passes.**