

13-Valent Pneumococcal Conjugate Vaccine

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Advisory Committee on Immunization Practices

Additional Meeting on Use of Pneumococcal Vaccines in Adults

August 13, 2014



Pneumococcal Vaccines Work Group

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Sandra Fryhofer (ACP, AMA)

Pneumococcal Vaccines Work Group: Terms of Reference

- 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

Focus of today's session

- Routine immunization with 13-valent pneumococcal conjugate vaccine (PCV13) for adults ≥ 65 years of age
- Proposal for a vote

PCV13 for Adults

- Licensed for use among adults ≥ 50 years old on 12/30/11
- FDA approved under the Accelerated Approval Pathway
- Based on non-inferior immunogenicity compared to PPSV23
- Indications
 - Prevention of pneumococcal disease (including pneumonia and invasive disease) in adults 50 years of age and older
 - Prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
- Post-approval condition of licensure: Randomized controlled trial of PCV13 against pneumococcal pneumonia among adults ≥ 65 years old in the Netherlands (CAPiTA)

Summary of Discussions in June 2014

- Evidence review and discussion
 - CAPITA results
 - Indirect (herd) effects of PCV13 use in children
 - Cost-effectiveness and public health impact of different adult pneumococcal vaccination strategies
- Input received
 - Factors to consider in selecting optimal strategy
 - Address decreasing utility in a setting of increasing herd effects
 - Sensitivity analysis around CE model inputs
- The WG narrowed down on one strategy
 - PCV13 use in sequence with PPSV23

Objective for today's session

- Specific policy option will be presented
- Will ask the committee to vote

Reasons for accelerated timeline including special meeting

- ❑ Deferred decision on recommendations in 2012 based on CAPITA (now available) and on herd effects
- ❑ Benefits of PCV13 among older adults will be greatest in the short term
- ❑ Almost 3 years since licensure and no additional evidence affecting decision is anticipated
- ❑ Opportunity to afford population benefit of optimal vaccination against pneumococcal disease with PCV13 and PPSV23
- ❑ Process of full implementation can only begin once recommendation is made

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 approved by ACIP and CDC Director