13-Valent Pneumococcal Conjugate Vaccine

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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

Outline

- Update on WG discussions related to 3-dose infant immunization schedule
- Focus of today's session: PCV13 use for adults

PCV13 3-dose schedule for infants

- GRADE review (Feb 2014 ACIP)
  - Strong quality evidence (type 2) and Category A recommendation for 3+0 and 2+1 vs. no vaccination
  - Limited evidence comparing 3-dose schedules to a 4-dose schedule
- Evidence from countries using 3-dose schedules is reassuring
- Continue to observe PCV13 direct and indirect impact in the US
- The Work Group continue to discuss with AAP/AAFP:
  - Careful consideration of implementation issues and potential impact on non-adherence
  - Survey of pediatricians and family practitioners to understand issues around hesitancy and refusals as they relate to PCV13
  - Survey or focus groups of parents related to potential policy change
  - Defining groups to be excluded from potential policy change
- Update ACIP at a future meeting

Focus of today's session

- Routine adult immunization with 13-valent pneumococcal conjugate vaccine (PCV13)

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 2012

- GRADE review and presentation to ACIP
  - Immunogenicity results from Phase III studies and from published literature
  - Cost-effectiveness and public health impact of different adult pneumococcal vaccination strategies
- Deferred recommendation until more data available
  - Efficacy against pneumonia (CAPiTA)
  - Indirect (herd) effects of PCV13 use in children
- Recommended a dose of PCV13 for adults with immunocompromising conditions (in addition to PPSV23)

Objective for today's session

- Information only session
  - Specific policy options will be presented
  - Will not ask the committee to vote
- Review results of CAPiTA and the new cost-effectiveness analysis
- Discuss considerations for PCV13 use among adults ≥65 years old

Today's presentations

PCV13 efficacy among adults: results of CAPiTA study	Rosalind Hollingsworth, Pfizer
Discussion/Q&A	
Potential public health impact and cost-effectiveness of PCV13 use in adults	Charles Stoecker, Tulane University
Considerations for PCV13 use among adults and policy options	Tamara Pilishvili, NCIRD, CDC
Discussion/Q&A	