

13-Valent Pneumococcal Conjugate Vaccine

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February 26, 2014



Pneumococcal Vaccines Work Group

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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

Focus of today's session

- Routine infant immunization schedule for 13-valent pneumococcal conjugate vaccine (PCV13)

Context for today's session

- **Evidence supporting use of 3-dose PCV schedules emerging**
 - A 3-dose PCV13 schedule is approved by the European Medicines Agency (EMA) and other licensing bodies
 - WHO recognizes a 3-dose schedule as an acceptable alternative to a 4-dose schedule*
 - 3-dose schedule routine in low-income countries
 - At least 21 high and 13 upper-middle income countries have introduced PCV13 or PCV10 with 3 doses or have switched from 4- to 3-dose schedule

*Pneumococcal vaccines WHO position paper. Wkly Epidemiol Rec, 2012

Context for today's session

- Evidence supporting use of 3-dose PCV schedules emerging
- Perceptions that the vaccine schedule has become crowded and confusing, and safety concerns over too many simultaneous injections have grown^{1,2}
 - May lead an increasing number of parents to delay or refuse recommended vaccines³
 - Rare safety issues associated with co-administration of routine vaccines are emerging (febrile seizure with co-administration of PCV, DTaP, and flu vaccines)

¹Bardenheier Arch Ped Adol Med 2004

²Gust Pediatrics 2008

³Freed Pediatrics 2010

Context for today's session

- Evidence supporting use of 3-dose PCV schedules emerging
- Perceptions that the vaccine schedule has become crowded and confusing, and safety concerns over too many simultaneous injections have grown
- **PCV7 use led to dramatic reductions in disease burden**
 - Reductions in invasive pneumococcal disease (IPD) and pneumonia in children and adults; reductions in otitis media in children
 - PCV7 serotypes have virtually been eliminated from all age-groups
 - Disease due to PCV13 serotypes is rapidly declining

Context for today's session

- Evidence supporting use of 3-dose PCV schedules emerging
- Perceptions that the vaccine schedule has become crowded and confusing, and safety concerns over too many simultaneous injections have grown
- PCV7 use led to dramatic reductions in disease burden
- US now has a mature PCV program

Can a 3-dose PCV13 schedule be included in the routine schedule for infants?

Objective for today's session

- Information only session; no specific recommendations will be presented
- Review GRADE of evidence and address ACIP questions from Oct 2013
- Discuss considerations for including a 3-dose PCV13 schedule for infants
- Questions for the committee
 - Is the evidence adequate to consider including a 3-dose PCV13 schedule for infants?
 - If not, what additional data or information would be required?

Today's presentations

Update on PCV13 direct and indirect effects & vaccine effectiveness	Matt Moore
Discussion/Q&A	
Reduced dose schedules of PCV13 for children: GRADE review of evidence	Sara Tomczyk
Considerations for reduced dose schedules of PCV13 for children	Tamara Pilishvili
Discussion/Q&A	