

Meningococcal Vaccines Work Group Update

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Advisory Committee on Immunization Practices
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Working Group Members

- **Cody Meissner, Chair- ACIP***
- **Kristin Ehresmann- ACIP***
- **Michael Marcy- ACIP***
- **Carol Baker- ACIP***
- **Marietta Vasquez- ACIP**
- **Doug Campos-Outcalt- ACIP**
- **Geoff Evans- HRSA**
- **Mike Brady- AAP**
- **Lucia Lee- FDA**
- **David Salisbury- UK**
- **William Schaffner- NFID**
- **Karen O'Brian- AAFP**
- **Jim Turner- ACHA**
- **Amy Middleman- SAM**
- **Martin Luta- CSTE**
- **Richard Clover**
- **Paul McKinney**
- **Paul Offit**
- **Georges Peter**
- **David Stephens**
- **Amanda Cohn- CDC**
- **Thomas Clark-CDC**
- **Nancy Messonnier- CDC**
- **Bill Atkinson- CDC**
- **Jonathan Duffy- CDC**
- **Shannon Stokley- CDC**
- **Ismael Ortega-Sanchez-CDC**

Meningococcal Vaccines

- Quadrivalent polysaccharide vaccine
 - MPSV4 (Menomune, sanofi pasteur)
- Conjugate vaccines
 - MenACWY-D (Menactra, sanofi pasteur)
 - Approved for 9 months through 55 years
 - MenACWY-CRM (Menveo, Novartis)
 - Approved for 2 through 55 years
 - HibMenCY-TT (MenHibRix, GlaxoSmithKline)
 - Approved for infant vaccine at 2,4,6 and 12 months
- Investigational vaccine for infant use
 - MenACWY-CRM

HibMenCY-TT

- On June 14, 2012 the FDA approved the license for MenHibrix manufactured by GlaxoSmithKline for active immunization for the prevention of *N. meningitidis* C and Y and *Haemophilus influenzae* type b. The indicated age range for use is 6 weeks through 18 months of age. MenHibrix is administered as a four dose series at 2, 4, 6 and 12-15 months of age.

HibMenCY-TT

- Non-inferior Hib responses when compared to Hib-TT
- Immunogenic against serogroups C and Y
 - Some children protected after 2nd dose
 - Persistence data will be presented at October meeting
- Similar safety profile compared to Hib-TT
 - No increased rate of adverse events

Infant Meningococcal Recommendations

- **October 2011 presentations presented Work Group rationale for no routine recommendation for infant meningococcal vaccines**
 - Declining disease rates now at historic lows
 - Low proportion of infant cases and deaths vaccine preventable
 - Multiple doses with potential need for booster doses
- **Language around no routine use of any meningococcal vaccine for infants**
 - Guidance for use and vote for each infant meningococcal vaccine as it is licensed

Infant Meningococcal Vaccines: Number Needed to Vaccinate (NNV)

Meningococcal incidence (Year Range Data)	Cases prevented (4 dose infant series)	Deaths Prevented	NNV to prevent one case	NNV to prevent one death
High Incidence (1997-1999)	307	20-30	11,000	127,000
Base-case (1993-2009)	135	5-10	25,000	325,000
Low Incidence (2007-2009)	44	2-4	76,000	642,000

*Data from Ortega-Sanchez CE model, presented at ACIP, October 2011

Issues Around HibMenCY

- **Guidance for use (Intervals, minimum and maximum age)**
- **Interchangeability with vaccines, incomplete series**
- **Use in special populations/ high-risk (bivalent vs quadrivalent)**
- **GRADE of immunogenicity and safety data**
- **Developing language for no routine recommendation**
 - Ensuring clarity that vaccine may be used

Anticipated October 2012 Discussions

- **Review Work Group considerations for HibMenCY use**
 - Safety, immunogenicity, antibody persistence
 - Epidemiology and potential impact of HibMenCY
 - Programmatic considerations
 - Cost-effectiveness analysis
- **Present GRADE evaluation of HibMenCY**
- **Review language options for no routine recommendation**
- **ACIP vote for language for no routine recommendation**
- **Consideration for inclusion in VFC program (under Hib or Meningococcal resolution)**

Additional Activities

- **ACIP Meningococcal Vaccines Statement in CDC clearance**
 - Anticipated publication 4-6 months
 - Updates all post-licensure data and recommendations made since May 2005
- **Continue GRADE MenACWY-Crm for infants**
- **A monovalent serogroup A vaccine in sub-Saharan Africa**
- **Early thoughts about serogroup B vaccine use**
 - Vaccines far from licensure in US but may be licensed in Europe in the near future
 - Use of these vaccines in other countries should inform future strategies in the US