

# **ACIP Combination Vaccines Working Group (WG)**

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# **ACIP--October 2007 Combination Vaccines WG Outlines**

- **Update on the WG activities**
  - Patricia Stinchfield, RN, MS, CPNP, WG chair
- **Impact of Combination Vaccines**
  - Gregory S. Wallace, MD, MS, MPH, NCIRD/CDC
- **Immunogenicity and Safety of Kinrix™: A Combination DTaP-IPV Vaccine in Children 4-6 Years of Age**
  - Wayde M. Weston, PhD, GlaxoSmithKline Biologicals

# ACIP Combination Vaccines Working Group

## Short-term goals

- Pentacel® vaccine (DTaP-IPV-Hib), Sanofi pasteur, was reviewed in anticipation of a future ACIP discussion
  - Biological License Application (BLA) for 4-dose primary series in children 2, 4, 6, and 15-18 months
  - FDA requested additional information, which resulted in an extension of the review clock for this BLA.
- Kinrix™ vaccine (DTaP-IPV), GlaxoSmithKline Biologicals, was reviewed in anticipation of a future ACIP discussion pending FDA licensure
  - BLA was submitted for this new pediatric booster vaccine for children 4 through 6 years of age; is under FDA review

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## Long-term goals

- Develop a revised statement, to replace the 1999 MMWR statement\*, on use of Combination Vaccines for discussion and approval by ACIP
- Review issues surrounding the availability and use of combination vaccines in the U.S. market

\* Combination Vaccines for Childhood Immunization  
*MMWR Vol 48/No RR-5, May 14, 1999*

***Combination Vaccines for Childhood Immunization***  
***MMWR Vol 48/No RR-5, May 14, 1999***  
**Major statements to review**

- Combination vaccines should be used to minimize the number of injections children receive
  - Practical for starting immunization series for children behind schedule
- Extra doses of vaccine antigens are justified when:
  - Products that contain only the needed antigens are not readily available or would result in extra injection
  - Potential benefits to the child outweigh the risk of adverse events associated with the extra antigen

## *Combination Vaccines for Childhood Immunization*

*MMWR Vol 48/No RR-5, May 14, 1999*

### **Major statements to review - cont.**

- The benefits and risks of administering the combination vaccine with an unneeded antigen should be compared
- The reactogenicity of the inactivated vaccine must be considered in balancing the benefits and risks of extra doses (risk of hypersensitivity reactions after diphtheria and tetanus-toxoid containing vaccines such as DTaP-Hib, DT)
- Conjugate vaccine carrier proteins: “administering large amounts of tetanus toxoid carrier protein simultaneously with PRPT- conjugate vaccine has been associated with a reduction in the response to PRP”

# *Combination Vaccines for Childhood Immunization*

## *MMWR Vol 48/No RR-5, May 14, 1999*

### **Other Important Issues**

- Interchangeability of formulations
- Interchangeability of vaccines from different manufacturers
- Impact on reimbursement policies:
  - “Administering extra antigens contained in a combination vaccine, when justified..., is acceptable practice and should be reimbursed on the patient’s behalf by the indemnity health insurance and managed- care systems. Otherwise...it might be discouraged...”
- Monitoring vaccine safety
- Monitoring vaccine efficacy
- Monitoring vaccine coverage

## Additional topics identified by the WG

- Impact of using combination vaccines on immunization schedule
- Programmatic, administrative, and financial “burden” on private providers in the current vaccine market
- Expressing the level of preference of combination vaccines vs. single-antigen ones
- Identify circumstances, if any, when single-antigen vaccines should be strongly considered, considered, or preferred

# Future Steps

- **Further review and communicate to the ACIP on combination vaccines new to the US market**
- **Further work on the revised statement, to replace the 1999 MMWR statement\*, on use of Combination Vaccines for discussion and approval by ACIP**
  - **Decide on how to incorporate the new statement on combination vaccines into the General Recommendations document**

*\*Combination Vaccines for Childhood Immunization  
MMWR Vol 48/No RR-5, May 14, 1999*

# ACIP WG Members

**ACIP chair: Patsy Stinchfield**

**ACIP members: Susan M. Lett**

**CDC co-lead: Angela Calugar**

## ➤ **CDC Staff:**

- **Jim Alexander – DVD/NCIRD**
- **Norma Allred – CCID/NCIRD**
- **Tom Clark – DBD/NCIRD**
- **Wan-Ting Huang – ISO/OCSO**
- **Andrew Kroger – ISD/NCIRD**
- **Nancy Messonnier – DBD/NCIRD**
- **Amy Parker – DVD/NCIRD**
- **Larry Pickering – CCID/NCIRD**
- **Jean C. Smith – CCID/NCIRD**
- **Sandra Steiner – CCID/NCIRD**
- **Tracy N. Thomas – ISO/OCSO**
- **Greg Wallace – ISD/NCIRD**

## ➤ **ACIP liaison and other members:**

- **Jonathan L. Temte – AAFP**
- **Jay Butler – AKA IHS**
- **Jeff Davis – WI DOH**
- **Jeffrey S. Duchin – NACCHO**
- **Sarah Long – COID/AAP**
- **Karen M. Farizo – FDA**
- **Theresa Finn – FDA**