

Combination Vaccines Working Group Advisory Committee on Immunization Practices (ACIP)

Arthur Reingold, MD

University of California – Berkeley
Chair, ACIP Combination Vaccines Working Group

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Work Group Members

ACIP Members

Art Reingold, Chair

Kelly Moore

Cindy Pellegrini

Ex Officio Member

Ann Schwartz, FDA

Liaison Representatives

Elizabeth Miller, AAPA

Elizabeth Rosenblum, AAFP

Kathy Edwards, AAP

Patsy Stinchfield, NAPNAP

CDC Co-leads

Gina Mootrey

Jennifer Liang

Work Group Members - SMEs

- ❑ Elizabeth Briere – Hib
- ❑ Andrew Kroger – General Recs, immunization program
- ❑ Anna Acosta, Jennifer Liang – pertussis
- ❑ Pedro Moro – immunization safety
- ❑ Sarah Schillie - hepatitis
- ❑ Tej Tiwari – diphtheria, tetanus
- ❑ Greg Wallace – polio

Terms of Reference

Review published and unpublished data related to the safety and immunogenicity of the

- **Quadracel DTaP IPV vaccine for children 4 through 6 years**
- **DTaP5-IPV-Hib-HepB, investigational pediatric hexavalent combination vaccine, 3 dose series for children at 2, 4, and 6 months**

Work Group Activities

❑ **Quadracel Vaccine**

- Safety and immunogenicity information presented at June ACIP
- MMWR Policy Note published September 4, 2015

❑ **DTaP5-IPV-Hib-HepB, Pediatric Hexavalent Combination Vaccine**

- Safety and immunogenicity presentation by Sanofi Pasteur and Merck to Work Group in July 2015

DTaP-IPV-Hib-HepB

Pediatric Hexavalent Combination Vaccine

Disease	Antigen(s)	Licensed vaccine containing same antigen(s)
Haemophilus influenzae type b	PRP-OMPC	PEDVAX HIB™
Hepatitis B	HBsAg	RECOMBIVAX HB™
Pertussis Diphtheria Tetanus	5 component acellular pertussis Diphtheria toxoid Tetanus toxoid	DAPTACEL™
Poliomyelitis	IPV inactivated poliovirus types 1,2,3	Ipol™

DTaP-IPV-Hib-HepB Pediatric Hexavalent Combination Vaccine

- ❑ BLA accepted by FDA for review October 2014**
- ❑ Proposed indication: 3-dose series in children from 6 weeks through 4 years of age, administered at 2, 4, and 6 months of age**
- ❑ No safety or immunogenicity concerns were identified by the Work Group**

Today's Session

- ❑ **Investigational pediatric hexavalent vaccine – safety and immunogenicity**
 - Dr. Andrew Lee (on behalf of Sanofi Pasteur and Merck)
- ❑ **Discussion**