

Pertussis Vaccines Work Group

Art Reingold, MD

Chair, ACIP Pertussis Vaccine Work Group

Advisory Committee for Immunization Practices

June 25, 2015

Work Group Members

(formation in April 2009)

ACIP Members

Art Reingold, Chair
Kathleen Harriman

Ruth Karron
Marietta Vázquez

Ex Officio Members

Xin-Xing Gu (NIAID)

Ann Schwartz (FDA)

Liaison Representatives

Richard Beigi (ACOG)
Albert Bourbon (AAPA)
Alexis Elward (HICPAC)
Christine Hahn (CSTE)

Jessica Kahn (SAM)
Sarah Long (AAP)
Elizabeth Rosenblum (AAFP)
Mark Sawyer (PIDS)

Stephanie Schauer (AIM)
Kenneth Schmader (AGS)
David Weber (SHEA)
Matthew Zahn (NACCHO)

Invited Consultants

William Atkinson
Carol Baker

Lance Chilton
Scott Halperin (Canada)

Peter McIntyre (Australia)
Paul Offit

CDC Lead

Jennifer Liang

Terms of Reference

- ❑ Review existing statements on infants and young children (1997), adolescent (2006), adults (2006), and pregnant and postpartum women and their infants (2008) and consolidate into a single statement.
- ❑ Review new data on Tdap including
 - Effectiveness of ACIP recommendations
 - Interval between Td booster and Tdap
 - Use of Tdap in adults ages 65 yrs and older
 - Pregnant and breastfeeding women
 - Use of Tdap
 - Cocooning strategies
 - Vaccinated HCP and need for postexposure prophylaxis
 - **Tdap revaccination**
 - Pregnant women
 - Healthcare personnel
 - **“Cocooning”**
- ❑ Review updated epidemiology of tetanus and diphtheria in the United States

Tdap products in United States

Both Tdap products are licensed for single use

- ❑ **BOOSTRIX® (GlaxoSmithKline Biologicals)**
 - Age indication: 10 and older

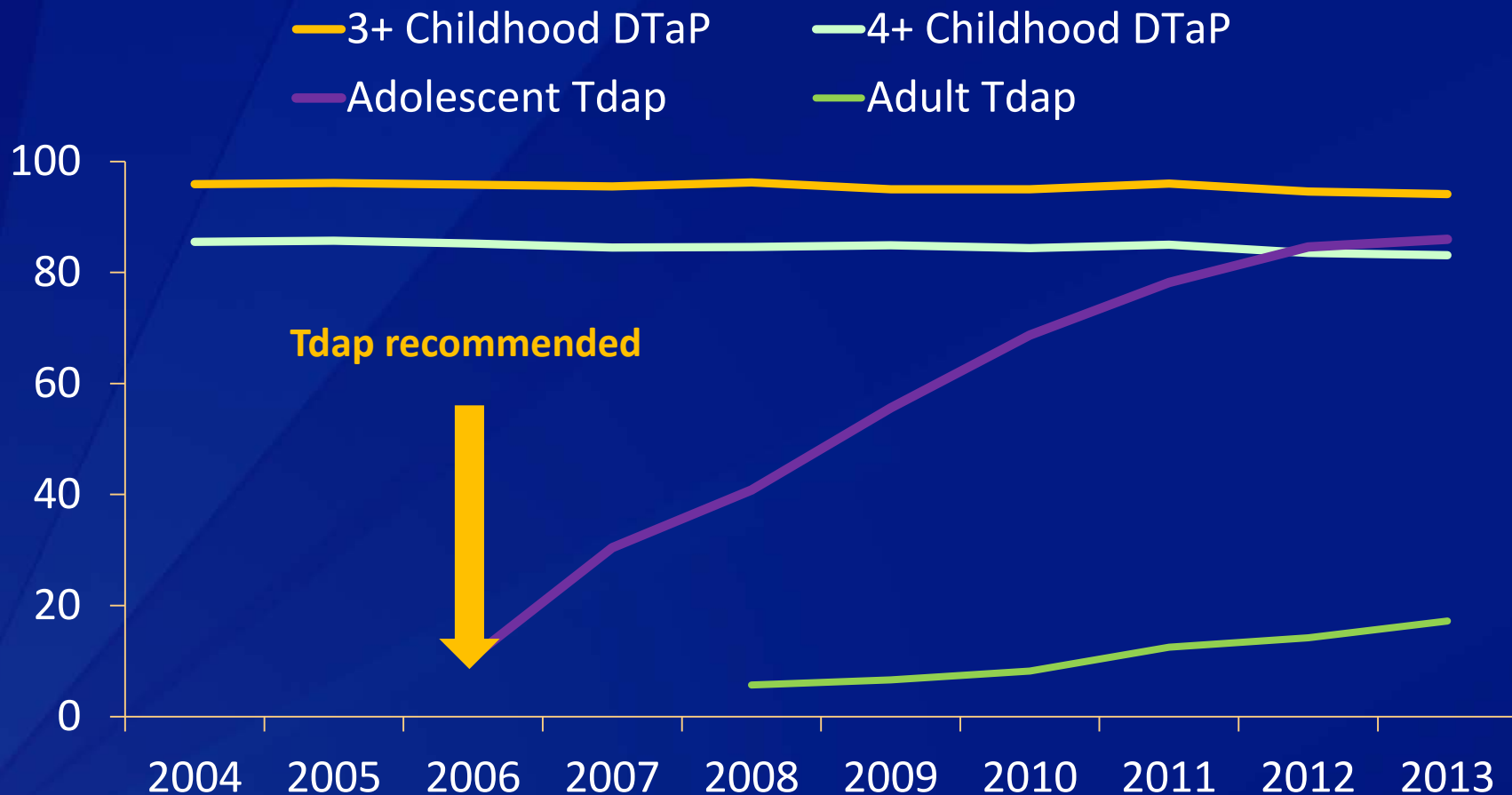
- ❑ **ADACEL™ (Sanofi Pasteur)**
 - Age indication: 10 through 64

Current ACIP Recommendations for Tdap* and Td

- ❑ A single Tdap dose for all persons aged 11 years and older, preferred administration at 11 or 12 years
- ❑ Pregnant women are recommended to receive Tdap with every pregnancy
- ❑ Decennial Td booster for those who have received 1 Tdap
 - 5 years for wound management

*Adacel (Sanofi Pasteur) is approved for use in persons aged 10 through 64 years; Boostrix (GSK) is approved for use in persons aged 10 years and older

High DTaP coverage among children and increasing Tdap coverage among adolescents* but adult Tdap[¶] coverage remains low



*CDC National Immunization Survey: DTaP among children aged 19 through 35 months, Tdap coverage among adolescents aged 13 through 17 years; [¶] Coverage among adults aged 19 through 64 years from National Health Information Survey

Safety monitoring for Tdap vaccine given during pregnancy in VAERS*

- ❑ **There have been 69 Tdap reports in pregnant women to VAERS since the last ACIP update in October 2014**
 - Tdap given during third trimester in 15/21 of reports with data on gestational age at time of vaccination
 - Conditions among 69 reports included:
 - No adverse event (35), Injection site reaction/shoulder or arm pain (19), Stillbirth (5), systemic reactions (3), Guillain-Barré syndrome (2), anaphylaxis allergic reaction (2), abdominal pain (1), multiple allergies (1), contractions/unspecified (1)

- ❑ **No safety signals identified in ongoing monitoring**

*Since October 2011, VAERS has received 221 total reports of Tdap given during pregnancy

CDC's Immunization Safety Office: Summary of Monitoring Activities for Maternal Tdap Safety

❑ Vaccine Safety Datalink (VSD)

- Kharbanda et al. Evaluation of the association of maternal pertussis vaccination with obstetric events and birth outcomes. JAMA 2014;312(18):1897-1904^a
 - *Conclusion: "... receipt of Tdap during pregnancy was not associated with increased risk of hypertensive disorders of pregnancy or preterm or SGA birth ... a small but statistically significant increased risk of chorioamnionitis diagnosis was observed."*
- Safety analyses in progress:
 - Interval between prior tetanus-toxoid containing vaccines and current Tdap vaccination
 - Concurrent administration of Tdap and influenza vaccines

❑ In a VAERS review, chorioamnionitis following receipt of any vaccines was uncommonly reported, representing 1% of pregnancy reports^b

❑ Clinical Immunization Safety Assessment (CISA) Project

- Implemented a prospective observational clinical study of Tdap safety in pregnant women (ClinicalTrials.gov NCT02209623)

^a Previously presented at the February 2014 ACIP meeting

^b Datwani H, et al. Vaccine. 2015 May 11. pii: S0264-410X(15)00594-0. doi: 10.1016/j.vaccine.2015.04.097

ACIP Conclusions June 2013

- ❑ **Public health impact of routinely recommending a second dose of Tdap would be limited**
- ❑ **No change to current Tdap recommendation**
 - Focus on preventing pertussis in infants
 - Pregnant women receive Tdap during each pregnancy
- ❑ **Supported WG to consider additional doses for special populations**
 - Health-care personnel (HCP)
 - Close contacts of infants (“Cocooning”)

ACIP Conclusions October 2014

- ❑ **No supportive evidence that additional doses would be beneficial in prevention of disease and transmission in a health-care setting**
- ❑ **No change to current ACIP Tdap recommendation for HCP**
- ❑ **CDC website: “Evaluating Revaccination of Healthcare Personnel with Tdap: Factors to Consider”**
 - www.cdc.gov/vaccines/vpd-vac/pertussis/tdap-revac-hcp.html

Today's Session

- ❑ “Cocooning” and Tdap vaccination Dr. Jennifer Liang
- ❑ Acellular pertussis vaccine effectiveness among children in the setting of pertactin-deficient *Bordetella pertussis*, Vermont, 2011-2013 Dr. Lucy Breakwell