

# Pertussis Vaccines Work Group

**Art Reingold, MD**

Chair, ACIP Pertussis Vaccine Work Group

Advisory Committee for Immunization Practices

October 29, 2014

# 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

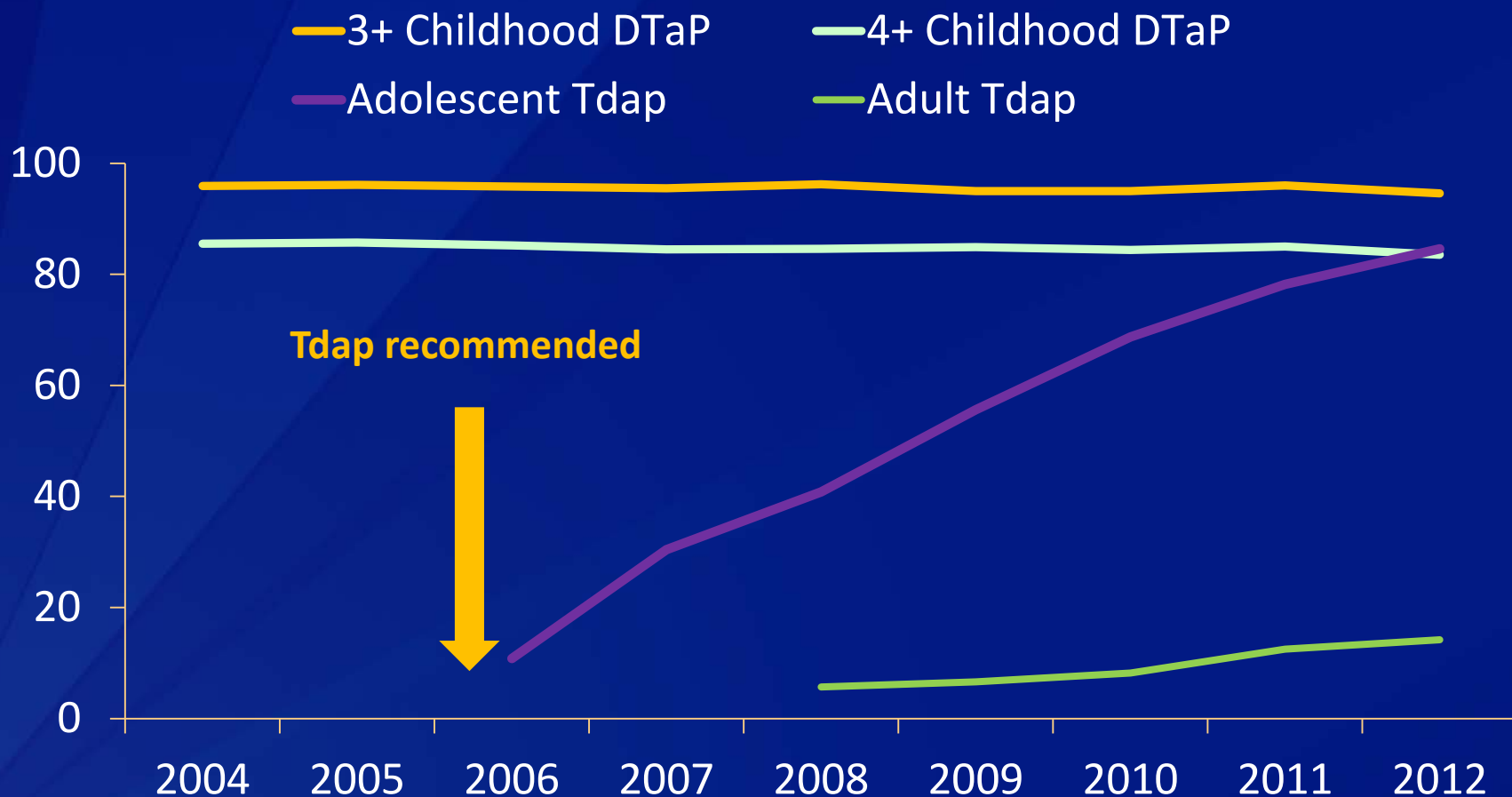
- ❑ **BOOSTRIX® (GlaxoSmithKline Biologicals)**
  - Age indication: 10 and older
  
- ❑ **ADACEL™ (Sanofi Pasteur)**
  - Age indication: 10 through 64

## 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<sup>¶</sup> coverage remains low



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

## **Safety monitoring for Tdap vaccine given during pregnancy in VAERS\* since last ACIP update Feb 2014**

- ❑ **There have been 62 Tdap reports in pregnant women to VAERS since the last ACIP update in February 2014**
  - Tdap given during third trimester in 66% of reports with data on gestational age at time of vaccination
  - 53 non-serious reports
  - 9 serious reports, including 1 death (neonatal demise due to umbilical cord occlusion with fetal vascular thrombus formation)
  - Conditions among other serious reports included:
    - Non-anaphylaxis allergic reaction (2), 1 report each of elevated blood pressure/abdominal pain, severe headache, rhabdomyolysis, multiple systemic symptoms (e.g. fever, chills, myalgias), pneumonia, hypoglycemia in an infant
- ❑ **Overall, no concerning pattern of adverse events**

\*Since October 2011 VAERS has received 152 total reports of Tdap given during pregnancy

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

- ❑ **Vaccine Adverse Event Reporting System (VAERS)**
  - No safety signals identified in ongoing monitoring
- ❑ **Vaccine Safety Datalink (VSD)**
  - Safety data on obstetric events and birth outcomes presented at February 2014 ACIP meeting
  - Analyses in progress:
    - Interval between prior tetanus-toxoid containing vaccines and current Tdap vaccination
    - Concurrent administration of Tdap and influenza vaccines
- ❑ **Clinical Immunization Safety Assessment (CISA) Project**
  - Implemented a prospective observational clinical study of Tdap safety in pregnant women\*

\* Vanderbilt University and Duke University; registered at [ClinicalTrials.gov](http://ClinicalTrials.gov) NCT02209623



## **ACIP Considerations for a Second Dose of Tdap June 2013**

- ❑ Recognition of increasing burden of pertussis**
- ❑ Second Tdap is safe and immunogenic**
- ❑ Protection wanes in few years after Tdap**
- ❑ Cost effectiveness model suggests with second Tdap, reduction of disease burden would be limited**

# 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

## Today's Session

- ❑ Tdap vaccine
- ❑ Pertussis in health-care personnel
- ❑ Impact of vaccinating health-care personnel
- ❑ Work Group conclusions
- ❑ Discussion