

Prevention of Pertussis Among Pregnant & Post Partum Women and Their Infants

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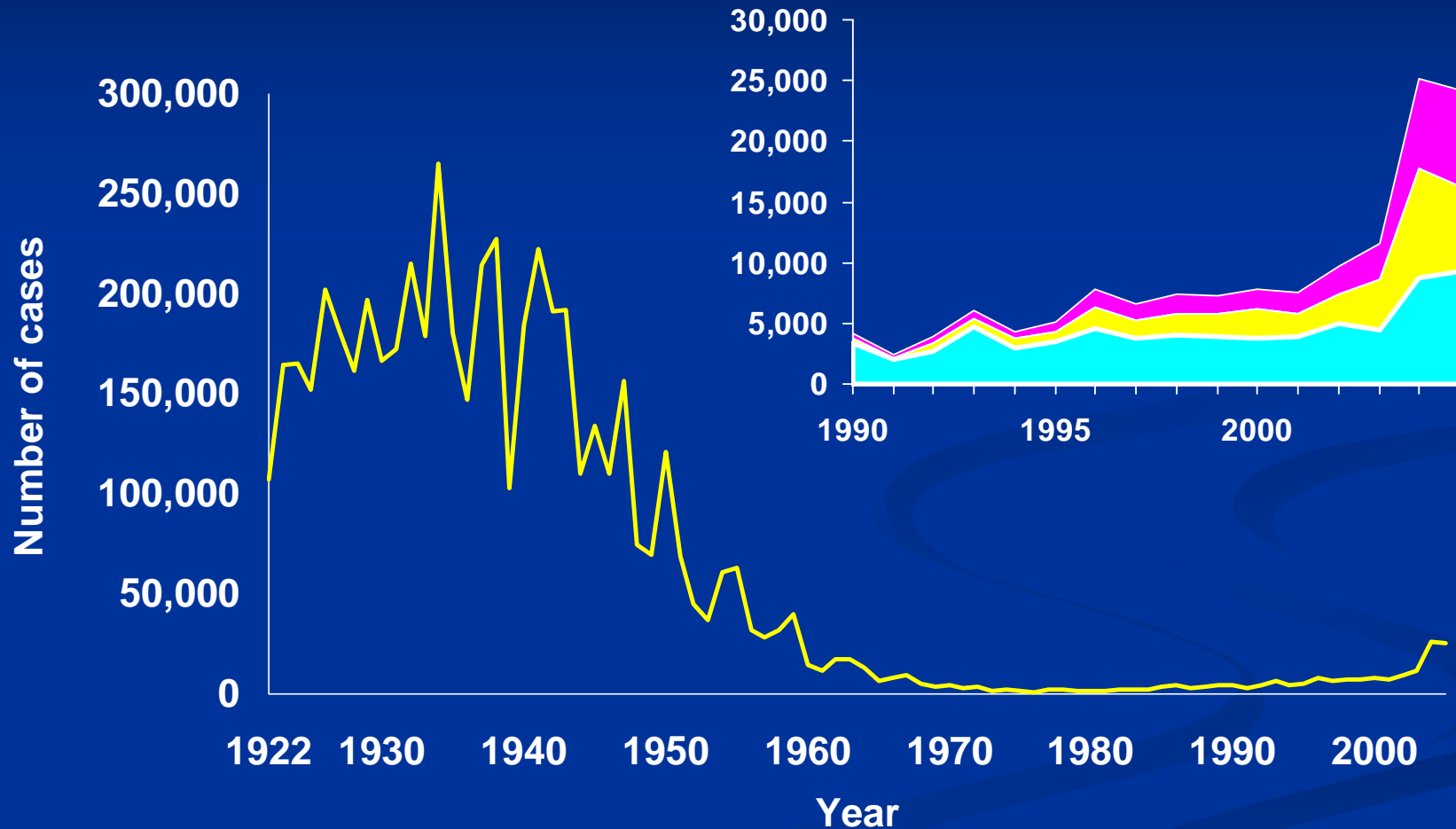
Pertussis and Adults

- Pertussis (whooping cough) – a poorly controlled vaccine-preventable disease
 - Incidence increasing
 - In 2005, 25,616 US cases reported (40 year high)
- Adults vulnerable to pertussis
 - 27% reported cases among adults
 - Pertussis immunity wanes 5 to 10 years after childhood DTaP* series
- First pertussis vaccines (Tdap)[†] for adolescents and adults licensed in 2005

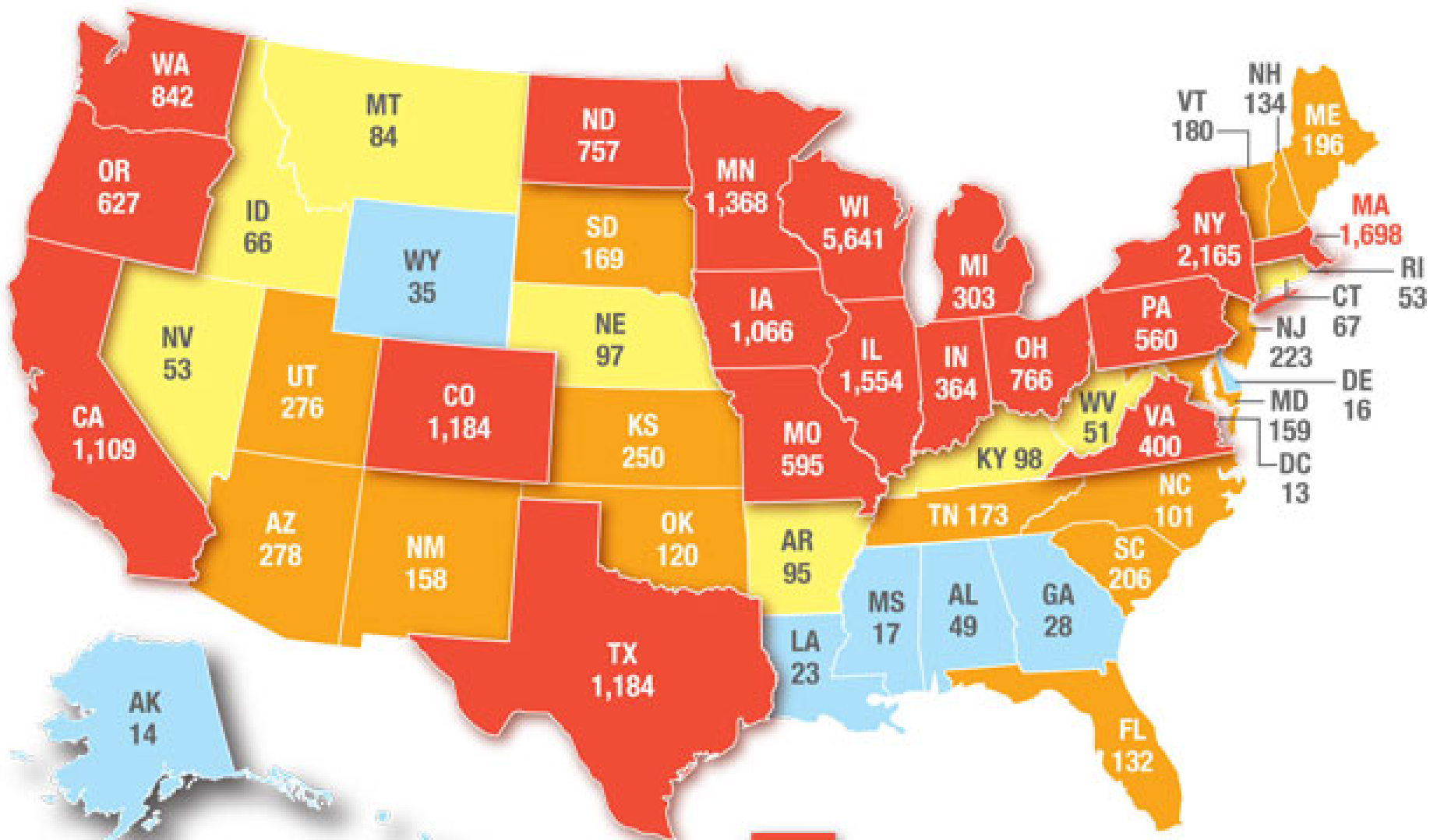
*Diphtheria and tetanus toxoids and acellular pertussis vaccine

†Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine

Reported Pertussis Cases – United States, 1922-2005*

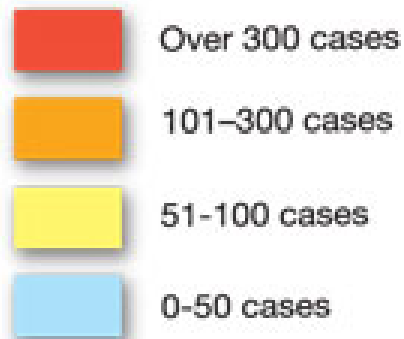


*1950-2005, National Notifiable Diseases Surveillance System and 1922-1949, passive reports to the Public Health Service, courtesy of Kristin Brown



U.S. Totals

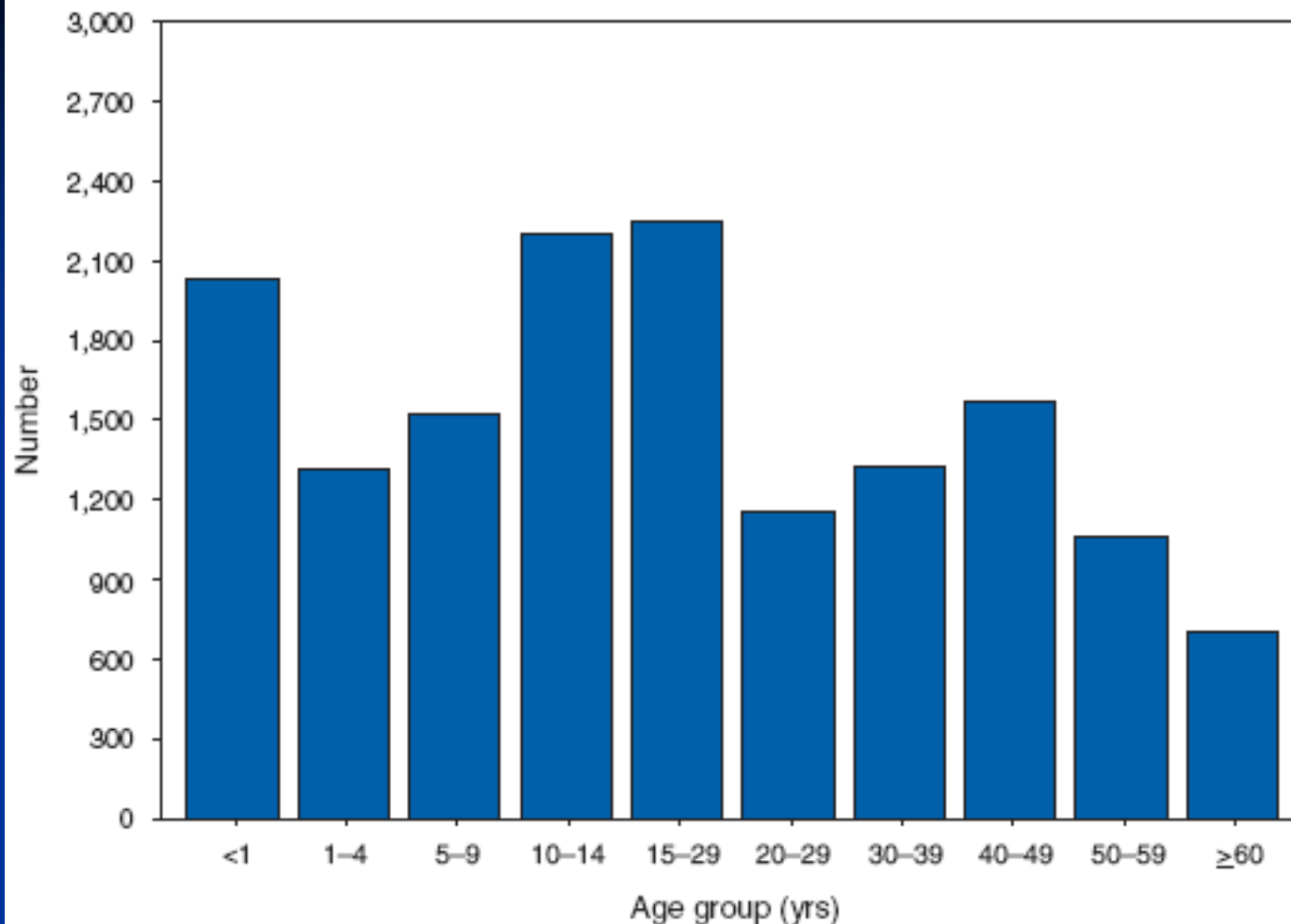
2004: 25,827



Clinical Pertussis

- Upper respiratory illness x 1-2 weeks, followed by cough illness
 - Median duration of cough illness >2 months
- Antimicrobials do not modify the course of illness after cough established
 - Will decrease infectivity of patients if given early
- Can result in repeated medical visits and time lost from work
- High risk groups for pertussis not well defined

PERTUSSIS. Number of reported cases,* by age group — United States, 2006



* Of 15,632 cases of pertussis, age was reported as unknown for 503 persons.

Pertussis is an acute, infectious cough illness that remains endemic in the United States despite longstanding routine childhood pertussis vaccination. Immunity to pertussis wanes 5–10 years after completion of childhood vaccination, leaving adolescents and adults susceptible to infection. Infants, especially those who are undervaccinated, are at increased risk for complicated infections and death from pertussis. Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (Tdap) vaccine is recommended for adolescents and adults, both to reduce the burden of disease in those age groups and to reduce transmission to vulnerable infants.

Selected Clinical Characteristics and Complications Among Adults >19 years with Reported Pertussis

Characteristic	Frequency (% reported) * N=1,139
Paroxysmal cough	84-86
Cough duration >9 weeks	55
Difficulty breathing	86
Post-tussive vomiting	45-54
Whoop	37-41
Weight Loss	33
Pneumonia (CXR confirmed)	2-5
Rib Fracture	4
Hospitalization	3

*Sources: Lee GM et al. Clin Infect Dis 2004;39:1572-80; National Notifiable Diseases Surveillance System and Supplemental Reported Pertussis Surveillance System, 1996-2004.

TABLE 3. Hospitalizations and complications among infants aged <12 months with pertussis, 2000–2004*

Complication	No.	(%)[†]
Hospitalization	6,114	(62.8)
Apnea	5,454	(55.8)
Pneumonia [§]	1,063	(12.7)
Seizures	146	(1.5)
Deaths	92	(0.8)
Total	12,174	(100)

* **Source:** CDC. National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System, 2000–2004. Atlanta, GA: US Department of Health and Human Services, CDC, 2005.

[†] Percentages are based on total number with information. For 20% of infants with cases, no information was available on hospitalization, seizure, or apnea; for 30%, no information was available on pneumonia.

[§] Radiographically confirmed.

Pertussis Transmission to Infants

- Infants <12 months of age greatest risk for death and complications from pertussis
 - From 2000-2004
 - Accounted for 92 / 100 U.S. pertussis deaths
 - Risk of death highest among youngest infants
 - Over 60% infants with pertussis hospitalized
- Adults transmit to infants*
 - Among 264 known source-cases
 - 55% identified as mother, father or grandparent
 - 51% were adults >19 years of age

* Bisgard KM, Pascual FB, Ehresmann KR, Miller CA, Cianfrini C, Jennings CE et al. Infant pertussis: who was the source? *Pediatr Infect Dis J* 2004; 23(11):985-989.

Pertussis in Health-Care Settings

- Health-care personnel (HCP) at increased risk of pertussis exposure and infection
- HCP can transmit to vulnerable patients, including infants
- Pertussis outbreaks reported in pediatric and adult inpatient wards, maternity units and obstetric units
- Infection control activities are resource-intensive, disruptive and costly

Routine Adult Tdap Use Health-care Personnel

- Recommendations supported by HICPAC
- Health-care personnel (HCP) in hospitals* or ambulatory care settings who have direct patient contact should receive Tdap as soon as feasible at an interval as short as 2 years from the last Td.
- Priority to HCP in contact with infants
- Hospitals and ambulatory care facilities should provide Tdap for HCP and use approaches that maximize vaccination rates.

*Hospitals, as defined by the Joint Commission on Accreditation of Healthcare Organizations, do not include long term care facilities such as nursing homes, skilled nursing facilities, rehabilitation and convalescent facilities. Ambulatory care settings include all outpatient and walk-in facilities.

Health Care Workers

- A 2007 study said 87% of health care workers didn't plan to get vaccinated against pertussis.
- "Patients should have the right and every expectation that they're not going to get diseases that they didn't have when they went into the exam room or hospital," said Greg Poland, MD, professor of medicine and director of the vaccine research group at Mayo Clinic in Rochester, Minn.

Hospital-Acquired Pertussis Among Newborns --- Texas, 2004

- On July 10, 2004, staff members at a children's hospital in Texas noted that six infants with pertussis diagnosed by clinical symptoms and confirmed by polymerase chain reaction (PCR) testing had all been born during June 4--16 at the same area general hospital. The infants had symptoms consistent with pertussis, including cough, congestion, cyanosis, emesis, or apnea...One staff member (HCW A) was identified as having directly cared for all six infants during their stay in the newborn nursery.

Use of Tdap Among Pregnant Women

- Infants <6 months of age at highest risk for complications and death from pertussis
- Passive maternal antibody could help protect young infants
- Most pregnant women have little or no antibody to pertussis (hence no transfer to infant)
- Tdap vaccination of childbearing-age women could boost maternal antibody
- Concern by some experts that passive antibody could blunt infant's response to DTaP
- No safety data among pregnant women

Use of Tdap Among Pregnant Women

- Any woman who might become pregnant is encouraged to receive a single dose of Tdap (Adacel only)
- Women who have not received Tdap should receive a dose in the immediate post-partum period
- Td generally preferred during pregnancy
- Clinician may choose to administer Tdap to a pregnant woman in certain circumstances (such as during a community pertussis outbreak)
- Pregnancy is not a contraindication for Tdap

Vaccination During Pregnancy

- Provisional recommendations
- Routine post-partum Tdap:
 - Pregnant women who have not received a dose of Tdap (including breastfeeding) should receive Tdap after delivery, before discharge from the hospital.
- Tetanus, diphtheria and neonatal tetanus protection:
 - Pregnant women for whom 10 years or more have elapsed since last Td booster may defer Td and use Tdap post-partum if tetanus protection is likely.
 - Td recommended if tetanus and diphtheria protection required during pregnancy
- Pregnancy not contraindication for Tdap

Sufficient tetanus protection is likely if:

- a pregnant woman aged <31 years has received a complete childhood series of immunization (4--5 doses of pediatric DTP, DTaP, and DT) and ≥ 1 Td booster dose during adolescence or as an adult (a primary series consisting of 3 doses of Td (or TT) administered during adolescence or as an adult substitutes for the childhood series of immunization),**
- a pregnant woman aged ≥ 31 years has received a complete childhood series of immunization (4--5 doses of pediatric DTP, DTaP, and/or DT) and ≥ 2 Td booster doses,
- a primary series consisting of 3 doses of Td (or TT) was administered during adolescence or as an adult substitute for the childhood series of immunization,** or
- a pregnant woman has a protective level of serum tetanus antitoxin (≥ 0.1 IU/mL by ELISA).

Special situations in which Tdap might be used might include instances when..

- a pregnant woman has insufficient tetanus or diphtheria protection until delivery, or
- a pregnant woman is at increased risk for pertussis.
- If Tdap is administered during pregnancy, the second or third trimester is preferred unless protection is urgently needed.
- ACIP recommends Td booster for wound management in pregnant women if 5 or more years have elapsed since the previous Td booster, and Tdap may be substituted with appropriate warning about lack of data for administration during pregnancy.

Persons at increased risk for pertussis might include adolescents aged 11--18 years, health-care personnel, and women employed in institutions in which a pertussis outbreak is occurring or living in a community in which a pertussis outbreak is occurring.

Tdap Products Licensed in the United States

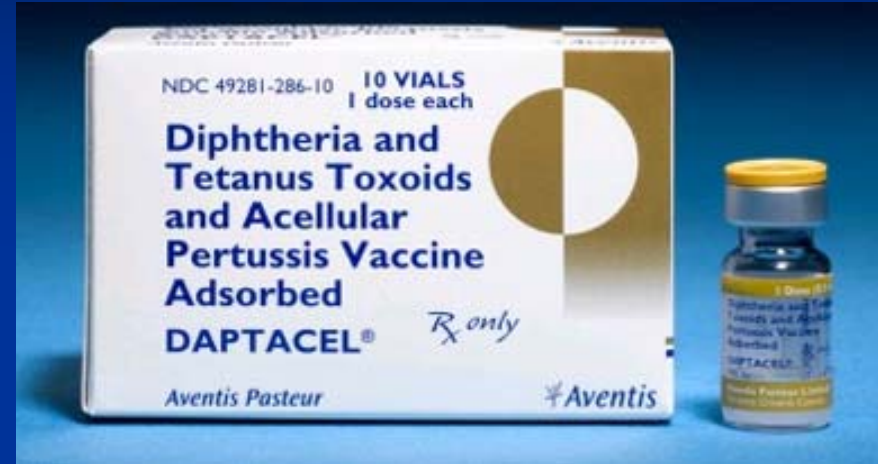
	BOOSTRIX[®] (GlaxoSmithKline Biologicals)*	ADACEL[®] (sanofi pasteur)[†]
Date of FDA licensure	May 3, 2005	June 10, 2005
Age Indication (years)	10–18	11–64
Usage	Active booster immunization for prevention of tetanus, diphtheria, and pertussis as a <u>single</u> dose	

*Product label available at http://us.gsk.com/products/assets/us_boostrix.pdf

[†]Product label available at <http://www.vaccineplace.com/products/>



Inadvertent Administration of Tdap (BOOSTRIX®) or Pediatric DTaP



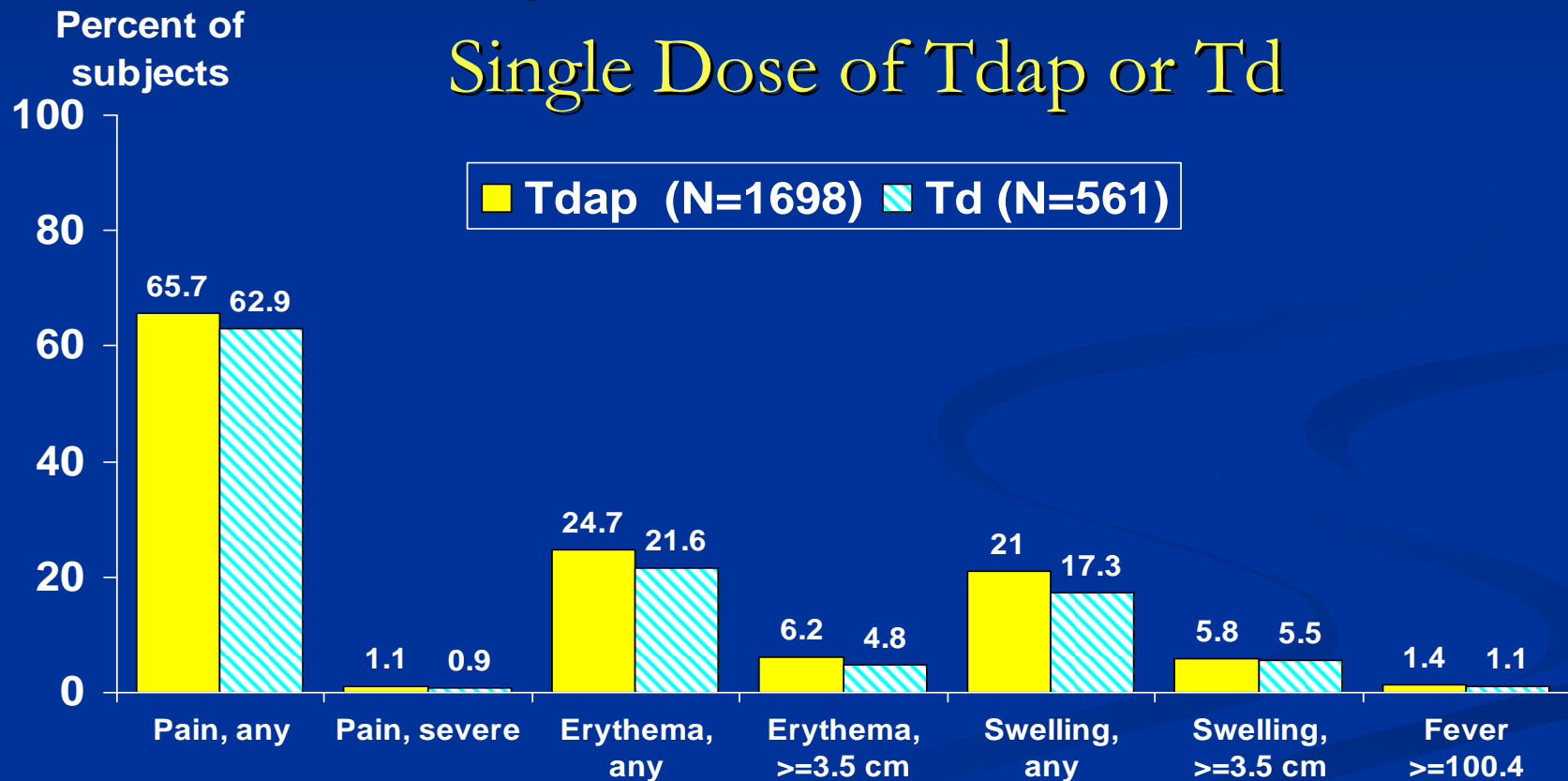
Source: www.vaccineshoppe.com

- If BOOSTRIX® or pediatric DTaP is administered to an adult aged ≥ 19 years, this dose should count as the Tdap dose and the patient should not receive an additional dose of Tdap (ADACEL®).

ADACEL[®] Safety

Rates of Selected Solicited Adverse Events

In Adults Aged 18—64 Within 15 Days After a Single Dose of Tdap or Td



Source: Product label available at <http://www.vaccineplace.com/products/>

Post Partum Vaccination (all ok for Nursing mothers)

- MMR
- Varicella
- Tdap
- HBV
- HAV
- HPV
- Influenza
- Pneumococcal (for at risk)

Routine Adult Tdap Use

Adults in Contact With Infants

- Adults who have or who anticipate having close contact with an infant aged <12 months should receive a single dose of Tdap
 - An interval as short as 2 years from last Td suggested
 - Ideally at least 2 weeks before contact with the infant.
- Infants should receive DTaP on schedule
- When possible, women should receive Tdap before conception.
- Pregnant women should receive Tdap in the immediate post-partum period.

<i>Infect Dis Obstet Gynecol.</i> 2006; 2006: 87040.	Promoting Tdap vaccine among adults in close contact w/ infants	Administering Tdap vaccine to adults in close contact w/ infants
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I would likely recommend Tdap vaccine for women during pregnancy if recommended by ACIP/ACOG

Agree/strongly agree	77%	<0.001	75%	<0.001
Neutral/disagree/strongly disagree	50%	-	60%	-

I would likely recommend Tdap vaccine for women immediately after delivery if recommended by ACIP/ACOG

Agree/strongly agree	85%	<0.05	83%	<0.05
Neutral/disagree/strongly disagree	59%	-	68%	-