



Updated ACIP statement for pertussis, tetanus and diphtheria vaccines

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on behalf of the Pertussis Vaccines Work Group

Advisory Committee on Immunization Practices

October 19, 2016

Outline

- Objectives of updated statement
- Current epidemiology of pertussis, tetanus and diphtheria
- List of current pertussis, tetanus and diphtheria vaccines
- ACIP recommendations and guidance
- Vote

Objectives of updated statement

- Provide overview of current epidemiology
 - Tetanus
 - Diphtheria
 - Pertussis
- Provide updated list of current vaccines
- Provide recommendations for routine vaccination and guidance for use in a single document
- Describes the process undertaken and the rationale used in support of these recommendations
- Serve as a resource for clinicians and public health providers

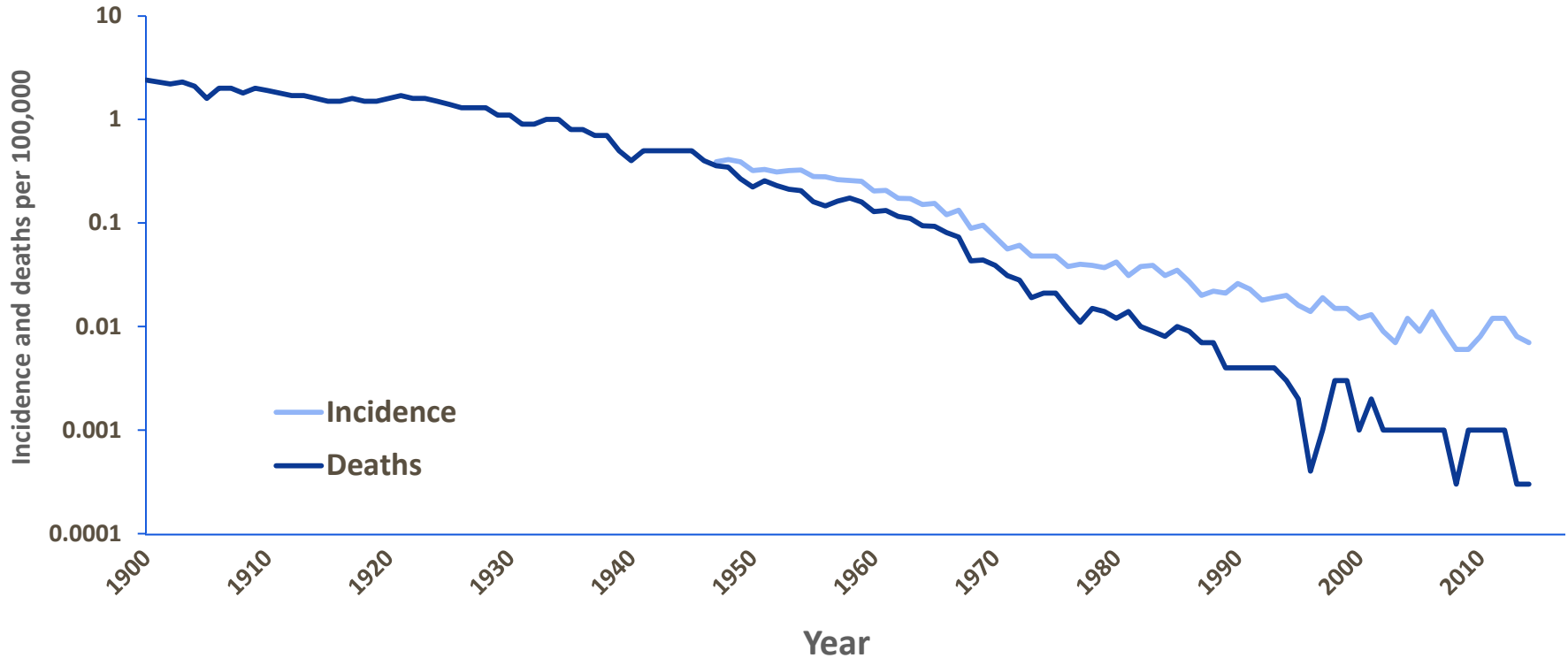
Statement Revision Activities

- Reviewed
 - Published DTaP and Tdap vaccine recommendations
 - Peer-reviewed literature
 - Surveillance data from the National Notifiable Diseases Surveillance System (NNDSS) and Enhanced Pertussis Surveillance* (EPS)
- WG reviewed draft statement and provided comments by email
- ACIP voting members reviewed draft statement and provided comments by email prior to October meeting

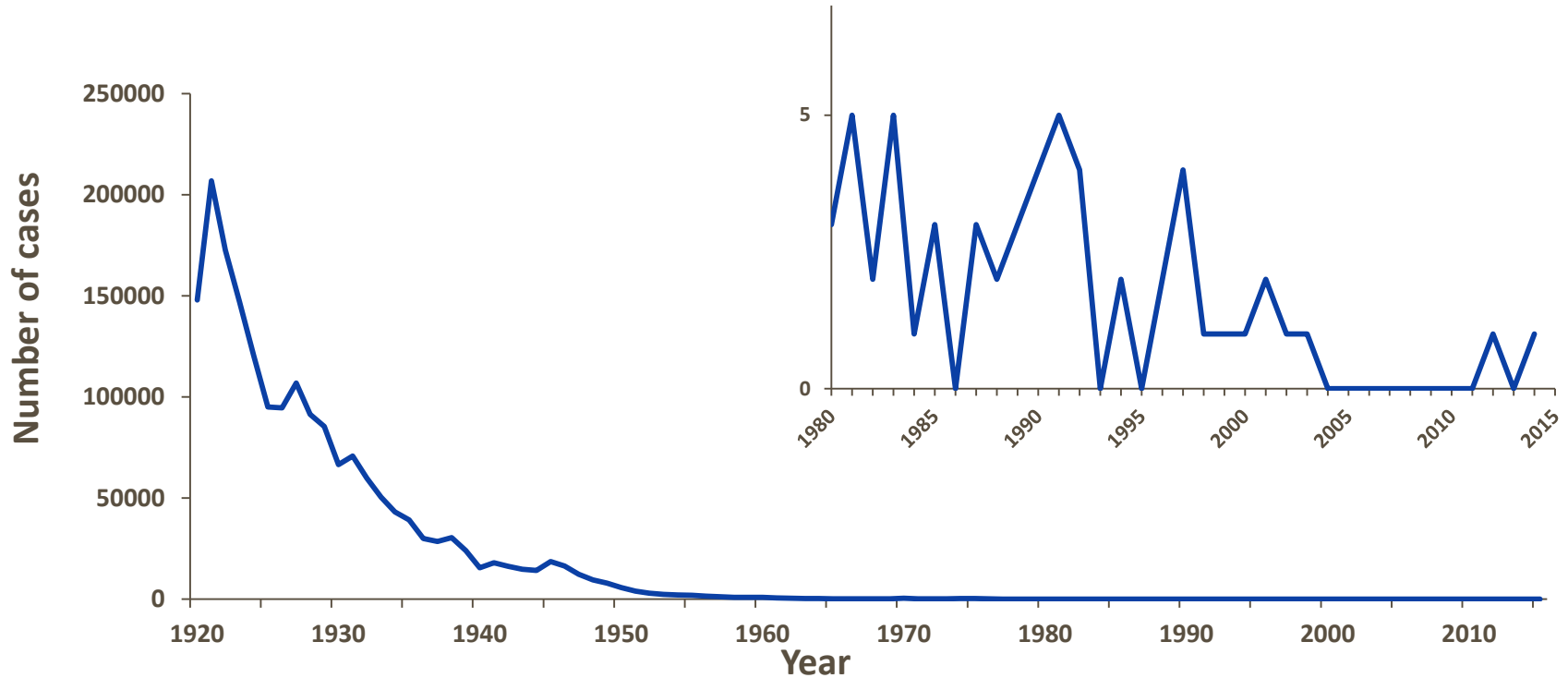
* EPS is a component of the CDC's Emerging Infections Programs network (EIP)

Summary of updated statement

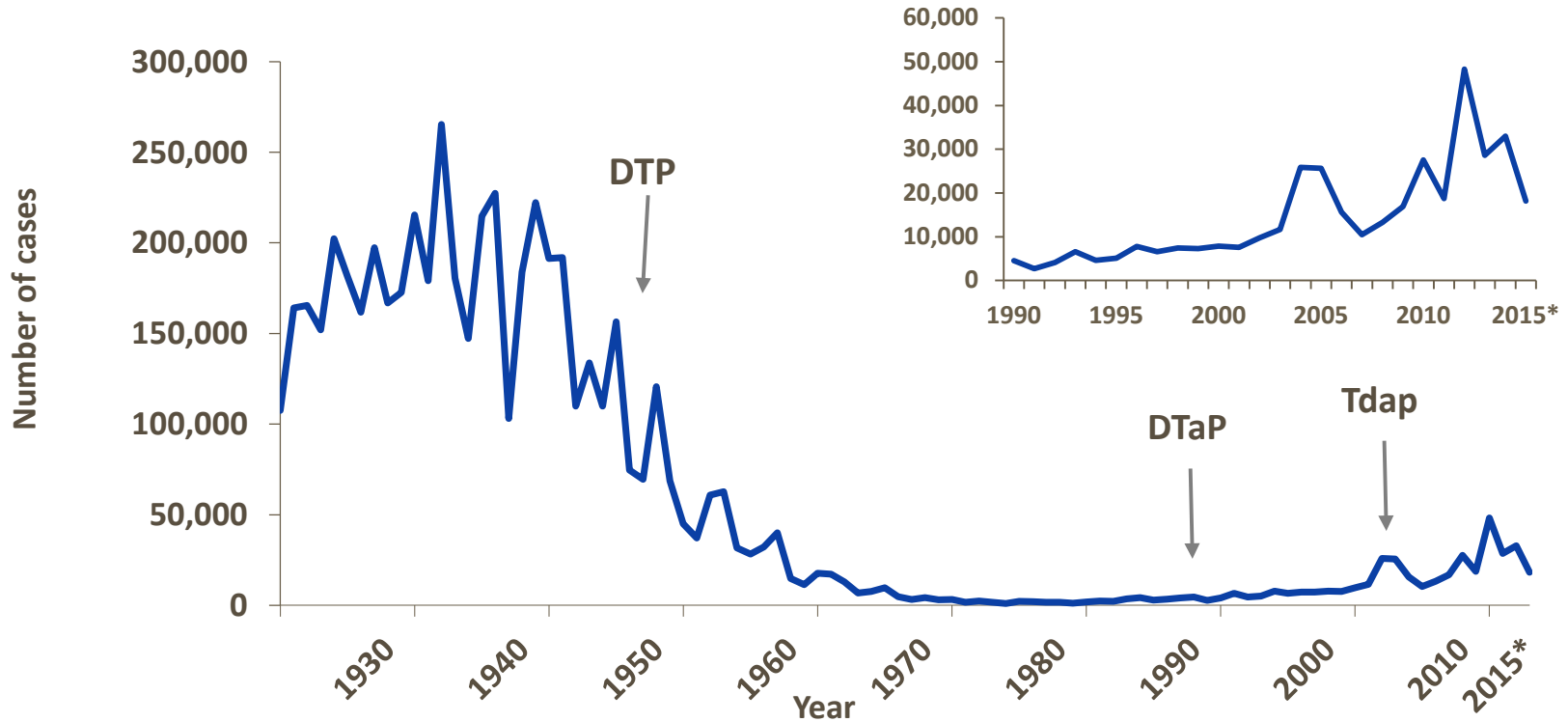
Annual incidence and deaths of tetanus -- United States, 1900-2014



Number of reported diphtheria cases -- United States, 1920-2015



Number of reported pertussis cases – United States, 1922-2015*



Sources: National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System and 1922-1949, passive reports to the Public Health Service

*2015 data are provisional

Currently licensed and available DTaP and DT vaccines – United States, 2016

Vaccine Type	Trade name	Manufacturer	Pertussis antigens (µg)				Diphtheria toxoids (Lf)	Tetanus toxoids (Lf)	Age for approved use				
			PT	FHA	PRN	FIM			2 mth	4 mth	6 mth	15-18 mths	4-6 yrs
<u>DTaP vaccines*</u>													
DTaP	Infanrix	GlaxoSmithKline	25	25	8		25	10	X [†]	X	X	X	X
DTaP	Daptacel	Sanofi Pasteur, Inc.	10	5	3	5	15	5	X [†]	X	X	X	X
<u>Combination vaccines with DTaP*</u>													
DTaP-IPV-HepB	Pediarix	GlaxoSmithKline	25	25	8		25	10	X [†]	X	X		
DTaP-IPV-Hib	Pentacel	Sanofi Pasteur, Inc.	20	20	3	5	15	5	X [†]	X	X	X	
DTaP-IPV	Kinrix	GlaxoSmithKline	25	25	8		25	10					X
DTaP-IPV	Quadracel	Sanofi Pasteur, Inc.	20	20	3	5	15	5					X
<u>DT vaccine*</u>													
DT	No trade name	Sanofi Pasteur, Inc.	-	-	-	-	6.7	5	X [†]	X	X	X	X

Abbreviations: DT= diphtheria and tetanus toxoids; DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepB = hepatitis B; Hib = *Haemophilus influenzae* type b; IPV = inactivated poliovirus; PT = pertussis toxin; FHA = filamentous hemagglutinin; PRN = pertactin; FIM = fimbriae

* Vaccine dosage and administration: 0.5mL intramuscular injection

† Licensed for use in infants as young as 6 weeks

Currently licensed and available Tdap and Td vaccines – United States, 2016

Vaccine Type	Trade name	Manufacturer	Age for approved use (years)	Pertussis antigens (µg)				Diphtheria toxoids (Lf)	Tetanus toxoids (Lf)
				PT	FHA	PRN	FIM		
<u>Tdap vaccines*</u>									
Tdap	Adacel	Sanofi Pasteur, Inc.	10--64	2.5	5	3	5	2	5
Tdap	Boostrix	GlaxoSmithKline	≥10	8	8	2.5	-	2.5	5
<u>Td vaccines*</u>									
Td	No trade name	MassBiologics	≥7	-	-	-	-	2	2
Td	Tenivac	Sanofi Pasteur, Inc.	≥7	-	-	-	-	2	5

Abbreviations: Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; Td = tetanus and diphtheria toxoids; PT = pertussis toxin; FHA = filamentous hemagglutinin; PRN = pertactin; FIM = fimbriae

* Vaccine dosage and administration: 0.5mL intramuscular injection

ACIP recommendations and guidance (1)

- Routine recommendations for DTaP/DT, Tdap and Td
 - Last ACIP statements published
 - DTaP: Infants and young children (1997)
 - Tdap: Adolescents (2006); Adults (2006); Pregnant and postpartum women and their infants (2008)
 - MMWR Policy Notes
 - Tdap administration regardless of interval since last tetanus-toxoid containing vaccine (2010)
 - Catch-up schedule for children aged 7 through 10 years: receive a single dose of Tdap (2010)
 - Routinely recommend a dose of Tdap for adults aged 65 and older (2012)
 - A dose of Tdap during every pregnancy (2012)

- No changes to previously published routine recommendations

ACIP recommendations and guidance (2)

- MMWR Notice to Readers
 - DTaP vaccines that became available after 1997 statement
 - Updates to label indications for DTaP and Tdap products
- Updated
 - Discontinuation of Monovalent Tetanus toxoid (TT) vaccine
 - Contraindications and Precautions consistent with AAP Red Book
 - For persons aged 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose may be given at age 11 through 12 years
 - In line with guidance of children for which Tdap is inadvertently administered

Today's vote

- Affirm updated statement:

Prevention of Pertussis, Tetanus and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

- No new vaccine recommendations
- To be updated/included:
 - “Guidance for use” of Tdap for pregnant women
 - Also include summary of supporting data
 - Table: Summary of Tdap safety studies in pregnant women and their infants

ACIP Pertussis Work Group Members

(July 2016)

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[¶] Former ACIP member during deliberations

Acknowledgements

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