



Background: Repeat Tdap vaccination

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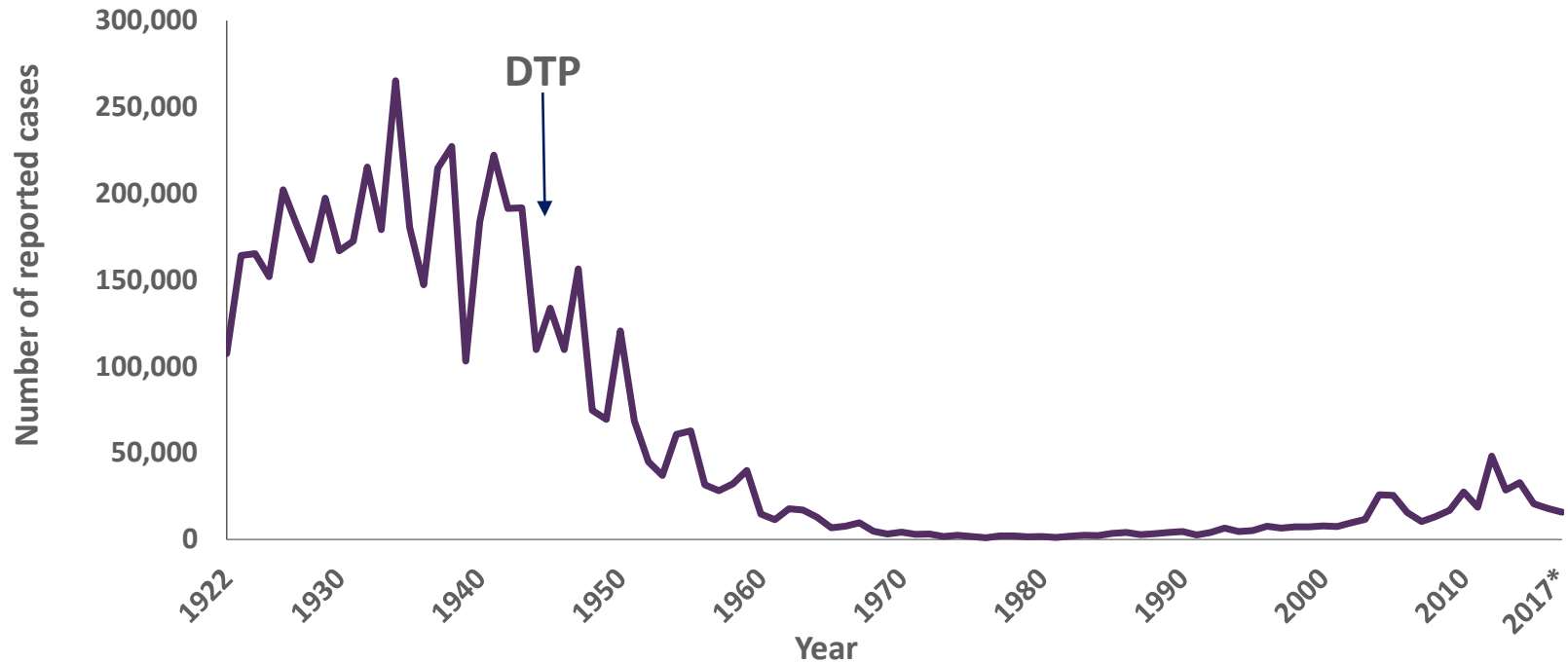
Advisory Committee on Immunization Practices

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Overview

- Pertussis epidemiology
- Available vaccines for adults and adolescents (Tdap and Td)
- Current ACIP recommendations for Tdap
- Previous work group and ACIP consideration of repeat Tdap vaccinations
- Rationale for revisiting repeat vaccination issue

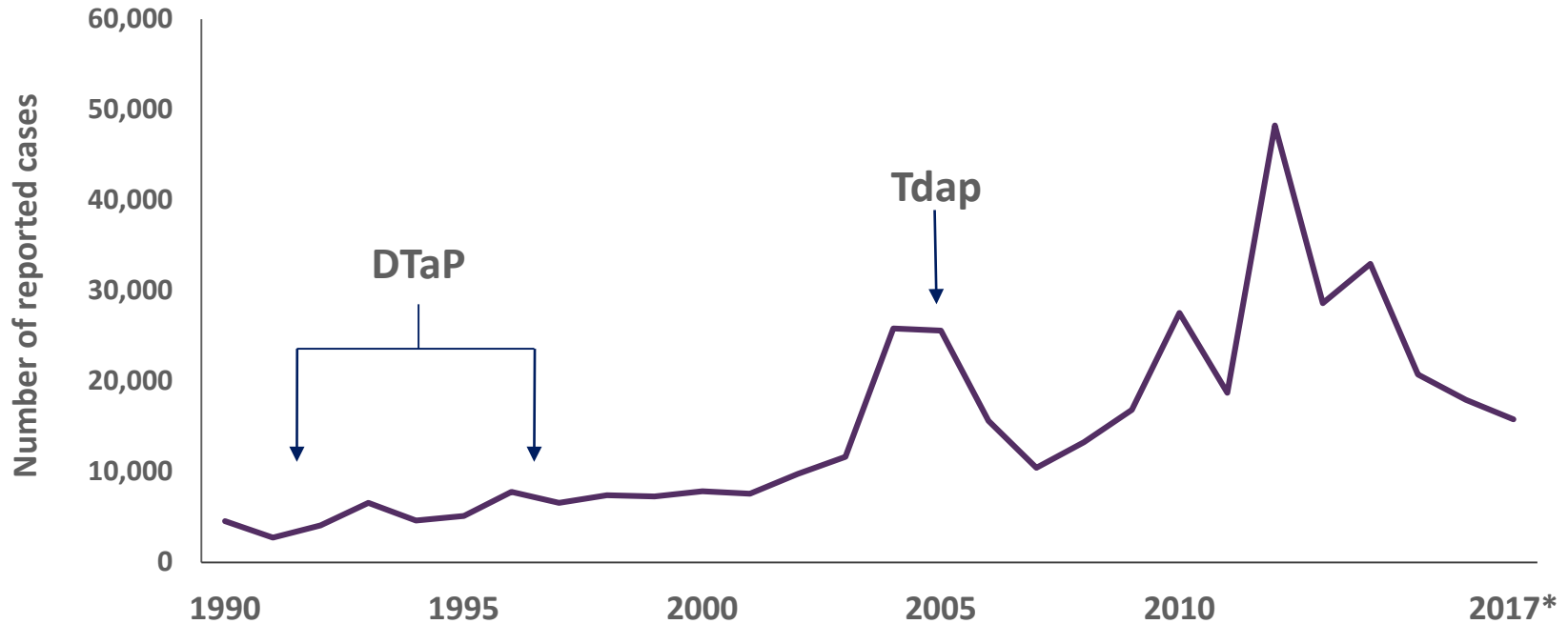
U.S. Reported Pertussis Cases: 1922-2017



*2017 data are provisional and subject to change.

SOURCE: CDC, National Notifiable Diseases Surveillance System and 1922-1949, passive reports to the Public Health Service

U.S. Reported Pertussis Cases 1990-2017



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SOURCE: CDC, National Notifiable Diseases Surveillance System and 1922-1949, passive reports to the Public Health Service

Tdap and Td vaccines licensed in the United States

Vaccine type	Trade name	Manufacturer	Pertussis antigens (μg)				Diphtheria Toxoids (Lf)	Tetanus Toxoids (Lf)	Age for licensed use
			PT	FHA	PRN	FIM			
Tdap	Adacel*	Sanofi	2.5	5	3	5	2	5	10—64 yrs
Tdap	Boostrix*	GSK	8	8	2.5	-	2.5	5	≥ 10 yrs
Td	Tenivac	Sanofi					2	5	≥ 7 yrs
Td	n/a	MassBiologics					2	2	≥ 7 yrs

* Licensed for single use only

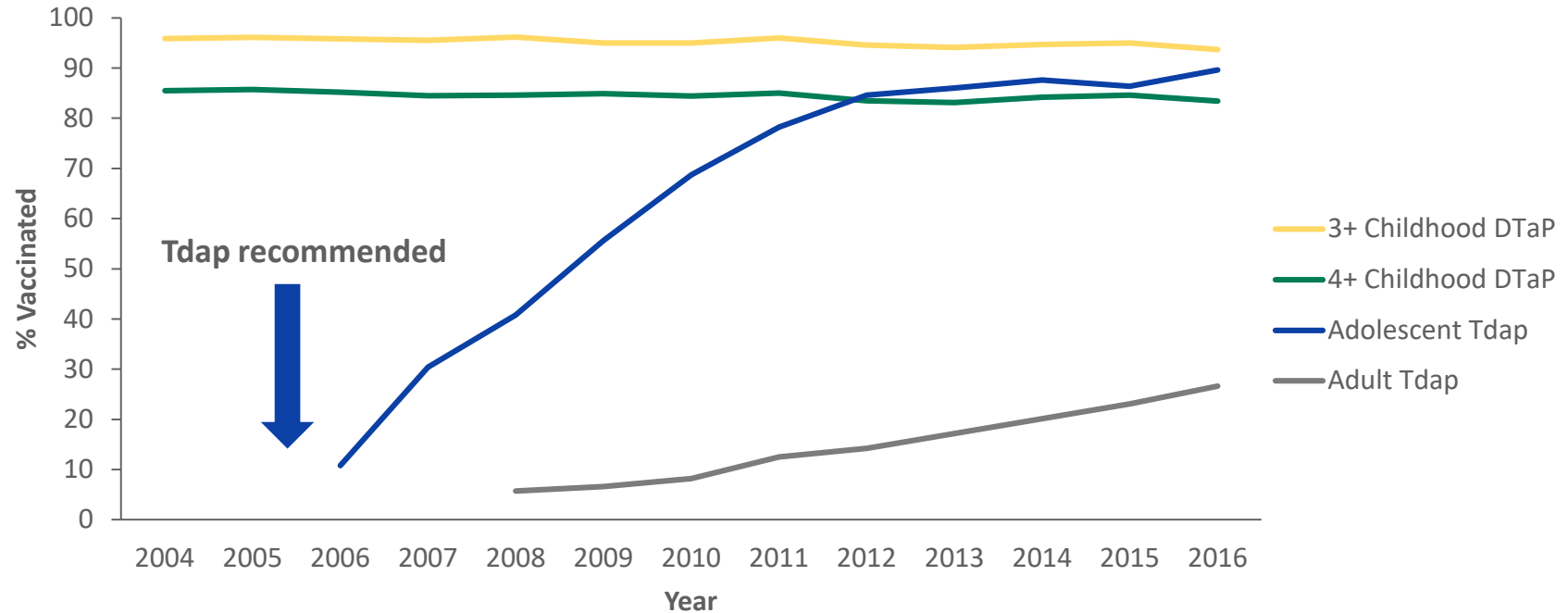
Abbreviations: Pertussis toxin (PT); filamentous haemagglutinin (FHA); pertactin (PRN); fimbriae (FIM)

Current ACIP Recommendations for Tdap in adolescents and adults in the United States

- **Single dose of Tdap:** Persons aged ≥ 11 years
 - Preferably at aged 11-12 years
- **Booster dose of Td every 10 years**
 - Single Tdap can replace decennial Td booster dose
 - Dose administered regardless of interval since last Td vaccine
 - 5 years if needed for tetanus prophylaxis for wound management
- **Tdap during every pregnancy**
 - No interval between repeat Tdap doses
 - Off label recommendation

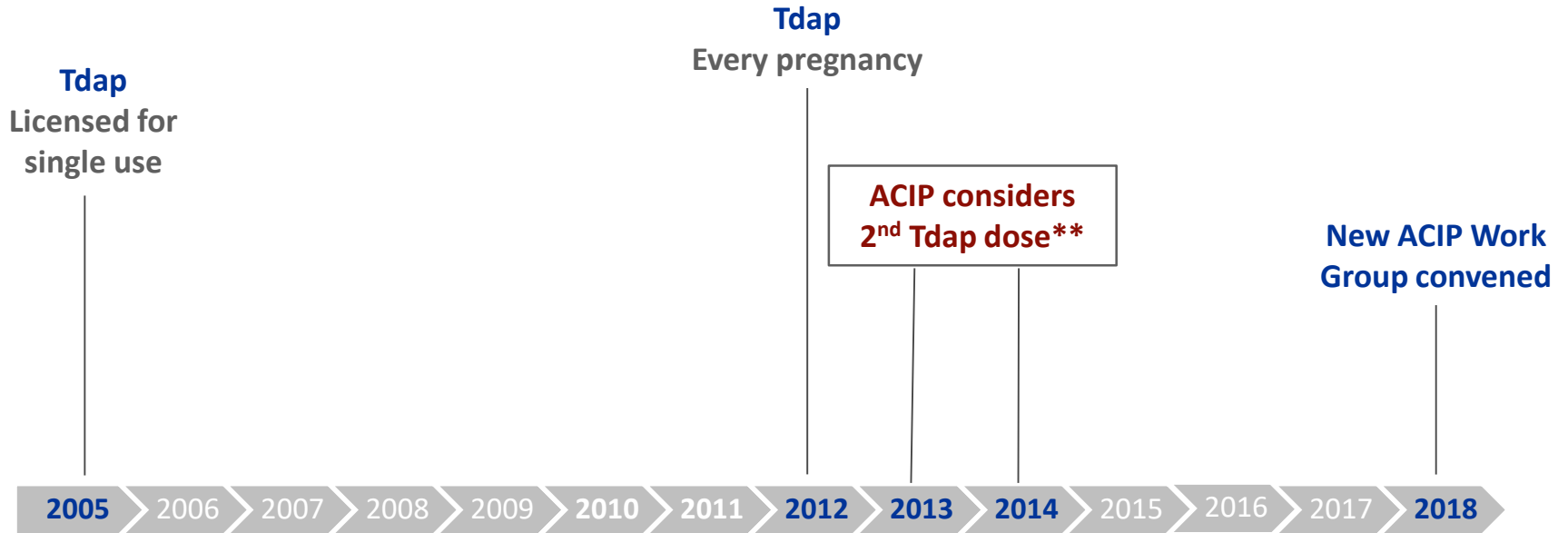


Pertussis Vaccination Coverage* Among The U.S. Population, 2004-2016



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

Adolescent and adult Tdap recommendations for in the United States



* Recommended during pregnancy for women who had not previously received a Tdap vaccination
** For the general population (2013); healthcare workers and those with contact with infants (2014)

Previous Work Group and ACIP discussions of repeat Tdap vaccination

- Evolving pertussis epidemiology
- Vaccine effectiveness and duration of protection
- Immunogenicity
- Safety of repeat Tdap vaccination
- Potential impact on pertussis disease burden
- Economic impact

Previous Work Group and ACIP discussions: Changing pertussis epidemiology

- Improved diagnosis and reporting
- Possible changes in circulating pertussis strains
- Evidence of waning of protection from acellular pertussis vaccines
 - Changes in age distribution of cases
 - Emergence of disease in adolescents who had received Tdap

Previous Work Group and ACIP discussions: Vaccine effectiveness (VE) and duration of protection

- Initial Tdap VE in adolescents:
 - Tdap VE high (~75%) within first year
 - Substantial waning in 2-4 years
- VE data consistent with pertussis epidemiology

Gustafsson et al. NEJM 1996; 334: 349-55; Rank C, et al. Pediatr Infect Dis J. 2009 Feb;28(2):152-3; Schmitt et al. JAMA 1996; 275: 37-41; Wei SC, et al. CID 2010; 51(3):315-321; Pichichero et al. JAMA 2005; 293: 3003-11; Ward JI et al. N Engl J Med. 2005 Oct 13;353(15):1555-63; Acosta A, et al. Pediatrics. 2015 Jun;135(6):981-9; Breakwell L, et al. Pediatrics. 2016 May;137(5).

Previous Work Group and ACIP discussions: Immunogenicity

- Initial Tdap
 - Rapid decline in first 1-2 years, slower decline over 10 years
 - Antibody levels higher than pre-vaccination, but after 10 years close to pre-vaccination
 - Antibody contributes to protection, but no well-established level of antibody correlates with protection
- Second Tdap
 - Antibody response similar to first Tdap in cohorts boosted after 5 or 10 years
 - Tetanus and diphtheria: Robust antibody response, persistence comparable to Td

Previous Work Group and ACIP discussions: Safety of repeat vaccination

- Second Tdap
 - Response at 5- and 10- year intervals:
 - Local reactions common, systemic reactions less common
 - Mild to moderate and self-limited
 - Frequency generally comparable to first Tdap
 - Serious AEs rare, not related to vaccine
 - Safety profiles comparable at the 5 and 10 year interval

Previous Work Group and ACIP discussions: Impact on disease burden and economic impact

- Initial Tdap:
 - Evidence of direct protection
 - Potentially limited impact on disease transmission and herd immunity
 - Evidence from animal models
 - Lack of epidemiologic data
- Second Tdap:
 - Specific revaccination strategies were not likely to be cost-effective
 - Economic impact of revaccinating a cohort at 16 and 21 years old
 - Reduction of disease burden would likely be limited

Previous Work Group and ACIP discussions: 2013 and 2014 Summary

- Increase in pertussis expected to continue
- First Tdap vaccination has high initial VE, but substantial waning of protection wanes within 2-4 years
- Second Tdap is safe and immunogenic
- Reduction of disease burden would likely be limited with second Tdap
- Given cost of Tdap compared with Td, specific revaccination strategies were not likely to be cost-effective

- **Conclusion:** Data did not support recommendation for second Tdap

Why consider repeat Tdap vaccination now?

- Application for FDA label change to remove “single use” language
 - Manufacturer of one Tdap product filed a Biologics License Application (BLA)
 - FDA accepted the application
 - Review expected to be complete by January 2019
- Repeat Tdap vaccination in clinical practice
 - Large retrospective study of repeat Tdap doses
 - Many providers not stocking both Td and Tdap
 - Allowing Tdap for the decennial Td booster would be easier for providers

Questions to be addressed by ACIP

- Should the current recommendation that non-pregnant adults receive a single lifetime dose of Tdap and Td boosters every 10 years be changed to allow any Td-containing vaccine (Tdap or Td) to be used for the decennial Td booster in adults?
- Should any Td-containing vaccine (Tdap or Td) be allowed for use for tetanus prophylaxis in the setting of wound management?

Questions for ACIP

- Are there specific data ACIP would like presented?
- Are there specific options or other considerations the Work Group should address?

Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

