



# Tdap and Td: Summary of Work Group considerations and proposed policy options

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# Agenda

- Work Group's assessment of catch-up immunization safety data
- Clarification of CDC guidance
- Summary of Work Group considerations
- Proposed text for policy options

# Work Group assessment: Safety of >1 dose of Tdap for catch-up immunization schedule

- Published studies reassuring
  - Data limited
  - Includes an RCT comparing safety and immunogenicity of Tdap v. Td for catch-up immunization schedule
- Available published and unpublished data on closely-spaced Tdap vaccines
  - No concerning safety signal, including in pregnant women
  - Data sparse on safety of multiple doses of Tdap during a single pregnancy
- Need for continued safety monitoring

**Work Group consensus:** Either Td or Tdap can be used for additional doses of the catch-up immunization schedule for persons  $\geq 7$  years, both in the general population and for pregnant women

# Clarification of CDC guidance: Tdap in persons aged 7–10 years

- **Current guidance:** Children 7–10 years who receive Tdap inadvertently or for catch-up immunization **should** receive Tdap again at age 11–12 years
- Questions from health departments, immunization programs, and providers about 10 year-olds who receive Tdap for school entry requirements
- Both Tdap vaccines are now licensed to 10 years of age
- **Clarification of guidance** in children 7–10 years who receive a dose of Tdap:
  - **Children 7–9 years:** receive adolescent Tdap at 11–12 years
  - **Children aged ≥10 years:** Tdap does not need to be repeated
- Similar changes made to inadvertent DTaP administration guidance
- Plan to include changes as “CDC Guidance” in Policy Note

## Should either Td or Tdap be allowed for use in settings where only Td is currently recommended for the decennial booster, tetanus prophylaxis for wound management, and the catch up immunization schedule?

| Criteria                              | Work Group Interpretation   |
|---------------------------------------|---|
| Benefits and Harms                    | <ul style="list-style-type: none"><li>• Increased flexibility for providers</li><li>• May be some additional benefit for pertussis control<ul style="list-style-type: none"><li>• Not enough evidence to recommend Tdap preferentially replace Td</li></ul></li><li>• No substantive safety concerns</li></ul> <p><b>Benefits outweighs potential harms</b></p> |
| Values, Acceptability and Feasibility | <ul style="list-style-type: none"><li>• Providers value flexibility</li><li>• Evidence of widespread use of Tdap instead of Td</li></ul> <p><b>Valued by stakeholders; change is acceptable and feasible</b></p>  |
| Resource Use                          | <ul style="list-style-type: none"><li>• Tdap more expensive than Td</li><li>• Economic analyses limited by uncertainty in key parameters</li></ul> <p><b>Economic impact not a major consideration</b></p>  |

# Policy options for ACIP consideration

| Policy issue   | Work Group Interpretation           |
|--|-------------------------------------|
| <b>Either Td or Tdap</b> can be used for the decennial Td booster  | We are in favor of the intervention |
| <b>Either Td or Tdap</b> can be used for tetanus prophylaxis in the setting of wound management  | We are in favor of the intervention |
| <b>Either Td or Tdap</b> can be used for additional doses of the catch-up immunization schedule for persons $\geq 7$ years, including for pregnant women | We are in favor of the intervention |

# Potential off-label recommendations

| Licensed Tdap product                           | FDA approved indications for usage and administration  | Potential off-label recommendations  |  |  |
|---|--|--|--|--|
|   |  | Decennial Td booster (adults only)   | Tetanus prophylaxis for wound management   | Catch-up immunization series <sup>1,2</sup>  |
| <b><u>Adacel</u></b><br><b>(Sanofi Pasteur)</b> | <ul style="list-style-type: none"> <li>Age: 10 through 64 years</li> <li>Routine booster<sup>3</sup> with a 2<sup>nd</sup> dose ≥8 years after first (any) Tdap dose</li> <li>Tetanus prophylaxis if ≥5 years since last tetanus containing vaccine<sup>4</sup></li> </ul> | <ul style="list-style-type: none"> <li>Age ≥65 years</li> <li>Any dose beyond 2<sup>nd</sup> <u>Adacel</u> dose administered ≥8 years from first Tdap</li> </ul> | <ul style="list-style-type: none"> <li>Age &lt;10 or ≥65 years</li> </ul>  | <ul style="list-style-type: none"> <li>Age 7 to 9 years or ≥65 years</li> <li>&gt;1 Tdap dose</li> </ul> |
| <b><u>Boostrix</u></b><br><b>(GSK)</b>          | <ul style="list-style-type: none"> <li>Age: ≥10 years</li> <li>Single dose<sup>3</sup></li> <li>Tetanus prophylaxis if no previous Tdap<sup>4</sup></li> </ul>   | <ul style="list-style-type: none"> <li>Any dose if previously received Tdap</li> </ul>   | <ul style="list-style-type: none"> <li>Age &lt;10 years</li> <li>Any dose if previously received Tdap</li> </ul> | <ul style="list-style-type: none"> <li>Age 7 to 9 years</li> <li>&gt;1 Tdap dose</li> </ul>              |

<sup>1</sup> Current catch-up immunization recommendations: persons with incomplete or unknown vaccine history should receive a single dose of Tdap as one dose (preferably the first) of the three-dose catch-up series. If additional doses are needed, Td is recommended. <sup>2</sup> Note on pregnancy: Both Tdap vaccines may be administered during pregnancy with the same intervals and restrictions (vaccine specific) as would apply to a non-pregnant individual. <sup>3</sup> Five or more years after a dose of DTaP or Td vaccine. <sup>4</sup> Please see Td package insert for indications and intervals for wound management

# Proposed Policy Language



# Decennial Td booster and tetanus prophylaxis: Proposed language

- **Decennial booster** in persons with documentation of previous Tdap (in persons aged 7–18 Years and  $\geq 19$  years):

*“To ensure continued protection against tetanus and diphtheria, booster doses of **either Td or Tdap** should be administered every 10 years throughout life.”*

- **Tetanus prophylaxis** for wound management in persons with previous documentation of Tdap:

*“For nonpregnant persons with documentation of previous vaccination with Tdap, **either Td or Tdap** should be used if a tetanus toxoid–containing vaccine is indicated.”*

## Catch-up immunization schedule: Proposed language, persons aged 7–18 years and ≥19 years

- *Persons aged (7–18 years and ≥19 years) who have never been vaccinated against pertussis, tetanus, or diphtheria should receive a series of three tetanus and diphtheria toxoid-containing vaccines, which includes **at least 1 dose of Tdap**. The preferred schedule is a dose of Tdap, followed by a dose of **either Td or Tdap** at least 4 weeks afterward and another dose of **either Td or Tdap** 6 to 12 months later.*

*Persons aged (7–18 years and ≥19 years) who are not fully immunized against pertussis, tetanus or diphtheria should receive 1 dose of Tdap (preferably the first) in the catch-up series; if additional tetanus toxoid–containing doses are required, **either Td or Tdap** vaccine can be used.*

# Catch-up Immunization and Prevention of Obstetric and Neonatal Tetanus: Proposed language

- **Proposed text:** The risk of neonatal tetanus is minimal if a previously unimmunized woman has received at least 2 properly spaced doses of tetanus toxoid–containing vaccine during pregnancy; one of the doses administered during pregnancy should be Tdap, administered according to the current guidance. ***If more than one dose of a tetanus-toxoid containing vaccine is needed, either Td or Tdap vaccine can be used for those doses.*** She should complete the 3-dose primary series at the recommended intervals.

## Summary: Proposed policy change

- Recommendations should be changed to allow either Td or Tdap vaccine to be used in situations where only Td vaccine is currently recommended for:
  - Decennial booster
  - Tetanus prophylaxis for wound management
  - Catch-up immunization schedule, including in pregnant women

# Questions?

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

