



## POLICY STATEMENT

# Additional Recommendations for Use of Tetanus Toxoid, Reduced-Content Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap)

## COMMITTEE ON INFECTIOUS DISEASES

**KEY WORDS**

Tdap vaccine, tetanus, diphtheria, pertussis, adolescents, adults, infants

**ABBREVIATIONS**

AAP—American Academy of Pediatrics

Tdap—tetanus toxoid, reduced-diphtheria toxoid, and reduced-content acellular pertussis vaccine

Td—tetanus and diphtheria toxoid vaccine

DTP—diphtheria and tetanus toxoids and whole-cell pertussis vaccine

DTaP—diphtheria-tetanus-acellular pertussis vaccine

CDC—Centers for Disease Control and Prevention

ACIP—Advisory Committee on Immunization Practices

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## abstract

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The American Academy of Pediatrics and the Centers for Disease Control and Prevention are amending previous recommendations and making additional recommendations for the use of tetanus toxoid, reduced-content diphtheria toxoid, and acellular pertussis vaccine (Tdap). Review of the results from clinical trials and other studies has revealed no excess reactogenicity when Tdap is given within a short interval after other tetanus- or diphtheria-containing toxoid products, and accrual of postmarketing adverse-events reports reveals an excellent safety record for Tdap. Thus, the recommendation for caution regarding Tdap use within any interval after a tetanus- or diphtheria-containing toxoid product is removed. Tdap should be given when it is indicated and when no contraindication exists. In further efforts to protect people who are susceptible to pertussis, the American Academy of Pediatrics and Centers for Disease Control and Prevention recommend a single dose of Tdap for children 7 through 10 years of age who were underimmunized with diphtheria-tetanus-acellular pertussis (DTaP). Also, the age for recommendation for Tdap is extended to those aged 65 years and older who have or are likely to have contact with an infant younger than 12 months (eg, health care personnel, grandparents, and other caregivers). *Pediatrics* 2011;128:809–812

## INTRODUCTION

The American Academy of Pediatrics (AAP)<sup>1</sup> and the Centers for Disease Control and Prevention (CDC)<sup>2</sup> currently recommend a single dose of tetanus toxoid, reduced-diphtheria toxoid, and reduced-content acellular pertussis vaccine (Tdap) instead of tetanus and diphtheria toxoid vaccine (Td) for adolescents aged 11 through 18 years of age who have completed the recommended pediatric-formulation diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP)/diphtheria-tetanus-acellular pertussis vaccine (DTaP) series in childhood; the adolescent dose of Tdap should preferably be given at a preventive care visit at 11 through 12 years of age. The CDC currently recommends a single dose of Tdap to replace a single decennial Td booster for adults 19 through 64 years of age who have not previously received Tdap and as soon as is feasible for health care providers who have direct patient contact.<sup>2</sup> Two Tdap vaccines are licensed in the United States—Boostrix (GlaxoSmithKline Biologicals, Research Triangle Park, NC), for persons 10 through 64 years of age, and Adacel (Sanofi Pasteur, Swiftwater, PA),

for persons 11 through 64 years of age. On October 27, 2010, the Advisory Committee on Immunization Practices (ACIP) of the CDC amended recommendations and made additional recommendations for use in those who have not received Tdap previously: (1) whenever indicated, regardless of interval since the last tetanus- or diphtheria-containing vaccine; (2) for children 7 through 10 years of age who did not receive the full recommended series of DTaP before 7 years of age; and (3) for certain adults aged 65 years and older. The CDC policy changes are published.<sup>3</sup>

The ACIP Pertussis Working Group, composed of liaison members from multiple organizations, including the AAP Committee on Infectious Diseases, reviewed published and unpublished data on Tdap immunogenicity and safety from vaccine trials and other relevant experiences in formulating its recommendations. The working group also considered the current epidemiology of pertussis, the need to protect vulnerable infants through encouragement and expansion of cocooning,<sup>4,5</sup> and data and expert opinion on barriers to receipt of Tdap. This vaccine policy statement expands previous AAP recommendations for Tdap<sup>4</sup> and will be incorporated into the 2012 *Red Book*.

### **No Minimum Interval Between Td and Tdap Is Necessary**

At the time of licensure of Tdap in 2005, there were few data on the reactogenicity of Tdap after a short interval from another tetanus toxoid- or diphtheria toxoid- containing vaccine. Thus, Tdap was recommended with a minimum interval of 5 years for standard use, and an interval as short as 2 years was acceptable when potential risk of pertussis was high.

Confirming adult immunization status by review of immunization records or recall is difficult and is an important barrier to achieving the vaccine coverage needed for this group. Accumulating data dem-

onstrate no increased risk of severe local reactions or serious adverse events for adolescents or adults who receive Tdap at short intervals after tetanus toxoid- or diphtheria toxoid- containing vaccines. Together, these findings support removal of any cautionary minimum interval regarding any tetanus toxoid- or diphtheria toxoid- containing vaccine when Tdap is indicated. Reports reviewed for safety of short intervals included Canadian children and adolescents with a DTP/DTaP/Td-to-Tdap interval as low as 2 years<sup>6</sup>; French adults 18 to 76 years of age with a Td/Td-inactivated polio vaccine (IPV)-to-Tdap/Td-IPV interval of 28 days to 2 years<sup>7</sup>; and health care personnel vaccinated in an institutional respiratory illness outbreak with tetanus toxoid (TT)- or Td-to-Tdap interval of less than 2 years.<sup>8</sup> The number of subjects in these studies is small; therefore, data do not exclude a significant but rare event. In addition, a postlicensure retrospective cohort study found that medically attended local reactions after Tdap were low (2.6 events per 10 000 Tdap vaccinations) and comparable with those after Td.<sup>9</sup> Since licensure, evidence on safety of Tdap in persons 10 through 64 years of age has been collected through the Vaccine Safety Datalink (VSD) and has revealed no association with several predetermined adverse neurologic events, including encephalopathy/encephalitis/meningitis, paralytic syndromes, seizure, cranial nerve disorder, or Guillain-Barré syndrome.<sup>10</sup> Postmarketing data from the Vaccine Adverse Events Reporting System (VAERS) 2 years after licensure also support the safety of Tdap.

### **Children 7 Through 10 Years of Age Who Were Not Fully Immunized With DTaP Should Be Given Tdap**

At the time of recommendation of universal Tdap for adolescents,<sup>1,2</sup> the AAP and ACIP recommended that children 7

through 10 years of age with a history of incomplete childhood immunization with DTP/DTaP should be given Td to complete the tetanus and diphtheria toxoid series, because Tdap is not licensed in the United States for children younger than 10 years. Although data on immunogenicity of Tdap in undervaccinated or completely unvaccinated children 7 through 10 years of age are limited, 2 studies of use of Tdap in place of the fifth dose of DTaP have shown similar immunogenicity to DTaP.<sup>11,12</sup> Lower rates of local reactions also were reported after Tdap in place of the fifth DTaP.<sup>11–13</sup> If a child 7 through 10 years of age is not fully immunized against pertussis (ie, has not received 5 doses of DTP/DTaP or 4 doses when the fourth dose was administered after the fourth birthday) or has an unknown or uncertain immunization history, a single dose of Tdap should be given. Only 1 dose of Tdap is recommended at this time, because Tdap vaccines are not licensed for multiple doses. If further doses of Td-containing vaccine are required, they are given on a catch-up schedule. Although Tdap could be substituted for any 1 of the 3 doses, the preferred 3-dose schedule would be Tdap followed by Td at 4 weeks and 6 to 12 months. Either Tdap product (Boostrix or Adacel) can be used for the underimmunized child 7 through 10 years of age. At this time, it is recommended that children who receive Tdap at 7 through 10 years of age should not be given the usual adolescent Tdap dose at the 11- through 12-year visit but should be given a booster dose of Td 10 years after their last dose of Td-containing vaccine (Tdap or Td). At the present time, only 1 dose of Tdap should be administered. A repeat dose is not advised.

### **Certain Adults Aged 65 Years and Older Should Be Given Tdap**

The objective for vaccinating adults aged 65 years and older is to protect

them from pertussis and to improve the cocooning of young infants who are too young to be protected by the DTaP series and who are at substantial risk of severe disease, hospitalization, and death should they be exposed and infected with *Bordetella pertussis*. Multiple studies have found that family members and extended family members, including grandparents, are source cases for most infants with pertussis. In 1 study of more than 1000 children 0 through 3 years of age, 35% of the children were cared for by grandparent(s) at least during one 3-month period. Health care personnel also are at potential risk of acquiring and transmitting pertussis. Although Tdap vaccines are not licensed for persons 65 years and older, unpublished immunogenicity and safety data as well as Vaccine Adverse Events Reporting System data are supportive of the recommendation that persons 65 years and older in the high-risk setting of potential transmission to young infants should be given Tdap. On February 23, 2011, the ACIP made provisional recommendations that all health care personnel, regardless of age, receive a single dose of Tdap as soon as is feasible if they have not previously received Tdap and regardless of the time since the last dose of Td. At this time, the CDC does not recommend immunizing all persons aged 65 years and older. However, there are no contraindications to immunizing persons in this age group, and anyone desiring vaccine can be immunized.

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## RECOMMENDATIONS

Recommendations for changes in and additional uses of Tdap:

- There is no minimum interval required or advised between receipt of a tetanus toxoid– or diphtheria toxoid–containing vaccine and Tdap when Tdap is otherwise indicated.
- A single dose of Tdap should be given to children 7 through 10 years of age who have incomplete or unknown pertussis vaccine history. Additional vaccines may be required on the basis of a catch-up schedule.
- A single dose of Tdap should be given to adults of any age (including those aged 65 years or older) who have not received Tdap previously, who are health care personnel, or who have or anticipate having close contact with an infant younger than 12 months, such as grandparents and other caregivers.
- A single dose of Tdap may be given in place of Td to any person aged 65 years or older who has not received Tdap previously.

At the time of the ACIP vote on these changes in Tdap recommendations in October 2010, the Vaccines for Children Program advisors concurred with coverage of Tdap for use relevant to the program. Tdap is set forth in the Vaccine Injury Table for eligibility to receive compensation under the Vaccine Injury Compensation Act. Because Tdap is a “covered” vaccine, such eligibility extends to the added recommendations mentioned here ([www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)).

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