

Notice to Readers: Food and Drug Administration Approval of a Fifth Acellular Pertussis Vaccine for Use Among Infants and Young Children --- United States, 2002



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On May 14, 2002, the Food and Drug Administration (FDA) approved for use an additional combined diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) (DAPTACEL™ Aventis Pasteur, Ltd. [Toronto, Ontario]) for the first 4 doses of the diphtheria and tetanus toxoids and pertussis vaccination (DTP) series administered to infants and children aged 6 weeks--6 years (before seventh birthday). DAPTACEL™ is the fifth acellular pertussis vaccine to be licensed for use among infants and young children in the United States. Of these five, three (Tripedia®, Infanrix™, and DAPTACEL™) are distributed in the United States.

DAPTACEL™ is approved for administration as a 4-dose series at ages 2, 4, 6, and 17--20 months. The Advisory Committee on Immunization Practices (ACIP), the Committee on Infectious Diseases, the American Academy of Pediatrics, and the American Academy of Family Physicians recommend that children routinely receive a series of 5 doses of vaccine against diphtheria, tetanus, and pertussis before age 7 years (1,2). The first 4 doses should be administered at ages 2, 4, 6, and 15--18 months and the fifth dose at age 4--6 years. The customary age for the first dose is 2 months, but it may be given as early as age 6 weeks and up to the seventh birthday. The interval between the third and the fourth dose should be at least 6 months. Data are insufficient to evaluate the use of DAPTACEL™ as a fifth dose among children aged 4--6 years who have received DAPTACEL™ for the previous 4 doses. DAPTACEL™ may be used to complete the vaccination series in infants who have received 1 or more doses of whole-cell pertussis DTP.

The following evidence supports the use of DAPTACEL™ for the first 4 doses of the diphtheria, tetanus, and pertussis vaccination series:

1. The rates of local reactions, fever, and other common systemic symptoms following receipt of DAPTACEL™ inoculations were substantially lower than those following whole-cell pertussis vaccination (administered as DTP for doses 1--3 in controlled clinical studies (3,4).
2. Efficacy of 3 doses of DAPTACEL™ against pertussis disease was assessed in a double-blind, randomized, placebo-controlled trial in Sweden (3). Infants were assigned randomly to be vaccinated with either DAPTACEL™, another investigational acellular pertussis vaccine, whole-cell pertussis DTP vaccine, or DT vaccine as placebo at ages 2, 4, and 6 months. The mean length of follow-up was 2 years after the third dose of vaccine. In this trial, pertussis was defined according to

the World Health Organization case definition (i.e., a paroxysmal cough illness lasting ≥ 21 days and confirmed by culture, serology, or epidemiologic link to a culture-positive household contact). The vaccine efficacy of DAPTACEL™ against WHO-defined pertussis was 84.9% (95% confidence interval [CI]=80.1%--88.6%) (3,4). The protective efficacy of DAPTACEL™ against mild pertussis (i.e., ≥ 1 day of cough with laboratory confirmation) was 77.9% (95% CI=72.6%--82.2%) (4). Although a serologic correlate of protection for pertussis has not been established, the antibody responses to the pertussis antigens in DAPTACEL™ among North American infants after 4 doses at ages 2, 4, 6, and 17--20 months was comparable to that achieved among Swedish infants in whom efficacy was demonstrated after three doses at age 2, 4, and 6 months (4).

Because of the reduced frequency of adverse reactions and demonstrated efficacy, ACIP recommends DTaP for all 5 doses of the routine diphtheria, tetanus, and pertussis vaccination series and for the remaining doses in the series for children who have started the vaccination series with whole-cell DTP vaccine (1). ACIP considers the data to be insufficient in terms of safety and efficacy to express a preference among different acellular pertussis vaccine formulations.

Whenever feasible, the same DTaP vaccine should be used throughout the entire vaccination series. Data are limited on the safety, immunogenicity, or efficacy of different DTaP vaccines when administered interchangeably in the primary or booster vaccination of a child. However, if the vaccine provider does not know or have available the type of DTaP vaccine the child to be vaccinated had received previously, any of the licensed DTaP vaccines may be used to complete the vaccination series (1).

References

1. CDC. Pertussis vaccination: use of acellular pertussis vaccine among infants and young children---recommendations of the Advisory Committee on Immunization Practices. *MMWR* 1997;46(No. RR-7).
2. CDC. Recommended childhood immunization schedule---United States, 2002. *MMWR* 2002;51:31--3.
3. Gustafsson L, Hallander HO, Olin P, et al. A controlled trial of a two-component acellular, a five-component acellular, and a whole-cell pertussis vaccine. *N Engl J Med* 1996;334:349--55.
4. Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DAPTACEL™) [Package insert]. Toronto, Ontario: Aventis Pasteur, Ltd., 2002.

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