

Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine and Guidance for Use as a Booster Dose

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On March 24, 2015, the Food and Drug Administration licensed an additional combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP) and inactivated poliovirus (IPV) vaccine (DTaP-IPV) (Quadracel, Sanofi Pasteur Inc.). Quadracel is the second DTaP-IPV vaccine to be licensed for use among children aged 4 through 6 years in the United States (1). Quadracel is approved for administration as a fifth dose in the DTaP series and as a fourth or fifth dose in the IPV series in children aged 4 through 6 years who have received 4 doses of DTaP-IPV-Hib (Pentacel, Sanofi Pasteur) and/or DTaP (Daptacel, Sanofi Pasteur) vaccine (2,3). This report summarizes the indications for Quadracel vaccine and provides guidance from the Advisory Committee on Immunization Practices (ACIP) for its use.

The ACIP Combination Vaccines Work Group, including liaison representatives from the American Academy of Pediatrics, the American Academy of Family Physicians, the National Association of Pediatric Nurse Practitioners, and the American Academy of Physician Assistants, reviewed data on the safety and immunogenicity of Quadracel vaccine. On the basis of the clinical data reviewed, expert opinion of the work group, and feedback from ACIP liaison organizations, ACIP endorsed the licensed indications for this vaccine. Both licensed DTaP-IPV vaccine formulations are included in the federal Vaccines for Children Program (4).

The individual antigens (diphtheria and tetanus toxoids; pertussis antigens [pertussis toxoid, filamentous hemagglutinin, pertactin, and fimbriae types 2 and 3]; and inactivated poliovirus types 1, 2, and 3) contained in a dose of Quadracel are identical to the antigens contained in Sanofi Pasteur's DTaP-IPV-Hib (Pentacel) vaccine (3,5). Quadracel contains no preservatives and is administered as an intramuscular injection, preferably into the deltoid muscle of the upper arm. One clinical trial conducted in U.S. children aged 4 through 6 years showed that Quadracel and separately administered DTaP (Daptacel) and IPV (Ipol, Sanofi Pasteur) vaccines had comparable safety and reactogenicity profiles, with or without a coadministered second dose of measles, mumps, and rubella (MMR) and varicella (VAR) vaccines (3). The immunogenicity of all antigens was noninferior among the treatment groups, with or without a coadministered second dose of MMR and VAR vaccines.

Indications and Guidance for Use

Quadracel is indicated for use as the fifth dose of DTaP and fourth or fifth dose of IPV in children aged 4 through 6 years who received DTaP-IPV-Hib (Pentacel) and/or DTaP (Daptacel) vaccine as the first 4 doses (2,3). This vaccine should not be administered to children aged <4 years or ≥7 years. If Quadracel vaccine is inadvertently administered before age 4 years for an earlier dose of the DTaP and/or IPV series and if minimum interval requirements have been met, the dose may be counted as valid for the DTaP and/or IPV series and does not need to be repeated (6). Note that the final dose in the IPV series must be administered at age ≥4 years regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose (7). Therefore, a dose of Quadracel vaccine administered before the fourth birthday cannot be counted as a valid final dose of IPV. Data are limited on the safety and immunogenicity of interchanging DTaP vaccines from different manufacturers (8).

ACIP recommends that, whenever feasible, the same manufacturer's DTaP vaccines should be used for each dose in the series. However, vaccination should not be deferred because the type of DTaP vaccine previously administered is unavailable or unknown (6).

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