

Thigh Is Acceptable Site for Fifth DTaP Dose

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FROM PEDIATRICS

Children receiving the fifth dose of the DTaP vaccine are significantly less likely to experience a local injection site reaction if they receive the injection in the thigh rather than the arm.

Of 233,616 children aged 4-6 years who received a diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccination in 2002-2006, only 1,017 (0.4%) experienced a local reaction that required medical attention, but the rate of reactions was 47.4 vs. 32.1 per 10,000 vaccinations for arm vs. thigh injections, respectively, Dr. Lisa A. Jackson of the Group Health Research Institute, Seattle, and her colleagues from the Vaccine Safety Datalink (VSD) team reported.

After adjustment for age, sex, and study site, the risk of a local reaction requiring medical attention was 78% higher with arm vs. thigh injections (Pediatrics 2011;127:e581-7). In children with a valid body mass index measurement, injection in the arm was associated with a 2.3-fold higher risk of a local reaction, and in that

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model, BMI also was shown to be an independent risk factor for a reaction. After adjustment for age, sex, and managed care organization site, similar associations of higher BMI and greater risk for a local injection-site reaction persisted among those who received an arm injection and in those vaccinated in the thigh, Dr. Jackson and her associates said, noting that the factors contributing to this association are unclear, but might be a result of an increased likelihood of inadequate intramuscular injection in larger children.

Children included in the study were from the VSD population; VSD is a collaborative project between the Centers for Disease Control and Prevention and a group of eight managed care organizations in the United States that was established in 1991 to monitor and evaluate vaccine safety. Injection-site reactions were identified by using administrative data, and were confirmed by a medical records review.

The findings confirm those from a previous prospective study of 1,315 children, who also had less redness and swelling at the injections site with thigh vs. arm injections, the investigators noted.

According to current recommendations from the CDC's Advisory Committee on Immunization Practices and the American Academy of Pediatrics, the deltoid muscle in the arm is the preferred site for intramuscular injections in children older than age 1 year, but those recommendations were based

on data from 18-month-old children, and reflected an increased likelihood of discomfort and difficulty with movement of the extremity when thigh injections were used. Indeed, in the current study, nearly 14% of children with a medically attended local reaction following thigh vaccination were noted to have had difficulty walking as a result, which raises the question of whether the lower risk of a reaction with a thigh

injection is counterbalanced by the risk of problems with ambulation.

However, the current data do not bear this out.

"If it is assumed that reactions resulting in a medical visit are reactions of greater concern to the parent, for whatever reason, it can be argued that, on balance, the risk of a concerning reaction is lower with thigh injections than with deltoid injections," they said.

Dr. Jackson received research funding (unrelated to DTaP vaccine) from Sanofi Pasteur and served as a consultant for GlaxoSmithKline. Coauthor Jennifer C. Nelson, Ph.D., reported serving as a statistical consultant to GlaxoSmithKline, and coauthor Dr. Roger Baxter reported receiving research grants from Sanofi Pasteur. The study received funding from the CDC through America's Health Insurance Plans. ■

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Indication

BESIVANCE® is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC coryneform group G, *Corynebacterium pseudodiphtheriticum*,[†] *Corynebacterium striatum*,[†] *Haemophilus influenzae*, *Moraxella lacunata*,[†] *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis*,[†] *Staphylococcus lugdunensis*,[†] *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius*.[†]

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The most common adverse events in clinical trials were conjunctival redness, blurred vision, eye pain, eye irritation, eye pruritus and headache, reported in approximately 1-2% of patients one year and older. Safety and effectiveness in infants below one year of age have not been established.

Please see the Brief Summary of the BESIVANCE® full prescribing information on the adjacent page.

*DuraSite.

[†]Efficacy for this organism was studied in fewer than 10 infections.

References: 1. Haas W, Pillar CM, Hesje CK, Sanfilippo CM, Morris TW. Bactericidal activity of besifloxacin against staphylococci, *Streptococcus pneumoniae* and *haemophilus influenzae* [published online ahead of print April 20, 2010]. *J Antimicrob Chemother*. 2010;65(7):1441-1447. doi:10.1093/jac/dkq127.

2. Proksch JW, Granvil CP, Siou-Mermet R, Comstock TL, Paterno MR, Ward KW. Ocular pharmacokinetics of besifloxacin following topical administration to rabbits, monkeys, and humans. *J Ocul Pharmacol Ther*. 2009;25(4):335-343.

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