

From ISMP Medication Safety Alert!® Acute Care Edition DTaP-Tdap Mix-ups Now Affecting Hundreds of Patients



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Abstract and Introduction

Introduction

The ISMP Medication Errors Reporting Program (ISMP-MERP) database contains hundreds of cases of accidental mix-ups between adult and pediatric products used to immunize patients against diphtheria, tetanus, and pertussis (whooping cough). Several reports involve errors that affected numerous patients. In one report alone, 80 clinic patients were given the wrong vaccine. In all, these mix-ups may be affecting thousands of patients given that not all cases are reported to ISMP.

We first reported this problem in 2006 (Institute for Safe Medication Practices. Adacel [Tdap] and Daptacel [DTaP] confusion. *ISMP Medication Safety Alert!* August 24, 2006). Part of the problem is that the official names of the products are very similar although stated in different order on the labels. One of them, diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), is sold under the brand names DAPTACEL and TRIPEDIA (Sanofi Pasteur), and INFANRIX (GlaxoSmithKline). This formulation is for *active immunization* of pediatric patients 6 weeks through 6 years of age. The other vaccine, tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap), is sold under the names BOOSTRIX (GlaxoSmithKline) and ADACEL (Sanofi Pasteur), and is meant to be used as *booster* shots for older children, adolescents, and adults.

These products are easy to confuse due to their similar names and abbreviations. The upper case letters in DTaP correspond with higher antigen quantity of the diphtheria and pertussis components, relative to Tdap and its lowercase letters. A larger amount of antigen is needed for initial immunization versus a booster shot. An adult who gets DTaP (higher amount of antigen) would not need to be revaccinated but would be more likely to have a sore arm at the vaccination site. But an infant/child who got Tdap would have received a lesser amount of antigen and may not respond adequately. Most reported events have occurred in clinics and doctor offices where the vaccines were chosen from stock supplies, or in hospital settings where the vaccines were mixed up and stocked in the wrong area of a refrigerated ADC cabinet.

The advice we gave in 2006 about preventing this mix-up stands. That is, share this article with professional colleagues who handle these products. Separate the pediatric and adult formulations in storage areas. Encourage prescribers to order the vaccines by brand name, not vaccine abbreviation. Consider including parents or caregivers by making them aware of the names of vaccines that are needed by writing them down beforehand or handing the patient a printed sheet that also details the purpose of each vaccine. (The Centers for Disease Control and Prevention [CDC] requires that vaccine information statements [VIS], which include age requirements, be given to parents and patients before each vaccination [www.cdc.gov/vaccines/Pubs/vis/default.htm].) Then ask the parents or caregivers to assist with verification of the vaccine before it's administered.

One hospital reported a significant reduction in mix-ups by employing a "time out" procedure before dispensing and administering these vaccines. Each "time out" is conducted by at least two clinicians and is guided by a laminated card with pictures of the two different products for reference. Another option is to document the vaccine, including lot number, on the vaccine form/log just prior to administration (but do not document actual drug administration on the MAR until after the vaccine has been given). Recognizing a major difference in lot number format from what is normally recorded

could help in recognizing that the wrong product is in hand.

After receiving earlier reports about product mix-ups, Sanofi Pasteur changed the color of the labeling for Daptacel and added statements on the product carton's front label panels for both Adacel and Daptacel that advise which is for adolescent/adult use and which is for pediatric use. Likewise, GlaxoSmithKline has taken steps to differentiate Boostrix and Infanrix to help ensure that they are administered properly. Similar to Sanofi Pasteur, they also label pre-filled syringes and employ vial caps with a unique color to differentiate each of its vaccines and have a statement on the packaging for Boostrix that the product is for adolescent and adult use.

While these improvements may have helped to some extent, unfortunately, we are still receiving frequent reports of mix-ups. We now believe more should be done to enhance vial label text to designate which is the pediatric versus adult vaccine.

We also think the abbreviations Tdap and DTaP are a big part of the problem, as is the ongoing problem of listing the nonproprietary name above the brand name on biologicals. This practice, which is inconsistent with CDER (Center for Drug Evaluation and Research) drugs, decreases recognition of brand names, which are much different in this case. This is a significant cause of medication errors with multi-ingredient vaccines, and efforts are needed to revise the Code of Federal Regulations (CFR). For example, if "Adacel" and "Daptacel" were prominently highlighted, we believe this would be helpful in preventing mix-ups between the two. Our thoughts have been shared with the FDA and the CDC.

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