Alphabet Soup: Confusion Between DTaP and Tdap

Author: Susan Paparella, RN, MSN, Horsham, PA
Section Editor: Susan Paparella, RN, MSN

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Tetanus is a potentially fatal infection caused by the gram-positive bacteria *Clostridium tetani,* which is found in soil and the feces of animal and humans. When this anaerobic organism enters the skin during a traumatic injury, often a puncture wound, the bacteria will incubate in an oxygen-depleted environment and produce a neurotoxin that can eventually invade striated muscle. Left untreated, toxicity characterized by prolonged contraction of the skeletal muscle will develop in patients exposed to tetanus. Spasms from tetanus exposure commonly develop in a descending manner, typically starting in the face and the jaw (thus the term "lockjaw"), which often is followed by difficulty swallowing, and eventually the spasms progress to other muscle groups in the body.[1,2] Mortality rates from tetanus have declined since the early 1900s as a result of better hygiene and wound management. The highest mortality rates for tetanus have been associated with unvaccinated individuals and persons older than 60 years. According to the 2005 statistics from the Centers for Disease Control and Prevention, 27 cases of tetanus were reported in the United States, two of which were fatal.[2]

A variety of vaccine products are available to protect individuals against tetanus infections. Daptacel or Tripedia (Sanofi Pasteur), often referred to as DTaP, contains diphtheria and tetanus toxoids and acellular pertussis vaccine absorbed; it also is sold under the brand name Infanrix (GlaxoSmithKline). This vaccine is produced as an active immunization for infants and children 6 weeks to 6 years old. Adacel (Sanofi Pasteur), which contains tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine absorbed, and which also is sold under the name of Boostrix (GlaxoSmithKline) and is known as Tdap, is indicated as an active *booster* immunization given as a single dose in persons aged 11 to 64 years. This product is also the first vaccine approved as a pertussis booster for adults.[3] Even though the components are the same, the relative amounts of the components are much greater with the infant vaccine because a larger amount of antigen is needed for initial immunization versus a booster shot. An adult who gets DTaP (with a higher amount of antigen) would not need to be revaccinated but would likely have a sore arm at the injection site. If an infant/child gets the Tdap, he or she would have received a lesser amount of antigen and may not respond adequately.[4]

Confusion between the various vaccine names and types is a problem commonly reported to the Institute for Safe Medication (ISMP).[3,4] The ISMP database (which is a voluntary reporting program for practitioners) actually contains hundreds of reports of accidental mix-ups between the adult and pediatric formulations, several of which involve multiple patients. In one report alone, 13 adults received Daptacel in error instead of Adacel, and in another report, 80 patients at a single clinic were given the wrong vaccine.[5] The similarities in the brand names, generic designations, and the common use of drug name abbreviations (DTaP and Tdap) were thought to have been the cause of the mix-ups. In 2007, Sanofi Pasteur changed the look of the drug carton and vial labels for both products. Likewise, GlaxoSmithKline has taken steps to differentiate Boostrix and Infarix to ensure that they are administered properly.[6] While this action by the manufacturers has certainly helped, it still has not eliminated the confusion entirely. The use of similar drug name abbreviations seems to be one of the biggest causes of confusion for practitioners.[4,7]

Susan Paparella, *Member, Bux-Mont Chapter*, is Vice President at the Institute for Safe Medication Practices (ISMP*), Horsham, PA, and a member of the Advisory Committee for the Institute for Quality, Safety, and Injury Prevention. *ISMP is a nonprofit organization that works closely with health care practitioners, consumers, hospitals, regulatory agencies, and professional organizations to educate caregivers about preventing medication errors. ISMP is the premier international resource on safe medication practices in health care institutions. If you would like to report medication errors to help others, E-mail us at: ismpinfo@ismp.org or call (800)FAIL-SAF(e). This Medication Error Reporting Program keeps information confidential and secure. We will include only the level of detail that the reporter wishes in our publications.

For correspondence, write: Susan Paparella, RN, MSN, Vice President, ISMP; E-mail: spaparella@ismp.org.

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Another factor is that a federal regulation "requires the listing of the nonproprietary names on labels of biologicals above the brand name, which is inconsistent with the way other drugs are labeled. The font size and type face must be at least as prominent as used for the brand name."[4] Adding to the confusion, some drug references, drug information databases, and wholesalers reference Adacel's components as diphtheria, tetanus, and acellular pertussis, rather than the way they are actually listed on the label, making confirmation of the product difficult.[3] In early 2010, ISMP issued an updated list of confused drug names based on reports received from November 2009 to February 2010. This listing includes the vaccines DTaP and Tdap and can be found at: http://www.ismp.org/Tools/confuseddrugnames.pdf.[8]

To help ED staff avoid selecting and administering the wrong tetanus vaccine, consider the following safety strategies[3,4]:

1. Store these products in separate locations in the refrigerator in clearly labeled bins.
2. Add auxiliary label alerts to the actual product stating "Adult" or "Pediatric."
3. Look at the way in which these products are displayed in the order entry system (or on a preprinted order form) and make adjustments as necessary to differentiate the selection of the right product. Ideally, encourage prescribers to order the vaccine by brand names, not the vaccine abbreviations (Tdap or DTaP).
4. Configure the order entry system to provide clinical decision support and not allow for the selection of the wrong vaccine product based on the patient's age.
5. Provide a soft active alert in the automated dispensing cabinet, requiring staff to answer the question, "Is this a pediatric patient?" or "Is this an adult patient?"
6. Have staff document the vaccine in a log, including the lot number, just prior to administration (and document the administration *after* it is actually given). This step may help staff recognize the difference in the lot number recorded, thus realizing that the wrong product has been selected. Make sure staff are supplying the required vaccine instruction sheet to all patients receiving vaccines[9]: http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-instructions.pdf.
7. Consider the use of a "time-out" or independent double check when a vaccine is selected for administration.
8. Share this article with ED colleagues so that they will recognize the difference in such products.[5] Use the free Food and Drug Administration videos on this subject located at http://www.accessdata.fda.gov/psn/transcript.cfm?show=57#6 to assist with staff education on this important issue.[10]

ISMP is continuing to work with the Food and Drug Administration to revise the Code of Federal Regulations to make the brand name Adacel and Daptacel more prominent on the label, to be consistent with the Center for Drug Evaluation and Research labeling practices, and, it is hoped, to make the selection of the tetanus product less confusing.[5] Until that time, take a few minutes to assess the risk for vaccine mix-ups in your emergency department and support the use of strategies that will enhance the safety of vaccine selection and administration.

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Submissions to this column are encouraged and may be sent to
Susan Paparella, RN, MSN
spaparella@ismp.org