

Milk-Allergic Kids: Reactions to Tdap Vaccine Lots

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FROM THE ANNUAL MEETING OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY

SAN FRANCISCO – Some lots of tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccine may contain milk protein, which puts milk-allergic children at risk for reactions, according to Dr. Hugh A. Sampson.

Seven milk-allergic children in his practice had severe anaphylactic reactions to either primary or booster shots of the Tdap vaccine (Sanofi Pasteur's Adacel) that were given between September 2007–March 2010.

"We were struck by the fact that just in our practice we had seven patients with milk allergy who reacted. You wouldn't anticipate that kind of number from one single practice. We believe it is due to contamination of milk protein in this

VITALS **Major Finding:** Seven milk-allergic children in one practice had anaphylactic reactions to Tdap vaccine; the amount of milk protein found in vaccine varied between two lots.

Data Source: A case series of seven milk-allergic children.

Disclosures: Dr. Sampson is a consultant for Genentech and holds shares in Herbal Springs LLC. Dr. Wood had no relevant disclosures.

vaccine," said Dr. Sampson, professor of pediatrics, allergy and immunology and dean for translational biomedical sciences at the Mount Sinai School of Medicine, New York.

The five boys and two girls (median age, 11 years; range, 5-17 years) had prior allergic reactions to cow's milk, including five severe reactions and four reactions to trace exposures. One was diagnosed with milk allergy based on serologic testing.

Dr. Sampson and his colleagues suspect it was milk protein in the vaccine after testing two vials from two lots by inhibition-enzyme linked immunosorbent assay. One vial "clearly had milk protein in it" (30 ng/mL). "The other did not," he said.

Bacterial growth media that are used to produce the vaccine contain casamino acids, according to Adacel labeling. These are derived from the milk protein casein.

As "with any process, there can be some variation, lots that for some reason seem to be higher in milk protein. Apparently, there were enough lots that we had seven children end up with anaphylactic reactions," Dr. Sampson said at the meeting.

He and his colleagues confirmed that two patients received shots from the same vaccine lot, but the vials used on the children were not available for testing.

Even so, "we certainly have circumstantial evidence that there is the possibility of sufficient milk protein in certain lots" that could potentially – if given to a person who is highly milk allergic –

cause a reaction, Dr. Sampson said.

The problem must be "uncommon or it would have shown up before," and there are no reports yet in the literature, said Dr. Robert A. Wood, a professor of pediatrics and chief of the division of allergy and immunology at Johns Hopkins Children's Center in Baltimore.

The children all had elevated, milk-specific IgE levels (most over 100 kUA/L) within 2 years of their reactions.

Each had symptoms consistent with anaphylaxis promptly after getting the shot, including wheezing and urticaria in five; sneezing, nasal congestion, and angioedema in three; and repetitive cough in two. Five were treated with antihistamines, three with epinephrine, three with inhaled beta-agonists, and two with corticosteroids.

Dr. Sampson and his colleagues are continuing to test additional vaccine lots

for milk protein. "There used to be a tremendous variation in the amount of egg protein in flu vaccine, and I think that's why, in egg-allergic children receiving flu shots, some of them had bad reactions [and] some of them did not. It just depended on the content of the egg protein in the lot," he said. "I think, with the Tdap vaccine, we are seeing basically the same thing. There are lots that for some reason seem to be higher in milk protein." ■

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