



The National Vaccine Injury Compensation Program (VICP)

Discussion of Petition to Add Food Allergies to Injury Table

Advisory Commission on Childhood Vaccines

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Overview



- Discuss email requesting that food allergies be added to the Vaccine Injury Table (VIT)
- Background on food allergies
- Review medical evidence regarding vaccines and food allergies



Background



- The National Childhood Vaccine Injury Act of 1986 (Act), as amended, authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table.
- The Act also permits the VIT to be modified through Federal rulemaking.
- The Act also states that any person may petition the Secretary to modify the VIT.



Background



- The statute states: “Any person (including the ACCV) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following – (A) Receipt of any recommendation of the Commission, or (B) 180 days after the date of the referral to the Commission, whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.” 42 U.S.C. § 300aa-14(c)(2).

- On September 19, 2015, a private citizen submitted an email to HHS and the Commission requesting that food allergies be added to the VIT.
 - The email asserts that food proteins present in vaccines cause the development of food allergies.



Background



- Food allergies are defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food.
- Food allergy reactions are generally classified as mediated through immunoglobulin E (IgE), non-IgE mediated, or a mixture of both.
- IgE mediated reactions are what cause severe reactions to food also known as anaphylaxis.

- On first exposure to a food allergen, individuals may not experience symptoms but their immune system produces IgE to that allergen.
- This first exposure is called sensitization.
- Sensitization can occur through the oral, skin or respiratory route.

- On re-exposure to the allergen, the IgE antibodies bind to the allergen.
- This results in a release of chemicals which can trigger a severe allergic response.
- Symptoms of this response can include hives, itching, nausea, vomiting, swelling of the mouth and throat, and low blood pressure.



Review of Evidence



- ACCV established “Guiding Principles for Recommending Changes to the Vaccine Injury Table” (Guiding Principles).
- These consist of two overarching principles:
 - The Table should be scientifically and medically credible; and
 - Where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners.

- To support the claim that food allergies are caused by vaccines, the petition cites two sources as evidence:
 - 2012 Institute of Medicine (IOM) Report, “Adverse Effects of Vaccines: Evidence and Causality”
 - V. Pool, et al. “Prevalence of anti-gelatin IgE antibodies in people with anaphylaxis after measles-mumps-rubella vaccine in the United States,” *Pediatrics*, 110, 6 (Dec. 2002): e71.)



- The 2012 IOM report reviewed 8 of the 12 vaccines covered by VICP and provided 158 causality conclusions.
 - It did not specifically evaluate evidence regarding a causal association between vaccination and food allergies.
 - It does not comment on the strength of the epidemiologic or mechanistic evidence regarding food allergies and vaccination.
 - Therefore, the IOM report does not support the petitioner's position for adding food allergies to the VIT.



Review of Evidence – Pediatrics Article



- The objective of this study was not to evaluate whether vaccines could cause food allergies.
- The purpose of the study was to examine whether people with anaphylaxis after the receipt of the measles vaccines had an unusual profile of self-reported allergies and whether they had higher levels of antibodies to gelatin.
- This was a case control study utilizing the Vaccine Adverse Event Reporting System (VAERS) database for cases of anaphylaxis and individuals from the Mayo Clinic and VAERS who did not have an adverse event to the measles vaccine as controls.



Review of Evidence – Pediatrics Article



- 57 individuals had anaphylaxis.
- 22 underwent IgE testing.
- The researchers found that there was a higher proportion of food allergies in the group with anaphylaxis as opposed to the control group.
- They also noted that a number of individuals who had anaphylaxis to the vaccine also had the IgE antibody to the gelatin.
 - None of these individuals reported an allergy to gelatin.



Review of Evidence – Limitations of Pediatrics Article



- This paper is not supportive of adding food allergies to the VIT.
 - It was not designed to determine the causality of food allergy, but rather whether severe allergic reactions to the measles vaccines could be due to gelatin.
 - Individuals in this study who had anaphylaxis to the measles vaccine and had antibodies to gelatin did not report a food allergy. This finding does not support a causal association between vaccines and food allergies, nor do the authors contend this in their study.



Review of Evidence – Limitations of Pediatrics Article



- There are limitations to VAERS, which is a passive reporting system,
- The primary purpose of VAERS is to look for signals for evidence of unexpected adverse events that would require further investigations to try to determine causal relationships.
- Thus, most VAERS reports alone are not utilized to establish definitive conclusions about causality.



Review of Evidence – Additional Data



- DICEP gathered additional data from the existing medical literature in addition to the evidence submitted in the petition.
- A literature search was conducted of the major medical databases searching for any articles linking the development of food allergies to vaccinations.
 - Collaboration with the National Institutes of Health Library, Office of Research Services
- Despite an extensive search, no published research was found that addressed any linkages or potential causality between vaccinations covered by the VICP and the development of food allergies in any population.



Review of Evidence – Additional Data



- Several recent reviews of the epidemiology and natural history of food allergies have been published but none discuss any role of vaccinations in the development of food allergies.
 - Savage, J. and C. B. Johns. (2015). “Food allergy: epidemiology and natural history.” *Immunol Allergy Clin North Am* 35(1): 45-59.
 - Lack, G. (2012). “Update on risk factors for food allergy.” *Journal of Allergy and Clinical Immunology* 129(5): 1187-1197.
 - Sicherer, S. H. (2011). “Epidemiology of food allergy.” *Journal of Allergy and Clinical Immunology* 127(3): 594-602.
 - Carrard, A., D. Rizzuti, et al. (2015). “Update on food allergy.” *Allergy*.
 - Chin, S. and B. P. Vickery. (2012). “Pathogenesis of food allergy in the pediatric patient.” *Curr Allergy Asthma Rep* 12(6): 621-9.
 - Allen, K. J. and J. J. Koplin. (2015). “Why Does Australia Appear to Have the Highest Rates of Food Allergy?” *Pediatr Clin North Am* 62(6): 1441-51.



Review of Evidence – Additional Data



- National Institute of Allergy and Infectious Diseases sponsored an expert panel to develop guidelines for the diagnosis and management of food allergies.
 - 34 professional organizations, federal agencies and patient advocacy groups all with expertise related to food allergies
- The Guidelines discuss prevention of food allergies, but make no mention of the role of vaccines in developing food allergies.
 - Did not list vaccination as a risk factor for developing food-induced anaphylaxis.
 - Did not identify the role of vaccination in developing food allergies as an area where future research is needed.



ACCV Recommendation Options



Option 1: Add food allergies to the Vaccine Injury Table.

Option 2: Do not add food allergies to Vaccine Injury Table.