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Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

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Abstract

Nobel Laureate Charles Richet demonstrated over a hundred years ago that injecting a protein into animals or humans causes immune system sensitization to that protein. Subsequent exposure to the protein can result in allergic reactions or anaphylaxis. This fact has since been demonstrated over and over again in humans and animal models. The Institute of Medicine (IOM) confirmed that food proteins in vaccines cause food allergy, in its 2011 report on vaccine adverse events. The IOM's confirmation is the latest and most authoritative since Dr. Richet's discovery. Many vaccines and injections contain food proteins. Many studies since 1940 have demonstrated that food proteins in vaccines cause sensitization in humans. Allergens in vaccines are not fully disclosed. No safe dosage level for injected allergens has been established. As a result, allergen quantities in vaccines and injections are not regulated. Allergen quantities in vaccine excipients are also not regulated. It has been demonstrated that a smaller quantity of allergen is needed to cause sensitization than elicitation. It is well recognized that many currently approved vaccines have enough allergen to cause anaphylaxis. Therefore, they contain more than enough allergen to cause sensitization. Children today have fewer childhood infectious diseases. They have less exposure to helminths. C-section birth rates have increased in the last few decades by 50%. C-section births are known to result in sub-optimal gut microbiome in the newborn. All the above result in an immune imbalance biased towards atopy. Vaccine schedules today include 30-40 shots. Up to five shots may be simultaneously administered in one sitting. Vaccines contain adjuvants such as pertussis toxins and aluminum compounds that also bias towards allergy. Adjuvants also increase the immunogenicity of injected food proteins. This combination of atopic children and food protein injection along with adjuvants, contributes to millions developing life-threatening food allergies. Given the scale and severity of the food allergy epidemic, urgent action is needed to change vaccine policy concerning vaccine specifications, manufacture, vaccine package insert documentation requirements, the Vaccine Adverse Event Reporting System (VAERS) and the National Vaccine Injury Compensation program. Many researchers have called for the removal of food proteins from vaccines and re-evaluation of adjuvants such as aluminum compounds. In the interim, food allergy warnings can be included in vaccine package inserts. Simultaneous administration of multiple vaccines can be stopped to avoid the combined negative effects of multiple food proteins and adjuvants.

Keywords: Vaccines; Food allergy; Adjuvant; Anaphylaxis; Precautionary principle; Prudent avoidance

Abbreviations: VAERS: Vaccine Adverse Event Reporting System; DTaP: acellular pertussis vaccine combined with diphtheria and tetanus toxoids; IgE: Immunoglobulin E; MMR: Measles, Mumps and Rubella vaccine; FDA: Food and Drug Administration; USP: United States Pharmacopeia; NIH: National Institutes of Health; NIAID: National Institute of Allergy and Infectious Diseases; IOM: Institute of Medicine

Background

More than 15 million Americans are estimated to suffer life-threatening food allergies. Many studies looking into the cause of food allergies do not seem to consider vaccines or injections as a cause [1,2,3].

Evidence

Brief history of allergens in vaccines and injections inducing allergy in healthy individuals

Nobel Laureate Charles Richet demonstrated over a hundred years ago that injecting proteins into humans or animals causes immune system sensitization to that protein. Subsequent exposure to the same protein can result in anaphylaxis. Let's call it the Richet allergy model. Wells [4] demonstrated in 1908 that injecting as little as 50 ng of ovalbumin into guinea pigs resulted in sensitization. Subsequent injections of ovalbumin resulted in an allergic reaction.

In 1940, Cooke et al. [5] describe induction of allergy by a tetanus vaccine. In 1952, Ratner et al. [6] were concerned about the possibility of sensitization to egg following the administration of influenza vaccines that are manufactured using chicken eggs. They studied a group of 319 subjects and found that 5 of them developed dermal sensitivity to egg following vaccination with vaccines containing egg proteins. All the subjects in the study were undergoing treatment for tuberculosis. The authors probably did not know that tuberculosis infection may offer protection against allergy [7]. They therefore found sensitization in 1.6% of vaccine recipients, even in a population that was protected from allergy, by tuberculosis infection. Yamane et al. [8] demonstrated a significant increase in anti-ovalbumin IgE in 36 out of 100 subjects following influenza vaccination.

In 1999, Nakayama et al. [9] found evidence of a causal relationship between administration of acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) and the development of gelatin allergy. Following this study, in 2003, Kuno-Sakai et al. [10] used gelatin-free DTaP vaccine to demonstrate that the development of gelatin allergy

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was indeed caused by gelatin present in the DTaP vaccines. In 2009, the US Dept. of Health and Human Services (HHS) charged the Institute of Medicine (IOM) with providing a thorough review of the current medical and scientific evidence on vaccines and vaccine adverse events.

The IOM has concluded in its 2011 report that

"Adverse events on our list thought to be due to IgE-mediated hypersensitivity reactions Antigens in the vaccines that the committee is charged with reviewing do not typically elicit an immediate hypersensitivity reaction (e.g., hepatitis B surface antigen, toxoids, gelatin, ovalbumin, casamino acids). However, as will be discussed in subsequent chapters, the above-mentioned antigens do occasionally induce IgE-mediated sensitization in some individuals and subsequent hypersensitivity reactions, including anaphylaxis" [11]. Ovalbumin would of course result in sensitization to egg. Casamino acid is derived from milk proteins and results in allergy to dairy.

Allergens contained in vaccines

Vaccines and injections contain food proteins such as chicken egg, casein, gelatin, soy, agar etc. [12]. They also contain ingredients such as Polysorbate 80 and sorbitol which are manufactured using food sources. Checking with a few suppliers, Polysorbate 80 is sourced from various food items such as coconut, palm, sunflower, tapioca, wheat, corn etc. Other vendors could be using other vegetable oils, legume oils and nut oils as the source for oleic acid used in the manufacture of Polysorbate 80. It is impossible to guarantee that these products do not contain residual allergen proteins from these food sources.

No specification to limit allergen content in vaccines

I was able to confirm with the Food and Drug Administration (FDA), the United States Pharmacopeia (USP) and vaccine maker Sanofi Pasteur that there are no specifications limiting allergen content in vaccines approved for use in the United States. In other words, no safe level has been established or enforced for allergens contained in vaccines. Vaccine excipient makers such as sorbitol, Polysorbate 80 manufacturers also have no limits on residual allergens in their injectable grade products. Since there are no limits, suppliers do not test for allergens in production. Further, residual allergens that may be present in the excipients are not even listed in the vaccine package inserts. O'Brien et al. [13] measured 7.4 mcg/ml of ovalbumin in influenza vaccines in 1967. Goldis et al. [14] measured as much as 38.3 mcg/ml in influenza vaccines as recently as 2008. The above observations are an obvious consequence of the lack of specifications or regulation of allergen content in vaccines.

Effect of adjuvants and multiple simultaneous vaccinations

Pertussis toxin and aluminum compounds act as adjuvants. These adjuvants are known to bias for IgE synthesis [15]. Injecting food proteins along with these adjuvants increases the immunogenicity of the food proteins that are present in the vaccines. With up to five shots administered simultaneously, numerous food proteins and adjuvants get injected at one time. This increases the probability of sensitization.

Atsuko et al. [15] not only accepted that vaccine antigens and vaccine components induced allergies, they also acknowledge the role of aluminum in IgE synthesis. Hence they worked on an alternative to aluminum based adjuvants.

Sensitization needs less injected allergen than elicitation

As demonstrated by Wells [4], the sensitization dose can be as little as 50 ng of ovalbumin. The elicitation dose was 25 mg. Likewise, Nakayama et al. [9] found that gelatin content in DTaP (48-200 mcg) was sufficient to cause sensitization but not enough to cause elicitation. MMR contained enough gelatin (0.2%) to result in elicitation [16].

DTaP followed by DTaP: Result: Sensitization but no elicitation.

DTaP followed by MMR: Result: Sensitization followed by elicitation.

Therefore, it is clear that any vaccine or injection that contains enough allergen to cause anaphylaxis has more than enough allergen to cause sensitization. Most vaccines have been known to cause anaphylaxis. So most vaccines contain more than enough allergen to cause sensitization.

Animal models and other similar allergy inducing mechanisms

The Richet allergy model is often used in the laboratory to induce food allergy in mice. Food proteins are commonly injected into mice along with alum as an adjuvant [17]. This is no different from vaccines containing food proteins along with adjuvants such as alum being injected into people.

There is also evidence of this allergy mechanism at work with tick bites. Tick bites have been shown to inject alpha-galactose into the body of the victim. The victim develops sensitivity to alpha-galactose. Since red meat contains alpha-galactose, the victims develop red meat allergy [18]. We have therefore seen multiple, varied and independent confirmations of Charles Richet's discovery in both humans and animal models.

Summary

Numerous studies have demonstrated that food proteins contained in vaccines/injections induce food allergy. The IOM's authoritative report has concluded the same. Allergen quantities in vaccines are unregulated. Today kids are more atopic. C-section births bias the newborn's immune system towards IgE synthesis due to sub-optimal gut microbiome [19]. C-section birth rates have gone up 50% in the last few decades. The vaccine schedule has increased the number of vaccine shots to 30-40 and up to five vaccines are simultaneously administered to children. Vaccines also contain adjuvants such as aluminum compounds and pertussis toxin that bias towards IgE synthesis. Given these conditions, the predictable and observed outcome is a food allergy epidemic.

Action

Obviously, as Kuno-Sakai et al. [10] have concluded, phasing out food proteins from vaccines and injections as soon as possible would be the real solution for food allergies caused by vaccines and injections.

Goldis et al. [13] have suggested alternative vaccine manufacturing methods to avoid contamination of vaccines with egg proteins.

Kattan et al. [20] have suggested eliminating casein from vaccines. Mark et al. [21] have suggested re-evaluation of aluminum compounds in vaccines due to its undesirable bias towards IgE synthesis.

Meanwhile, urgent action is needed to limit the problem. Unlike anaphylaxis, food allergies caused by vaccines may only be diagnosed weeks or months after vaccination.

If doctors are not informed of a possible link between vaccines and food allergies, either by vaccine package inserts or by peer reviewed published papers, [1,2,3] how are they going to make the connection and report the event to the Vaccine Adverse Event Reporting System (VAERS)? This makes VAERS ineffective to study this problem. The

Precautionary principle [22] states that lack of scientific consensus is not a reason for inaction when public safety is at risk. This principle is used by policy makers worldwide. Prudent avoidance [23] is a precautionary principle in risk management, stating that reasonable efforts to minimize potential risks should be taken when the actual magnitude of the risks is unknown. Applying prudent avoidance means we should immediately stop multiple vaccines being administered simultaneously. It is likely to reduce the probability of developing food allergies by reducing the amount, number of food proteins and adjuvants that are injected at one time. Perhaps no more than a vaccine a month should be allowed.

Using the precautionary principle, we should add a warning in vaccine package inserts about food allergy being a possible side effect. This will improve reporting and make VAERS useful in studying the problem further. The National Vaccine Injury Compensation Program requires victims to prove that the vaccine caused the injury. According to the precautionary principle, the burden of proof of product safety should fall on those producing, approving and prescribing the vaccine and not on the victims.

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