

Rita Hoffman

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Sent: Thursday, May 09, 2002 1:30 PM
Subject: IMPACT and anaphylaxis

Dear Impact Participants,

Re: Epidemic of Children with Anaphylaxis

I received some shocking information recently which I would like to share with you. Through the Access to Information Act I am in receipt of the Adverse Events voluntarily reported to Health Canada on the vaccines that my 8 year old anaphylactic child received as an infant. The particulars are:

Dec. 29/93

DPT-P 24008-11 exp. June '94 49 adverse events 1 death, 2 seizures/convulsions
 Hib 3A0896 exp. June '94 42 adverse events 4 seizures/convulsions

March 1/94

DPT-P 24009-11 exp. Nov. '94 76 adverse events inc. 3 seizures/convulsions
 Hibtitre 3J0158 exp. Nov. '94 6 adverse events inc. 1 seizure/convulsion

April 27/94

DPT-P 24010-11 exp. Nov. '94 111 adverse events inc. 8 seizures/convulsions
 Hibtitre 3C0629 exp. July '94 21 adverse events inc. 2 seizures/convulsions

June 1/95

DPT-POLIO + ACT HIB combined in one syringe
 DPT-P 24017-11 exp. June '96 664 adverse events inc. 34 seizures/convulsions
 Hib: K0421 exp. Apr. '96 6 adverse events

The 664 adverse events above is not a typing error. The 34 seizures/convulsions above is not a typing error. There are numerous blanks and zeros next to recovery, so I assume there has been no follow up on these children. And regarding the ones that show "recovered" - has there been a 2-3 year follow up on these children to see if they have developed ADD, ADHD, Autism, Diabetes, Anaphylaxis or Asthma?

I am hoping that IMPACT can answer the following questions:

1) I have read, but cannot confirm, that the CDC considers a "hot lot" one that generates reports of more than two deaths or two convulsions or a total of 10 adverse reports. If this is the case, the majority of the vaccines my child received should have been recalled. How many adverse events, convulsions and deaths does it take for Health Canada to act and remove a dangerous vaccine?

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2) Is the manufacturer of these vaccines notified of all of these adverse events? Have vaccine manufacturers ever initiated a recall of a vaccine?

3) How do you determine whether the adverse event is attributed to the DPT-P or the Hib when they were both given at the same time, and now in the same syringe? Could anyone provide me with safety studies relating to the DPT-P and Hib being given concurrently, and whether IgE levels were tested pre and post vaccination?

4) The National Report on Immunization, 1996 states: "If the number and type of reports for a particular vaccine lot suggested that it was associated with more serious adverse events or deaths than are expected by chance, the federal government has the responsibility and will, as well as the legal authority, to immediately recall that lot."

How many lots have been recalled by the Canadian Federal Government, and how many adverse events were connected with those recalls?

5) Has anyone connected with IMPACT investigated the "more than 700 case reports in a year and a half" of anaphylaxis, and the connection to the changing vaccination schedule?

Further to my investigation into my child's immune system malfunction, I will share with you the following submission to the Institute of Medicine's investigation last year into Multiple vaccines and the connection to immune system malfunction.

The final report issued by the IOM included the following which can be seen here:

http://www4.nationalacademies.org/news_nsf/isbn/0309083281?OpenDocument

"The committee looked at five studies examining multiple vaccinations and their potential to cause allergic diseases, which reflect a hypersensitivity of the immune system to relatively harmless agents in the environment, like pollens, dust mites, insect venom, and specific foods. Some, but not all, of these studies suggested that certain vaccines increase the risk of developing allergic disorders. Methodological weaknesses and inconsistent findings among the studies, however, led the committee to conclude that there is inadequate evidence to either accept or reject a causal relationship between multiple immunizations and increased risk of allergic diseases, particularly asthma."

Clearly, the Institute of Medicine has not ruled out a link between vaccines and atopy.

I am hoping that IMPACT can answer the above questions as well as the ones asked in the following submission, which remain unanswered to date. I look forward to hearing from any/all of you.

Thank you for your time.

Sincerely,
Rita Hoffman

Anaphylaxis Action

November 6, 2001

Immunization Safety Review Committee
National Academy of Sciences
Institute of Medicine FO 3009
2101 Constitution Avenue NW

11/6/2003

Washington, DC 20418

Dear Dr. McCormick, Chair & Committee,

Re: Epidemic of Children with Anaphylaxis

Thank you for the opportunity to submit the following information for your review of the possible association between multiple immunizations in newborns and infants and immune system dysfunction. We are writing in particular about the potentially life threatening allergic response called anaphylaxis.

The exact numbers of children affected by anaphylaxis are difficult to pinpoint. A study in Arch Intern Med 2001 Jan 8; 161 (1): 15-2, Anaphylaxis in the United States; an investigation into its epidemiology, concluded with "The occurrence of anaphylaxis in the US is not as rare as is generally believed. On the basis of our figures, the problem of anaphylaxis may, in fact, affect 1.21% (1.9 million) to 15.04% (40.9 million) of the US population." PMID 11146694

In June of this year an article by Associated Press Writer Jim Fitzgerald entitled Peanut Butter Wars Rage in Schools stated "Schools that haven't had a dangerously allergic pupil can expect one soon." And "peanut allergies among schoolchildren were rarely on the radar a decade ago, said Dr. Robert Goldman, a New York allergist and immunologist who specializes in pediatric cases." "Now I'm seeing a tremendous number of cases," he said. "It seems like the incidence is really increasing. As to why, I don't think anyone in the world could tell you for sure."

In Canada, the Anaphylaxis Canada's Summer 2001 newsletter states that "20% of Canadians suffer from some form of allergy and approximately 4% of children and 2% of adults have developed a potentially lethal allergy to food."

The cover story in the September 2000 issue of Professionally Speaking, the magazine of the Ontario College of Teachers is "An Abnormal Response to Normal Things." The article begins with "Teachers have to be aware that allergies can kill. A growing number of children are at risk - and a well-prepared teacher can make all the difference." The article explains that "About a decade ago, the sudden surge in highly allergic children entering school systems across the province caught many educators off guard."

Why the "surge" in anaphylactic children entering school a decade ago? These children were among the first to receive an additional vaccination, Hib meningitis. Is it possible that the Pertussis and Hib vaccine, both shown below to cause allergic responses, are creating a hypersensitive immune system in some children? Has any study looked into what happens to atopy incidence and IgE levels when 5 vaccines are given concurrently in infants?

CAN VACCINES CAUSE FOOD ALLERGIES?

JAMA 2001 Apr 4;285(13): 1746-8 Detection of peanut allergens in breast milk of lactating women states, "Most individuals who react to peanuts do so on their first known exposure".....and concluded "Peanut protein secreted into breast milk of lactating women following maternal dietary ingestion. Exposure to peanut protein during breastfeeding is a route of occult exposure that may result in sensitization of at-risk infants." PMID 11277829

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Women have been ingesting peanut protein while breastfeeding for decades. What has changed in the last 15 years to cause infants to develop life-threatening allergies to this legume? One change has been the vaccination schedule.

The Int Arch Allergy Immunol 1999 Jul; 119(3):205-11 Pertussis adjuvant prolongs intestinal hypersensitivity concludes: Our findings indicate nanogram quantities of PT (pertussis toxin), when administered with a food protein, result in long-term sensitization to the antigen, and altered intestinal neuroimmune function. These data suggest exposure to bacterial pathogens may prolong the normally transient immune responsiveness to inert food antigens. PMID 10436392

Does this study explain why babies and toddlers react on their first exposure to the peanuts or other antigens? The babies may have been sensitized by the vaccines to the proteins through breast milk or formula ingested at the time of vaccination. This would also explain why children are anaphylactic to a variety of proteins, such as different tree nuts, peanuts, eggs, legumes, milk, seeds, etc., depending on what proteins the mother ate at the time of vaccination.

IS THE INTRODUCTION OF THE HIB VACCINE CONNECTED TO THE INCREASE IN FOOD ANAPHYLAXIS IN CHILDREN?

Rates of anaphylaxis have increased dramatically since the introduction of the Hib vaccine.

Clin Exp Pharmacol Physiol 1979 Mar-Apr; 6 (2): 139-49 Comparison of vaccination of mice and rats with Haemophilus influenzae and Bordetella pertussis as models of atopy, states "The Haemophilus influenzae vaccinated experimental animal provides a model that is possibly more related to human atopy than the Bordetella pertussis vaccinated animal." PMID 311260

Ann Allergy 1979 Jan;42(1):36-40 states "To determine whether Haemophilus influenzae could be a factor in human atopy its effects were studied on the (para-)Sympathic Cyclic nucleotide-histamine axis in rats. Haemophilus influenzae vaccination induced changes in the cholinergic system compatible with higher cyclic GMP levels and enhanced histamine release. The authors suggest an involvement of the cholinergic system in Haemophilus influenzae vaccination effects. PMID 216288

Agents Actions 1984 Oct;15(3-4):211-5 entitled Bronchial hyperreactivity to histamine induced by Haemophilus influenzae vaccination states "..... This suggests hyperreactivity of the parasympathetic, cholinergic pathways as a result of H influenzae vaccination." PMID 6335351

Eur J. Pharmacol 1980 Apr 4;62(4):261-8 entitled The effects of Haemophilus influenzae vaccination on anaphylactic mediator release and isoprenaline-induced inhibition of mediator release states "These results indicate an increased sensitivity to antigenic challenge and suggest that the functioning of beta-adrenoceptors was decreased as a result of H. Influenzae vaccination." PMID 6154589

DOES THE PERTUSSIS VACCINE CAUSE ASTHMA, ALLERGIES AND ANAPHYLAXIS?

Pediatrics 1988 Jun (81) Supplement - Report on the Task Force on Pertussis and Pertussis Immunization - extract states, For more than 25 years, it has been known that pertussis vaccine is a reliable adjuvant for the production of experimental allergic encephalitis.

Bull Eur Physiopathol Respir 1987;23 Suppl 10:111s-113s A model for experimental asthma provocation in guinea-pigs immunized with Bordetella pertussis states, "Guinea-pigs were sensitized with killed Bordetella pertussis....the presence of the immediate type of immune response was verified by passive cutaneous anaphylaxis....B. pertussis not only alters adrenergic function but provocation in B. pertussis-sensitized guinea-pigs seems to be a good model for bronchial asthma. PMID 2889487

Pediatr Res 1987 Sep; 22(3): 262-7 Murine responses to immunizations with pertussis toxin and bovine serum albumin: I. Mortality observed after bovine albumin challenge is due to an anaphylactic reaction.....the results of our experiments have established that the disease induced by coimmunizing mice with Ptx and BSA is due to an immediate type hypersensitivity PMID 3309858

Infect Immun 1987 Apr.; 55(4):1004-8 Anaphylaxis or so-called encephalopathy in mice sensitized to an antigen with the aid of pertussigen (pertussis toxin), states, Sensitization of mice with 1 mg of bovine serum albumin (BSA) or chicken egg albumin (EA)...induced a high degree of anaphylactic sensitivity when the mice were challenged i.v. with 1 mg of antigen 14 days later. PMID 3557617

JAMA 1994 Aug 24-31;272(8):592-3 Pertussis vaccination and asthma: is there a link? A study of 450 children, 11% of the children who had received the pertussis vaccination suffered from asthma, as compared with only 2% of the children who had not been vaccinated. PMID 8057511

Allergy 1983 May; 38(4):261-71

The non-specific enhancement of allergy. III. Precipitation of bronchial anaphylactic reactivity in primed rats by injection of alum or B. pertussis vaccine: relation of response capacity to IgE and IgG2a antibody levels....These results show that injection of alum or B. pertussis without antigen can precipitate/enhance anaphylactic response capacity and production of specific and non-specific IgE and IgG2a. PMID 6307077

CAN VACCINE ADJUVANTS CAUSE ALLERGIES AND ANAPHYLAXIS?

Requests for information on the types of adjuvants used in human vaccines have not been answered to date. We did find that adjuvants are used to create allergic animals for scientific study and also that peanut oil has been used as an adjuvant. Peanut is by far the most common food to cause anaphylaxis in young children. Is peanut oil, or a similar protein or portion of a protein used in human vaccines as an adjuvant or "protein coat" in the Hib vaccine?? Aluminum has also been used as an adjuvant and is known to cause allergies according to the studies below. Could the adjuvants used in vaccines over the last 15 years be creating anaphylactic and allergic children?

J allergy Clin Immunol 2001 Apr.;107(4):693-702 Murine model of atopic dermatitis associated with food hypersensitivity states,"Female C3H/HeJ mice were sensitized orally to cow's milk or peanut with a cholera toxin adjuvant and then subjected to low-grade allergen exposure.....An eczematous eruption developed in approximately one third of mice after low-grade exposure to milk or peanut proteins.....This eczematous eruption resembles AD (atopic dermatitis) in human subjects and should provide a useful model for studying immunopathogenic mechanisms of food hypersensitivity in AD." PMID 11295660

Allergy 1980 Jan;35(1):65-71 Antigen-induced bronchial anaphylaxis in

actively sensitized guinea-pigs. Pattern of response in relation to immunization regimen....guinea-pigs sensitized with small amounts of antigen with alum produced IgE and IgG1 antibodies. PMID 11295660

Allergy 1978 Jun;33(3):155-9 Aluminum phosphate but not calcium phosphate stimulates the specific IgE response in guinea-pigs to tetanus toxoid. It is hypothesized that the regular application of aluminum compound-containing vaccines on the entire population could be one of the factors leading to the observed increase of allergic diseases. PMID 707792

Pediatr Allergy Immunol 1994 May;5(2):118-23 Immunoglobulin E and G responses to pertussis toxin after booster immunization in relation to atopy, local reactions and aluminum content of the vaccines. The role of aluminum for IgG and IgE responses to pertussis toxin (PT), as well as for side effects, was investigated in 49 children with known atopy status....the addition of aluminum to the pertussis vaccine was, thus, associated with a stronger IgG antibody response, but tended also to induce a stronger IgE antibody response. The correlation between total IgE and PT-IgE, which was most prominent in children with atopy, indicates that the role of immunization for the development of allergy merits further studies. PMID 8087191

Adv Drug Deliv Rev 1998 Jul 6;32(3):155-172 entitled Aluminum compounds as vaccine adjuvants stated, "Limitations of aluminum adjuvants include local reactions, augmentation of IgE antibody responses, ineffectiveness for some antigens and inability to augment cell-mediated immune responses, especially cytotoxic T-Cell responses. PMID 10837642

Annals of Asthma, Allergy and Immunology, Vol. 85, Number 1, July 2000 article T-cell subsets (Th1 versus Th2) includes figure 7 on page 15 - "Factors responsible for the imbalance of the Th1/Th2 responses which is partly responsible for the increased prevalence of allergy in Western countries. Risk for atopy - Th2, increased exposure to some allergens and Th2-biasing vaccines (alum as adjuvant)."

Vaccine 1992;10(10):714-20 Parameters affecting the immunogenicity of microencapsulated tetanus toxoid states "As expected, incomplete Freund's adjuvant (IFA) proved to be a more potent adjuvant than peanut oil....." PMID 1523381

Can J Comp Med 1985 Apr;49(2):149-51 compared 6 different adjuvants in swine including four mineral oil compounds, one peanut oil compound and aluminum hydroxide. PMID 4016580

C R Acad Sci Hebd Seances Acad Sci D 1975 Apr 7;280(13):1629-32 states....a stable water in oil emulsion can be produced by using metabolizable peanut oil with arlacel. When mycobacteria are added, a potent emulsified oil adjuvant is obtained which increases the immune response to BSA and to influenzae vaccine. PMID 811378

ARE MULTIPLE VACCINES CAUSING OUR IMMUNE SYSTEMS TO FAIL?

Immunology Today, March 1998, Volume 19, p. 113-116 states, "Modern vaccinations, fear of germs and obsession with hygiene are depriving the immune system of information input upon which it is dependent. This fails to maintain the correct cytokine balance and fine-tune T-cell regulation, and may lead to increased incidences of allergies and autoimmune diseases."

>From the journal Allergy 1999, 54, 398-399, Multiple Vaccinations effect

on atopy. "An increase in the incidence of childhood atopic diseases may be expected as a result of concurrent vaccination strategies that induce a Th2-biased immune response. What should be discussed is whether the prize of a reduction of common infectious diseases through a policy of mass vaccinations from birth is worth the price of a higher prevalence of atopy."

Journal of Manipulative and Physiological Therapeutics, Feb 2000;23(2):81-90, Effects of diphtheria-tetanus-pertussis or tetanus vaccination on allergies and allergy-related respiratory symptoms among children and adolescents in the United States. "The odds of having a history of asthma was twice as great among vaccinated subjects than among unvaccinated subjects. The odds of having any allergy-related respiratory symptom in the past 12 months was 63% greater among vaccinated subjects than unvaccinated subjects." PMID 10714532

Thorax 1998 Nov;53(11):927-32 Early childhood infection and atopic disorder, stated "Interpretation of the prediction of atopic disorders by immunization with wholecell pertussis vaccine and treatment with oral antibiotics needs to be very cautious because of the possibilities of confounding effects and reverse causation. However, plausible immune mechanisms are identifiable for the promotion of atopic disorders by both factors and further investigation of these association is warranted." PMID 10193389

Epidemiology 1997 Nov;8(6):678-80 Is infant immunization a risk factor for childhood asthma or allergy? This study followed 1,265 children born in 1977. The 23 children who received no DPT and polio immunizations had no recorded asthma episodes or consultations for asthma or other allergic illness before age 10 years; in the immunized children, 23.1% had asthma episodes, 22.5% asthma consultations, and 30% consultations for other allergic illness. Similar differences were observed at ages 5 and 16 years. PMID 9345669

Aerugi 2000 Jul;49(7):585-92, The Effect of DPT and BCG vaccinations on atopic disorders findings include, "From these results we conclude that DPT vaccination has some effect in the promotion of atopic disorders....." PMID 10944825

International Archives of Allergy and Immunology 121;1:2000,2-9, Genetic and environmental factors contributing to the onset of allergic disorders. "The increasing prevalence of allergy in developed countries suggests that environmental factors acting either before or after birth also contribute to regulate the development of Th2 cells and/or their function. The reduction of infectious diseases in early life due to increasing vaccinations, antimicrobial treatments as well as changed lifestyle are certainly important in influencing the individual outcome in the Th response to ubiquitous allergens.

In conclusion, living with anaphylaxis is to be continually on guard for minute quantities of everyday food or other substances that may cause death. Keeping anaphylactic children safe involves the whole community including the child, parents, teachers, bus drivers, caregivers, friends and family.

It is our hope that the Committee will investigate the questions we have raised and will recommend further investigation into the connection between vaccines and this most distressing allergic disease called anaphylaxis.

Your time is greatly appreciated.

11/6/2003

Respectfully yours,

Rita Hoffman