Assessment of adverse reactions to vaccines given to Greyson and Gwyneth with recommendations for clinical tests

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Abstract

Greyson and Gwyneth were perfectly healthy children prior to May 12, 2004 when each of them received eleven vaccines in one single visit to a health care provider. Greyson is a five year and two month old white male and his sister; Gwyneth is six year and 10 months old. They developed significant health problems after receiving these vaccinations.

In June of 2004, their mother, Janet Burton, consulted with me as a toxicologist and a pathologist with expertise in the area of adverse reactions to vaccines to evaluate the following: (1) her children's vaccination records and their adverse reactions to vaccines; (2) the validity of the vaccination procedure and the compatibility of these vaccines with the ages of her children; (3) the synergistic actions among vaccines given to her children in causing adverse reactions; (4) the health problems that can be caused by vaccinating Greyson and Gwyneth a second time on June 12, 2004; and (5) the predisposing factors that might increase her children's risk to be injured by vaccines.

Furthermore, Janet requested that I provide recommendations for clinical tests that monitor her children's adverse reactions to vaccines and my opinions on the risk verses benefit from vaccinating her children in the future. I described the children's vaccination history and their symptoms induced by the vaccines; provided a list of some of the adverse reactions described in the medical literature of vaccines given to Janet's children; and listed the problems with the protocol used by the health care provider.

Keywords: adverse vaccine reactions, risk factors, family history

Introduction

Vaccines like other medicines, are capable of causing serious health problems in children and adults as described in this report. Giving two healthy children eleven vaccines on a single visit without doing risk/benefit analysis or reviewing the family history for health problems caused by vaccines is not medically justified. In addition, giving these two children who are older than five years of age Pneumococcal Conjugate vaccine (PCV) and *Haemophilus Influenzae* (Hib) vaccine that are recommended for children ages of 2-15 months indicates serous problems with the practices of the health care provider who administered these vaccines. I believe that health care providers who give vaccines to children should familiarize their self with the adverse reactions of vaccines and the risk factors involved in causing health problems prior to giving vaccines to children. These measures will help to prevent injuring children with vaccines as it happed in this case.

1. Greyson and Gwyneth 's vaccination history and descriptions of adverse reactions to vaccines

Greyson is a five year and two month old white male (DOB: March 14, 1999). His weight and height are 42 lb and 44 inches, respectively. Gwyneth is a six year and 10 month old white female (DOB: July 3, 1997). Her weight and height are 58 lb and 48 inches, respectively. They live with their parents in Arizona and both were perfectly healthy prior to their vaccination with eleven vaccines on May 12, 2004 [1] .

They were never vaccinated prior to May 12, 2004 based on Janet Burton, their mother, who had a very bad experience with the vaccines when she vaccinated her daughter (Greyson and Gwyneth's older half-sister) with measles, mumps & rubella (MMR) at the age of 6 years. Their sister developed seizures at nine months after her second dose of MMR. She had grand mal seizures—severe enough to warrant hospitalization twice—for a few years following that event. She received her first MMR when she was an infant. Furthermore, Janet has believed that her children are in perfect health and they have no risk of getting health problems from an infectious agent. In this case the risk of her children are getting ill from vaccines will out weigh the benefit of the vaccines.

On May 12, 2004 Greyson and Gwyneth were taken by their father without consulting with their mother to a health care provider, who vaccinated each of them with the eleven vaccines listed in Table 1. These vaccines were administered intramuscularly in the arms and the legs. The general compositions of these vaccines are listed in Table 2. These vaccines include four live virus vaccines (Measles, Mumps, and Rubella (MMR) and Varicella).

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The children were return to their mother two days after vaccination and she observed the following symptoms resulting from their treatment with the vaccines. Both children showed signs of dehydration and had pain at the vaccines injection sites, which lasted for several days. Greyson displayed behaviors showing signs of hyperactivity for the first time in his life along with unstable body temperatures that made him hot one minute and cold the next. He also had dark circles around his eyes and his pupils were dilated. His appetite was reduced and he felt tired. He slept about two hours in the middle of the day, which is unusual for him. In addition, he had a sore throat, headache and complained of his eyes burning. He seemed forgetful and mentally unclear.

Furthermore, Greyson developed a new rash on both legs, especially his right thigh at six to eight days post vaccination. His mother also noticed two small patches approximately an inch in diameter on the right of his abdomen where the texture of his skin is rough and scaly in appearance. Three weeks later to present time, Greyson became hyperactive. He had spurts of energy that made him uncontrollable or containable and he has compulsive-type behavior.

Gwyneth felt unusually thirsty all afternoon and evening. She felt tired and slept 2 hours in the middle of the afternoon, which was unusual for her. At four to eight days following vaccination, she developed a sore throat and dry hives. Her appetite was reduced and she felt like vomiting after eating small amount of food. She woke up during the night hysterical with pain in her throat. She was feeling tired and she hardly dance at her dance class.

Janet Burton, has recently received the records of her children's vaccination from the health care provider who administered the vaccines to her children. She discovered from reading the records that Greyson and Gwyneth were scheduled to receive additional vaccines on or about June 12, 2004. She was also not consulted on this issue.

Janet has consulted with me as a toxicologist and a pathologist with expertise in the area of adverse reactions to vaccines to evaluate the followings: 1) Her children vaccination records and their adverse reactions to vaccines. 2) The validity of the vaccination procedure and the compatibility of these vaccines with the ages of her children. 3) The synergistic actions among vaccines given to her children in causing adverse reactions. 4) The health problems that can be caused by vaccinating Greyson and Gwyneth a second time on June 12, 2004. 5) The predisposing factors that might increase her children's risk to be injured by vaccines. Furthermore, Janet requested that I provide recommendations for clinical tests that monitor her children's adverse reactions to vaccines and my opinions on the risk verses benefit from vaccinating her children in future.

I evaluated the medical evidence concerning the vaccination of Greyson and Gwyneth with eleven vaccines on May 12, 2004. Below are the descriptions of adverse reactions of vaccines given to these children with my opinions and recommendations.

Table 1. Vaccines given to Greyson and Gwyneth on May 12/2004

Vaccine types	Producers	Lot numbers
Diphtheria, Tetanus Toxoids, and acellular Pertussis (DTaP)	SKB	21896A2
Inactivated Polio vaccine (IPV)	SKB	21896A2
Haemophilus Influenzae (Hib)	Merck	0341N
Hepatitis B (Hep B)	SKB	21896A2
Pneumococcal Conjugate Vaccine (PCV)	Lederle	495175
Measles, mumps & rubella (MMR)	Merck	0105N
Varicella	Merck	1151M

Table 2. Compositions of vaccines as described in the Physicians' Desk Reference [2, 3]

Diphtheria & Tetanus Toxoids and acellular Pertussis (DTaP): Each dose (0.5 mL) contains 0.625 mg aluminum; 25 Diphtheria toxoid; 10 tetanus toxoid; 25 μg pertussis toxin; 25 μg filamentous hemagglutinin; 8 μg pertacin; 2.5 mg 2-phenoxyethanol; 4.5 mg sodium chloride; and 0.1 mg formaldehyde.

Inactivated Polio Vaccine (IPV): Each 0.5 ml dose contains 40 D antigen units of type 1, 8 D antigen units of type 2, and 32 D antigen units of type 3 poliovirus. Also present are 0.5% of 2-phenoxyethanol and 0.02% of formaldehyde (Preservatives), 5 ng neomycin, 200 ng streptomycin, and 25 ng polymyxin.

Haemophilus Influenzae (Hib): Each 0. 5 ml dose of liquid HIB contain 7.5 microgram of Haemophilus b, 125 microgram of Nisseria menigitids, and 225 microgram of aluminum.

Hepatitis B vaccine: Each 0.5 mL dose contains 0.25 mg aluminum; 10 μg of hepatitis B antigen; 4.5 mg sodium chloride; 0.49 mg disodium phosphate dihydrate; and 0.35 mg sodium dihydrogen phosphate dihydrate.

Pneumococcal vaccine: Each dose (0.5 ml of vaccine) contains a mixture of purified polysaccharides of 23most prevalent or invasive pneumococcal types of Streptococcus Pneumonia dissolved in isotonic saline solution containing 0.25% phenol as preservative.

Measles, Mumps & Rubella (MMR): Each 0.5 ml dose contains not less than, 1000 TCD50 (tissue culture infectious doses) of measles virus: 20,000 TCID50 of mumps virus; and 1000 TCID50 of rubella virus. Each dose of vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg) sodium chloride, hydrolyzed gelatin (14.5 mg), human albumin (0.3 mg) fetal bovine serum (<1 ppm), and 25 microgram of neomycin.

Varicella virus vaccine: Each 0.5 mL dose containing a minimum of 1350 PFU (plaque forming unit) of Oka/Merck varicella virus and additives.

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2. Adverse reactions to vaccines.

Greyson and Gwyneth were administered eleven vaccines in a single visit on May 12, 2004 (Table 1)—although they were in perfect health and with minimal or no risk of developing illness from an infectious agent in the near future. In this case the risk of developing serious health problems from these vaccines out weighed the benefit.

Furthermore, two of the vaccines given [pneumococcal conjugate vaccine (PCV) and *Haemophilus influenzae* Type b (Hib)] have been approved and recommended only for children between the ages of 2 and 15 months. Greyson and Gwyneth are healthy and more than five years old and administering PCV and Hib has no scientific justification and does not follow the recommendations presented in the *Physicians' Desk Reference (PDR)* and provided by the U.S. Centers for Disease Control and Prevention (CDC) [3-6].

The vaccines given to Greyson and Gwyneth have been known to cause serious adverse reactions in some children that include the following: serous allergic reactions, upper and lower respiratory tract infections, ear infections, fever, encephalitis, neurological problems, deafness, pancreatitis, diabetes mellitus, poor appetite, loss of weight, thrombocytopenia, and even death. The following specific reactions have been reported following receipt of individual vaccines or groups of vaccines.

2.1. MMR Vaccines

Serous systemic adverse reactions have been reported in children who received the MMR vaccines. These include malaise, sore throat, cough, rhinitis, headache, dizziness, fever of 101oF (38.3°C) to 102.9°F (39.4°C), rash, nausea, vomiting, diarrhea, fever, regional lymphadenopathy, parotitis, orchitis, nerve deafness, vasculitis, otitis media, hearing loss, conjunctivitis, aseptic meningitis, measles, thrombocytopenia, and anaphylaxis [2:1820, 7-12].

Koga et al. described a case of a child who developed bilateral acute profound deafness and aseptic meningitis within 14 days after receiving MMR vaccines. The cause of this deafness was presumed to be the mumps vaccination. The bases of the presumption were as follows: The meningitis after MMR vaccination was elicited by the Polymerase Chain Reaction (PCR) method to be caused by the mumps vaccine. The complication of the central nervous system (CNS) after measles vaccination occured within 14 days after injection and the onset of vomiting and gait disturbance of the case occurred 24 days after vaccination [7].

Furthermore, a 7-year-old girl developed unilateral total loss of hearing 13 days following MMR vaccination and the live, attenuated mumps-virus vaccine was suspected to be the cause of the injury [8]. Stewart and Prabhum also reported 6 individuals, who developed hearing loss after the MMR immunization and MMR remained a possible etiology. They stated that any risk associated with attenuated viruses must be weighed against the risks of the natural diseases [9].

Cases of aseptic meningitis associated with MMR vaccines were sought in thirteen UK health districts following a reported cluster in Nottingham that suggested a risk of 1 in 4,000 doses. Cases were ascertained by obtaining vaccination records of children with aseptic meningitis diagnosed from cerebrospinal fluid (CSF) samples submitted to Public Health Laboratories or discharged from hospital with a diagnosis of viral meningitis. Both methods identified vaccination 15-35 days before onset as a significant risk factor and therefore indicative of a causal association. With both, half the aseptic meningitis cases identified in children aged 12-24 months were vaccine-associated with onset 15-35 days after vaccine. This study confirmed that the true risk was substantially higher than suggested by case reports from pediatricians, probably about 1 in 11,000 doses [10].

Furthermore, in Japan, at least 311 meningitis cases suspected to be vaccine-related were identified among 630,157 recipients of the measles-mumps-rubella trivalent (MMR) vaccine. These cases were identified based on the notification of cases and the testing of mumps viruses isolated from CSF for their relatedness to the vaccine by nucleotide sequence analysis [11].

Also, the U.S. Institute of Medicine (IOM) examined putative serious adverse consequences associated with administration of diphtheria and tetanus toxoids, measles, mumps, and measles-mumps-rubella vaccines, oral polio vaccine and inactivated polio vaccine, hepatitis B vaccines, and Haemophilus influenzae type B (Hib) vaccines. The committee spent 18 months reviewing all available scientific and medical data from individual case reports (published and unpublished) to controlled clinical trials.

The committee found that the evidence favored acceptance of a causal relation between diphtheria and tetanus toxoids and Guillain-Barre syndrome and brachial neuritis; between measles vaccine and anaphylaxis; between oral polio vaccine and Guillain-Barre syndrome; and between unconjugated Hib vaccine and susceptibility to Hib disease. The committee also found that the evidence established causality between diphtheria and tetanus toxoids and anaphylaxis; between the measles vaccine and death from measles vaccine-strain viral infection; between measles-mumps-rubella vaccine and thrombocytopenia and anaphylaxis; between the oral polio vaccine and poliomyelitis and death from polio vaccine-strain viral infection; and between the hepatitis B vaccine and anaphylaxis [12].

2.2. Varicella virus vaccine

In addition to the MMR vaccine, Greyson and Gwyneth received the varicella vaccine. The following is a list of the most frequently reported adverse reactions in children ages 1-12 years, who received the varicella vaccine. These illnesses include: upper respiratory illness, cough, irritability, nervousness, fatigue, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, skin rash, nausea, eye complaints, chills, lymphadenopathy, malagia, lower respiratory illness, allergic reactions (including allergic rash and hives), stiff neck, heat rash, arthralgia, ec-

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zema/dry skin/dermatitis, constipation, and itching. Furthermore, in a study consisting of 8,827 children who received the varicella vaccine, fever >102oF (38.9°C) developed in 14.7% between 0-42 days [2:1910].

2.3. *Haemophilus influenzae* type B (Hib)

Haemophilus influenzae type B (Hib) has been approved and recommended only for children between 2 and 15 months of age. Greyson and Gwyneth are healthy and older than five years of age and giving them PCV and Hib has no scientific justification and it does not follow the recommendations presented in the Physicians' Desk Reference (PDR) and provided by the US Centers For Disease Control and Prevention (CDC) [3, 6].

Three hundred sixty-five infants were inoculated with *Haemophilus influenzae* type B (Hib), and some of them developed systemic adverse reactions [2, 3]. In addition, Classen and Classen analyzed data from a Hib vaccine trial and identified clusters of extra cases of insulin dependent diabetes (IDDM) caused by the vaccine that occurred between 36 and 48 months post-immunization [13].

Furthermore, approximately 116,000 children in Finland were randomized to receive 4 doses of the Hib vaccine beginning at 3 months of age or one dose starting after 24 months of age. A control-cohort included all 128,500 children born in Finland in the 24 months prior to the Hib vaccine study. The difference in cumulative incidence between those receiving 4 doses and those receiving 0 doses is 54 cases of IDDM/100,000 ($p = 0.026$) at 7-years (relative risk = 1.26).

Most of the extra cases of IDDM appeared in statistically significant clusters that occurred in periods starting, at approximately 38 months after immunization and lasting approximately 6-8 months. In a second study, distinct rises in the incidence of IDDM in children occurred 2-4 years following the introduction of the MMR and pertussis vaccines [14].

2.4. Diphtheria, Tetanus Toxoids, and a cellular Pertussis (DTaP)

In the U.S., reports to the Vaccine Adverse Event Reporting System (VAERS), concerning infant immunization against pertussis between January 1, 1995 and June 30, 1998 were analyzed. During the study period, there were 285 reports involving death, 971 non-fatal serious reports (defined as events involving initial hospitalization, prolongation of hospitalization, life-threatening illness, or permanent disability), and 4,514 less serious reports after immunization with any pertussis-containing vaccine [15].

The whole-cell DTP vaccine has also been associated with acute encephalopathy [2]. A large case-control study that included children 2 to 35 months of age who received DTP was conducted in England to study the incidence of vaccine related neurological problems. Acute neurological disorders, such as encephalopathy or complicated convulsion(s) occurred in children who were more likely to have received the DTP vaccine 7 days preceding the onset than their age-matched controls. Among children presumed to be neurologically normal before entering the study, the relative risk (estimated by odds ratio) of a neurological illness occurring within 7-day period following receipt of DTP dose, compared to children not receiving DTP vaccine in the 7-day period before onset of their illness, was 3.3 ($p< 0.001$).

2.5. Hepatitis B vaccine

The database from the 1994 National Health Interview Survey (NHIS) in the USA that included 6,515 children less than six years of age who received the hepatitis B vaccine were analyzed to evaluate the vaccine related adverse reactions. Hepatitis B vaccine was found to be associated with prevalent arthritis, incident of acute ear infections, and incident of pharyngitis/nasopharangitis [16].

The above selected studies clearly show that the vaccines given to Greyson and Gwyneth cause serious health problems, even death in healthy in some otherwise healthy children. These children were in perfect health and with no known risk of getting infections. However, they have known risk of developing neurological damage from vaccines as previously occurred in their sister case.

3. Problems with methods used by the health care provider who vaccinated Greyson and Gwyneth on May 12, 2004

Vaccines like other medicines, which are capable of causing serious health problems in children and adults as described above. The health care providers who are licensed to administer vaccines to children must have some knowledge in the area of adverse reactions to vaccines and the recommendations presented in the PDR and provided by the U.S. CDC dealing with the administrations of these vaccines to children and adults.

My review of the evidence presented in this case has revealed the following serous problems dealing with a) the types and numbers of vaccines administered to Greyson and Gwyneth; b) the knowledge of the health care provider who administered vaccines to these children in the areas of adverse reactions to vaccines and the recommendations provided dealing with the use of these vaccines. Below is a list of the specific problems.

1) The health care provider administered eleven vaccines to each of these perfectly healthy children in one visit without doing analysis of risk and benefit or considering the synergistic actions among the components of these vaccines listed in Table 2 in causing health problems. These vaccines contain live viruses, various antigens, heavy metals, antibiotics, and preservatives. Additive and synergistic actions among these components in causing serious health problems can occur. I evaluated four cases of children who died as a result of adverse reactions to vaccines [17-22]. I also previously evaluated a case involving a healthy adult who developed serous health problems from vaccines [23].

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2) The health care provider administered [*Haemophilus influenzae* type B (Hib)] and Pneumococcal Conjugate vaccine (PCV) to Greyson and Gwyneth without any medical justifications. These vaccines have been approved and recommended only for children between 2 and 15 months of age. Greyson and Gwyneth are healthy and more than five years old and giving them PCV and Hib does not follow the recommendations presented in the *Physicians' Desk Reference (PDR)* and provided by the U.S. Centers For Disease Control and Prevention (CDC) [3-6].

3) The health care provider did not evaluate the family case history prior to giving the children vaccines that may cause neurological damage such as DTaP and MMR to found out if they are at high risk of developing neurological problems. The children half-sister developed seizure and suffered from epilepsy after receiving her second MMR vaccine at the age of six years as described in this report. The CDC reported moderate and severe health problems in children after DTaP vaccine. These include seizure, high fever, serious allergic reactions, long-term seizures, comma, and permanent brain damage [24].

Furthermore, the followings moderate and severe neurological and other health problems have been reported by the CDC in some children after MMR vaccines: seizure, joint pain, thrombocytopenia, serious allergic reactions, long-term seizures, deafness, comma, and permanent brain damage, deafness [25].

4) The health care provider neither consulted with the mother of the children concerning vaccination of her children on May 12, 2004 nor when making the second appointment to vaccinate the children again a month later on June 12, 2004.

5) The health care provider did not consider the adverse reactions caused by the vaccines given when making the decision to vaccinate the children again on June 12, 2004. Both Greyson and Gwyneth developed significant health problems and contact dermatitis after receiving the vaccines on May 12, 2004 as described in this report. These symptoms should have been taken into consideration when vaccinating these children again. Developing symptoms following the first exposure of individuals to antigens and chemicals present in vaccines indicate that these individuals are becoming sensitized to these agents. Exposure of individuals again to these agents especially within days or weeks may cause more serous illnesses than those induced by the previous exposure to these agents. Greyson and Gwyneth's sister developed seizure following her second vaccination with MMR at six years of age. She had been vaccinated with MMR as an infant.

4. Conclusions and Recommendation

Giving two healthy children eleven vaccines on a single visit without doing risk/benefit analysis or reviewing the family history for health problems caused by vaccines is not medically justified. In addition, giving these two children who are older than five years of age PCV and Hib vaccines that are recommended for children ages of 2-15 months indicates serous problems with the practices of the health care provider who administered these vaccines.

Below are my specific recommendations that I gave dealing with the issues of giving Greyson and Gwyneth vaccines in future and monitoring the damages caused by the vaccines given on May 12, 2004. My recommendations can be applied in cases similar to the cases of these two children.

1) These children should not be given PCV and Hib vaccines again because these vaccines are approved and recommended for children at the ages of 2-15 months.

2) These children should not be vaccinated on June 12, 2004 or in the near future without assessing the damage caused by the vaccines given on May 12, 2004.

3) The medical records of their older sister who developed seizure after receiving the second dose of MMR at the age of 6 years should be evaluated prior to vaccinating these children. The sister's medical records should be evaluated by an expert in the area of adverse reactions to vaccines to assess the risk of these children of developing serious neurological problems following vaccination.

4) The parents of these children and other caretaker should be consulted prior to giving these children vaccines and they should be given instructions to report adverse reactions to vaccines to the treating physicians.

5) The levels of aluminum and mercury should be determined in the urine and blood of Greyson and Gwyneth to get an idea about their exposure to these elements present in vaccines.

6) Greyson and Gwyneth should be evaluated by an allergist to determine their levels of sensitization to egg albumin and other components present in vaccines such as antibiotics, proteins, preservatives, and metals (Table 2).

7) Greyson and Gwyneth's physician should be consulted to order blood analyses that include complete blood cell count (RBC, white blood count and differential cell counts, platelet count); liver and kidney functions panels; clotting factors; electrolyte levels; and glucose levels. These children suffered from dehydration and vaccines are known to cause thrombocytopenia, liver and kidney damage, and diabetes.

8) Greyson and Gwyneth should be evaluated by a neurologist and a hearing specialist to assess any neurological and hearing problem that may be caused by vaccines.

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