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## VACCINES: AN ONLINE CONFERENCE

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### SUDDEN INFANT DEATH SYNDROME IN VAERS: A REVIEW

By RFD Columnist, F. Edward Yazbak, MD, FAAP

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**PART ONE HERE**

#### VAERS

"The Vaccine Adverse Event Reporting System is a cooperative program for vaccine safety of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of US licensed vaccines. This Web site provides a nationwide mechanism by which adverse events following immunization (AEFI) may be reported, analyzed and made available to the public. The VAERS Web site also provides a vehicle for disseminating vaccine safety-related information to parents/guardians, healthcare providers, vaccine manufacturers, state vaccine programs, and other constituencies."

**Only 10% of vaccine adverse events are ever reported to VAERS**, in spite of the efforts of the CDC and the vaccine immunization programs in the different states.

The vaccine authorities have always warned about misinterpretation of data and findings in VAERS reports. Their statement is clear.

**When evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. VAERS is interested in all potential associations between vaccines and adverse events. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event.**

## ONLINE CONFERENCE CENTER

Also By F. Edward Yazbak

**About Dr. Yazbak**

**January 12, 2004**

**HYPING VACCINES: AN INVESTIGATION**

Chickenpox, Lyme, Rotavirus, And A Highly Revealing Analysis Of Flu Statistics

**December 22, 2003**

**DR. ANDREW WAKEFIELD IS BEING BLAMED FOR THE DECLINE IN MEASLES, MUMPS AND RUBELLA VACCINATION IN THE UK. BUT THAT'S NOT WHAT REALLY HAPPENED. THE TREND STARTED YEARS BEFORE HE PUBLISHED HIS INITIAL RESEARCH ON REGRESSIVE AUTISM**

**December 4, 2003**

**A NOT-SO-PERFECT VACCINE: THE DIPHTHERIA, TETANUS AND ACELLULAR PERTUSSIS VACCINE: AN INVESTIGATION**

**November 4, 2003**

**VACCINATION, RUBELLA AND CONGENITAL RUBELLA SYNDROME**

Separating Fact From Fiction

The purpose of this review is to examine the subject of SIDS and vaccines by reviewing reports to VAERS, from the start of the program in 1990 through the end of 2002.

One should be extremely cautious in drawing conclusions. The fact that an infant died of SIDS shortly after receiving a certain vaccine should not imply that he or she died because of the vaccine. Infants almost always receive more than one vaccine at a time. The same report/case will be listed with each of the vaccines administered to the infant. As an example, in the first case listed with DTAP (Diphtheria, tetanus, acellular pertussis vaccine) the infant also received a dose of HIB (Hemophilus influenzae B) vaccine and therefore that case will also be listed under HIB. The only exception is in the nursery and the first month of life when the first dose of hepatitis B vaccine is usually administered.

**VAERS data search**

**Vaccines: DTAP, DTP, DTPH, HIB, HBHEPB, HEP, HEP (under age 1 month)**

DTP: Diphtheria, Tetanus and whole cell Pertussis (sometimes referred to as DTwcP)

DTPH: DTP + HIB

HBHEPB: HIB + Hepatitis B vaccine

HEP: Hepatitis B vaccine

	DTAP	DTP	DTPH	HIB	HB HEPB	HEP All ages	HEP Neonatal
<b>All reports</b>	<b>18,484</b>	<b>26,581</b>	<b>6,108</b>	<b>23,474</b>	<b>2,863</b>	<b>38,600</b>	<b>249</b>
<b>Deaths</b>	<b>416</b>	<b>942</b>	<b>237</b>	<b>866</b>	<b>123</b>	<b>753</b>	<b>32</b>
<b>% Of total</b>	<b>2.2</b>	<b>3.5</b>	<b>3.9</b>	<b>3.7</b>	<b>4.3</b>	<b>1.9</b>	<b>12.8</b>
<b>SIDS cases</b>	<b>243</b>	<b>568</b>	<b>144</b>	<b>513</b>	<b>78</b>	<b>416</b>	<b>21</b>
<b>% Of total</b>	<b>1.3</b>	<b>2.1</b>	<b>2.3</b>	<b>2.2</b>	<b>2.7</b>	<b>1.1</b>	<b>8.4</b>
<b>% Of deaths</b>	<b>58.4</b>	<b>60.3</b>	<b>60.7</b>	<b>59.2</b>	<b>63.4</b>	<b>55.2</b>	<b>65.6</b>

**Table I**

All reports: Number of reports filed with VAERS in which the vaccine was listed

Deaths: Number of reports of death for each vaccine

% Of total: The percentage of patients who died as compared to total reports for that vaccine.

SIDS cases: The number of reports for each vaccine where SIDS was listed as the cause of death

% Of total: The percentage of cases of SIDS per vaccine as compared to total reports

% Of deaths: The percentage of cases of SIDS compared to deaths for each vaccine

During the period reviewed, there was a gradual switch from DTP to DTAP. A reliable comparison of DTP and DTAP reports is impossible.

**In fact, a reliable comparison of the data in the table above is also impossible, because several vaccines were often administered together. The only exception is the Hepatitis B vaccination in the newborn period.**

Only the CDC and FDA have the needed information to prove or disprove the following suggestions from the above data:

**November 1, 2003**  
**A DETAILED REPORT ON VACCINES AND AUTISM, INCLUDING THE CURRENT CONTROVERSY BOILING OVER IN THE UK OVER THE MMR VACCINE**

**October 15, 2003**  
**THE SAGA OF PEDIATRIC HEPATITIS B VACCINATION**

When it comes to the Sad Saga of the mandated Pediatric Hepatitis B Vaccination Program, there are still, twelve years later, more questions than answers. Probably the most baffling question is: why was a new vaccine recommended for a vulnerable infant without risk/benefit analysis and in order to prevent a disease that was not an immediate threat and that had a decreasing incidence?

**October 10, 2003**  
**SIDS, VACCINES AND VAERS: A FOLLOW-UP**

On the basis of his investigation, a physician challenges statements made by the U.S. Institute of Medicine about Sudden Infant Death Syndrome and vaccines

**September 22, 2003**  
**SUDDEN INFANT DEATH SYNDROME AND THE VACCINE ADVERSE EVENT REPORTING SYSTEM: A REVIEW**

A Physician investigates sudden and unexpected deaths of apparently healthy infants and the possible link of some of these deaths to vaccines

**September 8, 2003**  
**SHAKEN BABY SYNDROME AND VAERS: A REVIEW AND ANALYSIS**

A physician investigates reports to the Vaccine Adverse Events Reporting System and finds that some parents who were accused of causing "Shaken Baby Syndrome" in their children were probably innocent



113478	M	NH	0424E	11/24/97	8/19/98	9 m.
117475	M	NH	1559E	10/24/98	12/21/98	2 m.
118117	M	WV	2612A2	5/29/98	1/19/99	8 m.
122713	M	NH	2930A2	3/3/99	5/27/99	2 m.
123168	M	NH	2930A2	3/24/99	6/1/99	2m.
126759	M	NH	0987H	11/7/98	8/4/99	9 m.
133751	M	NH	2948A2	5/27/99	2/7/00	8 m.
150249	F	NJ	Unknown	2/28/00	3/27/00	28 d.

Table II

Comments

Parents who are told that their infants' death is "unexplained" and doctors who have "diagnosed" SIDS are unlikely to report the case to VAERS as a vaccine adverse event. It is therefore certain that only a small number of cases is ever reported to VAERS.

New Hampshire

There is no reasonable explanation why 57% (12/21) of the above SIDS reports were from New Hampshire, a state with an estimated population of 1.3 million, when forty other states did not report a single case in that age group and with that particular vaccine, Texas and New York included. Two of the NH reports (108795 and 108796) were filed on the same day.

The fact that reports from New Hampshire were filed from 2 to 9 months after the infant's demise would suggest that the large number of reports from New Hampshire was not simply due to a unique heightened awareness among parents and doctors. The case from Maryland was filed just 6 days after the infant's demise, the one from Pennsylvania within 11 days and the one from California within 2 weeks.

It is unlikely that the "background" incidence of SIDS in New Hampshire is higher than that of the other 49 states combined. It would be interesting to know if the incidence of SIDS in infants under one month of age was just as high in New Hampshire before 1991, when the routine administration of hepatitis B vaccine in the newborn period was recommended.

Lot Numbers

Cases 91425, 97016 and 108796 received vaccines from lot 0165D. There were 14 reports with that lot. The only deaths were the above cases from NH.

Two other infants from NH, cases 122713 and 123168, received vaccines from lot 2930A2. A 3-month old female infant from California (case164442) received a dose of HEP from the same lot a month after case 123618 and was found dead two days later. The cause of death was also listed as SIDS. This was that baby's second dose of HEP. The baby received DTAP, HIB and IPV (Inactivated Polio Vaccine) on the same day.

Interesting Cases

Cases 51688, 59322, 83615, 100366, 118117 and 150249 will be discussed.

**Case 51688:** This female infant from Pennsylvania received a dose of HEP (lot

1116A2) on 3/29/93. Less than 48 hours later [at 5:00am on 3/31/93] she was brought to the local emergency room in full arrest

Findings: epistaxis (bleeding from the nose), heart arrest, fatty liver, petechiae on thymus, pericardium and pleura.

**This infant had evidence of bleeding and fatty infiltration of the liver.**

There were 65 reports to VAERS of bleeding with Hepatitis B vaccine. There were 719 reports listing liver problems.

There were 9 reports about HEP lot number 1116A2 with 3 deaths diagnosed as SIDS. The other two are cases 53486 and 55368.

**Case 53486:** This 2-month old female infant from Oregon received DTP, HIB, OPV (Oral Polio Vaccine) and Hepatitis B vaccine on 5/11/93. She died of SIDS on 5/14/93. The VAERS report was filed three weeks later.

**Case 55368:** A 2-month old male infant, also from Oregon who was born 5-6 weeks prematurely; He received his first dose of DTP, HIB, OPV and Hepatitis B vaccines on 6/24/93. He died 23 days later. HEM is listed under symptom (possibly hemorrhage). An autopsy was performed and "confirmed" SIDS, yet the report was filed one month later.

In another report (53601), a 3-month old male from DC received DTP, HIB, OPV and HEP from the same lot on 4/6/1993. On 4/11, the baby became "stuporous" and was rushed to the ER. He remained in the hospital several days. No further information is available.

**Case 59322:** This female infant from South Carolina received a Hepatitis B vaccination (lot 0942W) on 11/30/93 and died suddenly on 12/10/93. Although an autopsy was not mentioned, it appears that one was done as the infant apparently had a "cyst, edema, brain hemorrhage and lung disease". In spite of these findings, SIDS was listed as the cause of death. The report was filed on 2/2/94.

There were 33 reports to VAERS with lot number 0942W. One other infant, a 2-month old male from IOWA who also received DTP, HIB and OPV on 7/1/94 also died.

**Case 70603:** This female infant from New Hampshire received her first Hepatitis B vaccine (lot 1547W) on 6/24/94. She died 19 days later. At the time of death, the infant was receiving ampicillin. Antibiotic eye drops were also being used. Gastroesophageal reflux (GER) was listed as a pre-existing condition. It is reasonable to assume that the GER and whatever infection was being treated with ampicillin were not present when the infant was vaccinated but developed after vaccination. Though there is no mention of an autopsy, the cause of death was listed as SIDS. The report was filed 6 months later.

There were 32 reports with Hepatitis B Vaccine, lot 1547W. 14 children were taken to an ER and 4 were hospitalized. Three infants died.

The two other deaths were:

**Case 66741:** A 2-month old male, also from NH, who was given DTP, HIB and OPV with the hepatitis B vaccine on 8/29/94; He was irritable that day but "was fine, smiling and acted normal with good eating" the next morning. "He was put down for a nap and died 15-20 minutes later. Autopsy: consistent with SIDS". The VAERS report was filed 3 weeks later.

Case 69993: A 2-month old male from Ohio, who received DTP, HIB, OPV and Hepatitis B vaccine (1547W) on 12/1/94 and was apparently well for the following six days. He died on the 7<sup>th</sup> day post-vaccination (12/8/94). An autopsy was performed. The cause of death was listed as SIDS. The VAERS report was filed less than a month later.

**Case 83615:** This male infant from California was vaccinated on 2/26/96. The vaccine he received was from lot # 1196B. The infant developed a fever to 102 on the same day and again on 2/27 and 2/28. Blood culture grew a contaminant on 2/26 but was negative on 2/27. The report mentions "Sudden death" on 2/28/96 at 2:00pm. The report to VAERS was filed two weeks later.

**Was this death really "Sudden"? Fever for 48 hours is not a symptom of SIDS.**

Interestingly, case 83659, also an infant from California who was 1 week old, received a dose of hepatitis B vaccine from the same lot (1196B) on the same day and also developed a fever a few hours after vaccination. He expired the following day. Blood culture was negative. The cause of death was listed as "febrile illness" on the VAERS report.

There were 34 reports to VAERS in all with lot # 1196B and 12 patients were taken to an ER. In many cases, the infant or child had received other vaccines at the same time.

**Case 100366:** This male infant from Mississippi was vaccinated 7/6/97. At 5:30: am the following morning (20 hours after vaccination) he was found apneic and pulseless in his crib. The report states that there was apnea, pulmonary edema, encephalopathy, cardiac arrest, myocardial infarction and cerebral ischemia. The report goes on to say: "No evidence of severe hypoxic brain injury; autopsy without evidence of anomalies." The vaccine lot number was not listed.

**This infant died 20 hours after receiving a dose of hepatitis B vaccine. Encephalopathy is not a symptom of SIDS; few hours after a vaccination, it strongly suggests a vaccine reaction.**

**Case 118117:** This male infant from West Virginia was vaccinated on 5/29/98 (lot #2612A2). Symptoms listed: Sweating, irritable, crying, swollen injection site, hard to console. Infant was put to sleep in parents' bed at 2:00am, and was found dead at 4:00am, 16 hours after vaccination. Autopsy report: SIDS.

**This infant had symptoms suggesting a vaccine reaction and expired 16 hours after vaccination. Reporting the case to VAERS appears fully justified.**

There were 11 reports of ER visits after vaccination with HEP lot 2612A2.

Two of those reports are

Case 125097. A 5-year old boy from Louisiana, who received a dose from the same hepatitis B vaccine lot (and no other vaccine) on 7/20/1998, had a grand mal seizure 2 days later and 37 more seizures within 2 weeks. He now has epilepsy and takes Tegretol.

Case 114285: A 2-month old male infant from Georgia who received DTAP, HIB and OPV in addition to the dose of hepatitis B vaccine (lot 2612A2) at 9:00 am on 9/3/1998 and was found limp and blue by parents at noon.

**Case 150249:** This female from New Jersey was 7 days old when she was vaccinated on 2/28/2000. The vaccine lot number was not listed. On 3/3/2000, the child expired. The baby had no congenital anomalies. "Autopsy revealed cerebral edema and pulmonary edema. Cause of death determined to be SIDS."

## Was this a sudden and unexplained death?

### Were the cerebral and pulmonary edema found on autopsy terminal events of a SIDS death or was the death related to the vaccine administered 3-4 days earlier?

There were 5 reports to VAERS with cerebral edema and 9 reports with pulmonary edema in patients who had received a hepatitis B vaccination. Many had also received other vaccines at the same time.

## Discussion

Meaningful inferences are impossible because of the serious underreporting to VAERS.

It appears that SIDS is the diagnosis in the majority of deaths reported following DTAP, DTP, DTPH, HBHEPB, HIB, and Hepatitis B vaccination, the only vaccines reviewed.

It is likely that only some cases of SIDS associated with neonatal hepatitis B vaccination in New Hampshire have been reported to VAERS. Even if there were only 12 cases in the State in all in ten years of VAERS reports, then the number of cases in the rest of the Nation should have exceeded 2,500. There were only 9 reports filed.

In 15 of the 21 reports, there is no mention or indication of an autopsy. It is possible that autopsies were performed. By definition, (see paragraph 1), an autopsy is required to rule out other causes for the baby's demise.

In many reports, the case definition of SIDS is not being uniformly applied.

There were several cases, mostly in earlier years, where the diagnosis of SIDS after an autopsy, was neither supported by the symptoms nor by the pathological findings.

This review shows that some informed physicians and parents felt that, in spite of a diagnosis of Sudden Infant Death Syndrome, the demise of the infant was related to vaccination and reported the case to VAERS as an adverse event.

The New Hampshire Department of Health should review the situation. Parents, nationwide, would certainly appreciate the information.

New Hampshire physicians deserve credit for their effort at reporting adverse events.

The CDC and the FDA are still unable, in spite of all their efforts, to convince physicians and families to report all adverse events to VAERS.

Combination vaccines are probably as effective as their components. Some experts, the IOM included, have asserted that they do not cause more reactions and are just as safe as their components. This limited review suggests otherwise.

Recombinant Hepatitis B vaccination seems to have caused an inordinate number of adverse reactions.

Neonatal vaccination with Recombinant HEP was initiated in 1991. Young single mothers are less likely to question vaccinations and usually try to have the recommended immunizations administered to their infants and children on schedule, so as not to be accused of child neglect. The possibility that this is the

reason for the increase in the incidence of SIDS after 1991 in that particular group of children should be considered.

### **Conclusions**

A serious review of SIDS cases in the first month of life and their timing relative to Hepatitis B vaccination should be undertaken in every state.

A committee of the Institute Of Medicine should revisit the whole subject of Sudden Infant Death occurring shortly after pediatric vaccinations, whether the vaccines were administered alone, with others or as combinations. This time, serious analysis of VAERS reports should be an integral part of the investigation.

Primary physicians, ER teams and medical examiners should consider vaccinations shortly before an unexplained death in their differential diagnosis before certifying that the cause of death is "Sudden Infant Death Syndrome".

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