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Vaccines and sudden infant death: An analysis of the VAERS database 1990–2019 and review of the medical literature

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ABSTRACT

Although there is considerable evidence that a subset of infants has an increased risk of sudden death after receiving vaccines, health authorities eliminated "prophylactic vaccination" as an official cause of death, so medical examiners are compelled to misclassify and conceal vaccine-related fatalities under alternate cause-of-death classifications. In this paper, the Vaccine Adverse Event Reporting System (VAERS) database was analyzed to ascertain the onset interval of infant deaths post-vaccination. Of 2605 infant deaths reported to VAERS from 1990 through 2019, 58 % clustered within 3 days post-vaccination and 78.3 % occurred within 7 days post-vaccination, confirming that infant deaths tend to occur in temporal proximity to vaccine administration. The excess of deaths during these early post-vaccination periods was statistically significant ($p < 0.00001$). A review of the medical literature substantiates a link between vaccines and sudden unexplained infant deaths. Several theories regarding the pathogenic mechanism behind these fatal events have been proposed, including the role of inflammatory cytokines as neuromodulators in the infant medulla preceding an abnormal response to the accumulation of carbon dioxide; fatal disorganization of respiratory control induced by adjuvants that cross the blood-brain barrier; and biochemical or synergistic toxicity due to multiple vaccines administered concurrently. While the findings in this paper are not proof of an association between infant vaccines and infant deaths, they are highly suggestive of a causal relationship.

1. Introduction

1.1. International classification of diseases

There are 130 official ways for an infant to die. These official categories of death, sanctioned by the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC), are published in the *International Classification of Diseases* (ICD) [1–3]. When a baby dies, coroners must choose from among these 130 categories.

The official causes of death listed in the ICD include nearly every imaginable—and tragic—possibility. In fact, previous versions of the ICD listed "prophylactic inoculation and vaccination" as a separate cause-of-death category, with subcategories for deaths caused by specific vaccines. However, when the ICD was revised in 1979—and in subsequent updates to the ICD—all cause-of-death classifications associated with vaccination were eliminated. Since then, medical certifiers have been unable to list vaccination as an official cause of death because the ICD no longer contains a code for that possibility. This is odd because health authorities are aware that some children will become permanently disabled or die after receiving vaccines—the very reason Congress passed the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660), which created the Vaccine Adverse Event Reporting System (VAERS) and established the National Vaccine Injury Compensation Program (VICP).

Many parents don't realize that when they purchase vaccines, the cost is taxed and the money (75 cents per vaccine) goes into a trust fund managed by the Department of the Treasury to compensate them if and when those vaccines seriously injure or kill their babies. As of May 1, 2021, more than $4.5 billion was granted for thousands of injuries and deaths associated with vaccines. Numerous cases are still pending. Awards were issued for permanent injuries such as learning disabilities, seizure disorders, mental retardation, paralysis, and numerous deaths, including many that were initially misclassified as sudden infant death syndrome (SIDS) [4].

Since vaccine-related deaths are officially recognized by the federal government through the VICP but there are no official classifications for vaccine-related deaths in the ICD, an important question must be asked: What options are available to medical examiners for recording vaccine-

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related deaths?

1.2. Sudden Infant Death Syndrome (SIDS)

Prior to the introduction of organized vaccination programs, "crib death" was so rare that it was not mentioned in infant mortality statistics. In the United States, national immunization campaigns were expanded in the 1960s when several new vaccines were introduced and promoted. For the first time in history, most U.S. infants were required to receive several doses of DPT (diphtheria, pertussis, tetanus), polio, and measles vaccines. (The measles vaccine was administered at 9 months of age from 1963 to 1965 [5]). Mumps and rubella vaccines were also introduced in the 1960s. By 1969, an alarming epidemic of sudden unexplained infant deaths impelled researchers to create a new medical term—sudden infant death syndrome (SIDS) [6]. By 1972, SIDS had become the leading cause of post-neonatal mortality (infant deaths occurring between 28 days and 1 year of life) in the United States [7]. In 1973, the National Center for Health Statistics, operated by the CDC, created a new cause-of-death category to document deaths due to SIDS [8,9].

SIDS is defined as the sudden and unexpected death of an infant which remains unexplained after a thorough investigation, including performance of an autopsy and review of the clinical history [10]. Although there are no specific symptoms associated with SIDS, an autopsy often reveals congestion and edema of the lungs and inflammatory changes in the respiratory system [8,11].

In 1984, Congress held a hearing on vaccine safety. The suspected link between vaccines and sudden infant deaths was addressed. The following excerpt is from a statement made by a distraught grandmother testifying before the Congressional Committee [12]:

> My name is Donna Gary. Our granddaughter, Lee Ann, was just 8 weeks old when her mother took her to the doctor for her routine checkup. That included her first DPT inoculation and oral polio vaccine. In all her entire 8 weeks of life this lovable, extremely alert baby had never produced such a blood-curdling scream as she did at the moment the shot was given. Neither had her mother ever before seen her back arch as it did while she screamed. She was inconsolable. Four hours later, Lee Ann was dead. "Crib death," the doctor said—"SIDS." "Could it be connected to the shot?" her parents implored. "No." "But she just had her first DPT shot this afternoon. Could there possibly be any connection to it?" "No, no connection at all," the emergency room doctor said definitely.
>
> Are the statistics that the medical world loves to say, "There is no connection," really accurate, or are they based on poor diagnoses, poor record keeping? What is being done to provide a safer vaccine? How are physicians and clinics going to be held accountable to see that parents are informed of the possible reactions? And how are those children who should not receive the vaccine to be identified before they are damaged or dead?

Throughout the 1980s, sudden infant deaths continued to skyrocket. Parental concerns about an apparent link between childhood vaccines and SIDS reached a fever pitch. Many parents were afraid to vaccinate their babies. Authorities sought to reassure parents that vaccines are safe and claimed that sudden unexplained infant deaths (SUID) following vaccines were merely coincidental.

1.3. Back to sleep

In 1992, the American Academy of Pediatrics (AAP) [13] came up with a plan to reduce the unacceptable SIDS rate while reassuring concerned mothers and fathers that sudden unexplained infant deaths were not related to vaccines. The AAP initiated a national "Back to Sleep" campaign, telling parents to place their infants supine, rather than prone, during sleep. From 1992 through 2001, post-neonatal SIDS declined by an average annual rate of 8.6 % [9]. It seemed as though the "Back to Sleep" campaign was successful and that the real cause of SIDS was due not to vaccinations but from babies sleeping on their bellies.

However, a closer inspection of the ICD—the 130 official ways for an infant to die—revealed a loophole. Medical certifiers, such as coroners, could choose from among several categories of death when a baby suddenly expired. They didn't have to list the death as SIDS. Although the post-neonatal SIDS rate dropped by an average annual rate of 8.6 % from 1992 through 2001 following the AAP's seemingly successful "Back to Sleep" campaign, the post-neonatal mortality rate from "suffocation in bed" (ICD-9 code E913.0) *increased* during this same period at an average annual rate of 11.2 % [9]. *Sudden, unexplained infant deaths that were classified as SIDS prior to the "Back to Sleep" campaign were now being classified as deaths due to suffocation in bed.*

The post-neonatal mortality rate from "suffocation other" (ICD-9 codes E913.1-E913.9), from "unknown and unspecified causes" (ICD-9 code 799.9), and from "intent unknown" (ICD-9 codes E980-E989), all increased during this period as well [9]. In Australia, a similar subterfuge seemed to occur. Researchers observed that when the SIDS rate decreased, deaths attributed to asphyxia increased [14–16].

From 1999 through 2001, the number of U.S. deaths attributed to "suffocation in bed" and "unknown causes" increased significantly. Although the post-neonatal SIDS rate continued to decline, *there was no significant change in the total post-neonatal mortality rate.* According to Malloy and MacDorman [9], "If death-certifier preference has shifted such that previously classified SIDS deaths are now classified as 'suffocation,' the inclusion of these suffocation deaths and unknown or unspecified deaths with SIDS deaths then accounts for about 90 percent of the decline in the SIDS rate observed between 1999 and 2001 and results in a non-significant decline in SIDS (Fig. 1)."

The trend toward reclassifying sudden infant deaths under alternate ICD codes is an ongoing concern. From 1999 through 2015, the U.S. SIDS rate declined 35.8 % while infant deaths due to accidental suffocation increased 183.8 %. According to Lambert et al. [17], "There is evidence of a continuing diagnostic shift between SUID subtypes," but "there has been little change in overall SUID rates since 1999." Gao and colleagues [18] also documented a trend toward reclassifying SIDS cases under alternate ICD codes. Results of a Spearman's correlation analysis

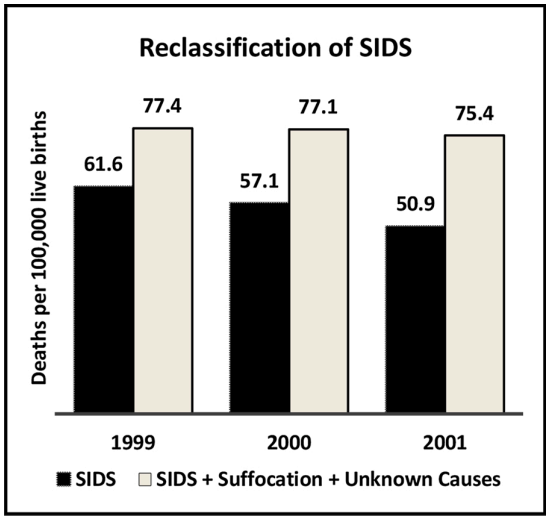

Fig. 1. Reclassification of SIDS to "suffocation in bed" and "unknown causes". The post-neonatal SIDS rate appears to have declined from 61.6 deaths (per 100,000 live births) in 1999 to 50.9 in 2001. However, during this period there was a significant increase in post-neonatal deaths attributed to "suffocation in bed" and "unknown causes." When these sudden unexpected infant deaths are combined with SIDS, the total SIDS rate remains relatively stable, resulting in a non-significant decline. Source: Malloy and MacDorman, 1993.

1999–2015 showed a significant relationship (r_s = -0.63) between decreasing mortality from SIDS and increasing mortality from unintentional suffocation (ICD-10 codes W75-W84). The increase in suffocation-related mortality occurred in all subgroups by sex, race, and ethnicity.

As described, the true extent of vaccine-related infant mortality has been obfuscated by three actions associated with pediatric death certification practices: 1) all cause-of-death classifications associated with vaccination were eliminated from the ICD, 2) SIDS became a commonly utilized cause-of-death category for at least some vaccine-related deaths (as confirmed by VICP awards that were initially misclassified as SIDS), and 3) SIDS cases were later reclassified under alternate ICD codes. Despite these hindrances to achieving an accurate account of vaccine-related infant mortality, there is an alternate way to assess the likelihood that a true relationship exists between infant vaccines and sudden infant deaths. A targeted evaluation of the VAERS database could be undertaken to determine whether infant deaths and SIDS cases tend to occur in temporal proximity to vaccine administration.

1.4. Analysis of the VAERS database, 1990–2019

The Vaccine Adverse Event Reporting System (VAERS) is a national safety surveillance program that collects information about possible adverse reactions to vaccines administered in the United States. Each report includes information about the patient, vaccines administered, and symptoms related to their adverse event. Since 1990, VAERS has received over 700,000 reports, which describe everything from mild side effects to serious life-threatening conditions, including hospitalization, permanent disability, and death. CDC considers VAERS an important vaccine safety assessment tool and regularly conducts its own studies using VAERS data. The VAERS database is also available to independent researchers. By monitoring adverse events documented in VAERS, it is possible to identify unusual patterns and important safety concerns.

In the study presented here, the timing and distribution of sudden infant deaths post-vaccination were assessed. If no relationship exists between infant vaccines and sudden infant deaths, the expectation would be for SIDS cases to be evenly distributed each day rather than clustering in the early post-vaccination period (Day 1 through Day 7). To test this hypothesis, the VAERS database was analyzed to ascertain the onset interval of infant deaths post-vaccination.

2. Methods

An online search of the VAERS database was conducted [19]. The database was filtered to only include reports with a vaccination date from 1990 through 2019, of infants (children < 1 year of age) who died within 60 days post-vaccination. In the first analysis (All Mortality), VAERS was filtered to include all reports of infant mortality regardless of whether "sudden death" or SIDS was listed in the report. In the second analysis (SIDS), the VAERS search was further restricted to only include reports that mentioned "sudden death" or "sudden infant death syndrome." In both analyses, deaths were stratified by the onset interval post-vaccination, that is, by the number of days that transpired between vaccination and death (range = 1–60 days, with Day 1 = Day of Vaccination). Pearson's chi-squared test was utilized to determine whether there was a statistically significant difference between the expected frequencies of infant mortality and the actual frequencies reported.

3. Results

3.1. Demographic data

There were 2989 infant deaths reported to VAERS with a vaccination date from 1990 through 2019. Of this total, 2605 (87.2 %) occurred within 60 days. Males comprised 58.2 % of this population, females made up 39.3 %, and in 2.5 % the sex was unknown. The male-to-female ratio was 59.7%–40.3% for the 2540 cases in which the sex was known. Infants less than 6 months of age comprised 86.5 % of all deaths while the remainder (13.5 %) occurred in older infants.

Of the 2605 infant deaths under consideration, 1048 (40.2 %) were labeled as SIDS, of which 60.5 % were male, 37.8 % were female, and in 1.7 % the sex was unknown. The male-to-female ratio was 61.6%–38.4% for the 1030 cases in which the sex was known. Infants less than 6 months of age comprised 89.9 % of all SIDS cases while the remainder (10.1 %) occurred in older infants. Additional demographic data can be found in Table 1.

3.2. Analyses

Of the 2605 infant deaths, 58 % clustered within 3 days post-vaccination and 78.3 % within 7 days post-vaccination. The remaining deaths occurred between 8 days and 60 days post-vaccination, an average of 11 per day (564/53 days) as compared to 760 infant deaths that occurred on Day 2 post-vaccination—a 69-fold increase (Table 2). If the 2605 deaths which occurred within 60 days of vaccination were randomly distributed throughout this interval, one would expect 43.42 deaths per day or 304 per week. The excess of deaths on the day of vaccination (43 were expected/440 occurred), within 3 days post-vaccination (130 were expected/1512 occurred), and in the first week post-vaccination (304 were expected/2041 occurred) were all statistically significant ($p < 0.00001$).

Of the 1048 SIDS cases, 51 % clustered within 3 days post-vaccination and 75.5 % within 7 days post-vaccination. The remaining SIDS cases occurred between 8 days and 60 days post-vaccination, an average of 4.8 per day (257/53 days) as compared to 277 SIDS cases that occurred on Day 2 post-vaccination—a 57-fold increase (Table 3). If the 1048 SIDS cases which occurred within 60 days of vaccination were randomly distributed throughout this interval, one would expect 17.47 SIDS cases per day or 122 per week. The excess of SIDS cases on the day of vaccination (17 were expected/131 occurred), within 3 days post-vaccination (52 were expected/534 occurred), and in the first week post-vaccination (122 were expected/791 occurred) were all statistically significant ($p < 0.00001$).

4. Discussion

The findings in this study revealed that infant deaths and SIDS cases were not randomly distributed each day. Instead, infant mortality and SIDS cases reported to VAERS tended to occur in temporal proximity to vaccine administration, that is, they clustered in the early post-

Table 1
Demographic data.

Demographic Category	All Mortality	SIDS
VAERS population	2605	1048
Male	1516 (58.2 %)	634 (60.5 %)
Female	1024 (39.3 %)	396 (37.8 %)
Unknown sex	65 (2.5 %)	18 (1.7 %)
Male/Female ratio*	59.7 %/40.3 %	61.6 %/38.4 %
< 6 months of age	2253 (86.5 %)	942 (89.9 %)
6 months < 1 year	352 (13.5 %)	106 (10.1 %)
0 < 3 months of age	1359 (52.2 %)	579 (55.2 %)
3 months < 6 months	894 (34.3 %)	363 (34.6 %)
6 months < 9 months	280 (10.7 %)	98 (9.4 %)
9 months < 1 year	72 (2.8 %)	8 (0.8 %)

Two infant populations in the VAERS database were analyzed: All Mortality and SIDS. In both populations, more males than females expired post-vaccination, and there were more reports of sudden death in younger infants as compared to older infants.

* This category provides the male-to-female ratio for the 2540 infant deaths and 1030 SIDS cases in which the sex was known.

Table 2
Onset interval of infant deaths post-vaccination, USA.

Onset interval post-vaccination	Events reported	Cumulative % of total events
Day of Vaccination	440	16.9 % (440/2605)
Day 2	760	46.1 % (1200/2605)
Day 3	312	58.0 % (1512/2605)
Day 4	214	66.3 % (1726/2605)
Day 5	131	71.3 % (1857/2605)
Day 6	92	74.8 % (1949/2605)
Day 7	92	78.3 % (2041/2605)
Days 8–60	564	100 % (2605/2605)
Total deaths	**2605**	

Fifty-eight percent of all infant deaths reported to VAERS occurred within 3 days post-vaccination; 78.3% occurred within 7 days post-vaccination. The remaining deaths occurred between 8- and 60-days post-vaccination, an average of 11 per day (564/53 days) as compared to 760 infant deaths that occurred on Day 2 post-vaccination—a 69-fold increase. Data obtained from VAERS 1990-2019, age < 1 year, deaths reported within 60 days from day of vaccination.

Table 3
Onset interval of SIDS post-vaccination, USA.

Onset interval post-vaccination	Events reported	Cumulative % of total events
Day of Vaccination	131	12.5 % (131/1048)
Day 2	277	38.9 % (408/1048)
Day 3	126	51.0 % (534/1048)
Day 4	110	61.5 % (644/1048)
Day 5	57	66.9 % (701/1048)
Day 6	39	70.6 % (740/1048)
Day 7	51	75.5 % (791/1048)
Days 8–60	257	100 % (1048/1048)
Total deaths	**1048**	

Fifty-one percent of all SIDS cases reported to VAERS occurred within 3 days post-vaccination; 75.5% occurred within 7 days post-vaccination. The remaining SIDS cases occurred between 8- and 60-days post-vaccination, an average of 4.8 per day (257/53 days) as compared to 277 SIDS cases that occurred on Day 2 post-vaccination—a 57-fold increase. Data obtained from VAERS 1990-2019, age < 1 year, SIDS cases reported within 60 days from day of vaccination.

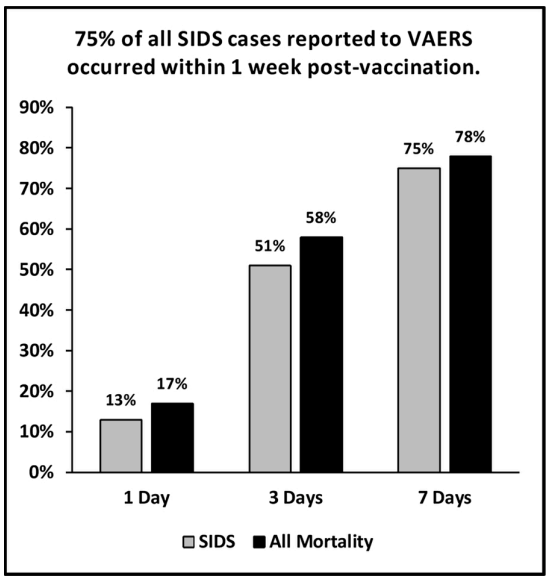

Fig. 2. Clustering of SIDS cases and all infant mortality post-vaccination. Of 1048 children who died from SIDS, 13 % expired on the day of vaccination, 51 % died within 3 days, and 75 % died within 7 days. Regarding the full population of 2605 infant deaths reported to VAERS (all mortality), a similar distribution of fatal events post-vaccination was observed. Source: VAERS 1990–2019; Miller 2021.

vaccination period—Day 1 through Day 7 (Fig. 2). Excess deaths were significantly greater than expected ($p < 0.00001$). Several theories regarding the pathogenic mechanism behind these fatal events have been proposed. According to Douglas Miller [20], neuropathologist and expert witness on SIDS, vaccines evoke the production of cytokines that can produce fever and inhibit the activity of 5-HT neurons in the medulla causing prolonged apneas and interference with auto-resuscitation. Matturri et al. [21] hypothesized that aluminum adjuvants in vaccines cross the blood-brain barrier "inducing neuronal molecular alterations in DNA, RNA, and proteins of brainstem neurons regulating vital functions, with consequent fatal disorganization of respiratory control in particularly predisposed infants." Miller and Goldman [22] suggested the potential for biochemical or synergistic toxicity due to multiple vaccines administered concurrently.

Within both of the analyses—All Mortality and SIDS—approximately 60 % of the victims were male. This is consistent with findings in other studies on SIDS throughout the world [23]. Some evidence suggests that males are more susceptible to infant deaths because they are more likely to be delivered prematurely. Infant mortality in preterm babies is more likely in males, and deaths occurring secondary to respiratory distress syndrome in preterm babies are more prevalent in males [24]. Moscovis et al. [25] suggested that an increase in testosterone in male infants could be "affecting dysregulation of the inflammatory responses to apparently 'mild' infections" contributing to the higher proportion of male SIDS victims. Kinney et al. [26] observed that "a substantial ablation (approximately 60 %) of medullary raphé neurons with a selective toxin for 5-HT decreases the CO_2 responses in NREM sleep in males only." In other words, SIDS may be more common in males because in the situation with a defective medullary 5-HT system they may be less capable of responding to the accumulation of carbon dioxide during sleep.

Additional demographic data in Table 1 shows significantly more reports of infant mortality in younger infants as compared to older infants ($p < 0.00001$). Goldman and Miller [27] found a significantly higher mortality rate for infants vaccinated between birth and 6 months of age when compared to infants vaccinated between 6 months and 1 year of age (RR = 3.0, 95 % CI 2.6–3.4). SIDS may be more common in younger infants because that's when SIDS is most likely to occur. However, Torch (1982) [28] found that unvaccinated babies who died from SIDS did so most often in the fall or winter while vaccinated babies died most often at 2 and 4 months—the same ages when infants received their initial doses of DPT.

4.1. Review of early evidence linking sudden infant death to vaccines

Although some studies were unable to find positive correlations between SIDS and vaccines [29–31], there is credible evidence that a subset of infants may be at increased risk of SIDS shortly after being vaccinated. For example, as early as 1933, Madsen [32] documented the sudden deaths of two infants soon after receiving their whole-cell pertussis vaccinations. The first child developed cyanosis and convulsions 30 min after vaccination and died a few minutes later. The second child developed cyanosis 2 h after vaccination and died. In 1946, Werne and Garrow [33] documented the sudden deaths of identical twin boys 24 h after diphtheria and pertussis vaccination. The babies had symptoms of shock throughout the night prior to their fatal reactions.

Although the simultaneous sudden deaths of twin infants—simultaneous SIDS—is rare, Werne and Garrow were not the only scientists to document this phenomenon and cite vaccines as a possible precipitating influence. Other cases have been reported in the medical literature and may indicate an environmental cause rather than a natural one. For example, Roberts [34] reported on twin boys who "simultaneously succumbed to sudden unexpected deaths" 3 h after DPT vaccination. The author concluded that "coincidences do occur and should be seen in perspective." Balci et al. [35] reported on identical twin girls, 15 weeks old, who both died suddenly 2 days after receiving oral polio, hepatitis

B, and DPT vaccines. They were found by their mother, "both in supine position" (as recommended by the AAP). The twins were healthy prior to the incident. Their deaths were recorded as SIDS. According to Bass [36], "the likelihood of twin infants dying suddenly and simultaneously of SIDS, a natural disorder, defies credibility." Mitchell et al. [37] published a case report describing 12-week-old identical twins who died "lying on their backs." Although their deaths were labeled SIDS, 5 days prior to death they each received multiple vaccines concurrently, including DTaP (diphtheria, tetanus and acellular pertussis), oral polio, hepatitis B, and *Haemophilus influenzae* type B (Hib). Huang et al. [38] published a case report describing the sudden deaths of 10-week-old twin male infants. Their mother found them lying on their backs, lifeless. Ten days earlier they had received their first doses of DPT and oral polio vaccines.

In the 1960s and 1970s, Aborigine infants began to mysteriously die at alarming rates. In some regions of Australia, 1 of every 2 babies succumbed to an unexplained death. Archie Kalokerinos [39], an Australian physician, solved the riddle when he realized the deaths were occurring shortly after the babies were vaccinated. Health officials had recently initiated a mass vaccination campaign to protect Aborigine babies; their deaths corresponded with the vaccination program. Kalokerinos realized that these babies were severely malnourished. Their undeveloped immune systems couldn't handle the additional stress of vaccination: "Some would die within hours from acute vitamin C deficiency precipitated by the immunization. Others would suffer immunological insults and die later from pneumonia, gastroenteritis, or malnutrition." Kalokerinos was able to save numerous babies from the same fate by administering small quantities of vitamin C (100 mg per month of age) prior to their vaccines.

Linus Pauling [39], who won a Nobel Prize in chemistry, supported the work of Kalokerinos:

> I believe that the conclusion reached by Dr. Kalokerinos—that the high infant mortality and generally high incidence of disease among the Aboriginal infants are to be attributed in considerable part to a low body-content of vitamin C—is correct. Moreover…the deficiency in vitamin C is exacerbated by immunizations, since it is known that immunization leads to destruction of vitamin C. Dr. Kalokerinos deserves much credit for having made these discoveries.

In Japan, from 1970 through 1974, there were 37 documented sudden infant deaths following pertussis vaccinations, inciting parents and doctors to reject the shot. In 1975, Japanese authorities reacted to these events by raising the age of vaccination from 3 months to 2 years. As a result, the number of vaccine injury compensation claims that were paid out for sudden deaths following vaccination dropped from 37 cases during a 5-year period to just 3 cases during the next 6-and-a-half years (from 1975 through August of 1981). The sudden death rate following vaccination dropped from 1.47 to 0.15 deaths per million doses—a 90 % improvement [40,41]. In addition, from the early 1970s (a period when 3-month-old infants were vaccinated) to the mid-1980s (ten years after the age of vaccination was raised to 2 years) the Japanese infant mortality rate (infant deaths per 1000 live births) declined from 12.4–5.0—a 60 % improvement [42]. A special Task Force on Pertussis and Pertussis Immunization investigated the Japanese data and published their report in the journal *Pediatrics*. According to Cherry et al. [41], "The category 'sudden death' is instructive in that it disappeared following both whole-cell and acellular vaccines when immunization was delayed until a child was 24 months of age." The special Task Force also made the following observation: "It is clear that delaying the initial vaccination until a child is 24 months, regardless of the type of vaccine, reduces most of the temporally associated severe adverse reactions."

There is additional evidence that delaying vaccinations until a later age could save babies from severe vaccine-related adverse reactions, including hospitalizations and sudden deaths. Goldman and Miller [27] investigated more than 38,000 infant reports filed with VAERS. Infant hospitalizations and deaths post-vaccination were evaluated relative to *all* infant adverse events post-vaccination, including those that were non-serious. The hospitalization rate for infants vaccinated shortly after birth was an astonishing 20.1 % but decreased in a statistically significant linear fashion to 10.7 % for infants vaccinated just prior to their first birthday. As previously noted, this study also found a significantly higher mortality rate for younger infants when compared to those that were vaccinated at a later age.

In 1978–1979, 11 babies in Tennessee died within 8 days following DPT vaccination [43]. Five of the babies died suddenly within 24 h of vaccination. Nine of the 11 babies had received their vaccine from the same lot. A subsequent investigation confirmed a greater than expected relationship between Lot #64201 of the DPT vaccine and SIDS. Initially, health authorities "did not feel that a causal relationship could be totally excluded." Later, the Food and Drug Administration (FDA) issued a revised statement that "experts…did not find evidence of a cause-effect relationship." Finally, the CDC claimed that the SIDS cases in Tennessee that occurred shortly after DPT vaccination were all a "coincidence." (After this incident, internal memos by the vaccine manufacturer revealed a new policy of limiting shipments of DPT vaccine so that no geographical location would receive all of the product from a single lot, confounding the ability to trace hot lots that might cause clusters of SIDS cases post-vaccination.)

In 1980, analyses of additional data collected by the CDC [44] revealed 23 reports of death within 28 days following DPT vaccination. Of the 23 deaths, 12 (52.2 %) occurred within 24 h and 18 (78.3 %) occurred within 1-week post-vaccination. In 16 of the 23 deaths, autopsy findings were consistent with SIDS. Of the 16 SIDS deaths, 6 (37.5 %) occurred within 24 h and 12 (75 %) occurred within 1-week post-vaccination.

In 1982, William Torch, MD [28], director of Child Neurology, Department of Pediatrics, University of Nevada School of Medicine, presented a study at the 34th Annual Meeting of the American Academy of Pediatrics on the relationship between DPT and SIDS. According to Torch, "Preliminary data on the first 70 cases studied shows that two-thirds had been immunized within 21 days prior to death. In the DPT-SIDS group, 6.5 % died within 12 h of inoculation, 13 % within 24

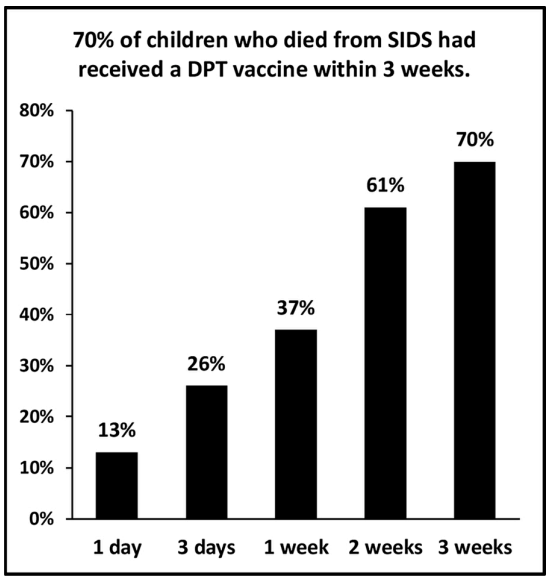

Fig. 3. The pertussis vaccine and SIDS.
In a preliminary study of 70 children who died from SIDS, more than two-thirds had received DPT within 21 days prior to death: 13 % died within 24 h, 26 % within 3 days, and 37 %, 61 %, and 70 % within 1, 2, and 3 weeks, respectively. Source: Torch, 1982.

h, 26 % within 3 days, and 37 %, 61 % and 70 % within 1, 2 and 3 weeks, respectively."(Fig. 3) Torch also found that unvaccinated babies who died from SIDS did so most often in the fall or winter while vaccinated babies died most often at 2 and 4 months—the same ages when initial doses of DPT were given to infants. He concluded that…

> DPT may be a generally unrecognized major cause of sudden infant and early childhood death, and the risks of immunization may outweigh its potential benefits. A need for reevaluation and possible modification of current vaccination procedures is indicated by this study.

In 1983, Baraff et al. [45] analyzed data associated with 27 infants that had been vaccinated within 28 days prior to their sudden deaths, which were classified as SIDS. They calculated the expected frequency of SIDS deaths per day and compared that with the actual number of sudden deaths in each of the 28 days post-vaccination. A statistically significant number of excess deaths happened during the first week post-vaccination: 6.75 sudden deaths were expected and 17 actually occurred ($p < 0.05$). The greatest number of excess deaths happened within 24 h post-vaccination: 0.96 sudden deaths were expected and 6 actually occurred ($p < 0.0005$). According to the lead author, "This study further substantiates the possible association between DTP immunization and SIDS."

In 1986, Torch [46] summarized case reports of more than 200 deaths that occurred following DPT vaccination, as reported by 37 authors in 12 countries. About half of these deaths occurred within 24 h, 75 % within 3 days, and 90 % within 1-week post-vaccination. For most of these deaths a specific cause could not be found, although many were labeled as SIDS.

In 1987, Walker and colleagues [47] found that DPT-vaccinated infants had a decreased risk of SIDS when compared to infants who did not receive DPT. Yet the authors seemed skeptical of this finding: "All candidate explanations for the observation of increased risk of SIDS in non-immunized infants hinge on an artifact of some sort. SIDS rates in the UK did not rise and fall with the mass abandonment of pertussis vaccination, nor with the ensuing epidemics of pertussis. It seems therefore unlikely that pertussis immunization protects against SIDS." Instead, "the major finding of the present study" was a statistically significant increased risk of SIDS in the early post-vaccination period. Babies died at a rate more than 7 times greater than expected in the period 0–3 days following DPT vaccination when compared to the period beginning 30 days post-vaccination (RR = 7.3, 95 % CI 1.7–31).

In 1990, Gilbert et al. [48] found that a higher proportion of SIDS babies than controls had been seen by a general practitioner during the previous week: 17.9 % versus 5.6 % (OR = 2.6, 95 % CI 1.2–5.7). However, it is unclear whether the babies were taken to the physician due to an illness or for a well-baby visit to receive vaccines. The median age of the babies was 3 months. According to the authors, "The parents of babies who died were more likely to have taken them to a general practitioner than parents of control babies. For this minority of babies who were seen by their general practitioner during the week before death, better understanding of the factors prompting contact with the general practitioner may enable some of them to be identified as at risk from sudden unexpected death."

In 1991, Scheibner and Karlsson [49,50] presented evidence at the 2nd National Immunisation Conference in Canberra, Australia on an association between DPT injections and cot death (SIDS). Karlsson, a biomedical engineer, developed a sophisticated microprocessor, Cotwatch, that was placed under infants' mattresses to precisely measure their breathing patterns before and after vaccination. The Cotwatch breathing monitor generated computer printouts in integrals of a weighted apnea (cessation of breathing) and hypopnea (abnormally shallow breathing) density (WAHD). The data revealed that pertussis vaccination caused an inordinate increase in episodes where breathing either nearly ceased or stopped completely (Fig. 4). These episodes

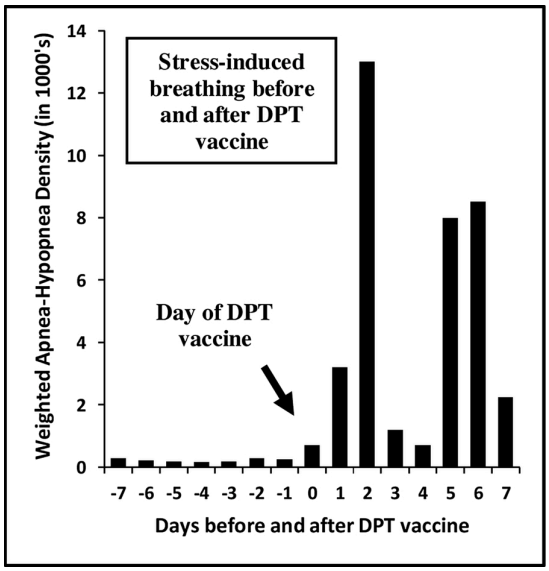

Fig. 4. The pertussis vaccine, stress-induced breathing, and risk of SIDS. This chart represents a 15-day record of one child's breathing pattern before and after receiving a DPT vaccine. Values above 1000 indicate acute stress-induced breathing, with episodes where breathing was either abnormally shallow or stopped completely. These increased stress levels in breathing continued for more than 6 weeks after vaccination. Source: Scheibner, 1993.

continued for several weeks post-vaccination.

When adverse reactions or deaths occur several days or weeks after vaccination, it is difficult to associate them with the vaccine. Yet, the Cotwatch computer printouts showed that increased stress levels in breathing continued for more than 6 weeks after vaccination. According to Scheibner, "babies experience flare-ups of stressed breathing after DPT and oral polio vaccines. These days are critical days." Although preliminary data by Torch in 1982 showed that two-thirds of SIDS babies had been vaccinated within 21 days prior to death, Scheibner's data indicated that "the recipients of a vaccine such as DPT and oral polio may react for more than 21 days after the vaccines are administered [50]."

In 1998, Ridgway [51] reviewed vaccine injury compensation claims filed with the VICP. Of 107 claims that led to early death following DPT vaccination, 73 (68.2 %) were awarded compensation. In 50 of the 73 compensated claims, autopsies had attributed the deaths to SIDS. The other DPT-related deaths were attributed to non-specific findings, other specific findings, pneumonia, and encephalitis.

In 2005, Von Kries et al. [52] analyzed the risk of sudden unexpected death in young children within 1–28 days following receipt of a hexavalent vaccine (6 vaccines in one jab for protection against diphtheria, tetanus, pertussis, hepatitis B, Hib, and polio). During infancy, standardized mortality ratios (SMR) were non-significantly higher than expected on the first day after receiving a hexavalent vaccine. In the second year of life, children were significantly more likely to die within 1 day (SMR = 31.3, 95 % CI 3.8–113) or 2 days (SMR = 23.5, 95 % CI 4.8–68.6) following hexavalent vaccination.

In 2006, Ottaviani et al. [53] published a case report documenting a 3-month-old infant who died suddenly and unexpectedly shortly following receipt of the 6-in-1 combination vaccine. After dissecting the brainstem and examining the cardiac conduction system, authors of the study made the following observation: "This case offers a unique insight into the possible role of hexavalent vaccine in triggering a lethal outcome in a vulnerable baby." They also noted that "any case of sudden unexpected death occurring…in infancy, especially soon after a vaccination, should always undergo a full necropsy study," otherwise a true association between vaccination and death may escape detection.

That same year, scientists associated with the Institute of Forensic Medicine in Munich, Germany (Zinka et al.) [54] reported that 6 children "were found dead without explanation" 1–2 days after hexavalent vaccination. The children underwent a forensic post-mortem examination: "In addition to neuropathological and histologic abnormalities, all of these children showed an extraordinary brain edema…. Increased tryptase levels and numbers of eosinophile granulocytes suggest that an anaphylactic reaction developed after the vaccination." The scientists reported these 6 cases "to direct attention to a possibly serious vaccination side effect." Although they were unable to prove that the infant deaths were caused by the multivalent jab, they felt that "it is important to inform vaccinating physicians and pediatricians, as well as parents, about such fatal complications after hexavalent vaccines. If broad use of hexavalent vaccines continues, extensive studies are most likely required to assess or exclude a relation between vaccination and death in infants." They also documented a 13-fold increase in sudden unexplained infant deaths from 2001–2004—after hexavalent vaccines were approved by the European Commission in October 2000—as compared with the prior period from 1994 to 2000.

In 2007, Soldatenkova and Yazbak [55] examined a relationship between hepatitis B vaccination and unexplained neonatal deaths. Of 29 deaths reported to VAERS as unexplained, 24 were attributed to SIDS. Of the 29 vaccinated neonates, 13.8 % died within 24 h, 32 % within 3 days, and 44.8 % expired within 7 days. The authors concluded that "a systematic review of neonatal SIDS and other unexpected infant deaths following the initial dose of hepatitis B vaccination should be undertaken at the international level."

4.2. Confidential report on SIDS

In 2011, a European hexavalent vaccine manufacturer, GlaxoSmithKline (GSK) [56], produced a confidential report on SIDS. (The report was made publicly available by the Italian Court.) Sudden deaths that occurred within 20 days after hexavalent vaccination were tabulated. The manufacturer concluded that the number of sudden deaths reported after receipt of its hexavalent vaccine did not exceed the background incidence or expected number of cases. However, despite the manufacturer's conclusion that its hexavalent vaccine does not increase the risk of sudden death, Table 36 on page 249 of the confidential report shows that 62.7 % of these deaths clustered within 3 days post-vaccination and 89.6 % occurred within 7 days post-vaccination. Perhaps more significantly, 97 % (65 of the 67 reported infant deaths) occurred in the first 10 days post-vaccination while just 3% (2 of the 67 infant deaths) occurred in the next 10 days (Table 4). Additionally, 6 of the 8 sudden deaths in children during their second year of life occurred in the first 3 days post-vaccination.

Table 4
Onset interval of sudden infant deaths after hexavalent vaccination, Europe.

Onset interval post-vaccination	Events reported	Cumulative % of total events
Day of Vaccination	16	23.9 % (16/67)
Day 2	13	43.3 % (29/67)
Day 3	13	62.7 % (42/67)
Day 4	8	74.6 % (50/67)
Day 5	7	85.1 % (57/67)
Day 6	3	89.6 % (60/67)
Day 7	0	89.6 % (60/67)
Day 8	2	92.5 % (62/67)
Day 9	1	94.0 % (63/67)
Day 10	2	97.0 % (65/67)
Days 11–20	2	100 % (67/67)
Total deaths	**67**	

Sudden infant deaths within 20 days after hexavalent vaccination were tabulated. Ninety-seven percent (65 of the 67 reported deaths) occurred in the first 10 days after vaccination while just 3% (2 of the 67 deaths) occurred in the next 10 days. Data obtained from a confidential report compiled by the hexavalent vaccine manufacturer, GlaxoSmithKline, 2011.

4.3. Recent evidence

In March of 2011, Japan temporarily suspended pneumococcal and Hib vaccinations when several infants and young children died within 3 days after receiving these shots either individually or in combination with other vaccines. Similar incidents occurred in France and the Netherlands [57]. That same year, Kuhnert and colleagues [58] published evidence of a 16-fold increased risk of sudden unexpected death following the fourth dose of a pentavalent (5-in-1) or hexavalent (6-in-1) vaccine. Traversa et al. [59] also found a statistically significant increased risk of sudden infant death shortly after the first dose of a hexavalent vaccine (RR = 2.2, 95 % CI 1.1–4.4). Miller and Goldman [22] found a significant relationship between international vaccination schedules and infant mortality rates: developed nations that require the most vaccines for their babies tend to have higher (worse) infant mortality rates ($r^2 = 0.98$). A possible explanation for this counterintuitive correlation was provided: the potential for biochemical or synergistic toxicity due to multiple vaccines administered concurrently.

In 2014, Matturri et al. [21] reported on their examination of 13 sudden infant deaths that occurred within 7 days of a hexavalent vaccine. Histological analyses of the brainstem and cerebellum revealed brain edema and congestion in all victims. Although a causal relationship between vaccination and SIDS was not proven, the authors hypothesized that vaccine components "could have a direct role in sparking off a lethal outcome in vulnerable babies." They elaborated on this theory:

> We know that many infants are vaccinated but not everyone dies or has an adverse reaction following vaccination. Hence, clearly there are both specific genetic and constitutional factors of susceptibility which could define how one reacts to a vaccine. We hypothesize that several compounds and immuno-potentiation adjuvants of the hexavalent vaccine might easily go beyond the blood-brain barrier (BBB), that in the first months of life is still immature and quite permeable, inducing neuronal molecular alterations in DNA, RNA, and proteins of brainstem neurons regulating vital functions, with consequent fatal disorganization of respiratory control in particularly predisposed infants. Notably, the neurotoxicity of the aluminium adjuvant in vaccine-relevant exposures has been experimentally demonstrated, including its ability to cross the BBB and induce inflammatory and neurodegenerative changes.

The authors recommend that all sudden infant deaths occurring shortly after hexavalent vaccination "are appropriately investigated and submitted to a post-mortem examination, particularly of the autonomic nervous system, by an expert pathologist to objectively evaluate the possible causative role of the vaccine in SIDS."

In 2015, another confidential report by GSK [60] was submitted to European vaccine regulators. Table 6 on page 445 of the report shows that 52.5 % of these deaths clustered within 3 days post-vaccination and 82.2 % occurred within 7 days post-vaccination, remarkably similar to the main findings in this current paper. Table 7 of the report shows that 97.9 % of all sudden deaths following the first dose of hexavalent vaccination (four doses are recommended) occurred in the first 10 days post-vaccination while just 2.1 % occurred in the next 10 days. Despite these apparent warning signals, the vaccine manufacturer, GSK, concluded that its multi-dose vaccine is safe and the European Medicines Agency (EMA), the regulatory authority tasked with overseeing vaccine safety in Europe, accepted the report at face value.

In a separate paper, Puliyel and Sathyamala [61] were critical of the manufacturer's claims regarding vaccine safety. For example, the CEO tacitly admitted that there was no active surveillance during the post-vaccination period and only sudden deaths spontaneously reported were included under the heading of "observed" deaths. Thus, observed deaths following hexavalent vaccination are underestimated. In addition, the vaccine manufacturer compared observed deaths to a

purported baseline of "expected" deaths. But expected deaths were based on the number of vaccine doses distributed. The report acknowledges that all doses of the vaccine distributed were not necessarily administered. Thus, expected deaths are likely to be inflated. (It should also be noted that the manufacturer's baseline of expected deaths is spurious for another more significant reason. Sudden deaths after hexavalent vaccination are being compared to a sudden death rate following decades of widespread immunization campaigns, not a true baseline of SIDS cases in unvaccinated children or during the previous era when comprehensive vaccine programs did not yet exist.)

Regarding sudden deaths in children over 1 year of age, cumulative deaths reported are lower in the latest Periodic Safety Update Report (PSUR-19) when compared to the PSUR-16. The numbers are not consistent. Deaths acknowledged in the PSUR-16 have been eliminated from the PSUR 19. When the missing numbers are re-included, the number of observed deaths is significantly higher than expected for the first 4 days post-vaccination. The vaccine manufacturer should have informed the EMA about the statistically significant increased risk of death in the 4-day post-vaccination period and explain why these deaths were excluded from the most recent PSUR. According to Puliyel and Sathyamala, "It is difficult to understand how the EMA accepted the PSUR-19 at face value. It may be argued that due diligence was not exercised, as a result of which numerous children were unnecessarily exposed to the risk of death."

Also in 2015, the CDC (Moro et al.) [62] characterized the main causes of death reported to VAERS from 1997 through 2013. The most common cause of death among 1244 child reports with autopsy findings or death certificates available for review was SIDS. Most SIDS cases were among infants 2–4 months of age. Among the 1165 infant reports, 86.2 % received multiple vaccines prior to death. The median onset interval, the period from vaccination to death, was 2 days. SIDS reports were most common among children who had received DTaP, hepatitis B, inactivated polio, Hib, and pneumococcal vaccines simultaneously prior to death. Despite these findings, CDC authors concluded that "no concerning pattern was noted among death reports submitted to VAERS…. The main causes of death were consistent with the most common causes of death in the U.S. population."

4.4. Vaccine court: deceased infant vs. U.S. government

On July 10, 2017, the United States Court of Federal Claims [20] issued a decision with regard to a claim filed with the National Vaccine Injury Compensation Program. Here are details of that case:

An African-American male infant, J.B., received seven vaccines at his 4-month well-baby visit. On the following day, he died during his nap. The medical examiner stated that the cause of death was SIDS and it was "natural." His parents filed a petition under the VICP. Petitioners allege that as a result of receiving vaccines for diphtheria, tetanus, acellular pertussis, polio, Hib, pneumococcal, and rotavirus, J.B. passed away from SIDS.

Expert testimony by Dr. Douglas C. Miller, a neuropathologist, stated that vaccinations can be an extrinsic risk factor in SIDS. He explained that when you receive one or more vaccines at once, as J.B. did, it evokes the production of cytokines. Physiological studies have shown that these can produce fever and inhibit the activity of 5-HT neurons in the medulla causing prolonged apneas and interference with autoresuscitation. Dr. Miller noted that J.B. was a "healthy infant…developing normally." He was "immunologically normal." After receiving vaccines, cytokines circulated into the central nervous system and interacted with the hypothalamus to provoke fever and act in the brainstem "which was already deficient in serotoninergic drive for respiratory effort, leading to an apneic episode from which he did not recover, i.e., SIDS."

Special Master Thomas L. Gowen issued his decision: "I have concluded that the petitioners have demonstrated by a preponderance of the evidence that the vaccines can and likely did play a critical role in this child's death by stimulating the production of inflammatory cytokines that suppressed the respiratory response system and caused the vulnerable infant to be unable to respond in the normal way to the accumulation of carbon dioxide in his system. The role of inflammatory cytokines as neuromodulators in the infant medulla has been well described and is likely the reason for a significant number of SIDS deaths occurring in conjunction with mild infection. I have concluded that it is more likely than not that the vaccine-stimulated cytokines had the same effect in this vulnerable infant during sleep. Accordingly, petitioners are entitled to compensation. A separate damages order will issue."

4.5. Case reports

In 2019, Japanese scientists (Osawa et al.) [63] investigated autopsy reports associated with sudden deaths in previously vaccinated children. Three of the children (2 infants and a 14-month-old child) died within 3 days post-vaccination. Here are summaries of the infant reports:

Case 1. A 3-month-old female baby developed cold symptoms on the day after receiving vaccines for Hib, pneumococcus, and rotavirus. One week earlier, the baby had also received vaccines for diphtheria, pertussis, tetanus, and polio. The infant was found limp in the evening and transported by ambulance to the hospital. The infant had shallow breathing upon arrival but she died after 12 h with little response to resuscitation.

Case 2. A 3-month-old male baby received 8 vaccines concurrently, for Hib, pneumococcus, hepatitis B, rotavirus, diphtheria, tetanus, pertussis, and polio. The infant exhibited cold-like symptoms continuously from the day of vaccination. He was found dead in the early morning of the third day.

The authors of this paper encourage forensic pathologists to "devote more attention to vaccination in sudden infant death cases."

4.6. Recent VAERS reports

Sudden infant deaths continue to occur shortly after receipt of vaccines. Here are summaries of 5 recent case reports filed with VAERS [19]:

#860135: On February 1, 2020, a 2-month-old female passed away from "cardiac arrest" 3 days after receiving 6 vaccines concurrently (diphtheria, tetanus, pertussis, hepatitis B, pneumococcal, and rotavirus).

#867981: On April 8, 2020, a 2-month-old female received 7 vaccines in the morning and "arrived in the ER deceased" by 1:30 pm that afternoon. According to the physician, the child's 2-month exam was normal prior to the immunizations.

#873934: On May 21, 2020, a 1-month-old male received 8 vaccines concurrently (diphtheria, tetanus, pertussis, polio, hepatitis B, Hib, pneumococcal, and rotavirus). Five days later, the child "was taken to the ER with sudden unexplained infant death."

#873474: On June 11, 2020, a 6-month-old male received 7 vaccines concurrently. Four days later, he "suffered cardiac arrest at home and died (sudden unexplained infant death)."

#883878: On September 1, 2020, a 3-month-old male received 7 vaccines concurrently. Two days later, he "experienced cardiac arrest" and was taken to the hospital emergency room but was unable to be resuscitated. No autopsy results were available at the time but SIDS is suspected.

4.7. Sudden unexplained death in childhood (SUDC)

Infants are not the only children at risk of sudden death. Sudden unexplained death in childhood (SUDC) is now a leading cause of death in toddlers (children 1–4 years of age). Although hundreds of SUDC cases are certified by medical examiners each year—392 cases were

recorded by the CDC in 2018—in a recent study by Crandall et al. [64], experts disagreed with the original certified cause-of-death in 40 % of cases, including many that were originally considered accidental or natural but adjudicated as "unexplained." There is a low rate of consistency and precision in death certification of SUDC, so true SUDC incidence is likely to be higher than official rates reported by the CDC. According to the authors of this study, "Future research should…provide more accurate cause-of-death certification in sudden pediatric deaths and explore potential causes for undetermined cases."

4.8. Comparison of studies

Seven studies and two confidential reports that were discussed in this paper—CDC 1980, Torch 1982, Baraff 1983, Torch 1986, Soldatenkova 2007, GSK 2011, GSK 2015, Miller 2021 (All Mortality), and Miller 2021 (SIDS)—confirm that sudden infant deaths in vaccinated babies tend to cluster in the early post-vaccination period, suggestive of a causal association. They all found that substantial proportions of infant deaths occurred within 1 day (mean = 25 %), 3 days (mean = 49 %), and 7 days (mean = 71 %) post-vaccination (Table 5). Six of the papers had a close concordance regarding proportions of infant deaths that occurred within 7 days post-vaccination (range = 75%–90%). Three studies found lower—but still substantial—percentages of infant deaths within 7 days post-vaccination (range = 37%–63%). In these latter 3 studies, a greater percentage of the remaining deaths occurred after the first week post-vaccination, possibly corroborating Scheibner's finding that an increased risk period for SIDS may persist several weeks after vaccination.

Variable proportions of infant deaths during the early post-vaccination period, as revealed in Table 5, could be a reflection of the different vaccines under consideration: DPT, hepatitis B, Infanrix hexa, or any combination of vaccines administered concurrently (as with the VAERS studies). Other factors that might influence proportions of infant deaths during the early post-vaccination period include: methods of data collection (e.g., passive reporting versus case reports), diverse populations (e.g., U.S., European, neonatal) or number of cases in the analysis. It should also be noted that some studies calculated all infant deaths that occurred "within 24 h after vaccination" while others simply counted first-day deaths up until midnight. If an infant was vaccinated in the afternoon and died early the next day, it would be counted as a death on the second day post-vaccination even though fewer than 24 h had passed. Finally, infant deaths in many of the study populations were passively reported, indicating that total cases were likely underestimated.

Table 5
Onset interval of sudden infant deaths post-vaccination: comparison of studies.

Study	Vaccine	Cases	% Died in 1 day	% Died in 3 days	% Died in 7 days
CDC 1980[a]	DPT	23	52 %	N/A	78 %
Torch 1982[b]	DPT	70	13 %	26 %	37 %
Baraff 1983[c]	DPT	27	22 %	33 %	63 %
Torch 1986[d]	DPT	200+	50 %	75 %	90 %
Soldatenkova 2007[e]	Hepatitis B	29	14 %	31 %	45 %
GSK 2011[f]	Infanrix hexa	67	24 %	63 %	90 %
GSK 2015[f]	Infanrix hexa	101	16 %	53 %	82 %
Miller 2021 (All Deaths)[g]	Any	2605	17 %	58 %	78 %
Miller 2021 (SIDS)[h]	Any	1048	13 %	51 %	75 %
Mean			**25 %**	**49 %**	**71 %**

Seven studies and two confidential reports confirm that sudden infant deaths in vaccinated babies tend to cluster in the early post-vaccination period, suggestive of a causal association. Substantial proportions of infant deaths occurred within 1 day, 3 days, and 7 days post-vaccination. Infant deaths in many of the study populations were passively reported, indicating that total cases were likely underestimated.

[a] Infant deaths and SIDS cases in a U.S. population.
[b] SIDS cases randomly reported in various countries.
[c] SIDS cases reported by coroners in Los Angeles, California.
[d] SIDS cases reported by 37 authors in 12 countries; death percentages are approximate.
[e] Passive reports of unexplained neonatal infant deaths in a U.S. population (VAERS).
[f] Passive reports of sudden infant deaths in a European population.
[g] Passive reports of infant deaths in a U.S. population (VAERS).
[h] Passive reports of SIDS in a U.S. population (VAERS).

4.9. Strengths and limitations

VAERS is a geographically diverse database that collects national data from all U.S. states and territories. Another advantage of VAERS is its ability to reveal patterns associated with the onset interval of adverse events post-vaccination. Tight onset intervals are, in fact, a primary requisite for determining whether petitions under the VICP will be eligible for compensation [65]. For example, with some vaccines the onset of specific injuries or death must occur within 72 h (3 days). Longer onset intervals are sometimes permissible depending upon the particular vaccine and type of injury under consideration, as defined in the VICP's Vaccine Injury Table. Regarding SIDS, petitioners must be able to show "a proximate temporal relationship between vaccination and injury [20]."

The main strengths of this paper are use of the VAERS database to identify unusual patterns and potential safety concerns associated with sudden infant deaths; relatively large populations of infant deaths (N = 2605) and SIDS cases (N = 1048) were available for assessment; and use of tight onset intervals, i.e., 1, 3, and 7 days, as a basis for determining whether there were statistically significant differences between the expected frequencies of infant mortality and the actual frequencies reported.

Although some studies were unable to find positive correlations between SIDS and vaccines, this paper corroborates and expands upon findings in other papers on SIDS that all revealed substantial proportions of infant deaths during the early post-vaccination period. The pooled results from this paper and several others (summarized in Table 5) reveal that about one-fourth, one-half, and three-fourths of all sudden deaths after vaccination happened within 1, 3, and 7 days, respectively.

The methodology utilized in this study to assess statistical significance, Pearson's chi-squared test, is the same standard utilized in the Baraff et al. study, which found that "the excess of deaths in the 24 h and first week following immunization were statistically significant." In addition, a robust review of the medical literature shows a well-established history of case reports, VICP awards, autopsies, studies and other evidence regarding a likely association between infant vaccines and sudden infant deaths.

The main weakness of this study is the potential for reporting bias. Doctors and parents may have been more likely to report a sudden death to VAERS when it occurred in close temporal proximity to vaccination than if it happened several days or weeks later. However, Table 2 shows that a smaller proportion of total infant deaths were reported on the day of vaccination (16.9 %) than on the day after vaccination (29.2 %), suggestive of an incubation period (the time after vaccination to develop the full reaction causing death). Table 3 shows a similar pattern, with a smaller proportion of SIDS cases reported on the day of vaccination (12.5 %) than on the day after vaccination (26.4 %). On Day 3 post-vaccination, reported infant deaths declined to 12 % (312/2605); reported SIDS cases declined to 12 % (126/1048) as well (Fig. 5).

There is biological plausibility for the incubation hypothesis, as explained by Douglas C. Miller [20], a neuropathologist who testified that vaccinations can be an extrinsic risk factor in SIDS. He described a series of physiological events that occur over time beginning with vaccination which evokes the production of cytokines that circulate into

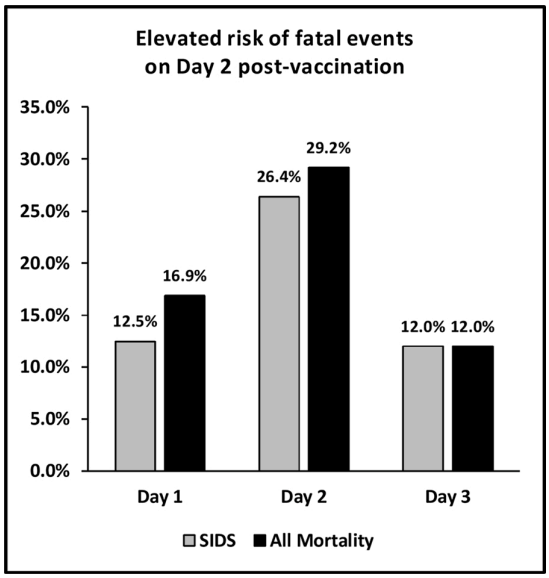

Fig. 5. Elevated risk of sudden infant deaths on Day 2 post-vaccination. Statistically fewer deaths occurred on the day of vaccination than on the day after vaccination, suggestive of an incubation period (the time after vaccination to develop the full reaction causing death). Thus, reporting bias is unlikely to be entirely responsible for the clustering of infant deaths and SIDS cases in the early post-vaccination period.

the central nervous system and interact with the hypothalamus to induce fever and inhibit the activity of 5-HT neurons in the medulla causing prolonged apneas and interference with auto-resuscitation. These cascading physiological events appear to peak on Day 2 post-vaccination when the greatest number of infant deaths and SIDS cases are reported. In fact, Miller testified that there is "an elevated risk for SIDS within the first 48 h following immunization." Foreign antigens, like those in vaccines, activate the production of cytokines "within hours" and peak "within 2 to at most 4 days," the period when a vulnerable infant who receives vaccines is most likely to suffer a fatal event, if one is to occur. Kashiwagi et al. [66] confirmed that a child will have elevated cytokine levels in the blood 24–48 hours post-vaccination.

The increased number of reported infant deaths on the day after vaccination as compared to the day of vaccination (760 versus 440), and the decreased number of reported infant deaths on Day 3 post-vaccination as compared to Day 2 (312 versus 760), are statistically significant ($p < 0.00001$). Similarly, the increased number of reported SIDS cases on the day after vaccination as compared to the day of vaccination (277 versus 131), and the decreased number of reported SIDS cases on Day 3 post-vaccination as compared to Day 2 (126 versus 277), are also statistically significant ($p < 0.00001$), providing evidence that reporting bias is unlikely to be entirely responsible for the clustering of infant deaths and SIDS cases in the early post-vaccination period.

VAERS is an important vaccine safety assessment tool. Numerous studies utilizing VAERS data are published every year. For example, the CDC (Su et al.) [67] recently analyzed the VAERS database to assess reports of myopericarditis following vaccination. The FDA [68] analyzed VAERS to determine the onset interval of idiopathic thrombocytopenic purpura (ITP) following MMR vaccination. (Most cases of ITP clustered between 3–4 weeks post-vaccination.) The CDC's and FDA's use of the VAERS database to reveal patterns and identify potential warning signs affirms the immense value of the raw data accessible to scientists and independent researchers conducting studies to evaluate the safety of U.S. mandated vaccines. However, just because a report is made to VAERS does not confirm that the adverse event was caused by a vaccine. Also, VAERS does not provide data on the number of individuals vaccinated, so rates of adverse events per vaccine doses administered cannot be determined. Nor does VAERS provide information regarding background incidence of adverse events in the general population.

Although the number of vaccine doses administered and the SIDS rate in the general population could be valuable metrics, they do not consider individualistic factors. For example, some infants may be especially susceptible or predisposed to a fatal vaccine reaction. Thus, even if there were no unusual patterns between observed deaths (reported in VAERS) and expected deaths (utilizing a population baseline), this would not be evidence that specific deaths occurring post-vaccination are not causally related—the very reason some pathologists recommend autopsies when sudden unexpected infant deaths occur soon after vaccination. Furthermore, immunization coverage rates are above 90 % in the United States. A true baseline of SIDS is more likely to be found in an unvaccinated population.

VAERS is a passive surveillance system, which means that reports about adverse events are not actively solicited or automatically collected. Moreover, parents are rarely warned to look for serious adverse reactions in their vaccinated children. Underreporting is a known limitation of passive surveillance systems; VAERS only captures a fraction of actual adverse events. A recent report prepared by Harvard Pilgrim Health Care [69] for the U.S. Department of Health and Human Services (HHS) found that "fewer than 1% of vaccine adverse events are reported." This means that infant deaths and SIDS cases that occur post-vaccination may be underreported by a factor of 100.

Available demographic data were limited to the sex and age of each child. It was not possible to examine infant mortality and SIDS cases by other potential risk factors, including race, socioeconomic background, smoking, nutritional status, breastfeeding, vaccinations during pregnancy, or gestational age at birth, each of which could affect health outcomes. This study did not assess the type or quantity of vaccines administered prior to the fatal incident, nor whether the death occurred after the first, second, or third round of vaccines.

4.10. More ICD categories concealing vaccine fatalities

"SIDS," "suffocation in bed," and death due to "unknown and unspecified causes," are just three of the 130 official cause-of-death categories that might be concealing fatalities that were actually due to vaccination. Several other ICD categories are possible candidates for incorrect infant death classifications: unspecified viral diseases, diseases of the blood, diseases of the nervous system, unspecified diseases of the respiratory system, cardiac arrest, and shaken baby syndrome. All of these official categories may be repositories of vaccine-related infant deaths reclassified as common fatalities.

For example, a vaccine against rotavirus-induced diarrhea (Rotarix) was licensed by the FDA in 2008. However, in a subanalysis of a large clinical study that evaluated the safety of this vaccine, *vaccinated babies died at a significantly higher rate than non-vaccinated babies* ($p = 0.04$) due to an increase in fatalities from pneumonia [70]. Using two different statistical methods, the FDA confirmed the significant findings with p values of 0.0345 and 0.0354. (One biologically plausible explanation is that natural rotavirus infection might have a protective effect against respiratory infection, so vaccinated babies, who are less likely to contract rotavirus, may be more susceptible to contracting pneumonia and dying [70].) Although these deaths appear to be vaccine related, coroners are likely to misclassify them as pneumonia.

Some infant fatalities that occur shortly after vaccinations are incorrectly classified as shaken baby syndrome. However, retinal and subdural bleeding can result from an adult that shook the baby *or from vaccine damage* [71]. Some parents have been wrongly convicted of killing their own baby when vaccines were the actual cause. According to Dr. Michael Innis [72], hematologist and expert on shaken baby syndrome, it is a frequent misdiagnosis: "Vaccines administered within 4

weeks of the onset of symptoms are the most common cause." This is another example showing how the true cause of death can be reclassified or hidden within the death tables.

The CDC [73] is aware that "some deaths that would have been classified as SIDS before 1999" are now being reclassified. This concerns the CDC "because inaccurate or inconsistent cause-of-death determination and reporting hamper the ability to monitor national trends, ascertain risk factors, and design and evaluate programs to prevent these deaths." Yet, when the ICD was revised in 1979 and health authorities eliminated all cause-of-death classifications associated with vaccination, they effectively compelled medical examiners to misclassify and conceal vaccine-related deaths. Thus, it is not possible to accurately monitor national trends regarding vaccine-related infant fatalities. To address this critical issue, health authorities should restore "prophylactic vaccination" as an official cause-of-death classification. Additionally, oversight of medical certification practices by independent experts is recommended to reduce incorrect or inconsistent cause-of-death determinations and prohibit vaccine-related infant deaths from being reclassified as ordinary mortality. In the meantime, parents should be warned that vaccine safety is overestimated when vaccine-related deaths are not being accurately documented.

5. Conclusion

This study found that a substantial proportion of infant deaths and SIDS cases occurred in temporal proximity to vaccine administration. The excess of deaths during these early post-vaccination periods was statistically significant ($p < 0.00001$). Several theories regarding the pathogenic mechanism behind these fatal events have been proposed, including the role of vaccine-induced inflammatory cytokines as neuromodulators in the infant medulla preceding an abnormal response to the accumulation of carbon dioxide; fatal disorganization of respiratory control induced by adjuvants that cross the blood-brain barrier; and biochemical or synergistic toxicity due to multiple vaccines administered concurrently.

There are 130 *official* ways for an infant to die, as categorized in the ICD, and one *unofficial* way for an infant to expire: from a fatal reaction to vaccines. When vaccine-related deaths are hidden within the death tables, it is difficult to monitor and prevent these deaths. In addition, parents are denied the ability to ascertain honest vaccine risk-to-benefit ratios and true informed consent to vaccination is not possible. This is why increased effort and transparency toward achieving an accurate account of vaccine-related infant mortality is a desirable goal.

The findings in this paper must be weighed against the strengths and limitations of the available data and study design. While this paper does not prove an association between infant vaccines and sudden infant deaths, it reveals unusual patterns and safety signals highly suggestive of a causal relationship. Additional investigation is warranted. Finding ways to increase vaccine safety, reduce inaccurate or inconsistent cause-of-death certification practices, and support families in their quest to make genuinely informed healthcare decisions, must be top priorities.

Author statement

NZM was responsible for all aspects of this paper, including conceptualization and design of the study, analysis and interpretation of the data, creation of figures and tables, research, writing, and critical revisions of the work.

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Declaration of Competing Interest

NZM has written and lectured on vaccine safety and was a paid consultant to Physicians for Informed Consent.

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