SIDS and VACCINATION - Abstracts

Pharmacoepidemiol Drug Saf. 2016 Nov 28. PMID: 27891698

Vaccination and unexplained sudden death risk in Taiwanese infants.

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Abstract

PURPOSE: In March 1992, eight infants who had died within 36 hours of receiving whole-cell pertussis vaccine (diphtheria, tetanus, and whole-cell pertussis [DTwP]) prompted the Taiwan health authorities to suspend its use. We conducted an investigation of vaccination and sudden unexplained infant death (SUID) and repeated it more recently after Taiwan switched to acellular pertussis vaccine (diphtheria, tetanus, and acellular pertussis [DTaP]) in 2010.

METHODS: All SUIDs aged 31-364 days during 1990-1992 and 1996-2013 were selected from the death registration databases. The case-control investigation matched each case to two controls on clinic, sex, and birth date, whereas the follow-up self-controlled case series study compared risk of death during the 30-day post-vaccination risk periods with those in the control periods within the same case.

RESULTS: Sudden unexplained infant death was associated with never receiving DTwP (odds ratio 2.28, 95% confidence interval 1.25-4.15) in the case-control investigation. The odds ratios within 0-1, 2-7, 8-14, and 15-30 days of DTwP administration were 1.18, 0.26, 0.50, and 0.77. In the 1996-2013 self-controlled case series studies, this temporal shift between DTwP and SUID was consistently observed for female (incidence rate ratio 1.70, 0.75, 1.01, and 0.84) but not male or DTaP recipients. A pooled analysis showed significant risk within 2 days of receiving DTwP in female infants (incidence rate ratio 1.66, 95% confidence interval 1.05-2.60).

CONCLUSIONS: Being unvaccinated and recent receipt of DTwP in female infants was significantly associated with SUID; the latter was consistent with a temporal shift pattern without overall increase in risk. The currently used pertussis vaccine, DTaP, did not increase risk of SUID.

Clin Infect Dis. 2015 Sep 15;61(6):980-7. PMID: 26021988 **Free full text**

Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013.

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Abstract

BACKGROUND: Vaccines are among the safest medical products in use today. Hundreds of millions of vaccinations are administered in the United States each year. Serious adverse reactions are uncommon. However, temporally associated deaths can occur following vaccination. Our aim was to characterize main causes of death among reports submitted to the US Vaccine Adverse Event Reporting System (VAERS), a spontaneous vaccine safety surveillance system.

METHODS: We searched VAERS for US reports of death after any vaccination from 1 July 1997 through 31 December 2013. Available medical records, autopsy reports, and death certificates were reviewed to identify cause of death.

RESULTS: VAERS received 2149 death reports, most (n = 1469 [68.4%]) in children. Median age was 0.5 years (range, 0-100 years); males accounted for 1226 (57%) reports. The total annual number of death reports generally decreased during the latter part of the study period. Most common causes of death among 1244 child reports with available death certificates/autopsy reports included **sudden infant death syndrome (n = 544 [44%])**, **asphyxia (n = 74 [6.0%])**, septicemia (n = 61 [4.9%]), and pneumonia (n = 57 [4.6%]). Among 526 adult reports, most common causes of death included diseases of the circulatory (n = 247 [46.9%]) and respiratory systems (n = 77 [14.6%]), certain infections and parasitic diseases (n = 62 [11.8%]), and malignant neoplasms (n = 20 [3.8%]). For child death reports, 79.4% received >1 vaccine on the same day. Inactivated influenza vaccine given alone was most commonly associated with death reports in adults (51.4%).

CONCLUSIONS: No concerning pattern was noted among death reports submitted to VAERS during 1997-2013. The main causes of death were consistent with the most common causes of death in the US population.

J Pediatr. 2015 Apr;166(4):992-7. PMID:25598306

Adverse events following Haemophilus influenzae type b vaccines in the Vaccine Adverse Event Reporting System, 1990-2013.

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Abstract
OBJECTIVE: To characterize adverse events (AEs) after Haemophilus influenzae type b (Hib) vaccines reported to the US Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting surveillance system.
STUDY DESIGN: We searched VAERS for US reports after Hib vaccines among reports received from January 1, 1990, to December 1, 2013. We reviewed a random sample of reports and accompanying medical records for reports classified as serious. All reports of death were reviewed. Physicians assigned a primary clinical category to each reviewed report. We used empirical Bayesian data mining to identify AEs that were disproportionally reported after Hib vaccines.
RESULTS: VAERS received 29,747 reports after Hib vaccines; 5179 (17%) were serious, including 896 reports of deaths. Median age was 6 months (range 0-1022 months). **Sudden infant death syndrome was the stated cause of death in 384 (51%) of 749 death reports** with autopsy/death certificate records. The most common non-death serious AE categories were neurologic (80; 37%), other non-infectious (46; 22%) (comprising mainly constitutional signs and symptoms); and gastrointestinal (39; 18%) conditions. No new safety concerns were identified after clinical review of reports of AEs that exceeded the data mining statistical threshold.
CONCLUSION: Review of VAERS reports did not identify any new or unexpected safety concerns for Hib vaccines. !!!!

Curr Med Chem. 2014 Mar;21(7):941-6. PMID: 24083600

Sudden infant death following hexavalent vaccination: a neuropathologic study.

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Abstract We examined a large number of sudden infant death syndrome victims in order to point out a possible causal relationship between a previous hexavalent vaccination and the sudden infant death. We selected 110 cases submitted to in-depth histological examination of the autonomic nervous system and provided with detailed clinical and environmental information. In 13 cases (11.8%) the death occurred in temporal association with administration of the hexavalent vaccine (from 1 to 7 days). In none of these victims congenital developmental alterations of the main nervous structures regulating the vital functions were observed. Only the hypoplasia of the arcuate nucleus was present in 5 cases. In one case in particular an acquired hyperacute encephalitis of the tractus solitarii nucleus was diagnosed in the brainstem. This study does not prove a causal relationship between the hexavalent vaccination and SIDS. However, we hypothesize that vaccine components could have a direct role in sparking off a lethal outcome in vulnerable babies. In conclusion, we sustain the need that deaths occurring in a short space of time 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.

Stat Med. 2011 Mar 15;30(6):666-77. PMID: 21337361

A modified self-controlled case series method to examine association between multidose vaccinations and death.

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Abstract The self-controlled case series method (SCCS) was developed to analyze the association between a time-varying exposure and an outcome event. We consider penta- or hexavalent vaccination as the exposure and unexplained sudden unexpected death (uSUD) as the event. The special situation of multiple exposures and a terminal event requires adaptation of the standard SCCS method. This paper proposes a new adaptation, in which observation periods are truncated according to the vaccination schedule. The new method exploits known minimum spacings between successive vaccine doses. Its advantage is that it is very much simpler to apply than the method for censored, perturbed or curtailed post-event exposures recently introduced. This paper presents a comparison of these two SCCS methods by simulation studies and an application to a real data set. In the simulation studies, the age distribution and the assumed vaccination schedule were based on real data. Only small differences between the two SCCS methods were observed, although 50 per cent of cases could not be included in the analysis with the SCCS method with truncated observation periods. **By means of a study including 300 uSUD, a 16-fold risk increase after the 4th dose could be detected with a power of at least 90 per cent**. **A general 2-fold risk increase after vaccination could be detected with a power of 80 per cent**. Reanalysis of data from cases of the German case-control study on sudden infant death (GeSID) resulted in slightly higher point estimates using the SCCS methods than the odds ratio obtained by the case-control analysis.

PLoS One. 2011 Jan 26;6(1):e16363. PMID: 21298113 Free PMC Article

Sudden unexpected deaths and vaccinations during the first two years of life in Italy: a case series study.

Traversa G, Spila-Alegiani S, Bianchi C, Ciofi degli Atti M, Frova L, Massari M, Raschetti R, Salmaso S, Scalia Tomba G; Hera Study Group.

Collaborators (218)

Abstract

BACKGROUND: The signal of an association between vaccination in the second year of life with a hexavalent vaccine and sudden unexpected deaths (SUD) in the two days following vaccination was reported in Germany in 2003. A study to establish whether the immunisation with hexavalent vaccines increased the short term risk of SUD in infants was conducted in Italy.

METHODOLOGY/PRINCIPAL FINDINGS: The reference population comprises around 3 million infants vaccinated in Italy in the study period 1999-2004 (1.5 million received hexavalent vaccines). Events of SUD in infants aged 1-23 months were identified through the death certificates. Vaccination history was retrieved from immunisation registries. Association between immunisation and death was assessed adopting a case series design focusing on the risk periods 0-1, 0-7, and 0-14 days after immunisation. **Among the 604 infants who died of SUD, 244 (40%) had received at least one vaccination.** Four deaths occurred within two days from vaccination with the hexavalent vaccines (RR=1.5; 95% CI 0.6 to 4.2). The RRs for the risk periods 0-7 and 0-14 were 2.0 (95% CI 1.2 to 3.5) and 1.5 (95% CI 0.9 to 2.4). The **increased risk was limited to the first dose** (RR=2.2; 95% CI 1.1 to 4.4), whereas no increase was observed for the second and third doses combined.

CONCLUSIONS: The RRs of SUD for any vaccines and any risk periods, even when greater than 1, were almost an order of magnitude lower than the estimates in Germany. The limited increase in RRs found in Italy appears confined to the first dose and may be partly explained by a residual uncontrolled confounding effect of age.

J Forensic Leg Med. 2007 Feb;14(2):87-91. PMID: 17654772

Simultaneous sudden infant death syndrome.

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Abstract The simultaneous sudden deaths of twins rarely occur and therefore it has received limited attention in the medical literature. When the deaths of the twins meet the defined criteria for sudden infant death syndrome (SIDS) independently and take place within the same 24 h range it can be called as simultaneous SIDS (SSIDS). The case(s): Twin girls (3.5-month-old) were found dead by their mother in their crib, both in supine position. The infants were identical twins and delivered at a hospital by cesarean section. Both infants were healthy and did not have any serious medical history. Two days prior to the incident, the twins had received the second dose of oral polio, DPT and the first dose of hepatitis B vaccines and they had fever on the first day of the vaccination and been given teaspoonful of acetaminophen. Death scene investigation, judicial investigation, parental assessment, macroscopic and microscopic autopsy findings and the toxicological analysis did not yield any specific cause of death. The case(s) were referred to a supreme board composed of multidisciplinary medical professionals at the Institute of Forensic Medicine, Ministry of Justice, in Istanbul. The Board decided that the available data was consistent with SIDS. These SIDS case(s) are presented because twin SIDS are rare and this is the first time that a simultaneous twin SIDS have been reported in Turkey. Simultaneous SIDS cases have many implications regarding definition, diagnosis and medico-legal approach.

Vaccine. 2006 Jul 26;24(31-32):5781-2; author reply 5785-6 PMID: 16084630

B. Zinka et al., Unexplained cases of sudden infant death shortly after hexavalent vaccination.

Virchows Arch. 2006 Jan;448(1):100-4 PMID: 16231176

Sudden infant death syndrome (SIDS) shortly after hexavalent vaccination: another pathology in suspected SIDS? [CASE STUDY]

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Abstract Experts from panels of the European Agency for the Evaluation of Medical Products have investigated whether there might be a link between hexavalent vaccines and some cases of deaths that occurred. Participants included pathologists with experience in the field of vaccines and sudden infant death syndrome who conducted autopsies. However, to the best of our knowledge, little, if any, attention was paid to examination of the brainstem and the cardiac conduction systems on serial sections, nor was the possibility of a triggering role of the vaccine in these deaths considered. Herein we report the **case of a 3-month-old female infant dying suddenly and unexpectedly shortly after being given a hexavalent vaccination**. Examination of the brainstem on serial sections revealed bilateral hypoplasia of the arcuate nucleus. The cardiac conduction

system presented persistent fetal dispersion and resorptive degeneration. This case offers a unique insight into the possible role of hexavalent vaccine in triggering a lethal outcome in a vulnerable baby. Any case of sudden unexpected death occurring perinatally and in infancy, especially soon after a vaccination, should always undergo a full necropsy study according to our guidelines.

Pediatrics. 2005 Jun;115(6):e643-6. PMID: 15930190

Probability of coincident vaccination in the 24 or 48 hours preceding sudden infant death syndrome death in Australia.

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Abstract

OBJECTIVE: Vaccination does not cause sudden infant death syndrome (SIDS). However, SIDS peaks at 2 months of age, when vaccination encounters are frequent. There are no published estimates using population data on age of death and immunization coverage to indicate to practitioners how often coincident vaccination may occur by chance. This study aimed to determine the probability that an Australian infant who has died of SIDS was vaccinated in the days before death.

METHODS: An analytical study of population death data and immunization coverage was conducted for Australian children who were born between April 1, 2002, and March 31, 2003. Also evaluated were Australian children who were registered as dying of SIDS between 1997 and 2001. The main outcomes measured were distribution of SIDS deaths by age and distribution of immunization coverage by age.

RESULTS: The probability of recent vaccination and SIDS coinciding varied by age and day of the week of death. The overall estimated probability of vaccination within the last 24 hours for a child who has died of SIDS in Australia is estimated as 1.3%. In the last 48 hours, it is 2.6%. With the average number of SIDS deaths for the period 1997-2001 equal to 130 cases per year, we estimated that a case of SIDS will occur when vaccination was given in the last 24 hours in 1.7 cases per year and within 48 hours in 3.5 cases.

CONCLUSIONS: Although coincident vaccination and SIDS should not be a frequent problem, it can be expected to occur at least annually in Australia by chance alone. The probabilities of vaccination by age estimated in this study can also be applied to estimate the probability of a vaccination encounter for children who have experienced any unusual medical condition or death, when these occurrences are known to be unrelated to vaccination. *NB. study cases limited to 48 hours post-vaccination.*

Pediatrics. 2004 Jul;114(1):e9-15. PMID: 15231967

A controlled study of the relationship between Bordetella pertussis infections and sudden unexpected deaths among German infants.

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Abstract

OBJECTIVE: This was a prospective, controlled, multicenter study to investigate the relationship between Bordetella pertussis infections and sudden unexpected deaths among German infants.

DESIGN: Between 1995 and 1997, all infants who died at 7 to 365 days of age and for whom autopsies were performed in 1 of 8 participating institutes of legal medicine were enrolled. During a standardized autopsy, nasopharyngeal specimens (NPSs) and tracheal specimens were obtained for polymerase chain reaction (PCR) assays to detect B pertussis. The oligonucleotide primers PTp1 and PTp2, which specifically amplify a 191-base pair DNA fragment of the pertussis toxin operon of B pertussis, were used. Two control subjects (matched according to residence, age, gender, and nationality) were enrolled for each case subject, via a network of pediatricians in private practice, and NPSs were obtained from those infants. Parents of case subjects and control subjects were asked to provide specific information on respiratory illnesses of the child, contact with a known case of pertussis, or close contact with a person with a cough illness during the 4 weeks before death or enrollment, as well as the child's pertussis immunization status. The pathologists performing the autopsies were unaware of the PCR results.

RESULTS: Enrolled were 254 infants (66% male) with sudden unexpected deaths and 441 matched control subjects. Autopsies according to protocol were performed for 234 of the case subjects (92%); a diagnosis of sudden infant death syndrome (SIDS) was made for 76%. For the remaining subjects, causes of death were respiratory or other infections (14%), congenital anomalies or organ failures (4%), aspiration (2%), or accidents or traumatic events (4%). PCR results were positive for B pertussis for 12 case subjects (5.1%) (all with SIDS or respiratory infections) and 5.3% of control subjects. Of the 12 case subjects with positive PCR results, 10 (83%) were male. Questionnaires had been returned by the parents of 5 of the 12 infants. Three had experienced a respiratory illness (all with cough), beginning 7, 14, and 19 days before death. None had a known contact with a case of pertussis. Four of 15 control infants (27%) with positive PCR findings for B pertussis had a cough illness, indicating possible pertussis, and 2 of those 4 developed typical symptoms (whooping). Background information was received from 116 parents (46%) of case subjects and from parents of all control subjects.

Upper respiratory tract infections within 4 weeks before death were reported for 53% of case subjects and 38% of control subjects. Also, fewer case subjects (33%) than control subjects (68%) had received age-adequate numbers of pertussis vaccine doses.
CONCLUSIONS: The concept of infection as a factor in SIDS is supported by a number of observations, including the seasonal distribution of the occurrence of SIDS; the high incidence of concurrent upper respiratory tract infections among infants dying as a result of SIDS; the peak age at 3 to 4 months; nicotine use in a child's household, which predisposes children to respiratory infections such as otitis media; and the protective role of breastfeeding. A prominent role might be suspected for B pertussis, for several reasons. 1) B pertussis infections in infancy are frequently associated with apneic spells, which are occasionally life-threatening and, if leading to death, might be reported as SIDS. 2) Epidemiologic evidence from the United Kingdom, Sweden, and Norway indicates that SIDS is associated with B pertussis infection. 3) In a previously published study, we detected B pertussis DNA in the nasopharynx of 9 of 51 consecutive infants (18%) with sudden unexpected deaths. This is the first prospective, controlled study to investigate the possible etiologic role of B pertussis in SIDS. Clinically unrecognized B pertussis infections were relatively frequent (5.3%) among control infants during the course of our study. The rate of infection was similar or perhaps greater for control subjects, compared with case subjects (1.7%), when only NPS results were compared. This may seem surprising but is supported by other studies, in which asymptomatic infections or mild respiratory illnesses were observed among infants exposed to B pertussis. Careful autopsies, including histologic evaluations of organ specimens and use of PCR to detect B pertussis in NPSs and tracheal specimens, represented a strength of this study. Our general findings were as expected. The majority of cases were classified as SIDS. The second largest group included infants for whom respiratory infections were found. The findings of various other diagnoses, which in several instances would have been undiscovered otherwise, emphasize the need for autopsies after unexpected infant deaths. What is the significance of the identified B pertussis infections in 12 cases? Several pieces of evidence support the plausibility of a cause-and-effect relationship. Eight of the 12 case subjects died before 6 months of age, the typical age for death attributable to pertussis. In autopsies, 9 of the subjects were found to have signs of respiratory infections; for 2 infants, the autopsies suggested that death was attributable to a respiratory infection. One additional infant (data not shown) had brain edema (which could have been attributable to hypoxemia during pertussis). Lower rates of completed primary series or age-adequate numbers of pertussis vaccine doses among case subjects than among control subjects may indicate that immunization against pertussis protects children from death attributable to unrecognized B pertussis infection. Moreover, a recent study indicated that immunization with diphtheria-tetanus-pertussis vaccine induces antibodies that cross-react with pyrogenic staphylococcal toxins, which have been implicated in several cases of SIDS. Other microorganisms may be involved in the sudden death of infants, as suggested in this study by the higher rate of a history of concurrent upper respiratory tract infections among case subjects, compared with control subjects. Similarly, in a Scandinavian study, 48% of 244 SIDS case subjects, compared with 31% of 869 control subjects, exhibited symptoms of upper airway infection during the last week before death or interview, respectively. Because SIDS is a diagnosis of exclusion, every attempt should be made to identify a cause of death during autopsy. This should include the search for pathogenic microorganisms in the respiratory tract with the use of PCR and other sensitive tests. In conclusion, B pertussis infection was found for 12 of 234 infants (5.1%) with unexpected deaths, and the infections might have contributed to the deaths.

Pediatrics. 2002 Nov;110(5):e64. PMID: 12415070

The triple risk hypotheses in sudden infant death syndrome.

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Abstract Sudden infant death syndrome (SIDS) victims were regarded as normal as a matter of definition (Beckwith 1970) until 1952 when Kinney and colleagues argued for elimination of the clause, "unexpected by history." They argued that "not all SIDS victims were normal," and referred to their hypothesis that SIDS results from brain abnormalities, which they postulated "to originate in utero and lead to sudden death during a vulnerable postnatal period." Bergman (1970) argued that SIDS did not depend on any "single characteristic that ordains a infant for death," but on an interaction of risk factors with variable probabilities. Wedgwood (1972) agreed and grouped risk factors into the first "triple risk hypothesis" consisting of general vulnerability, age-specific risks, and precipitating factors. Raring (1975), based on a bell-shaped curve of age of death (log-transformed), concluded that SIDS was a random process with multifactorial causation. Rognum and Saugstad (1993) developed a "fatal triangle" in 1993, with groupings similar to those of Wedgwood, but included mucosal immunity under a vulnerable developmental stage of the infant. Filiano and Kinney (1994) presented the best known triple risk hypothesis and emphasized prenatal injury of the brainstem. They added a qualifier, "in at least a subset of SIDS," but, the National Institute of Child Health and Development SIDS Strategic Plan 2000, quoting Kinney's work, states unequivocally that "SIDS is a developmental disorder. Its origins are during fetal development." Except for the emphasis on prenatal origin, all 3 triple risk hypotheses are similar. Interest in the brainstem of SIDS victims began with Naeye's 1976 report of astrogliosis in 50% of all victims. He concluded that these changes were caused by hypoxia and were not the cause of SIDS. He noted an absence of astrogliosis in some older SIDS victims, compatible with a single, terminal episode of hypoxia without previous hypoxic episodes, prenatal or postnatal. Kinney and colleagues (1983) reported gliosis in 22% of their SIDS

victims. Subsequently, they instituted studies of neurotransmitter systems in the brainstem, particularly the muscarinic (1995) and serotenergic systems (2001). The major issue is when did the brainstem abnormalities, astrogliosis, or neurotransmitter changes occur and whether either is specific to SIDS. There is no published method known to us of determining the time of origin of these markers except that the injury causing astrogliosis must have occurred at least 4 days before death (Del Bigio and Becker, 1994). Because the changes in neurotransmitter systems found in the arcuate nucleus in SIDS victims were also found in the chronic controls with known hypoxia, specificity of these markers for SIDS has not been established. It seems likely that the "acute control" group of Kinney et al (1995) died too quickly to develop gliosis or severe depletion of the neurotransmitter systems. We can conclude that the acute controls had no previous episodes of severe hypoxia, unlike SIDS or their "chronic controls." Although the average muscarinic cholinergic receptor level in the SIDS victim was significantly less than in the acute controls, the difference was only 27%, and only 21 of 41 SIDS victims had values below the mean of the acute controls. The study of the medullary serotonergic network by Kinney et al (2001) revealed greater reductions in the SIDS victims than in acute controls, but the questions of cause versus effect of the abnormalities, and whether they occurred prenatally or postnatally, remain unanswered. Hypoplasia of the arcuate nucleus was stated to occur in 5% of their SIDS cases by Kinney et al (2001), but this is a "primary developmental defect" according to Matturri et al (2002) with a larger series, many of whom were stillbirths. These cases should not be included under the rubric of SIDS, by definition. There are difficulties with Filiano and Kinney's (1994) explanation of the age at death distribution of SIDS. They postulate that the period between 1 and 6 months represents an unstable time for virtually all physiologic systems. However, this period demonstrates much less instability than does the neonatal period, when most deaths from congenital defects and severe maternal anemia occur. We present data for infants born to mothers who were likely to have suffered severe anemia as a consequence of placenta previa, abruptio placentae, and excessive bleeding during pregnancy; these infants presumably are at increased risk of hypoxia and brainstem injury. The total neonatal mortality rate in these 3 groups of infants is 4 times greater than the respective postneonatal mortality, and in the postneonatal period the non-SIDS mortality rate is between 14 and 22 times greater than the postneonatal SIDS rate in these 3 groups. A preponderance of deaths in the neonatal period is also found for congenital anomalies, a category that logically should include infants who experienced prenatal hypoxia or ischemia; this distribution of age of death is very different from that for SIDS, which mostly spares the first month and peaks between 2 and 3 months of age. Finally, evidence inconsistent with prenatal injury as a frequent cause of SIDS comes from prospective studies of ventilatory control in neonates who subsequently died of SIDS; no significant respiratory abnormalities in these infants have been found (Waggener et al 1990; Schectman et al 1991). We conclude that none of the triple risk hypotheses presented so far have significantly improved our understanding of the cause of SIDS. Bergman's and Raring's concepts of multifactorial causation with interaction of risk factors with variable probabilities is less restrictive and more in keeping with the large number of demonstrated risk factors and their varying prevalence. If prenatal hypoxic damage of the brainstem occurred, it seems likely that the infant so afflicted would be at risk for SIDS, but it is even more likely that their death would occur in the neonatal period, as we have demonstrated in infants who have known maternal risk factors that involve severe anemia. This is in contrast to the delay until the postneonatal period of most SIDS deaths. A categorical statement that the origin of SIDS is prenatal is unwarranted by the evidence. Brainstem abnormalities have not been shown to cause SIDS, but are more likely a nonspecific effect of hypoxia.

Over 600 cases of sudden infant death syndrome following vaccination were reported from 1990-1997.

- **GreenMedInfo Summary**

Pharmacoepidemiol Drug Saf. 2001 Jun-Jul;10(4):279-85.

The epidemiology of fatalities reported to the vaccine adverse event reporting system 1990-1997.

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Abstract

PURPOSE: To examine the fatalities reported to the federally administered Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system, in its first 7 years.

METHODS: The working data set included variables such as demographic information, dates of vaccination, adverse event onset and death, vaccines administered, and vaccination facility data. Frequencies for these data and state reporting rates were calculated.

RESULTS: A total of 1266 fatalities were reported to VAERS during July 1990 through June 1997. The number of death reports peaked in 1992-1993 and then declined. The overall median age of cases was 0.4 years, with a range of 1 day to 104 years. **Nearly half of the deaths were attributed to sudden infant death syndrome (SIDS).**

CONCLUSIONS: The trend of decreasing numbers of deaths reported to VAERS since 1992-1993 follows that observed for SIDS overall for the US general population following implementation of the 'Back to Sleep' program. These data may support findings of past controlled studies showing that the association between infant vaccination and SIDS is coincidental and not causal. VAERS reports of death after vaccination may be stimulated by the temporal association, rather than by any causal relationship.

Am J Forensic Med Pathol. 2001 Mar;22(1):23-32. PMID: 11444657

Simultaneous sudden infant death syndrome: a proposed definition and worldwide review of cases.

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Abstract Epidemiologic studies of sudden infant death syndrome (SIDS), the leading cause of death of infants during the postperinatal period (7-365 days), have mainly focused on the deaths of single infants. Simultaneous sudden infant death syndrome (SSIDS), the death of a pair of twins occurring at the same time, has received limited attention within the medical community. To the authors' knowledge, this article is the first to describe the 41 SSIDS cases cited in the world literature from 1900 to 1998 by the location of death, a summary of the circumstances surrounding the deaths, and evaluation of these cases in terms of a proposed definition of SSIDS. This evaluation critiques whether the 41 pairs of SSIDS cases adhere to a newly proposed definition of SSIDS. Twin infant deaths must meet all three criteria to be considered SSIDS. The study found that only 12 pairs of twins met all three criteria (29.2%), nine pairs met two criteria (21.9%), alternative cause of death was offered in five pairs of twins (12.1%) and in the remaining 15 pairs (36.6%), only limited information was available; therefore, no conclusions could be reached.

Am J Forensic Med Pathol. 2001 Mar;22(1):33-7. PMID: 11444658

Simultaneous sudden infant death syndrome: a case report.

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Abstract The first reported case of simultaneous sudden infant death syndrome (SSIDS) in Allegheny County, Pennsylvania, occurred on February 27, 1998. Two-month-old black fraternal twin girls were both found dead in their crib at the same time. After an in-depth death scene investigation, police investigation, toxicologic analysis, and complete autopsies, a specific cause of death could not be identified. The deaths of the two girls were therefore ruled simultaneous sudden infant death syndrome.

Pediatrics. 1999 Oct;104(4):e43. PMID: 10506268

Epidemiology of SIDS and explained sudden infant deaths. CESDI SUDI Research Group.

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Abstract

OBJECTIVES: To establish whether epidemiologic characteristics for sudden infant death syndrome (SIDS) have changed since the decrease in death rate after the "Back to Sleep" campaign in 1991, and to compare these characteristics with sudden and unexpected deaths in infancy (SUDI) from explained causes.

DESIGN: Three-year, population-based, case-control study. Parental interviews were conducted soon after the death and for 4 controls matched for age and date of interview. All sudden unexpected deaths were included in the study and the cause of death was established by a multidisciplinary panel of the relevant health care professionals taking into account past medical and social history of the mother and infant, the circumstances of death, and a full pediatric postmortem examination. Contributory factors and the final classification of death were made using the Avon clinicopathologic system.

SETTING: Five regions in England, with a total population of >17 million people, took part in the study. The number of live births within these regions during the particular time each region was involved in the study was 473 000.

STUDY PARTICIPANTS: Three hundred twenty-five SIDS infants (91.3% of those available), 72 explained SUDI infants (86.7% of those available), and 1588 matched control infants (100% of total for cases included).

RESULTS: Many of the epidemiologic features that characterize SIDS infants and families have remained the same, despite the recent decrease in SIDS incidence in the United Kingdom. These include the same characteristic age distribution, few deaths in the first few weeks of life or after 6 months, with a peak between 4 and 16 weeks, a higher incidence in males, lower birth weight, shorter gestation, and more neonatal problems at delivery. As in previous studies there was a strong correlation with young maternal age and higher parity and the risk increased for infants of single mothers and for multiple births. A small but significant proportion of index mothers had also experienced a previous stillbirth or infant death. The majority of the SIDS deaths (83%) occurred during the night sleep and there was no particular day of the week on which a significantly higher proportion of deaths occurred. Major epidemiologic features to change since the decrease in SIDS rate include a reduction in the previous high winter peaks of death and a shift of SIDS families to the more deprived social grouping. Just more than one quarter of the SIDS deaths (27%) occurred in the 3 winter months (December through February) in the 3 years of this study. In half of the SIDS families (49%), the lone parent or both parents were unemployed

compared with less than a fifth of control families (18%). This difference was not explained by an excess of single mothers in the index group. Many of the significant factors relating to the SIDS infants and families that distinguish them from the normal population did not distinguish between SIDS and explained SUDI. In the univariate analysis many of the epidemiologic characteristics significant among the SIDS group were also identified and in the same direction among the infants dying as SUDI attributable to known causes. The explained deaths were similarly characterized by the same infant, maternal, and social factors, 48% of these families received no waged income. Using logistic regression to make a direct comparison between the two index groups there were only three significant differences between the two groups of deaths: 1) a different age distribution, the age distribution of the explained deaths peaked in the first 2 months and was more uniform thereafter; 2) more congenital anomalies were noted at birth (odds ratio [OR] = 3.14; 95% confidence intervals [CI]: 1.52-6. (ABSTRACT TRUNCATED)

Ir Med J. 1998 Jan-Feb;91(1):17. PMID:9563248

Immunization and cot death.

Matthews T.

38,787 adverse events including infant death (highest in 1-3 month olds) after vaccination were reported between 1991-1994. (The authors speciously claim SIDS and not vaccination caused these deaths). GreenMedInfo Summary

J Pediatr. 1997 Oct;131(4):529-35. PMID: 9386653

Descriptive epidemiology of adverse events after immunization: reports to the Vaccine Adverse Event Reporting System (VAERS), 1991-1994.

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Abstract

OBJECTIVE: To provide an overview of the data, function, and performance of the Vaccine Adverse Event Reporting System.
DESIGN: Descriptive and correlational analyses.
SETTING: United States, 1991 through 1994.
SUBJECTS: Reports to the Vaccine Adverse Event Reporting System, a passive national surveillance system, that represents temporal (but not necessarily causal) relationships between vaccinations and adverse events.
MAIN OUTCOME MEASURES: Demographic variables, birth weight, vaccine type, severity of adverse event after immunization.
RESULTS: A total of 38,787 adverse events was reported during the study period without a clearly increasing or decreasing trend in the annual number of total reports or deaths. Of the deaths with known age, **72.4% were reported in the first year of life**, and 63.7% of these were male. The **peak age for death reports was 1 to 3 months**, with a gradual decline through age 9 months, after which death was relatively rare. Adverse events with onset of symptoms the day of vaccination accounted for 45.5% of total reports; 20.4% had onset of symptoms the following day. **Onset within 2 weeks after vaccination was noted for 92.5% of all reports. Simultaneous administration of multiple vaccines was noted in 75.7% of reports for immunizations at ages younger than 20 years**. In contrast, among those 20 years or older, only 6.0% of reports named multiple vaccines. Wide geographic variations were noted in adverse event reporting rates for children younger than 2 years, and the states with the lowest reporting rates of less serious events included the most populous states.
CONCLUSIONS: The peak age of deaths at ages 1 to 3 months could be expected on the basis of prior studies showing that sudden infant death syndrome deaths peak at that age, that most deaths in the Vaccine Adverse Event Reporting System are attributed to sudden infant death syndrome, and *that sudden infant death syndrome has not been associated with vaccination*.* The large number of reports and national coverage of the Vaccine Adverse Events Reporting System make it useful for monitoring the safety of vaccine lots and for accumulating case series to detect or better understand adverse events that may occur too rarely to be assessed in clinical trials or in the larger studies that are sometimes carried out by manufacturers after vaccine licensure (phase IV studies). ** SPIN*

Vaccination in infants less than 3 months is associated with an increased risk of sudden infant death syndrome.

Fundam Clin Pharmacol. 1995;9(3):263-70. PMID: 7557822

Sudden infant death syndrome and diphtheria-tetanus-pertussis-poliomyelitis vaccination status.

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France.

Abstract Because diphtheria, tetanus, pertussis and poliomyelitis vaccine is routinely given during the period of highest incidence of sudden infant death syndrome (SIDS), we carried out a retrospective case-control study to assess whether such vaccination increased the risk of SIDS. The vaccination status of 118 SIDS and 332 control children, matched for sex, date of birth and age of the victims at death, was compared: the victims of SIDS were not significantly more often vaccinated than control children, the odds ratio was estimated at 1.9 with a 95% confidence interval from 0.9 to 3.9. **There was a statistical difference between vaccination status of SIDS cases and controls aged less than three months. Nine percent of SIDS cases under 3 months had been vaccinated whereas the matched controls had not.** In our study DTCP vaccination was not a risk factor for SIDS; although **more of the SIDS infants less than 3 months of age had been vaccinated**. This result however, concerns only one subgroup of the population studied and needs to be confirmed with another study of only SIDS infants less than 3 months of age, because DTCP vaccination was not a risk factor for SIDS when considering the total sample of the study.

3. Dr. Viera Scheibner and Leif Karlsson, "Association Between Non-Specific Stress Syndrome, DPT Injections, and Cot Death," (2nd Immunization Conference, Canberra, Australia, May 27-29, 1991).

N Engl J Med. 1988 Sep 8;319(10):618-23. PMID:3261837

Risk of sudden infant death syndrome after immunization with the diphtheria-tetanus-pertussis vaccine.

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Abstract To evaluate recent immunization against diphtheria, tetanus, and pertussis (DTP) as a possible risk factor for sudden infant death syndrome (SIDS), we studied the rates of SIDS after the administration of DTP vaccine in a cohort of 129,834 children who were born in four urban Tennessee counties during the period from 1974 through 1984. All the children received at least one DTP immunization in the first year of life at county health-department clinics or from Medicaid providers. Computerized immunization records from these sources were linked with Tennessee birth and death certificates to establish the cohort, ascertain the timing of immunization, and identify cases of SIDS. These children represented 42 percent of the births in the four counties. Among these children, 204 deaths occurred at the ages of 29 to 365 days; 109 deaths were classified as due to SIDS. We estimated the risk of SIDS according to the length of time, up to 30 days, since DTP immunization and compared it with the risk 31 days or more after immunization to calculate the relative risk. With control for age, the relative risk from 0 to 3 days after DTP immunization was 0.18 (95 percent confidence interval, 0.04 to 0.8); from 4 to 7 days, 0.17 (95 percent confidence interval, 0.04 to 0.7); from 8 to 14 days, 0.75 (95 percent confidence interval, 0.4 to 1.5); and from 15 to 30 days, 1.0 (95 percent confidence interval, 0.6 to 1.6). A multivariate analysis in which we controlled for age, sex, race, year, birth weight, and Medicaid enrollment, produced similar results. We conclude that in this large population of children there was no increase in the risk of SIDS after immunization with the DTP vaccine.

Am J Public Health. 1987 Aug;77(8):945-51. PMID: 3496805 **Free PMC Article**

Diphtheria-tetanus-pertussis immunization and sudden infant death syndrome.

Walker AM, Jick H, Perera DR, Thompson RS, Knauss TA.

Abstract We compared the recency of diphtheria-tetanus-pertussis (DTP) immunization in healthy children with birthweights greater than 2500 gms who died of sudden infant death syndrome (SIDS) to that of age-matched reference children, using a modified case-control analysis. Focusing on very narrow time intervals following immunization, we found **the SIDS mortality rate in the period zero to three days following DTP to be 7.3 times that in the period beginning 30 days after immunization** (95 per cent confidence interval, 1.7 to 31). The mortality rate of non-immunized infants* was 6.5 times that of immunized infants of the same age (95 per cent CI, 2.2 to 19). The latter result and to some extent the former appear to be ascribable to known risk factors for SIDS. Although the mortality ratios for SIDS following DTP, as estimated from this study, are high the period of apparently elevated risk was very short, so that only a small proportion of SIDS cases in infants with birthweights greater than 2500 gms could be associated with DTP. * non-immunised status not confirmed.

Arch Dis Child. 1987 Jul;62(7):754-9. PMID:3498443 **Free PMC Article**

Vaccination and cot deaths in perspective.

Roberts SC.

Abstract In 1985 twin boys simultaneously succumbed to sudden unexpected deaths two to three hours after vaccination with diphtheria, tetanus, and pertussis vaccine (DTP). This occurrence again raises the question of whether an association of sudden infant death (SID) with vaccination is other than temporal. Taking the incidence of SID in conjunction with rates of infant vaccination in the United Kingdom, nine infants would be expected to die, each year by chance alone, suddenly within 24 hours of (and within each 24 hour period succeeding) vaccination with DTP. Twins are at a greater risk of SID than single born infants and occasionally are found dead together. A number of studies into DTP vaccination as a risk factor in SID have shown that SID is less common in vaccinated than in unvaccinated infants.

Am J Dis Child. 1985 Oct;139(10):991-4. PMID:3876024

Ventilatory pattern following diphtheria-tetanus-pertussis immunization in infants at risk for sudden infant death syndrome.

Keens TG, Ward SL, Gates EP, Andree DI, Hart LD.

Abstract To evaluate the effects of diphtheria-tetanus-pertussis (DTP) immunization on the ventilatory pattern during sleep in infants at increased risk for sudden infant death syndrome (SIDS), we performed overnight pneumograms (recordings of ventilatory pattern and electrocardiogram) on 30 control infants, 46 infants with unexplained apnea, and 33 subsequent siblings of SIDSvictims the night before and the night following a DTP immunization. Pneumograms were quantitated for total sleep time, longest apnea (in seconds), total duration of apneas longer than 6 s (in minutes), and total periodic breathing (in minutes). Following the DTP immunization there was no significant change in any criterion quantitated on pneumograms from any group except for a decrease in periodic breathing in the unexplained apnea group. We conclude that DTP immunization does not increase abnormalities of the ventilatory pattern as recorded by the pneumogram technique in infants at increased risk for SIDS.

***Vaccine Injury Compensation.* Hearing Before the Committee on Labor and Human Resources; 98th Congress, 2nd Session, (May 3, 1984), pp. 63-67.**

Pediatr Infect Dis. 1983 Nov-Dec;2(6):492-3. PMID:6657506

DTP and SIDS. *[Letter – no abstract]* Mortimer EA Jr, Jones PK, Adelson L.

S Afr Med J. 1983 Jun 25;63(26):1019-20. PMID:6857437

Three cot deaths in one family. A case report. Van Ieperen L.

Abstract A case of 3 cot deaths in one family is described. Owing to the unexplained nature of this type of death the police sometimes call for investigation. The legal aspects of this investigation are discussed.

Pediatr Infect Dis 1983 Jan-Feb;2(1):7-11. PMID:6835859

Possible temporal association between diphtheria-tetanus toxoid-pertussis vaccination and sudden infant death syndrome.

Baraff LJ, Ablon WJ, Weiss RC.

Abstract Because diphtheria and tetanus toxoids pertussis (DTP) vaccine is routinely given during the period of highest incidence of sudden infant death syndrome (SIDS), this study was undertaken to determine if there is a temporal association between DTP immunization and SIDS. Parents of 145 SIDS victims who died in Los Angeles County between January 1, 1979, and August 23, 1980, were contacted and interviewed regarding their child's recent immunization history. Fifty-three had received a DTP immunization. Of these 53, 27 had received a DTP immunization within 28 days of death. Six SIDS deaths occurred within 24 hours and 17 occurred within 1 week of DTP immunization. These SIDS deaths were significantly more than expected were there no association between DTP immunization and SIDS. An additional 46 infants had a physician/clinic visit without DTP immunization prior to death. Forty of these infants died within 28 days of this visit, seven on the third day and 22 within the first week following the visit. These deaths were also significantly more than expected. These data suggest a temporal association between DTP immunization, physician visits without DTP immunization and SIDS.

Pediatr Infect Dis. 1983 Jan-Feb;2(1):5-6. PMID:6835854

Sudden infant death syndrome, diphtheria-tetanus toxoid-pertussis vaccination and visits to the doctor: chance association or cause and effect? Fulginiti VA.

J Pediatr. 1982 Sep;101(3):419-21. PMID:7108666

Diphtheria-tetanus toxoids-pertussis vaccination and sudden infant deaths in Tennessee. Bernier RH, Frank JA Jr, Dondero TJ Jr, Turner P.

Lancet. 1982 Sep 25;2(8300):721. PMID:6126655

Immunization and cot deaths. Taylor EM, Emergy JL.

70% of SIDS Deaths Occur Within Three Weeks of DPT Vaccination

Torch WC. Diphtheria-pertussis-tetanus (DPT) immunization: a potential cause of the sudden infant death syndrome (SIDS). American Academy of Neurology, 34th Annual Meeting, 1982. Neurology 32(4).

Diphtheria-Pertussis-Tetanus (DPT) Immunization: A Potential Cause of the Sudden Infant Death Syndrome (SIDS) 10:00 AM 3

WILLIAM C. TORCH, Reno, NV

A recent report of eight DPT-associated cot deaths in Tennessee, and knowledge of four sudden deaths within 3½ to 19 hours of inoculation in Nevada (in three infants and one 3-year-old child) stimulated a study on the relationship of SIDS to DPT immunization in over 200 randomly reported SIDS cases. Preliminary data on the first 70 cases studied shows that ⅔ had been immunized prior to death. DPT #1, 2, and 3 were administered on the average at age 2, 4, and 6 months, respectively. In the DPT SIDS group, 6.5% died within 12 hours of inoculation; 13% within 24 hours, 26% within 3 days, and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively. Significant SIDS clustering occurred within the first 2 to 3 weeks of DPT #1, 2, 3, or 4. The age range of the DPT group was 59 days to 3 years (mean age, 3 months); for the non-DPT group, 17 to 172 days (mean age, 2 months). SIDS frequencies peaked at age 2 months in the non-DPT group, and had a biphasic peak occurrence at 2 and 4 months in the DPT group. DPT #1 and 2 were associated with more SIDS than #3 or 4 (ratio 30:11:4:1). Males and females were equally affected. Cot death occurred maximally in the fall/winter season in the non-DPT group, but was nonseasonal in the DPT group. Death occurred most often in sleep in healthy allergy-free infants following brief periods of irritability, crying, lethargy, upper respiratory tract symptoms, and sleep disturbance. Autopsy findings in both groups were typical of SIDS, (e.g. petechiae of lung, pleura, pericardium, and thymus; vascular congestion;

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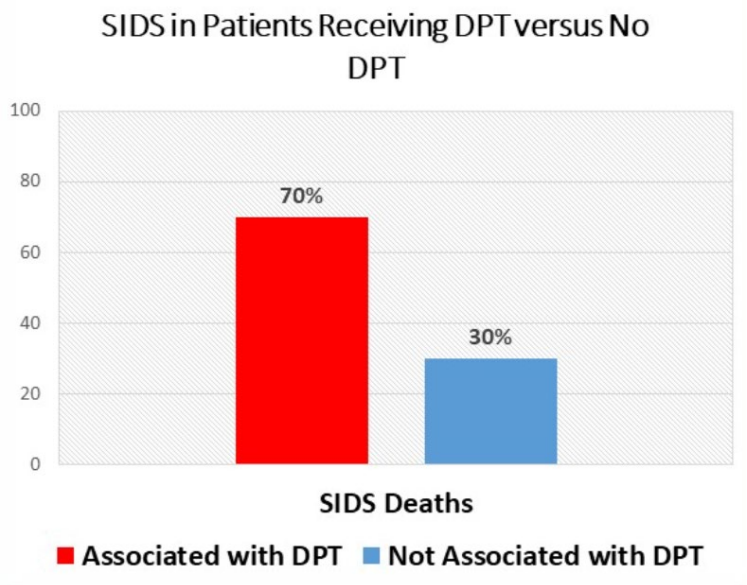
pulmonary edema; pneumonitis; and brain edema). In conclusion, these data show that DPT vaccination may be a generally unrecognized major cause of sudden infant and early childhood death, and that the risks of immunization may outweigh its potential benefits. A need for reevaluation and possible modification of current vaccination procedures is indicated by this study.



In a study of 103 children who died of SIDS, Dr. William Torch, of the U of Nevada School of Medicine at Reno, found that more than 2/3 had been vaccinated with DPT prior to death. Of these, 6.5% died within 12 hrs of

vaccination; 13% within 24 hrs; 26% within three days; and 37, 61, and 70% within one, two, and three weeks, respectively. He also found that SIDS frequencies have a bimodal-peak occurrence at 2 & 4 months - the same ages when initial doses of DPT are administered to infants.

"In the DPT SIDS group, 6.5% died within 12 hours of inoculation; 13% within 24 hours, 26% within 3 days, and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively."

Lancet. 1979 Aug 18;2(8138):354-5. PMID:89408
Deaths of infants after triple vaccine. Stewart GT.

Med J Aust. 1973 Jun 9;1(23):1146-8. PMID:4353505
Simultaneous sudden death in infancy in identical twins.
Beal S. *[No abstract]*

Dtsch Z Gesamte Gerichtl Med. 1965 Apr 1;56:66-73. PMID:14326575
[**SUDDEN DEATH IN CHILDHOOD AND PREVIOUS VACCINATION**]. [Article in German]
MAHNKE PF. [*no abstract*]

Ned Tijdschr Geneeskd. 1964 Oct 24;108:2061-3. PMID:14230242
[SUDDEN DEATH FOLLOWING SMALLPOX VACCINATION IN VERY YOUNG CHILDREN]. [Article in Dutch] DE VRIES E.