



Adverse Events during Pediatric Dental Anesthesia and Sedation: A Review of Closed Malpractice Insurance Claims

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Abstract: Purpose: The purpose of this study of closed malpractice insurance claims was to provide descriptive data of adverse events related to child sedation and anesthesia in the dental office. **Methods:** The malpractice claims databases of two professional liability carriers were searched using pre-determined keywords for all closed claims involving anesthesia in pediatric dental patients from 1993-2007. **Results:** The database searches resulted in 17 claims dealing with adverse anesthesia events of which 13 involved sedation, 3 involved local anesthesia alone, and 1 involved general anesthesia. Fifty-three percent of the claims involved patient death or permanent brain damage; in these claims, the average patient age was 3.6 years, 6 involved general dentists as the anesthesia provider, and 2 involved local anesthesia alone. Local anesthetic overdoses were observed in 41% of the claims. The location of adverse event occurrence was in the dental office where care was being provided in 71% of the claims. Of the 13 claims involving sedation, only 1 claim involved the use of physiologic monitoring. **Conclusions:** Very young patients (≤ 3 -years-old) are at greatest risk during administration of sedative and/or local anesthetic agents. Some practitioners are inadequately monitoring patients during sedation procedures. Adverse events have a high chance of occurring at the dental office where care is being provided. (*Pediatr Dent* 2012;34:231-8) Received July 29, 2010 | Last Revision November 15, 2010 | Accepted December 21, 2010

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In-office sedation usage by dentists to treat children has increased over the past 15 years. It is estimated that between 10% to 20% of children will require pharmacosedation to safely and efficiently complete dental treatment.^{1,2} Children present the highest risk and lowest error tolerance in patient safety during sedation procedures. Although rare, the most serious adverse outcomes of pediatric sedation are brain damage and death. Precipitating adverse events to these tragic outcomes are primarily respiratory in nature owing to the child's respiratory and cardiopulmonary physiology and anatomy. Less serious adverse events range from vomiting and increased secretions to prolonged sedation and recovery.³

Attempts made to extrapolate the annual number of pediatric dental sedations yield estimates of between 100,000 to 250,000.⁴ There is, however, currently no reliable measure of the number of adverse events associated with these sedations or their overall safety record. Furthermore, there is truly no effective manner by which to quantitatively measure anesthetic safety in dentistry for children. Numerous studies have addressed the clinical effectiveness of various sedation regimens and protocols, but while the occurrence of any adverse events is typically included, specific details pertaining to these events are rarely discussed.⁵⁻⁷

Different approaches that have been utilized to study adverse events related to sedation in dentistry include surveys of state dental boards that maintain incident records of major morbidity and mortality, reviews of the Food and Drug Administration (FDA) adverse drug event reporting system, and published case reports.⁸ In their oft-cited study, Goodson and Moore collected published reports, case histories, and court documents involving 14 incidents of life-threatening reactions after pediatric dental sedation; they concluded that polypharmacy with multiple central nervous system (CNS) depressant agents may lead to unpredictable and severe interactions.⁹ The FDA database was recently used in a large study of adverse sedation events in pediatrics, in which the authors identified that a disproportionate number of cases resulting in death or permanent neurologic damage involved anesthesia/sedation for dental procedures.^{10,11}

Another means for studying adverse events is to survey dental practitioners directly. Many surveys have been completed to identify trends in sedation usage, preferred sedation regimens, and assessments of sedation success. No published survey studies, however, have specifically targeted adverse outcomes and the events leading up to them.^{1,12-19}

Analysis of closed malpractice claims from insurance carriers is another method of studying adverse events related to sedation and anesthesia. A malpractice claim is a demand for financial compensation for an alleged injury resulting from medical care, and it is considered "closed" when it has been dropped, settled by the parties, or adjudicated by the courts.²⁰ Interestingly, if a clinician chooses to report an adverse event even before he or she knows whether or not there will be a demand for compensation, the malpractice carrier will open an incident report, which may be considered a claim under the

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insurance policy. Even if there was no injury and no lawsuit, this type of information might capture near-misses that would otherwise never be reported to state or federal agencies.

The field of medical anesthesiology has been studying anesthesia safety via closed claims analyses since the 1980s. Through extensive analyses of the American Society of Anesthesiology (ASA) closed claims data, trends in anesthetic injury have been noted over the years that have led to suggestions in risk management strategies to improve patient safety. One such trend was the finding that esophageal intubations represented a large subclass of respiratory events leading to claims. This finding from the closed claims analysis is credited as an impetus for current standards requiring end-tidal carbon dioxide (CO₂) monitoring.²¹ Another large subclass of respiratory events leading to claims was difficult tracheal intubations, which led to the development of the first published ASA practice guidelines for management of the difficult airway.²²

Thus, closed claims analyses can help identify important anesthetic complications, mechanisms of injury, and problem areas for future research opportunities. The closed claims study model has been utilized infrequently in the dental research community. Published dental closed claim reports have primarily analyzed claims generated from oral and maxillofacial surgeons, with no such reports specifically analyzing claims from pediatric dentists or claims specifically involving children.^{23,24}

The utilization of closed malpractice claims to study adverse events and outcomes during sedation and anesthetic administration has never been performed to study pediatric dental anesthesia.

The purpose of this retrospective closed malpractice claims study was to provide descriptive data of adverse events related to pediatric sedation and anesthesia during dental treatment to help understand etiologic factors and to suggest preventive measures to improve patient safety.

Methods

This study was approved by the Institutional Review Board of the University of Kentucky, Lexington, Ky. The malpractice claims databases of 2 leading dental professional liability insurers were searched using predetermined keywords for all closed claims involving anesthesia in pediatric dental patients from 1993 to 2007. Medical Protective (MedPro) was selected as a data source because it is endorsed by the American Academy of Pediatric Dentistry (AAPD), insures health care professionals in all 50 states, and has the largest pediatric dentist market share in the country. The Dentists Insurance Company (TDIC) represents primarily general dentists and is licensed to insure in 40 states. The entire dental claims databases of these 2 companies were searched using the following keywords, any of which could produce a positive search result: "pediatric dentist"; "anesth"; "sedat"; "oral med"; "IV"; "IM"; "child"; and "death."

The resulting claims were reviewed and then further selected using the following criteria. Claims involving oral surgeons as the treatment provider were excluded from the results; however, claims involving oral surgeons as the anesthesia provider were included. Also excluded were those claims that involved patients older than 13-years-old; involved treatment outside the dental office setting (ie, in a surgery center or hospital); and resulted from an event unrelated to the administration of a sedative and/or anesthetic. For example, a claim was excluded if it involved a child who had been sedated for

dental procedures and the claim was filed because the child's parent was dissatisfied with the particular type of restorative treatment provided. After excluding the nonrelated claims from the initial database query results, the final regression resulted in 17 unique claims. Due to the small number of resultant claims, quantitative statistical analyses were not performed.

The 17 claims meeting the selection criteria were reviewed, and as much of the following qualitative data as possible were collected using a standardized form created by the authors:

1. the patient's age, sex, weight, and health history;
2. classification of provider(s) for dental treatment and anesthetic administration;
3. the anesthetic/sedative technique used;
4. the dental procedure initiated and duration of procedure;
5. the setting of the dental procedure;
6. monitoring and personnel utilization;
7. specific drugs and dosages administered and routes of administration;
8. the setting of the adverse event;
9. the nature of the adverse event and any clinical clues noted leading up to the event;
10. intervention initiated for the adverse event; and
11. result and severity of any adverse outcomes.

A narrative summary of each reviewed claim was also obtained to provide a detailed description of the events and outcomes and to ensure that all potentially relevant information was recorded. The level of information contained within the claims varied significantly, with some claims including the complete dental record, narrative statements by involved personnel, expert reviews, deposition summaries, and the cost of the settlement or award. Other claims included only brief statements of the event and the outcome. This study's focus was not on quantitative analyses, but rather on giving a complete representation of all pediatric dental anesthesia-related malpractice claims that have occurred over the past 15 years from 2 leading insurance carriers. Hence, the decision was made to include all claims meeting the criteria even if specific details were sparse or unavailable.

To tabulate the outcomes of the adverse events, claims were classified as either having major outcome severity (ie, death or permanent brain damage) or minor outcome severity (ie, no significant morbidity). Even though previous closed claims studies have primarily focused on major morbidity and mortality, in this study both major and minor outcome severity were included to ensure that near-miss incidents would be captured.

For those claims in which local anesthetics and/or sedative agents were administered, drug dosages in milligrams/kilogram (mg/kg) were calculated using the patient's weight. If a patient's weight was unavailable from the claims information, a weight was estimated based on the 50th percentile for the child's sex and age.²⁵ To determine whether or not an overdose of local anesthetic was administered, the percent relative to the maximum recommended dose (MRD) for the patient's weight was calculated, and any dosage greater than 100% of the MRD was considered an overdose.²⁶ Sedative dosages were also calculated using the patient's weight or estimated weight as previously described; however, comparison to the MRD could not reliably be performed due to the somewhat inconsistent range of suggested pediatric dosing by drug manufacturers and authors of sedation studies. An attempt was

made to determine if an administered dose was either a weight-based or a fixed dose, but this, too, could not be reliably performed without making multiple assumptions, and was, thus, not reported.

Results

Table 1 illustrates the demographics and characteristics of the 17 claims. The ages of patients involved were 1- to 11-years-old, with a median age of 3-years-old, and 82% of the patients were younger than 6-years-old. An equal distribution of age was observed by type of anesthesia provider.

Most of the claims (76%) involved the administration of 1 or more sedative agents (with or without administration of a local anesthetic agent). The 1 claim involving a general anesthetic was included because it occurred in a dental office. Of the 13 claims involving sedations, 10 involved an oral drug administration, 1 involved oral and intramuscular administration, and the route was unknown in 2 claims.

Fifty-three percent of the claims (N=9) involved major outcome severity. Of these 9 claims, the average patient age was 3.6 (±1.87) years old, 67% (N=6) involved general dentists as the anesthesia provider, and 22% (N=2) involved local anesthesia alone. The outcome severity did not vary markedly when compared to the type of anesthesia administered or anesthesia provider.

The types of drugs and dosages administered in the claims involving sedation varied widely (Table 2). No single sedative agent was most frequently associated with major outcome severity.

Local anesthetic overdoses were observed in 41% (N=7) of the claims and ranged from 118% to 356% of the MRD (Table 3). Of these overdoses, 57% (N=4) were administered during sedation procedures, and 43% (N=3) occurred when local anesthetic was the only drug given. General dentists were the anesthesia provider in 86% (N=6) of the claims involving local anesthetic overdose followed by pediatric dentists (14%, N=1).

The location of adverse event occurrence was in the dental office where care was being provided in 71% (N=12) of the claims. Eight of these claims resulted in major outcome severity. The location of the adverse event in the remaining 29% (N=5) of claims was either at the patient's home, during transport, or at another dental office. Of these claims, only 1 resulted in major outcome severity.

Of the 13 claims involving sedation, definitive physiologic monitoring was utilized in only 1 claim (8%). The practitioner in this claim utilized pulse oximetry. In 46% (N=6) of the claims, monitoring was recorded as either "visual only" or "none." In the remaining 46% (N=6) of claims, the monitoring method could not be determined from the information contained within these claims. What follows is a brief synopsis of each claim.

Case 1. A 36-pound (16.4 kg), 3-year, 11-month-old male patient presented to a dental clinic for restorative treatment. The patient was given 50 mg of hydroxyzine (3 mg/kg) and 10 mg (0.6 mg/kg) of diazepam orally. One hour later, he was placed on a papoose board and given 2.5 cartridges of 2% lidocaine (90 mg, 5.5 mg/kg) along with 50% nitrous oxide (N₂O)/50% oxygen (O₂). Treatment was uneventful for 45 minutes until the patient exhibited signs of vomiting. His mouth and throat were suctioned, but nothing was retrieved. A few minutes later, he had a second episode of vomiting and

stopped breathing. The dentist checked for vital signs and, finding none, began cardiopulmonary resuscitation (CPR). Paramedics were called, and after their arrival, transported the child to the local hospital. His breathing was restored, but he suffered hypoxic brain damage and died 3 days later.

Demographic/characteristic	N (%)
<i>Patient's age (ys)</i>	
1-3	9 (53)
4-6	5 (29)
7-11	3 (18)
<i>Patient's gender</i>	
Male	10 (59)
Female	7 (41)
<i>Type of anesthesia administered</i>	
Sedation +/- local anesthetic	13 (76)
Local anesthetic alone	3 (18)
General anesthetic	1 (6)
<i>Type of anesthesia provider</i>	
General dentist	11 (65)
Pediatric dentist	4 (23)
Oral surgeon	1 (6)
Orthodontist	1 (6)
<i>Outcome severity</i>	
Major (death or brain damage)	9 (53)
Minor (no permanent morbidity)	8 (47)
<i>Adverse event location</i>	
At treating office	12 (71)
At home or another office	5 (29)
<i>Type of monitoring used (in sedation claims; N=13)</i>	
Pulse oximeter	1 (8)
Visual only or none	6 (46)
Could not be determined	6 (46)

Case no.	Age (ys, mos)	Sedative agent(s)	Mg	Mg/kg	Outcome
1	3, 11	Hydroxyzine	50	3	Death
		Diazepam	10	0.6	
2	8	Chloral hydrate	1,700	75	Brain damage
		Hydroxyzine	100	4.4	
3	5	Hydroxyzine	8.75	0.6	Death
		Diazepam	10	0.7	
4	2	Chloral hydrate	Unknown		Death
5	3	Meperidine	12	0.9	Death
		Promethazine	25	1.8	
6	3	Unknown			Death
10	7	Unknown			Recovery
11	5	Meperidine promethazine	Unknown		Recovery
12	11	Midazolam	Unknown		Recovery
13	2, 2	Chloral hydrate	250	23	Recovery
		Meperidine	50	4.6	
		Hydroxyzine	62	5.8	
14	4	Chloral hydrate	1,000	50	Recovery
15	5	Chloral hydrate	1,000	55.6	Recovery
16	3, 6	Chloral hydrate	1,000	52	Recovery

Case 2. A 50-pound (22.7 kg), 8-year-old male patient presented to a dental clinic for full-mouth caries removal and restorative treatment. The patient's medical history included attention deficit disorder, for which he was taking Adderall (amphetamine/dextroamphetamine). He was given 1,700 mg of chloral hydrate (75 mg/kg) and 100 mg of hydroxyzine (4.4 mg/kg) orally. Fifty minutes later, the patient was brought into the operator crying and anxious and was placed in a papoose. He then stopped crying and turned blue. The papoose was removed and the dentist administered O₂. It was determined that the child had no pulse. Paramedics arrived 8 minutes later and began resuscitation efforts. The child was transported to a local hospital where he remained in a coma for approximately 3 days. The child sustained hypoxic brain damage and required extensive rehabilitation therapy.

Case 3. A 30-pound (13.6 kg), 5-year-old female patient presented to a dental clinic for restorative treatment. The patient was given 8.75 mg of hydroxyzine (0.64 mg/kg) and 5 mg diazepam orally. After 15 minutes, the patient was brought into the operator where she vomited. Another 5 mg of diazepam (0.74 mg/kg total) was given orally. The child was still crying and anxious and was placed in a papoose board. Three cartridges of 2% lidocaine (108 mg, 7.9 mg/kg) were administered along with 50% N₂O/50% O₂. During the procedure, the child continued to cry. The patient's arm broke free from the papoose, which was missing one of its Velcro straps. The dentist stopped the procedure and instructed the dental assistant to restrap the free hand. The dentist removed a bite block and left a cotton roll in place.

In an effort to calm the child, the dentist covered the child's mouth so that the child would breathe the N₂O through the nasal hood. When the child's hand was restrapped, the dentist's hand was removed from the child's mouth. The child gasped and aspirated the cotton roll. The dentist attempted to remove the cotton roll with high-speed suction, which caused the throat to bleed. Paramedics were called and arrived within 4 minutes, but were unable to visualize the cotton roll due to the bleeding. After attempting to remove the cotton roll for 10 minutes, the child was transported to the local hospital. At the emergency room, the child was intubated and the cotton roll was removed. She was given O₂ and her circulatory system restarted spontaneously. The child was trans-

ported to a local children's hospital where she remained on life support for 2 days before being declared brain dead.

Case 4. A 2-year-old male patient presented to a dental clinic for treatment. The patient's medical history included Russell-Silver syndrome. The child was premedicated with chloral hydrate by mouth 1.5 hours prior to the procedure. Toward the end of the dental procedure, the dentist noted that the child's respiratory rate had slowed. Paramedics were called immediately, and the dentist began CPR. Paramedics arrived, intubated the child at the dental office, and transported him to a local hospital. The child was pronounced dead upon arrival at the emergency department.

Case 5. A 3-year-old female patient presented to a dental clinic for restorative treatment. Prior to the procedure, the child was administered 12 mg meperidine and 25 mg promethazine orally. The patient was also given 1.2 cartridges of 2% lidocaine (43.2 mg, 3.1 mg/kg) for local anesthesia. Treatment was completed without incident, and the patient was discharged into the parent's care. Four hours after leaving the dental office, the child's parent called the paramedics from home. The patient was transported to the emergency department where she was thought to be brain dead upon arrival. The patient was transferred to the intensive care unit and pronounced dead.

Case 6. A 3-year-old male patient presented to a dental clinic for treatment. Prior to dental treatment, the child was given a combination of drugs that had been prescribed for another patient. The amount and types of drugs administered is not known. The patient went into respiratory arrest at some point during the dental procedure. The paramedics were called and the patient was transported to the local children's hospital. Upon arrival, no brain activity was detected. The patient was pronounced dead the following day.

Case 7. A 2-year, 6-month-old female patient presented to a dental clinic for restorative treatment. The patient was administered 1.25 cartridges of 3% mepivacaine plain (67.5 mg, 5.2 mg/kg) for local anesthesia. During local anesthetic administration, the child was crying, but then fell asleep afterwards. After treatment was completed, which consisted of 4 stainless steel crowns, the child could not be aroused. The dentist carried the child next door to another clinic to receive assistance in resuscitative efforts. Paramedics were called and the child was pronounced dead upon their arrival.

Case 8. A 36-pound (16.4 kg), 4-year, 1-month-old male patient presented to a dental clinic for extensive restorative treatment involving 3 quadrants of decay. The patient's medical history included obstructive sleep apnea, and he was reported as being congested on the day he presented for dental treatment. The patient was placed in a papoose board and was administered 3 cartridges of 2% lidocaine (108 mg, 6.6 mg/kg) within 3 minutes. After a few minutes, the patient appeared to fall asleep. Within 15 minutes of beginning treatment, the dental assistant noticed that the patient's tongue was purple. He was unwrapped from the papoose.

The patient's vital signs were checked and there was no detectable pulse or breathing. CPR was started and the paramedics were called. Paramedics arrived within 4 minutes of the call and assumed the resuscitative efforts. The patient was intubated, after which a volume of thick, mucous-filled fluid was suctioned from his airway. When the paramedics' efforts to resuscitate the child were

Table 3. DETAILS OF CLAIMS INVOLVING LOCAL ANESTHETIC OVERDOSE

Case no.	Age (ys, mos)	Type of anesthesia*	Anesthesia provider†	Local anesthetic	% MRD	Outcome
1	3, 11	Oral sed, LA	GP	Lidocaine	125	Death
3	5	Oral sed, LA	GP	Lidocaine	180	Death
7	2, 6	LA	GP	Mepivacaine plain	118	Death
8	4	LA	GP	Lidocaine	150	Death
9	1, 10	LA	Pedo	Prilocaine plain	356	Recovery
13	2, 2	Oral and IM sed, LA	GP	Lidocaine	300	Recovery
14	4	Oral sed, LA	GP	Lidocaine	164	Recovery

* MRD=maximum recommended dose; oral sed=oral sedation; LA=local anesthetic; IM sed=intramuscular sedation; GP=general practitioner; pedo=pediatric dentist.

unsuccessful, the child was transported to the local children's hospital, where he was pronounced dead.

Case 9. A 1-year, 10-month-old female patient presented to a dental clinic for extractions and restorative treatment with stainless steel crowns. The child was struggling and crying and was placed in a papoose board. Once the patient was secured in the papoose, 40% N₂O/60% O₂ was administered, followed by 3 cartridges of 4% prilocaine plain. A fourth cartridge of 4% prilocaine plain was being administered. After injecting half the cartridge (252 mg total, 21.4 mg/kg), the patient began having seizures. Paramedics were called, and upon their arrival the patient was intubated and given diazepam. The patient was then transported to the hospital and observed in the pediatric intensive care unit for 1 day. She was then discharged the following day. The patient was followed by a neurologist for the following year and was determined to have not suffered any significant sequelae from the incident.

Case 10. A 7-year-old male patient was to be treated in a dental clinic for extractions. In preparation for the procedure, the treating dentist called into the local pharmacy a prescription for an oral sedative (type of sedative and dosage unknown). Following the instructions that the child's parent received with the prescription, 3 tablespoons of elixir were administered at home 1 hour prior to the dental appointment. When the patient arrived at the dental clinic, he was breathing but in a very sedated state. His vital signs were monitored, O₂ was administered, and the paramedics were called. No dental treatment was performed. The paramedics transported the patient to the local hospital where he was kept for overnight observation. He was discharged the next day without complications and attended school. It should be noted that in this case, the treating dentist claimed that the ordered prescription was for an at-home administration of 3 teaspoons of oral sedative rather than the 3 tablespoons that were given.

Case 11. A 5-year-old female patient with a history of asthma and respiratory problems presented to a dental clinic for extractions. The patient was given meperidine and promethazine (dose and route unknown) as well as N₂O/O₂ sedation (dose unknown). It is also assumed that the patient was given a local anesthetic agent, although the type and dosage was not reported. The treatment was completed uneventfully, and the patient was discharged into the parent's care. An unknown amount of time after leaving the office, the child's parent felt that the child was having difficulty breathing and called the paramedics. The child was transported to the hospital for observation, where it was determined that she had not suffered any cardiorespiratory compromise.

Case 12. An 11-year-old male patient presented to a dental clinic for treatment. Prior to the procedure, the patient received midazolam (dose and route unknown). The patient was monitored throughout the procedure with pulse-oximetry. At some point during treatment, the patient experienced a decrease in O₂ saturation levels due to airway obstruction by the tongue. Oxygen was administered and the paramedics were called. Upon the paramedics' arrival, the patient was found to be stable and no hospital transport was required.

Case 13. A 24-pound (10.9 kg), 2-year, 2-month-old male patient was scheduled for restorative treatment for extensive caries. The dentist provided a cocktail of medications with

instructions for the patient's mother to administer 2 teaspoons at bedtime and 1 teaspoon 1 hour prior to the appointment. Components of the oral cocktail included hydrocodone bitartrate, hydroxyzine (5.8 mg/kg total dose), and chloral hydrate (25 mg/kg total dose). Upon the patient's arrival at the dental clinic, he was still quite active, so he was placed in a papoose and the dentist attempted to administer N₂O unsuccessfully.

The dentist then gave the child 4 cartridges of 2% lidocaine (144 mg, 13.2 mg/kg) and 2 separate 25 mg intramuscular injections of meperidine (4.6 mg/kg). A bite block was placed in the child's mouth and treatment was initiated. During treatment, the child's parent, who was observing the procedure, noticed that the child was blue and did not appear to be breathing. The dentist administered naloxone (dose and route unknown), and the parent initiated CPR. Paramedics arrived and noted that the child was in respiratory arrest and having seizures. The child was transported to the local hospital, where he continued to have seizures for 30 minutes and remained unconscious for 3 hours. He regained consciousness and was discharged the following day in satisfactory condition.

Case 14. A 44-pound (20 kg), 4-year-old male patient presented to a dental clinic for restorative treatment with stainless steel crowns. The patient was premedicated with 500 mg chloral hydrate orally. Four cartridges of 2% lidocaine (144 mg, 7.2 mg/kg) were administered. The patient was apparently very calm, and restorative treatment was initiated. At some point during the procedure, the patient awakened and was given another 500 mg chloral hydrate orally (50 mg/kg total dose). Treatment was completed, and the patient was discharged. Five hours after initiating treatment, the patient was sleeping at home and could not be aroused. His parents transported him to the emergency department where he was treated and monitored for 4 hours. The child was then discharged in satisfactory condition.

Case 15. A 5-year-old male patient presented for restorative treatment with stainless steel crowns. The patient was given 1,000 mg chloral hydrate orally prior to the procedure. The patient did not appear to be sedated and was not cooperative for treatment. Because the patient was in pain, however, he was referred to another dental facility for emergency dental treatment. En route to the office, the patient fell asleep in the car. Upon arrival at the other dental facility, the dentist was concerned about the child's level of sedation and called the paramedics. The child was transported to the local hospital where he was monitored in the emergency department for 3 hours. He was then transferred to another hospital where he remained for overnight observation, and was released the following day.

Case 16. A 42-pound (19 kg), 3-year, 6-month old male patient presented for restorative dental treatment. The child was premedicated with 1,000 mg chloral hydrate (52 mg/kg) orally and then waited in the reception area. Approximately 15 minutes after drug administration, the patient became very groggy. He stood up, fell down, and bumped his head. The dental treatment was then performed without incident.

Case 17. A 3-year-old female patient presented to a dental clinic for restorative treatment. The patient was administered a general anesthetic by an oral and maxillofacial surgeon, who routinely worked with the treating dentist providing in-office anesthesia for the dentist's patients. The types of drugs and

dosages given were not reported. During treatment, the patient stopped breathing. Resuscitative efforts were initiated but were unsuccessful, and the patient was pronounced dead.

Discussion

Eighty-two percent of the claims in this study involved adverse event occurrences in patients younger than 6-years-old, which is not surprising, considering that this is the age group most commonly sedated in the dental office. Results of a 2000 survey of pediatric dentists indicate that 78% of sedated patients were younger than 6-years-old.¹ When considering the adverse events with major outcome severity (death or permanent brain damage), the average patient age was 3.6-years-old. This finding confirms that sedation risk and patient age are inversely related and reinforces the importance of heightened vigilance when sedating the very young patient, regardless of the number of event-free sedations a practitioner has performed.

The fact that general dentists were the most common anesthesia provider associated with adverse event claims (65% of the time) and with claims resulting in major outcome severity (67% of the time) could be due to several factors. It is unknown how many in-office sedations for children are provided by U.S. general dentists, and states' dental practice acts vary widely regarding the certification required to provide such sedation. Considering that 80% of U.S. dentists are generalists and most of the country's children are treated by generalists, one could speculate that there is simply a numerically greater chance of a claim being generated by a general dentist than a specialist.²⁷ Another possibility is that generalists were most commonly associated with adverse patient events because they have received less comprehensive training in the management and treatment of pediatric patients. In either case, it indicates that general dentists are providing sedation services to children and, thus, should have an in-depth knowledge of the current AAPD/American Academy of Pediatrics (AAP) Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.²⁸

The source of the claims data must also be considered when examining the anesthesia provider. Even though MedPro insures the largest market share of pediatric dentists in the country and TDIC represents primarily general dentists, both insurance companies represent both generalists and specialists. The overall proportion of generalists to specialists for each company is unknown; thus, it is not possible to draw conclusions from the proportion of claims generated by each provider group.

The fact that minor outcome severity occurred in 47% of studied claims indicates that nearly half of the anesthesia-related adverse events were either managed properly by health care personnel or were self-limiting. Whether an adverse event resulted in major or minor outcome severity did not appear to have any association with the type of anesthesia provider or type of anesthesia administered.

Seventy-six percent of the aforementioned claims involved the administration of 1 or more sedative agents (with or without concomitant use of a local anesthetic agent). While most sedative administration was via an oral route, both the drug regimens and the drug dosages associated with adverse events varied widely. No single sedative agent was most frequently associated with major outcome severity. This may suggest that the drug dosage administered is more important than the specific drug choice. Even though it cannot be definitively con-

firmed, it appears from the numeric dosage amount in many of the claims that a fixed dose of medications was administered rather than a weight-based dose. The use of standard fixed dosing is problematic and has consistently been discouraged, since a sedation regimen should be individually based on, among other things, patient temperament, age and weight, and the amount and difficulty of dentistry planned.

An unexpected finding was that 41% of claims (N=7) involved the administration of an overdose of a local anesthetic agent, ranging from 118% to 356% of the MRD. The widespread use of local anesthesia in dentistry is generally very safe and effective. Serious adverse reactions, though rare, are occasionally reported in the literature; when involving children they are usually the result of dose-dependent toxicity reactions.^{29,30} The present study's findings suggest that there continues to be local anesthetic overdoses resulting in significant morbidity and mortality in children. The local anesthetic preparation of lidocaine has been cited as the least likely to cause toxicity reactions in children due to its dosage, volume, and vasoconstrictor concentration.^{29,31}

It is interesting to note that 2% lidocaine was the most frequently implicated local anesthetic when a toxic overdose was given. This is very likely because it is a much more commonly used local anesthetic and would, thus, have a statistically greater chance of being associated with an adverse event. Another interesting observation, for which there is no apparent explanation, is that 3 of the claims involving the highest local anesthetic overdoses (164%, 300%, and 356% of the MRD) resulted in minor outcome severity.

In this study, local anesthetic overdoses were found to occur both during sedation visits and when a local anesthetic was the sole agent. These findings underscore the universal importance that all dental practitioners treating children should consistently calculate a weight-based MRD of both sedative agents and local anesthetics. Additionally, practitioners should adjust downward the doses of local anesthetic when sedating children with drugs that are known to cause respiratory depression. It has been well documented that sedation with opioids and other CNS depressant agents like chloral hydrate may increase the risk of local anesthetic toxicity due to their synergistic CNS depressing effects, especially in children.^{9,32}

It has also been stated that local anesthetic toxicity reactions may be masked by the administration of benzodiazepines during sedations, thus making it more difficult for the practitioner to recognize a local anesthetic overdose. The current study supports this, as the only 2 claims involving benzodiazepine sedatives, in which the outcome was death, also involved a concomitant local anesthetic overdose.

The fact that most claims in this study involved adverse events at the dental office (vs in transit or at home after discharge) indicates that the treating dental practitioner will likely be the first responder in managing adverse events when they occur. Unfortunately, of the adverse events in this study that occurred at the dental office, most resulted in major outcome severity. From the details available, it suggests that by the time the initial event was recognized by the dentist, too much time had already elapsed, which reduced the chance of success for resuscitation. This finding emphasizes the importance of the treating dentist and staff's ability to both diagnose and manage adverse events as they occur.

Only 1 of the 13 sedation cases reported the use of pulse oximetry monitoring during treatment. Of the remaining 12 cases, 6 involved "visual monitoring only" or "no monitoring," and in the remaining 6 claims, monitoring practices could not be determined. A major emphasis of the AAPD/AAP sedation guideline has been monitoring. Clinicians' lack of adherence to the guideline is troubling, especially considering that the pulse oximeter and precordial stethoscope have been indicated as minimum monitoring for moderate (previously called "conscious") sedation since the 1993 guideline revision. The sedation of children represents a continuum rather than a static sedated state, and "it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation."²⁸ This deeper, unintended level of sedation occurred in several claims in this study, as evidenced by patients who could not be aroused and patients who were only found to be in distress after cyanosis was noticed.

Although it has been stated frequently in multiple publications, it is worth repeating that proper monitoring of children during sedation is paramount in detecting the subtle physiologic changes that may precede a very severe outcome. The multifactorial nature of most of the adverse events presented in this study highlights the many different aspects of care that the dentist must be cognizant of to ensure patient safety. The importance of heightened vigilance during child sedations cannot be overstated enough.

In 2 of this study's claims, dentists instructed parents to administer sedation drugs at home. While neither case resulted in major outcome severity, it reveals that some dentists are directly violating the AAPD/AAP sedation guideline, which clearly states that prescription sedation medications are not to be administered at home without direct supervision by the dentist. While the current guideline acknowledges that adherence cannot guarantee a specific patient outcome, it has been suggested that, when the guideline is followed, significant morbidity and mortality are minimal. Retrospectively determining whether or not the guideline has been followed depends on proper documentation in multiple areas, including: preoperative health assessment; details of the medications ordered and given; personnel; monitoring; and postoperative discharge criteria. From the type—and sometimes lack—of data available in this study, the proportion of practitioners adhering to the guideline cannot be determined.

Since general dentists may be unfamiliar with the Academy's guideline, however, it is important that the AAPD sedation guideline be promulgated to general dentists with adherence strongly encouraged for all practitioners who sedate children. Additionally, it may be of benefit if, at the dental school level, students are made aware of the advanced didactic and clinical training required to sedate children as well as the necessary certification required by their state dental board. Only with proper education and strict adherence to the Academy's guideline will practitioners be most prepared to safely sedate children for dental procedures.

Limitations in this study are similar to those of any closed claims analysis, and these have been well documented.^{33,34} Malpractice claims are a highly selective subset and not necessarily a cross-section of all adverse events. Not all adverse events result in malpractice claims, and thus would not be included in a closed claims study. Since this study considers only 2 of the many malpractice companies' claims histories, it cannot be

stated that their claims data are necessarily representative of claims throughout the country.

Also, because the total number of anesthetic and sedative administrations is unknown, the incidence and, thus, risk of anesthetic-related adverse events cannot be calculated. Depending on the nature of the adverse event, it can take anywhere from 1 to 5 years from the date of injury for a claim to close. Thus, there is a period of time during which claims are not available for review even though adverse events have occurred. Therefore, any recent changes in anesthetic injury trends may not have been identified in this study. With the most recent AAPD sedation guideline being published in 2006, it is unlikely that any changes in practice as a result of the new guideline would be reflected in this study's results.

The following recommendations are made based upon the findings from this study:

1. All children should be weighed prior to dental treatment.
 - a. Weight-based dosages of both local anesthetics and sedative agents should consistently be calculated to minimize the risk of overdose toxicity reactions.
 - b. Local anesthetic doses should be lowered when given in combination with any CNS depressing sedative agents.
2. Proper monitoring consistent with the American Academy of Pediatric Dentistry sedation guideline should be observed by any dental practitioner administering sedative agents to children for dental treatment.
3. Since the treating dentist will likely be the first responder during an adverse event, the dentist and staff must be prepared to diagnose and begin treating such emergencies.
4. Vigilance to all details, however minor, and absolute compliance with the AAPD sedation guideline are necessary to ensure the safest environment when children are being treated with any medications in the dental office.

Conclusions

Based on this study's results, the following conclusions can be made:

1. Very young patients (3-years-old or younger) are at greatest risk during administration of sedative and/or local anesthesia agents.
2. Some practitioners are inadequately monitoring patients during sedation procedures.
3. Adverse events have a high chance of occurring at the dental office where care is being provided.

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References

1. Houpt M. Project USAP 2000: Use of sedative agents by pediatric dentists—15-year follow-up survey. *Pediatr Dent* 2002;24:289-94.
2. Saxen MA, Wilson S, Paravecchio R. Anesthesia for pediatric dentistry. *Dent Clin North Am* 1999;43:231-45, vi.
3. Cravero JP, Blike GT, Beach M, et al. Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: Report from the Pediatric Sedation Research Consortium. *Pediatrics* 2006;118:1087-96.
4. Wilson S. Pharmacological management of the pediatric dental patient. *Pediatr Dent* 2004;26:131-6.
5. Chowdhury J, Vargas KG. Comparison of chloral hydrate, meperidine, and hydroxyzine to midazolam regimens for oral sedation of pediatric dental patients. *Pediatr Dent* 2005;27:191-7.
6. Shapira J, Kupietzky A, Kadari A, Fuks AB, Holan G. Comparison of oral midazolam with and without hydroxyzine in the sedation of pediatric dental patients. *Pediatr Dent* 2004;26:492-6.
7. Torres-Perez J, Tapia-Garcia I, Rosales-Berber MA, Hernandez-Sierra JE, Pozos-Guillen Ade J. Comparison of three conscious sedation regimens for pediatric dental patients. *J Clin Pediatr Dent* 2007;31:183-6.
8. Krippaehne JA, Montgomery MT. Morbidity and mortality from pharmacosedation and general anesthesia in the dental office. *J Oral Maxillofac Surg* 1992;50:691-8; discussion 98-9.
9. Goodson JM, Moore PA. Life-threatening reactions after pedodontic sedation: An assessment of narcotic, local anesthetic, and antiemetic drug interaction. *J Am Dent Assoc* 1983;107:239-45.
10. Cote CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: A critical incident analysis of contributing factors. *Pediatrics* 2000;105:805-14.
11. Cote CJ, Karl HW, Notterman DA, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: Analysis of medications used for sedation. *Pediatrics* 2000;106:633-44.
12. Allen SC, Bernat JE, Perinpanayagam MK. Survey of sedation techniques used among pediatric dentists in New York State. *N Y State Dent J* 2006;72:53-5.
13. Acs G, Musson CA, Burke MJ. Current teaching of restraint and sedation in pediatric dentistry: A survey of program directors. *Pediatr Dent* 1990;12:364-7.
14. Flick WG, Katsnelson A, Alstrom H. Illinois dental anesthesia and sedation survey for 2006. *Anesth Prog* 2007;54:52-8.
15. Houpt M. Report of project USAP: The use of sedative agents in pediatric dentistry. *J Dent Child* 1989;56:302-9.
16. Houpt M. Project USAP: The use of sedative agents in pediatric dentistry—1991 update. *Pediatr Dent* 1993;15:36-40.
17. Klingberg G, Dahllof G, Erlandsson AL, et al. A survey of specialist pediatric dental services in Sweden: Results from 2003, and trends since 1983. *Int J Paediatr Dent* 2006;16:89-94.
18. Nathan JE. Management of the difficult child: A survey of pediatric dentists' use of restraints, sedation, and general anesthesia. *J Dent Child* 1989;56:293-301.
19. Wilson S. A survey of the American Academy of Pediatric Dentistry membership: Nitrous oxide and sedation. *Pediatr Dent* 1996;18:287-93.
20. MacRae MG. Closed claims studies in anesthesia: A literature review and implications for practice. *AANA J* 2007;75:267-75.
21. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: What have we learned, how has it affected practice, and how will it affect practice in the future? *Anesthesiology* 1999;91:552-6.
22. Practice guidelines for management of the difficult airway: A report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. *Anesthesiology* 1993;78:597-602.
23. Jastak JT, Peskin RM. Major morbidity or mortality from office anesthetic procedures: A closed-claim analysis of 13 cases. *Anesth Prog* 1991;38:39-44.
24. Deegan AE. Anesthesia morbidity and mortality, 1988-1999: Claims statistics from AAOMS National Insurance Company. *Anesth Prog* 2001;48:89-92.
25. Centers for Disease Control and Prevention. Clinical growth charts. Available at: "http://www.cdc.gov/growthcharts/clinical_charts.htm". Accessed April 27, 2010.
26. Malamed S. *Handbook of Local Anesthesia*. 5th ed. St. Louis, Mo: Mosby; 2004.
27. American Dental Association. Distribution of dentists. Available at: "https://www.ada.org/sections/professionalResources/pdfs/07_dod_highlights.pdf". Accessed April 27, 2010.
28. American Academy of Pediatric Dentistry. Guideline for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update developed through a collaborative effort between the AAPD and the American Academy of Pediatrics. Available at: "http://www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf". Accessed April 27, 2010.
29. Virts BE. Local anesthesia toxicity review. *Pediatr Dent* 1999;21:375.
30. Hersh EV, Helpin ML, Evans OB. Local anesthetic mortality: Report of a case. *J Dent Child* 1991;58:489-91.
31. Moore P. *Manual of Local Anesthesia in Dentistry*. 4th ed. Rochester, NY: Eastman Kodak; 1996.
32. Moore PA. Adverse drug interactions in dental practice: Interactions associated with local anesthetics, sedatives, and anxiolytics. Part IV of a series. *J Am Dent Assoc* 1999;130:541-54.
33. Lee LA, Domino KB. The Closed Claims Project: Has it influenced anesthetic practice and outcome? *Anesthesiol Clin North America* 2002;20:485-501.
34. Keats AS. The closed claims study. *Anesthesiology* 1990;73:199-201.