An Update on Pediatric Anesthesia Liability: A Closed Claims Analysis

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BACKGROUND: Respiratory complications were associated with half of pediatric malpractice claims from the 1970s to 1980s in the ASA Closed Claims Database. Advances in pediatric anesthesia practice have occurred in the 1980s and 1990s and may be reflected in liability trends.

METHODS: We reviewed 532 pediatric (age ≤16 yr) malpractice claims from our database over three decades (1973–2000), using logistic regression analysis to evaluate trends over time. Claims from 1990 to 2000 (1990s) were reviewed in detail to determine damaging events and injuries. Multiple logistic regression analysis evaluated factors associated with claims for death/brain damage (BD) compared with claims for less severe injuries.

RESULTS: From 1973 to 2000, there was a decrease in the proportion of claims for death/BD (P = 0.002) and respiratory events ($P < 0.001$), particularly for inadequate ventilation/oxygenation ($P < 0.001$). However, claims for death (41%) and BD (21%) remained the dominant injuries in pediatric anesthesia claims in the 1990s. Half of the claims in 1990–2000 involved patients 3 yr or younger and one-fifth were ASA 3–5. Cardiovascular (26%) and respiratory (23%) events were the most common damaging events. Factors associated with claims for death/BD in the 1990s when compared with claims for less severe injuries were cardiovascular events (odds ratio [OR] = 6.6, 95% confidence interval [CI] = 2.5–17.8), respiratory events (OR = 3.7, 95% CI = 1.5–9.4), and ASA status 3–5 (OR = 3.1, 95% CI = 1.3–7.8).

CONCLUSIONS: Death/BD remained the dominant injuries in pediatric anesthesia malpractice claims in the 1990s. Cardiovascular events joined respiratory events as the major sources of liability.

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The ASA Closed Claims Project was initiated in 1984 by the ASA to identify major areas of anesthesia-related patient injury, in an effort to design strategies that could lead to improvement of patient safety (1). An earlier review of closed pediatric anesthesia malpractice claims from 1970 to the early 1980s showed nearly half of pediatric injuries resulting in a malpractice claim were related to respiratory adverse events. The majority of these claims involved inadequate oxygenation or ventilation and most were judged as preventable with better pulse oximetry and end-tidal capnography monitoring (2). The Pediatric Perioperative Cardiac Arrest (POCA) Registry found that 20% of cardiac arrests in healthy children (ASA 1–2) during anesthesia were of respiratory origin (3).

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Since the mid 1980s, there have been important changes in pediatric anesthesia practice, including the development of new drugs and the standard use of respiratory monitoring (pulse oximetry and capnography). Use of respiratory monitoring in pediatric patients may be particularly important for reducing anesthesia-related injuries in children.

This analysis examined trends in pediatric anesthesia liability over three decades using the ASA Closed Claims Project Database to identify changes in patterns and mechanisms of injury associated with pediatric anesthesia. We hypothesized a reduction in the proportion of respiratory adverse events, particularly those preventable by pulse oximetry and capnography, over time. To evaluate factors associated with injuries in contemporary pediatric anesthesia practice, claims from the 1990s were reviewed in detail.

METHODS

ASA Closed Claims Database

The ASA Closed Claims Database contains information on 6894 closed anesthesia malpractice claims from 35 professional liability insurance companies throughout the United States. Claims for dental damage are excluded from the database. Study methodology has been described in detail (1,4) and is briefly

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summarized here. The data sources consist of hospital and anesthesia records, narrative statements by the personnel involved, expert and peer reviews, deposition summaries, outcome reports, and the cost of the settlement or award. A standardized form is used to collect information on patient characteristics, surgical procedure, anesthetic techniques, standard of care, damaging event, critical incidents, clinical manifestations, outcome, and narrative summary of events. The data were collected by practicing anesthesiologists from the ASA Committee on Professional Liability.

Study Population

Claims involving patients 16 yr of age or younger for injuries from 1970 to 2001 were eligible for inclusion in the study. Claims involving neonates from complications of obstetric anesthesia or from birth resuscitation ($n = 10$) were excluded, as the neonate was not under anesthesia. Claims with unknown year of event ($n = 5$) were also excluded from analysis. The final number of claims analyzed was 532, with 88 from the 1970s (1973–1979), 280 from the 1980s, (1980–1989), and 164 from the 1990s (1990–2000).

Definition of Variables

For the purpose of the analysis, ASA physical status was categorized in two groups (1–2 vs 3–5). Surgical procedures were grouped by system and anatomical localization into five categories: surgeries that involved the airway (ears, nose, throat, maxillofacial, and dental), thoracic and cardiovascular, abdominal, orthopedic, and other. The primary damaging event was defined as the event leading to the injury that caused the claim. For the purpose of the analysis, events were categorized as respiratory, cardiovascular, medication-related, equipment-related, and other. Medication-related events included wrong drug or wrong dose of oral, IV or inhaled anesthetics, adverse drug reactions, or malignant hyperthermia. For the regression analysis, patient injury was dichotomized as death and permanent brain damage (death/BD) versus all other claims. Complications were assessed by the on-site anesthesiologist reviewers for potential prevention by better monitoring, assuming optimum use of commonly available monitoring devices (5).

Statistical Analysis

Two separate analyses were performed. The primary analysis consisted of a description of trends of pediatric closed claims over time. Changes in patient demographic characteristics, physical status, type of surgical procedures, use of respiratory monitoring, primary damaging event, and severity of injury in the claims over time (as a continuous variable) were analyzed using univariate logistic regression analysis. The resulting odds ratios (OR) represent a change per year. A P value <0.05 was considered significant.

The secondary analysis focused on claims from 1990 to 2000 (in 1990s). A descriptive analysis of the most common damaging events and complications was performed. Logistic regression was performed to evaluate factors associated with claims for death/BD compared to claims for less severe injuries. Age (0–1 yr versus more than 1 yr and 0–3 yr vs 4–16 yr), ASA physical status (1–2 vs 3–5), type of surgical procedure (surgery involving the airway versus other), preventability by better monitoring (yes/no), type of damaging event (respiratory, cardiovascular, other), and year of event as a continuous variable were included in the analysis. Univariate logistic regression was followed by multivariate logistic regression including only the variables that were significant on the univariate analysis. Odds ratios were estimated by the maximum likelihood method. Multiple logistic regressions used forward stepwise selection criteria for including variables in the model (entry P value 0.05, removal P value 0.1, classification cutoff 0.5 and maximum iterations 20). Calculations were done with SPSS software 12.0 for Windows©.

RESULTS

The proportion of claims for patients 0–3 yr of age increased from 43% in the 1970s to 53% in the 1990s ($P = 0.04$, Table 1) mostly because of an increase in the proportion of patients 1–3 yr of age. In each decade, babies less than or equal to 1 yr accounted for approximately 25% of the claims. There were no significant trends in gender, ASA physical status, and type of surgical procedures (Table 1). Overall, 40% of the claims were in female patients and 77% in patients with ASA physical status 1–2. The most common surgical procedures involved the airway (dental, ears, nose, throat, and maxillofacial procedures, 33%) followed by abdominal procedures (21%), and thoracic/cardiovascular procedures (6%).

The proportion of claims due to respiratory events decreased (odds ratio [OR] = 0.93, $P < 0.001$, Figure 1) from an average of 51% in the 1970s to an average of 23% in the 1990s (Table 2). Inadequate ventilation and oxygenation decreased from 26% of total claims in the 1970s to 3% of total claims in the 1990s (OR = 0.87, $P < 0.001$, Table 2). The proportion of claims for death/BD decreased (OR = 0.95, $P = 0.002$, Figure 1) from an average of 78% in the 1970s to 62% in the 1990s (Table 2). The proportion of claims assessed as preventable by better monitoring decreased (OR = 0.884, $P < 0.001$, Figure 1) from an average of 63% in the 1970s to 16% in the 1990s (Table 2).

Death (41%) and BD (21%) were the most common complications associated with pediatric claims in the 1990s. Most other complications were temporary or nondisabling and included burns (6%), cardiac arrest (6%), nerve injury (5%), airway injury (4%), and skin inflammation (2%). Claims for death/BD most commonly involved younger patients (60% age 0–3 yr). One-third of claims for death/BD involved ASA 3–5 patients.

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Table 1. Patient and Case Characteristics per Decade ($n = 532$)

Characteristic	1970s ($n = 88$)	1980s ($n = 280$)	1990–2000 ($n = 164$)	OR (95% CI)	P value
Gender					0.25
Female	25 (28)[a]	117 (42)	65 (41)	1.02 (0.99–1.05)	
Male	59 (72)	160 (58)	95 (59)	Reference	
Age group					0.04
0–3 yr	38 (43)	137 (49)	87 (53)	1.03 (1.00–1.06)	
4 and older	50 (57)	141 (51)	77 (47)	Reference	
ASA physical status					0.08
ASA 1–2	67 (84)	196 (77)	116 (79)	Reference	
ASA 3–5	13 (16)	57 (33)	41 (21)	1.03 (1.00–1.07)	
Type of surgical procedure					0.91
Dental/ENT/maxillofacial	24 (28)	93 (34)	58 (35)	1.00 (0.97–1.03)	
All other	63 (72)	184 (66)	106 (65)	Reference	
Abdominal	23 (26)	66 (24)	28 (17)		
Thorax/heart	7 (8)	12 (4)	14 (9)		
Orthopedic	10 (12)	34 (12)	17 (10)		
Other	23 (26)	72 (26)	47 (29)		

OR = odds ratio; CI = confidence interval; ASA = American Society of Anesthesiologists; ENT = ears, nose, throat.
Missing data are excluded. OR and P value are given by logistic regression analysis.
[a] Values given in parentheses indicate the percentages.

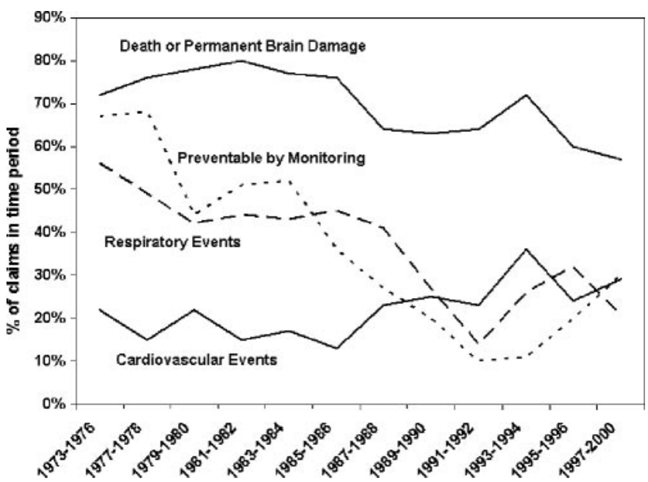

Figure 1. Trends over time. Outcome, type of event, and prevention by better monitoring. Years are grouped for illustration.

In the 1990s, cardiovascular events (26%) and respiratory events (23%) were the most important damaging events (Table 3). Of the 37 respiratory events, airway obstruction including laryngospasm ($n = 8$) was most common, followed by aspiration ($n = 6$) and premature extubation, esophageal intubation, and inadequate ventilation or oxygenation ($n = 5$ each). Five of six aspiration events occurred during or after extubation following tonsillectomy and adenoidectomy. Two of the cases involved aspiration of adenoidal tissue after immediate extubation, and the other three episodes involved aspiration of blood; one during transport and the other two at home after discharge. Difficult intubation occurred in only one claim. There were only four pediatric claims from the 1990s in which a laryngeal mask airway (LMA) was used. Two were for wrong side surgery, one for a postoperative malignant hyperthermia event, and one for laryngospasm treated with succinylcholine, with persistent neuromuscular blockade in the recovery room.

One unrecognized esophageal intubation occurred during an emergency intubation in which a capnograph was not initially present. In another claim, the capnograph reading of zero was misinterpreted as equipment failure, and in two claims, the patient was initially thought to have bronchospasm rather than esophageal intubation (one with an initial false-positive end-tidal CO_2 reading from mask ventilation and the other one in which end-tidal CO_2 was not documented). In a bleeding tonsil case, the patient had a recognized esophageal intubation, but aspirated.

A large number of cardiovascular events (17 of 42) were unexplained, as no specific clinical cause could be identified, but these events were clearly cardiovascular in origin. Almost half of these may have been related to cardiovascular depression from halothane ($n = 7$, 5 in patients with congenital heart disease and two in normal children), a combination of halothane and succinylcholine ($n = 2$), or a combination of halothane and local anesthetic ($n = 2$). The remaining unexplained cardiovascular events occurred during spine surgery ($n = 3$), in association with possible sepsis ($n = 2$), and unknown ($n = 1$). Undiagnosed congenital or acquired heart disease was found on autopsy in five cases (cardiomyopathy [$n = 3$], viral myocarditis [$n = 1$], and bicuspid aortic valve with aortic stenosis [$n = 1$]). The most common specific cardiovascular events involved inadequate intravascular fluid resuscitation ($n = 10$) and excessive blood loss ($n = 4$). Four of the blood loss and fluid resuscitation claims were craniotomies in patients ≤1 yr old; two craniosynostosis repairs, one tumor resection, and one epidural hematoma. In all the cases, the blood loss estimate was insufficient and the intravascular fluid replacement inadequate. The most common equipment-related claim was for burns associated with the use of

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Table 2. Primary Damaging Events and Outcomes per Decade (n = 532)

	1970s (n = 88)	1980s (n = 280)	1990–2000 (n = 164)	OR (95% CI)	P value
Primary event					
Respiratory events	45 (51)[a]	116 (41)	37 (23)	0.93 (0.91–0.96)	<0.001
Inadequate ventilation/oxygenation	23 (26)	40 (14)	5 (3)	0.87 (0.83–0.92)	<0.001
Cardiovascular events	17 (19)	51 (18)	42 (26)	1.03 (1.00–1.07)	=0.05
Equipment	8 (9)	32 (11)	25 (15)	1.03 (0.99–1.07)	=0.17
Medication	5 (6)	24 (9)	22 (13)	1.03 (0.99–1.08)	=0.17
Other	2 (2)	24 (9)	27 (16)	1.09 (1.04–1.14)	<0.001
None/unknown	11 (13)	33 (12)	11 (7)	0.95 (0.91–1.00)	=0.04
Outcome					
Death/permanent brain damage	69 (78)	209 (75)	102 (62)	0.95 (0.92–0.98)	=0.002
Other	19 (22)	71 (25)	62 (38)		
Prevention[b]					
Better monitoring would prevent	50 (63)	110 (41)	25 (16)	0.884 (0.854–0.915)	<0.001

OR = odds ratio; CI = confidence interval. OR and P value are given by logistic regression.

[a] Values given in parentheses indicate the percentages.

[b] Missing data are excluded.

Table 3. Primary Damaging Events 1990–2000

	n^a	%
Respiratory	37	23
Airway obstruction	8	5
Aspiration of gastric contents	6	4
Premature extubation	5	3
Esophageal intubation	5	3
Inadequate ventilation/oxygenation	5	3
Difficult intubation	1	1
Other	7	4
Cardiovascular	42	26
Unexplained cardiovascular event	17	10
Inadequate or inappropriate fluids	10	6
Other	15	9
Equipment	25	15
Warming equipment or cautery	7	4
Gas delivery	6	4
Central or peripheral lines	5	3
Other	7	4
Medication	22	13
Wrong drug or dose	10	6
Adverse drug reaction	6	4
Malignant hyperthermia	6	4
Other events	27	16
Surgical issue or patient condition	16	10
Wrong procedure or location	5	3
Miscellaneous	6	4
No event or unknown	11	7

[a] n = 164.

hot water and hot saline bottles, warming blankets, and electrocautery. Medication-related claims were primarily because of wrong dose (n = 7) or wrong medication (n = 3) administered (Table 3). Four claims associated with dosing errors involved excessive doses of inhaled anesthetics and three claims involved other drugs. Other drug reactions included malignant hyperthermia (n = 6), hyperkalemia after succinylcholine administration (n = 2), allergic reactions from antibiotics (n = 2), and interactions of halothane with epinephrine (n = 1) and lidocaine (n = 1).

On univariate analysis, age, ASA physical status, type of damaging event, and preventability with better monitoring were associated with claims for death/BD compared to less severe injuries in the 1990s (Table 4). Age of 0–3 yr was also associated with claims for death/BD (Table 4). However, age less than or equal to 1 yr was not a statistically significant predictor of outcome. On multivariate analysis, the factors associated with death/BD (Table 4) were cardiovascular events (OR = 6.6, 95% confidence interval [CI] = 2.5–17.8), respiratory events (OR = 3.7, 95% CI = 1.5–9.4), and ASA physical status 3–5 (OR = 3.1, 95% CI = 1.3–7.8).

DISCUSSION

Although there has been a steady downward trend in claims for death/BD, these remain the dominant complications in pediatric anesthesia malpractice claims in the 1990s. Cardiovascular events have joined respiratory events as the major sources of liability in the 1990s.

Methodologic Issues

It is important to recognize that closed claims analysis has many well-described limitations (1,4,6). Our claim sample may be subject to selection and geographic bias, as well as bias toward more severe outcomes and substandard care (6). The information comes from closed malpractice claims and reflects the liability profile and not the safety profile of pediatric anesthesia practice. Attorneys use screening criteria for filing a successful lawsuit, such as evidence of negligence, potential damages, and a projected significant financial compensation, explaining why claims without substantial recoverable damages are usually not pursued (7). Therefore, our findings may reflect changes in legal strategies and statutes of limitations rather than changes in pediatric patient safety.

Estimates of patient safety or risk are not possible, as denominator data are not available. Given the lack of denominator and control group, the analysis is based on differences in proportions of damaging events and severity of outcomes over time. The decrease in a particular category may be partly explained

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Table 4. Factors Associated with Death and Permanent Brain Damage 1990–2000

Variables	Univariate analysis OR (95% CI)	Univariate analysis Significance	Multivariate analysis OR (95% CI)	Multivariate analysis Significance
Age				
0–3 yr	2.06 (1.08–3.91)	0.03	NS	NS
ASA physical status				
3–5	2.35 (1.05–5.24)	0.04	3.13 (1.26–7.79)	0.014
Type of surgical procedure				
Dental/ENT/maxillofacial	0.63 (0.33–1.22)	0.17	NA	NA
Type of damaging event				
Respiratory events	3.85 (1.62–9.13)	0.002	3.72 (1.47–9.42)	0.006
Cardiovascular	7.42 (2.83–19.46)	<0.001	6.59 (2.45–17.77)	0.000
Preventability by better monitoring				
Yes	3.66 (1.19–11.24)	0.02	NS	NS
Year of event[a]	0.99 (0.88–1.12)	0.93	NA	NA

OR = odds ratio; CI = confidence interval; ASA = American Society of Anesthesiologists; ENT = ears, nose, throat.

OR and *P* value are given by logistic regression. Multivariate mode used forward stepwise selection and maximum likelihood method.

[a] OR for year of event per year. For other OR, reference group is all the other claims (data not shown).

by an increase in another category. Logistic regression analysis of trends over time and associated factors is limited to the closed claims population, and not the general anesthesiology population at large (8,9).

Trends Over Time

The significant increase over time in the proportion of claims in younger patients (<3 yr) may reflect current pediatric anesthesia practice, in which a significant proportion of pediatric patients are neonates or under 3 yr of age (10). Improved survival from congenital conditions, as well as new surgical techniques may account for this trend.

Death (41%) and BD (21%) remain the dominant complications in pediatric anesthesia claims in the 1990s, despite a steady downward trend ($P = 0.002$) in these complications over the decades. In contrast, claims for adults also include regional, obstetric, and pain management claims involving minor injuries such as headache, back pain, and emotional distress (1). The decrease in the proportion of claims for pediatric death/BD may be related to the increase in use of pulse oximetry and capnography. Inadequate ventilation and oxygenation showed a dramatic decrease ($P < 0.001$) from the 1970s (26%) compared to the 1990s (3%). Other factors related to pediatric anesthesia, such as the introduction of sevoflurane, a safer inhaled anesthetic in children (11), might explain our findings. Sevoflurane has less potential for producing bradycardia (12) and myocardial depression (13,14) when compared with halothane. However, the closed claims data cannot eliminate changing legal strategies as responsible for our results and cannot determine cause/effect relationships.

1990s Claims Analysis

In contrast to earlier decades, in which respiratory events resulted in the most liability in pediatric anesthesia malpractice claims (2), in the 1990s, cardiovascular events (26%) joined respiratory events (23%) as being the most important. The decrease in respiratory events, with the marked decrease in claims because of inadequate oxygenation and ventilation, may be attributable to prevention by capnography and pulse oximetry. Respiratory events not preventable by respiratory monitoring (e.g., airway obstruction, aspiration of gastric contents, premature extubation) remained a significant liability. The widespread use of the LMA may have also decreased respiratory complications, particularly difficult intubation and esophageal intubation. However, the impact of the LMA on liability cannot be assessed as yet from the available data. The increase in the proportion of cardiovascular events may result from improved ability to exclude respiratory causes. For instance, arrhythmias, hypotension, or multifactorial cardiac events may have been attributed to respiratory mechanisms in the absence of capnography and pulse oximetry. When these same signs occurred in the presence of respiratory monitors, indicating the absence of hypoxemia and/or hypercarbia, then the mechanism of injury was more appropriately attributed to a cardiovascular mechanism.

Our findings differ from prospective quality improvement studies of complications in pediatric anesthesia, in which the most common adverse events were of respiratory origin (53%–77%), with cardiovascular events far less common (10%–12%) (15–17). In one of the studies (15), the most common respiratory event was hypoxemia, defined as oxygen saturation by pulse oximetry below 90%. The authors pointed out that this desaturation could be considered as a "normal" event in the course of an anesthetic of a child with an upper respiratory tract infection. In a second study (16), laryngospasm was the most common (35%) respiratory event and, in all cases, resolved with conventional treatment. In both studies (15,16), none of the patients who had a respiratory event suffered a major complication. The fact that malpractice claims

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are biased toward more severe and permanent injuries probably explains the discrepancy in results between quality improvement studies and our closed claims analysis.

Our finding that ASA 3–5 increases the odds of claims for death/BD compared to claims for less severe injuries is consistent with other reports (3,18). In a prospective study of postoperative outcome in pediatric and adult patients, ASA physical status 3–4 was found to be a predictor of perioperative cardiac and pulmonary morbidity (18). ASA physical status 1–2 had mortality rates of 0.1%–0.7%, while the mortality rate for ASA 3 was 3.5% and for ASA 4 was 18.3% (18). The POCA Registry found that ASA physical status 3–5 increased the odds (12.99, 95% CI = 2.9–57.7) of mortality after a cardiac arrest compared to ASA physical status 1–2 (3). The most common cause of cardiac arrest in the POCA Registry was medication-related events (37%), mostly associated with relative overdose of halothane. However, only five of the 55 events in this category resulted in death ($n = 3$) or permanent injury ($n = 2$) (3). When the patients were divided by ASA physical status in the POCA Registry, the most common causes of cardiac arrest in the ASA physical status 3–5 group were of cardiovascular and respiratory origin (3).

Our closed claims analysis points out several preventable causes of patient injury in pediatric anesthesia. These include early detection of bleeding and aspiration after tonsillectomies and adenoidectomies, prompt recognition and treatment of blood loss in infants, avoiding the use of hot water and saline bottles for rewarming, and appropriate doses of medication for pediatric patients.

In the 1990s, cardiovascular events became a major source of liability in pediatric anesthesia and were strongly associated with claims for death/BD. In many claims, the etiology of the cardiovascular event was not known. Half of the unexplained cardiovascular events may have been associated with cardiovascular depression from halothane. Nearly one-third of these events occurred in patients with unsuspected congenital or acquired heart disease. These findings are consistent with the POCA Registry, which found that patients under 6 mo of age and patients with significant underlying heart disease were more susceptible to halothane-induced cardiac arrest (3). Because sevoflurane results in less cardiac depression than halothane (12–14), its use may reduce unexpected cardiac arrests. Increased research as to why cardiovascular events occur and how they may injure the pediatric patient may help improve patient safety in pediatric anesthesia.

The policy implications of our findings, beyond the importance of more research, are unclear. Because closed claims data do not reflect all injuries and lack denominator data, our data cannot address whether pediatric anesthesia specialists provide safer care for younger and high-risk children (19) or what type of case should be performed at what type of facility.

In summary, death/BD remained the dominant injuries in pediatric anesthesia malpractice claims in the 1990s. Cardiovascular events and respiratory events that were not preventable by respiratory monitoring were major sources of liability. Understanding and preventing adverse cardiovascular events in the pediatric anesthesia patient may help improve patient safety.

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