

# CLOSED CLAIMS STUDIES IN ANESTHESIA: A LITERATURE REVIEW AND IMPLICATIONS FOR PRACTICE

Meghan G. MacRae, RN, PhD  
Rochester, New York

## 2006 STUDENT WRITING CONTEST WINNER

*Historically, closed malpractice claims have been used to identify and examine potential causes for adverse anesthesia outcomes. In the United States, the American Association of Nurse Anesthetists and the American Society of Anesthesiologists have compiled and analyzed such data. In all claims filed, respiratory events were most common, and the most common outcome class was brain damage or death. These findings and others led to improved practice standards, including end-tidal carbon dioxide and pulse*

*oximetry monitoring. Although some researchers have cited closed claims studies as evidence of anesthesia risk trends, the nature of the data makes it inappropriate for calculation or comparison of risk. Further work is needed to elucidate some mechanisms of injury and to develop interventions to maximize patient safety.*

**Key words:** Adverse outcomes, anesthesia risk, closed claims, malpractice.

Ethical considerations preclude direct, prospective experimentation to quantify risks and predict outcomes associated with differences in anesthetic practice. Prospective nonexperimental studies become prohibitively expensive for rare events, such as anesthesia incidents. Retrospective studies are, therefore, the norm, as they are in most healthcare research.<sup>1(p188)</sup> Random or comprehensive review of medical records for rare events is generally impractical.<sup>2</sup> Previously identified anesthesia incidents, however, offer an alternative and concentrated data source for examination of possible causes, precipitating events, and outcomes. One such source is the closed malpractice claim.

This literature review will describe the 2 major US databases of closed anesthesia-related malpractice claims, summarize the findings of the database analyses, discuss limitations of using closed claims data, identify practice changes precipitated by the analyses, and suggest areas for further research.

### History and review of literature

A *malpractice claim* is a demand for financial compensation for an injury resulting from medical care,<sup>3</sup> and it is *closed* when it has been dropped or settled by the parties or adjudicated by the courts.<sup>4</sup> In 1974, the National Association of Insurance Commissioners conducted the initial research using closed claims to identify malpractice risks.<sup>3</sup> At that time, anesthesiologists represented 3% of insured physicians but accounted for 11% of the total dollars paid for patient injury, and 90% of these payments involved care

below the standard.<sup>2,5</sup> Consequently, anesthesia-provider liability insurance costs rose dramatically in the 1980s.<sup>2,6</sup> In 1985, the American Society of Anesthesiologists (ASA) started the Closed Claims Project to improve patient safety and address rising insurance costs by identifying the scope and cause of significant anesthesia-related patient injuries.<sup>2,5,7-9</sup> Because those data primarily reflected physician providers, the American Association of Nurse Anesthetists (AANA) began examination of closed claims involving Certified Registered Nurse Anesthetists (CRNAs) and published its initial findings in 2001.<sup>3</sup>

The ASA Closed Claims Project (ASA-CCP) has conducted annual reviews of anesthesia-related malpractice claims of the 35 participating insurance carriers.<sup>8,10,11</sup> Hundreds of volunteer physician anesthesiologists have reviewed case files (typically hospital records, anesthetic records, narrative statements of involved personnel, expert and peer reviews, deposition summaries, outcome reports, and settlement or award details) and recorded findings using a standard data collection form.<sup>2</sup> The database has been updated annually with data collected and reviewed the previous year.<sup>8</sup> At last report, the database contained data for 6,894 claims<sup>9</sup> representing events occurring since 1962.<sup>12</sup> Posner<sup>4</sup> categorized the data according to timing of the event that led to the claim: 12% from 1970 through 1979, 54% from 1980 through 1989, and 33% from 1990 through 1999, most before 1995. These figures reflect the average 5-year lag time from event to case closure.<sup>4,7</sup>

By contrast, the AANA closed claims database

reflects 223 cases from a 1-time review effort by 8 CRNAs of the records of the St Paul Fire and Marine Insurance Company.<sup>3,13</sup> This insurance provider was the “largest single insurance carrier for CRNAs”<sup>13</sup> but has since withdrawn from offering malpractice insurance.<sup>14</sup> All cases represented in the AANA database occurred between 1989 and 1997 and were closed between 1995 and 1997.<sup>3,13</sup>

Both databases exclude dental claims, such as chipped teeth, and cases in which an anesthesia provider was named as a defendant but did not contribute to the adverse event or for which insufficient data existed to reconstruct the basic sequence of events or the nature of the injury.<sup>3,9</sup> Although the data collection tools have not been published, Petty et al<sup>10</sup> reported the major instrument categories for each database. Members of the ASA have limited access to the data through standardized queries submitted to the ASA-CCP.<sup>2,9,15,16</sup> No access mechanism was identified for AANA data. Each organization has published closed claims findings almost exclusively in its own publications, ie, *Anesthesiology*, *ASA Newsletter*, and *AANA Journal*.

- *Overall findings.* Published studies of anesthetic morbidity and mortality date to at least 1858.<sup>3</sup> Publications before closed claims analyses focused on faulty judgment and drug-related errors as primary causes and identified respiratory insufficiency, gastric aspiration, and drug overdose as precipitating events.<sup>3</sup> Because the cause is often difficult to ascertain from closed claims data, recent researchers referred to “events,” which appeared to herald or precipitate the “outcome” or ultimate injury.

The ASA-CCP data for relatively recent incidents (since 1990) reflected an outcome of death or brain damage in 31% to 32% of all claims.<sup>4,7,17-19</sup> This outcome was precipitated by a respiratory event in 45% of these cases and, more specifically, was attributable to inadequate ventilation (7%), esophageal intubation (7%), or difficult intubation (12%).<sup>7,18</sup> The percentage of death or brain damage outcomes attributable to a cardiovascular event was 25%.<sup>2</sup> Nerve injury represented the second most common outcome at 21% of all claims.<sup>4</sup> Other outcomes reflected as a percentage of total claims were airway injury (8%), burns (6%), awareness or emotional distress (5%), eye injury (5%), backache (5%), headache (5%), pneumothorax (4%), aspiration pneumonitis (3%), and newborn injury (1.5%).<sup>4</sup>

Initial AANA data analysis by Jordan et al<sup>3</sup> showed that CRNA-related incidents reflected an outcome of death or brain injury in 44% of all claims. Of all

CRNA-related claims, 39% reflected a contributing respiratory event, and 68% of claims reflecting a respiratory event had a death or brain damage outcome. Therefore, 61% of the reported CRNA-related death or brain injury outcomes may be attributable to a respiratory event. Other findings by Jordan et al<sup>3</sup> included the following:

1. CRNA lack of vigilance was a contributing factor in 79% of claims.

2. Worse outcomes were correlated with inappropriate care, lack of vigilance, preventable outcomes, and respiratory or airway incidents.

3. Worse outcomes were not correlated with preoperative physical status, patient age, type of surgery or procedure, type of anesthetic, age of anesthesia provider, or year of certification of the CRNA.

4. When comparing CRNAs working with an anesthesiologist with CRNAs working without an anesthesiologist, there were no significant differences in outcome, injury severity, appropriateness of care, adequacy of preinduction activities, vigilance of the CRNA, preventability of outcome, use of pulse oximetry or inspired oxygen monitoring, or presence of a contributing respiratory or airway incident.

In a novel analysis, Kremer et al<sup>20</sup> studied the AANA data for evidence of cognitive biases that might have contributed to the outcome. Anchoring, hindsight bias, and use of the availability heuristic were each evident and resulted in reluctance to accept the seriousness of the situation or failure to consider the full range of possible diagnoses. The most comprehensive interpretation of the data as a whole, however, came from Crawforth<sup>21</sup>: “[Errors] were caused by a multiplicity of factors. An individual may have placed the proverbial ‘last straw’ on the adverse event, but in no instance was the basis of any claim an isolated action.”

- *Sympathetic blockade and cardiovascular events.* Early analysis of the first 900 ASA-CCP claims revealed 14 cardiac arrest deaths during spinal anesthesia.<sup>22</sup> The precipitating events were thought to be undetected respiratory insufficiency and sympathetic blockade.<sup>22</sup> Subsequent work by Thrush and Downs<sup>23</sup> explained that if the sympathetic system is blocked by a spinal anesthetic and a vasovagal reaction occurs, an imbalance between the parasympathetic and sympathetic systems might be exacerbated in susceptible individuals with increased vagal tone, an estimated 7% of the population. Cheney<sup>2</sup> recommended administration of epinephrine early in resuscitation, and Thrush and Downs<sup>23</sup> recommended prophylactic administration of atropine.

Kopp et al<sup>24</sup> found that in patients undergoing neuraxial anesthesia who had a cardiac arrest, the anesthetic contributed to 54% of the cardiac arrests. They also found that survival rates after cardiac arrest were higher for patients with neuraxial anesthesia (65%) compared with general anesthesia (31%). This research was based on a retrospective review of all reported cardiac arrests during anesthesia at a single institution, not on closed claims data.

The ASA-CCP data reflected an increase in the proportion of death and brain damage claims attributable to a cardiovascular event from 13% in the 1970s to 25% in the 1990s; but this increase may simply reflect the decreased proportion of claims attributable to a respiratory event.<sup>2</sup>

• *Respiratory events.* Initial ASA-CCP analyses identified respiratory events as the single largest class (34% of all claims).<sup>25</sup> Respiratory events were associated with death or brain damage in 85% of those claims.<sup>25</sup> Inadequate ventilation was thought to be a factor in 38% of respiratory event claims, and 72% of these claims were thought preventable with better monitoring.<sup>25</sup> The findings were reinforced by Tinker et al,<sup>26</sup> who asserted that 93% of preventable incidents could have been prevented with a combination of pulse oximetry and capnometry. In 1990, pulse oximetry was included in the ASA Standards for Basic Intra-Operative Monitoring.<sup>27</sup> Subsequent claims showed that only 7% of the death or brain damage outcomes were thought to be due to inadequate ventilation,<sup>7,18</sup> and Cheney<sup>19</sup> reported that inadequate ventilation events leading to death or brain damage decreased significantly when pulse oximetry was used.

Larson and Jordan,<sup>28</sup> in analysis of CRNA-related claims, reported that 9% of claims for respiratory incidents involved endobronchial intubation, which was thought to contribute to inadequate ventilation. Their recommendation was for providers to be aware of tube markings and recommended depths for common populations.

According to the early data analysis by Caplan et al,<sup>25</sup> the second largest subclass of respiratory events leading to claims was esophageal intubation (18% of respiratory events). In the claims for esophageal intubation events in which postintubation breath sounds were documented, Caplan et al<sup>25</sup> found that 48% documented the intubation as tracheal. Cheney<sup>2</sup> credited this study with guiding the ASA Committee on Standards to require end-tidal carbon dioxide verification of endotracheal intubation. Subsequent claims attributed only 7% of the respiratory event–related death or

brain damage outcomes to esophageal intubation.<sup>7,18</sup> Miller<sup>29</sup> pointed out that none of the claims data reflected practice since widespread use of the laryngeal mask airway, which was expected to further decrease frequency of these incidents. Cheney<sup>17,19</sup> reported that end-tidal carbon dioxide verification of intubation was inversely correlated with death or brain damage when esophageal intubation did occur.

The third largest subclass of respiratory events leading to claims was difficult tracheal intubation (17%).<sup>25</sup> Practice guidelines for management of the difficult airway were first published in 1993.<sup>18,19,30</sup> In an evaluation of their effectiveness, Peterson et al<sup>31</sup> found that after publication of the guidelines, difficult airway claims associated with death or brain damage during induction decreased from 62% to 35%. Nevertheless, for the same period, Moody and Kremer<sup>32</sup> reported that 27% of respiratory events in CRNA-related claims had no documented airway assessment; so, simple practice improvements could still reduce risk associated with difficult airways. Peterson et al<sup>31</sup> also found that death or brain damage was correlated with development of an airway emergency, as were persistent intubation attempts during an airway emergency. They recommended development of additional management strategies for difficult airways encountered during maintenance, emergence, or recovery from anesthesia to complement the apparently successful induction algorithm. The most recent practice guideline conceded that the literature did not adequately address extubation strategies for the difficult airway.<sup>33</sup>

Aspiration was considered the primary or secondary damaging event in 3.5% of all claims.<sup>34</sup> Of these events, 67% occurred during induction, and 11% of these claims showed documented cricoid pressure. Of the aspiration claims, 60% were associated with an outcome of death or brain damage compared with 43% of nonaspiration claims. Nevertheless, Cheney<sup>34</sup> concluded, “aspiration of gastric contents is not a major liability hazard for the anesthesiologist.” These data also reflect practice before the widespread use of the laryngeal mask airway.

In research by Domino<sup>35</sup> and Domino et al,<sup>36</sup> airway trauma was identified in 6% of the ASA-CCP claims. Of these claims, 38% showed difficult intubation to be a contributing factor, and in 9%, the patient sustained brain damage or died. Sites of injury included the larynx (34%), pharynx (17%), esophagus (16%), trachea (14%), and temporomandibular joint (10%). Laryngeal injury was usually associated with appropriate care (83% of these cases) and most

often resulted in vocal cord paralysis (31% of these cases). Retropharyngeal abscess and/or mediastinitis developed in 61% of the claims for perforation injury of the esophagus or pharynx, and 31% of these claims showed death as the ultimate outcome.<sup>36</sup> Elderly women were represented in a greater percentage of esophageal injury claims compared with other claims, although no mechanism was apparent.<sup>36</sup> In only 51% of the claims for perforation injury were there signs of pneumothorax and/or subcutaneous emphysema; consequently, the researchers recommended alerting the surgeon and patient to watch for signs and symptoms of mediastinitis or retropharyngeal abscess when intubation is difficult or initially esophageal.<sup>36</sup>

- *Nerve injury.* Since 1990, 17% of all claims in the ASA-CCP database related to a nerve injury outcome.<sup>37</sup> In all data collected in the ASA-CCP, ulnar nerve injuries were the most commonly claimed nerve injury (25%), followed by injuries to the brachial plexus (19%); 86% of claimed ulnar nerve injuries were sustained during general anesthesia.<sup>37</sup> Although ASA-CCP research reported that these peripheral nerve injuries seemed to occur in the presence of adequate positioning and padding,<sup>37,38</sup> AANA data showed the use of padding was undocumented in 57% of nerve injury claims, patient positioning was undocumented in 55%, and improper patient positioning was identified in 36%.<sup>39</sup> Cheney et al<sup>38</sup> compared the claims reflecting injuries since 1990 and found that spinal cord injury claims had surpassed ulnar nerve injury claims and were associated with neuraxial blocks in anticoagulated patients and with blocks for chronic pain.

- *Central venous catheter complications.* Recent studies of ASA-CCP data showed an increase in the proportion of claims related to central venous catheter (CVC) complications from 13.5% before 1990 to 16.5% before 2004 and an increase in CVC-related claims with an outcome of death (42% to 47%).<sup>40-42</sup> Of the CVC-related death claims before 1990, 75% were due to cardiac tamponade or vascular injury.<sup>40</sup> For all claims before 2004, events by proportion of CVC-related claims included the following: wire or catheter embolus, 18%; cardiac tamponade, 15%; carotid artery puncture or cannulation, 15%; hemothorax, 14%; pneumothorax, 13%; and pulmonary artery rupture, 6%. These events were thought to be preventable in at least 45% of the claims by implementing the following: (1) ultrasound-guided catheter placement, (2) transduction of a pressure waveform to confirm cannulation of a vein, (3) chest radiograph, or (4) interval or continuous monitoring of a pressure waveform.<sup>41,42</sup>

- *Burns.* Kressin<sup>43</sup> analyzed burn outcome claims in the ASA-CCP database. Of the claims, 2% were for burn injuries and were attributed to the following events: intravenous (IV) bags or bottles, 35% of burn claims; warmers, 23%; cautery fires, 19%; cautery burns without fire, 12%; lasers in the airway, 2%; magnetic resonance imaging at the site of pulse oximetry, 2%; retractors, 1%; defibrillator paddles, 1%; and electrocardiographic leads, 1%. A 1994 analysis of the data showed 64% of burn claims were related to the use of heated IV bags or bottles as warmers,<sup>44,45</sup> but claims since 1994 showed that IV bags or bottles contributed to only 12% of burn claims.<sup>43</sup> The majority of cautery fires occurred to the face during plastic surgery under monitored anesthesia care.<sup>43</sup> Almost all (93%) of claimed burn outcomes were temporary or nondisabling.<sup>43</sup>

- *Postoperative visual loss.* Recognition of the prevalence of perioperative ischemic optic neuropathy through closed claims data analyses led to the creation of the Postoperative Visual Loss Registry in 1999 for anonymous physician submissions.<sup>46</sup> By using Postoperative Visual Loss Registry data, Lee<sup>47,48</sup> found that 81% of submissions were related to ischemic optic neuropathy and correlated with large blood loss, prolonged hypotension, prone positioning, and vaso-occlusive disease. Central retinal artery occlusion accounted for an additional 13% of submissions and was correlated with direct pressure on the globe, emboli, and low retinal perfusion pressure. Of patients sustaining ischemic optic neuropathy, 39% recovered at least partial sight, whereas none of the patients sustaining central retinal artery occlusion recovered. Eye loss due to regional block is addressed in the *Special settings or circumstances* section.

- *Intraoperative awareness.* According to ASA-CCP data, 2% of all claims involved intraoperative awareness.<sup>7,49,50</sup> Of these cases, 75% resulted in recall of events during anesthesia. Of these, care was judged substandard in 42% and was attributed to inadequate anesthesia: failure to turn on the agent vaporizer, vaporizer malfunction, or failure to anesthetize sufficiently during induction.<sup>49,50</sup> The remaining 25% of these cases resulted in inadvertent paralysis of a conscious patient. Care was judged substandard in 94% to 96% of these cases and was attributed to medication error: an infusion of succinylcholine from an unlabeled, misread, or mislabeled bag or a bolus of succinylcholine from a mislabeled or misread syringe.<sup>49,50</sup> Grinblat<sup>51</sup> advised providers to allow patients reporting anesthesia awareness to discuss their experiences and feelings fully, to document the patient's report thoroughly, and to provide support.

- *Medication errors.* Bowdle<sup>52</sup> found 4% of claims related to medication administration errors with no change in frequency over time. The most common errors were incorrect dose (31%), substitution of the incorrect drug (24%), and administration of a drug not intended to be given (17%). The most common medications were succinylcholine (17% of medication claims), usually resulting in awareness with paralysis or prolonged blockade, and epinephrine (8%), usually resulting in death or major morbidity. Of the medication claims, 58% were associated with death or major morbidity.

- *Gas delivery device problems.* Of all ASA-CCP claims, 2% were related to problems with the anesthesia machine.<sup>12,53</sup> Of these claims, 75% documented misuse, and the rest were machine failures. Caplan et al<sup>12</sup> found the problem related to the breathing circuit in 39% of the gas delivery claims and to the vaporizers, ventilators, or oxygen supply lines or tanks in 49%. Although the primary anesthetist was responsible for the reported misuse in 70% of the applicable claims, in 30% of misuse claims, ancillary personnel crossed supply lines at the machine, crossed central supply lines, delivered the wrong central tank, flushed central oxygen lines with nitrogen without notification, installed a 1-way valve backward, or applied 50 psi oxygen to an endotracheal tube postoperatively. Misconnections and disconnections, often associated with barotrauma or pneumothorax, accounted for one third of the claim events. All vaporizer problems that led to brain damage or death occurred before 1985; later claims resulted in delivery of less agent than intended and consequent intraoperative awareness.<sup>12</sup> Recommendations for prevention included redesign of the breathing circuit, strategies and education for ancillary personnel, and ensuring that appropriate monitors are functioning at all times.<sup>12</sup>

- *Special settings or circumstances.* As anesthetic use outside of the operating room has increased, so has concern for liability and patient safety in these settings. Monitored anesthesia care targets a level of sedation between that of conscious sedation and general anesthesia<sup>54</sup> and was represented in the claims for death outcomes at the same rate as general and regional anesthesia.<sup>55</sup> Precipitating events were categorized as respiratory (26%), unknown (23%), cardiovascular (10%), and IV complications (7%).<sup>55</sup>

Ambulatory surgery-related claims composed 23% of the total ASA-CCP data.<sup>56</sup> Posner<sup>56</sup> found that these claims had a higher percentage of monitored anesthesia care or regional anesthesia, regional anesthesia-related events, and temporary or nondisabling

injuries but a lower percentage of respiratory events. By contrast, office-based anesthesia, which composed 0.3% of all claims, reflected a higher percentage of death, respiratory events, preventable outcomes, and drug errors or reactions.<sup>57</sup> Neither study addressed the use or availability of resuscitation equipment or the success of resuscitation efforts.

Zeitlin<sup>58</sup> reported that 7% of closed claims events developed in the postanesthesia care unit. Of these claims, 75% had death or brain damage as an outcome, and 39% were thought preventable with pulse oximetry or capnometry compared with 29% of other claims. This early study probably reflected few data after basic monitoring became the standard of practice.

The proportion of claims related to nonoperative pain management (NOPM) has increased during the last 3 decades to 10% of all claims in the 1990s.<sup>59-61</sup> Inadequate follow-up care was identified as a contributing factor in 24% of NOPM claims (16% of all other claims),<sup>61</sup> and 40% of NOPM claims were due to epidural steroid injury.<sup>60</sup> Outcomes included nerve injury or paralysis or paraplegia (23% of all NOPM claims), pneumothorax (21%), brain damage or death (9%), postdural puncture headache (8%), no pain relief (8%), meningitis (6%), infection at the injection site (4%), and retained catheter (3%).<sup>60</sup> Kalauokalani<sup>61</sup> also found that the anesthetic record was inadequate in 74% of NOPM claims (50% of all other claims).

Regional anesthesia claims were related to neuraxial block cardiac arrest (30% of regional anesthesia claims), pain management (23%), and intravascular injection (10%).<sup>62</sup> Although death-related claims were relatively low, at 2.6%, eye loss accounted for 22% of the claims of permanent injury related to a regional anesthetic.<sup>62</sup> Lee et al<sup>63</sup> reported an increase in the percentage of permanent injury due to eye blocks from 2% of all regional anesthesia claims in the 1980s to 7% in the 1990s.

When compared with other claims, obstetric event claims had death as an outcome less frequently: maternal deaths composed 19% to 22% of all obstetric claims, neonatal deaths composed 27%, and newborn brain damage composed 14% to 22%.<sup>21,64-66</sup> The most common event related to maternal death was failure to secure an airway.<sup>21</sup> When compared with nonobstetric claims, more patients who are obese are represented in obstetric claims (25% vs 19%), and this may contribute to difficult intubation.<sup>66</sup> Commonly reported outcomes were maternal headache, pain, back pain, and emotional distress (47% of all obstetric claims)

and were correlated with patient dissatisfaction with care and more frequent use of regional anesthesia.<sup>64,65</sup> The researchers noted the importance of anticipating and preparing for airway difficulties and using protocols specific to the obstetric population, which consider the concurrent needs of mother and child.<sup>21,64-66</sup>

Patients younger than 16 years were represented in 10% of all claims.<sup>67</sup> Morray et al<sup>67</sup> found these claims to have a higher percentage of death outcomes, 50% compared with 35% in adults, and a higher percentage of respiratory events, 43% vs 30%. A more recent study, however, found only 25% of the pediatric claims from the 1990s were associated with respiratory events and that this decrease coincided with a drop in monitor-preventable events.<sup>68</sup> Cardiovascular events represented 27% of pediatric claims in the 1990s.<sup>67</sup> Recognition of this led to creation of the Pediatric Perioperative Cardiac Arrest Registry in 1994, which is composed of anonymous physician submissions of cases requiring chest compressions or resulting in death during anesthesia or in the postanesthesia care unit.<sup>6,7,68,69</sup> Analysis of Pediatric Perioperative Cardiac Arrest Registry data showed that 67% of cardiac arrests occurred during maintenance anesthesia, 56% of events were attributable to cardiovascular causes (eg, electrolyte imbalance, fluid therapy, hemorrhage, and cardiopulmonary bypass), 42% of patients had no discernible precipitating injury, and 43% of patients died within 24 hours.<sup>70,71</sup> Jimenez<sup>68</sup> also reported that medication events were related to wrong dose in 53% of relevant claims, which might be due to relatively complex pediatric dosing.

Sharar<sup>72</sup> found that 4.8% of claims between 1987 and 1999 involved trauma anesthesia care. Of these, 72% involved emergency anesthesia and surgery and 51% of the patients were classified as ASA physical status III to V. Nontrauma claims, by contrast, involved emergency anesthesia in only 18% of the claims, and 34% of patients were classified as ASA physical status III to V. Nevertheless, when compared with nontrauma claims, trauma claims were not significantly different in the proportion of claims for aspiration, brain damage, difficulty of intubation, intraoperative awareness, standard of care, or adequacy of records. Sharar<sup>72</sup> found more trauma claims associated with an outcome of death (40.3% compared with 23.4%).

Consent was identified as a liability issue in 1% of the ASA-CCP database claims.<sup>73,74</sup> For these claims, the provider failed to honor a patient request, such as a request that no medical resident be involved, or

failed to discuss a specific complication or change in anesthesia plan.

## Discussion

• *Limitations.* Closed claims data do not necessarily reflect the frequency of occurrence of outcomes or events. Some injured patients do not file claims, but some patients who were not injured do file claims.<sup>2</sup> Furthermore, these databases contain no data on the total number of anesthetics delivered, so they cannot be used to calculate or compare risk.<sup>2,10,66</sup> Nevertheless, researchers seem challenged to word conclusions in a way that does not overstate the findings: “The 1990s present a profile of fewer claims for death and brain damage and fewer respiratory system mishaps than preceding decades. This improved injury profile is reflected in fewer payments.”<sup>4</sup> Similar statements were made by Caplan<sup>7</sup> and by Cheney<sup>34</sup> who said: “This suggests that strategies for prevention of aspiration in the OB patient were incorporated into clinical practice in the 1980s.” Decreased risk cannot be concluded from closed claims data. Surprisingly, the following passage from Ross<sup>75(p188)</sup> followed a lengthy explanation of closed claims limitations with regard to risk estimation:

Setting aside these limitations, the Closed Claims database does provide valuable information. The data allow comparison of claims made in obstetrical anesthesia cases versus those in other anesthesia specialties, looking for differences in patterns of injury or outcomes. One is also able to answer a number of important questions such as: Which injuries are most common in obstetrical anesthesia?

The use of parametric statistics is only appropriate when a sample is taken randomly. Clearly, closed claims data do not adhere to this assumption, and only nonparametric tests should be used. Although most research reported chi-square or other nonparametric comparisons, Cheney<sup>2</sup> used the Z-test, a parametric statistic.

Retrospective data cannot be used to test hypotheses; therefore, no cause and effect conclusions can be drawn from closed claims data. Again, researchers' conclusions could give a misimpression that causality had been elucidated: “Research findings reported here demonstrate that incomplete preinduction activities can contribute to damaging events and adverse outcomes in anesthesia.”<sup>32</sup> The finding of incomplete preinduction activities for some cases with adverse outcomes says nothing about cases with positive outcomes and whether they were associated with complete preinduction activities.

Because claims for which a lawsuit was filed eventually amassed considerable documentation, these cases were more likely to meet the completeness cri-

terion for inclusion in a database,<sup>9</sup> which could exacerbate problems of systematic sampling bias. In addition, the recognized lag time of 6 months to 10 years increases the risk of premature analysis, although the timing of the study did not always accommodate this limitation; for example, Cheney<sup>62</sup> published "High-severity injuries associated with regional anesthesia in the 1990s" in 2001.

Reviewers necessarily experienced some hindsight bias.<sup>3</sup> Although reliability was reportedly "within the accepted range" for the ASA-CCP data,<sup>2</sup> Caplan and Posner<sup>76</sup> found that the judgment of appropriateness of care is subjective and influenced by a finding of permanent injury. Specifically, the researchers provided case details to reviewers but changed the outcome from temporary injury to permanent injury. Reviewers were twice as likely to find care less than appropriate when told the outcome was permanent injury. Posner et al<sup>77</sup> also found that reviewers agreed on the appropriateness of care for 62% of cases and disagreed for 38%; chance agreement was expected to occur 40% of the time. Bias should also be expected in the original anesthetic records and other case documentation because their preparers cannot be impartial.<sup>3,10</sup>

Failure to recognize these limitations may contribute to a perception that anesthetic risk has decreased by at least an order of magnitude during the last 2 decades.<sup>78(p32)</sup> In response to claims of extreme rarity of anesthetic incidents and as an illustration of the limitations of nonstandardized methods and nonrepresentative sampling, Lagasse<sup>79</sup> undertook a literature review study of published anesthesia-related perioperative mortality rates. Contrary to the Institute of Medicine's report<sup>78</sup> that anesthesia deaths have decreased from 2 in 10,000 in the 1980s to 1 in 200,000 to 300,000 at the time of the report, Lagasse<sup>79</sup> found the following:

1. Anesthesia-related mortality as determined by peer review had been stable during the previous decade at 1 in 13,000.

2. Incidents for patients classified as ASA physical status I through V averaged 1 in 500 anesthetics.

3. The wide range reported in the literature reflected differences in operational definitions, reporting sources, and risk stratification.

- *Practice changes.* According to Cheney,<sup>2</sup> the 1990 study by Caplan et al<sup>25</sup> compelled the ASA Committee on Standards to require (1) intraoperative and postanesthesia pulse oximetry,<sup>26</sup> (2) end-tidal carbon dioxide verification of endotracheal intubation,<sup>25</sup> and (3) difficult airway practice guidelines.<sup>30,33</sup>

According to Cheney<sup>6</sup> and Caplan,<sup>7</sup> a cooperative

effort between the ASA-CCP and the Quality Assurance Committee of the American Academy of Pediatrics established the Pediatric Perioperative Cardiac Arrest Registry in 1994 in response to research by Murray et al<sup>67</sup> and Morray.<sup>69</sup> Similarly, the Postoperative Visual Loss Registry, another ASA-CCP cooperative effort, complements eye injury closed claims data.<sup>46</sup>

Research also showed that a considerable number of malpractice actions against anesthesiologists were unfounded and that providers are at risk for litigation in the absence of deviation from standards of care.<sup>80,81</sup> Nevertheless, over time, fewer claims have resulted in payments to plaintiffs.<sup>4,82</sup> There have been significant decreases in liability premiums for anesthesiologists during the last 2 decades,<sup>2,18,83</sup> although that trend seems to be reversing.<sup>14,84-86</sup>

## Summary and further research directions

These studies suggest the following:

1. Errors in judgment and performance occur and can have serious consequences.

2. Monitors and alarms are invaluable, particularly end-tidal carbon dioxide detectors, pulse oximeters, oxygen analyzers, and ventilator disconnect alarms.

3. Anesthetists must be familiar with and use the alarms and recommended preuse equipment checks.

4. Incidents detected with noninvasive blood pressure measurement are late in development.

5. A stethoscope should be available to clarify ambiguous or confusing information.<sup>10</sup> Other researchers have made recommendations for building on these studies:

1. Identification of ways to use the data as an "early warning system,"<sup>83</sup>

2. A prospective study comparing occurrence of spinal cord injury in vascular surgery patients requiring systemic heparinization with and without neuraxial block,<sup>2</sup>

3. Identification of the mechanism for the possible increased risk of airway injury in elderly women,<sup>36</sup>

4. Additional study of the suggested relationship between eye injury and independent CRNA practice,<sup>3</sup>

5. Collaborative research efforts between physician and nurse anesthetists,<sup>21</sup>

6. Further investigation of cognitive issues such as the pursuit of a plan in direct conflict with clinical evidence (eg, continued and repeated attempts to intubate), the interactions of multiple factors that culminate in an adverse event, the effects of stress and conflicting goals on the occurrence of critical events, and the analysis of narrative portions of the AANA database,<sup>21</sup>

7. Development of standardized assessment and

perioperative event forms to maximize available information, establish appropriate denominators for risk estimation, test cause and effect hypotheses, and tease apart outcomes due to patient predisposition or risk factors,<sup>87</sup>

8. Availability and use of resuscitation equipment for office-based anesthesia and the effect on success of resuscitation, and

9. An updated examination of postanesthesia care unit claims.

The usefulness of closed malpractice claims research is evident. The insights gained from examining these data have been and will continue to be important contributions toward ensuring patient safety. At a time when healthcare reform proposals legitimately embrace improving patient safety, the profession is well served by those who work to extract as much as possible from closed claims data. Care must be taken not to overstate the findings, however, because these data are not appropriate for calculation or comparison of risk. Future research would ideally include greater interdisciplinary collaboration with unwavering focus on the common goal of providing the safest care possible.

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#### AUTHOR

Meghan G. MacRae, RN, PhD, is a student at the University at Buffalo State University of New York Nurse Anesthetist Program, Buffalo, NY. Email: [meghanmacrae@yahoo.com](mailto:meghanmacrae@yahoo.com)