

# Patient Injuries from Anesthesia Gas Delivery Equipment

## A Closed Claims Update

Sonya P. Mehta, M.D., M.H.S.,\* James B. Eisenkraft, M.D.,† Karen L. Posner, Ph.D.,‡  
Karen B. Domino, M.D., M.P.H.§

### ABSTRACT

**Background:** Improvements in anesthesia gas delivery equipment and provider training may increase patient safety. The authors analyzed patient injuries related to gas delivery equipment claims from the American Society of Anesthesiologists Closed Claims Project database over the decades from 1970s to the 2000s.

**Methods:** After the Institutional Review Board approval, the authors reviewed the Closed Claims Project database of 9,806 total claims. Inclusion criteria were general anesthesia for surgical or obstetric anesthesia care ( $n = 6,022$ ). Anesthesia gas delivery equipment was defined as any device used to convey gas to or from (but not involving) the airway management device. Claims related to anesthesia gas delivery equipment were compared between time periods by chi-square test, Fisher exact test, and Mann–Whitney U test.

**Results:** Anesthesia gas delivery claims decreased over the decades ( $P < 0.001$ ) to 1% of claims in the 2000s. Outcomes in claims from 1990 to 2011 ( $n = 40$ ) were less severe, with a greater proportion of awareness ( $n = 9$ , 23%;  $P = 0.003$ ) and pneumothorax ( $n = 7$ , 18%;  $P = 0.047$ ). Severe injuries

### What We Already Know about This Topic

- Anesthetic gas delivery systems (primarily anesthesia machines) have improved markedly in the last 3 decades, as has provider training
- Their effect on anesthetic practice and patient outcomes remains unknown
- The authors thus queried the Closed Claims database and evaluated trends from the 1970s to the 2000s

### What This Article Tells Us That Is New

- The number of claims related to gas delivery, their severity, and their fraction of the total decreased markedly
- Provider error continues to contribute, as does failure to complete a full machine check

(death/permanent brain damage) occurred in supplemental oxygen supply events outside the operating room, breathing circuit events, or ventilator mishaps. The majority (85%) of claims involved provider error with ( $n = 7$ ) or without ( $n = 27$ ) equipment failure. Thirty-five percent of claims were judged as preventable by preanesthesia machine check.

**Conclusions:** Gas delivery equipment claims in the Closed Claims Project database decreased in 1990–2011 compared with earlier decades. Provider error contributed to severe injury, especially with inadequate alarms, improvised oxygen delivery systems, and misdiagnosis or treatment of breathing circuit events.

**D**ESPITE a low incidence of anesthesia machine problems during anesthesia care, ranging from 0.06%<sup>1</sup> to 0.4–0.7%,<sup>2,3</sup> anesthesia gas delivery equipment plays an important role in critical incidents, constituting 20% of reported events.<sup>4</sup> Cassidy *et al.*<sup>4</sup> examined critical incident reports concerning anesthesia equipment reported to the United Kingdom National Reporting and Learning System from 2006 to 2008. Gas delivery equipment events included ventilator problems (17.9% of incidents), leaks in circuit (9.6%), vaporizer problems (5.1%), and gas supply problems (1.9%).<sup>4</sup> Although these events had potential to create harm, serious patient injury did not occur due to prompt detection and intervention.<sup>4</sup>

The rarity of anesthesia gas delivery equipment problems renders it difficult to study prospectively. Closed

\* Fellow, ‡ Research Professor, Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington. † Professor, Department of Anesthesiology, Icahn School of Medicine at Mount Sinai, New York, New York. § Professor, Departments of Anesthesiology and Pain Medicine, and Neurological Surgery (Adjunct), University of Washington.

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Address correspondence to Dr. Domino: Department of Anesthesiology and Pain Medicine, University of Washington, Box 356540, 1959 N.E. Pacific Street, BB1431, Seattle, Washington. kdomino@uw.edu. Information on purchasing reprints may be found at [www.anesthesiology.org](http://www.anesthesiology.org) or on the masthead page at the beginning of this issue. ANESTHESIOLOGY's articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

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claims are informative as a source of data on relatively rare events that may reveal recurrent patterns of events and injuries that are not feasible to study through classic prospective research designs. Thus, closed claims analysis has the potential to reveal valuable patient safety data that are otherwise unavailable for study. A previous (1997) review of closed anesthesia malpractice claims in the American Society of Anesthesiologists (ASA) Closed Claims database found severe injuries (death and permanent brain damage) in most (76%) of the 72 gas delivery equipment events.<sup>5</sup> Misconnects and disconnects of the breathing circuit were the most common causes of patient injury.<sup>5</sup> The majority (78%) of gas delivery equipment-related injuries were judged as being preventable with the use or better use of monitoring.<sup>5</sup> Improvements in anesthesia gas delivery equipment design,<sup>6,7</sup> declaring as obsolete older equipment that lacked certain safety features,<sup>||</sup> standard use of respiratory monitoring, and increased attention to provider training (including emphasis on correct performance of anesthesia machine pre-use check-out procedures<sup>##</sup>)<sup>8</sup> have occurred over the past 2 decades. Because these improvements may prevent patient harm resulting from equipment failures and provider error, we reviewed recent (since 1990) claims in the Closed Claims database related to gas delivery equipment. We hypothesized that claims associated with anesthesia gas delivery equipment would decrease over time.

## Materials and Methods

The ASA Closed Claims database is a structured evaluation of adverse anesthetic outcomes obtained from the files of 35 professional liability insurance companies. Claims for dental damage are not included in the database. The individual companies contributing to the database have varied over time, but the sample has remained relatively constant in overall geographic scope and market share since project inception. The methodology has been well described.<sup>9</sup> Claim files include any demand for payment, whether or not a lawsuit was filed or payment ultimately made to the plaintiff. In brief, closed claim files typically consisting of the hospital and medical records, narrative statements from involved healthcare personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury awards were reviewed on-site at the

professional liability company by practicing board-certified anesthesiologists. The on-site reviewer completed a standardized form for each claim with information on patient characteristics, surgical procedures, sequence and location of events, critical incidents and injuries, severity of injury, standard of care, outcome, and payments. Each claim was assigned an injury severity score using the insurance industry's 10-point severity scale that ranges from 0 (no injury) to 9 (death).<sup>10</sup> The injury-causing event was determined by the on-site reviewer and later confirmed by the Closed Claims Committee. The on-site reviewer wrote a detailed claim summary narrative of the sequence of medical events to describe and explain the circumstances and outcomes of each claim.

Inclusion criteria for this report were all claims for surgical or obstetric anesthesia using general anesthesia or combined general plus regional anesthesia technique from a total database of 9,806 claims. Restricting the analysis to general or combined anesthesia techniques removes potential bias created by changes in claims such as the increase in chronic pain management claims over time or change in surgical anesthesia (increase in regional anesthesia or monitored anesthesia care). Claims involving gas delivery equipment problems were compared with all other claims meeting study inclusion criteria (acute and chronic pain management claims not included) to describe trends in anesthesia gas delivery equipment claims over time.

## Definition of Study Variables

Gas delivery equipment was defined as any device used to convey gas to or from (but not involving) the endotracheal tube or mask.<sup>5</sup> Gas delivery equipment was classified as anesthesia machines, ventilators, vaporizers, breathing circuits, and supplemental oxygen supply (tanks or delivery tubing) using definitions previously established.<sup>5</sup> The anesthesia machine included components situated between the fresh gas tank or supply line inlets of the anesthesia machine and the common gas outlet of the anesthesia machine, excluding the vaporizer. The vaporizer included equipment situated between the incoming gas supply port of the vaporizer and the gas outlet of the vaporizer. The ventilator included equipment components situated between the incoming gas supply ports of the ventilator and the gas delivery outlet of the ventilator. Breathing circuits were defined as inspiratory and expiratory limb components that originate at the common gas outlet of the anesthesia machine or at the gas delivery outlet of the ventilator, and terminate at the connection to the endotracheal tube or mask. This included the inspiratory and expiratory unidirectional valves, carbon dioxide absorber canister, adjustable pressure limit ("pop-off") valve, and waste gas scavenging system. Supplemental oxygen supply included delivery tubes used to convey oxygen from a wall oxygen source to devices (*e.g.*, masks, nasal cannula, self-inflating manual ventilation device (SIMVD; *e.g.*, Ambu® bag; Ambu, Inc., Glen Burnie, MD; Mapleson

|| American Society of Anesthesiologists (ASA) guidelines for determining anesthesia machine obsolescence (posted 2004). Available at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx#rec>. Accessed April 29, 2013.

# FDA publishes final version of revised apparatus checkout: Anesthesia Apparatus Checkout Recommendations, 1993. Available at: [http://www.apsf.org/newsletters/html/1994/fall \(Article #8\)](http://www.apsf.org/newsletters/html/1994/fall%20(Article%20#8).htm). Accessed April 29, 2013.

\*\* ASA Recommendations for Pre-Anesthesia Checkout Procedures (2008). Available at: <http://www.asahq.org/For-Members/Clinical-Information/2008-ASA-Recommendations-for-PreAnesthesia-Checkout.aspx>. Accessed April 29, 2013.

F/Jackson-Rees circuit), as well as supply tanks or lines, including equipment components, storage units, gas cylinders, or pipelines connected to the fresh gas supply inlets of the anesthesia machine.

For each gas delivery equipment claim that occurred in 1990 or later, the following factors contributing to the adverse event were classified by two of the authors (Drs. Domino and Eisenkraft): equipment failure, provider error, and preventable by appropriate preanesthesia machine check-out. Equipment failure was defined as an unexpected malfunction of a device, despite routine maintenance and previous uneventful use.<sup>5</sup> Provider error was defined as fault or human error associated with the preparation, maintenance, or deployment of a device.<sup>5</sup> A case was coded as preventable if a standard preanesthesia machine equipment check-out would have detected the malfunction or faulty set-up. In the case of disagreement on classifications, discussion of the case was used to achieve agreement.

Each claim was classified into a single primary outcome using the outcome with highest severity score. For example, if death resulted after an intermediate outcome such as pneumothorax or brain damage, the outcome was classified as death. Permanent brain damage was defined as brain damage with a severity of injury score of 6–8. Claims were grouped into time periods of 1970–1989 *versus* 1990–2011 for analysis of changes in gas delivery equipment outcomes and payments.

### Statistical Methods

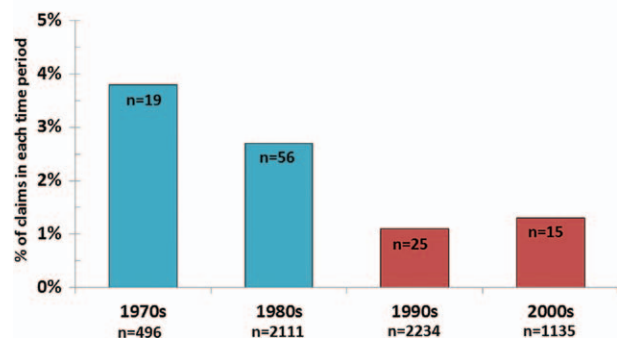
The proportion of gas delivery equipment claims was compared with other claims over decades with the chi-square test. Gas delivery equipment claims from 1970 to 1989 were compared with 1990–2011 using Fisher exact test for proportions and Mann–Whitney U test for payment amounts with Monte–Carlo significance calculated from 10,000 random tables (SPSS version 18.0.3; IBM, Chicago, IL). Kappa was calculated for classifications of provider error, equipment failure, and preventable by preanesthesia machine check. Payments were adjusted to 2012 dollar amounts using the Consumer Price Index.<sup>††</sup> All tests were two-sided with the threshold of statistical significance set at a *P* value of less than 0.05.

## Results

### Trends Over Decades

Anesthesia gas delivery equipment claims decreased as a proportion of general anesthesia claims over time, representing 4% of claims from the 1970s, 3% from the 1980s, 1% from the 1990s, and 1% from 2000 to 2011 (*P* < 0.001; fig. 1). The most recent anesthesia gas delivery equipment event in the Closed Claims database occurred in 2006, whereas there

### Anesthesia Gas Delivery Claims Over Time

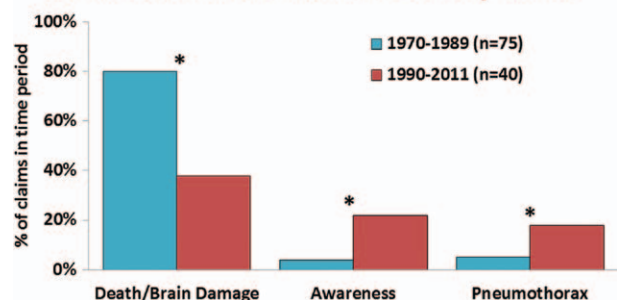


**Fig. 1.** Gas delivery equipment claims decreased in the 1990–2011 compared with earlier decades. Claims with missing data excluded. Total number of included claims (general anesthesia or general anesthesia plus regional anesthesia) in time period listed below each bar. *P* < 0.001 by chi-square test.

were 110 other claims meeting inclusion criteria from 2007 to 2011 (the most recent event being in 2011).

The outcomes in anesthesia gas delivery equipment claims from 1990 to 2011 were less severe than in earlier claims (fig. 2). Although death/severe brain damage represented 38% (*n* = 15) of the 40 gas delivery equipment injuries in 1990–2011, these outcomes were reduced by approximately one-half compared with the 1970s–1980s (*P* < 0.001; fig. 2). Awareness was more common in 1990–2011 claims (23%, *n* = 9; *P* = 0.003) than in earlier gas delivery claims, followed by pneumothorax in 18% (*n* = 7; *P* = 0.047 compared with 1970–89). There was no statistically significant difference between the occurrence of any pneumothorax between the earlier and later gas delivery equipment claims (16 *vs.* 25%; *P* = 0.243). However, more (67%) of the earlier claims with pneumothorax resulted in death or brain damage (primary outcome), whereas in more of the later claims (70%) the pneumothorax was the primary outcome (*P* = 0.087). This trend in outcome of pneumothorax reflected the severity of the initial insult rather than difference in resuscitation technique between the two time periods.

### Outcomes in Anesthesia Gas Delivery Claims



**Fig. 2.** The outcomes in anesthesia gas delivery equipment claims from 1990 to 2011 were less severe than in earlier claims. One claim with missing year of event excluded. Pneumothorax excludes claims in which it resulted in death or brain damage. \* *P* < 0.05 by Fisher exact test.

<sup>††</sup> Available at: [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm). Accessed February 25, 2013.

Demographics of patients were similar in the two time periods, with the exception of more outpatient procedures in 1990–2011 claims (table 1;  $P = 0.014$ ). However, no gas delivery claims originated in offices (in contrast to 41 of other claims meeting inclusion criteria). Cardiac anesthesia cases constituted 6% of delivery equipment claims, and did not differ between the two time periods.

Most gas delivery equipment claims involved lawsuits, with no difference over time. A lawsuit was filed in most (90%) of anesthesia gas delivery equipment claims, similar to other general anesthesia claims (87%;  $P = 0.571$ ). A lawsuit was filed in 87% of 1970–1989 gas delivery equipment claims compared with 91% of 1990–2011 claims ( $P = 0.750$ ). Most ( $n = 32$ , 80%) of the 1990–2011 claims resulted in payment, similar to earlier claims, but the magnitude of payments was smaller ( $P = 0.002$ ) in 1990–2011 claims (table 1).

### 1990–2011 Gas Delivery Claims

Vaporizers ( $n = 14$ , 35%), supplemental oxygen supply equipment ( $n = 11$ , 28%), and breathing circuits ( $n = 8$ , 20%) were the most common sources of gas delivery equipment problems, accounting for greater than 80% of gas delivery equipment claims in 1990–2011 (table 2). Ventilators and anesthesia machine problems occurred in fewer

claims (table 2). The majority of recent gas delivery equipment claims involved provider error ( $n = 34$ , 85%), either with equipment failure ( $n = 7$ , 18%) or without ( $n = 27$ , 68%; table 2). Equipment failure alone occurred in a minority of claims ( $n = 5$ , 13%). One third of claims were considered preventable by preanesthesia machine check ( $n = 14$ , 35%; table 2), attributable to claims related to vaporizers, anesthesia machines, or breathing circuits. None of the supplemental oxygen supply or ventilator claims were judged as preventable by preanesthesia machine check.

**Vaporizers.** The most common outcome from vaporizer problems ( $n = 14$ ) was light anesthesia ( $n = 10$ , 71%) resulting in awareness ( $n = 9$ ) or patient movement during surgery resulting in eye injury ( $n = 1$ ). Reasons for light anesthesia included failure to turn on the vaporizer due to lack of familiarity with equipment or memory lapse ( $n = 3$ ), failure to notice that the vaporizer was empty ( $n = 2$ ), vaporizer not mounted correctly ( $n = 2$ ), vaporizer malfunction ( $n = 2$ ), and a leak in the vaporizer caused by a missing O-ring ( $n = 1$ ). One case of vaporizer malfunction was discovered by end-tidal agent monitoring. Fresh gas flow rates for light anesthesia cases were not reported. The remaining vaporizer claims involved unintentional volatile anesthetic agent overdoses ( $n = 3$ , one of which resulted in severe brain damage), and carbon monoxide poisoning from the interaction

**Table 1.** Patient and Case Characteristics in Anesthesia Gas Delivery Equipment Claims

	1990 or Later <i>n</i> = 40	1970–1989 <i>n</i> = 75	<i>P</i> Value
Sex			0.732
Female	25 (64%)	45 (61%)	
Male	14 (36%)	29 (39%)	
Age in years			
Mean (SD)	40 (22)	35 (21)	0.230
Age group			1.00
Pediatric	7 (18%)	13 (17%)	
Adult	33 (82%)	62 (83%)	
ASA physical status			0.234
1–2	22 (63%)	36 (75%)	
3–5	13 (37%)	12 (25%)	
Emergency	5 (14%)	18 (34%)	0.029
Inpatient vs. outpatient			0.014
Inpatient	27 (73%)	41 (93%)	
Outpatient	10 (27%)	3 (7%)	
Liability			
Lawsuit filed	35 (88%)	68 (91%)	0.750
Payment made	32 (82%)	59 (87%)	0.511
Payment amount			
Median	\$202,980	\$818,805	0.002
Interquartile range	\$92,336–\$722,415	\$222,768–\$2,463,142	

One gas delivery equipment claim had unknown year of event. *P* values by *t* test (age in years), Mann–Whitney U test (payment amount), chi-square test (sex; ASA physical status; emergency; inpatient vs. outpatient; payment made), and Fisher exact test (lawsuit filed). Claims with missing data excluded. Percentages based on time period (columns). Payment amounts adjusted to 2012 dollars by Consumer Price Index: [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm). Accessed February 25, 2013.

ASA = American Society of Anesthesiologists.



**Table 2.** Provider Error, Equipment Failure, and Prevention (1990 or later)

Type of Equipment	Provider Error Only	Equipment Failure Only	Both	Preventable by Preanesthesia Check
Vaporizer * n = 14	8 (57%)	3 (21%)	2 (14%)	6 (43%)
Supplemental oxygen supply n = 11	11 (100%)	0	0	0
Breathing circuit n = 8	2 (25%)	1 (13%)	5 (63%)	6 (75%)
Ventilator n = 5	5 (100%)	0	0	0
Anesthesia machine n = 2	1 (50%)	1 (50%)	0	2 (100%)
Total n = 40*	27 (68%)	5 (13%)	7 (18%)	14 (35%)

Percentages based on type of equipment (row %). Percentages may sum to >100% or <100% due to rounding. Kappa: equipment failure or not (0.61), provider error or not (0.64), preventable by preanesthesia machine check or not/not applicable (0.74). All disagreements were resolved through consensus discussion between the two reviewers.

\* One vaporizer claim had no error identified.

of desflurane with desiccated Baralyme® (Allied Healthcare Products, Inc., St. Louis, MO) (n = 1, resulting in low severity injury).

**Supplemental Oxygen Supply.** Supplemental oxygen supply events (n = 11) occurred outside the operating room and involved equipment misuse of supplemental oxygen delivery tubing (n = 9) or supply tanks (n = 2). Outside locations included the postanesthesia care unit (n = 5), nonoperating room sites (n = 3), intensive care (n = 1), and transport (n = 2). Actions of technicians (n = 2) and nurses (n = 5) contributed to the injury in 75% of oxygen supply events. Improvised delivery devices in spontaneously breathing patients included oxygen delivery tubing, mask, or nebulizer placed at the end of the endotracheal tube (n = 5), anesthesia circuit connected at one end to an oxygen tank and at the other end to a humidifier (n = 1), use of nonbreathing circuits with hyperinflation of the reservoir bag (n = 2), and excessive oxygen flow rates to deliver a tracer to an intubated patient undergoing a nuclear medicine procedure (n = 1). Continuous inflow of oxygen into the lungs with impediment of exhalation resulted in barotrauma. All supplemental oxygen delivery tubing claims resulted in pneumothorax, leading to cardiac arrest in four of nine claims, and resulting in death/brain damage in three of these four claims. In the two oxygen supply tank claims, carbon dioxide was accidentally substituted for oxygen for patient transport to the intensive care unit. Both cases resulted in patient death. In both cases, the appearance of the oxygen and carbon dioxide tanks was similar. In one case, the labels were in different colors (green *vs.* gray), but room lighting in the cardiac catheterization lab may have obscured this difference. In the other case in the operating room, a change in vendors resulted in similarity of the oxygen and carbon dioxide tanks.

**Breathing Circuits.** Out of the eight breathing circuit injuries, death/brain damage occurred in half (n = 4); the remaining involved temporary injury. Causes of breathing

circuit claims events were mostly difficult to impossible ventilation. Most events involved obstruction of the circuit due to sticking inspiratory or expiratory unidirectional valves (n = 4) or plastic from the circuit blocking the lumen of the circuit (n = 1). Misconnects occurred in two claims: positive end-expiratory pressure valve connected to the inspiratory limb of a circle system (n = 1) and incorrect placement of the reservoir bag (n = 1). In four claims, the anesthesiologist reintubated the patient's trachea in response to difficult ventilation and in four claims, the anesthesiologist mistakenly diagnosed and treated the difficulty in ventilation as bronchospasm. Ventilation was successful by use of an SIMVD in three low severity claims, whereas death or permanent brain damage occurred in claims in which SIMVD ventilation was not attempted despite availability (n = 2), not available in the ambulatory surgery center (n = 1), or used too late after cardiac arrest when recommended by a consultant (n = 1). A wire spark melted the breathing circuit and caused a burn in one claim. None of the breathing circuit claims were related to disconnections.

**Ventilators.** Ventilator claims arose from death (n = 4) or severe brain damage (n = 1) due to provider failure to turn on the ventilator. All of these claims involved failure to resume mechanical ventilation in various clinical scenarios: after position change (n = 2), upon transfer of an intubated intensive care patient to the operating room (n = 1), after discontinuation of cardiopulmonary bypass (n = 1), and after discontinuing it during placement of a chest tube (n = 1). In most cases (n = 4), the provider disabled or turned off the ventilator alarms or disconnected monitors.

**Anesthesia Machine.** Anesthesia machine claims (n = 2) resulted in case cancellation, but no residual sequelae. In one claim, a pediatric patient became hypoxemic and sustained a cardiac arrest due to a machine leak that prevented ventilation (no SIMVD immediately available), but resuscitation

was successful without apparent injury. The anesthesia provider did not perform a machine check before the start of the case, and an SIMVD was not available in the operating room. The second claim involved a stuck oxygen valve which resulted in spontaneously increased nitrous oxide flow rates.

## Discussion

Claims for injuries related to anesthesia gas delivery equipment in the ASA Closed Claims Project database decreased as a proportion of general anesthesia malpractice claims over time, representing only 1% of general anesthesia claims in 1990–2011. The severity of injury also decreased, with a higher proportion of claims for awareness in 1990–2011. The majority of injuries related to gas delivery equipment resulted from provider error.

The limitations of closed claims analysis have been previously described, including selection bias, lack of denominators, and nonrandom, retrospective data collection.<sup>9</sup> The database only includes claims against anesthesiologists; some gas delivery claims may have been only against equipment manufacturers. However, there is no reason for any difference over time in whether an anesthesiologist was cited as a defendant. Although a lawsuit was filed in most claims, many claims are settled out of court. Many lawsuits are filed to maintain options in the face of statutes of limitations. Tort reform would not necessarily affect claims rates, as claims are generally filed before lawsuits.

There are published case reports of anesthesia gas delivery equipment problems that are not included in the Closed Claims Project.<sup>11–13</sup> Many incidents do not result in claims.<sup>14</sup> The Closed Claims Project represents a subset of injuries that have occurred nationally, some possibly publicly disclosed and some not otherwise published or available as public records.

There is a delay of 2–7 yr from injury for resolution of a claim and its incorporation into the database, resulting in a lower number of claims collected after 2006. Although it is possible that additional anesthesia gas delivery equipment claims from 2000 to 2011 remain open and therefore not represented in this report, the consistent trend since 1990 suggests that a substantial increase beyond the 1% rate reported is unlikely for 2000–2011. To model the effect of incomplete data collection on the 2000–2011 rate of gas delivery equipment claims reported herein, it is reasonable to assume that the 2000–2011 claims included in this report account for approximately half of all claims in this time period that will ultimately be included in the database. Based on that assumption, an additional 30 gas delivery claims would produce a rate of 2.6% of the additional 1,135 claims collected rather than the 1.3% ( $n = 15$  of 1,135 general anesthesia claims) reported herein. Given

that we are consistently finding 0–2 additional anesthesia gas delivery equipment claims in our new data each year, collection of an additional 30 gas delivery claims from 2000 to 2011 seems highly unlikely.

Anesthesia gas delivery equipment problems occur infrequently,<sup>1–3</sup> yet form common critical incidents during anesthesia care.<sup>4</sup> Fasting and Gisvold<sup>1</sup> found that gas delivery equipment problems were the most common equipment problem in their hospital from 1996 to 2000, with the anesthesia machine, breathing circuit, and vaporizers accounting for 31%. In most cases, problems can be averted by careful preanesthesia machine check-out and vigilance. A previous closed claims study revealed severe injuries from gas delivery equipment.<sup>5</sup> Our current review of closed anesthesia claims from 1990 to 2011 found a decrease in both the number and severity of injury in claims related to gas delivery equipment. Improvements in anesthesia machine, ventilator, and circuit design; standard use of respiratory monitoring with audible alarms; and enhanced provider training, including standardized preanesthesia machine check-out procedures, may have contributed to the reduction in number and severity of claims related to anesthesia gas delivery equipment. Almost all (86%) recent gas delivery claims were associated with provider error and a third were judged as preventable by correctly performed preanesthesia machine checks.

The proportion of claims involving awareness associated with vaporizer problems was greater in 1990–2011 compared with the 1970s–1980s. We found only one claim associated with carbon monoxide poisoning from the interaction of a volatile anesthetic agent with desiccated Baralyme®, and no claims involving overheating of carbon dioxide absorbers such as reported by Fatheree and Leighton,<sup>11</sup> Wu *et al.*,<sup>12</sup> or Castro *et al.*<sup>13</sup> Vaporizer problems accounted for 5% of critical incident reports concerning anesthesia equipment,<sup>4</sup> most often from misfit of vaporizers onto the back bar of the anesthesia machine, and failure to perform a leak test.<sup>4</sup> An anesthesia machine low pressure system leak test performed during the preanesthesia machine check should detect improper mounting of a vaporizer on the back bar of the machine and exclude a leak from the vaporizer when it is in the “on” or “off” position.<sup>15</sup> Improved vigilance and monitoring of end-tidal anesthetic agent concentrations can readily detect most vaporizer problems.<sup>16,17</sup> The current ASA Standards for Basic Anesthesia Monitoring<sup>‡‡</sup> do not require monitoring of anesthetic agents (or nitrous oxide) in the inspired gas mixture. However, as more practitioners are now using agent analysis, it may become a *de facto* standard of care.

Improvisation of supplemental oxygen supply lines in patient transport, in postanesthesia care unit and intensive care unit, and in nonoperating room sites resulted in pneumothorax (often leading to death). In many of these cases, nurses or technicians contributed to the problems, often associated with lack of familiarity and improvised systems. Wax *et al.*<sup>18</sup> reported use of an improvised system for delivering

‡‡ Standards for Basic Anesthetic Monitoring (effective July 1, 2011). Available at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>. Accessed April 29, 2013.

supplemental oxygen to a spontaneously breathing, intubated patient for transport to the postanesthesia care unit, resulting in barotrauma.<sup>18</sup> In another report, during resuscitation of a patient with postpartum hemorrhage, a trainee, unnoticed, connected the oxygen delivery (at 10 l/min) tubing directly into the tracheal tube connector causing pulmonary barotrauma with a fatal outcome.<sup>19</sup> Use of standard transportation oxygen supply line equipment, total avoidance of improvised delivery devices, and improved education for personnel outside the operating room who participate in oxygen delivery equipment set-up may help to prevent such errors.

Unlike the previous closed claims analysis,<sup>5</sup> there were no claims for breathing circuit disconnects and few claims for breathing circuit misconnects, suggesting that improvements in breathing circuit design, ventilator design, and respiratory monitoring/alarms have improved patient safety. Instead, misdiagnosis of stuck inspiratory/expiratory valves caused half of the breathing circuit events. Prompt use of a SIMVD or other means of ventilation in the advent of difficult or impossible ventilation may prevent injury. Item 1 of the ASA 2008 preanesthesia check-out guidelines includes verification that a SIMVD is available and functioning.¶¶ In a study of missed steps in the preanesthetic set-up, the availability of an SIMVD and a working suction were the ones most frequently missed.<sup>20</sup> The importance of having a tested functioning SIMVD immediately available cannot be overemphasized. Malfunctioning unidirectional valves in the breathing system can be readily detected by a preanesthesia machine check-out or by use of a dedicated valve testing device.<sup>21</sup> Using simulation, most examinees were able to correctly identify expiratory valve malfunction on the anesthesia machine.<sup>22</sup> Failure of an expiratory unidirectional valve leading to rebreathing of carbon dioxide, while described in the literature,<sup>23</sup> was not observed in our claims analysis.

Disposable breathing circuits may have manufacturing defects that can have fatal consequences.<sup>24</sup> Monteiro *et al.*<sup>24</sup> reported three cases in which foreign bodies were lodged within the breathing circuit, which led to the inability to ventilate patients due to complete obstruction. Malfunction of a positive end-expiratory pressure valve resulted in pressures of 50–60 cm H<sub>2</sub>O causing pneumothorax.<sup>25</sup> At the time, the Food and Drug Administration Anesthesia Apparatus Checkout Recommendations (1986) did not provide guidance to the assessment of properly functioning positive end-expiratory pressure valves before the start of the case.<sup>25</sup>

Ventilator problems involving sudden failure or sustained or increased positive pressure account for almost 20% of critical incidents relating to anesthesia equipment.<sup>4</sup> With automatically enabled breathing circuit low pressure, continuing pressure, high pressure alarms, and high pressure release valves, these events should be readily detected and treated. However, our closed claims analysis found death/brain damage due to provider failure to resume ventilation after positioning, transport, or surgical procedures, including

cardiopulmonary bypass. Disabled or disconnected alarms contributed to delays in recognition and poor outcomes. The incorporation into an anesthesia ventilator of a limited time ventilation pause control (rather than operation of the ventilator on/off switch) might be helpful in situations in which ventilation must be briefly interrupted.

Schmid *et al.*<sup>26</sup> observed a high rate of alarms in elective cardiac surgery, occurring at a mean of 1.2 alarms/min. Most were hemodynamic alarms without therapeutic consequences, such as during electrocautery use or blood drawing. In contrast, ventilator alarms accounted for only 16% of alarms.<sup>26</sup> This high rate of false alarms may cause providers to ignore alarms, even when they are important for patient safety. Eden *et al.*<sup>27</sup> developed a computerized algorithm that detects separation from cardiopulmonary bypass based on physiological variables, which leads to an increase in the rate of reactivation of ventilator alarms.

In summary, anesthesia gas delivery equipment claims and their severity of injury in the ASA Closed Claims database decreased in 1990–2011 compared with earlier decades. Provider error, by both anesthesia providers and others (technicians, nurses), continues to contribute to severe injury, especially with inadequate use of alarms, improvised oxygen delivery systems, and failure to ventilate manually in the event of difficult or impossible ventilation using the anesthesia machine and breathing circuit.

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## References

1. Fasting S, Gisvold SE: Equipment problems during anaesthesia—Are they a quality problem? *Br J Anaesth* 2002; 89:825–31
2. Schwilk B, Muche R, Treiber H, Brinkmann A, Georgieff M, Bothner U: A cross-validated multifactorial index of perioperative risks in adults undergoing anaesthesia for non-cardiac

- surgery. Analysis of perioperative events in 26907 anaesthetic procedures. *J Clin Monit Comput* 1998; 14:283–94
3. Bothner U, Georgieff M, Schwillk B: Building a large-scale perioperative anaesthesia outcome-tracking database: Methodology, implementation, and experiences from one provider within the German quality project. *Br J Anaesth* 2000; 85:271–80
  4. Cassidy CJ, Smith A, Arnot-Smith J: Critical incident reports concerning anaesthetic equipment: Analysis of the UK National Reporting and Learning System (NRLS) data from 2006–2008\*. *Anaesthesia* 2011; 66:879–88
  5. Caplan RA, Vistica MF, Posner KL, Cheney FW: Adverse anesthetic outcomes arising from gas delivery equipment: A closed claims analysis. *ANESTHESIOLOGY* 1997; 87:741–8
  6. American Society for Testing and Materials: Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines. F1161–88. Philadelphia, American Society for Testing and Materials, 1989
  7. American Society for Testing and Materials: Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components ASTM F1850-00. West Conshohocken, American Society for Testing and Materials, 2000 (reapproved 2005)
  8. Olympio MA, Goldstein MM, Mathes DD: Instructional review improves performance of anesthesia apparatus checkout procedures. *Anesth Analg* 1996; 83:618–22
  9. Cheney FW, Posner K, Caplan RA, Ward RJ: Standard of care and anesthesia liability. *JAMA* 1989; 261:1599–603
  10. Malpractice Claims: Final Compilation. Edited by Sowka M. Brookfield, National Association of Insurance Commissioners, 1980
  11. Fatheree RS, Leighton BL: Acute respiratory distress syndrome after an exothermic Baralyme-sevoflurane reaction. *ANESTHESIOLOGY* 2004; 101:531–3
  12. Wu J, Previte JP, Adler E, Myers T, Ball J, Gunter JB: Spontaneous ignition, explosion, and fire with sevoflurane and barium hydroxide lime. *ANESTHESIOLOGY* 2004; 101:534–7
  13. Castro BA, Freedman LA, Craig WL, Lynch C III: Explosion within an anesthesia machine: Baralyme, high fresh gas flows and sevoflurane concentration. *ANESTHESIOLOGY* 2004; 101:537–9
  14. Localio AR, Lawthers AG, Brennan TA, Laird NM, Hebert LE, Peterson LM, Newhouse JP, Weiler PC, Hiatt HH: Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III. *N Engl J Med* 1991; 325:245–51
  15. Myers JA, Good ML, Andrews JJ: Comparison of tests for detecting leaks in the low-pressure system of anesthesia gas machines. *Anesth Analg* 1997; 84:179–84
  16. Hendrickx JF, Carette RM, Deloof T, De Wolf AM: Severe ADU desflurane vaporizing unit malfunction. *ANESTHESIOLOGY* 2003; 99:1459–60; author reply 1460
  17. Geffroy JC, Gentili ME, Le Pollès R, Triclot P: Massive inhalation of desflurane due to vaporizer dysfunction. *ANESTHESIOLOGY* 2005; 103:1096–8
  18. Wax DB, Bhagwan S, Beilin Y: Tension pneumothorax and cardiac arrest from an improvised oxygen delivery system. *J Clin Anesth* 2007; 19:546–8
  19. Singh S, Loeb RG: Fatal connection: Death caused by direct connection of oxygen tubing into a tracheal tube connector. *Anesth Analg* 2004; 99:1164–5
  20. DeMaria S Jr, Blasius K, Neustein SM: Missed steps in the preanesthetic checkout. *Anesth Analg* 2011; 113:84–8
  21. Eappen S, Corn SB: The anesthesia machine valve tester: A new device and method for evaluating the competence of unidirectional anesthetic valves. *J Clin Monit* 1996; 12:305–9
  22. Ben-Menachem E, Ezri T, Ziv A, Sidi A, Berkenstadt H: Identifying and managing technical faults in the anesthesia machine: Lessons learned from the Israeli Board of Anesthesiologists. *Anesth Analg* 2011; 112:864–6
  23. Thorning GP, Groba CB: Critical incident due to a corroded expiratory valve. *Anaesthesia* 2005; 60:823–4; discussion 824
  24. Monteiro JN, Ravindran MN, D'Mello JB: Three cases of breathing system malfunction. *Eur J Anaesthesiol* 2004; 21:743–5
  25. Anagnostou JM, Hults SL, Moorthy SS: PEEP valve barotrauma. *Anesth Analg* 1990; 70:674–5
  26. Schmid F, Goepfert MS, Kuhnt D, Eichhorn V, Diedrichs S, Reichensperner H, Goetz AE, Reuter DA: The wolf is crying in the operating room: Patient monitor and anesthesia workstation alarming patterns during cardiac surgery. *Anesth Analg* 2011; 112:78–3
  27. Eden A, Pizov R, Toderis L, Kantor G, Perel A: The impact of an electronic reminder on the use of alarms after separation from cardiopulmonary bypass. *Anesth Analg* 2009; 108:1203–8