CLINICAL INVESTIGATIONS

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Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment

A Closed Claims Analysis

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Background: Anesthesia gas delivery equipment is a potentially important source of patient injury. To better define the contribution of gas delivery equipment to professional liability in anesthesia, the authors conducted an in-depth analysis of cases from the database of the American Society of Anesthesiologists Closed Claims Project.

Methods: The database of the Closed Claims Project is composed of closed US malpractice claims that have been collected in a standardized manner. All claims resulting from the use of gas delivery equipment were reviewed for recurrent patterns of injury.

Results: Gas delivery equipment was associated with 72 (2%) of 3,791 claims in the database. Death and permanent brain

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damage accounted for almost all adverse outcomes (n = 55, 76%). Equipment misuse was defined as fault or human error associated with the preparation, maintenance, or deployment of a medical device. Equipment failure was defined as unexpected malfunction of a medical device, despite routine maintenance and previous uneventful use. Misuse of equipment (n = 54,75%) was three times more common than equipment failure (n = 17, 24%). Misconnects and disconnects of the breathing circuit made the largest contribution to injury (n = 25, 35%). Reviewers judged that 38 of 72 claims (53%) could have been prevented by pulse oximetry, capnography, or a combination of these two monitors. Overall, 56 of 72 gas delivery claims (78%) were deemed preventable with the use or better use of monitors. The year of occurrence for claims involving gas delivery equipment ranged from 1962 to 1991 and did not differ significantly from claims involving other adverse respiratory events.

Conclusions: Claims associated with gas delivery equipment are infrequent but severe and continue to occur in the 1990s. Educational and preventive strategies that focus on equipment misuse and breathing circuit configuration may have the greatest potential for enhancing the safety of anesthesia gas delivery equipment. (Key words: Anesthesia: claims; complications; injuries. Equipment: misuse; failure.)

ALMOST every piece of medical equipment carries some risk for misuse or failure. Anesthetic gas delivery devices are a particular concern because they exhibit several basic features that may predispose to critical events and subsequent patient injury. These include the presence of multiple connections, the use of complex mechanical components, and variations in manufacture and design.

We used the database of the American Society of Anesthesiologists (ASA) Closed Claims Project to conduct a detailed analysis of adverse outcomes associated with the use of gas delivery devices. The purpose of this study was to identify patterns of causation and strategies for prevention of injury that might not be evident from the study of isolated case reports or from data obtained under disparate investigative conditions.

Methods

The ASA Closed Claims Project is a structured evaluation of adverse anesthetic outcomes obtained from the closed claims files of 35 US professional liability insurance companies. Claims for dental damage are not included in this project. The database for the present study consists of 3,791 claims for adverse outcomes that occurred between 1961 and 1994. Three fourths (76%) of these claims occurred between 1980 and 1990.

A detailed description of the data collection process has been reported. In brief, a closed claim file for an adverse anesthetic outcome typically consists of relevant hospital and medical records, narrative statements from involved health care personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury award. Each claim is reviewed by a practicing anesthesiologist according to a standardized set of instructions. The reviewer uses a standardized form to record information on patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestations of injury, standard of care, and outcome. An adverse outcome is deemed preventable with better monitoring if the reviewer believes that the use or better use of any monitoring device probably would have prevented the outcome, regardless of whether such monitor was available at the time of the event. The reliability of reviewer judgments has been found to be acceptable.²

For the present study, *gas delivery equipment* was defined as any device used to convey gas to or from the endotracheal tube or mask. Claims involving endotracheal tubes and masks have been studied separately³⁻⁵ and thus were not included here. Each claim related to a problem involving gas delivery equipment was assigned to one of six basic equipment groups: anesthesia machine, breathing circuit, supplemental oxygen delivery tubing, gas supply tank or line, vaporizer, or mechanical ventilator (table 1).

Each claim file was examined for evidence of equipment misuse or failure. *Equipment misuse* was used to characterize claims in which the injury originated from human fault or error associated with the preparation, maintenance, or deployment of a medical device. An example of equipment misuse is the installation of a PEEP valve on the inspiratory limb of the breathing circuit. *Equipment failure* was used to characterize claims in which the device appeared to malfunction unexpectedly, despite routine maintenance and previous uneventful use. An example of equipment failure is a unidirectional ventilator valve that suddenly failed to open. A designation of *uncertain* was applied to cases in which the claim file did not contain enough information to distinguish between a primary role for

Table 1. Equipment Groups

Equipment Group	Description
Anesthesia machine	Equipment 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 Note: The vaporizer is considered
	separately; see below.
Breathing circuit	Inspiratory and expiratory limb
Dreathing circuit	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
	Note: The CO ₂ canister, scavenger system and expiratory valves are included in this group; the endotracheal tube and mask are excluded (see Methods)
Supplemental oxygen delivery tubing	Tubing used to convey oxygen from a wall oxygen source to devices such as masks and nasal cannulae
Supply tank or line	Equipment components, storage units, gas cylinders, or pipelines connected to the fresh gas supply inlets of the anesthesia machine
Vaporizer	Equipment components situated between: The incoming gas supply port of the vaporizer, and The gas outlet of the vaporizer
Ventilator	Equipment components situated between: The incoming gas supply ports of the ventilator, and The gas delivery outlet of the ventilator

misuse or failure. In keeping with Cooper's classification scheme,⁶ breathing circuit disconnects that persisted to the point of patient injury were considered examples of faulty intraoperative maintenance and thus were classified as equipment misuse.

Each claim was further characterized by an initiating event, a mechanism of injury, and an adverse outcome. An *initiating event* was defined as the aspect of equipment usage or function that was identified in the records as the key or critical starting point for evolution of the injury. An example of an initiating event is the detachment of a ventilator hose from the breathing circuit. *Mechanism of injury* was defined as the physiologic process or abnormality that played the primary role in producing the adverse outcome. Overdose of an inhalational anesthetic is an example of a mechanism

Table 2. Adverse Outcomes

Equipment Group	Death	Brain Damage	Awareness/Fright	Recovery Delayed	Tracheostomy Scar	Pneumothorax
Breathing circuit (n = 28)	10	10	1	5	1	1
Vaporizer (n = 15)	7	3	5	0	0	0
Ventilator (n = 12)	7	5	0	0	0	0
Supply tanks or lines (n = 8)	6	2	0	0	0	0
Anesthesia machine $(n = 5)$	3	0	1	0	1	0
Supplemental O_2 tubing $(n = 4)$	1	1	0	0		0
Total $(n = 72)$	34 (47%)	21 (29%)	7 (10%)	5 (7%)	2 (3%)	3 (4%)

of injury. Adverse outcome was defined as the actual injury sustained by the patient.

Several specific terms were used to describe recurrent initiating events. A *disconnect* was defined as the loss of attachment or continuity in a breathing circuit that was initially configured in a functional and conventional manner. A *misconnect* was defined as a nonfunctional and unconventional configuration of breathing circuit components or attachments. An *oxygen switch* was defined as the unintended substitution of an oxygen supply tank or supply line with another tank or line that did not contain or convey 100% oxygen.

Payments for settlement and jury award were expressed in original dollar amounts, without adjustment for inflation. Because payments did not exhibit a normal distribution, the median and range were used as descriptive measures. Statistical comparisons of payment distributions were made using the Kolmogorov-Smirnov test, with $P \leq 0.05$ considered significant. The same method was used to compare the distribution of occurrence dates for gas delivery claims *versus* other claims.

Results

Gas delivery equipment accounted for 72 of 3,791 claims (2%) in the ASA Closed Claims database. The

Table 3. Occurrence Sites

	Occurrence Site			
Equipment Group	Operating Room	PACU	ICU	
Breathing circuit (n = 28)	26	1	1	
Vaporizer (n = 15)	15	0	0	
Ventilator (n = 12)	8	2	2	
Supply tanks or lines (n = 8)	8	0	0	
Anesthesia machine (n = 5)	5	0	0	
Supplemental O ₂ tubing (n = 4)	0	3	1	
Total $(n = 72)$	62 (86%)	6 (8%)	4 (6%)	

PACU = postanesthesia care unit; ICU = intensive care unit.

most common adverse outcomes were death and brain damage (n = 55, 76%; table 2). Almost all adverse events associated with gas delivery equipment occurred in the operating room (n = 62, 86%; table 3). The breathing circuit was the most common source of injury, accounting for 28 of 72 claims (39%; table 2). Vaporizers (n = 15), ventilators (n = 12), and supply tanks or lines (n = 8) accounted for 49% of gas delivery claims. Events associated with the anesthesia machine were comparatively rare (n = 5, 7%).

Equipment misuse (n = 54, 75%) was three times more frequent than equipment failure (n = 17, 24%; table 4). Two thirds of claims involving misuse (38 of 54, 70%) resulted directly and almost exclusively from the actions of the primary anesthesia provider (i.e., anesthesiologist or nurse anesthetist). In the remaining 16 claims (30%), misuse resulted, at least in part, from the contributory actions of ancillary personnel such as technicians, engineers, suppliers, or nurses in the postanesthesia care unit (PACU) or intensive care unit (ICU). The role of ancillary personnel was especially prominent in claims involving a switch in oxygen supply (all seven cases). The contributory actions in these cases included crossed installation of supply lines at the back of the anesthesia machine by technicians (four cases), crossed installation of central supply lines by construction per-

Table 4. Misuse and Failure

	Claims Characterized by			
Equipment Group	Misuse	Failure	Uncertain	
Breathing circuit (n = 28)	26	2	0	
Vaporizer (n = 15)	7	8	0	
Ventilator (n = 12)	8	3	1	
Supply tanks or lines (n = 8)	7	1	0	
Anesthesia machine (n = 5)	2	3	0	
Supplemental O ₂ tubing (n = 4)	4	0	0	
Total $(n = 72)$	54 (75%)	17 (24%)	1 (1%)	

sonnel (one case), delivery of the wrong central tank by a gas supplier (one case), and unannounced nitrogen flushing of central oxygen lines by service engineers (one case). Actions of nursing personnel contributed to four of the six injuries that took place in the PACU. Three of these claims involved supplemental oxygen supply tubing that had been misused by creating a direct attachment between the wall oxygen source and the endotracheal tube. One other PACU claim involved a disconnect that occurred while a ventilator-dependent patient was left unattended by the recovery room nurse. Nurses or respiratory therapists played a contributory role in three of the four injuries that took place in the ICU by disabling a low-pressure disconnect alarm, by using a ventilator that had a misinstalled valve, and by creating a direct attachment between the wall oxygen source and the endotracheal tube (one case each). One intraoperative event involving the breathing circuit was linked to backward installation of a one-way valve by a service technician.

Two initiating events accounted for more than one third of all gas delivery claims (n = 25, 35%): misconnects (n = 14, 19%) and disconnects (n = 11, 15%). The three most frequently specified sites for disconnects and misconnects were the junction between the breathing circuit and the gas delivery outlet of the ventilator (9 of 25 cases, 36%), the junction between the distal end of the breathing circuit and the endotracheal tube (4 of 25 cases; 16%), and a location on the inspiratory limb of the breathing circuit that allowed the interposition of a PEEP valve (3 of 25 cases; 12%). The site of misconnect or disconnect was unspecified or unknown in 6 of 25 cases (24%). Other types of initiating events occurred at a frequency of 10% or less and usually were characterized by operator errors such as failure to turn on a device, selecting the wrong knob or dial, or the misinstallation of valves, gas lines, or gas tanks (table 5). Switches involving oxygen supply more often were associated with supply lines (six cases) than supply tanks (one case).

Inadequate oxygenation was the primary mechanism of injury in approximately half of the claims (n=38, 53%). This mechanism was associated with all disconnects, oxygen supply switches, and failures to turn on the ventilator. Two other mechanisms of injury accounted for most of the remaining claims: excessive airway pressure (n=13,18%) and overdose of inhalational anesthetic (n=12,17%). Claims involving excessive airway pressure exhibited two recurrent errors: incorrect connection of a breathing circuit hose to the

Table 5. Initiating Events

Equipment Group	Initiating Event	Number of Claims	% OF 72
Breathing circuit	. Hillian parani	S-malaticale	grieften 8
(n = 28)	Misconnect	14	19
	Disconnect	11	15
	Leak	1	1
	Valve failure	1	1
	CO ₂ canister defect	1	1
Vaporizer (n = 15)	Valve failure	5	7
	Leak	2	3
	Wrong dial/setting	2	3
	Tipped over	1	1
	Hooked up backward	1	1
	Not turned on	1	1
	Knob turned		
	inadvertently	1	1
	Uncertain	2	3
Ventilator (n = 12)	Not turned on	3	4
	Valve misinstalled	2	3
	Wrong ventilator		
	chosen	1	1
	Valve failure	1	1
	Wrong setting	1	1
	Uncertain	4	6
Supply tanks or			
lines (n = 8)	Oxygen switch	7	10
	Uncertain	1	1
Anesthesia machine			
(n = 5)	Leak	3	4
	Wrong knob turned	1	1
	Uncertain	1	1
Supplemental O ₂	Direct connection-		
tubing $(n = 4)$	wall to patient	4	6

ventilator (five cases), and use of supplemental oxygen delivery tubing in a PACU or ICU setting to create a direct connection between a source of wall oxygen and the endotracheal tube (four cases). Overdose of inhalational anesthetic was associated with three basic problems: valve malfunction within the vaporizer (five cases), spillage of liquid inhalational agent into the breathing circuit (two cases), and choice of the wrong dial or setting (two cases).

Most of the gas delivery claims resulted from events that took place in the decade of the 1980s (n = 49, 68%), with occurrence dates ranging from 1962 to 1991 (table 6). Injuries related to gas delivery equipment represented 2% (53/3,037) of all claims occurring during or after 1980 and 1% (18/1495) of all claims occurring during or after 1985. The distribution of occurrence dates for gas delivery claims was not significantly different from other types of adverse respiratory events. Gas delivery claims tended to be earlier in occurrence than nonrespiratory claims ($P \le 0.01$, table 6). Of note,

claims involving anesthesia machines, ventilators, and oxygen supply lines and tanks all predated 1990. Claims resulting from breathing circuits, vaporizers, and supplemental $\rm O_2$ tubing continued to occur in the 1990s.

A focused analysis of the eight claims involving vaporizer failure revealed an interesting contrast between older and newer claims. Six of the eight claims for vaporizer failure occurred before 1985, and all six resulted in brain damage or death. The initiating event in five of the six claims was vaporizer valve malfunction (spool valve or check valve). In one of the six claims, an initiating event was not explicitly identified, but liquid inhalation agent was found in the CO₂ canister, and experts who reviewed the case cited similar problems with that model of vaporizer. In contrast, the two more recent claims involving vaporizer failure (1990 and 1991) were associated with intraoperative awareness. Both of the recent claims were caused by the delivery of inhalation agents at concentrations that were lower than intended. In one case, inadequate agent delivery was attributed to a leak produced by a missing vaporizer O-ring. In the other case, the claim file simply indicated that the vaporizer underwent subsequent testing and that the device was "not delivering the prescribed concentration."

Reviewers judged that the use or better use of monitoring could have prevented injury in 56 of 72 gas delivery claims (78%), including 11 (61%) of the 18 claims occurring between 1985 and 1991. Reviewers identified a preventive role for the following monitors: pulse oximeter (35 cases), capnograph (25 cases), anesthetic agent analyzer (12 cases), oxygen analyzer (9 cases), airway pressure alarm (7 cases), and precordial or esophageal stethoscope (1 case). In 9 of 56 cases (16%), a mechanical monitor or alarm (e.g., oxygen analyzer, high- or low-pressure circuit alarm, oxygen-ratio monitor controller) that could have played a preventative role was physically present as an anesthesia machine attachment or component, but was either turned off or broken. In three cases (5%), a mechanical monitor or alarm that could have played a preventative role was not physically present as an attachment or component on the anesthesia machine. Claims that reviewers did not consider preventable with better monitoring (16 of 72; 22%) typically involved situations in which the initiating event progressed rapidly to a point at which it created an injurious physiologic process. Examples include barotrauma produced by attaching an endotracheal tube directly to a 50 psi source of oxygen and

Table 6. Year of Event

Equipment Group	Median	Range	
Breathing circuit (n = 28)	1981	1962-1990	
Vaporizer (n = 15)	1984	1978-1991	
Ventilator (n = 12)	1982-1983	1980-1988	
Supply tanks or lines (n = 8)	1977	1975-1983	
Anesthesia machine (n = 5)	1980-1981	1977-1987	
Supplemental O ₂ tubing (n = 4) All gas-delivery equipment	1986-1987	1977-1991	
events $(n = 72)$	1982	1962-1991*	
Other adverse respiratory			
events (n = 1,058)	1983	1961-1993	
Other claims (n = 2,661)	1984	1966-1994*	

 $^{^*}P$ < 0.01 between the distribution of occurrence dates of gas-delivery equipment events and other (nonrespiratory) claims.

cardiovascular depression produced by spilling liquid inhalation agent into the breathing circuit.

Overall, 38 claims (53%) were considered preventable if a pulse oximeter, capnograph, or a combination of these two monitors had been used. Of note, there were two claims in which human factor issues related to judgment and attention negated the preventive value of pulse oximetery or capnography. In the first case, the pulse oximeter indicated the presence of hypoxemia, but the anesthesiologist interpreted the low reading as an artifact of probe position. In the second case, the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass. The delayed detection of apnea was attributed to the fact that the audible alarms for the pulse oximeter and capnograph had been disabled during bypass and had not been reactivated. Both patients sustained permanent brain damage.

Payment for settlement or jury award was received in 76% of claims involving gas delivery equipment. The median payment in these claims was \$306,000 (range, \$542 to \$6,337,000). This is comparable with the payment for other adverse respiratory events in the Closed Claims database (median, \$230,000; range, \$390-\$6,300,000), but significantly higher than nonrespiratory events (median, \$50,000; range, \$15-\$23,000,000; P < 0.01 between payment distributions).

Discussion

During the past two decades, large-scale surveys of anesthetic outcome have identified gas delivery equipment as a small but recurrent cause of serious injury.^{7–13}

These studies attribute approximately 1 - 5% of anesthesia-related death and brain damage to problems with gas delivery equipment. The ASA Closed Claims Project provides similar data, with gas delivery equipment accounting for 3% of claims for death (34/1277) and 5% of claims for brain damage (21/466).

Gas delivery equipment plays a prominent role in critical incident studies, often contributing to more than 20% of all reported events. 6,14-19 In contrast, claims involving gas delivery equipment account for only 2% (72/3791) of the overall ASA Closed Claims database. This difference may result, at least in part, from a key distinction between closed claims and critical incidents. Almost all claims in the ASA Closed Claims database (97%) involve an identifiable injury. Critical incidents are events that have the potential to cause injury. Thus, many critical incidents are detected and remedied before an identifiable injury occurs. For example, only 17% of critical incidents in Cooper's 1978 study⁶ had more than a transient physiologic effect, and only 26% of incidents in the recent Australian Incident Monitoring Study²⁰ were associated with either a major physiologic change, morbidity, or death. From this perspective, it is not surprising that gas delivery equipment accounts for a comparatively small proportion of claims in the Closed Claims Project. A willingness (or reluctance) to volunteer reports about certain types of critical incidents also may contribute to some of the observed differences. Finally, gas delivery claims may be underrepresented in the Closed Claims database because some equipment-related lawsuits may be filed against manufacturers instead of anesthesiologists.

Gas delivery depends on the use of equipment with multiple connections and moving parts. On this basis, one might expect equipment failure to play a particularly important role. Instead, the frequency of equipment misuse was three times greater than equipment failure (75% vs. 24%). This is consistent with previous studies, 6,14-16 which have emphasized the prominent role of human error in equipment-related critical incidents and adverse outcomes. In the present study, the breathing circuit made the single largest contribution to misuse of gas delivery equipment (26 of 54 claims involving misuse, 48%; table 4). This is a notable finding. particularly when one considers the physical simplicity of the breathing circuit compared with the complexity of ventilators, vaporizers, and anesthesia machines. Almost all adverse outcomes resulting from the breathing circuit involved a misconnect or disconnect (25/28, 89%; table 5). This feature suggests that human factors associated with making and maintaining breathing circuit connections are a particularly appropriate target for injury prevention. Two recent overviews suggest that this problem may require focused educational efforts and perhaps a fundamental re-evaluation of breathing circuit design.^{21,22}

Another distinctive feature of breathing circuit claims was the observation that misconnects (14) were as prevalent as disconnects (11; table 5). This differs from critical incident studies in which disconnects usually outnumber misconnects by a factor of two or more. 16-18 Although the disparity may simply be a result of the small number of cases, the finding may reflect a key difference in the speed of evolution for high- and lowpressure injuries of the airway. Misconnects typically occur in an intact circuit, and thereby lead to high airway pressure and the potential for pneumothorax. If a pneumothorax ensues, especially in the setting of mechanical ventilation, it may rapidly progress to a state of severe cardiorespiratory depression or arrest. In contrast, disconnects produce partial or complete disruption of breathing circuit integrity and thereby lead to low airway pressure. If circuit disruption is incomplete or if the clinical setting is compatible with respiratory reserve (i.e., high FiO₂ and a low or normal Pa_{CO₂}), the evolution of hypoxia and hypercapnia may be slow enough to permit detection and correction of the problem before substantial injury occurs. We speculate that the relative prominence of breathing circuit misconnects in the ASA Closed Claims database reflects the comparatively swift and poorly reversible cascade of events that accompany high airway pressure. These observations underscore the importance of breathing circuit monitors that can issue prompt alarms for highand low-pressure conditions.

An interesting aspect of the present study was the observation that ancillary personnel can make an important contribution to the anesthesiologist's liability. Misuse of equipment by technicians, engineers, nurses, and respiratory therapists contributed to patient injury in one fifth of all claims related to gas delivery equipment (16 cases). Ancillary personnel played an especially prominent role in claims involving switches in oxygen supply and the misuse of supplemental oxygen tubing. These findings suggest a role for preventive strategies and educational efforts that extend beyond the boundaries of the operating room and intraoperative anesthesia.

Inspection or "checkout" of anesthesia apparatus often is cited as a practice that can reduce the likelihood

of equipment-related injury. 6,14-18,23-25 In the present study, we were unable to make a formal evaluation of such protocols because the claim files did not contain enough detail to reliably assess the merits of specific checkout procedures. From an informal perspective, we can offer a potentially useful observation. Checkout protocols typically entail four basic activities: verification of back-up equipment and supplies (e.g., pressurized gas cylinders); inspection of equipment configurations (e.g., breathing circuit connections); inspection of equipment mechanics (e.g., proper action of unidirectional valves); and preparation of monitors (e.g., calibration, verification of function, and activation of alarms). It is noteworthy that most adverse outcomes in the present study were considered preventable with the use or better use of monitors (56 of 72 claims, 78%). Moreover, 9 of the 56 preventable outcomes (16%) occurred in cases where the monitor was turned off or broken. These features suggest that the effectiveness of checkout protocols may be enhanced by emphasizing the basic aspects of monitor selection and use.

The limitations of closed claims analysis have been described in previous reports. 1,3,4 These limitations include the inability to provide numerical estimates of risk (because of lack of denominator data), the absence of rigorous comparison groups, a probable bias toward adverse outcomes, and partial reliance on data from direct participants rather than impartial observers. The use of a large group of reviewers increases concerns about interrater reliability, but tests of Closed Claims reviewers have demonstrated statistically significant agreement for basic aspects of clinical care.2 It is important to remember that judgments of preventability in this study are based on the assumption of optimal use of monitors, the correct identification of all detectable problems, and the timely implementation of appropriate remedies. Thus, the estimates given here should be regarded as near-maximal or ideal values.

Two additional limitations of closed claims analysis may affect the applicability of these findings to current practice. The first limitation concerns the age of claims. For rare events, long periods of data collection are necessary because recurrent patterns of injury are difficult to discern when the acquisition interval is short and the number of available claims is small. Further, the Closed Claims database cannot capture the most recent claims because a 3- to 5-year interval typically elapses between the occurrence date of a claim and its actual entry into the project database. This interval reflects the process of claim assessment and resolution and the

logistical tasks associated with scheduling reviews and deploying reviewers to distant sites. The second limitation concerns missing or unavailable information. This second limitation occurs because data of potential interest (such as equipment model numbers and dates of manufacture) are sometimes absent in the claim file or overlooked during the onsite review. Taken together, these two limitations make it difficult to determine if the basic patterns of injury observed in gas delivery claims are relevant to the mix of equipment that is now in clinical use. Although we cannot address this issue in a rigorous manner, some insight can be gained by examining the recent literature for letters and case reports that describe problems associated with gas delivery equipment. A MedLineTM search of the anesthesiology literature between January 1990 and December 1995, plus a Current ContentsTM search in 1996, yielded 10 English-language letters and case reports involving the breathing circuit, 26-30 vaporizer, 31,32 ventilator, 33,34 and anesthesia machine.³⁵ The presence of these case reports suggests that problems with gas delivery equipment have not been completely resolved by the evolution of equipment design and the availability of newer devices. From this perspective, some of the insights available from closed claims analysis still may be applicable to contemporary clinical practice and risk-management efforts.

In summary, claims involving gas delivery equipment represent a small fraction of the ASA Closed Claims database. These claims are characterized by high severity of injury, high cost, and a prominent role for equipment misuse. The breathing circuit represents the single largest source of gas delivery equipment claims, and almost all of these claims result from misconnects or disconnects.

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References

- 1. Cheney FW, Posner K, Caplan RA, Ward RJ: Standard of care and anesthesia liability. *JAMA* 1989; 261:1599-603
- 2. Posner KL, Sampson PD, Caplan RA, Ward RJ, Cheney FW: Measuring interrater reliability among multiple raters: An example of methods for nominal data. Stat Med 1990; 9:1103-15 (Published erratum appears in Stat Med 1992; 11:1401)
- 3. Caplan RA, Posner KL, Ward RJ, Cheney FW: Adverse respiratory events in anesthesia: A closed claims analysis. Anesthesiology 1990; 72:828-33
- 4. Cheney FW, Posner KL, Caplan RA: Adverse respiratory events infrequently leading to malpractice suits. A closed claims analysis. Anesthesiology 1991; 75:932-9
- 5. Gild WM, Posner KL, Caplan RA, Cheney FW: Eye injuries associated with anesthesia: A closed claims analysis. Anesthesiology 1992; 76:204-8
- 6. Cooper JB, Newbower RS, Long CD, McPeek BJ: Preventable anesthesia mishaps: A study of human factors. Anesthesiology 1978; 49:399-406
- 7. Utting JE, Gray TC, Shelly FC: Human misadventure in anesthesia. Can Anesth Soc J 1979; 26:472-8
- 8. Hovi-Viander M: Death associated with anesthesia in Finland. Br J Anesth 1980; 52:483-8
- 9. Keenan RL, Boyan CP: Cardiac arrest due to anesthesia. A study of incidence and causes. JAMA 1985; 253:2373-7
- 10. Buck N, Devlin HB, Lunn JN: The Report of a Confidential Inquiry into Perioperative Deaths. London, Nuffield Provincial Hospitals Trust, 1987
- 11. Holland R: Anesthesia-related mortality in Australia. Int Anesthesiol Clin 1984; 22:61 71
- 12. Tiret L, Desmonts JM, Hatton F, Vourc'h G: Complications associated with anesthesia. A prospective study in France. Can Anesth Soc J 1986; 33:336-44
- 13. Chopra V, Bovill JG, Spierdijk J: Accidents, near accidents, and complications during anesthesia. A retrospective analysis of a 10 year period in a teaching hospital. Anaesthesia 1990; 45:3-6
- 14. Chopra V, Bovill JG, Spierdijk J, Koornneef F: Reported significant observations during anesthesia: A prospective analysis over an 18-month period. Br J Anaesth 1992; 68:13-7
- 15. Craig J, Wilson ME: A survey of an esthetic misadventures. Anaesthesia 1981; $36{:}933{\:\raisebox{-.3pt}{\text{--}}}6$
- 16. Cooper JB, Newbower RS, Kitz RJ: An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthesiology 1984; 60:34-42

- 17. Kumar V, Barcellos WA, Mehta MP, Carter JG: An analysis of critical incidents in a teaching department for quality assurance. A survey of mishaps during anesthesia. Anaesthesia 1988; 43:879-83
- 18. Russell WJ, Webb RK, Van der Walt JH, Runciman WB: The Australian Incident Monitoring Study. Problems with ventilation: an analysis of 2000 incident reports. Anesth Intensive Care 1993; 21:617-20
- 19. Webb RK, Russell WJ, Klepper I, Runciman WB: The Australian Incident Monitoring Study. Equipment failure: An analysis of 2000 incident reports. Anesth Intensive Care 1993; 21:673-7
- 20. Webb RK, Currie M, Morgan CA, Williamson JA, Mackay P, Russell WJ, Runciman WB: The Australian Incident Monitoring Study: An analysis of 2000 incident reports. Anesth Intensive Care 1993; 21:520-8
- 21. Simon BA, Lovich MA, Sims N, Cooper JB: The time has come for evolution of the breathing system. J Clin Monit 1993; 9:60-3
- 22. Adams AP: Breathing system disconnections. Br J Anesth 1994; 73:46-54
- 23. Whitcher C, Ream AK, Parsons D, Rubsamen D, Scott J, Champeau M, Sterman W, Siegel L: Anesthetic mishaps and the cost of monitoring: A proposed standard for monitoring equipment. J Clin Monit 1988; 4:5–15
- 24. Charlton JE: Checklists and patient safety. Anaesthesia 1990; 45:425-6
- 25. March MG, Crowley JJ: An evaluation of anesthesiologists' present checkout methods and the validity of the FDA checklist. Anesthesiology 1991; 724-9
- 26. Smith CE, Otworth JF, Kaluszyk P: Bilateral tension pneumothorax due to a defective anesthesia breathing circuit filter. J Clin Anesth 1991; 3:229-34
- 27. McEwan AI, Dowell L, Karis JH: Bilateral tension pneumothorax caused by a blocked bacterial filter in an anesthesia breathing circuit. Anesth Analg 1993; 76:440-2
- 28. Needleman S, Kaplan RJ: Unusual source of air leak in a pediatric anesthesia breathing circuit. Anesth Analg 1995; 81:654
- 29. Kshatri AM, Kingsley CP: Defective carbon dioxide absorber as a cause for a leak in a breathing circuit. Anesthesiology 1996; 84:475-6
- 30. Biro P: Unusual cause for a circle system leak. Anesth Analg 1996; 83:196
- 31. Sinclair A, van-Bergen J: Vaporizer overfilling. Can J Anesth 1993; $40{:}77{\,{ ext{-}}\,88}$
- 32. Meister GC, Becker KE Jr: Potential fresh gas flow leak through Drager Vapor 19.1 vaporizer with key-index fill port. Anesthesiology 1993; 78:211 2
- 33. Sprung J, Samaan F, Hensler T, Atlee JS 3rd, Kampine JP: Excessive airway pressure due to ventilator control valve malfunction during anesthesia for open heart surgery. Anesthesiology 1990; 73:1035-8
- 34. Slinger PD, Scott WA, Kliffer AP: Intraoperative awareness due to malfunction of a Siemans 900B ventilator. Can J Anesth 1990; 37:258-61
- 35. Mendel P: Oxygen supply failures revisited. J Clin Monit 1994; 10:405-6