Anesthesiology
70:572–577, 1989

CLINICAL INVESTIGATIONS

Prevention of Intraoperative Anesthesia Accidents and Related Severe Injury through Safety Monitoring

*John H. Eichhorn, M.D.**

Among 1,001,000 ASA Physical Status I and II patients (a subset of the 1,329,000 anesthetics administered from 1976 through mid-1988 in the nine component hospitals of the Harvard Department of Anaesthesia), there were 11 major intraoperative accidents solely attributable to anesthesia (five deaths, four cases of permanent CNS damage, and two cardiac arrests with eventual recovery) among the 70 cases reported to the insurance carrier. Review of these accidents revealed that unrecognized hypoventilation was the most common cause (seven cases). These seven accidents and one other due to discontinuation of inspired oxygen in all likelihood would have been prevented by appropriate response to earlier warnings generated by the "safety monitoring" principles mandated by the Harvard minimal monitoring standards. Analysis suggests capnography (although not mandated) would be the best monitor of ventilation. An important associated issue was the apparent inadequacy of supervision of residents and C.R.N.A.s. The eight preventable accidents represent 88% of the projected insurance payout. Only one accident occurred after the 1985 adoption of the standards (in the month following their implementation). From that time through mid-1988, there have been 319,000 anesthetics without a major preventable intraoperative injury. Although not statistically significant, the accident rate in the target population of healthy people is reduced more than threefold. This and the case analyses support the contention that nearly all the inevitable mishaps (technical or from errors in judgement) that occur during anesthesia can be identified through safety monitoring early enough to prevent most major patient injuries. This improved clinical outcome should lessen the medical-legal and malpractice insurance burdens of anesthesiologists. (Key words: Complications: accidents; death. Monitoring: capnography; oximetry. Standards.)

PREVENTION OF SEVERE intraoperative anesthesia-related patient injuries was the primary goal of the "Harvard Standards" (Department of Anaesthesia Standards of Practice I—Minimal Monitoring).[1] These standards mandate behaviors and the use of basic equipment intended to provide the earliest possible warning of impending disaster during anesthesia for surgery. This is "safety monitoring" as opposed to physiologic monitoring, such as measurements of pulmonary artery pressure. While early warnings generated by safety monitoring do not guarantee a correct response to the alarm, it is reasonable to assume that the earliest possible warning will minimize the probability of damage to the patient. A corollary of preventing anesthesia catastrophies should be a decrease in the number and severity of malpractice claims. This should lead eventually to a slower rise, or even a decrease, in malpractice insurance premiums.

The Harvard standards were used as background material during formulation of the American Society of Anesthesiologists' (ASA) Standards for Basic Intra-Operative Monitoring adopted October 21, 1986. The ASA standards "encourage" capnography and oximetry, rather than just listing them among possible monitoring methods. The Massachusetts Board of Registration in Medicine in 1987 mandated that "all licensees shall adhere" to the ASA monitoring standards. Further, on July 1, 1987, the Massachusetts Medical Malpractice Joint Underwriting Association offered a 20% discount on liability insurance premiums to anesthesiologists who agreed to utilize pulse oximetry and capnography whenever physically practical as part of adhering to the ASA standards.

It is unlikely that a prospective clinical trial intended to prove that safety monitoring prevents patient injury will be undertaken. Catastrophic adverse outcome directly attributable to anesthesia care is so rare (on average once during the working lifetime of a typical anesthesiologist) that two very large groups of patients (several million each), one with and one without safety monitoring, would be required to reach statistical significance. Furthermore, securing approval from institutional review boards, insurance companies, investigators, and (most importantly) volunteer patients for the "no monitoring" control group seems unworkable in the current ethical and medical-legal climate. Yet, major investments of effort and money are being made on the intuitive assumption that safety monitoring will prevent anesthesia-associated severe patient injury.

This article is accompanied by an editorial. Please see: Orkin FK: Practice standards: The Midas touch or the emperor's new clothes? ANESTHESIOLOGY 70:567–571, 1989.

* Assistant Professor of Anaesthesia.

Received from the Department of Anaesthesia, Beth Israel Hospital and Harvard Medical School and The Charles A. Dana Research Institute, Boston, Massachusetts. Accepted for publication September 22, 1988.

Address reprint requests to Dr. Eichhorn: Department of Anaesthesia, DA-717, Beth Israel Hospital, 330 Brookline Avenue, Boston, Massachusetts 02215.

Because the value of safety monitoring is not easily tested by traditional scientific methodology, a retrospective analysis of all case records from the insurance carrier covering the nine component hospital anesthesia departments affiliated with Harvard Medical School was conducted. The purposes were: 1) to identify intraoperative accidents solely attributable to anesthesia and causing severe injury of healthy patients, 2) to determine whether earlier warning from minimal monitoring as prescribed in the Harvard standards (and the presumed correct response) could have led to prevention of the accidents, and 3) to examine what impact the 1985 adoption of the standards might have had on the incidence of these accidents. The standards[1] mandate the continuous presence of an anesthesiologist/anesthetist in the operating room during a case, determination of blood pressure and heart rate at least every 5 min, continuous ECG display, continuous monitoring (by at least one of a variety of means) of ventilation and circulation, use of an inspired oxygen concentration monitor, use of a breathing system disconnection monitor during mechanical ventilation, and availability of a means of measuring patient temperature.

Materials and Methods

The Harvard malpractice insurance carrier (the Controlled Risk Insurance Company Ltd.—CRICO) supports a very active loss prevention/patient safety program through a second company (the Risk Management Foundation) owned by the hospitals. It is the opinion of the insurance program officials and the component hospital department heads that the insurance company is aware of all the cases within the system having liability implications involving healthy patients who could reasonably expect to suffer no adverse consequences from anesthesia.

For the 12½-yr period from the inception of the liability insurance program in 1976 through mid-1988, 1,329,000 anesthetics were administered in the nine hospitals. Seventy cases came to the attention of the insurance carrier and all were reviewed. Although usually settled internally by the hospitals, 12 cases involved damage to teeth during airway manipulation. Among the remaining 58 cases, 11 were major intraoperative accidents, the criteria for which are listed in table 1.

The intent was to examine obvious sudden or relatively sudden accidents, rather than questions of management, such as the adequacy of blood and fluid replacement during a long case. Because only insurance cases were considered, there were no cases of "near-accidents" not involving injury. These criteria excluded from consideration injuries and deaths resulting from events originating during postanesthesia or ICU care, or during transport of a patient. Also excluded were positioning injuries, two extremity burns from peripheral nerve stimulator use, and two cases of fatal hepatic necrosis following halothane.

TABLE 1. Criteria for a Major Intraoperative Accident

1. ASA physical status I or II patient
2. Physiologically stable patient
3. Intraoperative occurrence
4. Related only to anesthesia care
5. Resulting in either:
   a. Outcome graded on the NIAC severity of injury scale[2] as "permanent major," "permanent grave," or "death" (nine cases);
   b. Cardiac arrest with eventual recovery (two cases).

Case files of the 11 major intraoperative accidents were reviewed and summarized. In a manner similar to morbidity/mortality case conferences, conclusions were drawn from all available information, including personal knowledge of the cases. In two of the eleven cases, there were incomplete or disputed facts. These cases were evaluated in light of all available records, depositions (from principles and experts), testimony, and court decisions. For each of the 11 cases, the analysis contains the author's opinions formed from weighing probabilities based on the available data.

Accident and death rate changes were each evaluated using a two-by-two Fisher exact test.[3]

Intraoperative Accident Cases*

Case 1. A 27-yr-old male with severe arthritis receiving long-term steroid therapy had major gastric bleeding at about 7 A.M. By 8 A.M. the patient's trachea had been intubated and endoscopy was being performed. The bleeding was not controlled. The patient was taken to the angiography suite where he was anesthetized (including 50% N_2O) using a spare anesthesia machine that had the oxygen flow meter on the left and did not have an oxygen concentration monitor. The attending anesthesiologist (who had been with the patient all day) was relieved by a resident shortly before 6 P.M. About 45 min later, the successful arterial embolizations were complete but the room lights were still dimmed. The resident, who later admitted unfamiliarity with the anesthesia machine, turned off the left knob and turned up the right knob. In 4–5 min, the room still relatively dark, the patient had a cardiac arrest. He was resuscitated but had massive brain damage and died.

Analysis: Preventable by a functioning oxygen concentration monitor with a correctly set lower limit alarm. Note that this assumes the resident would have recognized the alarm and responded by administering oxygen.

Associated issues: Dangers of keeping old, unfamiliar equipment. Relief protocol assuring relieving anesthetist fully aware of situation, including equipment. Inadequate supervision of resident.

Case 2. A 28-yr-old female had routine induction of general endotracheal anesthesia for a mastectomy and was receiving oxygen, nitrous oxide, and halothane by spontaneous ventilation with alleged intermittent assistance by breathing bag compression. Subsequently, a "low-dose" succinylcholine infusion was started. The surgeon later stated the patient was struggling to breathe but could not do so adequately and her ventilation was not being assisted. He also stated that several times he announced the blood was dark. The anesthesia record shows

* Identifying data are altered in three summaries to preserve confidentiality.

brief tachycardia and diastolic hypertension followed by bradycardia and cardiac arrest. The patient was resuscitated but had massive brain damage and died. Review concluded there was unrecognized hypoventilation and the case was settled without trial.

Analysis: Preventable by continuous monitoring of ventilation. Observation of the reservoir breathing bag or auscultation of diminished and irregular breath sounds would have been a warning. An irregular or diminishing capnogram or rising end-tidal CO_2 reading likely would have given earlier warning.

Associated issues: Failure of the surgeon to express his concern more forcefully. Failure of the anesthesiologist to act on the surgeon's concern about dark blood. Use of succinylcholine during spontaneous ventilation.

Case 3. A 49-yr-old female having a cervical spine fusion was nasotracheally intubated by a third-year anesthesia resident. The patient's lungs were mechanically ventilated and the patient was paralyzed. Thirty minutes into the case (prone position), a sudden decrease in blood pressure and heart rate was noted by the medical student monitoring vital signs. It was alleged that the ECG monitor was only functioning intermittently (blackouts of the screen) and that the resident was distracted attempting to investigate and repair the faulty monitor. There are disputed statements, but an eventual conclusion that there was disconnection of the breathing circuit from the endotracheal tube. The patient was turned supine and resuscitated but suffered central nervous system damage.

Analysis: Preventable by disconnect and ventilation continuous monitoring.

Associated issues: Inadequate supervision of medical student and anesthesia resident. Persistent use of faulty equipment that should have been immediately taken out of service.

Case 4. A 16-yr-old male having an elective plastic surgical repair of the anterior chest had his trachea intubated with a red rubber endotracheal tube that was correctly inserted but protruded fairly far out the corner of the mouth. An oxygen monitor was operating and an esophageal stethoscope had been inserted. The surgeon was asked twice early in the case not to lean his arm on the draped face and tubing. After 1¾ hr, the resident (in the first month of clinical training) was sent for a break by the attending anesthesiologist. The patient's lungs were being mechanically ventilated with 4 liters N_2O, 2 liters O_2, and 2% enflurane and the attending observed the chest rise and fall while hearing good breath sounds *via* the esophageal stethoscope. When the resident returned, the attending departed. About 15 min later (during which time it appears the breath sounds were not ausculted), there was bradycardia and the blood was noted to be dark in color. The resident administered atropine three times and then called for help. A passing attending entered, viewed the scene, and told the resident to look at the tubing under the drapes. When the drapes were lifted, the endotracheal tube was seen to be kinked just below the 15 mm connector. This was corrected and the patient's lungs were ventilated with 100% O_2, but the heart rate was 30 and the blood pressure 0. The patient was resuscitated. The wounds were closed and the patient taken to ICU with seizures. There was central nervous system damage that was initially severe but improved over time.

Analysis: Preventable by continuous ventilation monitoring. Earliest warning would have come from capnography.

Associated issues: Surgeon's apparent tendency to rest arm on/near patient's face. Inadequate supervision of resident. Teaching of response protocols for untoward developments.

Case 5. A 37-yr-old male with achalasia presented for esophageal surgery. A Carlens double lumen endotracheal tube was inserted and correct position confirmed by auscultation. Anesthesia and controlled ventilation were begun. Arterial blood gases on 0.5 FI_{O_2} were P_{O_2} 174 mmHg, P_{CO_2} 40 mmHg, and *p*H 7.40. One and three-quarters hours into the case, there was concern about oxygenation during one-lung ventilation (1.0 FI_{O_2}: P_{O_2} 74 mmHg, P_{CO_2} 53 mmHg, *p*H 7.23). PEEP was suggested and 5 cm H_2O was added by the C.R.N.A. to the circuit by a weighted-ball type valve. In about 3 min, there was bradycardia to 30 and then cardiac arrest. The patient was turned, CPR started, and the Carlens tube removed. The patient's trachea was reintubated with a 8.0-mm endotracheal tube. The anesthesia breathing circuit was reattached, but ventilation by compression of the reservoir bag was impossible. While an emergency tracheostomy was being done, an attending anesthesiologist arrived and quickly noticed that the ball-type PEEP valve was in the inspiratory limb of the breathing circuit, completely obstructing flow. It was removed and the patient's lungs were easily ventilated through his new tracheostomy. The patient eventually recovered.

Analysis: Preventable by continuous ventilation monitoring. Complete absence of ventilation should be detected immediately by observation and any of several monitors.

Associated issues: Inadequate supervision of the C.R.N.A. Use of unfamiliar equipment.

Case 6. A 36-yr-old, 250-pound male, outpatient, presented for excision of a neuroma from a knee scar. Premedication was iv diazepam, 5 mg. General anesthesia was begun with O_2/N_2O and 1% enflurane breathed *via* face mask and, immediately thereafter, the patient was given 375 mg thiopental at 8:15 A.M. Subsequent events are disputed, but the surgeon was closing the wound when there was an "anesthesia problem." There had been bradypnea followed by cyanosis, hypotension, ventricular ectopy, and then fibrillation. An attending anesthesiologist responded to an emergency call for help from the C.R.N.A. between 9:05 and 9:10 A.M., intubated the trachea, and directed a full resuscitation. The patient suffered major hypoxic central nervous system damage and died. The anesthesia record during surgery is inadequate, but review of the facts led to the conclusion there was unrecognized hypoventilation and the case was settled without trial.

Analysis: Preventable by continuous ventilation monitoring. Auscultation of breath sounds would have revealed the slowing respiratory rate. Capnography would have given an even earlier warning.

Associated issue: Inadequate supervision of the C.R.N.A.

Case 7. A 35-yr-old male suffered trauma and was anesthetized for repair of tibial and fibular fractures and wiring of a fractured jaw. Thirty-six hours later, he returned to the operating room for application of external fixation to his fractured pelvis, his jaw still wired closed. The patient was 5'10", 180 pounds, and received a T6 sensory level subarachnoid block from 14 mg tetracaine. The record states O_2 was "blown over" his face with tubing under the drape. After the case was underway, the attending anesthesiologist was relieved by a resident. During the first hour of the spinal anesthetic, because of "restlessness," the patient received iv 15 mg diazepam, 200 μg fentanyl, and 5 mg droperidol. The presumed antecedent bradypnea was not noticed because the patient developed apnea, bradycardia, and cardiac arrest. Arterial blood gasses were P_{O_2} 7 mmHg, P_{CO_2} 58 mmHg, and *p*H 7.26, and after 8 min of resuscitation were (during 1.0 FI_{O_2}) P_{O_2} 210 mmHg, P_{CO_2} 77 mmHg, and *p*H 7.21. There was major central nervous system damage.

Analysis: Preventable by continuous ventilation and/or circulation monitoring. Relative hypoxemia can present as restlessness. Pulse oximetry would warn of this. Qualitative capnography (simple presence or absence of exhaled CO_2) can be employed in awake patients, but even observation of the level of consciousness and the quality of ventilation should prevent an accident of this type.

Associated issues: Poor judgement to induce anesthesia in a patient whose jaw is wired shut. Inadequate supervision of resident.

Case 8. A 62-yr-old woman presented with a large pharyngeal mass for pan endoscopy, mapping, and biopsy. After pre-oxygenation, thiopental and succinylcholine were given, but tracheal intubation could not be achieved. Positive pressure ventilation *via* mask was used until, eventually, blind orotracheal intubation was thought successful. Mechanical ventilation was begun. Reportedly, the chest rose and fell.

Eight minutes later, there was the onset of cyanosis and bradycardia. Resuscitation included immediate tracheostomy; no tube was seen in the trachea. It was concluded that there had been an esophageal intubation. The patient never awakened and later died.

Analysis: Probably preventable by monitoring of ventilation, including volume of exhaled gas. Clearly preventable by capnography. Earlier recognition than occurred might have come from oximetry.

Associated issues: Judgement to use muscle relaxation rather than spontaneous ventilation or awake intubation in a patient with a pharyngeal mass.

Case 9. A custom-designed modification of a set of 12-yr-old anesthesia machines (involving changing the copper kettle from a top-loading type to a more safe side-filling model) was done by an outside service technician from an equipment manufacturer. On one of the machines, the tubing to the vaporizer was reconnected incorrectly. The gas in-flow tubing was directed to the out-flow connection and vice versa. For the third case after the anesthesia machine was returned to service and the first using this vaporizer, isoflurane was put in the copper kettle. Mechanical ventilation was used. The C.R.N.A. was surprised at the rate of disappearance of isoflurane from the vaporizer. The original partial bottle and two new 100-cc bottles were consumed. Upon opening the third new bottle, the C.R.N.A. called the attending anesthesiologist, who arrived promptly, heard the story, and quickly discovered the tubing connection error. Isoflurane was discontinued and the process of changing the anesthesia machine had started when the 42-yr-old female patient developed bradycardia and suffered a cardiac arrest. She was resuscitated, was later found to have a myocardial infarction, and eventually recovered. Inspection of the anesthesia machine suggested liquid isoflurane had entered the fresh gas output.

Analysis: Probably not preventable by *intraoperative* safety monitoring. Unclear if vital sign monitoring according to the standards would have impacted this sequence of events or not, but this accident was clearly preventable by checking of the anesthesia machine modification during and after the work as well as immediately prior to this anesthetic.

Associated issue: Inadequate supervision of the C.R.N.A.

Case 10. A 56-yr-old woman underwent extensive orthopedic surgery after insertion of an intra-arterial catheter and a pulmonary artery catheter. Induction of anesthesia followed by tracheal intubation with a plastic soft-cuff endotracheal tube were unremarkable. Eight hours into the case, there was an audible airway leak with bubbling in the mouth. There was no change in the capnogram or end-tidal CO_2 value. The ventilator low-pressure alarm was not activated. More air was added to the cuff without change. Upon laryngoscopy, the cuff was seen in the larynx above the vocal cords. The fixation of the tube to the lips with tape had not changed. The attending anesthesiologist deflated the cuff and attempted to advance the tube with the aid of McGill forceps, but he could not do so. The tube was removed. Ventilation *via* mask with 100% O_2 was very difficult. Blood pressure increased. When a new tracheal tube was finally inserted, the heart rate was 40 and then cardiac arrest occurred. CPR was necessary for 5 min. The patient claims to suffer residual central nervous system damage.

Analysis: Not preventable by intraoperative safety monitoring. The hypoventilation after removal of the first endotracheal tube was not undetected. It was well recognized and the subject of intense corrective effort that was not successful in time to prevent cardiac arrest.

Case 11. A 32-yr-old woman was undergoing a bone and free flap graft for reconstructive plastic surgery. When the vessel grafting was complete, the surgeon states he requested the anesthetist give 50 cc of dextran 40 iv. The anesthesia resident states the surgeon requested 500 cc of dextran 40, which was then given as an iv bolus. Shortly thereafter, bradycardia followed by cardiac arrest occurred and the patient could not be resuscitated from what was diagnosed as a refractory pulmonary edema presumably related to the dextran.

Analysis: Not preventable by intraoperative safety monitoring.

Associated issue: Inadequate supervision of the resident.

TABLE 2. Accident and Death Rate Among ASA Physical Status I and II Patients Before and After Adoption of Monitoring Standards

Dates	ASA P.S. I & II Patients	Intraoperative Accidents*	Associated Deaths
1/76–6/85	757,000	10 (1/75,700)	5 (1/151,400)
(Standards adopted 7/85)			
7/85–6/88	244,000	1 (1/244,000)	0 0
		$P = 0.21$	$P = 0.25$

* See table 1 for criteria.

The total projected insurance loss for all eleven cases is $5,391,000 and for the eight cases judged preventable by minimal intraoperative safety monitoring is $4,756,000. Thus 8/11 or 73% of the number of cases representing 88% of the projected insurance payout for major intraoperative anesthesia accidents could have been prevented. Parenthetically, the total projected insurance loss for all 70 cases through mid-1988 fluctuates, but the prevention of the eight major intraoperative accidents would have saved at least 65–70% of the total projected insurance loss.

The accident and death rates for the subject population are shown in table 2. The number of ASA physical status I and II patients was calculated by survey of each of the nine component hospitals and multiplication of the proportion times the number of cases at each for the respective periods.

Discussion

The results of this analysis of cases are consistent with suggestions[4–6] that unrecognized hypoventilation is the commonest intraoperative anesthesia accident leading to severe patient injury. Breathing system component disconnection has been cited as the most frequent anesthesia-related mishap or "critical incident."[7] One provocative review stresses the role of the "relatively simple" technologies of inspired oxygen concentration monitors and disconnect alarms in potential prevention of hypoxic accidents.[8] In Keenan's report of intraoperative cardiac arrests,[9] 11 of the 20 "avoidable" cases were attributed to "failure to ventilate." More recently, a preliminary report from the Closed Claims Study of the ASA Committee on Professional Liability revealed that of 624 claims of all types (excluding tooth injury), 193 were respiratory mishaps, including 80 classified as inadequate ventilation and 41 as esophageal intubation.[10] The report states, "Overall, 69% of respiratory-related claims were judged preventable with better monitoring." The case analysis methodology of the Closed Claims Study is similar to that used in this review and has revealed a previously unrecognized incidence of cardiac arrest during spinal anesthesia.[11,12]

Intraoperative anesthesia accidents due to unrecognized hypoventilation have consistently been considered "preventable."[4,9,10,13,14] Disconnection of system components and other failures of ventilation may increase due to the increasing complexity of current delivery systems. It is intuitively reasonable to conclude that protocols de-

signed to provide immediate warning of the onset of hypoventilation (or inadequate inspired oxygen concentration) will allow time for appropriate responses to prevent accidents. This analysis of 11 cases of intraoperative anesthesia accidents strongly supports this conclusion. Hypoventilation caused harm in eight cases. Six (and probably seven) would have been detected in time to avoid any patient injury by continuous monitoring of ventilation (the esophageal intubation would have been detected best by capnography). The episode of hypoventilation during the changing of a dislodged endotracheal tube would not have been prevented. The one case involving accidental inadequate inspired oxygen concentration would clearly have been prevented by the subsequently mandated (Harvard and ASA) oxygen monitor with a functioning low concentration limit alarm in use. In all eight cases of preventable severe injury (four deaths, three permanent CNS injuries, and one cardiac arrest with eventual recovery), averting damage would have required that: 1) safety monitoring behaviors would be practiced and monitoring equipment would be functioning correctly with correct alarm limit settings where applicable, and 2) there would be no competing situations (emergency or otherwise) that could draw the attention of the anesthetist away from monitoring.

Errors in clinical judgement led to several of the causes of injury. Better education, more emphasis on crisis-response protocols, and closer supervision all can help to reduce judgement errors. However, judgement errors will continue to occur. Safety monitoring attempts to identify the resulting untoward occurrences as early as possible, before the situation is irreversible and the patient is injured.

The best methods of monitoring to achieve the earliest possible warnings are debatable and have been reviewed.[15–19] The most effective monitors of ventilation and circulation may vary with the types of cases or among practitioners and institutions. Capnography is arguably the best continuous monitor of ventilation, and pulse oximetry may be the best for the adequacy of circulation. However, capnographs and oximeters may not function correctly and may fail to reveal dangerous circumstances. Aspirating capnographs can be disabled by humidity. Oximeters may not function in obese, edematous, or vasoconstricted patients. Mishaps may even be caused or exacerbated by misinterpretation of or distraction by capnographs and oximeters. The analysis of the seven cases of unrecognized hypoventilation suggests that functioning capnography and/or oximetry could have given an earlier, clearer warning of the problem and impending injury. These devices are frequently used to fulfill the mandates of the Harvard and ASA standards, but they are not, at this time, required. Whether use of these or any other technologies will be incorporated into promulgated standards of practice remains to be seen. What *is* required now is continuous monitoring of ventilation (and oxygenation/circulation). This is the central concept of safety monitoring.

Comparison of morbidity and mortality rates in anesthesia is difficult because of: 1) the unwillingness of physicians and insurance companies to open their files on adverse events, 2) the lack of truly large-scale studies, and 3) markedly differing definitions of anesthesia-related incidents. Death rates vary widely in 13 studies (1947–77) with disparate methods and criteria.[5] A popularly cited (but old) anesthesia mortality estimate is one death per 10,000–20,000 healthy people.[1,4,8] Using the Harvard experience from 1976 through mid-1988 involving 1,001,000 "healthy" patients, the 11 accidents and five deaths yield rates of one accident in 91,000 and one death in 200,200 anesthetics. The latter is similar to that reported by Lunn and Devlin[20] in a British study conducted in 1986 covering 486,000 anesthetics revealing a rate of death solely attributable to anesthesia of one in 185,056 anesthetics.

Whether adoption of the Harvard minimal monitoring standards had an impact on the outcome of practice with respect to intraoperative accidents as defined for the purpose of this analysis is too early to tell. However, table 2 shows a reduction in the accident rate among ASA physical status 1 and 2 patients from 1/75,700 anesthetics to 1/244,000, a 3.22-fold decrease. Furthermore, there have been no deaths since the standards were adopted. These data are not yet statistically significant, illustrating the problem of small numerators over large denominators.

The one intraoperative accident since institution of the standards occurred during the month after their implementation. From that time through mid-1988, 319,000 total anesthetics were given without an intraoperative anesthesia accident meeting the criteria of this analysis (table 1). Simple extrapolation from the former rate and the Lunn study allows speculation that, during this period, one to three accidents and, possibly, even one death might have been expected.

Exactly what role safety monitoring mandated by the standards played in the apparent reduction in the rate of accidents and deaths cannot be determined. The majority of practitioners in the nine hospitals practiced the principles outlined by the standards at the time of their implementation. There has been no disciplinary action for failure to comply. Informal, small-sample surveys at the larger hospitals suggest observance of the standards is very good but not perfect. Further, there are other factors that may have helped improve outcome. Oximetry became more available and there was a study involving intense feedback of information to clinicians about potentially adverse events.[21] Awareness was heightened by creation of the Anesthesia Patient Safety Foundation and publicity about the Massachusetts state regulations. While a general improvement in practice may have had an im-

pact, it is reasonable to argue that safety monitoring mandated by the Harvard standards is, at least, a component of the preliminary suggestion of improvement in intraoperative accident and death rates.

The Risk Management Foundation has closely followed the rate of major anesthesia accidents. In 1986, as an acknowledgement of a trend toward fewer major intraoperative accidents and as an encouragement to anesthesiologists (and other physicians) to engage in prospective risk management, the CRICO insurance underwriters lowered the risk classification of insured anesthesiologists. The projected 48% premium increase for that year was thus reduced to a 16% increase. In 1988, there was a further reduction in the "relativity rating" for anesthesiologists and this led to a 5% decrease in the premium for malpractice coverage.

An important issue revealed by the analysis of these cases is the apparent inadequacy of attending anesthesiologists' supervision of intraoperative anesthesia care. This may merit as much attention as safety monitoring. Of the 11 accidents, five involved residents and three involved C.R.N.A.s. Although an attractive speculation, whether closer supervision of those administering anesthesia at the time of the initial mishap (independent of patient monitoring) would have prevented the accidents cannot be known. The results of this case analysis do not apply only to anesthesia care involving residents and C.R.N.A.s, but to anesthesia practitioners of all backgrounds and skill levels. However, expectation that safety monitoring will give earlier warning of untoward developments must not substitute for close supervision.

Whether safety monitoring principles should be codified in formal standards can be debated.[22] However, the standards exist and have been widely circulated. The goal of accident prevention is not debated and should not be affected by the form of the effort. This analysis supports the contention that the large majority of intraoperative anesthesia-related incidents leading to death and permanent central nervous system damage in healthy people can be prevented. Beyond improving care, doing so will improve both the medical-legal climate and the malpractice insurance burden for all anesthesiologists.

The author wishes to thank Mr. James Holzer and the staff of the Risk Management Foundation for their cooperation, and also wishes to thank the other members of the Harvard Risk Management Committee: Drs. Jeffrey B. Cooper, David J. Cullen, James S. Gessner, Robert S. Holzman, Ward R. Maier, and James H. Philip for their thoughtful review of this manuscript. Guidance for the statistical evaluation was provided by John Orav, Ph.D., and associates from the Biostatistical Consulting Laboratory of the Harvard School of Public Health.

References

1. Eichhorn JH, Cooper JB, Cullen DJ, Maier WR, Philip JH, Seeman RG: Standards for patient monitoring during anesthesia at Harvard Medical School. JAMA 256:1017–1020, 1986
2. Brunner EA: The National Association of Insurance Commissioners' closed claim study. Int Anesthesiol Clin 22(2):17–30, 1984
3. Zar JH: Biostatistical Analysis. Englewood Cliffs, Prentice-Hall, 1984, pp 390–395
4. Pierce EC, Cooper JB (eds): Analysis of Anesthetic Mishaps, International Anesthesiology Clinics, Vol. 22(2). Boston, Little, Brown and Company, 1984
5. Duberman SM, Bendixen HH: Mortality, morbidity and risk studies in anaesthesia, Epidemiology in Anaesthesia. Edited by Lunn JN. London, Edward Arnold Ltd, 1986, pp 37–73
6. Taylor G, Larson CP, Prestwich R: Unexpected cardiac arrest during anesthesia and surgery. JAMA 236:2758–2760, 1976
7. Cooper JB, Newbower RS, Long CD, McPeek B: Preventable anesthesia mishaps: A study of human factors. ANESTHESIOLOGY 49:399–406, 1978
8. Emergency Care Research Institute: Death during general anesthesia. J Health Care Tech 1:155–175, 1985
9. Keenan RL, Boyan CP: Cardiac arrest due to anesthesia. JAMA 253:2373–2377, 1985
10. Caplan RA, Posner K, Ward RW, Cheney FW: Respiratory mishaps: Principle areas of risk and implications for anesthetic care (abstract). ANESTHESIOLOGY 67:A469, 1987
11. Caplan RA, Ward RJ, Posner K, Cheney FW: Unexpected cardiac arrest during spinal anesthesia: A closed claims analysis of predisposing factors. ANESTHESIOLOGY 68:5–11, 1988
12. Keats AS: Anesthesia mortality—A new mechanism (editorial). ANESTHESIOLOGY 68:2–4, 1988
13. Marx GF, Mateo CV, Orkin LR: Computer analysis of post anesthetic deaths. ANESTHESIOLOGY 39:54–58, 1973
14. Lunn JN, Muskin WW: Mortality Associated with Anaesthesia. London, Nuffield Provincial Hospitals Trust, 1982
15. Philip JH, Raemer DB: Selecting the optimal anesthesia monitoring array. Med Instrum 19:122–126, 1985
16. Gravenstein JS: Essential monitoring examined through different lenses. J Clin Monit 2:22–29, 1986
17. Hope CE, Morrison DL: Understanding and selecting monitoring equipment in anaesthesia and intensive care. Can Anaesth Soc J 33:670–679, 1986
18. Whitcher C, Ream AK, Parsons D, Rubsamen D, Scott J, Champeau M, Stenman W, Siegel L: Anesthetic mishaps and the cost of monitoring: A proposed standard for monitoring equipment. J Clin Monit 4:5–15, 1988
19. Block FE: A proposed standard for monitoring equipment: What equipment should be included (editorial)? J Clin Monit 4:1–4, 1988
20. Lunn JN, Devlin HB: Lessons from the confidential inquiry into perioperative deaths in three NHS regions. Lancet 2:1384, 1987
21. Cooper JB, Cullen DJ, Nemeskal R, Hoaglin DC, Gevirtz CC, Csete M, Venable C: Effects of information feedback and pulse oximetry on the incidence of anesthesia complications. ANESTHESIOLOGY 67:686–694, 1987
22. Eichhorn JH: Are there standards for intraoperative monitoring? Advances in Anesthesia, Vol. 5. Edited by Stoelting RK, Barash PG, Gallagher TJ. Chicago, Year Book Medical Publishers, 1988, pp 1–24