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## ***Relationship between Malpractice Litigation and Human Errors***

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IN medical malpractice litigation, negligence is the predominant theory of liability. The basic elements of a malpractice claim are duty, negligence, causation, and damage.<sup>1</sup> *Duty* refers to the practitioners responsibility to treat a patient according to the standard of care. *Negligence* is defined by law as a deviation from the accepted standard of care and, therefore, a breach of duty. *Causation* requires that the patient's damage is the result of negligence, and damage infers harm, detriment, or loss sustained by reason of an injury.<sup>2</sup> Much of our current knowledge of medical malpractice comes from the Anesthesia Closed Claims Database, which was established in 1985 by the American Society of Anesthesiologists and is based on a limited number of reviews of closed malpractice claims.<sup>3</sup> These retrospective reviews suggest that a malpractice claim can result in a financial award even in the absence of negligent care.<sup>4</sup> Conspicuously missing from these reviews, however, are uncompensated pa-

tients whose injuries were the result of deviations from the standard of care that did not result in closed claims. Without this information, the true relation between injury caused by human error and malpractice claims cannot be determined. In this investigation at a university hospital, cases involving legal action against anesthesia providers were compared to deviations from the standard of care by anesthesia providers that resulted in disabling patient injuries as judged by peer review to determine the relation between these two occurrences.

### **Materials and Methods**

A published model of structured peer review<sup>5</sup> was used by the Department of Anesthesiology to identify human error on the part of the attending anesthesiologist, resident anesthesiologist, or nurse anesthetist that resulted in patient injury at a university hospital over a 3-yr period. During the same time period cases involving legal action against an anesthesia provider were identified by the hospital's Risk Management Department. Human error resulting in patient injury and legal actions were compared to determine their relative frequencies and relation, if any, in this setting. Attribute control charts were then applied to determine the predictability of each occurrence.

### **Data Collection**

All cases exhibiting an adverse perioperative outcome at a university hospital between January 1, 1992, and December 31, 1994, were referred to the Department of Anesthesiology. Sources for initial referral were the anesthesiologist (resident, attending, or both), other clinical personnel (nurses, operating room technicians, and others), the medical care review team (several trained chart reviewers employed by the hospital), or any combination of the three. Anesthesiologists reported occurrences of adverse outcomes on a continual basis by filing a written

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**Table 1. Types of Human Errors**

Error	Example
Improper technique	A short catheter placed in an internal jugular vein dislodges and results in hematoma formation
Misuse of equipment	Neglecting to perform the prescribed equipment check results in equipment failure that contributes to patient death
Disregard of available data	Failure to avoid known drug allergen results in unplanned hospital admission
Failure to seek appropriate data	Failure to check appropriate extubation criteria results in premature extubation, subsequent respiratory failure, and need for reintubation
Inadequate knowledge	Incorrect interpretation of hemodynamic variables results in pulmonary edema

report, which included a narrative of the events, with the Department at the time of each occurrence. Other clinical personnel submitted traditional "incident reports" directly to the Department or indirectly through the medical care review team. The medical care review team screened incident reports and examined the inpatient medical records within 24 h of admission or surgery and at least every 4 days thereafter. Cases noted by the medical care review team to involve an adverse perioperative outcome were reported to the Department on a monthly basis. Similarly, adverse outcomes occurring postoperatively in ambulatory surgical patients were detected by clinical personnel through a follow-up phone call on the first postprocedure day, response to a written survey, or at readmission to the hospital. A single case could produce two or more adverse outcomes and be referred from multiple sources. Referrals received after a particular case was discussed by the Department quality assurance committee were discarded unless new information was provided.

Each case was reviewed by the same preliminary committee, consisting of two anesthesiologists from the Department, to verify the occurrence. Contact was made with the anesthesiologist involved or the medical record was reviewed so that an abstract could be prepared for presentation to the Department. The Department (approximately 25 staff anesthesiologists and 36 resident anesthesiologists) met on a monthly

basis to participate in peer review of the cases reported to date and to reach a consensus regarding the error analysis.

*Defining Deviations from the Standard of Care*

Structured peer review was used by the Department to identify human error or deviations from the standard of care on the part of the anesthesia provider (physician or nurse). To determine this incidence, a standardized model of structured peer review<sup>5</sup> was applied to all adverse perioperative outcomes. The principle underlying this peer review process is that all adverse outcomes are the result of "error," either human or system. *Error* here was defined as an act that through ignorance, deficiency, or accident departs from or fails to achieve a desired outcome.<sup>6</sup> This definition of error allowed reviewers to look at the system as critically as they looked at each other, thus making peer review less threatening. Nominal definitions for subcategorizing these two types of errors were used to add structure and increase the objectivity of the peer review process. Human error included failing to perform a technique properly, misuse of equipment, disregarding available data, failing to seek appropriate data, and responding incorrectly to available data because of a lack of knowledge. These human errors were considered deviations from the standard of care. System errors, conversely, result in adverse outcomes that might otherwise be considered unavoidable and ordinarily dropped from the peer review process.

**Table 2. Types of System Errors**

Error	Example
Technical accident	Postdural puncture headache follows a properly performed spinal anesthetic
Equipment failure	Equipment malfunction results in death despite proper maintenance and checks
Communication error	Medical consultant's report is delayed when following the usual channels of communication
Limitation of therapeutic standards	Appropriate resuscitative efforts result in death of a multiple trauma victim
Limitation of diagnostic standards	Preoperative assessment fails to predict difficult airway management
Limitation of available resources	Lack of available blood products results in death due to massive bleeding
Limitation of supervision	Attending anesthesiologist is unable to prevent a resident anesthesiologist from committing a human error because of multiple supervisory responsibilities

**Table 3. Negligence Identified by Peer Review**

Occurrence(s)	Peer-Review Analysis		Injury Severity Code
	Type of Error	Error Category	
Unplanned hospital admission, perioperative myocardial infarction	Human error	Failure to seek appropriate data	4
Respiratory failure requiring reintubation after general anesthesia	Human error	Failure to seek appropriate data	3
Respiratory failure requiring reintubation after general anesthesia	Human error	Disregard of available data	3
Respiratory failure requiring reintubation after general anesthesia, bradycardia requiring treatment	Human error	Failure to seek appropriate data	3
Mortality, undetected esophageal intubation	Human error	Disregard of available data	5
Respiratory failure requiring reintubation after general anesthesia	Human error	Failure to seek appropriate data	3
Mortality, cardiac arrest under anesthesia care	Human error	Disregard of available data	5
Aspiration pneumonitis	Human error	Disregard of available data	3
Mortality, cardiac arrest while under anesthesia care	Human error	Failure to seek appropriate data	5
Failed regional anesthetic, respiratory failure requiring reintubation after general anesthesia	Human error	Failure to seek appropriate data	3
Respiratory failure requiring reintubation after general anesthesia, cardiac arrest while under anesthesia care	Human error	Failure to seek appropriate data	3
Pneumothorax requiring chest tube	Human error	Failure to seek appropriate data	3
Problems with fluid and blood product management, pulmonary edema	Human error	Failure to seek appropriate data	3

System errors included accidental occurrences resulting from performing a technique properly, equipment failure despite proper use, missed communication while following established protocol, inability to diagnose a disease process because of limitations of our currently available screening and monitoring standards, inability to treat a disease process because of limitations in our current standards of care, and inability to meet the demands for resources of equipment or personnel. Supervision by an attending anesthesiologist working with more than one resident or nurse anesthetist was viewed as a unique resource for which limitations were recorded separately from other resources. Of note, the peer review process of the Department of Anesthesiology considers human error on the part of nonanesthesia practitioners to be system errors if they are outside the control of the anesthesia provider. The error categories are summarized in tables 1 and 2, with common examples of each.

*Defining Legal Action*

The institution’s Risk Management Department tracked all cases of legal action against anesthesia providers and categorized them into one of three levels: (1) letters of intent (any written correspondence suggesting that the anesthesia provider could be named as a potential defendant in a malpractice suit); (2) malpractice claims (lawsuits filed against the anesthesia provider); and (3) closed claims (malpractice claims for which a judgment or settlement had been recorded). The extent

of each legal action was recorded as of December 31, 1997. In no case was the legal action known at the time of the peer review.

*Stratifying Severity of Injury*

All cases undergoing peer review were assigned a severity of injury code by the Department. The code divided severity of injury into one of five strata: (1) no change in hospital course, (2) increased care or risk without injury, (3) increased care or risk with reversible injury, (4) increased care or risk with permanent injury, and (5) death. Cases in which human error resulted in an injury severity score of three or greater were considered disabling and worthy of consideration for compensation under malpractice law.

*Statistical Analyses*

All cases involving deviations from the standard of care resulting in patient injury and cases that resulted in letters of intent, malpractice claims, or closed claims were recorded separately on statistical process control (SPC) charts. Deviations from standard of care and all legal actions were reported for the month in which the anesthetic was administered. The statistical process control charts used were attribute u-charts, which reflect the number of “defectives” as a proportion of variable sample size. The monthly sample size for each group of occurrences was the total number of anesthetics performed. Upper control limits were set at three standard deviations from the average-proportion defective. Sys-

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**Table 4. Legal Actions Identified by Risk Management**

Occurrence(s)	Legal Action	Peer-Review Analysis		Injury Severity Code
		Type of Error	Error Category	
Damage to larynx	Letter of intent	System error	Limitation of diagnostic standards	4
Poor fetal outcome	Letter of intent	System error	Limitation of therapeutic standards	4
Central nervous system injury	Claim	System error	Limitation of diagnostic standards	4
Peripheral nervous system injury	Closed claim	System error	Limitation of diagnostic standards	3
Soft tissue injury	Claim	System error	Limitation of therapeutic standards	3
Soft tissue injury	Claim	System error	Limitation of diagnostic standards	3
Dysrhythmia requiring treatment	Letter of intent	System error	Limitation of therapeutic standards	3
Soft tissue injury	Letter of intent	System error	Limitation of therapeutic standards	3
Damage to larynx or trachea	Letter of intent	System error	Limitation of therapeutic standards	4
Peripheral nervous system injury	Letter of intent	System error	Limitation of therapeutic standards	4
Perioperative mortality	Letter of intent	System error	Limitation of therapeutic standards	5
Peripheral nerve injury	Letter of intent	System error	Limitation of diagnostic standards	4
Soft tissue injury	Letter of intent	System error	Limitation of therapeutic standards	4
Peripheral nerve injury	Letter of intent	System error	Limitation of therapeutic standards	4
Peripheral nerve injury	Claim	System error	Limitation of therapeutic standards	4
Perioperative mortality	Letter of intent	System error	Limitation of therapeutic standards	5
Pneumothorax	Letter of intent	System error	Limitation of therapeutic standards	4
Peripheral nerve injury	Letter of intent	System error	Limitation of therapeutic standards	4

tems were considered to be out of control, or unstable, if a point fell outside of the control limits or a run or a trend was detected. A run was defined as a succession of seven points that were above or below the average. A trend was defined as a succession of seven points that were rising or falling. In a stable system without special causes for variation, a run or a trend has approximately the same probability of occurring as a point outside of the control limit, or  $P = 0.005$ .<sup>7</sup>

The relation between deviations from the standard of care and legal action was evaluated using a correlation coefficient. This relation was considered statistically significant if  $r > 0.8$ .

## Results

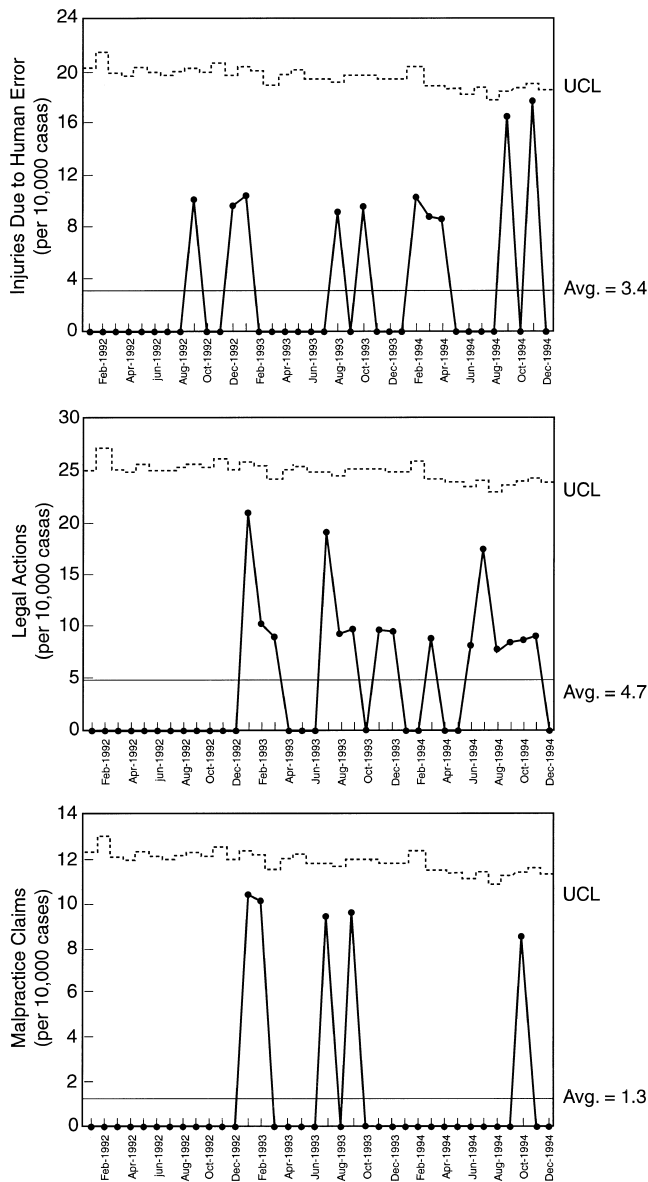
During the period from January 1, 1992, through December 31, 1994, there was a total of 37,924 anesthetics performed at the university hospital. From these, the Department reviewed 734 cases involving adverse outcomes, of which 229 resulted in disabling patient injuries (severity score of three or greater). Of the total 734 adverse outcomes, the peer review process determined that system error contributed to 644 (88%) and human error, or deviations from the standard of care, contributed to only 90 (12%). Of the 90 adverse outcomes in which deviations from the standard of care occurred on the part of the anesthesia provider, 13 resulted in a disabling patient injury. The occurrences, reporting

source, type of error, and severity of injury for these 13 cases are summarized in table 3. The incidence of anesthesia providers contributing to disabling patient injury through deviations from the standard of care was 3.4 per 10,000 anesthetics.

Eighteen cases involving legal action were identified for this time period, as summarized in table 4. The anesthesiologist was the sole defendant named in only two malpractice claims, one of which resulted in a \$60,000 award. A single letter of intent also named the anesthesiologist as the sole defendant. In the 15 additional legal actions, the anesthesia provider was named as codefendant in three claims and implicated in 12 letters of intent. The incidence of all legal actions against the anesthesia practitioners in our sample was 4.7 per 10,000 anesthetics, and the single judgment against a practitioner in our sample represents an incidence of 0.26 per 10,000 anesthetics.

Comparison of legal action and deviations from the standard of care showed the two groups to be statistically unrelated. None of the 13 cases in which a disabling injury was caused by deviations from the standard of care, as determined by peer review, resulted in legal action; and none of the 18 cases involving legal action were found to be caused by human error on the part of the anesthesia provider.

The application of statistical process control revealed that the 13 human errors resulting in disabling patient injuries, 18 cases involving legal actions, and 5 malprac-



**Fig. 1.** Attribute control charts for patient injuries caused by human error by an anesthesia provider, legal actions against an anesthesia provider, and malpractice claims in which an anesthesia provider was named as a defendant. Attribute u-charts show the monthly incidence of these occurrences per 10,000 anesthetics. Tests for special causes of variation show these systems to be in statistical control. AVG = average; UCL = upper control limit.

tice claims were stable over time. The attribute u-charts showing monthly occurrences of these three categories are shown in figure 1. The control chart shown in figure 2, however, demonstrates that the single closed malpractice claim represents a system that is out of control.

## Discussion

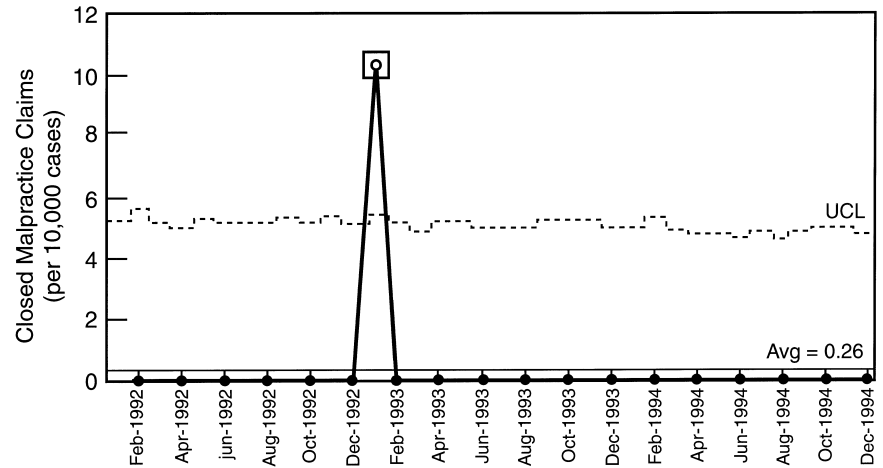
Current data suggest that a considerable amount of malpractice actions against anesthesiologists is unfounded. Anesthesiologists are at risk for litigation in the absence of deviations from the standard of care. Previous reports from the Anesthesia Closed Claims Database agree with these findings.<sup>4</sup> In the current study, none of the 18 cases involving a malpractice claim or a letter of intent were judged by peer review to be caused by deviations from the standard of care. In fact, the single closed claim against an anesthesiologist in this study, in which the plaintiff was compensated by \$60,000, did not involve human error when judged by a group of peers. This lack of a relation between malpractice litigation and human error has been suggested by the Harvard Medical Practice Study,<sup>8-11</sup> but remains open to considerable debate.<sup>12,13</sup>

More striking in the current study, however, is the finding that patients who are victims of disabling injuries resulting from deviations from the standard of care are often not compensated by our legal system. Although the authors know of no previous reports of these uncompensated patients in anesthesiology, their existence has been suggested by the previously cited retrospective chart reviews in other specialties.<sup>9,10</sup> Our peer review process identified 13 cases in which human error on the part of the anesthesia practitioner resulted in a disabling patient injury. These human errors were either the result of failure to seek appropriate data (69%) or disregard of available data (31%), and the severity of the injuries ranged from transient respiratory failure necessitating mechanical ventilatory support to death.

The discrepancy between the peer review findings and appropriate legal action can be explained in one of two ways. Either the peer review process is incapable of correctly identifying deviations from the standard of care or the legal system is a poor method of determining which patients deserve compensation because of malpractice. The latter seems more likely because several measures have been taken to improve the reliability of the peer review process. Use of multiple reviewers who meet to discuss the case has been shown to markedly increase consensus among reviewers.<sup>14-16</sup> During the course of this study, the faculty of the Department remained relatively constant so that the members of the peer review group remained stable. Structured assessment procedures have also been recommended to decrease differences in reviewers' understanding of their task and thus to increase the objectivity of implicit peer

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**Fig. 2.** Attribute control chart for closed malpractice claims. Attribute u-chart shows the monthly incidence of closed malpractice claims against anesthesiologists per 10,000 anesthetics. The single closed malpractice claim in January 1993 represents an unstable system when sampled monthly.



review.<sup>15</sup> By using nominal definitions for categorizing peer review opinions regarding adverse outcomes, the error analysis was relatively easy to apply so that the errors could be reliably identified and grouped. Structured peer review and a stable pool of reviewers allows the error categories to become more sharply defined over time.<sup>5</sup> Shared expertise in a particular area also improves agreement among reviewers.<sup>17</sup> All of our reviewers were anesthesiologists or resident anesthesiologists as defined by the composition of the Department. Although some investigators have suggested that outcome data be withheld when determining appropriateness of care,<sup>18</sup> others have suggested that outcome data are necessary to assure adequate agreement among multiple reviewers.<sup>15</sup> A recent study of structured peer review models showed no relation between severe outcomes and subsequent classification as human error.<sup>19</sup> This same study showed that the peer review model used by the authors has excellent inter-rater reliability when used in the manner described previously.

Although the legal system uses a structured review mechanism, expert witnesses are not allowed to discuss the case in a group. Multiple studies have shown that simply providing structure to a peer review process is insufficient to promote adequate agreement among reviewers.<sup>19-21</sup> Although the jurors who make the final decision are allowed to participate in group discussion, they are not the reviewers who share an area of expertise related to the case. Another potential weakness of the legal process for establishing deviations from the standard of care is the ephemeral nature of juries. Jurors change from case to case and are not afforded the op-

portunity to improve inter-rater reliability through experience, as seen in the departmental peer review process.

If peer review is a reliable method of detecting deviations from the standard of care, it could aid the legal system as a means of determining which patients to compensate for medical malpractice.<sup>8,14</sup> In fact, a fault-based administrative alternative to the tort system for resolving medical malpractice claims was proposed by the American Medical Association/Specialty Society Liability Project in the 1980s.<sup>1</sup> Opponents of this idea would say that physicians should not be policing themselves. Clearly, there may be a conflict of interest if physicians are allowed to review cases that could result in their own financial losses, but this study shows that peers are willing to assign human error in the absence of legal action. The peer review process in our study suggests that one patient was wrongly compensated and 13 others did not get what they deserved. It seems that establishment of a peer review board without economic considerations to bias judgment would be a relatively facile task. Certainly, it presents no more potential for bias than the tort system in which a point of view is advocated by legal counsel, even in the absence of sincere conviction, primarily for the purpose of monetary gain. In fact, legal decisions are often based on economic issues before reaching the structured review mechanism of a jury trial.

Although it is common for the legal system to consider economic issues in individual cases, global economic issues deserve further consideration. If peer review could be established for the identification of malpractice, the authors posit that their findings would be sim-

ilar to this study. Attribute control charts show that deviations from the standard of anesthesia care leading to disabling patient injury are in control and therefore represent a stable process. That is to say that malpractice, as identified by peer review, occurs with a frequency that is predictable. Assuming that all patients injured caused by deviations from the standard of care should be compensated, and a national scale for compensation could be established, then predicting the cost of this stable system would be relatively easy. Although the same can be said for the overall occurrence of malpractice claims, this is in contrast to the monthly occurrence of closed malpractice claims, which is out of control. Predictability of malpractice claims accounts for a great deal of the profit margin in the malpractice insurance industry because it is far more difficult to insure an unstable system than a stable system.<sup>5,22</sup> Our data suggest that it would be equally feasible to insure malpractice identified by peer review, as it would for malpractice identified by the tort system.

In addition to predictability and justifiable patient compensation, peer review may be applicable as a measure of clinical competence.<sup>23</sup> Presently, closed medical malpractice claims adjudicated in favor of the plaintiff and resulting in monetary compensation are recorded in the National Practitioner Data Bank. Federal law requires hospitals to consult the data bank every 2 yr as an indication of the clinical competence of employees when determining whether to continue or grant privileges. Our findings, however, suggest that there is little or no relation between malpractice litigation and deviations from the standard of care. Hence, the idea of using the National Practitioner Data Bank to judge clinical competence is misguided. Conversely, peer review judgments may bring us closer to that goal by providing more credible feedback to physicians and their employers. Arguably,<sup>24</sup> credible feedback from peers has an increased likelihood of resulting in behavior modification with associated performance improvement on the part of practitioners.<sup>1,25</sup>

In summary, a considerable amount of anesthesia malpractice litigation appears groundless. Practitioners are placed at risk for litigation, and plaintiffs can receive awards in the absence of negligence. Likewise, patients who are the victim of deviations from the standard of care resulting in disabling injuries are often not compensated by our legal system. If peer review could aid the legal system as a means of detecting deviations from the standard of care it would offer the advantages of being more applicable to judging clinical competence and

more justifiable in compensating injured patients. Also, deviations from the standard of care, as determined by peer review, represent a stable process and, therefore, these occurrences are predictable in terms of frequency and cost.

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