Standards for Patient Monitoring During Anesthesia at Harvard Medical School

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As part of a major patient safety/risk management effort, the Department of Anaesthesia of Harvard Medical School, Boston, has devised specific, detailed, mandatory standards for minimal patient monitoring during anesthesia at its nine component teaching hospitals. Such standards have not previously existed, and resistance to the concept was anticipated but not seen. The standards are technically achievable in all settings and affordable in terms of effort and cost. Early detection of untoward trends or events during anesthesia will result in prevention or mitigation of patient injury; this, in turn, may also help counter the explosive increases in anesthesia-related malpractice actions, settlements, judgments, and insurance premiums. The committee process used is applicable to the promulgation of standards of practice for all medical specialties and any organized group of medical practitioners.

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PHYSICIANS traditionally have resisted standards of practice that prescribe specific details of their day-to-day conduct of medical care. In spite of this, as the first part of a risk management/quality assurance program, the Department of Anaesthesia of Harvard Medical School, Boston, has devised and implemented, at its nine component teaching-hospital departments, standards for minimal patient monitoring during anesthesia. Standards such as these have not previously existed at Harvard. Reported herein is the process used to balance physician autonomy in daily practice with the large general goal of improving patient care, which, in turn, should mitigate the malpractice crisis.

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History

Adverse outcome from anesthesia has recently received increased attention.[1-3] Estimates of morbidity and mortality rates vary widely and are mostly extrapolated from comparatively small samples. Among the approximately 20 million patients anesthetized annually in the United States, 2000 or more may die of causes primarily attributable to anesthesia; the majority of these deaths are thought to be preventable.[1-3] The rate of preventable morbidity is even less easily estimated. Because major anesthetic accidents often lead to catastrophic results, consequent malpractice settlements and awards are frequently large (estimated to average over $100 000 and to range up to $41 million [United Press International, Sept 27, 1984]).

The nine teaching-hospital departments composing Harvard Medical School's Department of Anaesthesia include academic centers, specialty hospitals, and community-oriented hospitals. Together they administer approximately 100 000 anesthetics annually. All are insured under Harvard's own medical malpractice insurance company. The risk management arm of this insurance carrier expressed concern to the anesthesia department heads about the number of incidents and claims and the associated indemnity involving anesthesia care during the period 1976 through 1984. A risk management committee of six senior staff members was appointed to investigate the concerns and, if appropriate, suggest action.

The committee began by evaluating (without patient identification, to preserve confidentiality and prevent institutional bias) all the anesthesia-related claims and incidents on file with the insurance carrier. Of the cases involving major morbidity or death, most were believed to be preventable. Examining these cases, the committee concluded that more meticulous monitoring of the patients would help prevent such anesthesia accidents.

The committee reviewed practices of patient monitoring during anesthesia (then existing at Harvard, in the local community, and nationally). Controversy ensued about whether the committee should offer "suggestions," "guidelines," "recommendations," or actual "standards of practice." Basic monitoring practices were thought to be so important in accident prevention that they must be mandatory. Thus, "standards" was favored to ensure that each hospital department would *require* its members to institute a minimal level of monitoring for every patient anesthetized. The traditional resistance "on principle" to external imposition of methods of medical practice was anticipated. However, it was believed that this degree of emphasis was necessary to achieve the goal of anesthetic accident prevention. The anesthesia department heads unanimously joined the insurance carrier's enthusiastic support of this approach.

Only vague or general standards of practice exist in American medicine. Obstetrics/gynecology has organiza-

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tional standards[4] detailing the makeup of a hospital service, privileges, record keeping, and stipulations, for example, that a history must be taken on a new patient. The American Academy of Pediatrics issues recommendations on vaccination protocols, breast-feeding, nutrition, and many other general topics. The Joint Commission on Accreditation of Hospitals has process-oriented standards that focus on organizational and physical structure, but relatively little on the details of actual daily medical practice. In anesthesia, there are voluntary product performance standards for many of the medical devices used, such as anesthesia machines, endotracheal tubes, and ventilators. These have been developed by committees comprising both manufacturers and anesthesia clinicians. The American Society of Anesthesiologists has general guidelines for practice, including, for example, that patients should be evaluated preoperatively. However, specific standards for the minute-to-minute conduct of anesthesia practice have never been promulgated.

Objectives of the Standards

The goals of the Harvard minimal monitoring standards are as follows:

1. To improve patient care, thereby reducing the number of adverse outcomes arising from anesthesia accidents. An additional secondary result should be a reduction in the number of malpractice claims, which will indicate improvement in care and also may slow the accelerating rise in insurance premiums or even lead to premium reduction for anesthesia practitioners.

2. To enhance detection of relatively low-frequency events, using principles derived from a large collective experience. An individual anesthetist's personal experience would suggest that preventable serious injuries or death occurs very rarely; therefore, it is unwarranted for individuals to develop standards of care based solely on their own adverse experiences.

3. To provide a means for objective evaluation. An individual practitioner, a supervisor, or a department head can observe (and quantify, if desired) whether actual patient monitoring practice measures up to clear criteria. This can help reinforce the subjective clinical impression that someone is a low-risk or, conversely, a high-risk anesthesiologist or anesthetist. Such observations are process audits, as distinct from outcome audits that evaluate the result of care, independent of how it was rendered. Studying relatively rare but serious adverse outcomes after they happen is valuable; focusing on the "process" or conduct of patient monitoring in anesthesia may *prevent* such an outcome.

4. To establish a precedent. The anesthesia risk management committee is in the process of developing additional standards of practice for other aspects of care for the Department of Anaesthesia at Harvard Medical School.

Criteria for the Standards

No experimental data exist from which a set of standards for minimal monitoring during anesthesia can be objectively derived. There is need for a balance between not enough and too much monitoring. It is assumed that the anesthetist will pay attention to the monitors and respond correctly to their output data. Among the factors weighed to optimize the set of measurements and alarms were availability; cost; simplicity of use; intraoperative distracting influence; the relative sensitivity, specificity, and predictability (freedom from breakdown or aberrant output) of each monitoring modality; and, finally, whether the standards represented "reasonable care"[5] consistent with applicable court decision precedents. Unable to use a classic scientific approach to analyze these factors, the committee adopted an intuitive approach requiring agreement to be forged from widely divergent opinions.

The actual daily practice in the anesthesia departments associated with Harvard Medical School was the starting point in evaluating what patient monitoring is desirable and then what should be mandatory. This was correlated with the insurance claim data. For example, one anesthesia death occurred when an old anesthesia machine without an oxygen monitor was used in an x-ray suite during a procedure. In the relative darkness, the wrong flow-meter knob was turned and the oxygen was shut off. This accident would have been prevented by a functioning oxygen monitor with a lower-limit alarm. One of the standards mandates monitoring of breathing system oxygen during *all* general anesthetics.

The standards had to be realistic, technically achievable, and affordable in terms of both personnel and equipment utilization. It was recognized, however, that certain hospital departments would need to change some practices and add new equipment if the standards were fully implemented. The standards were written to make compliance easy and desirable for the individual practitioner.

During the development process (members' individual efforts plus about 20 hours of full-committee meetings over eight months), committee members sought input from persons at all levels within their respective departments. Efforts were made to informally canvass senior members of all nine departments and others with known interest. One hospital department has a formal patient safety group that reviewed and accepted the proposed standards and also gave input to the committee. Suggestions were accepted or rejected by committee agreement.

The Standards

The standards for minimal monitoring during anesthesia are reproduced in the Table. The intent and reasoning for most of the specific items are self-explanatory. Their applicability was limited to situations under the control of the various departments of anesthesia (excluding, for example, nonanesthetists using heavy sedation in offices or clinics). While three of the standards apply to all regional anesthetics, epidural *analgesia* for labor or pain management was specifically excluded because the risk was judged to be extremely low (no related claims at Harvard from 1976 through 1985) and because the cost (requiring the physical presence of anesthesia personnel in each room throughout the entire duration of analgesic action) would be prohibitively high. The preface also reiterates that these standards describe *minimal* required monitoring, and that it is expected and appropriate that some or all of the requirements will be routinely exceeded.

The standard for continuous monitoring was the most difficult to formulate. It may appear too lenient. It was difficult to try to cover all situations without excessive detail or multiple exceptions. The standard is written to stress unequivocally that *intermittent* observations alone are insufficient. This is the only standard for which individual departments may change the criteria or add their own. Any such modification must be approved by the group of nine department heads to prevent any one department from circumventing the spirit of the standard by diluting it. Presently, seven of the nine hospitals have or are installing at least stand-alone end-tidal carbon dioxide monitoring, pulse oximetry (noninvasive arterial oxygen saturation monitoring), or mass spectrometry in every operating room. The committee expects that one or more of these

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Minimal Monitoring
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These standards apply for any administration of anesthesia involving department of anaesthesia personnel and are specifically referable to preplanned anesthetics administered in designated anesthetizing locations (specific exclusion: administration of epidural analgesia for labor or pain management). In emergency circumstances in any location, immediate life support measures of whatever appropriate nature come first with attention turning to the measures described in these standards as soon as possible and practical. These are minimal standards that may be exceeded at any time based on the judgment of the involved anesthesia personnel. These standards encourage high-quality patient care, but observing them cannot guarantee any specific patient outcome. These standards are subject to revision from time to time, as warranted by the evolution of technology and practice.

Anesthesiologist's or Nurse Anesthetist's Presence in Operating Room
For all anesthetics initiated by or involving a member of the department of anaesthesia, an attending or resident anesthesiologist or nurse anesthetist shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics, and monitored intravenous anesthetics. An exception is made when there is a direct known hazard, eg, radiation, to the anesthesiologist or nurse anesthetist, in which case some provision for monitoring the patient must be made.

Blood Pressure and Heart Rate
Every patient receiving general anesthesia, regional anesthesia, or managed intravenous anesthesia shall have arterial blood pressure and heart rate measured at least every five minutes, where not clinically impractical.*

Electrocardiogram
Every patient shall have the electrocardiogram continuously displayed from the induction or institution of anesthesia until preparing to leave the anesthetizing location, where not clinically impractical.*

Continuous Monitoring
During every administration of general anesthesia, the anesthetist shall employ methods of continuously monitoring the patient's ventilation and circulation. The methods shall include, for ventilation and circulation each, at least one of the following or the equivalent†:
For Ventilation.—Palpation or observation of the reservoir breathing bag, auscultation of breath sounds, monitoring of respiratory gases such as end-tidal carbon dioxide, or monitoring of expiratory gas flow. Monitoring end-tidal carbon dioxide is an emerging standard and is strongly preferred.
For Circulation.—Palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, pulse plethysmography/oximetry, or ultrasound peripheral pulse monitoring.
It is recognized that brief interruptions of the continuous monitoring may be unavoidable.

Breathing System Disconnection Monitoring
When ventilation is controlled by an automatic mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of any component of the breathing system. The device must give an audible signal when its alarm threshold is exceeded. (It is recognized that there are certain rare or unusual circumstances in which such a device may fail to detect a disconnection.)

Oxygen Analyzer
During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system will be measured by a functioning oxygen analyzer with a low concentration limit alarm in use. This device must conform to the American National Standards Institute No. Z.79.10 standard.*

Ability to Measure Temperature
During every administration of general anesthesia, there shall be readily available a means to measure the patient's temperature.
Rationale.—A means of temperature measurement must be available as a potential aid in the diagnosis and treatment of suspected or actual intraoperative hypothermia and malignant hyperthermia. The measurement/monitoring of temperature during *every* general anesthetic is not specifically mandated because of the potential risks of such monitoring and because of the likelihood of other physical signs giving earlier indication of the development of malignant hyperthermia.

*Under extenuating circumstances, the attending anesthesiologist may waive this requirement after so stating (including the reasons) in a note in the patient's chart.

†Equivalence is to be defined by the chief of the individual hospital department after submission to and review by the department heads, Department of Anaesthesia, Harvard Medical School, Boston.

monitoring modalities may be incorporated in future revisions of the Harvard standards.

Realities of practice were recognized. Most alarms for warning of breathing system disconnection during mechanical ventilation (one of the most frequent causes of major anesthesia accidents)[1-3] operate by sensing the absence of a cyclic pressure. While these alarms are valuable and important, there are several mechanisms for failing to detect a discontinuity in the breathing system (false-negative) with the potential for a serious accident, and this is noted in the standard.

The temperature monitoring standard includes a written rationale because of the intense debate within anesthesiology on the subject. Monitoring temperature is generally very useful. However, its utility as the primary diagnostic criterion for the very rare (but often catastrophic) syndrome of malignant hyperthermia is controversial. Also, the practicality of requiring temperature measurement during every single case, however brief, was weighed. If individual departments choose to mandate temperature measurement in all children or even in all patients, this is clearly their prerogative.

Implementation

After the committee achieved agreement, the standards were presented to the nine department heads who, after incorporating their few suggestions, voted unanimously to adopt them as official Harvard-wide policy. Each department head was then responsible for implementation within his department. The set of standards was presented to the members of the various departments as an accomplished fact, not open for further discussion of this edition. Some practitioners thought the standards too lenient, some too strict, and many predicted no impact on their practice because they already routinely met the standards.

Among the immediate tangible impacts were that one hospital purchased more oxygen monitors so that there would always be a replacement instrument available. Another hospital provided free earpiece stethoscopes to all staff, who previously had to purchase their own (few did). The purchase of pulse oximeters (including one for each operating room at three hospitals) at an average of about $5000 each was a

capital expense encouraged, at least in part, by the standards process. Also, from their own clinical experience, committee members believe there was a heightening of awareness about anesthesia accidents and the use of patient monitoring to prevent them.

Audits (random visits to operating rooms during which an impartial observer completes a checklist of monitoring in use) of compliance with the standards have begun and are complete in two departments. In one, the continuous circulation monitoring standard was not met in half the observed cases. After discussion with the quality assurance committee of that department, remedial action to encourage adoption of new habits was instituted. In the other department, this circulation monitoring standard was not met in only 3% of cases, but the interruptions in continuous ventilation monitoring were more than "brief" in 25% of cases.

There is, as yet, no formal procedure for sanctioning noncompliance by either an individual or a department. The insurance carrier acknowledges that an accident occurring during known violation of the standards would be more difficult to defend in a malpractice action. However, legal counsel is of the opinion that documented compliance with the standards would be an aid to defense against a malpractice claim. Further, the committee believes that the positive effects of the standards outweigh any legal consideration. The insurance carrier is closely monitoring incidents and claims for a reduction in the number involving anesthesia care, but it is anticipated that it will take some time before sufficient data accumulate to make such an assessment.

Comment

Standards in medical care take many forms. They can be criteria for clinical teaching[6] or clinical skills.[7] A discussion of the outcome of care[8] raises the important question of whether standards in general should codify current practice and validate the existing, declare an ideal that may be impossibly high, or strike a balance in between. The latter is the course chosen by the Harvard Department of Anaesthesia risk management committee, which also agreed with the suggestion[9] that any standards, to be effective, must be limited and specific. Identifying a specific area (patient monitoring) related to a specific concern (adverse anesthesia outcomes) was the critical step that allowed formulation of a set of process standards that can be realistically expected to influence behavior in the target group of practitioners. Such definition would be a key element in efforts by other specialities to start writing detailed standards of practice, standards for either process or outcome of care.

Opinions and practices in medicine vary among institutions and regions. These standards illustrate that, with effort, agreement among several groups of practitioners with different approaches to the same type of activity can be achieved and a basic minimum standard developed. Such agreement could occur at the institutional, local, state, regional, or national level. The Harvard standards for minimal monitoring during anesthesia focus on behavior and habits rather than on expensive technology. They are fundamental minimal standards that would be achievable in the smallest rural community hospital. The average cost, per anesthetic administration, of providing for an electrocardioscope, oxygen monitor, and breathing system disconnection alarm is about $5,[1] much less than the present average per anesthetic cost of malpractice insurance (approximately $53 in 1985 at Harvard, ie, the total of anesthetist malpractice premiums divided by the number of cases). The expense for monitoring is minimal compared with the cost of *defending* even one minor malpractice claim (before including any possible settlement). It has been considered valid[10] for large academic medical centers to set standards that, over time, might be applied to smaller hospitals. While the committee is interested in seeing replication of this standard-setting process rather than the wide adoption of the Harvard standards, it was aware of this eventual possibility and deliberately avoided unrealistic requirements for extraordinarily costly and rapidly changing state-of-the-art high technology. Writers of standards (process or outcome) in other fields must continually be aware of these issues.

Virtually all US physicians are concerned over the very large increase in both the number of malpractice actions and the resulting monetary settlements and awards. The consequent astronomical increase in malpractice insurance premiums is causing modification or even closing of some physicians' practices. Legislative relief or protection is being sought in many ways, with little sympathetic response from lawmakers.

Perhaps the best way to counter this seemingly out-of-control situation is to work even harder on patient safety and medical care quality assurance. Adherence to specific written standards of practice seems a logical component of these efforts. However, such standards have been avoided because of the traditional perception that physicians are automatically opposed to "big brotherism" imposition of authority. The Harvard Department of Anaesthesia experience demonstrates that this need not be the case. Referable to a laudable desire to improve care by reducing accidents and resultant injuries, realistic well-defined standards were created. They were accepted with minimal resistance for three reasons: (1) the desirable goal, (2) the lack of major or disruptive mandated changes in practice, and (3) the potential for reduction in malpractice claims and premiums.

These particular standards may not be applicable verbatim to all departments of anesthesia. What *is* applicable, however, is the process described above by which they were promulgated. While the strong commitment of chiefs of service to adopting and enforcing standards clearly helps the process, even in more loosely organized departments, groups, or specialties, with sufficient effort, this approach could be used. Insurance carriers may provide the impetus, but physician leadership is required. Even constituting a committee is a positive, consciousness-raising step. The Harvard anesthesia example is probably best applied to the other procedure-oriented specialties, but the model is valid for all of American medicine.

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