Special Article

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Risk Management in Anesthesia

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Adverse patient outcomes are the focus of risk management (RM) in anesthesia. The first and critically important point is a major effort to prevent adverse patient outcome caused by anesthesia care. The other component is a specific program to deal with an adverse outcome should it occur - in an attempt to limit the damage both to the patient and to the anesthesiologist. All anesthesia care (like all of life) has some risks. With careful "management", these risks can be kept to an absolute minimum for all involved.

Because anesthesia care is facilitative rather than therapeutic, the outcome of anesthesia care has been traditionally measured in terms of the absence of "complications". Some principles of anesthesia RM may appear somewhat "defensive," as if anesthesiologists almost expect to be targets in the medical-legal system. Part of RM is intended to help reduce liability exposure and this must take into account some features of the medical-legal system, especially issues raised in the "malpractice crises" of the 1970's and 1980's. It appeared that the crunch of the astronomically high settlements and legal awards (that fueled skyrocketing malpractice insurance premiums) was lessening in recent years. It has been suggested, however, that this is merely a phase in a cycle which will inevitably reverse itself[1]. Further, there may be a new trend back to somewhat increased insurance premiums. In any case, awareness of medical-legal implications is clearly necessary and case precedents have revealed specific factors that make the defense against a malpractice suit more difficult. While, in theory, no practice decisions should be influenced by legal concerns ("defensive medicine"), the huge potential financial and emotional impact of a malpractice suit (even a frivolous one) justify attention to and application of RM strategies. This is intended to promote optimal care and, thus, to minimize the likelihood and severity of malpractice suits.

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Classic Risk management

RM terminology originated in business and industry. Medical practitioners often think they understand these terms, but they usually do not, particularly when attempting to communicate with hospital administrators, insurance company personnel, and regulatory/accrediting inspectors. Many medical practitioners still associate "risk management" with reams of apparently irrelevant paperwork demanded as fuel by a self-sustaining bureaucracy composed of nonmedical personnel. Overzealous early emphasis on the "clipboard mentality" of compiling statistics, doing "audits", and rifling out forms may still "turn off" anesthesiologists, who are accustomed to hands-on activity with rapid feedback. Nonetheless, it is very important to realize that RM not only is here to stay, but also has the potential - properly utilized - to be enormously beneficial in anesthesia. The concept of "risk management" has been traditionally associated with the financial/economic side of business or professional activity. It started with the insurance industry recognizing "risk": certain activities predictably lead to a degree of "loss". This risk then became the subject of efforts to: (1) plan to pay for the loss and (2) try to reduce the likelihood and/or magnitude of loss. Thus, there was an attempt to control or "manage" the known risk.Regarding anesthesia, it was

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clear that data "demonstrate that anesthetic mishaps, although relatively few in number, present considerable risk of loss in the areas of hospital cost, human suffering, and the integrity of the medical profession" and, as a result, providers "have developed formal programs to systematically identify and control risks that may lead to patient injury or financial loss".[2] Financial loss usually means settlements and judgments associated with malpractice claims and suits. RM emphasizes prevention of any loss-generating adverse incident or outcome. However, a key traditional component also is the effort to limit financial loss once an incident has occurred. A common impression is that the hospital or insurance company Risk Manager is the person to call as soon as an accident and/or injury is identified. While this is true, there needs to be a shift in perception to the fact that prevention is primary and damage control (financial or otherwise), when needed, is a secondary part of the process.

Classic risk management involves four steps: (1) identification of a problem (actual or potential injury or loss), (2) assessment and evaluation of the problem (determining the cause of injury or loss), (3) resolution of the problem (modification or elimination of the cause, by change-change of practice, procedures, equipment, or behavior, and enforcement, with sanctions if necessary), and (4) follow-up on the resolution (to verify the desired result and to ensure continued effectiveness). A minor example involved corneal abrasions during facial surgery, discovering the cause, and making remedial changes.

A much larger scale example involved the standards for intraoperative monitoring. Notification from the insurance carrier that there was an unacceptably high number of major anesthesia malpractice claims led to the committee that eventually evolved the original "Harvard standards"[3]. Unrecognized hypoventilation (mainly), inadequate inspired oxygen, and other factors were identified in the evaluation process. The resolution involved the changes of the implementation and enforcement of the standards. The follow-up studies suggested a positive impact of the changes[4]. The related history of the development of monitoring standards in the US through the American Society of Anesthesiologists, in many other countries through anesthesia organizations, and for the world by the International Task Force on Anesthesia Safety (and then adopted by the WFSA) is well known. All these activities constitute an enormous and classic risk management effort.

More is being written about risk management in anesthesiology[5,6]. Discussion of specific monitoring equipment, teaching techniques, and case analysis methods is valuable, but is only one small component of a comprehensive RM program in anesthesia. A genuine program must cover all relevant aspects of practice and must emphasize the creation of optimum conditions of the "what" and the "how" of anesthesia practice and optimum preparation, awareness, and skill of the anesthesiologists. This will help both to prevent adverse outcomes of anesthesia and to minimize their impact when they occur.

ELEMENTS OF RISK MANAGEMENT IN ANESTHESIA

Managed Care Impact, Peer Review Organizations, and "Production Pressure"

The enormous emphasis on cost cutting in medical care has created an entire new set of liability risks for physicians, including anesthesiologists. Patients (or their survivors) who believe they were wrongly denied justified care are suing both their HMO/MCO and the physicians who accepted the denials of care which appear to have contributed to poor outcomes. Most publicized cases so far involve refusal to cover diagnostic work-ups (e.g. breast lump) or treatments such as marrow transplants (an $89 million jury verdict). Very importantly, most MCO's are structured under federal laws that make them exempt from negligence claims, leaving the physician as the only "deep pocket" in sight. Anesthesiologists are likely to face denial of MCO coverage for work-up (such as a cardiac echo) of worrisome preop findings, for preop admissions to "tune up" chronically ill patients, for invasive monitoring intraop, and for postop admission "for monitoring and care" of patients scheduled for only outpatient surgery. One step removed but employing similar ideas are peer review organizations (PRO) which seem to have evolved from guardians of the quality of care into "watchdogs" devoted to trying to limit the cost of heath care services[7]. With both, inevitably, there will be frustration. However, the anesthesiologist must put the welfare of the patient first and push hard to do what is obviously reasonable. It is critical that all these efforts advocating increased involvement and care be scrupulously documented. Although not thoroughly tested yet by legal precedents, this may help defend against any

later negligence claim against the physician. These efforts may even mean postponing a scheduled case [explain the reasons to the irate surgeon because he would be a defendant too] or absorbing the cost of postoperative monitoring. Even though bad results are very rare and almost always, one would probably "get away with it," anesthesiologists must not be pressured into doing what they know is unwise and even unsafe. In the event of an adverse outcome, there is no legal weight whatsoever in the defense of saying, "The HMO made me do what I knew was poor care (or even dangerous)".

Similar is the new "production pressure" on anesthesiologists, which can even degenerate into a form of economic credentialing in that anesthesiologists who are judged too slow between cases or who use too many expensive monitors and medications may face loss of patients from an MCO or even privileges at a facility. Intense pressure to go very fast using as few people and resources as possible will lead to cutting corners and danger to patients. Safe, reasonable care must prevail because, again, citing the pressure is no legal defense.

Credentialing and clinical privileges

With the radical changes in fundamental patient-doctor relationships in recent years and the accelerated new changes from managed care, there seems to be a common public perception that the medical profession is inadequately policed. Therefore, there has been intense public and political pressure on legislatures, regulatory/licensing agencies, and institutional administrators to identify: (1) fraudulent, criminal, and deviant physicians and, (2) the incompetent (for whatever reason) or simply poor-quality practitioners who have frequent or severe enough adverse results to attract attention. Also, there is the recognition that some physicians applying for privileges may stretch -the truth, either by exaggeration of past status and experience or by omitting key events with negative implications (license suspensions, privilege restrictions, etc.). The risk management implications are very clear. It is reasonable to assume that there will be a lesser likelihood of complications in the practice of those who are appropriately educated, trained, and experienced. Further, unfortunately, it has become very important to consider legal doctrines such as "vicarious liability" and "agency". Specific applicability may vary among cases and locations. However, basically, if an individual, group, or institution hires a physician or even simply approves a physician (such as by securing or granting privileges), the individual or group may be held liable along with that physician for the consequences of his/her actions. This, of course, would be especially likely if it were later discovered that there was something questionable in that physician's past that the credentialing process failed to reveal. Accordingly, credentialing must be taken much more seriously than even a few years ago. This may be annoying, both for the physician who must secure copies of ail manner of records and for those who must review and verify them. However, the honest majority must recognize that such efforts are intended to protect patients and also the integrity of the profession. It is similar to the annoyance caused by the metal detectors and baggage screening at airports, which is tolerated in the interest of the safety of all concerned.

When an applicant physician is being considered by an anesthesia department or group, references must be thoroughly verified. This raises another type of legal problem. If a physician is leaving a position for adverse reasons, colleagues at the former location may be reluctant to supply details for fear of being sued for defamation of character, liable, etc. Written references that say very little or seem to have implications "between the lines" must be followed up on with private telephone calls. Also, when a new physician assumes the new position, there must be a thorough orientation and checkout to prevent errors caused by unfamiliarity.

Hospitals have very specific responsibilities in granting clinical privileges and the anesthesiologists should satisfy themselves that the hospital is verifying all credentials as well as checking with the National Practitioner Data Bank. Very importantly, the periodic renewal of privileges must be taken just as seriously as the initial granting. While there may be personal reluctance to revoke/restrict a colleague's hospital privileges and a fear that this will bring a retaliatory lawsuit, there are legal precedents holding a hospital and/or its medical staff liable if the incompetence of a physician was "known or should have been known" but was not addressed.

Should all anesthesiologists have "blanket privileges" to undertake any anesthetic challenge, from the tiniest critically ill premature through hypothermic total circulatory arrest to the most complex CT-controlled neurolytic pain block ? This is a "hot topic" today and has major political and eco-

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nomic implications. The risk management considerations in this question are strong if practitioners who are not really qualified or experienced enough are allowed, or even expected due to peer or scheduling pressures, to undertake major challenges for which they are not prepared. The likelihood of complications will be increased and the difficulty of defending the practitioner against a malpractice claim in the event of a catastrophe is significantly increased. There is no clear answer on the question of procedure-specific privileges. Ignoring issues of qualifications has clear negative potential. On the other hand, total adoption of such a system likely soon would result in an anesthesia department or group divided into many small "fiefdoms" with consequent further atrophy of clinical skills outside one's specific area(s). This is both anti-intellectual and stifling for the individual as well as a disservice to the profession and its future. Each anesthesia department or group will need to address these issues. At the very least, the common practice of every applicant for new or renewal privileges checking off each and every line on the printed list of anesthesia procedures should be reviewed.

Policy and Procedures

Developing written policies and procedures often is perceived by physicians as merely more bureaucratic drudgery. This is much less likely to be so for a practitioner who has turned to a detailed, carefully thought out procedure manual during an actual or impending emergency and found the necessary information to deal with a problem or even prevent an adverse patient outcome. Creating or updating such a manual (prototype examples exist[8]) forces physicians to think about some things that are and some that are not everyday events. This type of a review in and of itself is healthy. It often reveals "an accident waiting to happen" that can be corrected. Such a manual logically is divided into two parts: organizational and procedural. Included under organization is the delineation of privileges and responsibilities of, and expectations for all involved personnel as well as a communications section with the verified addresses, telephone and pager numbers, and how to reach all clinical personnel. The intent is to minimize difficulty when help is needed. Critically important is the delineation of call responsibilities (not a call schedule), a detailed listing of what is expected of each call person when on call with regard to physical presence at what hours, telephone availability, pager availability, maximum permissible distance from the institution, etc. It is vital to have all call duties spelled out clearly, prospectively, in print. Unfortunately, this often becomes a key element in the aftermath of an accident in which, it is charged, the appropriate personnel were not available or could not he found. The RM implications are clear: (1) qualified help should be available through an agreed-upon mechanism; this helps optimize care and reduce complications; and (2) it would be extraordinarily unfortunate following a catastrophe to rind members of a group pointing fingers at each other trying to shift responsibility and thus blame for an emergency call that was not answered.

The procedural component gives specific outlines of proposed courses of action for particular circumstances. Frequently, there are copies of, reference to, or paraphrase of the statements, guidelines, and standards appearing in the back of the ASA Directory. Also included are references to and/or specific protocols for the areas mentioned in the JCAHO standards. Lists of potential other topics are available.[6,8] A thorough, carefully conceived policy and procedure manual is a valuable RM tool. Many of the components promote practices that will prevent adverse events, will help in management of crisis (e.g., malignant hyperthermia), or will facilitate communication in difficult situations (e.g., refusal of blood). Ideally, each staff member would review the manual at least annually and sign off in a log indicating current familiarity with its contents.

Equipment: Maintenance and Records

Overt equipment failure is rare in anesthesia practice compared to human error, but there is belief that the large majority of equipment-related problems - that do occur (aside from clear misuse or unfamiliarity) could be prevented by correct maintenance and servicing. There is an excellent published summary of a complete program for anesthesia equipment.[9] A distinction is made between equipment failure due to progressive deterioration - which should be preventable because it is observable - and catastrophic failure, which often is not preventable. Emphasis is placed on preventive maintenance for mechanical parts and involves periodic performance checks every four to six months. Also, there is an annual safety inspection of each anesthetizing location covering 49 points and including the surrounding area and the immediate location as well as the equipment itself.

Overall, the general principles of equipment handling are straightforward. Prior to purchase, it must be verified that a proposed piece of equipment

meets all applicable standards. Complex equipment such as anesthesia machines and ventilators should be assembled and checked out by a representative from the manufacturer or its agent. There are potential adverse legal implications of relatively untrained personnel certifying a particular piece of medical equipment, even if they do it perfectly. It is also very important legally to involve the representative in preservice and in-service training for those who will use the new equipment. Further, upon its arrival, each individual piece of equipment gets a sheet or section in the master equipment log and this must have the make, model, serial number, and in-house identification for it. This not only allows immediate identification of any equipment involved in a future recall or product alert but also serves as the permanent record of every problem, problem resolution, maintenance, and servicing occurring until that particular piece is scrapped. The question of who should maintain and service anesthesia equipment has been widely debated and has significant RM implications. Some groups rely on "factory" service representatives for all attention to equipment, while others engage independent service contractors, and still other (usually larger) departments have access to personnel (either engineers and/or technicians) in their institution. The single underlying tenant is simple: the person doing preventive maintenance and service must be qualified. Whether an engineering technician who spent a week at a course at a factory can perform the most complex repairs depends on a variety of factors which can be investigated by the physicians ultimately using the equipment in the care of patients. Failure to he involved in this oversight exposes the practitioners to increased liability in the event of an untoward outcome associated with improperly maintained or serviced equipment. Aside from preventive maintenance and servicing, there must be adequate day-to-day clinical maintenance of equipment. Inadequate service in this area truly creates "an accident waiting to happen." An improperly installed canister of carbon dioxide absorbent is only one of multiple possible examples of potential danger from inadequate routine technical support.

When anesthesia equipment becomes obsolete and should be replaced is another question difficult to answer. Replacement of obsolete anesthesia machines and monitoring equipment is one key element of a risk modification program. Ten years has been cited as an estimated useful life for an anesthesia machine. Certainly, anesthesia machines more than 17 years old do not meet the safety standards now in force for new machines (such as vaporizer lockout and fresh gas ratio protection) and do not incorporate the technology that advanced very rapidly during the 1980's, much of it being directly intended to prevent untoward incidents. Note that some anesthesia equipment manufacturers, anxious to minimize their own potential liability, have refused to support (with parts and service) some of the oldest of their pieces (particularly gas machines) still in use. This is a very strong message to practitioners that such equipment must be replaced as soon as possible.

Lastly, should equipment fail, it must be removed from service and a replacement substituted. Groups are obligated to have sufficient backup equipment to cover any reasonable incidence of failure. The equipment removed from service must be clearly marked with a prominent label (so it is not returned into service) containing the date, time, person discovering, and the details of the problem. The responsible personnel must remove the equipment, make an entry in the log, and initiate the repair. As indicated below regarding response to an adverse event, a piece of equipment involved or suspected in an anesthesia accident must be immediately sequestered and not touched by anybody - particularly not by any equipment service personnel. If a severe accident occurred, it may be necessary for the equipment to be inspected at a specific later time by a group consisting of qualified representatives of: the manufacturer, the service personnel, the plaintiff attorney, the insurance companies involved, and the practitioners defense attorney. Also, major equipment problems should be reported to the Medical Device Problem Reporting system of the U.S. FDA via the Device Experience Network (telephone 800-638-6725).

Informed Consent

Informed consent is obtained by discussing the potential risks and benefits of a proposed action and any available alternatives and then ascertaining that the patient (or agent) understands and agrees to what is being proposed. There may be some residual debate as to whether there needs to be a separate informed consent for the anesthesia for a planned surgical operation or whether consent to the operation implies consent for the anesthesia. Now, most anesthesiologists obtain a separate informed consent because there are wholly separate identifiable "material risks" associated with the anesthetic independent of the surgery. This has become the expected standard of care. It is inadequate to expect the surgeon to

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fully discuss the anesthetic and, particularly, any special anesthesia implications of the patient's medical condition. In the discussion, what risks should be disclosed to obtain truly informed consent for anesthesia ? There needs to be a balance between giving enough information that would be significant for a "reasonable person" to make a decision and frightening the patient with a long list of potential, extremely rare, severe complications. "Negligible" risks are not "material" and need not he detailed. Exactly what this means in anesthesia care remains to be defined over time. Using an analogy to automobile accidents, it is definitely possible to mention death as a risk to every patient without scaring them. Of course, patient questions must be answered. Thorough documentation of the consent discussion is necessary and a preprinted form alone is inadequate because it can be signed with no understanding. A separate anesthesiologist's note is needed. All this will not prevent charges of lack of informed consent in lawsuits, but will significantly aid in the defense.

Record Keeping

Innumerable anesthesia malpractice cases have been lost, even when there probably was no malpractice, due to inadequate, incomplete, or illegible anesthesia records. The anesthesia chart is the cornerstone of all the information about an anesthetic case for RM purposes. The old dictum, "If you didn't write it down, it didn't happen" is still very much applicable in a legal sense. Even the very best anesthetic care cannot be defended, or even referred to, if there is no clear record that such care took place. This applies to pre and postoperative evaluation and care as well as intraoperative management. Also, obviously, if there is an adverse event, it must be carefully summarized in the chart. This should be done as soon as possible, but not in the heat of the moment. Careful thought, probably with the help of an uninvolved colleague, must go into the penning of this note as it will be microscopically scrutinized by a great many people for a long time.

Meaningful Morbidity and Mortality Conferences and Continuing Education

Another cornerstone of anesthesia risk management in the group/departmental meeting, case conference, M & M, etc. at which problem or interesting cases are thoughtfully discussed. At least monthly meetings are required by the JCAHO, but this should not be the driving force. Such meetings allow the classic risk management process to work. True discussion, without finger-pointing, about what happened and what could be different next time can really influence the practice patterns of a group or department. Likewise, genuine continuing education efforts of various types contribute to the quality of care and, thus, in turn, to the avoidance of adverse anesthesia events.

Response to and Adverse Event

Even with the very best of practice, it is likely that each anesthesiologist at least once in his/her professional life will be involved in a major anesthesia accident. Precisely because such an event is so rare, very few are prepared for it. It is probable that the involved personnel will have no relevant past experience regarding what to do. Although an obvious resource is another anesthetist who has had some exposure or experience, there may not be one of these either. The basic outline of an appropriate immediate response to an accident is straightforward and logical[10]. However, unfortunately, the principle personnel involved in a significant untoward event may react with such surprise or shock as to temporarily lose sight of logic. At the moment of recognition that a major anesthetic complication has occurred or is occurring, help must be called. A sufficient number of people to deal with the situation must be assembled as quickly as possible. For example, in the event an esophageal intubation goes unrecognized long enough to cause a cardiac arrest, the immediate need is for enough skilled personnel to conduct the resuscitative efforts, including making the correct diagnosis and replacing the tube into the trachea. Whether the anesthesiologist apparently responsible for the complication should direct the immediate remedial efforts will depend on the person and the situation. In such a circumstance, it would seem wise for a senior or supervising anesthesiologist quickly to evaluate the scenario and make a decision. This person becomes the "incident supervisor" and has responsibility for helping prevent continuation or recurrence of the incident, for investigative activities, and for ensuring documentation while the original and helping anesthesiologists focus on caring for the patient. As noted, involved equipment must be sequestered and not touched. If the accident is not fatal, continuing care of the patient is critical. Measures may be instituted to help limit anoxic brain damage. Consultants may be helpful and should be called without hesitation. If

not already involved, the chief of anesthesiology must be notified as well as the facility administrator and risk manager and, possibly, the anesthesiologist's insurance company. The surgeon of record probably will first notify the family, but the anesthesiologist and others (risk manager, insurance company loss control officer, or even legal counsel) might appropriately be included at the outset. Full presentation of facts as they are best known with no confessions, opinions, speculation, or placing of blame is the best presentation. Any attempt to conceal or shade the truth will later only confound an already difficult situation.

Obviously, comfort and support should be offered, including the services of facility personnel such as clergy, social workers, and counselors. Ideas on dealing with a death have been offered.[11]

The primary anesthesia provider and any others involved must document relevant information. Never change any existing entries in the medical record. Write an amendment note if needed with careful explanation of why amendment is necessary, particularly stressing explanations of professional judgments involved. State only facts as they are known. Make no judgments about causes or responsibility. The same guidelines hold true for the filing of the incident report in the facility, which should be done as soon as is practical. Further, all discussions with the patient or family should be carefully documented in the medical record. While opinions may vary by location, there has been a strong suggestion that the involved practitioners make their own set of more complete notes, *including* personal opinions and observations about competence and performance, as soon as possible after the event. These will be extremely valuable 4-5 years later preparing for testimony, but it is critical that these notes are immediately placed, as they are written, in the hands of the practitioners attorneys, thus preventing later "discovery" of the notes by anyone else.

Follow-up after the immediate handling of the incident will involve the primary anesthesiologist but should again be directed by a senior supervisor who may or may not be the same person as the incident supervisor on the scene at the time. The follow-up supervisor verifies the adequacy and coordination of ongoing care of the patient and facilitates communication among all involved, especially with the Risk Manager. Lastly, it is necessary to verify that adequate postevent documentation is taking place.

Unpleasant as it is to contemplate, it is better to have a plan ahead of time and execute it in the event of an accident. Vigorous immediate intervention may well improve the outcome for all concerned.

DISCUSSION

In anesthesia risk management, the two themes of quality of patient care and concern about liability exposure are intertwined. Especially in this era of managed care's influence and the resultant new risks, doing everything possible first to maximize the quality of care should help "manage" or minimize the risks of adverse events, which, in turn, minimizes the consequent risk of malpractice claims and suits. Anesthesiologists should not dwell on legal fears. This is inappropriate and taxing. Application of the anesthesia risk management principles presents here should minimize risks for both patient and anesthesiologist. In spite of the debate, it is clear that anesthesia has become safer (as shown by the major reductions in malpractice insurance premiums specifically for anesthesiologists). Careful attention to risk management as outlined here will help continue the trend.

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