24 Medicolegal Aspects of Regional Anesthesia

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The purpose of this chapter is to present basic medicolegal principles, to report published guidelines that establish professional standards, and to summarize recent publications concerning medicolegal issues specific to the practice of regional anesthesia. Those interested in reading a meticulous dissertation concerning the legal aspects of medicine should consult a law text covering that field of jurisprudence. One could peruse a contemporary textbook of anesthesiology; such publications devote at least one exhaustive chapter to the subject.

The Physician–Patient Relationship

Fundamentally, the physician–patient relationship is ethical in nature. One of the first people to offer his perception of the relationship was Hippocrates (c. 460–370 B.C.). He did so not in his famous "Physicians' Oath," but in another of his works, *Epidemics*, book 1, section 11:

> "As to diseases, make a habit of two things – to help, or at least to do no harm."[1]

To support this teaching, his "Physicians' Oath" contains two references to the "do no harm" doctrine. Taken out of context, these references have been translated as follows:

> I will apply dietetic measures for the benefit of the sick according to my ability and judgement; I will keep them from harm and injustice.

And

> Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief . . .[2]

Hippocrates was Greek. Therefore, the famous Latin phrase "Primum non nocere" cannot be attributed to his original work. Nevertheless, Hippocrates' ancient admonition to do no harm still constitutes the ethical tenet on which the physician–patient relationship is based.

Unfortunately, some patients do experience harm while under the care of a physician. This fact has led to the establishment of the massive and complex medicolegal system that exists today to deal with "malpractice." The medicolegal ramifications of

harm resulting from the practice of regional anesthesia will be discussed later in this chapter. First, a few basic legal principles and professional guidelines will be set forth to lay the foundation for further considerations.

The Legal Definition of the Physician–Patient Relationship

A legal relationship is established when a physician accepts the duty to care for a patient. The patient (or his legal surrogate), after fulfilling the requirement of understanding and accepting the terms and information included in an informed consent disclosure, voluntarily agrees to enter into a physician–patient relationship. The duties of the physician to the patient include the following[2]:

1. To adhere to accepted "standards of care"
2. To practice in a "reasonable and prudent" manner
3. To obtain informed consent from the patient before entering into the relationship
4. To maintain medical records
5. To examine the patient
6. To use consultants and referring physicians when appropriate

Many situations will arise when the conditions set forth in this section will be difficult, impossible, or inappropriate to fulfill. For example, in an emergency, when an unconscious patient cannot respond to the physician and no surrogate is present, informed consent cannot be obtained. Another patient may be unable to understand the information contained on the hospital's standard "Informed Consent" statement. Moreover, the patient may not be of legal age and his parent may demand a standard of care that the physician considers immoral or unreasonable. Many other factors may confound the establishment of a normal physician–patient relationship. In general, when the care to be rendered is elective in nature, the physician must fulfill all of the requirements necessary to establish a legal physician–patient relationship. When the care to be given is emergent in nature, the physician must assume the duty to care for the patient and to practice within the "standards of care" at all times.

Informed Consent

Over the past 48 years, the concept of informed consent has evolved to its current definition.[3] Informed consent is rendered by an autonomous, reasonable patient who has been appropriately informed about the procedure or treatment plan he is to undergo. The physician must assure that the patient receives and understands all of the "information that the hypothetical reasonable patient would consider important to make a decision."[3] Included in this information is a description of ". . . those risks which are reasonably likely to occur in any patient under the circumstances, and to those which are reasonably likely to occur in particular patients because of their condition."[2] Benefits to be expected from the procedure must be set forth as well as alternative treatment plans. An anesthesiologist should inform the patient if he or she, or another care team member, is to administer the anesthetic. If a patient does not want to hear all of the "gory details," the physician must document that the patient does not wish to be informed, note such on the chart, and ask the patient to countersign the chart.[2] Verbal, written, and implied informed consent is valid. However, it is obvious that a written consent is easiest to prove should the necessity arise.

Much has been written concerning the ethical considerations of informed consent. The American Society of Anesthesiologists' *Syllabus on Ethics*,[4] 1999, devotes an entire section to the informed consent issue. A pertinent quotation from this publication follows[4]:

> The most common theory of suit relating to informed consent is negligence. Negligence means that the anesthesiologist did not provide sufficient disclosure to permit a patient to make an informed decision.

The anesthesiologist should treat the patient as a reasonable, autonomous person. The quality as well as the quantity of the information presented to the patient must be considered. With respect to regional anesthesia, it may not be enough to tell a patient that one risk of neuraxial anesthesia is "epidural hematoma." The patient may think that a "hematoma" is some sort of vegetable! It is more honest, accurate, and ethical to tell the patient what an "epidural hematoma" is and to describe the complications that it can cause. Speak to the patient in his language.

Professional Guidelines and Statements

A professional society publishes guidelines and statements that codify principles considered fundamental to defining its purpose and existence. The American Society of Anesthesiologists (ASA) has published many guidelines and statements that address the Society's position on every aspect of anesthesia practice. All of these can be examined on the Society's Web site: www.asahq.org. Guidelines and statements do not carry the weight of law. They do not represent rules of practice expounded by the Society. In fact, ASA specifically states that certain circumstances may be encountered when the guidelines do not apply. However, in general, the guidelines of the ASA do establish standards of care.

All physicians who practice regional anesthesia should read and understand all of the guidelines and statements of the professional societies with which they are affiliated. Particularly pertinent to the practice of regional anesthesia are these published by the ASA:

1. Guidelines for the Ethical Practice of Anesthesiology[4]
2. Guidelines for Regional Anesthesia in Obstetrics[5]
3. Statement on Regional Anesthesia[6]

These Guidelines and Statement are presented in the Appendices of this chapter.

To deviate from the guidelines is permissible. If a practitioner does so, he or she should document *in writing* the reasons for their decision.

Risk Management and Quality Assurance

The purpose of risk management and quality assurance programs is to decrease the likelihood of causing preventable injury to patients and to assure that the level of care rendered meets or exceeds the expected standards. Excellent chapters covering these topics are published in standard anesthesiology textbooks.[7–9] The ASA has published its Quality Management Template: October 2004[10] that deals comprehensively with the subjects. Physicians who incorporate risk management and quality assurance programs into their practices will at least fulfill institutional, legal, organizational, and professional obligations. The impact of a malpractice lawsuit may very well be moderated to the benefit of the defendant if appropriate risk management and quality assurance programs are in effect before an untoward event happens. Hopefully, these programs will help physicians to adopt new policies, practice habits, and protocols to make anesthesia delivery safer for the patient.

Malpractice: Basic Legal Considerations

Although physicians may become involved with the criminal legal system, the vast majority of medical malpractice litigation deals with civil concerns dealt with by tort laws. Although grounds for medical malpractice may include battery and abandonment, most of the time negligence on the part of the physician is claimed by the

plaintiff. To prove medical malpractice, a plaintiff must establish the following[9] (with modification):

1. Duty: That the physician owed him a duty
2. Breach of duty: That the physician failed to fulfill his duty
3. Proximate cause: That a reasonably close causal relation existed between the physician's acts and the resultant injury
4. Damages: That actual damages resulted because of the acts of the physician

The following legal definitions are presented as these terms turn up in every article on the subject of medical malpractice. All of the definitions are quoted from Black's Law Dictionary, 8th Edition, 2004.[12]

1. Tort: A civil wrong, other than breach of contract, for which a remedy may be obtained, usually in the form of damages; a breach of duty that the law imposes on persons who stand in a particular relation to one another.
2. Duty: A legal obligation that is owed or due to another and that needs to be satisfied; an obligation for which somebody else has a corresponding right.
3. Malpractice: An incidence of negligence or incompetence on the part of a professional. To succeed in a malpractice claim, a plaintiff must also prove proximate cause and damages. Medical malpractice: A doctor's failure to exercise the degree of care and skill that a physician or surgeon of the same medical specialty would use under similar circumstances.
4. Negligence: The failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation.
5. Standard of care: In the law of negligence, the degree of care that a reasonable person should exercise.
6. Damages: Money claimed by, or ordered to be paid to, a person as compensation for loss or injury. Damages may be actual, discretionary (for pain and suffering), or exemplary (punitive).
7. Proximate cause: A cause that is legally sufficient to result in liability; an act or omission that is considered in law to result in a consequence so that liability can be imposed on the actor.

The most common allegation of a medical malpractice complaint is that the plaintiff was injured by a physician who acted negligently. The physician's practice deviated from accepted standards of care causing injury to the patient. Compensation for the injury has a monetary value in the form of damages.

Because plaintiff attorneys usually receive a percentage of the damage settlement, the damages are set as high as possible.

What to Do if Sued

One of the most enduring and thoughtful theses on this subject was written by John H. Tinker, MD and William W. Hesson, JD.[13] Their disquisition should be read in its entirety and is referenced for that purpose. In the limited scope of this chapter, a few of their more pertinent quotations, observations, and suggestions are presented.

Quotations from Tinker and Hesson[13]:

1. It is important to understand, at the outset of this chapter, that anyone can sue anyone for anything.[13]
2. In other words, after we [physicians] create expectations of excellence, when something goes awry, it is natural for the patient to assume that something has been done wrong – somebody was negligent, either by omission or commission.[13]
3. It is a basic tenet that it is extremely unlikely, if not impossible, to perform procedures with a zero complication rate.[13]
4. The message here is to expect litigation from poor results or complications, whether expected or unexpected, whether the patient was informed or not.[13]

5. When a physician gets sued, he or she must not allow any recriminations that may occur to affect care of present or future patients.[13]

6. Throughout the whole process, though many physicians have become quite cynical, it must be remembered that underneath the inevitable mountain of paper, the oscillation of emotions, the sometimes misleading testimony, and numerous other problems there is a patient. That patient or family *still deserves our attention and care even if they have brought suit against us*.[13]

Tinker and Hesson address many other topics such as the trial process, the attorney defendant relationship, expert witness testimony, and how to prepare for a deposition and an appearance in the courtroom. They advise the physician-defendant on how to act as well as how to react. Their presentation is prudent and essential reading. To summarize their suggestions, the physician should act professionally, honestly, and cooperatively with his attorney. He should not take the allegations of the suit personally. He should not let it ruin his life and career. He should allow his attorney to do his job. He should do everything possible to discover the facts. Finally, he should not forget that a *patient* feels that he has been wronged. That patient is entitled to learn the truth.

The Expert Witness

Expert witnesses are used by plaintiff and defense attorneys to render opinions as to whether or not standards of care have been breached. If breached, did the physician's act or omission cause an injury to the patient? Qualifications of an expert witness vary. Must the expert be in active practice? Is a retired physician competent to be an expert? Must the expert be board certified? Does he need certification in the same specialty as the defendant? How much money does the physician make from expert testimony? Does the expert have any conflicts of interest with either party in the suit? Each state has its own set of rules and qualifications required of the expert witness.

The ASA has published guidelines concerning expert witness testimony (see Appendices of this chapter).[14] Interestingly, the Society has adopted review procedures for expert witness testimony.[15] An ASA member may file a complaint with the Society if he deems that "sworn expert testimony"[15] rendered in a legal proceeding is in violation of the Society's guidelines. The complaint can be filed only after all judicial proceedings of the suit from which the complaint had arisen have been completed. Eventually, if the Society's Judicial Council determines that an expert witness's testimony is in violation of guidelines, the Council may recommend "an appropriate sanction – censure or suspension or revocation of membership – to the Board of Directors for final action."[14] All of the preliminary proceedings of the Society are confidential. "Only if the board imposes a sanction shall that fact be made public."[14] For an honorable expert witness, a sanction from the Board of the ASA would constitute a significant reprimand. For the less than honorable witness, such a sanction would be inconsequential. The Society has set reasonable and fair standards that its members should observe if they accept the responsibility and the pecuniary rewards of serving as an expert witness.

Medicolegal Aspects of Regional Anesthesia: Conclusions from Morbidity Studies

Many international studies present morbidity data associated with regional anesthesia. Chapter 23 of this book reports findings from the major studies. Because much of the data is derived from medicolegal sources, pertinent comments concerning each study's implications are presented in this chapter. The reader may refer to the previous chapter to review each study in more detail.

American Society of Anesthesiologists' Closed Claims Project

Publications authored by investigators of the ASA's Closed Claims Project constitute the most thorough and scholarly body of literature dealing with the medicolegal aspects of American anesthesia practice.

The ASA's Closed Claims Project has been collecting anesthesia malpractice claim data for more than 30 years.[15] The database for the Project consists of a standardized collection of information obtained from the detailed analyses of more than 6000 anesthesia malpractice law suits that had been "closed" by the time each analysis had been conducted.[16] "Closed" is defined as settled. Data are obtained voluntarily from insurance carriers who cover approximately 50% of American anesthesiologists.

The limitations of the study have been published elsewhere.[15–18] These include the lack of a denominator, reliance on voluntary cooperation offered by the insurance carriers, and concerns over biases relating to changing patterns of practice, poor inter-rater reliability, the study's retrospective design, and outcome severity. Nevertheless, the Project's investigators have uncovered patterns and trends that ". . . discern how the process of care contributes to the genesis of adverse outcomes."[16] Some of the objectives of the Project have been to define the damaging events and adverse outcomes associated with the delivery of anesthesia care, to hypothesize the mechanism of the events, to ascertain whether current standards of patient monitoring could have prevented some of the events, to report financial settlement patterns, and to evaluate the appropriateness of care rendered. Much other information is presented in the Project's many publications. Suffice it to say that the ASA's Closed Claims Project collects, analyzes, and reports data eventuated by interactions at the anesthesiology practice/medicolegal system interface.

Conclusions

Conclusions drawn from analysis of the ASA's Closed Claims Project regional anesthesia data[19] include the following:

1. "Nearly half of the damaging events for both obstetric and nonobstetric neuraxial anesthesia claims were block related."[19]
2. "The most common damaging event for these high severity injuries in obstetric and nonobstetric groups was neuraxial cardiac arrest."[19]
3. "Ninety percent of claims for neuraxial cardiac arrest resulted in death or permanent brain damage."[19] The authors cautioned that appropriate early treatment with epinephrine ". . . may not guarantee a good outcome during neuraxial cardiac arrest."[19]
4. "Unintentional intravascular injection was the second most common damaging event in obstetric claims but accounted for only 2% of nonobstetric claims with high-severity outcome."[19]
5. Regional anesthesia techniques associated with neuraxial cardiac arrest included the following:
    a. Spinal: 70%
    b. Lumbar epidural: 25%
    c. Caudal epidural: 2%
    d. Thoracic epidural: 1%
    e. Combined spinal/epidural: 1%
6. With respect to neuraxial cardiac arrest, "Resuscitation was delayed in 91% of obstetrics claims compared with 45% of nonobstetric claims as judged by two or more ASA Closed Claims Project Committee reviewers."[19]
7. Despite the widespread availability of capnography and pulse oximetry in the 1990s, outcome for neuraxial cardiac arrest was not significantly different between the 1980s and 1990s.[19]

8. "Combined analysis of obstetric and nonobstetric neuraxial claims associated with hematoma revealed that almost three fourths of these claims had evidence of either an intrinsic (one obstetric claim with severe preeclampsia) or iatrogenic coagulopathy."[19]

9. Data of the Closed Claims Project demonstrates that "an increased motor block out of proportion to the infused local anesthetic is the most common presenting symptom"[19] of a potentially problematic epidural hematoma although many have suggested that back pain is the cardinal symptom. Early treatment of an epidural hematoma is essential to favorable outcome!

10. Eye "injuries were usually permanent and related to the block technique, and more than half of the claims resulted in blindness."[19]

11. Damaging events might have been prevented by better use of available monitors, the application of safer techniques (such as topical anesthesia for cataract surgery), and a more vigilant practice of anesthesia.

Of the lumbar and thoracic epidural blocks, 52% were associated with unintentional subarachnoid injection. Therefore, 84% of the neuraxial cardiac arrest claims were associated with subarachnoid injections.

ASA's Closed Claims Project: Chronic Pain Management

Fitzgibbon et al.[21] reported a Closed Claims Project analysis of injuries associated with chronic pain management. Many of these claims are associated with regional anesthetic techniques.

Relevant clinical suggestions based on the findings of their study include:

1. A test dose should be used when administering a regional block.
2. The volume of solution injected into the epidural space should not exceed that of a typical intrathecal test dose.
3. The addition of local anesthetics and opioids to epidural steroid injections can lead to more severe outcomes (death and brain damage). Are these adjunctive drugs really necessary?
4. "... It is important to establish a monitoring system for pneumothorax and to instruct patients as to the symptoms and signs of a pneumothorax after intercostal nerve blocks, stellate ganglion blocks, trigger point injections, and brachial plexus blocks."[21]

ASA's Closed Claims Project: Obstetric Anesthesia

Davies et al.[22] presented Closed Claims Project data analyzing 792 obstetric-related claims from the 1970s, 1980s, and 1990s.

Although an in-depth analysis of damaging events and specific injury patterns was not presented, the abstract reported significant data related to regional anesthesia.

Results

1. The proportion of cesarean delivery claims associated with general anesthesia decreased in the 1980s and 1990s as compared with the 1970s, whereas the proportion of regional anesthesia claims increased.
2. Lumbar epidurals were more common in cesarean delivery claims in the 1980s and 1990s as compared with the 1970s.
3. Spinal anesthesia for cesarean delivery data showed no differences between epochs.
4. The proportion of vaginal delivery claims associated with regional anesthesia increased over the decades.
5. Claims for maternal death decreased over the decades.
6. Claims for maternal nerve injury and back pain increased in the 1990s compared with the 1970s.
7. Newborn brain damage decreased in the 1990s compared with the 1980s.

Conclusions

Davies et al.[22] summarized their findings as follows:

1. The change in cesarean delivery–related claims reflected the increased use of regional anesthesia versus the declined use of general anesthesia for cesarean delivery.
2. This change may have been related to the decreased number of claims for maternal death and neonatal brain damage.
3. The increased use of regional anesthesia may have accounted for the increased number of claims of maternal nerve damage and back pain.
4. ". . . Changing medicolegal strategies and other factors may also have contributed to the reduction in severe outcomes in OB claims over the decades."[22]

Hopefully, a more detailed analysis of obstetric-related claims will be forthcoming.

Canadian Closed Claims Review: Regional Anesthesia Morbidity

Smedstad (Chapter 23) suggests that an anesthesiologist can minimize the risk of a lawsuit by obtaining appropriate consent, by good record keeping, by taking note of preexisting conditions, by utilizing appropriate monitoring, and by avoiding the use of the wrong drugs. A few other conclusions are offered in the article by Peng and Smedstad[23]:

1. "Good communication before, during, and after the procedure may prevent a malpractice claim."[23]
2. Before an anesthesiologist performs an eye block, he or she should be fully trained and familiar with the anatomy as well as the potential complications of the various techniques.
3. With respect to neuraxial blocks, should a patient experience pain on needle insertion or injection of local anesthetic or steroid, follow-up contact with the patient should be conducted.
4. Thorough documentation at all steps of anesthetic care must be recorded in the chart. Neat, thorough charting in the operating room can prevent an unfavorable legal outcome.

Medicolegal Claims: An Australian Study

A review of the Australian study published by Cass[24] is presented in Chapter 23. Medicolegal conclusions from his study follow.

Conclusions

The Australian study shared many of the limitations with the closed claims studies discussed previously. It is also somewhat limited in scope. However, the following observations can be made in summarizing the data:

1. Neuraxial blocks were the most frequently cited techniques related to malpractice claims.
2. Inadequate analgesia with neuraxial blocks was a repeated source of litigation.
3. Injury related to eye blocks had a relatively high settlement cost.

Overall Conclusions of the Malpractice Claims Studies

Closed claims analyses reveal, organize, and evaluate fallout from interactions between anesthesiologists and the legal system. Although the studies cited in this chapter suffer from methodologic limitations, they impart valuable information. They analyze medicolegal data associated with claims resulting from the practice of regional anesthesia. Analysis of the data suggests "trends" on how the practice of anesthesia might be

made safer. Studies should be designed to test hypotheses that are formulated after consideration of these suggestions. Future claims reports from localities in which all misadventure, injury, and poor outcome must be reported by law will be extremely useful. These data will be more complete and a known denominator will allow investigators to document the incidences and the true magnitude of the types of problems that lead to lawsuits.

Additional Considerations Regarding the Practice of Regional Anesthesia: Medicolegal Implications

The practitioner of regional anesthesia should consider the medicolegal implications of three additional controversial subjects.

Performing Regional Blocks on Anesthetized Patients

Regional blocks are routinely performed on anesthetized pediatric patients.[24] In addition, many anesthesiologists perform a multitude of blocks on anesthetized or heavily sedated adult patients. They offer the block under anesthesia with due consideration to the comfort of the patient. Advocates of the practice claim that it should be left up to the individual practitioner to consider the risks and benefits involved. They cite breaches of judgment and technique as the main causative factors of poor outcome with respect to the practice.[25] However, the safety of this practice has been questioned by many authors in the recent literature.[26–31] These authors argue that the general anesthetic or heavy sedation would mask typical patient responses to needle trauma or the deposition of local anesthetic in the wrong place. Philip Bromage[32] has termed this type of injury ". . . an example of the most florid form of 'masked mischief,'" Rosenquist and Birnbach[31] ask in an editorial, "Will your patient thank you?" should the practice lead to a serious neurologic injury. They further opine, "If and when more safety data [concerning the practice] are available, this point should be revisited."[31] Debate over administering blocks to anesthetized patients is ongoing and is heated at times. Keep in mind that should an anesthesiologist be faced with a lawsuit resulting from this practice, the plaintiff will have absolutely no problem finding an expert witness to condemn him. This knowledge should not dictate the way an anesthesiologist practices. However, one should remember the ancient advice *primum non nocere* before electing to administer a block to an anesthetized patient. Safety of the practice has been questioned by many.

Awareness "Under Anesthesia"

The regional anesthesia practitioner must be aware that there is a movement afoot that is gaining momentum: the phenomenon of awareness under anesthesia. Companies that market various types of electroencephalogram monitors, talk-show hosts, certain hospital regulatory authorities, and especially trial lawyers are aware of this specter and are doing their best to warn the public of its existence. Those who practice regional anesthesia may be particularly vulnerable to lawsuits concerning awareness because their patients are usually not "asleep." The closed claims studies clearly documented that lawsuits claiming "inadequate anesthesia/analgesia" have already been adjudicated. Was there a component of unexpected awareness related to the claim? In the process of obtaining informed consent, due consideration should be given to discussing with the patient the proposed degree of sedation, what the patient will feel when a block is administered, what the patient may "feel," hear, or otherwise sense in the operating room, and what he or she might remember of the perioperative experience. Often a patient will say something like, "I'll agree to a spinal, but I don't want to hear, feel, or remember anything in the operating room." The anesthesiologist must address these concerns. Finally, BEWARE of what the surgeon has told the patient.

He might have said to the patient: "Anesthesia will pop in an epidural. You won't feel a thing. You'll be asleep anyway!" If the physician takes the time to listen, he would be surprised to hear what the patient has to tell him.

Can Regional Anesthesia Worsen Medicolegal Risk?

A provocative article by Wedel[33] asks: "Can Regional Anesthesia Worsen Outcome? Medicolegal Risk." In certain cases, perhaps it might. The ASA's Closed Claims Project has documented that most nerve injury claims involved general anesthesia (general anesthesia 61% versus regional anesthesia 36%).[33] Most of the time, the etiology of the injury could not be specified. This causes "breach of duty" and "causation" problems for the plaintiff. However, when a nerve injury occurs after administration of a regional block, the plaintiff's lawyer may invoke the doctrine of res ipsa loquitur "the thing speaks for itself." If the theory is proven, the burden of proof shifts to the defendant to show that he did not cause the injury. This may prove difficult. After all, "he stuck a needle into the patient!" Wedel writes, "Whether an increased medicolegal risk is associated with regional as compared with general anesthesia is unclear. Analyses of closed claim data are simultaneously reassuring and concerning."[33] Although this warning should be considered, the anesthesiologist cannot allow himself to practice "legal medicine." Clearly, regional anesthesia has certain advantages over general anesthesia in many cases. In the end, how one practices anesthesia is a medical, not a legal issue.

Recommendations

The following recommendations are made concerning ways to avoid a lawsuit, to practice safer anesthesia, and to better understand the legal system.

1. Act professionally at all times.
2. Keep meticulous records.
3. Know the guidelines and statements of your specialty.
4. Practice only the standards of care.
5. Adopt risk management and quality assurance protocols.
6. Understand your duties to the patient: physician/patient relationship.
7. Consider your informed consent obligations seriously.
8. Never coerce a patient into accepting a given anesthetic plan.
9. Examine the patient. Document preexisting conditions.
10. Know the patient's history and medication regimen.
11. Examine all laboratory data preoperatively (e.g., coagulation status of the patient).
12. Practice only those techniques in which you are fully trained and proficient.
13. Carry adequate malpractice insurance.
14. Make the acquaintance of an excellent malpractice defense lawyer before you need him. If you require his professional expertise, listen to him and do what he tells you to do!
15. If possible, establish a professional relationship with a malpractice defense attorney that will allow you to review legal/medical records generated in a lawsuit. This practice is often helpful to the lawyer and always educational for the physician. Learn how lawyers think, write, and speak.
16. Be honest.
17. As a defendant, do not let the rigors of a lawsuit affect your care of patients.
18. Expect to be sued at some point in your career. Be prepared to deal with it.
19. Often, a lawsuit is just a matter of money (some for the plaintiff, a lot for the lawyers). If you know that you have acted properly, do not take it personally.
20. Remember: If you are sued, there exists a patient who feels that he has been wronged. He is entitled to know the truth.

Conclusion

This chapter has discussed the medicolegal aspects of regional anesthesia. Basic legal principles have been presented. Standards of care have been addressed. Closed claims data have been analyzed. These data were obtained from examinations of lawsuits that involved claims alleging malpractice related to the administration of regional anesthetics. It is hoped that these analyses demonstrated how practitioners of regional anesthesia have become involved with the medicolegal system. Closed claims studies report historical findings. In the future, controlled, prospective studies may better define the types of practices that could bring an anesthesiologist into contact with that system. Hopefully, future research will define ways not only to avoid legal problems, but to make the practice of regional anesthesia safer for patients.

References

1. Respectfully Quoted: A Dictionary of Quotations Requested from the Congressional Research Service. Washington DC: Library of Congress; 1989. Bartleby.com, 2003. Available at: www.bartleby.com/73/847.html. Accessed February 9, 2006.
2. Edelstein L. The Hippocratic Oath: Text, Translation, and Interpretation. Baltimore: Johns Hopkins Press; 1943. Available at: www.pbs.org/wgbh/nova/doctors/oath_classical.html. Accessed February 9, 2006.
3. American Society of Anesthesiologists. Professional Liability and the Anesthesiologist. Park Ridge, IL: ASA; 1992:2–3. Available at: www.asahq.org/publicationsAnd Services/professional.html. Accessed February 9, 2006.
4. American Society of Anesthesiologists. Syllabus on Ethics. Park Ridge, IL: ASA; 1999: A-1.
5. American Society of Anesthesiologists. Guidelines for the Ethical Practice of Anesthesiology. Park Ridge, IL: ASA; 2003.
6. American Society of Anesthesiologists. Guidelines for Regional Anesthesia in Obstetrics. Park Ridge, IL: ASA; 2000.
7. American Society of Anesthesiologists. Statement on Regional Anesthesia. Park Ridge, IL: ASA; 2002.
8. Eichhorn JH. Risk management. In: Benumof JL, Saidman LJ, eds. Anesthesia and Perioperative Complications. St. Louis: Mosby Year Book; 1992.
9. Vitez TS. Quality assurance. Risk management. In: Benumof JL, Saidman LJ, eds. Anesthesia and Perioperative Complications. St. Louis: Mosby Year Book; 1992.
10. Kroll DA, Cheney FW. Medicolegal aspects of anesthetic practice. In: Barash PG, Cullen BF, Stoelting RK, eds. Clinical Anesthesia. 2nd ed. Philadelphia: Lippincott-Raven; 1996:115–125.
11. American Society of Anesthesiologists. Quality Management Template. Park Ridge, IL: ASA; 20 as Ref. 15: 115.
12. Garner BA. Black's Law Dictionary. 8th ed. St. Paul: Thompson/West; 2004.
13. Tinker JH, Hesson WW. What to do if sued: an analysis of the allegations of malpractice brought against an anesthesia provider. Risk management. In: Benumof JL, Saidman LJ, eds. Anesthesia and Perioperative Complications. St. Louis: Mosby Year Book; 1992.
14. American Society of Anesthesiologists. Guidelines for Expert Witness Qualifications and Testimony. Park Ridge, IL: ASA; 2003.
15. Scott M. ASA adopts review procedure for expert witness testimony. ASA Newslett 2003;67(12). Available at: www.asahq.org/Newsletter/2003/12-03/scott.html. Accessed February 9, 2006.
16. Posner KL. Data reveals trends in anesthesia malpractice payments. ASA Newslett 2004;68(6). Available at: www.asahq.org/Newsletter/2004/06_04/posner06_04.html. Accessed February 9, 2006.
17. Caplan RA. The ASA closed claims project: lessons learned. ASA Annual Meeting Refresher Course Lectures 2004; Lecture 118:1–7.

18. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future? Anesthesiology 1999;91:552–556.
19. Lee LA, Domino KB. The closed claims project. Has it influenced anesthetic practice and outcome? Anesthesiol Clin North Am 2002;20(3):485–501.
20. Lee LA, Posner KL, Domino KB, Caplan RA, Cheney FW. Injuries associated with regional anesthesia in the 1980s and 1990s. Anesthesiology 2004;101:143–152.
21. Fitzgibbon DR, Posner KL, Domino KB, Caplan RA, Lee LA, Cheney FW. Chronic pain management. Anesthesiology 2004;100:98–105.
22. Davies JM, et al. Trends in obstetric anesthesia malpractice claims of the last three decades. Anesthesiology 2004;101:A1231.
23. Peng PWH, Smedstad KG. Litigation in Canada against anesthesiologists practicing regional anesthesia. A review of closed claims. Can J Anaesth 2000;47(2):105–112.
24. Cass NM. Medicolegal claims against anaesthetists: a 20 year study. Anaesth Intensive Care 2004;32(1):47–58.
25. Markakis DA. Regional anesthesia in pediatrics. Anesthesiol Clin North Am 2000; 18(2):355–381.
26. Fischer HBJ. Performing epidural insertion under general anaesthesia. Anaesthesia 2000; 55:288–289.
27. Benumof JL. Permanent loss of cervical spinal cord function associated with interscalene block performed under general anesthesia. Anesthesiology 2000;93(6):1541–1544.
28. Bromage PB, Benumof JL. Letter: paraplegia following intracord injection during attempted epidural anesthesia under general anesthesia. Reg Anesth Pain Med 1998; 23(5):520–521.
29. Benumof JL. Comment on "perioperative interscalene blockade: an overview of its history and current clinical use." J Clin Anesth 2003;15:489.
30. Kao MC, Tsai SK, Tsou MY, Lee HK, Guo WY, Hu JS. Paraplegia after delayed detection of inadvertent spinal cord injury during thoracic epidural catheterization in an anesthetized elderly patient. Anesth Analg 2004;99:580–583.
31. Rosenquist RW, Birnbach DJ. Editorial: epidural insertion in anesthetized adults – will your patients thank you? Anesth Analg 2003;96:1545–1546.
32. Bromage PR. Masked mischief. Reg Anesth 1996;21(6S):62–63.
33. Wedel DJ. Can regional anesthesia worsen outcome? Medicolegal risk. Reg Anesth 1996; 21(6S):71–74.
34. Kroll DA, Caplan RA, Posner K, Ward RJ, Cheney FW. Nerve injury associated with anesthesia. Anesthesiology 1990;72:202–207.

Bibliography

Sanbar SS, ed. Legal Medicine. 6th ed. Philadelphia: Mosby; 2004.

Appendices

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Appendix I: Guidelines for the Ethical Practice of Anesthesiology

(Approved by House of Delegates on October 3, 1967, and last amended on October 15, 2003.)

Preamble

Membership in the ASA is a privilege of physicians who are dedicated to the ethical provision of health care. The Society recognized the Principles of Medical Ethics of the American Medical Association (AMA) as the basic guide to the ethical conduct of its members.

AMA Principles of Medical Ethics

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients but also to society, to other health professionals and to self. The following principles adopted by the AMA are not laws but standards of conduct that define the essentials of honorable behavior for the physician.

I. A physician shall be dedicated to providing competent medical care with compassion and respect for human dignity.
II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception to appropriate entities.
III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
IV. A physician shall respect the rights of patients, colleagues, and other health professionals and shall safeguard patients' confidence within the constraints of the law.
V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
VI. A physician shall, in the provision of appropriate patient care except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
VII. A physician shall recognize a responsibility to participate in activities contributing to improvement of the community and betterment of public health.
VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
IX. A physician shall support access to medical care for all people.

AMA, 2001

The practice of anesthesiology involves special problems relating to the quality and standards of patient care. Therefore, the Society requires its members to adhere to the AMA Principles of Medical Ethics and any other specific ethical guidelines adopted by the Society.

Medical Direction

Medical Direction is anesthesia direction, management, or instruction provided by an anesthesiologist whose responsibilities include:

a. Preanesthetic evaluation of the patient.
b. Prescription of the anesthesia plan.
c. Personal participation in the most demanding procedures in this plan, especially those of induction and emergence, if applicable.
d. Following the course of anesthesia administration at frequent intervals.
e. Remaining physically available for the immediate diagnosis and the treatment of emergencies.
f. Providing indicated postanesthesia care.

An anesthesiologist engaged in medical direction should not personally be administering another anesthetic and should use sound judgment in initiating other concurrent anesthetic and emergency procedures.

ASA Ethical Guidelines

There may be specific circumstances when elements of the following guidelines may not apply and wherein individualized decisions may be appropriate.

I. Anesthesiologists have ethical responsibilities to their patients.

1. The patient–physician relationship involves special obligations for the physician that include placing the patient's interests foremost, faithfully caring for the patient, and being truthful.
2. Anesthesiologists respect the right of every patient to self-determination. Anesthesiologists should include patients, including minors, in medical decision making that is appropriate to their developmental capacity and the medical issues involved. Anesthesiologists should not use their medical skills to restrain or coerce patients who have adequate decision-making capacity.
3. Anesthetized patients are particularly vulnerable, and anesthesiologists should strive to care for each patient's physical and psychological safety, comfort, and dignity. Anesthesiologists should monitor themselves and their colleagues to protect the anesthetized patient from any disrespectful or abusive behavior.
4. Anesthesiologists should keep confidential patients' medical and personal information.
5. Anesthesiologists should provide preoperative evaluation and care and should facilitate the process of informed decision making, especially regarding the choice of anesthetic technique.
6. If responsibility for a patient's care is to be shared with other physicians or nonphysician anesthesia providers, this arrangement should be explained to the patient. When directing nonphysician anesthesia providers, anesthesiologists should provide or ensure the same level of preoperative evaluation, care, and counseling as when personally providing these same aspects of anesthesia care.
7. When directing nonphysician anesthesia providers or physicians in training in the actual delivery of anesthetics, anesthesiologists should remain personally and continuously available for direction and supervision during the anesthetic; they should directly participate in the most demanding aspects of the anesthetic care.
8. Anesthesiologists should provide for appropriate postanesthetic care for their patients.
9. Anesthesiologists should not participate in exploitive financial relationships.
10. Anesthesiologists share with all physicians the responsibility to provide care for patients irrespective of their ability to pay for their care. Anesthesiologists should provide such care with the same diligence and skill as for patients who do pay for their care.

II. Anesthesiologists have ethical responsibilities to medical colleagues.

1. Anesthesiologists should promote a cooperative and respectful relationship with their professional colleagues that facilitates quality medical care for patients. This responsibility respects the efforts and duties of other care providers, including physicians, medical students, nurses, technicians, and assistants.
2. Anesthesiologists should provide timely medical consultation when requested and should seek consultation when appropriate.
3. Anesthesiologists should cooperate with colleagues to improve the quality, effectiveness, and efficiency of medical care.
4. Anesthesiologists should advise colleagues whose ability to practice medicine becomes temporarily or permanently impaired to appropriately modify or discontinue their practice. They should assist, to the extent of their own abilities, with the reeducation or rehabilitation of a colleague who is returning to practice.

5. Anesthesiologists should not take financial advantage of other physicians, nonphysician anesthesia providers, or staff members. Verbal and written contracts should be honest and understandable, and should be respected.

III. Anesthesiologists have ethical responsibilities to the healthcare facilities in which they practice.

1. Anesthesiologists should serve on healthcare facility or specialty committees. This responsibility includes making good-faith efforts to review the practice of colleagues and to help develop departmental or healthcare facility procedural guidelines for the benefit of the healthcare facility and all of its patients.
2. Anesthesiologists share with all medical staff members the responsibility to observe and report to appropriate authorities any potentially negligent practices or conditions that may present a hazard to patients or healthcare facility personnel.
3. Anesthesiologists personally handle many controlled and potentially dangerous substances and, therefore, have a special responsibility to keep these substances secure from illicit use. Anesthesiologists should work within their healthcare facility to develop and maintain an adequate monitoring system for controlled substances.

IV. Anesthesiologists have ethical responsibilities to themselves.

1. The achievement and maintenance of competence and skill in the specialty is the primary professional duty of all anesthesiologists. This responsibility does not end with completion of residency training or certification by the American Board of Anesthesiology.
2. The practice of quality anesthesia care requires that anesthesiologists maintain their physical and mental health and special sensory capabilities. If in doubt about their health, then anesthesiologists should seek medical evaluation and care. During the period of evaluation or treatment, anesthesiologists should modify or cease their practice.

V. Anesthesiologists have ethical responsibilities to their community and society.

1. An anesthesiologist shall recognize a responsibility to participate in activities contributing to an improved community.
2. An anesthesiologist who serves as an expert witness in a judicial proceeding shall possess the qualifications and offer testimony in conformance with the ASA "Guidelines for Expert Witness Qualifications and Testimony."

Appendix II: Guidelines for Regional Anesthesia in Obstetrics

(Approved by House of Delegates on October 12, 1988, and last amended on October 18, 2000.)

These guidelines apply to the use of regional anesthesia or analgesia in which local anesthetics are administered to the parturient during labor and delivery. They are intended to encourage quality patient care but cannot guarantee any specific patient outcome. Because the availability of anesthesia resources may vary, members are responsible for interpreting and establishing the guidelines for their own institutions and practices. These guidelines are subject to revision from time to time as warranted by the evolution of technology and practice.

Guideline I

REGIONAL ANESTHESIA SHOULD BE INITIATED AND MAINTAINED ONLY IN LOCATIONS IN WHICH APPROPRIATE RESUSCITATION EQUIPMENT AND DRUGS ARE IMMEDIATELY AVAILABLE TO MANAGE PROCEDURALLY RELATED PROBLEMS.

Resuscitation equipment should include, but is not limited to, sources of oxygen and suction, equipment to maintain an airway and perform endotracheal intubation, a means to provide positive pressure ventilation, and drugs and equipment for cardiopulmonary resuscitation.

Guideline II

REGIONAL ANESTHESIA SHOULD BE INITIATED BY A PHYSICIAN WITH APPROPRIATE PRIVILEGES AND MAINTAINED BY OR UNDER THE MEDICAL DIRECTION[a] OF SUCH AN INDIVIDUAL.

Physicians should be approved through the institutional credentialing process to initiate and direct the maintenance of obstetric anesthesia and to manage procedurally related complications.

Guideline III

REGIONAL ANESTHESIA SHOULD NOT BE ADMINISTERED UNTIL: 1) THE PATIENT HAS BEEN EXAMINED BY A QUALIFIED INDIVIDUAL[b]; AND 2) A PHYSICIAN WITH OBSTETRIC PRIVILEGES TO PERFORM OPERATIVE VAGINAL OR CESAREAN DELIVERY, WHO HAS KNOWLEDGE OF THE MATERNAL AND FETAL STATUS AND THE PROGRESS OF LABOR AND WHO APPROVES THE INITIATION OF LABOR ANESTHESIA, IS READILY AVAILABLE TO SUPERVISE THE LABOR, AND MANAGE ANY OBSTETRIC COMPLICATIONS THAT MAY ARISE.

Under circumstances defined by departmental protocol, qualified personnel may perform the initial pelvic examination. The physician responsible for the patient's obstetric care should be informed of her status so that a decision can be made regarding present risk and further management.[b]

Guideline IV

AN INTRAVENOUS INFUSION SHOULD BE ESTABLISHED BEFORE THE INITIATION OF REGIONAL ANESTHESIA AND MAINTAINED THROUGHOUT THE DURATION OF THE REGIONAL ANESTHETIC.

Guideline V

REGIONAL ANESTHESIA FOR LABOR AND/OR VAGINAL DELIVERY REQUIRES THAT THE PARTURIENT'S VITAL SIGNS AND THE FETAL HEART RATE BE MONITORED AND DOCUMENTED BY A QUALIFIED INDIVIDUAL. ADDITIONAL MONITORING APPROPRIATE TO THE CLINICAL CONDITION OF THE PARTURIENT AND THE FETUS SHOULD BE USED WHEN INDICATED. WHEN EXTENSIVE REGIONAL BLOCKADE IS ADMINISTERED FOR COMPLICATED VAGINAL DELIVERY, THE STANDARDS FOR BASIC ANESTHETIC MONITORING[c] SHOULD BE APPLIED.

Guideline VI

REGIONAL ANESTHESIA FOR CESAREAN DELIVERY REQUIRES THAT THE STANDARDS FOR BASIC ANESTHETIC MONITORING[c] BE APPLIED AND THAT A PHYSICIAN WITH PRIVILEGES IN OBSTETRICS BE IMMEDIATELY AVAILABLE.

Guideline VII

QUALIFIED PERSONNEL, OTHER THAN THE ANESTHESIOLOGIST ATTENDING THE MOTHER, SHOULD BE IMMEDIATELY AVAILABLE TO ASSUME RESPONSIBILITY FOR RESUSCITATION OF THE NEWBORN.[c]

The primary responsibility of the anesthesiologist is to provide care to the mother. If the anesthesiologist is also requested to provide brief assistance in the care of the newborn, the benefit to the child must be compared with the risk to the mother.

Guideline VIII

A PHYSICIAN WITH APPROPRIATE PRIVILEGES SHOULD REMAIN READILY AVAILABLE DURING THE REGIONAL ANESTHETIC TO MANAGE ANESTHETIC COMPLICATIONS UNTIL THE PATIENT'S POST-ANESTHESIA CONDITION IS SATISFACTORY AND STABLE.

Guideline IX

ALL PATIENTS RECOVERING FROM REGIONAL ANESTHESIA SHOULD RECEIVE APPROPRIATE POSTANESTHESIA CARE. AFTER CESAREAN DELIVERY AND/OR EXTENSIVE REGIONAL BLOCKADE, THE STANDARDS FOR POSTANESTHESIA CARE[d] SHOULD BE APPLIED.

1. A postanesthesia care unit (PACU) should be available to receive patients. The design, equipment, and staffing should meet requirements of the facility's accrediting and licensing bodies.
2. When a site other than the PACU is used, equivalent postanesthesia care should be provided.

Guideline X

THERE SHOULD BE A POLICY TO ASSURE THE AVAILABILITY IN THE FACILITY OF A PHYSICIAN TO MANAGE COMPLICATIONS AND TO PROVIDE CARDIOPULMONARY RESUSCITATION FOR PATIENTS RECEIVING POSTANESTHESIA CARE.

[a]The Anesthesia Care Team (approved by ASA House of Delegates 10/26/82 and last amended 10/17/01).
[b]For Perinatal Care (American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 1988).
[c]Standards for Basic Anesthetic Monitoring (approved by ASA House of Delegates 10/21/86 and last amended 10/21/98).

ASA House of Delegates 10/21/86 and last amended 10/21/98.
[d]Standards for Postanesthesia Care (approved by ASA House of Delegates 10/12/88 and last amended 10/19/94).

Appendix III: Statement on Regional Anesthesia

(Approved by ASA House of Delegates on October 12, 1983, and last amended on October 16, 2002.)

Although scope of practice is a matter to be decided by appropriate licensing and credentialing authorities, the ASA, as an organization of physicians dedicated to enhancing the safety and quality of anesthesia care, believes it is appropriate to state its views concerning the provision of regional anesthesia. These views are founded on the premise that patient safety is the most important goal in the provision of anesthesia care.

Anesthesiology, in all of its forms, including regional anesthesia, is the practice of medicine. Regional anesthesia involves diagnostic assessment, the consideration of indications and contraindications, the prescription of drugs, and the institution of corrective measures and treatment in response to complications. Therefore, the successful performance of regional anesthesia requires medical as well as technical

expertise. The medical component generally comprises the elements of medical direction and includes:

a. Preanesthetic evaluation of the patient
b. Prescription of the anesthetic plan
c. Personal participation in the technical aspects of the regional anesthetic when appropriate
d. Following the course of the anesthetic
e. Remaining physically available for the immediate diagnosis and treatment of emergencies
f. Providing indicated postanesthesia care

The technical requirements for regional anesthesia will vary with the procedure to be performed.

The decision as to the most appropriate anesthetic technique for a particular patient is a judgment of medical practice that must consider all patient factors, procedure requirement, risks and benefits, consent issues, surgeon preferences, and competencies of the practitioners involved. The decision to perform a specific regional anesthetic technique is best made by a physician trained in the medical specialty of anesthesiology. The decision to interrupt or abort a technically difficult procedure, recognition of complications and changing medical conditions, and provision of appropriate postprocedure care is the duty of a physician. Regional anesthetic techniques are best performed by an anesthesiologist who possesses the competence and skills necessary for safe and effective performance.

Appendix IV: Guidelines for Expert Witness Qualifications and Testimony

(Approved by ASA House of Delegates on October 14, 1987, and last amended on October 15, 2003.)

Preamble

The integrity of the litigation process in the United States depends in part on the honest, unbiased, responsible testimony of expert witnesses. Such testimony serves to clarify and explain technical concepts and to articulate professional standards of care. The ASA supports the concept that such expert testimony by anesthesiologists should be readily available, objective, and unbiased. To limit uninformed and possibly misleading testimony, experts should be qualified for their role and should follow a clear and consistent set of ethical guidelines.

A. Expert Witness Qualifications

1. The physician (expert witness) should have a current, valid, and unrestricted state license to practice medicine.

2. The physician should be board certified in anesthesiology or hold an equivalent specialist qualification.

3. The physician should be familiar with the clinical practice of anesthesiology at the time of the occurrence and should have been actively involved in clinical practice at the time of the event.

B. Guidelines for Expert Testimony

1. The physician's review of the medical facts should be truthful, thorough, and impartial and should not exclude any relevant information to create a view favoring either the plaintiff or the defendant. The ultimate test for accuracy and impartiality is a willingness to prepare testimony that could be presented unchanged for use by either the plaintiff or defendant.

2. The physician's testimony should reflect an evaluation of performance in light of generally accepted standards, reflected in relevant literature, neither condemning

performance that clearly falls within generally accepted practice standards nor endorsing or condoning performance that clearly falls outside accepted medical practice.

3. The physician should make a clear distinction between medical malpractice and adverse outcomes not necessarily related to negligent practice.

4. The physician should make every effort to assess the relationship of the alleged substandard practice to the patient's outcome. Deviation from a practice standard is not always causally related to a poor outcome.

5. Fees for expert testimony should relate to the time spent and in no circumstances should be contingent upon outcome of the claim.

6. The physician should be willing to submit such testimony for peer review.