



1-1-2012

Preventing Malpractice: Professional Self-Regulation and the Quality of Care in Anesthesiology

James K. Schepers

Follow this and additional works at: <http://scholarship.law.nd.edu/ndjlepp>

Recommended Citation

James K. Schepers, *Preventing Malpractice: Professional Self-Regulation and the Quality of Care in Anesthesiology*, 3 NOTRE DAME J.L. ETHICS & PUB. POL'Y 249 (1988).

Available at: <http://scholarship.law.nd.edu/ndjlepp/vol3/iss2/6>

This Commentary is brought to you for free and open access by the Notre Dame Journal of Law, Ethics & Public Policy at NDLScholarship. It has been accepted for inclusion in Notre Dame Journal of Law, Ethics & Public Policy by an authorized administrator of NDLScholarship. For more information, please contact lawdr@nd.edu.

STUDENT COMMENTS

PREVENTING MALPRACTICE: PROFESSIONAL SELF-REGULATION AND THE QUALITY OF CARE IN ANESTHESIOLOGY

JAMES K. SCHEPERS*

INTRODUCTION

Recent discussions of medical cost containment focus primarily on ways to reduce rapidly-spiralling medical costs. In seeking methods to control medical costs, however, few discussions recognize that the high cost of medical care also reflects the high cost of medical error. The costs of compensating an injured patient or the patient's family are manifested in malpractice insurance premiums and ultimately passed on to the consumer. While some medical mishaps may not be preventable, reducing the amount of malpractice should help limit medical costs. In addition to other measures to contain medical costs, the fundamental problem of professional self-regulation must be addressed, that of simply reducing the incidence of malpractice.

This article discusses professional self-regulation within the medical profession and within the specialty of anesthesiology.¹ Recent studies of anesthetic mishaps show a need for

* B.A. 1983, Calvin College; M.A. 1984, University of Michigan; J.D. 1988, University of Notre Dame 1988; Thos. J. White Scholar 1986-1988.

1. Anesthesiology is defined by the American Association of Anesthesiologists as a discipline within the practice of medicine specializing in:

- A. The medical management of patients who are rendered unconscious and/or insensible to pain and emotional stress during surgical, obstetrical and certain other medical procedures (involves preoperative, intraoperative and postoperative evaluation and treatment of these patients);
- B. The protection of life functions and vital organs (e.g. brain, heart, lungs, kidneys, liver) under the stress of anesthetic, surgical and other medical procedures;
- C. The management of problems in pain relief;
- D. The management of cardiopulmonary resuscitation;
- E. The management of problems in pulmonary care;
- F. The management of critically ill patients in special care units.

increased professional self-regulation within this specialty. After outlining current methods of professional self-regulation, the Health Care Quality Improvement Act of 1986 and the Harvard Medical School standards for anesthesia monitoring are reviewed. Using anesthesiology as an example of the larger profession, the tension between controlling medical costs and improving the quality of care is then explored. In considering ethical implications of professional self-regulation and anesthesiology practice, it is concluded that providing an acceptable level of care should not be sacrificed for personal gain, efficiency, or cost containment.

I. THE NEED FOR MORE EFFECTIVE SELF-REGULATION IN ANESTHESIOLOGY

The vast majority of general anesthetics administered in the nation's hospitals are safe and uneventful. Nevertheless, despite advanced anesthetic drugs, complex monitoring equipment, and extensive training of anesthesiologists and anesthesiologists, anesthetic mishaps still occur.² A study by physi-

2. In July 1978, seven-year old Gene Schneider underwent surgery in Lansing, Michigan for a tonsillectomy and bilateral tympanotomy, a minor ear operation. [A tympanotomy is defined as a surgical puncture of the tympanic membrane to reduce pressure in the middle ear. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1414 (26th ed. 1985).] A nurse-anesthetist provided anesthesia under the supervision of her employer, an anesthesiologist. [A nurse-anesthetist or anesthetist is a registered nurse with additional training in anesthesia. Depending on variations in nurse's training and anesthesia training, an anesthetist may have from two and one-half years to six years of training. An anesthesiologist is a physician with specialized training in anesthesia. A five-year residency in anesthesia is completed following four years of college and an additional four years of medical school.] During surgery the child suffered a cardiac arrest; although he was resuscitated, the child never regained consciousness. Six days later, after a test failed to reveal brain wave activity, he was taken off the respirator. The pathologist determined anesthesia caused the child's death. The child's parents sued the anesthetist, anesthesiologist, and hospital claiming several acts of malpractice including anesthetic overdose, inadequate monitoring, and failure to follow adequate standards for the administration of anesthesia. The nurse-anesthetist and anesthesiologist settled the claim before trial for \$257,739. The trial court returned a verdict against the hospital for \$742,000., which on appeal was reversed and remanded. *Theophelis v. Lansing General Hosp.*, 366 N.W.2d 249 (Mich. App. 1985), *vacated* 384 N.W.2d 823 (Mich. App. 1986). The case is currently being reviewed by the Michigan Supreme Court. 426 Mich. 863 No. 78166 (Oct. 22, 1986).

In September 1981, Mrs. Brenda Worthy gave birth without anesthesia and underwent surgery the following day for tubal ligation. Central Anesthesia Associates, P.C., (CAA) a group of eight anesthesiologists, provided

cians from the Harvard Medical School Department of Anesthesia recognized that "[a]mong the approximately 20 million patients anesthetized annually in the United States, 2000 or more may die of causes primarily attributable to anesthesia."³ Another study estimated the anesthesia-related mortality rate to lie in the range of 1 per 4,000 to 1 per 10,000 patients, resulting in 2,000 to 5,000 deaths annually.⁴ An analysis of claims for death or brain damage related to anesthesia in the United Kingdom produced nearly identical conclusions. From a five-year study of one-third of all hospitals in Great Britain, anesthesia mishaps were the sole cause of death in 1 of 10,000 patients, and may have contributed to the deaths of 1 of 1,700.⁵

The anesthesia-related death of only one patient in four thousand or of only one patient in ten thousand administrations might be dismissed as a marginal level of error, a regrettable but unavoidable transaction cost. Because every administration of general anesthesia is inherently dangerous, a certain percentage of mishaps is statistically foreseeable. An adverse reaction to anesthesia, for example, cannot be clinically predicted or prevented. The intrinsic risk of administration, however, fails to account for current mortality rates. Of the two thousand to five thousand annual deaths attributable

anesthesia. Ms. Castro, a student nurse enrolled at the anesthesia school operated by CAA, administered the anesthesia but was not supervised by an anesthesiologist or anesthesiologist, a violation of state law. *Central Anesthesia Associates P.C. v. Worthy*, 325 S.E.2d 819 (Ga. App. 1984), *aff'd*, 333 S.E.2d 829 (Ga. App. 1985).

Allegedly as the result of improper anesthesia procedures, Mrs. Worthy suffered a cardiac arrest and subsequent brain damage. Mrs. Worthy remains comatose.

Each of the CAA anesthesiologists at the hospital during Mrs. Worthy's surgery denied responsibility for her care. The surgery took place in an operating room on the seventh floor of the hospital; the only CAA anesthesiologist responding to an emergency alarm came from his office on the second floor. The trial court ruled the administration of anesthesia by CAA was negligent as a matter of law and reserved issues of causation and damages for a jury. This determination was upheld by both the Court of Appeals of Georgia and the Georgia Supreme Court.

3. Eichhorn, Cooper, Cullen, Maier, Philip, and Seeman, *Standards for Patient Monitoring During Anesthesia at Harvard Medical School*, 256 J.A.M.M.E.D.A. 1017 (1986) [hereinafter *Harvard Anesthesia Standards*].

4. Pierce, *Historical Perspectives*, in *ANALYSIS OF ANESTHETIC MISHAPS. INTERNATIONAL ANESTHESIOLOGY CLINICS 1-16* (Pierce and Cooper, eds. 1982).

5. Green and Taylor, *An Analysis of Anesthesia Medical Liability Claims in the United Kingdom*, in *ANALYSIS OF ANESTHETIC MISHAPS. INTERNATIONAL ANESTHESIOLOGY CLINICS 74* (Pierce and Cooper, eds. 1982).

to anesthesia,⁶ the Harvard study concluded "[t]he majority of these deaths are thought to be preventable."⁷ Again, the study of anesthesia-related deaths in Great Britain supports this finding. In using higher figures of anesthesia-related mishaps, one death in ten thousand patients, the authors conclude the primary cause for seventy percent of the anesthesia-related deaths was an error of judgment by the anesthetist.⁸

Studies of insurance claims support these findings of a significant amount of human error during administration of general anesthesia.⁹ A review of 1,500 major claims submitted to the St. Paul Companies for the years 1976 to 1978 identified 308 claims relating to anesthesia. While the authors realized some of these mishaps likely resulted from unforeseeable adverse reactions to the anesthetic agents, they contended "more obvious and logical causes of misadventure usually surfaced, most commonly in the form of human errors, failure to cope with acute yet common situations, and lapses in vigilance of otherwise competent individuals."¹⁰ They concluded, "[i]n a reconstruction of the events leading to these claims, there is clear evidence of a relaxing of the vigilance once regarded as the hallmark of the competent anesthetist. In some cases, we question that this vigilance had ever been acquired."¹¹

To reduce the incidence of anesthetic mishaps in its university hospitals, the physicians from the Harvard Department of Anaesthesia recently formulated mandatory standards for the administration of anesthesia.¹² The professional association for nurse-anesthetists, the American Association of Nurse Anesthetists (AANA) has formally endorsed these

6. Pierce, *Risk Modification in Anesthesiology*, 1 ANESTHESIA PATIENT SAFETY FOUND. NEWSL. 25 (1986) [hereinafter Pierce, *Risk Modification*].

7. Harvard Anesthesia Standards, *supra* note 3, at 1017.

8. Green, *supra* note 5, at 74.

9. Davis, *An Analysis of Anesthetic Mishaps from Medical Liability Claims*, in ANALYSIS OF ANESTHETIC MISHAPS. INTERNATIONAL ANESTHESIOLOGY CLINICS 31 (Pierce and Cooper, eds. 1984).

10. *Id.* at 38. Another study of insurance claims from the St. Paul Company illustrates the extremely high cost of anesthetic mishaps. Twenty-three percent of anesthesia claims from 1981 to 1985 from the St. Paul Company were for cardiac arrest and other catastrophic claims. The average cost for each of these 273 claims was \$131,459. Of course, this cost is passed on to anesthesiologists and to the public. See Wood, *Anesthesia Claims Decrease*, 1 ANESTHESIA PATIENT SAFETY FOUND. NEWSL. 21, 23 (1986).

11. Davis, *supra* note 9, at 40, 41.

12. Harvard Anesthesia Standards, *supra* note 3, at 1017.

standards.¹³ The Harvard study addresses several issues concerning the administration of anesthesia and professional self-regulation. On a technical level, the physicians have postulated seven standards for minimal patient monitoring during anesthesia.¹⁴ If followed diligently, the standards may help reduce the amount of malpractice in anesthesiology. While emphasizing the need for more effective professional self-regulation, the study overlooks several troubling issues: whether by its very nature professional self-regulation can be truly effective, and whether mandatory standards can improve professional self-regulation and reduce the amount of human error in anesthesiology.

II. CURRENT METHODS OF SELF-REGULATION

In establishing standards to reduce the incidence of human error within anesthesiology, the Harvard physicians acknowledge the weakness of current methods of professional self-regulation. Regulation of the medical profession is achieved through several levels of formal disciplinary mechanisms, such as state medical boards and hospital regulations. Informal disciplinary measures among physicians, such as social stigmatism, may in some cases provide additional professional controls.

A. Formal Medical Regulation

State medical boards are the primary formal mechanism to ensure competency and to discipline members of the profession. Physician competency is determined by examining and licensing medical school graduates, renewing licenses to practice, and requiring continuing medical education.^{15*} Formal self-discipline is achieved through disciplinary hearings conducted by the state medical boards. An investigation and hearing are typically initiated after a complaint alleges a violation of the state licensing statute, such as "unprofessional conduct," "professional incompetence," unethical business practices, or substance abuse.¹⁶ Sanctions range in severity

13. AANA Board endorses Harvard Anesthesia Standards for Monitoring Patients and FDA Check-out Procedure for Anesthesia Apparatus, AANA NEWS BULL., Dec. 1986, at 1.

14. The Harvard Anesthesia Standards, *supra* note 3, are set forth in Appendix A.

15. S. GROSS, OF FOXES AND HEN HOUSES: LICENSING AND THE HEALTH PROFESSIONS (1984) at 83.

16. J. PETERS, K. FINEBERG, D. KROLL, AND V. COLLINS, ANESTHESIOLOGY

from censure of the physician to revocation of the license to practice. According to the Federation of State Medical Boards, in 1986 state medical boards across the country revoked the licenses of 458 practitioners, placed the licenses of 528 practitioners on probation, suspended the licenses of 335 practitioners, and undertook 981 "other regulatory actions" including license limitations or denials, reprimands, or admonishments.¹⁷ The 1986 total of 2,302 formal disciplinary actions marked an increase of 9.2 percent over the official 1985 total of 2,108 disciplinary actions.¹⁸ In 1985 state medical boards revoked the licenses of 406 practitioners, placed the licenses of 491 practitioners on probation, suspended the licenses of 235 practitioners, and undertook 976 "other regulatory actions" as defined above.¹⁹ The 1985 total of 2,108 formal disciplinary actions represented a 37 percent increase over the 1,540 actions taken by state medical boards in 1984.²⁰ According to the American Medical Association, there were 528,000 practicing physicians in the U.S. in 1985.²¹ Although state medical boards report differing rates of physician discipline,²² the national average in 1985 was 3.9 reported disciplinary actions per 1,000 physicians.

To complement the disciplinary action exercised by respective state medical boards, comprehensive hospital regulations provide several additional levels of review for those physicians affiliated with a hospital.²³ Hospitals generally have

AND THE LAW (1983) at 142 [hereinafter Peters].

17. Galusha and Breden, *Official 1986 Federation Summary of Reported Disciplinary Actions*, 75 FEDERATION BULL. 46 (1988).

18. *Id.* at 42.

19. Breden and Galusha, *Official 1985 Federation Summary of Reported Disciplinary Actions*, 73 FEDERATION BULL. 300 (1986).

20. *Id.* at 301. The 1984 statistics are as follows: according to the Federation of State Medical Boards, in 1984 state medical boards across the country revoked the licenses of 302 practitioners, placed the licenses of 296 practitioners on probation, suspended the licenses of 190 practitioners, and undertook 752 "other regulatory actions." Letter from Dale G. Breden to James Schepers (Oct. 2, 1986).

21. *Physician Characteristics and Distribution in the U.S.*, AM. MED. A. (1986).

22. According to the Public Citizen Health Research Group, state rates of "serious medical disciplinary action" including license revocations, suspensions, and probations in 1983 ranged from 5.2 actions per 1,000 physicians to no disciplinary actions taken in nine states. See *Doctor Discipline: A Necessary Cure for the Malpractice Crisis*, Health Letter, PUB. CITIZEN HEALTH RES. GROUP, Nov./Dec. 1985 at 8.

23. The only formal disciplinary controls over physicians in private practice is provided by the state medical boards. Because this paper deals

instituted a system of in-house peer review, in which colleagues review each others performance on a regular basis and offer suggestions and criticisms. Because each hospital faces liability for the actions of its affiliated physicians and patient care, the hospital administration is expected to scrutinize each physician's performance when hospital privileges are annually renewed.²⁴

Hospitals may choose to meet standards of accreditation promulgated by the Joint Commission on the Accreditation of Hospitals (JCAH).²⁵ Hospitals have strong incentives to comply with JCAH standards, for accreditation ensures eligibility for federal reimbursement funds.²⁶ The JCAH standards for anesthesiology outline education and staffing requirements, procedures for the delivery of anesthesia, and requirements for quarterly review of the quality of anesthesia services.²⁷

Federal regulation of hospitals, and by implication, of physicians, has been achieved through the use of Professional Review Organizations (PROs), as part of a 1972 amendment to the Social Security Act.²⁸ The PRO program was established to control both the cost and quality of medical care funded by the federal government. These goals are accomplished through a system of peer review. The admission and continued care of each patient under a federal reimbursement program is reviewed by a non-physician coordinator, in consultation with a physician advisor. If the admitting physician cannot justify the admission or services given to the patient, funding is terminated. The quality of care provided patients is also reviewed by analysts and physicians examining the medical records of patients. If patient care does not meet the criteria for care developed by the national PROs, problems and proposed solutions are directed to the hospital administrator and board of trustees.²⁹

The various levels of formal self-discipline provided by state medical boards and hospitals are subject to inherent

with professional self-regulation and the ethical implications regarding general anesthesia, which is normally administered in the hospital setting, the difficulties of disciplining the physician not affiliated with a hospital are not addressed.

24. Peters, *supra* note 16, at 204.

25. *Id.* at 212.

26. *Id.*

27. *Id.* at 214-217.

28. *Id.* at 157.

29. *Id.* at 157-163.

weaknesses. One difficulty with formal self-discipline derives from the training and organization of the medical profession. Because clinical experience places primacy on personal experience and each practitioner's evaluation, physicians face a fundamental problem when dealing with self-regulation.³⁰ Review of another physician's practices is often viewed as a "direct conflict with the individual physician's control of the care of his individual patient."³¹ Any attempt to control the quality of care provided by a physician tends to be seen as "a punitive measure threatening their [each physician's] professional standing and dignity."³²

This professional disdain for review is compounded by other functional weaknesses of the state medical boards. Although state medical boards should emphasize both initial and continuing physician competency, the lack of funding and investigative staff limits medical board review. In most states, the licensing and renewal fees collected by the medical board are turned over to the state, and the state then determines the appropriate amount of funding.³³ Once initial competency is achieved, few methods are available to insure the maintenance of the original proficiency. Mandatory continued medical education as a condition of re-certification might promote expertise, but there is little evidence that such courses will correct improper practices. In addition, the requirements for continuing medical education are easily met or simply evaded by practitioners.³⁴

The lack of effective sanctions also hampers disciplinary boards. Although the state medical boards have a wide variety of sanctions at their disposal, the range of severity of these sanctions and the protection they offer to the public is skewed. While professional censure or admonishment may provide the necessary impetus for a practitioner to correct his conduct, these minor sanctions are generally not revealed

30. E. FRIEDSON, *PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE* (1970) at 366 [hereinafter Friedson].

31. R. MCCLEERY, *ONE LIFE — ONE PHYSICIAN: AN INQUIRY INTO THE MEDICAL PROFESSION'S PERFORMANCE IN SELF-REGULATION* 12 (1971).

32. *Id.*

33. Peters, *supra* note 16, at 144.

34. Interview with Kraft Ritter, M.D., practicing anesthesiologist, in South Bend, IN (Sept. 24, 1986). (Continuing Medical Education is most often presented in the daily or weekly seminar setting; while each participant must sign in at the presentation to document his or her presence, there is no method of insuring their attendance beyond the roll call, much less insuring the participant's attentiveness.)

to the public, so there is very little external pressure to conform to professional norms. Just as censure may be excessively mild, limitation or revocation of a physician's license to practice may be an extremely harsh sanction. This lack of intermediate sanctions reinforces the view of sanctions as punitive rather than rehabilitative. Providing mediocre physicians incentives for improvement may be more effective than either admonishment or the threat of severe punishment.

B. *Informal Medical Regulation*

A second area of self-regulation often overlooked within the profession is founded on social controls rather than governmental regulation. While informal discipline may be extremely effective because of its personal nature, this individual aspect renders its use equally problematic.

For a variety of reasons many physicians are reluctant to resort to formal disciplinary proceedings. A physician may lack certainty of another's incompetency or may follow the adage "but for the grace of God, there go I." Rather than relying on formal controls, physicians may resort to informal measures characterized as "talkings-to."³⁵ If unsolicited peer advice fails, adverse social and economic sanctions might be used. Such devices include refusing to ask a physician for advice, avoiding the colleague, refusing to refer patients to another, and failing to arrange for cross-coverage with the physician in question.³⁶ The same measures used to chastise a physician suspected of incompetency, however, can be used to discourage a reporting physician. A physician instituting disciplinary proceedings may endanger the trust and respect of peers, thus risking social and economic sanctions similar to those directed against unfit colleagues. While informal disciplinary controls can be powerful, there is no method to control their application, whether justified or not.

The shortcomings inherent in the system of informal control have been described as problems of observability, leverage, and norms.³⁷ Cases of gross malpractice are not usually observed firsthand, but knowledge of incompetency is developed from a series of incidents and related inferences. Although several peers may harbor suspicions about the offending physician, these beliefs must coalesce to form a collective

35. Friedson, *supra* note 30, at 149.

36. *Id.* at 151.

37. *Id.* at 152.

judgment. Because the system of social controls lacks formal procedure, reaching this "critical mass of discontent" may take considerable time.³⁸

Just as the slow process of reaching consensus hampers social controls, problems of leverage or credibility also limit its effectiveness. The opinion of one conscientious physician may be discounted by peers and dismissed by the offending physician. When several physicians share a belief, their opinion may gain sufficient weight to influence a colleague. Moreover, for a collective judgment to have any effect, the offending colleague must be susceptible to the weight of opinion. If the incompetent physician does not value his professional standing or the opinion of the professional community, well-meaning pleas from colleagues fail. "*They [personal sanctions] punish him only insofar as he is sensitive to the good opinion of those particular individuals who exclude him.*"³⁹ (emphasis in original)

Physicians may also be reluctant to initiate disciplinary actions against a peer for fear of litigation. An Oregon physician subjected to an array of informal controls and to formal hearings by the state medical board retaliated by suing his reviewing colleagues for anti-trust violations.⁴⁰ Dr. Timothy Patrick worked one year with the Astoria Medical Clinic, a group of eleven local physicians, before establishing an independent practice in the area. Clinic physicians failed to give referrals or consultations to Patrick, refused to enter cross-coverage agreements, and accused Patrick of stealing clinic patients.⁴¹ Patrick and Clinic physicians were also engaged in peer-review proceedings at the local hospital. When the hospital began proceedings to terminate Patrick's privileges, at the urging of a Clinic physician, Patrick resigned from the hospital.

As part of this long-standing dispute, Patrick filed suit in 1981 against the Clinic physicians under the Sherman Anti-trust Act. In 1984 the case resulted in a \$2.2 million judgment against the Clinic physicians for anti-trust violations.⁴² This judgment was reversed in 1986. The Supreme Court recently granted a petition for writ of certiorari in *Patrick* to

38. *Id.* at 148.

39. *Id.* at 151.

40. *Patrick v. Burget*, 800 F.2d 1498 (9th Cir. 1986), *cert. granted*, 108 S.Ct. 65, 98 L.Ed.2d 29 (1987).

41. *Id.* at 1502.

42. *Id.* at 1505.

review the state-action doctrine as it applies to peer review systems.⁴³

In addition to demonstrating several weaknesses and the conflicts of interest inherent in professional self-regulation, *Patrick* carries a much greater significance because of its potential chilling effect on peer review. Physicians are expected to regulate their profession because other members of society lack the requisite knowledge and expertise. If physicians are unwilling to engage in stringent peer review because of possible retaliatory litigation, the medical profession, including anesthesiology, must either accept outside sources of control or devise alternative methods of professional self-regulation.

III. IMPROVING PROFESSIONAL SELF-REGULATION

Medical costs could be contained and the quality of care improved by seeking methods to reduce the incidence of malpractice. Within the profession as a whole, the Health Care Quality Improvement Act of 1986⁴⁴ ("Act") strengthens current means of state and hospital peer review. By improving the effectiveness of professional self-regulation, this law should help reduce the amount of malpractice. Within the specialty of anesthesiology, the Harvard Medical School standards for continuous monitoring are designed to reduce human error by raising the minimum level of patient care.

A. *The Health Care Quality Improvement Act of 1986*

By encouraging professional self-regulation, Title IV of the Act is a significant effort to help reduce the amount of malpractice. Title IV addresses malpractice in two ways: it protects professional review activities by physicians and health care entities by a grant of limited immunity, and it requires reviewing boards and hospitals to report all disciplinary actions to state medical boards and to a national database.

In many respects, the Act may be seen as a response to issues raised in *Patrick*.⁴⁵ To promote effective peer review by state medical boards and hospital review committees, the Act

43. *Id.* 108 S.Ct. at 65, 98 L.Ed.2d at 29.

44. Health Care Quality Improvement Act of 1986, 42 U.S.C.A. §§ 11101, 11111-11115, 11131-11137, 11151-11152 (West, 1987 Pamphlet) [hereinafter Health Act of 1986].

45. *Patrick*, *supra* note 40.

grants immunity to participants in the reviewing process.⁴⁶ So long as information is not known to be false, persons providing information to the reviewing body are protected from civil liability.⁴⁷ Members of the reviewing board, in turn, are protected from liability for damages if the professional review activity⁴⁸ meets requirements for good faith,⁴⁹ due process,⁵⁰ and reporting.⁵¹

To meet the good faith requirements of the Act, review must be conducted with a reasonable belief it will insure quality care.⁵² Due process requirements increase the fairness of any review proceedings. A physician facing professional review must be accorded the following rights to meet due process: to notice of the review, to a hearing held before a person not in direct competition with the physician, to legal representation, to call witnesses, and to receive written copies of the proceedings and the decision.⁵³

The Act also conditions immunity from liability on extensive reporting requirements. Professional review boards, as well as insurance carriers, are required to report information about adverse decisions and medical malpractice claims to the State Board of Medical Examiners.⁵⁴ Hospitals must report staff review actions that involve the surrender or suspension of clinical privileges for 30 days or more.⁵⁵ Other professional review actions affecting membership in a professional society, such as censure or the revocation of the physician's license, must also be reported.⁵⁶ Insurance carriers must also report all payments and settlements deriving from malpractice coverage, including the physician's name, the amount of payment, name of any affiliated hospital, and a description of the claim.⁵⁷ Insurance carriers failing to provide this information could be fined up to \$10,000.⁵⁸ The

46. Health Act of 1986, *supra* at note 44, § 11111.

47. *Id.* at § 11112.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.* at § 11134.

52. *Id.* at § 11112.

53. *Id.*

54. *Id.* at § 11134.

55. *Id.* at § 11133.

56. *Id.*

57. *Id.* at § 11131.

58. *Id.*

State Medical Boards, in turn, are required to forward disciplinary information to a national database.⁵⁹

Conditioning immunity on reporting requirements also addresses the difficulty of tracing physicians who frequently move to escape a history of incompetence.⁶⁰ When faced with a physician suspected of incompetence, some hospitals may have requested a physician's resignation rather than initiating formal review procedures.⁶¹ In this way the offending hospital would protect its reputation, its patients, and the immediate community while the physician, armed with a clean employment record, was free to practice elsewhere. Under the new law, hospitals or reviewing boards failing to report review actions would lose their immunity from liability.⁶² Immunity for reviewing physicians is necessary because the comprehensive reporting system places a premium on disciplinary activities. Because the results of most review proceedings will no longer be easily hidden or avoided, the physician in question might resort to litigation to challenge an unfavorable review action.⁶³

To complement the effectiveness of the reporting requirements, hospitals are required to examine the record of each physician applying for clinical privileges and to review biannually the records for those already on staff.⁶⁴ If this information is not obtained, the hospital is presumed to have actual knowledge of that physician's background⁶⁵ and may face liability for the physician's actions.

The 1986 Act remedies one of the major weaknesses of the self-regulation by the medical profession. Under the grant of immunity, local and state review boards following proper procedures may conduct stringent investigation without fear of retaliatory litigation or liability for damages. In addition to protecting the activities of review boards, the reporting requirements of the Act help coordinate disciplinary efforts. While the system of self-regulation still suffers inherent limitations, these reforms should help tighten professional regulation and thereby improve the quality of health care. By reducing the amount of injury and death caused by incompetent physicians, the Health Care Quality Improve-

59. *Id.* at §§ 11132, 11133.

60. H.R. Rep. No. 903, 99th Cong. 2nd Sess., pt. 1, at 3 (1986).

61. Ritter, *supra* note 34.

62. Health Act of 1986, *supra* at note 44, at § 11111.

63. H.R. Rep. No. 903, *supra* note 60, at 3.

64. Health Act of 1986, *supra* at note 44, § 11135.

65. *Id.*

ment Act should also aid cost containment efforts.

B. *The Harvard Standards for Anesthesia Monitoring*

The Harvard Medical School standards for continuous monitoring during the administration of anesthesia focus on a central issue in medicine, that of preventing error as a means to reduce the incidence and costs of malpractice.⁶⁶ The standards for anesthesia practice resulted from a study of the nine university hospitals affiliated with the Harvard Medical School. A risk management group reviewed eight years of anesthesia-related insurance claims from these hospitals and found the majority of cases involving serious injury or death to the patient were preventable.⁶⁷ The committee concluded "more meticulous monitoring of the patients would help prevent such anaesthesia accidents."⁶⁸

The promulgation of the Harvard standards represents a major shift for the practice of anesthesiology and for the medical profession.⁶⁹ During their study controversy developed about whether to offer broad guidelines for care or detailed, mandatory standards of practice, for "only vague or general standards of practice exist in American medicine."⁷⁰ Although "specific standards for the minute-to-minute conduct of anesthesia practice have never before been promulgated,"⁷¹ they concluded "[b]asic monitoring practices were thought to be so important in accident prevention that they must be mandatory."⁷²

The Harvard standards are offered as a precedent for all practitioners.⁷³ It is widely accepted, however, that the level of expertise and patient care is higher in university hospitals than in community hospitals. This difference among teaching practice and local medical practice is reflected by two significant omissions: the standards fail to address the wide variation in training among nurse-anesthetists and the standards fail to recognize the economic conflict of interest arising from the use of attenuated care.

66. Harvard Anesthesia Standards, *supra* note 3.

67. *Id.* at 1017.

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* at 1018.

72. *Id.* at 1017.

73. *Id.* at 1018.

In current anesthesia practice, an anesthesiologist, a physician with additional training or board specialization in anesthesia, bears primary responsibility for patient care. While the anesthesiologist might personally attend the patient throughout the administration, a nurse-anesthetist, a registered nurse with additional training in anesthesia, may assist the anesthesiologist. Often times, as illustrated by the Schneider and Worthy cases, the anesthesiologist selects the proper anesthetic agent and the means of administration but is not present during surgery. The nurse-anesthetist, acting under the anesthesiologist's authority, administers the anesthesia, monitors the patient, and supervises the patient's recovery. While this method of practice is widely-used, efficient, and normally presents few technical difficulties, this attenuated care system raises several troubling questions.

The goal of this supervisory system is to provide acceptable patient care in a cost-efficient manner. The role of the nurse-anesthetist in an attenuated care system, however, lacks certainty. While the anesthesiologist bears primary responsibility for patient care, the degree of independent judgment exercised by individual nurse-anesthetists remains unclear. As illustrated by the JCAH standards for anesthesiologists and nurse-anesthetists,⁷⁴ their duties and responsibilities overlap to a great extent. Both anesthesiologists and anesthetists may select the proper anesthesia and procedures for administration, induce anesthesia, and manage the patient throughout the procedure.⁷⁵

Because of lack of uniformity in training, the ability of different nurse-anesthetists to exercise judgment and fulfill this role is unclear.⁷⁶ A nurse-anesthetist is defined as a registered nurse with additional training in the administration of anesthesia.⁷⁷ A registered nurse may have from two to four years of training, and anesthesia training programs vary in length from six months to two years. Thus a nurse-anesthetist with two and one-half years of training may be performing essentially the same duties as an anesthetist with six years of education and training.⁷⁸ Although some nurse-anesthetists

74. Peters, *supra* note 16, at 214.

75. *Id.*

76. Interview with Ms. C. Kil Gillis, BSN, former instructor of nursing, Memorial Hospital, South Bend, IN and law student, Notre Dame Law School, in South Bend (Feb. 23, 1987) [hereinafter Kil Gillis]. Telephone interview with Ms. L. Dykhouse, Registered Nurse (Feb. 11, 1987).

77. Kil Gillis, *supra* note 76.

78. *Id.*

could exercise a substantial degree of professional judgment, others require much closer supervision. While the practice of attenuated care depends heavily on the abilities of the individual anesthetist, the competency and quality of care provided by nurse-anesthetists as a class may vary widely. Although standards relating to technical aspects of practice may reduce technical error, "inexperienced personnel and inadequate monitoring"⁷⁹ are problems of training and staffing, not primarily technical problems.

The foremost concern raised by the practice of attenuated anesthetic care involves a conflict between patient care and economic considerations. Although proper patient care should be the primary consideration, recent studies of anesthetic malpractice claims prove current anesthetic practices are not wholly effective.⁸⁰ One study of anesthetic mishaps concluded "[a]lleged negligence during anesthesia was found to be due, in part, to inexperienced personnel and inadequate monitoring, often because a supervising anesthesiologist had too heavy a case load."⁸¹ While supervising several nurse-anesthetists, each working in a different operating room, the anesthesiologist might still meet the duty of care prescribed by the profession and advocated by the Harvard standards. This method of practice might reduce the cost of each administration of anesthesia, but use of an attenuated care system also provides an economic reward to the anesthesiologist. Anesthesiologists might well earn much more money by loosely supervising several nurse-anesthetists than by monitoring each anesthesia personally. Providing attenuated supervisory care may be adequate in most instances, but this is simply not providing optimal care. If an emergency arises during the administration of anesthesia, the anesthesiologist should be available immediately to offer the expertise needed to prevent patient injury or death. The nurse-anesthetist, because of a lesser degree of training, may be ill-prepared to deal with such a situation. Because of the possibility of such emergencies, use of an attenuated care system is questionable at best. Efforts to contain costs and provide normally-adequate patient care should not be used to justify a lack of proper care in a small number of emergencies. Should

79. Peters, *supra* note 16, at 5, (quoting Hirsch and White, *The Pathologic Anatomy of Medical Malpractice Claims*, 6 LEGAL ASPECTS OF MED. PRACTICE 26-28 (1978)).

80. *Id.*

81. *Id.*

the anesthesiologist forgo a lucrative method of practice to ensure patient safety? Close supervision of anesthetists or direct involvement by the anesthesiologist are more defensible means of practice, for these methods increase the level of patient care.

While acceptance of the Harvard standards might produce uniformity in the quality of anesthetic care, the promulgation and use of standards raises additional questions. The process of formulating standards is itself subject to inherent limitations. The Harvard standards are based on eight years of data, ending in 1984.⁸² Given the rapid development of medical knowledge and technology, standards may easily become dated, even only a few years after introduction. To be sure, the authors of the Harvard study call for timely revision.⁸³ While standards may provide firm basis for a minimal level of care, this level is only relevant for a comparatively short term, for as long as the standards are current and updated. It should be recognized, however, that this minimal level of care, by the nature of standards, will perennially be several years behind the level of present technology and practices.

A second functional weakness for standards involves the nature of standards. As the authors admit, they struggled with the question of trying to "codify current practice and validate the existing, declare an ideal that may be impossibly high, or strike a balance in between [current practice and the ideal practice]."⁸⁴ While the Harvard group opted to strike a balance between existing practice and an ideal practice, any other segment of the medical profession seeking to codify its practices must address the same difficulty. Although the standards proposed by the Harvard group are the first of their kind, the authors declare this "model is valid for all of American medicine."⁸⁵ Another group following this model might choose only to codify existing practices. While such weak standards might be readily accepted, they would have little practical validity.⁸⁶ If standards are perceived as signifying effective self-regulation, widespread adoption of standards could produce a masking effect. Those areas of medicine with standards in force would be seen as taking effective measures

82. Harvard Anesthesia Standards, *supra* note 3, at 1017.

83. *Id.* at 1020.

84. *Id.*

85. *Id.*

86. *Id.*

to ensure quality, regardless of the efficacy of their respective standards.

The setting of standards for anesthesia monitoring should improve the minimal level of care within the specialty and reduce malpractice. By failing to address non-technical areas such as the use of attenuated care, however, the standards ignore significant weaknesses within anesthesiology.

IV. ETHICAL CONCERNS FOR PROFESSIONAL SELF-REGULATION AND ANESTHESIOLOGY

Concern for the quality of care provided with an attenuated care system in anesthesiology reflects a broader issue facing the medical profession. Professional self-regulation is based in part on effective formal controls such as review boards. Reliance solely on formal disciplinary measures is misguided, however, for professional self-regulation is primarily based on individual discipline and individual morality. Such measures as the Health Care Quality Improvement Act should increase the effectiveness of formal self-regulation and peer review. Better use of these methods of discipline should produce a minimally adequate level of care. The fundamental questions of professional self-regulation, however, are ethical. How might physicians be encouraged to go beyond the minimum standard to provide a greater level of care?

The level of care a physician should provide can be explained by postulating a continuum of professional behavior. On one extreme, a physician's performance might be incompetent or negligent; on the opposite extreme, the physician could provide care approaching the outer limit of medical knowledge and expertise. Between these two extremes of performance lies an area of acceptable professional conduct ranging from providing minimally adequate care to providing optimal care, the level of care generally available in the health care system.

This range of acceptable conduct can be expressed in terms of Lon Fuller's distinction between the morality of duty and the morality of aspiration.⁸⁷ The morality of duty prescribes what is simply necessary for mere achievement. In contrast, the morality of aspiration sets forth "a rather general idea of the perfection we ought to aim at" while not "afford[ing] us any certain and infallible directions of acquiring

87. L. FULLER, *THE MORALITY OF LAW* 5 (1964).

it."⁸⁸ Using Fuller's terminology, a physician has a morality of duty to perform at least at a minimally adequate level. This is consistent with the physician's legal duty to provide competent care, as determined by the standard of ordinary and reasonable care. Beyond this mere legal duty, however, the physician also has a moral responsibility to provide an optimal level of care. This moral imperative to provide a generally attainable level of care corresponds with Fuller's morality of aspiration.

The range of acceptable professional conduct within anesthesiology should also be defined using the morality of duty and the morality of aspiration. The morality of duty, of providing an adequate level of care, is or should be set by hospital review boards and state medical boards. The Harvard Standards for anesthesia monitoring would simply refine this process by mandating specific practices and a specific level of care required of nurse-anesthetists and anesthesiologists. The morality of aspiration for the practice of anesthesiology is not defined by a set of standards or guidelines. The anesthesiologist should surpass mere competency and strive to provide the best care readily available in the health care system.

The level of human error in current anesthesiology practice fails to meet the range of acceptable professional conduct as defined by the morality of duty and the morality of aspiration. In most administrations of anesthesia under the current system of attenuated care, the minimally required level of care is sufficient to avoid patient injury. Studies suggest, however, that up to one-half of current anesthetic mishaps are caused by improper monitoring.⁸⁹ This level of human error is not morally defensible. It is not immoral that mistakes are committed, for a bad outcome in itself does not involve morality. Attenuated care is not flawed merely because of the rate of anesthetic mishaps. Under the attenuated care system, however, patient injury or death occurs because of human error, and these errors could have been avoided if anesthesiologists were nearer to hand. The attenuated care system is not flawed because a significant portion of these mishaps could, and should, be prevented.

The ethical shortcomings of the attenuated care system become most acute when preventable human errors are accepted simply because use of attenuated care is efficient — efficient both in containing the cost of each administration of

88. *Id.* at 6.

89. Pierce, Risk Modification, *supra* note 6 at 25.

anesthesia and in producing an economic benefit to the anesthesiologist.

The attenuated care system provides adequate care under normal circumstances and allows for the efficient distribution of anesthetic services. Efficiency alone, however, cannot justify the level of adverse outcomes in current anesthesia practice. The quality of care and additional increment of patient safety from increased monitoring should not be sacrificed for cost containment. This is not to postulate that to save a life any expense is always justified. Proper monitoring during anesthesia is not a heroic effort to prolong life or to avoid an inevitable death, but to prevent human error. Moreover, the nature and resultant expense of anesthetic mishaps may well turn the cost-containment argument on its head. Improving the level of monitoring during anesthesia, either by increasing the use of instruments or by closer supervision by the anesthesiologist, might well be less expensive than the costs of medical insurance and of awards for patient injuries and deaths. It is not a question of how the profession might afford closer supervision, but how anesthesiologists can afford *not* to provide closer supervision and better monitoring during anesthesia.

Anesthesiologists, both as individual practitioners and as members of the profession, should also address the ethical tension between economic gain and patient care inherent in an attenuated care system. The use of an attenuated care system in anesthesiology may emphasize economic security at the expense of patient safety. Loose supervision of a number of nurse-anesthetists may produce efficiency and economic gain, yet this method of practice might also lead to catastrophic results in a small percentage of cases. Close supervision of anesthesia administrations, either by utilizing fewer nurse-anesthetists or by increasing direct involvement by the anesthesiologist, should produce better care by reducing human error and the incidence of malpractice. Close supervision, however, may increase the cost of administration while reducing anesthesiologists' incomes. A central question facing anesthesiology and the larger profession does not involve technical expertise or cost efficiency, but ethics: how "does the profession organize itself in such a way as to prevent the practitioner's natural concern with his own economic security and advancement from dominating his ethical concern with the good of his clientele?"⁹⁰ In an acceptable form of profes-

90. Friedson, *supra* note 30, at 362.

sional organization the tension between economic security and patient care would be minimized, if it even existed. Primacy must be placed on professional responsibility — to care for patients — while worries of income levels should receive secondary or tertiary consideration.

Impetus for a renewed sense of professional responsibility should come from at least four different areas. First, the American Society of Anesthesiologists (“ASA”) should encourage changes in the profession designed to improve patient care. For example, the ASA has formally adopted standards for anesthesia monitoring similar to those proposed by the Harvard study.⁹¹ The ASA has also attempted to define the proper functioning of the attenuated care system. As stated in the ASA Guidelines for the Ethical Practice of Anesthesiology:

* * *

The Society recognizes that the personal provision of anesthesia care by the anesthesiologist must remain a desirable primary goal. It also believes that a proper concern for its members is the establishment of an acceptable environment within which medical direction of the anesthesia care team may be carried out so as to provide better anesthesia care for more patients.⁹²

While the ASA has also defined “medical direction”⁹³ within these guidelines as a method of providing proper pa-

91. The ASA standards for anesthesia monitoring are set forth in Appendix B. Although similar to the standards promulgated by the Harvard Medical School, these are not as comprehensive. In addition, the ASA standards suffer from the same weaknesses and limitations as the Harvard standards, as discussed. AM. SOC’Y OF ANESTHESIOLOGISTS, STANDARDS FOR BASIC INTRA-OPERATIVE MONITORING (amended Oct. 21, 1986).

92. AM. SOC’Y OF ANESTHESIOLOGISTS, GUIDELINES FOR THE ETHICAL PRACTICE OF ANESTHESIOLOGY (amended Oct. 14, 1987) [hereinafter ASA Guidelines for Ethical Practice].

93. The ASA defines medical direction as:

Anesthesia direction, management or instruction provided by an anesthesiologist whose responsibilities include:

- a. Pre-anesthetic 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.
- d. Following the course of anesthesia administration at frequent intervals.
- e. Remaining physically available for the immediate diagnosis and treatment of emergencies.
- f. Providing indicated post-anesthesia care.

An anesthesiologist engaged in medical direction should not per-

tient care, establishing an "acceptable environment" for medical care has not been addressed. Instead, the ASA has failed to recognize the economic implications of the attenuated care system. In its statement of policy, the ASA asserts, "It is the official policy of The American Society of Anesthesiologists, Inc. that an anesthesiologist is free to choose whatever arrangement he prefers for compensation of his professional services. The Society does not consider the compensation arrangement so chosen to be a matter of professional ethics."⁹⁴

The attenuated care system in anesthesiology is not only an efficient method of providing anesthesia services, it is also a lucrative compensation arrangement. When patient care is compromised because of the professional's compensation arrangement, as it is in a small number of cases with attenuated care, this should certainly be a matter of professional ethics. The ASA should do more than suggest that "personal provision of anesthesia care" is a "desirable primary goal."⁹⁵ Measures to improve patient monitoring and care need be taken. For example, the ASA has officially supported programs to "provide accredited educational programs and national credentials for Respiratory Therapists."⁹⁶ The ASA, however, has not taken a similar position to establish uniform educational requirements for nurse-anesthetists. Rather than merely ratifying the existing practices and arrangements within the profession, the ASA should take the lead in improving patient care.

Second, both hospitals and insurers should also provide incentives to improve the level of patient care during the administration of anesthesia. In an age of medical parsimony, however, it must be recognized that the most powerful rationale for making changes will be that of economic efficiency. Use of an attenuated care system may be attractive initially, for it offers efficient use of professional resources while reducing the cost of each administration of anesthesia.

sonally be administering another anesthetic, and should use sound judgement [sic] in initiating other concurrent anesthetic and emergency procedures.

ASA Guidelines for Ethical Practice, *supra* note 98.

94. AM. SOC'Y OF ANESTHESIOLOGISTS, STATEMENT OF POLICY (amended Oct. 14, 1987).

95. ASA Guidelines for Ethical Practice, *supra* note 98.

96. AM. SOC'Y OF ANESTHESIOLOGISTS, STATEMENT REGARDING RESPIRATORY THERAPY LICENSURE (amended Oct. 16, 1985).

When considering the enormous cost of each error involving anesthesia, however, it may well be less expensive overall to shoulder the added costs of increased supervision.⁹⁷ Until it is established that closer supervision of anesthesia is truly cost-effective, neither hospitals nor insurers can be expected to support changes in the established system of care.

Third, medical schools and teaching hospitals should continue to seek improved methods of care. Despite its shortcomings, the study which formulated the Harvard standards was commendable. If the attempt to contain medical costs by improving patient care "is valid for all of American medicine,"⁹⁸ the results of these efforts should be equally instructive.

Fourth, the profession and the ASA is composed of individual anesthesiologists. Each should examine carefully their current methods of practice and decide whether these provide an acceptable margin of safety for each of their patients. The individual practitioner, above all, must choose whether to place primacy on professional responsibility or on economic security and advancement. This choice may also be expressed by the morality of duty and the morality of aspiration: the professional might choose only to meet the minimally required level of care, and choose to be content with professional mediocrity; or the professional may follow an aspiration, striving to provide each patient with the best care available. At its fundamental level this choice turns on trust. Since no amount of formal or informal regulation of the professional can transform a simple duty into the requisite aspiration, society and each patient must trust the professional to make the proper decision.

CONCLUSION

As witnessed by studies of the specialty of anesthesiology, improvements are needed in current anesthetic practices. While both formal and informal methods of professional self regulation help to define a minimally acceptable standard of

97. For example, a study by the St. Paul Insurance Company found twenty-three percent of anesthesia claims were for catastrophic incidents, each of which cost an average of \$131, 459. See *supra* note 10. Similarly, the authors of the Harvard Anesthesia Standards cite an estimate that anesthesia malpractice settlements and awards average over \$100,000 and range up to \$41 million. Harvard Anesthesia Standards, *supra* note 3, at 1017 (quoting United Press Int'l, Sept. 27, 1984).

98. Harvard Anesthesia Standards, *supra* note 3, at 1020.

care for the medical profession, these attempts at regulation suffer shortcomings. By increasing the effectiveness of peer review, the Health Care Quality Improvement Act should strengthen self-regulation and refine the level of acceptable care.

The Harvard Anesthesia Standards represent one of the first attempts to establish mandatory standards of medical care. Reliance on these standards and on similar standards adopted by the ASA should improve the level of patient care in anesthesiology. The standards fail to address, however, two problems in the attenuated care system: the training of nurse-anesthetists and the conflict between economic considerations and patient care. Uniformity in the education and utilization of nurse-anesthetists should increase the level of current monitoring, thereby reducing the current rate of anesthetic error. The tension between patient care and compensation arrangements inherent in the attenuated care system can be resolved only by re-emphasizing professional responsibility. Whether undertaken to contain costs or to improve the profit margins of insurers, hospitals, or physicians, the relentless search for efficiency in medicine should not be allowed to encroach upon the quality of patient care.

Appendix A

HARVARD MEDICAL SCHOOL STANDARDS FOR PATIENT MONITORING DURING ANESTHESIA

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 anesthesia, 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, e.g., 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 impracticable.*

ELECTROCARDIOGRAM

Every patient shall have the electrocardiogram continuously displayed from the induction or institution of anesthesia

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

until preparing to leave the anesthetizing location, where not clinically impracticable.

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.

BREATH 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.)

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

** 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.

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

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 the potential risks of such monitoring and because of the likelihood of other physical signs giving earlier indication of the development of malignant hyperthermia.

Appendix B

AMERICAN SOCIETY OF ANESTHESIOLOGY STANDARDS FOR BASIC INTRA-OPERATIVE MONITORING (APPROVED BY HOUSE OF DELEGATES ON OCTOBER 21, 1986)

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgement [sic] of the responsible anesthesiologist. They are intended to encourage high quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards addresses only the issue of basic intra-operative monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual* monitoring may be unavoidable. *Under extenuating circumstances, the responsible anesthesiologist may waive the requirement marked with an asterisk (*); it is recommended that when this is done, it should be so stated, (including the reason) in a note in the patient's medical record.* These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

STANDARD I

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

OBJECTIVE

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary

* Note that "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

absence of the person primarily responsible for the anesthetic, the best judgement [sic] of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

STANDARD II

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

OXYGENATION

OBJECTIVE

To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

METHODS

- 1) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*
- 2) Blood oxygenation: During all anesthetics, adequate illumination and exposure of the patient is necessary to assess color. While this and other qualitative clinical signs may be adequate, there are quantitative methods, such as pulse oximetry, which are encouraged.

VENTILATION

OBJECTIVE

To ensure adequate ventilation of the patient during all anesthetics.

METHODS

- 1) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. While qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds may be adequate, quantitative monitoring of the Co_2^* content and/or volume of expired gas is encouraged.
- 2) When an endotracheal tube is inserted, its correct

positioning in the trachea must be verified. Clinical assessment is essential and end-tidal CO₂ analysis, in use from the time of endotracheal tube placement, is encouraged.

- 3) When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.
- 4) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

CIRCULATION

OBJECTIVE

To ensure the adequacy of the patient's circulatory function during all anesthetics.

METHODS

- 1) Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*
- 2) Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*
- 3) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

BODY TEMPERATURE

OBJECTIVE

To aid in the maintenance of appropriate body temperature during all anesthetics.

METHODS

There shall be readily available a means to continuously measure the patient's temperature. When changes in body temperature are intended, anticipated or suspected, the temperature shall be measured.

