

Chapter

The history of anesthesia and perioperative monitoring

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Introduction

The discoveries that facilitated patient monitoring in the perioperative period occurred long before the introduction of clinical anesthesia. Respiratory patterns had been described since antiquity. The rise of scientific methods in Renaissance Europe led to the initial experiments in hemodynamics – specifically, animal experiments demonstrating that blood flows under pressure. The earliest source that cited correct observations of arterial and venous flow and pressures was William Harvey's *De Motu Cordis*, published in 1628.¹ In the following century, Stephen Hales offered the first quantification of arterial blood pressure measured in the horse.² The first cardiac catheterization was performed by Claude Bernard in 1844.³

Soon after the introduction of clinical general anesthesia by W. T. G. Morton in 1846 and John Snow in 1847, the need to monitor patients was recognized by the leaders of the new specialty. The first documented death under chloroform anesthesia (that of fifteen-year-old Hannah Greenier in 1848) led the early practitioners to highlight the importance of monitoring simple vital signs – respiration, pulse, and skin color. Since that time, patient safety concerns have invariably driven the development of monitoring modalities and standards in perioperative monitoring practice. This chapter recounts important milestones of perioperative patient monitoring and the historical events and clinical developments that influenced them.

Early advocacy of monitoring the pulse and respiration

As news of the Boston public demonstration reached London late in 1846, John Snow, M.D. personally adopted the technique, publishing his series of eighty anesthetized patients, ranging in age from children to octogenarians, in *Inhalation of the Vapour of Ether in Surgical Operations*. He mentioned the customary monitoring under anesthesia to include respiration depth and frequency, muscle movements, skin color, and stages of excitation or sedation. Although the pulse was continually palpated, its characteristics were not considered worth studying.⁴ By 1855, the Edinburgh surgeon James Syme, M.D., lectured on the importance of monitoring respiration

and explained in his surgical lectures that, in his opinion, chloroform was safer than ether anesthesia if it was administered properly. The key, however, to proper administration was monitoring the patient's respiration.⁵

Joseph Lister, M.D., the founder of the principles of antiseptics in surgery, was an eminent surgeon in Scotland and the United Kingdom from the 1850s through the 1890s. He protested against palpation of the pulse as “a most serious mistake. As a general rule, the safety of the patient will be most promoted by disregarding it altogether, so that the attention may be devoted exclusively to the breathing.”⁶ Dr. Lister's instruction to the senior students who served as his anesthetists was “that they strictly carry out certain simple instructions, among which is that of never touching the pulse, in order that their attention may not be distracted from the respiration.” His airway management strategy included “the drawing out of the tongue” and he believed that the services of special anesthetists were unnecessary if simple routines were followed by his assistants while administering chloroform.

Joseph Thomas Clover, M.D., was the leading clinical anesthetist in Victorian England during his professional life, from the beginning of his anesthesia practice in 1846 until his death in 1882. In 1864, the Royal Medico-Chirurgical Society established a committee to investigate chloroform fatalities, and as an expert assistant to that group, Dr. Clover described his innovations in apparatus and animal experimentation with anesthetics. He strongly advised that the pulse be continuously observed during an anesthetic and that irregularities such as a diminution should alert the anesthetist to discontinue the anesthetic. He also advised monitoring the pulse continuously while administering an anesthetic. “If the finger be taken from the pulse to do something else, I would give a little air.”⁷ James Young Simpson, M.D., also voiced caution during the administration of chloroform when snoring ensued and the pulse became “languid.”⁸

With continuing deaths associated with chloroform use, a group led by Edward Lawrie formed a commission in Hyderabad, India to investigate causes. In 1888, the first commission report asserted the safety of chloroform anesthesia.⁹ In 1889, the Second Hyderabad Chloroform Commission concluded that chloroform deaths were related to respiratory depression and not a directly injurious effect on the heart. The commission

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reported that anesthetists should be guided entirely by respiration, as pupil size and pulse were not significant enough to monitor.^{10,11}

Auscultation of heart tones

The earliest clinical account of auscultation in the operating room was reported in 1896 by Robert Kirk, M.D., of the Glasgow Western Infirmary. An ordinary binaural stethoscope lengthened by Indian rubber tubing was first used. Later, 200 patients anesthetized with chloroform were auscultated using a “phonendoscope” with timing of heart rate and rhythm by a watch.¹² Dr. Kirk was involved at the time with the Glasgow Committee on Anesthetic Agents and saw the stethoscope as a clinical research tool to assess the effects of chloroform on cardiac physiology.

Charles K. Teter, D.D.S., described the benefits of using a stethoscope during anesthesia, especially in poor-risk patients.¹³ He praised the convenience of the flat Kehler stethoscope, which “will usually stay without being held” on the precordium. When necessary, adhesive tape prevented its being dislodged. Dr. Teter praised the stethoscope because “uninterrupted information will be given to any and all change[s] in the heart beat and respiration.” He expressed his feeling of confidence when “every variation of heart sound is at once discernable, and what might be serious complications can be averted by the premonitory symptoms thus made manifest.”¹³

The strong advocacy of routine, continuous monitoring of cardiac and respiratory sounds under anesthesia by Harvey Cushing, M.D., gave impetus to the widespread clinical use of intraoperative auscultation¹⁴ (see Figure 1.1). An esophageal stethoscope was described in 1893 by Solis-Cohen¹⁵ for diagnostic purposes, but it was not adopted as a routine monitoring technique until nearly seventy-five years later.



Figure 1.1. Early stethoscopes used for intraoperative monitoring are displayed. (Courtesy of the Wood Library-Museum of Anesthesiology, Park Ridge, IL)

The anesthesia record

Once the idea that monitoring patients under anesthesia was clinically useful and early tools were developed to do so, the anesthetic record could not be far behind. B. Raymond Fink, M.D., credits the first anesthetic record to A. E. Codman, M.D., at the Massachusetts General Hospital in 1894¹⁶ (Figure 1.2). Dr. Codman's chief, F. B. Harrigan, M.D., recommended recording the patient's pulse during an anesthetic. This practice was encouraged by Dr. Cushing, who published a classic paper in 1902 reproducing an actual patient's anesthetic record.¹⁷ Dr. Cushing's initiatives were not accepted easily, and opponents to the newer devices to measure temperature, pulse, blood pressure, and the auscultation of the heart were castigated by an editorial in the *British Medical Journal* claiming that “by such methods we pauperize our senses and weaken clinical acuity.”¹⁸

Indirect measurement of arterial blood pressure

In 1901, during a visit to Italy, Harvey Cushing met Scipione Riva-Rocci, who, a few years earlier, had developed a practical sphygmomanometer for measuring blood pressure indirectly.¹⁹ Subsequently, Cushing recommended the routine use of this sphygmomanometer to determine blood pressure during anesthesia.²⁰ Because the return-to-flow method was employed by palpation of the radial pulse, only the systolic pressure could be determined. Furthermore, this was inaccurate, as the cuff used was a bicycle inner tube, which gave excessively high values owing to the ratio of the region of compression to arm circumference. At that time, however, normal values for systolic blood pressure were unknown and the instrument provided the first clinical example of following trends of blood pressure change during surgery.

In 1905, Korotkoff described the sounds heard when flow occurs distal to the deflating cuff.²¹ This, together with the use of a wider cuff advocated by von Recklinghausen,²² allowed more accurate determination of blood pressure and is the basis of current auscultatory blood pressure monitoring. Further advances in the indirect measurement of blood pressure largely involved the development of alternative means of “sensing” systolic and diastolic points and automating the process.

In 1931, von Recklinghausen²³ described a semiautomated device for measuring blood pressure, known as an oscilometer. A double-cuff system was used, with the proximal cuff occluding the artery and the distal cuff acting as the sensor to detect the onset of arterial pulsations. The introduction of ultrasound into clinical medicine in the 1940s allowed the application of the Doppler principle to detect blood flow²⁴ and movement of the arterial wall under the distal edge of the sphygmomanometer cuff.²⁵ The Arteriosonde (Roche) used ultrasound at 3 mHz that reflected off the vibrating arterial wall, which the practitioner heard as an electronically conditioned audible signal. The device was accurate and found its greatest application for measurement of blood pressure in infants.²⁶ The

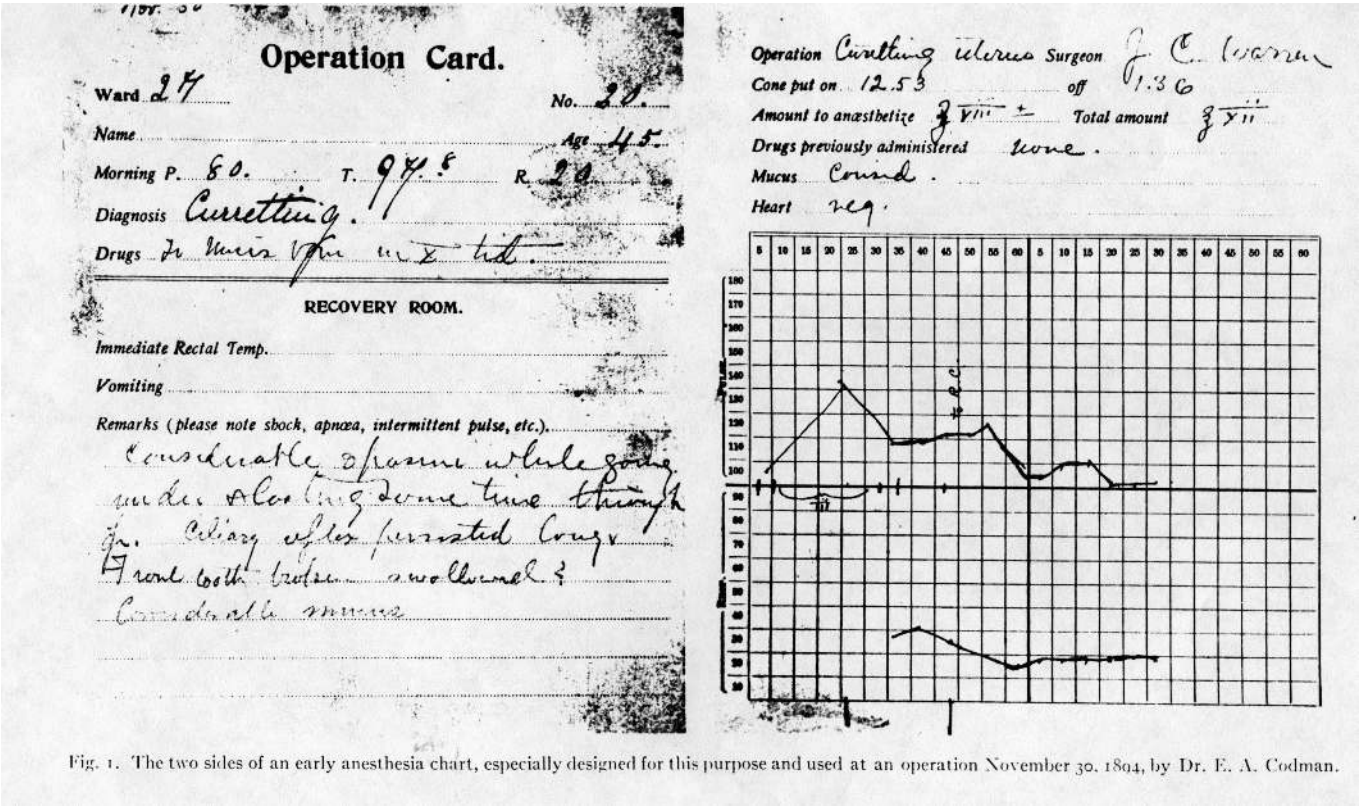


Figure 1.2. One of the first known anesthesia records is reproduced. (Courtesy of the Wood Library-Museum of Anesthesiology, Park Ridge, IL)

desire for more automated and rapid acquisition of noninvasive blood pressure led to the development of automated devices has allowed frequent estimation of indirect blood pressure. The first wide commercial success was the Dinamap (Critikon), which essentially was an automated oscillotonometer. The instrument was simple to use and produced accurate results.²⁷

Eye signs of anesthesia depth

Although Snow and other early leaders of the specialty described the monitoring of depth of anesthesia, the individual given greatest credit for standardizing the process was Arthur Guedel, M.D. The eye signs of ether anesthesia were the most significant contribution to his schematic approach to identifying signs of anesthesia.²⁸ The eye signs included the activity of motor muscles of the eyeball, pupillary dilation, and, later, the eyelid reflex. The eyelid reflex was tested by gently raising the upper eyelid with the finger. If the reflex was present, the eyelid would attempt to close at once or within a few seconds. The corneal and eyelash reflexes known today were not mentioned.²⁹

The setting for these contributions was the complete lack of trained anesthesia specialists when the United States entered World War I.³⁰ Dr. Guedel experienced a crush of casualties from a major battle, where his staff of three physicians and one dentist ran as many as forty operating room tables at a time. He concluded that additional anesthesia care providers would have to be trained quickly to meet this overwhelming need and

created a school that trained physicians, nurses, and orderlies in open-drop ether.²⁹ He prepared a chart of his version of the signs and stages of ether anesthesia, the most common agent in use at the time because of its wide margin of safety (Figure 1.3). Armed with their charts, the trainees went out to nearby hospitals to work on their own, as Dr. Guedel made weekly motorcycle rounds to check on his trainees at the six hospitals for which he was responsible.³⁰

Direct measurement of arterial blood pressure

Poiseuille, in 1828, described the mercury manometer.³¹ In 1847, Karl Ludwig made use of Poiseuille’s device and applied it to his invention of the kymograph.³² A column of mercury on the kymograph moved, and thus directed a floating needle against a moving drum. This device allowed animal hemodynamic physiology to be recorded continuously for research purposes. The application to humans, however, was limited by problems of vascular access and control of bleeding and infection. Almost one century later, direct recording of arterial blood pressure continued to be difficult, even though problems of sepsis and coagulation were solved.

The discovery of plastic “nonthrombogenic” sterile tubing and its medical applications occurred in 1945–46. In 1949, Lyle Peterson and Robert Dripps described the technique of percutaneous placement of a plastic catheter for continuous measurement of arterial blood pressure during anesthesia and surgery.³³

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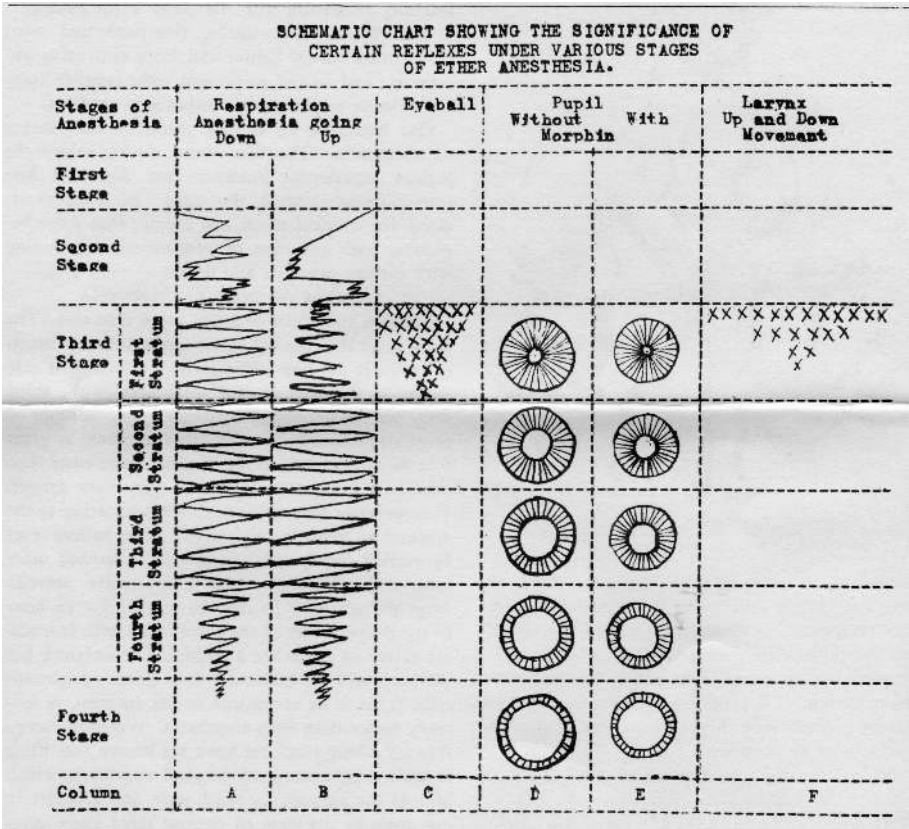


Figure 1.3. One version of Guedel’s chart demonstrating stages of ether anesthesia. (Courtesy of the Wood Library-Museum of Anesthesiology, Park Ridge, IL)

The value of this measurement was widely recognized, but the technique remained unpopular. The recording equipment was impractical and too expensive.

The technique of surgical cut-down was used to gain access to peripheral arteries during cardiac surgery in the 1950s. In 1960, the catheter-over-the-needle technique was introduced, and the wide medical application of polytetrafluoroethylene (PTFE; Teflon, Dupont, Inc.) Teflon made possible convenient percutaneous access, leading to easier and smoother percutaneous placement of cannulae for continuous monitoring of arterial blood pressure by surgeons, anesthesiologists, and intensive care specialists. Simultaneous technological advances in pressure transducers, continuous flush systems, and transistor-based display and recording equipment made invasive arterial monitoring commonplace.

The electrocardiogram in the operating room

In 1918, Heard and Strauss³⁴ reported two cases of atrioventricular rhythm, one of which occurred immediately following ether anesthesia. They reported that “no other cases of nodal rhythm have been observed by us in a series of 21 cases in which electrocardiographic records have been taken during anesthesia.” No further details were given. Levine³⁵ reported two cases of paroxysmal atrial tachycardia under ether anesthesia, documented by electrocardiography.

The first prospective study of the practical use of the electrocardiograph (ECG) for monitoring patients in the operating room was reported in 1922. Lennox, Graves, and Levine³⁶ studied fifty operations performed on forty-nine patients at the Peter Bent Brigham Hospital in Boston. The monitoring method was onerous. The electrocardiographer was summoned by a buzzer in the operating room at the beginning and end of the operation and during critical moments in the operation. ECG tracings were produced by a string galvanometer, at average intervals of 2.5 minutes. For a permanent record, photographic paper had to be exposed to light. The heart rate calculated from the ECG tracings was much higher than the count of the anesthetist. The most marked discrepancies usually occurred during induction of anesthesia, when the pulse rate was taken by a nurse from the ward. Abnormalities of conduction (displacement of pacemaker) were found in 15 (30%) of the cases and 11 cases developed premature beats, seven of them ventricular in origin. None of these premature beats was noted by the anesthetist. Analysis of the patients’ characteristics, type of surgery, and type of anesthesia failed to demonstrate predisposing factors apart from alterations in vagal tone.

The value of the electrocardiogram during surgery was demonstrated by further similar studies.^{37–39} The intermittent nature of the recording and the inevitable delay in developing ECG tracings on photographic paper, however, limited the usefulness of these observations for diagnosis and therapy.

Direct-writing ECG recorders eliminated the delay associated with processing films but were impractical for obtaining continuous records.⁴⁰

In 1952, Himmelstein and Scheiner described a cardiotoscope, which permitted continuous display of the ECG on a cathode ray screen.⁴¹ The heart rate, obtained by measuring the time interval between successive beats, appeared as a moving line on the calibrated screen of a cathode ray tube. A direct writing cardiograph could be attached to the instrument to obtain permanent records.

With the advent of continuous ECG monitoring devices, the routine use of the ECG to detect abnormalities of rhythm and rate became practical, albeit too expensive for routine use. Several reviews and studies^{42,43} documented the type and incidence of dysrhythmias that could occur during anesthesia. Lead II was usually monitored because the axis paralleled the normal P wave vector, facilitating easy recognition of dysrhythmias. The application of the ECG to detect myocardial ischemia during anesthesia was first proposed by Kaplan and King.⁴⁴ In patients undergoing stress tests, Blackburn⁴⁵ had previously found that the majority of ischemic episodes could be detected by precordial lead V₅ of a 12-lead electrocardiogram. Kaplan⁴⁶ demonstrated successful use of a modified CM₅ lead in anesthetized patients. This lead was practical with three-lead ECG systems, then in common clinical use in the operating room.

Central venous and pulmonary artery catheterization

Werner Forssmann is credited with being the first person to pass a catheter into the heart of a living person⁴⁷, using himself as the subject. He passed a ureteral catheter through one of his left antecubital veins, guiding it by fluoroscopy into his right atrium, and then confirming the position by chest roentgenogram. In 1930, Klein reported eleven catheterizations of the right side of the heart, including catheterization of the right ventricle and measurement of cardiac output in humans, using Fick's principle.⁴⁸ In the 1940s, catheterization of the right side of the heart began to be used to investigate problems of cardiovascular physiology by Cournand,⁴⁹ who later received the Nobel prize (together with Forssmann) for his pioneering efforts.

In 1947, Dexter⁵⁰ and Werko⁵¹ reported on oxygen saturation in the pulmonary artery and demonstrated, for the first time, the value of the pulmonary artery wedge pressure in estimating left atrial pressure. In 1970, a balloon-tipped flow-guided catheter technique was introduced by Swan and Ganz, making possible the use of the catheter outside the catheterization laboratory in intensive care units and operating rooms.⁵²

Monitoring of oxygenation, blood gases, and acid–base status

As related by John W. Severinghaus, respiratory physiology became important when World War II pilots trying to fly higher

than their enemies became hypoxic (without cabin pressurization), lost consciousness, and crashed. Physicist Glen Millikan (1906–1947) developed oximetry in 1940 as a pilot warning device, but the technology became practical only when pulse oximetry was introduced in approximately 1980. The polio epidemics drove the development of artificial ventilation, with the need for carbon dioxide analysis to guide the ventilation of a paralyzed patient. The mid-20th-century advances in the use of hypothermia and cardiopulmonary bypass necessitated frequent monitoring of oxygenation and acid–base status.⁵³

Severinghaus built a cuvette for the carbon dioxide electrode and mounted it in a 37°C water bath. His modifications of Stow's invention cut analysis time from an hour to two minutes. Clark had built a successful bubble-type blood oxygenator to perfuse livers.⁵⁴ To measure PO₂ in the oxygenator, he turned to polarography. In 1954, Clark made an electrically insulated polarographic sensor with cathode and reference electrode combined, permitting it to work in either air or liquid.

With Clark's approval, Severinghaus used his electrode and his modification of Stow's carbon dioxide electrodes in a blood gas analyzer. Severinghaus displayed the first blood PO₂ and PCO₂ analyzer at the fall American Society of Anesthesiologists meeting in 1957.⁵⁵ The addition of a pH electrode completed the modern arterial blood analysis device.

In the 1960s, with the advent of oxygen therapy and positive pressure ventilation of premature infants, it became apparent that excessive oxygenation was associated with blindness. Transcutaneous blood gas monitoring was developed primarily to avoid oxygen-induced retinopathy of prematurity. A skin surface oxygen electrode heated to 44°C accurately monitored PaO₂.⁵⁶ Severinghaus further developed a transcutaneous PCO₂ electrode⁵⁷ and combined oxygen and carbon dioxide electrodes under a single membrane.⁵⁸

Neuromuscular monitoring

At the time when d-tubocurarine (1942), alcuronium (1964), and pancuronium (1967) were the staple relaxants, Christie and Churchill-Davidson⁵⁹ and Katz⁶⁰ first popularized the use of peripheral nerve stimulation in the mid-1960s (the Block-Aid monitor) to evaluate neuromuscular function. This device applied a twitch (every four seconds) or tetanic stimulation (30 Hz on demand). These investigators popularized the observation and recording of adductor responses from the thumb, elicited via the ulnar nerve at the wrist.⁶⁰ Shortly thereafter, Ali and others (1971)⁶¹ introduced train-of-four (TOF) stimulation, and Lee (1975)⁶² further popularized this technique by quantifying and correlating depth of blockade (percent twitch inhibition) according to the TOF count.

The TOF technique has remained the most useful method of evaluation of neuromuscular function in clinical anesthesia practice for more than thirty years because of its simplicity and ease of evaluation and because the stimulus pattern creates its own internal standard each time the response is evaluated; that is, the strength of the fourth response is simply compared with

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that of the first without the need for establishment of a baseline prior to the administration of neuromuscular blocking drugs.⁶³

Safety-driven monitoring standards

As recounted by Ellison Pierce, the latest historical drivers of improvements in anesthesia monitoring were a combination of media attention to anesthetic deaths and a malpractice insurance rate crisis of the 1970s and 1980s.⁶⁴ The field of anesthesia safety research was advanced in 1978 with the publication of Jeffrey Cooper's first paper describing critical incident analysis applied to anesthesia.⁶⁵ Cooper stated, "Factors associated with anesthetists and/or factors that may have predisposed anesthetists to err have, with a few exceptions, not been previously analyzed. Furthermore, no study has focused on the process of error – its causes, the circumstances that surround it, or its association with specific procedures, devices, etc. – regardless of final outcome."

Data for this first critical incident technique study were obtained from 47 interviews of staff and resident anesthesiologists. In a follow-up paper published in 1984, the database was enlarged to include 139 practitioners and 1089 descriptions of preventable critical incidents.⁶⁶ Cooper proposed corrective strategies to lessen the likelihood of an incident occurring, including using appropriate monitoring instrumentation and vigilance.⁶⁷

Major mortality studies have come from the United Kingdom, where Lunn and associates established a confidential, anonymous system to report anesthesia deaths associated with surgery. Their initial report was published in 1982, and anesthesia was considered partly or totally causative of mortality in one or two cases per 10,000 and to be totally causative in nearly 1 per 10,000. Their monitoring-related findings were that large numbers of patients did not have blood pressure recorded intraoperatively and did not have intraoperative monitoring with the electrocardiogram.⁶⁸

The Closed Claims Project of the American Society of Anesthesiologists (ASA) found that adverse respiratory events constituted the single largest class of injury, some 35 percent of the total.⁶⁹ The first three mechanisms of adverse respiratory events were inadequate ventilation (38%), esophageal intubation (18%), and difficult intubation (17%), and the majority of respiratory claims were lodged before widespread adoption of pulse oximetry and capnography. The reviewers concluded that better monitoring would have prevented adverse outcomes in three-quarters of the respiratory claims, compared with only around 10 percent in the nonrespiratory cases.

There is indirect evidence that the advent of ASA basic monitoring standards has diminished the incidence of adverse respiratory events in anesthesia. Eichhorn reviewed 1 million anesthetics administered to ASA physical status 1 and 2 patients at the various Harvard hospitals between 1976 and 1985, and noted 11 major intraoperative anesthesia accidents (2 cardiac arrests, 4 cases of severe brain damage, and 5 deaths).⁷⁰ The most common cause (7 of 11) was an unrecognized lack of ven-

tilation. He concluded that these seven, as well as one other, in which oxygen was discontinued inadvertently, would have been prevented by "safety monitoring." Of the next 300,000 anesthetics after the institution of the Harvard capnography and pulse oximetry monitoring standards in 1985, there were no major preventable intraoperative anesthesia injuries.

The evidence-based monitoring standards and guidelines that emerged in the 1980s and 1990s have changed the practice of anesthesia and evolved over time. The ASA and peer organizations embraced evidence-based standards and practice parameters related to basic monitoring standards, transesophageal echocardiography, and pulmonary artery catheterization (<http://www.asahq.org/publicationsAndServices/sgstoc.htm>, accessed February 7, 2011).

In conclusion, the history of anesthesia monitoring is a fascinating prelude to the remainder of this text. A remarkable group of perioperative physicians who were dedicated to improving patient outcomes persevered to advance the specialty, despite resistance from peers who did not share their vision. The gradual advance in the quality and sophistication of instrumentation and the regression of clinician observations of physical signs is another theme that is remarked on by every chronicler of anesthesia history. The recent decades have also brought the rise of standards in monitoring practice. The history of anesthesia clearly shows how safer anesthesia practices have arisen through improved patient monitoring. The lesson to be taken from this chapter is that we still have the capacity for further improvements in perioperative patient safety, and that we will remember most clearly those perioperative physicians who advance that goal.

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Chapter

2

Medicolegal implications of monitoring

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Introduction

If you have never received a letter with the return address of an unknown law firm, consider yourself lucky. In the case of a malpractice proceeding, you will open the letter and typically find your name in a long list of defendants. Sometimes the letter is anticipated, but often, the precipitating events occurred so long ago that the details are difficult to recall.

Whatever the circumstances, a malpractice suit unleashes a sequence of events with an unpredictable outcome. The trial venue, the quality of the attorneys, the members of the jury, the expert witnesses involved, the ability of the plaintiff to engender sympathy, the perceived credibility of the defendant, and the quality of the documentation all play a role in the ultimate outcome. The plaintiff's attorney will leave no stone unturned in building the case for malpractice. Because physiologic monitoring is essential to safe patient care, the plaintiff's attorney is likely to scrutinize how the patient was monitored in building the case. The intent of this chapter is to explore the ways in which physiologic monitoring and exposure to malpractice liability are related. The intent is not to offer a comprehensive discussion of the nuances of malpractice liability. If you are named in a malpractice suit, there is no better resource than a skilled defense attorney.

In a chapter titled "Medical Liability and the Culture of Technology," Jacobsen argues, "The history of medical liability is a struggle between technological advances and injuries suffered when those advances fail."¹ He goes on to observe that technical advances empower physicians to tackle ever more complex and challenging medical problems with the attendant increased risks. In some cases, the outcome is a return to the previous state of health, but that is not always the case. The public, on the other hand, demands – and has come to expect – perfect outcomes. Although a physician may clearly understand that a less-than-perfect outcome is much better than even more severe disability or death, the patient perceives only the loss of his or her health. Physiologic monitoring has facilitated increasingly complex surgical procedures for sicker patients. Even the most confident clinician would be unlikely to attempt to provide anesthesia for liver transplantation using just a finger on the pulse. The most sophisticated monitoring, however, cannot prevent undesired outcomes in sick patients undergoing complex procedures and the resulting exposure to malpractice suits.

Although the proliferation of technology can increase the potential for malpractice liability, Jacobsen recognizes that the specialty of anesthesiology provides one example in which technology, and patient monitoring in particular, has actually reduced malpractice liability by reducing the risk of serious injury. For a number of years, anesthesiology ranked at the top of the medical specialties in malpractice claims and the severity of patient injury. In 1986, the Harvard Medical School Department of Anesthesia adopted a minimum standard for patient monitoring during anesthesia.² This standard included provisions for monitoring ventilation, preferably by capnography. Interestingly, pulse oximetry, which had only recently been introduced, was advocated as a means to monitor the circulation, not oxygenation. The primary goal of the Harvard standard was to improve patient safety by reducing adverse events, with a secondary goal of reducing malpractice claims. Malpractice insurance carriers became convinced of the value of these guidelines to mitigate malpractice exposure and, in an effort to catalyze more widespread adoption, offered to reduce premiums to practices that adhered to the monitoring guidelines. The result was a significant reduction in the number and severity of claims against anesthesiologists.³ A review of 1175 closed malpractice claims filed between 1974 and 1988 underscores the potential for physiologic monitoring to reduce malpractice claims. The reviewers determined that one-third of the injuries could have been prevented by the use of monitoring devices, most notably pulse oximetry and capnometry.⁴

Establishing monitoring standards was facilitated by the development of monitoring devices that were easy to use and cost-effective. The resulting outcome clearly established the relationship between physiologic monitoring and patient safety. The motivation for these efforts was to reduce the risk of patient injury. The financial realities of the malpractice system created the business case, as avoiding even one wrongful death or hypoxic injury suit would pay for multiple patient monitors.

Risk management strategies typically focus on adherence to the standard of care, the importance of documentation, and the patient–physician relationship. Monitoring patients appropriately reduces the risk of significant injury and is therefore an important part of risk management in anesthesia. As a result of the Harvard experience, the American Society of Anesthesiologists (ASA) established a standard for anesthetic monitoring.

Monitoring in Anesthesia and Perioperative Care

It is notable that the ASA has chosen to include the word “standard” in the title of this document, which establishes the content to indicate the standard of care.* As we will see, this monitoring standard is the most unambiguous evidence that can be presented in court for the standard of care because it does not require the opinion of an expert witness. Furthermore, there is good evidence from the ASA closed-claims database that when adherence to a standard of care can be demonstrated, there is a reduced chance of payment for a malpractice claim.⁵ To better understand the importance of the standard of care, consider the elements of proof that are required in a malpractice proceeding.

Burden of proof

Although the outcome of a malpractice suit can sometimes seem capricious, the burden of proof that must be satisfied by the plaintiff’s attorney is well defined. Understanding the burden of proof is a useful foundation for evaluating the role of any aspect of care that is used to build a case for malpractice.

In the broad sense, health care malpractice liability arises from five areas of exposure:⁶

- Professional negligence (substandard care delivery)
- Intentional misconduct
- Breach of a therapeutic promise (breach of contract)
- Patient injury from dangerous treatment-related activities, regardless of fault (strict liability)
- Patient injury from dangerous devices (product liability)

Of these areas of exposure, professional negligence is the most common basis for suit against an individual health care provider. Most of the discussion in this chapter focuses on the role of physiologic monitoring in establishing a case for negligence against a health care provider. Physiologic monitors can be involved in a suit related to strict or product liability. In the latter case, the liability suit would typically be directed toward the manufacturer, and debate would ensue about whether it was the device or failure to use it correctly that caused the injury.

Negligence is defined as “conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.”⁷ When professional negligence is considered, the “standard” by which the care is measured is considered to be the minimally acceptable practice. Practitioners accused of negligence in a malpractice case are judged not by the standard set by the most skilled practitioner, but by the standard set by an ordinary practitioner under usual circumstances. The role of the expert witness is therefore to articulate not how he or she personally would have treated the patient, but what is generally considered to be the minimal safe practice standard. Different rules can be applied to defining the

minimal safe practice standard. In some cases, the professional is held to the standard in his or her geographic practice area so, for example, a rural physician in a community hospital is not held to the same standard as a physician with the resources of a tertiary-care urban hospital. For individual specialties, the standard could be applied to a reasonably prudent professional in the same specialty.

Negligent acts can be acts of commission or omission. In the former case, the liable party must *do* something that, under similar circumstances, a reasonably prudent professional would have done differently or not at all. An act of omission is the *failure to do* something that a reasonably prudent professional would have done under the same circumstances. An act of commission in patient monitoring, for example, would involve using a monitoring device that exposes a patient to injury when using that device would not be considered standard of care. An act of omission in patient monitoring would involve failing to use a monitoring modality that is considered the minimal safe practice. The terminology “reasonably prudent professional” is an attempt to create an objective standard for evaluating a person’s actions. In the case of an anesthesia provider, the “reasonably prudent” definition would indicate an individual who is trained and licensed in accordance with applicable laws and professional standards.

The failure to follow indicated monitoring standards is not in itself sufficient proof of negligence. The plaintiff’s attorney has the burden to prove the following four elements:⁸

- The professional had a duty to care for the patient.
- The professional breached the duty to care for the patient by providing substandard care.
- The injury suffered by the patient was caused by the breach of duty.
- The damages to the patient are compensable.

Of these four elements, the second and third can be related to the manner in which a physiologic monitor is used. Using a device that may cause injury when the device is not indicated, or failing to use a device when it is indicated, are examples of substandard care absent a compelling explanation by the provider. Other examples would include pulmonary artery rupture from placing a pulmonary artery catheter that is not indicated, or hypoxic injury when a pulse oximeter is not used.

The burden of proof also requires that the injury suffered by the patient be related to the breach of duty to provide care consistent with the prevailing standard. In the strictest definition, one would need to establish a clear link between the aspect(s) of the care that are substandard and the injury suffered by the plaintiff. Given the uncertainties of medicine, it is not always possible to establish direct causation for a particular injury. The plaintiff’s attorney may argue that breach of duty need not be proven based on the principle of *res ipsa loquitur*, or “the thing speaks for itself.” This burden of proof is not as rigorous as in the case of strict professional negligence, as a causative link between the care lapse and the injury is not required. To argue

* The ASA also issues “Guidelines” and “Statements” that are intended to provide information about practice decisions but are not considered a standard of care. The distinction is important in a malpractice proceeding. For more information, see <http://www.asahq.org/publicationsAndServices/sgstoc.htm>.