

## CHAPTER 2

## Patient Safety and Outcomes

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In 1885, Corning described epidural anesthesia, while August Bier introduced intrathecal (spinal) anesthesia. The introduction of various types of local anesthetic drugs with different durations of action and better spinal and epidural needles led to the development of regional anesthesia as a specialty.

Anesthesiology began evolving as a specialty among physicians in the early part of the 20th century and led to the formation of professional societies. The first organization in America was the Long Island Society of Anesthetists, formed in 1905. This organization later became the New York Society of Anesthetists and subsequently became the American Society of Anesthesiologists (ASA). Francis Hoeffler McMechan founded the International Anesthesia Research Society (IARS), which together with the ASA are the premier American organizations in anesthesiology today. After World War II, specialties within anesthesia began to thrive, and pediatric, obstetric, pain, critical care, vascular, cardiac, thoracic and other distinct fields continue to evolve.

The story about the development of the field of anesthesiology is incomplete without mentioning the immense work of former ASA President Ellison “Jeep” Pierce and the ASA leadership (1984) in championing the cause of patient safety. The mortality attributed to anesthesia has seen a dramatic decrease from 1:2,680 in the 1950s to 1:200,000 in the 1990s. Evidence is accumulating that anesthesiologists are experiencing the greatest decline in the incidence of medical liability claims of any specialty, according to the Anesthesia Patient Safety Foundation.

The art and science of anesthesiology continues to grow and evolve. We are continually challenged with advances in technology, by our own drive to make anesthesia safer than ever, and to make the perioperative experience better for our patients. Anesthesiologists today are involved in diverse areas such as molecular biology, tissue engineering, novel drug delivery techniques, nanotechnology and functional imaging research. We are pioneers in incorporating simulators as a tool for education and fostering safe practices. We are also in the forefront in studying and integrating complementary and alternative medical practices into the mainstream of medicine.

We have come a long way, but we still have a long road ahead in our quest to make the perioperative experience a safe and pleasant one for our patients. We have some answers, but there are still a lot of questions that need to be answered by painstaking research. This is an exciting and challenging phase in the growth of this specialty and all associated with it!

## References:

1. Smith HM, Bacon DR. The History of Anesthesia, Clinical Anesthesia. Edited by Barash PG, Cullen BF, Stoelting RK. Philadelphia, LWW; 2006:3-26.
2. Stoelting RK. A historical review of the origin and contributions of the Anesthesia Patient Safety Foundation. *ASA Newsletter*. 2005:25-27.
3. Wetchler BV. Ellison C. Pierce, Jr., M.D., to receive ASA's highest honor. *ASA Newsletter*. 1997;61(10):21.

The specialty of anesthesiology has been lauded as one in which safety has always been of paramount importance. In the landmark Institute of Medicine report, *To Err is Human*, anesthesiology was cited as the specialty to emulate with respect to improving safety. The first study of anesthetic safety (and risk) occurred shortly after the first report of the delivery of anesthesia for an operative procedure in 1846. Subsequently, Ruth et al. helped to establish the first anesthesia study commission to analyze perioperative deaths in 1935.<sup>1</sup> They relied on voluntary submission of cases and determined the cause of death by majority vote. This was followed by a report by Beecher and Todd of anesthetic death in 10 institutions, published in 1954.<sup>2</sup> The cause of mortality was determined at the local institution by a consensus reached between a surgeon and the chief anesthesiologist. Overall, the chance of mortality was 1:75 cases. They reported that anesthesia was the primary cause of mortality in 1:2,680 cases, and was either the primary or contributory cause of mortality in 1:1,560 cases. Surgical error in diagnosis, judgement or technique was the primary cause of death in 1:420 cases, while patient disease was the primary cause in 1:95 cases. Over the past five decades, most anesthesiologists believe that anesthetic risk has decreased.

The importance of perioperative mortality in England led to the development of the Confidential Enquiry into Perioperative Deaths (CEPOD), which assessed nearly a million cases of anesthesia during a one-year period in 1982.<sup>3,4</sup> Deaths within 30 days of surgery were included in the study. There were 4,034 deaths in an estimated 485,850 operations, resulting in a crude mortality rate of 0.7 to 0.8 percent. Surgery had contributed totally or partially in 30 percent of all patients. Progression of the presenting disease had contributed to death in 67.5 percent of all patients, with progress of an intercurrent disease being relevant in 44.3 percent of patients. Anesthesia was considered the sole cause of death in only three individuals, for a rate of 1:185,000 cases, and anesthesia was contributory in 410 deaths, for a rate of 7:10,000.

The accumulating data clearly demonstrate that risk directly attributable to anesthesia has declined over time. The etiology for this reduction in mortality is unclear. Numerous factors have been implicated in the improved outcome, including new monitoring modalities, new anesthetic drugs and the changes in the anesthesia workforce. However, it is difficult to document reduced risk related to any one factor. Interestingly, although newer monitoring

modalities, particularly pulse oximetry, would be expected to lead to improved outcomes, no randomized trial has been able to document such a conclusion.<sup>5</sup>

Studies similar to the CEPOD study have not been performed in the United States, most likely because of the legal system. Therefore, information related to perioperative mortality had to be obtained from other sources. This basic concept led to the formation of the American Society of Anesthesiologists Closed Claim Study. The Committee on Professional Liability of the American Society of Anesthesiologists conducted a nationwide survey of closed insurance claims for major anesthetic mishaps. Both fatal and nonfatal outcomes were reviewed and a series of landmark papers discussing both the potential etiology and treatment of morbidity and mortality were also studied. For example, cases involving unexpected cardiac arrest during spinal anesthesia were observed in 14 healthy patients from the initial 900 claims.<sup>6</sup> Two patterns were identified: oversedation leading to respiratory insufficiency and inappropriate resuscitation of high spinal sympathetic blockade which led to general recommendations for perioperative care.

### Improving Anesthesia Safety

Over the past several decades there have been numerous major initiatives to improve the safety of anesthesia. In 1984, Cooper, Kitz and Ellison hosted the first International Symposium on Preventable Anesthesia Mortality and Morbidity (ISPAMM) in Boston. Approximately 50 anesthesiologists attended the meeting from around the world and, after much debate, established a series of definitions of outcome, morbidity, and mortality. Such meetings have been held every two years since the first symposium.

The Anesthesia Patient Safety Foundation (APSF) was established as a result of the Boston meeting. The society has been active in publishing widely-circulated newsletters and awarding annual grants. Similar societies have now been established in countries outside the United States, and a National Patient Safety Foundation has also been created based on the APSF model.

Starting with the American Society of Anesthesiologists Closed Claims Study, there has been a great deal of interest in establishing guidelines for best and safest practice. Practice policies or guidelines are the summation by clinicians of the available evidence about the benefits and risks of a treatment plan. Guidelines are a method of codifying recommendations regarding the use of a given technology. There are several types of recommendations that fall into the general category of a practice parameter. A standard implies that a therapy or practice should be performed on patients with a particular condition. Standards are only approved if an assessment of the probabilities and utilities of the group indicates that the decision to choose the treatment or a strategy would be virtually unanimous. If a particular therapy or strategy is considered standard, it is cost-effective for those to whom it is being recommended. Standards are intended to



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be applied rigidly. The American Society of Anesthesiologists has established Standards for Intraoperative Monitoring, which was developed from safety guidelines adopted at the Harvard hospital system. Guidelines are intended to be more flexible than standards, but should be followed in most cases. Depending on the patient, setting, and other factors, guidelines can and should be tailored to fit individual needs. Like standards, guidelines should be cost-effective. There have been a number of guidelines adopted by the American Society of Anesthesiologists for diverse issues such as the difficult airway, use of pulmonary artery catheter, and use of blood components. The goal is to define the evidence upon which optimal practice can be based.

Finally, there is a great deal of interest in the use of anesthesia simulators to train and test individuals and their ability to react to simulated crises. Standardized scenarios have been developed upon which comparisons between individuals can be made. Current research is ongoing to determine how best to utilize this technology in anesthesia training and potentially in recertification.

### References:

1. Ruth HS. Anesthesia study commissions. *JAMA*. 1945;127:514.
2. Beecher HK, Todd DP. A study of deaths associated with anesthesia and surgery. *Ann Surg*. 1954;140:2-34.
3. Lunn JN, Devlin HB. Lessons from the confidential enquiry into perioperative deaths in three NHS regions. *Lancet*. 1987;2:1384-6.
4. Buck N, Devlin HB, Lunn JL. Report of a confidential enquiry into perioperative deaths. London: The King's Fund Publishing House; 1987.
5. Moller JT, Svernilid I, Johannessen NW, Jensen PF, Espersen K, Gravenstein JS, Cooper JB, Djernes M, Johansen SH. Perioperative monitoring with pulse oximetry and late postoperative cognitive dysfunction. *Br J Anaesth*. 1993;71:340-7.
6. Caplan RA, Ward RJ, Posner K, Cheney FW. Unexpected cardiac arrest during spinal anesthesia: a closed claims analysis of predisposing factors. *Anesthesiology*. 1988;68:5-11.