Chapter 31

Quality Assurance, Patient and Provider Safety

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For maximum impact, it is recommended that the case study and questions found on page xxxiii are reviewed before reading this chapter.

Key Learning Objectives

- Learn about the need for and history of patient safety
- Discuss anesthesia-related patient safety data
- Understand national initiatives to improve patient safety

Anesthesiologists are responsible for taking their patients safely through the stresses of surgery, while preserving and protecting their vital functions. They become the **advocates for the anesthetized patient**, who has been rendered unconscious. Patient safety is of utmost concern, and the field of anesthesiology has long been recognized as a leader in patient safety efforts.

The History of Patient Safety

In its early days, anesthesia was perceived to have a high risk of mortality, and medical liability insurance premiums reflected this perception. However, a concerted effort led by the American Society of Anesthesiologists (ASA), in collaboration with a number of other groups, has resulted in paying greater attention to patient safety and the issues of preventable adverse outcomes. The Anesthesia Patient Safety Foundation was formed in 1985 with the vision that "no patient shall be harmed by anesthesia", and has been a champion for patient

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safety ever since. Significant advances in monitoring during anesthesia, such as pulse oximetry, have subsequently been responsible for a decline in adverse events.

Quality Assurance

Quality has been described in literature as the product of two factors: the science and technology of health care and the actual application of that science and technology in practice. Quality assurance (QA) refers to the process of determining whether patient services meet or exceed expected standard. QA helps maximize the quality of patient care, so that all patients receive the care they deserve.

In the United States, there is room for improvement in the quality of health care. Although the US spends nearly $2.4 trillion a year on medical care (the most money of all advanced industrialized countries), we still trail some industrialized nations when it comes to many measures of health care quality.

Health care quality and patient safety go hand-in-hand. Issues around safety in healthcare were brought to the forefront of public attention in 1999 with the publication of the Institute of Medicine's report entitled "*To Err is Human.*" This widely publicized report estimated that medical errors occur in approximately 7 % of all patients, and that between 44,000 and 98,000 deaths occur annually in the US as a result of medical error. This is almost three times the fatality rate on US highways.

While a number of external organizations such as the Joint Commission (formerly known as JCAHO) and state licensing boards evaluate health care quality, the primary responsibility for patient safety and quality of health care provision rests upon anesthesia providers.

The ASA Closed Claims Study

The ASA Closed Claims Study, which began in 1985, has played an important role in the identification of anesthesia-related adverse events. This project is an ongoing, detailed analysis of closed anesthesia liability claims to identify significant patterns of injury. The current database contains over 7,700 cases, and the majority of cases are from 1980 to 2001. Most cases involve healthy adults undergoing nonemergency surgery under general anesthesia. These data provide an important opportunity to identify how anesthesia care contributes to adverse outcomes, since outcomes are not confounded by disease processes.

Table 31.1 ASA Closed Claims Study – most common adverse outcomes

Adverse outcome (N = 7,740)	% of claims	Median payment ($)	Range of payment ($)
Death	29	338,000	353–17,934,000
Nerve damage	19	92,650	394–10,716,000
Permanent brain damage	10	1,216,950	5,950–35,960,000
Airway trauma	7	72,000	34–2,115,000
Eye damage	4	97,600	37–3,335,000
Injury to newborn	3	667,069	3,966–15,822,000
Stroke	3	301,250	7,050–24,966,195
Pneumothorax	3	62,900	465–13,950,000
Back pain	3	26,400	2,240–1,782,500
Headache	3	18,300	884–874,500
Aspiration pneumonitis	3	301,750	573–3,450,000
Myocardial infarction	2	218,000	7,600–1,810,500
Burn, thermal	2	49,995	5,025–844,800
Skin reaction	2	21,788	488–727,500
Awareness	1	37,463	1,940–846,000
Meningitis	1	101,219	4,608–873,000

Table 31.1 shows the most common adverse outcomes listed in the ASA Closed Claims Database with corresponding lists ranges of payments for the claim. It is evident that adverse outcomes occur in groups in a small number of specific categories. More than half of all adverse outcomes are found in three categories: **death, nerve damage, and brain damage.** The significance of identifying these large groups of injuries is that research and interventions can be more effectively directed at a few large areas of clinical practice, potentially resulting in substantial improvements in patient safety. In the past, this technique was used successfully by the American Society of Anesthesiologists to focus attention on monitoring standards and specific guidelines for high-frequency adverse events, leading to the promulgation of the ASA Standards for Basic Anesthetic Monitoring (see next page).

The publication of guidelines by the ASA for managing issues with high rates of adverse outcomes has led to a significant decline in these adverse outcomes (Table 31.2). For example, difficult airway management during induction of anesthesia has long been regarded as one of the most challenging issues

Table 31.2 ASA Standards for Basic Anesthetic Monitoring

Standard 1: Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care	
Standard 2: During all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature shall be continually evaluated	
Oxygenation	Oxygen analyzer for inspired gases
	Observation of the patient
	Pulse oximetry
Ventilation	Auscultation of breath sounds
	Observation of the patient
	Observation of the reservoir bag
	Capnography (carbon dioxide monitoring)
Circulation	Continuous ECG display
	Heart rate and BP recorded every 5 min
	Evaluation of circulation
	Auscultation of heart sounds
	Palpation of pulse
	Pulse plethysmography
	Pulse oximetry
	Intraarterial pressure tracing
Temperature	Monitor temperature when changes are intended, anticipated, or suspected

in anesthesia patient safety. However, an analysis of claims associated with difficult airway management during induction of anesthesia shows a marked, statistically significant decrease in the incidence of death and brain damage (62 % vs. 35 %, $p < 0.05$) in the period after the publication of the ASA Difficult Airway Algorithm (1993–1999), when compared with period before the publication of the airway guidelines (pre-1993). The ASA Difficult Airway Algorithm has been reproduced in Appendix A.

Challenges Facing the Anesthesia Provider

The operating room is a unique environment and presents challenges to even the most vigilant anesthesiologist. Environmental factors such as noise, multiple alarms, and continuous movement through the operating room of members of the team can all distract attention. Human factors like fatigue and sleep deprivation can also affect monitoring and cognitive tasks. In addition, with

the emphasis on enhanced productivity, "production pressure" may force errors and compromise patient safety.

Automated information systems that provide automated anesthesia record-keeping have become increasingly popular. They have been shown to be of great benefit in support of patient care and safety, and enhancement of clinical quality improvement programs. These systems are increasingly being implemented in various anesthesia departments to support a number of functions, including real-time clinical decision support.

Steps to Ensure High Quality Anesthesia Care and Patient Safety

In order to optimize patient safety and ensure high quality care, the following principles should be taken into consideration by the anesthesia practitioner.

1. *Make patient safety a priority.* Be an advocate for your patient, always.
2. *Thorough planning.* Follow the Boy Scout motto of "Be Prepared." Practice meticulous preoperative planning, and formulate a plan for intraoperative as well as postoperative care. Have a back-up plan in mind. However, at times, it may not be possible to plan far ahead because of the unpredictable nature of the operating room environment. Even when under pressure, slow down, think things through rationally and clearly and formulate a plan of action.
3. *Vigilance.* Monitoring the patient involves not only electronic monitoring but also astute clinical observation. Chest rise, mucus membrane color, furrowing of the brow are just a few signs that can provide a wealth of information about the patient. Be aware of what is happening in the operating room at all times, and keep an eye on what's going on across the drapes. Listen out for indicators of potential problems like for the increasingly frequent sound of the suction catheter heralding an increase in blood loss.
4. *Teamwork* is essential for efficiency and excellence. Make a point to **introduce yourself** to the other members of the team, for it is through the collective efforts of the team striving together toward a common goal that high standards of patient care can be met.
5. *Detailed, accurate record keeping* is a medico-legal requirement. During "Adverse Events" there is often no time to fill out the chart, but do so later in spite of any emotional distress you may be feeling. Keep it brief, factual, and accurate. Remember, if something is not documented, it didn't happen.

6. *Postoperative patient checks* allow anesthesia providers to document the overall impact of the care they provide. This feedback is critical to understand the downstream effects of the clinical decisions made in the operating room.

Common Perioperative Complications

Dental Trauma

Dental injuries are a common complication during anesthesia and pose a significant cost. In a study of 598,904 cases at a large institution, it was found that approximately 1:4,500 patients who received anesthesia sustained a dental injury that required repair or extraction. Half of these injuries occurred during laryngoscopy and endotracheal intubation, and the teeth that were most commonly involved were the upper incisors. Obtaining a dental history and oral examination as part of the preoperative anesthesia assessment can alert one to those patients at high risk of dental injury. It is important to inquire about the presence of crowns, fixed partial dentures or bridges, and porcelain veneers, as teeth with dental work tend to be more fragile. Patients with poor dentition with risk factors for difficult intubation have the highest risk, however even sound teeth can be damaged. The use of mouthguards during intubation is controversial, as this may limit available space and make laryngoscopy more difficult. Being cognizant of the risk of dental injury with every laryngoscopy is the best means of prevention.

Eye Injury

Perioperative visual loss is an alarming complication of anesthesia, with the incidence ranging from 0.002 % of all surgeries (excluding eye surgeries) to 0.2 % of cardiac and spine surgeries. Anterior ischemic optic neuropathy (AION) occurs more commonly with cardiac surgery, while posterior ischemic optic neuropathy (PION) occurs in patients during spine and neck procedures. Patients present with bilateral visual loss upon awakening from anesthesia. The mechanism for perioperative visual loss is presumed to be ischemia, and risk factors include long duration in the prone position, excessive blood loss, hypotension, anemia, hypoxia, excessive fluid replacement, use of vasopressors, elevated venous pressure, head positioning, and a preexisting vascular susceptibility such as occurs in smokers and patients with diabetes mellitus. Awareness of these risk factors and interventions to minimize them can help limit the frequency of this dreadful complication.

Corneal abrasions are another minor but bothersome complication of anesthesia as they are extremely painful. These may be due to direct trauma to the eye, as can occur with carelessness during mask ventilation. More frequently, they occur due as exposure keratitis due to failure of the eyelids to close fully, resulting in drying of the cornea. Corneal abrasions can be prevented by taping the eyelids closed, or the use of paraffin-based ointments.

Peripheral Nerve Injuries

Peripheral nerve injuries can occur during regional or general anesthesia, and can have profound consequences for the patient from the resulting disability. Patient positioning is the usual cause of peripheral nerve injury, with ulnar neuropathy being the most common type of injury. Injuries may be due to external pressure or nonanatomical positioning, and may occur more frequently with old patients, thin patients, and patients with vasculopathies such as smokers and diabetics. When positioning, the head and neck should be kept in neutral position, the arms should not be extended more then 90° and should be supinated. Sand with shoulder abduction and lateral rotation should be minimized to prevent brachial plexus injury. Padding should also be used on pressure points. With meticulous attention to detail during positioning, the occurrence of these injuries can be minimized.

Intraoperative Recall

The problem of awareness during general anesthesia has received much public attention recently and is a prime concern with patients. Awareness has been shown to have a frequency of less than 1 in 500 general anesthetics, but the consequences in terms of patient distress are profound. The ASA advises specific interventions to help reduce the risk and impact of intraoperative awareness, beginning with the preoperative identification of risk factors. These include a prior episode of intraoperative awareness, a history of anticipated difficult intubation, receiving high doses of opioids for chronic pain, substance use/abuse, ASA status 4–5, and limited hemodynamic reserve. In addition, there are certain surgical procedures with an increased risk of intraoperative awareness, such as cardiac, trauma, emergency, and cesarean sections. Some anesthetic techniques can also increase the risk of intraoperative recall, such as using a low MAC of anesthetic or total intravenous anesthesia in the presence of paralysis. The use of brain function monitors for the assessment of the depth of anesthesia has enjoyed increasing popularity, but studies about the actual effectiveness in reducing incidence of awareness remain ongoing.

The Future

The growing burden of healthcare costs has resulted in an increased pressure on anesthesiologists to improve the quality and safety of healthcare in a cost-effective manner. It is recognized that adherence to evidence-based practices may improve outcomes. Evidence-based practice also provides an opportunity for decreasing health care costs by minimizing expensive, preventable complications. Various initiatives have also been instituted as a means of improving quality at lower costs. The Leapfrog Group, which is a consortium of large corporations concerned with improving the "value of the health care dollar," has a website "dashboard" which shows how well hospitals are progressing in implementing various quality "leaps," such as rapid response teams and intensivist staffing of ICUs.

Pay-for-Performance

The pay-for-performance concept uses a variety of incentives to encourage delivery of evidence-based practices. It is also a vehicle to promote better patient outcomes as efficiently as possible. In 2006, the Institute of Medicine (IOM) put forward a statement on pay-for-performance, defining which practices should be rewarded, and how they should be implemented. The IOM recommended that rewards be given for high quality clinical care and to those providers who communicate well with patients and coordinate care effectively. Pay-for-performance programs ultimately reward health care that is of high clinical quality, patient-centered, and lower cost. For anesthesia providers, some specific metrics might include on-time antibiotic administration and maintenance of intraoperative normothermia.

Medicare

The Centers for Medicare and Medicaid Services (CMS) have recently implemented a program, where hospitals are evaluated on their performance in multiple clinical areas. These hospitals will be given financial incentives where the top 10 % performing centers would receive a 2 % bonus, the second 10 % would receive a 1 % bonus, and the bottom 30 % would suffer a 2 % decrease in payments in year 3 of the program. Current programs include the Medicare's Physician Quality Reporting Initiative (PQRI) through which hospitals are eligible for a 1.5 % bonus on Medicare cases for 80 % compliance in the appropriate timing of prophylactic antibiotics.

With these measures in place, quality assurance, and patient safety have become mandated areas of focus for anesthesia providers. It is important to remember, however, that the ultimate responsibility to ensure that our patients receive the best care lies with each of us.

Case Study

An anxious 48-year-old patient is in the preoperative holding area awaiting outpatient surgery under general anesthesia. With her is her husband, an expert on risk assessment in nonmedical industries, and her father, a retired surgeon in his late 1970s. She is anxious because her father has told her stories of surgery in the 1950s and 1960s, when he remembers significant numbers of patients dying or suffering significant morbidity. Her husband has worked in aviation, industrial process design, and is a "six sigma black belt." All three acknowledge your assurance that the practice of anesthesia is remarkably safer now, but ask you to explain some of the safety advances that characterize anesthesiology today and explain the improvements.

You have just finished setting up the operating room for this case. What safety features of the modern anesthesia machine can you point to in reassuring the patient and her family?

There are quite a few features of a modern anesthesia machine, even those that do not have the most recent electronic controls built in. These include:

- Safety indexed gas lines
- Pin indexed cylinder connectors
- Failsafe valve
- Minimum oxygen flow whenever machine is on
- Knurled flowmeter knobs with standardized textures and positions on the machine
- Oxygen always rightmost in sequence of gas flowmeters to guard against upstream leaks
- Built-in inspired oxygen monitors and alarms
- Low pressure (disconnect) alarm
- All vaporizers standardized to clockwise-off
- Safety fillers for vaporizers
- Vaporizer interlock to prevent multiple agent administration
- Standardized machine checkout, either manual or automatic, before each case

What are some of the monitoring developments since the 1950s that have improved safety?

Numerous monitors have been added to the manual blood pressure cuff and finger on the pulse of the mid-twentieth century. Electrocardiography, automatic blood pressure monitoring with alarms, pulse oximetry, capnography, agent and inspired gas monitoring, neuromuscular blockade monitoring, and consciousness monitoring are all routinely found in the modern OR. Interestingly, although without a doubt the introduction of these monitors paralleled the decline in anesthesia-related mortality and morbidity, it has been difficult to prove a causal relationship. For example, a large meta-analysis of randomized trials of pulse oximetry showed that it reliably detected episodes of hypoxemia but did not affect postoperative outcomes! One explanation for this paradox is the concept of "learning contamination bias," which means that anesthesiologists have learned so much from the use of the monitor that even when it is absent, they employ tactics that prevent episodes of hypoxia. Examples include preoxygenation, use of oxygen during transport to the PACU, and use of high-flow oxygen when discontinuing nitrous oxide administration.

What drug-related advances and procedures have you employed that have enhanced safety?

The use of standardized color-coded drug labels and the use of standardized concentrations of drugs are two practices that help reduce drug errors. Anesthesiologists also have learned from human performance studies to use safe practices such as "3 looks" when drawing up medications (before drawing, during drawing, after complete before setting down the vial) or positioning drugs in a standardized way on the anesthesia cart. Development of shorter acting drugs (fentanyl and derivatives, low solubility and minimally biotransformed inhalation agents) and drugs with a greater margin of safety between therapeutic and toxic doses have also helped. Other practices include checking blood with two people, pharmacy-mixed drug infusions, computerized infusions pumps with safety programs to limit errors in setting, and in some settings bar codes to verify drug identity.

What communication procedures will you employ that enhance safety?
In nearly every US operating room, the Joint Commission "safety pause" or "time-out" is performed prior to incision, in which the anesthesiologist, surgeon, and circulating nurse (and sometimes the patient) verbally state and agree on the planned procedure. An advancement of this idea is the WHO surgical safety checklist, which adds such practices as "once around the room" checks with all personnel regarding potential concerns. We also have standardized record keeping in the OR, whether manual or electronic and automated, and practice provider-to-provider anesthesia handoff procedures and standardized handoffs in PACU or ICU.

What other safety procedures are routine for all anesthetics in modern practice?
Anesthesiologists note and ensure pressure point and eye protection, assessment of the airway and teeth prior to and following induction, and in some settings temperature, radiation, or laser protection. A key development in the last half-century has been the simple presence of qualified anesthesia personnel in the OR at all times.

The patient's husband asks if anesthesia is "six sigma?"
Six sigma is a term first coined in industrial process improvement by Motorola. It subsequently spread to many other industries and certification as an expert, or "black belt" is possible from several organizations. The term applies to industrial processes achieving a defect or failure rate of less than 3–4 per million (which is not, ironically, the same as six standard deviations or "sigma" from the mean but is commonly accepted as the working definition of the term). Motorola pioneered a single-minded attention to quality improvement in the late 1980s and claimed to have achieved this level of quality in many of its manufacturing processes, saving tens of billions of dollars in the act. Virtually no process in medicine even approaches this level of quality but anesthesiology has likely come the closest, at least when defined as anesthesia-related mortality. In the 1940–1950s, Beecher and Todd estimated anesthesia mortality to be about 1 in 2500; by the 1980s, Eichhorn estimated it to be 1 in 200,000, which is fairly close to the six sigma target. However, others have cautioned that other methodologies put the number at 1 in 46,000. So the answer must be a qualified "maybe" or perhaps "probably" and only vigilant efforts to continue to drive the number toward zero by anesthesia professionals can ensure that the field can earn such an honor.

Suggested Further Reading

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