Patient Safety 2003: What Have We Learned? Where Are We Going? The OR, the ICU, and Beyond

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By the end of the lecture, the participant will be able to:

- Know the origin and strategy of the American Society of Anesthesiologists (ASA) Closed Claims database.
- List the most common adverse outcomes in the operating room (OR).
- Recognize the clusters of adverse outcomes identified by the database.
- Understand adverse factors associated with perioperative nerve injury.
- Explore factors specifically associated with ulnar nerve injuries.
- Recognize perioperative safety practices and the recommendations of AHRQ.
- Become familiar with concepts related to High-Reliability Organizations (HRO).

Primum Non Nocere

Hippocrates noted this admonition in Epidemics, Book I, Second Constitution: "to do good or to do no harm." Similarly, the Institute of Medicine (IOM) defined safety as "freedom from accidental injury." The essence of patient safety is just that: to do no harm. However, as health care becomes more complex, the opportunity for error and injury increases. This complexity, combined with the fallibility of human performance, results in unexpected, serious, or even fatal untoward medical incidents. These occurrences complicate the care of hospitalized patients in general, and surgical patients in particular. Until recently, medical personnel and health care administrators were reluctant to fully acknowledge this situation, thereby failing to capitalize on significant opportunities for improvement by utilizing experience from other industries, as well as the unique experience and perspective of the Anesthesia Patient Safety Foundation (APSF). For instance, anesthesiology is acknowledged as the leading medical specialty in addressing issues of patient safety in the operating room (1,2). Why? In part, clinicians working in anesthesiology tend to be risk-averse and focused on patient safety, as anesthesia is without therapeutic benefit of its own.

This lecture will explore current concepts of patient safety in the perioperative setting, focusing on the operating room and associated patient care areas. We will explore strategies to minimize risk in critical components of care identified by epidemiological studies such as the ASA Closed Claims database. One of the concerns identified in this database is the increasing percentage of claims made regarding nerve injury. We will therefore explore perioperative ulnar neuropathy in detail to illustrate relevant issues. Furthermore, the Institute of Medicine (IOM) has awakened all of medicine, the public, and the politicians to the issue of medical mistakes and their consequences. Specific examples will illustrate the chain of events that often lead to accidents (Normal Accident Theory). In addition, current recommendations by the Agency for Healthcare Quality and Research (AHRQ) will be summarized and discussed. Last, concepts of resource management utilized in other high-risk endeavors (such as nuclear power and the aviation industry) will be introduced by examination of strategies used in high-risk organizations (HRO).

The Problem

"Hospital care is not very good…You're likely to get sicker or more injured by mistakes made by poorly trained or overworked staff." Is this a comment about medical care from the nineteenth century? Sadly, no. One-half of Americans surveyed by The National Coalition on Health Care agreed with this statement in 1998 (3). Indeed, the majority of Americans no longer have complete confidence in hospital care (3). Are these concerns justified? As noted in the Institute of Medicine (IOM) report (4), almost 4% of hospitalized patients in New York suffered an adverse event in 1984. If these numbers are extrapolated to the country as a whole, up to one million patients are injured in hospitals each year, resulting in >100,000 deaths annually (4,5). However, these data are open to substantial debate both in terms of attribution of causality, and the fact that many of these patients are already very ill and likely to die anyway (6,7). Nonetheless, by any account, the incidence of injury and death attributable to apparently preventable aspects of care (including outright "errors") is a large number that demands attention. The figures exceed or even dwarf the rates of death and injury from other causes of prominent concern to the public. For instance, in 1984 (the same year as the data from the original medical error studies) there were only 52 fatalities in 8 fatal accidents in commercial aviation in the US (major and commuter airlines).

ASA Closed Claims Data Base

The Committee on Professional Liability of the American Society of Anesthesiologists initiated the closed claims study in 1985 (8). The closed claims files of 35 medical insurers (providing coverage for 0.50% of anesthesiologists in the US) currently contain >5480 cases. The safety strategy of analyzing closed malpractice claims utilizes only a small fraction of the total events that occur, but attempts to glean the maximal amount of information from each incident (8). In addition, the data involves a large group of patients that are NOT severely compromised medically so that important insights are available into how the process of care contributes to adverse events of typical patients. The types of adverse outcomes and demographics show tight clustering, and are outlined in Tables 1 and 2. Note that just three categories account for nearly two-thirds of all adverse outcomes: death, nerve injury, and brain damage. The mechanisms for these adverse outcomes are largely related to three categories: respiratory events (26–30%), equipment problems (10%), and cardiovascular events (9%).

However, there are obvious limitations of this type of analysis as well. First, many injuries and probably all "near-misses" do not result in formal litigation or insurance claims. Indeed, we have no valid estimate of what the denominator (the total number of uneventful anesthetics administered during this same time period) should be for the events documented in the closed claims database. Second, the participating insurance companies cover only approximately half of US anesthesiologists (14,500); thus, many claims fall outside the information envelope. Third, the timing of closed claims means that the entry of data and its analysis will lag several years behind actual current practice trends. Nonetheless, some patterns are clear. There is a downward trend in the occurrence of claims for severe patient injury such as brain injury or death, whereas claims for injury to peripheral nerves and the spinal cord are increasing. Therefore, we will therefore explore recent insights and research into perioperative nerve injury.

Safety Issue: Perioperative Nerve Injury

Nerve injuries now represent the second largest class of adverse outcome (Table 1) in the ASA Closed Claims Study database (9,10). Note that just three peripheral nerve distributions (the ulnar nerve, the brachial plexus, and the lumbosacral roots) account for more than half of all nerve injury claims (Table 3) (10). However, spinal cord injuries were the leading cause of claims for nerve injury during the 1990s and had the largest median payment (>$250,000) of any nerve injury settlements (10).

Table 1. Types of Anesthesia Incidents

Adverse Outcome	Frequency (%)
Death	32
Nerve Injury	16
Brain Damage	12
Airway Trauma	6
Aspiration	2

Table 2. Patient Demographics

Demographic Variable	Percentage (%)
Age >18 yr	90
Nonemergency	73
ASA Status I–II	70
General Anesthesia	70
Male	41

Peripheral nerve injuries may result from a number of elements, including excessive pressure or compression, stretch (most peripheral nerves are intolerant of stretch beyond 10% of their normal length), ischemia (several reports suggest the ulnar nerve is more susceptible to ischemia than either the radial or median nerves), metabolic derangement, direct trauma or laceration of a nerve during surgery, and other, yet unknown factors (11). Although the true mechanism(s) of anesthesia-related neuropathy remain undefined, it is tempting to assume that external pressure on the ulnar nerve coursing within the rigid bony compartment of the superficial condylar groove at the elbow is the sole cause of perioperative ulnar nerve compression, ischemia, and neuropathy (12–14). Unfortunately, this unproven hypothesis regarding ulnar neuropathy sometimes leaps from medical theory to legal fact, where some plaintiffs presume that "but for negligence" ulnar nerve injury would not occur. In some nerve injury cases, a legal doctrine may be invoked, termed, res ipsa loquitur, or, "the thing speaks for itself." This shifts the burden of proof to the defendant to prove that he or she did NOT cause an event that resulted in the ulnar nerve injury. It fails to recognize, however, recent medical and neurological observations regarding ulnar neuropathy reviewed below.

Perioperative Ulnar Neuropathy

Ulnar neuropathy is the most common perioperative nerve injury, generating one-quarter to one-third of

Table 3. Nerve Injuries Associated with Anesthesia and Surgery

Injured Nerve	% Nerve Claims	% Male	% Female
Ulnar	28	75	23
Brachial plexus	20	40	58
Lumbosacral roots	16	29	71
Spinal cord	13	52	48
Sciatic	4		
Median	4	≈42	≈58
Radial	3		

nerve injury claims. These injuries may result in chronic pain, permanent disability, economic damages, and litigation (9,15). Only one claim in 20 identifies the proposed mechanism of nerve injury, and in over two-thirds of cases the ASA closed claim reviewers judged that the standard of care had been met. Indeed, in 27% of cases, ulnar nerve injury occurred despite the documentation of specific protective padding at the elbow. Nonetheless, payments for ulnar nerve damage still range from $2,000–$330,000 (9).

Neuropathies have been reported after general, regional, and monitored (MAC) anesthetics. Retrospective studies suggest perioperative ulnar neuropathy occurs as infrequently as 0.04% after noncardiac surgery, or as often as 33% after cardiac surgery (11). However, recent prospective data defines the incidence as 1:215 (0.5%) in adults undergoing noncardiac surgery (15,16). Numerous factors have been observed coincident with perioperative ulnar nerve injury, including induced or prolonged hypotension, automated blood pressure cuffs, subclinical diabetes or other unrecognized medical illness, local anesthetic toxicity, manipulations of the brachial plexus during cardiac surgery, and, of course, positioning during anesthesia (14). In addition, factors such as extremes of body habitus, prolonged hospitalization, and male sex are associated with increased risk of ulnar neuropathy (15). Furthermore, it is much more common for nerve damage to manifest itself perioperatively in nerves with chronic, subclinical dysfunction. This is termed the "double-crush" syndrome, which clinically implies that nerves with some pre-existing dysfunction are at much greater risk of injury (despite appropriate care) than normal, healthy nerves. Interestingly, most patients who develop ulnar neuropathy report symptoms 2–7 days after surgery (16). This supports our contention that ulnar neuropathy is most often caused by factors other than positioning and padding of extremities during surgery. Indeed, accumulating evidence suggests ulnar nerve injury can occur at any time during hospitalization, (16,17) and that it occurs with nearly equal incidence (0.2%; confidence interval, 0.02%–0.73%) in medical patients admitted to the hospital for several days (Table 4) (17).

Table 4. Incidence of Ulnar Neuropathy in Hospitalized Patients

	Surgical Patients (after 48 h)	Medical Patients (after 72 h)
Prospective incidence	7/1,502	2/986
Percent	0.0047	0.002

Investigations and Anesthetic Implications

Until recently, there was no consensus regarding such "simple" factors as positioning of the arm during anesthesia to minimize pressure applied to the ulnar nerve (18,19). Therefore, we studied arm positioning in normal, awake volunteers, where we found forearm position to be a robust and significant factor in determining pressure over the ulnar nerve (Fig. 1) (20). Supination minimized direct pressure exerted over the ulnar nerve, even when one accounted for (or perhaps because of) the fact that this position produces the least contact area between the ulnar nerve and the weight-bearing surface. Although supination minimized direct pressure, pronation of the forearm produced the largest pressure to the ulnar nerve. With the forearm in neutral orientation, pressure over the ulnar nerve actually decreased as the arm was abducted from 30° to 90°. Thus, we strongly endorse the current ASA Practice Advisory for upper extremity positioning, which recommends that arms be positioned to decrease pressure on the postcondylar groove (the ulnar groove). When the arms are tucked at the side, a neutral forearm position is recommended. When arms are abducted on arm boards, either supination or a neutral forearm position is acceptable (21).

We further characterized ulnar nerve response to various experimental stressors (stretch, pressure, and ischemia) in both men and women using alterations in current perception threshold (CPT) as a marker of ulnar nerve dysfunction. CPT analysis allowed us to differentiate nerve fibers subtypes and experimentally induced changes in nerve function (unmyelinated C fibers = slow, sympathetic pain; A-δ fibers = fast pain sensation; and A-β fibers = light touch). Across all subjects, nerve ischemia produced with an arm tourniquet instantly inhibited all three fiber subtypes. Conversely, ulnar nerve stretch was produced by flexion of the arm at the elbow to 110° and produced inhibition of only the C fibers. Last, direct pressure on the ulnar nerve inhibited both types of pain fibers (C and A-δ fibers) (Table 5) (22). This alteration in pain fiber function was 70% greater in males ($P = 0.003$) and is consistent with the three-fold greater frequency for perioperative ulnar nerve dysfunction reported in men (Table 3).

In a related study, we determined the onset of clinical paresthesia compared to the onset and severity of

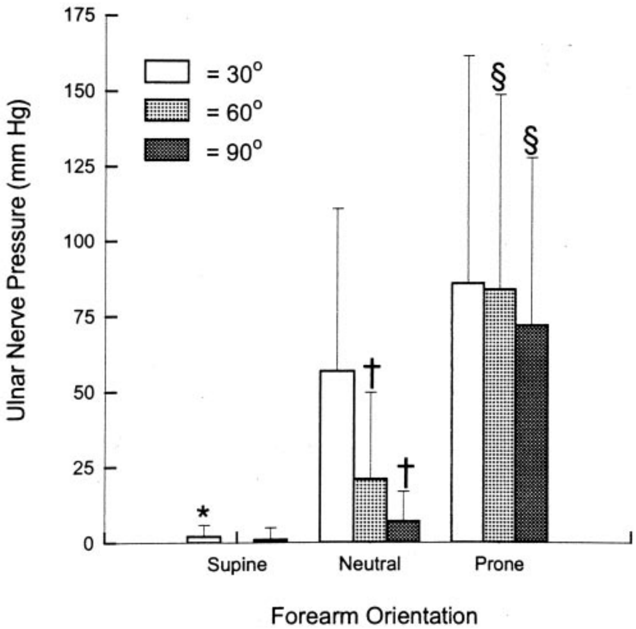

Figure 1. Plot of peak ulnar nerve pressure with the forearm in supination, pronation, or neutral (thumb up) orientation, concurrent with the arm abducted 30°, 60°, or 90° at the shoulder. *P < 0.01 comparing 90° abduction to both 30° and 60° abduction with the forearm in neutral orientation. In supination, the pressure over the ulnar nerve is uniformly low and most of the data are clustered around the zero line. (Reprinted with permission from Prielipp RC et al. Anesthesiol Clin North Am 2002;20:1–15.)

somatosensory evoked potential (SSEP) electrophysiologic changes. We studied a group of 16 male volunteers while applying intentional pressure directly to the ulnar nerve. Significant alterations in ulnar nerve SSEP signals were detected in 15 of 16 awake male volunteers in response to application of direct pressure to the ulnar nerve. Two of the 4 subjects with severe SSEP changes and 5 of 11 subjects with intermediate changes (total, 7 of 15) did not perceive a paresthesia, even as SSEP amplitude decreased between 23% and 72%. Extrapolation to the clinical setting would suggest that up to one-half of male patients who experience pressure on peripheral nerves (sufficient to precipitate electrophysiologic changes in nerve function) may be "at risk" because they do not perceive a concurrent paresthesia of that ulnar nerve. This data confirms that ulnar nerve compression and dysfunction can occur in the absence of perceived symptoms.

Thus, the real etiology of ulnar neuropathy may be prolonged periods of bed rest in the supine position (17,20). If one observes supine patients, they tend to flex their elbows naturally to a "resting angle" often greater than 90°. Figure 2 illustrates how this position tightens the cubital tunnel retinaculum and directly compresses the ulnar nerve at the elbow. Our recent CPT volunteer study also supports such a mechanism of injury, whereby extreme elbow flexion precipitates ulnar nerve pain fiber dysfunction. Why do males predominant in cases of ulnar nerve injury by a ratio of 3:1? (10) Part of the gender predisposition may be a result of anatomical differences of the elbow specific to males (23); for instance, the tubercle of the coronoid process is larger, and therefore the nerve and blood supply less protected by subcutaneous fat, than in women (Fig. 3).

Moreover, our data provide evidence that changes in ulnar nerve function can occur in the absence of clinical paresthesia in awake unsedated males. We believe the mechanism for this observation may be the greater alteration in pain fiber function of the ulnar nerve in men (compared with women) subjected to sustained flexion and pressure at the elbow.

Lower Extremity Neuropathies

Injury to nerves of the lower extremities may also be secondary to direct surgical trauma, central or lumbar plexus anesthetic blockade, compressive stockings and wraps, or problems with patient positioning devices. The incidence of lower extremity neuropathy is 1.5% (confidence interval, 0.8%–2.5%) in patients undergoing general anesthesia in lithotomy position (24). The frequency of lower extremity neuropathy increases after 2 h of lithotomy positioning (24). Nerve paresthesia occurs in the obturator, lateral femoral cutaneous, sciatic, and peroneal nerves, and (unlike ulnar neuropathy) is detected within 4 h surgery. The affected nerves rarely manifest motor dysfunction. Fortunately, symptoms usually resolve within 6 mo, with few permanent neuropathies or disability. Because the duration of the lithotomy position is a prominent risk factor, minimizing the duration of lithotomy position probably reduces the risk of these lower extremity nerve injuries. In addition, the ASA Task Force recommends avoidance of stretch of the hamstring muscle group beyond a "comfortable range," and padding to avoid pressure over the peroneal nerve at the fibular head (21).

A Broader View of Medical Mishaps: A Look at Accident Theories

Exploring the etiology of medical mishaps is neither simple nor straightforward. Thus, it is appropriate to examine accidents in systems designed and operated by humans. One theory of organizational safety is the called Normal Accidents Theory (NAT), which describes the complexity of a system and the tight coupling of interactions between its subsystems (25). Many medical authorities cite the theories of Professor James Reason (2,25) in this regard, noting that accidents are almost always the result of a chain of events and rarely happen as a single event or in isolation. This sequential theory of accident causation is sometimes explained by Reason's "Swiss cheese" model (Fig. 4), whereby accident triggers are normally interrupted by various

Table 5. Ulnar Nerve Function during Experimental Nerve Stress

Stimulating Frequency	Fiber Type	Fiber Function	Experimental Nerve Stress-Induced Changes		
			Stretch	Pressure	Ischemia
5 Hz	C	Slow pain	–	+	+
250 Hz	A-δ	Fast pain	–	+	+
2000 Hz	A-β	Light touch	–	–	+

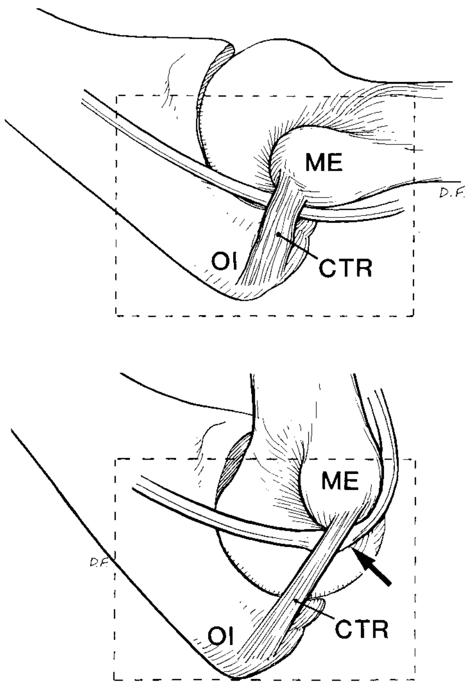

Figure 2. This figure illustrates how the cubital tunnel retinaculum is lax in extension (top frame, highlighted in dashed box), but becomes taut in flexion (bottom frame) causing compression of the ulnar nerve, denoted by the arrow. (Reprinted with permission from O'Driscoll SW, et al. J Bone Joint Surg (Br) 1991;73-B:613–7.)

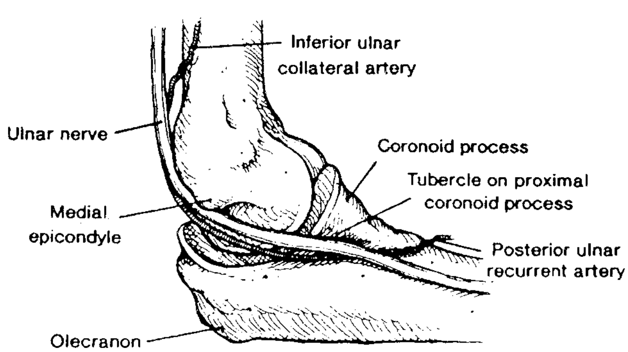

Figure 3. The ulnar nerve and its primary blood supply in the proximal forearm, the posterior ulnar recurrent artery, are very superficial and appear to be susceptible to compression from external pressure as they pass posteromedially to the tubercle of the coronoid process. (Reprinted with permission from Contreras MG, et al. Anesth Analg 1998;86:S164.)

safety barriers. Obviously, no accident barrier can be 100% perfect, so the system is still vulnerable to specific unforeseen sequence of events whereby certain

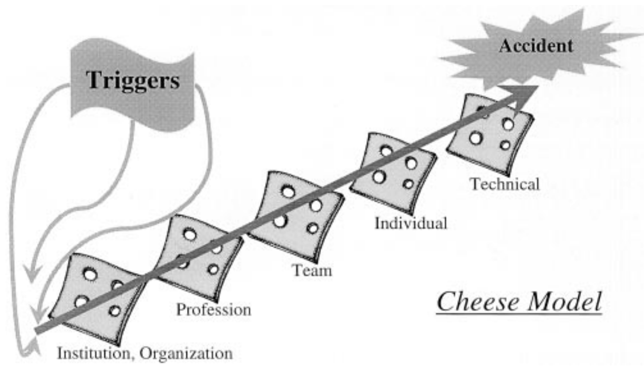

Figure 4. Graphic of James Reason's Swiss Cheese theory, a sequential theory of accident causation.

rare deficiencies (or holes) in the barriers align. Reason described four levels of such barriers, each one influencing the next: 1) organizational, 2) supervisory, 3) preconditions for unsafe acts (such as fatigue), and 4) the operators themselves. The consequences and results of such sequential failure are usually unanticipated and may be catastrophic. These models can be extremely helpful to analyze complex systems, and provide a framework to categorize patterns of failures.

Example: Ventilator Equipment Failure and an Institutional Response

This example has been summarized from the *APSF Newsletter* 1998:13(3):26 -7.

The Patient. A 41-yr-old, 90-kg male underwent uneventful aortic valve replacement surgery and was transported to the intensive care unit (ICU) with stable vital signs. He was placed on a Bourns Bear 2® ventilator after a standard circuit pressure check of the system. The ventilator settings were IMV = 8 breaths/min, tidal volume of 1000 mL, Fio$_2$ at 80%, and zero positive-end expiratory pressure.

Within 40 s of initiation of mechanical ventilation, acute hypotension developed (BP = 60/40 mm Hg). Urgent evaluation by the surgical house staff focused on a presumed bleeding source or possible cardiac or aortic valve complication; these people were unfamiliar with the Bourns Bear 2$^{0eg;}$ ventilator. Fortunately, evaluation by an experienced attending intensivist noted the needle of the proximal airway pressure gauge was increasing with each breath (without returning to zero during exhalation), as the ventilator was "stacking" each inspiratory breath one upon another. The patient was removed from the ventilator and hand ventilated with 100% Fio_2. Immediately after removal from the ventilator circuit, the patient's chest visibly decreased in diameter, with stabilization of his BP and peripheral perfusion.

The ventilator circuit was inspected, and the problem was identified as a faulty exhalation valve within the patient manifold assembly (Fig. 5). When the valve was disassembled, a 1-cm tear was found in the main body of the valve (Fig. 6). The exact age of this valve could not be determined, but this particular ventilator had not been utilized in the ICU (stored in a basement warehouse) for more than 9 mo. The exhalation valve on a Bear 2 tube ventilator is a mushroom-shaped, silastic membrane located in the patient manifold within the center of the expiratory limb. In this case, the disruption of the valve membrane caused initial expiratory gas in the ventilator circuit to distend the body of the valve, functionally creating an obstruction in the expiratory limb of the circuit. The ventilator therefore "stacked" each inspiratory breath one upon another, resulting in marked air trapping and hypotension.

The ventilator malfunction described above illustrates safety principles at the institutional level. Immediately after the incident, a multidisciplinary team of physicians, respiratory therapists, nurses, and hospital administrators met to review pertinent factors. Detailed analysis of this incident led to recognition of several important safety principles and revision of hospital and ICU policies. One recurring theme was the issue of aging equipment and the debate regarding labeling it "obsolete" and removing it from service versus placing such equipment in a backup mode to be utilized only when patient census and demands are at a peak. Although this practice extends the useful life of older generations of equipment in the ICU, we found it had unexpected consequences, as illustrated by this case. Although recycling medical equipment seems very efficient from a financial perspective, we now recognize that use of unfamiliar medical devices contributes to adverse events and errors in patient management. The APSF and others have long recognized the potential for problems when new equipment is inserted into service without complete staff training and education. This case illustrates that reintroduction of old equipment may manifest the same limitations and potential for adverse incidents and applies equally to the OR and to the ICU. Furthermore, we now recognize that although overt equipment problems are a relatively uncommon source of anesthesia mishaps in the OR (constituting only 14% of the total number of preventable accidents) (26), the situation is more common in the ICU. Others report that equipment problems may be the most common source of ICU adverse incidents.

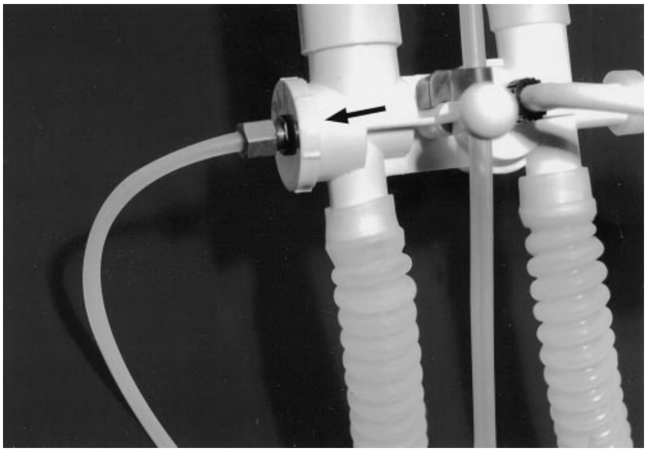

Figure 5. Patient manifold assembly of ventilator with arrow showing location of exhalation valve. (Reprinted with permission from Prielipp RC et al. APSF Newsletter 1998;13(3):26–7.)

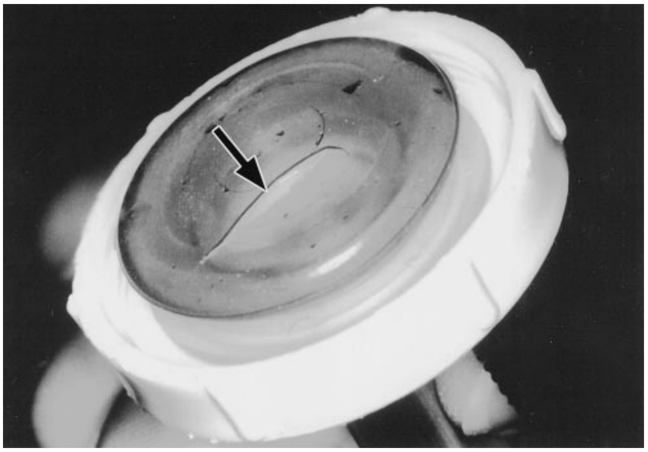

Figure 6. Close-up view of tear in main body of valve membrane. (Reprinted with permission from Prielipp RC et al. APSF Newsletter 1998;13(3):26–7.)

Safety Throughout the Hospital: The Institute of Medicine and AHRQ

Medical and public attention has increasingly focused on patient safety since the publication of the IOM (Institute of Medicine) report citing widespread (some say epidemic proportions) of patient injury and death while receiving medical care (4). The AHRQ, a component of the US Department of Health and Human Services, therefore published, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." This report is AHRQ publication 01-E058, and is available via their website (http://www.ahrq.gov/clinic/ptsafety/). A patient safety practice is defined as a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.

The exhaustive AHRQ evidence-based search identified 79 practices focused primarily on hospitalized patients, especially those in the ICU or undergoing surgery. The top 11 safety practices recommended by this report were rated most highly because of corroborating clinical evidence, and therefore the AHRQ advocates their widespread implementation:

- Regular venous thromboembolism prophylaxis for patients at risk.
- Use of perioperative β-blockers whenever possible.
- Routine use of maximal sterile barriers while placing central venous catheters.
- Appropriate use of antibiotic prophylaxis in surgical patients.
- Greater attention to the informed consent process, such as asking patients to recall and restate their understanding of the discussion.
- Continuous aspiration of subglottic secretions (CASS) to decrease the incidence of ventilator-associated pneumonia (VAP).
- Optimal use of pressure-relieving bedding materials to reduce pressure ulcers.
- Real-time ultrasound guidance during insertion of central venous catheters.
- Patient self-management for warfarin.
- Appropriate provision of early enteral nutrition for critically ill and surgical patients.
- Use of antibiotic-impregnated central venous catheters.

However, contrarian opinions exist. Dr. Lucian Leape et al. rebutted the AHRQ's requirement for scientifically vigorous, evidence-based safety interventions cited above. He opines that such a weighty standard overlooks many, perhaps the bulk of, key safety practices (27). The application of the "classic academic medical model rather than human factors, engineering, or safety theory models" that have proven successful in other industries omits many vaunted safety efforts, such as computerized physician order entry (CPOE) (27). Furthermore, Dr. Leape notes the giant strides in improving aviation and anesthesiology safety were largely been based on experience and expert opinion (e.g., there are no randomized trials of various flight checklists or new flight instruments to prove they reduce aviation crashes). Sometimes the burden of proof needs to be on those who advocate the status quo to prove that the current system is safe. If hospital implementation demands incontrovertible proof for acceptance of each new safety practice, long delays and inaction will surely result.

Patient Safety and the Future: High-Reliability Organizations (HRO)

Characteristics of "high reliability organizations" (HRO) are common in nuclear power plants, aircraft carriers, and large electrical power plants (2), and can be applied to your operating room. HRO describes a process that focuses on organizational structure to improve efficiency and safety, rather than micromanagement of the technical aspects that facilitate various functions.

Few would argue that perioperative and anesthesia care of seriously ill patients is appropriately classified as a potentially "high-hazard" activity (4). As in the aviation and nuclear power industries, routine day-to-day actions within these environments may result in serious injury or even death. Patients (and society) depend on organization and individual provider safety to prevent accidents. As previously noted, one of the theories of organizational safety is the Normal Accidents Theory (NAT) (25). A classic example is the link between a leaking O-ring on the solid rocket booster and the space shuttle Challenger explosion (28). A postaccident analysis demonstrated how several defensive barriers had breakdowns, or holes in them (the so-called Swiss cheese model) (28). With NAT theory, many management efforts to prevent accidents actually increase the opacity and complexity of various systems and may in fact increase the likelihood of a mishap.

By contrast, HRO theory provides that the proper structure of people, monitors, and processes can manage highly hazardous activity with excellent performance. The core characteristics of HRO recognize that traditional measures of safety are indirect and are difficult to interpret because of inherent noise in the system. Another hurdle is the fact that feedback is often "negative"—fewer accidents or critical incidents are difficult to measure and have little intrinsic reinforcement value. Thus, the link between expenditure of resources and improved safety is less direct, and often, less certain.

Some of the important characteristics of HRO organizations are listed in Table 6. Conversely, there are many "enemies" of HRO, including a process called "normalization of deviance." (25) This incremental process is a gradual erosion of normal procedures (standard operating procedures) that would never be tolerated if suggested in one giant leap. Instead, small incremental deviations are observed and, lacking an accident, become "normalized." Such gradual erosion from the norm were repeatedly observed and described by NASA in the years leading up to the Challenger accident. Many clinicians can cite examples of "normalization of deviance" within their operating rooms and ICU. Compromises in patient care accumulate until there is an accident (like the explosion of the Challenger or the preventable death of a patient)—a wake-up call—that startles people back into an examination and strict application of their process and procedures (28).

Table 6. Features of a High-Reliability Organization (HRO) That May Be Most Applicable to the Delivery of High-Acuity Medical and Perioperative Health Care

Widely shared and understood central organizational goals.
A commitment to safety is articulated at the highest levels of the organization and translated into shared values, beliefs, and behavioral norms throughout all organizational levels.
The organization provides the necessary resources, incentives, and rewards to allow this to occur.
Key equipment is available and in top working order.
There is openness about errors and problems; they are reported when they occur.
Information-rich data bases are used to support the core goals.
Organizational learning is valued; the response to a problem is focused on improving system performance.
Vigilance is prized, and rewarded.
Safety is valued as the primary priority, even at the expense of "production" or "efficiency."
Personnel are rewarded for erring on the side of safety even if they turn out to be wrong.
Unsafe acts are rare despite high levels of production.
A hierarchical structure which honors collegial decision-making, regardless of rank.
Reliance on professional judgment, regardless of position of rank.
Communication between workers and across organizational levels is frequent and candid.

Summary

The IOM report, (4) and other recent "headline" events have focused the spotlight on patient safety in hospitalized and surgical patients. Anesthesiologists were among the first and most widely recognized medical experts to adopt models for institutional safety from the aviation and nuclear power industries. Leaders in professional societies such as the Anesthesia Patient Safety Foundation were remarkably successful in organizing multiple constituencies to focus on the single goal of patient safety. Although we acknowledge our successes, there is a need to understand, promote, and translate the safety principles and strategies proven to reduce errors in the OR to other high-intensity patient-care areas around the hospital. These strategies include thorough critical event analysis, application of new multidisciplinary systems design, widespread application of patient simulation, routine use of modalities such as practice parameters and checklists, and adoption of the principles of high-reliability organizations. The goal is always the same: "Primum non nocere."

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