Principles of Surgical Patient Safety

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Learning Objectives

- Identify the current challenges to surgical patient safety and the lessons learned from other high reliability industries.
- Explain the impact of effective communication on improving patient outcomes.
- Recognize the role of patient safety checklists in preventing adverse surgical outcomes.
- Establish the need for surgeon leadership and individual accountability for building a sustained culture of patient safety.

44.1 Introduction

No surgeon in the world would get up in the morning with the intent of creating a surgical complication. Beyond a doubt, surgeons and patients are intrinsically aligned in their intent of avoiding complications and adverse events. In spite of this natural bond, surgeons have historically fallen short of rising up as unwavering stewards for patient safety. Unquestionably, surgeons do *not* appreciate when their hospital administrators dictate how patients should be treated, and they are intrinsically averse to filling out forms and adhering to regulatory compliance-mandated paperwork and protocols. Yet, the unintentional void created by the absence of surgeon leadership in the field of patient safety has been filled by other stakeholders, including patient advocacy groups, malpractice lawyers, and legislators [1, 2]. The antiquated paradigm of patient safety standards being driven by a fear of medicolegal repercussion has escalated to an unjustified and fiscally irresponsible practice of "defensive medicine." The unintentional fallout from practicing defensive medicine is a drastic exacerbation of health care costs, with little or no benefit to the patient, in conjunction with an increased risk for collateral damage by the overuse of diagnostic testing [3]. This notion reflects directly on the paradigm shift in the initial assessment of the polytrauma patient, where the historic standard of care per the ATLS® guidelines consisted of a physical head-to-toe exam with limited use of conventional imaging [4]. In contrast, the diagnostic trauma work-up in the twenty-first century is almost invariably based on multi-slice CT scanning, which puts patients at an incremental long-term risk of radiation-induced cancer, and deprives the next generation

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of surgeons of the skill set of performing a thorough clinical exam [5].

Further challenges for patient safety include the wide variation of surgical indications worldwide, the inequity of access to surgery for disparities, and a questionable long-term sustainability of surgical quality at the current rate of progress associated with increasing costs for modern and innovative procedures [6]. Considering that around 200 million surgical procedures are performed worldwide every year, even a conservative low estimate of 1–2% average complication rates implies at least 2–4 million patients annually suffer harm from their surgical care. Strikingly, in the twenty-first century, we still have to come to terms with the absurd reality that it is significantly safer to board a commercial airplane, a spacecraft, or a nuclear submarine, than to be admitted to a U.S. hospital for surgical care [7]. What can surgeons do to protect their patients from the hidden dangers of an imperfect health care system? The most intuitive solution is to avoid complications from surgical treatment that is either not indicated or not beneficial for patients. In other words, avoiding unnecessary surgery could be considered the most pragmatic approach towards reducing preventable surgical complication rates [8]. Ironically, surgeons appear to have a lower threshold for recommending surgery to their patients, with a higher level of confidence, than they would recommend for themselves under the exact same case scenario [9]. The evident variation in non-surgical treatment recommendations indicates a substantial influence of surgeon bias in surgical decision-making [10]. These provocative insights unveil that surgeons are potentially biased towards recommending unnecessary surgery. Unequivocally, any postoperative complication that originates from a procedure that was not stringently indicated in the first place is by definition 100% preventable.

Dr. Arnold S. Relman (June 17, 1923 to June 17, 2014), the late editor of the *New England Journal of Medicine*, stated the following insightful quote: "*Of all the forces coming together to harm or even kill the patient, their physician should not be one of them!*" This notion provides an irrefutable imperative for surgeons to embrace the concept of "shared decision-making" as a core pillar in the partnership with their patients and thereby improving patient safety and reducing the rate of preventable complications resulting from variability in non-surgical care [11].

44.2 From "Blame and Shame" to High Reliability

The historic approach to medical errors and surgical complications has consisted of blaming the surgeon who delivers direct patient care under the "blame and shame" paradigm. This antiquated culture of patient safety is based on the erroneous assumption that surgical errors may be prevented in the future by admonishing, blaming, suing, or firing surgeons. In contrast to "blame and shame," accountability entails that surgeons are in charge of their patient's safety *independent of the outcome* [6]. The modern paradigm of patient safety revolves around "systems thinking" and "high reliability" in order to account for the notion that humans are prone to committing errors [12]. The hallmark of a "high reliability organization" (HRO) is not that it is error-free, but that errors do not disable it [7]. High reliability science represents the study of organizations in high-risk industries, such as commercial aviation and nuclear power technology, that maintain safety through redundant back-up options in case of failure under hazardous conditions [7]. Unfortunately, errors in the surgical care of our patients frequently lead to unintentional harm on first occurrence in absence of a "fail-safe" back-up option, and our health care industry still shows significant gaps in achieving high reliability in a sustainable fashion. This notion is exemplified by current statistics which reveal that medical errors represent the third leading cause of death in the United States, after cardiovascular disease and cancer [13]. When comparing the evidence-based estimate of more than 400,000 preventable annual deaths occurring in US hospitals every year to professional aviation, this statistic is analogous to three Jumbo jets crashing each day, all year long, in perpetuity [14]. In this hypothetical

scenario, the Federal Aviation Administration (FAA) would likely ground all commercial airplanes until the underlying error is recognized and irrevocably fixed. In contrast, the medical profession continues to accept errors that lead to preventable patient harm as an unfortunate and inevitable "side effect" of modern health care [7].

Intriguingly, as it relates to the field of surgery, adverse events and complications are more frequently related to errors occurring *before* or *after* the procedure than by technical mistakes by a surgical blade "gone wrong." These include (1) a breakdown in communication; (2) a delay in diagnosis or failure to diagnose; or (3) a delay in treatment or failure to treat [15]. Surgeons are presented with challenges that reach far beyond pure technical aspects—the decision of initiating appropriate and timely surgical care, weighed against the risk of providing delayed or negligent care by choosing observation and/or non-operative treatment ("*to cut or not to cut*"). Many of the current limitations to the creation of a globally recognized and consistently practiced culture of patient safety stem from the lack of surgeon-driven leadership [3, 16]. Transparent leadership and credible role modelling are the prerequisites to ensure the unreserved buy-in by all members of the health care team for adoption of safety practices, including strict adherence to patient safety checklists and core measures [17, 18]. From a pragmatic standpoint, surgeons can drive their own "high reliability practice" by adopting two fundamental standards that have proven to decrease variability in surgical care and improving patient safety: Effective communication and surgical safety checklists [15].

44.3 Effective Communication

Patient harm resulting from surgical complications is frequently derived from a communication breakdown within the care team rather than from a technical complication in the operating room [19]. Published studies on closed claims by the American College of Surgeons revealed about 25% of all claims related to patients who sustained surgical harm were attributed to a breakdown in communication [20]. Of these, 85% of adverse events related to communication breakdown occurred by verbal communication. While most surgeons perceive themselves as "good communicators," in reality, less than 20% of all physicians have been formally trained on how to communicate with patients [21]. Ironically, the main predictor of patients' perceptions of whether quality care was provided has no correlation with objective metrics of clinical care, but rather with the patients' subjective perceptions of the *quality of communication* with their surgeon. Evidence-based approaches for improved communication are widely published and available as resources for physicians [19]. Multiple studies have shown that effective communication with patients is associated with a decreased incidence of claims and lawsuits, better clinical outcomes, improved patient compliance with recommended treatment regimens, and decreased unplanned readmission rates [19].

44.3.1 Readbacks

The first fatal airplane crash in history occurred on September 17, 1908, when the aviation pioneer Orville Wright's co-pilot died in a failed flight attempt. Since that time, aviation safety standards have significantly improved. The current risk for an American dying in an airplane crash is about 1:500,000, compared to the 1:20,000 chance of dying in a car accident [22]. The standardized use of "readbacks" represents a fundamental pillar of commercial aviation safety [23]. In essence, a formal readback by the recipient of verbally communicated information ensures a standardized two-way communication [24]. In the health care setting, readbacks represent a proven standard of structured language used to provide clarity and accuracy of verbal orders and critical test results, as mandated in the National Patient Safety Goals (NPSG's) by the Joint Commission [6]. While the current debate in the field is related to optimizing the modality of readbacks, this crucial form of communication is still virtually non-existent among surgeons. The renowned surgeon Dr. Eddie Hoover

characterized the problem with the following quote: "*Getting surgeons to readback orders and instructions will age you 10 years, yet the Navies of the world have demonstrated for eons that it improves efficiency, promotes safety, and saves lives*" [25]. This notion provides the basis for a call for formal verbal "readback orders" among surgeons and other healthcare professionals in the perioperative setting with the goal of avoiding or reducing the high incidence of adverse surgical events related to a breakdown in communication.

44.3.2 SBAR

Verbal communication must be timely, precise, directed, and understood. The "SBAR" framework (Table 44.1) represents another best practice standard of effective communication derived from a high reliability industry, such as naval nuclear submarine technology [7, 26]. The SBAR mnemonic is simple, streamlined, and highly effective in avoiding miscommunication in the perioperative setting [21].

44.3.3 AIDET

The AIDET mnemonic represents an established and widely disseminated proven framework for successful communication between surgeons, their patients, and patients' families (Table 44.2). Similar to other checklists, the AIDET mnemonic ensures not to skip any piece of information that may be important from the patients' perspective [21].

Table 44.1 The "SBAR" mnemonic for improved effective communication

S—Situation
"*The situation is…*" (What is going on with the patient?)
B—Background
"*The background to the situation is…*" (What is the clinical background or context?)
A—Assessment
"*My assessment of the situation is…*" (How do I interpret the problem?)
R—Recommendation
"*My recommendation is…*" (What do I recommend to resolve the problem?)

In summary, effective communication in health care can be dramatically improved by the use of standardized communication frameworks [19]. Furthermore, the quality of communication has been shown to correlate with the patients' perception of the quality of care provided. In the current age of patient-centered care, surgeons have an obligation to move on from being technically excellent, to mastering non-technical skills. Effective communication will improve the surgeon–patient relationship and overall patient outcomes.

44.4 Surgical Safety Checklists

Most surgeons are intrinsically opposed to the use of checklists, as those appear to be imposed and mandated by third party entities and appear to question the surgeons' clinical and technical expertise for safely managing the surgical care of their patients [27]. Clearly, checklists do not make a surgeon any "smarter," more knowledgeable, better trained, or more technically skilled [28]. However, checklists provide a safeguard and protection from the human error of forgetting or skipping important steps in a process, particularly when considering the high-stress and high-acuity environment, such as the trauma bay or the operating room [28]. Atul Gawande, the world-renowned patient safety "guru" and one of the innovative founders of the "Safe Surgery Saves Lives" campaign and WHO surgical safety checklist [29, 30], provided a compelling argument for the use of checklists in his bestselling book "The Checklist Manifesto" [31].

> *In a complex environment, experts are up against two main difficulties. The first is the fallibility of human memory and attention, especially when it comes to mundane, routine matters that are easily overlooked under the strain of more pressing events. A further difficulty, just as insidious, is that people can lull themselves into skipping steps even when they remember them. Checklists seem to provide protection against such failures.*

Table 44.2 The "AIDET" mnemonic: A standardized framework for effective communication with patients and patient families

A—"Acknowledge"
Greet people with a proactive and friendly approach. Look them in the eyes and smile. Use their names if you know them. The first delivered impression is the most important and lasting impression. Establish a preferred rapport with the patient and patient family.
Example: "*Good morning Mr. Smith. Welcome to the Medical Center XYZ. We have been expecting you and we are glad that you are here. Would you please take a moment to confirm that we have your most current information?*"
I—"Introduce"
Introduce yourself politely. Tell the patient who you are and how you are going to help. Explain your role, function, experience, and skill set. Escort people where they want to go, instead of pointing or giving directions.
Example: "*Mr. Smith, my name is Anne. I will be performing your sonography today. I am a certified ultrasonographer and I perform about 20 such procedures each day. The doctors say that my skills are among the best. Do you have any questions for me?*"
D—"Duration"
Outline the expected duration and wait time. Keep in touch regularly to ease the perception of prolonged wait times. Let people know if there is a delay and provide realistic expectations of expected times. Fix unnecessary wait times where necessary.
Example: "*Dr. Stahel had to take care of an emergency. He was concerned about you waiting to be seen, and he wanted to let you know that it may be about 30 min before he can see you. Are you able to wait, or would you prefer to run some errands and come back later?*"
E—"Explain"
Tell the patient what to expect. Communicate all steps in the process and address any questions that the patient may have. Make time to help by recognizing and diminishing the patient's anxieties and uncertainties.
Example: "*The test will take about 30 min. The first step is for you to drink this solution, and then we'll have to wait 20 min before drawing a blood sample. Would you like to read while you wait?*"
T—"Thank"
End the conversation with the patient by a standardized "*Thank you!*" Foster an attitude of gratitude. Use reward and recognition tools, as appropriate.
Examples: "*Thank you for choosing our hospital.*"—"*Thank you for your trust.*"—"*Thank you for taking the time for this visit—it has been a privilege to care for you.*"
Finalize the communication and interaction with the patient by the standard question: "*Is there anything else I can do for you today?*"

The "Universal Protocol" by the Joint Commission represents the paradigm of a standardized, simple, and pragmatic surgical safety checklist. This is designed to avoid the "worst case scenario" complications in surgery, including operating on the wrong site or on the wrong patient [32–34]. The Universal Protocol was introduced in 2004 to United States hospitals participating in the Medicare/Medicaid program (CMS) as a mandatory quality assurance checklist [35], consisting of the following three components:

1. A pre-procedure verification process.
2. Preoperative surgical site marking.
3. A surgical "time-out" immediately prior to starting the procedure.

44.4.1 Pre-procedure Verification

About one-third of all wrong-site and wrong-patient procedures have their genesis before patient admission to the hospital [32]. Potential scenarios include inaccurate clinic note dictations related to a wrong side, the mislabelling of radiographs or other diagnostic tests, or a mix-up of patients with similar or identical names. The rationale for conducting a pre-procedure verification process is to confirm (1) patient identity, (2)

the nature of the planned procedure, and (3) the correct surgical site [35]. Each patient is unequivocally identified by an identification bracelet which includes the patient's name, birth date, and a medical record number. The pre-verification process further ensures presence and adequacy of all relevant documents, including written informed consent and a current history and physical exam. The surgeon's surgical plan and the team's understanding of the planned procedure must be confirmed to be consistent with the patient's expectations. A checklist is used to review and verify that all documents and pertinent information are available, accurate, and completed, prior to moving the patient to the operating room [35].

44.4.2 Surgical Site Marking

Surgical site marking is performed as part of the pre-procedure verification process in the preoperative holding area [36]. The following best practice standards should be taken into consideration for a safe and accurate surgical site marking [35]:

- Site marking must be performed by a licensed practitioner who is a member of the surgical team and will be present during the surgical "time-out" and during the procedure. Under ideal circumstances, site marking should be performed by the surgeon.
- The surgical site is marked in the preoperative holding area, before moving the patient to the operating room or to an interventional procedure room.
- The patient should be actively involved in confirming the correct surgical site marking, whenever possible.
- The site marking must be unambiguous by the use of unequivocally defined terminology, such as "YES," "GO," "CORRECT," or "CORRECT SITE." Surgical site marking with an "X" should be avoided as this may be misunderstood as "not this side." The specific modality of marking must be defined in the respective facility's policies and procedures.
- Additional marking of the contralateral side (e.g., "no" or "not this side") is contraindicated, as this creates confusion and increases the risk of wrong-site surgery.
- The surgeon's responsibility of correct site marking should be confirmed by adding the surgeon's initials. The only exception is a surgeon with the initials "N.O." since this may be confused with a "no" and imply that the marked site should not be operated on.
- Surgical site marking must be applied with indelible ink on skin, using permanent markers. The markers must be resistant to the surgical preparation process and remain visible at the time of skin incision. It should be noted that sterile markers are not required, since the published literature demonstrates that the use of non-sterile markers does *not* increase the risk of postoperative infections (Fig. 44.1).
- The marking should be applied at or near the incision site. The side, level, and location of the procedure must be unequivocally defined by the marking, whenever possible (left vs. right; medial vs. lateral; flexor vs. extensor surface, etc.)
- Knowledge of contraindications for surgical site marking, including premature infants (risk of permanent tattoo), mucosal surfaces, teeth, and patients refusing a surgical site marking for personal reasons.
- Increased awareness in all cases where precise site marking is not possible (see below).
- Defined alternative processes should be implemented for any circumstance where surgical site marking is not feasible, to include pre- and intraoperative radiological diagnostics (e.g., spinal level marking with a needle, intraoperative arteriogram or cholangiogram, etc.)

There are specific instances in which surgical site marking may not be feasible, for technical or anatomic reasons. For example, site marking is impracticable on mucosal surfaces and on the teeth. Site marking is furthermore contraindicated in premature infants due to the risk of inducing a permanent tattoo on the skin. In addition, some surgical sites are inaccessible to accurate external marking, including internal organs (general surgery), brain and spine (neurosurgery), vessels (interventional vascular procedures), and the pelvis (orthopedic sur-

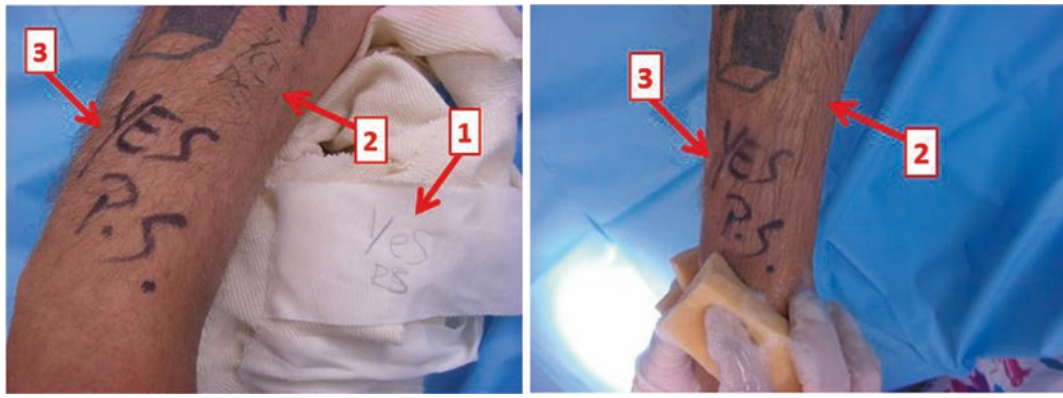

Fig. 44.1 Clinical example of correct vs. incorrect modalities of surgical site marking. (Adopted with permission from: Stahel PF et al., *Patient Saf. Surg.* 2009, 3:14. Creative Commons 4.0 International License). Upper panel: This patient was scheduled for a surgical procedure on the right forearm. The surgical intern marked and initialed the site on the dressing, which came off prior to surgery (1). The resident then corrected the mistake by marking the surgical site on the skin using a regular pen. Neither the marking, nor the initials, are unequivocally legible (2). Finally, the attending surgeon marked the site again with a permanent marker and included his initials (3). Lower panel: During the surgical preparation, the site marking with the regular pen was washed off (2), whereas the permanent marker remained visible throughout the surgical preparation (3). This example emphasizes the crucial importance of using a permanent marker, large and well legible letters, and to sign the marking with the surgeon's initials. "YES" is the designated, standardized identifier for the correct surgical site at this surgeon's facility

gery). Rarely, patients may refuse surgical site marking for cosmetic or other personal reasons [35].

An alternative process to site marking must be in place for all these circumstances. Radiological diagnostics may need to be consulted pre- and intraoperatively to determine the surgical site with accuracy. Unlike symmetric external body parts (extremities, eyes, ears), any *occult* surgical site cannot be easily confirmed and marked prior to surgery. Thus, these particular circumstances mandate the intraoperative localization and confirmation of the correct site (e.g., correct spine level by intraoperative fluoroscopy), in conjunction with a careful evaluation of preoperative imaging studies, such as CT, MR, angiography, or cholangiography.

44.4.3 The Surgical "Time-Out"

The time-out represents the last part of the Universal Protocol "checklist" and is performed immediately before the initiation of the planned procedure in the operating room [35]. The time-out represents the final recapitulation and reassurance of accurate patient identity, surgical site, and planned procedure. In addition, the following items are confirmed during the time-out: correct patient positioning, known allergies, the need for perioperative antibiotics, the availability of relevant documents and diagnostic tests, instruments, and implants [37]. The following aspects should be taken into consideration for a "best practice" time-out:

- The time-out process must be standardized and defined in the policies and procedures of each respective facility.
- The time-out is called by a designated member of the surgical team, e.g., the circulating nurse or the surgeon.
- A "two-stage" time-out process allows for the patient to be awake and participate in the verification process of patient identity, surgical site, and planned procedure (so-called awake time-out) prior to induction of anesthesia. This is followed by a second final time-out

after surgical prepping and draping, and immediately before skin incision.
- All members of the surgical team (i.e., surgeon, anesthesiologist, CRNA, circulating nurse, operating room technician, radiology technician, etc.) must be present in the operating room and actively participate in the time-out prior to skin incision.
- During the time-out, all non-essential activities are suspended to an extent which does not compromise patient safety.
- The time-out must be repeated intraoperatively for every additional procedure performed on the same patient.

In essence, the three individual steps of the Universal Protocol checklist are intended to ensure correct patient identity, correct procedure, and correct surgical site. More importantly, this checklist empowers *any* member of the team to speak up and stop the procedure whenever there is an apparent inconsistency or risk to patient safety, independent of the hierarchy and culture in the operating room. Pitfalls and limitations which may render the checklist less effective are hidden in each component of the protocol [38]. The degradation of surgical safety checklists to a "robotic-hackneyed ritual" can be mitigated by the surgeon's personal ownership and leadership with an unwavering and credible commitment to the checklist [27, 39, 40].

44.5 The Next Frontier of Patient Safety: Individual Accountability

Surgeons are under an increasing amount of pressure and expectation to perform at the highest level. They must deliver absolute diagnostic accuracy and infallible surgical quality under the conflicting paradigm of patient safety and maximal cost efficiency. In addition, surgeons are expected to have the highest standards of ethical values and professionalism, to be respected role models, dedicated teachers, academic researchers, successful administrators, and entrepreneurs. These expectations are analogous to the task of squaring the circle. As the historic paradigm has shifted in the past two decades from a "*culture of blame and shame*" to a "*culture of systems safety,*" we have now reached a tipping point in which the expectations of "the system" are at their limit. A physician-driven approach is therefore needed to build and sustain a "*culture of individual accountability*" beyond systems safety. A classic example is represented by hand hygiene—a simple core measure with immense impact on patient safety as it relates to preventing hospital-acquired infections. International estimates show that overall compliance with hand hygiene among health care personnel is as low as 10–30%. A "perfect system" may provide staff training programs and logistic support, including door signs and hand sanitizer dispensers in- and outside of patient rooms. However, in absence of individual accountability and physician leadership, the expected goal of 100% hand hygiene compliance remains utopic. How is it possible that low-wage workers in the meatpacking industry are able to sustain 100% compliance with hand hygiene protocols? Intriguing insights from our own experience reveal that hand hygiene compliance rates drop from more than 90% when staff feel observed and monitored, to less than 40% when unobserved. This phenomenon likely relates to the "Hawthorne effect" by which a subject's behavior changes as a result of being observed and reflects poorly on the individual accountability of "*doing the right thing*" for our patients at all times. Senior surgeons therefore have the obligation to step up and to be respected role models to their junior colleagues in training by teaching non-technical virtues, including the unwavering advocacy for patient safety, strict professionalism, effective communication, and individual accountability [41, 42]. The ultimate benchmark for the success of surgeon mentors is to produce trainees who will be better surgeons and stronger patient advocates than their predecessors, by embracing patient safety as a core surgical responsibility.

44.6 Conclusion

The last frontier in surgical patient safety is for surgeons to step up and embrace patient safety as a core surgical responsibility. Adherence to best practice safety protocols, including surgical safety checklists, in conjunction with mastering non-technical skills, such as effective communication and individual accountability, will likely promote the field of surgery to the next high reliability industry with sustained excellent patient outcomes.

Key Concepts

- Medical errors currently represent the third leading cause of death in the United States.
- Most adverse events in surgery originate from a breakdown in communication, rather than from technical surgical errors.
- Established scripted mnemonics for effective communication improve the surgeon-patient partnership and reduce the risk of preventable complications due to communication breakdown.
- Surgical safety checklists prevent the accidental omission of critical steps in the perioperative process and improve patient safety assurance, in analogy to other high-risk industries, such as professional aviation.

Take Home Messages

- The legendary Flight Director of the lunar Apollo missions, Gene Kranz, stated in the wake of the Apollo 1 disaster in 1967: "*From this day forward, Flight Control will be known by two words: 'Tough and competent'. Tough means that we are forever accountable for what we do or what we fail to do. We will never again compromise our responsibilities. Competent means we will never take anything for granted. We will never be found short in our knowledge and in our skills.*"
- It is time for surgeons to become "*tough and competent*" for patient safety!

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