Surgical Patient Care

Improving Safety, Quality, and Value

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Foreword I

Sixteen years ago the Institute of Medicine reported that healthcare in the United States was not as safe as it should be. The report indicated that as many as a million people are injured each year and at least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented.[1] John James, in an article published in 2013, estimated the true number of premature deaths associated with preventable harm to patients at more than 400,000 per year.[2] While there is little information regarding the number of patients associated with surgical complications, there are 51.4[3] million inpatient and 53[4] million outpatient surgeries performed a year in the United States. One study conducted at a university teaching hospital with a level 1 trauma designation revealed that despite mortality rates that compared favorably with national benchmarks, a prospective examination of surgical patients revealed complication rates that were 2–4 times higher than those identified in an Institute of Medicine report.[5] Almost half of these adverse events were judged contemporaneously by peers to be due to provider error (avoidable). Errors in care contributed to 38 (30 %) of 128 deaths. Recognition that provider error contributes significantly to adverse events presents significant opportunities for improving patient outcomes. In another study, researchers looked at hospitals enrolled in the American College of Surgeons National Surgical Quality Improvement Program. Out of 1500 general surgery patients, 11.3 % were readmitted to the

[1] http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

[2] James, John A New Evidence-based Estimate of Patient Harms Associated with Hospital Care, Journal of Patient Safety September 2013 vol 9 No 3 p 122 http://journals.lww.com/journalpatientsafety/Abstract/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx

[3] National Hospital Discharge Survey: 2010 table, Procedures by selected patient characteristics—Number by procedure category and age; http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm. Accessed May 27, 2016.

[4] US Outpatient Surgery Passes Inpatient to 53 Million a Year; http://www.tampabay.com/news/health/us-outpatient-surgery-passes-inpatient-to-53-million-a-year/1124313. Accessed May 27, 2016

[5] Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients, Arch Surg. 2002 May;137(5):611–7.

hospital within 30 days with postoperative complications. Of the readmissions, 22.1 % were due to surgical infections.[6]

In all locations across this country where surgical intervention takes place, despite the implementation of several specific interventions such as the use of checklists, pre-op briefings, time-out procedures, and debriefings, significant progress in keeping patients free from harm has not been made. It is reported that 40 wrong patient, wrong site, wrong side, and wrong procedure surgeries occur weekly in the United States.[7,8]

All practitioners approach their profession with the best of intentions. They want to provide quality care to the patients who come to be healed or to have their lives saved. The question to be answered is why, despite all these efforts and billions of dollars, do these statistics continue to reflect a lack of significant progress to create a safe surgical environment? Surgery is a very complex environment and Atul Gawande, MD, MPH, captured the reality of this by stating "In surgery, you couldn't have people who are more specialized and you couldn't have people who are better trained. And yet we see unconscionable levels of death and disability that could be avoided."[9]

The premise of this book is that delivering surgical care is complex, complicated, and requires multidisciplinary collaboration. The editors of this book have brought together an impressive group of multidisciplinary authors representing a global perspective on safety, quality, and reliability across the continuum of care for the surgical patient.

Healthcare reform has brought many changes to healthcare; the focus on accountability for quality (value-based reimbursement) instead of volume has had an impact on the outcomes of surgical care as viewed by providers, payers, patients, and their families. This shift cannot occur without a change in the culture. The authors recognize that system-wide and deep human factors training are fundamental to developing the teamwork and robust communications that are essential to create a high-reliability organization focused on preventing harm to patients. The important connection between patient and healthcare worker safety, often overlooked, is highlighted and included in the review of the fundamental principles of the science of safety.

There are significant challenges to provide safe, high-quality, cost-efficient care in the high technology environment of the operating room. This book helps to demystify many of the perioperative never events, patient injuries, and procedural errors that occur in the operating room through the use of evidence-based information, guidelines, and examples of checklists and forms that will be valuable additions to the tool kits for developing high-reliability organizations.

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[6] http://www.fiercehealthcare.com/story/surgical-patients-bounce-back-post-op-complications/2012-08-29

One in 10 Surgical Patienhttp://www.fiercehealthcare.com/story/surgical-patients-bounce-back-post-op-complications/2012-08-29its Readmitted with Postop Complications

[7] Project Detail: Wrong Site Surgery Project. Joint Commission Center for Transforming Healthcare. http://www.centerfortransforminghealthcare.org/projectsdetail.aspx?Project=3. Accessed April 22, 2016.

[8] Seiden, S., Barach, P. Wrong-side, wrong procedure, and wrong patient adverse events: Are they preventable? *Archives of Surgery*, 2006;141:1–9.

[9] Gawande AA. How do we heal medicine? (video) TED.com. Filmed March 2012. http://www.ted.com/talks/atul_gawande_how_do_we_heal_medicine. Accessed May 15, 2016.

Healthcare is highly regulated by government agencies, insurers, and voluntary agencies. The editors have included an extensive review of the systems that have been developed and are vital to maximizing patient and healthcare worker safety; however, they also make the point that each individual practitioners and the leadership of the facility have responsibility and accountability to create a harm-free environment. While the systems are an excellent adjunct to creating a safe environment, they must be scientifically based, focused on outcomes of care, and make sense and meaning to the users. The authors identify that a culture of safety must have the active support of the C-suite and be valued as a top priority and be articulated at the highest level of the organization including the Board of Directors.

The chapter on "Patients and Families as Coproducers of Safe Outcomes" identifies the essential role that *patients and families* have in protecting themselves. The reluctance of patients and their advocates to ask questions of healthcare providers is no longer acceptable. They must be invited and learn to accept the responsibility to ask questions about their care, and to be very vigilant about the proposed procedure being planned and to pay attention to all details of their care. Appropriate questions to ask include, "what procedures are in place to avoid: a wrong site surgery, medication errors, and surgical site infections?"

The future of surgical care and outcomes is directed by the shift to value-based reimbursement. This requires that management and clinicians rely on data in a new way, for example including process improvement projects, measuring workflow, exploring new systems of delivery of care to the surgical patient, and the use of registries to improve outcomes. Facilities have a plethora of robust data that needs to be distilled to make the necessary connections to predictive analytics. Predictive analytics systems are being used, for instance, to understand which patients are at higher risk for hospital readmission, to reduce hospital stays after joint replacement, and to anticipate staffing needs which reduce overtime[10] and the relationship between culture and safety outcomes.

This book offers a unique perspective on care of the surgical patient as it includes contributions from all members of the surgical team including patients and other scientific disciplines with relevant and valuable applications for the healthcare field. *Surgical Patient Care: Improving Safety, Quality and Value* reflects the goals of all the team members who care for surgical patients and are focused on advancing on the journey to high reliability of surgical intervention. This will only be accomplished by day to day recognition that concern for patient safety must be constant and woven into the values of the institution. This book is an outstanding resource and I highly endorse it. It should be a required book in every operating room and hospital C-suite around the world to assist the surgical team and the hospital leadership on their journey to improve safety, quality, and value for surgical patient care.

Linda Groah, MSN, RN
Executive Director and CEO of the Association
of periOperative Registered Nurses

[10]Karyn Hede, Moneyball Mindset, H&HN April 2016 p 23

Foreword II

Over the last 40 years, many high-risk industries have made great progress in managing the challenges of improving safety and reducing harmful events. They have created the conditions through which errors are considered inevitable and provide opportunities to learn and improve; systems are built that mitigate accidents and prevent them causing serious harm; there is an understanding that a human factors approach creates teams of employees trained in nontechnical as well as their traditional technical and clinical skills. These changes, and others, have delivered safer air travel, safer nuclear power plants, and safer construction sites.

The majority of healthcare systems, and the hospitals and other organizations within them, have talked a good game but they have not embraced these fundamental changes. The result is that, by 2016, researchers at Johns Hopkins University were estimating that medical error-related deaths were the third most common cause of death of Americans, only surpassed by cancer and cardiovascular disease.

There is clearly a need to establish much greater understanding, amongst healthcare professionals, health system leaders, patients, and families, as to how risks arise in healthcare. Through this will come a more widespread commitment to change in the way that care is currently designed and delivered. Too often, patient safety has been an interest of academics and enthusiasts and not the mainstream providers of care.

Patient safety thinking and research has tended to become fragmented. It has taken a number of directions over the last decade: studies have elucidated the extent of harm to patients and sought to explain its causation; risk and adverse events have been documented in various clinical specialities (e.g., anesthetics), in treatment areas (e.g., medication), in demographic groups (e.g., neonates), or in settings (e.g., operating rooms); problems with an established pattern of harm have been reconceptualized and studied in patient safety terms (e.g., healthcare infection); technological and other solutions to reduce risk have been evaluated.

Whilst the safety concepts and interventions from other disciplines have been applied to medicine and healthcare, it is often difficult for students and practitioners to find the theory, practical implications, evidence-based solutions, and thought leadership in one place.

This book fills this gap admirably. Although ostensibly about surgery, it deals with the key themes and concepts in patient safety, many of which are applicable much more widely across medicine and healthcare. It will be a trusty companion for surgeons but also those who wish to learn, those who are looking for new research directions, those who aspire to lead, and those who need a new source of inspiration to reignite their passion for patient safety.

Sir Liam Donaldson
World Health Organisation
Patient Safety Envoy

Foreword III: What Pilots Can Teach Hospitals and Healthcare About Patient Safety

Qantas Flight QF32 proved to me the need for leadership and well-trained, experienced teams. QF32 was a *black swan* event*, an unexpected, improbable event that had significant outcomes. Engine number two exploded on my Airbus A380 4 min after take-off from Singapore airport on the 4th of November 2010. Five hundred pieces of shrapnel cut more than 650 wires, damaged 21 of the 22 aircraft systems, starting a 4-hour crisis that challenged the 25 crew and pilots. QF32's repair was probably the longest and most expensive in aviation history.

QF32's resilience was a team win. Within 2 hours of the engine exploding, about 1000 specialists had amassed to support us from many locations as we made our approach to Changi airport in Singapore. The last passenger disembarked the aircraft after another 2 hours. There was no panic. There were no injuries. Teams of experts saved the lives of 469 passengers and crew and saved tens of thousands of family and friends from traumatic stress.

QF32 reinforced our passengers' perspectives of aviation safety. (1) Our passengers value the extra training that crews receive in value-added airlines. The thousands of hours of deliberate practice pilots conduct in simulators paid dividends. Everyone delivered excellence under pressure without panic. For me, QF32 reinforced my values that leaders who set a caring culture and build great teams achieve remarkable outcomes.

When we look deeper, QF32's success is not due to me, the crew, or the passengers. The foundation for QF32's success lies in the special culture and resilience systems that exist throughout most of the aviation industry.

Pilots and surgical clinicians manage risks and mitigate threats to prevent death. Both of our industries face threats from technology, the environment, resources, humanity, and change. When we analyze disasters, we find a sameness in the causes. Most aircraft crashes, like the majority of adverse events in healthcare, are the result of failures in resilience, particularly human errors in communication, leadership, and decision-making.

The collision of two Boeing 747 jumbo jets at Tenerife in the Canary Islands in 1977 is the world's worst aviation accident. Five hundred and eighty three people perished in this preventable accident, making it also the

*black swan event - a completely unexpected event with significant impact that is usually inappropriately rationalized because of hindsight bias (after: Taleb, Nassim Nicholas (2010) [2007]. The Black Swan: the impact of the highly improbable (2nd ed.). London: Penguin)

best example of human factors taking lives. At that time, the 747s had been operating for less than 7 years and sales were booming. The 747 was the first in a series of new generation, high capacity aircraft, so something had to be done in this growing industry to ensure this accident never occurred again. NASA convened a panel to address aviation safety and created the concept called Cockpit Resource Management (CRM).

The Federal Aviation Administration (FAA) legislated that all military and airline pilots receive CRM training. The aim of CRM was to teach crews to improve their personal skills, communication, and how to build effective teams that make better decisions. The idea of CRM was to make better leaders who would build resilient teams. It was a challenge to convince autocratic captains to defer to their subordinates. The captains who complained most about CRM were the ones who needed CRM training the most.

The basic tenets of CRM are to avoid, trap, or mitigate the consequences of errors resulting from poor decisions and unexpected failures. The steps involve (i) Detect the problem; (ii) Access knowledge to understand the implications and limitations; (iii) Prioritize events; (iv) Select the appropriate action; and (v) Execute.

CRM deals with expecting and managing errors, not about preventing errors. CRM starts with acknowledging our humility and accepting our vulnerabilities that we all make mistakes. Pilots are taught, to recognize human limitations and the impact of fatigue. They identify threats and effectively communicate problems, support and listen to team members, resolve conflicts, develop contingency plans, and use all available resources when making decisions.

After proving a success in the cockpit, CRM expanded to include the cabin crew. This CRM became known as Crew Resource Management. Today CRM encompasses experts in all teams that aspire to a common goal. CRM has never and will never be called “Captain Resource Management.” CRM is about optimizing and amplifying team performance not the captain’s performance.

CRM is the catalyst producing efficient teams in normal and emergency situations. Crews have roles, tasks, and procedures for normal occasions. CRM also provides the team environment and behaviors to solve problems when the unthinkable black swan happens, and when checklists and standard operating procedures (SOPs) are irrelevant.

We don’t know what the next black swan will be, where or when it will strike. By definition our prepared defences will fail. Our survival depends on enabling teams of experts to synthesize their knowledge and experience to create novel solutions.

CRM is more than checklists. CRM has hooks into more than 40 human and corporate factors. Human factors can be subclassed into five categories (leadership, management, teamwork, skills, and personality). Corporate factors can be subclassed into six categories (governance, safety management systems, safeguards, communications, and risk). Checklists provide a small but important part of these frameworks.

Great leaders exhibit CRM skills. Pilots and physicians tend to be highly skilled, technical, Type A personalities. We are confident and intensely strong

willed because these are the traits required to make life-and-death decisions in seconds. These skills however do not make us resilient. Resilient leaders also exhibit personal humility. They know teams are always more creative than individuals. So great leaders channel their egos into the larger goal. They genuinely understand empathy, teamwork, and deferring to expertise.

Teamwork multiplies the leader's skills. That's why great leaders enable even greater teams. That's why great leaders call success "team successes" and claim failures as their own. Teams are reflections of their leaders and their CRM skills. Whenever I am a passenger on an aircraft, it takes me just a few seconds to sense the leaders' culture—by observing the mood of the crew.

CRM is being infused into the medical industry. A growing number of healthcare providers learn from aviation successes, accidents, and near misses—more specifically, the safety systems in place in airlines that prevent accidents reoccurring. In the last 5 years, several major hospitals have hired professional pilots to train their critical care staff members on how to apply aviation safety principles to medical work. For example: playing music during operations that distracts others is the antithesis of CRM.

Though healthcare experts disagree on how to incorporate aviation-based safety measures, few argue about the parallels between the two industries or the value of borrowing the best practices from each other. CRM creates a culture of pooling skills, listening, identifying threats, trusting and deferring to experts, reducing risks, and correcting errors. CRM is ultimately about saving lives.

Despite these important steps, healthcare remains dangerous to patients. Governance is needed at the highest levels to install and audit similar systems in medicine that have existed in aviation for decades. This includes creating and harmonizing world standards for certification, training, safety, investigation, and reporting.

Qantas flight 32 proves it is possible to build expertise to survive a black swan event. Mining, nuclear, and aviation industries operate successfully on the premise that failure is never an option. Look inside these high-reliability organizations and you'll notice unique behaviors. These companies have a chronic unease for the status quo, expect failure, do not simplify, and defer to trained experts.

Aviation is a risk-laden but heavily regulated industry. Regulators set and audit harmonized standards that are "written in blood". Safety management systems espouse corporate cultures that trust and defer to expertise. For the individual passenger and their loved ones, our dedication to a lifetime of learning and training gives those at the edge of chaos at the coalface the best skills to survive the threats of technology, complexity, crisis, and change.

There are many keys to organizational resilience. Training for the known knowns gives us a degree of personal resilience for the normal and perfect storm events. Higher skills are required to survive black swan events. Surviving black swans requires synthesizing all of our knowledge, training, experience, teamwork, leadership, decision-making, threat and error management, and crisis and stress management to handle events as a team that we never explicitly trained for or expected.

These keys are useless without personal qualities, values, and a climate of psychological safety. (2) Our values determine WHY we do the things we do. It starts by taking 100 % responsibility and offering no excuses. My "WHY" is ensuring every spouse or parent should expect their loved one home for dinner after flying on my aircraft. Whatever happens at any stage in the process—I am responsible. There are no limits. I will do everything possible to ensure my passengers' safety. Sheryl Sandberg, Facebook's COO, says it best: "Nothing at Facebook is someone else's problem! When you see something that's broken, go fix it."

Neuroscience provides clues how on to motivate and empathize with others and to lead effective teams. We are in a better space to remain mindful and calm in emergencies, to influence and lead others when we understand the science of how our mind works in crisis. I use this knowledge to calm passengers and reduce their dread of flying.

Doctors and pilots learn from each other's professions even though a *chasm separates our safety performance* at the individual, crew, and organization levels. Pilots of big jets might have the lives of up to half a thousand passengers in their hands on any flight. In 2014, 641 people died in 3.3 billion passenger flights. Looking from another perspective that's 12 fatal aircraft accidents in 38 million flights. If we accept the statistic that 400,000 people that die unnecessary deaths in American hospitals every year, then the same number (641 passengers) that died in 2014, die every 14 hours in American hospitals.

I have had some experience with medical failures. My mother (1974) and uncle (2009) died from unnecessary medical mistakes. My good friend Peter was the unfortunate recipient of double wrong-sided eye surgery in 2015. In Peter's case the surgeon paused for 30 min after realizing the first mistake on the first eye, before returning to make another mistake on the other eye. The surgeon disclosed these errors days days later when Peter's asked why his vision had deteriorated. The mistake was reported to health authorities only after Peter's wider search for help.

"Aviation is safe" a doctor said recently, "because pilots are the first to the scene of an accident." I said, "If this is true, then patient safety might improve if doctors die with their patients."

Sometimes the safest decision before starting an operation is to STOP! The pilots' mantra is, "Safety before Schedule." This means safety is our number one priority. Everyone is not just empowered, but expected to STOP! an operation they think is unsafe. In medical terms, this means every nurse is expected to STOP! a surgery if the surgeon has not washed his hands. If the doctor does not stop, then the nurse should contact the CEO and expect to be backed up and not censured or demoted.

All great aviation, mining, and exploration companies have cultures that demand employees to call STOP! For example, every employee at Arrow Energy in Australia carries a card attached to their key ring giving them the authority to call STOP! for any unsafe activity. Instructions include a mobile number to call 24 hours a day if the operation is not stopped. The mobile phone number belongs to the CEO. I have called STOP! many times during my career. Calling STOP! is one reason why these high-risk industries are

safe. So "Safety before schedule" really means "safety before rank," "safety before time," "safety before secrecy," and "safety before money." "Safety before schedule" is also the reason why I do not wear a watch.

Airlines use safety management systems (SMSs), training, and checking systems to enhance resilience. SMSs define organizational structures, policies and procedures. They include CRM, risk, fatigue, audits, reporting, investigations and crisis management.

Pilots must satisfy onerous training and checking requirements. I am checked and recertified seven times every year. Physicians' competencies are rarely checked in most countries, after their initial certification. In some countries like the UK and the USA, their knowledge (but not skills or attitudes) is checked online (and alone) only once every 5 years. Good airlines provide deliberate practice and immersive training to develop pilots' skills that exceed minimum standards. Deliberate practice enables skills to be learned 30 % faster than normal training techniques.

"Surgical Patient Care" is fortunately a better path to resilience than putting one's life on the line and risk "being the first to the scene of an accident." Resilience is a learned skill requiring expertise, standards, and shared values. Resilience requires a commitment to a lifetime of learning. No one is born resilient and what got you here will not get you there.

Overconfidence breeds complacency, mediocrity, ignorance, and bias. The saying is "Chefs are as good as their last meal" applies to aviation, because "Pilots are only as good as their last landing". There is no relief when aspiring to resilience. I aim for excellence knowing I will never achieve it. I have a chronic unease for the status quo. I know surviving one encounter provides no insurance for the future. I am therefore dedicated to a lifetime of learning—a challenge that lies just as far ahead of me today as it did 40 years ago.

Resilience starts with a fierce will to excel. It also requires a sense of humility and vulnerability and a chronic unease not just that accidents might happen, but that they will. Richard Feynman said, "When playing Russian Roulette, the fact that the first shot got off safely is little comfort for the next."

Survival requires an obsession with process, quality, human factors, leadership, and teamwork. It requires individuals to step up, stop a drift toward failure, and stop the normalized deviance like the January/July Effect in hospitals in which patients are endangered in a cycle that repeats itself every year. (3) The January/July Effect is not new. Fresh but inexperienced medical graduates turn up for work in hospitals. The avoidable death rate spikes in hospitals when inexperienced graduates deliver medical care without sufficient medical supervision. If this spike had appeared in aviation industry, then the safety authorities would have analyzed the cause and made changes to correct the problem, all within the first or second cycle. The January/July Effect has continued, mostly unabated in the medical industry for over 25 years.

"Surgical Patient Care" is a must read for healthcare providers, administrators, and physicians who are serious about delivering safe and exceptional service. World leading industry leaders share knowledge and experience to improve safety. There are pearls of wisdom for regulators as well as safety and investigation authorities. Corporate directors and executives should enjoy

the discussions of governance, culture, safety management systems, safeguards, and risk. Everyone will enjoy the insights to improve human performance, target excellence, and achieve resilience.

I have known Doctor Paul Barach (one of the four editors of this book) for many years. Our friendship has been a voyage of discovery. A world authority on medical safety, Paul also understands where medical and aviation safety intersects.

I extend my best wishes to you, the reader. That you are reading this book means we share a passion for knowledge and aspire to expertise, personal resilience, and the best customer care. "Surgical Patient Care" analyses the same "elements of resilience" that exist in aviation. Just as aspiring pilots in my profession must read "Handling the Big Jets" by D.P. Davies, "Surgical Patient Care" should become a mandatory go-to reference for governments, organizations, and clinicians who want to do better and deliver safe care for every patient.

We don't know if we will survive the next black swan event. We don't know when and where it will strike. When we commit to a life of learning, gaining experience and leaderships skills, we'll become intrepid leaders of intrepid teams. At this point we will have the highest resilience and best able to save lives.

Captain Richard Champion de Crespigny
Qantas Pilot in Command of Flight QF32 and Author
of the Award Winning Book "QF32"

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Culture: The Building Block for Successful Partnering with Patients

At publication of this book, approximately 400,000 people will die every year as a result of a serious safety event making medical errors the third most common cause of death in the United States. Some will dispute this figure arguing that the data is not accurate and in fact much lower. Regardless of whether the actual number is 100,000 or 400,000 dead considering that there is roughly 5000 acute care hospitals in the United States, 20–80 patients will die at each facility because of a mistake—statistics we simply should not ignore. These are patients—people—that are dying as a result of our errors, and while it sounds shocking and perhaps a little embellished to use the term *kill*, we *kill* these people.

The statistics should shock us but they don't. As healthcare professionals, we see a slow trickle of these errors as well as millions of others that don't result in death because they show up in reports one data point at a time as nameless and faceless people. Our awareness and concern would turn to outrage if patients were killed in bulk and every time a mass killing occurred, we saw a headline warning of the dangers of healthcare. It would not only raise awareness to the problem, but would terrify us as providers for us or our loved ones to be a patient.

The root causes of these errors are complex and multidimensional. People are living longer, patients are sicker with an explosion of chronic disease and worsening social determinants of illness, medical technology and innovation is rapidly expanding and stressing our ability to keep up, and we struggle to manage the increasing regulatory burden and other external influences that make care delivery more sophisticated and at the same time more complicated. All of this strains our systems and challenges our caregiver's ability to take care of patients. Our ability to pay attention to the "little things" that cause problems becomes less, and the pressures on healthcare organizations, leaders, and frontline caregivers to accommodate these pressures today are unprecedented and worsening. Sadly, they create cynical, dejected, and burnt-out clinicians.

Some would say that a loose definition of culture is "the way we do things around here." If this is true, then this textbook should be the operating manual for every surgical department in the United States and around the world. The chapters in this book represent a "how-to" approach to address many of the issues we struggle with, and through clearly articulated strategy and process, suggest ways to make the practice of surgery better and more broadly to help transform healthcare overall. Executing on this body of work will make what

we do more effective and efficient, and help us conquer our challenges with the "little things" that lead to patient harm. But our efforts will not be complete and we will not achieve high performance or reliability in our work unless we begin to more prescriptively focus on the development of our healthcare culture as well.

In healthcare, culture is a topic often championed by our leaders but it typically remains a poorly defined and an invisible concept to our managers. There is a tendency to recognize the mythical impact of culture on what we do, but misunderstood as to how it can be leveraged by us every day to improve our healthcare operations. Culture and organizational climate in healthcare, unlike most industries, is a critical element that not only supports what we do, but ultimately ensures our success in delivering high-quality and reliable care to patients.

There are many different formal definitions of culture that encompass a wide variety of adjectives. One definition that is particularly fitting for healthcare is articulated by the team at Forester Research: "A system of shared values and behaviors that focus employee activity on improving the customer experience." If we substitute patients for customers and adopt our broader definition of the patient experience as it relates to safety, quality, and service, then this definition becomes more aligned with the work ahead of us and is consistent with the results we are starting to see in applying this data.

The patient experience has typically been defined incorrectly as making patients happy or improving patient satisfaction. Nothing could be farther from the truth, and in fact, the patient experience is more closely aligned with the mission of healthcare and the patient promise of delivering safe, high-quality care, in an environment of patient centeredness than it is with purely satisfaction. Medicare's inpatient Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey has nine questions about how we communicate with patients, three questions each on nurse, physician, and medication communication. Certainly, if the survey was designed to measure happiness, we would not need nine communication questions. However, when nurses improve communication at the bedside, medication errors, falls, and pressure ulcers are reduced—and those are safety considerations. When physicians communicate more effectively with patients and nurses, compliance with treatment and coordination of care improve respectively—both quality issues. It is also true that patients are happy when we communicate more effectively, but if we focus on the broader objective of improving overall communication, we have touched safety, quality, and the experience of care and thus improved not only each of those critical drivers, but the effectiveness of care delivery and deliver better value as well.

The importance that culture plays in supporting this assertion is indisputable. Press Ganey has correlated its engagement database of over 1.8 million caregivers against its HCAHPS database that includes 52 % of hospitals in the United States. Organizations where employees and physicians are more engaged and aligned around patient centricity have been shown to have higher patient experience metrics. The same correlations can be seen with the Centers for Medicare and Medicaid services value-based purchasing program (VBP): high employee and physician engagement equates to better performance on

VBP, and while providers often detest linking what we do to improved financial performance, the reality is that financial performance improves as well.

There is a more important piece to this story beyond just experience and financial metrics. As it turns out, similar relationships are seen in publicly reported safety metrics. Evidence is increasing, as more studies are published every year, linking higher performance on outcomes and experience of care with improved clinical performance (1). In one of the best published studies to date, a group examined data looking at 180,000 surgical patients from 102 hospitals comparing HCAHPS performance against surgical complications as reported in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. They found that in organizations with higher performing patient experience, mortality and minor complications were lower, and rescue rates from serious complications were higher (2).

Admittedly it would be a leap to suggest a causal association that improving patient experience leads to improved clinical outcomes; however, the correlations are clear and when you look at the association more broadly, the common foundation of improved performance is through caregiver engagement, which speaks directly to our healthcare culture. When organizations support a healthy workforce culture, where people are entering their organizations thinking about the higher purpose of taking care of patients, engaged in their work, free from harassment and bullying, trust their leaders and feel valued, healthcare delivery on multiple fronts is better. To deliver on the patient promise, achieve better operational performance and high reliability, and improve healthcare overall, we must recognize the role that our culture plays and the imperative to leverage this critical component of our organizations in our work. *So, where do we start*?

Cultural transformation starts by getting people to talk about it and empower every leader to manage it. Our cultures are our people and people are difficult to change, and that message is never accepted with open arms. We are all familiar with Peter Drucker's adage "culture eats strategy for breakfast." With this in mind, we must be thoughtful about how we discuss and approach our work in order to transform or evolve our culture to meet the requirements of the future.

The words we use are important. Imagine if a healthcare leader walks into a room full of physicians and proclaims that we have to change our culture. The message from that statement is that everything we are doing today is somehow wrong and the inference is that there is a personal responsibility for the organization's problems. The tone is negative and there is a connotation of blame and shame. When talking to healthcare professionals, whether physicians, nurses, or others, vocabulary, language, and respect matter. The conversation on cultural change needs to start with validating the work caregivers do every day to take care of patients—that it is hard work and these people are universally committed to doing a good job. Recognize them for their achievements, and then ask them to help with your initiative to evolve the culture to where it needs to be. Cultural transformation is the ultimate team sport and we need our people to enthusiastically own their culture and help transform it.

Just as we measure the voice of the patient to understand how we are delivering care, we must measure the voice of our caregivers through engagement to understand how well we are managing the organization. Just asking employees what they think is not good enough and often our leaders and managers have blind spots about how well they are managing people. Organizations must understand how their people are feeling, thinking, and behaving. Implementing employee, nurse, and physician engagement surveys can provide valuable information that can be used to help identify opportunities for improvement.

We must work to level our cultures and message the "why we are in healthcare" to reenergize our shared sense of purpose. We talk about our people being a group of highly functioning, cohesive professionals focused on the task of keeping patients at the center of our work. The reality is that, through decades of history, we have created tribes of different subcultures—physicians, nurses, administrators, and others that do not function in a unified fashion creating silos that don't work well together. We must level the power differentials and recognize that every role is necessary and no one is more important than someone else. People are different and the competencies they bring support different activities, but everyone is critical to the mission and this demands mutual respect and humility. All people enter healthcare because of a desire to help people; we are altruistic, compassionate, and empathetic. However these characteristics are degraded by the "hamster wheel" of everyday clinical operations and the hard work of taking care of patients. In healthcare, we are very efficient at calling out problems and blaming people for errors. Accountability is critical to our work but it cannot come at the expense of validating the importance and commitment of the work of our caregivers.

Our leaders and managers must be developed with critical competencies to help them become better at their jobs. One example is high reliability. Healthcare is an industry that requires us to function consistently and reliably, similar to other high-reliability industries such as the airlines, nuclear power, and the military. Mistakes in our industry have devastating consequences and result in poor, inconsistent outcomes and death. Reliability is the probability that a system, structure, component, process, or person will successfully perform the intended function(s). A critical component to achieving a high-reliability operating system is how an organization develops trust among and between its leaders and workers, and teaches their leaders and managers to drive toward high reliability as an operating chassis to improve performance in all areas of operations, including clinical delivery.

We must work to eradicate the slow growing cancers that erode the effectiveness of our cultures. Our caregivers—physicians and nurses—are experiencing record levels of burnout, stress, and compassion fatigue. Most of this is being driven by the increasing operational burden of healthcare, burdensome information systems that add work due to poor human factors, design, coupled with the taxing demands of taking care of patients. Burnout must be recognized, validated, and organizations must take steps to deal with it.

Bullying remains prevalent in healthcare; both overt acts that are relatively easy to recognize, and microaggressions, insidious personal attacks which are more difficult to spot. It should trouble us that there are terms such

as vertical and horizontal violence that describe how we interact with our colleagues: physicians, nurses, or staff intimidating their peers—that's horizontal violence; and those who intimidate their subordinates—that's vertical violence. Medicine has made progress but we have more work to do. This author knows from personal experience that this type of emotional violence is still rampant in medical and surgical training having experienced bullying by staff physicians both as a resident and a fellow. It takes courage and personal responsibility to stand up against this behavior regardless of our role and wherever we witness it, but we must if we are to promote the environments that will allow our people to flourish.

As leaders we must be mindful of the programs we develop and institute. Despite our best intentions, we implement programs that work to erode our culture. We create new initiatives couched in fancy slogans; our efforts to cut costs become "cost repositioning," or "value realignment," or "care transformation." We use these techniques to act as a crutch for our inability to effectively communicate and manage change, and we insult our employees by failing to give them credit for understanding the real meaning behind what we are doing. This creates suspicion and fuels distrust, as our caregivers walk around wondering, "… am I going to lose my job?" In such an environment, the opportunity to message partnership and engagement is lost, and our cultures suffer.

We must promote greater interprofessional cooperation and teamwork. Nurses talk negatively about physicians, physicians talk negatively about nurses, and often both professionals talk negatively about the organizations and their leaders for which they work. Unfortunately much of this behavior plays out in front of patients. Eliminating this childish, unprofessional behavior requires us to improve teamwork, which is one of the ultimate ironies in healthcare. We know the importance of high-performing teams in our industry and we preach how essential it is to everything we do, but we spend little time teaching it. Promoting teamwork and interprofessional relationships are an element of our cultures and lead to a healthier working environment. Healthcare workers often throw their colleagues under the bus for sport.

We will continue to fight these battles on the back end through cultural development and transformation efforts, but we should find strategies to be more proactive. Instead of investing all of our resources and putting all of our focus on changing, what if we put some of our resources on developing people before they ever reached our cultures? Organizations across the country spend millions of dollars working to transform their people to work better together, develop missing competencies, and enhance the work of managing healthcare. Imagine if instead of retooling on the back end, healthcare invested more on the front end to develop our professionals of the future. Many physicians attended medical schools that were physically attached to nursing schools, but not once in 4 years did those young aspiring professionals ever share a class together. There is some interaction when these students begin their clinical exposure in hospitals, but usually they are learning in parallel with little or no overlap or formal interaction. Even after graduation, physicians are launched into their postgraduate training and nurses begin their career in mostly separate trajectories.

Not starting this process at the beginning, rather than later on in their careers after they have established their own work patterns, is a lost opportunity for all of us. Some academic organizations do this now, but the development stops at graduation. Instead of having the experience learning stop at graduation, what if we continue training doctors and nurses together—while physicians are in postgraduate education and young nurses have started their career? And not just cohorting doctors and nurses together, but other health professionals as well.

Our mission is to teach the healthcare professionals of the future the skills they need to be successful, but our imperative is to develop the humanity, humility, truthfulness, and behaviors that form the culture of the organizations that we are responsible for leading. We can tackle this critically important issue of cultural development by driving and insisting upon more interprofessional education and interaction among aspiring professionals.

Patients come to medicine at the most challenged time of their lives with anxiety, fear, despair, and uncertainty. Our collective responsibility is to protect them from harm and reduce their suffering by fulfilling our promise to provide safe, high-quality care in an environment where they leave feeling, knowing, and believing that we actually cared for them as people. This requires us to raise the bar on improving safety, quality, and their experience. While we struggle with many top-of-mind issues and competing interests, we must be reminded of the need to keep patients at the center of our work, meet their needs, and reduce their suffering. Healthcare will only be successful if we recognize the need to improve our operations and reform our cultures to become higher performing organizations.

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Preface

"The last part of surgery, namely operations, is a reflection on the healing art; it is a tacit acknowledgment of the insufficiency of surgery. It is like an armed savage who attempts to get that by force which a civilized man would get by stratagem."

—Lectures on the Principles of Surgery at St. George's in London, John Hunter, 1786

The field of surgery and surgical illness care has developed faster than nearly all other fields in medicine. Although the fundamental biological substrates contributing to surgical disease are far from being completely understood and there are great variations in the manifestations and complexity of illnesses, there are, nevertheless, well-established treatment options for correction and palliation of most medical conditions and the associated pathophysiology is, generally, well understood. In recent years, global expenditures for health have risen substantially, particularly for infectious diseases. Although conditions amenable to surgery account for 28 % of the global burden of disease, the external funds directed toward global surgical delivery are low. Given the large global demand for surgical care and the crosscutting nature of surgery, scale-up of basic surgical services is crucial to strengthening health systems worldwide.

It seems, however, that despite unprecedented levels of spending on surgical care, preventable medical and surgical errors have not been reduced, uncoordinated care continues to frustrate patients, caregivers, and providers, and healthcare costs continue to rise. There are, of course, many possible factors at the root of these conditions, including the inexorable and ongoing introduction of new technologies that alter rather than improve systems of care, the lack of engagement of frontline staff in strategic decision-making and change, the lack of appreciation for the complex sociotechnical challenges in the operating room, and the limited but evolving ability to collect and analyze meaningful clinical data as applied to quality and safety metrics.

High reliability—or consistent performance at high levels of safety over prolonged periods—is a hallmark for non-health-related, high-risk industries, such as aviation and nuclear power generation. Moving surgical care from low to high reliability is centered on supporting and building a culture of trust, transparency, and psychological safety among surgical team members. This remains a major obstacle in moving healthcare toward safer, high-valued care. In the face of health reform and increased competition in the market, moving to high reliability requires adopting and supporting a culture

Fig. 1 High-reliability organizations and their organizational culture*

that appreciates the relationships among a variety of organizational and technical risk factors and their effects on patient harm and procedural inefficiency. This concept (Fig. 1) underscores the central role of creating an organizational culture of safety that enables improving surgical safety and quality and providing high value surgical care. This requires that clinicians acknowledge their primary responsibility to care for patients and their families as well as to manage processes for optimization, standardization, and continuous measuring and monitoring of outcomes.

This book focuses on safety, quality, and reliability along the surgical health continuum, particularly the perioperative environment with its unique socio-technical issues and challenges. The book is designed to grow a larger appreciation for what brings surgical clinicians joy and supports their surgical expertise and how other experts can better design tools and systems that can better meet clinician's needs. While it is intended as a "go-to" resource for all healthcare professionals that interact with surgical patients, it is primarily designed for the frontline practitioner, those at the "sharp end." The strong interprofessional and cross-disciplinary orientation of this book is by intentional design and is organized using a "systems" framework throughout its pages using the conceptual model depicted (Fig. 2.)

There is worldwide fascination and concern with what happens in the operating room, fueled by well-publicized breakthroughs, feats of technology, but also investigations, inquiries, and sensational media. More recently, apart from the occasional new gadgets developed to be used on patients, attention has been directed at high variability and suboptimal surgical results. A consistent theme in safety inquiries is that many staff, patients, and managers have raised concerns previously about the unsafe conditions under which care is provided to patients. For example, the events surrounding the Veterans Health Affairs scheduling affair, UK Bristol Royal Infirmary, the Japanese Gunma Hospital Inquiry and the Canadian Manitoba Healthcare inquiries—all came to light thanks to courageous whistleblowers—highlight the importance of climate of safety in which engaged leaders and clinicians appreciate

*The more I know, the less I sleep, Global perspectives on clinical governance. Lead author Marc berg, Paul Barach co-author, KPMG Global Health Practice. December 2013.

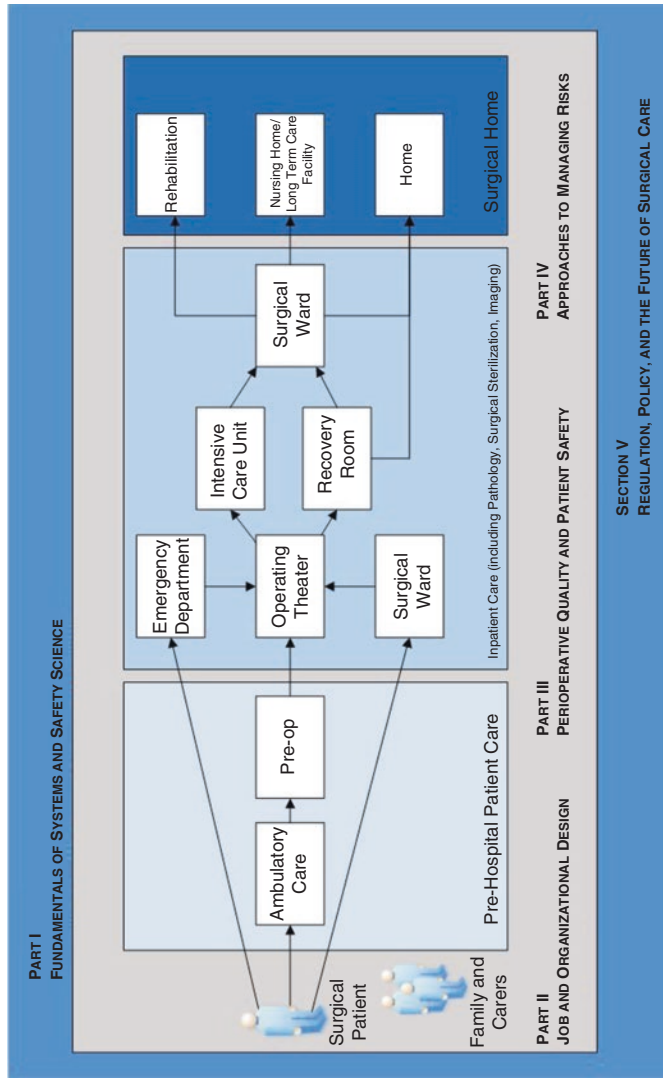

Fig. 2 Conceptual model.

the impact of human factors and systems effects in improving outcomes in complex surgical procedures.

Several factors have been linked to poor outcomes in surgical care including low institutional and surgeon- or operator-specific volumes, case complexity, team coordination and collaboration, communication across elements of care, clunky technology and human machine interfaces, and systems failures. Safety and resilience in these organizations can be ultimately understood as a specific characteristic of the system—the sum of all its parts plus its design, relationships, and interactions. Further, many regulatory and government agencies are examining more closely the impact of procedural volume, management of risk and mitigation strategies, and environments of care on the outcomes of surgery in the field. Delivering reliable surgical care is complex, challenging, and expensive and requires an "all hands on deck" approach. The need for heightened situational awareness, heightened communication practices, and an emphasis on the potential for failure should be essential characteristics of the surgical workforce.

The expanding scope of procedures and technology in surgery adds exponential complexity which is highly dependent on a sophisticated organizational structure, the coordinated efforts of a team of individuals, high levels of cognitive and technical performance, and robust and reliable communications. Performance and outcomes have been shown to depend on complex individual, technical, and organizational factors and the interactions among them. These shared properties rely on the specific context of complex team-based care, the acquisition and maintenance of individual technical and nontechnical skills, the role and consequences of technology, and the impact of working conditions on team performance.

The study of human factors is fundamentally about understanding how to optimize socio-technical systems and the complicated relationship between people, tasks, and dynamic environments. An organizational accident model proposes that adverse incidents be examined both from an organizational perspective that incorporates the concept of active and latent conditions and from an individual perspective that considers the cascading nature of human error. Although a particular human action or omission may be the immediate or suspected cause of an incident, a closer analysis usually reveals a preceding series of events and departures from safe practices, usually influenced by the working environment and the wider organizational context and working conditions.

Performance and outcomes depend on complex individual, technical, and organizational factors and the interactions among them. Interventions to improve quality and strategies to implement change should be directed to improve and reduce variations in care and outcomes. To achieve these objectives, it is imperative there be an appreciation of the relevant human factors on the ground, including an understanding of the complexity of interactions between the:

- technical task
- treatment environment (noise, interruptions, distractions, etc)
- consequences of rigid hierarchies within the staff
- adequacy and completeness of briefing and debriefing
- cultural norms that resist change

In addition, the evolving regulatory environment employs strategies such as public reporting and financial penalties for underperformance. Proscriptive rules, guidelines, and checklists have the potential to raise awareness and prevent harm; however, to provide a safe system for patients and their families, we need to understand and improve systems, rethink design and work practices, and sustain a nimbleness or innovation that supports developing resilience to recover from adverse events and to predict and prevent future events.

We believe that innovation in surgical patient care is best designed in concert with those on the front lines of healthcare delivery—patients and clinicians—and by incorporating relevant knowledge from other scientific disciplines such as operations research, organizational behavior, industrial and human factors engineering, and psychology. Our focus in this book is to bring even more scientific discipline and measurement to the design, oversight, and measurement of surgical care to best engage all clinical and administrative healthcare professionals.

The editors feel that the ideas in this book could not be timelier and we are indebted to the wonderful contributions from surgical leaders and experts across many disciplines from around the world. We hope this book provides readers with a roadmap for how to "think differently" as well as a common reference source of current initiatives in outcomes analysis, quality improvement, and patient safety, with the ultimate goal of advancing and optimizing surgical care. Moreover, we hope the content and the authors of this text will inspire readers, engagement, change, and that, through collaboration and sharing, surgical care will be enriched and improved across the world. We hope you will find this book helpful and trust you will enjoy reading it as much as we have enjoyed preparing it.

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—Juan A. Sanchez

To the love of my life Julie, my best friend, and most trusted advisor, and my three awesome boys, Harrison, Tore, and Elijah—they have inspired me to do everything possible to improve healthcare. This has been possible by the wisdom and collaboration of my cherished colleagues and mentors. Finally, I want to dedicate this book to my father, Harold Barach, a compassionate physician who supported me on this book but who died in January, before the book was completed. He profoundly shaped my life through his unconditional love and started me on the journey of becoming a healer. And to my mother, Frances Barach, who inspired me with love and guidance to never take no for an answer.

—Paul Barach

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—Julie K. Johnson

To my parents David and Marilyn Jacobs for giving me the opportunity, to my wife Stacy for supporting and loving me, to our children Jessica and Joshua for making us proud and motivated, and to our patients, who represent the rationale for this initiative.

—Jeffery P. Jacobs

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Part I

Fundamentals of Systems and Safety Science

The Burning Platform: Improving Surgical Quality and Keeping Patients Safe

1

Juan A. Sanchez and Kevin W. Lobdell

"It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things."

—Niccolò Machiavelli, The Prince

Introduction

The ability of healthcare to save and extend life and improve the quality of life for the ill is a testament to the success of human competencies, technology and scientific inquiry. Perhaps as a result, most healthcare systems are challenged by issues of access, quality, and cost. Although most institutions and systems provide safe and effective care for the vast majority of patients most of the time, unwanted variation in quality and safety is common [1, 2]. The causes for this are many and not always well understood but, in general, they result from [1] an increasingly complex healthcare environment, [2] rapidly exploding medical knowledge; [3] poor evidence for the treatments available; and [4] an overreliance on subjective judgment [3].

A RAND Corporation analysis highlights opportunities to improve the healthcare system in which some people receive more care than they need and others receive less, and yet others get little access to care [4]. In this study, approximately 50 % of those seeking healthcare received the recommended preventive care. For acute care, 70 % received the recommended treatment and 30 % of patients received contraindicated care. For chronic diseases, 60 % of patients received the recommended care and 20 % received contraindicated care. These studies strongly suggest that, too frequently, care delivered in developed countries does not meet professional standards or best practices. In fact, the US healthcare system gets it "right" only 55 % of the time [5].

Adverse events in the course of delivering surgical care reminds us that "therapy" can harm patients, their families, and even front-line workers. The term "nosocomial conditions," from nosocomium, (*nosos*, Greek, "disease"), an archaic term for hospital, reflects the reality that these conditions are caused by exposure to the healthcare system in contrast to the more specific term "iatrogenesis" (*iatros*, Greek, "physician") in which harm is caused as a result of an individual physician [6]. This distinction highlights that substandard care and patient harm can no longer be attributable to one individual but are rooted in the characteristics of the system which conspires with human fallibility to create opportunities for mistakes, lapses, and unintended events [7].

While the identification of what is substandard medical care may be open to vigorous debate, definitions of medical error and adverse events are

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much more obvious and there is ample evidence that the current surgical environment is dangerous and can unintentionally harm patients [8, 9].

It is important to distinguish poor outcomes due to the nature and progression of disease and expected rates of complications from substandard medical care. Unfortunately, this distinction is not always obvious and poor outcomes are often misattributed to patient comorbidity. Additionally, evidence-based medicine and tools to standardize processes of care (care pathways and treatment algorithms) may not be properly implemented or may not produce the desired results. This chapter is intended to provide a broad overview of the major factors contributing to the disparity between the practices we know are effective and the real-world state of surgical care with the intention of helping perioperative teams "hardwire" optimal processes and practices to close this gap [10].

Each member of the healthcare team must be skilled, competent, and unbiased in their ability to choose the right therapy for their patients [11]. The healthcare system fails when thoughts, decisions, and actions deviate from this fiduciary and ethical duty. Patient safety can be seen as the "low-hanging fruit" of the quality "tree." Efforts to improve quality must begin with avoiding patient harm [12]. Evaluation and reporting of "near misses" is an essential activity in order to promote organizational learning and continuous improvement [13]. Reporting, however, alone does not appear to capture many of these events [14–18]. Quality cannot be reliably improved when unsafe systems, unmitigated hazards, and other safety-related issues persist throughout the system.

Numerous studies have concluded that "the burden of harm conveyed by the collective impact of all of our health care quality problems is staggering" [19]. In "To Err is Human: Building a Safer Health System (1999)" and its subsequent publication "Crossing the Quality Chasm: A New Health System for the 21st Century (2001)," the Institute of Medicine highlighted the serious and pervasive nature of the US healthcare quality problem [20, 21]. These have become clarion calls suggesting that reforms at the margins are inadequate and that a true transformation of the healthcare system is required. These and other reports raised the public consciousness the issues of patient safety and quality and called for system redesign by defining six major aims for system transformation (Table 1.1) [21].

Table 1.1 The Institute of Medicine's six aims for healthcare system redesign

Healthcare should be
• Safe
• Effective
• Patient centered
• Timely
• Efficient
• Equitable

Threats to Patient Safety

Progress in science and technology has led to dramatic, worldwide improvements in health and longevity. However, this progress is associated with a level of complexity, distractions, and system opacity, which hampers our ability to reliably produce optimal and safe outcomes [22].

Healthcare can be viewed as a complex adaptive system and concepts from complexity science and engineering will undoubtedly play an increasing role in the design of new care delivery systems and models [3]. Numerous studies document the worldwide unacceptable rates of patient harm and the negative consequences of variations in care [23–29]. In addition, poor quality, i.e., the difference between optimal outcomes and what actually exists, is characterized by overuse, underuse, and misuse of healthcare resources [30–35]. Although progress to date has been slow, continued efforts to understand the root causes of suboptimal levels of quality will ultimately lead to a more reliable, high-value healthcare system [36, 37].

Poor quality and errors stem from a fragmented, multilayered, and "siloed" system of care with diffuse accountability, staggering amount of information, and pressures to function at the margins of the system's capacity [38]. When combined with human fallibility, complexity leads to process variability and poorly coordinated medical care as well as inconsistent standards and inadequate care transitions (Table 1.2) [7, 39]. Other factors such as strong production pressures, time constraints, and a rigidly hierarchical culture

Table 1.2 System threats to safety [39]

• Complexity
• Variability
• Inconsistent standards
• Poor care transitions
• Absence of error traps and barriers (e.g., forcing functions)
• No training to handle the unexpected
• Time constraints
• Hierarchical culture
• Human fallibility

also contribute to a system of unreliable, inconsistent, and too often dangerous care.

Avoidable Errors

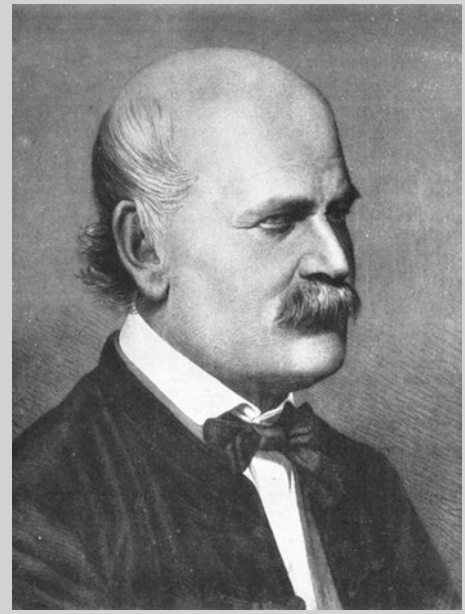
Many patients are injured during the course of their treatment and some die from these injuries. In New York hospitals, for example, 3.7% of patients out of 30,121 randomly selected records suffered adverse events during their hospitalization and approximately 70% of these resulted in disability lasting less than 6 months, 2.6% caused permanently disabling injuries, and 13.6% led to death [25]. In a study of hospitals in Colorado and Utah, surgical adverse events accounted for two-thirds of all events [40].

Serious, entirely preventable surgical events, known as "never events," continue to occur despite extensive efforts to thwart them. Perioperative mistakes such as retained surgical equipment, burns and positioning injuries, as well as wrong-site, wrong-patient, and wrong-procedure events should never occur in any patients [9, 41]. When combined with other events such as medication errors, accidental punctures and lacerations, and other mistakes, these events constitute considerable aggregate risk for the surgical patient.

The US Centers for Disease Control and Prevention (CDC) estimates that each year 1.7 million HAIs occur in US hospitals each year, resulting in 99,000 deaths and an estimated $20 billion in healthcare costs [42]. Healthcare-acquired conditions such as infections are a costly plague to patients and the healthcare system. When patients are admitted to a hospital, they should not suffer a preventable healthcare-associated infection (HAI). Unfortunately, surgical team members still have low hand washing compliance rates upon entering the operating room ranging from 2.9 to 10%, thus contributing to surgical infections [43, 44]. Unfortunately, HAIs affect 5–10% of all hospitalized patients in the USA annually [42]. HAIs such as surgical site infections, pneumonia, and infections of implanted devices can lead to death or serious chronic disability and are largely if not entirely preventable.

In New York City, hospital-acquired staphylococcus infections alone cost $400 million. In 2014, a survey by the CDC which described the burden of HAIs in US hospitals reported that about 75,000 patients with HAIs died during their hospitalizations [42]. More than half of these occurred outside of the intensive care unit. Most alarming is that many hospital-acquired bacterial infections have developed resistance to, at least, one of the antibiotics traditionally used to treat them [45]. Antibiotic stewardship and infection-reduction programs include discriminate antibiotic therapy as well as reliable use of appropriate infection prevention measures (hand hygiene, skin preparation and depilation techniques, gloves, gowns, air handling, cleaning, etc.) [46].

Profiles in Surgical Patient Safety



Ignaz Philipp Semmelweis: The Epidemiologic Approach to Patient Safety [47, 48]

Puerperal "(childbed) fever in Vienna during the 1840s resulted in high rates of mortality for both mother and child following delivery. Dr. Semmelweis, a German-Hungarian physician, found that the prevalence of this condition varied between two different obstetrical clinics. By analyzing records at the Vienna General Hospital, he correlated the rise in the rate of this condition at the clinic attended by physicians with the institution of postmortem examinations at the hospital. The other maternity clinic, which was exclusively staffed by midwives, had a threefold lower incidence of childbed fever. Semmelweis proposed that the practice of washing hands with chlorinated lime solutions in 1847 reduced mortality to below 1%. The notion that physicians could transfer disease from the autopsy room to other patients resulting in their death was strongly resisted and doctors were offended at the suggestion that they should wash their hands. His ideas earned widespread acceptance only after his death, when Louis Pasteur confirmed the germ theory and Joseph Lister developed other hygienic methods. Semmelweis' findings laid the groundwork for the science of hospital epidemiology and efforts to control healthcare-associated infections.

Ignaz Semmelweis 1860 (Copper plate engraving by Jenő Doby) Benedek, István (1983) Ignaz Phillip Semmelweis 1818–1865, Gyomaendrőd, Hungary: Corvina Kiadó ISBN: 9631314596. plate 15. Public Domain

Variation

Research indicates that unnecessary variation harms patients, leads to poor quality, and results in high levels of waste [2, 49–51]. Furthermore, it appears that much of the current variation in surgical care reflects inconsistent application of evidence-based practice standards as applied to clinical decision making and the use of technology or methods for which there is no evidence or wide acceptance. Much practice variation and many clinical decisions seem to be influenced by non-patient-related factors such as geographic, age-related, racial, socioeconomic, and ethnic disparities that have been demonstrated to exist for a variety of conditions [52–56].

The rates of many surgical procedures including vascular surgery, coronary artery bypass operations, lung surgery, and other types of procedures vary as much as tenfold across geographic regions [1, 2, 49, 52, 57, 58]. Substantial practice variation has also been shown to exist between surgeons, even within the same medical center [59]. For example, when selecting patients with prostate cancer for radical prostatectomy, a study demonstrated considerable variability among surgeons at a high-volume academic center [60]. The study suggested that publicly reporting individual practice patterns at the surgeon level could potentially decrease the overtreatment of low-risk prostate cancer [61]. These phenomena are not due solely to insurance coverage variations and they are well found in countries with universal health coverage such as Great Britain and Canada [62].

In another example, poor adherence to well-accepted national guidelines for preoperative testing has been shown to lead to overuse. Feng et al. found that women undergoing mid-urethral sling surgery were subjected to unnecessary testing during preparation for surgery [63]. In this study, approximately two-thirds of complete blood counts and coagulation profiles were not indicated. Additionally, 22% of chest radiographs and 6% of electrocardiograms were not obtained despite being indicated. One study demonstrated that 31% of patients undergoing total knee arthroplasty did not have an indication for the procedure and an additional 21% had inconclusive indications [30].

The appropriateness criteria have not been developed for most common surgical procedures and many of the existing ones are outdated [32, 34, 64–69]. It is anticipated that investments in comparative effectiveness research will yield meaningful contributions towards the development of appropriateness criteria and reduce practice variation in the future. A broad, coordinated effort will be required to ensure adherence to

practice guidelines and other tools which promote the application of evidence-based practice standards to address variation in the use of surgical procedures. Ultimately, an approach which incorporates a shared decision-making paradigm involving patients and physicians should ensure that proper diagnostic evaluation has been done and appropriate treatments are offered [67].

Studies have found that only between 10 and 20 % of routine medical practice has a basis in scientific research [70–72]. Much of what is done in clinical practice is based on tradition or opinion in the absence of valid clinical knowledge or with inadequate evidence for what is best for a given patient. Quite often, these treatments are effective, but the lack of concrete data underscores the need for healthcare organizations and individual practitioners to follow their outcomes and compare them to other centers. Risk-adjusted surgical registries such as the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) allow opportunities for improvement to continuously improve the efficiency and effectiveness of surgical care [73].

Profiles in Surgical Patient Safety

Florence Nightingale: Nursing Pioneer

Probably most known for her work during the Crimean War where Florence Nightingale found camp hospitals overcrowded, undersupplied, and unsanitary. She transformed hospitals into a healthy and healing environment resulting in a drop in mortality from 40 to 2 % [74]. Nightingale's statistical data analysis of her experiences led to significant advances in public health throughout Britain. Under her leadership, nurses helped transform hospitals from places to die to sanctuaries of care. Her influential book "Notes on Nursing: What it is, and What it is Not" described that hygiene, sanitation, fresh air, proper lighting, a good diet, quiet, and comfort were necessary conditions for hospitals. Nightingale established a Nursing School at St. Thomas' Hospital in 1860 to teach her principles of nursing practice [75]. Her students went on to staff many hospitals in Britain and abroad and spread her nursing education system to other countries. Through her work on hospital operations, sanitation, and other public health issues, as well as contributions to healthcare statistics, she is responsible for elevating the profession of nursing to professional status.

Overuse

Effective care occurs when the benefits of an intervention outweigh the risks. Overuse occurs when patients receive treatments, tests, or medications when there is no evidence that such treatment will improve a patient's outcome and may expose the patient to unnecessary risks. The associated cost from overuse is staggering, particularly for certain conditions and procedures. It has been estimated, for example, that the number of unnecessary hysterectomies in the USA impacts approximately 80,000 women and adds a cost of $320 million annually [76].

Underuse

Underuse occurs when healthcare providers neglect to give patients medically indicated care or to fail to follow accepted practices. Care for vulnerable individuals such as the elderly and children falls short of acceptable standards for a wide variety of conditions. Patients do not receive the appropriate and timely care necessary which often leads to additional and more severe complications resulting in poor outcomes and adding to healthcare costs needlessly. An in-depth study of lower extremity vascular procedures for critical limb ischemia, for example, showed a significant variability of amputation rates when comparing areas with different intensity of vascular care suggesting that patients in some areas are far less likely to receive limb salvage procedures [77].

Disparities in Surgical Care

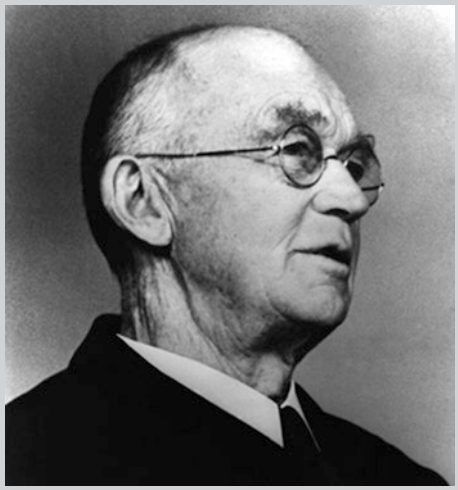
The care provided to different segments of the population does not appear to be evenly distributed and many studies have documented racial and socioeconomic disparities in both treatments and outcomes [54–56]. For example, in patients with early-stage non-small-cell lung cancer (NSCLC), receiving of curative-intent surgery was significantly less for black patients than for whites in every state in the USA [52]. Such unequal care has been documented for a number of different surgical treatments such as obesity surgery, cancer care, and cardiovascular procedures [2, 62, 78].

Disparities also occur in populations with special vulnerability to adverse events such as the very old, mentally ill, trauma patients and the very young often due to their inability to participate actively in their own care mainly due to communication barriers [53, 79]. Older people, for example, may suffer varying degrees of impairment in vision and hearing as well as cognitive deficits and may not be able to understand or communicate with their caregivers. These problems are compounded when serious illness or trauma occurs contributing to these difficulties and potentially leading to errors [80]. Infants and children are also at greater risk of serious errors particularly related to medications with devastating effects [71, 81]. In culturally and ethnically diverse populations, individuals with limited language skills or literacy are also vulnerable to disparities and communication failures often occur which potentially lead to misunderstandings and errors [82–84].

Measuring Surgical Quality

Quality can be assessed both explicitly and implicitly. Explicit quality measures are developed prospectively and are well defined. Explicit measures are evidence based and their construct validity and reliability have been verified through independent observations. Unfortunately, the majority of surgical care currently can only be evaluated implicitly. Implicit measurements of quality are generally based on subjective evaluation [67, 85–87]. While clinical databases and disease registries such as NSQIP and the Society of Thoracic Surgery's National Databases have developed well-defined process and outcome measures, they are only applicable to a limited range of surgical procedures and participation is voluntary [73, 88]. Much of what constitutes "surgical care" currently falls outside the range of our ability to objectively compare and mostly relies on subjective interpretation. Furthermore, implicit quality measures are based on expert judgment by peers or by proxies of quality including processes of care but do not measure true quality. For example, using the perspective of the three domains of quality proposed by Donabedian (structure, process, and outcomes), structural measures such as hospital or surgeon volume are relatively easy to obtain [85]. However, the relationship between volume and quality is not always clear. In general, hospitals or surgeons performing large numbers of a particular surgical procedure may have lower mortality; however, other factors including severity case-mix and other unmodifiable, often, intangible factors also contribute to poor results. Adjusting for risk requires the use of sophisticated analytic methods with inherent limitations and not all risk factors can be captured. Furthermore this approach is currently limited to a narrow range of procedures.

Profiles in Surgical Safety



Ernest Amory Codman and Hospital Standardization [89]

A Boston surgeon, Dr. Codman is known more than anything else for his advocacy of the "End Result Idea," the premise that hospital staffs should follow every patient they treat long enough to determine whether or not the treatment was successful, and then learn from failures and how to avoid them. Although controversial at the time, his ideas were the basis for the subsequent hospital standardization movement advanced by the American College of Surgeons, and were the precursor to the Joint Commission in the USA. The Joint Commission is an organization devoted to setting standards of healthcare quality worldwide. Dr. Codman was a crusader for data-driven, evidence-based, and patient-centered surgical care.

Certain process measures, such as the timeliness and appropriateness of administering prophylactic antibiotics, are currently in use as an index of surgical quality for the purpose of payment of hospitals in the USA [90]. This approach to ensuring quality using vetted, evidence-based metrics may address the lowest common denominator but it relies on a process that is only indirectly related to outcomes and the infrequency of the adverse events (i.e., surgical infections) makes a causal inference difficult in the practitioner's mind. Reporting a limited number of process and structure measures does not provide a true picture of surgical quality and may not get at the root causes of poor outcomes [91]. In contrast to structure and process, measures of outcome provide a more global assessment of quality and are what ultimately matters most to patients [92]. The use of outcome measures as indicators of surgical quality is difficult and complicated by confounding variables and other factors. Adjusting for risk factors is not an exact science and insufficient evidence exists as to what specific prognostic factors actually impact outcomes. Additionally, there are multiple methodologies for case-mix adjustment and the use of these different methods can potentially provide differing results [93].

How does one determine what is an acceptable outcome in, say, herniorrhaphy? Is it an absence of hernia recurrence at 30 days? At a year? Most current surgical outcome measures, as reported to registries and regulatory agencies, are limited to in-hospital or 30-day mortality and morbidities [32]. Peer review of other outcome measures such as readmissions, infections, and complications, ostensible defects in the provision of surgical care, may be of some value but is difficult to collect if patients do not always return to the same institution for care particularly if the procedure is done at independent facilities such as free-standing ambulatory surgery centers (ASC) unless a mechanism exists regionally to capture this information.

The importance of accurately collecting clinical indicators of surgical quality cannot be overstated. This information is central to improving quality and the feedback allows individual hospitals and surgeons to gauge and monitor their own quality and compare themselves to other centers and practitioners using an "apples-to-apples" (i.e., risk-adjusted) approach. Public information on relative rankings of surgeons or institutions may stimulate improvement and the formation of intramural and multiorganizational collaborative groups coalescing around quality and sharing best practices. When data used for analysis is based on information reported following discharge and abstracted by trained but nonclinical

coders, only the most obvious and direct outcome measures can be reliable. Such use of administrative data, generated for the purpose of obtaining reimbursement by hospitals, may not reflect actual clinical quality although this data is often more accessible and less costly to acquire.

Profiles in Surgical Patient Safety

Dr. Lucian L. Leape: The First Study of Iatrogenesis

In his 1991 landmark paper, Dr. Leap and his colleagues described the Harvard Medical Practice Study, a sample of 30,195 randomly selected hospital records which identified 3.7% with disabling injuries caused by medical treatment [94]. Leape's publication, Error in Medicine, in JAMA in 1994, called for the application of systems theory to prevent medical errors. His work led ultimately to the Institute of Medicine's landmark publications, To Err is Human and Crossing the Quality Chasm, Dr. Leape has devoted his entire career to the cause of preventing medical errors and protecting patient safety. Professor Leape has testified before a subcommittee of the US Senate on improving patient safety. The Lucian Leape Institute at the National Patient Safety Foundation was founded in 2007 to further strategic thinking in patient safety.

Conclusions

It has become patently obvious that the levels of quality and harm in modern surgical care are not acceptable. An understanding of the causes of poor quality, inappropriate variability, and medical errors is central to delivering value to the surgical patient. The surgical environment is a socio-technical system with great complexity and, thus, "target rich" for mitigating hazards and addressing poor and inconsistent quality. Meaningful change will require an "all-hands-on-deck" approach by surgeons, nurses, and others involved in the care of surgical patients in transitioning to a team-oriented, systems-based work.

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Risk Factors and Epidemiology of Surgical Safety

2

Oliver Groene

"You cannot swim for new horizons until you have courage to lose sight of the shore."

—William Faulkner

A Framework to Study Errors and Harm

Hundreds of people are admitted to hospitals every year. In the UK, there are about 17 million hospital admissions annually; about one-third of admissions are for a surgical procedure. In high-income countries most procedures are conducted safely; yet, unfortunately some patients experience adverse events, resulting in harm or even death. The proportion of patients experiencing harm remains significant, despite the major focus on improving patient safety in the last decade [1].

There are many ways to define harm. The WHO/World Alliance for Safer Healthcare defines healthcare-related harm as '*an injury arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury*' [2]. Harm may result in temporary or permanent lessening of body sensory, motor, physiologic or intellectual function. The definition clearly relates harm to actions of healthcare provision although it fails to capture harm from acts of omission. Others suggest a broader definition that covers patient harm resulting from acts of commission (affirmative actions such as incorrectly conducted procedure) or acts of omission (such as failure to treat a condition), as well as unintended complications of healthcare [3]. Preceding harm and adverse events are incidents or near misses, unintended or unexpected incident that could have harmed patients, but did not [4].

In this chapter we consider harm as an adverse outcome of structural and process factors within hospitals. Brown et al. proposed a framework to study these relationships, building on Donabedian's structure-process-outcome model and the work of James Reason on latent and active errors [5]. In the framework, *management processes* cover for example human resource policies: training of new staff or management of the supply chain. Latent errors related to such management processes might expose clinicians to outdated work practices or indirectly put patients at risk. *Clinical processes* cover the adoption of particular safety/evidence-based practices and the quality of procedure. Active errors in clinical processes directly put patients at risk and may cause harm or death. The model is important for an understanding of a systems perspective on latent and active errors, and the complex relationship between wider management processes, clinical processes, and patient outcomes [6]. Latent and active errors may lead to an adverse event (or patient incident), but not all adverse events also cause a permanent harm to the patient (Fig. 2.1).

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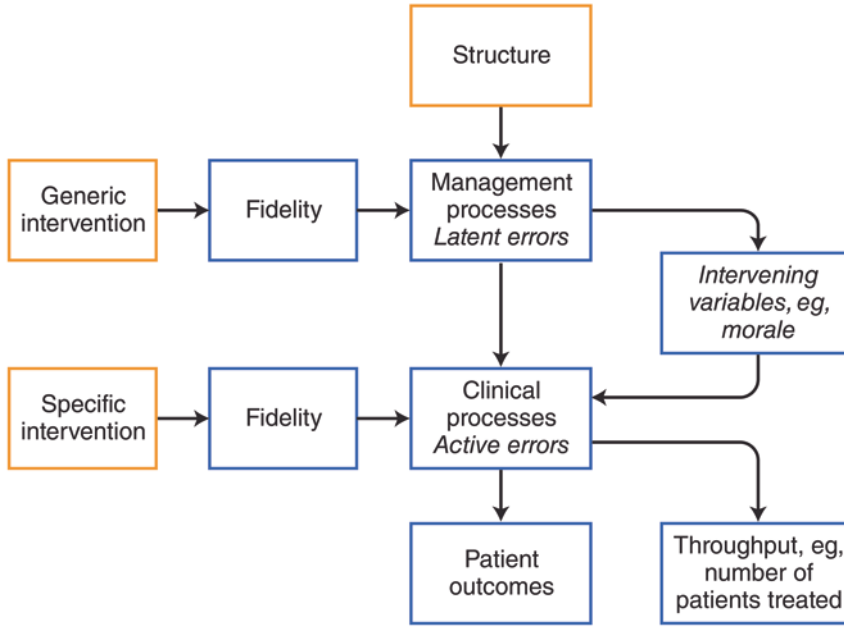

Fig. 2.1 General and specific interventions across the system and evaluation end points (modified from Brown et al.)

This epistemology of surgical safety is applicable to a wide range of settings. In low-income countries many people don't have access to safe surgery and the study of surgical safety differs methodologically, because of lack of access to high-quality data and care.

Nevertheless, data on surgical safety in low- or middle-income countries is starting to emerge [7]. It represents a significant problem, especially considering the global strategy towards universal healthcare coverage (which currently may imply access to unsafe surgical practices).

The Scale of Harm in Surgery

There have been major achievements in surgery in the last 100 years, made possible through infection prevention, safe anaesthesia, modern operation theatres and minimal invasive techniques. The World Health Organization (WHO) estimates that about 234 million major surgical procedures are undertaken every year worldwide [8]. Despite improvements in surgical safety, reducing the amount of harm caused by surgery remains a challenge, as the nature of surgery changes and becomes much more complex, involving an ever-increasing number of team members in surgical preparation, conducting the procedure and providing complex follow-up care.

For example, the number of team members (surgeons, anaesthesiologists, operating room nurses) directly involved in a typical surgical procedure might be, six, but the total number of staff involved in organising, administering and delivering the clinical care process leading to, and following from, the surgery might be ten times this number [9]. Due to the complexity of the care pathway, perioperative care processes are becoming more prone to both latent and active errors. Patients may experience severe harm and even death even if the actual surgical operation is uneventful, because of latent and active errors in recognising and effectively managing a major complication following the surgery [10, 11].

The United Kingdom's National Reporting and Learning System (NRLS), the largest repository of patient safety incidents worldwide, gives

Table 2.1 Selected results of retrospective care record reviews (after deVries [13])

Study	Harvard Medical Practice study	Quality in Australian Health Care study	Utah and Colorado Study	Vincent et al. study	Adverse events in New Zealand Public Hospitals	Canadian Adverse Event Study
Country	USA	Australia	USA	England	New Zealand	Canada
Year	1984	1992	1992	1998	1998	2000
Cases reviewed	30,121	14,179	14,700	1014	6579	3745
Adverse event rate	3.8 %	16.6 %	3.9 %	10.8 %	11.2 %	6.8 %
Preventable adverse events	1.0 %	8.5 %	0.9 %	5.2 %	4.8 %	2.8 %

an indication of the scope of incidents and harm: About 1.3 million incidents were reported by NHS organisations between July 2011 and June 2012 in England, although it is recognised that probably only about 25 % of incidents in hospitals are reported. The majority of incidents (875 k) caused no harm, with 7773 causing severe harm and 3263 resulting in death. The most common type of incident reported was a patient accident (25.8 %), followed by treatment/procedure (12.7 %) or medication error (12.1 %) [12].

The most detailed data on patient harm comes from retrospective care record reviews. This method traditionally consists of two stages: a nurse reviewer identifies patient records where certain preset criteria suggests patient harm, followed by a second-stage review by an experienced clinician who judges whether patient harm indeed occurred, and whether it was due to acts of omission or commission. Compared to routine data sources, the method has the advantage of being based on a rich description of the care pathway and supported by explicit standards and criteria. However, the review has also been shown to have low inter-rater reliability, particularly regarding the assessment of the causes of patient harm and its preventability.

A meta-analysis of the seminal retrospective case record reviews, which included 74,485 patients, found an adverse event rate of 9.2 %. Of these nearly half (43.5 %) were deemed preventable [13]. Surgery was the largest area where adverse events occurred (39.6 % of all cases), followed by drug-related events (15.1 %). The rates of harm measured differed substantially between individual studies, mainly because the methods and the definition of harm varied.

Selected results of seminal retrospective care record reviews are presented in Table 2.1.

Key areas for surgical safety relate for example to site infections, anaesthesia or retention of instruments [14]. Surgical site infections account for 15 % of all nosocomial infections and in surgery represent the most common nosocomial infection (37 %) [15]. The overall risk of acquiring a surgical site infection is low (2–5 % of all surgical patients); however, considering the volume of operations the absolute number of surgical infections is significant. Patients with a surgical site infection need a longer hospital stay, have higher rates of readmission and are at high risk of substantial permanent morbidity, or mortality [16]. The retention of objects after surgery is another rare event, but where it happens it can cause major morbidity and mortality. A study at the Mayo clinic found that in one of every 5500 operations a foreign object was retained, in the majority of cases (68 %) surgical sponges. The greatest risk from retained objects is an infection, but surgical instruments can also cause perforations and granulomas [17]. Anaesthesia has become very safe in developed countries. Studies vary in suggesting that an adverse event leading to death occurs in every 10,000 to every 185,000 patients; that is, even in the worst case an anaesthesia-related death will be a very rare event. However, in developing countries anaesthesia represents a tangible risk, leading to a death in every 3000 patients (Zimbabwe) or even every 150th patient (Togo). The causes are predominantly

related to airway problems or anaesthesia in the presence of hypovolaemia.

Despite the advances in surgical safety, with the increasing volume of operations and the complexity of procedures and team organisation a systematic approach towards improving perioperative safety is needed. Considering the large volume of surgical procedures and the rates of harm caused by surgery, WHO considers surgical safety as a public health crisis, particularly in low-income countries.

Solutions to Prevent Errors and Harm in the Perioperative Arena

Since the publication of the influential 'To Err is Human' report in the year 2000, there has been substantial increase in research on improving surgical safety. Early findings on evidence-based strategies are summarised in the AHRQ report 'Making Health Care Safer: A Critical Analysis of Patient Safety Practices' [18]. However, the report also identified major gaps in knowledge, in particular the limitations in the epistemology for the study of patient safety, the relevance of context factors for the implementation and the impact of the broader health system environment. Since then a major international effort has focused on reviewing patient safety practices, supporting original research and widening the scope of implementation efforts. An update of strategies to improve patient safety was published in 2013, based on a review of strategies contained in Making Health Care Safer, Joint Commission standards, Leapfrog Group strategies [19]. The report identified 22 strategies ready for adoption, with a 'top ten' list of patient safety strategies that were so strongly recommended for adoption that the authors stated that 'our expert panel believes that providers should not delay adopting these practices'. Of the top ten patient safety strategies, recommendation number 1 relates specifically to the perioperative area, namely the introduction of preoperative checklists and anaesthesia checklists to prevent operative and post-operative events (Chap. 26) (Text Box 2.1).

Text Box 2.1: Strongly Encouraged Patient Safety Practices (Modified from Shekelle et al.)

- Preoperative checklists and anesthesia checklists to prevent operative and post-operative events
- Bundles that include checklists to prevent central line-associated bloodstream infections
- Interventions to reduce urinary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols
- Bundles that include head-of-bed elevation, sedation vacations, oral care with chlorhexidine and subglottic suctioning endotracheal tubes to prevent ventilator-associated pneumonia
- Hand hygiene
- The do-not-use list for hazardous abbreviations
- Multicomponent interventions to reduce pressure ulcers
- Barrier precautions to prevent health care-associated infections
- Use of real-time ultrasonography for central-line placement
- Interventions to improve prophylaxis for venous thromboembolisms

Six of the recommended patient safety strategies are very germane to the perioperative area, namely obtaining informed consent on potential risk of procedure, team training, computerised provider order entry, use of surgical outcome measurements and report cards, rapid-response systems, use of complementary methods for detecting adverse events or medical errors to monitor for patient safety problems, simulation exercises, or documentation of patient preferences for life-sustaining treatment.

This list also demonstrates that in order to improve surgical safety, a broader view of the surgical pathway is needed than encompassed by the activities and actual procedure conducted in the operating theatre. Improving safety and quality in the surgical domain requires actions that go beyond the responsibility of the surgical microsystem where the problem is observed (for example the failure to rescue after high-risk surgery) [20, 21].

The international DUQuE Consortium conducted the largest collaborative project investigating the effects and impact of quality management systems in European hospitals [22]. It formulated and tested hypotheses regarding the implementation of quality management systems, their associations with other factors known to affect quality and their effect on quality of care in various care pathways that reflect the diversity of hospital operations [23]. In addition, the consortium conducted a series of systematic reviews of the key strategies to improve quality and safety in hospitals, extracting information on their effectiveness and on contextual factors affecting their implementation [24]. Based on this body of work, seven key strategies to improve quality and safety were recommended [25] (Table 2.2).

Despite the emerging evidence on the impact of strategies to improve quality and patient safety, questions have been raised why the progress is so slow, with some studies even suggesting an increasing incidence of patient harm over time [1]. According to Shojania and Thomas this is because (a) the identification of interventions to reduce patient safety problems has been slower (and many interventions have been less effective) than expected, (b) the patient safety practices demonstrated to be effective (see above) are not sufficiently implemented on a wide scale, and (c) the measurement of improvement efforts is much harder than the measurement of problems [26, 27].

This is demonstrated by the concerted effort to improve patient safety on the one hand, and an assessment of the implementation progress in the hospital setting of the recommended patient safety practices. International patient safety efforts include the Global Patient Safety Alliance launched by the WHO and the Health Care Quality Indicator Project led by the Organization for Economic Co-operation and Development (OECD). In Europe, the Safety Improvement for

Table 2.2 Seven key strategies to improve quality and safety in hospitals (modified from Groene, Kringos, Sunol [25])

Strategy	Evidence
Aligning internal organisational processes with external pressure	There is mounting evidence from close to 100 scientific studies to suggest that undergoing external assessment improves the organisation of work processes, and promotes changes and professional development
Putting quality high on the agenda	Simply put, research suggests that hospitals in which leaders are involved in quality reach better quality-of-care outcomes. Lack of senior leadership affects patient care even where patient care in clinical units is pursued by competent and dedicated professionals
Implementing supportive organisation-wide systems for quality improvement	Multiple quality systems operate within any hospital. These quality systems need to be well aligned to maximise impact and minimise unnecessary bureaucracy or documentation that takes time away from patient care
Assuring responsibilities and team expertise at departmental level	High-quality care cannot be provided without well-trained and motivated professionals. A key strategy to improve the quality of care is thus the recruitment, retention and development of professionals with the right competences
Organising care pathways based on evidence of quality and safety interventions	The majority of hospital departments still follow a traditional organising principle according to the medical specialisation. To better respond to current patient's needs, an organisation based on care pathways should be pursued in which all clinical activities are centred on the patient's overall journey

(continued)

Table 2.2 (continued)

Strategy	Evidence
Implementing pathway-oriented information systems	Hospital information systems (covering computerised clinical decision support systems in hospitals, electronic health records, computer-assisted diagnosis, reminders for preventive care or disease management or drug dosing and prescribing) have an enormous potential to improve quality and safety of healthcare. The effectiveness of computerised clinical decision support systems has been evaluated by more than 300 studies
Conducting regular assessment and providing feedback	Audit and feedback are key quality improvement strategies, which can be applied individually or as part of multifaceted interventions. Audit and feedback have been well researched in more than 100 studies to support the assumption that professionals improve their performance when feedback demonstrates deficiencies in process or outcomes of care

Patients in Europe (SImPatIE) project established a common European vocabulary and a set of indicators and internal and external instruments to improve safety in healthcare. The European Network for Patient Safety (EUNetPaS) created an umbrella network of all European Union (EU) member states and stakeholders to enhance collaboration in the field of patient safety. The joint action on Patient Safety and Quality of Care has identified activities and tools for mutual learning among all EU member states. In an assessment of the implementation of patient safety practices and the evidence-based organisations of patient care according to the recommendations of the agencies above, they found in a large random sample of EU hospitals that neither patient safety practices nor were routinely followed with a substantial variation in how care was delivered between departments and hospitals. This raises serious concerns regarding the delivery of optimal care and indicates substantial room for improvement [28].

Surveillance and Monitoring of Surgical Safety

The capacity of countries and hospitals to assess the amount of harm caused differs substantially. As referred to above, the majority of studies on adverse events have used the retrospective case record review. The method has the advantage that assessments are conducted by clinicians with experience in the content area, but has shown to have limited inter-rater reliability between clinicians that are judging whether an adverse event occurred or whether harm was preventable. The method is also costly and time consuming and therefore not well suited for routine assessments and monitoring. Various alternative sources exist to assess adverse events. For example, in England there are about 50 National Clinical Audits that prospectively collect national level data for a range of conditions that involve a surgical procedure, such as cancer surgery, cardiac surgery or orthopaedic surgery replacement. These National Clinical Audits collect data, for example, on complications during index hospitalisation, unplanned admission to ICU or return to theatre [29]. However, these National Clinical Audits do not cover the whole spectrum of patient care delivered and they differ significantly in terms of methodological robustness, scope and reporting mechanisms [30].

Another source of data is hospital administrative data, which have been used previously to construct patient safety indicators in the USA and its use in monitoring healthcare quality and safety [31]. The quality of administrative data has improved a lot in the last decade. It now includes more clinically relevant data items, coding of data have improved and data on a large number of patients can be extracted easily, it provides the statistical power for the study of rare events that other methods might lack.

In England, Hospital Episode Statistics (HES) have been used extensively to assess and monitor patient safety. For example, an assessment of

Hospital Episode Statistics found that about 2.2% of all hospital admission records contain one or more of the 41 adverse events or misadventure codes that are used to document surgical or obstetric harm or other complications [32]. HES data has been used to explore specific measures of patient harm based on the patient safety indicators developed by the Agency for Health Care Research and Quality (AHRQ) and subsequently adapted internationally [33]. Examples of patient safety events that can be monitored using this data include catheter-related bloodstream infections, post-operative DVT and pulmonary embolism, post-operative sepsis, accidental puncture or laceration, or a foreign body left in the body during a procedure. These indicators can be computed by using algorithms that combine the coding of primary and secondary diagnoses with a range of procedure codes [34]. In addition, HES can be used to identify possible proxy measures of harm such as emergency readmissions to a hospital after an index admission for a surgical procedure. An overview of British studies suggested that 15.6% of readmissions could be avoided, but estimates vary largely depending on the clinical condition or type of codes considered [35].

Importantly, in deciding how to monitor and assess surgical safety, the level of granularity and the intended purpose need to be clearly specified. Levels of granularity include the health system level, the institutional (hospital) level, the team level and the individual surgeon level. It is important to emphasise that an indicator that is valid and reliable at one of these levels is not neccesarily valid and reliable at another level. This is first because of the differences in the underlying denominators which impact on the signal-to-noise rate and the possibility to reliably detect the event, and secondly, because of differences in the attribution of this event to an act of omission or commission, resulting from a latent or active error. Most patient safety indicators have been validated at a fairly high level (health systems or institution) and are not fit for reporting at the team or surgeon levels. Furthermore, when comparing outcomes between hospitals, risk adjustment for patient characteristics is crucial because, when patient populations differ between hospitals, differences in outcome may represent differences in baseline risk rather than in quality of care. Insufficient case-mix adjustment can lead to unfair comparisons. This is of particular relevance where surgery bears substantial risks [36].

In the UK, an ambitious surgeon reporting programme has been implemented in 2015, brought on by various high-profile scandals about bad-quality care. Today, surgeon reports are seen as a central tool for quality improvement. Since 2013 individual surgeons' outcomes are made public via NHS choices. Data is published for 5000 consultant surgeons in 12 specialties (adult cardiac surgery, bariatric surgery, colorectal surgery, endocrine and thyroid surgery, head and neck cancer surgery, interventional cardiology, lung cancer, neurosurgery, orthopaedic surgery and upper gastrointestinal surgery). Data source and measures vary among specialties, but all include mortality rates for their patients (Table 2.3).

Whether surgeon reports can be an incentive for quality improvement cannot be easily answered [37]. From a behavioural economics perspective, these reports can be seen as a 'nudge' that provides feedback to intrinsically motivated surgeons, who will then act accordingly and try to improve. Because of the methodological limitations of the underlying data it is also possible that the data causes more harm than good, by unnecessarily alerting surgeons and the public, or by creating pressures to avoid particular patient groups [38].

In order to support the improvement of quality and safety in surgery, a stronger focus should be on the upstream determinants of safety, or as in Brown's framework the management processes leading to active error, rather than mortality and morbidity outcomes only [6, 39]. This should include an assessment of the implementation of established patient safety practices and a timely monitoring of team based process measures that are clearly linked to patient outcomes [40].

Table 2.3 Clinical example of the data included on surgical report cards

	Procedures included	Total cases included	Number of consultants	Mean procedures/consultant	Outcome measure	Mean rate
Cardiac surgery	Adult cardiac operations	Approximately 100,000	248	Unclear	In-hospital mortality	3.1 %
Vascular surgery	Infrarenal abdominal aortic aneurysm repair (AAA) and carotid endarterectomy (CE)	21,266 AAA: 15,751 CEA	458 AAA: 429 CEA	32 AAA: 31 CEA	AAA repair: In-hospital mortality	2.2 % (AAA)
					CEA: 30-Day stroke/ mortality	2.4 % (CEA)
Thyroid and endocrine surgery	Thyroid operations: Lobectomy, isthmusectomy, and total thyroidectomy	13,233	125	Unclear: Approximately 91	In-hospital mortality; re-exploration for re-bleeding; readmission rate; proportion of patients who developed late hypocalcaemia; length of hospital stay (all first-time thyroidectomy)	0.1 % In-hospital mortality
						1 % Re-exploration for re-bleeding
						2 % re-admission
						9 % Hypocalcaemia
Orthopaedic surgery	Hip replacement, and knee replacement	Unclear	Unclear	63 Hip: 54 Knee	90-Day mortality	0.6 % Hip replacement
						0.4 % Knee replacement
Urology	Nephrectomy	5449	283	14	30-Day mortality; rate of post-operative complications; transfusion rate; and length of hospital stay	<3 %
						<9 %
						<15 %
Upper GI surgery	Oesophagectomy or gastrectomy with curative intent	2381	163	14 (median)	30-Day mortality rate	2 %

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Concepts and Models of Safety, Resilience, and Reliability

3

Jonathan Gao and Sidney Dekker

"This place would be a lot safer if I could just get rid of the nurses who make mistakes"

—Nurse Manager

Introduction

Approaches to safety have often considered the "human" factor in an organisation or operation as a major contributor to unwanted outcomes. Most responses to this "problem" involve trying to exert more control over people [1]. This can happen through the generation of policies, guidelines, and prescriptions, and of course the enforcement of procedures. While these may make intuitive sense for some, research suggests that such a view may not be valid as an extensive focus on failures creates the erroneous impression of humans as a liability, and ignores the many other instances of humans contributing to success and resilience [2]. Not only are people crucial in the creation of safety in the messy details of everyday work, there are also an enormous number of other factors (many of which are beyond control of the human at the sharp end) that are behind the creation of success and the occasional failures.

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Normal Accident Theory

With the rapid advancement of technology, many organisations today are complex systems, and these systems interact with an equally (if not more) complex environment [3, 4]. Complexity has been argued to render these organisations accident prone in two ways. First, minor failures between multiple components within a system can interact in incomprehensible or difficult-to-follow ways to produce a larger failure. Second, the complexity of these systems makes it difficult for any one individual to fully comprehend every single process involved in keeping the system functional [4, 5]. Therefore, when an accident occurs, operators within the system may find it difficult to remedy the situation. Most retrospective responses to such issues rely on adding more components or layers of defences, such as an extra alarm or another backup power generator. However, this only adds to the system's complexity and might lead to even more unintended interactions and consequences. Given that failures involving complex component interactions are unusual and often unforeseen, they are not considered when we attempt to determine the probability of an accident occurring. Therefore, it is likely that the actual probability is much higher than we think.

Of course, not all organisations or surgical operations may encounter accidents since they are loosely coupled [3]. In such systems, the

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continued functioning of a component is rarely dependent on the functioning of other components [3, 6]. For instance, the performance of a medical faculty in a university is rarely dependent on the performance of the business faculty. This is not the case for tightly coupled systems such as the operating room, where the function of the surgeon depends greatly on the function of another component such as the anaesthesiologist, and thus an issue with one of them is likely to lead to an issue with the other. In turn, other personnel (e.g. nursing and the recovery room staff) who rely on them will experience disruption to their work as well. These disruptions and issues may interact with one another in an unforeseeable manner, causing an accident. In sum, organisations that operate using systems that are both complex and tightly coupled will likely experience an accident and numerous near misses at some point in time [3, 7]. These accidents are an expected by-product of a complex and tightly coupled system, and therefore seen as "normal". Hence the term normal accident theory.

Complexity Science

Some might still argue that accidents are a result of human error [8, 9]. This section discusses complexity and explains why blaming accidents on human error alone may be a simplistic approach that misses the bigger picture. We will look at the underlying assumptions, and argue why these assumptions may not be realistic, especially in a medical or surgical setting.

The perception of accidents as the simple product of human error usually contains at least four underlying assumptions. First, it assumes that the system involved solely operates in a linear manner [10]. In other words, A only causes B, B only causes C, and so on. Second, it assumes that since the system operates in a linear manner, it therefore follows that with sufficient knowledge, an operator within the system can or should be able to predict the outcome of their actions. Therefore, when an adverse event occurs, such as a wrong-sided surgery, the surgeon is often blamed for not having anticipated the outcome. Third, it assumes that the linear manner in which the system operates means that it is possible for one to reverse the linear process to discover the cause of an accident. In other words, since C is only caused by B and B is only caused by A, this means that A is the source (or root cause) of the problem. Fourth, it assumes that it is possible for investigators to collect all the information necessary to form a true story of what exactly happened to give rise to the adverse event.

However, these assumptions may not be realistic, especially in the domain of healthcare and in highly complex surgical microsystems [11]. There are many examples which indicate that not all systems operate purely in a linear manner. For instance, the performance of a nurse in a hospital is potentially influenced by a plethora of factors like the nurse's case load, whether there is a staff shortage, the type of observation charts used, the noise level and lighting within the wards, and whether the nurse is interrupted [12–16]. Likewise, the performance of a surgeon can be affected by factors such as disruptions, fatigue, and stress levels [17–19].

Since the healthcare system operates in a complex manner, it stands to reason that the second assumption of outcomes being predictable is likely to be false. A complex system like healthcare is likely to experience a huge amount of interactions, some of which are non-linear, among all of its components [20–22]. These interactions can take a range of forms, such as the interactions between staffs across multiple disciplines or small physiological changes within a patient interacting to cause major disruptions in the patient's health. Systems of such complexity mean that it is impossible for any one individual to fully comprehend all the tasks necessary to keep it functional [4, 5]. Given the complexity and interactivity involved, outcome prediction is near impossible.

Following from the above, the third assumption is likely to be false as well. Since the healthcare system is immensely complex and highly interactive, finding out the factors contributing to an accident is not as easy as simply reconstructing a linear process [10]. Moreover, not all accidents have a cause, as discovered during the

investigation into the accidental shooting of two US Black Hawk helicopters by two US fighter jets. This shooting is thought to have happened due to the many local units each developing their own procedures and routines to manage local demands. The development of local procedures and routines is a normal occurrence, as the original plans do not always suit the local situation. However, the differences in procedures and routines among the various units made it difficult for these units to act smoothly and successfully in a tightly coupled situation, leading to the shooting [23, 24]. Lastly, this assumption also depends on the accident investigator being given full access and the ability to gather all the necessary information to reconstruct an accurate picture of the accident. As will be argued below, it is highly unlikely for that to happen.

The fourth assumption regarding an investigator being able to gather all the necessary information to reconstruct an accurate picture of the adverse event is likely to be an invalid assumption, for the following reasons. First, systems that are highly complex and interactive tend to continuously evolve, thereby retarding any attempts at retrospective analysis especially for an outsider unfamiliar with the nuance changes in complex systems [25]. Second, a huge amount of information might be lost or difficult to obtain in the course of accident investigations since one's behaviour can be influenced by a multitude of factors, such as unwritten routines or subtle oral or behaviour influences by other supervisors or staff members [26].

Third, research has shown that memory is unreliable and highly context dependent [27–30]. The way in which a question is phrased has the capacity to alter answers and memories. Furthermore, people are also susceptible to incorporating misinformation from various sources into their memory of an accident. Thus, this might hinder or at least affect attempts at information gathering and increase the chance of hindsight bias [31].

Lastly, the process of reconstructing a representation of an accident is at risk of succumbing to the hindsight bias [31]. Given that the outcome of an accident is already known, it is easy for accident investigators to determine which behaviour or decision led to the accident and wonder why the people involved failed to notice the same things. In doing so, the challenges that these people faced are trivialised and the bigger picture, that such accidents are mostly the product of complex and interactive systems, is missed.

In summary, attributing adverse events to human error hinges on the four assumptions being valid. However, these assumptions are unrealistic in complex and interactive systems like healthcare. Rather than looking at accidents using a linear approach, we should perhaps follow in the footsteps of high-reliability organisations (see section "Principles of High Reliability") and adopt a systems approach instead, which is well suited for complex settings such as in surgical setting. Essentially, this approach takes the view that an individual failure is a symptom of a larger problem within the system, which enables organisations to learn from their mistakes and improve the system [32–34].

It should be noted that such an approach does not mean that humans are entirely blameless, as there are scenarios in which pursuing individual responsibility might be necessary [35]. However, most errors are arguably committed by proficient and well-meaning operators who possess a finite capacity (as do all humans) and who face numerous challenges when carrying out their duties [31, 36]. Thus, the focus here should not be on punishing them, but to examine the means of improving the system in order to alleviate some of their difficulties and attenuate future adverse events [32, 36].

Safety Drift and Procedural Violations

Safety Drift

Healthcare systems are vastly complex and set in an environment that is equally (if not more) complex [3, 4]. Besides consisting of a multitude of individual components (e.g. doctors and nurses, technological artefacts, regulatory pressures), systems of such complexity also possess subsystems

(e.g. anaesthesiology team, general surgery team) that are working to achieve their own goals [31]. These goals are not always compatible, however, resulting in conflicts that need managing. Those involved would have to make decisions based on the situation and some of these decisions might require the sacrificing/trade-off of safety to achieve a particular production goal or to live up to other duties [37, 38]. Typically, this trade-off does not yield any immediate negative consequences [39]. Therefore, those involved would be misled into assuming that the trade-off is acceptable and it becomes part of the normal process. When another conflict emerges and another trade-off is made with no adverse results, this second trade-off might be once again be assumed to be acceptable and becomes part of the normal process. This process (known as normalisation of deviance) will repeat itself, slowly nudging the system towards greater risks until an adverse event takes place.

Despite the risks involved, those within the system are unlikely to be aware of this drift to failure as signs are typically only noticed by those outside of the system (e.g. accident investigators) after an accident has occurred [24]. To those within the system, seemingly poor decisions in hindsight are actually rational, given the contemporaneous circumstances [31]. While seemingly a bad phenomenon, the drift away from safety is not necessarily a negative indicator of an organisation's performance [24]. Rather, it is simply a by-product of a complex system adapting to the challenges from both within itself and the environment. The challenge is to ensure that the clinicians involved understand the role and importance of these trade-offs (i.e. clinical sensemaking) [40].

Features of Drift

So what are the elements that contribute to a system drifting towards failure? At present, it is theorised that at least five factors are involved, namely (a) scarcity and competition, (b) decrementalism, (c) sensitivity to initial conditions, (d) unruly technology, and (e) contribution of protective structure [24].

Scarcity and competition refer to an organisation experiencing a lack of resources, and facing intense competition [24]. Rasmussen suggested that a typical organisation has to work within three boundaries, the first being economic, the second being safety, and the third being workload [41]. Working beyond the economic boundary means that the organisation would not be able to maintain itself financially, while crossing the safety boundary means that the organisation's operation is highly dangerous (e.g. patient's well-being may be endangered). Lastly, exceeding the workload boundary means that the people and/or the technologies within the organisation are no longer capable of carrying out their work. As mentioned earlier, organisations generally drift away from the safety boundary to satisfy production pressure since the loss of safety is rarely felt while the reaching (or not reaching) of production pressure is tangible [37].

Decrementalism means that an organisation moves to the edges of the safety boundary over a series of small steps (instead of instantaneously), as it attempts to meet production pressure, as explained earlier [24]. This should not be confused with normalisation of deviance, which refers to trade-offs made in response to abnormal situations (e.g. high demands) being seen as the new norm.

Sensitivity to initial conditions (otherwise known as the butterfly effect) essentially argues that seemingly small factors in a system's starting conditions can lead to large failures, as these factors interact in novel ways to give birth to unintended consequences, pushing an organisation towards the edge of the safety boundary [24]. Unruly technology refers to the gap that exists between how designers of a technology think it will work, and how the technology actually works when exposed to the environment [24, 42]. For instance, the introduction of poorly designed health information technology in some hospitals has been argued to cause issues such as (a) making it difficult for physicians to gain a proper understanding of a patient's condition, and (b) producing reports that lack information value, due to the technology's insistence of using standard phrases [43].

The last factor is the contribution of protective structure, which suggests that the protective

structure that was deliberately created to keep the operation safe can end up contributing to a drift towards failure [24]. One example is a safety or governance department that, through its generation of many different layers of defence and guidelines, actually contributes to complexity, thereby rendering real sources of risk less visible to the sharp end users.

Possible Means to Reduce Potential for Drift

Despite the potential for drift to result in unwanted consequences, a definitive solution to reduce an organisation's potential for drift does not appear to exist. Nonetheless, this section will be devoted to the exploration of some of the ideas in the hopes that some would find it useful.

As suggested earlier, signs of drift are not always obvious to those within the organisation [24]. Therefore, one plausible approach of reducing an organisation's potential for drift is to study how decision makers make sense of the information environment (e.g. why they take in certain bits of information and ignore others) as well as how they make and rationalise their decisions [44]. However, this may not be a fruitful endeavour since an organisation's drift into failure is usually only known after an accident has occurred and any knowledge gleaned might be specific to that accident and have little applicability in other contexts.

Arguably, a decision maker must pay attention to multiple sources of information and invite doubt to make the best possible decisions [45]. But this may be an idealistic notion as decision makers may be bombarded with an enormous amount of information, which would require a long time to process, and immense cognitive resources [24]. Furthermore, tell-tale signs of drift may be weak or unbelievable, and hence go unnoticed [37].

Another potential approach would be to move the organisation away from the safety boundary, reducing the likelihood that it will be crossed and produce an accident [41]. Examples include reducing production pressure or investing in proven safety methods. However as with the above, expecting an organisation to reduce production pressure might be wishful thinking. Even if an organisation chooses to invest in proven safety methods, it is highly likely that production pressure will follow this increase as staffs would be expected to produce a greater output with the same resources (i.e. be more efficient) [37].

In sum, while there has been several suggestions on ways to diminish an organisation's potential for drift, these suggestions each come with their own caveat. Nevertheless, this does not mean that it is impossible to reduce an organisation's drift potential since there may be other solutions that have yet to be explored. For example, Rochlin and his colleagues have observed that the various subsystems on board a naval aircraft carrier were able to balance multiple constraints and pressures to consistently produce smooth performances [5]. Perhaps an in-depth study on how these subsystems co-operate and negotiate with one another might yield some useful information.

Procedural Violations

As argued earlier, drift is not an indicator of an organisation's failing, but a sign of it adapting [24]. It can appear in many forms, such as procedural violation (also known as workarounds). Workarounds appear to be frowned upon as it deviates from rules and regulations, which some consider sacred [46]. Such a viewpoint may have its merits, for deviations from rules and regulations have resulted in unwanted results. For instance, it was argued that non-compliance with rules and regulations contributed to an incident where the wrong patient was given an invasive procedure.

However, it might be a mistake to assume that all forms of procedural violations are bad. For example, one form of medical guidelines in the USA specified the use of levofloxacin for community-acquired pneumonia [47]. But others have suggested that a physician should not always follow these guidelines as levofloxacin is an expensive form of antibiotics that not all patients can afford, and not having antibiotics could lead

to patients' conditions worsening [48]. To avoid this outcome, physicians need to deviate from the rules and regulations and prescribe a different and more affordable form of antibiotics. Furthermore, each patient has their own unique co-morbidities and medical history, making it near impossible to create a set of guidelines to address each case. Under such circumstances, physicians should be allowed to act as they see fit instead of being penalised for not complying with procedures. In other words, procedural violation may not always be a bad thing as it captures the local wisdom of the providers.

Stretching the Limits of Adaptive Capacity

As argued above, healthcare organisations have to adapt to multiple constraints both within itself and the environment [24, 31]. One way of doing so would be to stretch its adaptive capacity. Adaptive capacity refers to a system's ability to adjust its actions in response to high production pressure, such as a hospital temporarily using stretchers or chairs in the hallways when there are insufficient beds to accommodate a sudden spike in demand [49, 50]. When a system attempts to adapt itself to handle a particular type of disruption, it will inevitably become less adept at handling other types of disruptions [51]. When these other disruptions actually happen, the system's adaptive capacity will be tested and failure is a real possibility. Since failure is an unwelcome result, it is therefore important for a system to know where it stands in terms of its adaptive capacity, the type of problems that can arise in an adaptive system, and the means of stretching this finite resource if necessary [52]. For a system to figure out where it stands in terms of adaptive capacity, it should possess at least the following *three characteristics*: (a) capacity to reflect on how well it has adapted, (b) awareness to know what it is adapting to, and (c) changes within its environment [51].

There are three potential ways by which an adaptive system can break down [51]. The first is decompensation, which essentially refers to a system's adaptive capacity being unable to keep up with a disruption that has occurred. In the initial phases of decompensation, the system automatically attempts to compensate when a disruption takes place and is somewhat successful in doing so, hence masking the problem as it continues to fester. Eventually, the system's adaptive capacity would be drained, causing a sudden collapse and failure.

The second issue is one that has been discussed earlier, namely the possibility of various subsystems having conflicting goals with one another, leading to each subsystem taking actions that may benefit them individually but limits the system's adaptive capacity [51]. The final possibility is that the system may persist in using outdated practices even though the environment has changed and despite the introduction of new practices.

Given the importance of adaptive capacity in ensuring that a surgical system remains functional, it is therefore necessary to figure out the means of stretching this finite resource to avoid a system failure [52]. One plausible way might be to stay sensitive to indicators that the system is silently compensating for disruptions and to take remedial actions immediately when these indicators display abnormal signs [51]. However, this might not be an easy task since it requires one to be able to successfully differentiate between good adaptive behaviours (e.g. workarounds to increase efficiency) and bad adaptive behaviours (disruptive behaviours that indicate that the system is on the path to failure).

Resilience

A second means of dealing with constraints and complexities would be to apply the principles of resilience engineering. Resilience is defined as the ability of a system to adapt its functioning prior to, during, or following any changes or disruptions to sustain regular operations under all conditions [53]. The key term in the definition is adapt, meaning that resilience is about the system's ability to adjust its functioning to meet challenges. A system that is able to sustain regular operations under all conditions is not

necessarily resilient, since this can be easily achieved via inefficient means such as stockpiling an absurdly large amount of resources (e.g. having multiple empty wards in a hospital in case of an emergency). Hence, adaptation is important.

However, some form of excess resources may still be necessary for the system to draw upon in times of need, meaning that not all excess resources should be removed under the pretext of efficiency [52]. Therefore, one possible problem with resilience engineering would be the difficulty in determining whether a set of spare resources should be removed for efficiency or retained to achieve resilience. Whether a system can successfully manage this is likely to depend on how it implements and sustains the four pillars of resilience. For example, if a system is proficient in predicting future threats (one of the four essential pillars of resilience), it should be able to determine if the extra resources available would be useful in helping it achieve resilience by allowing it to better meet challenges, or if the extra resources are a hindrance as it prevents the system from operating efficiently.

Four Pillars of Resilience

Given the apparent benefits of resilience (i.e. able to handle disruptions), healthcare systems might consider adopting at least some of its principles. Currently, it is argued that a resilient system should possess four key abilities, namely (a) the ability to respond to disruptions, (b) the ability to monitor ongoing developments, (c) the ability to predict potential threats and opportunities, and (d) being able to learn from both failures and success [54].

For a system to be able to respond to disruptions, it should come up with a list of potentially disruptive events and develop a set of possible responses to these events, so that it may react appropriately in a timely manner when the disruption occurs [53]. For the list to be effective, the disruptive events that are being included should be rigorously examined on a frequent basis to ensure their relevance and timeliness.

In terms of developing a set of responses, the system needs to be able to verify its effectiveness as well as consider appropriate means of maintaining such responses [53]. As mentioned above, having an absurdly large amount of excess resources (e.g. dozens of empty beds) might be an effective response, but it is certainly not efficient and is costly to maintain in the long run.

For a system to have the capacity to monitor ongoing developments, a list of valid and reliable indicators needs to be developed and continuously monitored [53], in other words, an organisational dashboard of indicators that can consistently yield useful information. An example of a poor indicator would be the number of human errors committed, since it depends on unrealistic assumptions and misses the bigger picture, as argued earlier.

Additionally, these indicators are unlikely to always remain relevant, and thus should be constantly revised and updated [53]. A clear set of guidelines is necessary to guide this revision process as the typical approach is to simply revise the indicators after an accident has occurred. Such an approach is inadvisable because of two reasons, namely (a) it holds the unrealistic expectation that indicators should be able to predict all adverse events, which is unlikely to happen due to complexity, and (b) revisions based on this approach usually do not yield effective solutions due to a heavy focus on face validity. Aside from the above, the development of suitable monitoring indicators requires the consideration of other factors as well, such as the predictive value of the indicators, the means by which the indicators are measured, and whether the information provided by the indicators refer to temporary or permanent events.

To determine if a system is capable of predicting both potential threats and opportunities, the assumptions that it holds about the future should be examined [53]. If a system perceives the future to be a replication of the past, or that past events can be used to deduce future events, then the system is unlikely to possess the ability to predict potential threats or opportunities as the past may not always be a good indicator of the future [53, 55].

If a system perceives future events to be a phenomenon caused by the complexity and interactions both within itself and the environment, then it might be able to successfully predict potential threats and opportunities.

Lastly, a resilient system might display the willingness to learn from both failures and successes, since both types of events arguably share the same underlying processes save for the recovery from failure [53]. Academics studying resilience have argued for the importance of studying success as it provides useful information for the occurrence of failures, the rationale being that there are no magical processes that only manifests themselves when an accident happens, but otherwise remain dormant [54, 56]. Instead, if an accident happens, it is likely that the underlying causes have been around for a while and are only made obvious by the accident. Furthermore, understanding how success happens and investing in it can not only reduce the possibility of things going wrong, but can potentially increase productivity as well. For a system to truly be resilient, all four components are thought to be essential. However, the importance of each component in a particular system generally depends on the system in question and is highly context dependent.

Limitations of Resilience

Despite the positive sides to resilience engineering, it still possesses some limitations which could mitigate its effectiveness. Many of its recommendations are vague and thus hinder attempts at implementing them. For example, it recommends that a resilient system should develop both a list of plausible disruptive events and a set of responses to these disruptions [53]. However, it may not always be clear as to which events should be included on the list, and which events should be excluded.

Moreover, as a system seeks to improve its performance in dealing with a particular set of disruptive events, it will inevitably experience some form of setback in dealing with other types of events [51]. Therefore, when these other types of events do happen, failure becomes a real possibility.

Principles of High Reliability

Concept and Characteristics of High Reliability

Despite the problems mentioned above, some complex and tightly coupled organisations have been able to defy the odds and limit failures, yet consistently produce high performance [5]. Such organisations are said to possess high reliability. In an attempt to understand how these organisations managed such a feat, different groups of researchers have studied these organisations and identified different sets of characteristics which they believe might be the key. The lists that these researchers came up with share several similarities, but possess some differences as well. Therefore, this section will first discuss the common characteristics before looking at the differences observed.

Common Characteristics of High Reliability

The first characteristic of high-reliability organisation is their proactive approach towards risk management. Rather than aiming to prevent failures, which would be an impossible enterprise, these organisations choose to make allowances within their systems for them [33, 34, 57]. Additionally, they obsess over failures and regard them as symptoms of a larger problem within the organisation. As such, personnel are encouraged to (a) report errors (and are rewarded for doing so), (b) learn from near misses, (c) avoid being overconfident, and (d) be aware of the potential for small failures to interact and produce an exponentially larger failure.

The second characteristic of high-reliability organisation is their appreciation of the complexity involved in the daily operations of the organisation, and knowing that they can never fully comprehend it [33, 34]. Therefore, they do not become overconfident but instead continue to remain hyper-vigilant for possible disruptions. Furthermore, they understand that the system's complexity means that it is impossible for a single individual to fully master every single task

needed to keep the organisation operational [5]. Therefore, tasks are broken down into smaller tasks, with a specific group attending to each smaller task.

The third characteristic of high-reliability organisation is their deference to experts instead of authority [5, 34]. In this case, experts do not refer to those with the most experience, as experience may not always be the best indicator of expertise. Instead, expert here refers to the person who has the specific set of knowledge needed to respond appropriately to the situation at hand, regardless of the person's authority [58].

Different Characteristics

As mentioned in the introduction to this section, some differences exist between the two lists of characteristics of a high-reliability organisation. By differences, we mean that one group of academics have proposed a particular characteristic (e.g. continuous learning) as a contributing factor to high reliability, while another group of academics have not.

The first characteristic is the habit of continuous learning. While on board an aircraft carrier, Rochlin and colleagues observed that personnel of high-reliability organisations are continuously learning, with new methods of work constantly being introduced, and conventional means always being scrutinised for flaws [5]. However, this does not mean that procedures are always changing. Rather, new methods are only accepted after its benefits are proven.

The second characteristic is constant communication among personnel, even when there is a lull in activities [33]. Such behaviours not only keep communication channels open and help everyone to stay updated, but they also permit trust to grow and experienced members of the team to spot signs that might indicate potential trouble.

The third and final characteristic is the display of sensitivity to the needs and requirements of those working at the front line [34]. As stated above, healthcare organisations today operate under incredibly complex and regulatory situations, meaning those at the front line of the organisation are required to adapt to changing circumstances on a frequent basis in order for the organisation to operate safely. Conversely, those who work at the back end are typically temporally and spatially removed from the front line and hence have a limited understanding of what is actually happening at the sharp end [4]. High-reliability organisations are aware of this and therefore attempt to be sensitive to the needs of the front line to close this gap.

Limitations

While the works on high-reliability organisations have produced fascinating and useful information that all organisations can apply, they are not without flaws. A common criticism of studies on high-reliability organisations is that they have been focusing mainly on unique organisations like the Navy or air traffic control, and hence the applicability of principles gleaned from these organisations to other settings remains to be seen [59, 60]. Furthermore, these unique organisations often do not face production pressure unlike other organisations in domains like healthcare, where medical staff have to attend to a large number of patients in a small amount of time and where technology continues to curb their autonomy [61]. Hence, it may be unrealistic to expect organisations with these constraints to achieve high reliability [62].

Such concerns are certainly valid, and while a few studies have displayed some level of success in applying high-reliability principles in a healthcare setting, many questions remain unanswered and hence additional empirical research is necessary [63–65]. For example, Madsen and his colleagues found that although their implementation of high-reliability principles improved the performance of a paediatric intensive care unit, medical staff from other departments resisted the change. Furthermore, these improvements were abandoned when the implementers left the unit. Therefore, further research could examine the optimal means of introducing high-reliability principles with minimal resistance, as well as looking at ways of ensuring that these principles are sustained in the long run. This means addressing the barriers to culture

and organisational change that can get in the way of moving towards higher reliability of care [66].

Besides facing different challenges (e.g. production pressure), high-reliability organisations and normal organisations may also differ in other ways, which could make the application of high-reliability principles difficult. One instance would be personnel selection. Given the stringent nature of the recruitment practices used by air traffic control and the Navy, it is plausible that the personnel within these organisations are not representative of the personnel that one might find in a typical organisation [67, 68].

Also, a study in Germany discovered that individuals low in agreeableness, neuroticism, and openness to experiences were more likely to choose military service over community service [69]. This might mean that individuals with particular personality traits are more likely to join the Navy, and these traits in turn make it easier for the Navy to achieve high reliability. This is purely conjuncture, given that the study was conducted in Germany, whereas the studies on high reliability in the Navy were carried out in the USA. Extensive empirical studies are needed to determine if there is any truth to the speculation.

Surgical Microsystems

Aside from the teachings of high reliability, the idea of surgical microsystems has been touted as another possible contender for those seeking to manage the various constraints in the domain of healthcare while maintaining a high level of performance [65, 70]. According to Sanchez and Barach, the concept of microsystems originated from Quinn's works regarding intelligent enterprises [65, 71]. In the domain of healthcare, a microsystem refers to a small group of individuals delivering a service to a particular group of patients for a certain purpose. For example, a surgical ICU can be considered as a microsystem as it is made up of a group of people (e.g. healthcare practitioners and the patients' family) working together to care for the patient with the goal of helping the patient recuperate. It is proposed that the microsystems are the building blocks of a system and thus any attempts at improving the healthcare system to cope with the multitude of constraints should begin at this micro level [70].

Characteristics of Surgical Microsystems

Sanchez and Barach suggest that a good surgical microsystem should possess the following principles, some of which are similar to the principles of high reliability [65]. First, there should be an acknowledgement of the fallibility of humans, and the acceptance of accident (or errors) as normal. Instead of pursuing individual responsibility when something goes wrong, it should focus on the complex systemic factors behind the incident.

Second, a good microsystem needs to possess chronic unease, a state where an individual (or in this case, a microsystem) is concerned that potential risks are not being properly managed [65, 72]. It has been suggested that such an unease is useful as it keeps people alert to possible dangers and reduces the potential for complacency. Third, it is essential that communication channels remain open and dissenting views are not swept aside. Additionally, workers should be provided with proven tools that can help reduce the potential for errors. One example might be the redesign and usage of clinical charts that were specially designed to be user friendly using applied human factor principles [73].

Fourth, the reporting of errors and near misses should be encouraged, and the learning value of near misses needs to be appreciated [65]. Fifth, patients should not be excluded from communication channels and in face communication needs to be designed around the needs of the patient care with the focus on co-producing exceptional outcomes with the patients [74]. In other words, when a patient is erroneously exposed to danger, a good surgical microsystem should pay attention to the patient's side of the story in order to gain a better understanding and learn from this safety breach. Lastly, effective microsystems need to base their system on proven human factor

principles to optimise performance, support staff engagement, and attenuate impact of errors and other constraints such as providing nurses with user-friendly clinical charts [65, 73, 75, 76].

Conclusions

Rapid technological advancement has led to organisations becoming complex systems and dealing with a complex environment, making accidents a normal part of operations [3, 4]. Arguments that these accidents are caused by human errors hinge on several unrealistic assumptions being valid, and do not address the complexity in today's surgical world [10]. Such complexity creates multiple challenges and constraints for both the system and its subsystems, which forces them to adapt in ways that could cause a drift towards failure [24, 31, 37]. To manage these issues, systems can learn to stretch their adaptive capacity, attempt to become more resilient, apply the same principles as high-reliability organisations, and/or learn from clinical microsystem wisdom [5, 33, 34, 51–54, 65]. While each of these ideas come with their own limitations, they are nevertheless an excellent starting point for anyone seeking to improve performance and safety in the surgical care of patients across the perioperative continuum.

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Surgery Through a Human Factors and Ergonomics Lens

4

Ken Catchpole

"Formal accident investigations usually start with an assumption that the operator must have failed, and if this attribution can be made, that is the end of serious inquiry. Finding that faulty designs were responsible would entail enormous shutdown and retrofitting costs; finding that management was responsible would threaten those in charge, but finding that operators were responsible preserves the system, with some soporific injunctions about better training."

—Charles Perrow, 1984, p. 146

Introduction

Human factors engineering (HFE) is the science and practice of understanding and improving the relationship between people and things. It should generally be considered synonymous with ergonomics, though there may be subtle differences in the use of the terms. HFE is based on the premise of designing work to human abilities, in contrast to the more traditional concept of adapting humans (via training) to work requirements. In a complex system, both may be required. The premise of HFE is that training alone is expensive, time consuming, unreliable, and cannot overcome many barriers to performance, and that instead we can leverage a knowledge of how humans naturalistically understand and respond to the world to enhance their ability to reach goals. Thus, training in conjunction with the design of tasks, technologies, and environment to support human abilities is more likely to be successful than just training alone.

The discipline has its origins in the scientific management principles of Gilbreth [1] and Taylor [2], combined with understanding of human psychology, physiology, anthropometry, and biomechanics among a range of other disciplines which emerged in the twentieth century. HFE became a discipline of its own in the 1940s, at a time when aircraft were becoming exponentially more complicated, and sequences of studies demonstrated a range of mismatches between human perceptual and cognitive abilities, and what they were being required to do. It emerged that human errors were predisposed to designs that required human operation and intervention, but did not account for their limitations. For example, on some aircraft the gear and flap levers were located close to each other, and felt the same in the pilot's hand, which made it easy to confuse them [3, 4]. The time and visual demands of the tasks in which they were being used (takeoff and landing) meant that pilots used touch to activate them, with a mistake being recognizable only after the aircraft had subsequently entered a risky state. The solution was to change the shape and feel of the levers so they could not easily be confused. These concepts were extended in the 1950s and 1960s to the understanding of accidents such as Three Mile Island, and in the increasing mismatches between what humans were required to do in increasingly complex technological systems, and their abilities to do them [5]. It was recognized that accidents were happening not because people were fallible and technologies

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were not, but that failures happened where technological weaknesses amplified human weakness, and vice versa [6, 7].

Acknowledging that systems of work were a combination of humans, technologies, processes, policies, management, and training became known as socio-technical systems theory. In particular, the implication was that when things go wrong, to look only at human failures is to ignore the complexity of those accidents, and thus ignore a range of potential areas for improvement. One core principle of HFE is to understand and reduce the mismatch between human and system, and thus, through this socio-technical understanding, provide more highly functioning overall performance.

A more modern example of how the understanding of human cognitive process can shape designs that reduce errors and the need for training, while nearly invisibly enhancing performance, ability, and satisfaction, is found in windows, icons, menus, pointers (WIMPS) interfaces, upon which our interactions with personal computers are now based. These "direct manipulation" concepts were first developed at Xerox-PARC in Palo Alto in the early 1970s, and were leveraged by Apple for their first Macintosh computers a decade later, as a response to the existing DOS-based command-line interfaces that were opaque, required expert knowledge of computer functions, and did not facilitate human conceptual understanding of natural human interaction mechanisms. Thenceforth, the idea of "desktops," "files," "worksheets," and "trashcans" was developed to mimic the office concepts that novice users would immediately recognize, and could directly interact with without needing to understand precisely how the computer worked. This opened the use of personal computing to the general population, which previously had been the preserve of enthusiasts and engineers. The more recent extension of this has been in touch-screen interfaces on mobile and tablet devices that add familiar gestures (pointing, pinching, swiping) to allow more naturalistic interactions immediately, flawlessly, and without needing to use or understand menu or icon selections. Once again, moving from an unnatural method of interaction to a more natural one Apple (and to a lesser extent Nintendo with their Wii games console) reduced the need for a conceptual understanding of an interface, thus reducing the need for training, while increasing ease and pleasure of use, even with products that were otherwise technically inferior. The difference was that anyone could use them.

These examples demonstrate some of the principles that HFE science and practice seek to spread. All systems require people; and in every system, there will be fallible users prone to errors, whose performance is shaped by things beyond their control (and often beyond their awareness or conception). Yet, it is people who create safety in complex systems by accounting for variations that systems designers cannot appreciate [8]. It is thus technological systems that are fundamentally fallible, and humans the "elastic glue" that holds the system together (or the "vehicle suspension" that smooths over the unpredictable and uneven "road" surface) [9]. As our systems of work become more complex, opportunities for mismatches between human abilities and work demands increase, and the more important HFE becomes. Healthcare systems are no different. In the next section we explore some of the most popular and influential HFE concepts in more detail.

Humans and Automation

There is no question that the increasing complexity and sophistication of machines can enhance human abilities and system performance. Machines can do repetitive tasks faster, more reliably, and with more force, and precision, day-in day-out than humans generally can. Latterly, they can process more information in more complex ways using sophisticated algorithms that humans are capable of. Yet, at some point, these technological systems need attention and management by humans. They can break down, are inflexible, work reliably only within the parameters for which they have designed, and can demonstrate huge deviations from acceptable performance when their data inputs become unreliable or corrupted. Conversely, humans have evolved to work in highly varying circumstances, can still make effective decisions despite uncertainty or lack of data, and can trade speed for accuracy (or vice versa) at a moment's notice. In fact, designers

seeking to mimic human activities—such as developing machine vision—have quickly recognized how complex the adaptations and judgments that humans are able to make about their environment must be, given the complexity of the world around them. The way humans interact with the naturally unpredictable and chaotic world around them is deceptively complex and it is a strength that humans are not purely information processors [9]. These different strengths of humans and machines—and how we can design ways for them to work together the best—have been of interest in HFE for 50 years.

The initial approach to human-machine integration was to automate tasks that machines could do, and let the humans do the rest ("take up the slack"). The approach, pioneered famously by Fitts [10], was to produce lists of functions ("Fitts Lists") that machines should do, and functions that humans should do. However, this had a number of disadvantages. In particular, systems designed around these principles relegated previously skilled humans to "passive monitors," supervising the machines and waiting for things to go wrong [11]. When the machines inevitably did go wrong, control was quickly passed to the human who was already conceptually and actively distant from the situation, and not necessarily at full awareness (since passive monitoring is not a task that humans are naturally good at). They were suddenly confronted with a cascade of complex events and system breakdowns beyond their comprehension, with important information either hidden or not easy to discern among a huge number of displays, alarms, warnings, and other environmental cues, and without a mental model of what was happening [9]. This set up the human to make bad decisions and accidents resulted. This can still be seen in accidents today, such as Air France Flight 447.

On the 1st June 2009, an Air France Airbus A330 flight 447 from Rio de Janeiro to Paris experienced a high-altitude stall and crashed into the South Atlantic. The event was triggered when a pitot tube (which measures airspeed) froze over and malfunctioned. This caused the autopilot to disconnect, though the cause of the disconnection (conflicting airspeed readings) was not displayed prominently. The pilot in control pulled back on the stick to raise the nose and presumably, in the absence of visual cues at night, over the sea, in adherence to the pilots' heuristic of "staying high and fast." However, this caused the aircraft to stall, which sounded a stall warning. As the aircraft slowed, the stall warning then stopped automatically, as it was programmed to do, when airspeed dropped below a minimum. This created confusion, as it would then sound again when the pilot pushed the stick forward (which will usually take an aircraft out of a stall). In the absence of reliable speed information, this created further confusion. The pilots then became uncertain about which instruments to trust, and appeared to utilize the flight director (one of the main guidance displays) even though it was reading incorrectly. The problem of freezing pitot tubes was known, with nine incidents in the previous year, and the aircraft in question was due to have them replaced on return to Paris. However, the pilots may not have been aware of this potential threat [12]. The confusion was never resolved, and the aircraft hit the sea, killing all on board.

The idea that "replacing" the human, who is seen as weak and fallible and only there to support the technology, has given way to a different philosophy, which recognizes that humans are essential—and indeed create safety in complex systems. This creates the opportunity for a different approach, to support humans with automation (and not the other way around). Humans should stay in control, actively monitor the systems of work, and be directly involved in delivery by selecting or deselecting automated systems according to their experience and knowledge of the complex components of the tasks which machines are not engineered for. This allows the humans in the system to manage their skills and experience better, and successfully create flexibility and resilience, while also taking advantage of a range of reliable automatic assistive functions. This is seen on most modern aircraft (for example, where an autopilot can make fuel use more efficient), software (such as spelling and grammar checking), and more recently many driving aids and automated driving solutions. The mixed success of these approaches means that there is still much work to do to understand how best to help humans and machines to work together. These

surprising and perhaps counterintuitive effects of socio-technical systems [13] have generated a number of themes, collectively referred to as "ironies of automation," such as the following [14]:

- Automation does not simply "replace" humans—instead it transforms work, and creates new roles for people.
- Automation does not always free up mental resources and attention—instead it can create new mental demands, especially in busy, critical, or time-pressured moments—and usually requires the operator to monitor the technology in addition to the task.
- Instead of requiring less knowledge, it requires different knowledge and a new set of skills, often in addition to the existing skills (which need to be actively maintained to avoid fading of those skills).
- Instead of providing flexibility, automation creates a wealth of new modes and functions that need to be understood and that require new opportunities for omissions, failures, errors, and misunderstandings.
- Rather than necessarily increasing safety, the introduction of new technology must pay for itself by doing things faster and more cheaply than before, which can place new throughput and economic demands on other, equally weak, parts of the system.

Many of these issues have been uncovered in infusion pumps [15], electronic health records [16], laparoscopic surgery [17], surgical robots [18], and a range of other clinical and nonclinical contexts. In essence, we have learned that discussions which focus on replacing the human with technology, usually underestimate the extent and value of human contributions to performance and safety, and will likely create a range of new problems. However, if we approach automation design from the point of view of helping the human to achieve their goals, by supporting adaptive human sensemaking and decision making within a complex system, we stand a greater chance of avoiding catastrophes and creating success.

Human Factors in Device Design

A resident attending a crash call was the first to arrive at the bedside. Treatment was started, and the resident, working closely with a nurse, decided that IV access was needed. Knowing that the crash cart contained a intraosseous injection device, the resident asked for this from the nurse. This technique for rapidly obtaining a route for IV drugs is based on a spring-loaded needle that is fired into the bone from a tube about 2″ wide and 6″ long. To activate, it is placed onto the skin and the tube pressed forward by the thumb or palm of the hand. The tube is symmetrical with an arrow directing the user towards the needle end of the device. The nurse unwrapped the device, and handed it to the resident. However, as the patient was a below-knee amputee, the resident needed to take more care to locate the appropriate place for the injection. He put down the device, found the right location, picked it up again, and fired it. Unfortunately, in the time pressure, uncertainty, and novelty of the situation, he had unknowingly reversed the device, which was now in the wrong direction. The needle went into his hand.

Designs can predispose to errors, or can guide users towards the right methods and modes of operation [19]. The wrong buttons in the wrong place, displays that are unclear, labels that are ambiguous, or devices that allow unsafe configurations can all contribute to an error. In the above example, if this device had been asymmetric or felt different in the resident's hand the error could have been prevented. For example, similar bone injection devices have a pistol grip, where the direction is immediately apparent to the user—who may not have time or be too distracted to look. Similar to the flaps and gear levers on 1940s' aircraft, this resident was set up to fail by design. Fortunately they were not seriously hurt, but could no longer lead the crash call, delaying treatment initially, but eventually without an obvious effect on outcome. In healthcare, which is much more complex than aviation, where incidents are much more numerous, and without reliable objective accident analysis metrics, these

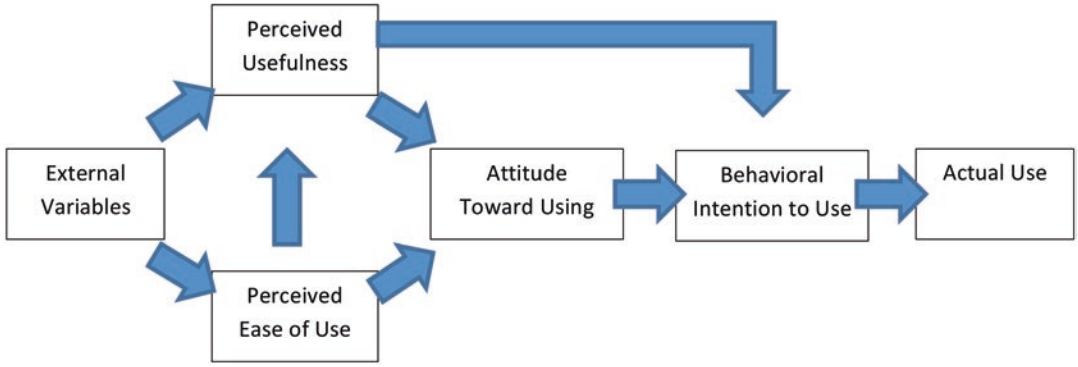

Fig. 4.1 The technology acceptance model [20]

error-inducing designs in healthcare frequently go unnoticed.

When we think about technology, we usually think in terms of what it can do (the functionality), rather than what people need to do to make it work (the usability). However, the functionality of a device (i.e., what it can do) is only as good as the usability (how we can do it). A good rule of thumb is that the more functionality a device has the less usable it becomes, but a device with limited functionality can still be limited by poor usability. In effect, usability is always important, but dramatically increases as a device becomes more complex. This complex interplay between functionality and usability also helps to consider acceptability—the likelihood that a device will be adopted and used. The device must also be used appropriately, be reliable, fit into normal working practices, be accessible and understandable, inform decision making, and lead to demonstrably better performance. In 2016 the FDA released new guidance for the consideration of HFE in the design and testing of medical devices [21], which requires the human to be considered—and users tested—from early concept stages to final evaluation. However, HFE is rarely considered in local procurement practices, and the FDA guidance cannot account wholly for the complexity of work. The technology acceptance model (TAM) [20, 22] illustrates this relationship between ease of use and perceptions of utility (see Fig. 4.1).

The key themes in human-centered design are the following:

- Design for the user population: The device should be designed for a carefully identified group of users (not just "experts" or "opinion leaders"). They should be involved at every stage of the design process (including conception), with testing conducted throughout with a chosen sample of those anticipated users. One in ten users will be color-blind. Older users may not have the digital dexterity of younger users.
- Designs should be adapted to users, not users to designs. Relying on training, memory, warnings, or instructions as a solution to a design problem is weak, expensive, and error inducing.
- Affordances: Designs should reflect intended use. For example, a handle on a door that you pull, or a push-plate on a door that you push.
- Consistency: The way users interact with devices should, as far as possible, not vary when using similar functions. For example, changing between numeric keypads with "telephone" type and "calculator" type will predispose a keying error.
- Redundancy: There should be multiple failure avoidance mechanisms built in. For example, to make a clear distinction on an important dimension, the color, look, and feel should all be different.
- Control and display compatibility: How you change something on a device should reflect how it is being changed in the real world.
- Functional grouping: Similar functions, displays, and switches regularly used together should be located together. Some anesthetic machines have the power switch located closer

to the suction container than the suction power switch. This predisposes to errors.
- Understand contexts of use: Where the device is used needs to be considered within a design. The environment, the physical space, interactions with other devices, people, or tasks all affect usability. If an item is to be used while gloved, this may reduce tactile cues.
- Procurement: The people who purchase devices for an organization should be the people using them. For many high-cost purchases, user trials would be highly beneficial and cost effective.

Cognition in Context

Humans make decisions within a broad systems context, and problems with decision making are more common than errors in technical skill [23]. Cognition within work contexts and how it leads to decision making have been of extensive interest in HFE and applied psychology research. Traditional clinical decision making tends to focus on which decision from several is best, often based on comparative evidence-based studies. In contrast, HFE focuses on the mental processes by which an understanding is reached and how a decision is made. It is often focused on process decisions—how we set goals and reach them, or how we navigate a patient through the complex sequence of care required to deliver the appropriate care. In this section we consider three different but dominant paradigms of relevance, situational awareness, naturalistic decision making, and distributed cognition.

Of the three paradigms in this chapter, situational awareness (SA) [24, 25] is perhaps the simplest to understand. As with much HFE work, SA research stems from aviation research, where situational awareness was considered to be a deciding factor in air combat success. Subsequent studies arrived at three levels of perceptual and cognitive processing that can be considered in most dynamic, rapidly changing high-technology tasks. The three levels are the following:

- Level 1 SA: Noticing ("What?"): This is the basic perceptual level of SA where important elements in the environment become salient to the observer/operator via the basic senses. They might register a change in blood pressure, or a distinctive smell, a vibration or a touch, or the presence of absence of a sound. Without awareness of these stimuli, the next level of SA cannot be reached.
- Level 2 SA: Understanding ("So what?"): This is the interpretative stage, where the operator applies meaning to the data they have become aware of in stage 1. It is one thing to recognize a change in the environment, and another to know what it means for the task at hand. Technical training is often focused at this stage. In air combat, knowing what speed you are at combined with the optimal turning speed for your aircraft helps you to understand how close to an optimal turning state your aircraft is currently in. In healthcare, for example, this would be understanding the hemodynamic implications of different arterial pressure locations and measurements.
- Level 3 SA: Projecting ("Now what?"): The highest form of SA is being able to predict future states of the system you are working in. Noticing and understanding what is happening, and applying your previous expertise to make predictions about what will happen next, enable the human to respond in the most appropriate way to move closer to the desired goal. In the original air combat scenario, thinking ahead allowed the pilot to avoid getting into low-energy states that an enemy could take advantage of, and instead allowed the pilot to move into a firing solution position. In cardiac surgery, understanding the trajectory of a patient's vital signs, and responding early if the predicted outcome is undesirable, yields safer, more responsive care. Projecting is the most challenging level of SA.

The more expertise you have, the better able you are to rise up through the levels of SA; while the higher your workload, the more distractions there are, or the more unpredictable or complex the situation is, the more cognition will reside in the lower

levels. The less able we are to project into the future, the more likely we are to arrive at a point that is undesirable, unsafe, or even more error inducing. This is why experienced pilots may tell you that they will always anticipate where their aircraft will be in the future, and never aim to fly in a reactionary way—which means that they can plan more effectively, and will stay out of serious trouble. When they can no longer do this, they know that they are in a risky situation.

A simple example of how the three levels of SA interact can be found in driving. Imagine you are driving along a highway and slower moving traffic is merging from an on ramp. You see a car on the on ramp moving slower than you (Noticing/Level 1 SA). You understand that this means that there is a risk of collision and that you may need to make a decision to alter your course (Understanding/Level 2 SA). You recognize that your car and the merging car will arrive at about the same time at the point where the ramp merges with the highway (Projecting/Level 3 SA). This means that you need to decide to speed up, slow down, or change lanes. You look in your mirrors and check your blind spot seeing, that there are no other cars nearby (Level 1 SA). You realize that this means that you can move into the middle lane (Level 2 SA) and that there is time to execute this move in plenty of time before your paths cross (Level 3 SA). You therefore decide to move into the middle lane. The more cars there are on the road with differing speeds and locations, the more variant your or the speed of the merging car is, or the worse the visibility or shorter the timescale, the more difficult this decision will be, and thus the more risk will be experienced. This is also affected by driver fatigue, experience, distractions, alcohol, automation (which often reduces awareness), and even the familiarity they have with the vehicle and the road on which they are travelling.

Thus, the concept of situational awareness helps us to understand how information is used to make accurate decisions; and how the clarity of the information, the environment, the training and expertise of the human, and their active involvement in the task over time helps us to make safe and appropriate decisions within complex, unpredictable, changing situations [26]. The best decisions are made when key information is presented clearly and understood by someone with enough expertise and who has been involved in the task long enough to predict what is going to happen next and account for it.

In situations where the goals, and ways to achieve them, may not be as straightforward, the naturalistic decision-making paradigm [27] can be useful. It helps us understand how human decision making is mediated by technological, organizational, and environmental contexts in greater uncertainty, and less dynamic or fluid situations. It has been extremely influential in the science of applied cognition, especially in military operations [28], although it has not been widely applied in healthcare. Decisions are not necessarily logical, linear, and evidence based. Instead, they are based on a wider view of multiple patients, expertise, systems complexity, behavioral intention, individual beliefs, and current understanding of the system. This research has led to a number of conclusions that often run counter to how clinical decision making is usually considered, such as the following [29]:

- Experienced decision makers can draw on patterns to handle time pressure and never even compare options.
- Expertise in decision making does not depend upon learning rules and procedures but on tacit knowledge.
- Problems are not always solved by a clear description of goals at the outset, since many projects involve wicked problems and ill-defined goals.
- Humans do not make sense of the world as "information processors" by fusing multiple data streams into eventual understanding—instead, experience and understanding define the important data streams, and most data is ignored.
- Uncertainty is not necessarily reduced through more information—too much data reduces performance, while uncertainty can stem from an absence of contextual cues that accompany data.
- Decision making is not necessarily improved by understanding assumptions since we may be unaware of our most flawed assumptions.

Moving towards more complex, team-based tasks, studies of human-system relationships in socio-technical environments have also led us to consider that cognition and decision making are not purely the properties of what occurs in the head of one individual. In fact, cognitive processes are often shared between different individuals working together through communication and shared culture; across material environments which aid in recall and action through cognitive artifacts such as computer displays or handwritten notes; and across time, where strategies, approaches, protocols, cultures, and artifacts accumulate over time. This is known as distributed cognition. The classic text by Hutchins ("how a cockpit remembers its speed") [30] considers the aircraft cockpit as the cognitive unit, and the people, displays, and procedures all components of how cognition is successfully distributed to achieve an understanding of the world that would be impossible for any one component alone. More recently, this approach has been used in anesthesia and other healthcare-related settings [31], considering the following:

- How information flows in tasks and between people.
- How tools and representations of work (such as protocols or checklists) are structured and how they affect the work.
- How the physical layout of a room or environment affects the distribution of information.
- How the social structure—roles, relationships, knowledge, and goals—affects the "cognition" of the whole.
- How the whole changes over time.

This alternative approach to the reductionism found in more traditional science and engineering approaches has yet to be well recognized within healthcare, but would seem extremely apt for understanding the complex, highly distributed tasks found in cardiac surgery. In particular, perfusion management requires the complex coordination of people, equipment, information, and tasks in order to perform appropriately. No one person has full knowledge of every aspect of this task. Thus, perhaps we should consider "how an operating room manages cardio-pulmonary bypass."

Performance-Shaping Factors

In this final section, we explore how environmental factors often outside the control of the human can affect human performance. These "performance-shaping factors" include fatigue, noise and vibration, lighting, temperature and humidity, and physical constraints of the workspace. A huge number of experimental studies have explored the effects of these different stressors on a variety of tasks. They can also be considered in terms of staff safety, offering environmental risks. There is a growing interest in these factors and the role they play in patient outcomes. Though there are many models, the general concept is that these factors adapt cognitive capacity downwards, increasing errors. This creates further opportunities for failure that further reduce human capacity, leading to a spiral of increased risk. Fatigue, for example, compromises perceptual abilities, increasing the chances of errors, and decision making, reducing the likelihood of appropriate responses. Noise can mask important communication, and can either reduce or exacerbate fatigue, depending on the types of noise and individuals experiencing it. Interruptions and distractions divert attention from the primary task, which can reduce hand-eye coordination, create task fragmentation, increasing the chances of forgetting or omitting steps, and introduces delays while the human switches away from, and then back to, the primary task. Temperature and humidity increase physiological stress, can lead to dehydration and fatigue, and can also create interruptions, for example, while the human wipes their brow or clears fogging of a lens or goggles (Fig. 4.2).

In surgery, there has been considerable interest in exploring how task deviations occur through these performance-shaping factors, and how they contribute to patient outcomes. The seminal study by Carthey and de Leval in congenital heart surgery found that enough of these small problems that

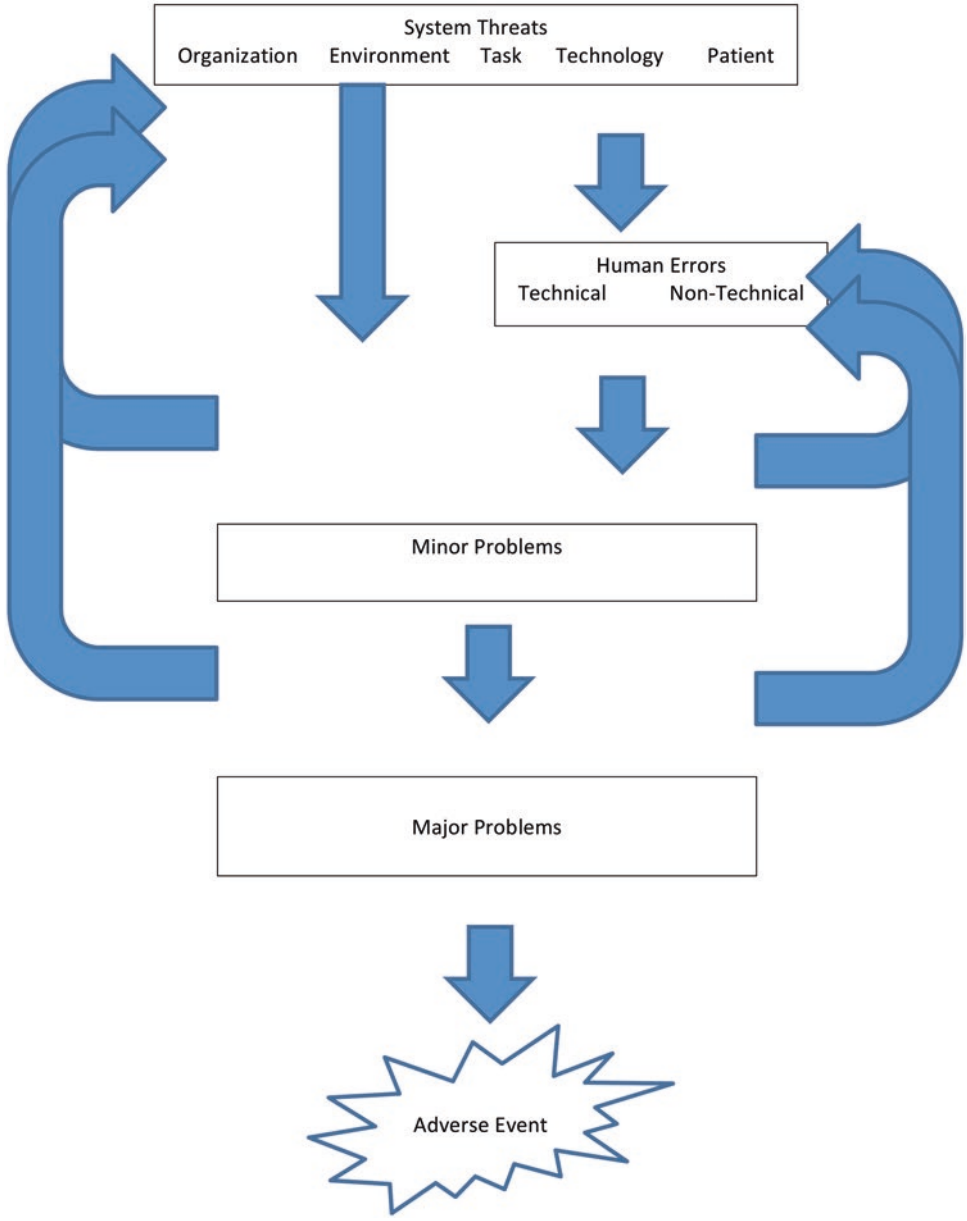

Fig. 4.2 A human factor engineering model of threat and error in surgical care [32, 33]

were not appropriately accounted for contributed to increased length of stay and the chance of death in arterial switch operations [34]. Subsequent studies video recorded and analyzed in detail the sequences of events to allow exploration of how those minor process deviations occurred and the causes [35, 36]. This found a model where system threats—from organization, environment, task, technology, and patient—could generate performance-reducing problems. They could also generate human errors—either technical (clinical skills or expertise) or nontechnical (teamwork, decision making, awareness), which would also create performance-reducing problems [37, 38]. In some situations, they could be resolved with no further effects. In others, they could combine, especially with

communication failures, absences of staff, equipment failures, or awareness failures, to create more serious situations. This would set up a cascade of events leading to a far more risky and potentially adverse situation [35]. At the same time, in the USA, similar studies were being conducted, showing similar effects [39]. Later studies [40] have explored these work environments, expanding our understanding of where the interoperative risks to our patients might lie. This is summarized in the excellent paper published in Circulation [41] that reviews a vast range of work in this area, which encompasses over 400 papers, and covers safety culture, physical environment, and communication and teamwork.

Beyond cardiac surgery, this work has been replicated and expanded in a range of other intraoperative settings including laparoscopic [42], vascular [43], orthopedic [36, 44, 45], trauma [46–49], robotic [18, 50–52], and neuro and maxillofacial [53]. Early emphasis on teamwork and checklists is slowly giving way to a more complex and richer understanding of how sociotechnical system configurations contribute to success or failure in surgery. While this complexity may take time to elucidate and understand [54], it offers many new ways to think about how improvements in the efficiency, safety, and quality of surgical care might be delivered.

Summary

The primary purpose of this chapter has been to describe in some detail several selected theories and concepts derived from human factor engineering and research that could be applied to surgery. While some examples have been provided, there is a huge range of applications for this type of approach. There are many devices in the OR that are poorly designed and predispose to error. Few considerations are given to how OR teams make decisions, the importance of situational awareness, and distributed cognition. Automation is often assumed to perform better than humans, but this is not always the case, and increasing technology always increases complexity and creates unexpected effects. Direct observations of processes and performance-shaping factors in cardiac operating rooms have allowed us to begin to explore how the human factor lens can help us understand why we do what we do, why things go right and why things go wrong, and what we might do—aside from trying harder—to achieve more of the former, and less of the latter.

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The Relationship Between Teamwork and Patient Safety

5

Sallie J. Weaver, Lauren E. Benishek, Ira Leeds, and Elizabeth C. Wick

"The way a team plays as a whole determines its success. You may have the greatest bunch of individual stars in the world, but if they don't play together, the club won't be worth a dime."

—Babe Ruth

Introduction

The publication of the National Academy of Medicine's (formerly the Institute of Medicine) report *To Err is Human* in 2000 marked one of the most prominent public acknowledgments of the error-prone nature of modern medicine. Medical errors were estimated to be the attributable cause of death in 50,000–100,000 hospitalized patients per year [1]. Although surgery-specific error rates have been difficult to obtain, the magnitude of 50 million surgical procedures in the USA per year has spurred increasing interest in what leads to surgical complications [2]. Importantly, serious complications are thought to occur in two to five million cases with up to half of these leading to death within 30 days of surgery [1, 3]. Although a systems-oriented lens highlights that there are likely a number of factors contributing to these complications, studies demonstrate that the quality of teamwork processes—an overarching term for teaming concepts that includes communication, coordination, collaboration, situational monitoring, backup behavior, planning, debriefing, and other behaviors—accounts for significant variation in technical surgical errors [4–7]. For example, a study of 300 surgical cases combining observations of teamwork collected by trained observers with retrospective chart review found that the odds of complication was nearly five times higher ($OR_{adjusted} = 4.85$, 95% CI: 1.30–17.87) when fewer teamwork behaviors (e.g., information sharing, situation monitoring) were observed, after controlling for patient characteristics [8].

Breakdowns in teamwork and communication are common risk factors for unintended events, including retained surgical instruments and sponges [9]; wrong-side/wrong-site, wrong-procedure, and wrong-patient events [10]; and inadvertent disease transmission to transplant recipients [11]. Analyses of 258 closed malpractice claims from multiple liability insurers involving surgical errors resulting in patient injury implicate communication breakdowns in 24% of cases [12]. Studies of claims involving trainees across disciplines implicate teamwork breakdowns in up to 70% of closed cases [13]. Additionally, the Joint Commission, a

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national accreditation organization tracking sentinel events, also routinely finds communication in the top three persistent root causes of patient safety issues in US hospitals [14]. Furthermore, teamwork and communication processes have also been associated with case efficiency [15], OR utilization and scheduling [16, 17], and burnout [18, 19].

Also known in the surgical literature as "nontechnical skills," teamwork in the operating room and across the perioperative care continuum has been a topic of study for over two decades [20, 21]. This work highlights examples of effective and ineffective teamwork in practice (see Table 5.1), critical teaming skills, and interventions designed to strengthen effective teamwork in practice.

The evidence across disciplines and settings identifies multiple hallmarks of effective teams. These "expert teams" and effective team members are committed to (1) actively and transparently sharing unique information; (2) developing and maintaining shared similar mental models of the team's goals, tasks, and interdependencies; (3) backing each other up as appropriate; (4) using strategies that facilitate collective sensemaking and closing the loop to ensure shared understanding of information and tasks; (5) believing in the importance of the team's goal, believing that teamwork is critical to achieving this shared goal, and taking other's behavior into account; (6) mutually monitoring the situation and team progress in order to adapt or adjust their collective strategy or individual contributions as needed; (7) discussing interdependencies in order to coordinate their actions and tempos; and (8) mutually trusting that their fellow team members will perform their roles and protect the interests of the team [24, 25]. Additionally, the evidence underscores that generalizable teaming skills and attitudes can be developed through well-executed, systems-oriented team training interventions [26, 27]. In this chapter we summarize the science examining team effectiveness, offering practical strategies for optimizing teaming across the perioperative continuum, and also highlighting where empirical evidence remains sparse.

Defining Teams, Teamwork, and Multi-Team Systems

A team is defined as an identifiable group of two or more people working interdependently toward shared, mutual goals that could not be accomplished effectively, if at all, by a single person. [28, 29]. Teamwork refers to the behaviors (e.g., communicating and sharing information, checking for mutual understanding), attitudes (e.g., belief in the collective ability of the team and need for teamwork), and cognitions (e.g., shared mental models) teams use to communicate, coordinate, and collaborate their efforts to achieve shared, collective goals. Studies of teamwork in surgery and other domains of care reflect the heterogeneity of teams and teaming in practice. Teams can be defined in terms of patient population (e.g., pediatric surgical teams) [30], disease or procedure types (e.g., colorectal surgery teams, surgical oncology teams), professional identity (e.g., surgical ICU nursing teams), setting (e.g., ambulatory/day surgery team), and crisis scenarios (e.g., rapid response teams) [31].

Teams can also vary in the degree to which the roles contributing to team goals and the individuals filling each role remain stable over time. A simple 2×2 typology of healthcare team composition developed by Pamela Andreatta [32] is helpful for understanding and comparing teams with (1) stable roles and stable personnel; (2) stable roles, but variable personnel; (3) variable roles, yet stable personnel; and (4) variable roles combined with variable personnel. For example, surgical teams may be static or dynamic (i.e., ad hoc), with more handoffs occurring among dynamic teams that, in turn, demand more explicit communication and coordination to be optimally effective [33]. Different people may switch into and out of the same role during a defined period of time (e.g., a new relief circulator may join a case while others go to lunch or break) and different roles may join or leave as needed (e.g., a specialist may participate in a portion of a case). Across the perioperative care continuum teams can also

Table 5.1 Three examples of teamwork and communication in practice

Example type	Example
Clinical care: Ineffective (from Hu et al. [22])	Scrub technician: Dr. Smith, would you mind confirming what would you like this specimen labeled?
	Surgeon: We already talked about it
Clinical care: Effective (from Hu et al. [22])	Surgeon: You guys are going to put in a central line? Or what do you want to do?
	Anesthesia attending: Well, we … I need to talk to you about it. Her INR is 1.4. I'm not a big fan of sticking her neck
	Surgeon: Sounds fair to me
	Anesthesia attending: So if we do … I'm wondering if we can put in a groin, like if you guys put in a groin line in
	Surgeon: So I'll tell you what … Why don't we see what you get here? This is going to be one of those situations where we could make an incision and know whether this is going to be hard or not. We wouldn't want to do anything like a big groin line
	Anesthesia attending: Right, and I think that's right
	Surgeon: But we'll prep everything out and … then if we get in and we decide, "Yeah, this is going to be scarier than we wanted," we'll put in a groin line
	Anesthesia attending: That sounds great
	Surgeon: Sound good?
	Anesthesia attending: I think that's the perfect plan
	Surgeon: Okay, perfect
Improvement: Effective	Multiple members of a surgical team have expressed concern at what they feel is an unusually high number of surgical site infections being reported for last quarters' colorectal cases
	The institution has in place a comprehensive unit-based safety program (CUSP) team for its colorectal surgery service line [23]
	This multidisciplinary surgical improvement team has decided to address the increased surgical site infection rate for this quarter's project
	A round of brainstorming with surgeons, anesthesiologists, nurses, and scrub technicians is used to generate ideas about what may be contributing to the increased infection rate
	Multiple team members mention concerns about "dirty" and "clean" instrument handling
	Once surgical instruments are contaminated by stool during the latter half of colon resection, "dirty" items are supposed to be set aside to reduce wound contamination during skin closure where the risk of surgical site infection is highest
	Team members note that perhaps the segregation of contaminated instruments is not occurring 100 % of the time
	They then find themselves overwhelmed by the number of possible reasons why instruments are being mishandled, which include lack of training, a rushed atmosphere, and inadequate spare instruments
	Rather than trying to address all of these reasons individually, the team comes up with a simplified solution that should cover all causes
	A small, second sterile surgical "closure tray" will be added to these cases to ensure optimal sterility for final skin closure
	The team then enlists the help of their administrative champion to demonstrate the potential cost savings of reduced surgical site infections while advocating for the additional surgical equipment needed for each case
	One month later, the closure tray has been added to each colorectal procedure
	By the next quarter, surgical site infection rates following colorectal cases are below their pre-intervention baseline

address different types of tasks. For example, team-based work can focus on (1) advice and involvement (e.g., unit, service line, or departmental patient safety or quality improvement teams), (2) production and service (e.g., central sterile processing teams), (3) projects and development (e.g., research teams focused on innovation), and (4) action and negotiation (e.g., direct care team involved in a particular case, rapid response teams) [34]. Surgical teams in the operating room are most often discussed as action teams, defined as "highly skilled specialist teams cooperating in brief performance events that require improvisation in unpredictable circumstances" ([34], p. 121). However, it is critical to remember that direct care is not the only type of team-based work important for safe, high-quality, high-value surgical care. Clinicians, nonclinical perioperative staff, and administrators also participate in project teams and advice/involvement teams dedicated to improving care safety, quality, and value.

While many generalizable teaming processes are important across different team types and different types of team-based work, these typologies are helpful for considering situations or team configurations in which some team behaviors, attitudes, or cognitions may need more (or less) attention in practice. For example, teams that vary in roles or personnel must consider allocating slightly more time and attention to developing and reestablishing shared mental models about the strategies that will be used to coordinate their actions compared to relatively more static teams. Conversely, while highly stable teams working together over time can develop the shared cognitive structures and behavioral norms that enable them to adapt efficiently when needed, they can also become overly reliant on implicit coordination strategies, missing opportunities to explicitly verify information or shared understanding which can lead to glitches and unintended errors [35].

While a co-located multidisciplinary team may complete a particular surgical procedure, a microsystems-oriented lens emphasizes thinking of the perioperative continuum of care as the work of a team of teams [36]. Effective, efficient, and safe surgery often requires the collective efforts of five to six different teams plus individual collaborators. For example, care transitions across a preoperative clinic team, a preoperative evaluation or testing center, a prep area or regional anesthesia team, an intraoperative team, a PACU team, and a postoperative floor care team. Intraoperative surgical teams depend on teams working in central sterile processing and supply chain teams for the tools and materials they need to complete their work. These teams, in turn, depend on the intraoperative team to send back tools and alert them when changes in kits or supplies are needed. Collectively, all of these teams are working toward the shared, mutual goal of providing highest quality, safe care for each individual patient. However, the interdependencies among the multiple players that must align their efforts to carry out a single case are often underappreciated and not clearly understood in practice.

Such complex networks of teams, known as multi-team systems (MTSs), are defined by two or more component teams that work interdependently and interface directly in order to achieve at least one overarching shared goal that any one of the individual teams could not achieve on its own [37, 38]. Each component team works toward its own proximal goals in addition to the overarching, more distal MTS goal(s), and sometimes team goals may compete with the overarching MTS goal [39]. For example, team scientists parsimoniously describe the work of an MTS responding to a car accident, including a fire crew, emergency medical team, surgical team, and postsurgical care team as core component teams working interdependently to achieve their mutual distal goal, survival of the patient, while also working toward their own proximal goals (e.g., stabilizing and transporting the injured person) [37]. The MTS concept is helpful in considering teamwork in surgery given the number of teams and players that must align their efforts and information in order to achieve safe, effective, efficient care for each patient undergoing surgery. Studies of MTSs also highlight key teaming processes that are even more critical in such contexts. For example, boundary spanning—actively reaching out and interacting across team boundaries—is a critical skill for teams working as part of an MTS. Explicit forms of coordination and

communication also become more important in MTS settings given that only a few members of each component team may ever directly interact with one another.

Models of Teams and Teamwork

Numerous models in the social and organizational sciences describe teams, their development, processes, and factors that influence their effectiveness. It is outside the scope of this chapter to offer a thorough history of team performance models; however, understanding the theoretical foundations of healthcare team processes and performance is critical for developing the skills and interventions that support expert teams (for comprehensive reviews see Mathieu [40] and Cannon-Bowers [41]).

Early thinking about teamwork was largely linear, evidenced by conceptual models adopting what is known as an input-process-output (IPO) approach to depicting teamwork performance effectiveness. Inputs were defined as antecedents or contextual factors (e.g., characteristics of individual members, the practice environment, or organization) that impact the affective, behavioral, and cognitive teaming processes believed to be the mechanisms through which teams achieve collective outcomes.

Although a useful starting point for understanding and describing teamwork, the traditional IPO model does not adequately capture the dynamism and adaptive nature of teamwork over time [42]. Furthermore, conceptualizations of teamwork processes were vague, leading Marks, Mathieu, and Zaccaro [43] to formally define them as "members' interdependent acts that convert inputs to outcomes through cognitive, verbal, and behavioral activities directed toward organizing taskwork to achieve collective goals" (p. 357). Yet, this definition still failed to account for the affective (e.g., trust) and cognitive (e.g., shared awareness) drivers of teamwork. Marks et al. [43] termed these mechanisms *emergent states* and defined them as "properties of the team that are typically dynamic in nature and vary as a function of team context, inputs, processes, and outcomes" (p. 357).

Building on these conceptual advancements, Ilgen and colleagues [44] introduced the input-mediator-output-input (IMOI) model of team performance, which differed from IPO models in two major ways. First, *process* is replaced with *mediator*, which subsumes both emergent states and processes as defined by Marks et al. [43]. Second, the IMOI model acknowledges that team performance can be episodic and recursive [43] such that outcomes from past performance periods can influence subsequent performance. Take as an example an uncommon but critical surgical emergency like cardiac arrest during an otherwise uneventful low-risk cholecystectomy. The well-trained operating room team performed all of the routine portions of the surgical encounter correctly (e.g., "time out" to review surgical plan, close oversight of the sterile field, good communication between surgeon and anesthesiologist), but early into the case it was noted that the patient was hypotensive and lost his pulse. Every member of the team scrambled into action to perform CPR and reestablish circulation. Although the patient survived, team members later shared that the disruptive event illuminated multiple issues that had gone previously unnoticed (e.g., the "crash cart" was not stored in its appropriate place in a hallway alcove; roles were not clearly assigned in the transition from routine operating roles to arrest team; postarrest infusions were not readily available). In preparation for the next intraoperative arrest, the members of the team initiated a quality project with the OR team nurse educator to develop a daily checklist to ensure that equipment, roles, and medications were available at all times. As a result of these efforts, the surgical team felt that it was more effectively ready to handle the next intraoperative emergency.

Healthcare Specific Models

Despite burgeoning interest, well-developed, yet practically relevant models of healthcare teamwork delineating critical antecedents, processes, and outcomes across the care continuum are still rare [45]. One example is the integrative (healthcare) team effectiveness model (ITEM) [31].

This model depicts contextual factors (e.g., team training) as critical inputs that influence elements of team task characteristics, including task type (e.g., project vs. patient care), team features (e.g., level of interdependence), and team composition (e.g., discipline, tenure), which in turn drive team processes and emergent states. It notably includes forces external to the organization, such as social, regulatory, and policy factors, that affect mediators of team performance. Furthermore, team outcomes are distilled into a 3×2 framework that encompasses the level of analysis (e.g., patient, team, and organizational) and the nature of the measure (e.g., objective vs. subjective). Reflecting the same limitation of other IPO models, ITEM is linear in nature and therefore does not fully represent the progressive nature of teamwork. This problem would be easily solved with the inclusion of a feedback loop. Moreover, it seems unlikely that some external factors demonstrate a direct relationship to task design characteristics.

Other healthcare teamwork models are limited to specific contexts as a result of the difficulties with creating practical models that span the generalities of very different healthcare teams. For example, after a systematic review of 35 peer-reviewed articles investigating teamwork in the ICU, Reader and colleagues [46] presented a framework of ICU team performance. The framework centers on team processes such as communication, leadership, and coordination, and connects them to patient- and team-focused outcomes. Consistent with IMOI models, the authors note that psychosocial factors (i.e., emergent states) influence team outcomes and include a feedback loop linking outcomes to inputs.

In an effort to integrate aspects of both within- and between-team interactions while acknowledging the dynamic, episodic nature of team performance, Weaver et al. [45] advanced a model of healthcare teamwork for patient safety (Fig. 5.1). This model shows how macro (e.g., national, organizational), meso (e.g., department, and unit), and micro (e.g., individual patients or providers) level factors, such as environmental characteristics (e.g., social policy and regulatory programs), organizational characteristics (e.g., physical layout, management structure, technology), patient characteristics (e.g., comorbidities, knowledge, attitudes, and behaviors), task characteristics (e.g., interdependencies, procedural steps), and individual team member characteristics (e.g., education, previous experience, personality), influence within- and between-team performance and effectiveness. Although depicted as individual boxes for the sake of parsimony, these characteristics should be considered in singularity but rather as a constellation of factors that shape the context in which teamwork occurs. The pattern of these factors has a much stronger influence than any one factor by itself.

Moderators, such as team training and culture (i.e., shared, multidimensional values, believes, and perceptions of the work environment), are also shown to influence the relationship between inputs and team processes. Moderators are inputs that can change the nature of a relationship between two other factors. For example, training team members in generalizable teamwork competencies can help ad hoc teams overcome the disadvantages associated with a lack of previous experience working together [47].

One aspect of Weaver et al.'s model is that inputs are shown to affect both intra- and inter-team processes and emergent states, which subsequently impact intra- and inter-team outcomes. The model is one of the first to address care as the work of an MTS. Weaver et al.'s model demonstrates the complexity of these systems and showcases inter-team processes (e.g., boundary spanning, entrainment, collaborative sensemaking) needed in order for multiple teams to collaborate together successfully.

Practical Principles for Effective Teaming in Surgery

In the surgical suite, patient care requires vigilant synchronization of efforts in a team with fluid membership, including highly specialized clinicians with diverse knowledge, skills, and attitudes (KSAs) [48]. Most surgical procedures

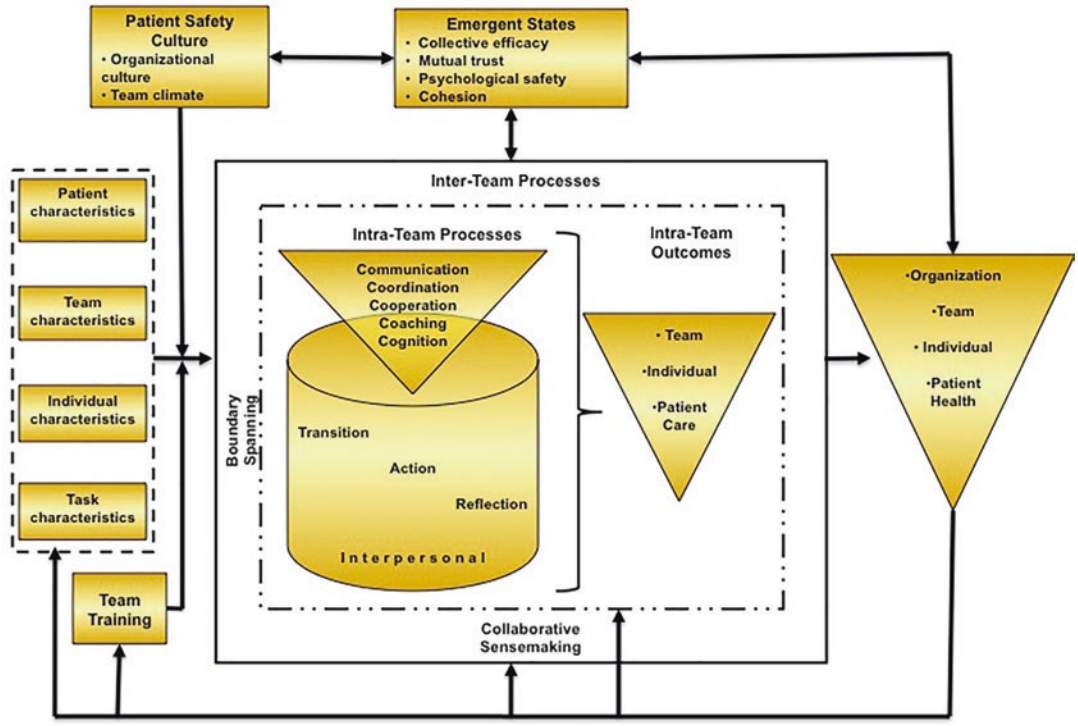

Fig. 5.1 An integrated model of team effectiveness for patient safety in healthcare, Weaver et al. [45]. Reprinted with permission from Oxford University Press, USA

require at least four multidisciplinary team members: an anesthesia provider, a surgeon, a circulating nurse, and a scrub nurse or technician [49]. Each is responsible for a specific role necessitating unique educational background and experience. Despite these differences, they must be able to effectively perform interdependently to ensure safe and successful surgery.

Research on teamwork has amassed a vast body of literature describing a wide array of shared KSAs necessary for teams to accomplish their task(s) [50]. Many reviews exist to address the different factors that can impact teamwork [34, 40, 41, 51, 52]. However, few offer practical guidance needed by surgeons and other medical professionals to enact and optimize effective teamwork [53]. Salas and colleagues [45, 54, 55] sought to create a parsimonious summary of our current knowledge about teamwork and package it in a way that would be more practically useful than previous frameworks. The result was the "Cs of Effective Teamwork," a simple framework describing a set of critical considerations for teamwork. The Cs include processes and emergent states (e.g., cooperation, conflict, coordination, communication, coaching, cognition) as well as influencing conditions (e.g., composition, culture, and context) that impact the aforementioned processes. See Salas et al. [55] for complete discussion of the framework's development.

The Cs heuristic is a useful tool for organizing what healthcare leaders and team members need to know to practice effective teamwork. Adaptations of the Cs heuristic has already been applied to the medical context in order to explain team effectiveness for patient safety [45] and as a framework for guiding the planning and development of interprofessional medical education [54]. Table 5.2 defines each component of the framework and provides an example of how it can manifest within a surgical team.

Membership and Team Life Span Considerations

As acknowledged in both the ITEM model [31] and Weaver et al.'s healthcare teamwork model [45], team composition can affect the mechanisms that determine team effectiveness. Yet, the implications of ad hoc team membership for patient safety need further consideration. Surgical teams, particularly in emergency or after-hours procedures, often are ad hoc; that is, they come together with the purpose of completing a single surgical procedure before disbanding. Unstable team membership across cases ensures that team composition and relative status of individual members change [56] from procedure to procedure, creating additional teamwork challenges for surgical teams. It may be difficult to establish rules and norms unless some core members remain constant (cf. Arrow & McGrath [57]), though a core group of members accustomed to working together can create dysfunctional status hierarchies [56]. Such

Table 5.2 Cs of team performance (adapted from Weaver et al., [45] and Salas et al. [55])

Component	Definition	Clinical context	Example
Cooperation	The motivational drivers of teamwork. In essence, the attitudes, beliefs, and feelings of the team that drive behavioral action	Surgeons, nurses, and OR staff bring unique skill sets and perspectives to the care of patients	An effort to improve patient flow in the OR focuses on better integrating the anesthesia, surgical, and nursing needs of the patients from contributions of each team member
Conflict management	Proactively managing perceived incompatibilities in the interest, beliefs, or views held by one or more team members	Different team members' unique viewpoints and training make conflicting beliefs likely in the OR	While preparing a difficult surgical field involving a patient's complete upper extremity, a surgeon and circulator nurse reconcile different approaches to sterile preparation of patients
Coordination	The enactment of behavioral and cognitive mechanisms necessary to perform a task and transform team resources into outcomes	OR teams maintain well-established workflows so that standardized processes proceed with limited oversight	An OR completing a case pages overhead, "OR6 out, moderate turnover" and all processes required to clean the room with the appropriate thoroughness, prepare for the next patient, and obtain any special equipment occur automatically within a prespecified time period
Communication	A reciprocal process of team members' sending and receiving information that forms and re-forms a team's attitudes, behaviors, and cognitions	OR teams iteratively share and receive both old information and any new changes while patients are proceeding through a surgical workflow to ensure that all team members remain well informed	During a "time out" procedure, a patient's identification, existing medical problems, surgical plan, special precautions, and team introductions are formally reiterated to confirm full team agreement
Coaching	The enactment of leadership behaviors to establish goals and set direct that leads to the successful accomplishment of these goals	Effective OR teams include responsive third-party support that can intervene when necessary	The OR charge nurse performs further information-gathering with other OR teams when a circulator nurse reports that case carts are being sent to rooms without complete instrument trays

(continued)

Table 5.2 (continued)

Component	Definition	Clinical context	Example
Cognition	A shared understanding among team members that is developed as a result of interactions including knowledge of roles and responsibilities; team mission objectives and norms; and familiarity with teammate knowledge, skills, and abilities	OR teams have narrowly defined roles with minimal overlap to ensure focus on critical safety-related activities	Anesthesia care of the surgical patient proceeds with virtually no intervention from the surgeon because the guidelines for safe anesthesia care and triggers for further intervention have already been agreed upon at the institutional level
Composition	Individual factors relevant to team performance; what constitutes a good team member; what is the best configuration of member knowledge, skills, and attitudes; and what role diversity plays in team effectiveness	Roles in the OR are specific and each representative member of the team is specifically assigned to effectively provide their role in patient care	Scrub assistants are assigned to cases appropriately based on their experiences with the instruments and equipment necessary for a particular case
Context	Situational characteristics or events that influence the occurrence and meaning of behavior, as well as the manner and degree to which various factors impact team outcomes	OR design should incorporate purpose-built spaces for resource-intensive cases	Cardiothoracic ORs are larger than average rooms to accommodate the additional equipment for cardiopulmonary bypass
Culture	Assumptions about relationships and the environment that are shared among an identifiable group of people and manifest in individuals' values, beliefs, norms for social behavior, and artifacts	Effective OR teams should facilitate continuous quality improvement and prioritize patient safety	Administrators encourage frontline quality improvement ideas and champion these proposals through appropriate channels

hierarchies can have implications for the integration of new or rotating team members.

Though quantitative research into the effects of surgical team membership is somewhat sparse, extant literature suggests that surgical team size and continuity of membership may influence performance [58–60]. For example, Xu and colleagues [61] found evidence that team members' familiarity contributed to reductions in operative time, even when controlling for individual surgeon experience. Though further research is needed to understand the precise mechanisms through which membership dynamics operate, these findings suggest that changing membership can be disruptive to some surgical team processes. While unclear what the implications are for patient safety and other performance effectiveness outcomes, it certainly seems likely that changing membership limits team efficiency.

To reduce the negative impact of these challenges, all staff participating in operative procedures should be competent in transportable or task-contingent teamwork KSAs. Cannon-Bowers, Tannenbaum, Salas, and Volpe [62] developed a 2×2 framework of teamwork competencies that defines the intersection of competencies related to the team (team specific vs. team generic) and those related to the task (task specific vs. task generic). Transportable competencies have the widest range of applicability as they are both task and team

generic, meaning that they can be generalized to any task or team context. TeamSTEPPS 2.0® (http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/index.html) is an example of a training program that has been created to teach transportable teamwork competencies to clinicians. Task-contingent competencies, on the other hand, are only applicable to certain team tasks (e.g., knowledge of the steps involved in a particular surgical procedure) but like transportable competencies, they are team generic. A minimal level of proficiency with transportable or procedure-contingent (i.e., task-contingent) teamwork competencies would allow staff to be effective team members regardless of their rotating memberships.

Interventions to Develop and Support Effective Teaming in Surgery

Over three decades of evidence underscores that expert healthcare teams and expert care providers who are effective at teaming invest time in developing and practicing teamwork skills [25, 63, 64]. Existing evidence demonstrates that systems-oriented team-training interventions that are mindfully implemented with mechanisms to support sustainment can be effective in reducing surgical morbidity and mortality, improving quality and safety indices, and can contribute to improvements in surgical patient satisfaction [65–68]. For example, Neily et al. conducted one of the more robust studies demonstrating both the association between teamwork and improved healthcare quality, as well as a beneficial teamwork-based intervention bundle within the Veterans Affairs hospital network [65, 66, 69, 70]. Over 100 sites, totaling 182,409 procedures, were included. The intervention group implemented a bundled intervention that included team training, operative briefings, and pre-procedure checklists that included a hard stop that prevented the operation from proceeding unless all team members actively participated in the interventions. These hospitals experienced an 18% reduction in surgical mortality versus a 7% reduction in propensity-matched patients at control hospitals ($p=0.01$).

Return on investment analysis has also demonstrated the impact of systematic interventions on teamwork in practice. For example, one large academic system implemented a comprehensive crew resource management intervention, one form of team training, across six perioperative service lines. The system demonstrated 15.6% fewer hospital-acquired surgical site infections than expected over a 3-year evaluation period resulting in cost-saving estimates of $895,906 to over $2.3 million dollars [71].

There are multiple types of team training and examples of their implementation in perioperative and other clinical settings. These are summarized in Table 5.3.

However, this existing evidence underscores that developing and maintaining effective teaming skills and habits go beyond classroom-based team training interventions. Effective teaming in practice is maintained by team-oriented mindsets, system structures that facilitate communication, coordination, and collaboration, and good teamwork habits [26]. For example, effective teaming in practice requires relinquishing an attitude of individuality focused on individual expertise, contributions, or leadership that has tended to characterize surgical practice to an attitude that recognizes interdependencies and value collaboration. In an observational study of complex surgical cases, teams working with surgeons adopting a transformational (i.e., team-oriented) leadership style demonstrated 3 times more information-sharing behavior ($p<0.0001$) and were 5.4 times more likely to speak up ($p=0.00005$) [22]. Additionally, they were 12.5 times less likely to demonstrate poor teamwork behaviors ($p<0.0001$). For perioperative leaders in particular, it is important to emphasize and reinforce that surgical care is the work of multiple individuals and teams who are mutually dependent on one another. This includes recognizing and reinforcing care providers and support staff across the perioperative continuum that invest in proactively communicating, coordinating, and collaborating within and across team or disciplinary boundaries.

Additionally, system structures (e.g., checklists, integrated EHRs, interdisciplinary meetings, and rounds) and teaming habits (e.g., briefing,

Table 5.3 Team training strategies (adapted from Salas, Weaver, Rosen, and Gregory [72])

Team training strategy	Definition	Primary teamwork competencies targeted	Best practices
Assertiveness training	Focuses on communication strategies that support task-relevant and team performance-relevant assertiveness	• Backup behavior	• Define training objectives around task-relevant assertiveness and differentiate from aggressive behaviors
		• Closed-loop communication	• Compare/contrast effective and ineffective assertiveness
		• Conflict management	• Include realistic time pressures or other stressors to allow practice using and reacting to appropriate assertiveness
		• Mutual trust	
		• Psychological safety	
		• Leadership	
Cross-training	Team members learn the roles that comprise the team and the tasks, duties, and responsibilities fulfilled by fellow team members	• Accurate and shared mental models of team roles and responsibilities	• Degree of interdependency and specialization should drive the type of cross-training you choose
			• Clarify interdependencies, define roles and responsibilities of other team members
			• Provide opportunities to shadow another role if possible
			• Facilitates reasonable expectations of one another
Error management training	Active learning strategy in which participants are encouraged to make errors during training scenarios, analyze these errors, and practice error recognition and management skills	• Collective efficacy	• Ensure trainees understand purpose: to encounter errors and to have opportunities to practice managing them in a safe environment
		• Cue-strategy associations	• Frame errors as positive opportunities for learning
		• Shared mental models	• Embed the opportunity to make errors into training scenarios by providing minimal guidance during scenario
		• Team adaptation	• Follow the scenario with immediate feedback and discussion to facilitate learning
Guided team self-correction	Team training strategy designed around a cycle of facilitated briefings and debriefings that occur around a training scenario or live event	• Backup behavior	• Define the targeted teaming skills at the beginning
		• Collective orientation	• Record positive and negative examples of each teaming skill during team performance episode
		• Closed-loop communication	• Classify and prioritize observations, diagnose strengths and weaknesses, and identify goals for improvement before beginning debrief
		• Cue-strategy associations	• Set the stage for team participation and solicit examples of teamwork behavior during debrief
		• Mission analysis	
		• Mutual trust	
		• Shared mental models	
		• Team adaptation	
		• Leadership	

(continued)

Table 5.3 (continued)

Team training strategy	Definition	Primary teamwork competencies targeted	Best practices
Metacognition training	Teaches strategies for analyzing, updating, and aligning team mental models of the team's task, coordination strategy, and contingency plans	• Cue-strategy associations	• Develop training objectives around cognitive processes such as planning, monitoring, and reanalysis
		• Mission analysis	• Structure metacognitive practice tasks around a task or subject that trainees have preexisting knowledge about
		• Shared mental models	
		• Team adaptation	
Team adaptation and coordination training (TACT)	Develops transportable teamwork competencies and tools (e.g., checklists) that can support effective team processes. Crew resource management training is a form of TACT	• Backup behavior	• Develop training objectives that target generalizable, transportable teaming skills, team-specific competencies can also be incorporated for intact teams
		• Closed-loop communication	• Train intact teams together if possible
		• Cue-strategy associations	• Create opportunities for guided and unguided practice
		• Mission analysis	• Develop feedback mechanisms that engage self-reflection and team self-correction following practice opportunities
		• Mutual performance monitoring	• Develop tools that support effective teamwork, but recognize that tools alone (e.g., checklists) cannot optimize team performance
		• Leadership	
		• Shared mental models	

debriefing, semi-structured handover processes) that are mechanisms for facilitating communication and coordination are critical elements of effective teamwork in practice [26, 64, 73]. For example, mechanisms for proactively addressing potential communication breakdowns or differences in mental models such as preoperative briefings and postoperative debriefings have been associated with improvements in compliance with evidence-based practices, early detection of potential safety hazards, improved communication among perioperative personnel, and decreased complications [74–77]. Their effectiveness, however, is moderated by their implementation [78], with multiple observational studies often demonstrating wide variation in participation, topics discussed, and quality [79–81]. Though briefings and debriefings are helpful, they are not a panacea for eliminating the risk of error and require mindful implementation. They are mechanisms for strengthening effective teamwork habits (e.g., situation monitoring, and transparent and proactive communication, such as speaking up with concerns or asking for clarity) and are difficult to implement effectively. Existing studies demonstrate that briefings are most effective when implemented in a team-oriented environment with a positive safety culture, and benefit from engaged, safety-oriented leadership [82–84].

Conclusions

Current evidence suggests that surgical environments are at high risk for serious medical errors and frustration when teaming and communication are poor or break down. Effective teamwork does not happen naturally or magically however. Just

as expert players in team sports must invest time to develop their teaming skills, so too must expert clinicians and perioperative support staff mindfully develop, practice, and sustain effective teaming skills. Expert teaming also does not mean that things will always go according to plan and that there will be no surprises. Effective teams are more able to efficiently and accurately adapt and recover, however, when the unexpected occurs.

In this chapter, we defined teams and teamwork, and summarized significant models of teamwork. Additionally, we summarized a simple framework for defining six key teaming behaviors and the evidence concerning strategies for developing and sustaining effective teaming in practice. The existing evidence underscores bundled team training interventions as effective strategies for improving surgical care processes, outcomes, and perioperative culture of safety. It also highlights that surgeons, other direct care providers, and support staff along the perioperative continuum can directly contribute to maintaining a context for effective teaming by adopting a team-oriented mindset in their daily work, recognizing and reinforcing others when they demonstrate effective teaming behaviors, and committing to actively participate in team-strengthening activities such as briefings and debriefings. Committing to demonstrate and role-model effective teaming attitudes and behaviors in practice are powerful mechanisms for meaningfully optimizing surgical care processes and outcome for patients, as well as the daily work experiences of the teams, and team of teams, working to provide world-class surgical care.

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Enterprise Risk Management in Healthcare

6

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"Risk management is a culture, not a cult. It only works if everyone lives it, not if it's practiced by a few high priests."

—Tom Wilson

Overview of Enterprise Risk Management

All organizations face risk and virtually all activities of an organization involve risk. Risk can be defined as an event or a circumstance that can have a negative impact on the organization, and it creates uncertainty in both planning and operations. As a result, organizations manage risk by first identifying and analyzing it, and then determining whether and how it should be modified. Enterprise risk management (ERM) may be thought of as a process embedded into an organization and is devoted to finding and managing all types of risks. The American Society for Healthcare Risk Management defines ERM in this way: "Enterprise risk management in healthcare promotes a comprehensive framework for making risk management decisions which maximize value protection and creation by managing risk and uncertainty and their connections to total value" [1]. ERM is integrated risk management that recognizes the fact that risks are not isolated but are interconnected and at times cascade to create patient harm. Furthermore, it provides a framework to recognize and manage all potential threats to the organization.

From the standpoint of an operating room environment, ERM is looking outward to identify risks in other areas of the organization, that while not restricted to the operating room may impact perioperative patient care. This chapter provides an overview of risk management principles and

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how risk should be in surgical services. Although there is certainly some overlap with this chapter, surgical and operating room risks are covered in greater detail in Chapter 33.

Principles of Risk Management

Principles of risk management have been described by various organizations and are well summarized in the ISO 31000:2009 risk management standard [2]. The key principles are summarized in Table 6.1.

The ISO 31000 standard describes a risk management framework that becomes part of the management system of the organization. The process of creating this framework is described in Table 6.2.

Table 6.1 Principles of risk management

• Create and protect value
• Be part of all processes
• Be part of decision making
• Be used to handle uncertainty
• Be systematic and timely
• Be based on the best data
• Be tailored to the environment
• Consider human factors
• Be transparent and inclusive
• Be responsive and iterative
• Support continual improvement

Table 6.2 Creating a risk management framework

• Writing a risk management policy with indicators and objectives
• Evaluating and describing the external environment and internal environment
• Identifying risk owners within the organization with assigned accountability and responsibilities
• Developing an organization-wide risk management plan
• Allocating resources
• Establishing internal communication mechanisms
• Developing an external communication plan
• Making the risk management process part of the organization's management approach and culture

Risk Management in Healthcare Organizations

Risk and patient safety are closely connected in healthcare organizations, and the disciplines of safety and risk management are therefore interrelated. While accreditation organizations such as The Joint Commission and DNV Healthcare have definite requirements related to patient safety and risk, most organizations go beyond these basic requirements and have adopted a business or quality management system incorporating risk analysis and patient safety as key elements [3]. This approach relies on the Donabedian model of healthcare delivery in which structure is created by the organization to ensure timely, efficient, and safe healthcare process delivery with favorable outcomes for the patients served [4]. The first step in assessing ERM is to identify where risk resides within the organization.

Identifying Risk

Risk can be categorized for any organization at the enterprise level, and commonly used risk domains in healthcare are listed in Table 6.3. The domains are described with simple definitions and specific examples. The last column is devoted to key risk indicators (KRIs). A KRI is a metric for measuring how risky an organizational process or service line is and can be thought of as an early warning indicator of a potential event that may harm the process/organization/patient. Ideally the KRI is a leading indicator with a predictive value related to the particular risk identified. The ERM goal is to identify risks throughout the organization using risk domains as a guide, and then to summarize the risks on a risk map/organizational dashboard or domain list as shown in Table 6.3. Measuring, quantifying, comparing, and prioritizing risks are the next steps.

Measuring Risk

In Chapter 33 we provide several examples of surgical risk and describe the technique of measurement for individual risk parameters based on a failure mode effect analysis (FMEA). A standard

Table 6.3 Sample risk domains

Risk domains	Description	Examples	Key risk indicators
Operational	• Risks resulting from failed processes or systems	• Failure to diagnose	• Number of active lawsuits
		• Insufficient discharge planning	• Readmission rate
		• Poor maintenance of equipment or facility	• Average age of plant/equipment
Clinical/patient safety	• Risks associated with care delivery	• Inconsistent clinical appointment process	• Patient satisfaction with clinical appointments
		• Failure to monitor reappointment	• Reappointment failure rate
		• Failure to appropriately credential new technology procedures	• Complication rates associated with new technology
		• Failure to monitor patient complaints	• Patient survey—perception of safety within the hospital
Strategic/external	• Risks associated with strategy and the direction of the organization	• Competition	• Market share of major service lines
		• Relationships with physicians	• Physician turnover
		• Regulatory changes	• Physician and staff satisfaction survey results
Financial	• Risks and decisions associated with the financial stability of the organization	• Payment system changes	• Days cash on hand
		• Access to capital	• Expense per adjusted discharge
		• Revenue enhancement	• Long-term debt to capitalization
			• Operating and total margins
Human capital	• Workforce-related risks	• Disruptive behavior	• Delinquent chart rate
		• Hiring and retention	• Employee turnover
		• Physician shortage	• % of RNs contracted through agencies
		• Organizational change	• State medical school retention rate for in-state residencies
			• Leadership change/year
Legal/regulatory	• Risks associated with failing to understand and monitor legal and regulatory mandates and laws	• ACO issues	• Total cost of care
		• HIPAA, FTC issues	• Annual legal expenses
		• Conflicts of interest	
		• ACA issues	
Technology	• Risks associated with monitoring, managing, and understanding all of the technology used by the organization	• IT/EHR issues	• EHR downtime episodes/month
		• Robotics and certification	• Robotic complication rate
		• Multiple vendors	• Number of vendors for specific service lines/implants/procedures
Hazard	• Risks related to hazards causing business interruption or major catastrophe with effects upon patient care delivery and safety	• Natural disaster	• Monthly disaster plan review rate
		• Failure to plan for crisis contingencies	• Number of crisis mock exercises per quarter
		• Failure to provide redundancy and backup systems	

ACA affordable Care Act, *ACO* accountable care organization, *EHR* electronic health record, *FTC* Federal Trade Commission, *HIPAA* Health Insurance Portability and Accountability Act, *IT* information technology

Fig. 6.1 Calculation of Risk Score

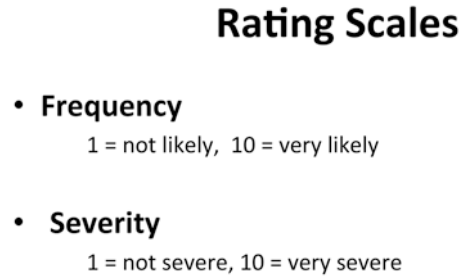

Fig. 6.2 Rating scales for calculating Risk Scores

FMEA utilizes three parameters to calculate a risk priority number (RPN) for each risk identified. The three factors are frequency of occurrence, severity, and likelihood of detection. Although this rating system works well in the clinical setting, most organizations with formal ERM systems utilize a simpler version with only the parameters of frequency (likelihood) and severity (impact) to derive a Risk Score that typically is in the range of 1–100 (in the case of a scale of 1–5 rather than 1–10 for each factor, the range would be 1–25). Scales of 1–5 for each parameter are easier to use and make decisions while scales of 1–10 afford more precision and are preferred in engineering work (Figs. 6.1 and 6.2).

After the risks have been categorized and listed using a risk domain, a Risk Score is assigned to each specific risk identified. For example, the risk of *failure to appropriately credential new technology procedures* may be assigned a frequency score of 2 (since the credentialing is usually done correctly) and a severity score of 6 (because the patient safety risk and liability may be high if a mishap occurs involving a provider who has not been credentialed appropriately). The Risk Score in this case would be 12. Risks may be scored using this system and they can then be grouped and compared. The numbers assigned to each risk are estimates derived by the team performing the assessment, although various data sources may certainly be used to improve accuracy in making the estimates. Risks with higher Risk Scores, or those above a given threshold value, may then be carefully evaluated and monitored.

Culture

The culture of an organization is of immense importance, and developing a great culture focused on improving patient safety and quality is paramount to success. A major component of a just culture in healthcare is trust. Without trust among peers, subordinates, clinicians, providers, and administration, many healthcare organizations will merely go through the motions and never achieve true quality improvements. Healthcare organizations, and hospitals in particular, are often highly political with poor lines of communication among various departments, and may harbor tension between administration and those clinicians that serve the needs of the patient. Individuals at varying levels within the organization may have personal agendas that impact honest communication and limit the sharing of information that would enhance higher quality and patent outcomes. One noted hospital turnaround executive, when asked how he had been so successful with institutions that struggled to provide good results,

stated, "It's simple. When faced with any decision I always ask if this action will improve servicing the needs of the patient and improve quality. If the answer is no, then we don't do it."

Communication and trust must drive culture with an unwavering focus on the needs of the patient [5]. If a policy or procedure does not improve patient outcomes, then it shouldn't be adopted. In many instances, the larger and more complex the organization, the more the tendency to focus on organizational rather than customer (i.e., patient) needs. As healthcare moves to increased transparency and disclosure of both quality and costs, patients will demand higher quality services at a lower cost in the new retail environment. The organizations that can make significant improvements in patient outcomes will have the upper hand in attracting and retaining patients. This will not be accomplished without breaking down the communication barriers and increasing trust through a broader enterprise-wide risk management structure.

Risk is inherent in every business, and organizations that embed risk management practices into business planning and performance management are more likely to achieve their strategic and operational objectives [6]. Healthcare is often characterized by the statement, "good people, bad system." Frequently the "system" (administration, politics, bureaucracy, regulations) gets in the way of individuals doing their job or doing the right thing when it is needed. The ERM processes should include both identifying issues that get in the way of better quality and patient outcomes and documenting situations in which successful workarounds occurred to avoid a bad outcome. Due to incident reporting mandates, there is often a focus on bad outcomes with limited learning about what was done correctly [7]. The true learning that should be taking place to improve quality comes from the avoidance of a bad outcome or "near miss," with appropriate recording of the events and subsequent follow-up using an organizational structure such as a morbidity and mortality conference. A number of organizations have utilized various programs supporting a culture of ERM, including Organizing for High Reliability (HRO), Crew Resource Management (CRM), and TeamSTEPPS (from AHRQ) [8].

Avoiding a Culture of Fear

One barrier to improved patient outcomes and quality has been the pervasive culture of fear in many organizations that usually stems from a combination of a strict clinical hierarchy and the threat of litigation. Unfortunately, this culture of fear has been fairly common in healthcare. Concerns over patient privacy, reputational risk, and cost of litigation in both settlement value and impact on medical malpractice premiums have stifled open communication and learning [9]. Such concerns also inhibit reporting of near misses, which are critical for an organization to study in order to learn and improve [10]. Tort reform and reduced frequency and severity of claims have improved the market conditions and availability of medical malpractice insurance over the past several years. Consequently, there is an opportunity to break this cycle of fear and communicate appropriate information in order to improve both patient experience and outcomes.

Some healthcare organizations avoid any discussions involving errors or mistakes that take place in the hospital setting for fear of discovery in a litigated matter [11]. As a result, they may not always be forthright with patients and relatives regarding the specifics of the event that occurred. Communicating, studying, and understanding what went wrong benefit everyone and lead to higher patient quality in the future [12]. Effective apologies, experts tell us, are those that are made as quickly as possible after the event, and should occur within 24 h to be effective [13]. There has been interest in such programs as "Sorry as a strategy," and related "I'm sorry" legislation that has evolved over the last 10 years. These strategies have created progress towards breaking the culture of fear, but only if implemented on an enterprise-wide basis, since they will not be as effective and could potentially be more damaging when applied inconsistently [14, 15].

Investing in an enterprise-wide risk management strategy can be time consuming and involves a significant investment for many organizations. A comprehensive risk program is a

wise investment for an organization interested in improving quality, lowering costs, and reducing risks for the patients it serves.

Defining a Culture of Prevention

Much has been written about the complexities of understanding and establishing a culture of safety. This concept is illustrated by the onion model of Schein adapted as the Helsinki Onion and the Culture of Prevention [16]. One can immediately appreciate the complexity surrounding the path to building a culture that moves "from risk to a zero incident organization." A safety culture is defined as "the ways in which safety is managed in the workplace, and often reflects the attitudes, beliefs, perceptions and values that employees share in relation to safety" [17]. The first step in establishing a culture of safety is to study the current state of an organization utilizing a risk assessment. If an organization is indeed defined by its culture, harnessing that culture requires understanding the culture through two lenses: vertical alignment and horizontal alignment. That means evaluating leadership all the way from the CEO down to the managerial level, and then performing a horizontal examination of each through a common framework.

The following case study uses a four-dimension framework: just culture, organizational structure, engagement, and alignment measures. Nested within the four dimensions are 21 analysis measures, including measures from just culture, ethics, leadership, and staff attitudes and behaviors. The analysis measures provide an assessment of how well the staff feel they are delivering high-quality and safe care to the patients. Figure 6.3 illustrates

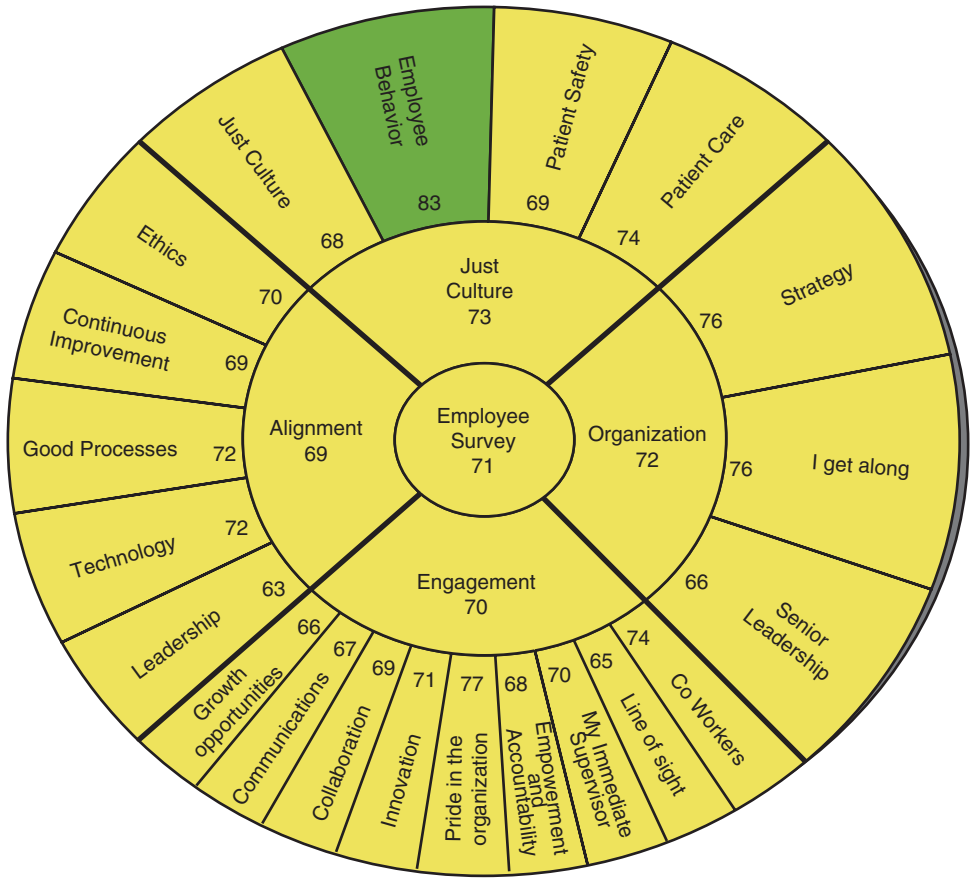

Fig. 6.3 The employee survey and four-dimension framework: just culture, organizational structure, engagement, and alignment measures

the important cultural measures of this hospital study. The findings of our survey suggest that a fundamental set of behaviors must exist before operational actions will have any significant impact in implementing a culture of safety and prevention.

1. **A Culture of Prevention is more easily established when leadership first creates a culture of "continuous improvement."**
   The question which was asked in the study: "Compared to last year, we have made improvements in serving our patients and in patient safety."
   - **35 %** of respondents answered: **"A Great Deal"**
   - **36 %** of respondents answered: **"Somewhat"**
   - **17 %** of respondents answered: **"Not Really/No change"**

   Continuous improvement could be an important strategic objective in developing a culture of patient safety. The following two figures illustrate the tangible impact on employee perceptions, culture, and patient safety performance when people perceive that there has been **"A Great Deal"** of improvement or **"Not Really/No Change"** (Figs. 6.4 and 6.5). The 103 respondents that voted **"A Great Deal"** of improvement showed remarkable scoring results (80 and above is green) against all 21 culture measures (Fig. 6.4). Contrast that to the findings illustrated in Fig. 6.5 where 49 respondents voted **"Not Really/No Change"** to the same question. Scores of 55 and below are red, and it is worth noting the low scores on *Patient Care and Patient Safety* in the just culture dimension.
2. **A culture of prevention is enhanced when there is a caring culture.**
   The question asked in the study: "My immediate supervisor cares about my personal growth and development."

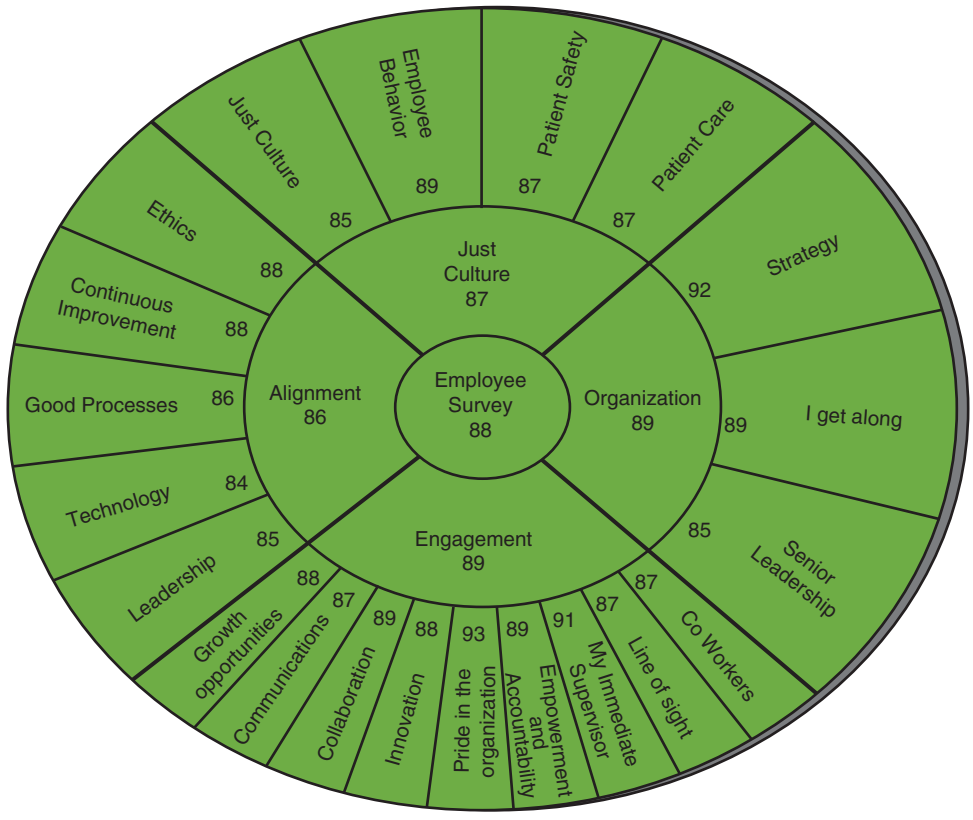

Fig. 6.4 Respondents that voted "A Great Deal" of improvement ($n = 103$)

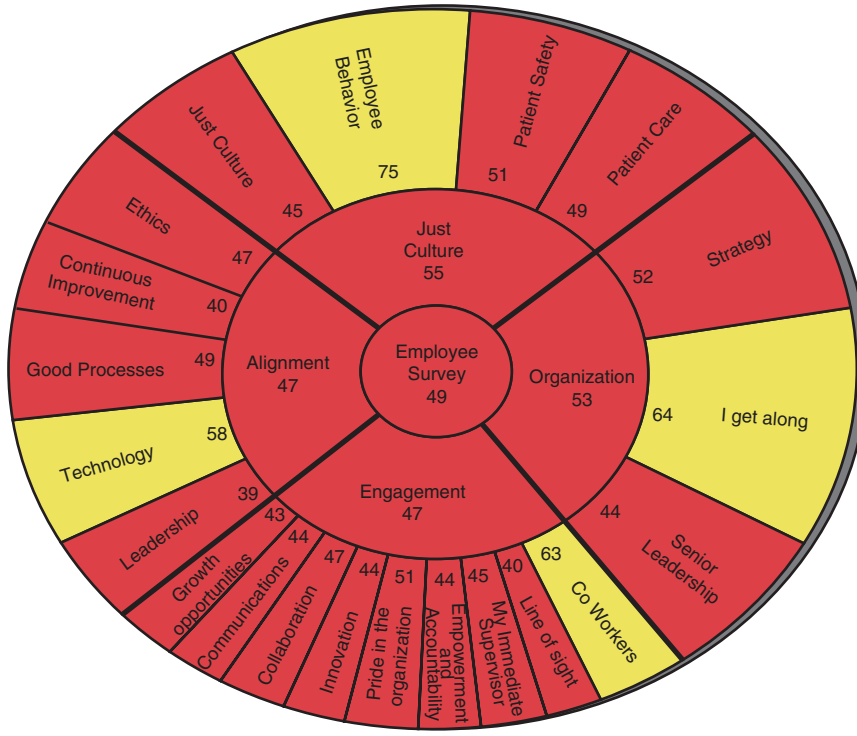

Fig. 6.5 Respondents that voted "Not Really/No Change" in response to question of making improvements ($n=49$)

- **57 %** of respondents answered: **"Yes"**
- **25 %** of respondents answered: **"Not Sure"**
- **10 %** of respondents answered: **"No"**

Table 6.4 lists the top ten scores in the study of people who perceive that their managers care about their growth and development. The behavior scores that are core to patient care and safety rank at the top, and pride of employment has the strongest score. Managers who care about their workgroups have workgroups who are proud to work for the organization (Figs. 6.6 and 6.7).

3. **A culture of prevention is enhanced when there is leadership excellence.**

   The following are six commonly recognized leadership qualities that need to be present in the minds of the employees for any successful change. In this case study the survey answers are in italics following each of the six leadership qualities and the numbers in red indicate overall scores of the client organization.

   1. **Top Management Sponsorship**
      - *I feel that our senior leadership openly and honestly works with the staff to improve our workplace* ***68***
      - *Our senior leadership manages the facility extremely well* ***67***
   2. **A Shared Vision**
      - *Our senior leadership has a clear vision that has been articulated and well defined* ***68***
   3. **Corporate Culture That Motivates and Promotes Change**
      - *Our facility has an entrepreneurial spirit-supporting people in coming up with new and fresh ideas* ***69***
      - *The doctors, nurses, and administration work in harmony as a united business unit* ***67***
   4. **Honest and Timely Communication**
      - *I can speak openly and truthfully about business or patient issues to anyone in the organization* ***65***
      - *I feel that our senior leadership openly and honestly works with the staff to improve our workplace* ***68***
   5. **Ownership of Change by Middle Management**
      - *When something goes wrong, we correct the underlying reasons, or "root*

Table 6.4 Top scores of employees who feel that managers care about their growth and development

No.	Factor	Item	Score
1	Employee behavior	Nurses should always question decisions made by an attending if they perceive a problem with patient care or safety	**93**
2	Pride in the organization	I am proud to work for this facility	**93**
3	Employee behavior	I would report at-risk patient safety behavior from any of my coworkers to my immediate supervisor	**92**
4	My immediate supervisor	My immediate supervisor values me	**92**
5	My immediate supervisor	My immediate supervisor cares for me	**92**
6	My immediate supervisor	My immediate supervisor constantly promotes patient safety as a core value	**90**
7	My immediate supervisor	My immediate supervisor has the necessary skills to lead me	**89**
8	I get along	I trust and get along with coworkers in my work unit	**89**
9	Pride in the organization	If a friend was seeking employment, I would wholeheartedly recommend this medical center as a great place to work	**89**
10	Pride in the organization	I have a bright future working in this facility	**89**

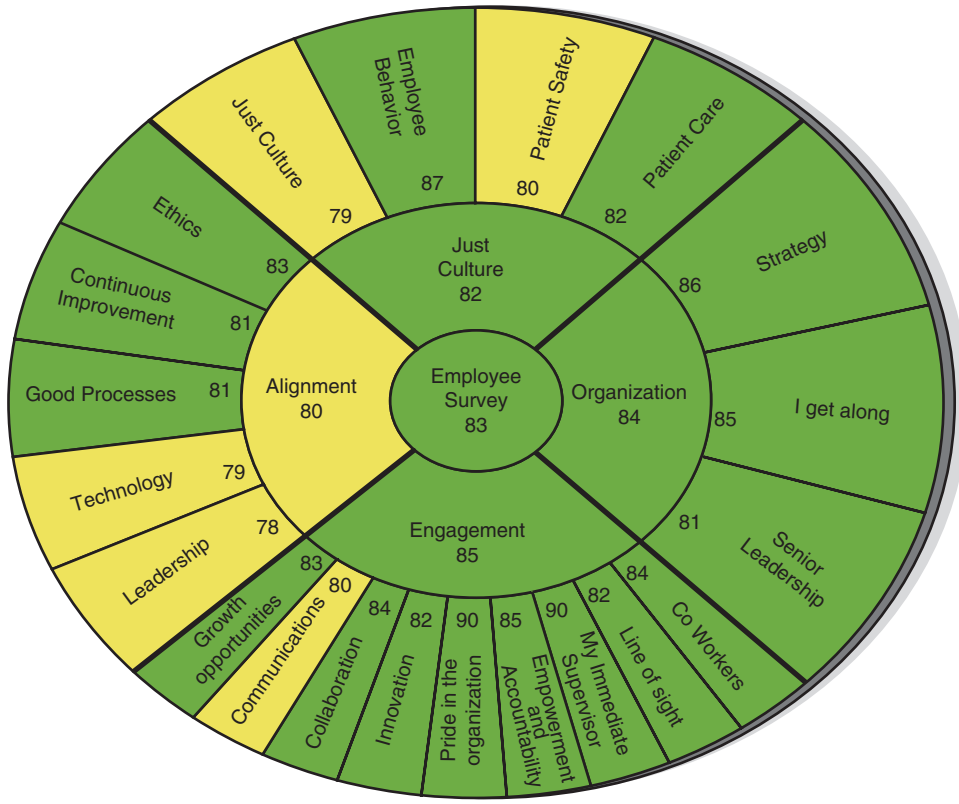

Fig. 6.6 Respondents who felt that their immediate supervisor cares about their personal growth and development ($n = 167$)

cause," so that the problem will not happen again ***68***

- *I believe that leadership and my immediate supervisors are on the same page* ***67***

6. **Employee Involvement**
   - *If I have a great idea and it's within the facility guidelines, I feel free to act on it* ***69***

The leadership scores recorded in this study were low and indicate that leadership must work to improve the scores in order to successfully implement a culture of prevention at this hospital (Table 6.5). Seven senior leadership strategic competencies were measured in the risk assessment.

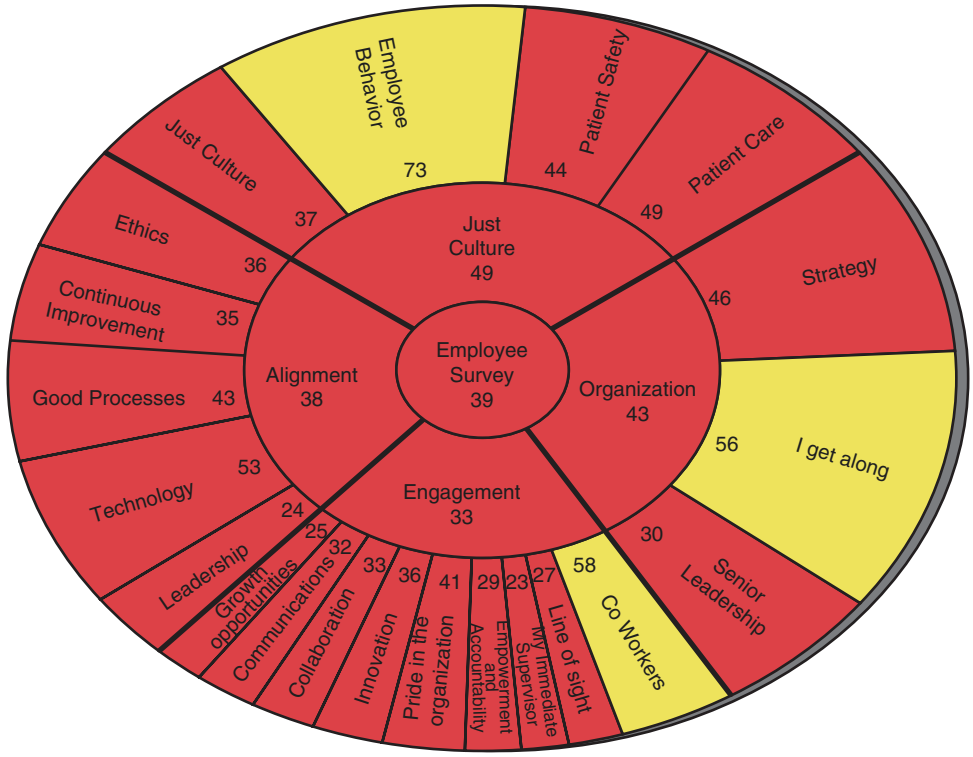

Fig. 6.7 Respondents who did not feel that their immediate supervisor cares about their personal growth and development ($n=28$)

Table 6.5 Senior leadership scores

Our senior leadership has a clear vision that has been articulated and well defined	**68**
Our leaders always demonstrate that safety and patient care is their overriding value and priority	**76**
I believe that the senior leadership is concerned about the well-being of the employees	**71**
Our senior leadership manages the facility extremely well	**68**
I feel that our senior leadership openly and honestly works with the staff to improve our workplace	**68**
I believe that leadership and my immediate supervisors are on the same page	**66**
Senior leadership acts consistently with the medical center's stated values	**70**

Role of the Chief Risk Officer

Many organizations have established the position of chief risk officer (CRO) with a responsibility for oversight of the entire enterprise. The main responsibilities associated with the position include:

- Developing the risk framework with risk domains
- Identifying, monitoring, and managing potential emergent risks
- Identifying risk drivers and key risk indicators
- Utilizing data models to describe and quantify risk across the organization
- Describing how risk principles fit into and affect the overall business strategy and strategic plan of the organization

Success of the CRO is measured by demonstrating reduced risk throughout the organization while putting in place mechanisms to change the culture by ensuring more open communication and implementation of a system to support reporting of errors and near misses [18].

Medicolegal Aspects of Patient Safety

Healthcare reform has made population risk management a necessity for payers and providers [15]. A focus on lower costs and better population health has created incentives and challenges for both parties. Health plans and payers face pressure to control costs, manage risk, and improve quality of care. Today, new value-based healthcare models such as accountable care organizations (ACOs) are increasing the need for payers to measure provider performance and manage population health at the same time.

Payers look at broader, aggregate data to determine overall pricing on the population they are insuring and adjust rates accordingly based on experience and acuity. Although many surgical procedures are of higher risk and more costly for health insurance companies, the companies still rely on actuarial projections for these procedures and frequently seek out best practices from provider networks. To manage populations and new risk pools effectively, payers as well as providers will require enhanced clinical capabilities and sophisticated data analytics [19].

Information Technology/Security/HIPAA

Emerging threats from recent data breaches at major US organizations raise questions about the effectiveness of current security tools and approaches. Over the past decade, tens of billions of dollars have been spent by private and public enterprises to bolster security; yet preventing malicious attacks has not always been successful. In addition to businesses, one-third of all Americans have had their personal health information (PHI) compromised since 2010. This does not include unreported breaches. Seven of the ten largest healthcare data breaches in 2015 were hacker attacks affecting approximately 92 million individuals. Healthcare, at 43% of reported data breaches, has the highest percent for the third straight year. Twenty percent of incidents in 2015 involved "rogue" employees [20]. Many organizations have resorted to a back-to-basics approach focused on people, processes, and technology and view the function of security as a strategic enabler of new initiatives.

Understanding Health Information Privacy

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides federal protections for individually identifiable health information. Currently, the Privacy Rule is balanced to permit the disclosure of health information needed for patient care and other important purposes. The rule specifies a series of administrative, physical, and technical safeguards for covered entities and their business associates to use to assure the confidentiality, integrity, and availability of electronic protected health information [21].

Entities and Business Associates

The HIPAA Rules apply to covered entities and business associates. Individuals, organizations, and agencies that meet the definition of a covered entity under HIPAA must comply with the rules' requirements to protect the privacy and security of health information and must provide individuals with certain rights relative to their health information. If a covered entity engages a business associate to help it carry out its healthcare activities and functions, the covered entity must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do. It also requires the business associate to comply with the rules' requirements to protect the privacy and security of protected health information. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of the HIPAA Rules. If an entity does not meet the definition of a covered entity or business associate, it does not have

Table 6.6 Examples of covered entities

A healthcare provider	A health plan	A healthcare clearinghouse
Doctors	Health insurance companies	Entities that process nonstandard health information they receive from another entity into a standard (i.e., standard electronic format or data content), or vice versa
Clinics	HMOs	
Dentists	Company health plans	
Chiropractors	Government programs such as Medicare, Medicaid, and veterans' programs	
Nursing homes		
Pharmacies		
Psychologists		

to comply with the HIPAA Rules. See definitions of "business associate" and "covered entity" at 45 CFR 160.103 [22]. A "covered entity" is defined in Table 6.6.

Office for Civil Rights Pilot Privacy, Security, and Breach Notification Audit Program

Use of new health information technologies continues to expand and provide many opportunities and benefits for consumers. Nevertheless, these technologies pose new risks to consumer privacy. Due to these increased risks, HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH) include national standards for the privacy of protected health information, security of electronic protected health information, and breach notification to consumers. The HHS is also required by HITECH to perform periodic audits of covered entity and business associate compliance with the HIPAA Privacy, Security, and Breach Notification Rules. The HHS Office for Civil Rights (OCR) enforces these rules, and in 2011, OCR established a pilot audit program to assess the controls and processes covered entities have implemented to comply with them. Through this program, OCR developed a protocol, or a set of instructions, and then used it to measure the efforts of 115 covered entities. As part of OCR's continued commitment to protect health information, the office instituted a formal evaluation of the effectiveness of the pilot audit program [23].

Case 1: A Children's Hospital Fined $40,000 for Data Breach

In May 2012, an unencrypted, children's hospital-issued laptop was stolen from a physician who was presenting at a conference. The physician had recently received an e-mail from a colleague containing the protected health information of approximately 2100 patients, 1700 of which were under 18 years old. The PHI included names, birth dates, diagnoses, procedures, and dates of surgery. Although the physician "took steps that he thought were adequate to remove the protected health information from the laptop," the information remained on the computer, according to a news release. The children's hospital agreed to settle data breach allegations for $40,000 and to take steps to prevent future security violations, according to the attorney general of the state involved [24].

Case 2: Academic Medical Center Fined $1,500,000 for Deficiencies in HIPAA Compliance Program

A large urban university recently agreed to settle potential violations of the HIPAA of 1996 Privacy and Security Rules, including a $1,500,000 monetary settlement and corrective action plan to address deficiencies in its HIPAA compliance program. In September of 2010, the HHS OCR received notification from the hospital regarding a

breach of unsecured electronic protected health information (ePHI). On November 5, 2010, HHS notified the hospital of HHS' investigation regarding the hospital's compliance with the Privacy and Security Rules promulgated by HHS pursuant to the administrative simplification provisions of the HIPAA of 1996. The HHS investigation indicated that the hospital failed to conduct an accurate and thorough risk analysis that incorporates all information technology (IT) equipment, applications, and data systems utilizing ePHI, including the server accessing NYP-ePHI. It was also alleged that the hospital failed to implement processes for assessing and monitoring IT equipment, applications, and data systems that were linked to NYP patient databases prior to the breach incident and failed to implement security measures sufficient to reduce the risks of inappropriate disclosure to an acceptable level [25].

How the OCR Enforces the HIPAA Privacy and Security Rules

The OCR is responsible for enforcing the HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164, Subparts A, C, and E). One of the ways that OCR carries out this responsibility is to investigate complaints filed with it. The OCR may also conduct compliance reviews to determine if covered entities are in compliance, and it performs education and outreach to foster compliance with requirements of the Privacy and Security Rules. This office also works in conjunction with the Department of Justice (DOJ) to refer possible criminal violations of HIPAA.

The OCR may only take action on certain complaints. If OCR accepts a complaint for investigation, it will notify the person who filed the complaint and the covered entity named in it. Then the complainant and the covered entity are asked to present information about the incident or problem described in the complaint. The OCR may request specific information to get an understanding of the facts, and the covered entities are required by law to cooperate with complaint investigations.

If a complaint describes an action that could be a violation of the criminal provision of HIPAA (42 U.S.C. 1320d-6), OCR may refer the complaint to the DOJ for investigation. The OCR reviews the information, or evidence, that it gathers in each case. In some cases, it may determine that the covered entity did not violate the requirements of the Privacy or Security Rule. If the evidence indicates that the covered entity was not in compliance, OCR will attempt to resolve the case with the covered entity by obtaining information on voluntary compliance, corrective action, and/or resolution agreement. Most Privacy and Security Rule investigations are concluded to the satisfaction of OCR through these types of resolutions. When completed, the OCR notifies in writing the person who filed the complaint and the covered entity of the resolution result [26].

Security Risk Assessment

The Security Risk Assessment is critical. It is one of the first things Centers for Medicare and Medicaid Services (CMS) or OCR asks for in an audit. Risk assessment should be a fundamental part of the overall security management program. During a Meaningful Use (MU) audit, CMS will ask for a copy of the entity's risk analysis completed before or during the attestation period. However, during a breach of PHI investigation, OCR will request a copy of the entity's risk analysis from the previous 6 years. Complying with HIPAA is serious business. The audits examine key areas of HIPAA compliance, especially those problem areas pinpointed during OCR's breach investigations, such as a lack of comprehensive, timely risk assessment, and mitigation. A comprehensive approach to risk assessment controls will help prevent, identify, and respond to a data breach. There must be thorough vulnerability scanning and penetration testing. Log and event monitoring and social engineering data are vital [27].

Business Associates and Risk Assessments

Business associates (BA) that have not performed a security risk assessment and do not have an appropriate security program in place are a risk to their organization. Steps to decrease the likelihood

of a breach by an entity's business associates include the following:

- Prioritize risk of BAs based on services provided and use/storage of ePHI.
- Request that higher risk BAs provide evidence of risk assessment.
- In the absence of a risk assessment, ask BA for a Service Organization Control report or anything that will show that the BA has its own HIPAA Security Program in place and would not be found in willful neglect during a breach audit.
- Consider the policy for BAs that provides high-risk services and does not provide evidence of a current security risk assessment.

Common CMS Audit Findings

The most common audit findings are lack of disseminated policies and procedures. Unencrypted mobile or removable devices, shared IDs, and passwords, texting, e-mail, and mobile apps are common vulnerabilities found in audits. Another common issue is unattended legacy systems and shared drives.

Policies and Procedures: Problem Areas

- IT risk management program: All facilities must have an IT risk management program. Often these are found to be either missing, incomplete, or disconnected from the compliance office.
- Policies: There are currently too many weak or missing HIPAA security policies. Zero tolerance is expected for future audits.
- Procedures: Many procedures still lack periodic monitoring designed for early detection of problems.
- Mobile and removable devices: Lack of encryption is a serious problem and is responsible for many security breaches. Encryption is important in this area.
- Inventory: RFID and Lo-jack-type firmware are helpful assets for achieving accurate accounting of your essential inventory and change control.
- Shared IDs and passwords: Many physicians and staff don't truly understand their personal liability. Problems are passive education, lack of awareness, and lack of access to provisioning. Unused legacy or archived systems, multiple administrators of websites, and only one ID for the hospital are concerns.
- Personal e-mail: For personal e-mail, all employees and all physicians (employed or not) should have an exchange account for e-mail. Antivirus tools don't address today's malware. Problems occur when medical devices supported by clinical engineering are on an old, unsupported server. Other concerns are phishing, e-mail harvesting, and ransomware.
- Unattended legacy systems: Include shared data, open database links related to report writing, and administrative IDs.
- Forgotten items: Forgotten items are old EHRs, financial data, decision support systems, and backups. Conversion to data on shared drives, a product of hospital IT evolution, may seem like a good idea but may be hazardous.
- Shared drives: There are often thousands of unencrypted files found on shared Word and Excel drives that pose a security risk to the organization.

The Evolving Role of the Risk Manager

Once an organization has decided to invest in an enterprise-wide risk strategy, one of the challenges is to identify the appropriate team leader for the role. In our experience, the risk manager has a wide variety of responsibilities, and in many instances the role is uniquely defined by the risk profile of the organization or the reporting relationship to those having responsibility for the function. The healthcare risk manager can mean different things to different organizations, with the job of managing the following three primary functions of risk management:

- Risk mitigation (safety and loss prevention)
- Risk financing (insurance procurement)
- Claims/litigation management (both insured and self-insured)

Reporting relationships and position in the organizational chart directly impact the level of authority, involvement, and trust that these senior risk executives will enjoy. Traditionally, risk managers have reported through legal, finance, administration, operations, and sometimes even directly to the CEO. The position within the organization will have a direct impact on how "enterprise-wide" the role truly is, since access to information, general communication, and accessibility to key senior executives is critical. The actual role of the healthcare risk manager varies as much as the individual skills and job description. One overriding common theme among all healthcare risk managers is that each day provides a new challenge. The various skills required include those of a crisis manager, patient advocate, physician intermediary, accountant, therapist, and actuary.

Important and far-reaching changes have been felt throughout the healthcare industry, and the role of the risk manager continues to evolve in order to manage these trends. The acquisition of provider groups by hospitals and the integration of provider networks to offer broader population health management to the community have served as an impetus for further evolution of the risk manager role. Healthcare risk managers must be deeply involved with the merger and acquisition function not only from a due diligence standpoint, but also in supporting the integration of the newly acquired organization which often will have different systems, policies, procedures, and culture.

In view of the diverse skill sets required of the risk manager, we believe that the demand for a truly qualified healthcare risk manager capable of operating at an enterprise level across the various functions of an organization will only increase in years to come.

Formal Risk Reporting and Risk Data Management

Patient safety event reporting and quality data can help your organization improve its healthcare delivery. To help healthcare organizations improve patient safety, Congress established patient safety organizations (PSOs) and the Network of Patient Safety Databases (NPSD) as resources to promote shared learning and enhance quality and safety nationally. Hospitals and other providers can take full advantage of PSOs and the NPSD by:

- Joining a PSO to be part of a privileged, protected, and confidential environment for analysis of patient safety and quality information in all healthcare settings
- Agreeing to release non-identifiable patient safety event data for analysis at the national level
- Using feedback from PSOs and the NPSD to guide patient safety and quality interventions and identify areas for further improvement

The *Patient Safety and Quality Improvement Act of 2005* and the Patient Safety Rule established a framework by which information voluntarily reported or discussed by doctors, hospitals, and other healthcare providers regarding patient safety events and quality of care is protected from disclosure. The Act provides specific legal protections for privileged and confidential event-level data voluntarily submitted by healthcare providers to PSOs and allows shared learning to enhance quality and safety nationally. The Agency for Healthcare Research and Quality (AHRQ) is establishing the NPSD to serve as a resource for healthcare providers and PSOs to analyze and learn about threats to patient safety and how to avoid them. Patient safety event data go through multiple steps in the processes of de-identification, analysis, and reporting of meaningful results for patient safety improvement. Key players in the analysis process are the following:

- **PSOs**: Entities that can be public or private organizations, to collect, aggregate, and analyze information regarding the quality and safety of care delivered in any healthcare setting. The Act extends legal privilege and confidentiality protections to healthcare providers who voluntarily submit patient safety event information to PSOs. Hospitals and other healthcare providers may voluntarily submit patient safety event-level data to PSOs on a privileged and confidential basis for the aggregation and analysis of patient safety events. PSOs analyze the data and provide

feedback to the submitting healthcare providers. PSOs also provide a protected space for members to discuss patient safety and quality topics. AHRQ is responsible for officially listing PSOs.

- **PSO Privacy Protection Center (PSOPPC)**: The Patient Safety Act authorizes the creation of a NPSD to which PSOs can voluntarily contribute patient safety and quality information. The Patient Safety Act and Rule require that information be made non-identifiable prior to submission to the NPSD. The PSOPPC is responsible for ensuring the privacy of facilities, providers, and patients by de-identifying and aggregating patient safety event data before providing the data to the NPSD. All information identifying individual and institutional providers, patients, and provider employees reporting patient safety events is removed. Hospitals and other healthcare providers that are members of a PSO can authorize the PSOPPC to submit non-identifiable patient safety event data to the NPSD. With the advantage of larger report volumes, data analysis conducted by the NPSD can more easily identify trends and patterns in incidents, near misses, and unsafe conditions; detect contributing factors; and analyze rare patient safety events [28].

Patient Safety and Quality Improvement Act of 2005 Statute and Rule

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) establishes a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and healthcare quality issues. To encourage the reporting and analysis of medical errors, PSQIA provides federal privilege and confidentiality protections for patient safety information, called *patient safety work product*. The PSQIA authorizes the Department of Health and Human Services (HHS) to impose civil monetary penalties for violations of patient safety confidentiality. PSQIA also authorizes the AHRQ to list PSOs. The PSOs are the external experts that collect and review patient safety information [29].

Understanding Patient Safety Confidentiality

The PSQIA establishes a voluntary reporting system to enhance the data available to assess and resolve patient safety and healthcare quality issues. Patient Safety Work Product (PSWP) includes information collected and created during the reporting and analysis of patient safety events. The confidentiality provisions will improve patient safety outcomes by creating an environment where providers may report and examine patient safety events without fear of increased liability risk. Greater reporting and analysis of patient safety events will yield increased data and better understanding of patient safety events.

Enforcement of the confidentiality of patient safety work product is crucial to maintaining an environment for providers to discuss and analyze patient safety events, identify causes, and improve future outcomes. The enforcement provisions are found at Subpart D of the Patient Safety Rule [26]. The OCR seeks voluntary compliance with the confidentiality provisions by providers, PSOs, and responsible persons that hold PWSP. They may conduct compliance reviews and investigate complaints alleging that PSWP has been disclosed in violation of the confidentiality provisions. If OCR determines that a violation has occurred, the OCR may impose a civil money penalty of up to $11,000 per violation. The OCR provides technical assistance to persons seeking to comply with the confidentiality provisions and public information regarding the administration of the enforcement program [26].

Common Formats

PSOs are required to collect and analyze data in a standardized manner. The AHRQ created the Common Formats, which are common definitions and reporting formats to help providers uniformly report patient safety events and support efforts to eliminate harm. Common Formats delineate definitions, data elements, and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events. Their purpose is to promote rapid learning about the underlying causes of risks and harm in the delivery of healthcare and to share those findings widely, thus creating a national learning system for quality improvement strategies [30].

The AHRQ Common Formats include:

- Definitions of patient safety events and event descriptions
- Examples of patient safety population reports
- Technical specifications for use by software developers, PSOs, and data vendors
- A user's guide that describes how to use the formats
- A metadata registry with data element attributes

Report Types from the NPSD

Organization submit data to the NPSD, and the data becomes part of a national database that reports on incidents, near misses, and unsafe conditions. Reports can be broken out by specific types of events and harm levels, such as medication events, falls, pressure ulcers, device mishaps, and health information technology errors. The NPSD compiles this information into aggregated tables and charts showing the number of reported events organized by circumstance, impact, and contributing factors. Based on the NPSD analysis, report users will be able to compare their organization's pattern of patient safety events with all events reported nationwide. As participation grows, the NPSD will be able to provide additional breakouts of results by provider characteristics such as size, specialty, and type of ownership.

Value to Providers

The stage has been set, now that PSOs can aggregate event-level data, for breakthroughs in our understanding of how best to improve patient safety. Hospitals and other providers benefit from participating because they can:

- Compare results at the national level, across PSOs, and across a larger group of provider types
- Discover underlying causes of incidents, near misses, and unsafe conditions in healthcare delivery
- Seek additional expertise for decreasing events and improving quality
- Identify patterns of rare events, supported by larger report volume

Patient Safety Evaluation System

On March 11, 2014, CMS issued the final rule implementing a number of provisions of the ACA, including the provision that hospitals must satisfy certain patient safety and quality improvement requirements to contract with a qualified health plan (QHP) through health insurance exchanges. The ACA requires QHPs to contract with hospitals that have more than 50 beds only if they meet certain patient safety standards, including the use of a patient safety evaluation system (PSES) and a comprehensive hospital discharge program. The date for implementation of PSESs by hospitals is January 1, 2017 [31].

A PSES is not the same as an event reporting system. An organization's reporting system may be incorporated into the PSES but the system needs a separation between what information is protected as non-disclosable PSWP from discoverable and disclosable information that is not protected under the PSQIA. Disclosable information is usually that information relating to an event with harm that is reported to risk management where there may be legal requirements relating to the event. Nevertheless, a copy of the event can still be sent to the PSO where research and analysis can be performed on the event. In

such a case all the work done on the case is protected PSWP and cannot be disclosed to interested parties who do not have business associate agreements in place with the PSO or the submitting organization.

Reporting Preventable Errors or Preventing Preventable Errors?

In surgical practice there are more near-miss events than harmful events to patients [32]. Some would argue that there are 40-fold more near misses than there are adverse events. Unsafe conditions and hazardous situations occur hundreds of times before a sentinel event occurs and is reported. In general, professionals do not take the time to document no-harm events and they do not always share them with the organization [33]. Ideally, what should transpire once an event occurs is immediate documentation of the encounter and sharing it with peers and the C-Suite so the organization can implement preventive action.

Today when every caregiver has a smartphone in their pocket, it is possible to document all observations in seconds and communicate unsafe conditions by taking a photo and recording a description of what needs fixing. This does not disrupt the clinician's workflow and enables real-time communication and learning within the organization. Of course, this workflow needs to consider HIPAA guidance and constraints.

Event Underreporting

The Office of the Inspector General (OIG) published a report stating that only 14% of documented events in the medical record that relate to patient safety were actually reported to the quality department for analysis and process improvement action [34]. This suggests that 86% of what is documented in the medical record as a quality issue is never addressed for organizational learning and the prevention of future harm. It has also been estimated that less than 10% of all reportable events are reported by physicians [35]. This may be due to the fact that many physicians do not see value in reporting because they perceive that it will not make a difference and do not want to risk having their reputations tarnished. However, under the PSQIA, the information will go into the PSES and the identity of the provider will not be disclosed. Therefore, if more organizations participate with a PSO, more information will be collected and organizations will become more effective in preventing harm rather than underreporting harm.

Federally Listed Patient Safety Organizations

There are a total of 81 PSOs in 29 states and the District of Columbia currently listed by the AHRQ. A healthcare provider can only obtain the confidentiality and privilege protections of the Patient Safety Act by working with a federally listed PSO. The "Listed PSO" logo is available for use by PSOs that are currently listed by the HHS Secretary. Healthcare providers considering working with a PSO are advised to review this directory to ensure that the entity's PSO certifications have been accepted in accordance with Section 3.104(a) of the Patient Safety Rule.

The "AHRQ Common Formats" logo may be displayed by any organization that is using the Common Formats developed by AHRQ. An entity does not need to be listed as a PSO to use the Common Formats and thus display the logo. The Formats are available in the public domain to facilitate their widespread adoption and implementation. Entities that display the logo should use the Common Formats as a whole; however, entities that have a limited focus may display the logo when using Common Formats that pertain only to that area [30].

Summary

Enterprise risk management is an important and complicated discipline which touches all aspects of a healthcare organization. Important concepts related to risk identification and measurement,

culture, and culture assessment are discussed initially. Patient safety and privacy, HIPAA, and other medicolegal aspects of risk in the healthcare setting are next reviewed in detail. The chapter concludes with a discussion of issues related to government programs such as PSOs, PSESs, and using Common Formats in risk reporting.

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The Patient Experience: An Essential Component of High-Value Care and Service

7

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"We cannot direct the wind but we can adjust the sails."

—Author Unknown

Abbreviations

AAIM	Alliance for Academic Internal Medicine
ACP	American College of Physicians
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CER	Comparative effectiveness research
FACIT	Functional Assessment of Chronic Illness Therapy
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HRQL	Health-related quality of life
HVC	High-value care
NCCN	National Comprehensive Cancer Network
PCORI	Patient-Centered Outcomes Research Institute
PRO	Patient-reported outcomes
PROMIS®	Patient Reported Outcomes Measurement Information System
PROMS	Patient Reported Outcome Measures
SPORT	Spine Patient Outcomes Research Trial

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By the year 2020, healthcare expenditures are projected to reach nearly 20% of the gross domestic product, a spending rate described as highly unsustainable by economists. Approximately 30% of healthcare costs (over $750 billion annually) has been identified as wasteful spending that if eliminated would not negatively affect care quality [1]. Examples of waste include preventable hospitalization and rehospitalization, overuse and misuse of diagnostic testing, and excessive use of emergency department services [2]. A myriad of factors are influencing rising healthcare costs, including the aging population, novel devices, drugs, tests, and procedures. However, healthcare innovations are

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also contributing to improved patient outcomes; thus evaluating the value of healthcare services is of great importance and necessary for reducing extraneous healthcare spending [3].

For decades, efforts to enhance quality and safety practices and slow the rate of increasing healthcare costs have been undertaken. Due to the exorbitant spending projections, scholars, organizations, and practitioners have endeavored to shift healthcare reform efforts from a fee-for-service model to one that places emphasis on the delivery of high-value care. Value-based health care is a reform effort that aims to control unnecessary healthcare expenditures by focusing on the value of healthcare interventions and services determined by evaluating the costs in light of benefits and risks while considering quality care outcomes prioritized by patients [4]. Screening protocols, procedures, and interventions are now being chosen or disregarded based on their ability to produce good value (medical benefits commensurate with costs) based upon patient preferences [4]. An intervention is deemed high value when the health benefits justify the costs. The higher the benefit, the more justifiable the cost of the intervention that delivers that benefit. High-cost interventions in which the net benefit outweighs the costs could therefore be considered a good value. Conversely, low-cost interventions that provide little to no net benefits are considered to have low value, in spite of the low price tag [3]. Although the cost of care is important, value-based healthcare delivery is organized around the patient by aiming to meet a set of defined patient needs [5]. In short, the objective of high-value care is to improve health outcomes that are important to patients in a cost-effective and efficient manner. This chapter provides an overview of high-value care, reviews the patient's role in value-based care, and outlines the integral role of patient-reported outcomes (PROs) while highlighting specific tools for outcome assessment.

What Is High-Value Care?

Considerations of restructuring into a value-based healthcare system began with Porter and Kaplan's pioneering work at Harvard Business School, and called for an overarching strategy to reduce healthcare costs by improving value for patients [6]. Within their seminal works, the authors defined value as patient outcomes relative to the amount of money spent [7–10]. Since Porter and Kaplan's initial call for systematic change, many healthcare organizations and national institutes have begun to support value-based initiatives and are in the process of developing and implementing plans for restructuring healthcare organizations and care processes—the ultimate goal being a reconfiguration of the US healthcare delivery system to reduce costs while simultaneously enhancing quality and efficiency.

Growing support for value-based health care is evidenced by the American College of Physicians (ACP) High-value Care (HVC) initiative, a broad program that aims to enhance physicians' ability to provide optimal patient care while simultaneously reducing unnecessary healthcare costs. The goals associated with the HVC initiative involve providing recommendations to clinicians regarding best available practice, to notify clinicians when evidence is lacking, and to assist clinicians in providing the best possible health care [11], including development and dissemination of condition-specific recommendations for high-value diagnostic services [12]. Increasingly, medical professionals are taking on more responsibility to reduce healthcare costs by becoming cost-conscious and decreasing unnecessary interventions that provide little to no benefit. The need for training in value-based care is further evidenced by a recent proposal to include medical resident training on practicing high-value, cost-conscious care as a seventh core competency for physicians by the Accreditation Council for Graduate Medical Education [2]. Likewise, in a joint endeavor, the ACP and the Alliance for Academic Internal Medicine (AAIM) developed an High-value care (HVC) Curriculum, which aims to help internal medicine residents in providing value patient care by teaching them how to identify system-level opportunities to reduce wasted costs and improve patient outcomes. In addition to learning how to balance benefits with potential harms and costs, medical residents actively learn methods of practicing evidence-based shared decision making with patients [13].

Further, the American Recovery and Reinvestment Act of 2009 (ARRA) allocated over $1 billion to support comparative effectiveness research (CER), defined by the Institute of Medicine as "… the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve the delivery of care." The goal of CER is to promote informed decision making by consumers, clinicians, purchasers, and policy makers to improve healthcare delivery [14].

In order to fully comprehend value-based care, one must first understand the value equation. The *value* in high-value care is defined as the following: value equals quality over cost or $V = Q/C$ [15]. *Cost* (the denominator) refers to the economic cost over the full cycle of care for a medical condition, not simply the cost of individual services [9, 15]. When conducting value and/or cost assessments, health organizations and providers must consider any and all downstream costs (e.g., subsequent testing, treatment, follow-up, conditions due to treatment complications) in the equation [3, 4]. *Quality* (the numerator) in the equation represents outcomes of importance to patients (e.g., health status, care cycle and recovery, health sustainability).

Porter and Kaplan outline a six-component strategy for the effective implementation of a value-based healthcare system: (1) organize into integrated practice units; (2) assess outcomes and costs for every patient; (3) bundle payments for care cycles; (4) integrate healthcare delivery systems; (5) expand geographic reach; and (6) develop an information technology platform to enable and support the above. This chapter focuses on component two as it relates to the scope of this chapter—outcomes of importance from the patient's perspective (for further information on the other five components, see [16]).

Measurement of outcomes and costs is essential to improving value; without these data, clinicians do not have the information required to validate choices, guide advancement, learn from others, or encourage collaboration and change [5]. To date, our healthcare system does not measure outcomes and costs by medical condition for individual patients. Instead, outcomes are assessed in terms of process measures (e.g., emergency department visits, hospital admissions, readmission rates, mortality rates), safety measures (e.g., medication errors, central line infection rates, postoperative complications), and patient-reported satisfaction [15, 17]. Current standards for outcome assessment cover little breadth in terms of the outcomes that are actually important to patients. To enhance value, outcome measurement must include health circumstances identified by patients as most relevant to their quality of life [9]. While the above is important when investigating organizational process outcomes, in order to assess the true value of health care, clinicians must gain insight into the outcomes that are of concern to patients [18].

This is why one of the most emphasized strategies for implementing a value-based care model centers on the measurement of health outcomes and costs for each patient over the full cycle of care. Value-based initiatives support outcome assessment by medical condition rather than by intervention or specialty. In 2010, Porter recommended a three-tier hierarchy for assessing health outcomes of concern to patients. The hierarchy tiers include health status achieved, recovery process, and health sustainability [17]. The first level of recommended outcomes include health status achieved that involves mortality rates and functional status, which are top concerns for patients. The second outcome tier refers to the cycle of care and recovery, which includes the level of discomfort during treatment, diagnostic errors, delays in the treatment process, duration of hospital stay, treatment-related discomfort, complications, adverse events, and the time required to resume normal activities, including work. The third tier relates to the sustainability of health including the nature of recurrences, level of function maintained, and long-term consequences of therapy (e.g., care-induced illnesses). For further details on the three-tier outcome hierarchy, see Porter [9].

Ideally, patient outcomes will be measured and publicly reported. Public reporting of outcomes provides a level of transparency not currently available which will benefit patients and providers [19]. The publication of condition-specific outcomes enables patients to become

informed healthcare consumers armed with choice in deciding a provider, but it also increases pressure on providers to adopt best practices and improve care practices based on what actually matters to patients. The standardization of outcome measures by condition will enable comparisons to be made across providers and organizations which will then stimulate improvements in practice and patient outcomes on both a national and global scale [16]. Efforts to develop, standardize, and distribute efficient outcome measures are currently under way and have made great progress, and will be highlighted later in this chapter.

In its current state, our healthcare system is unable to assess condition-specific costs for each patient for a full cycle of care. Healthcare organizations are currently reimbursed on a fee-for-service basis and are department based rather than patient or condition based. Moreover, healthcare accounting systems based on overall department budgeting are unable to provide accurate estimates of service costs on a patient or even condition level [16]. To ascertain value, it is recommended that healthcare providers calculate costs based on the medical condition over the full cycle of care. Tracking expenses incurred over the full care cycle involve recognizing all resources utilized to care for the patient (e.g., equipment, facilities, personnel), capacity costs of supplying resources, and care-associated support costs (e.g., administration, IT). Only then can the actual cost of condition-specific care be compared with quality (patient outcomes) to determine the value of healthcare services [16].

Research conducted within the Spine Center at Dartmouth-Hitchcock is a good example of value-based health care. Dartmouth's Spine Center conducted a 5-year, multisite study, Spine Patient Outcomes Research Trial (SPORT), to compare the three most common back conditions (i.e., intervertebral disc herniation, spinal stenosis, degenerative spondylolisthesis) and PROs to gain insight into whether surgery produces better outcomes over nonsurgical therapies (i.e., physical therapy, medication, other noninvasive therapies). Results of the trial in intervertebral disc herniation patients revealed that both surgical and nonsurgical groups improved posttreatment; however, patients who received a discectomy recovered more quickly [20]. Results of the spinal stenosis trial uncovered that surgical intervention resulted in better pain and function PROs than nonsurgical therapies [21]. Likewise, the surgical patients in the degenerative spondylolisthesis trial reported greater improvements in pain, function, and disability than those receiving nonsurgical therapies [22]. For all three conditions, the results of a 4-year follow-up study showed that patients maintained the reported gains from surgical intervention 4 years after surgery [20, 22, 23]. Further cost-benefit analyses of longitudinal PRO data on productivity loss, use of resources, and health-related quality of life (HRQL) revealed that when assessed over 4 years, surgery provides good value for patients in the three diagnostic groups [24]. Currently, the Spine Center at Dartmouth-Hitchcock implements these principles in the practice of spinal care, by conducting detailed intake assessment that incorporates PROs and visual decision aids, and engages in shared decision making with their patients to develop a personalized plan of care in light of patient priorities to determine whether patients are more likely to benefit from nonsurgical therapies or surgery [25].

What Is the Patient's Role in High-Value Care?

Many efforts at healthcare reform have focused the structure and design around physicians and institutions; however, in these efforts, the patient was commonly left out. In 2001, the Institute of Medicine's landmark report, *Crossing the Quality Chasm*, presented patient-centered care as a fundamental step towards improving US healthcare quality. Patient-centered care is defined as "care that is respectful and responsive to individual patient preferences, needs, and values" [26]. The report further recommended that patient values should be considered as guides to all clinical decisions. Patient-centered care involves ensuring

that treatment decisions align with the patient's values and preferences. When faced with making a decision among treatment options, patients often experience a state of heightened uncertainty, also known as decisional conflict [27]. The quality of a decision involves the degree in which a patient's decision is congruent with their values and evidence-based knowledge. One way to practice patient-centered care and to enhance the value of health care is to invite patients and family members to actively participate in clinical decision making in ways that reduce decisional conflict and enhance decision quality.

Shared Decision Making

In order to achieve optimal decisions in line with the patient's values and preferences, both providers and patients must engage in a process of shared decision making [28]. Shared decision making involves active collaboration among patients and providers for the development of a mutually agreeable plan of care [27]. To enhance patient participation in shared decision making, patients need more information, such as guidance for personalized care planning and self-management, resources for decision support, and social support from family and peers [29]. When given these resources and opportunities for active participation, the result is often better health outcomes and reduced waste, resulting from increased participation, better treatment adherence, more appropriate use of services, reduced elections for major surgery, more realistic risk perceptions, improved knowledge and understanding, enhanced self-management and coping skills, reduced decisional conflict, and greater match between chosen treatments and patient values and priorities [27, 29, 30]. In fact, shared decision making was investigated in the context of elective surgery—the results revealed that shared decision making improves patient decisions to undergo elective surgery and helps reduce decisional conflict and overuse of surgical care [27]. While the use of shared decision making in elective surgery appears promising, future research is needed to obtain more information regarding the impact on surgical utilization.

Shared decision making has been championed as a successful method of enhancing patient- and family-centered outcomes while reducing waste—and therefore is one method of practicing value-based care [27]. The Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI) both increased funding for research aimed at developing shared decision making support tools, testing implementation, and reporting results [31, 32]. Likewise, the Informed Medical Decisions Foundation provides resources and guides to help patients understand the importance of engaging in shared decision making and information to assist them in that process [33].

A well-informed patient is one who is both aware of and understands the potential risks and benefits of diagnostic and treatment options. Patients tend to overestimate benefits and underestimate harms when faced with a choice of treatments [34]. These results support the need for providers to actively engage patients in healthcare decisions by clearly communicating the benefits and potential risks associated with different choices. Clinicians, therefore, have an important role in encouraging and inviting patients to actively participate in healthcare decision making; however, this is not necessarily a straightforward task.

Patient understanding is a fundamental component of value-based care. Patient knowledge and understanding require that clinicians engage patients in direct discussions of diagnosis, prognosis, treatment options, and end-of-life care preferences (e.g., palliative, hospice care) [35]. In order to educate patients and engage them in shared decision making, providers must be able to effectively communicate with their patients. To implement value-based care by engaging patients in shared decision making, physicians must be effective at not only assessing risks, but also communicating those risks to patients in an intelligible manner. However, physician competencies in communication skills and risk assessment have been described as poor and thus require training

to improve their skills in communicating numerical information to patients which is necessary if providers are to effectively discuss risks and benefits of different treatment options. Patient perspectives and input should be included in efforts aimed at enhancing provider communication skills, especially the skills needed to intelligibly discuss risk. Inclusion of patient voices in these efforts will reinforce the central role of the patient in creating value. In value-based health care, medical decision making is inherent to value, and patient understanding of risks versus benefits is essential in these efforts [35].

Decision Aids

Decision aids are useful tools that aid physicians in communicating objective information about treatment options, ensuring that the patient understands that a decision must be made, and providing the patient opportunities to make decisions about their care, if desired [36]. Decision aids are commonly used when more than one option for screening or treatment exists [28]. In addition to helping doctors discuss important information, decision aids are also used to help educate patients by informing them of the risks and benefits of treatment options and providing them with tailored evidence to consider in light of their particular condition. Sometimes, decision aids include a section aimed at clarifying patient values, which benefits both patients and providers when discussing and deciding upon the most appropriate options based on patient preferences in light of evidence-based knowledge [27]. Decision aids can be delivered through different modalities (i.e., video, online, paper), and are used to enhance patient understanding of treatment options and the potential outcomes and to further assist patients in developing and discussing educated preferences with their clinicians.

Like shared decision making, decision aids provide many benefits including improvements in patient-provider communication and collaboration, information exchange (i.e., risks, benefits, options), treatment adherence, patient satisfaction, and ultimately closing the gap between patient values and choices [36–38]. When outcome probabilities are included in decision aids (particularly when presented quantitatively) patients have more accurate perceptions of risk [38].

Decision aids have received support among surgeons, although there has been minimal progress towards incorporating decision aids into standards of care. Despite the lack of nationwide progress for integrating decision aids into healthcare delivery, a few research hospitals are leading the way [36]. One example is the Spine Center and Adult Reconstruction division of the Department of Orthopaedics at Dartmouth-Hitchcock Medical Center. Together, this team is working with the Center for Shared Decision-Making to implement the use of shared decision making tools into standard care by providing orthopaedic patients opportunities to engage in informed choice by encouraging them to borrow a DVD and take home a symptom-rating worksheet. The worksheet asks patients questions about their preferences, values, and decisional conflict to aid them in choosing the most appropriate treatment option [39]. Decision aids, like those utilized by Dartmouth's Orthopaedics department, provide a structure for discussing the benefits and risks of treatment options in light of patient priorities and values. Use of decision aids provides patients a voice by enabling them to become informed participants when choosing care options that provide optimal value. In addition to decision aids, supportive services should be available to aid patients and families when communicating with clinicians about their preferences and values while they are learning about, processing, and deciding among treatment options [28]. Only through communication and understanding of evidence-based knowledge can patients have realistic expectations regarding their healthcare options.

Barriers to Shared Decision Making and Value-Based Care

Despite the vast benefits and avenues for enhancing value in health, there are barriers to shared

decision making and barriers to value-based care implementation efforts for both clinicians and patients. An investigation into clinician readiness to openly discuss high-value care during patient and family consultations revealed that although physicians held favorable views of high-value care, they commonly chose to avoid explicit references to value in their interactions with patients [40]. Likewise, while evidence suggests that most patients are open to participating in healthcare decision making [27, 29], some groups may be less open to the idea. For example, disadvantaged groups and older adults are less likely than young educated adults to report wanting an active role in shared decision making; however, many of the former claim that they would like the opportunity to learn about choices from their doctors [29]. On the other hand, evidence suggests that when patients know that they have treatment options, most want to engage with their physicians to make an optimal choice [28].

Although open communication and transparency regarding a need to weigh benefits in light of potential costs are standard recommendations for implementing value-based care, a qualitative investigation into patient thoughts on discussing cost with healthcare providers as part of making treatment choices suggests that these conversations may be more difficult than anticipated. Results from a large focus group study revealed that insured patients were resistant to the idea of considering costs when deciding among similar treatment or diagnostic options. Analysis of the focus group data uncovered four barriers to patients considering cost when making healthcare decisions: preference for no risk versus minimal risk, assumptions that cost is indicative of quality, a belief that choosing a more expensive option is a way to get back at insurance companies, and misperceptions that rising healthcare costs can be reduced through federal budgeting rather than individual action [41].

The results of the focus group study are at odds with numerous reports of the positive outcomes associated with shared decision making. One potential reason for this discrepancy is that discussing hypothetical situations about cost considerations when making healthcare decisions may have heightened anxiety, especially in light of the pervasive rhetoric concerning healthcare rationing. Research into patient perspectives might produce different results if interviews are conducted following a clinical encounter in which the provider incorporated cost discussions. More qualitative research is needed to investigate patient perceptions of value-based healthcare initiatives and practices. Qualitative methods are a useful approach for learning about patient preferences to aid cost-reduction efforts and enhance the value of care based on patients' lived experiences that influence outcome priorities [42]. Insights gained through qualitative studies will aid researchers, clinicians, and policy makers in developing the most appropriate decision aids, communication training for medical practitioners, and protocols for sharing information regarding risks and benefits that are based upon patient values. Moreover, public perceptions concerning cost considerations in healthcare decision making must undergo a significant shift for both patients and providers, in order to set the stage for informed patient-provider value-based decision making in light of risks, benefits, and patient priorities.

How Do We Measure Quality?

Armed with information and opportunities for open dialogue concerning health decisions, patients can become active participants in their own health management ensuring that choices made are in line with their preferences and priorities and thus obtain value in health care. As previously discussed, a key component of high-value health care is patient perspectives of the quality of healthcare practice and delivery [43]. Value means that the medical benefits or outcomes (quality) are commensurate with economic costs. While qualitative methods are important for designing and aiding in the implementation of value-based care practices, it is not a reasonable approach for assessing, public reporting, and comparing quality on a national scale. As previously discussed, assessment of patient outcomes is vital to the practice of high-value care.

In order to achieve high value, the outcomes assessed must represent those prioritized by patients [9], but how do we measure quality?

Patient-Reported Outcomes

Provision of patient-centered care promotes low cost and high-value care [44]. Patient-centered care is associated with reduced healthcare utilization [45], fewer hospitalizations and readmissions [46], fewer diagnostic tests and specialty referrals [47], and reduced costs. Thus, measurement and public reporting of PROs is regarded as a necessary means for promoting and enhancing patient-centered care by advancing accountability and quality endeavors towards care that is truly centered around its patients [48]. In order to extend assessment of patient outcomes beyond survival, clinical efficacy, and adverse events, we must assess PROs to determine the impact of the disease and treatment upon patient function and overall well-being [49].

PROs are representations of how patients feel and/or their functional abilities within the context of their own health and daily life. PROs include self-report of symptoms, functional status, and more general perceptions of general health and well-being. Common PRO domains include health-related quality of life, functional status, symptoms and symptom burden, and experience of care. For an overview of PRO characteristics, see Fig. 7.1 [50]. PROs can be used in a variety of ways to promote value in health, including, but not limited to, aiding patients and providers in making informed healthcare decisions, monitoring outcomes and the progress of care, enhancing healthcare service quality, tracking and reporting performance of healthcare delivery systems, and for use when developing policies for health service reimbursement and coverage [50].

PROs are tools that enable the elicitation, collection, and assessment of PRO information. A PRO measure, referred to by some as PROM, is "any standardized or structured questionnaire regarding the status of a patient's health condition, health behavior, or experience with health care that comes directly from the patient" [50]. PRO measures are standardized tools—developed through qualitative methods to identify top

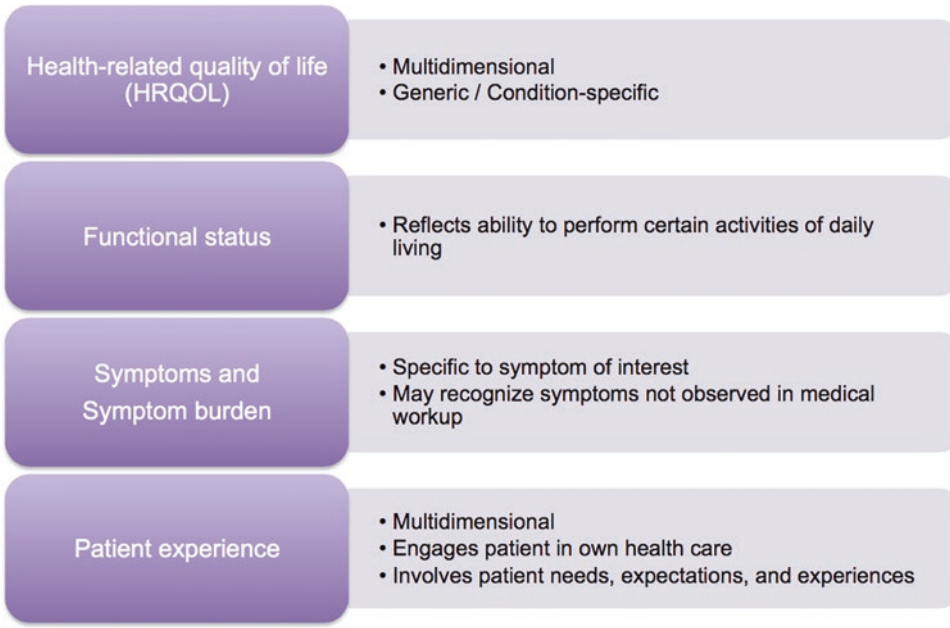

Fig. 7.1 Characteristics of patient-reported outcomes

patient concerns—that allow comparison of quantitative data across patient groups and/or providers [50]. The use of PRO measures has been described as critical to enhance understanding of how treatments impact patient functioning and well-being from the perspective of patients themselves [49]. They show immense promise for enhancing value in health by strengthening supportive care, improving symptom control, and enhancing the quality of healthcare delivery [51]. Moreover, implementation and discussion of actual patient reports during clinic visits can help facilitate shared decision making, resulting in improved patient satisfaction with provider communication, particularly regarding emotional concerns [51, 52].

Health-related quality of life (HRQL) measures are multidimensional and commonly encompass the physical, emotional, and social well-being associated with illness and/or treatment [50]. The Patient Reported Outcomes Measurement Information System (PROMIS®) is a good example of an HRQL measurement tool that provides patient-reported health status measures for physical, mental, and social well-being [53]. PROMIS tools are available for use across various conditions and chronic diseases and in the general population. Clinicians can use PROMIS measures to understand how treatments affect patient function and the symptoms they experience. Such information is useful for enhancing patient-provider communication, informing treatment plan design, and improving chronic illness management [53]. Neuro-QOL is another HRQL measurement system that captures different areas of functioning and well-being in adults and children with neurologic diseases [54]. Neither PROMIS nor Neuro-QOL specifies a disease within the item phrasing, making possible a comparison across conditions [54, 55]. In order to assess the value of healthcare services, patient HRQL must be included in the calculation.

Functional status is included in Porter's three-tier outcome hierarchy. Functional status measures assess the patient's ability to perform basic and advanced activities of daily living. For example, functional status could include cognitive function, physical function, and sexual function [50].

Symptoms and symptom burden are also important outcome measures for assessing value. Symptom assessment should be conducted prior to beginning treatment and should be continually assessed throughout recovery to determine treatment effectiveness. Patient symptoms commonly occur in clusters rather than in isolation. Symptom burden is a concept that refers to the impact of multiple symptoms on the patient, encompassing both the severity of symptoms and the impact of the symptoms from the patient's perspective [56]. For example, the PROMIS Pain Interference is a highly reliable and valid measure that enables quantification of the impact of pain on functioning that can be used across conditions [57].

Likewise, the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue questionnaire can be used to accurately measure symptoms and symptom burden. The FACIT-F is not condition specific, and therefore can be used for comparisons between a variety of conditions [58, 59]. There are, however, disease-specific FACIT questionnaires such as FACIT-Dyspnea, which is a measurement tool that has been specifically tailored to assess dyspnea for chronic obstructive pulmonary disease [60]. Additional examples of disease-focused symptom assessments tools can be obtained from the National Comprehensive Cancer Network (NCCN), which catalogues disease-specific symptom indexes for various types of cancer. In collaboration with the NCCN, Cella and colleagues addressed the need for brief and clinically relevant measures by creating a series of 11 disease-specific symptom indexes (bladder, brain, breast, colorectal, head and neck, hepatobiliary, kidney, lung, lymphoma, ovarian, prostate) that reflect the highest priority symptoms and concerns of patients [61, 62]. While HRQL, functional status, and symptom PROs are necessary to assess the quality of health care, the patient experience is another type of PRO that must be included as a measure of quality in high-value calculations.

Patient Experience of Care

Patient ratings of healthcare experiences are central to the provision and promotion of patient-centered care, which in turn enhances the value of care. Patient experience involves the perceived needs, care expectations, and actual experience of care received [63–67]. In the past, patient experience and healthcare quality were assessed through patient satisfaction PROMs. Patient satisfaction is a construct that includes multiple dimensions such as evaluations of patient-provider communication, level of trust or confidence in physicians, treatment affordability, service availability, quality-of-care facilities, and satisfaction with treatment explanations and medications [68, 69]. However, in recent years, the construct of patient satisfaction has been criticized for its lack of clarity in how it is defined and its basis upon subjective patient experiences, which are largely influenced by patient care preferences and expectations [43, 70]. Today, patient-reported experience has been distinguished as a more objective measure of patient experience and care quality. Often, patient satisfaction is conflated with patient experience creating confusion between the two; yet the two concepts are distinct [43].

Patient experience is a multidimensional construct that involves patient feedback on what actually happened during the course of care including observable processes and outcomes, objective experiences, and subjective experiences [48]. Patient experience, therefore, involves a range of variables including experiences with scheduling appointments, wait times, facility cleanliness, provision of information, and interactions with all healthcare staff (e.g., doctors, nurses, assistants, receptionists). Thus, patient experience consists of patient reports of what happened as well as the patient's evaluation or ratings of the experience reports [43, 48].

Patient-reported experience measures are tools used to evaluate the patient-centeredness and quality of health care. They obtain patient feedback on specific care experiences that capture key components of patient-centered care [48, 71]. Experience of care measures yield valuable insights into the quality of healthcare delivery from the patient's perspective. Moreover, enhanced patient experience is associated with promising outcomes, such as increased adherence, improved clinical outcomes, improved patient safety, enhanced clinical effectiveness, and reduced healthcare utilization [48, 72, 73]. In 1995, AHRQ began the Consumer Assessment of Healthcare Providers and Systems (CAHPS) project, a multi-year initiative to promote and support assessment of patients' healthcare experiences through the development of standardized questionnaires and resources that provide both patients and providers with intelligible and comparative information [74].

Likewise, in a joint effort, Centers for Medicare and Medicaid and AHRQ developed the CAHPS Hospital Survey (i.e., HCAHPS). HCAHPS is the first standardized, publicly reported, national survey of patients' perspectives of hospital care in the US. HCAHPS is a 32-item standardized survey of patient perspectives regarding hospital care that enables objective comparisons of hospital performance on topics important to patients. HCAHPS measures nurse and doctor communication, level of responsiveness to patient needs, pain management, communication regarding new medications, provision of critical information at discharge, patient understanding of care needed following discharge, reports on patient room cleanliness and quietness, likelihood to recommend to friends and family, and an overall hospital rating. HCAHPS survey results are publicly reported four times per year on the Hospital Care website, which allows comparisons across national, regional, and local hospitals. The website also provides HCAHPS Star Ratings that summarize and legibly report results to make it easier for consumers and patients to identify and compare hospitals on healthcare quality and excellence. HCAHPS is among the measures identified in the Patient Protection and Affordable Care Act of 2010 for use in calculating value-based incentive payments in the Hospital Value-Based Purchasing program [75]. Both the CAHPS and HCAHPS are measures that assess patient experience on healthcare dimensions for which patients are the only or best informational source [70].

Measuring Quality in Surgical Care

To date, no validated measurement system of surgical care quality exists. In order to align health care with efforts to improve quality, Mayer and colleagues (2009) suggested a multidimensional approach to assess the quality of surgical care that incorporates measures of both clinical and PROs over the full cycle of care [76]. Clinical pathway measures include structured measures (e.g., ratios of doctors to population served, doctors and nurses per bed, management capabilities), process measures (e.g., preoperative, intraoperative, postoperative facets of care), clinical outcome measures (e.g., procedure-specific outcomes, 30-day mortality, follow-up diagnostics, length of stay, readmission rates), and economic measures (e.g., the amount of cost created per unit of quality-adjusted output). In addition to measuring clinical pathways, the quality framework must include PRO measures. For Mayer and colleagues, these measures include patient-reported treatment outcome measures (e.g., patient reports of treatment outcomes including symptoms and/or functional status), HRQL measures (e.g., general, physical, social/family, emotional, functional well-being), and patient satisfaction/experience (e.g., patient expectations and characteristics, psychosocial determinants, interpersonal aspects, care accessibility and convenience, care environment, care continuity).

While great strides have been made in outlining high-value care principles and priorities, much work is yet to be done. The transformation into a high-value healthcare delivery system will require participation from every stakeholder in the healthcare system. Clinicians must open their minds beyond traditional clinical practice and begin to prioritize the needs and values of patients, which should be a central focus of healthcare delivery regardless. Patients too must be open to change in how health care is delivered and be open to considerations of cost when choosing among screening or treatment options. Patients play a significant role in producing high-value care, which involves engaging in shared decision making with providers, becoming well-informed participants, and taking a more active role in their health and healthcare planning. Incorporating PRO measures into standard care practice will not only help providers assess the impact of treatments on patients, but it will also give providers an opportunity to facilitate shared decision making and to practice medicine that is centered around the patient. Most of all, the priorities and preferences of patients must be considered when determining the value of screening or treatments, and PRO measures are valuable tools for achieving such goals. In sum, high-value care enables the practice of patient-centered care by ensuring that healthcare decision making and choices are both responsive and considerate of individual patient needs and priorities while simultaneously enhancing efficiency and reducing costs.

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8 Patients and Families as Coproducers of Safe and Reliable Outcomes

Helen Haskell and Tanya Lord

"We are at our best when we give the doctor who resides within each patient a chance to go to work."

—Albert Schweitzer

"The secret of the care of the patient is in caring for the patient."

—Francis Peabody

Introduction

When describing the optimal relationship between doctor and patient, terminology has historically been problematic. This is in part due to the fact that the definition of the optimal doctor-patient relationship has long been a moving target. The term "patient-centered care," as used in the Institute of Medicine's *Crossing the Quality Chasm,* says little of the role of the patient, who can thus be interpreted to be the passive recipient of the doctor's attentions [1]. "Patient activation," in which patients are encouraged to participate in their own care according to their assessed health literacy and motivation, conjures up the image of a mechanical patient operating on demand [2]. The currently favored term, patient engagement, has a more egalitarian sense, but still can imply an arms-length transaction more than an authentic partnership.

However much we may struggle with terminology, most of us know—or think we know—what "it" is supposed to be: a mutually productive team of two (or more) working within a system that supports their aligned goals in service of the patient's well-being. The real question is one of power dynamics, as the ideal role of the patient has evolved from a person gratefully following doctor's orders, to one who is gently encouraged to try his or her wings, to an active partner in the therapeutic process [3].

In this slow march toward inclusiveness, the next and perhaps most transformative step may be the theory of co-production. The concept of co-production has its roots in the public service sector, where it is thought of as a way to make public services more efficient and responsive to the customer, as in, for example, familiar initiatives like recycling and neighborhood associations. Its applicability to healthcare service has been extensively discussed by Batalden et al. [4], who point out that it is a deceptively obvious term. Co-production puts the emphasis on the contribution of the beneficiary to the service delivery process, and incorporates the concept that greater involvement leads to greater investment on both sides [5, 6]. It includes aspects of the parties' relationship that extend beyond the

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immediate interaction, and it has the potential, in the best of all worlds, to be greater than the sum of its parts (Fig. 8.1). Yet co-production is all around us. Like Moliere's bourgeois gentleman, who had been speaking prose all his life without knowing it, we coproduce whether we intend to or not. The goal is that we should create the conditions for coproducing well.

Healthcare support in the community has been a ready target for co-production schemes. One of the best known applications—born, appropriately enough, in a hospital room—is Edgar Cahn's concept of Time Dollars, in which individuals "pay" into a reciprocal web of services using the skills they have available. In his account of the genesis of the Time Dollar theory, Cahn spoke movingly of the power of reciprocity and his sense of needing to "give back" after his feelings of helplessness as a heart attack patient. Time Dollars are a successful concept that has been integrated into public services around the world, proving particularly beneficial in community support of the elderly [7, 8]. Other forms of co-production—involving citizens in planning and design of government services or providing them with stipends rather than prepaid services—have become part of public policy in many places. Scotland, which has embarked on a national program of co-production, uses co-production models in a range of community services, including dementia care, eldercare, and services for children and youth [9].

Clinical services have been a more difficult nut to crack, both because of their individualized nature and because of long-held attitudes of deference and authority on the part of both patients and clinicians. Yet an increasing number of researchers are convinced that the principles of co-production hold the solution to major problems in our healthcare delivery system, by their promise of grounding healthcare in the context of health, grounding health in the context of community, and informing both with the open exchange of ideas [4]. Co-production in healthcare services outside the hospital has gained steam with projects such as the UK's People Powered Health project [10, 11]. Elements of co-production undergird the venture philanthropy model of organizations such as the Cystic Fibrosis

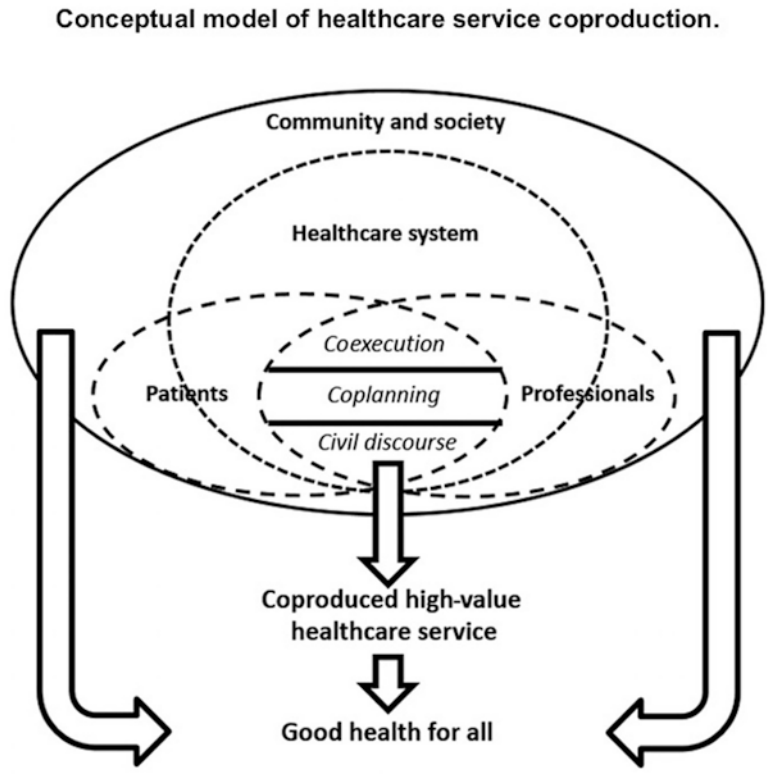

Fig. 8.1 Conceptual model of healthcare service co-production showing the interconnectedness of community, healthcare system, professionals, and patients. Reproduced from BMJ Qual Saf, Co-production of healthcare service, Batalden M, Batalden P, Margolis P, et al. Epub 2015 Sep 16. © 2015 with permission from BMJ Publishing Group Ltd

Foundation and the community-based model of the Institute for Healthcare Improvement's "100 Million Healthier Lives" campaign [12, 13]. Other initiatives, such as Mayo Clinic's Minimally Disruptive Medicine, use similar principles to create a dialogue that takes into account the toll that medical interventions can exact on patients' daily lives [14, 15]. Overall, the aim of co-production in healthcare has been on blurring the lines between clinic and community and encouraging partnerships that take into account the lived reality of all sides. Implicit in this is the idea of continuous improvement made possible by feedback and collaboration.

Most thinking around co-production of healthcare services has focused on the management of chronic illness. But while it may be true that chronic illness accounts for a sizeable chunk of healthcare spending, coordination of multiple chronic conditions is fortunately not yet the experience of most people [16]. This leaves the problem of just what co-production should look like for the majority of patients. Envisioning an ideal system is particularly challenging in the episodic world of surgery, where relationships may be fleeting and patients incapable of participating actively during the most significant part of the interaction. Surgery obviously occupies a central spot in the house of medicine, however, and a surgical procedure, even a minor one, is a major life event for most patients. Productive—co-productive—patient relationships are needed in surgery more than anywhere. The theories and methods of co-production do not radically change within healthcare. Whether in a surgical situation or other clinical encounter, the concept of including patients and families as equal partners should apply equally.

In Scotland, Bovaird and Loeffler emphasized four aspects of co-production of a public service project, as illustrated in Fig. 8.2:

- Co-commissioning (planning the larger policies and prioritizing the agenda within which the service will take place)
- Codesign (planning the service)
- Co-delivery (managing and performing the service)
- Co-assessment (monitoring and evaluation) [5, 17]

While not every one of these aspects is involved in every project, all projects include one or more of them. Taken together, these four parts of the whole provide a powerful framework for looking at co-production in the surgical environment. Quality and safety discussions in surgery often give short shrift to the complex human context in which the surgical process occurs, and the needs, desires, and fears of those involved. Yet the failure to give sufficient weight to the human elements of culture, judgment, and relationships,

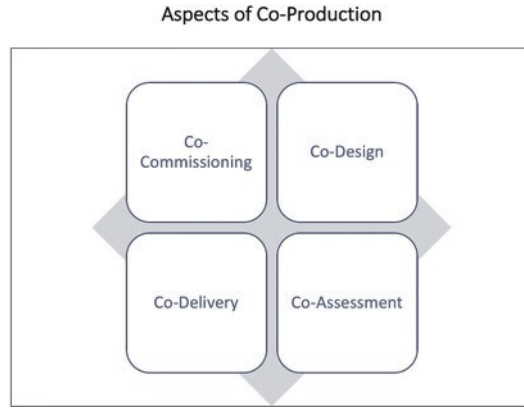

Fig. 8.2 Aspects of co-production. An illustration of four aspects of co-production as conceptualized by Bovaird T, Loeffler E, The role of co-production for better health and wellbeing: Why we need to change. In: Loeffler E, Power G, Bovaird T, Hine-Hughes F (eds). Co-production of health and wellbeing in Scotland. Birmingham: Governance International; 2013

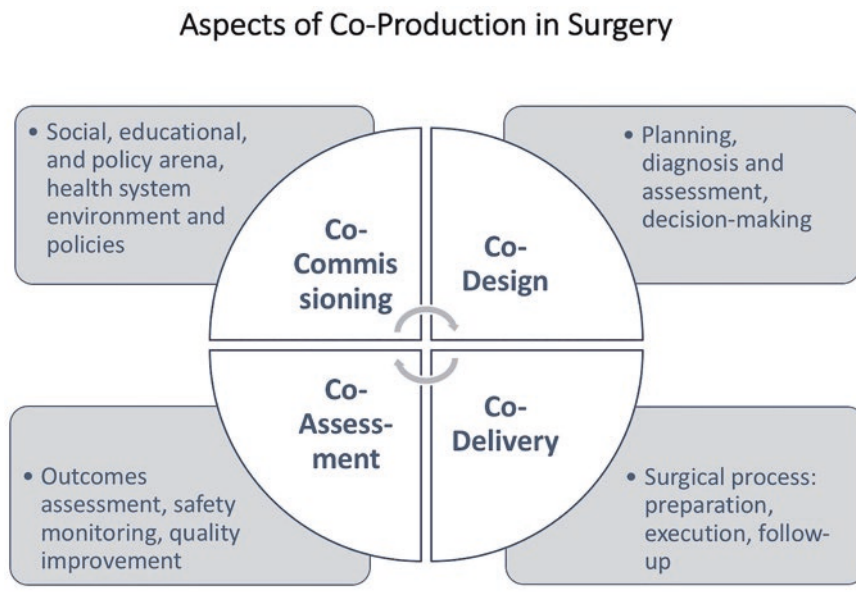

Fig. 8.3 Aspects of co-production in surgery. Co-commissioning, the broader social and educational framework within which patients and professionals operate, sets the stage for the personal interaction within which patient and professional codesign the patient's treatment and co-deliver the healthcare service of surgery and associated care. Co-assessment allows patient and provider to work together to inform and improve the other aspects of the surgical process (© 2016 Helen Haskell)

especially as they relate to the patient, is arguably one reason we have not made more progress in improving safety in spite of nearly a generation of patient safety efforts. Conscious attention to this underlying structure, and use of existing and emerging concepts and programs, can give insights into ways to improve surgical safety by facilitating the ability of both patient and doctor to engage in effective co-production (Fig. 8.3).

Co-commissioning

Co-commissioning in the sense intended here consists of setting the stage for effective collaboration through environmental and educational factors that reach beyond the individual doctor-patient relationship. Perhaps the most important of these concepts is access to information. Effective co-production means a prepared patient making an informed decision. While not all patients have the resources or the inclination to inform themselves on medical issues, a remarkable number do so when it concerns their own health. In that respect the Internet has been an astonishing leveler in terms of healthcare information. The Pew Internet and American Life Project, which tracked trends in Americans' use of electronic media, reported in 2013 that 85 % of all Americans used the Internet, with many who do not own computers accessing it entirely through their cell phones. Of Internet users, nearly three-fourths researched health matters online. More than half of those used the Internet to look for an online diagnosis. And in general, their information was correct: about four out of five who took their findings to a physician had their accuracy confirmed [18].

This entree to a wider world of information, historically unavailable outside medical libraries, is in itself an upheaval in the doctor-patient dynamic. Of particular interest in this respect is the ePatient movement, begun by health informatics professor Dr. Tom Ferguson and continued after his death in 2006 by a group of his colleagues calling themselves the e-Patient Scholars Working Group. Their 2007 white paper, "e-Patients: How they can help us heal healthcare," could be considered a co-production manifesto [19]. Its premise

was that the disruptive technology of the Internet had sparked a Kuhnian paradigm change that would lead to greater equality and collaboration between patient and doctor, the synergy of which would unleash new potential in medicine. To a large extent this has come true, as patients, doctors, and researchers have begun to work together to create enhanced technologies, creative databases, and new methods of exchanging information. Perhaps most critically, and central to Ferguson's vision, a web of online communities has sprung up that provides patients with personal support, patient-level expertise, and medical references on a myriad of topics, including medical conditions from which people once suffered in isolation. One of the more broad based of these online communities is the ePatient movement itself, which lives on as the web-based Society for Participatory Medicine, a group that encourages the use of social media, data sharing, and technological innovation [20].

For all its innovation, the ePatient movement has not concerned itself directly with safety and quality. Public transparency on safety measures is instead derived largely from online databases and rating services, particularly hospital ratings, created over the past decade by organizations like HealthGrades, Consumer Reports, and the Leapfrog Group.[1] Online healthcare measurement has also emerged, somewhat unexpectedly, as a journalistic specialty. Once primarily concerned with reporting on accomplishments of local hospitals, healthcare journalism has transformed itself into a rapidly growing investigative field driven by keen interest in big data, patient safety, and perceived conflict of interest [24]. One of the most active investigative healthcare journalist groups, the nonprofit news organization ProPublica, has created physician-specific public databases including pharmaceutical payments to doctors, Medicare Part D prescribing patterns, and Medicare Part B services provided. ProPublica also maintains the controversial Surgeons' Scorecard, which analyzes individual surgeons' complication rates for eight common surgical procedures [25–29]. A similar national surgeon rating system published by Consumers' Checkbook includes a wider range of procedures and specialties, but restricts its listings to highly rated surgeons [30]. Registries, another potentially invaluable resource for patients, now sometimes include not only pooled data but also access to mobile health applications that allow patients to contribute, receive, and act upon health information [31]. Registries are seldom publicly reported, however. Among a handful of notable exceptions are the heart surgery registries published by Consumer Reports and the Society of Thoracic Surgeons, which include star ratings for adult and pediatric surgeries as well as more detailed underlying numbers on pediatric mortality [32–34].

This data revolution has occurred in the context of an ambitious social and policy agenda set by government and leaders in the medical community. Most large public databases in the United States are created from data made available by the Centers for Medicare and Medicaid Services (CMS) as part of an effort to increase healthcare transparency.[2] This effort includes CMS's own, usually less detailed, online rating sites: Hospital Compare, Nursing Home Compare, Dialysis Compare, and Physician Compare [41–44]. The 2010 Affordable Care Act also specifically includes provisions aimed at enhancing the patient voice in healthcare. One such initiative is the Patient-Centered Outcomes Research Institute (PCORI), designed to give patients a defining role in healthcare research, including setting the direction of research, reviewing proposals, and participating in grants [45]. The Partnership for Patients, a large patient safety program that included most American hospitals, made patient engagement a central tenet of its work, with patients an integral presence in patient safety education, and patient

[1]Associated websites are HealthGrades: Find a Doctor [21]; Consumer Reports: Doctors & Hospitals [22]; and Leapfrog's Hospital Safety Score [23].

[2]This built on earlier reporting by the states. Many state governments still require public reporting of hospital-acquired infections, including procedure-related surgical site infections that are not reported federally [35]. Information on heart surgery outcomes, once much heralded but now largely superseded by national reporting on Medicare's Hospital Compare site, is also still available on some state websites [36–40].

and family advisory councils becoming part of the fabric of hospitals across the country [46]. This was part of a National Quality Strategy with three aims (better care, healthy people and communities, and affordable care) and six priorities, the top two of which are patient safety and patient engagement [47]. This is loosely based on the Institute for Healthcare Improvement's Triple Aim, whose three intertwined goals are part of a vision of an integrated system emphasizing macro system integration, value-based financial management, redesigned care models, population health management, and close involvement of and responsiveness to patients and families [48].

In this age of technological advances information may still not be accessible to patients in a timely manner when surgery is not preplanned or elective. In all cases the sharing and ensuring of accurate treatment- or condition-specific information should still be primarily the responsibility of the physician and other hospital staff.

Codesigning

Codesigning—the process through which the patient and the surgical team come together for diagnosis, assessment, and planning of future treatment—is the customization of the patient experience within the larger medical and social framework. This is necessarily about communication. Analyses of closed claims by the malpractice insurer CRICO have demonstrated the critical role of communication in patient care. While the intricacies of the patient's role in diagnosis are beyond the purview of this chapter, it is worth repeating that accurate diagnosis is the foundation of good medicine, and effective communication is the key to diagnostic accuracy. In an analysis of over 23,000 diagnostic errors, CRICO found that 58 % occurred during the assessment phase [49]. In surgical cases specifically, CRICO found communication breakdown to be a factor in one-fourth of malpractice payouts between 2009 and 2013, with nearly two-thirds of these featuring breakdowns between provider and patient [50]. In another report focused on surgical closed claims, over half were found to reflect inadequate informed consent [51].

Probably the biggest impediment to open communication is the much-deliberated power gradient between doctor and patient. Patients are often intimidated by a doctor's medical knowledge, by the doctor's ability to make decisions that affect the patient profoundly, and by the alien clinical environment in which the medical encounter occurs. As a consequence, patients may hesitate to volunteer information, ask questions, or even correct misperceptions, particularly if the doctor seems overly self-assured or hurried. This can be true even of very experienced patients, who may fear antagonizing their healthcare providers if they come across as too well informed [52, 53]. Alternatively, and counter-intuitively, highly educated professionals may be reluctant to ask questions out of what they consider the respect due to a fellow professional [54]. Often, however, the patient and family may not only have the most complete available knowledge of the patient's medical history but also the most complete copy of the patient's medical record. Most critically, the patient and family alone can transmit information about the patient's life circumstances and the light they can shed onto possible diagnoses and the potential effectiveness, ineffectiveness, or even possible harmfulness of specific treatments [55, 56].

If the problem lies in imbalance of power, then the solution may be to move the fulcrum. In the information age, this necessarily begins with improved communication. "ePatient Dave" deBronkart, a kidney cancer patient who has gained notoriety as a blogger and speaker, recently wrote about what he considered the nearly ideal experience of his wife's knee replacement surgery. A major source of satisfaction was his wife's surgeon's quick responses to questions sent through secure e-mail. DeBronkart quoted the surgeon as saying, "Most people are too afraid to ask questions … so I offer platforms to communicate which are less imposing than sitting on a cold bench in my office with the clock ticking" [57].

Such strategies are part of what is rapidly turning into a deluge of communication technologies, as patients wake up to the possibilities presented

by greater access to their medical information. Among these is the highly publicized Open Notes project, which allows patients to look at doctors' notes from their office visits, and has received a thumbs-up from a resounding 99 % of early users [58, 59]. Patient portals, after a rocky start, are becoming an indispensable patient resource as they expand to include such conveniences as online prescription refills and scheduling of office visits, in addition to e-mail communication with doctors and online test results [60]. Patients are also increasingly interested in electronic access to their entire medical record: nearly 90 % of surveyed Open Notes patients indicated a desire for real-time access to inpatient records, while an online survey by the research and management company Accenture reported that 41 % of (presumably highly engaged) respondents said that they would switch providers to have access to their complete records [59, 61]. Patients' and doctors' views of the value and challenges of shared medical records differ substantially, however; while doctors worry that attempts to avoid offending patients may result in less than candid medical assessments, patients are more concerned about being able to correct errors and misperceptions and using their knowledge to help bridge communication gaps. More broadly, patients use access to their notes to refresh their memories, to keep a personal record, and to share their medical information with relatives [62].

The most difficult topic in presurgical communication remains the perennial issue of informed consent. The patient's right to and interest in informed consent have evolved over decades as court decisions and changes in public attitude have gradually eroded the "therapeutic privilege" to withhold information [63]. Informed consent matters to patients: in surveys the vast majority of people, even those with limited health literacy or poor English-language proficiency, say that they want to take an active role in healthcare decisions. This is true even of patients who say that they prefer that their physicians make the final decision [64].

The question that continues to swirl around the issue of informed consent is exactly what it should consist of. Shared decision making—i.e., providing detailed information on options and supporting the patient in the decision process—has gained wide currency in recent years. At the heart of shared decision making is the clear explanation of harms and benefits using such concepts as absolute (rather than relative) risk and communication strategies like "chunk and check" and teachback [65]. Decision-making tools, an important part of the process, are now available in a variety of media for many common conditions, as are general decision aids like the Ottawa Personal Decision Guide [66, 67]. But while useful, decision aids can be a relatively facile approach to a topic fraught with complexity. While patients may find it easier to absorb information from an electronic or video-based decision tool, most people also want to have an in-depth discussion with their physician that covers the evidence, patient preferences, and patient's circumstances [64]. If evidence-based options are genuinely equivalent, patients may benefit from more guidance than many currently receive in balancing available options with their own life situations. On the other side of the equation, guidelines that seem unambiguous on their face may gloss over patients' personal preferences and concerns as in, for example, the risk of bleeding from warfarin. Drawbacks of any intervention may loom much larger for individual patients than guideline writers could foresee, and may also warrant physician assistance in exploring the nuances of the decision [68]. Perhaps the key to finding the right balance of information given during a consent for surgery discussion lies in the very nature of co-designing the partnership between the patient and the physician. Even in a very brief encounter it is possible to assess a patient's needs and desires as they pertain to informed consent.

Other gaps relate to the patient's experience of surgery. Patients often have an unrealistic image of the benefits of surgery and may have little understanding of the realities of postsurgical recovery or the possibility of a less than optimal outcome [69]. In a survey of incoming patients at a major teaching hospital, nearly half of patients who were scheduled to go to the intensive care unit postsurgically were unaware of that fact, while a substantial minority were ambivalent

about undergoing surgery at all. Half did not have advance directives [70]. A study of Medicare patients between 2002 and 2006 found that 96 % of patients diagnosed with stage IV cancer underwent invasive procedures, with one in four having a procedure in the last month of life [71]. Lilley et al. [72] attribute this to a "fix-it" model of surgical success that focuses on the disease at the expense of the patient. Diffusion of responsibility may also play a role, as patients move among different specialists who may defer to each other until the patient is at a point of crisis. Surgeons, to whom almost all these patients come at some point, may be in a unique position to engage the patient and family in critical discussions around patient goals and quality of life.

Other difficult issues that are of intense interest to patients are cost (a source of great anxiety in the USA in the era of narrow insurance networks, whose enrollees may be left with ruinous bills from out-of-network providers they did not know were involved in their care) and infection and complication rates, which have some online availability at state websites and CMS's Hospital Compare, but are generally not specific enough to be of help to most patients. Genuinely relevant information is often available only from the healthcare provider. As the pace of healthcare picks up, patients are also increasingly concerned about working conditions in surgical suites, not least the issues of resident supervision and fatigue. In spite of the Accreditation Council on Graduate Medical Education requirement that residents and faculty inform patients of their respective roles, the extent of resident participation in surgery remains profoundly unclear to patients [73]. In a 2012 survey conducted at a tertiary care center, 94 % of respondents initially agreed to consent to trainee involvement in their surgery, a percentage that fell to 18 when they learned that residents could operate without direct supervision [74]. Public opinion on fatigue is also strikingly at odds with that of the medical profession. In a 2010 telephone survey of the general public, respondents dramatically underestimated the number of hours that resident physicians work, with most believing that residents' shifts were 12 h or less. Over 80 % believed that fatigue correlates with medical errors, and only 1 % thought that residents should be allowed to be on duty over 24 h [75]. In both surveys, more than 80 % of respondents said that patients should be informed of residents' level of supervision or sleep deprivation and that this information could change their decision to consent to surgery [76]. This unambiguity of opinion makes it clear that failing to acknowledge the full circumstances of a patient's surgery deprives patients of information they want and need, but may not know that they do not have. If patients and providers are to work in productive partnership, clear explanation of the contribution made by all partners is an essential part of the conversation.

Co-delivery

In 2012, Leonard Kish described the astonishingly improved outcomes of patient-centered medical programs and declared patient engagement to be "the blockbuster drug of the century" [77]. Current patient-centered surgical programs, ranging from various degrees of prehabilitation to complete programs like Enhanced Recovery after Surgery and the Perioperative Surgical Home, employ a combination of standardization, personalization, and close attention to patient status with the intent of controlling variation in care and holding down costs. Common aspects are preoperative patient screening, education, and conditioning; use of standard protocols and guidelines; personalized care planning; minimal use of opioids; early mobilization; and standardized post-discharge communication and care [78–82]. These programs have largely been developed using standard improvement techniques to combine advances from many different fields, with close involvement of the patient and family a key component from planning through post-discharge [80, 83]. Comprehensive surgical pathways have had a transformative effect on more easily standardized procedures like joint replacements and some gastrointestinal surgeries. The aim of minimizing disruption of the patient's normal physiology has mitigated formerly dreaded aspects of surgery like prolonged fasting and opioid-induced grogginess and nausea, with accompanying

increase in patient satisfaction. At the same time, the combination of individualization of care with standardization of processes has led to reductions in adverse events, infection rates, lengths of stay, and readmissions, a testament to the interrelationship of patient engagement and patient safety [84, 85].

Comprehensive surgical programs are founded on the idea that surgery is a team endeavor including the patient and family and extending beyond the operating room. One obvious barrier to effective teamwork is disequilibrium of knowledge. In the case of patients and families, this applies not just to the details of the patient's medical condition but to the system within which healthcare is provided. This topic, a source of intimidation for most patients, is seldom addressed in information given to patients. For many nonmedical people, one of the most confusing aspects of medical care is the sheer multiplicity of members of the healthcare team. Although patients may rapidly pick up terms like "resident" and "tech," they often do not really understand the roles or even the identities of the people they meet. Experience suggests that this confusion may be hard to overcome, but identification of caregivers is a common patient request. Written or visual explanations of the people involved in their care and when they should be called upon can help reduce patients' sense of helplessness in the unaccustomed world of the hospital or surgery center [86–89]. Simple communication strategies for all team members ("Smile," "Sit down," "Introduce yourself") also go far toward creating good patient relations [90].

The importance of family and other designated support people as part of the patient's care team can hardly be overestimated. Family members can and should be deliberately looped in throughout the surgical process, including by telephone if necessary in the planning and post-discharge periods. On the day of surgery, families are typically grateful for regular updates delivered via electronic tracking boards, nurse liaisons, or mobile device applications that can transmit video, photographs, or messages from the operating room [80, 91, 92]. Especially postoperatively, families are de facto coproducers who can fulfill their roles most effectively if they are armed with information, encouragement, and support. This includes information about signs and symptoms that can be expected in a postsurgical patient, those that are cause for concern, and an explanation of monitors to which the patient may be attached. For hospital inpatients, a constellation of well-studied policies including bedside change of shift, scheduled bedside rounding, daily care plan summaries, and instruction in fall prevention can be used to facilitate family involvement. The whiteboard is also an invaluable tool for relaying names, contact details, questions, and updates. Encouragement of journaling by patient and family, both in hospital and at home, allows for coordinated tracking of the patient's progress by family and surgical team [80, 93–97].

The most important transition that a patient makes is from hospital or surgical facility to home or rehabilitation center. While discharge planning is an advanced science in some arenas, pitfalls remain in even the best planned discharges. A successful discharge process involves the patient and family closely and for elective patients may begin as early as the decision for surgery [98]. It is important to have an understanding of the conditions into which the patient will be discharged, to verify that patients and families have a realistic understanding of the process of recovery and expected outcome, and to be sure that they have information they need to manage home care. Like all patient information, discharge instructions should be in everyday language. Standardized processes like AHRQ's IDEAL Discharge and Project RED provide checklists for important discharge components, including medication reconciliation, follow-up appointments, and signs and symptoms for families to watch for [99, 100]. Surgical patients, even same-day surgery patients, can feel isolated and unprepared after being discharged to home and often are alarmed by difficulties in reaching their surgical team. Having a 24-h telephone number they can call with any concerns and receiving a call from a representative of the surgical team soon after discharge do much to alleviate those fears and deal with problems as they arise [101]. Scheduled calls with specific questions routinely after patient discharge inquiring about the patient's progress may reveal

unexpected minor complications (e.g., lacerations, teeth damage, hair loss, etc), opportunities for education or intervention to ward off complications, as can telephone availability of and on-call surgeon [80, 102]. A wound care app to allow patients to communicate easily with, and send photos to, their surgical team has been enthusiastically received by early users [103, 104].

It has long been recognized that patients may develop deleterious conditions as a result of hospitalization [105, 106]. In 2013, Harlan Krumholz noted that a majority of hospital readmissions were for causes other than that of the original hospitalization. He blamed depersonalization, poor nutrition, lack of sleep, excessive blood draws, and other disruptions for causing physiologic derangement and depletion of reserves in vulnerable hospital patients, and called this condition "posthospital syndrome" [107, 108]. Krumholz suggested that patients be assessed for cognitive and physical impairments potentially arising from their hospitalization and that post-discharge support be adjusted accordingly. He also suggested that, like discharge planning, planning to prevent unneeded readmissions should be pushed back into the hospital stay, by seeking to minimize stressors like sleep disruption, unneeded pain, and inappropriate use of sedatives [109]. Other measures that Krumholz recommends to help prevent patient disorientation are reminiscent of those practiced at hospitals following the Planetree model of patient-centered care. These include allowing patients to wear their own clothes, providing a cheerful noninstitutional decor, and tailoring the diet to include healthy appealing foods to which the patient is accustomed [107, 108, 110].

Co-assessment

It is a truism that is not often given enough import in medicine: the only person who knows the actual outcome of the patient's treatment is the patient. The obvious corollary is that any serious review of outcomes must give prominence to the patient's experience [111]. There seems to be little question that patients report more, and more severe, symptoms and complications than doctors do. Examples include Mannion et al. [112], who reported that surveyed spine patients recorded 40 % more complications than their surgeons did, and that patients and physicians often reported entirely different complications. Franneby et al. [113] found that hernia repair patients recorded a complication rate 4.5 times higher than their surgeons. Basch [114] reported that cancer patients recorded more severe symptoms, earlier and more frequently than their doctors, and that patients' reports had a closer correlation to their functional status than the doctors' did. This difference of perception has significant implications not only for informed consent but also for treatment decisions and the overall value of interventions to patients [115]. In addition, patients and providers may have different measures of surgical success. The goal of most patients is their own global well-being, a fundamentally different concept of success from many current measures that emphasize process over outcome and clinical over functional status [116]. Patient-reported outcome measures are beginning to proliferate, however, and in research, especially pharmaceutical research, patients have become sought-after partners, as funders and researchers have come to recognize that the voice of the end user has significant value [117–120]. A similar claim can be made for patient safety and quality, where patients also often have very different perspectives from healthcare professionals, a fact that has long been underappreciated [121, 122]. In the face of the new push toward transparency, that wall is beginning to crumble.

One factor that has revolutionized thinking around the patient role in the USA is the linking of Medicare reimbursement with the Hospital Consumer Assessment of Healthcare Providers and Systems patient experience survey (HCAHPS), now publicly reported by hospital on Medicare's HospitalCompare website [123]. Hospitals now expend significant resources on improving the patient experience. While healthcare professionals do not always view HCAHPS as quality improvement per se, patient satisfaction has been documented to have a positive effect on patient outcomes, and some if not most HCAHPS questions (e.g., How often did you get help as soon as you wanted it? How often were your room and bathroom kept clean?) are directly or indirectly

aimed at patients' perception of safety and quality of care [124–126]. Nevertheless, there is concern that patient satisfaction is being used as a proxy for quality of care and that, in spite of years of refinement, surveys may not be the most direct way to elicit problems with safety and quality. Two recent studies have found good correlation between HCAHPS scores and patient reviews of hospitals on the online rating site YELP, best known for restaurant and hotel ratings [127, 128]. There are advantages to YELP: YELP reviews are generally easier to find than the HospitalCompare website where HCAHPS scores are housed (only 6% of survey respondents had heard of HospitalCompare) and they were also found to address domains of quality that HCAHPS did not, including nuanced aspects of nursing quality and staff attitudes. Further blurring the line, YELP has since entered into a partnership with the healthcare journalism organization ProPublica, which has aided them in adding statistics from HospitalCompare to their hospital listings [129].[3]

Along the same lines, Tsianakis and colleagues found that British breast cancer patients gave differing accounts of their care depending on whether they were providing the information via survey or interview. This appeared to be at least partly because the surveys did not anticipate and therefore did not explicitly cover areas that turned out to be of importance to patients. Among the problems that surfaced more often in patient narratives than in surveys were concerns about outpatient surgery, including feeling rushed, being separated from family too soon, and not having procedures explained beforehand. One interviewee was quoted as saying, "A lot of the things are quite brutal and you're not told they're going to happen. It's just like, 'Now we're going to do this to you,' and you do begin to feel humiliated because you're constantly naked and having horrible things done, injections and poked around. You feel like you're a bit of meat on a conveyor belt." These sentiments, not surprisingly, did not emerge on the formal survey [131].

The authors proposed that, where interviews are not an option, open comments (similar to the structure of YELP reviews) should be encouraged and scrutinized on surveys. In open-ended patient commentary, it is clear that patients and families not only report aspects of their care not otherwise captured but also place a priority on interpersonal relations and being treated with dignity and respect, factors not always covered in standard healthcare surveys (although they are in HCAHPS) [132].[4] These studies suggest, at a minimum, that there is much to be gained from an expanded role for patients in assessment of quality of care and healthcare delivery, but also that patient input could help reshape the definition of quality and safety.

Though not yet supported by research, an effective method of working with HCAHPS results is to bring them to the hospital's patient and family advisory council for review. Council members are often able to provide insight and the additional information necessary to promote changes.

The issue of data collection methodology has in some ways been overtaken by technology, as hospitals have begun arming nurses with electronic tablets to use in rounding on patients. Failure to rescue, a significant driver of hospital mortality, is associated with miscommunication by bedside caregivers and often with failure to heed families' concerns [134–137]. In the UK, nurses collect vital signs on tablets with applications that track trends and alert them to potential patient deterioration, an innovation considered to have averted many cases of failure to rescue [138]. In the USA, nurse rounding with tablets is becoming commonplace for a variety of quality improvement and data collection purposes, including routinely inquiring about and resolving patient concerns and collecting data to compare trends in quality concerns and patient satisfaction [94, 139, 140]. While the ultimate aim may be to

[3] Although there has also been considerable interest in mining social media for patient opinion, a recent feasibility study of Twitter comments had somewhat less robust results, possibly an indication of the limitations of the medium. About 1000 English-language patient tweets were identified over a 9-month period, of which 14% explicitly concerned surgical errors and approximately half expressed an emotional reaction [130].

[4] Even in written complaints to medical boards, patients often focus on the issue of doctors' rude behavior, even when it has occurred in the context of severe medical errors [133].

improve patient satisfaction scores, these practices embed the patient voice, make patient feedback part of the nurses' daily operations, and create the potential to deal with emergencies as they occur. Other real-time solutions include taking advantage of existing resources, not necessarily technological, to prevent adverse events: critical care outreach nurses who round proactively on high-risk patients; patient-activated rapid response systems, a vital "911" safety valve for family members of deteriorating patients; and mining rapid response reports, especially patient-initiated calls, to look for patterns that could shed light on patient concerns that might flag potential patient safety problems [141–143].

An even more direct way to get the patient perspective is the technique of shadowing, especially as refined by the University of Pittsburgh's Patient and Family Centered Care Innovation Center. In this effective, low-tech methodology, shadowers accompany patients through their experience of care to look for gaps and deficiencies in the process. A multidisciplinary workgroup, including patients, then "writes the ideal experience" of care and designs solutions [144]. Shadowing can find system flaws that interviewing and surveys do not, and may reveal "touchpoints" of interaction with the system of which caregivers were unaware. The discovery that total joint patients often had parking issues, for example, was a touchpoint leading to the idea of valet parking at orthopedic centers. One executive commented after using shadowing for quality improvement, "I am no longer a fan of surveys. Everyone always told us how nice we were, and gave us high scores. Shadowing, however, showed us our real opportunities to improve the patient experience" [145, 146]. Using former patients or other non-hospital employees as shadowers can add another layer of insight that might otherwise be missed.

Probably the most critical moment in patient-provider relations is the moment when a patient has been seriously harmed by his or her medical care. Traditionally, many institutions have advised physicians to withdraw from communication with such families, on the assumption that any situation involving potential compensation is necessarily adversarial. For families, the descent of this curtain of silence is almost invariably seen as a profound betrayal of trust; for many people it is more traumatic than the medical injury itself [147]. Providers, too, suffer from this approach, which not only shatters the doctor-patient relationship but also assails the physician's essential role as benevolent professional. "Communication and resolution" programs now in place at many major medical facilities have shown that the financial costs of a lawyer-driven system generally exceed those incurred with more humane and proactive treatment of both patients and caregivers. The major advantage of communication and resolution programs, however, is the ability to create conditions under which relationships can heal and participants can learn from errors [148–151].

Research also indicates that patients and families, by dint of their often-uninterrupted presence at the bedside, can provide insights into safety events and hazards that otherwise go undetected [122, 152, 153]. One clear implication is that event reviews or root-cause analyses are likely to be incomplete without the patient perspective, whether in the form of interviews with the affected families or through participation by affected families or other patient representatives on the root-cause analysis committee itself. This kind of participation is increasingly occurring as hospitals and even practices recognize the importance of the patient point of view. For some families, the knowledge that learning and improvements have come from their devastating medical experience offers comfort and a basis to build trust [154–156]. As healthcare moves toward a more inclusive and transparent way of engaging and caring for families following adverse outcomes it is important to recognize the continued need to personalize care. Patients and their families come into healthcare with varying experiences, thoughts, values, fears, and desires. When this individualism is recognized as an asset and seen as the key to safer care, then true co-production can be achieved.

The Bigger Picture

These initiatives are all part of a larger trend. If healthcare facilities are truly to operate in the interests of patients, then the voices of patients

need to be heard not just as patients but as collaborators, partners, and educators. To a significant extent, this is happening. Patient and family advisory councils, a classic example of co-commissioning, are now embedded in the culture of many hospitals [46]. As health systems consolidate, the concept of patient and family advisory councils is spreading to ambulatory care [157, 158]. Nationally, the belief is gaining currency that a primary concern of patient advisory bodies should be safety and quality, as is the idea that the system as a whole can benefit from having patients on committees throughout the institution. Patients are increasingly serving on quality committees and governing boards, on improvement projects, and as instructors in capacities ranging from employee orientation to medical school lecturers. They are involved in federal research grants and serve on committees that decide policy, endorse quality measures, approve medications, and more [45, 159–161]. Although a minimum standard has yet to be set for institutions, the goals of patient engagement are clearly based on the principles of co-production. Recent definitions stress the interactive and comprehensive nature of patient engagement, while various frameworks, including an eight-part Patient Engagement Roadmap, describe strategies and tactics for creating partnership from the individual patient encounter up through national policy [162–164].

These ideas are not unprecedented. In fact, they really are the foundation of much of modern medicine before the influx of technology. In the past, country physicians knew the patients they were treating. They often visited them in their homes and they understood the specific dynamics and support structure of each family. In more recent decades these concepts have been reintroduced and reinvigorated by patient-centered organizations like the Institute for Patient- and Family-Centered Care, the Picker Institute (whose patient questionnaires formed the basis for the current HCAHPS survey), and Planetree (which had patient libraries and patient-friendly hospitals dating back to the 1970s and 1980s) [165–167]. The historic principles of patient-centered care, like those of co-production, rest on the fundamental desire for respectful relationships, personal treatment, and open access to information that is a recurring theme of patient response to the healthcare system. As patients are well aware, disrespect has the power to harm, and depersonalization and lack of transparency can be among the most damaging forms of disrespect. Reciprocity, as Edgar Cahn articulated, is also a fundamental source of respect and self-respect, and a key driver in patients' desire to be part of the system. Although the disruptive potential of health information technology has opened new avenues for communication and information sharing, the blueprint for effective co-production, like much in medicine, is not entirely new. What is different now, perhaps, is the accumulating will to act on it.

Every patient who receives and every provider who offers healthcare services come with a unique set of skills, desires, strengths, and weaknesses that impact their approach to co-production. Improving healthcare cannot be accomplished solely by error-proofing processes or by creating a series of standard work. Safer healthcare and safer surgeries need to rely on the fundamental thing that humans are designed to do: build connections and relationships with each other. All improvement methods are made more effective when patient and families are included in their development, implementation, and evaluation, both at the bedside and within the organization [168]. Whatever terminology comes in and out of favor, the concept of partnering, knowing patients as individuals, and working together for healthier lives and communities should never go out of style.

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9 Tools and Strategies for Continuous Quality Improvement and Patient Safety

Julie K. Johnson and Paul Barach

"Everyone has two jobs: to do their work and to improve their work."

—Paul Batalden, M.D.

A History of Quality Improvement

Continuous quality improvement (CQI) is both a management philosophy and a management method. It offers an approach, a set of tools, and a way of thinking about how to transform clinical flow and operations to achieve better results for patients and teams [1]. The evolution of CQI in health care may be traced to the pioneering work of Florence Nightingale in 1850s. Nightingale used empiric observations and robust statistical methods to link unsanitary conditions with the high number of preventable deaths during the Crimean War [2]. In the 1960s, an approach known as *Kaizen* (literally "change good" or "improvement") was introduced in Japan [3]. Grounded in local village knowledge and practices, the key features of *Kaizen* include the following:

- The ideas come from the workers themselves; thus they are less likely to be radically different and, and therefore, easier to implement and less prone to induce resistance.
- Small improvements are less likely to require major capital investment than major process changes.
- Employees will continually seek ways to improve themselves by improving their own performance while encouraging workers to take ownership for their work, thereby improving worker motivation and engagement.

From *Kaizen* came "quality function deployment," which combined quality assurance and quality control with function deployment in value engineering [4]. Quality function deployment (QFD) helped to focus improvement efforts on the customer's needs by attending to and respecting the voice of the customer (VOC) and by translating these needs into design and engineering characteristics for a product or service [5]. QFD is a process of developing customer needs into actionable responses.

The same concepts and activities are now often referred to as "quality improvement" or "quality management" or even sometimes simply as "improvement" [6]. These concepts have now spread throughout the world and across multiple economic sectors, including health care. What was originally called *total quality management* (TQM) in the manufacturing industry evolved

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into *continuous quality improvement* (CQI) as it was applied to healthcare administrative and clinical processes.

Cross-disciplinary learning between manufacturing and health care was spurred during the 1990s by the increasing awareness that health care was lagging behind other industries in providing poor and uneven value [7]. This highlighted the need to focus on reducing waste, inefficiencies, and harms. This awareness of the limitations of traditional methods to improve patient outcomes and contain costs forced health care to look to other domains for solutions [8]. However, from the perspective of healthcare providers, the industrial perspective of quality is limited in that it (1) ignores the complexities and dynamic nature and nuances of the patient–practitioner relationship; (2) downplays the knowledge, skills, and intrinsic motivation, as well as the ethical obligations of practitioners; and (3) provides less emphasis on influencing professional performance through "education, retraining, supervision, encouragement, and censure" [1].

Avedis Donabedian conceptualized quality as a chain linking structure, process, and outcomes and [9] suggested that the fundamental soundness of healthcare quality traditions can be appreciated and, at the same time, the industrial model of quality calls attention to several important considerations [8]:

1. The need for even greater attention to consumer requirements, values, and expectations
2. The need for greater attention to the design of systems and processes as a means of quality assurance
3. The need to extend the self-monitoring, self-governing tradition of physicians to others in the organization
4. The need for a greater role by management in assuring the quality of clinical care
5. The need to develop appropriate applications of statistical control methods to healthcare monitoring
6. The need for greater education and training in quality monitoring and assurance for all concerned

CQI is distinguished in health care by the recognition that service excellence and high-value outcomes are predicated on meeting the patients' needs. Meeting these needs is the key to sustaining quality. However, these needs may change over time with changes in expectations associated with education, economics, technology, and culture. Such changes, in turn, require continuous improvements in the administrative and clinical methods that affect the quality of patient care.

Approaches to Quality Improvement

Several successful, multilevel, broad-based approaches have evolved across a range of clinical disciplines. These approaches can be thought of as an umbrella that encompasses specific change methods. The most notable of these approaches are the plan-do-study-act (PDSA) cycle, the model for improvement, lean manufacturing, and Six Sigma—each will be described below. Another common approach to quality improvement—the quality improvement collaborative—is described in Chap. 45.

Walter Shewhart, at Bell Laboratories, introduced the iterative approach called **plan-do-**

Fig. 9.1 The plan-do-study-act cycle

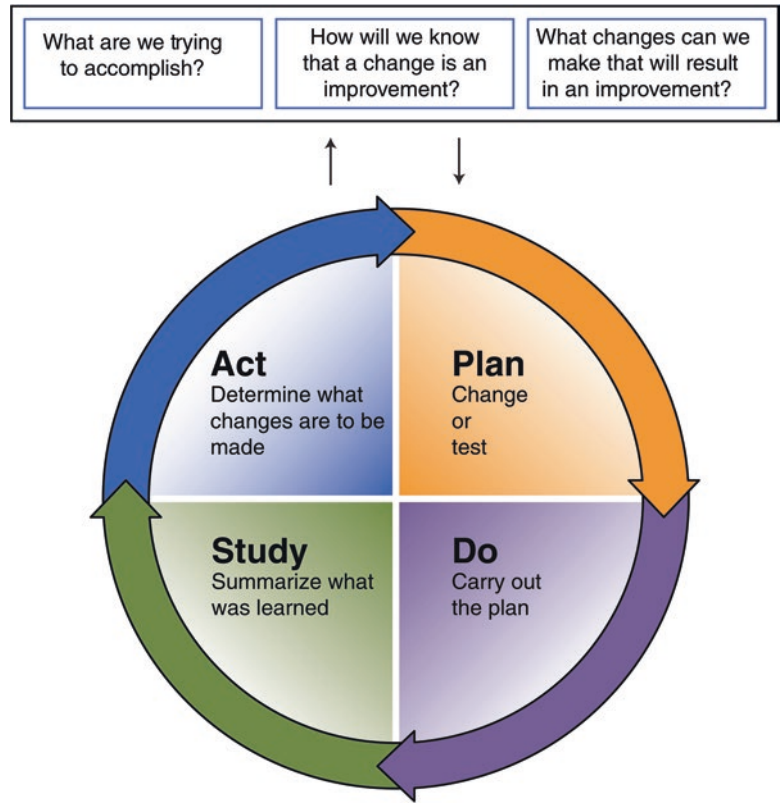

Fig. 9.2 The model for improvement, which incorporates the plan-do-study-act cycle

study-act (PDSA; Fig. 9.1) [10] (although the PDSA cycle is often attributed to Deming, he himself referred to it as the Shewhart cycle) [11]. The **model for improvement** (Fig. 9.2), which was introduced in 1992, integrates the PDSA cycle as its core method [6]. Central to its application are three key and recurring questions:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What change can we make that will result in an improvement?

The wide use of the PDSA cycle and the model for improvement in health care is the direct result of their elegance and simplicity, as well as the transferability and application of these approaches across multiple care and nonhealth settings.

In the 1980s the Motorola Corporation developed the **Six Sigma methodology** [12]. Six Sigma starts with a process-mapping activity that involves elements of defining what a business does, assigning responsibilities, identifying performance standards, and deciding how success will be determined (see below). After these critical elements have been defined, Six Sigma analyzes each through the DMAIC methodology (improve, and control) [13, 14].

"**Lean**," also known as "lean manufacturing," "lean enterprise," or "lean production," is a CQI approach that considers as wasteful any resources that are allocated to any goal other than creating value for the customer and that are thus targets for elimination [15]. Value is defined from the customer's perspective and includes any action or process for which a customer would be willing to pay.

For many, lean is an approach to improvement that helps to identify and steadily eliminate waste in processes (or *muda*, in Japanese). As waste is eliminated, quality improves and production time and costs are reduced. Essentially, lean is centered on *preserving value with less work*. Lean should

optimize the trade-off between productivity and quality and highlights the axiom that improved quality translates to improved profitability, or good quality is good business.

Quality Improvement Tools

Several CQI tools can help understand and improve surgical care [16]. The most relevant tools for surgical settings are checklists, process flow maps, Ishikawa diagrams (cause-and-effect diagram), run charts, and control charts.

Checklists

Among the basic tools of quality, the checklist has received the most attention (and press) for improving patient safety. Evidence supports greater adoption of checklists in surgery [17] and in other medical specialties [18–20]. In June 2008, the Safe Surgery Saves Lives Initiative of the World Health Organization (WHO) released the WHO Surgical Safety Checklist. In a little more than 2 years, more than 3900 hospitals in more than 122 countries were registered in the initiative. Of these 3900 hospitals, more than 1800 have reported using a checklist in at least one operating room [21, 22].

The Dutch SURPASS study, conducted from October 2007 to March 2009, found that hospitals using checklists had surgical complication rates that were more than one-third lower, and death rates that were almost one-half lower (from 1.5 to 0.8 %), than they were in hospitals not using checklists [23].

Researchers at Stanford found that the observed-to-expected mortality ratio declined from 0.88 in quarter one to 0.80 in quarter two, with the use of a modified version of the WHO Surgical Safety Checklist [21, 22]. The use of checklists also improved communication among the surgical team, and thus the quality of care. Quality was measured by the frequency with which staff reported "Patient Safety Never Events" (i.e., the kind of events that should "never happen"). The number of Patient Safety Never Events related to errors or complications decreased from 35.2 to 24.3 %.

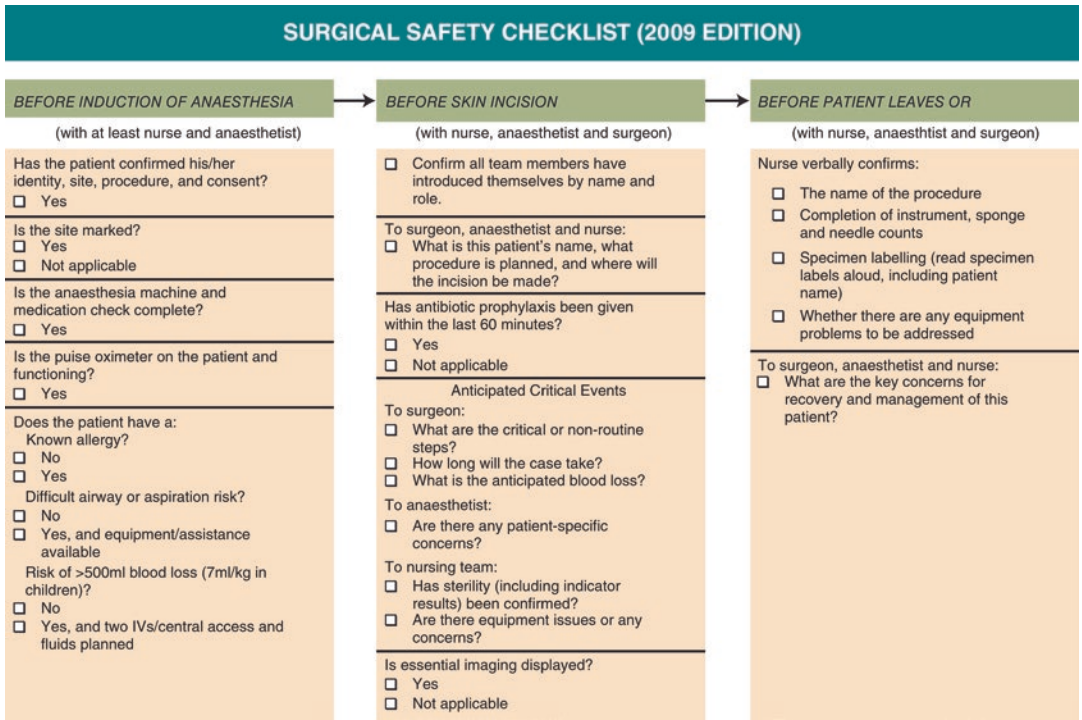

Fig. 9.3 A surgical safety checklist template modified from the World Health Organization

The website Safesurg.org provides resources for implementing the WHO checklist or for modifying an existing checklist. Modified checklists created by other institutions can also be downloaded (Fig. 9.3) [24]. Modifying checklists to fit local practices and needs is encouraged to enhance acceptance.

Although checklists have been widely adopted, their effectiveness has been highly variable if they are casually applied only as tick-box forms and in a top-down approach [25]. Ineffective top-down engagement and inauthentic partnering and engagement with clinicians inhibit positive behavior change and encourage normalized deviance [26]. Introducing a checklist in an environment characterized by a lack of trust causes clinicians to feel jeopardized professionally and personally, and encourages gaming of clinical metrics and measurements [27]. Effective adoption requires local championship, sustained clinician engagement, and a commitment to teamwork [28, 29].

Process Maps

A process map or flowchart is a visual representation of the care process that is created with information provided by team members. The process mapping exercise can help clinicians clarify through visualization what they know about their environment and determine what they want to improve about it [30]. The process maps use common flowchart symbols and can describe the current state or baseline, the improved state in transition, and the optimal state [31]. The exercise helps clinicians make assumptions and expectations explicit and can provide insights into reflecting on their current state and, importantly, into how to improve the process of care or to overcome barriers they perceive to its improvement [32]. Working with clinicians to understand their clinical sensemaking is essential if they are to become and sustain their interest and engagement in long-term continuous improvement [27].

A high degree of process awareness often drives the design changes needed to sustain improvement. Process mapping describes precisely what an individual provider is required to do and when, in terms of cognitive processes, actions, or both, to achieve the system's goal. Data are collected from observations or interviews that carefully break down complex clinical processes into discrete, measurable, and clear tasks [32]. Team members can gain insights into how they and their colleagues perceive the same tasks and hopefully come to a shared understanding of the process.

Ultimately, improving patient outcomes requires appreciating the inherent links between process and results. Process maps help focus improvement efforts, not for the individual, but for the entire clinical microsystem [33]. Visualizing the process can also help identify inefficiencies (e.g., parallel or redundant processes that have emerged for whatever reason), clarify roles, and reduce ambiguity among team members, all of which can help coordinate patient care. This process is particularly useful in improving surgical patient transitions of care and avoiding readmissions and bounce back to the intensive care and high-dependency units [34, 35].

Process maps show how interactions occur, uncover variations, and make the invisible process visible. Process maps can be created at different levels of detail to illustrate the major phases or detailed activities in that process. It is important to map the current process, not the desired process, to identify opportunities for improvement. We have used process mapping in multiple settings to better understand the processes of care, including pediatric cardiac surgery (Figs. 9.4, 9.5, and 9.6), and to summarize the data on near misses and adverse events (Fig. 9.7) [32, 37].

Ishikawa Diagrams

Ishikawa diagrams, also known as "cause-and-effect diagrams," "fishbone diagrams," and "root-cause analyses," are visual representations of the sources of variation in a process [38]. The diagram is often created by brainstorming with key stakeholders to identify the causes of the effects of a process. The causes are generally allocated to five general main headers/categories:

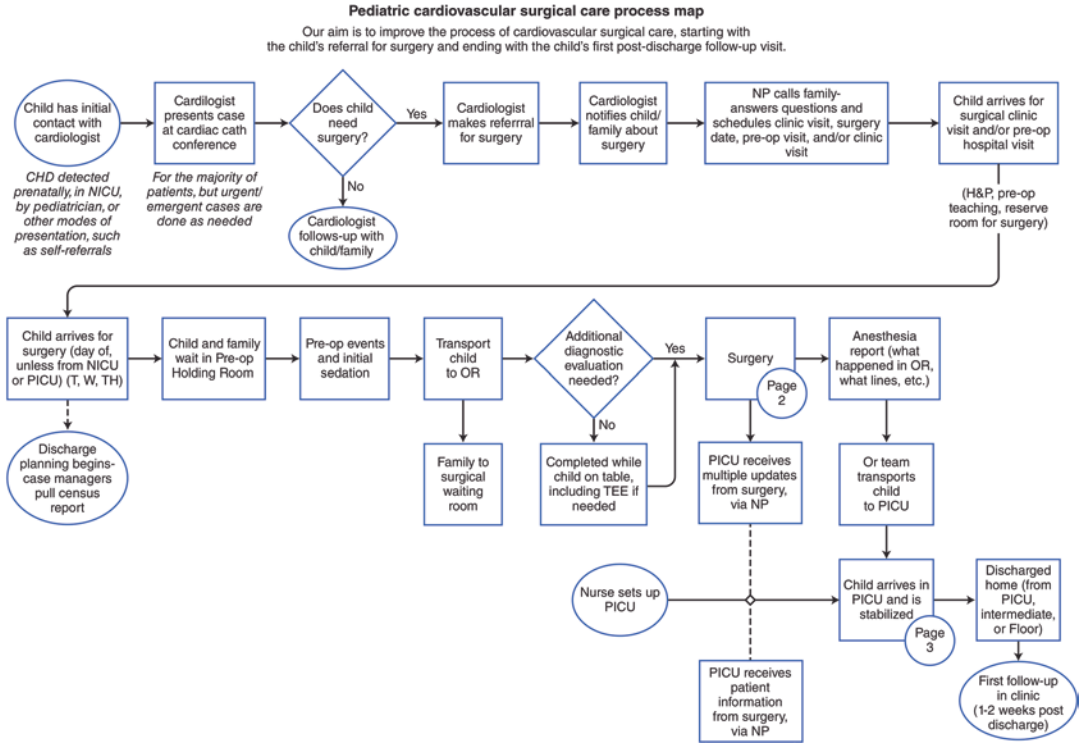

Fig. 9.4 A process map of pediatric cardiac and cardiac surgical care. Preoperative processes

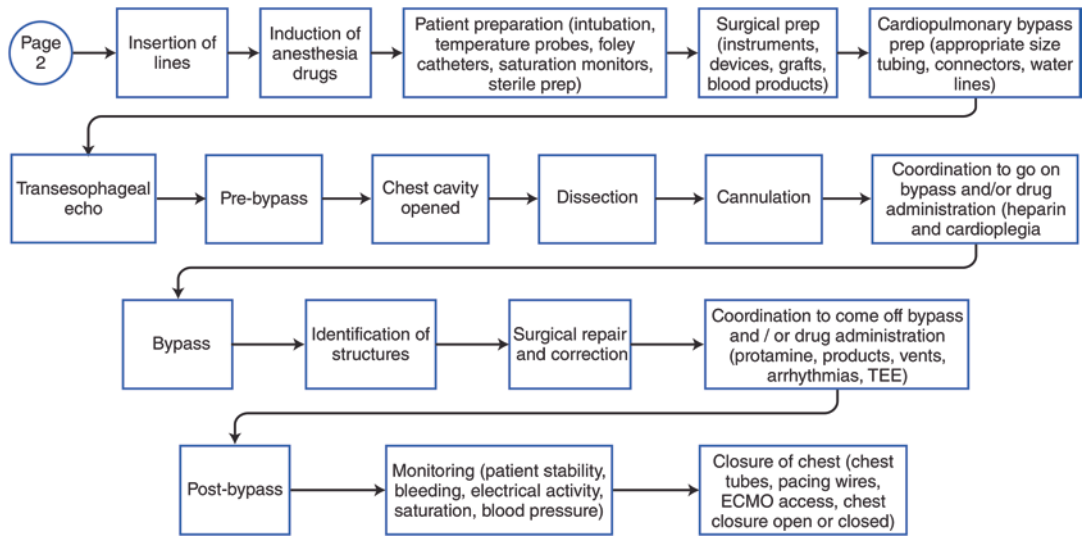

Fig. 9.5 A process map of pediatric cardiac and cardiac surgical care. Operative processes

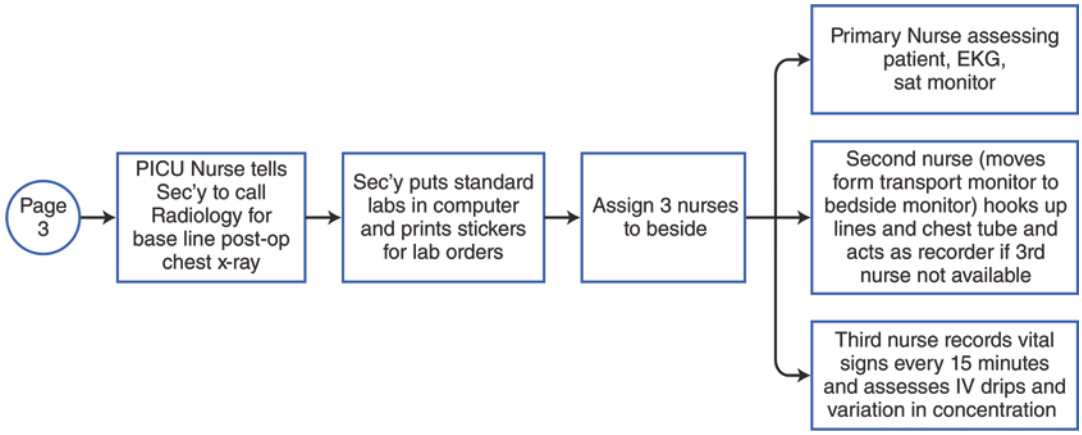

Fig. 9.6 A process map of pediatric cardiac and cardiac surgical care. Postoperative processes

place (environment), equipment, procedures and methods (processes), people (patients and providers), and policies (Fig. 9.8) [39]. Routine root cause analysis with Ishikawa diagrams can be very powerful in analyzing surgical adverse events. A detailed analysis in one major hospital over 4 years (Table 9.1) established the fact that excellent surgical outcomes depend on integrating individual, team, technical, and organizational factors [40].

Reviewing the root cause categories helps the team estimate the resources needed to address the causes of process variation. These diagrams help identify potential improvements and which improvements might be transferable to another setting.

Run Charts and Control Charts

Two of the most powerful CQI tools are run charts and control charts [10, 41]. These tools are valuable for analyzing variability in clinical processes [42], in part because the data usually does not go beyond what is generally collected to meet reporting requirements.

The run chart is a simple plot of a measurement over time with a line drawn at the median value. The data can be related to patients, organizations, or clinical units. Run charts are particularly useful because they can reveal subtle changes over time that would otherwise go noticed. A run chart is a graphic representation of process performance data tracked over time and represents continuous data. Important uses of the run chart for improvement are to:

- Display data to make process performance visible
- Determine whether tested changes improve the process or endpoints
- Determine whether the changes are lasting
- Allow for a temporal view of data versus a static view [43]

For example, a team wanting to improve patient outcomes might measure time to extubation for patients undergoing closure of an atrial septal defect or ventricular septal defect. Team members start by plotting the data over time in a run chart for 30 consecutive patients (Fig. 9.9), where the time to extubation ranged from 2 to 48 h after the procedure, with a median of 14 h. As the team changes the process, they can continue plotting data to determine whether the changes decreased time to extubation and thus improved overall care.

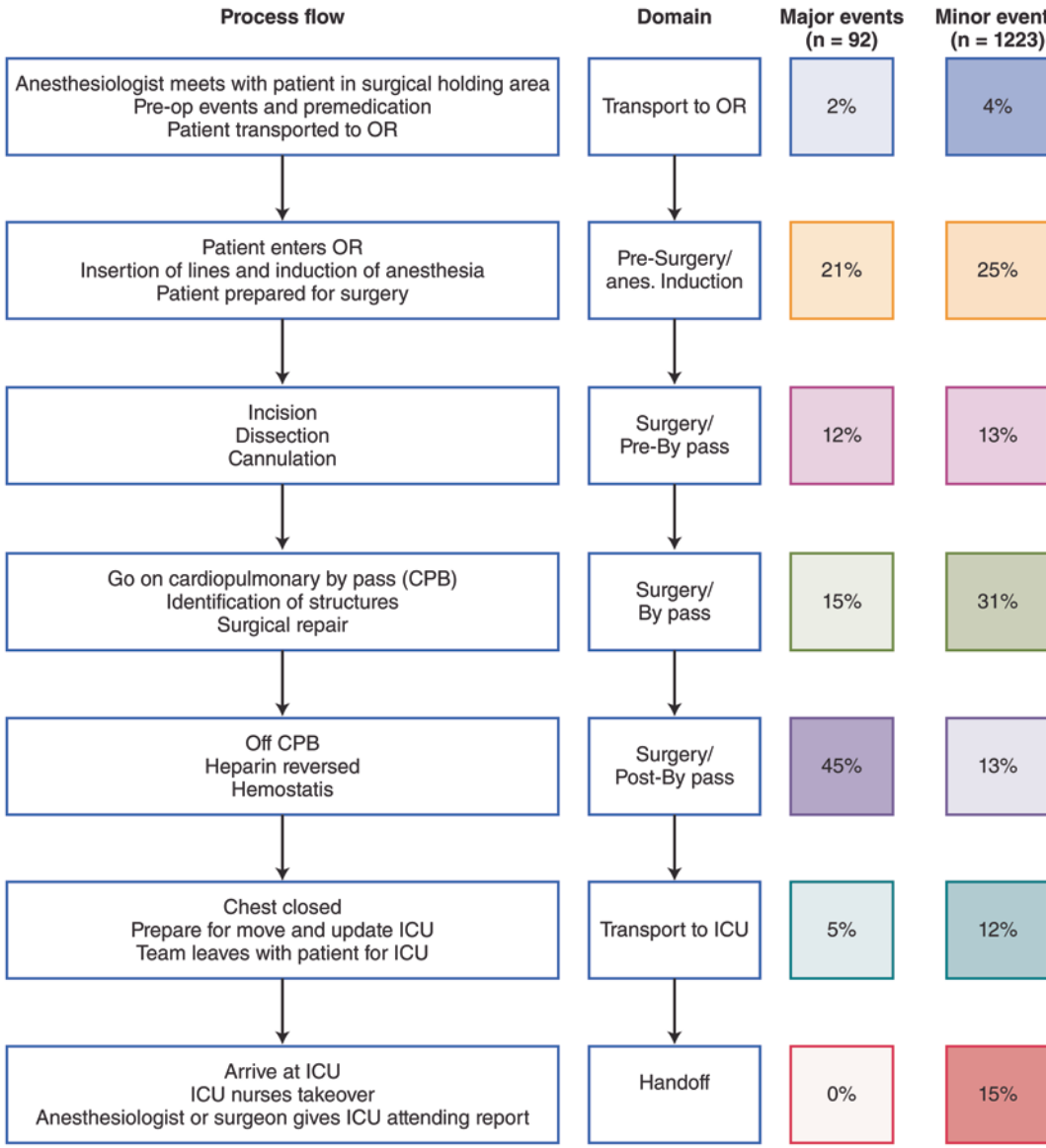

Fig. 9.7 A process map showing minor and major adverse event data in pediatric cardiac surgery [36]

The control chart was developed by Shewhart in the 1920s to improve industrial manufacturing [10]. Like run charts, control charts display data over time, but control charts provide upper and lower control limits of variation that help determine whether a process is stable or unstable (Fig. 9.10). Control limits are calculated using median values and the moving ranges of the data. The factors leading to instability must be addressed before the process can be improved.

Shewhart and Deming defined two types of variation in a process. Briefly, "common cause variation" is the usual, historical, quantifiable variation in a system, whereas "special cause variation" is unusual, not previously observed, nonquantifiable variation [44]. In surgical procedures, common cause variation might include fluctuations in the severity of a patient's risk factors, the skills of operating team members, or changes in equipment settings [45]. Common

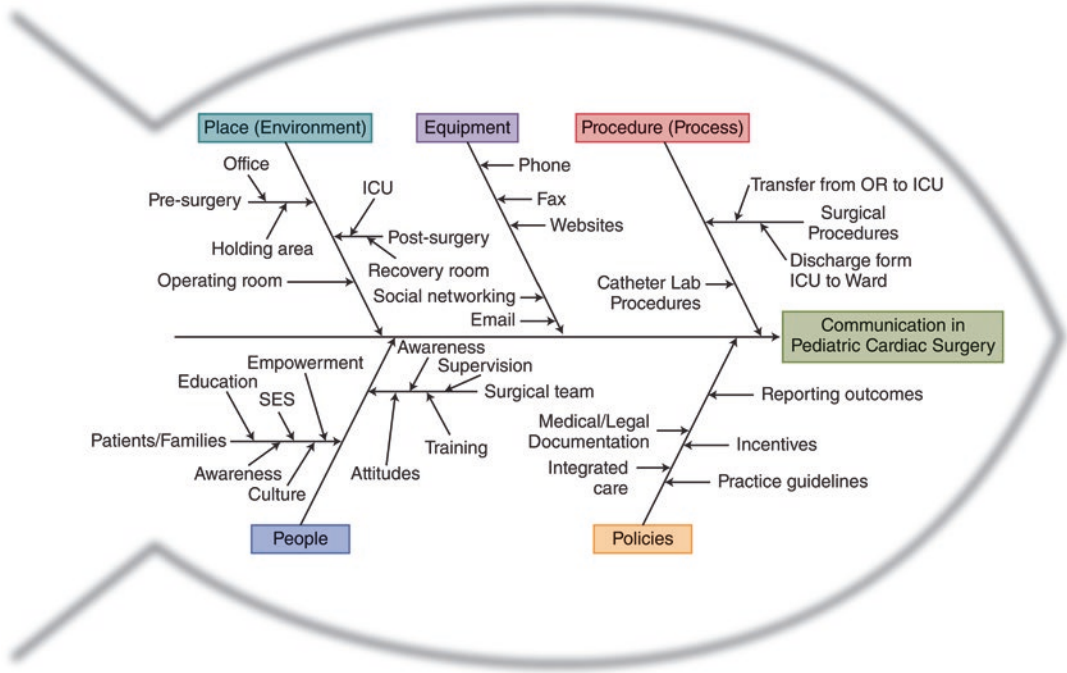

Fig. 9.8 An Ishikawa diagram for pediatric cardiac surgery [16]

Table 9.1 Results of a surgical adverse event root cause analysis

Theme	Issues identified
Failure to recognize or respond appropriately to the deteriorating patient within the required time frame	• Postsurgery complications
	• Postoperative sepsis
	• Postoperative hyponatremia
Workforce availability and skills	• Orientation, training, and supervising new or junior members of the surgical team, especially outside normal working hours
Transfer of patients for surgery	• Difficulty in organizing an OR for surgery
	• Failure to hand over information about patient acuity
Trauma management	• Coordination and response of trauma teams
	• Clinical decision-making process for trauma patients
	• Coordination of care between multiple clinicians
Access to emergency operating room	• Antepartum hemorrhage and emergency cesarean
	• Urgent orthopedic procedure
	• Urological complications requiring urgent OR
Missed diagnosis	• Thoraco-lumbar fracture in a trauma patient
	• Brain abscess mistaken for cerebral metastasis
	• Subarachnoid hemorrhage thought to be drug overdose
Unexpected procedural complications	• Airway obstruction after thyroidectomy
	• Failed intubation
Sentinel events	• Wrong-site procedure—spinal fusion at wrong level
	• Retained surgical products requiring surgical removal

Adapted from Cassin B, Barach P. Making sense of root cause analysis investigations of surgery-related adverse events. *Surg Clin North Am* 2012:1–15. doi:10.1016/j.suc.2011.12.008

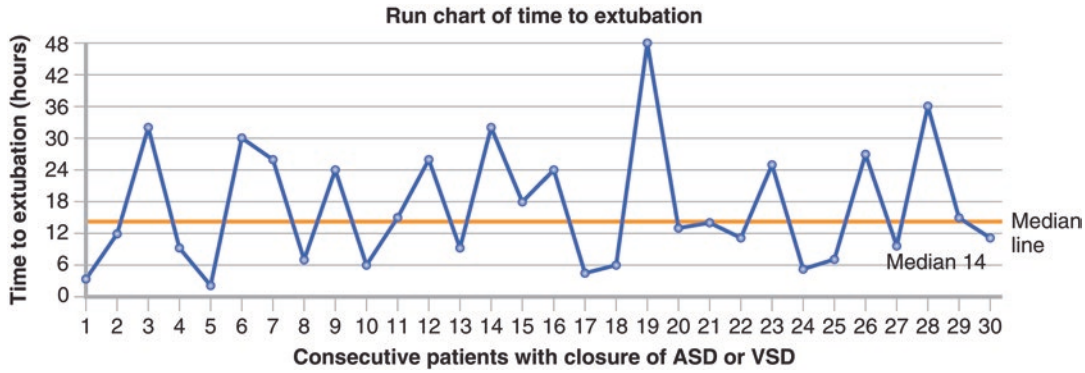

Fig. 9.9 A run chart of time to extubation for patients undergoing closure of atrial septal defect and ventricular septal defect in the ICU

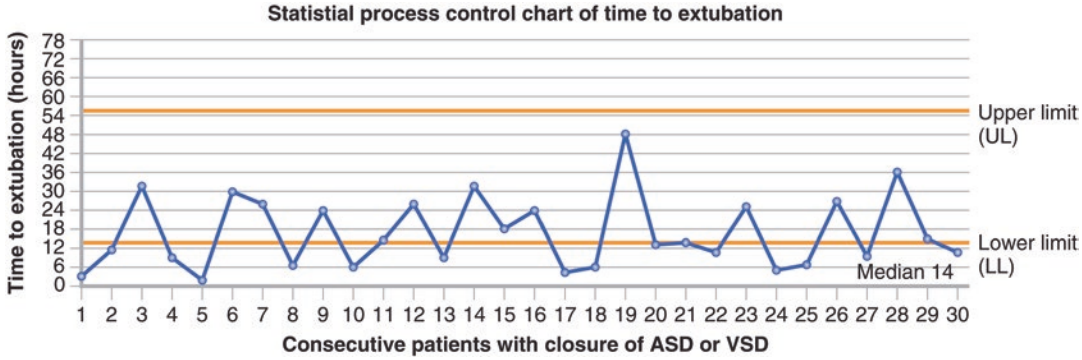

Fig. 9.10 A control chart of time to extubation for patients undergoing closure of atrial septal defect and ventricle septal defect in the ICU. The chart shows that the variation is the result of common cause variation and not special cause variation. That is, without any changes to the process, the time to extubation will continue to fall within a range that will not exceed the upper control limit of 55 h

cause variation suggests that improving outcomes will require changing the processes that produced the results. Special cause variation is the result of factors extraneous to the process, for example, variation introduced by a new manager, drive for more productivity, or equipment breaking during a procedure. It is not possible to predict (or control) variation caused by special causes [46].

If the control chart indicates that the process is currently under control (i.e., it is stable, with variation only coming from sources common to the process), then data from the process can be used to predict the future performance of the process. If the chart indicates that the process is not under control, the chart can help determine the sources of variation, which can then be eliminated to bring the process back under control (Fig. 9.8). These data can inform the team about when to act, but also, especially in systems that are constantly tweaking their systems, when to hold and not to act, depending on the cause of the variation.

The control chart illustrates the variation that is due to a common cause and not to a special cause variation. What this means in our example about when to extubate the patient is that *without any changes* to the process it will be difficult to predict the time to extubation and if it will continue to fall within a range that does not exceed the upper control limit (of 55 h).

Control charts are appropriate for analyzing data from procedures that are performed frequently, and consistently, and with relatively standard methods [45]. In addition, patients should be separable into more homogeneous subsets for analysis, for example, by stratifying them by procedure, and the procedures should have a documented range of favorable and unfavorable outcomes.

Conclusions

The most progressive view of quality is that it is defined entirely by the customer and is based upon that person's evaluation of his or her entire customer experience. This chapter describes several CQI tools that can be part of improving the processes and outcomes of surgical patient care. Detailed descriptions of how to apply the tools are beyond the scope of this chapter. Improving teamwork is an important factor in improving patient outcomes. In fact, it is a requirement for using these CQI tools effectively. Indeed, ongoing quality improvement efforts are not about which tools are used but about how these tools can produce insight, provide feedback, engage the team members, and track patient progress. Their purpose is to help people function as a team, as well as to improve patient outcomes.

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10 The Future and Challenges of Surgical Technology Implementation and Patient Safety

Chandler D. Wilfong and Steven D. Schwaitzberg

"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science."

—Albert Einstein

Surgery is a rapidly evolving field with advancing techniques and technologies driven by innovation and research. The current state of surgery is changing with a focus on robotics, advanced minimally invasive techniques, new operative equipment, and educational techniques including telesurgery and telementoring, as well as promising fields such as tissue engineering and nanosurgery.

The Current State of Robotic Surgery

Robotics within the field of surgery brings three obvious capabilities to the surgeon. They are tremor reduction, scaling, and wristed articulation at the level of the tissue especially in small spaces. These inherent features of robotic should not be contiguous with product features and options that the various medical devices will feature on the market. The da Vinci® Surgical System (Intuitive Surgical, Sunnyvale CA, USA) is a computer-assisted robotic surgical system that is widely employed in various surgical specialties. The da Vinci® Surgical System is not technically a robot, but a computer-assisted telemanipulator. The surgeon generally sits at a console within the same operating room and directs the robotic arms to perform minimally invasive surgical procedures. The computer system enhances the surgeon's abilities by scaling the movements of the surgeon's hands to articulating surgical instruments, as well as reducing tremor, allowing a full range of motion that is not possible with current laparoscopic instruments. These functions theoretically allow the surgeon to perform more complex maneuvers and surgical procedures. A second operative console is available to allow surgeons to work in tandem in a training configuration within the same procedure. There are further optional technologies that couple with the platform such as Firefly™ imaging technology. Indocyanine green (ICG) dye is injected into the bloodstream. A near-infrared laser (803 nm) illuminates the tissue where the dye is excited and fluoresces, showing blood vessels as well as the biliary tree (Fig. 10.1).

The da Vinci® Surgical System is widely employed across multiple surgical specialties to perform minimally invasive procedures such as prostatectomy, gynecologic procedures, gastrointestinal procedures such as Heller myotomy, Nissen fundoplication, gastric bypass, colectomy,

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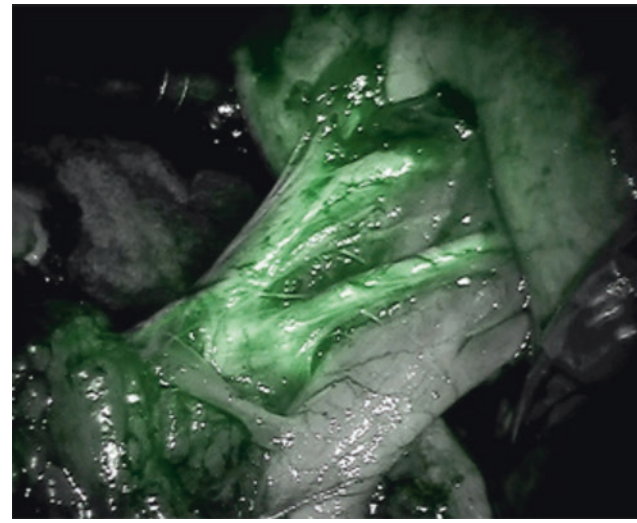

Fig. 10.1 The renal hilum, Intuitive Surgical

rectal surgery, hepatic, and pancreaticobiliary surgery. The Society of American Gastrointestinal and Endoscopic Surgeons Technology and Value Assessment Committee reviewed the safety and efficacy of robotic assisted surgery in gastrointestinal procedures in July 2015. A comprehensive review of current available literature demonstrated a non-inferiority in all reviewed gastrointestinal surgeries; however, a demonstrable benefit in improved surgical outcome or decreased length of stay was not observed.

There are a number of current trials investigating the efficacy of robotic surgery, particularly in pelvic surgery, across multiple specialties. The ROLARR trial is an ongoing international, multicenter, randomized, controlled, unblended, parallel group trial of robotic total mesorectal excision (TME) versus laparoscopic total mesorectal excision. The benefits of laparoscopic TME compared to open TME have been evaluated in multiple studies, and there are clear short-term benefits to a minimally invasive approach. The da Vinci® surgical system offers theoretical benefits when operating in the confined area of the pelvis, which could translate into a decrease in the technical difficulties associated with laparoscopic TME. Many centers are employing robotic procedures based on these theoretical benefits. The ROLARR trial is a practical trial designed to evaluate the benefits of robotic TME.

Robotic surgery is associated with an inherent increase in procedural costs. Over 500,000 robotic assisted procedures were performed worldwide in 2013; yet despite the widespread incorporation of robotic procedures, the added benefit versus cost remains unclear. Insurance providers generally reimburse robotic procedures at the same level as laparoscopic cases, despite the increased cost of using the robot system, such as required service charges by the robotic company, as well as increased consumable charges associated with each procedure. Schwaitzberg [1] investigated the financial viability of performing outpatient, robotic assisted procedures on the current platform and concluded that, depending on payer source, it is unlikely that robotic assisted outpatient procedures can be financially viable until such time that acquisition and tooling prices come down to a lower price point (Fig. 10.2).

The future of robotic surgery will undoubtedly include a variety of platforms outside of the currently employed console-based platform. Miniature robots will most certainly play a role in advancing minimally invasive surgical techniques of the future. These robots will be deployed through a small primary incision and will be configured inside of the abdomen or chest or specialize functions and controlled wireless fully from the exterior. In addition, the opportunity for non-console robots really functioning as specialized hand instruments will bring these capabilities on an as-needed basis to selected portions of the procedure.

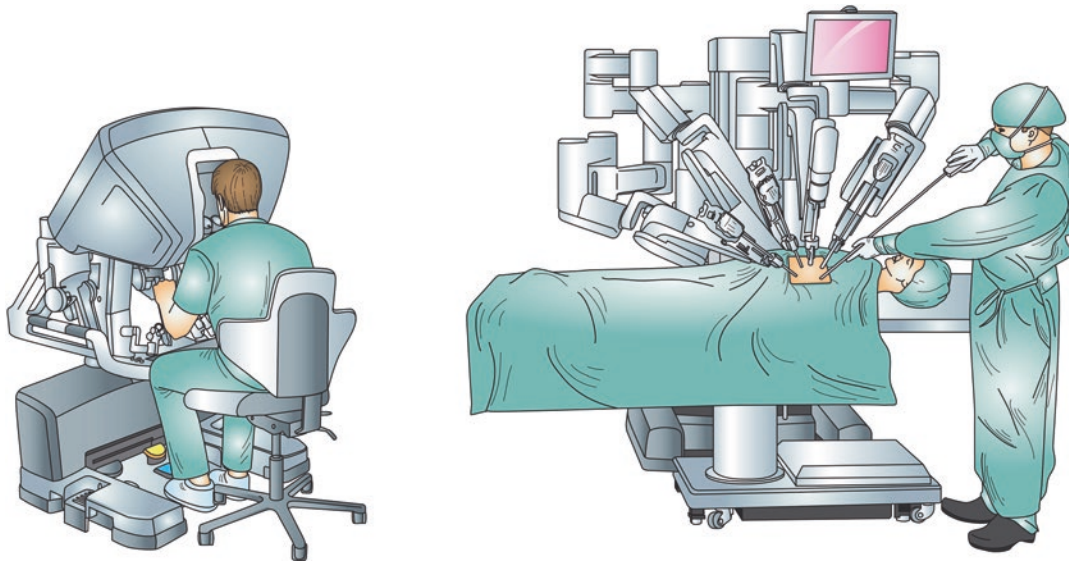

Fig. 10.2 The future of robotic surgery will undoubtedly include a variety of platforms outside of the currently employed console-based platform

The ARES, or Assembling Reconfigurable Endoluminal Surgical system (Scuola Superiore di Studi Universitari e di Perfezionamento Sant'Anna), is a prototypical, ingestable, component-based miniature robotic platform that the patient ingests in multiple components. The components then assemble within the fluid-distended gastric lumen to perform procedures. The theoretical applications for this platform are wide ranging, but could include pH sampling, biopsies, direct optical vision, and even DNA analysis (Fig. 10.3).

The hurdles in implementing newer robotic technologies in vivo are many, including the power source, location monitoring, tool payload, maneuverability, propulsion but also important human factors and ergonomic aspects addressing human limitations [2].

Endoluminal Surgery and NOTES

Current trends and surgery and therapeutic endoscopy suggest that these fields are intersecting to perform certain types of procedures in an increasingly less invasive fashion. This intersection will require the development of new devices in order to perform these innovative procedures. Endoluminal techniques such as per oral endoscopic myotomy (POEM) for the treatment of achalasia and endoluminal mucosal as well as full-thickness resections are already being performed. For instance, in Asia endoscopic resection of very early malignancies is routinely performed on therapeutic endoscopic platforms. Further advancements in endoluminal therapies are on the forefront of surgery.

NOTES or surgery through natural orifices of the body, often referred to as "incisionless" surgery, has the potential to eliminate complications associated with incisions in surgery. There are several proposed benefits to patients with these approaches including decreased postoperative pain, shorter hospital stays, faster postoperative recovery, and elimination of surgical site infections and abdominal wall hernias. Performing surgery via transvaginal, transgastric, and transanal approaches is appealing, but is not a widely adopted practice at this time. There are many technical challenges associated with NOTES surgery, however, particularly associated with the technical difficulty of the procedures given the current instrument technologies. The majority of NOTES procedures are therefore performed as hybrid procedures with laparoscopic assistance.

There is a large amount of variation present in NOTES procedures at this time. The route of

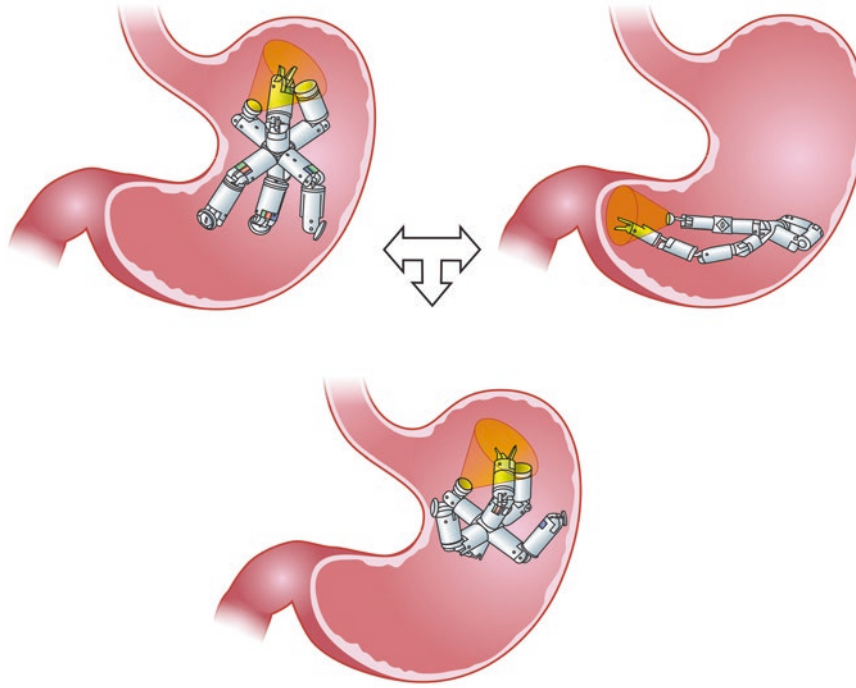

Fig. 10.3 The hurdles in implementing this technology in vivo are many, including the power source, location monitoring, tool payload, maneuverability, and propulsion

entry: transgastric versus transvaginal, rigid versus flexible endoscopes, and the number and site of access points: True NOTES versus hybrid notes with laparoscopic assistance. A literature review by Chellali et al. [3] showed that 90 % of NOTES procedures reported are performed with hybrid laparoscopic assistance, and that a transvaginal approach was employed in the majority of cases (86 %). The most common procedure performed was cholecystectomy, comprising 84 % of reported cases. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) created the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) in order to assess the feasibility and safety of NOTES procedures. EURO-NOTES was also established in Europe to serve similar purposes. A review of current literature does not clearly establish the role or safety for NOTES procedures, although it does provide a proof of concept with hundreds of procedures performed. NOSCAR is currently investigating the efficacy of NOTES cholecystectomy in a multicenter human clinical trial in the USA.

Analysis of current NOTES literature does support a prolonged operative time in both hybrid NOTES and total NOTES procedures. Chellali et al. [3] reviewed a series of NOTES cholecystectomies recorded on video and surmise that the prolonged operative time is, at least in part, a result of instrumentation that is not adequately designed for these newly appointed tasks [4]. Reviewed the currently available multibranched laparoscopic and endoscopic instrumentation in light of the criteria suggested by NOSCAR findings. Future facilitation of NOTES procedures will require the design and implementation of less cumbersome instruments that will allow the surgeon to perform more complex bimanual tasks requiring triangulation, such as intracorporeal suture tying.

POEM is a procedure in which a gastroesophageal myotomy is made using a therapeutic endoscope via a transmucosal incision in the mid-esophagus for the treatment of achalasia. A submucosal tunnel is made along the length of the esophagus and the circular muscle fibers are

incised, performing the myotomy. POEM was initially described in 2008 by Inoue, and has subsequently come to be performed in more than 50 centers worldwide. Several studies comprising hundreds of patients have been reported, confirming the safety and efficacy of POEM. The success rates of achalasia treatment using POEM are greater than 90 %, generally evaluating the symptoms using the Eckhart score. Postoperative gastroesophageal reflux symptoms have been reported in patients greater than 1 year postoperatively at rates between 35 and 40 %. These results are consistent with postoperative reflux rates in laparoscopic Heller myotomy. POEM represents a minimally invasive, incision-free alternative to laparoscopic Heller myotomy that has been reported as successful treatment in nearly all types of achalasia, including patients with previous interventions, as well as patients with sigmoid esophagus.

Telesurgery and Telementoring

The widespread adaptation of minimally invasive techniques faces several hurdles. One of the largest hurdles involves the dissemination of techniques and skills outside of residency training to surgeons in the community. Residency training represents the ideal setting for educating surgeons under the direct oversight of experienced surgeons on a day-to-day basis. New technologies and techniques are constantly under development throughout a surgeon's career. There is a need to develop robust and validated assessment tools for surgical competency given growing potential for patient harm with more advanced surgical tools [5]. The current method for a surgeon to learn a new technique frequently involves a course or simulation that is insufficient to fully develop the necessary skills. A novel approach to the continued training of practicing surgeons has been implemented by a number of groups, including Ponsky et al. as described in 2014 [6]. The Karl Storz VisitOR1 telementoring robot cart was used to stream the procedure to a virtual mentor experienced in the procedure. The VisitOR1 robot cart allows the mentor to provide real-time advice on the procedure, including telestration capabilities. Previous studies have demonstrated equivalent levels of skill acquisition between surgeons that were remotely mentored and locally mentored in laparoscopic nephrectomy, Nissen fundoplication, and laparoscopic colectomies. This demonstrates the potential of telementoring to provide surgeons with the ability to further their training throughout their career irrespective of the availability of local expert mentors. Other questions arise around how best to prepare/rehearse given potential evidence about optimal techniques for performing physical rehearsal and warm-up. Preliminary findings suggest that preoperative rehearsal or warm-up can improve the performance of operators or operating teams, but there is a paucity of objective evidence and comparative clinical studies in the existing literature to support their routine use [7].

There is debate about the relationship between the telementor and practicing surgeon, and therefore the liability of the mentor. Some argue that the mentor is directly involved in intraoperative decision making, and therefore responsible for patient care. Other parties believe that the responsibility lies with the primary surgeon, and the mentor is only advising the primary surgeon, and not liable for patient care or outcome [8]. Currently, it is important that the primary surgeon be able to complete the procedure on his/her own, and that the mentor be present for guidance on optimal technique. Regardless, telementoring represents an avenue for continuing education and live intraoperative training of surgeons, without regard to geographic boundaries for the future (Fig. 10.4). Simulation-based training in conjunction with deliberate practice activities such as reflection, rehearsal, trial-and-error learning and feed- back in improving the quality of patient care will become mainstream in assessing expertise [9].

The Future of the Operating Room

The operating room of the future will revolve around integrated technology. Current modern advances present in many operating rooms

Fig. 10.4 VISITOR1® mobile telementoring system. ©2016 Photo Courtesy of KARL STORZ Endoscopy-America, Inc.

revolve around decreased level of invasiveness in surgical procedures [10]. Minimally invasive technologies such as image-guided procedures, telesurgery, hybrid vascular procedures, robotic surgery, and single-incision or natural orifice laparoscopic procedures are becoming more prevalent, and with them their associated technological advancements. Procedures that have always required a traditional operating room setting will now demand advanced imaging capability along with endoscopic technologies [11]. Surgeons, OR staff, and anesthesia staff will want access to up-to-date patient information, vital signs, documentation, and procedure-related imaging in real time in the operating room.

Hybrid operating rooms are being widely employed across the USA in multiple fields, particularly cardiovascular surgery, vascular surgery, neurosurgery, and orthopedic surgery. Vascular and cardiovascular surgeons routinely perform hybrid procedures that involve endovascular interventions with more traditional surgical procedures to treat disease processes involving the heart valves as well as peripheral vascular disease, and others [12]. Hybrid operating suites have rapidly become the standard of care for vascular surgeons performing stent graft repair of abdominal aortic aneurysms as well.

Trauma surgery represents an area of growth for hybrid operating suites in the future. Traumatic injury remains one of the most potentially preventable causes of death in modern society, and exsanguination represents the most potentially preventable cause of death in traumatically injured patients who arrive at the hospital. Modern trauma systems and advances in surgical care means that the most commons sites of life-threatening hemorrhage are extra-abdominal sites, such as the pelvis, which often require interventional procedures in order to obtain hemostasis. Trauma surgeons are often faced with the difficult decision requiring triage of the exsanguinating patient to either the operating room or the angiography suite. Hybrid operating suites designed to treat the exsanguinating patient, such as the RAPTOR (resuscitation with percutaneous treatments and operative resuscitations) suite described by Kirkpatrick et al. [13], have the potential to offer life-saving therapy to patients with life-threatening injuries in multiple sites at the same time, and will likely grow in number in the future. The RAPTOR operating room is designed to function as a location for resuscitation, imaging, interventional radiology, as well as open surgery. Currently, there are no studies to support the use of hybrid operating suites in trauma resuscitation; however, despite the high cost of instituting the technology, there are select centers around the world that are implementing the technology.

However some adjunctive technologies in the operating room of the future may be helpful such

as automated sponge counting technology using methods such as RFID tracking or radiofrequency detection of retained surgical sponges in the abdomen/chest. The future of the operating room is also a future of improved workflows and enhanced patients' safety. Trauma hybrid rooms are going to require more awareness and attention to the team functions, communication and ability to work seemlesslly together [14]. These opportunities have less to do with technological advances as they do with *human* advances. The checklist, preoperative briefing, and postoperative debriefing are all examples of needed human engineering advances in the field of team work and communication as noted in other chapters of this book.

Tissue Engineering

Tissue engineering is a broad multidisciplinary field that originated with the goal of developing complex tissues and organs in order to facilitate patient treatment, particularly those with end-organ failure. Tremendous strides have been made in the field of transplant surgery; however, there remains a much larger need for organ transplantation than there is a supply of donor organs.

Many advances have been made over the last two decades in the field of tissue engineering, with the potential to have a large impact on the practice of surgery in the future. Surgeons, in particular, possess the skill sets that will allow the implementation of the technology created by tissue engineering.

Approximately 250,000 ventral hernia repairs are performed each year in the USA alone, and even with modern techniques employing synthetic mesh implantation, recurrence rates remain as high as 20 %. Synthetic polypropylene-based meshes elicit significant inflammatory response when incorporated into a hernia repair, however, resulting in dense scar and adhesion formation. Acellular dermal mesh products have been shown to incorporate into the host tissue and result in fewer omental adhesions in preclinical models, but have high hernia recurrence rates. Adipose-derived stem cells have been shown to have excellent regenerative capabilities and multiple studies have shown them to augment wound healing through increased vascularization and cellular infiltration. Preclinical models have shown that by harvesting adipose-derived stem cells and seeding acellular meshes prior to hernia repair, the meshes achieve more rapid vascular and cellular infiltration into the native tissues. Explantation of the repaired hernia in a preclinical rat model also demonstrated improved tensile strength in comparison to acellular dermal mesh controls. The ideal mesh would provide tensile strength equal to the normal architecture of the abdominal wall and also incorporate into the tissues of the patient. Tissue-engineered meshes may one day provide improved materials for hernia repair.

Stem cell and mature cardiac myocytes have been investigated in multiple different iterations in conjunction with cardiac patches to repair congenital heart defects. The theoretical benefits of a tissue-engineered patch have the potential to overcome the shortcomings of purely synthetic cardiac patches. The materials currently used are nonliving, noncontractile, not electrically active, and do not have the ability to grow with the patient. The complications associated with these features include potentially fatal arrhythmias and high re-operative rates as the patients grow leading to a risk of sudden cardiac death 25–100 times higher than the normal population. A tissue-engineered approach to repair of congenital heart defects that can contract, integrate electrically, and fully incorporate and grow with the patient has the potential to eliminate these risks. There are many obstacles to overcome in order to create such a functional implant.

Multiple products based on tissue engineering concepts are available for use in the USA in the field of wound care. Apligraf and Dermagraft are products based on temporary scaffolding materials seeded with human neonatal foreskin fibroblasts that are approved by the FDA for treatment of burns, diabetic foot ulcers, as well as chronic venous stasis ulcer disease. OrCel is a skin substitute composed of neonatal keratinocytes and fibroblasts on a bovine collagen sheet that has been shown to improve wound healing and reduce scarring compared to traditional dressings. Despite the benefits of using these products,

the neonatal cells only persist on their engineered matrices for a period of weeks. The next generation of biologic wound care dressings are likely to incorporate autologous stem cells into engineered scaffolds to promote skin regeneration.

A large number of studies exist confirming the ability to use stem cells to produce functional cells of the body with a range of success. The current clinical applications of these cells have generally failed to show long-term improvements in outcomes, largely due to the inability of the cells to fully mature and function in the complex system of the human body. Research has turned to utilizing scaffolds to provide the stem cells with structure and promote incorporation. Another issue in translating stem cell research from in vitro models to in vivo applications is the issue of vascularity. An implanted conduit would require a robust blood supply, and the formation of a de novo blood supply is poorly understood. The possibility of grafting stem cells into a "free flap" has been demonstrated in preclinical models. Decellularized organ scaffoldings have also been examined in cardiac, lung, and liver models with success in instituting partial organ function in in vitro models.

Surgeons will need to develop new skills that needed to implement these technologies in the future, indicating a continued need for collaboration between tissue engineers and surgeons to bolster the field of regenerative surgery.

Immunotherapy in Surgery

Knowledge of the interaction between cancer and the immune system has increased substantially over recent years and corresponding improvements in immunotherapy have followed. Surgeons play an integral role in these treatment strategies and knowledge of immunology and immunotherapy treatment options will become increasingly important in the coming years.

Advanced solid tumors have historically had poor outcomes despite maximal therapy. Despite immune system recognition, as well as surgical and cytotoxic therapies, the tumor microenvironment represents an immunosuppressed environment that allows tumor growth and progression via various mechanisms. Several immunotherapy strategies have evolved over the last decade targeting these mechanisms within the tumor microenvironment.

Adoptive cell transfer of tumor-infiltrating T-lymphocytes has been evaluated in multiple solid malignancies, particularly melanoma, as described by Rosenburg et al. in multiple studies. A host tumor is harvested and the tumor-infiltrating T-lymphocytes are isolated, and then expanded ex vivo. The tumor-infiltrating T-lymphocytes are then infused into the patient, following patient lymphodepletion to enhance tumor response. Patients with metastatic melanoma demonstrate response rates from 49 to 72 %, with a complete durable response in up to 40 % of patients, extending beyond 3–7 years. Response rates in these patients are independent of previous treatment strategies. Solid malignancies other than melanoma present a challenge in using this strategy, however, because they demonstrate significantly lower number of tumor-infiltrating T-lymphocytes. The ability to genetically engineer T-cells has presented the opportunity to apply adoptive cell transfer to a wider range of solid malignancies, with ongoing evaluation of colorectal cancers, prostate cancer, sarcomas, and others.

Checkpoint blockade therapy including CTLA-4 inhibitors and PD-1 inhibitors has been shown to be effective in treating metastatic melanoma and is currently being evaluated for efficacy in multiple solid malignancies. Combination therapy involving both CTLA-4 and PD-1 inhibitors in early clinical trials have shown a response rate of 40 % in advanced metastatic melanoma, with an acceptable side effect profile.

Advances in immunotherapy present an emerging therapeutic option for patients with advanced solid malignancies that are resistant to conventional therapies. Adoptive cell transfer represents a treatment option that is limited to large centers, although it is continuing to be offered at more institutions. Checkpoint blockade therapy represents an immune-based chemotherapeutic option that can be widely incorporated into multidisciplinary approaches in a widespread setting, with surgeons being an integral part of the treatment approaches.

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Part II

Job and Organizational Design

Organizational and Cultural Determinants of Surgical Safety

11

Kathleen M. Sutcliffe

"Judges possessing outcome knowledge may, for example, tend to reverse their temporal perspective and produce scenarios that proceed backward in time, from the outcome to the preceding situation. Such scenario retrodiction may effectively obscure the ways in which events might have taken place, much as solving a maze backward can obscure the ways in which one might have gotten lost entering from the beginning."

—Fischoff, 1975, p. 298

Introduction

This chapter explores some fundamental ideas about organizational and cultural determinants of surgical safety. We propose that the success of individuals and teams involved in providing safe and reliable care is more or less fueled by organizing processes and the cultures in which caregivers are embedded. By privileging process and culture we offer a systemic lens on the underpinnings of safety in complex healthcare systems and move beyond medicine's prevailing focus on individual excellence and achievement as the sole means to assuring safe and reliable care.

The ideas discussed in this chapter derive from years of research exploring the problem of safety in complex sociotechnical systems in disciplines such as organization and management theory, cognitive psychology, sociology, and human factors engineering. Research from these disciplines over the past two decades, possibly as a consequence of the IOM's *To Err is Human* [1] advising health care organizations to attend to the wisdom of organizations in high-hazard industries, has begun to penetrate the patient safety literature [2]. This cumulative body of research provides some insight into how organizing and culture might enable safe care. Although health care has enthusiastically sought to craft interventions based on this research, the enthusiasm for interventions in some cases has outstripped the evidence supporting them ([3]: 1). That is, even with respect for the best of intentions this enthusiasm sometimes has led to superficial application of particular ideas without a solid grasp either of the underlying concepts or the mechanisms through which they exert their influence [4, 5].

In this chapter we aim to remedy this state of affairs. We are mindful that innovations are best designed by people who have deep contextual knowledge and are close to the work. Thus, we do not aim to be prescriptive. Rather the intention is to provide a general and wide-ranging overview of some basics related to processes of organizing and culture. By enriching understanding of these essentials, we hope that clinicians will be better prepared to contextualize these ideas and more successfully apply them to their own surgical care improvement efforts.

The chapter unfolds as follows. We start by examining some basic assumptions related to the challenges of achieving safety in complex, dynamic, open systems. We follow with a discussion of two orientations toward safety, essential organizational processes and practices, and

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evidence linking these to outcomes. We then turn to the concepts of safety culture and safety climate. We explore how they are defined, how they exert their influence, and how culture and climates are enabled, enacted, and elaborated. We follow with some evidence linking safety climate and outcomes. We end with some implications for practice and concluding comments.

Open System Assumptions

It is important to keep our eye on some key assumptions about complex sociotechnical systems and their safety, as they are critical for understanding the bounds of organizational and cultural interventions. First, when people in health care refer to systems or systemic error, they often have in mind a rational closed mechanical system comprised of explicit roles, rules, routines, and relationships intentionally created to achieve some well-defined objective. In closed systems, "goals are known, tasks are repetitive, output of the production process somehow disappears, and resources in uniform qualities are available" ([6]: 5). But health care systems defy that description. Viewing systems as closed or mechanical misses the fact that much medical care is delivered by transient, temporary teams, assembled in various contexts (e.g., the operating room or at the bedside), and often with new or unfamiliar players (e.g., rotating interns/residents, floating nurses) ([7]: 169). Transient systems have to be continually reconstituted. Viewing systems as closed also overlooks the fact of equifinality—meaning that the same results may be achieved with different initial conditions and through many different paths or trajectories. Although health care organizations are loosely coupled [8] in the sense that their various parts work fairly independently, patient outcomes often are determined by the combined product of these constituent loosely coupled parts.

A second important assumption is that system safety is an illusory concept. There *are no* safe systems/organizations if only because past performance cannot determine the future safety of any entity [9, 10]. Safety is a moving target: A good day yesterday does not necessarily mean a good day today.

Third, safety is a dynamic non-event [11]. It is dynamic in the sense that safety is preserved by timely human adjustments; that is, problems are fleetingly under control due to compensating adaptations. It is a nonevent because successful outcomes rarely call attention to themselves. In other words because safe outcomes do not deviate from what is expected, safety is in some ways invisible. When there is nothing to capture people's attention, they see nothing and they presume that nothing is happening and that nothing will continue to happen if they continue to act as they have acted before.

A fourth assumption is that adverse events and outcomes in health care sometimes occur because of mistakes in performance and execution, but mistakes in perception, conception, and understanding more often lead to unsafe conditions and ultimately to greater harm [12, 13]. This is nicely captured by sociologist Marianne Paget's [14] observation that medical work unfolds in real time and is "an error-ridden activity … inaccurate and practiced with considerable unpredictability and risk."

Finally, most accidents and failures in complex systems are not the result of the actions of any single individual (even though there is a tendency to blame single individuals). Nor are they the result of a single cause [15]. Small incidents often link together and expand [10]. This is why it is important to be able to catch and correct small mistakes and errors before they grow bigger. When problems are small, there are often more ways to solve them. When they get bigger, they tend to get entangled with other problems and there are fewer options left to resolve them.

Together these assumptions highlight the challenges of safety and reliability in complex systems (see Box 11.1). Achieving safe and reliable outcomes in error-ridden, unpredictable open systems such as those found in health care means accepting the realities of dependence, loose connections, keeping up with environmental demands, redoing processes and structures that keep unraveling, and expecting the unexpected [16]. But that doesn't mean that people who

Box 11.1: Safety Challenges in Complex Open Systems

- There are big differences between closed and open systems and these matter for safe care. Health care systems are open and loosely coupled; their various parts work independently, but outcomes are determined by the product of these parts.
- In open systems there is equifinality; the same results may be achieved with different initial conditions and through many different paths. There is no one right way to organize in open systems.
- System safety is an illusory concept. There are no safe systems and organizations because past performance cannot determine the safety of any entity.
- Safety is a dynamic nonevent. Safety is dynamically preserved by timely human adjustments. Safety is a nonevent because successful outcomes do not call attention to themselves. Just because nothing is happening does not mean that nothing is being done to make that happen. We never have a complete understanding of all the factors that are keeping a unit/organization safe.
- Medical work is a dynamic unfolding activity. Mishaps and adverse outcomes may be a result of problems with execution and performance, but misperceptions, misconceptions, and misunderstandings ultimately lead to greater harm.
- Most accidents and failures do not result from a single cause or the actions of a single individual. Small incidents often link together and expand. It is important to catch problems in their early stages when there are more ways to solve them. As they get bigger the solution space gets smaller.

inhabit those systems are left helpless. In the following section we explore organizational determinants, particularly organizing processes and their role in producing dynamic nonevents [17].

Safety in Health Care: The Role of Organizing Processes

Researchers have identified a number of properties of safe and reliable organizations. Although the specific attributes vary between studies, there are a number of commonalities. Many properties such as good technology and task and work design, highly trained personnel, well-designed reward systems, continual training, frequent process audits, and continuous improvement efforts are ubiquitous. Research outside of health care for several decades has linked bundles of these properties to higher performance [18], and research in health care also suggests that these elements matter. For example, in a study of 95 hospital nursing units Vogus and Iacobucci [19] found that the use of a bundle of organizational work practices that included rigorous selection of employees (particularly for interpersonal skills), extensive and regular training and development, and continuous work process improvement activities was directly and indirectly associated with fewer medication errors and patient falls. These basic organizational features, similar to those that one would find in any high-performing organization, although necessary to safety and reliability are not sufficient. Although these properties may provide the scaffolding for other critical organizational processes and outcomes [19], in some ways we might think of them as contingencies or boundary conditions. Their presence (or absence) strengthens (weakens) the effects of other determinants. Consequently, in this chapter we are more concerned with the distinctive properties found in what are known as high-reliability organizations (HROs), prototypical organizations such as aircraft carriers, air traffic control (and commercial aviation more generally), and nuclear power-generation plants (see [20–22]) that operate complex technologies in complex, dynamic, interdependent, and time-pressured social and political environments.

Although diverse, studies have shown that these high-risk organizations share a set of operating commonalities and characteristics that enable nearly error-free performance in settings in which errors should be plentiful (see Box 11.2).

Box 11.2: Attributes of Highly Reliable Organizations

- HROs exhibit attributes found in most high-performing organizations including:
  - Outstanding technology and task and work design
  - Exquisite selection mechanisms and highly trained personnel
  - Effective reward systems
  - Continuous training
  - Frequent process audits and continuous improvement efforts
- HROs have distinctive properties including:
  - An organization-wide sense of vulnerability
  - A widely distributed sense of responsibility and accountability
  - Widespread concern and pessimism about misperception, misconception, and misunderstanding that is generalized across tasks, operations, and assumptions
  - Redundancy and a variety of checks and counter checks
  - A climate and culture of trust and respect
  - Heedful coordination among people/units both upstream and downstream
  - Habits of thought and action aimed at:
    Examining failure as a window on the health of the system
    Avoiding simplified assumptions about the world
    Being sensitive to current unfolding situations
    Developing resilience to manage unexpected surprises
    Locating expertise and creating mechanisms for decisions to migrate to those experts

HROs possess highly trained personnel, continuous training, effective reward systems, frequent process audits, and continuous improvement efforts. But, more distinctively, the most highly reliable organizations are characterized by organizational processes and practices that foster an organization-wide sense of vulnerability; a widely distributed sense of responsibility and accountability for reliability; widespread concern about misperception, misconception, and misunderstanding that is generalized across a wide set of tasks, operations, and assumptions; pessimism about possible failures; redundancy; and a variety of checks and counter checks as a precaution against potential mistakes. In part, these distinctive capabilities emerge from two complementary logics to which we now turn.

Two Approaches to Safety Management

Broadly speaking, complex organizations pursue two basic logics to manage risks and achieve safe and reliable (i.e., continually error free) performance. Wildavsky [23] contrasts these logics and Schulman [12] analyzes them as they pertain to health care. The first logic is one of anticipation/prevention. The second logic is one of resilience/containment. We outline these two basic orientations in the following paragraphs.

Anticipation/prevention. Advocates of anticipation suggest that errors can be eradicated or precluded—that intolerance (e.g., zero defects) of preventable harm is desirable and achievable [24] by using tools of science and technology to better control the behavior of organizational members to perform safely and effectively. This requires organizational members and other stakeholders (e.g., public, regulators) to define and identify the events and occurrences that must not happen, identify all possible causal precursor events or conditions that may lead to them, and then create a set of detailed operating procedures, contingency plans, rules, protocols, and guidelines for avoiding or preventing them. A commitment to anticipation and prevention removes uncertainty; reduces the amount of information that people have to process, which potentially decreases the chances of memory lapses, judgment errors, or other biases that can contribute to

crucial failures; provides a pretext for learning; protects individuals against blame; discourages private informal modifications that are not widely disseminated; and provides a focus for any changes and updates in procedures [25].

The logic of anticipation/prevention is based on Perrow's [26] notion of second-order behavioral controls. Perrow [26] classifies control mechanisms into first order, second order, and third order. First-order controls such as direct supervision, inspection, or surveillance, although they are expensive and reactive, are straightforward and obtrusive means for controlling behavior. Second-order controls (i.e., bureaucratic controls) such as standardization, specialization, and hierarchy are more efficient than direct controls and are less obtrusive. In theory, they work by reducing the range of stimuli people have to attend to so that they have fewer opportunities to make decisions that maximize personal interests rather than the organization's interests. Third-order controls, also known as control through culture (to be discussed more fully later in this chapter), are fully unobtrusive and work by controlling the cognitive premises (e.g., norms, assumptions, values, and beliefs) that underlie action.

The idea behind second-order control is that consistent error-free outcomes will be produced in the future if people repeat patterns of activity that have worked in the past. In routine, stable, certain situations, where tasks are analyzable and repetitive actions can be identified and predictably will lead to desired outcomes, a logic of anticipation makes sense. Naturally this description fits some tasks, work roles, and work settings (e.g., laboratories, pharmacies) better than others. But, it may not fit all. Certainly, recent research demonstrates the value of behavioral routines (e.g., checklists) and standardizing work (e.g., [27]). But, in nonroutine situations it is sometimes impossible to write detailed operating procedures to anticipate all the situations and conditions that shape people's work. Moreover, even if procedures could be written for every situation there are costs of added complexity that come with too many rules. This complexity increases the likelihood that people will lose flexibility in the face of extensive rules and procedures. Thus, although compliance with detailed operating procedures is critical to achieving safe and reliable performance in many instances (e.g., checklists for pre- and post-procedural briefings, or for reducing infection rates), partly because it creates operating discipline, blind adherence to rules can sometimes reduce the ability to adapt or to react swiftly to surprises. Assuming that invariant operating procedures and routines are the only means through which safe outcomes occur conflates variation and stability and makes it more difficult to understand the mechanism of safe performance under trying conditions. Safety is broader and more far reaching. For a system to remain safe and reliable, it must somehow handle unforeseen situations in ways that forestall unintended consequences. That is, it must organize for transient reliability [17]. This means that it must continuously manage fluctuations in job performance, human interaction, and human-technology interaction, which necessitates capabilities for resilience/containment.

Resilience/containment. A logic of resilience/containment focuses on the ability to absorb strain, bounce back, and cope and recover from challenging or untoward events. It also reflects an ability to learn and grow from previous episodes of resilient action. Capabilities for resilience can be traced to dynamic organizing practices (which themselves should become habits [28] or routines [22]). These organizing practices enhance people's alertness and awareness to details so that they can detect subtle ways in which contexts vary and call for contingent responding. In other words, resilience works by increasing the quality of attention among the members of a unit, organization, or system as well as increasing flexibility and capabilities to respond in real time, reorganizing resources and actions to maintain functioning despite peripheral failures.

Particular organizing principles and a microsystem of "mindful" organizing practices provide the foundation for beliefs and actions in the safest and most highly reliable organizations. First, highly reliable organizations are preoccupied with failures. Through various practices such as pre- (and post) procedural briefings (see [29]) for example, they conduct proactive and preemptive

analyses of possible vulnerabilities, and pay close attention to identifying and understanding what needs to go right, what could go wrong, how it could go wrong, and what has gone wrong, and why. Second, highly reliable organizations avoid simplifying their assumptions about the world. They do this through practices that actively seek divergent viewpoints, seek to question received wisdom, uncover blind spots, and detect changing demands, for example through interdisciplinary rounding, purposely seeking additional "eyes" for particular actions or procedures, or using exacting communication protocols that highlight what to look out for during transitions [30]. As an aside, it is important to note that we aren't saying that organizations should not seek to streamline or reengineer unwieldy processes; rather we are highlighting the fact that when people coordinate their actions in order to communicate they tend to simplify their observations and discussions. Thus they miss a lot. To build a more complicated picture of the situations they face, highly reliable organizations try to complicate their understandings. Third, highly reliable organizations are sensitive to what is happening right now, how situations are unfolding. Their goal is to develop and maintain an integrated big picture of the current situation through ongoing attention to real-time information so that they can make a number of small adjustments to forestall the compounding of small problems or failures. They do this, for example, using huddles to preemptively assess current situations so as to identify vulnerabilities such as inadequate information, staff, or resource shortages in order to make adjustments before harm is caused [31]. The three principles discussed above focus on anticipation and prevention. Although highly reliable organizations seek perfection, they know they won't achieve it and develop skills for resilience, recovery, and containment.

Highly reliable organizations build resilience primarily by enlarging response repertoires, through ongoing training and simulation, varied job experiences, learning from negative feedback, and ad hoc networks that allow for rapid pooling of expertise [19]. And finally, the most highly reliable organizations improve capabilities for containment and recovery by seeking to understand expertise in their organization and develop flexible decision structures. Through understanding and locating pockets of expertise and creating mechanisms to shift decision making to experts when problems begin to materialize, highly reliable organizations increase the likelihood that capabilities will be matched with new problems and that emerging problems will get quick attention before they grow bigger [31].

In combination, these two approaches for achieving safe and reliable performance enable people and organizations to deal with inevitable uncertainty and imperfect knowledge. That is, as leaders and organizational members pay close attention to the social and relational contexts in which they work; as they continuously and habitually engage in everyday routines and practices and interact to develop, refine, and update shared understandings of the situations they face; and as they develop their capabilities to act on those understandings, they increase the likelihood that they will be able to prevent or avoid organizational mishaps (e.g., errors, adverse events) or will be able to mitigate and cope with them and their consequences as they unfold. In the following section we explore some recent evidence of the efficacy of these approaches to safe outcomes.

Organizational Determinants and Safe Outcomes: Some Evidence

Research exploring organizational processes and their effects on outcomes has grown over the past several decades. For example, the president and chief executive officer of the Joint Commission, Mark Chassin, and his coauthor Jerod Loeb [32] have suggested that organizing processes and practices have great purchase for enabling safer and more reliable health care. Theory certainly has grown, but empirical research testing theory and particular hypotheses such as hypotheses related to criterion measures such as employee behaviors (e.g., procedural compliance, reporting), patient and/or worker injuries, adverse events, or other outcomes (e.g., litigation costs)

has lagged. Still evidence is beginning to accumulate and we describe some of the findings below.

Knox and his colleagues [33] studied hospital obstetrical units and found that those with better safety performance and fewer malpractice claims were distinguished by particular organizational practices that included, among other things, specific protocols for running shift nursing reports and physician sign-outs and frequent "decision-to-incision" drills (pp. 27–28). Roberts and colleagues [34, 35] conducted a qualitative longitudinal study of a pediatric intensive care unit (PICU) and found lower levels of patient deterioration in the unit were associated with the introduction of particular organizing practices such as continual in-service training designed to help providers to interpret and question data and working hypotheses and collaborative rounding by the entire care team that enabled increased sensitivity and a clearer understanding of evolving patient and organizational situations. Finally, an action research study of five intensive care units by Hales et al. [36] investigated linkages between the introduction of particular organizing practices and multiple forms of costs and found evidence of a decrease in the number of negative incidents between a nurse and patient's family, a 50% reduction in the number of failed nurse supervisor inspections, and a slight improvement in patients discharged alive. However, for other costs (e.g., patient length of stay, cost per patient) there were no effects. Ndubisi [37] found that three processes aimed at care reliability, information reliability, and preemptive conflict handling were positively associated with hospital patient orientation, satisfaction, and, in turn, patient loyalty in a hospital setting.

Vogus and Sutcliffe [38] in a large-sample study of inpatient units similarly found positive benefits to particular safety organizing practices. Fewer medication errors occurred over the subsequent 6 months on units that proactively and aggressively engaged in activities aimed at collecting, analyzing, and disseminating information from errors as well as proactively checking on the unit's vital signs [38]. The negative association between safety organizing practices and medication errors was stronger when registered nurses reported high levels of trust in their nurse managers and when units reported extensive use of standardized care protocols. Earlier we mentioned research by Vogus and Iacobucci [19] that showed positive associations between bundles of organizing practices (e.g., selective staffing, extensive training, developmental performance appraisal, decentralized decision making), use of safety organizing processes, and performance reliability (e.g., reductions in medication misadministration and patient falls). Moreover, engaging in these coordinative practices appeared to enhance levels of trust and respect in communications and interactions.

To summarize, the above studies—consistent with findings from industries outside of health care—support the idea that particular organizational attributes and organizing processes positively influence safety and reliability. Other more limited studies, for example studies of checklists and preoperative briefings (e.g., [29]: 1115–1117), also suggest that with relatively little cost, these kinds of processes can have salutary effects on intermediate outcomes such as surgical flow disruptions, miscommunication events, and even reduced waste.

We now turn our attention to safety culture and climate. Safety culture and climates are, in part, by-products of organizational properties and interrelated organizing processes and practices. Thus it isn't surprising that culture is frequently mentioned in studies emphasizing organizational processes. Still, safety culture is often discussed with *in*sufficient richness so that we can understand how it works. In the following section we explore culture, how it is defined and shaped, and how it exerts its influence, and with what specific effects.

Safety in Health Care: The Role of Culture and Climate

Just as culture is used to explain the orderliness and patterning of much of our life experience, organizational culture is used to describe aspects of everyday life in organizations. Culture operates as a "medium of lived experience" ([39]: 1), a system of symbols and meanings that both enables and constrains social practice and action (e.g., [40, 41]).

Organizational culture is often defined as that which is shared—shared norms, values, beliefs, and assumptions—which may serve to guide behavior and action. We say *may* serve to guide behavior and action in part because people can espouse values, beliefs, and assumptions but not act on them [41, 42]. Consequently, culture is not an infallible form of behavioral control even though it is often alleged as a primary cause of myriad organizational accidents and catastrophes (see [43]). Even the strongest culture cannot eliminate all untoward events, especially in technologically complex and dynamic industries where things are not completely understood [9, 43].

If organizational members share behaviors, beliefs, values, and assumptions, the assumption is that they tend to adopt similar styles, modes of conduct, and perceptions of how the organization does or should function. But studies show that cultures are not monolithic and can vary widely within a single organization. In fact, there is extensive evidence that organization-wide integration, consensus, consistency, and clarity are rare and that it is just as likely that cultures are fragmented or differentiated ([42]: 537–538, [44]). These differences are not necessarily bad. They can be important and valuable organizational resources as they provide a diversity of perspectives and interpretations of emerging problems.

Safety culture refers to the shared values, attitudes, and patterns of behavior regarding safety (i.e., concern about errors and patient harm that may result from the process of care delivery) [10].[1] It is used to describe organizational cultures in which there is widespread understanding and acceptance that "safety comes first" and in which a majority of organizational members direct their attention and actions toward improving it [5]. Safety culture has been thought to be a subcomponent of organizational culture although there is growing controversy as to whether safety culture and organizational culture are indistinguishable. Experts recently have argued that safety cultures do not exist separately from their organizations; organizational culture influences safety ([40]: 2–25). Moreover, some scholars propose that safety culture, like organizational culture, should be normatively neutral and descriptive [43, 46]. However, as it is currently defined and used in research and practice, safety culture itself is seen as positive and "lead[ing] to increased safety by fostering, with minimal surveillance, an efficient and reliable workforce sensitized to safety issues" ([43]: 351). Yet, in doing so, it fails to encompass the complex relationship between an organization's culture and its safety performance ([46]: ix).

The related concept of *safety climate*, defined broadly as organizational members' socially shared perceptions of existing safety policies, procedures, and practices, reflects the extent to which leaders, through their own behaviors and through their organizational policies, value, promote, and reward safety relative to other competing priorities [47]. It is generally agreed that safety climate is an overt manifestation of safety culture: specific, identifiable policies and procedures that capture the surface features of culture. In other words, safety culture is expressed through safety climate, which is why in this chapter we use the terms safety culture and safety climate interchangeably.

Climate research is rooted primarily in a social psychological framework, whereas organizational culture is rooted in anthropology. Climate researchers generally use more quantitative approaches such as surveys, while culture researchers use more qualitative techniques such as in-depth ethnography. Current approaches to assessing safety culture in hospitals and other

[1]The concept of safety culture was virtually absent from the academic and popular literatures until the 1980s (although a reference to safety climate first appeared in a 1951 study examining an association between psychological climate and accidents in the automotive industry [45]). The concept of safety culture was given legitimacy by the International Atomic Energy Agency (IAEA) in a 1986 report on the Chernobyl accident. The US Nuclear Regulatory Commission in a policy statement on nuclear plant operations referenced the idea of safety culture again 3 years later. In March 2011, the US Nuclear Regulatory Commission approved a new "Safety Culture Policy Statement" in which the commission defined nuclear safety culture and articulated key traits of a positive safety culture.

health care organizations using questionnaires (e.g., surveys) are more appropriately thought of as assessing safety climate [48]. Questionnaire approaches are "only capable of sensing transient, surface features discerned from the workforces' attitudes to safety at a given point in time—a snapshot of the prevailing safety culture" ([49]: 657). Although safety climate data typically are collected at the individual level, some experts claim that climate is only meaningfully assessed at the subunit/group level or the organizational level as these levels reflect the effects supervisors/leaders have on safety [50].

How Does Culture Control and Develop?

If we think about culture as the "frames of reference for meaning and action, which encompass the skills, beliefs, basic assumptions, norms, customs and language that members of a group develop over time" ([40]: 79), we have a better idea of the mechanisms through which culture controls and unobtrusively guides behavior. Recall our earlier description of Perrow's [26] notion of third-order control—control of decision premises. The presumed mechanism is a kind of motivational component that relates to expectations about the consequences of particular behaviors (e.g., such as risk taking, procedure violation, or unsafe behaviors such as not washing one's hands, or not reporting errors). First-order controls such as direct supervision, inspection, or surveillance and second-order controls such as standard operating procedures are conventional means to directly control behavior. Control through culture, although hard to achieve, is necessary in complex decentralized systems and organizations, and especially when work is nonroutine, less analyzable, and uncertain, as it is for many professional disciplines, such as health care. In organizations with strong safety cultures, there is "tight social coupling around a handful of core cultural values, and looser coupling around the means by which these values are realized" [22]. In this way, culture is a way of seeing and acting that is simultaneously a way of not seeing and not acting ([51]: 284), which highlights the fact that culture can be a source of blind spots [52].

Culture is acquired through social learning and socialization processes; it is learned over time as groups solve problems. Strong cultures are also a function of the stability of a group as well as the length of time that it has existed. From a vast array of safety culture studies we know that effective cultures are enabled by organizational leaders through their actions and the management systems they create, are enacted by organizational members when they put the organization's safety policies and procedures into practice, and are continually shaped and elaborated over time [5]. Specifically, cumulative research findings suggest that safety cultures are promoted by four factors that we consider below.

First and foremost, safety is thought to be a function of management actions, particularly the commitment to safety demonstrated by senior management (top leaders as well as direct supervisors). This commitment is expressed in the goals leaders set, where they focus their attention, and other communications and information that signal what is and is not important, and how organizational members should act and interpret events. Management commitment to safety is also expressed in other management actions such as resource allocations, technology (including personal protective equipment availability), training expenditures, systemic policies and procedures (e.g., care pathways), and information and reporting system design. Notice that these latter behaviors are aimed at creating a more or less comprehensive safety management system, which is a broad dimension that fuels culture. Second, safety culture is thought to be a function of widespread shared attention to and concern for possible hazards and their impacts upon people (including work pressure hazards such as lack of staffing and time to complete tasks) and widespread information about how these hazards are being handled. Third, safety culture is a function of realistic and flexible norms and rules about handling hazards. And, fourth, culture is enabled through continual reflection upon practice through monitoring, analysis, and feedback systems, and continuous process improvements.

A close examination of the above elements might suggest that enabling a safety culture is a top-down process, but this ignores the criticality of diffuse, ongoing organizational discourse and communication regarding the way "safety is handled around here" ([52]: 188). Shaping safety culture is as much a bottom-up process as it is top down. It flows from employee sensemaking of the overall pattern of signals sent by organizational leaders as well as their sensemaking of the organization's operating system (e.g., technology, practices, sets of rules and policies) to fathom the hidden underlying core values and assumptions that constitute the organization's culture [53]. As employees make sense of discrepancies between espoused and enacted priorities (e.g., differences in declared organizational policy and informal supervisory practice), they discern the collective unconscious values, beliefs, and assumptions [41]. The ongoing process of the social verification of culture shapes role behavior considered appropriate and subsequently enacted [53]. Safety culture then, as we noted earlier, is a dynamic process that is continually supported and shaped, which makes it hard to control.

Safety Culture and Outcomes: Some Evidence

We noted earlier that empirical evidence linking organizational attributes and safety outcomes has begun to accumulate, although outcome studies are relatively uncommon. The same is true for research linking safety culture with safety outcomes (e.g., patient and organizational outcomes, and employee behaviors). Although evidence is sparse, some exists and below we highlight two reviews of recent findings.

Flin and colleagues [54] reviewed 12 health care studies to better understand the dimensions assessed by safety climate surveys in health care and their psychometric properties. Three findings stand out. The first is that researchers have paid rather limited attention to the psychometric properties of safety climate measures (e.g., validity and reliability). If health care managers are to rely on these indicators as a valid assessment of their safety culture, good measurement is critical. The second is that there is considerable thematic overlap between the instruments used to measure safety climate in health care and instruments used in other industries. In other words, the core dimensions commonly assessed in health care are consistent with how safety culture is studied and assessed in other industries (and are similar to the dimensions that we discussed earlier). Finally, with just a couple of exceptions (see [55, 56]), few studies have examined the relationship between work unit safety climate and patient outcomes such as rates of adverse events. Still Flin et al.'s analysis provides growing evidence of significant associations between safety climate scores in health care and workers' safety behaviors (again consistent with studies in industries outside of health care).

DiCuccio [57] more recently reviewed 17 studies exploring associations between safety culture and "nurse-sensitive" patient outcomes (p. 135) (e.g., assessments of patient/family satisfaction or assessments of direct patient safety outcomes such as falls, medication errors, mortality). The findings show that progress is being made in terms of measurement and method—both are becoming more rigorous and systematic. However, studies linking culture and outcomes still are sparse and there is a dearth of evidence supporting statistically significant associations between safety culture and outcomes. This suggests, all in all, that the state of safety culture research in health care is in its nascent stages and there is much work to be done. Still research outside of health care suggests that safety culture matters. This state of affairs may signal that researchers might want to focus their efforts on developing and testing middle-range theories—that is to develop and test models that aim to better understand the underlying more proximal mechanisms rather than distal outcomes. Given the complexity of health care systems, that may be where the purchase is.

Implications

Safety in health care is both elusive and challenging. Safety demands seeing what is not there, an accident in the making [58]. It is an "ever-

receding chimera, observable only when it ceases to exist" ([43]: 395). This makes it difficult to manage because people often don't know how many mistakes they could have made but didn't, which means that they have at best only a crude idea of what produces safety and how safe they are. Safe outcomes are also constant, which means that there is nothing to pay attention to [11]. This complicates learning because system safety feedback is often discontinuous and indirect. It is discontinuous because recorded accidents, incidents, and even near misses are relatively rare events and indirect because these data only reflect a system at a moment in time rather than necessarily indicating its intrinsic resistance to operational hazards [59]. As a result, safe performance relies on making the unthinkable cognizable, the invisible apparent such that accidents in the making can be more readily detected, and producing a "dynamic nonevent" through patterns of practice that shape perceptions, conceptions, and understanding that permit contingent responding.

Practically speaking, in health care, just as it is the case in just about all organizations, service and production goals may compete or may be perceived as competing with safety [60]. Production is often seen as an acute problem needing to be addressed immediately, whereas safety is a more chronic concern [61]. When safety concerns are chronic, it is easier for complacency to set in and resources to be diverted to more pressing concerns. Moreover, the champions of safety are often external organizations (regulators, social movements, media, public) or safety specialists who may be seen as interfering with (and not understanding) the legitimate service and production work of the organization [60]. These factors make the achievement of safe and reliable care even harder. That is why enacting recurring organizing processes and actively shaping culture are crucial. They work together to overcome inertia and complacency and avoid the practical drift away from safe practice. The common thread in "safe" cultures is intelligent wariness and the commitment and motivation to enact daily behaviors and activities that increase mindfulness and keep complacency at bay.

Conclusion

In this chapter we have explored organizing and culture as two means to attack the safety problem. We have tried to show that although some consider these to be all-purpose solutions, they are not infallible. Thus it is critical to understand that you don't get safety behind you. Still, organizations, their units, and their members that organize in particular ways repeatedly and continually are likely to achieve greater safety and reliability than those organizations that don't, in part because of the binding safety cultures that they create through the enactment of these processes and associated activities. If we take seriously the idea that the only realistic goal of safety management in complex health care systems is to develop an intrinsic resistance to its operational hazards, our perspective provides insight into how to foster this intrinsic resistance. Studies showing the efficacy of organizing and culture for medicine and health care are in their nascent stages, but evidence is building to suggest that these ideas are worth paying attention to.

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The Role of Architecture and Physical Environment in Hospital Safety Design

12

Charles D. Cadenhead, Laurie Tranchina Waggener, and Bhargav Goswami

"Architectural space, however large or small, joins and then bends attention to new thoughts."

—Ann Cline, Architect

Introduction

Surgical programs vary greatly by size of hospital and type of services provided. A small rural hospital is very different from a very large, tertiary teaching hospital in an urban setting. This chapter attempts to target the middle ground—not the rural hospital, and not the largest hospital. Elements of both are very interesting and provide learning opportunities for each other; however, including the full range of programs with all subtle differences would warrant a book unto itself.

A Little History and Modern-Day Statistics (Figs. 12.1 and 12.2)

Surgery, as a topic of healing, is found in ancient illustrative images and texts from China, India, and Greece. Early Europe contributed to the field starting during the Age of Enlightenment. But what we think of as modern surgery has largely been made possible by two significant mid-nineteenth-century discoveries. The first was alleviating pain and the second was infection control. Without these advances the science of invasive surgery could not have taken place. Much of the design of contemporary surgical facilities is about these two topics.

Pain control, now thought of as anesthesia, began to change the face of surgery in the 1840s with the discovery of chemicals such as ether and chloroform. Until this time, surgeries were limited to quick procedures causing terrific pain to the patient. Indeed, the shock of the procedure and loss of blood could do more harm than the act itself. These new chemicals allowed operations to be longer and more invasive, and therefore educating the surgeon further in the use of surgery to cure certain maladies.

Some 20 years later, Joseph Lister, a British surgeon following research done by the French chemist Louis Pasteur, found that by cleaning his instruments with carbolic acid he could reduce the incidence of gangrene. Following this, he further realized the importance of using sterilized instruments, leading to the use of sterile instruments and materials in operating theaters. He introduced the steam sterilizer, and enforced handwashing and, ultimately, the wearing of

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Fig. 12.1 The Old Operating Theatre, London, UK (Photograph by Mike Peel)

Fig. 12.2 New Hybrid Operating Room, Rome, Italy

gloves during surgery. This, combined with anesthesia, made possible the modern surgical programs we know today.

In 2012, there were 36.5 million hospital stays in the USA. Of these, about 22 % were surgical stays, or approximately eight million. In 2011, there were over 15 million operating room procedures performed in US hospitals. The 2011 average hospital cost for all stays was $10,600 per stay; the average hospital cost for a surgical stay was $21,400, about twice that of the overall average. Surgery is an expensive service to provide and requires a disproportionate amount of a hospital's budget. It also has the potential to be

the greatest revenue and profit generator of all service lines. For this reason, if no other, doing it well, doing it safely, is very important to those that provide the skills and manage the service.

The Surgical Suite

Program Building Blocks

All surgical suites are made up of the same basic programmatic areas. They vary in design approach, hospital attitude toward space, cost, square footage allocation, and regulatory interpretation.

1. Public areas (waiting, reception/business, family amenities)
2. Preoperative area
3. Operating and procedure rooms
4. Postanesthesia care unit (sometimes referred to as the PACU or recovery room)
5. Phase 2 recovery area
6. Staff support areas (Fig. 12.3)

For preliminary planning, Fig. 12.4 suggests what might be expected in departmental gross square feet (DGSF) per operating room (OR) for different types of hospitals or outpatient surgical centers. These DGSF figures include all the rooms that make up the seven programmatic areas listed above, plus the circulation required to connect these areas. Design approach, which will be discussed further, also affects DGSF/OR. Not included in the DGSF area are elevators, stairs, outside walls, or engineering systems.

In general, these facility categories differ in expected surgical case acuity and specialties, equipment technology needs, staff numbers, teaching programs, and, possibly, research activities. Competition between hospitals for physicians and patients can impact square footage in the form of spacious, hospitable lobbies, and family-centered amenities.

Comparing four US hospital surgical departments in greater detail, Fig. 12.5 describes the total square footage, distribution of spaces by the seven program areas, surgical procedure numbers, and design layout. Two are located in the northeast and two are located in the south. These hospitals vary in when they were built and how they have expanded over the years. This comparison highlights regional responses to programs and how programs evolve over time.

With adequate data in planning a new surgical suite, the purpose of comparing numerous similar surgical programs is to evaluate the overall size of the department and the distribution of spaces within it against programs offering similar services. It is a quick way to identify areas that should be further assessed. In such an exercise, one may identify ORs that are smaller than expected, or circulation that is inadequate in contemporary surgical suite planning. These comparisons, when conducted in early planning, illuminate areas warranting further discussion or might serve as a final cross-check, validating that all process flow issues have been addressed sufficiently.

Surgical Suite Organization and Design

As with complex puzzles, there are numerous organizational plan layouts used in surgical suite design. Within bounds, there is no wrong or right plan. Architects and medical planners have preferences in what they do, as do surgeons and staff in their own work. For programs of differing sizes, characteristics, and regional locations, we have successfully designed surgical suites using virtually all possible configurations. One layout does not fit all, and the designer should take care not to impose a predisposition on every new client. Building consensus with multiple users of the surgical suite is very important (physicians, nurses, techs, administration, facility management, and others) [1]. We have found that frequent communications with all involved, and early participation in option exploration, is critical to completing design with a hospital team that endorses and supports the project. Planning work sessions, something we call "gaming" (Fig. 12.6), can bring all stakeholders to the table. This method uses nontechnical, non-drawing methods to encourage all to participate in the creation of their future workplace.

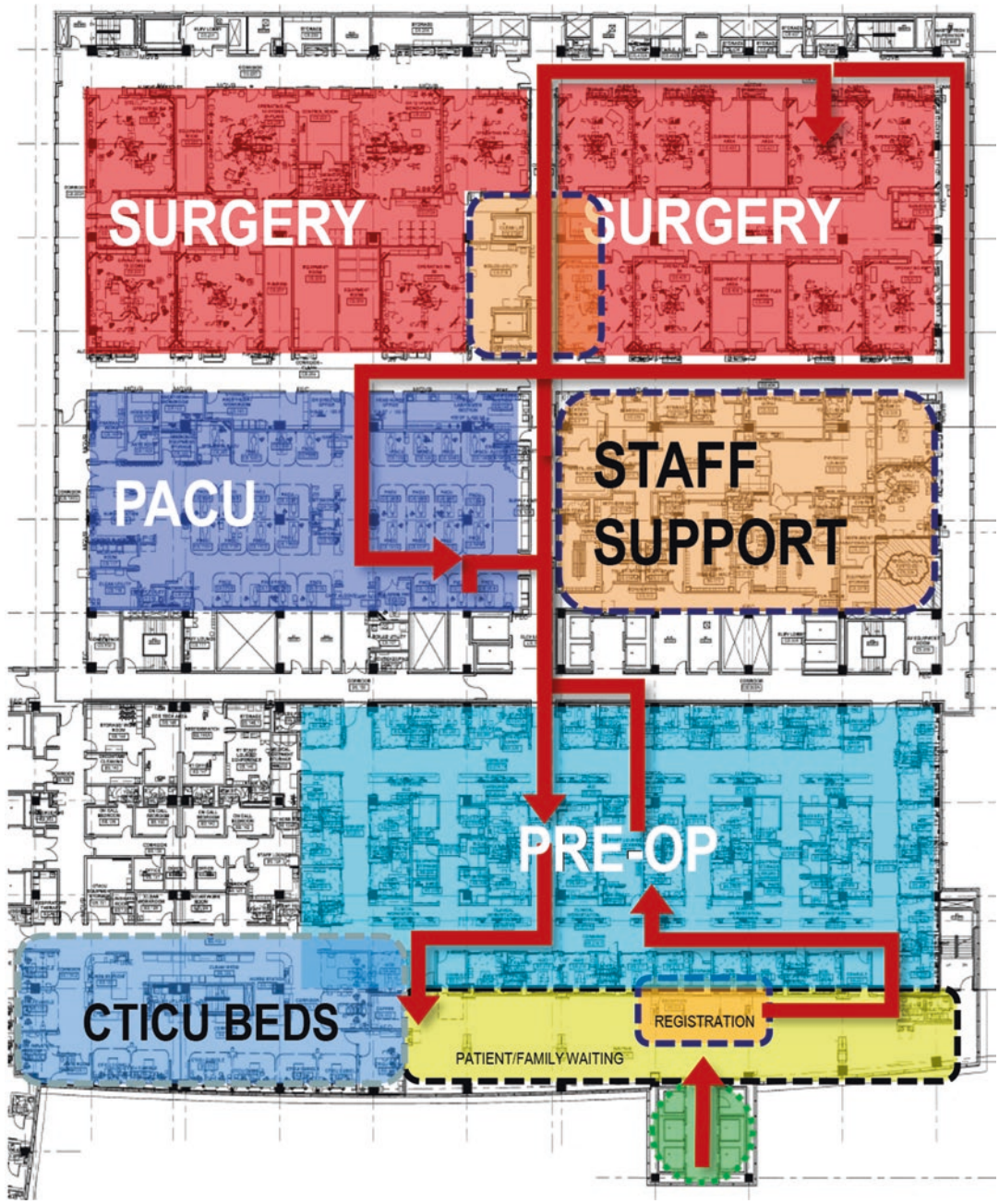

Fig. 12.3 Surgical program blocks (courtesy of WHR architects)

AMBULATORY SURGERY FACILITY	COMMUNITY HOSPITAL	REGIONAL HOSPITAL	ACADEMIC MEDICAL CENTER
> 3,000	3,500 – 4,000	4,000 – 4,500	> 4,500

Fig. 12.4 Departmental gross square feet per operating room for total departmental size calculation (courtesy of WHR architects)

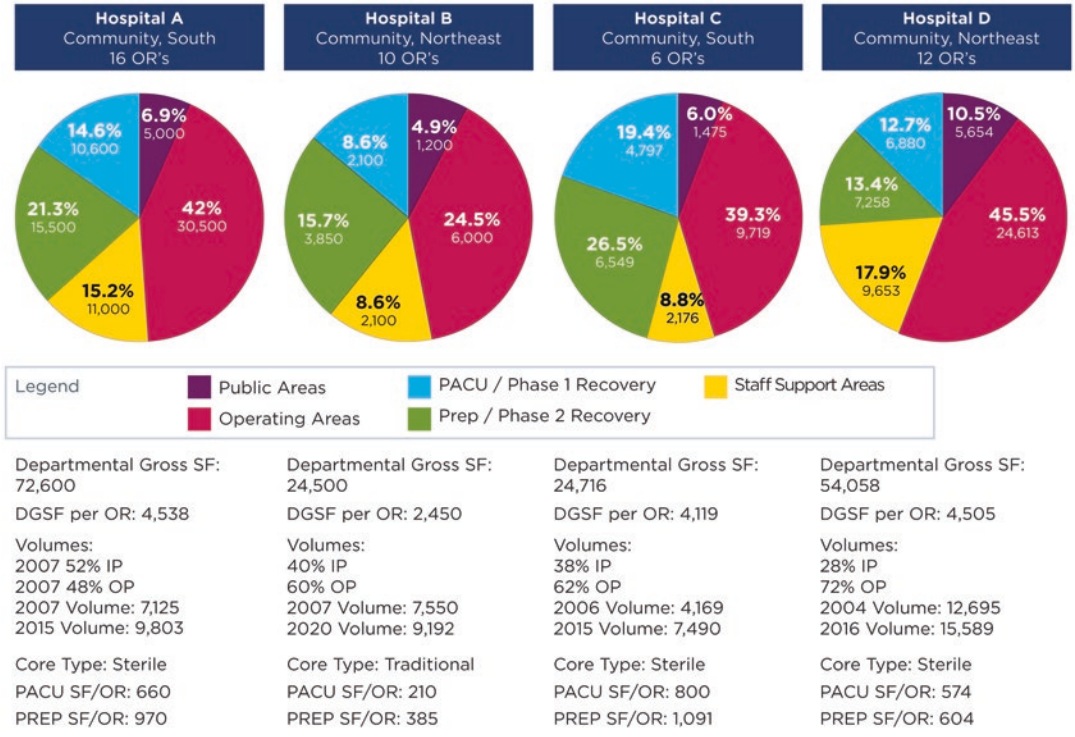

Fig. 12.5 Allocation of square footage by function within department (courtesy of WHR architects)

Fig. 12.6 Gaming work session (courtesy of WHR architects)

Suite Layouts

There are three conventional suite layouts. Each has been used, with various changes and combinations over the decades, most with a high degree of success.

1. First, and perhaps the one that has been in use the longest, is called a *traditional layout*, or a double-loaded corridor plan. This is similar, in concept, to a hotel corridor with doors on both sides (hence "double-loaded"). While currently not seen so often in the USA, this shape and layout are currently used in Europe where daylighting regulations require all rooms where people work to have direct access to daylight. The wings in European hospitals are narrow, as compared to the large treatment blocks seen in the USA, to allow for this daylighting. This does mean that surgical suites can become long, requiring greater travel distances.
2. Second, referred to as a *pod design*, groups ORs by specialty. Supporting spaces, such as sterile supply, may be to the rear of the suite, moving clean materials to the ORs and returning soiled materials after cases are complete. Preoperative and PACU spaces may be located to facilitate entering patients presurgery, and departing patients postsurgery.
3. Third, referred to as a *sterile core design*, or racetrack, arranges ORs in a loop around a sterile supply room. In this manner, sterile supplies can move directly into the OR as the next case is being set up [2]. This reduces the movement of sterile carts in congested corridors. In large suites, either the sterile core becomes very long or it is broken into several sterile cores with fewer ORs around it.

New Layouts and Flow

A somewhat new surgical suite layout has evolved out of healthcare's interest in "*lean process*." Simply described, the patient's movement is one-way, or linear. They do not return to a space previously used. In theory, this is to increase efficiency and throughput, and enhance the patient experience (Fig. 12.7).

Fig. 12.7 Plan of a lean surgical suite (courtesy of WHR architects)

Another change in this plan type is the inclusion of staging rooms. Located outside of each OR, this allows scrubbed technicians and nurses to set up tables for the next case while the previous case continues [3]. This is thought to reduce room turnover time and improve throughput (see **A**, Fig. 12.7). Flow station rooms are also added outside of each OR as a place for surgeons to do postoperative documentation and prepare for the next case (see **B**, Fig. 12.7). There are still points of traffic crossings and walking distances may not actually be shorter than in other layouts.

Suite Layout Characteristics

Surgical suite layout characteristics, or attributes, generally fall into the following categories. Each layout organization has advantages and disadvantages, and no layout will be perfect.

1. Flows and circulation (patients, staff, materials; mixed, segregated)
2. Access (by user) and travel distances (sensible access and connection; short distances from origin to destination)
3. Specialty grouping vs. standardized rooms (centralizing alike rooms; standardizing as many rooms as possible)
4. Flexibility and growth (accommodation for change; preplanned ability to expand)

Public Areas

Public areas serve many different populations—the arriving patient and accompanying friend or family member, the hospital staff receiving the patient, hospital business staff related to financial and consent matters, seating for those waiting, and amenities ranging from consultation rooms, toilets, nourishments, educational resources, and access to computers or workspaces.

It should be noted that initial impressions affect the opinion of safety and quality expectations of everyone. If the built environment is well organized, appears clean and well maintained, and is pleasing to the eye, the patient will begin their personal experience with a better impression and higher expectation [4]. The same is true for staff. The environment delivers a message [5] (Fig. 12.8).

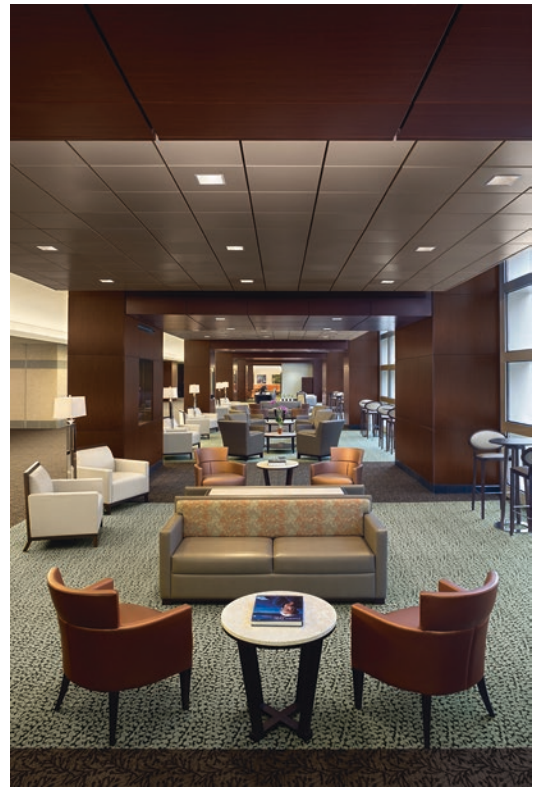

Fig. 12.8 Surgery reception and waiting lounge, Houston Methodist Hospital, Houston, TX (courtesy of WHR architects)

Preoperative Areas

For those working in hospitals and surgical programs, it is easy to forget how anxious and concerned the patient and family can be. They do not know what to expect and their image of what they are going to experience may be based on popular television shows or movies. If they are the patient, they may be whisked off, stripped of their clothes and belongings, poked and examined, asked questions by multiple people they

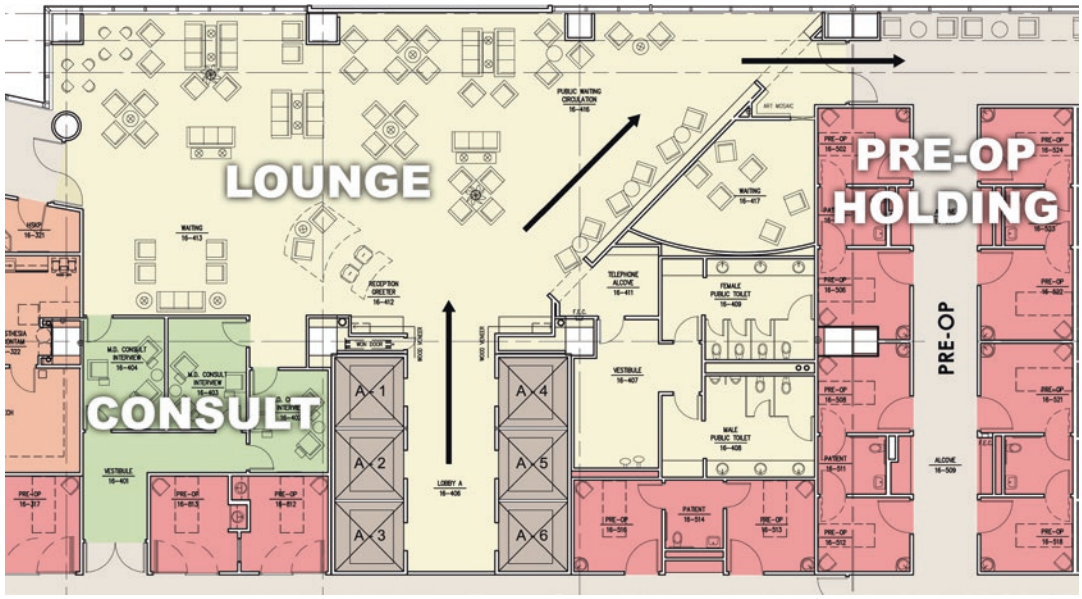

Fig. 12.9 Partial plan of a pre-op suite, Houston Methodist Hospital, Houston, TX (courtesy of WHR architects)

have never seen before, and medicated. If they are unlucky, all this happens in front of other unfortunate patients encountering this same experience.

To a large degree, the hospital's culture and attitude toward design can mitigate the effect of these experiences. Being guided through the preoperative path by a caring and empathetic individual is reassuring. The built environment can also improve this experience. Private preoperative rooms have shown to provide privacy, better communications, and comfortable space for family, providing the patient with dignity at a time when they are feeling vulnerable [6] (Fig. 12.9).

Operating Rooms

To the surgeon and certain members of the OR staff, this is the center of the world. The experience of the provider and the impact on the patient are highly influenced by the environment and the human factors under which they perform [7, 8]. It is where they spend long hours, and endure standing in uncomfortable surgical garb under lights, doing precise work. More frequently now, they may be sharing the room with a robot and/or colleagues of different specialties in hybrid operating rooms. They can rearrange the room, control the intensity and color of lighting, and speak real time to fellow surgeons or a medical class across the corridor or across the globe. Pathology reports and images are called up for integrated display on large, crystal-clear screens around the room.

Operating Room Size

Not very many years ago, operating rooms were considered large if they exceeded 400 ft^2. In recent years the size of ORs, while always a point of much debate in design sessions, has appeared to stabilize with more rational discussion around the equipment and staff numbers to be accommodated [3]. Today, general ORs range around 550 SF to 650 SF, while hybrid ORs, containing multiple fixed equipment setups, may be as large as 1000 SF [9] (Fig. 12.10).

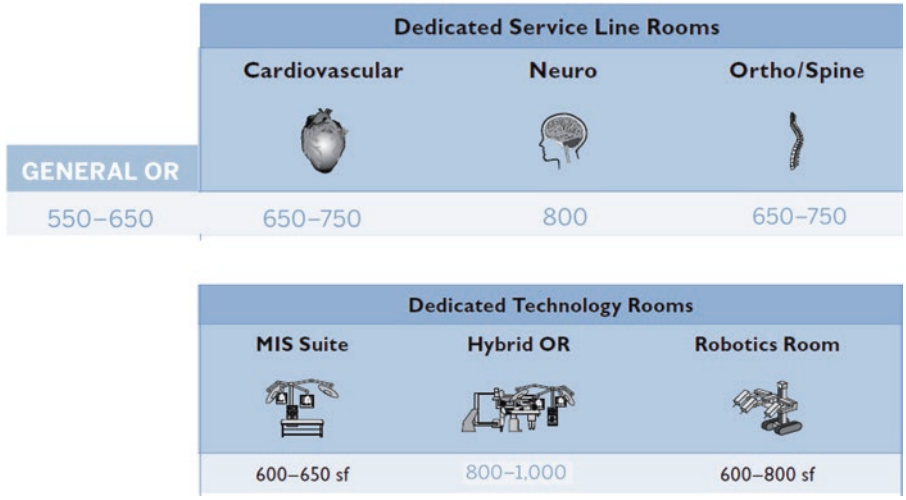

Fig. 12.10 OR sizes by specialty, based on Advisory Board findings

Fig. 12.11 Houston Methodist Hospital, OPC OR desk (photograph courtesy of WHR architects)

Communications in the OR

In addition to integrated information system display, the value of improved communications in generating better situational awareness and coordination among OR staff has been identified [10]. We have designed several approaches to accommodate documentation staff workspace during cases and have seen other designs while touring OR suites around the country. Two are included here. The Methodist desk (Fig. 12.11) is designed in a curved shape and is same handed in all ORs within this suite. The second (Fig. 12.12) is a tee-shaped desk adapted into a large OR. The shape allows the occupant to slide in and out easily. Designs for two staff members that encourage communication, meeting, and computer access during surgery [11] create environments that create more collaboration and trusting settings.

Fig. 12.12 OR desk (courtesy of WHR architects)

	1	2	3
Specialty ORs	Allows advanced interventional—but potentially low volume—procedures for one specialty	Relevant to one specialty; can lead to resentment from other surgeons	Facilitates currently popular procedures or techniques that may fall out of favor
Universal ORs	Allows advanced interventional procedures for many specialties	Encourages collaboration between specialties	Provides flexibility for future clinical innovation

Fig. 12.13 Advantages of universal OR design (WHR architects)

Universal ORs

The increase of OR sizes and rapid changes in surgery have led to the concept of developing the universal OR, one that can accommodate multiple equipment arrangements and meet the needs of multiple case types. The cost and disruption of renovating ORs are very expensive. To some, the incremental initial cost is well worth the while (Fig. 12.13).

Planning for Change

For many of the reasons that universal ORs are of interest, preplanning for OR change is beneficial. If planned during design, the steps needed for smart flexibility serve are reasonable anticipation of the future. Figure 12.14 illustrates preplanning the conversion of ORs into interventional imaging rooms, connecting to surrounding ORs. This speeds up the future conversion and reduces cost.

Postanesthesia Care Unit

This is the critical care unit of surgery. In fact, many critical care units were originally surgery recovery rooms. Currently, most recovery rooms continue to be open bay spaces with curtains providing separation between patients. Primarily this space is the

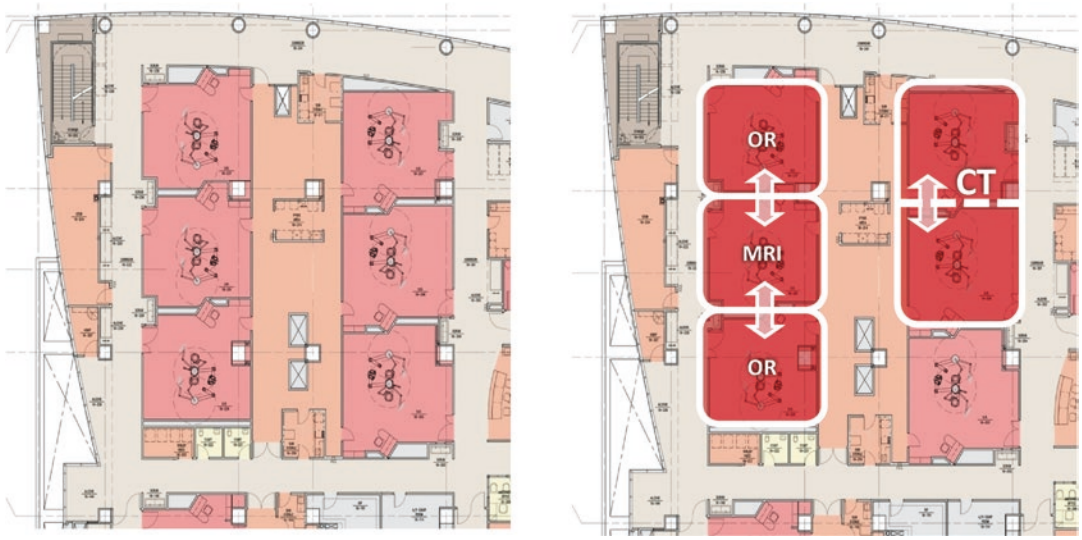

Fig. 12.14 OR planning for future change (WHR architects)

domain of the anesthesiology care team bringing the patient out of anesthesia after surgery. Once the patient is stable, the patient is moved to their hospital room or to stage 2 recovery until they are ready to be discharged home.

In large surgical programs, with adequate numbers of specialty surgery patients, postsurgical patients may be moved directly from the OR to a critical care unit for recovery. In some cases, these are specialty critical units matching the patient's type of surgery, e.g., a cardiovascular or neurosurgical ICU [12]. In this situation, it is not infrequent that the patient is cared for in a private ICU room (Fig. 12.15).

Fig. 12.15 An ICU recovery position (photograph courtesy of WHR architects)

Phase 2 Recovery

Most hospital surgical suites perform both inpatient and outpatient surgery. When outpatient surgery is included, a Phase 2 recovery room is required. This area is to be connected to the PACU, but must be a separately identified area. The hospital has the choice of using open bays, cubicles, or private rooms for this use. If the hospital uses private rooms for preoperative patients, it is possible to use these same rooms for Phase 2 recovery. This allows privacy for the recovering patient and room for a family member to join them. The private room brings the same benefits as described under the preoperative area discussion above.

Fig. 12.16 A Surgical Staff Lounge, Houston Methodist Hospital, Houston, TX (courtesy of WHR architects)

Physician and Staff Support Areas

Support space for surgical staff is very different, and much improved over the years regarding provisions for quality downtime and access to nature. Creating environments to support this highly skilled group is recognized as important to staff wellness and improved operations (Fig. 12.16). The staff lounge in the photograph illustrates many decisions initially not obvious. It suggests a series of decisions made by hospital administration to locate this lounge on an outside window wall with great views to the surrounding medical center and natural light, both providing positive distractions and respite from the OR. In addition to a delightful environment, nourishment is provided and comfortable furniture is available for relaxation. Adjacent to this lounge, located only steps from the OR, are education spaces used by all surgical staff, physicians, and fellows.

Workspace for surgical staff is another opportunity to create positive places for people. The following image illustrates a work environment located so that those needing quiet, hence the glass, can still have visual access to an outdoor rooftop garden. At first glance, you wouldn't realize that this garden is located four levels above ground (Fig. 12.17).

The Details: Design Thinking, Processes

Understanding the Needs of the Patient

Listening to the voice of the customer, the patient, today's hospital administrators, front-line practitioners, and healthcare interior designers learn what patients expect in their hospitalization. Survey reports reveal that patients need to be heard, to rest, to have access to their health information, and, understandably, to be discharged without hospital-acquired conditions [13]. Publicly available data reveals how patients perceive not only the physical environment but also the providers who work in the healthcare environment based on the physical surroundings and the demeanor of the front-line practitioner [13]. Never events, a term introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), referred to preventable harm episodes such as wrong-site surgery as episodes which should never occur [14]. This term was introduced in response to the groundbreaking IOM report, *To Err is Human* [15]. Sixteen years after this report, patients continue to experience preventable harm and often struggle to have their voice heard, and

Fig. 12.17 Entry to administrative services (photograph courtesy of WHR architects)

costs continue to rise. Early communication between hospital leadership and the design team regarding mission, vision, and goals and process improvement solutions will empower the architect to plan for the safest and most reliable environment [16]. Additionally, early communication is essential for the general contractor to develop a construction budget with any accuracy, and is crucial for goals and evidence-based design solutions to be realized in the built environment.

Understanding the Needs of the Perioperative team

Healthcare architects and interior designers must also listen and understand with great depth the voice of the other customer: the multidisciplinary team of perioperative services. Architecture firms that are the best equipped to apply evidence-based design strategies will need the perioperative service-line goals embraced by the organization. Consequently, the time to review and revise operational information, patient throughput, and workflow strategies should be discussed in process improvement discussions rather than in the design phases of the physical environment according to the Commonwealth Fund 2013 publication [17]. Understanding the systems approach to planning for a safe workspace is essential to fully understanding the operational as well as the environmental causal factors to adverse events [17]. According to Carayon et al. [18], most errors in patient care arise not from the solitary actions of individuals but from conflicting systems in which multiple people interact. The built environment creates the setting and physical environment to support safer, reliable, and exceptional service [19]. A poorly designed perioperative service-line environment can complicate workflow and introduce inefficiencies creating patient harm and dissatisfaction [19, 20]. Application of design thinking in the predesign phase offers the opportunity for innovative strategies in addressing safety, efficiency, and value [21].

Lean Design

Pre-design operational improvement using the Lean Six Sigma process improvement techniques can significantly change design requirements for spaces and square footage in key departmental areas [22, 23]. Engagement in such techniques often results in a reduction in square footage which results in added value. When reviewing patient

Selected Proposed Goals	Room Type	Environmental Attributes	Environmental Performance
Patient & family engagement	Patient access offices, PACT* Offices, clinic exam rooms	Flooring facilitates use of mobility devices; furniture layout offers eye to eye communication; furniture offers seating for patient advocate. Illumination provides accuracy in various tasks per various age groups. Acoustical privacy & speech recognition.	Flooring surface texture offers slip resistance yet ease of mobility for mobility devises. Arm chairs facilitate safe sit – to – stand for elderly. Furniture configuration offers seating arrangements at a table or desk. Indirect lighting follows IES** and EHFS*** recommendations for screen based tasks, and paper based tasks including reading of medication labels. Ceiling tiles >.85 NRC rating; soft surface flooring in non-clinical spaces.
Consultation			
Evaluation			
Assessment of discharge resources			
Medication reconciliation			
Consent process			

Fig. 12.18 PSH-proposed preoperative goals and recommended design elements

flow from the patient experience perspective, there is an opportunity to identify potential bottlenecks in the patient flow and the identification of breakdowns or barriers in the continuum of care. Design optimally will then follow process improvement strategies [24].

Working Definitions

For the purpose of addressing patient safety, patient experience, and human performance, this section uses the following working definitions:

1. *Patient safety*—reduction of environmental elements correlated with falls, infection transmission, and medication errors
2. *Patient experience*—satisfaction with and positive perception of privacy, noise, communication, environmental cleanliness, service, and personal safety
3. *Human performance*—prevention of human error through knowledge and specification of furnishings and surface finishes which support ergonomics and human factors, facilitating a level of cognitive and technical performance, robust communication, and teamwork

Using the proposed, patient-centric perioperative surgical home (PSH) phases as a framework for design considerations [25], this section will propose environmental attributes relative to facilitating service-line issues articulated in the literature [25, 26]. See Figs. 12.18, 12.19, and 12.20.

Selected Proposed Goals	Room Type	Environmental Attributes	Environmental Performance
Reduce case delays by medically optimizing patient.	Patient access offices, PACT*, Pre-op/ Prep/ Hold, OR scheduling department offices, OR Control stations, collaboration space as indicated by perioperative team.	Infrastructure required for robust integrated electronic medical record to provide continuity of goals and care plan, established in preoperative phase.	Flooring and ceiling materials should to reduce ambient noise levels to enhance human performance. Ceiling tiles >.85 NRC rating. Task chairs, key board trays and modular furniture should be selected for compliance with ergonomics in addition to allowing for sit – to – stand work postures. Furniture configuration offers seating arrangements at work surfaces for planned collaboration efforts for patient readiness. Indirect lighting follows IES** and EHFS*** recommendations for screen based tasks and paper based tasks with small font sizes & poor contrast, such as medication labels.
Integrate an ambulatory and inpatient medical health record			
Enterprise – wide scheduling			
Standardized equipment	OR, Interventional procedure rooms, clean core, staging areas.	Standardized room elevations, standardized stocking processes.	Locations of supplies provides visibility and privacy for efficient and safe sterile picking without distractions.

Fig. 12.19 PSH intraoperative goals and recommended design elements

Preoperative Phase: Opportunity for Enhanced Communication

Admission department processes provide optimal time and location for care providers to obtain critical information regarding the patient's current medications, language barriers, level of education, and any functional activity limitations at home. This important information facilitates clear communication of the patient's needs throughout the care continuum and in planning and facilitating the patient's readiness for discharge and management for their needs at home or another level of care facility [27, 28]. This phase of perioperative services has historically been associated with long wait time and time-fragmented admitting processes. In 2003 the Institute for Healthcare Improvement (IHI) emphasized the need to improve patient flow and patient access processes to include smoothing of the flow of patients in and out of institutions, which would help to reduce wide fluctuations in occupancy rates and prevent surges in patient

Selected Proposed Goals	Room Type	Environmental Attributes	Environmental Performance
Practitioners follow specific and personal recovery plans	PACU, ICU or Acute Care Patient Room	Immediate access to electronic medical record. Access to clean supplies at bedside. Access to nutrition supplies. Patient fall precautions for patient egress from gurney. Patient room layout and interior finishes facilitate activities of multi-disciplinary team such as PT, OT, Pharmacy and Social Services.	PACU flooring and ceiling materials should to reduce ambient noise levels for patient comfort for human performance. Ceiling tiles >.85 NRC rating. PACU flooring surface texture addresses slip and fall and ease of surface cleaning. PACU task chairs, key board trays and modular furniture should be selected for compliance with ergonomics in addition to allowing for sit – to – stand work postures. PACU and Patient room lighting follows IES** and EHFS*** recommendations for screen based tasks, and paper based tasks, including reading medication levels. Patient room furniture configuration facilities face to face communication with allied health professionals: PT, OT, Pharmacy, RRT, Social Services, Dietitians, Case managers. Patient room furniture configuration offers seating arrangements at work surfaces for planned teamwork regarding for patient readiness.
Discharge readiness protocols			

Fig. 12.20 PSH postoperative goals and recommended design elements

visits that lead to overcrowding, poor handoffs, and delays in care, thus contributing to safety and quality of care [29]. Improved communication at this point in the patient journey has the potential for enhanced medical record accuracy and continuity of communication throughout the perioperative patient journey [27]. Responding to these recommended process improvement strategies has significant implications in planning and design of this important front door for patients and families, in particular the unplanned admission.

Multiple Points of Entry: Designing for Safety, Efficiency, and Comfort

Large academic medical centers often struggle with managing the multiple ways patients arrive for preoperative services. Given the multiple care pathways in which patients may enter a hospital, opportunities to standardize and streamline documentation, communication, and handoffs can be accomplished in tandem with new staffing practices in this area. Crucial conversations regarding integration with robust information technology services before expansion renovation and new construction are vital.

Multiple points at which patients and families can be more engaged for more robust communication and documentation preoperatively include:

1. Direct admit—unplanned from doctor's office
2. Admit from the ED—unplanned
3. Admit for elective surgery—planned
4. Same-day admit for elective surgery—planned
5. Admit via ambulance, patient on gurney from another facility—planned and unplanned

Facility design considerations worth noting for embedding patient safety at entry points noted above include the following:

1. What number of offices for enhanced, engaging, and private communication for patients scheduled for elective procedures
2. Size and quantity of private spaces and/or offices required to accommodate the slower process times for infirmed and elderly while providing space for engaging patient advocates such as adult children
3. Means for safe boarding of patient arrivals on gurneys via ambulance (from nursing homes)
4. Waiting accommodations of the contagious and noncontagious patients in addition to the cycle time associated with the assessment of the unplanned admission
5. Planning considerations for robust IT for continuity of patient information throughout continuum of care

Interior Architecture and Design Considerations

Surface performance characteristics during preoperative phase include the following:

Patient Safety

1. Hard surface flooring—surface texture and door thresholds should offer resistance against slips, trips, and falls. Surface gloss finish should provide minimal glare and reflectivity from ceiling-mounted ambient light sources [30].
2. Soft surface flooring—surface density and pile height should facilitate use of mobile devices while offering postural stability for elderly gait patterns [31].
3. Lighting—points of medication prep and administration should include task lighting per recommendations of the Human Factors and Ergonomic Society of North America in addition to design options reducing interruptions of practitioners during critical processes [32].
4. High-touch surfaces—should be chemically compatible with facility disinfection and comport to the CDC protocols of surface cleaning of high-touch, environmental surfaces [33].
5. Handwashing sinks—should be located within the sightlines of front-line practitioners as well as patients and families in waiting areas. Additional hand-sanitizing options should be offered in waiting areas.
6. Furniture—specification of chairs with arms should be considered to facilitate a safe stand-to-sit and safe sit-to-stand access to furniture.

Patient Experience

1. Flooring—should offer visual and physical comfort associated with a welcoming and caring environment. Soft surface flooring offering noise-reducing attributes should be highly considered in places of patient and family waiting.
2. Ceilings—noise reduction coefficient should be ≥ 0.80 to reduce ambient noise associated

with multiple conversations within waiting areas finished with hard surface flooring [34].
3. Walls—should be strategically placed to provide privacy at multiple points of perioperative surgical patient arrival.
4. Furniture—room configuration for private spaces should facilitate furniture layouts that enhance eye-to-eye contact between patient and practitioner [35].
5. Positive distractions should provide stress-reducing attributes within waiting areas [36].
6. Navigation—architectural elements, use of color, art, or sculpture should provide memorable impressions to facilitate ease in navigation to destination points throughout the continuum. Areas of rest including benches with arms are encouraged as respite places for the patients with dyspnea and other cardiovascular impairments.

Interior Specifications to Facilitate Optimal Human Performance

1. Floors—should provide the optimal sound-absorbing properties and matte surface gloss to reduce ambient noise and glare associated with worker fatigue.
2. Walls and/or private spaces—should be provided for enhanced communication, assessment, and comprehension for both patient and provider at multiple points of perioperative surgical patient arrival.
3. Ceilings—noise reduction coefficient should be ≥0.80 to reduce ambient noise including loud alarms that lead to alarm fatigue for enhanced speech recognition in addition to accuracy in simple and complex tasks [37].
4. Indirect lighting—should be provided to enhance accuracy of screen-based tasks.
5. Low light reflectance value of surface color and low gloss rating.
6. Adjustable, ergonomic task lighting for paper-based tasks.
7. Flooring surface texture which facilitates surface cleaning while reducing ambient glare.

Opportunities for Efficiency, Patient Safety, and Patient Experience in Pre-op, Prep/Hold

The pre-op, prep/holding area becomes an adjunct access point, providing an opportunity to identify any items missed during the admission process. Anecdotal patient and family feedback expressed to healthcare administrators reveals that lack of acoustical privacy coupled with discussion of hospital costs, signing of consent forms, and exchange of other personal information is correlated with patient dissatisfaction and best conducted before this point of care. Understanding the operations of these departments guides the hospital planner in addressing patient concerns as well as the needs of the front-line practitioner in this department. Among the most pressing:

1. Enhanced visibility of nurse to multiple patients
2. Acoustical privacy for patients and family
3. Spatial accommodations for family presence
4. Acoustical design to enhance caregiver recognition of alarms and speech recognition
5. Access to supplies for anesthesia services and nursing staff
6. Appropriate lighting to facilitate patient calm and comfort while facilitating safe procedures
7. Immediate access to handwashing sinks

Designing for high visibility while providing a calm, supportive, and private space for patients and families remains challenging for architectural designers. While one cannot refute the importance of high visibility and patient safety, anecdotal reports reflect high patient satisfaction with private prep/hold rooms with connecting toilet rooms. Establishing a list of priorities in pre-design regarding operational process flow, safety, and experience will be valuable information to share with the architectural planners and designers.

Intraoperative Phase

The Details of Human Performance

The Complex Workspace of Surgical and Anesthesia Service

An understanding of the relationship of environmental factors on patient safety, well-being, and worker effectiveness is crucial [30, 31, 38]. The interior designer current with the design research literature should be able to apply the correlation of illumination levels, ambient noise levels, and flooring surface characteristics relative to human fatigue and potential human error [31]. The workspaces where invasive procedures occur are challenging spaces for designers to influence human performance relative to high ambient noise and prolonged time standing. The rigors of cleaning protocols, maintenance of air pressures, required illumination levels, and code requirements render this environment quite harsh and unforgiving as a place of work. Reengineering these spaces to accommodate the growing human factor literature is key to creating optimal outcomes [39, 40]. In this highly regulated environment, there are many protocols of which the architect and interior designer must adhere. The most widely used building code in the USA is the International Building Code (IBC) [41].

Fig. 12.21 Authorities having jurisdiction over construction projects

It must be noted that many jurisdictions have additional governing bodies which have final ruling over interior finishes and the assemblies of interior finishes. The diagram (Fig. 12.21) illustrates these entities. The building type, the number of people using the building, and how the building will be used in terms of activities will also determine products and the proper assembly of products regarding fire and the health safety and welfare of individuals in the building. Additional regulatory agencies exist at the local level in the jurisdiction of the project. Examples include local municipal ordinances, health codes, and zoning regulations. Figure 12.1 illustrates the examples of such agencies.

Additionally, owners need to be informed that the final governing publication regarding minimal requirements might be the Facility Guidelines Institute (FGI)'s Guidelines for Design and Construction of Health Care Facilities. In a similar manner with other code research, one must inquire regarding the latest adopted publication [34] in the jurisdiction. The latest edition was published in 2014 with the next publication due to be published in 2018 and will be available at www.fgiguidelines.org. The FGI guidelines are a valuable reference for the perioperative team to review in preparation for renovation and new construction projects.

Patient safety/human error literature reveals that current topics are complex and solutions providing positive outcomes are yet to be realized. Root-cause investigations of wrong patient, wrong site, and wrong procedure patient errors (WSPE) consistently reveal communication and coordination issues as prominent underlying factors [42, 43]. Adverse events such as unintended retention of foreign body rank second to WSPE according to the Joint Commission sentinel event 2014 report [44]. Kao et al. [45] note that crew resource management training has positive impacts on behavior and attitudes in anesthesia, emergency medicine, and surgical services; however investigations regarding impact on outcomes are lacking. Additionally, human factor analysis provides another approach to learning more about near misses and errors by examining activities in the surgical environment such as technical

and nontechnical demands, mental work load, and interaction with the equipment, work environment, and team dynamics [46].

Observing for Errors and System Factors

In an exploratory study using a systems approach, [47], researchers conducted direct observation during cardiac surgery to identify teamwork problems, equipment factors, extraneous distractions, training-related issues, and resource accessibility and the association with surgical flow disruption. This study observed that operative errors that occur during cardiac surgery are associated with surgical flow disruptions, specific to teamwork-related disruptions. Moorthy et al. [48] demonstrated, using motion analysis, that operating room stress in the form of a competing task, noise, or need for speed all resulted in decreased dexterity and increased errors. Studies following team performance after training in simulated environments report enhanced teamwork but further research is indicted to correlate this training with outcomes. Design opportunities to contribute to safe workspace practices during surgery are the use of floor patterns and change of color material to clearly delineate the functional zones with the OR [19]. Defining policy and service research outcomes more clearly around the functional zones relative to the anesthesia workspace, the perfusion workspace, the sterile field, and the circulating field, perhaps nondisruptive workflow pathways are needed if we are to make the design of these spaces more evidence driven [49].

Lighting and Performance

Insufficient illumination that increases the risk for eyestrain, musculoskeletal discomfort, and headaches and can negatively affect the individual's work performance [50] is another recognized concern in areas of fine and complex tasks. Surgery is visually demanding and requires a good visual environment with efficient illuminance and minimal glare. High luminance contrasts, which can cause eyestrain and problems seeing clearly, are common in operating rooms due to high illuminance levels from surgical luminaires and low illuminance in surrounding areas [51].

Surgeons are consistently exposed to high illumination when focusing on the surgical cavity. It is critical to increase the general lighting in an operating room, especially around the operating table, to decrease the luminance contrasts and facilitate the operating personnel's visual ability. Scrub nurses are exposed to various levels of illumination within brief moments as focus shifts from the surgical cavity to the nearby instrument table. Shifting from high illuminance levels to lower requires an adaptation response which causes larger cognitive loads and impacts productivity. The anesthesia services focus on monitors and can best be served with lower level of general room illumination. Research identifying the optimum lighting levels from the operating table to surrounding areas is needed. Hemphälä demonstrated that surgical caregivers performed best when surgical light illuminance and general lighting illuminance contrasts were minimized and when surgical lamps were not on their highest possible setting [52, 53]. Lighting design for enhanced productivity of all job descriptions needs to be a top priority for insuring productivity in the operating room. To circumvent indirect glare associated with high illuminance and highly reflective surfaces, it is recommended the perimeter walls are painted in a pigment which contributes to a low luminance, such as a 40–60 % light reflective value (LRV) [54].

Human Needs

Front-line practitioners require convenient access to water during the course of their shift and the perioperative team is no exception. Research findings indicate that dehydration negatively impacts cognition, energy levels, and memory recall in young adults [55]. Hydration stations are important considerations in healthcare design and should be adjacent to other key support spaces located within the process flow of staff [24].

Interior Architecture and Design

Surface performance characteristics for optimal human performance in surgery include the following:

1. Floors—should provide the reduction in noise secondary to impact and footfalls.
2. Floors—surface gloss should have a matte gloss rating to reduce glare associated with worker fatigue [54].
3. Floors—surface visual texture should be minimal, void of aggregates that would hinder the identification and retrieval of objects on the floor.
4. Flooring surface texture which facilitates surface cleaning while reducing slip and fall.
5. Walls—surface color should have a light reflectance value of between 40 and 60% to reduce the percentage of reflected incident light into the eyes [50].
6. Surfaces—should be selected to achieve the recommended range for sound in operating rooms (40–50 dBA) [34].
7. Ceilings—where code permits, gasketed ceiling tiles with an NRC ≥0.80 should be specified to reduce ambient noise for enhanced speech recognition and intelligibility.
8. Lighting—reduction in illumination contrast between surgical field and circulating field.

While there is a great need to improve the evidence around the human factors that contribute to safe and reliable surgical team performance, knowledge of the current issues should stimulate design thinking to address these potential correlations [20]. There are multiple implications regarding the built environment's impact on enhanced sound attenuation for adequate speech recognition, communication and perioperative teamwork, improved illumination and visualization during surgical procedures, and, most importantly, improved surgical flow and utilization of physical resources. Only through an enhanced understanding of the underlying issues and processes that are currently not working in hospitals today that a design team can truly respond with the most appropriate workspace design for this high-risk environment.

Postoperative Phase

Design research literature is rich with publications correlating elements in the built environment enhanced recovery, pain tolerance, and sleep quality necessary to avoid readmission. The literature reveals that views to nature and access to daylight have positive outcomes on patients and well as the front-line practitioner [56, 57]. Most importantly the built environment, including the PACU, ICU, and acute care patient room in particular, should be planned and finished with materials that support prompt ambulation, physical therapy, nutrition counseling, and visits with social workers. Many institutions bring all the services to the patient rather than transporting patients to the services. Designing rooms that look to nature vs. walls can reduce nursing stress levels and improve patient services [58].

Flooring surface texture specification not only should address ease of surface cleaning but also can serve as an element that contributes to safe ambulation. Other environmental factors include proper illumination from electrical light sources, surface gloss, and elements to support ambulation, such as handrails. There is a paucity of evidence regarding design features that minimize patient falls, in addition to inconsistency in reporting findings, diversity of research methods, small sample sizes, and numerous confounding factors [6, 30, 31]. It is important to note that lighting not only supports safe ambulation but also is necessary to reduce human error during medication administration.

Handwashing is the single most important aspect of preventing transmission of infectious diseases and yet evidence suggests highly variable rates of handwashing in and around the operating room [59]. The literature reveals that the location of sinks in the path of the providers' workflow process improves handwashing compliance [60, 61]. Despite efforts to achieve

handwashing compliance, infection transmission via hand contact continues to be a prominent adverse event in hospitals today. According to Zimring et al., architects and interior designers should be considering that designing for no-touch is encouraged moving forward in facility design [61]. The inclusion of antimicrobial properties into surfaces results in a reduction of microbial loading on surfaces in the laboratory; however the research which correlated to positive outcomes in the field is minimal to date [62]. Reducing the environmental factors associated with transmission by hand contact requires surface products that (1) are chemically compatible with facility cleaning agents, (2) withstand the contact time of the cleaning agent, and (3) withstand the friction of surface rubbing.

Finally, family engagement has strong positive outcomes on reducing stress levels, offering social support, and facilitating compliance with discharge instructions [63]. Careful consideration in designing accommodations for family is a valuable process. Offering the amenities for comfortable waiting, sleeping, and remote access to work results in a return on investments as well as healthcare consumer loyalty.

Patient Well-Being and Family Satisfaction

1. Ceilings—noise reduction coefficient should be ≥0.80 to reduce ambient noise-associated improved sleep quality and stress reduction.
2. Furniture—room configuration should facilitate furniture layouts that enhance eye-to-eye contact between patient, family, and multidisciplinary postoperative team.
3. Positive distractions—should provide stress-reducing attributes associated with pain tolerance and stress reduction.
4. Wayfinding—architectural elements, use of color, art, or sculpture should provide memorable impressions to facilitate ease in navigation to destination points throughout the continuum. Areas of rest including benches with arms are encouraged as respite places for the patients with dyspnea.

Form Follows Safe Surgical Function

Given the persistent adverse events reported by the Joint Commission, a future of financial rewards being tied to quality and service in lieu quantity of procedures, the perioperative surgical service line is poised to explore and eradicate the pernicious problems associated with the surgical hospitalization. From bottlenecks in throughput to excessive hunting and gathering of instruments during a procedure, renovation and new construction is a once-in-a-lifetime opportunity for creating a surgical workplace that meets the needs of the front-line practitioners.

Focusing on efficiency, effectiveness, and service for both the provider and the patient (a human-centered approach) will certainly raise the bar in meeting the triple-aim goals. Using the previous chapters in this book can serve as a checklist in addressing safe surgical care in addition to efficient care. It is wise for physicians and administrators to be in alignment with a strategic vision for safe perioperative services before design begins.

Key Steps for Pre-design

1. Form a task group.
2. Include front-line practitioner super users.
3. Formulate a strategic action plan to improve processes based on baseline data.
4. Use design thinking and/or engage Lean Six Sigma consultants.
5. Test operational changes before architectural programming and planning begins.
6. Evaluate the likelihood/readiness in adoption of processes.
7. Keep current quality metrics transparent to influence behavior change.
8. Engage healthcare-credentialed architects and interior designers.

A building cannot change culture, and improve outcomes as one sole intervention to a service line. Architects must now come to the table with more than a physical product created in a vacuum. A human-centered approach using a multidisciplinary team can create solutions to new processes, services, IT-powered interactions,

ways of communicating, and ways to reduce system failures. Through advances in material science and manufacturing, design professionals are now, and will continue to be, equipped with enhanced finish performance characteristics to enhance human performance and well-being [64]. It is also hopeful that in the very near future, construction regulations will offer the designer opportunities to increase the specification of noise reduction materials in order to facilitate speech recognition and cognitive performance while meeting infection transmission protocols in procedure rooms.

Form must follow well-designed operations, operations grounded in safety. Cultural change, teamwork, and coordination augmented by technology across the continuum must be a system-wide vision for value-based, evidence-based design to come to realization. The architect and interior designer must also come to the table with suggestions and current trends, for augmenting the necessary cultural change by virtue of the built environment.

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Building Surgical Expertise Through the Science of Continuous Learning and Training

13

Peter Hani Cosman, Pramudith Sirimanna, and Paul Barach

"Coming together is a beginning. Keeping together is progress. Working together is success."

—Henry Ford

Learning and Expert Decision Making

Learning is the acquired, relatively permanent or persistent change of behavior or behavior potential resulting from instruction, training, and practice (intentional learning) or experience (incidental learning) [1]. In the context of professional training at a graduate level, it is goal oriented and motivated by progress towards independent practice. In this setting, it is more than just factual acquisition; instead, it is building upon, and being shaped by, previously established knowledge, leading to the development of expertise in a particular domain. Learning in the clinical domain is thus facilitated by the principles of adult learning—or andragogy, as elucidated by Malcolm Knowles [2]—in that learning is:

- Autonomous and self-directed
- Experiential
- Relevant and goal directed
- Heuristic

In 1984, Kolb described an experiential learning model, which postulated that learning occurs through a cycle of reflective observations of concrete experiences in order to gain an understanding of what can be learned from each experience [3]. New ideas are then applied to future experiences, renewing the cycle. While this model is readily applicable to many aspects of medical education, the unique necessity to regularly perform technical tasks requiring complex motor skills within surgery results in the need for an additional approach to learning. In this regard, the three-staged model of motor skill acquisition defined by Fitts and Posner has been suggested as a theoretical framework uniquely positioned for learning surgical skills [4]. This model initially involves understanding of the relevant task with the aid of instructor explanation and demonstration (cognition),

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followed by practice using instructor feedback to identify and eliminate errors (association). Finally, with repetitive practice, the learner performs the task with little or no cognitive input. Training to this "automated" phase can, indeed, result in the development of technical proficiency, but the attainment of surgical expertise and decision making requires the development of other cognitive attributes [5]. This is supported by the notion of "routine" experts that are skilled executors of certain tasks but are unable to adequately adapt to "variations from the norm." As such, many professionals may not attain true expertise. At present, there are no validated tools that reliably distinguish between or predict those who will and those who will not attain true expertise [6].

Characteristics of Expertise and Expert Behavior

Many descriptions of what determines expertise are qualitative in nature, with limited concrete measures available. In the most general terms, the hallmark of expert performance is extemporaneous, reliably reproduced, faster output of a consistently higher quality domain-specific product [7]. The actions of skilled experts in domain-specific tasks tend to be more fluid than those of novices [8], and tend not to be under conscious control directly, but rather hierarchically, through a higher level architecture of stratified control, allowing them to divide their attention between a number of tasks, without commensurate loss of performance [9]. Experts are better than novices at pattern recognition within their area of expertise, and can more reliably predict forthcoming events and potential problems on the basis of limited information [10]. They display superior problem-solving skills within their domain, and have more efficient memory-handling algorithms for domain-specific knowledge, as well as measures for qualitative analysis of problems on the fly [11], often referred to as "cognition in the wild." Experts monitor their own performance and are skilled at detecting and correcting errors in their own task execution, whereas novices are dependent on external feedback as the principal method of error detection [12].

Within the surgical domain, some have defined expert status as "experienced surgeons with consistently better outcomes than nonexperts" [13]. While operative volume has been shown to be an important determinant of outcome [14], variations in performance exist between surgeons with high and very high volumes making it difficult to define minimum volume requirements as a sole criterion for expertise. Moreover, the number of years of experience has been shown to be a poor predictor of performance [15]. Indeed, for some cognitive tasks, more experienced surgeons have worse performance as a result of decay of previously obtained skills [16]. Recent studies have found that expert surgeons demonstrate greater dexterity, consistency, and automaticity of performance, thus freeing up cognitive decision space [13, 17]. This ability to automate actions has been demonstrated by the facility to perform tasks seemingly without any attentional effort and with the cognitive reserve to be able to multitask without loss of efficiency [17]. Beyond this capability, experts have a greater ability to monitor and analyze their own performance and, importantly, identify and correct errors prospectively [18, 19]. In contrast, nonexperts lack this key insight and require external evaluators to do this. Experts perform physical rehearsal and warm-up with preliminary findings suggesting that preoperative rehearsal or warm-up can improve the performance of operators or operating teams [20]. Indeed, experts use forward reasoning to rapidly formulate diagnoses and management strategies, making fewer cognitive errors, but will revert to backward reasoning when unusual clinical patterns occur [18, 21–25]. This nimbleness is a mark of true expertise and allows them to develop reliable mental models to address a wide variety of cognitive challenges.

It is well known that individual trainees acquire skills at varying rates and some may not ever be able to achieve certain proficiencies. Further, surgeons with equivalent operative experience demonstrate varying levels of skill [26, 27]. Equally, some with varying operating experience have been shown to have similar levels of performance [26, 27]. Neurophysiological analyses have suggested that this disparity may be

explained by differences in motor learning capability, cortical function, and neuroplasticity, where experts have been shown to activate a smaller neural networks allowing a more efficient control of movement and the development of automaticity [28, 29].

Significant variation in clinical competencies exists between individual healthcare providers that may contribute to a large variation in patient outcomes and inefficient use of resources. Although increasing experience plays an essential role in achieving proficiency, completing more procedures does not necessarily ensure that expertise will be attained if reflection, feedback, and learning are limited. Utilizing examples from sports and music, Ericsson hypothesized that years of deliberate practice, rather than the mere accumulation of experience, is a unifying feature of all experts [30]. Deliberate practice is defined as a "structured activity, which is designed to develop a critical aspect of current performance." The development of expertise is thought to be a consequence of the amount of domain-specific deliberate practice accumulated by individuals throughout their career, rather than mere exposure to the performance domain. Deliberate practice provides an opportunity for error detection and correction, repetition, access to feedback, complete concentration, and full attention. The hallmark of deliberate practice is a deep desire to receive specific feedback to identify weaknesses and improve performance [31]. These areas of performance weakness can be practiced "deliberately" by constructing and seeking out training opportunities in order to improve performance. Studies in several domains have demonstrated that the attainment of expertise occurs after 10,000 h of a concerted cycle of deliberate practice [30].

The relationship between expert performance and volume of domain-specific deliberate practice has been consistently demonstrated across diverse professional domains, including sport [32], music [31], business [33], nursing [34], and academia [35]. These studies suggest that engagement in structured practice leads to the development of task-specific knowledge that helps skilled individuals focus their attention on more pertinent areas of the display, making it easier to surmise situational probabilities from events previously experienced. These task-specific adaptations enable the more effective processing of contextual information [36].

Broadly, clinical decision making involves two types of mental processes that exist on a spectrum, from subconscious, automatic decision making based on experience and pattern recognition to a conscious, analytical, thoughtful process [37]. The former is faster and consumes little cognitive energy and is more commonly used by expert surgeons. However, they are also able to seamlessly switch between these processes prospectively when required. Although the attainment of technical proficiency is seen as the predominant goal of most surgical trainees, achieving status as an expert surgeon requires a more holistic set of competencies. Indeed, it is clinical decision making that often differentiates experts from nonexperts more than technical skills per se. These individuals display the ability to utilize a wide range of conscious and unconscious thought processes to make accurate and rapid clinical decisions consistently, while being able to adapt to the changing demands of the patient, the team, and the context. In particular, they are able to make accurate decisions with regard to when operative or nonoperative management is required, ensuring that the right operation is performed in the right patient with the right resources and perhaps, more importantly, deciding not to proceed when operating on the patient is not in the patient's best interest. Experts make astute decisions regarding preparing patients for surgical procedures, and, importantly, are able to monitor and detect subtle deviations from the usual postoperative course, and act accordingly to ensure early rescuing of patients while optimizing outcomes.

As mentioned, while the attainment of expertise is the common goal of all surgical trainees, some have controversially suggested that not all trainees have the innate ability to reach such proficiency and selection of trainees should focus on identifying those that are most likely to succeed [38]. Further, becoming a surgical expert requires more than achieving expertise in technical skills but in fact requires a suite of both technical and nontechnical competencies including the right attitudes. Proficiently working within a team is

crucial to efficient and effective delivery of surgical care [39]. These topics are discussed in the next sections.

Learning Within the Surgical Microsystem

Clinical microsystems provide a conceptual and practical framework for thinking about the organization and delivery of care. Formed around a common purpose or need and often embedded within larger organizations, a clinical microsystem is a small, inter-reliant group of people working together regularly to care for specific patient groups [40]. It is characterized by a common aim, a subpopulation of patients, shared work processes, and a shared information environment [41]. Optimally functioning clinical microsystems deliver the best quality healthcare services, so understanding what is most important to the people who make up the microsystem is key to continuous improvement. The main driver and facilitator of learning within this environment is its internal climate and culture [42]. Awareness of the presence and support of the microsystem by its members, and support for its activity by the broader organization within which it is embedded, is therefore, essential for the function of the microsystem—a critical factor in its key purpose of continuous quality improvement and the provision of reliably safe clinical care [43].

This environment socializes the team members, and affords the acquisition of unique set of technical, but mainly nontechnical, skills, and some of which can only be attained with great difficulty outside of the relevant micro-system [44]. General microsystems include doctors, nurses, other healthcare providers, administrative support such as clerks and biomedical engineers, and health information technologies that support them. Understanding the interdependent interfaces and subtleties of communication between staff of differing disciplines is explored by participation in interdisciplinary learning activities, often enhanced by simulation-based learning activities. Leadership and teamwork are also important aspects of the microsystem's success [45], and attention given to providing constant ongoing staff training and workplace assessment of these nontechnical skills will yield dividends in terms of improved quality and efficiency in delivery of care to patients [46]. Given this reliance on continuous training, thought ought to be given to the best way to incorporate training into the microsystem's schedule, and the various training needs of its members.

Learning at Various Stages of Training/Levels of Expertise

Dreyfus and Dreyfus proposed a model of skill acquisition [47] that describes how students acquire new skills through formal instruction and practicing. The original model proposes that a student passes through five distinct and immersive stages: novice, competence, proficiency, expertise, and mastery which correspond to four binary qualities around: recollection (non-situational or situational); recognition (decomposed or holistic); decision (analytical or intuitive); and awareness (monitoring or absorbed). In the novice stage, a person follows rules as given, without context, with no sense of responsibility beyond following the rules exactly. Competence develops when the individual develops organizing principles to quickly access the particular rules that are relevant to the specific task at hand; hence, competence is characterized by active *decision making* in choosing a course of action. Proficiency is shown by individuals who develop *intuition* to guide their decisions and devise their own rules to formulate plans. The progression is thus from rigid adherence to rules to an intuitive mode of reasoning based on *tacit knowledge*. This model leads to five defined roles, through which learners can progress in either direction and share elements of two stages at different times in their learning journey [48] (Fig. 13.1).

With specific reference to psychomotor skills, learning occurs in three phases [49], although the entire process of learning is a continuous, not a discrete, phenomenon. The first is the *declarative stage* (composition, cognitive stage), in which the basic rules of a task are articulated and learnt. Next is the *associative stage* (proceduralization stage), during which the procedures of the task

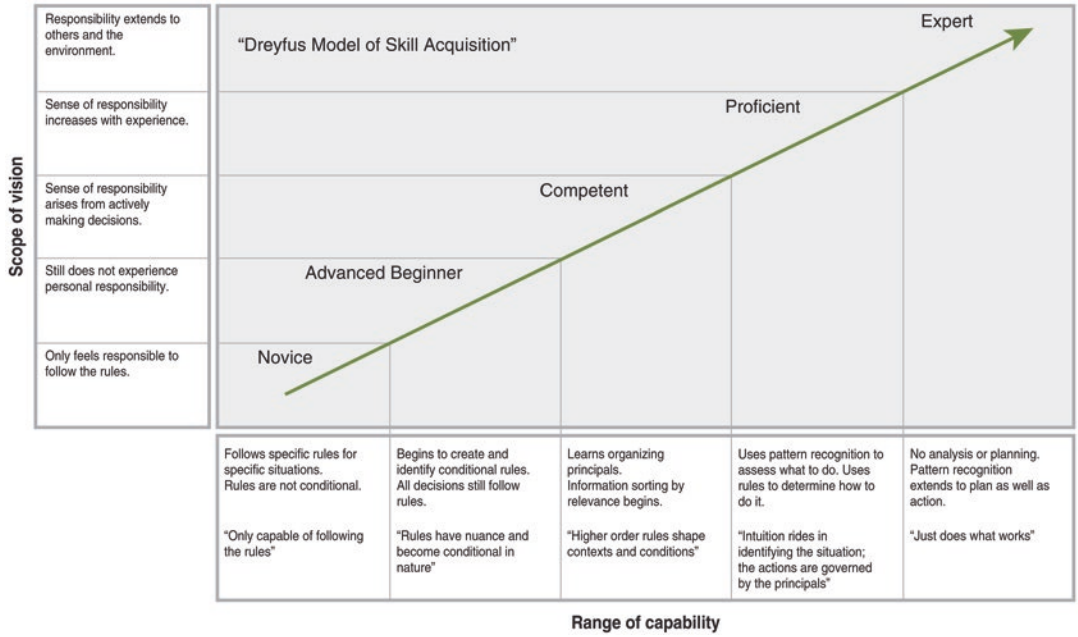

Fig. 13.1 Dreyfus model of skill acquisition [47]

become more fluent. Finally, during the *autonomous stage*, the procedures become automated, being performed more rapidly and with greater immunity to disruption by external conditions such as noise, interruptions, etc. The most dramatic and rapid changes in performance are seen in the first phase, and a plateau is reached by the third stage, although performance slowly continues to improve by small increments over long periods associated with ongoing practice (Fig. 13.1).

The first two stages are associated with the evolution of increasingly more appropriate mental representations of action [50]. This Kantian representation—also known as a schema—

> *"… is a spatially and/or temporally organized structure in which the parts are connected on the basis of contiguities that have been experienced in space or time. A schema is formed on the basis of past experience with objects, scenes, or events and consists of a set or (usually unconscious) expectations about what things look like and/or the order in which they occur."* [51]

This mental organization is not peculiar to experts; according to the Gestalt theory of psychology, schemata underpin all our experience of the world, and cause us to perceive things the way we do [52–54]. The principles that govern their formation and function are common to all humans, which is why we can agree on many facets of experience, despite each individual's complete ignorance of another's experience. According to the Gestalt view, our experience of objects in the real world consists of a number of facets of each object—such as color, texture, odor, and so on—each of which generates a particular stimulus. Our immediate mental state, together with our previous experiences, determines the relative value we attach to each facet of an object. Although the sensory abilities of experts do not differ from those of novices, their perception of entities specific to their domains is different. The pattern of relative importance of the facets of an object in experience that are pertinent to the expert's function is—in a manner of speaking—imprinted on his or her memory. This explains the expert's superior cognitive processing in approaching or performing a task, and this is what training for that task must accomplish [55].

Within the schema is housed the action plan [56], a hierarchy of seven levels of sensorimotor representation postulated by Saltzman [57]. The seven levels are defined in Table 13.1. Experts performing a psychomotor task within their skill

Table 13.1 Saltzman's levels of sensorimotor representation [57]

Level of representation	Characteristics	Example
1. Conceptual	This level involves highly abstract symbolic components integrated within a logical or propositional framework	"Perform a mass abdominal closure," and "Make a circumareolar incision." Specific spatiotemporal parameters are defined only insofar as they relate to operational components of the entities to be manipulated
2. Environmental space motion	At this level, the interaction space is defined, along with quantitative representations of the relative positions of the objects within it to be manipulated	"Take 2 cm bites, 1 cm apart," and, "Start at the 4 o'clock position, and finish at the 8 o'clock position," exemplify this level of control
3. Effector	At this level, a particular effector system will be selected to perform the task, and its relationship with the task objects will be quantitatively defined	"Pick up the fascia with the forceps in your left hand," and "Hold the scalpel in your right hand"
4. Body-space motion	At this level, the higher order information is translated into specific instructions on movement of the performer's body within space. Transformation of the environmental spatiotemporal action trajectory is translated into body-relevant terms	"Hold the forceps like a pencil," and "Keep your elbows by your sides"
5. Joint motion	The angle of each joint between the fingertips and trunk is defined for proper execution of the task, along with kinematic changes in the angles over time, angular velocity, and angular acceleration. Experts can ignore the redundant degrees of freedom in their joints, identifying only those that are necessary for task completion; by contrast, novices cannot predict which degrees of freedom are redundant for a particular task	Maintaining a fluid and flexible, nonrigid posture in those joints not involved in performing the task
6. Joint torque	This is a function of the angular displacement, velocity, and acceleration of a joint, and determines the amount of force applied to objects in the task. Adjustments at this level result in greater or lesser amounts of traction applied to tissues	
7. Muscle	At this level, the relevant muscle groups to be activated are determined, as is the required neural input	

domain generally operate at the conceptual level of representation, regarded as the highest order or most abstracted level of control. In contrast, novices training to achieve expert-level proficiency in a particular skill are likely to require instruction and repetitive feedback at most, if not all, levels of sensorimotor control.

Mental schemata are also responsible for the general popularity of "mind maps" as an aide-mémoire based on the organization of vari-

ous related pieces of information into a structured framework [58]. One aspect which does set experts apart from the remainder of the population, however, is that they possess highly developed and structured mental representations for information within their area of expertise [59], which facilitates their professional functionality. This ability is specific to their knowledge domain, but does not extend to general function in common tasks [60]. It is for this reason that correlations have been found between surgical proficiency and visuospatial ability [61].

Successful execution of a task, then, is predicated on the presence within the performer's mind of a schematic model of the task synthesized during the course of training. Proficiency in task performance emerges when the trainee's performance matches his or her mental schematic of the task, as long as the model is sufficiently sophisticated to encompass the task parameters outlined below [62]:

1. *Task content, type, input, output*
   The actions or processes which constitute the task define the nature of the task itself, that is, whether it is predominantly sensory, cognitive, or motor, or a combination of two or more abilities. These broad classifications of task type can be further stratified by the type of activity involved. Knowledge of the material—the "task substrates"—required to complete the task and a mental model of the end product are essential.
2. *Contextual conditions*
   Factors beyond the immediate constituents of the task which may affect task performance must also be recognized.
3. *Frequency and duration*
   Tasks may involve several iterations of subordinate processes; the operator must know how to determine the appropriate number of repetitions. Timing factors may also play an important part in successful task execution.
4. *Criticality*
   Certain elements of a task may be pivotal to its successful execution. Awareness of such elements allows the performer to take steps to ensure optimum performance of these elements.
5. *Indications of difficulty*
   Recognizing the signs of potential difficulties is the first step in preparing for these contingencies. One feature of expert performance is awareness of all contingencies during task performance, and prior preparation of strategies to avoid difficulty [60], or to attenuate its effects should it eventuate. This suite of skills may explain the benefits of rehearsal before procedures.
6. *Cue indications*
   Information from the task environment is necessary for decision making during certain tasks, and for monitoring performance. These cues also assist in coordinating task execution by indicating the deployment of subordinate processes at the appropriate time [63].
7. *Conditions which initiate and end the task*
   The operator must be able to correctly match initiation of a task to the circumstances that require it. Similarly, he or she must be able to recognize the achievement of the goal conditions that the task is designed to fulfil, as well as be able to recognize circumstances leading to futile pursuit of the goal, under which it is more prudent to abort the task.
8. *Constraints/aids provided by environmental or technological factors*
   The operator must also know the resources available to assist in task completion, as well as the various factors that may limit an aspect of performance. Taken to its extreme, this principle directs the operator to be aware of his or her own limitations, and of any conditions that may place successful task completion beyond the resources at his or her disposal.
9. *Alternative means of reaching the desired outcome*
   Achieving the goal conditions may occasionally necessitate use of an alternative to the task in question, and the operator must be prepared for such strategy changes.

The scope of the foregoing list of elements which form the mental construct of a task indicates that two classes of knowledge are essential to achieving proficiency in a psychomotor skill. *Declarative knowledge* (semantic knowledge, conceptual knowledge, or factual knowledge)

relates to the principles underlying the task. *Procedural knowledge* (operational knowledge), on the other hand, relates to the internal task structure. Declarative knowledge does not appear to enhance task performance, and its utility depends on the way it is presented to the learner. Measures of this kind of knowledge are not good predictors of task performance [64], and it does not affect skill transfer [65], although it may improve long-term retention. Procedural knowledge, on the other hand, is important for effecting skill transfer [66].

Recruiting and Training the Surgical Team

Recruiting the most suitable candidates is a task that has continuously challenged surgical educators worldwide. Indeed, identification of appropriate selection criteria is an onerous task, often supported by scant evidence [67]. However, this controversial topic has gained much interest in recent times, particularly given the increased economic pressures, growing cost of training, and accountability placed upon training bodies. This, coupled with the reduction in working hours available for training, means that selection of trainees that are most likely to succeed through training is vital [68–70]. Traditionally, selection of prospective surgeons into training programs is based largely on three aspects: clinical experience and academic achievements, referee reports, and performance at interview. In Australia and New Zealand, this highly competitive process adheres to the aforementioned principles, where a self-reported structured curriculum vitae (CV) is scored according to strict criteria with points given for clinical experience, publications and presentations, teaching, higher degrees, and postgraduate prizes. Further, referee reports are collated from nominated clinical supervisors that involve scoring applicants according to the Royal Australasian College of Surgeons (RACS) competencies of medical and technical expertise, clinical decision making and judgment, collaboration and communication, professionalism academic, teaching, and leadership aptitudes. Finally, applicants are scored during a semi-structured interview consisting of a number of clinical and nontechnical skill stations that aim to assess these competencies. A recent study evaluating the predictive validity of this process demonstrated that those who obtained high score in the CV component of the selection process did not score higher in any subsequent objective work-based assessments during training. In contrast, referee reports and interview scores, as well as the overall score, positively correlated with performance during subsequent objective work-based assessments during the training program [71].

This traditional selection process has been controversially criticized by some for not including assessment of abilities that are fundamental to surgical practice, such as psychomotor skills [68]. Recent advancements in surgical practice—in the form of endoluminal techniques, complex laparoscopic procedures, microsurgery, and robotic surgery—require surgeons to possess a number of critical abilities across the cognitive, psychomotor, and visuospatial domains beyond those required for traditional surgical modalities [68, 72–77]. Further, some of these fundamental abilities have been considered largely innate, and it is debated whether these abilities can be acquired and mastered through training at all [77]. This clearly has implications for the benefit, cost-effectiveness, and safety of individuals without these innate abilities undergoing the lengthy, rigorous, and expensive process of surgical training. Within other high-risk industries, like aviation and the military, assessments of attributes deemed important for performance are incorporated into the selection process [78]. Cuschieri and colleagues surveyed the opinion of senior surgeons and surgical leaders from Europe and the USA with regard to the attributes they considered to be important for selection of surgical trainees [79]. The authors concluded that innate dexterity including the abilities of spatial perception, hand-eye coordination, aiming, multi-limb coordination, and hand-arm steadiness and the ability to interpret and manipulate images is considered by this group of expert surgeons to be an important selection criteria. Indeed, when these fundamental abilities were present in a trainee, improved performance correlated with shorter time to proficiency during endoscopic performance [76].

These provocative studies raise questions about the reliability and validity of the trainee selection process in surgery, as well as identifying those who may require additional training to achieve competence. As a result, tests of technical skills and fundamental abilities are included in the selection process for Higher Surgical Training at the Royal College of Surgeons in Ireland [80]. Candidates are required to complete a full day of assessments including a ten-station surgical skills Objective Structured Clinical Examination (OSCE), where they are tested on skills acquired during basic surgical training. These include suturing, knot-tying, basic anastomosis, and basic endoscopic and laparoscopic skills. Additionally, candidates undergo a variety of validated assessments of psychomotor skills, visuospatial ability, and perception.

Training the Surgical Team

To meet the demands of increasingly complex healthcare associated with delivering high-quality, efficient surgical care, the concept of the surgical team has changed significantly [81]. No longer can the surgeon operate as a patriarchal figure issuing orders with regard to all aspects of patient care. In order to provide the highest quality holistic and efficient care, surgeons must work collaboratively as equals with nursing, allied health, other medical, and administrative colleagues. Together this group of individuals constitutes the surgical team with the shared goal of delivering the best care possible for their patients. Working within such an intricate system containing so many moving parts poses another challenge to surgical trainees beyond the pursuit of technical excellence. Furthermore, traditionally, surgical training programs focus little on training and assessing skills required to be a proficient collaborator.

In 2008, the American College of Surgeons (ACS) and Association of Program Directors in Surgery (APDS) united to create Phase III of the ACS/APDS National Curriculum [82]. Contained within this was a course of team training modules that incorporated a number of validated simulation scenarios to be used with human patient simulators. These modules were specifically designed to teach a wide range of team-related competencies including communication skills, critical language, assertive and closed-loop communication, active listening, and leadership. The scenarios involve laparoscopic crisis, laparoscopic troubleshooting, latex allergy anaphylaxis, patient handover, preoperating briefing, as well as trauma team training [83]. Performance during the modules is assessed by specific assessment tools, but other validated nonproprietary instruments can also be used, such as the NOTECHS (non-technical skills) scale [83] and other frameworks [84]. Despite this, it has been reported that 21% of 117 surveyed program directors were unaware of this curriculum [85]. Further, the implementation rate of Phase III was only 16% [85]; lack of faculty-protected time and personnel, significant costs, and resident work-hour restrictions were suggested as reasons for this low figure [85].

Crew resource management (CRM) within healthcare is a concept that describes the principles of individual and crew behavior during ordinary and crisis situations, and aims to optimize available resources and develop skills in dynamic decision making, interpersonal behavior, and teamwork that lead to safe outcomes [86–88]. Emerging from other high-risk industries, such as aviation, CRM has been successfully applied to healthcare since the mid-1980s with a number of variants and hybrids being developed [89]. The development of the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™) program, as a variation of CRM, by collaboration between the Agency for Healthcare Research and Quality and the United States Department of Defence has provided a standardized evidence-based curriculum for team training for healthcare providers [90, 91]. At its core, TeamSTEPPS™ aims to teach four fundamental competencies that constitute teamwork (leadership, situation monitoring, mutual support, and communication) with the aid of patient scenarios, case studies, multimedia, and simulation [92]. Having been implemented in multiple regional training centers around the USA and Australia [93], the TeamSTEPPS™ program has been shown to enhance teamwork within the operating room, improving operating room efficiency and reducing patient safety concerns in the process [94, 95]. Additionally, it has been demonstrated to increase perceptions and attitudes with

regard to patient safety culture, teamwork, and communication [42, 94, 96]. A recent study investigated the use of CRM within the surgical ward environment, in which surgical trainees participated in simulated ward-based scenarios of a deteriorating postoperative patient before and after CRM training [97]. CRM training improved clinical assessment and decision making and resulted in improvements in teamwork, communication, and leadership [97].

Effective and efficient teamwork within the operating room (OR) is crucial to prevent process failures and adverse patient events during an operation [98]. The OR team is further subdivided into specialized collaborations that include the surgical team (surgeon, surgical assistant, and scrub nurse), anesthetic team (anesthesiologist and anesthetic nurse), and theatre nursing staff (scrub nurse and scout nurse) [81]. Teamwork can have a huge impact in the OR on patient safety and resulted in development of strategies to reduce complications such as medication errors, positioning errors, and more, and train individuals to work efficiently and collaboratively not only within their own sub-team, but also within the entire OR team. The development of simulated ORs that replicate the entire OR environment has provided a unique opportunity [44] to cultivate a number of nontechnical skills, including command, control, and conflict resolution teamwork [99]. Real equipment as well as virtual reality and mannequin simulators are incorporated into this simulated setting [100]. This allows trainee surgical, anesthetic, and nursing staff to interact and practice teamwork skills together, while simultaneously performing technical tasks, during a variety of routine and crisis scenarios, just as they would in "real life" [40, 99, 101]. Indeed, Gettman et al. demonstrated an improvement of the teamwork, communication, and laparoscopic skills of trainees undergoing training within a simulated OR [102]. Further, the simulated OR was validated as realistic and representative of actual practice [102]. Other studies have similarly shown the benefits of collaborative training within a simulator OR environment on trainees' nontechnical skills including teamwork and situational awareness [103]. Widespread use of simulated ORs for training is still limited due to a lack of appreciation of the benefits of training, potential savings in operations, harm reduction, and building trust between team members. Recently, virtual reality models of the OR have been developed and used for team training [104], but further research is needed to appreciate the ethical dimension, effectiveness, transfer of training and demonstrate the effect on team skills on patient outcomes [105, 106].

Assessing Expertise

Surgical expertise encompasses a wide range of competencies. Holistic analysis of a surgeon's professional and technical performance ideally incorporates reliable assessments of these individual competencies. Assessment of surgical expertise must start with shared evidence driven definitions and has been compartmentalized into technical and nontechnical skills, with a variety of methodologies developed to do this [107, 108]. Some of these are discussed below, but ultimately, the most important and relevant measure of expertise, using an expert performance and assessment approach, [5] is a robust evaluation of patient process and outcomes measures, both at the level of the individual practitioner [109] and at the microsystem level [84]. Just as error detection and analysis reflect expert performance by an individual [110], the same strategy applied to teamwork will yield dividends in terms of the team's collective expertise [40, 44].

Technical Skills

There are a multitude of methods for measuring technical skills in surgery that use varying degrees of complexity [111, 112]. These range from measurement of simple metrics, such as time and dexterity, through to global and procedure-specific rating scales and error-based checklists, as well as more complex assessments of higher level cognitive function using gaze tracking and functional brain imaging.

Motion analysis systems, such as the Imperial College Surgical Assessment Device (ICSAD), use an electromagnetic tracking system that

monitors the motion through space of sensors placed on the dorsum of the surgeon's hands to record a variety of dexterity parameters, such as time to task completion and economy of motion [99]. This system has been validated as an objective assessment tool, and can distinguish between surgeons of differing skill levels [113, 114]. Likewise, virtual reality surgical simulators provide an opportunity for users to practice tasks of varying complexity and produce similar objective measures of dexterity, as well as record errors made, in real time. Not only have such models been validated as accurate assessment tools, but they have also been used to evaluate expert skill level to generate performance goals for trainees to practice within structured curricula [115, 116].

In contrast to the aforementioned dexterity assessment tools, direct observational assessment tools utilize rating scales to quantitatively assess the quality of operative performance. Broadly classified into global and procedure-specific rating scales, these tools require an observer to evaluate performance. Global rating scales, such as the Objective Structured Assessment of Technical Skill (OSATS) scale, assess generic operative skills, such as respect for tissue and instrument handling. The OSATS scale has been demonstrated to be a reliable and valid method of assessing operative skill in both the simulated and actual operating room environment [114, 117]. Nevertheless, the lack of ability to provide feedback on specific aspects of a particular procedure has led to the development of procedure-specific rating scales. These allow objective assessment of performance during individual operations to define specific areas of weakness that then can be practiced deliberately. Such tools have been developed and validated for a number of operations including cholecystectomy, gastric bypass, and colorectal, ear, nose, and throat, and cardiac surgery [44, 114, 118–122]. In a landmark publication, Birkmeyer demonstrated that superior performance by expert surgeons during gastric bypass surgery—as assessed by a procedure-specific rating scale—was associated with fewer postoperative complications, reoperation rates, readmissions, and, crucially, mortality [109].

More recently, more sophisticated methods of assessing surgical skill have been developed, such as gaze tracking and functional brain imaging. By using stationary cameras or cameras integrated into standard eyeglasses to record corneal reflection of infrared light, pupil position can be tracked to generate a map of the surgeon's focus of attention during surgery [84, 123]. Additionally, other eye metrics can be obtained, including fixation frequency and dwell time; these indicate the degree of importance ascribed by the surgeon to a particular stimulus. In addition, pupillary dilation is a surrogate marker of effort and concentration. Indeed, a recent systematic review concluded that gaze tracking is feasible and valid as an objective measure of ability, and can produce reliable quantitative data differentiating between varying levels of surgical skill [123].

Similarly, the use of functional brain imaging provides a novel approach to measuring surgical proficiency. Functional magnetic resonance imaging (fMRI) has been utilized in other highly skilled domains such as sport and music [124, 125]. In a recent feasibility study using fMRI, Morris measured the blood oxygen level-dependent signal changes (BOLD) in specific brain regions while subjects performed and imagined performing hand tying of surgical knots [126]. Decreased BOLD activity was observed during knot-tying by experts when compared to novices. Further, increased BOLD activity was observed in experts when imagining performing hand ties compared to novices. This study demonstrated that using fMRI to assess surgical skill was feasible and specific regions of interest were identified through brain mapping.

Increasingly, attention has been directed to the concept of the learning curve in surgery. As a strategy, preoperative warmup and pre-procedure rehearsal exercises performed by surgeons at all levels of expertise lead to improved performance during the operative procedure [24, 127], but also serve to document a surgeon's learning curve by longitudinal analysis of repeated performance.

Nontechnical Skills

Nontechnical skills (NTS) encompass a range of competencies, including communication, teamwork, leadership, decision making, situational

awareness, managing stress, and coping with fatigue. In contrast to methods of evaluating technical skills, the assessment of NTS almost exclusively relies on rating scales and checklists that include specific definitions and examples of behaviors representing superior or substandard performance at each measured NTS. These tools can be used in both the simulated and actual clinical environment, and rely on direct observation of subjects. Surgeons have been shown to be reasonably accurate at self-assessing their technical skill, but lack sufficient insight to accurately self-assess their own NTS [128]. Several instruments have been created to evaluate NTS with considerable overlap, demonstrating the importance of some of these competencies to a number of academic surgical teams. Some of these instruments are discussed below.

One of the pioneering tools for NTS assessment is the Observational Teamwork Assessment for Surgery (OTAS) tool, which was developed in 2006 [129] to comprehensively assess the interprofessional teamwork of an entire operating room team, including communication, coordination, cooperation/backup behavior, leadership, and team monitoring/situation awareness. While it is valid and reliable, OTAS requires real-time observation, and raters must be adequately trained to use the scale [130].

Non-Technical Skills for Surgeons (NOTSS) was also developed in 2006 through cognitive task analyses with expert surgeons to identify five categories of NTS, including situational awareness, decision making, task management, leadership, and communication/teamwork [131]. While NOTSS has been demonstrated as a reliable assessment of surgeons' NTS [132], novice assessors tended to score lower than expert assessors, again indicating the need for formal training in using NOTSS [133]. Crossley evaluated NOTSS as a real-world assessment tool using a mix of minimally trained assessors and demonstrated evidence to suggest that the scale is reliable and feasible to be used in the actual operating room [134]. Developed using a similar methodology to NOTSS, the Anaesthetists' Non-Technical Skills (ANTS) and Scrub Practitioners' List of Intraoperative Non-Technical Skills (SPLINTS) rating scales have also been shown to be reliable and valid in assessing NTS of anesthetists and instrument nurses [135, 136].

The revised NOn-TECHnical Skills (NOTECHS) rating scale is a validated and reliable instrument adapted from the aviation industry by Sevdalis and colleagues [137] for use in the operating room, and designed to measure the NTS of both the individual surgeon and the team as a whole [138]. Categorizing NTS into five domains, including communication/interaction, situational awareness/vigilance, cooperation/team skills, leadership/managerial skills, and decision making, the NOTECHS rating scale can be used in real time and requires minimal prior training for assessors [138]. Mishra developed the Oxford NOTECHS, as a variant of the original scale, with the aim of assessing the NTS of the entire operating room team [139], and a modified, higher resolution version was subsequently developed, with an increased number of performance indicators, particularly in the normal spectrum of behavior [140]. Further modifications of NOTECHS include the trauma NOTECHS (T-NOTECHS), which allows assessment of NTS that are crucial for effective and efficient management of trauma [141, 142]. Henrickson Parker and colleagues conducted focus group discussions to identify leadership characteristics of a surgeon [143]. These included maintaining standards, managing resources, making decisions, directing, training, supporting others, and coping with pressure. From this, the Surgeons' Leadership Inventory (SLI) was developed and subsequently demonstrated to be a reliable means of assessing leadership with the operating room [143].

"Failure to rescue" patients whose condition deteriorates during the postoperative course has been suggested to be responsible for a large proportion of variability seen in patient outcomes within surgery. As stated previously, experts are able to monitor and detect subtle deviations from the usual postoperative course, and act swiftly to prevent such failures. The ability to develop these skills and conduct an efficient, accurate, and safe ward round requires the same deliberate practice required to master technical skills in the operating room. Recent development and validation of the Surgical Ward care Assessment Tool (SWAT) has enabled evaluation of patient assessment and management by surgeons [144]. This instrument comprises a checklist of assessment tasks, rang-

ing from reviewing the vital signs chart and laboratory test results to performing a physical examination of the abdomen. Additionally, the checklist includes a number of management tasks, such as reviewing requirements for analgesia, antibiotics, and fluids. Further, the authors modified the T-NOTECHS scale to produce and validate the W-NOTECHS rating scale. For each NTS domain—including leadership, cooperation, resource management, communication and integration, assessment and decision making, global awareness, and coping with stress—five-point Likert scales were used to rate performance. Both the SWAT and W-NOTECHS scales have been demonstrated to reliably assess performance during ward rounds and provide structure for the development of expertise in the art of conducting a ward round through a cycle of objective assessment and deliberate practice [145].

Entrustable Professional Activities

Judging when trainees are equipped for independent unsupervised practice is a challenging endeavor for both supervisors and trainees. Premature unsupervised care can place patients at an undue risk of harm, increasing the ethical and legal accountability for the supervisor and healthcare organization. A recent meta-analysis [146] found that clinical supervision of medical practitioners performing surgical procedures significantly reduced the operative mortality by one-third, and the risk of complications by two-thirds following nonsurgical invasive procedures.

Further, giving trainees inappropriate responsibilities can negatively affect their learning. Conversely, affording capable trainees too little independence can have a detrimental impact on their ability to achieve competence and either slow or arrest their development. Educational psychologists describe both of these conditions as "destructive friction" [147]. Giving trainees the responsibility to perform tasks that are only narrowly beyond the limits of their ability has been suggested to stimulate learning and is termed "constructive friction" [147–149]. However, there is a lack of evidence to support this in clinical practice [150]. Nevertheless, a time must come for all trainees to practice independently for the first time, and a number of solutions to this difficult decision have been proposed. One suggestion is to establish a requirement for trainees to achieve a minimum number of attempts, in order to overcome the learning curve for a particular task, prior to allowing independent practice [151]. A counterargument accounts for the variable learning curves of different trainees and supports the use of careful consideration and individualized assessment of trainee competency, stage of training, and appropriateness of the patient for independent practice [152].

The term "entrustable professional activity" (EPA), coined by ten Cate [153], describes professional tasks that "together constitute the mass of critical elements that operationally define a profession." Each EPA is defined as a unit of work that trainees are required to master during their training, but necessitate entrustment by their supervisors once they are deemed competent for independent practice. This concept was used by ten Cate and Scheele [154] to define five levels of responsibility of proficiency. These *include*:

1. Has knowledge
2. May act under full supervision
3. May act under moderate supervision
4. May act independently
5. May act as a supervisor and instructor

Further, they suggested the utilization of EPAs as the backbone for competency-based curriculum development, by awarding a "statement of awarded responsibility" (STAR) for specific EPAs, the threshold at which entrustment of independent practice can be clearly demarcated and formalized. At least four factors were hypothesized as likely to influence such entrustment decisions. Firstly, the type of EPA should be considered. Supervisors should expect trainees to have slow learning curves for complex, high-risk EPAs, whereas those EPAs that are frequently encountered by trainees should be associated with a steeper learning curve. Secondly, supervisors should consider the environment in which the trainee is practicing: Are there adequate resources available should a trainee fail the EPA? Does the curriculum demand a STAR for the trainee's stage

of training? Thirdly, the supervisor must assess and make a deliberate decision regarding each individual trainee's competence with each EPA. Finally, the supervisor must be comfortable with the EPA, as well as be able to assess the other factors accurately and competently.

Allied to this, Choo et al. conducted a qualitative analysis of the factors that influence how supervisors' and trainees' perceptions of trust impact decision making [155]. Some supervisors reported using perceived trainee confidence as a barometer of their true ability and comfort, while others reported overconfidence, as defined by the inability to recognize limitations, as a red flag for the need for increased scrutiny. Indeed, the most important trainee attribute that led to development of supervisor trust was adequate medical knowledge. Further attributes that contributed to entrustment included demonstration of judgement and applying evidence-based medicine, leadership skills, anticipated specialty, and ability to recognize limitations. Additionally, several supervisors described the use of an early litmus test to determine the degree of entrustment throughout the trainee's rotation. An important attribute highlighted by supervisors included the quality and nature of the trainee's communication skills. An inability to reliably or effectively communicate patient status or supervisor concerns was deemed as a reason for closer supervision. The clinical experience, knowledge base, and personal involvement in patient care of the supervisor also were demonstrated to play a role in entrusting trainees with independent practice. Supervisors deemed that increased case complexity, presence of legal or ethical issues, and greater urgency and severity of the clinical scenario were drivers of more supervisor input. Decision making with regard to patient discharge and transfer was also seen as requiring greater supervision, regardless of case complexity [156]. Other important factors with regard to entrusting trainees to practice independently included those that relate to the context and environment within which the EPA occurs. This included physical proximity of the supervisor, institutional culture, work load, trainee experience and level, time of day, and efficiency pressures. Additionally, team dynamics also play a crucial role in entrustment decisions. Good supervisor-trainee rapport within a collaborative environment was more likely to result in greater trainee autonomy.

Findings such as those mentioned above can aid the development of evaluation tools to provide structure for entrustment decisions and assess whether trainees are ready to practice unsupervised. Moreover, recognizing the varying learning curves of trainees and utilizing EPAs and STARs can allow the development of competency-based curricula where training is flexible and learning is not only safe [157] but of maximum benefit to the trainee [158]. Multiple studies have demonstrated that the information included in the Performance Evaluation of surgical trainees moving from rotation to rotation or from residency to fellowship and onto jobs, can at times fail to reliably predict residents/trainees' future performance [159, 160]. This faulty transfer of information can lead to harm when poorly prepared trainees fail out of residency or, worse, are shuttled through the medical education system without an honest accounting of their performance. Such poor learner handovers likely arise from two root causes: (1) the absence of agreed-on outcomes of training and/or accepted assessments of those outcomes, and (2) the lack of standardized ways to communicate the results of those assessments. To improve the current learner handover situation, an authentic, shared mental model of competency is needed; high-quality tools to assess that competency must be developed and tested; and transparent, reliable, and safe ways to communicate this information must be created. The CLASS model includes a description of the learner's Competency attainment, a summary of the Learner's performance, an Action list and statement of Situational awareness, and Synthesis by the receiving program. This model also includes coaching oriented towards improvement along the continuum of education and care [161].

Future Directions

Surgical teams make fewer mistakes than do individuals, especially when each team member knows his or her responsibilities, as well as those of the other team members. However,

simply bringing individuals together to perform a specified task does not automatically ensure that they will function as a team. The role of the clinical microsystem as the unit of training and measurement is key. Surgical teamwork depends on a willingness of clinicians from diverse backgrounds to cooperate in varied clinical settings (i.e., clinic, operating theatre, intensive care unit, surgical wards) towards a shared goal, communicate, work together effectively, and improve.

To achieve high reliability and consistent performance, each team member must be able to (1) anticipate the needs of the others; (2) adjust to each other's actions and to the changing environment; (3) monitor each other's activities and distribute workload dynamically; and (4) have a shared understanding of accepted processes, and how events and actions should proceed (shared mental model).

Teams outperform individuals especially when performance requires multiple diverse skills, time constraints, judgment, and experience. Nevertheless, most people in healthcare overlook team-based opportunities for improvement because training and infrastructure are designed around individuals and incentives are all individual based. Teams with clear goals and effective communication strategies can adjust to new information with speed and effectiveness to enhance real-time problem solving. Individual behaviors change on a team more readily because team identity is less threatened by change than are individuals.

Future work should continue to evaluate the selection, upskilling, timing, duration, and impact of sustainability of team training. This includes evaluating the impact of team training on patient safety outcomes, evaluating team training in other settings (e.g., emergency department, outpatient surgical care settings), examining the comparative effectiveness of different methods for delivering team training, and examining implementation methods to support sustaining behavior changes achieved through training. For example, there is little evidence available to date that provides insight into the frequency of retraining or dedicated practice needed to develop and maintain effective teamwork skills. Additionally, there is a need to examine how dynamic team composition (i.e., changes in team membership, absence of key members) moderates team processes and the effects of team training.

Turning surgical care experts into expert teams requires substantial planning and practice. There is a natural resistance to move beyond individual roles and accountability to a team mindset. One can facilitate this commitment by (1) fostering a shared awareness of each member's tasks and role on the team through cross-training and other team training modalities; (2) training members in specific teamwork skills such as communication, situation awareness, leadership, "follower-ship," resource allocation, and adaptability; (3) conducting team training in simulated scenarios with a focus on both team behaviors and technical skills; (4) training team leaders in the necessary leadership competencies to build and maintain effective teams; and (5) establishing reliable methods of team performance evaluation and rapid feedback.

The roadmap for future research must include how expertise is developed and sustained and how teamwork training should be structured, delivered, and evaluated to optimize patient safety in the perioperative setting. For teamwork skills to be assessed and have credibility, team performance measures must be grounded in team theory, account for individual and team-level performance, capture team process and outcomes, adhere to standards for reliability and validity, and address real or perceived barriers to measurement. The interdisciplinary nature of work in the perioperative environment and the necessity of cooperation among the team members play an important role in enabling patient safety and avoiding errors. Training team leaders and surgical teams in this manner will lead to better satisfaction, joy at work, and reduced burnout of surgical team members.

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Promoting Occupational Wellness and Combating Professional Burnout in the Surgical Workforce

14

Ross M. Ungerleider, Jamie Dickey Ungerleider, and Graham D. Ungerleider

"It matters that life lives through you."

—Roger Keyes

Hokusai says look carefully.
He says pay attention,
notice.
He says keep looking,
stay curious.
Hokusai says there is no end to seeing.
He says look forward to getting old.
He says keep changing, you just get more who you really are.
He says get stuck, accept it, repeat yourself as long as it is interesting.
He says keep doing what you love.
He says keep praying.
He says every one of us is a child, every one of us is ancient, every one of us has a body.
He says every one of us is frightened.
He says every one of us has to find a way to live with fear.
He says everything is alive—shells, buildings, people, fish, mountains, trees, wood is alive. Water is alive. Everything has its own life. Everything lives inside us.
He says live with the world inside you.
He says it doesn't matter if you draw, or write books. It doesn't matter if you saw wood, or catch fish. It doesn't matter if you sit at home and stare at the ants on your veranda or the shadows of the trees and grasses in your garden.
It matters that you care.
It matters that you feel.
It matters that you notice.
It matters that life lives through you.
Contentment is life living through you.
Joy is life living through you.
Satisfaction and strength is life living through you.
He says don't be afraid. Don't be afraid.
Love, feel, let life take you by the hand.
Let life live through you.
—Roger Keyes

The following is from a Wikipedia page:

> Jonathan Drummond-Webb (29 August 1959–26 December 2004) was a South African pediatric heart surgeon. He committed suicide. His suicide note indicated professional frustration may have been a factor in his death.

The following is from a The *Chicago Sun Times* (July 3, 2010):

> A (pediatric cardiac) surgeon apparently shot his wife and killed himself Friday, a month after she filed for divorce and sought an order of protection against him, according to police and court records. Dr. Hani Hennein, 52, was found dead of a self-inflicted gunshot wound at the family home in the 700 block of South Hillside Avenue just after 7 a.m., police said.

The following are from stories relayed to us (names withheld and details altered to obscure identities):

> I've been a pediatric cardiologist for 26 years and I'm nearing what should be the most rewarding

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part of my life, but I've never been more depressed. Our children are grown and my wife and I find that we have little in common. I feel angry all the time. I'm overweight, out of shape and on a statin. I'm not sure what has happened to my life.
Or
I was on call the night my mother called me to tell me my grandfather had died. She had called several times during the past hour, but I was busy and ignored the calls. When I had a break I called her back. That's when she told me the news and I snapped back a response: "Mom, I'm on call. I'm busy. I can't deal with that right now and I have call this weekend, too. I can't get away. I can't come for the funeral." That was 13 years ago. My grandfather was one of the most important people in my life and I didn't go to his funeral because I didn't think that I had enough control over my life to tell my boss that I had to go. I still regret that. Every day. I regret the kind of person I was becoming. I hope my grandfather up there understands. I hope someday I will understand. Right now, I just feel really sad that I let that happen.

The following could be you:

I remember the day I got into medical school and it was one of the most exciting days in my life. My life was so unencumbered back then. Now I just feel overwhelmed. My work no longer gives me joy—it feels like a burden—an obligation. I don't have any time for myself. I have trouble keeping up with my friends. It seems I have to work harder (for less) and between the increasing demands of my practice, my family and trying to pay off my education debt I feel like I'm barely making it. I'm not living my life. I'm *enduring* my life.

How does this happen? It's not a part of the dream we had as we entered the profession of medicine. But somewhere in between the excitement of that early dream and the poignancy of the stories above is the reality that many of our colleagues find themselves experiencing.

Burnout and Distress

The literature on burnout and distress in today's physicians is disturbing. Over the past decade, articles have begun to avalanche into the medical, business, and social sciences literature about professional "burnout." Highly trained professionals, in what should be the prime of their personal and professional lives, are showing up depressed, anxious, depersonalized, addicted, divorced, and disillusioned and in various states of *disease*. If they show up at all. Burnout and distress contribute to absenteeism, which in its most severe form can lead to suicide.

Given this sobering introduction, it might be attractive to change the title of Willie Nelson's famous song to "*Mommas, don't let your babies grow up to be doctors*." In the pages that follow, we will provide a brief overview of the current state of this problem and its implications for both safety and quality. More importantly, we will also make suggestions that we hope will help you, personally, find protection, recovery, and, quite possibly, renewal for your dreams.

Physician distress is not a "new" problem. Articles describing "burnout" among physicians, nurses, and even hospital administrators began appearing in the late 1970s [1–4]. A quick search of medical database publications indicates that the appearance of literature related to burnout is doubling every decade. Although there were only a handful (less than 100) of articles on burnout in the 1970s, there were close to 1000 (776) in the 1980s; over 2000 in the 1990s (2041); and over 4000 (4092) in the first decade of this century and halfway through the current decade there have been 3418 referenced papers related simply to burnout—predicting over 7000 publications on burnout alone in the decade between 2011 and 2020. If the search is expanded to include topic titles such as depression, suicide, marital distress, compassion fatigue, and substance abuse among physicians, and even the more hopeful title of *wellness*, the amount of published material is overwhelming. This has become an issue of global warming proportions!

In 2008, the American College of Surgeons (ACS) Committee on Physician Health and Competency conducted a survey of its membership using a validated instrument for burnout, quality of life (QOL), and career satisfaction. The sample size was a staggering 7905 surgeons. Collectively, 40 % of surgeons met the criteria for burnout, 30 % screened positive for depression, and 28 % had a mental QOL score at least ½ standard deviation below that of the US population [5, 6]. Younger surgeons (our future) and those with children between the ages of 5 and 21 were a higher risk as were surgeons whose compensa-

tion was based entirely on billing/productivity, and those who spent more nights on call per week. There is an increasing body of evidence that burnout, and its related distress factors, can have a significant adverse effect on patient safety and quality of patient care, and even contribute to medical errors [5, 7–11].

Although burnout and related forms of distress (a sense of feeling overwhelmed and of low accomplishment, anxiety, depression, depersonalization, and health issues related to stress) may likely occur in many professions, it does appear that healthcare professionals are particularly vulnerable, and women may be more susceptible than men [12]. Medicine attracts a diverse group of individuals, some of whom are *genuinely altruistic* (meaning they value placing the needs of others above their own), while others have *self-serving altruism* (meaning they need to feel that they have helped others in order to feel good about themselves). Students applying to medical schools are often *high achievers*, *ambitious*, *competitive*, *idealistic*, and *perfectionistic* (a combination that leads to high expectations and a loud internal (and sometimes external) "critical" voice when results are less than desired). Many physicians are by nature comfortable with a life of "delayed gratification" that can contribute to a "suffer now to reap eventual rewards" mentality. In our own (now close to 20 years of) work with physician and other healthcare professional clients, we have noticed the consistency with which they value teachers or colleagues who "are always in the hospital," who "don't ever seem to go home—they are here 7 days a week," or who "spend their time writing, teaching and achieving recognition" beyond what their "normal" colleagues do. The type of "role modeling" described above may be detrimental in the long run, as noted by some well-known experts in the field of physician well-being, who suggest that these "heroes (of our young, emerging healthcare workforce) lead lives that are desperately out of balance" [13]. Ultimately, this creates the sad irony that the physicians who are respected for their responsibility to care for others are the ones who seem to most neglect themselves and those who are close to them. Few, if any, medical schools do a credible job of teaching wellness skills such as meditation, perspective-taking (a method of valuing the perspective of another as a credible part of the "truth"), self-compassion, stress/self awareness, stress/self management, or other forms of self-care, leadership, and personal growth. Physicians are taught to be "knowers" (they are tested for "knowing" and not for skills such as willingness to learn, persevere, or think differently), and as such they are constantly hard on themselves and on their colleagues who might let them down. This is not really an issue of balance as much as it is one of values [14].

Burnout was previously thought to be a late career phenomenon, but more recent studies suggest that young physicians today have nearly twice the incidence of burnout compared with their older colleagues [15]. One recent review looking at physician satisfaction and burnout at different career stages [16] suggests that mid career appears to be a particularly challenging time for physicians. However, early career is also a risk period and the appearance of burnout and related distress syndromes has been described in resident physicians [17–21] and more recently in medical students [22–29]. One explanation for this might be in the enlightening research from Robert Sapolsky who has studied the response of primates to hierarchical stress. Primates with less influence in decisions tend to have the higher level of stress-related cortisol and are more likely to withdraw from social interaction. This not only helps us understand why younger physicians who generally are lower in the hierarchy experience burnout and distress from feeling helpless and having no power, but it might also help us understand why physicians in general are now becoming despondent as they begin to feel disenfranchised from healthcare policy decisions that affect their lives as well as how they are told to practice medicine [30]. Other evidence points to burn-out contributing to acting out in unprofessional and disruptive manner in and around the operating room [31]. Furthermore, these pressures can have a lasting effect on technical and non technical aspects of patient care [32].

Beginning in 2012, we began collecting longitudinal data related to burnout and distress in students enrolled at Wake Forest University School of Medicine. We now have 4 years of data and the only longitudinal data of medical student distress that we know of. Previous studies on medical student, resident, or physician distress have been generated from single time frame evaluations of the study population. Under IRB approval, we obtained information pertaining to burnout and distress using the Medical Student Well-Being Index (MSWBI) [24]—a validated instrument for evaluating burnout, anxiety, depersonalization, a sense of feeling overwhelmed, fatigue, and stress-related health issues. We surveyed all medical students in every class for 4 years at various periods during their medical education. Our results were remarkably similar from class to class and composite data are displayed in Fig. 14.1. Figure 14.2 displays the rising incidence of burnout and "near burnout" as medical students progress through their education at Wake Forest University School of Medicine.

Our findings indicated that except for anxiety (approximately 30 % of students at orientation report feeling anxious), students begin medical school with a low level of other distress elements. However, by the time they have been in school for only a couple of months, we begin recording increasing levels of depression, depersonalization, and a sense of feeling overwhelmed. What is particularly notable about the data on our students is the periodic effect of life events on their well-being. Although most distress elements seem to diminish during breaks and then increase during times of stress—such as around the time of preparation for the ABMLE step exams (1 > 2)—depersonalization (question # 2 in Fig. 14.1) does not diminish and continues to increase throughout medical education. This suggests that once depersonalized, students remain depersonalized, although anxiety, depression, and a feeling of being overwhelmed may vary depending on other life events. By the time the students reach their fourth year, almost half (44 %) are depersonalized. As a whole, males are also *more likely* than females to feel depersonalized (26 % vs. 21 %; z value = 2.72) and *less likely* to feel depressed (22 % vs. 34 %; z-value = 5.2), overwhelmed (24 % vs. 35 %; z-value = 4.9), or anxious (37 % vs. 58 %; z-value 8.6) as they proceed through medical school. In addition, Caucasian (nonminority) students are *less likely* than non-Caucasian (minority) students to become depersonalized (23 % vs. 29 %; z value = 2.2), and are less likely to feel depressed

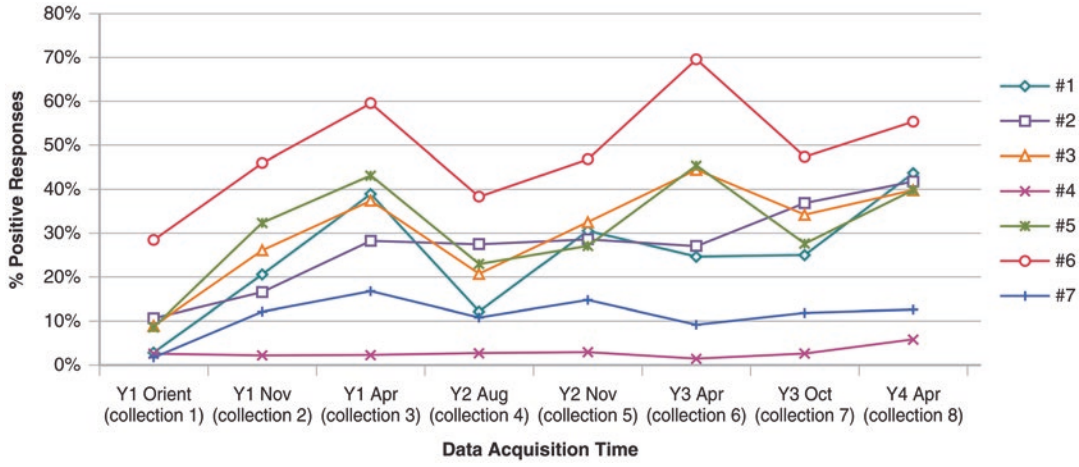

Fig. 14.1 *% Positive responses over time by MSWBI question (composite of all classes).* Percentage (*vertical axis*) of positive ("yes") responses to each MSWBI question for *all students* grouped by collection period (*horizontal axis*). *Question 1* measures emotional exhaustion (EE), *question 2*—depersonalization (DP), *question 3*—depression (DEP), *question 4*—fatigue (FT), *question 5*—sense of feeling overwhelmed (OVRW), *question 6*—anxiety (ANX), and *question 7*—major stress-related health impairments (HEALTH)

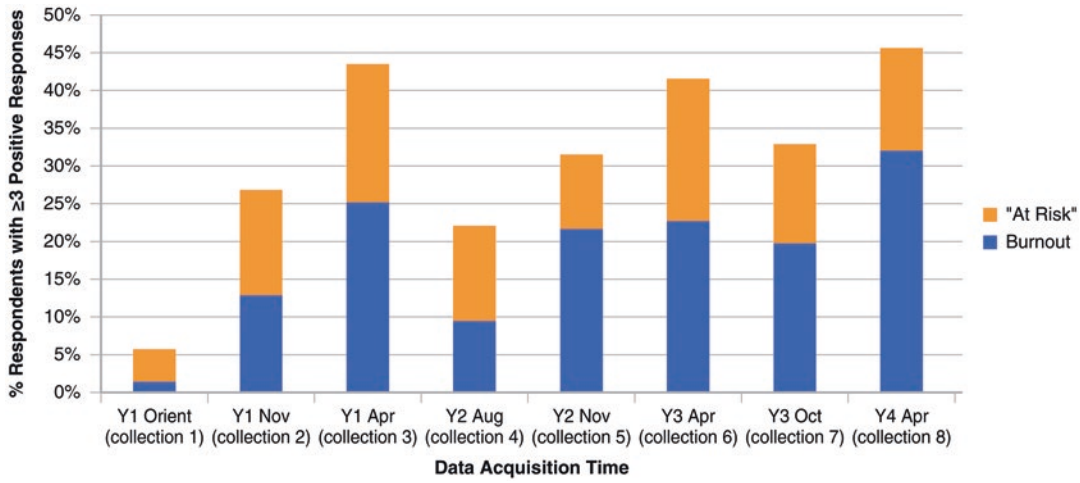

Fig. 14.2 *% At risk (3 positive responses) and burnout (≥4 positive responses) over time (composite of all classes).* Percentage of students (for each collection period) who are "burned out" or "approaching burnout" and consequently "at risk" for serious burnout-related consequences (health impairments, dropping out of school, suicidal ideation, etc.). "At risk" defined as 3 positive response to MSWBI questions on an individual survey and burnout defined as ≥4 positive answers to MSWBI questions. Proportions for burnout were calculated as total number of yes responses out of seven on a given survey rather than using question-specific parameters

(27 % vs. 36 %; z-value 2.89) or overwhelmed (28 % vs. 34 %; z-value 2.2) as they proceed through medical school.

Depersonalization invites more than lack of empathy. Depersonalization can contribute to lack of conscience (with implications for professional integrity), lack of the ability to perform self-reflection (a critical quality for leadership and creating emotionally intelligent relationships), lack of imagination, energy, intuition, and moral imperative. This can lead to problems in building trust, working effectively with others, being skillful in action, and in managing moods and emotions—all qualities essential for safe and effective healthcare delivery. In a study of burnout and medical errors among American surgeons, Shanafelt et al. [7] found that whereas a one-point increase in emotional exhaustion resulted in a 5 % increase in the likelihood of reporting a medical error, a one-point increase in depersonalization resulted in an 11 % increase of reporting a medical error. There is ample evidence that feelings of depersonalization are associated with the risk of non-empathic and morally suspect behaviors, as well as with physical, emotional, and mental problems [33, 34].

Students who provide ≥4 positive answers to the questions in the MSWBI meet the criteria for burnout as described in the literature. Previous studies have suggested that once someone has provided a score of 4 or more positive answers, they are also at risk ("15-fold compared to students with no distress conditions") [23] for serious thoughts of dropping out of medical school [23, 35], having suicidal ideation [23, 25, 27, 28, 36], poor mental quality of life [35], or high fatigue [26, 33]. In our study, we also considered students with at least three positive answers to be an "at-risk" group for burnout. Using this definition, almost half (46 %—combining those students who are either "burned out" or "at risk for burnout") of our students seem to be at risk for major negative life events by the time they begin their fourth year of school (Fig. 14.2).

The implications of this study are evident. Medical school literally makes people sick. They don't come in sick, but by the time they near completion of their studies they have experienced progressive emotional exhaustion, depersonalization, depression, anxiety, irritability, and a sense of being overwhelmed. One out of ten students report that they have developed stress-

related impairments to their health—a problem that is virtually absent when they begin school. Burnout and distress have a negative impact on quality of life, and both appear and increase inexorably throughout medical school.

These are new, but not surprising data, which indicate that the conditions that result in burnout and distress occur *prior to becoming a doctor*, and therefore we believe that they should be urgently addressed during medical training, across the entire spectrum of healthcare. Einstein once famously stated "you can't solve a problem with the same minds that created it." We would add that you can't solve a problem that you can't/won't acknowledge. Unfortunately, it has been our experience that when the very medical leaders who can influence change are presented with these data, they either diminish or normalize the importance of the information, or claim that this is simply pervasive and not something they can change, (perhaps due to their own depersonalization and burnout?) In the early 2000s the ACGME (Accreditation Council for Graduate Medical Education) initiated the *Outcomes Project* that introduced the requirement that physicians become competent in a variety of areas beyond medical knowledge and patient care—ironically this was implemented as a method to cultivate patient-centered care, reduce medical error, and move healthcare towards a system that was "safe, equitable, efficient, timely, and equitable" [37, 38]. These *competencies*, as they were termed, included professionalism which required that residents demonstrate "responsiveness to patient needs that supersedes self interest" [39]. This is the conundrum to which healthcare providers are held accountable. How can they take care of themselves when there is *always* a sick patient in need of attention that would *supersede one's own needs*? Of course the patient should always "come first." And we would remind you, "so should you." In the remainder of this chapter, we will suggest ways that this can be possible.

Wellness

If our current medical culture promotes burnout and distress, then it becomes incumbent upon each of us to take back control of our lives and create for ourselves a personal culture of wellness. Wellness entails much more than the absence of burnout. That would be like defining health as the absence of disease [39]. Wellness embodies energy and vitality. Wellness embraces joy and playfulness. Wellness promotes resilience, learning, self-compassion, creativity, and relationship. Wellness requires a healthy mind, body, and heart—and the behaviors consistent with those. Wellness encompasses all the important aspects of our lives and exists in numerous dimensions, including mental, physical, emotional, spiritual, and relational. This section will discuss basic tenets of wellness and suggest ways that might help you better manage the demands of your professional life [40].

Medical centers, hospitals, and practices have become increasingly aware of the challenges their healthcare workers face, and this has led to increased efforts to prevent burnout. Some programs have instituted wellness programs [39], including coaching, opportunities for encouraging and promoting physical exercise (the Cleveland Clinic provides pedometers to all employees and encourages them to take 10,000 steps/day—a virtual impossibility for surgeons who stand in one place for extended periods of time), stress management training, and other support systems [39, 41, 42]. Many medical centers are changing their cafeterias to environments dedicated to healthier eating with more transparent nutritional information and some have gone so far as to remove unhealthy items (such as fried foods or foods with high sugar content) entirely from their campus. Others have suggested that wellness become a quality indicator against which to measure the successfulness of our organizations [43]. Despite these efforts, a human dilemma continues to plague healthcare professionals when they are asked (either directly or indirectly) to strictly adhere to the belief that professionalism requires placing the patients' needs above one's own needs—creating the unintended consequence of perpetuating a culture of self-denial (food, rest, basic hygiene, self-care) leading to burnout, depression, depersonalization, and unresolved stress with resultant manifestations for our health and even for our survival. The reality is that we are not "limitless resources" [44]. This dilemma

summons the challenge of crafting systems of abundance and inclusion that allow for both care of patients and caring for the caretakers—ourselves. In recent years, this has spawned a preponderance of literature addressing concepts of work–life balance—a curious term since it invites us to think that there might be a magical and static formula that will protect both us and our careers from unraveling into a loosely recognizable jumble of our dreams and hopes.

Work–life balance is not possible. There is no formula that will create a balanced life that fits for all of us. Life is challenging, sometimes messy, and potentially invigorating.

Decisions about managing the demands of work and life require *choice* [14, 40]. How we understand and manage our process for making choices contributes to our ability to be "well." In the sections below, we provide an overview of some important research that relate to creating a life of intra- and interpersonal wellness. We then offer a few suggestions that may help you begin this journey.

Research Behind Wellness

Flexibility and Congruence: Choice becomes more consistent with wellness (our physical, mental, emotional, spiritual, and relational wellness) when it remains connected to our values. We described this in an article we published several years ago, and we have reproduced part of that article below [40]:

We were once asked to give a talk to a large group of surgeons on how to create a balanced life. We followed an expert in time management. His talk comprised an informative sequence of slides that provided advice on how to be organized and efficient from the time you got up in the morning until you went to bed at night. The audience was busy writing notes on every bulleted point. So were we. Here was a lecture full of useful information. We would never again have an excuse for failing to get our tasks done. And we would be able to expect the same efficiency from others. What a wonderful prescription for success. With the audience now fully cognizant of how much more productive we could all be, we began our talk with a story about time management as we see it. If you take a large jar and fill it with some big river rocks, is it full? "Of course not," replied this now well-attuned audience. All right then, what if we then took scoops of pebbles and poured them into the jar to fill those spaces between the rocks. Is the jar full? "No," replied the audience. There is still space. So, what if we then sifted in a bunch of sand and gently shook the jar to make certain it invaded whatever space is left. Is it full? "No." Apparently the previous speaker had made quite an impression. Well, what if we now fill the jar with water. Is it full? "Yes," sighed the audience. "We believe you have now filled the jar." So, we asked, what is the point of all this. Our time management guru, who was still in the audience, blurted out the obvious: "Just what I was mentioning. You can get a lot more into your day than you imagine." Well, we replied, that would seem to be the case. We offer another thought that we would like you to consider: If you don't get those big rocks in first, you'll never get them in later. Those big rocks are the secret for being intentional. They are the core elements of your life. If you lose touch with them, you will lose your foothold on the foundation that can support and balance your life.

Achieving balance in professional life has been a hot topic in the past few years at many medical meetings. We are frequently asked to speak about this, and we are often in the audience as others give their views on the subject. Balance, contrary to the opinions of some, is not about creating equal parts of work and time with the family. Balance is about choice. "Who are you and what do you want?" These seem like such simple questions, but many of us go our entire life and never answer either. The numbing and insatiable addiction to the external validation that comes from performance recognition can have us lose sight of ourselves. Begin to believe that you are defined by your performance, and at some point in your life, you may, having travelled far from who you are and the dreams that you held for yourself, become focused solely on the performance required for the next award. It's as if you set out to be some thing, and you forgot how to be some one.

There is a classic scene in the movie *City Slickers*, with Billy Crystal and Jack Palance. Palance plays the part of Curly, a wizened cowboy who takes middle-aged business men on cattle drives to help them get away from the crises of their lives. Billy Crystal (Mitch) is struggling with how to handle numerous stresses in his life and he is riding alongside Curly when he gets a famous dose of Curly's wisdom.

> Curly: "Mitch, How old are you? 38?"
> Mitch: "39."
> Curly: "Yeah, you all come up here about the same age. Same problems. Spend about 50 weeks a year getting knots in your rope and then you think 2 weeks up here will untie them for you. None of you get it. (Pause. They stop riding and just look at each other. CURLY continues). You know what the secret of life is?"
> Mitch: "No. What?"
> Curly: "This." (He holds up his index finger.)
> Mitch: (Trying to be funny, and dismissive of his feelings) "Your finger?"
> Curly: "One thing. Just one thing. You stick to that, everything else don't mean s**t."
> Mitch: "That's great, but what's the one thing?"
> Curly: "That's what you gotta figure out."

That "one thing" might be to figure out your big rocks, those things that give your life a meaningfulness that you feel somewhere in the middle of you. And make choices with them in mind.

Articles by us, and others, have described the dynamic and often competing energy between the needs (hopes, wishes, demands) of *ourselves* (our own deep wants that we have frequently been taught to suppress as irrelevant), *others* (with whom we are in relationship—either at home or at work), and our *context* (the current situation, environment, professional expectation, etc.) [14, 45–47]. This ability to be aware of the needs of self, other, and context and then to be able to manage these needs forms the basis for emotional intelligence and many other important leadership and life management strategies [48–53]. In order to become skillful in this practice, it is critical to develop unflinching self-awareness, empathic openness to others, and an ability to be *c*urious, *o*pen, and able to *a*ccept without judgment, but rather with the ability to simply *l*ove what is present (COAL) [54–56]. Physicians are acculturated to "know" answers which leads them typically to judge (triage, evaluate, interrogate or criticize) and to take action (cure, treat, offer expert advice, or fix something) much more than they are taught to be curious (to "not know") and simply notice, or explore to understand by asking (without interrogating and by exposing the vulnerability of a "beginner's mind") [57–59].

Developing a sense of self is perhaps the most challenging skill for a physician and yet without developing this, wellness is elusive. We are not talking here about the "aggrandized sense of self" that is often wrapped up in the protected cocoon of grandiosity from our acclaim or achievements, but rather the genuine sense of self that sees and accepts all of our self-aspects including our limitations, mistakes, and longings without shame and with compassion and love [60, 61]. It's that part of us that may keep us awake at three in the morning wondering how our life took the path we now find ourselves on. That sense of self is authentic and it needs to be listened to [62]. It is through attuning to your own voice that you will be able to find and stay on your path to wellness.

Our most current thinking about work and life is what we term, *Work Life Flexibility and Adaptability*, and is illuminated in a story we published many years ago (when the field around us still tried to encourage the concept of *balance*) and we were struggling with better ways to teach skills for achieving something that looks like balance but that feels much more *congruent with honoring the needs of self, other, and context* [14]. Congruent decision making invites and encourages us to stay present and attuned as we explore and hold in regard the complexity of competing and divergent needs. The consequences of ignoring this information, or suppressing it as irrelevant, enhance the likelihood of living with continually unmet needs

which is a major contributing factor to burnout and distress [45–47, 58, 63, 64]. *When we achieve a sense of congruence, our choices invite us to have greater compassion for the difficulty of what we do*. This story (and others) [14, 40] has helped numerous colleagues understand the competing variables that must all be valued and honored in order to make choices that remain connected to the delicate essence of our lives—choices that respond to what is happening in the *now*, and that don't get stuck repeating tired patterns that may not serve us well any longer.

In an address to the International Conference on Communication in Healthcare [44], Charles Hatem suggests that attentiveness to wellness can lead to *renewal*. Renewal is a hopeful term; and that is appropriate because hope is a key ingredient for change. Renewal invites us to return to our self, which can be daunting to healthcare workers who have been taught to ignore their own needs. This invitation to return to our self brings to mind the prophetic words of T.S. Elliot:

> We shall not cease from exploration,
> And the end of all our exploring
> Will be to arrive
> Where we started
> And know the place for the first time.

Often referred to as the poet laureate for corporate America, David Whyte once wrote [65]:

> *In effect, if we can see the path ahead laid out for us,*
> *There is a good chance it is not our path;*
> *It is probably someone else's we have substituted for our own.*
> *Our own path must be deciphered every step of the way*.

In healthcare, we have been taught to pay attention to the needs of others and to the demands of the context, but returning to the sanctity of the self is an important theme in the "hero's journey" that many professionals complete during the course of their career [62]. It is a journey of spiritual awakening among physicians, and it is the journey that leads to wellness. In this sense, spirituality is defined as the reality of our commitment to a larger set of transcendent values as a framework for what we do, and properly acknowledged and incorporated, this becomes a key part of the front-wheel drive in our lives [44, 62, 66].

Integration and the Window of Tolerance

In our work with numerous professionals, including many in highly stressful healthcare endeavors, a common theme we have observed among those who are in distress or who are burned out has been lack of integration. We view integration as an essential skill for achieving wellness.

Integration is the ability to *link differentiated parts into a whole that is flexible, adaptive, coherent, energized, and stable* (FACES) [56, 58]. You might want to imagine integration as a river (as portrayed so elegantly by Dan Siegel) [56]. The river (which symbolizes your life) is constantly flowing past two banks. On the left bank is rigidity and on the right bank is chaos—neither is an integrated or desirable bank to rest on. In order to stay in the river (of integration), one must avoid becoming overly differentiated (not allowing the feelings, opinions, or information from others to influence us)—which leads to chaos (imagine if your family or team was comprised of people who were totally differentiated and unable to take any influence from (link to) each other—theirs was the only opinion or knowledge that counted—it would be chaos). On the other bank is rigidity, which is the result of too much linkage—where people "fuse" in their beliefs (such as creating protocols and policies that apply to all and from which there is no room for differentiation). In our healthcare culture, we have been encouraged to link to the point of rigidity and deviation (including introduction of wellness programs) is considered irrelevant, at best; and disruptive at worst. When that culture becomes pervasive, we have become grounded on a riverbank and are no longer able to value differentiated parts. FACES reminds us that to stay in the river, we need to adopt the seemingly paradoxical ability to be *flexible* yet *stable* [58]. To do this requires we (1) adapt to what is happening now (within (self), among (others), and between (context)) and treat that information with *coherence* (harmonious connection of equally valuable parts) while appreciating the *energy* available to us with this awareness.

These skills empower us to consider emerging possibilities and free us to make choices that remain stable (connected to our values and goals) while allowing infinite flexibility (potential for creativity and non-automaticity).

If the river of integration symbolizes our journey through life, obstacles that float towards us create challenges to which we have a variety of responses. On some occasions those challenges become intolerable and we react. One way of reacting is to *fight* (akin to throwing an instrument, or yelling at someone) or *flee* (we simply leave—perhaps saying who needs to put up with this anymore, I deserve better). Another way that we react to a challenge, when it becomes intolerable, is we *freeze* or *collapse* (simply disengage or shutdown). This would be similar to avoiding a conflict or even deciding to quit a job—get a divorce. Each of us has a window of tolerance that we can notice. Our window of tolerance may be big for some people or circumstances, and very small for other people or circumstances. When we get outside our window of tolerance (as manifested by fight, flee, freeze, or withdraw), it is an opportunity to learn and be curious (remember COAL). We insert this to remind you of the advice from Hokusai (see beginning quotes) because the path to wellness doesn't require perfection; it only requires presence, including that you simply notice. Life, living through you, restores the ability to notice, and use that awareness to treat yourself as one of your own best friends.

Mechanical vs. Complex Adaptive Systems

As mentioned in the earlier section on burnout and distress, our cultural demand for perfectionism and our resultant shame when we can't achieve that impossible goal are factors that contribute to our inability to be well. Lack of understanding on the part of healthcare professionals and leaders in distinguishing the difference between mechanical and complex adaptive (biological) systems perpetuates and exacerbates this problem.

Table 14.1 Mechanical vs. complex adaptive systems

Mechanical system	Complex adaptive system
Predictable, routine	Unpredictable, variable
Task orientation—valuing of consistency and checklists	Relationship orientation—valuing of differences
Emergent behavior discouraged	Emergent behavior encouraged
Interrogate, judge, fix	Explore, understand, join
Spreadsheets, charts, graphs, protocols to enhance or measure reproducibility and comparability	Collaboration, connection, and inquisitiveness to enhance or stimulate change and growth
One correct answer (truth)	Multiple possibilities
Linear thinking	Systems thinking

In their first report, *To Err is Human* (published in 1999) [37], the Institute of Medicine (IOM) called attention to the difference between mechanical and complex adaptive systems. Not only is it important to understand this difference as it relates to patient safety, but it is also critically relevant to your own safety and wellness. Table 14.1 compares some of the important characteristics of each. Mechanical systems are expected to perform in a predictable and routine fashion. An elevator, car, airplane, or heart lung machine is a mechanical system. When you push the button for the fifth floor in an elevator, depress the accelerator on a car, pull back the throttle in an airplane, or turn up the speed of a roller head on a pump, you anticipate a predictable result. You don't just anticipate it, you expect or even demand it. If you don't get that result, you might declare the system to be "broken" and in need of repair, and a repairperson would come and *interrogate* (analyze), *judge* (declare the nature of the problem), and *fix* the malfunction. Mechanical systems lend themselves to task orientation and protocols [67]. Emergent (creative or innovative deviations from protocols) behavior is simply discouraged. You wouldn't want to push the button on an elevator for the fifth floor and have it take you instead to the third floor because that has been the more popular floor today. Mechanical systems work because of consistency—there is one

correct answer—and it is in the owner's manual. Mechanical systems lend themselves to charts and graphs for measuring results because all the systems are the same and are comparable. Mechanical systems are robotic, not human. How would you like to be interrogated, judged, and fixed? Unfortunately, our medical culture often tries to do this to us. No wonder we become unwell.

Complex adaptive systems are unpredictable and variable. We hope for a certain range of performance and when we don't get what we desire, our approach is more often to *explore* (with genuine, open-minded curiosity) in order to *understand* (learn) so that we can *join* (connect to) the system in a way that can help us better manage future relationships to it. Farming is an example of a complex adaptive system. The farmer can learn all they can about the characteristics of the soil, the climate, and other factors that would guide them to plant a certain type of crop, and then they have to watch and see what happens. If they don't get a desirable result, it won't help them to blame the weather, criticize the soil, or punish the seeds. They are better served by trying to understand what happened and how this might influence what they do the next year. They might decide to try something that others in the area haven't tried and this could lead to a remarkable outcome. Errors are understood as opportunities to learn rather than failures that create shame [68]. How many of you would like to be explored with genuine curiosity in order to be understood so that your ideas and energy can be connected in a meaningful and appreciated way to the energy of your group? Complex adaptive systems thrive on this type of emergent (innovative) behavior for change and growth, and these systems invite multiple possibilities or solutions—they are life enhancing, not life restricting. In fact, research has suggested that one of the most powerful behaviors for creating vibrant and resonant relationships and teams is the ability of people to accept influence from one another, regardless of their title or position in the hierarchy [30, 69, 70]. Complex adaptive systems are human and welcome all that comes with that—including, and perhaps requiring, wellness.

In medicine, we work with both mechanical and complex adaptive systems simultaneously. It is important that we don't get them confused.

All of the above information informs ways we can choose to utilize for constructing our lives. In the section that follows we will offer numerous ways for you to recover and renew—which techniques you choose will be a matter of personal fit and comfort.

The Healthy Mind Platter

In 2012, David Rock, Dan Siegel, and colleagues introduced the concept of the *healthy mind platter* [71] (see Fig. 14.3), based on substantial research in the fields of physiology, neurology, biology, business, and medicine. These seven neurocognitive activities nurture the mind, the body, the brain, and our spirit, reconnecting us to our wholeness and allowing us to renew. Below, the items on the platter are briefly described, using information and segments from Rock and Siegel's important article.

Sleep Time

Research has shown that sleep is critical for homeostatic restoration, thermoregulation, tissue repair, immunity, memory processing and consolidation, learning, and emotion regulation. Increasing evidence about noisy and disruptive alarms contribute to disrupted sleep by physicians, to altered physiological vital signs, elevated levels of stress and medical errors [72, 73]. Accordingly, sleep deprivation can be more lethal than food deprivation. Belief that you are a *mechanical system* that doesn't require sleep is not a path to wellness. Recent studies strongly point to the fact that sleep is far more important than is generally recognized, and though people in general (and in healthcare specifically) don't get enough of it, there are easy steps to start remedying this problem. Adding a nap to one's day or an extra 20 min to one's sleep cycle (or both) can yield major benefits to cognition, emotional regulation, and general performance for the complex adaptive system called by your name.

Fig. 14.3 The healthy mind platter

Play Time

Playfulness enhances our capacity to innovate, adapt, and master changing circumstance. In this sense, playfulness is a way to expand our windows of tolerance and improve our capacity to be flexible, adaptive, coherent, energized, and stable. It is not just an escape. Play can help us integrate and reconcile difficult or contradictory circumstances. And, often, it can show us a way out of our problems. All mammals play; yet it is ironic how our healthcare culture suppresses that, because what we do, after all, is "serious business." It turns out that play is also "serious business" [71]. Numerous studies have documented the impact of positive emotions on team and individual performance [69, 74–77] and play invites positive emotions, which have been documented as being critical for optimal performance [69, 74–76]. Equally important benefits of play is that it can facilitate learning and play can help in the development of flexible emotional responses to unexpected events (our window of tolerance) where individuals experience a loss of control, and which can be a major form of stress [30, 71, 78]. Play, or "having fun," is not healthy when it is structured to tease, belittle, or in any way deride a team member [58], but in its pure and spontaneous form, it allows humans to practice the novel motor and social skills that will prove to be essential for survival in the workplace jungle.

Downtime

This is the most counterintuitive component of the healthy mind platter, and possibly the most misunderstood. It is also extremely challenging for most people in the healthcare profession. Downtime does not refer to hobbies (focus time) or sports (physical time) but rather to a very specific activity: "inactivity," or "doing nothing that has a predefined goal." Downtime is actually intentionally having no intention, of consciously engaging in doing nothing specific. Downtime is simply "hanging out, being with one's surroundings, being spontaneous, having no particular goal or focus." Unfortunately, most of the words used by busy/successful professionals to describe downtime have a negative connotation—words like idling, hanging around, loafing, lazing, goofing off, and chilling out. During downtime, we do much more than slumber, rest, and go "off-line." Researchers have shown that insight is preceded and aided by disconnecting from deliberate, goal-directed, conscious thinking and permits the process of *integration*, or the linking of differentiated parts, to unfold. Numerous studies have demon-

strated the superiority of unconscious thought vs. conscious, logical reasoning in creating clearer, and more innovative decisions [79, 80]. In their book *The Break-out Principle* [81], Herbert Benson and William Proctor explain that the best way for solving thorny issues or complex problems is first to struggle with it, through problem analysis or fact gathering, up to the point where one stops feeling productive and starts feeling anxious and stressed. This is the signal for the second step: "distracting" oneself from the problem. There are many ways of doing this, including visiting a museum, taking a hot shower, listening to some calming music, or going for a walk. According to the authors, the key is "to stop analyzing, surrender control, and completely detach (oneself) from the stress producing thoughts." This typically leads to what the authors call "the breakout": a sudden insight or a new perspective that sheds a whole new light on the problem at hand. The very fact that unconscious thought and incubation time are conducive to better decision making and insight has profound implications for self-leadership. Downtime connects the left brain's clutter of facts with the right brain's ability to synthesize and innovate [82, 83] and the result is integration of our cerebral hemispheres in a way that restores wholeness, and with that, a connection to wellness.

Time-In (Reflection, Attunement, Mindfulness)

Time-in is characterized by a very particular type of conscious, focused attention on the inner life of the self in the here and the now. Time-in focuses attention on one's intentions and highlights awareness of awareness itself—the two fundamental elements of being mindful [55]. Time-in develops the capacity to be present with experience in a way that invites one to simply notice (see what Hokusai says at the beginning of this chapter) without judgment while promoting curiosity and acceptance. This awareness is essential for maintaining congruence and for cultivating attunement (to self, others, and context). The literature on mindfulness-based stress reduction (MBSR) is growing rapidly and there is little argument that mindfulness practices pay great dividends in maintaining a healthy physiological and psychological state. Unlike time-out, time-in is time spent paying attention in a particular way, on purpose, in the present moment. Many medical schools are now including mindfulness meditation practices as a part of their curriculum in an attempt to enhance wellness. There are a variety of ways to introduce mindfulness and awareness as an antidote to the automaticity of your life and these include mindful meditation techniques, reflective journaling, or other awareness-inviting practices. For more information on some of these you may wish to visit the following websites:

http://ggia.berkeley.edu/practice/expressive_writing?utm_source=GG+Newsletter+Feb+17+2016&utm_campaign=GG+Newsletter+Feb+17+2016&utm_medium=email#data-tab-how (Greater Good at Berkley and J.W. Pennebaker, PhD)

http://homepage.psy.utexas.edu/homepage/faculty/pennebaker/home2000/WritingandHealth.html (JW Pennebaker, PhD)

http://www.drdansiegel.com/resources/wheel_of_awareness/ (Daniel Siegel, MD)

http://self-compassion.org/category/exercises/ (Kristen Neff, PhD)

http://marc.ucla.edu/body.cfm?id=22 (Guided Meditations at UCLA)

http://www.simplybeing.org.uk/index.php/weblinks

Connecting Time

Social connection is a basic human need, much like water, food, and shelter, and a sense of belonging is essential for wellness [84]. From our earliest days of life, our connections to others provide a source of feeling seen, safe, and secure. It is not surprising that these same feelings of safety and attunement (seeing and feeling seen by others) describe the sense of belonging that is a core element for the ability to form and maintain a highly functional medical team [57, 58]. One of the most powerful measures of social support is whether a person has an intimate, confiding relationship, typically a spouse or a lover; friends or relatives function similarly but less powerfully [85]. In repeated studies, the connec-

tion to another human being has been demonstrated to relieve stress, improve outlook, and mitigate the enormity of an impending challenge. Furthermore, it has been shown that individuals who have diminished social connections may experience higher levels of stress and react more negatively to stress (have a narrower window of tolerance). Given that stress is an important cause of sleep problems, burnout, and depression, the buffering effect of social support on stress is pertinent to our discussion of how the Healthy Mind Platter provides the "nutrition" needed for wellness. A recent article in Harvard Business Review on how successful businesses "manage their emotional culture" introduces the term *companionate love.* In organizations where employees felt and expressed companionate love towards one another, people reported greater job satisfaction, commitment, and personal accountability for work performance [86]. This was contrasted to cultures of fear (defined by *threat rigidity)*, where employees felt intimidated, afraid of doing something for which they might be blamed, and not sure who they could trust. In the latter organizations, burnout (manifested by all the distress elements measured and discussed above as well as by high employee turnover) was high. Organizations that cultivate connections do a lot to invite wellness because the need to belong and to feel valued is a basic human need.

Physical Time

There is little that needs to be emphasized here. Most of us are aware of the numerous wellness benefits of exercise and other forms of physical activity (such as sports, hobbies, or playing). In an article in the New York Times [87], Sandra Aamodt and Sam Wang, respectively, editor in chief of Nature Neuroscience and associate professor of molecular biology and neuroscience at Princeton, take a critical look at computer programs to improve brain performance. The digital brain health and fitness software market is a booming business. According to the 2010 industry report called "Transforming Brain Health with Digital Tools to Assess, enhance and Treat Cognition across the Lifespan: The state of the Brain Fitness Market 2010" the size of the worldwide market in 2009 was $295 million dollars, a 35% growth since 2008, and representing an annualized growth rate of 31% since 2005. According to Aamodt and Wang:

> *"[a]dvertising for these products often emphasizes the claim that they are designed by scientists or based on scientific research. To be charitable, we might call them inspired by science—not to be confused with actually proven by science. One form of training, however, has been shown to maintain and improve brain health—physical exercise."*

And they end their article by stating:

> "*So instead of spending money on computer games or puzzles to improve your brain's health, invest in a gym membership. Or just turn off the computer and go for a brisk walk."*

Exercise improves executive function and moderate exercise reduces stress, decreases anxiety, and alleviates depression [88]—all of the factors that contribute to burnout and deprive us from wellness. While we sometimes consider physical activity to be important for our bodies, the increasing data on how important it is for our brains emphasizes why it is a staple in our quest for wellness.

Focus Time

Focus time is the time we are able to focus, stay focused, and refocus efficiently and effectively. To focus is to pay close attention. There is a direct relationship between stress, focus, and health. One could even propose that the capacity to focus attention is an ongoing indicator of mental fitness. The ability to remain focused by sustaining attention is a function of self-control, and appears to depend on a limited resource. Just as a muscle gets tired from exertion, acts of self-control cause short-term impairments (mental depletion) in subsequent needs for self-control, even on unrelated tasks. When this happens, we can begin to feel overwhelmed and incapable, beginning a slide towards distress and burnout. Focus time requires the ability to refocus following distraction or during multitasking (as we continuously switch the spotlight of our attention back and forth between different stimuli). Performing surgery is an extreme example of focus time. However, many surgeons have told us that after a

particularly challenging procedure that has required them to focus (and block out distractions) over an extended period of time, they need to return to the quiet of their office and have some "downtime" recovering. To achieve the wellness benefits from focus time, we accept that our culture invites distractions that constantly occupy our attention and can serve to drain our energy. An example of this is the experience commonly described by people who begin a mindful meditation practice—they become disturbed that their mind is so distractible and they believe that they are not succeeding at meditating. They are actually noticing what is already there—our minds are in constant movement, attending to the plethora of demands in our life. Simply noticing this is the first gift from meditation. The gift is in noticing and accepting without judgment [89]. Ability to enhance and to maintain focus can be practiced with meditation, but also with hobbies that require attention to a task. Over time, this helps individuals combat the feelings of being overwhelmed (burned out) that so often accompany multitasking and extended needs for focus. Practicing focus promotes wellness by helping us learn how to minimize the "switching time costs" from multitasking that tend to deplete us.

Additional Wellness Tips

Practicing wellness extends beyond including exercise, rest, and nutrition as part of our daily routine. Wellness affects our entire being and is accompanied by the qualities we need to not only prevent burnout, but also thrive—qualities like resilience, creativity, courage, and joy. Ironically, in a recently published survey of cardiac surgeon members of the Congenital Heart Surgeons Society (CHSS) and the European Association of Congenital Heart Surgeons (EACHS), many pointed to these latter qualities as the reason for their success [59]. When we have conducted leadership and team trainings, we sometimes ask three questions. The first is what are the responsibilities of a leader or of a high-performing team member? We often garner a long list of important tasks and performance imperatives that are expected from leading people in our profession—including (but not limited to) decision making, vision crafting, consistency, knowledge, competent (or better) skills, ability to innovate or improvise, manage people, etc. Our second question is similar to the one asked in the survey mentioned above: What are the qualities demonstrated by these high performers or leaders? The list invariably includes attributes like integrity, courage, resilience, self-accountability (absence of blame), perseverance, positivity during adversity, creativity, curiosity, humility, and compassion. Our third question is the more difficult one for people to answer: How do you teach (or manifest) these latter qualities? In a culture that mandates perfection, and evaluates us simply by the one-dimensional outcome of patient survival, where do we measure qualities such as perseverance, grit, integrity, or courage? How do we reward compassion, innovation, or resilience—especially since each of these qualities is often associated with failure and struggle [90]? And if we can't find a way to value and celebrate the emergence of these attributes that are essential to wellness and wholeness, why are we surprised when they get so suppressed and buried that the human spirit in us becomes burned out, depressed, discouraged, overwhelmed, and depersonalized?

In healthcare we are so accustomed to seeking the answers "out there." But to cultivate the qualities mentioned above, the solution lies within us [62] and is beautifully illustrated by the words of Ralph Waldo Emerson:

> What lies behind us
> And what lies before us
> Are tiny matters
> Compared to what lies within us.

Release Yourself and Others from Unnecessary Judgements

Our medical culture can be merciless. Patients come to us for solutions to problems that are not always solvable. Our profession demands that we hold ourselves accountable to perfection and yet *life is so fragile and unpredictable that no one has yet been able to get out of it alive*. This creates an

impossible expectation (that with the right skills, we can prevent the inevitable) and yet most of us have readily embraced and agreed to sign up for the challenge. When a patient survives, we are happy to take the credit and use it to exalt the magnificence of our program (and in some cases, a team member may be happy to adorn themselves with individual credit). And when a patient dies, we take it personally—which is really hard to do, so in many organizations, the blame for something that might have been inevitable lands some*where*, and often in some*one*. If this is hard to read, it is even harder to witness, and yet the number of programs that now get scrutinized, reviewed, and criticized is growing annually—and you would be surprised to know that many of these are among our nation's most exemplary sites. It is enough to make you sick—and in fact, it will. No one of us can survive this type of pressure and remain "well" [91, 92].

So the next time there is an unwanted outcome and the "witch hunt" has gotten under way, simply disengage yourself. It's "their" stuff and you simply don't need to own it. We all do the best we can, and if we can maintain a hold on wellness, we'll survive to be able to help the next patient. Protect yourself from being the container for disappointment and simply *refuse to take it personally*. The problems we sometimes are asked to solve are simply bigger than any of us. In fact, they may not even be problems, which invites this reframe (from a famous Taoist tale):

Once upon a time in a village in ancient China there was an old man who lived alone with his son. They were very poor. They had just a small plot of land outside the village to grow rice and vegetables and a rude hut to live in. But they also had a good mare. It was the son's pride and joy, and their only possession of value.

One day the mare ran away.

The old man's friends came to him and commiserated. "What a wonderful mare that was!" They said. "What bad fortune that she ran off!"

"Who can tell? It is neither good nor bad, it just is." The old man said.

Two weeks later the mare returned accompanied by a fine barbarian stallion. Friends and neighbors all came around and congratulated the old man. "Now you have your mare back, and that stallion is as fine as any in the land. What a stroke of good fortune!"

"Who can tell? It is neither good nor bad, it just is." The old man said.

Two weeks later the son fell off the stallion while riding and broke his leg. Friends of the old man came to him to express their sympathy. "It's too bad your son broke his leg, and right before the planting season, too. What bad luck!"

"Who can tell? It is neither good nor bad, it just is." The old man said.

Two weeks later, war came to the land, and all able-bodied young men were drafted. The troop that contained the men from the village was at the front in a bloody engagement, and the entire troop was lost. All the men from the village died in battle.

The young man with the broken leg stayed home. His leg healed. He and his father bred many fine horses, and tended their fields.

When something happens at work, don't judge it. Judgment not only invites blame but it can be a hallmark for lack of accountability—a deadly trait in a leader. Life experiences provide us with an opportunity to learn. In that way, it is neither good nor bad, it just is. What you do with it—that is the key to wellness.

One technique that helps with this reframe is to *Tell Another Story.* In cases where you find yourself caught up in judgment, remember that you are a complex adaptive system working in a complex profession—and take the invitation to think creatively. What could be an alternative story (stories) that can explain someone's behavior, or help you understand their perspective? What might be another way of looking at an outcome as something from which you can gain a new insight or something positive?

Embrace Joy and Gratitude

You have likely spent many years becoming a capable professional in our field and it has taken sacrifice. Years of studying, nights on call, family events missed, commitment to learning, and constantly getting better. You have developed yourself into a precious and valuable resource. Take a moment to breathe and appreciate your-

self for all you have learned and all you have accomplished. Take another breath and appreciate yourself for how much you care. Let that in. Can you allow yourself to feel grateful for all you have learned? Can you find a way to have compassion for that part of you that cares so much for others? Can you reconnect to that core inside you, that core you know is there, and find joy that you have done something so meaningful with your life. You can take that joy and gratitude with you wherever you go. It can go a long way towards helping you achieve wellness.

Some ways to connect to gratitude are to spend the first few minutes each morning and each evening before bed, reminding yourself of the things for which you have gratitude. You might also consider sending a short note or e-mail to someone for whom you are grateful. Even more powerful is to call them up, or visit them in person, and read your words to them.

Photographic Proof

See if you can locate a photograph of yourself when you were younger. Perhaps you can find several. Take some time and reconnect to that person. There is a lot of information in that photograph. Hokusai says to notice. What can you notice? Notice your posture or your countenance. Notice where you were at the time the photograph was taken. Who were you with? Who took the photo? Where are those people today? If you could say something to that younger you, what would you say? If that younger you could say something to you, what would he or she say? What would you imagine some of the real people whose stories we shared at the beginning of this article might have said to their younger selves, and what might their younger selves have said to them? Imagine if you shared your photograph with other members of your team—would they recognize you—the you that you know is there, still inside you? Would you feel safe sharing that part of you? Or would it feel scary, and perhaps make you feel vulnerable? What does that mean? If you have trouble even thinking of doing the above, what does that mean?

This is simply a way for you to reconnect to who you are and what is valuable about you—not to your title, or to your accomplishments. Not to your possessions or net worth or last patient outcome; but to your real value—the parts of you that are dear and that need to be embraced and loved and protected so that you don't lose them. This is photographic proof that you are whole and valuable and preserving the unique and valuable "you" in a culture that wants to transform humans into robots is what the rest of this article has been about.

Several years ago we were blessed to participate in a conference and serve on a panel with Irish poet, John O'Donohue, whose work we have quoted in the past [40]. John died (young) a few years later of a heart attack, as he was slowing down his life, trying to enjoy the fruits of his labors and embrace his important relationships. We want to end by sharing with you a blessing of his for your work and we hope you can carry this with you as you move forward.

For Work
John O'Donohue

May the light of your soul bless your work
With love and warmth of heart
May you see in what you do the beauty of your soul
May the sacredness of your work bring light and renewal
To those who work with you
And to those who see and receive your work
May your work never exhaust you
May it release wellsprings of refreshment
Inspiration and excitement
May you never become lost in bland absences
May the day never burden
May dawn find hope in your heart
Approaching your new day with dreams
Possibilities and promises
May evening find you gracious and fulfilled
May you go into the night blessed, sheltered and protected
May your soul calm, console and renew you

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Executive Leadership and Surgical Quality: A Guide for Senior Hospital Leaders

15

Susan Moffatt-Bruce and Robert S.D. Higgins

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives."

—William A. Foster

Introduction

Since the early 1990s when reports of the Veterans Administration collaborative efforts to assess and improve surgical outcomes were published, quality assessment and process improvement initiatives have gained progressive importance in the daily function of the modern department of surgery. In 1994, the National VA Surgical Quality Improvement Program (NSQIP) was established in all 132 VAMC's performing surgery [1]. In 1998, Khuri et al. presented the first national, validated, outcome-based, risk-adjusted report outlining structure, data collection, analysis and reporting of surgical outcomes. Validation of these process improvement efforts more than a decade later suggest that continuous quality assessment in NSQIP, and these programs enhance surgical outcomes [2].

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It is with this background that we examine the role of department and hospital leadership in the development and institution of these quality improvement efforts. Historically, the Institute of Medicine has defined the quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This clearly applies to the field of surgery. In many surgical quality programs, however, indicators were and often continue to comprise the traditional measures—complications and deaths reported in a peer review conference setting—rather than more positive components of quality. In the context of the Affordable Care Act, the modern surgical leadership team must develop a vision consistent with what CMS has defined patient safety efforts as "initiatives that go beyond the current Quality Assessment and Assurance (QAA) provision, and aim to significantly expand the intensity and scope of current activities in order to not only correct quality deficiencies (quality assurance) but also to put practices in place to monitor all services to continuously improve performance" (Section 6102 (c) of the Affordable Care Act).

In this chapter, we will define the role and responsibilities of the surgical quality officer, goals of the program, training and resources necessary to implement a successful value-based quality program, and strategies necessary

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to achieve departmental and institutional goals that are deemed successful. The ultimate goal is to establish a "culture of surgical safety" and "continuous improvement" that systematically ensures in the words of Director Clancy of the Agency for Healthcare Research and Quality—"Getting the right care to the right patient at the right time—every time."

Role and Responsibilities for Successful Oversight

Healthcare and the provision therefore is a remarkable combination of skill, clinical judgment, and teamwork. Those that work within it are indeed privileged to be a part of the profession of treating the ill, reducing suffering, and sometimes, simply supporting the patient and family. However, there are times when our care, despite our best intentions, does not produce the outcomes we had intended and may even cause harm to the patient. More than a decade ago, the Institute of Medicine released its famous report, "To Err Is Human," which set an ambitious agenda for the world to reduce the number of patients harmed by medical errors and preventable adverse events [3].

Who is the Chief Surgical Quality and Patient Safety Officer?

The infamous "call to arms" that started more than a decade ago has included creating a culture of safety and accountability. Changing culture is hard work and it takes more than a checklist to achieve a safe environment for our patients and surgical teams. Creating a culture of safety means ensuring that the highest quality of care is not just a project or flavor of the month, but rather at the core of what we do every day for every patient. Creating this environment for a surgical department should ideally be the primary strategic responsibility of the Chief Surgical Quality Officer (CSQO). While no one person can be responsible for all patients and outcomes, the CSQO has the privilege and responsibility of enthusing and supporting every surgeon, every nurse, every resident and student to ensure the best outcomes. The quality and patient safety field is, out of necessity, developing into a discipline or expertise in how to truly engage with organizational culture and translate quality and patient safety goals and objectives into concrete aims and metrics that can be tracked using disciplined approaches [4].

Traditionally, CSQO's were the chief medical officers in smaller hospitals or the Chair of Surgery in other hospitals with smaller departmental structures; often the role of the CSQO was perceived as something "extra" or as a compliance requirement to supplement the "real work" of patient care. Often, the "safety officer" or "quality assurance person" was little respected nor heeded. In today's healthcare environment, with public reporting of medical errors and support for the concept that most patient injuries are a result of system failures and not bad doctors, the role of the CSQO is critical [5–7]. The CSQO must have the ability to acknowledge these root causes, develop countermeasures, and impact change. Additionally, the CSQO must have essential leadership traits which include the ability to assess clinical practice gaps, understand the science of improvement and reliability, foster transparency, engage other physicians and nurses, and set clear outcomes and measurable metrics [8–11].

Identifying the right CSQO, means finding an individual that embraces change and values continuous performance improvement. The CSQO must be able to lead initiatives, address issues, generate support from other surgeons, and engage the right team. Often, these leaders need training in process improvement and conflict resolution [12]. They need dedicated time to network with others, attend national conferences in Quality and Patient Safety, conduct meaningful rounding, and actively work with other team members on projects and rapid cycle improvement. Experience dealing with administrative issues such as resource allocation, contracting, finance and budgeting, and strategic planning may be very helpful in that these administrative skills may facilitate

goal setting and outcomes measurement. The time must be protected and supported by the Department Chair and hospital administration as truly value added and should therefore be appropriately compensated [13, 14].

Lastly, the ideal CSQO should have clinical experience that has allowed him or her to have achieved a level of clinical expertise that is appreciated and recognized by other surgeons and team members. The CSQO should be at a point in their career whereby they can still maintain their surgical skill with a smaller volume of cases. In academic medical center settings, it is unlikely that a junior assistant professor would have achieved this stature within the first few years after residency. Similarly, a surgeon at the end of their career may not be the ideal candidate. The idea of using quality and patient safety as an "exit strategy" flies in the face of having a CSQO that is current, innovative, and continuously improving [15].

Training and Resources Required for Success

The CSQO must engage with fellow surgeons and develop a team approach to continuous improvement. Additionally, designing reliable processes that mitigate human error involves critical assessment of current processes, careful planning, and the use of the science of reliability. Learning the science of reliability is essential to the CSQO role as well as to fellow team members [16]. Most healthcare leaders and surgeons did not learn the science of reliability; just culture or performance management in their professional training and some may not even know that it exists. The CSQO is responsible for engaging surgeons in improvement initiatives which have historically been a challenge for healthcare organizations because surgeons' primary professional focus is their own practice—the quality of care they personally deliver and the economics associated with that care. In many instances, the priorities of surgeons can seem out of alignment with the quality issues that face the healthcare system as a whole [17]. At best, surgeons have often perceived that they have little time to spare for the departmental or organizational quality agenda. At worst, relationships become strained when there is a tension between the surgeons and the agenda of the department as it works within the healthcare system. This can be affected by the various employment models for surgeons.

Since most surgeons have had little training in just culture development, continuous improvement, high reliability or even quality data collection and analysis, additional and dedicated training is highly advantageous. There are different degrees to which the CSQO and fellow surgeons can be trained and can range from online modules, which take 12 h, to a Master's in Operational Excellence or Business Administration which can take 2 years. Table 15.1 lists a number of potential and graduated training opportunities. At a minimum, training in Six Sigma or Lean concepts is recommended. While there is no "one size that fits all," as training is completed, the CSQO will find that they are better able to address quality issues and are more able to engage surgeons successfully because they understand the failure modes and how to facilitate the solutions [18]. Additionally, this training will allow the CSQO to represent the Department of Surgery more appropriately at the healthcare system level with a very sound understanding of national quality metrics and ranking systems, such as U.S. News and World Report, which are heavily influenced by surgical performance.

Reporting Structure and Administrative Committee Support

Continuously improving our processes to ensure safe and high quality care is not only what the public demands of us; it is now tied to our reimbursement. Authorized by the Affordable Care Act, the Hospital Value-Based Purchasing (VBP) program is the beginning of a historic change in how Medicare pays healthcare providers and facilities—for the first time hospitals across the country will be paid for inpatient acute care services based on care quality, not just the

Table 15.1 Training and professional development

Programs	Details	Link
American Society for Quality Learning Institute	ASQ delivers Lean Sigma training using D-M-A-I-C methodology with integrated Lean tools and techniques	http://asq.org/healthcare-use/training/overview.html
STEEEP Academy (safety, timeliness, efficacy, efficiency, equity, and patient-centeredness)	The STEEEP Academy teaches healthcare leaders the theory and techniques of rapid-cycle quality improvement	http://www.baylorhealth.edu/STEEEPGlobalInstitute/STEEEPAcademy/Pages/default.aspx
National Committee for Quality Assurance	NCQA offers a host of live educational seminars and just-in-time webinars	http://www.ncqa.org/EducationEvents.aspx
Institute for Healthcare Improvement	Conferences, In-Person Training, Web-based Training, Audio and Video Programs, IHI Open School, IHI Fellowship Program	http://www.ihi.org/education/Pages/default.aspx
		http://www.ihi.org/education/IHIOpenSchool/Pages/default.aspx
Emory University	Lean Six Sigma Certificate Program	http://ece.emory.edu/sixsigma/
Health Resources and Services Administration	Quality Improvement & Risk Management Training	http://www.hrsa.gov/publichealth/guidelines/qualityimprovement.html
US Department of Health and Human Services		
TeamSTEPPS	TeamSTEPPS is a teamwork system designed for healthcare professionals	http://teamstepps.ahrq.gov/
AHRQ		
World Health Organization	WHO Patient Safety has developed a range of training materials and tools	http://www.who.int/patientsafety/education/en/
US Cochrane Center	Web course created by the United States Cochrane Center as part of a project undertaken by Consumers United for Evidence-based Healthcare (CUE)	http://us.cochrane.org/understanding-evidence-based-healthcare-foundation-action
Understanding Evidence-Based Healthcare		
• Johns Hopkins Bloomberg School of Public Health		

Johns Hopkins Medicine	*Workshops and e-Learning*	http://www.hopkinsmedicine.org/armstrong_institute/training_services/workshops.html
Armstrong Institute for Patient Safety and Quality	The Armstrong Institute hosts training workshops throughout the year targeted to a wide range of healthcare professionals, from front line staff to executives	
Intermountain Healthcare	The Advanced Training Program (ATP) offers a course for healthcare professionals who need to teach, implement, and investigate quality improvement	http://intermountainhealthcare.org/qualityandresearch/institute/courses/atp/Pages/home.aspx
Duke University	Patient Safety—Quality Improvement	http://patientsafetyed.duhs.duke.edu/
	EBM workshop	http://sites.duke.edu/ebmworkshop/
Six Sigma Green Belt Healthcare	Focuses on Six Sigma Green Belt training on healthcare applications	http://cpd.engin.umich.edu/professional-programs/six-sigma-greenbelt-healthcare/index.htm
University of Michigan		
Masters of Operational Excellence	An 18-month degree focusing on developing leaders leadership in the emerging, rapid and continuous improvement environment found in leading service, healthcare, and manufacturing organizations	http://fisher.osu.edu/mboe/
Fisher College of Business, The Ohio State University		

quantity of the services provided. In order to succeed and sustain gains in reducing care-associated adverse events while continuing to fund our mission to provide high quality care, healthcare institutions must embrace standardized, evidence-based practices as well as purposeful engagement of the entire healthcare team. Human factors and in particular, unanticipated events in the operating room during high acuity surgery are a stark and often unnerving reality [19, 20]. Therefore, we as surgeons, partnering with the CSQO and hospital administration, must be responsible to develop a strong safety culture that demonstrates effective coordination of care, identifies gaps and engages caregivers who proactively and thoughtfully bring solutions forward to provide the highest quality of care for all patients [21].

Every department of surgery and healthcare institution is structured a little differently. Nonetheless, some form of departmental Quality Committee, that is aligned with the healthcare institution is essential. The true north for such a committee should be providing the highest quality of care for all surgical patients, which implies care that is safe, efficient, effective, patient centered, timely, and equitable [22]. It is the responsibility of the CSQO to ensure that all of these Institute of Medicine aims are fulfilled within a department and health system so that the delivery of quality care is given equal attention and prioritization. To that end, the departmental Quality Committee should have a representative from each surgical division within the Department. Meetings are typically monthly and often the timing may need to be creative to accommodate surgical schedules. Additional key members of the committee include representatives from the operating room—particularly nursing, the surgical intensive care unit, the surgical care unit, and pharmacy. Data managers and/or epidemiologists and hospital quality administrative support are essential. Other invited guests should be chosen depending on the topic being discussed. For example, infectious disease representatives and infection control staff would be appropriate when discussing wound infection rates. Residents and medical students should always be encouraged to attend. Risk managers and compliance representatives may be appropriate at times but should not dominate the conversations. Quality managers and data analysts that assist with data collection and process improvement should be considered a part of the committee and not simply facilitators of the process. Table 15.2 considering busy operating schedules, each divisional quality lead should have an alternate and at a minimum, each divisional lead should complete basic Quality and Patient Safety training prior to being nominated to the departmental committee. The reporting of the departmental quality committee should be to the Hospital or System level Quality and Patient Safety Committee, and the CSQO should be an active member of a larger hospital oversight committee. Similarly, the CSQO should identify a Co-chair of the Departmental Quality Committee to attend the system level meeting when he or she is unavailable to ensure a continued presence at the health system level.

Table 15.2 Department of surgery quality committee membership

CSQO
Divisional or departmental representatives (and alternate)
Perioperative nursing
Surgical intensive care nursing
Surgical unit floor nursing
Pharmacy
Epidemiology
Chief residents
Quality managers
Data analysts
Ad Hoc members: risk management, infection control, etc.
Medical students

As each hospital or medical center may be organized differently, the above Quality committee structure should be considered flexible. For example, if a hospital has multiple surgical departments, then a representative of each department should be a member of the committee, rather than divisional members. In addition, at large members are important to help message to the middle part of the organization.

Strategic Alignment and Leadership

Although the CSQO charge may vary from institution to institution, in addition to eliminating adverse events, he or she will often be asked to lead efforts to balance a sometimes conflicting set of responsibilities. This list includes, but is not limited to, educating surgeons and trainees about quality and process improvement, achieving compliance with a growing list of external mandates that may not always seem rational, standardizing and streamlining care pathways, ensuring appropriateness, and making difficult decisions about resources. The CSQO requires a unique skill set, including not only the ability to listen and a willingness to work for consensus, but also the authority and fortitude to make some decisions that may not always be greeted with enthusiasm. Ultimately, the CSQO is responsible for aligning the Department of Surgery with hospital or institutional initiatives. Often, hospital goals or key result areas are significantly impacted by surgical services and outcomes. Having the department understand how their performance impacts the institution as a whole is vital to sustained improvements. Clear definition of the reporting structure and quality oversight is key, and understanding that not only is the reporting fixed, but that the ultimate responsibility of the leadership and board can be leveraged is often very helpful. An example of one is provided in Fig. 15.1. Impacting mortality and reducing sentinel events, including retained foreign bodies and wrong site procedures, the CSQO may serve as the project leader or champion for programs aimed at process improvement [23–25]. Approaches such as team training or Crew Resource Management are really surgically driven programs that have been shown to improve outcomes [26–30]. Without the leadership and direction of the CSQO and key members of surgical departments and divisions, such programs are unlikely to be successful and could serve as a source of frustration for all surgeons involved. The CSQO should be the advocate for the individual surgeon when these initiatives are being rolled out while he or she is leveraging the institutional support to render the initiative successful [31]. Sentinel events often can only be addressed after thorough root cause or common cause analysis. To that end, the CSQO may serve as the lead physician on these workgroups and be responsible for devising and implementing countermeasures to prevent them from happening again. Inherent to this process is the sharing of often sensitive data when a surgeon or surgical team has been involved in a "never event" [32]. By focusing on the systems issues and sharing the fixes, the CSQO can further the culture of safety and continuous improvement, without compromising the integrity of the surgeon. Using the departmental Quality Committee, to share events and patient safety opportunities is an appropriate venue that is safe and productive. Opportunities that have been realized through careful analysis could be shared using standardized storytelling which could be distributed electronically or in poster format in resident rooms or the perioperative surgeon's lounge as seen in Fig. 15.2 [33].

Resources and Relationships Critical to Success

Over the past 25 years, measurement of healthcare processes and outcomes has been evolving and rapidly changing. Initially, the focus was on data collection and reporting. Of late, there is a push from business groups, state and national agencies, and most importantly, patients to ask questions about healthcare outcomes, cost, and patient experience. To address these questions at the surgical divisional or departmental level, there must be good and validated data. According to Provost and Murray, "Data are documented observations or results of performing a measurement process. Data can be obtained by perception or by performing a measurement process." [34]. In order to leverage data and create ultra-safe environments for patients, not only are resources needed, but a relationship between departments, clinical and administrative, must be forged and maintained.

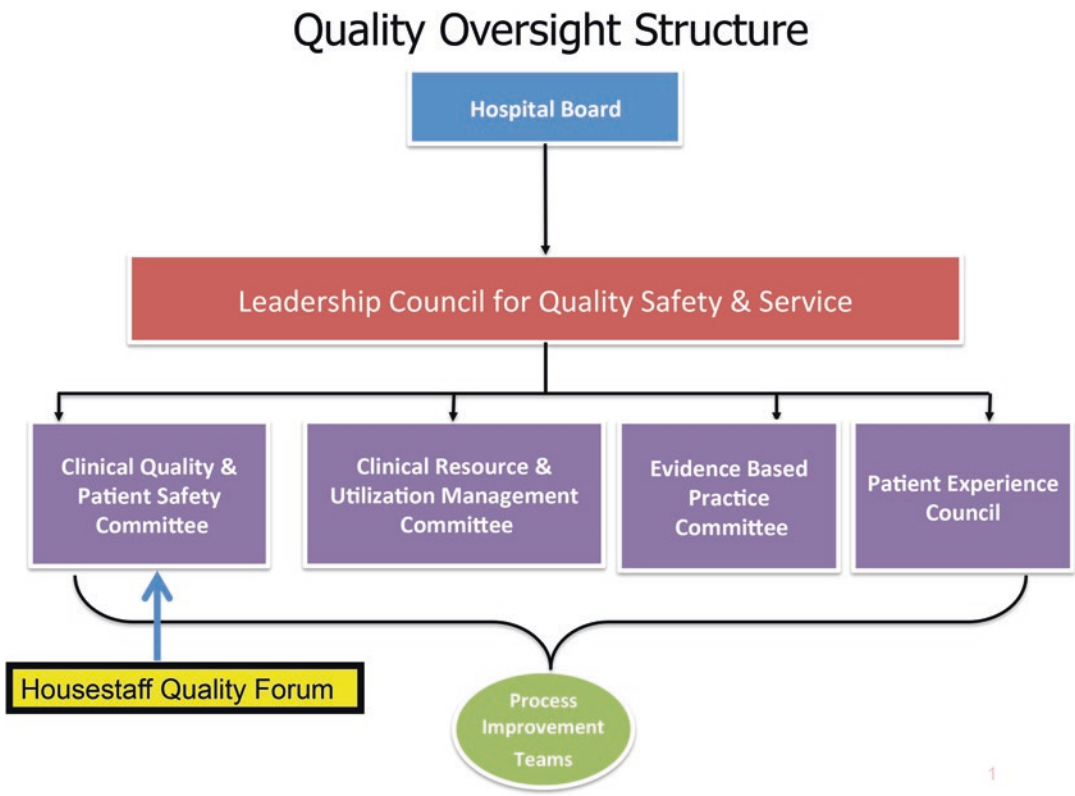


Fig. 15.1 *Quality oversight structure*. An example of a quality oversight structure is provided, whereby the hospital or health system board is ultimately responsible for quality and patient safety. The Leadership Council comprises key clinical and administrative leaders in the organization and to which the subcommittees responsible for quality, resource utilization, evidence-based practice, and patient experience report. The individual department quality committee would report to the Clinical Quality and Patient Safety Committee

Developing a Culture of Safety and High Reliability at All Levels

The root causes for most events that occur among surgical patients include lack of communication, lack of teamwork, lack of patient involvement, lack of reliable processes, lack of organizational emphasis on safety and reliability, and the inability of the department or organization to continuously learn from its mistakes [35]. Understanding that a just culture is one of trust, not only a culture in which people are encouraged to provide essential safety-related information, but also a culture in which it is clear about where the line must be drawn between acceptable and unacceptable behavior as defined by James Reason's five-part algorithm for creating accountability [36].

Despite a dedicated interest at many levels to ensure the highest quality of care for patients, studies have shown that progress in patient safety has been exceedingly slow, secondary to lack of both clarity regarding the definition and standard methodology to assess iatrogenic patient harm [37]. Additionally, some researchers believe that there is a lack of will at the senior leadership level and consequently a lack of resources and focus on the hard work necessary to redesign systems for high reliability performance [10, 38]. There continue to be reports of fear and intimidation that are still uncomfortably widespread in healthcare, and in surgical disciplines in particular, which leads to an overwhelming reluctance of physicians and staff to escalate concerns about safety or reveal their own errors or near-miss events [10, 38, 39].

√ Scenarios

A patient in the OR undergoing a facial fracture repair had surgical lubricant placed on a corneal shield instead of ophthalmic lubricant. The corneal shield was placed in the eye during surgery. Exposure to surgical lubricant led to chemical injury of the cornea. The cornea injury improved and the patient was discharged with required follow-up to determine the long-term impact of the chemical injury.

√ Process Issues

- There was a misconception that surgical lubricant is acceptable for use in the eye and could be placed on a corneal shield.
- Ophthalmic lubricant is used every time a corneal shield is inserted, but was not on surgeon preference cards for procedures.
- Ophthalmic lubricant is only located in the anesthesia carts and was not available to the circulating nurse in the operating room. The item was passed from anesthesia to the surgical resident and did not follow the policy requiring items passed on the surgical field be handled by the circulating nurse.

√ My Role

- **Look Alike Products:** Unfortunately many products look similar, read labels and their contents carefully. Attempt not to locate look alike products together.

Fig. 15.2 *Lessons learned poster*. When serious safety events occur, it is the responsibility of the CSQO to share lessons learned and what process issues were addressed. Posters like this can be used in email alerts or in the surgeons' lounge to reach a broad audience in a productive fashion

Nevertheless, there are several examples of remarkable and measurable advances in patient safety in individual health systems [39, 40]. A number of notable organizations and programs were able to achieve and sustain significant reductions in preventable adverse events and hospital acquired infections with a reduction in sentinel events, reduction in risk-adjusted death rates, improvement in safety attitude/culture throughout the organization, and increased reporting with more effective investigation into patient safety incidents [40, 41]. The common theme among all of these successes is that improved patient safety metrics have translated into improved staff morale and reduced costs resulting from shorter hospital lengths of stay.

The most significant characteristic shared by organizations that have made progress in patient safety and consistently good outcomes has been consistent and genuine engagement by leadership [14, 41]. There is an increasing focus on the importance of leadership, specifically with regard to the education of physicians, reflected in new requirements and guidance of the Accreditation Council for Graduate Medical Education [42]. Nursing leadership has also been highlighted for its critical role establishing a culture of safety and improving clinical outcomes by directly affecting clinical workflow and patient-care processes at the bedside [43]. Effective process redesign focuses on both the reduction of errors and identification of risks to ensure that errors are caught and patients are not harmed.

Much research has been done on what exactly this "culture of patient safety" entails. A robust survey of California hospitals found seven characteris-

tics that were key: (a) commitment to safety at the highest level, (b) necessary resources for safety are provided, (c) safety is the highest priority, (d) all coworkers communicate effectively about safety concerns, (e) hazardous acts are rare, (f) there is transparency in reporting and discussing errors, and (g) safety solutions focus on system improvement, not individual blame [10]. Building and nurturing a culture of patient safety is directly correlated with improved clinical outcomes and reduced errors, such as shorter length of stay, fewer medication errors, lower rate of ventilator-associated pneumonia, lower catheter-related bloodstream infections, and most significantly, a lower risk-adjusted mortality [44].

In order to achieve a culture of safety and these improved outcomes, leaders must demonstrate that they value transparency and encourage disclosure of adverse events [21]. By analyzing these events, organizational learning and system changes are then possible to prevent similar errors from occurring. There are several validated administrative and clinical tools effective in establishing a culture of safety [41]. It is essential to first accurately measure the safety culture. This will provide the organization with baseline data important in assessing the effect of any intervention. The survey most frequently used is the Hospital Survey on Patient Safety Culture that was developed by the federal Agency for Healthcare Research and Quality. This tool has been used extensively to develop patient safety programs in hospitals across the country and AHRQ now publishes comparative data to support continuous improvement and collaboration [45]. Another powerful leadership tool in the hospital setting is Patient Safety Leadership WalkRounds, in which a senior leader undertakes walking rounds to discuss patient safety with staff and patients/families. Safety issues are recorded, prioritized, and addressed with system wide changes at subsequent meetings. This has been an effective tool in demonstrating that senior leadership value patient safety and will address adverse events and vulnerable systems in a nonpunitive manner [40, 46].

The use of Crew Resource Management across entire departments and hospitals has been part of a culture transformation [26–29, 31]. Team training uses crew resource management theory from aviation that has been adapted for healthcare [21, 31, 47, 48]. The Veterans Health Administration (VHA), the largest integrated healthcare system in the United States, implemented a national operating room team training program and studied the outcomes [20]. The investigators found that with every additional 3 months of team training completed, mortality was reduced in all types of surgical patients undergoing a variety of cases of differing levels of complexity. Team training, as it currently exists in our operating rooms, relies heavily on checklists and effective care transition communications. The use of these checklists has been shown to globally reduce morbidity and mortality as made evident by the World Health Organization's Safe Surgery Saves Lives program [22]. Since this seminal publication, the Safe Surgery Checklist, as popularized by Dr. Atul Gawande, has spread from the operating room to every aspect of patient care. Dr. Pronovost's success in reducing central line infections to almost zero in intensive care units using a standardized checklist is another prime example of a hardwired "safety tool" improving care [49]. However, after considering the findings of Hu et al., and Urbach et al., [50], perhaps we have been overly prescriptive in hard wiring processes without prior engagement of surgical teams, and rather than capitalizing on what surgeons are traditionally known for- resilience. The investment in such programs is real, but the results can be impressive [31, 51].

The Lucian Leape Institute at the National Patient Safety Foundation has endorsed five overarching principles for transforming hospitals and clinics into high-reliability organizations. These include transparency in disclosing errors and quality problems, integration of care across teams and disciplines, engaging patients in safety, restoring joy and meaning in work, and reforming medical education to focus on quality and safety [41].

Worker satisfaction is critical to get any buy-in in a patient safety culture. It directly correlates with improved patient satisfaction and outcomes. Transparency is essential to understand the current

state of patient safety and to develop a learning culture in which mistakes inform system-wide change and there are no punitive consequences for disclosing medical errors. This will align with healthcare providers' ethical obligation to disclose medical errors and apologize for patient harm. Patients and their families should be engaged in their clinical care through informed medical decisions and self-management [52–54].

Data Analytics and Validation

There are currently many sources of surgical data and analysis that are required to evaluate the performance of surgeons as well as divisions and departments as a whole. The registries that are currently the most developed and are likely to be found within a surgical department can involve almost any surgical discipline. It is the responsibility of the CSQO to have a sound understanding of the data collection methodology, the analysis and the reporting mechanism associated with the registries the Department of Surgery intends on implementing. A dedicated surgeon champion should be identified for the different registries, separate from the CSQO, and they can assist in the analysis of results and drive change. Table 15.3 is a listing of the most commonly used surgical databases.

Metric Development and Goal Setting

To measure quality, the CSQO and key surgical leaders will need to take several steps. First, the aims must be set, that is, to make the data collection relevant, all measurement should be directly connected to the departments, hospital and health systems goals. Next, priorities for quality and patient safety efforts for the department must be established, such as reducing surgical site infections and these must be in alignment with the institutional priorities and efforts. After selecting the specific measure, there must be consensus on the operational definition so that when the data is finally collected and presented there is no "the data is incorrect" mentality [55, 56]. Developing a data collection plan and the actual acquisition of data will likely require hospital or health system support. The CSQO needs to understand this process well enough to represent the department at health system budget and resource meetings. Lastly, there must be a plan to analyze the data with the appropriate stakeholders and be transparent with sharing the results, good or bad. Taking action to improve outcomes is an interprofessional process that starts with good data, appropriate analysis, and being grounded in the aims and goals of the surgeons, divisions, and department as a whole. Table 15.4 is an example of metrics and goals set at an institution level.

Table 15.3 Surgical quality improvement registries

Specialty	Database	Link
All surgical specialties	National Surgical Quality Improvement Project (NSQIP) (*Essential, small/rural hospital, procedure targeted version or pediatric version*)	http://site.acsnsqip.org/
	Bari NSQIP (Bariatric Surgery)	http://www.mbsaqip.org/
Cardiac and thoracic surgery	Society of Thoracic Surgeons Quality database	www.sts.org
Vascular surgery	Society of Vascular Surgery Quality Improvement program	http://www.vascularqualityinitiative.org/
Trauma surgery	Trauma Quality Improvement program	http://www.facs.org/trauma/ntdb/tqip.html
Transplant surgery	Scientific Registry of Transplant Recipients	http://www.srtr.org/
All surgical specialties	University Health System Consortium (UHC)	https://www.uhc.edu/

Table 15.4 Goals and metrics for success (system level). The goals for quality and patient safety improvement need to be established yearly. The previous year's success and the goals need to be clearly defined. The means by which the data will be collected and validated need to be transparent

Performance incentive metrics	Baseline year ("threshold") FY15	FY16 ("target") goals	Current performance	Description (health system)
CAUTI (per 1000 foley days/Standardized Infection Ratio—SIR)	1.156	0.854	0.75	All patients anywhere in the hospital that develops a UTI with a foley in
CLABSI (per 1000 line days/SIR)	0.577	0.46	0.71	All patients anywhere in the hospital that develops a BSI from a Central Line
cDiff (per 10,000 patient days/SIR)	0.824	0.75	0.74	All patients anywhere in the hospital that develop C diff
SSI Colon Surgery (per 100 procedures/SIR)	0.982	0.751	0.47	Deep infections after any sort of colon surgery
Hand hygiene	90 %	95 %	93 %	Rate from observation program of clean in/clean out
Mortality index	0.64	0.63	0.65	UHC all inpatient mortality index
Sepsis mortality index	0.88	0.89	0.84	UHC mortality index for patients with a sepsis diagnosis code
PSI 90	0.64	0.62	0.66	Composite measure: PSI 03 Pressure Ulcer Rate; PSI 06 Iatrogenic Pneumothorax Rate; PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate; PSI 08 Postoperative Hip Fracture Rate; PSI 09 Perioperative Hemorrhage or Hematoma Rate; PSI 11 Postoperative Respiratory Failure Rate; PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate; PSI 13 Postoperative Sepsis Rate; PSI 14 Postoperative Wound Dehiscence Rate; PSI 15 Accidental Puncture or Laceration Rate
PSI 12 Post Op PE/DVT rate	9.18	7.87	6.41	Rate per 1000 discharges

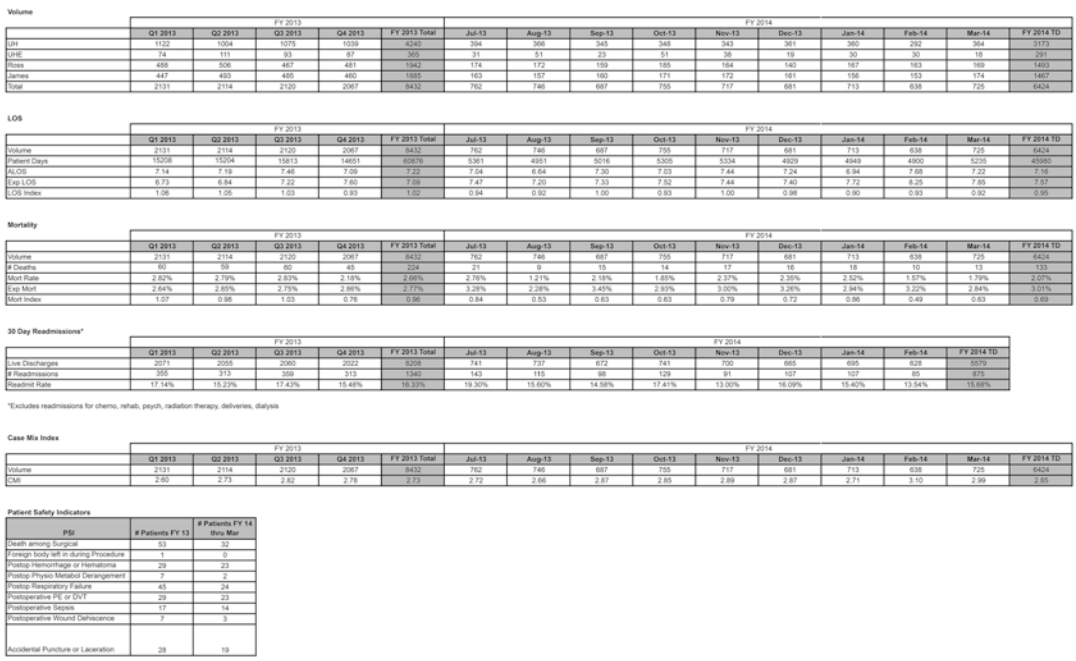
Total falls per 1000 patient days	1.64	1.55	1.44	All falls and benchmarked with NDNQI
Injury falls per 1000 patient days	0.37	0.32	0.35	Falls with injury level 1 or higher benchmarked with NDNQI
Overall 30 days all cause readmission rate	13.20%	11.90%	13.30%	All cause readmissions back to OSUWMC for any reason
HCAHPS overall rating	75.30%	79.40%	78.20%	Percent of those surveyed who gave scores of "9" or "10" if patients would recommend OSUWMC
HCAHPS doctor communication	81.10%	82.80%	82.30%	"How well did the doctors treat with courtesy and respect, listen carefully, explain things"
HCAHPS nurse communication	80.30%	81.00%	81.50%	How well did nurses treat with courtesy and respect, listen carefully, explain things, answer the call button
CGCAHPS	90.80%	96.00%	90.80%	Would you recommend this provider's office (yes-definitely)
CGCAHPS test results	76.90%	94.00%	87.30%	Follow up to give test results (yes)
Medicare spending per beneficiary	0.998	0.98	0.998	Cost for 3 days prior, inpatient stay, and 30 days post

The data collected by the CSQO and shared with divisions and surgeons often rolls up into national rankings and grading systems. Therefore, the CSQO must understand, at a minimum, how the surgical data and indicators affect the Joint Commission accreditation status, the Centers for Medicare and Medicaid Value-Based Purchasing program, and the U.S. News and World Report rankings. To that end, division quality and patient safety cards need to be formulated, reviewed monthly, and be part of the leadership's compensation as to the success or challenges. Figure 15.3 is an example of a General Surgery divisional scorecard that is in alignment with the institutional metrics and goals. Lastly, as each surgeon influences the performance of the department and the institution, individual scorecards are essential (Fig. 15.4). The metrics that formulate these scorecards must be in alignment with the division and the institutional as a whole (Fig. 15.5).

Continuous Improvement Training and Support

Healthcare providers involved in improving our care delivery system must be able to create a just and accountable culture, implement highly reliable systems, and foster transparency. Additionally, designing reliable processes to mitigate human error involves critical assessment of current processes, careful planning, and the use of the science of reliability. Learning the science of reliability is essential as understanding the fundamental cornerstone of all projects is continuous process improvement.

Since most healthcare providers have had little training in just culture development, high reliability or even quality data collection and analysis, additional and dedicated training in process improvement is highly advantageous. There are different degrees to which healthcare team members can be trained, and can range from online modules, which take 12 h to



Volume

	FY 2013					FY 2014									
	Q1 2013	Q2 2013	Q3 2013	Q4 2013	FY 2013 Total	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	FY 2014 TD
UH	1122	1004	1075	1039	4240	394	366	345	348	343	381	360	292	364	3173
UHE	74	111	93	87	365	31	51	23	51	36	19	30	30	16	291
Ross	488	506	467	481	1942	174	172	159	185	164	140	167	163	169	1493
James	447	493	485	460	1885	163	157	160	171	172	161	156	153	174	1467
Total	2131	2114	2120	2067	8432	762	746	687	755	717	681	713	638	725	6424

LOS

	FY 2013					FY 2014									
	Q1 2013	Q2 2013	Q3 2013	Q4 2013	FY 2013 Total	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	FY 2014 TD
Volume	2131	2114	2120	2067	8432	762	746	687	755	717	681	713	638	725	6424
Patient Days	15208	15204	15813	14651	60876	5361	4951	5016	5305	5334	4929	4949	4900	5235	45980
ALOS	7.14	7.19	7.46	7.09	7.22	7.04	6.64	7.30	7.03	7.44	7.24	6.94	7.68	7.22	7.16
Exp LOS	6.73	6.84	7.22	7.60	7.09	7.47	7.20	7.33	7.52	7.44	7.40	7.72	8.25	7.85	7.57
LOS Index	1.06	1.05	1.03	0.93	1.02	0.94	0.92	1.00	0.93	1.00	0.98	0.90	0.93	0.92	0.95

Mortality

	FY 2013					FY 2014									
	Q1 2013	Q2 2013	Q3 2013	Q4 2013	FY 2013 Total	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	FY 2014 TD
Volume	2131	2114	2120	2067	8432	762	746	687	755	717	681	713	638	725	6424
# Deaths	60	59	60	45	224	21	9	15	14	17	16	18	10	13	133
Mort Rate	2.82%	2.79%	2.83%	2.18%	2.66%	2.76%	1.21%	2.18%	1.85%	2.37%	2.35%	2.52%	1.57%	1.79%	2.07%
Exp Mort	2.64%	2.89%	2.75%	2.96%	2.77%	3.28%	2.28%	3.45%	2.93%	3.00%	3.26%	2.94%	3.22%	2.84%	3.01%
Mort Index	1.07	0.98	1.03	0.76	0.96	0.84	0.53	0.63	0.63	0.79	0.72	0.86	0.49	0.63	0.69

30 Day Readmissions*

	FY 2013					FY 2014									
	Q1 2013	Q2 2013	Q3 2013	Q4 2013	FY 2013 Total	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	FY 2014 TD	
Live Discharges	2071	2055	2060	2022	8208	741	737	672	741	700	665	695	628	5579	
# Readmissions	355	313	359	313	1340	143	115	98	129	91	107	107	85	875	
Readmit Rate	17.14%	15.23%	17.43%	15.48%	16.33%	19.30%	15.60%	14.58%	17.41%	13.00%	16.09%	15.40%	13.54%	15.68%	

*Excludes readmissions for chemo, rehab, psych, radiation therapy, deliveries, dialysis

Case Mix Index

	FY 2013					FY 2014									
	Q1 2013	Q2 2013	Q3 2013	Q4 2013	FY 2013 Total	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	FY 2014 TD
Volume	2131	2114	2120	2067	8432	762	746	687	755	717	681	713	638	725	6424
CMI	2.60	2.73	2.82	2.78	2.73	2.72	2.66	2.87	2.85	2.89	2.87	2.71	3.10	2.99	2.85

Patient Safety Indicators

PSI	# Patients FY 13	# Patients FY 14 thru Mar
Death among Surgical	53	32
Foreign body left in during Procedure	1	0
Postop Hemorrhage or Hematoma	29	23
Postop Physio Metabol Derangement	7	2
Postop Respiratory Failure	45	24
Postoperative PE or DVT	29	23
Postoperative Sepsis	17	14
Postoperative Wound Dehiscence	7	3
Accidental Puncture or Laceration	28	19

Fig. 15.3 *Division level scorecards*. Using hospital resources that have access to system level data, scorecards can be generated that focus on efficiency metrics including length of stay and all-cause readmissions as well as quality metrics including mortality. Case mix index can be a surrogate marker for appropriate documentation and clinical documentation programs that may have been instituted

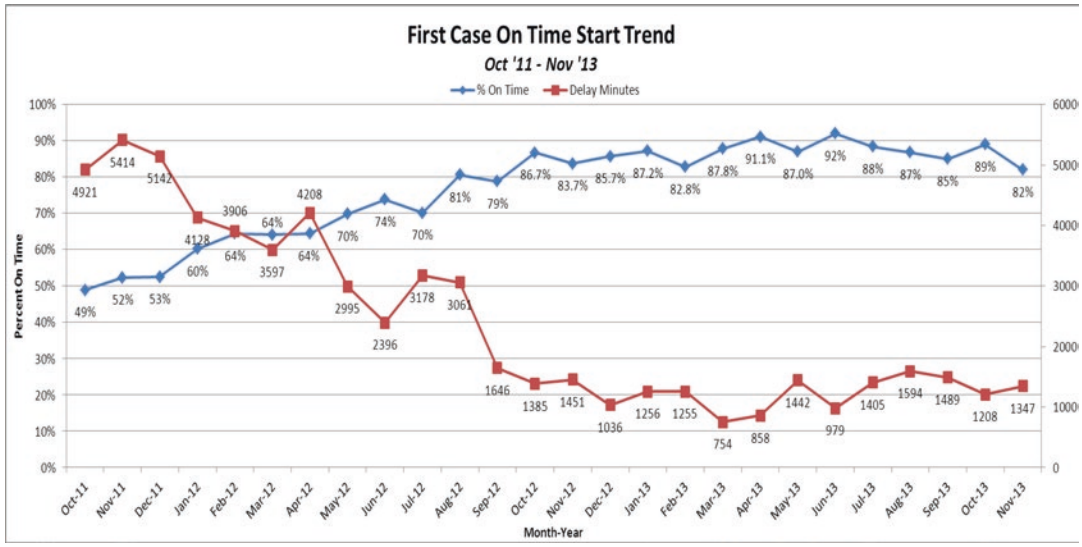


Fig. 15.4 *Surgeon-specific scorecards*. Surgeons should be able to see their own performance on a quarterly to semiannual basis. This can be provided through dedicated, secure web sites or in a written format. The data should include acceptable quality data bases including NSQIP and STS as well as institutional data. Mortality and peer review of clinical care should be included in the scorecard. HCAPS and patient complaints should be shared through this format. There should always be a peer comparison and a trend over time that can be reviewed

Master's in Operational Excellence or Business Administration which can take 2 years as mentioned earlier in the chapter (Table 15.1).

Management techniques from business and industry including Lean, Six Sigma and the Toyota Production System (TPS) have often been studied in relation to healthcare process improvement for many years [7–10, 13, 14, 19]. These techniques share common foundations such as maintaining respect for people and focusing on continuous improvement. But across approaches there also exists a tension between medical and business approaches to process improvement [15, 19, 20]. In practice, Lean and other process improvement methodologies must take into account the context and environments in which they are applied, with long-term success only possible if organizations can change behaviorally and culturally to embrace a focus on continuous improvement [57]. As a performance improvement process, for example, Lean philosophy calls for value creation through elimination of waste. These wastes are common in all industries and perhaps are most evident in healthcare [22, 23].

Innovation in Process Improvement: Engaging the Team

In traditional healthcare organizations, however, responsibility and accountability for patient safety, patient satisfaction, staff satisfaction, and operational efficiency have resided with senior leaders who are not clinically responsible for the patients. What is needed, in most instances, is a more grass roots approach that engages those on the front lines of healthcare to identify challenges, implement solutions, and sustain change in the areas of quality, patient safety, resource utilization, patient experience, and financial responsibility [58]. Really that should be termed continuous improvement rather than process improvement. The traditional model of rapid cycle improvement addresses one issue at a time, but teams outside the clinical area are likely to be less successfully sustained. We proposed a more bottom-up, grass roots approach that engages those on the front lines of healthcare to identify challenges, implement solutions, and sustain change in the areas of quality, patient safety, resource utilization, patient experience, and financial responsibility.

Status	Indicator	Peers Score	Target	SPC Alert	Current Period
A - Volume and Acuity					
▼	Ambulatory Surgery Cases	22	n/a		Q1 2014
▼	CMI	6.25	n/a		Q1 2014
▲	IP Discharges	85	n/a		Q1 2014
✕ ▲	IP LOS Index (Obs_Exp)	0.80	0.95		Q4 2014
▲	IP Procedures	215	n/a		Q1 2014
▼	Observation Cases	20	n/a		Q1 2014
▲	Outpatient Visits	400	n/a		Q1 2014
	Consult Volume	20	n/a		Q1 2014
B - Patient Care					
—	Missed Major Dx on Autopsy	0	n/a		Q1 2014
✕ ▼	IP Mort Index (Obs_Exp)	1.00	0.63		Q1 2014
▼	Mortalities Reviewed	11	n/a		Q1 2014
▲	Mortalities Sent for Peer Review	1.0	0		Q1 2014
▼	Mortality Peer Review #1 Score 4 or 5	0.00	n/a		Q1 2014
▼	Mortality Peer Review #2 Score 4 or 5	0.00	n/a		Q1 2014
	Post Op Mortality in 48 Hrs	0.00	n/a		Q1 2014
▲	Quality Management Events	1.00	n/a		Q1 2014
▼	Quality Management Events - Standard of Care Not Met	0.00	n/a		Q1 2014
✕ ▲	ReAdmit 30 Days (All Cause)	11.3%	10.60%		Q1 2014
▲	PSI 15 Accidental Puncture/Laceration	0.33	5		Q1 2014
—	PSI 6 Iatrogenic Pneumothorax	0.00	n/a		Q1 2014
—	PSI 9 Postop Hemorrhage/Hematoma	1.00	2		Q1 2014
—	STS - Mortality Risk Adjusted Index (ISO AVR)	0.00	n/a		Q1 2014
—	STS - Mortality Expected Rate (ISO AVR)	0.0%	n/a		Q1 2014
★ —	STS - Mortality (ISO AVR)	0.0%	1.7%		Q1 2014
✕ ▲	STS - Complication Stroke Permanent (ISO AVR)	2.3%	1.3%		Q1 2014
★ —	STS - Deep Sternal Infection (ISO AVR)	0.0%	0.3%		Q1 2014
★ —	STS - PostOp Renal Failure (ISO AVR)	0.0%	1.6%		Q1 2014
★ —	STS - ReOp for Graft Occlusion (ISO AVR)	0.0%	0.1%		Q1 2014
★ —	STS - Tamponade Requiring ReOp (ISO AVR)	0.0%	2.6%		Q1 2014

Status	Indicator	Peers Score	Target	SPC Alert	Current Period
▲	STS - Mortality Risk Adjusted Index (ISO CAB)	0.73	n/a		Q1 2014
▲	STS - Mortality Expected Rate (ISO CAB)	1.5%	n/a		Q1 2014
✕ ▲	STS - Mortality (ISO CAB)	1.9%	1.5%		Q1 2014
✕ ▲	STS - Complication Stroke Permanent (ISO CAB)	2.1%	1.4%		Q1 2014
✕ ▼	STS - PostOp Renal Failure (ISO CAB)	2.2%	1.9%		Q1 2014
✕ ▲	STS - ReOp for Graft Occlusion (ISO CAB)	1.0%	0.3%		Q1 2014
★ —	STS - Tamponade Requiring ReOp (ISO CAB)	0.0%	1.6%		Q1 2014
✕ ▼	STS - Mortality All Cases	2.0%	1.8%		Q1 2014
—	PSI 12 DVT/PE	3	n/a		Q1 2014
—	PSI 14 PostOp Wound Dehiscence	0.00	n/a		Q1 2014
✕ ▼	SSI CABG Procedures	2.0%	1.49%		Q1 2014
✕ ▲	STS - Deep Sternal Infection (ISO CAB)	05%	0.4%		Q1 2014
C - Medical and Clinical Knowledge					
—	Formal Peer Reviews	0.00	n/a		Q1 2014
E - Interpersonal and Communication					
—	Patient Complaints	0.00	n/a		Q1 2014
★ ▼	Patient Satisfaction (IP-HCAHPS) Score Avg	90%	85.2%		Q1 2014
▲	Patient Satisfaction (IP-HCAHPS) Survey Count	25	85		Q1 2014
✕ ▼	Patient Satisfaction (MedOff-CGCAHPS) Score Avg	92%	96.0%		Q1 2014
▲	Patient Satisfaction (MedOff-CGCAHPS) Survey Count	20	n/a		Q1 2014
F - Systems Based Practice					
	Consult TAT Comply Rate	95%	n/a		Q1 2014
	Consult TAT Comply in 24hr Rate	93%	n/a		Q1 2014

Profile Generated 05/08/2016 21:17:50.

SPC Alert Legend

Most recent period is below Lower Control Limit
Most recent period is above Upper Control Limit
Process shift: Most recent 8 periods are all above the Center Line
Process shift: Most recent 8 periods are all below the Center Line
Most recent 6 periods are all increasing
Most recent 6 periods are all decreasing
Green border: The alert is in a positive direction
Red border: The alert is in a negative direction
No border: There is no target direction for the indicator

Fig. 15.5 *Quality metrics and incentives*. Working with the CEO of the health system, quality, patient safety, and efficiency goals have been established. One year and 3 year goals have been established. The responsible party for the success of these goals is listed and includes the CMO, CQO, CFO, CEO, and department chairs. These goals are then used in the compensation and incentive basis of key leader contracts

As performance and quality improvement are important elements of all population health management approaches, we sought to explore how a performance improvement strategy focused on patient safety improvement could be developed and deployed in a large academic medical center. Operations councils were created that were an extension of the process improvement models, including Lean and Six Sigma, because they employ traditional process improvement techniques with a focus on building a collaborative culture that incorporates front line staff in the process.

Each Operations Council identified a facilitator who was part of the front line staff that could dedicate time to being trained as a Yellow Belt Lean Six Sigma facilitator while still staying clinically active. The facilitators were nurses, pharmacists, and technicians. The facilitators completed Lean Six Sigma Yellow Belt training through Ohio State's Fisher College of Business in their first year of Operations Council deployment. All process improvement projects had to be in alignment with the health system key result areas of Innovation and Strategic Growth, Productivity and Efficiency, Quality, and Service and Reputation.

Overall, Operations Councils have reduced medication harm events, mortality, and patient safety events among patients who arrive with life-threatening and difficult care issues, contributing to

VBP Metrics	Baseline Year 1 (FY14)	Baseline Year 2 (Threshold) FY2015	Year 1 Goal	Stretch Goal	Responsible Parties
PSI 90	0.65	0.64	0.62	0.59	ALL
HCAHPS Overall Rating	73.7%	75.3%	79.4%	84.6%	ALL
HCAHPS Doctor Communication	80.5%	81.1%	82.8%	85.2%	ALL
HCAHPS Nurse Communication	81.0%	80.3%	81.0%	83.5%	CMO, CNO, CNE, CQO
AMI 30 Day Mortality	0.96	1.07	0.93	0.81	CQO, CMO, CEO
PC-Elective Delivery Prior to 39 weeks	5.7%	3.4%	2.9%	2.1%	CQO, CMO, CEO
CAUTI	1.634	1.156	0.854	0.00	ALL
SSI Colon Surgery	1.028	0.982	0.751	0.00	ALL
Medicare Spending Per Beneficiary VBP Points	0.997	0.998	0.98	0.82	ALL
Readmissions CHF	18.9%	22.0%	18.3%	16.2%	CQO, CMO, CEO, UH
Readmissions AMI	11.8%	11.2%	9.6%	8.1%	CQO, CMO, CEO
Readmissions PN	16.6%	14.9%	11.6%	9.9%	CQO, CMO, CEO, UH
Readmissions COPD	18.8%	19.9%	15.9%	13.2%	CQO, CMO, CEO
Readmissions HIP and KNEES	3.9%	2.9%	2.5%	1.8%	CQO, CMO, CEO
Total Falls per 1000 patient days	2.10	1.64	1.55	1.15	CMO, CNO, CNE, CQO
Injury Falls per 1000 patient days	0.37	0.32	0.28	0.15	CMO, CNO, CNE, CQO
ALOS Index	0.99	0.98	0.97	0.94	ALL

Fig. 15.6 *On time start improvements as a result of front line engagement*. As a result of countermeasures put in place by the key stakeholders of the process in the perioperative arena, the on time start times improved from 35% to over 80%. The number of delay minutes has dropped from a peak of 5414 to 1347 min. Sustainability will be ensured by continuous monitoring and establishing accountability

a 22% reduction in patient safety events across the entire medical center over the past 2 years [31, 34].

In the perioperative arena, the Operations Councils have been trying to improve on time starts. By approaching this age-old problem from the front line, surgeons and nurse engagement was assured and facilitated the preoperative readiness, continuous measurement and feedback, leveraged informatics support and continuous cost analysis of delays. As a result of countermeasures put in place by the key stakeholders of the process in the perioperative arena, the on time start times improved dramatically across the entire medical system from 35% to over 80% (Fig. 15.6). The number of delay minutes has dropped from a peak of 5414 to 1347 min. Sustainability will be ensured by continuous monitoring and establishing accountability.

Performance Management and Accountability

Managing the Tension Between Quality, Efficiency, and Patient Satisfaction

With the passage of the Affordable Care Act authorizing the use of Hospital Value-Based Purchasing (HVBP) contracts, the landscape for hospital reimbursement has again changed. The Centers for Medicare & Medicaid Services (CMS) HVBP program now reimburses hospitals for an increasing number of patient experience elements, including measures of both quality and patient satisfaction. This has led to segmentation of the concept of patient experience.

For example, US healthcare systems tend to have a variety of departments that govern the patient experience. Although all health system leaders are tasked to improve HVBP measures, the involvement of these different leaders perpetuates the problems of a fractured health system as each tries to maximize his or her piece of the reimbursement pie. Thus, although the elements of patient experience may be interconnected, the result of this varied involvement promotes siloed thinking because of competing priorities.

Despite the ostensible aim of CMS to be inclusive of all elements of quality, the result of HVBP contracts in most health systems is fragmentation of the quality goal instead of encouraging consideration of a holistic patient experience.

The pressures of HVBP have created a tension among the organizational priorities of safety, efficiency, and patient satisfaction. We propose that the solution to this problem is to incentivize a cultural shift within healthcare systems toward

patient-centered care (PCC), possibly through including PCC measures in the CMS HVBP formula. There is evidence that PCC improves clinical outcomes and patient experiences, and PCC can be justified on the basis of a business case [5]. Yet PCC requires a change in organizational culture from being "provider focused" or "reimbursement focused" to "patient focused," and this can only occur with the engagement of top leadership and a strategic vision that prioritizes PCC [6]. To make this change within their organizations, health system managers should focus on improving meaningful communication between patients and hospital staff, including requiring staff training in PCC and communication skills. Additionally, within the healthcare delivery system there is an opportunity and need to establish patient expectations [53, 54].

As healthcare organizations make the transition to value from volume considerations, we must stay true to the core of our missions and consider the many aspects of patient experience including patient safety, satisfaction, and quality. By integrating and not segregating these elements, we can keep in mind the true, multidimensional experience of patients [59, 60].

Dash Boarding and Bench Marking for Surgeons and Departments

There are many quality and patient safety metrics for which surgeons can be held accountable. Ideally, these should be in alignment with the institutional goals, and the targets should be set in keeping with system expectations (Table 15.4). Each division should have goals as seen in Fig. 15.3 and then each cardiac surgeon and general surgeon should also have goals as detailed in Fig. 15.4. The surgeon-specific metrics must be set in relation to his/her peers and be measured no more than every quarter. Every surgeon should have access to his/her data and the division head and department Chair should attest to having reviewed them every 6 months. Surgeons should be able to help influence their metrics to which they are held accountable, and be part of the process improvement projects that influence their success. Lastly, in as much as registry data is clinically validated and within the realm of surgeon control, it should be used as much as possible in the benchmarking for surgeons relative to their peers both institutionally as well as nationally. The level of transparency is somewhat dependent on the state in which the medical center is found, but more transparency drives more improvement in that surgeons are naturally proud and competitive.

Incentives and Compensation Aligned with Outcomes

There are many models of incentive and compensation and each institution will have their own. One example of a scorecard that aligns institution goals with 1 and 3 year success and assignment of responsible parties is seen in Fig. 15.5. While the incentive model of metric success has long been used, more CEO and Chairmen are moving toward at-risk dollars that are only captured with successful attainment of goals [61]. Among some key top institutions, performance-based pay is more prevalent in primary care than in subspecialties, and the most consistently identified performance domains are quality, service, productivity, and citizenship. Interviewed organizations tie a relatively low percentage of total compensation to performance. Procedural specialties often remained RVU or adjusted RVU based for all forms of compensation. At the Cleveland Clinic, Mayo Clinic, and Iora Health, for example, physicians are 100 % salaried. At Group Health and Kaiser Permanente (Southern California) more than 90 % of total physician compensation is salary. Importantly, even organizations that tie little or no compensation to performance attempted to track and encourage performance on a variety of metrics by conducting internal performance reviews. Furthermore, performance data for individual physicians is transparent in most systems; physicians are able to see their own performance and rank, as well as that of their colleagues.

At most organizations, senior leaders set overarching strategic aims, and then work closely

with front line physicians and department chiefs to develop fair and meaningful performance metrics. Most organizations use a combination of group and individual metrics to make allocation decisions about compensation. Across large systems, the most consistent performance domains are quality, service, productivity (generally measured by RVUs), and teamwork or citizenship. Most organizations have less than 10% of total compensation at risk, with payments distributed across three to five different domains, each containing several metrics but that consistently approaches with many metrics—and little at-risk compensation for each metric offers weak incentive to achieve any particular goal [61].

Future Leadership in Value-Based Care

Academic Development of Administrative Roles and Outcome Researchers

Surgeons have the unique ability to influence healthcare. As clinicians, innovators, and researchers, we can help to formulate how we will be measured and set forward standards to which we need to adhere. As such, more and more surgeons are taking on administrative roles, both large and small, in hospitals and healthcare systems [63]. To that end, surgeons need basic training in management techniques and tools, as well as the support of leadership to enable them to succeed. The time spent in administrative roles must be seen as important as in the operating room when these surgeon-administrators are able to influence the outcomes and efficiencies of a healthcare environment. With the current value-based care transformation paradigm, the time for change is upon us and we must train and enable our future surgeons and junior faculty to not only understand the changing landscape but to also be able to influence it. In addition to leadership support for this new type of surgeon-leader, there must be some basic infrastructure in place in every surgical department including data analytics for both quality and financial outcomes. As leaders we can only influence what we can measure; and measurement and change is the responsibility of the CSQO as well as surgeon-leaders who are facilitating administrative changes needed for the healthcare of tomorrow.

Succession Planning for Quality Leaders

Despite tremendous advances in healthcare, we continue to fall short in providing the best care to surgical patients. No one surgeon can fix or transform healthcare and we are now on a journey from systems organized around individual surgeons to a team-based approach focused on patients and families [14]. Surgeons must be part of this revolution and engage in the shared purpose of providing value-based care to all patients. Engaging surgeons in change requires clarification of goals and defining value-based care—ultimately, patients must be first in the equation. Interprofessional care should be the standard to which the CSQO adheres and should really foster the training and development of not only faculty but also medical students and residents, so they take away the right attitudes towards patient care and how to get to reliable outcomes [42, 64]. The ACGME has established the Clinical Learning Environment Review (CLER) program as a key component of the Next Accreditation System with the aim to promote safety and quality of care by focusing on six areas important to the care in teaching hospitals and to the care residents will provide during a lifetime of practice after completion of training. The six areas encompass engagement of residents in patient safety, quality improvement and care transitions, promoting appropriate resident supervision, duty hour oversight and fatigue management, and enhancing professionalism [39, 42, 44]. With current medical student curriculum development and resident requirements, the CSQO should lead by example; engaging all members of the team, both early and late career surgeons, so that our transformation to provide

truly value-based care is sustainable. We should pay special attention to the learns transitions of surgical trainees as they progress from students to residents and fellows and onto full fledged surgeons [62].

Key Points

- Medical errors most often evolve as a consequence of more than one simultaneously co-occurring contributing factor.
- In patient safety, identification of opportunities for improvement is more productive than assigning blame.
- There are many examples of how patient safety can be improved by instituting coordinated approaches to error identification and reduction.
- The role of leadership is essential in promoting and maintaining the culture of patient safety.
- Among evolving trends is the increasing direct involvement of patients and their families in safety initiatives.

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16 Information Technology Infrastructure, Management, and Implementation: The Rise of the Emergent Clinical Information System and the Chief Medical Information Officer

Jon David Patrick, Paul Barach, and Ali Besiso

"We are drowning in information, while starving for wisdom. The world henceforth will be run by synthesizers, people able to put together the right information at the right time, think critically about it, and make important choices wisely."

—Edward O. Wilson, *Consilience: The Unity of Knowledge*

Introduction

Over the past 30 years Health information technology (HIT) has been positioned as a battle between two classes of technology solutions, that is Clinical Enterprise Resource Planning (CERP aka EMR) versus best-of-breed systems. The CERP systems are provided by the largest vendors as whole of hospital or whole of organization solutions intended to satisfy all users in the organization. Experience shows that they fail to fulfil that promise. Best-of-breed solutions are tailored to suit a particular community of users to perform specialized tasks such as surgical scheduling, tracking, and clinical details. These systems get higher rankings from users for usability and efficiency but create problems for IT departments by requiring individual maintenance tasks for each installed system, and silo data which is needed for back office administration and analytics. In the last 10 years, the best-of-breed solution has been in retreat with the onslaught of CERP vendors holding sway over the decision makers with a promise of increased revenue for more detailed billing and common access to all data [1]. At the same time, the clinicians at the coalface of care are complaining bitterly about CERP systems, which have unsuitable interfaces [1], add more work, and fail to respond to change requests [2].

We argue there is a distortion in the nature of the IT processing requirements in this current juxtaposition, and a new paradigm of service description and function would significantly improve the performance of staff and the determination of the return on investment (ROI) in HIT investment and impact on patient outcomes, staff satisfaction, and revenue optimization.

Understanding the value of any IT investment requires identifying the usability criteria of the

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technology, how to evaluate the usability for the real staff users, and how to determine their improved productivity and subsequently the ROI [3]. In this context, we consider usability is a general term applicable to all aspects of the acquired HIT and not the narrower sense used in user interface studies [4].

The Three Level Hierarchy Paradigm for Healthcare HIT

We posit that there are three major levels of HIT services that are required in any extensive health system, and that they need to be served by different technologies having different end users working for the different outcomes. Each of these levels needs to justify their rationale for a particular type of HIT by defining their own usability requirements.

Level 1. Departmental HIT for coal face clinical work: this is the context of clinical care where the importance of usability lies in screen real estate, data flow, and workflow. The most important aspect of the HIT is to support staff caring for the patient. For the HIT to fulfil basic usability, it must support work in its most detailed way, that is, it must fit closely to the daily operations of the people using it, acting like a silent colleague, by never interrupting or dragging the staff away from their work, by being available to provide exactly what is needed easily and readily at the moments of highest crisis. In cognitive science terms, HIT needs to reduce the workload of data collection and analysis on providers so that they can apply their cognitive skills to clinical management and not to user interface navigation. Crucially just as clinical practice changes, so must this Clinical Information System (CIS) be nimble and change too; otherwise, over time it will regress away from fulfilling the dynamic needs of busy clinical providers.

Level 2. Intra-organizational HIT for Data Management: At the hospital and whole organization context, the HIT has to support the whole of organization activities and support the sharing of appropriate data across the many departments participating in the organization. The administrators are interested in whole of hospital usability, which is dominated by the back-office functions of the organization. As many people have to use such a system and the work is less dynamic and more static, CERP systems is the best way to systematically define this wide range of activities such as billing and supply management enabling analytics across disparate collection sources of data and fulfiling all the legal and accounting record keeping responsibilities of large health delivery organizations. The CERP has often been touted as a whole of organization solution without accounting for variable contexts within the organization. This has led to CERP solutions being imposed on clinicians at the coalface of care with conviction from the administration that it would solve data collection and management problems, but unwittingly creating much extra work, so worsening their productivity and quality of patient care [5].

Level 3. Interorganizational IT for sharing data rapidly: The whole of system needs, e.g., a State health department, has to deal with usability across multiple hospitals and organizations and can only assess that by enabling the collection of standardized data across all organizations. Fundamentally, usability for this group is the interoperability, and their focus is about creating effective interoperability across all health institutions in the jurisdiction. It is true that both levels 1 and 2 have an interest in interoperability, but it neither has the core role nor the massive scale for implementation that is required at Level 3.

When we embrace the varied requirements at these three contextual levels, we will see real productivity emerge from HIT. Otherwise, we will continue to squander money on lofty business plans serving personal goals and making the work harder for the clinicians at the coalface of care while endangering patients.

An Integrated Architecture for HIT Usability

In an assessment of the different requirements between the three levels of HIT, there arises a tension between usability and interoperability. The value of each of these functions to an organization needs to be assessed to understand the

competing tensions between the 3 levels of HIT function and to enable a mature discussion about the trade-offs needed when making informed choices about opting to procure significant technology acquisitions.

Interoperability is undoubtedly valuable in many settings and has proven a useful improver in productivity. Interoperability is wanted because clinicians want to have more reliable information by linking clinical care systems with ordering/results systems (pathology and radiology) in order to:

- Interpret the patient's condition,
- Use most current, up-to-date patient records to save costs on retesting,
- Understand the decisions of prior carers in the patient's journey,
- Avoid contradictory treatments (including contradictory meds).

However, interoperability has a limited effect in clinical care and ROI, even though every clinician can give an example of where it would have helped them and it wasn't available. How do clinicians manage without interoperable systems: (a) not badly; (b) they haven't had it for a long time; (c) there is no study of the effect of not having it but it is likely to show small results only; (d) because clinicians are well trained and conscientious; (e) yes, they would like it but its impact would be low; and, (f) yes, everyone has examples where it would have helped.

But, the contribution of interoperability is not so great that clinicians can't do without it because: (a) its scope is very localized to individual situations; (b) the complexity of providing it everywhere is gigantic; (c) the co-operation required from unwilling vendor partners is monstrous; and (d) for vendors, it is a large task with relatively small value.

System Adaptability

One of the major themes across the HIT field is the need for better adaptability of a feature of a system or of a process. In ecology, adaptability has been described as the ability to cope with unexpected disturbances in the environment. Consequently, adaptability and efficiency are held to be in opposition in biological and ecological systems, requiring a trade-off, since both are important factors in the success of such systems [6]. To determine the adaptability of a process or a system, it should be validated concerning some criteria [7]. HIT is under constant scrutiny to deliver better user interfaces and this is often couched in calls for more usability research.

There is much reference to the academic usability research and its failure to impact delivered products from vendors [8]. While the vendors are variously reported as claiming, it is not needed or they are doing it anyway. We present here a new way to view usability as the importance of being able to adapt a system rapidly and easily. Such a technology would enable the efficient and inexpensive means of changing a system when it is needed or a new idea of processing or workflow is introduced. To our knowledge, it is not recognized as part of the paradigm of "usability" but we believe that is where it is most appropriately positioned.

Immediate Adaptability (IA)

Most academic researchers on HIT usability and safety concede that there is little impact of this work on vendor product design or thinking [9]. Furthermore, usability research at *any* point in time can become moribund or irrelevant because technology moves on or the context of use of the product changes while it is in situ, e.g., work practice changes due to new medical practices and government legislation. The literature of professional lists, blogs, and newsletters is replete with examples of complaints from physicians that they cannot get change to their user interfaces because the vendor will not accept the changes or it will take inordinate amounts of time and money to complete [10].

We understand that vendors are reluctant to make changes because it increases their cost of maintenance, potentially increases the complexity of their product, and the financial reward may be insufficient [11]. While complaints about the usability of interfaces in most publications are

couched as "usability" problems that does not address the functional behavior required of the software and thus imposes huge cognitive loads on nurses and physicians [12]. What are physicians implicitly complaining about? That the software is not adaptable or what is practically the same: that adaptations cannot be made immediately or within days, but remarkably takes, months, or years due to the complex designs. In short, they are actually asking for "immediate adaptability" in the software to avoid conditions that facilitate or actually enable errors [13].

Objections to Immediate Adaptability (IA)

EMR systems built by large vendors have code development operations similar to Enterprise Resource Planning (ERP) ventures like the large multinational company SAP, arguably the most successful ERP provider globally. We identify big health vendor EMR technology as Clinical ERP (CERP). Smaller but older vendors no doubt have similar models. Only recent vendors appearing in the last 10 years are likely to have different software approaches. The problems with IA for CERP are that it ostensibly requires the vendor to:

- Give up control of the design of their CERP to the user community.
- Have highly qualified programmers on call to respond when users require changes.
- Have built-in mechanisms to manage automatic version control, including roll back.
- Have built-in mechanisms to manage data such that data collected before a given change remains available after the change.
- Change their interoperability functions on-demand to send and receive data from dynamically changing EMRs.
- Have confidence that their technology can undergo continuous changes.

These criteria would not just increase the cost to maintain CERP technology, but also raise protests from vendors that maintaining large systems cannot be sustained intellectually as the systems are too complex to change rapidly and thus vulnerable to creating unexpected consequences. This protest would seem to be entirely valid. It is this very scale and complexity that inhibits changes to "usability" beyond the minimum, not to mention to support IA. The best-of-breed HIT system vendors have done a better job with usability because they do not suffer the same complexity problem, and their aim is to deliver a smaller range of functionality; however, IA would still be a difficult concern for them.

The technical difficulty in delivering IA can be discerned from the process of creating a CERP system in the first place. The process is a sequence of tasks consisting of requirements gathering, systems analysis, data modeling, code writing, systems testing, and deployment. The CERP providers have escaped part of this process by removing the first two steps on the basis that they have built so many systems they know the generalizations of clinical requirements and analyses. Indeed, they have built large code repositories relying on these generalizations and are unwilling to change them because changes will affect so many of their products and customers. Moreover, the code bases are so large that they are unwilling to risk a large number of unexpected consequences from changes.

The CERP approach was state-of-the-art in the general IT industry of the 1980s, but it is now outdated for most modern applications. The method suits large volume data transactions with stable patterns of work and processing such as in banking and insurance industries, which may be acceptable for back office work, including health organizations. This does not suit the needs of dynamic clinical workplaces where workflow is as important as data capture, data volumes are relatively low, local data flow and analytics are crucial for efficiency, and staff need to run continuous process improvement capabilities. In fact, imposing immutable CERPs on patient-facing clinical operations blocks processes to create clinical efficiencies and productivity, as is frequently testified in the protests from clinicians in many fora [14]. These systems encourage "work-arounds," defeating many of the HIT benefits and opening the door to patient harm.

The professional discussion lists have many conversations about how different HIT systems

need more cross-consistency because as staff move from one clinical site to another, they have an extra cognitive load to learn how to use the many different systems leading to errors, waste of time, and potential patient harm [15]. Training for CERP systems is both highly costly and difficult, hence the complaints. A system optimized for IA will be customized for its community of use and so staff working across multiple communities will need to train on different IA systems. Would the same objection apply? Most likely not. CERP "solutions" that fit the local workflow poorly will need significant workarounds in addition to the standard training that still has to be learned by migratory workers. Claims that the same technology from the same vendor has the same workflow and functions are often spurious—there are cases where two large systems, ostensibly the same, cannot even communicate with each other. Furthermore, locally designed systems customized to the needs of the clinical ecology are truly optimal for the local workflow and so training on them is about learning how the local community actually works, surely a necessary criteria for successful healthcare [16]. Training on locally designed systems has little training costs for local users and modest costs for new users. Also, they are of significant value where senior staff responsible for the training of junior staff use the IA system to train them in the processes of work and thus increase reliability and safety.

It is often the case that a CERP system is training staff in processes that are considered undesirable, whereas an IA system would enable the senior staff to create an ideal training system. This over time would lead to better standardization of work practices where appropriate, and easier adoption of these better practices as they are defined by the professional community because the IT behavior is immediately adaptable [17].

Functional Specifications of IA Clinical Information Systems

The intrinsic definition of an immediately adaptable system is in the name: *immediate*. We consider this to be a period of hours or days, not weeks, months, or years! However, the requirements as defined by the complaints to the professional discussion lists and elsewhere have a wider ranging scope.

The *first level of the problem* is the concept of the EMR which describes a medical record as placed into an electronic storage bin instead of a filing cabinet. Such an EMR fits the CERP model that is focused on collecting content and storing it on a large scale and then processing the data for highly stable requirements, e.g., billing. Furthermore, the CERP methodology requires deconstructing the data into normalized storage structures of permanent definition and storage representation. In the CERP paradigm, the "efficient" storage of data is paramount to the processes of "capturing" the data and only then subsequently "reusing" the data, that is, moving the data from the context in which it is collected to the contexts in which it is reused, which unfortunately blight the storage efficiency criterion by the effort and complexity of programming for the internal movement of the data. This involves elaborate methods for putting data into fixed data structures and reading it back out whenever it is called for. Intrinsically, the storage mechanisms are tightly coupled with the data capture and display processes. As an alternative, modern web technologies enable a significant loosening of this coupling but the CERP developers have been slow to embrace these innovations due to their years of investment in older software engineering and data management methods.

The greatest limitation of installed CERP systems is the effort, cost, and risk associated with changing the structures by which the data is defined and stored when a new data element needs to be inserted into a design, or changing the semantic meaning of an existing data item. This requires changing the underlying storage design and creating the code to store that data element and to retrieve it at all the points where it is reused *without disrupting anything of the existing processings*. The large vendors, whose systems have thousands of data tables that are beyond the scope of any one person or even a team of engineers to comprehend, are aware that their data management is brittle where even a single accident in a new design or coding can

bring down the entire system. This is one of the crucial reasons for the very strong resistance to modifications of CERP systems.

The process of separating the captured data in one context, storing it in a rigid data structure, and then moving it for reuse into another context is fundamental to moving away from the idea of an EMR model, towards one of a Clinical Information System (CIS). A CIS is a software technology that is integrated into the processes of the users so as to support their work in the most active and sense-making manner possible [18]. Critically, it is NOT a system that cements the processes of data collection and dissemination as found in a CERP EMR system. A CIS matches the users requirements for both the flow of data from one context to another, and their movement through activities of work that the users have to perform in a seamless manner such as when a surgical patient is moved from admissions to preoperative suite, operating room, and then to the intensive care unit. A CIS supports both dataflow and workflow for the user in a transparent and measurable way. The third key benefit of the CIS is the physical screen layout and design. The optimal design of a CIS is a dominant part of clinical usability research, but, due to the nature of the CERP methodology, very few usability discoveries have been incorporated into present CERP systems [19].

An IA-CIS has to be easily and readily changeable and accept real-time changes (or nearly so). An underlying architectural consequence of real-time changeability is that it has to have dynamic data structures along with revision control that does not affect the previous versions of storage organization or access to previously recorded data so that real-time use is uninterrupted and seamless.

We have named the data flow requirement of IA-CIS: native interoperability. The idea is that data created or input at one point in a data flow can be referred to by its name wherever else it needs to be reused. There should be no need to write code to read tables to transfer such data, but rather it should behave more like a link. Thus, when you invoke the name of the data at a time for its reuse in a new context, it appears at that point of invocation, without needing to do anything else. This introduces interesting questions about the protocols for naming data but stable solutions are available to solve them [20].

IA implies real-time design, which requires a design toolkit for specifying all the requirements of the user including, data definition, screen layout and behaviors, business rules, data flow, and workflow. Underlying these design utilities is a need to use a design language universal to all CIS designs that become the specification of the operational system. This has an important consequence: the design of the users' system is independent of the software that manages their data. The benefit is that design can be changed without affecting software code, and code be changed without necessarily effecting designs. Software maintenance is done independently of any CIS design processes. This radically simplifies the nature of system maintenance as there is no enmeshment of a given system design and the program code required to implement it. This is a radical departure from present system architecture and software engineering practice.

Furthermore, it opens the door for usability research to be directly incorporated into an operational system. To support usability research, the only software engineering requirement is to have a library function that performs according to the usability task being investigated. If the feature to be investigated is not available in the design tool kit, then the only software engineering task is to enhance the design tool to carry the function as an element of the design toolkit. To create an executable instantiation of the design as defined in the design language, there needs to be libraries for all design functions and auto generation of data structures that are invoked at the point of real-time system generation.

While not an absolute requirement for an IA-CIS, built-in analytics are needed to achieve the user demands in order to pursue Continuous Process Improvement (CPI) for clinical care [21]. The role of using a CIS for improving direct operational workflow is fundamental to its conception. However, optimizing the CIS over time requires the analysis of the behavior of the CIS and the users as an integrated entity. This analysis is best achieved by having analytical tools built

into the CIS that can actively monitor the CIS and its users to establish the value of changes as they are implemented [22]. Omitting analytics functionality as an intrinsic part of the CIS will severely limit the ability of the user team to identify behaviors of the microsystem (staff, technology, equipment, etc.) that warrant change and later to measure those changes.

A Generic Architecture for IA-CIS: Repurposing the EMR Model

The IA-CIS methodology is in some ways a counter positive to the CERP. Over time, the CERP methodology has diminished the role of requirements gathering and systems analysis to the point, where it serves only to direct system configuration of fixed data structures and concomitant code bases. IA-CIS does the opposite: it treats requirements and design as the primary function of creating a system for the specific needs of the user community. It then generates an implementation process from the choices defined in the design, creating dynamic storage structures served by an engineered library of adaptabilities.

The value of CERP-engineered systems lies in their capacity to massage large volumes of data for repetitive, infrequently changing processing. The disadvantage is their inability to satisfy the needs for representing intricate and different workflows in multiple clinical contexts. Although all clinical contexts are ostensibly the same, actually they are steeped in subtle and significant differences both between medical specialties and across institutional contexts, with the added complication of fast-changing and diverse work that needs to adapt practices immediately for any number of social, legislative, or professional reasons. Using an IA-CIS for clinical care systems will reduce the maintenance load on the CERP so they don't have to be continually adaptable and hence will lower the costs of managing them. The CERP will contribute better to the HIT ecology if it is rightly positioned as the data warehouse backbone of the organization fed by the highly efficient limbs manifest as IA-CISs.

We can achieve better care, more satisfied users and less expensive outlays by repurposing CERP systems for back office functions and removing them from the clinical coalface locations where IA-CIS technology can provide better support for work and better efficiency gains for the relative costs of installing them. Customization of IA-CIS is the most likely pathway for reducing workarounds, but with the more important positive benefits of increasing data collection completeness, improving patient safety, enabling cultures of continuous process improvement, and, of course, both simplifying and accelerating training [23].

An important extension to the IA-CIS is that it is a coherent method for creating a single application for one clinical department that can be repeated for many clinical departments in the organization. Although each department designs their own system as an autonomous community, they all use the same design tools and the same instantiation library; hence, the technical implementation can house them all in the same software installation. This is equivalent to providing multiple customized best-of-breed systems in the one software installation. This architecture introduces a different type of interoperability, that is, CIS to CIS by means of within-system native interoperability. So while users are operating under the belief they are autonomous, they are actually all working within one infrastructure with a single data management process that enables the direct sharing of data (given the appropriate permissions) and introduces an inherent cohesion that is not part of the consciousness of the different user communities but nevertheless enables interoperability at a subliminal level. Figure 16.1 is a high-level diagram showing multiple systems including clinical care, research, and registry systems built on the one software platform using native interoperability to share data with each other and a single gateway to communicate with external systems.

IA-CIS do not solve the problems of interoperability between different systems supplied by various vendors. Hence, it is unavoidable that a CERP system and an IA-CIS will have to use

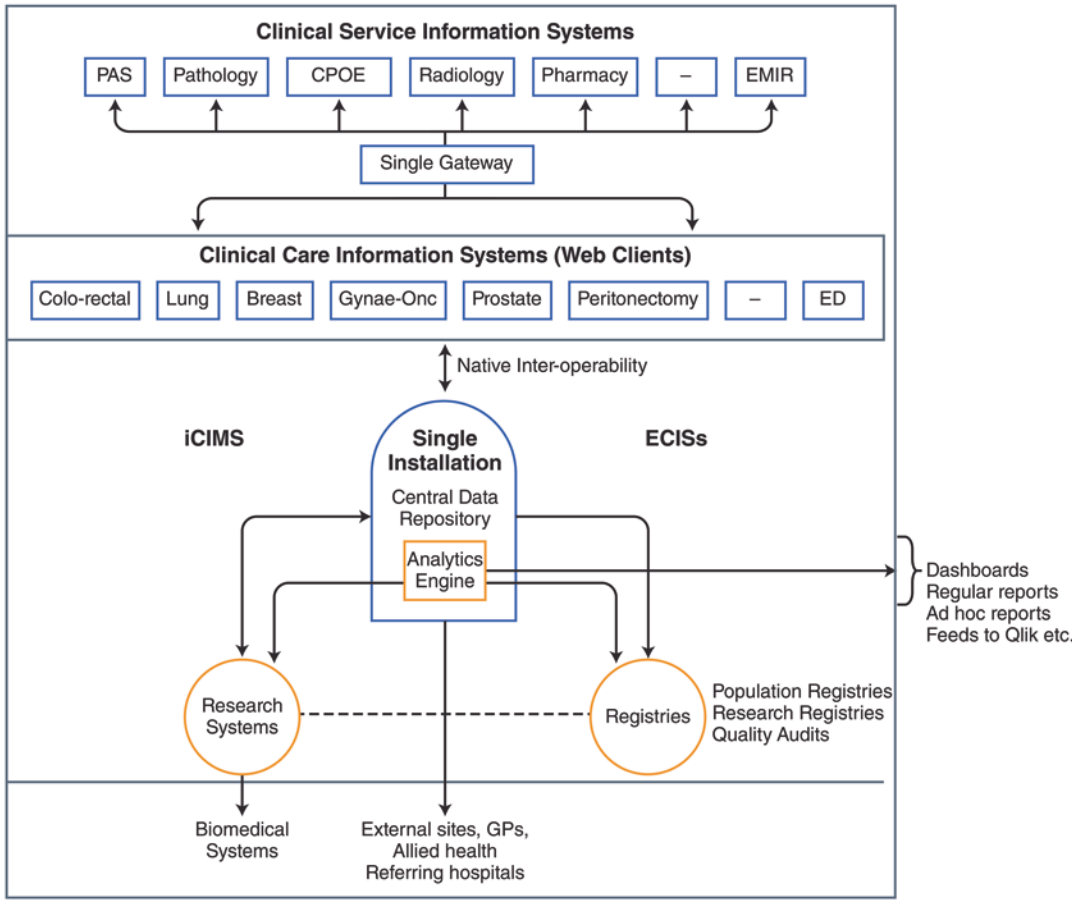

Fig. 16.1 An architectural diagram of the relationship between clinical care information systems and clinical research systems and registries as part of the ECIS paradigm

some external coding standard to share data between each other. Methods for solving this problem are well established by HL7 or ODBC direct procedure calls. (ODBC Direct is an alternate mode of Data Access Objects (DAO) that accesses ODBC data sources directly, and taking full advantage of the remote data source's processing capabilities.) But within the IA-CIS paradigm, the problem is solved at a much more efficient level by native interoperability.

The IA-CIS also has another significant advantage in that it eliminates silos of data, and maintenance and support for multiple systems. In this data architecture, it is important not to take a stance that assumes all data needs to be available in one place. Most data needs to be usable by the people who collect it, and then appropriate selected pieces passed on to those who have secondary use purposes. Just as the results of every research experiment are not required by the back office so not every action taken by the clinical staff needs to be defined by the back office. Autonomy at the front office with a requirement to deliver the essentials to the back office enhances the efficiency of both communities.

There is an argument in some circles that there needs to be a single source of truth which can only be provided by a CERP. This is a false assertion when it is claimed. The extensive dispersion of a complex care process delivered by many disciplines with many different technologies has already led to an irreversible distribution

of data across multiple information systems, such as surgery, radiology, pathology, and pharmacy. Advocates for this position, who already operate multiple systems successfully, use this as an argument to exclude evaluating the local systems value. The solution proposed here is to ensure that local systems have appropriate interoperability and support.

The imposition of inefficient and burdensome HIT in clinical workers has led to a Stockholm-like syndrome and worse such as:

> *"It is well understood in psychology that when people repeatedly experience unpleasant events over which they have no control, they will not only experience trauma, but will come to act as if they believe that it is not possible to exercise control over any situation—indeed, that whatever they do is largely futile. Attempts to remedy the operational and social disadvantage of clinicians subjected to inefficient systems depends, fundamentally, on understanding the effects of past trauma and its potentially cumulative effects."* [24]

In summary

- Front-line staff productivity will make greater gains from immediate adaptability than interoperability,
- Organizations will better protect patients with immediate adaptability technology,
- Interoperability, CERP, and best-of-breed systems each represent usability at different types of context, and
- ROI needs to be interpreted and assessed at their appropriate context, and efforts to conflate them into alternative competitive solutions is a misunderstanding of their different contributions.

An Architecture That Supports the Levels of HIT Context

A data architecture to satisfy all the requirements of the three levels of health organizations has to have these features:

Feature 1. Immediate adaptability for the Level 1 context so that patient-facing clinicians can work within a paradigm of continuous process improvement. Intra-interoperability with other non-service clinical departments is useful but not essential in that it enables in-hospital information to be provided in a more amenable manner, but the care of patients will continue regardless of its absence.

Feature 2. Intra-interoperability between specialty clinical systems and service clinical departments for the Level 1 context is useful so that the normal operational care of patients can run smoothly with the service disciplines which service many of specialties with the same service functions such as pathology, imaging, and pharmacy. This local intra-interoperability has for the most part been solved by the use of certain standards such as HL7 messaging and DICOM picture standards. Immediate adaptability has not been strongly advocated by the service clinical departments, probably because of the more routine nature of their work and smaller extent to which the information system capabilities effect their work processes.

Feature 3. Analytics is an important function at each of the levels of HIT context, but it is a different type of analytics for each. Clinical care units need analytics to understand the statistical profile of their operational activities, while a health organization needs analytics to understand the trends of activities aggregated over multiple units of activity, that is, what is common between each of their different clinical units. They also have to investigate the relationships between the costing of activities and the resources they put into those activities. Finally, they need to develop models of future activities to support resource planning and allocation.

Feature 4. Inter-interoperability requires the sharing of data within a large Level 3 organization such as a multihospital organization or a state or provincial government with many disparate health services. These organizations are dominated by the effort at getting data it can standardize for predictive analytics and to identify both acute and long-term health trends, in the first case to react to public health scares, and in the latter case to plan the delivery of health resources at a society wide scale. These orga-

nizations reduce the health organizations data to a "common data set" of limited dimensions, as it is too difficult to get data from many different types of health organizations to do anything that might be more reliable. The interoperability problem at this level is much greater than at the intra-level because there is a large number of organizations to deal with and so the complexity of the task is exponentially larger than at the intra-level. Adaptability of clinical information systems is of little consequence at this level because they are only dealing with a synthesis of data collected from many diverse settings. Often this is the level at which HIT acquisitions are determined and hence the success of CERP vendors who appeal to the HIT problem at this level.

We are advocating for a new architectural configuration that embodies methods for tackling these problems. The inherent notion is to change the common architecture of the Level 2 context so that it has the benefits of the Level 1 architecture without its drawbacks for Level 2, and the benefits for the Level 2 context without the disadvantages it creates for the Level 1 users. Conceptually, this requires a shift to a new viewpoint of CIS architecture in that it inserts the ideas of immediate adaptability, user-controlled design, native interoperability, and in-built analytics into the debate and aligns those ideas with the established technology of data warehousing.

The Architecture in Practice: Clinical Care Information Systems (CCIS) and Clinical Services Information Systems (CSIS)

We define two classes of health information technology (HIT): Clinical care information systems (CCIS) and clinical services information systems (CSIS). The CSIS are systems required by most of the clinical departments in a hospital setting such as surgery, pathology, radiology, pharmacy, and EMR. The CCIS are the systems required by the clinical specialties that in the past have used best-of-breed solutions but now are being swept into the EMR vortex. Crucially, when they are drawn into an EMR solution, they lose the ability to have the system adapted to their needs, and they are provided with workflows that predominantly make their work less efficient, require more manpower, and lead to much pushback.

Effectively, the work of a data warehouse is being harnessed to serve the work of a dynamic workplace with shifting practices, workforce, and demands on the capacity to adapt and change. The need for a CCIS solution is readily defined in a few criteria: Immediate adaptability (and hence near real-time adaptation), user-controlled design, native (in-built) interoperability, and in-built analytics. The software engineering solution for these criteria produces a very different type of architecture that creates the optimal blending of function of levels 1 and 2 systems while overcoming most of the drawbacks.

The software architecture as explained below has been implemented after a number years of experimentation and has demonstrated the proposed benefits are real. Underneath these four criteria is a key architectural requirement that the means of designing such systems has to be systemized [25]. The architecture has at its kernel a design tool that enables a user to create a design of an information system, this includes screen design, data flow design, and workflow design. The design is maintained internally in a design database in the form of a design language. Adding new design functions requires adding the capability of describing them to the design team and developing a formal method of expressing them in the design language. Then, the library code needs to be written which is invoked on calling the feature in a particular CIS. The data modeling function is managed internally by the software and is not available for the user to be concerned with or to tamper with. It is a basically an object-orientated strategy using relational stores for the management process. The critical objects are the screens or forms into which is embedded the dataflow, workflow, data management, and business rules.

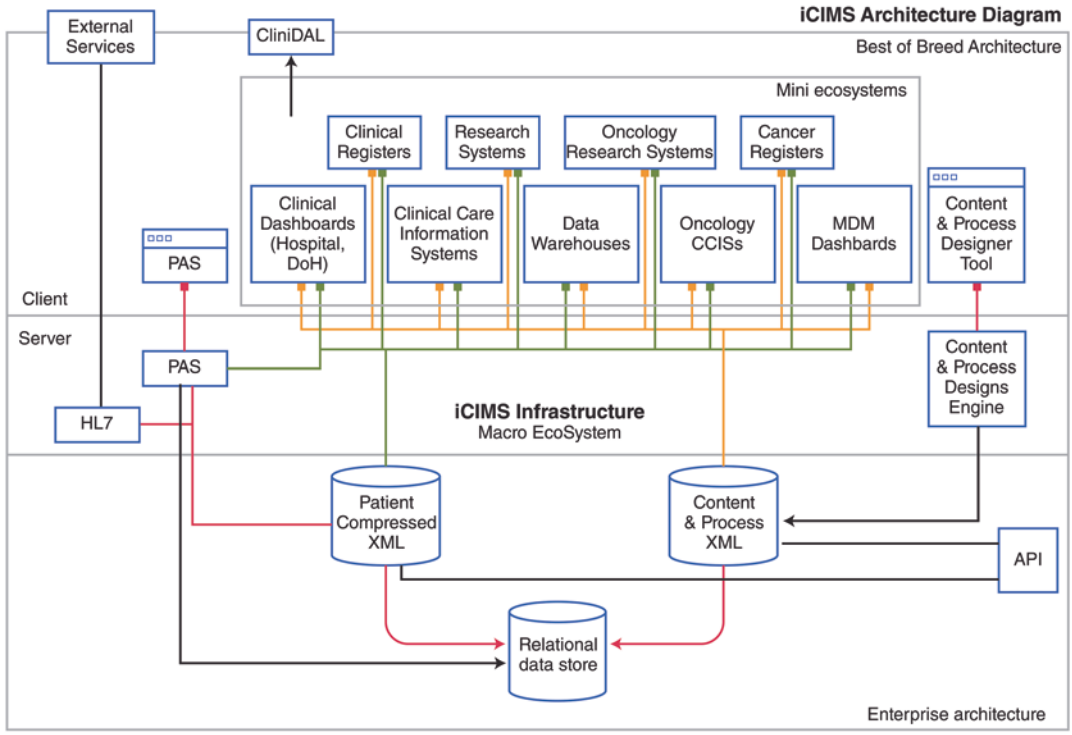

Fig. 16.2 ECIS architecture supporting a variety of clinical information systems within its own paradigm

Years of work since the original publication have solved many of the technical problems and demonstrated that a feasible and practicable solution can be achieved. Figure 16.2 displays the basic engineering architecture for creating multiple CISs in the one software environment and the access to the data via APIs, HL7 messaging, and a clinical data analytics language (CLINIDAL).

There are some interesting emergent properties from this approach that strengthens its merits:

Property 1. Painless expansion and incremental design: Firstly, a system runs by invoking the design which is executed by a library function. A system that is defined entirely by the act of design intrinsically means that only the design has to be changed to create a new function in the CIS. Subsequently, a design can be prepared to cover a minimally necessary amount of workflow and then be added to regularly over time. This in effect enables a system to be not only a mechanism for experimental design with a roll back that can be executed at any time, but also a strategy for incremental development where after completing and operationalizing one subsystem the next most suitable subsystem can be chosen for implementation.

Property 2. Multisystem design on the one software platform: With a functionality to continuously expand one system, it is entirely possible to create a different clinical system on the same platform. There are an unlimited number of CISs that can be created and operate from the one software installation. So although this architecture is a pseudo-best-of-breed technology, it is also a multi-best-of-breed solution, effectively allowing users to create systems *as if* they are wholly autonomous, but all the while the underlying infrastructure is using the same code and data management strategies behaving like an enterprise architecture.

Property 3. User-controlled design: It is an advancement on user-directed design that enables the user to specify exactly the design they want. It is often the case that users don't understand what they really want until after they have been disillusioned by being delivered something they thought they wanted. With real-time adaptation, the user can experiment with designs to their own knowledge depth and revert to older designs if new ones are proven to be non-optimum.

Property 4. Rapid prototyping: The ability to modify implementations at will means that prototypes can be built rapidly, tested, adapted, and generally system development be progressed at a faster rate than other technologies.

Property 5. Automatic version control: The design is implemented in such a way that it stores all versions of all designs; this includes screen designs, embedded business rules, data flows, and workflows. Hence, all version control is an in-built feature of the design tool, and reversion back to an earlier version of the system can be achieved by just nominating the version number.

Property 6. Universal data storage: Because all CISs built within this paradigm use the same design language and storage management functions they all use the same data storage to preserve patient data. Hence, all systems have access to all other systems data provided appropriate permissions are set.

Property 7. Universal attribute coding: To ensure that data elements can be semantically shared the system has a mechanism for identifying a variable by its SNOMED CT concept identifier, or any other useful data standard the user wishes. In this way, the semantics of data fields between systems is well defined making data sharing much more reliable.

Property 8. Radically reduced maintenance: An interesting emergent property of this paradigm is the significantly reduced software maintenance required for the installed software. This approach effectively separates the process of CIS design from the preparation of executable program code. The design is the responsibility of the clinical team and the software that of the software team. There is very limited overlap and the software team does not have the workload of understanding or managing the system design. They are only required to ensure the code computes correctly.

Figure 16.3 demonstrates the manner in which the EMR can be repurposed as a data warehouse and the clinical care and clinical services can fulfil their own roles while delivering information to each other and to the EMR as each needs.

This technology supports a methodology for creating user designs with an incremental iterative feedback process. We denote the underlying architecture, as Emergent Clinical Information Systems (ECIS), which automatically uses a predefined run-time library of code to directly execute the user designs; hence, no programming is required to move from design to implementation. The ECIS architecture is defined on the principle of *Ockham's Razor of Design*, *i.e.,* the principle that simplicity is preferred to complexity in *design*, so that given the choice between functionally and simplicity, simplicity will always take higher consideration. In the ECIS, this means that the elements of design that are engineered for the designer are a minimum number of design objects with maximal generalization [25]. The CIS design is created by a principle of *Agile Design* where designs are created and tested incrementally within an iterative process.

With this functionality, the capacity to make near real-time adaptation of an implementation is made available, giving enormous power to the design team to explore alternative designs before commissioning a specific implementation. At the same time, the underlying data management for all CISs built in the ECIS paradigm is the same, and hence it has the unification of the code base and data stores in a single application. In essence, it is a best-of-breed solution on the user side and an enterprise system on the server side. The ECIS model with user-controlled design, real-time changeability, native interoperability to move data from the collection process to where it has to be reused, and in-built analytics to monitor the effect of change represents a much superior approach to providing effective methods for Clinical Process Improvement (CPI) in any clinical setting.

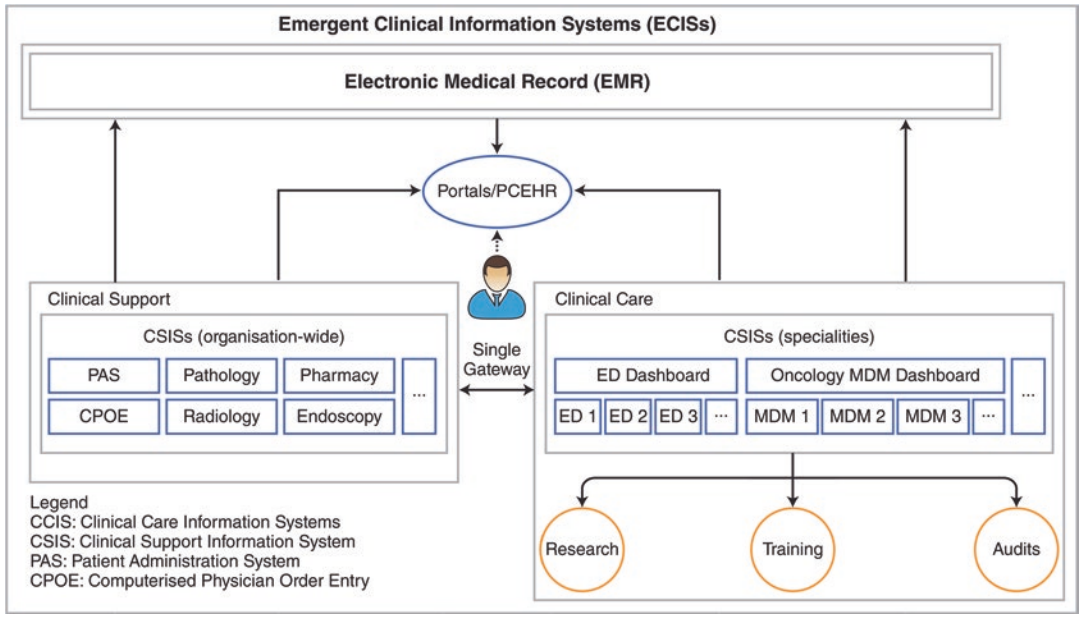

Fig. 16.3 An ECIS configuration with an external EMR acting as a data warehouse and other clinical service information systems (CCIS)

Case Study Results

The system development approach espoused in this chapter has been tested in a practical setting with the development of a number of oncology systems but by far the largest is an Emergency Department Information System (EDIS) at Nepean Hospital, NSW, Australia. A prototype of the idealized technology was built and subsequently the ED staff created their ideal design for an EDIS that was optimized for their environment. The system was denoted as Nepean Emergency Department Information Management System (NEDIMS). NEDIMS performance was compared to the incumbent CERP, from one of the large international EMR providers. A full report on the project has been prepared and is available on request [26], and some of the results most pertinent to emergency medicine have been published [27] which is followed by an editorial on the merits of the technological approach [28].

The evaluation of the NEDIMS system had these objectives:

1. Assess the capacity of staff to design their own CIS;
2. Assess the capacity of the ECIS technology used for the design process to satisfy all the demands of the design team;
3. Assess the differences between the NEDIMS and the CERP for:
   (a) Efficiency of operation;
   (b) Cognitive load;
4. Assess the effect of the clinicians' design on:
   (a) Workarounds;
   (b) Paper processes;
5. Assess the trainability of NEDIMS;
6. Build a model of patient journeys and assess it for differences between NEDIMS and the CERP for that model;
7. Identify the processes of interruptions and consider methods for minimizing them;
8. Make a qualitative assessment of the differences between the two systems for patient safety, staff productivity, and clinical audit;
9. Assess the costs and ease of modifying the system and provide an evaluation of the ROI in making those changes.

A process analysis for each of the six activity centers in the ED is described: Clerking, Triage, CIN (Clinical Initiatives Nurse), Fast Track, Acute Care, and Nurse Unit Manager (NUM). The process analysis formed the basis of understanding the design needs of the department. It was also used subsequently to identify the task types that needed to be used in the quantitative comparison between the two systems. A total of 43 task types were identified of which 27 were present in the CERP system, 40 were present in NEDIMS and 14 were completed on paper.

The department staff were observed for 22 days where each task instance was measured for time duration and number of mouse clicks in live usage on the CERP and paper forms. A total of 722 task instances were recorded from 43 task types. Subsequently, 374 matched observations of 17 task types were measured for those tasks that could be repeated in NEDIMS of which 332 were matched task instances between NEDIMS and the CERP, the remainder being matched to paper forms.

The results demonstrated that NEDIMS is about 40 % more efficient than the CERP using directly measured times and on normalized results greater than 50 % more efficient [26]. NEDIMS was better on 14 out of 16 tasks for time costs of which 7 were statistically significant for NEDIMS and 2 were significantly better for the CERP.

The cognitive load, as represented by click counts, showed that NEDIMS significantly reduced the cognitive load on users by up to 30 % overall. In 9 out of 16 tasks, the NEDIMS required fewer clicks to get the same job done, of which 5 were statistically significant with 5 significantly fewer for the CERP.

A number of workarounds discovered in the process analysis phase of the research were identified and the efforts to eliminate or minimize them in NEDIMS revolved around the current workflow processes of the department. For instance, terminals were used by multiple staff but they often would leave the terminal due to interruptions or to collect other information. When they return to the terminal, they assume that the current session is under their own account when in fact, in the time of their absence from the terminal, another staff member needed the terminal and switched accounts. The first user continues entering data into a patient record without realizing they are working under the name of a different staff member, which becomes apparent when they have to try to save and commit the record and they do not have the password of the logged on user. As a result, they sometimes need to redo potentially long tasks such as ordering tests after restarting the system with their own credentials. NEDIMS implemented a validation step of "signing off" that allowed switching accounts seamlessly.

A model of patient journey through the department consisted of four scenarios of short and long Fast Track patients and short and long acute care patients in a proportional ratio of 15:15:30:30. The resulting analysis showed that NEDIMS would provide a staff time saving of on average 23.9 h per day [26].

A qualitative analysis of opinions from staff comparing the two systems on three key performance criteria of patient safety, staff productivity, and clinical audit over 19 tasks, giving a total of 57 cases. It showed NEDIMS was ranked higher on 39 cases, the CERP for two cases; the two systems were equal for 15 cases and one case non-determinable.

The time cost of the effort in remodeling the designs showed that the time-savings were returned within a few days to a week of operations in the department; hence, the return-on-investment indicates a high yield under the ECIS methodology. The total cost of designing and testing NEDIMS amounted to about 140 person days, which will be regained by the department after about 50 days of operations.

Finally, here is the conversation that transpired between the process analyst who helped install a cancer CIS using this technology and clinical staff at the St. George Hospital, Sydney, a sister hospital to Nepean Hospital in New South Wales, Australia, about the impact of the ECIS methodology in supporting their EMR needs:

> *Senior Nurse: "I am the worst person in the unit for IT, I know nothing about it and if anything will go wrong it will happen with me."*
>
> Process Analyst: *"I spent a lot longer than I would normally explaining the system, about 10–12 minutes then I got her to go through the whole system and there was not one problem."*

Subsequently after system testing Senior Nurse, *"you know I think it is so good I could have gone through the whole system without your help. This is great because it is just the way we imagined it would be and it is exactly the way we work."*

Conclusions and Some Observations About the Future of HIT

Engaging and supporting clinical staff in the design and testing processes of HIT, in a manner that reflects their local workflow processes, ensures it is better suited to their needs and will be a better aid to their work than an incumbent CERP system. Information systems designed for and by a clinical team using a technology that enables real-time adaptation provides much greater efficiency for the staff in decreasing the time to complete standard tasks. Additionally, it creates a continuous process improvement environment that enables the workflow processes to be adapted dynamically to optimize the efficiency improvement, and the ECIS technology enables measurement and recoupment of the costs of supporting the ongoing adaptation of these processes.

The ECIS model of system development posits that a system is never "truly complete" but rather it is evolutionary, being stable for certain constraints and time and nimble enough to be changed as the clinical ecology around it changes. ECIS provides an efficient and inexpensive methodology on which to achieve those changes. Hence, the point in time when a system should be commissioned is when the community of users believes it can give them efficiency gains without unacceptable negative downsides. From that point on, it needs to be added to at will with few barriers to innovation. Indeed, the community of users can reliably identify the next most valuable activity to computerize in order to gain the maximum efficiency given their system's current capabilities. Such egalitarian decision-making makes for an orderly and systematic progression in computerizing their work activities and ensures much higher engagement [29]. Hence, the ECIS model is a new paradigm, a credible alternative to a large-scale sudden-death system changeover using many foreign, impractical workflows. It capitalizes on local knowledge and wisdom, flexible work practices and heuristics, and optimizes the local environment in contrast to clunky, slow moving enterprise solutions.

The ECIS technology enables a new HIT architecture that propels the needs of the patient-facing staff to the forefront of the HIT, which can bring significant advantages in efficiency and ROI for health organizations as well as enhancing workplace satisfaction. The shifting of emphasis on the role and function of HIT requires a shift in perceptions on how to utilize whole-of-organizations CERP installations. This means being thought of more as a data warehouse, something that such systems are more akin to and can serve better the needs of organizational infrastructure.

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Redesigning Hospital Alarms for Reliable and Safe Care

17

Paul Barach and Juan A. Sanchez

"Even the boy who cried wolf was right about the wolf once."

—Sherry Thomas

Introduction

Noise levels in hospitals have been rising for decades and are far higher than guideline values established by the World Health Organization. Alarms contribute significantly to noise pollution in healthcare facilities. Alarm safety is one of healthcare's most high-profile and intractable problems. A phenomenon known as "alarm fatigue," including limited capacity to identify and prioritize alarm signals, has led to delayed or failed alarm responses and deliberate alarm deactivations. Alarm fatigue has been implicated, according to federal agency reports as well as in the lay press, in patient morbidity and deaths, some highly publicized. Between 200 and 566 patient deaths have been reported to have died from 2005 to 2014 as a result of alarm mismanagement; these numbers are likely to be underestimates.[1] Many factors contribute to alarm fatigue, but perhaps most significant is a reported false alarm rate of as high as 90 % among millions of alarm signals. These large numbers of clinically irrelevant signals directly contribute to staff desensitization. In addition, high background noise levels in critical care and variable acuity units and in operating rooms contribute to alarm response failures. They do this by further increasing the cognitive load on staff; escalating distraction and irritability; and complicating discernment, attribution, and communication.

If, however, alarms are intended to maintain a level of situational awareness, designers need to engineer monitoring devices able to do some or all of the following: distinguish artifact from real patient status changes, determine whether these changes are contextually important, convey the source of the alarm to the receiver, and allow prioritization when operational attention is directed elsewhere (e.g., during line placement) or when multiple alarms sound.

Multiple levels of influence and opportunities for system intervention and innovation exist to facilitate timely and reliable alarm responses. These include addressing the broader acoustic context, clinician responsibility, deployment and

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[1] ECRI Institute. ECRI Institute releases top 10 health technology hazards report for 2014. November 4, 2013. https://www.ecri.org/Press/Pages/2014_Top_Ten_Hazards.aspx Accessed January 3, 2014.

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teamwork training, threshold-setting guidelines, improved user interfaces, and algorithms balancing alarm specificity with sensitivity. Monitoring devices that process complex data streams should produce clinically relevant alarm signals in an environment which is optimized for discernment and attribution and with user interfaces designed for timely interpretation, prioritization, and prompt action. Hospitals need a system-wide alarm management policy and protocols that define the alarm management strategy for alarmed medical equipment, and delineate how caregivers/nurses should respond to alarm conditions and signals.[2] Involving patients in the redesign of hospital acoustic environments may also improve patient experiences and satisfaction with their hospital care.

The Detrimental Impact of Noise and Alarms on Patients and Providers

Noise and sound characteristics have been demonstrate to negatively impact both patients and clinicians. In the 150 years since Florence Nightingale wrote about the adverse effects of noise on hospital patients, others have noted the problem, but it is still not recognized as a major cause of harm.

Hospital noise is considered pandemic, dangerous, annoying, and consistently leads to the lowest average HCAPHS (Hospital Consumer Assessment of Healthcare Providers and Systems) scores and is the lead patient safety goal for the National Patient Safety Foundation and The Joint Commission.[3] Critical, and less well understood or appreciated, is that the quality (characteristics) of the physical environment of sound, more than simply its volume (collectively, the "soundscape"), is significantly detrimental to the delivery of medical care and the well-being of both medical staff and patients. It directly contributes to medical error and patient harm.

Hospital noise routinely exceeds international WHO noise acceptable standards and is more than just an annoyance [1]. The World Health Organization (WHO) established hospital noise guidelines in the 1999 publication "Guidelines for Community Noise" to better understand and address the negative effects of noise, stating that perception of sounds is of major importance for human wellness [2]. According to WHO, excess noise can result in impairment of functional capacity or an impairment of capacity to compensate for stress. The WHO recommended a hospital sound level maximum (Lmax) of 40 decibels (dB) and 35 dB for patient rooms. Current hospital noise levels significantly exceed these numbers by an average of 30–40 dB [3]. Hospitals historically have not conformed to recommended or legislated sound levels [4]. It is not unusual for Emergency Departments, operating rooms (ORs), and intensive care units (ICUs) to have average noise levels in the 73–77 dB range with paging and surgical equipment producing intermittent noise spikes of over 90 dB [5, 6]. Consequently, noise in healthcare environments is becoming recognized as a serious health issue, increasing staff stress and absenteeism, hindering patient healing, and causing patient injury and even death [7, 8].

A growing body of research about the harmful effects of noise in the healthcare environment along with the new financial and regulatory incentives has advanced noise control in healthcare facilities to a top priority. High noise levels in trauma units can also detrimentally affect short-term memory tasks, mask task-related cues, impair auditory vigilance (for instance, the ability to detect and identify alarms), and cause distractions during critical periods [9]. A review of the literature by Ulrich et al. found more than 1200 studies linking the physical environment to patient and staff outcomes in areas of stress, fatigue, patient safety, outcomes, costs, and overall healthcare quality [10]. Dickerman et al. also found a direct link between patient care quality, patient health outcomes, and hospital design, supporting the link between hospital environments as a promoter of stress for patients and staff [11].

Poor acoustic clinical environments are also associated with an excessive cognitive load on clinicians [12] and interference with speech and communication, both of which can increase the

[2]See Johns Hopkins Hospitals clinical alarm management policy http://hpo.johnshopkins.edu/hopkins/policies/39/11305/policy_11305.pdf?_=0.231088243942.

[3]http://www.jointcommission.org/assets/1/18/jcp0713_announce_new_nspg.pdf.

risk of medical errors and patient harm [13, 14]. As an example, alarm fatigue, the clinician desensitization to incessantly beeping alarms amounting to hundreds of alerts a day (up to 90 % false or not relevant) is a national problem blamed for dozens of deaths each year, as overwhelmed staff do not respond or fail to respond with urgency [15]. Caregivers must exert greater effort to maintain accuracy which, in turn, increases physiological responses and fatigue [16]. Busch-Vishniac found noise levels at John Hopkins University Hospital were high enough to affect speech comprehension (speech intelligibility) [1]. Reduction in speech comprehension is also known to increase performance errors. Murthy and Rataplan found noise levels interfered with attending and resident interactions in more than a third of shift-change communication [6, 17]. Excessive noise levels can induce and exacerbate anger, annoyance, displeasure, and staff burnout [18]. Excessive noise is a stressor to both patients and staff. While researchers have noted improved patient outcomes and staff satisfaction in hospitals with perceived good acoustic environments, the reverse has also been demonstrated [19, 20]. Babisch's work illuminates the physiological effect of the noise–stress relationship. The impact of noise on medical errors and patient harm is summarized in Table 17.1 [21].

In addition to documented cardiovascular responses to stress, there are long-term health effects for individuals exposed to noisy environments. Excessive noise causes problems with concentration, fatigue, uncertainty and lack of self-confidence, irritation, misunderstandings, decreased working capacity, problems in human relations, and optimal decision integrity [22]. More studies to understand these ill effects will require transdisciplinary work using more sophisticated methods, tools, and techniques.

Table 17.1 Impact of noisy healthcare facilities on patients and providers

Medical errors
Impaired communication and concentration
Disorientation and distraction
Elevated blood pressure and stress levels
Auditory habituation or ear fatigue
Rule breaking behaviors (such as turning off alarms)
Sleep disruption and loss of sleep that is essential for healthy recovery
Startle response

Like many innovations, alarms were first developed as safety devices for an exceedingly small group of high-risk patients. Because clinical events and hemodynamic alterations often presage harm in this population, alarms have been highly successful at averting complications. Encouraged by these benefits, the medical community expanded this model to lower risk populations. Moreover, innovations in bioengineering and computer science have successfully embedded all types of alarms into an expanding portfolio of physiologic monitoring equipment with variable impact on patient care. The consequence of this well-intentioned technological evolution and generalization is epitomized in the din of chirps, beeps, bells, and gongs that typify hospitals today. It is, thus, not surprising that concerns regarding safety have emerged, even in populations for whom these protective devices were once considered most valuable.

Characteristics of Systems and Risk Management Framework

A surgical healthcare system includes several subcomponents. Foremost among these are those surgical or clinical processes, which are used to treat patients directly. Another component is technology, medical and nonmedical including information systems, diagnostic systems, imaging systems, as well as mundane technologies such as floor cleaning equipment, supply ordering, and distribution technologies [23]. Additionally, there is organization, the administrative arrangement that includes policies, procedures, strategies and tactics, management tools, business plans, etc. Providers are another subsystem. They include professional, technical, administrative, management, patient, public, government, and others. Finally, there is the physical environment including the architecture, engineering, interior design, and other environmental conditions which, in aggregate, impact a large number of organizational characteristics [24].

Charles Perrow studied major accidents and discovered that systems, rather than individuals, were often at fault [25]. Perrow and James Reason have redefined how we should understand the causes of accidents and how we fix problems [26]. One of Perrow's contributions was to describe how the components of systems are interrelated. He defined two dimensions, complexity and coupling, which predict how systems function. There are many other subcomponents of systems, some of which are hidden, and require "operators" to use a great deal of short-term memory, cognitive work, or computing power. The planning, designing, and construction of healthcare facilities involve physical structures and processes that are tightly coupled in that there is no "wiggle room" in the connections. If one component fails, the adjoining components are immediately impacted, sometimes in unforeseen ways.

Noise engineers and medical personnel generally have been working separately on noise issues, with limited progress and implementation of their findings. With increased urgency for quality and performance improvement, multidisciplinary teams have been formed to produce actionable research and evidence-based design initiatives [27]. This collaboration between medicine and engineering has produced data on physiological responses, healthcare outcomes, and economic impact, which have considerable influence on policies relating to noise, in contrast with the historic assumption that noise is nothing more than an annoyance.

Human Factors and Situation Awareness in Understanding Optimal Alarm Management

Human factors (also known as ergonomics) is the study of human interactions with tools, devices, and systems with the goal of enhancing safety, efficiency, user satisfaction, interpretability, and ease of action [9]. Nearly half a century of research and hands-on experience have produced a substantial body of scientific knowledge about how people interact with each other and with technology [28]. These "performance shaping factors" must be understood and incorporated in alarm design to enhance provider responsiveness [29]. For example, current medical device interfaces should be able to minimize false alarms produced by irrelevant signals such as patient repositioning, suctioning, and oral care, which can alter heart and respiratory rates, as well as dislocating sensors.

Human factors research is of great relevance in designing spaces for managing surgical patients and intensive care patients [30] and in considering the impact of the many "performance shaping factors" that can degrade human capabilities (Table 17.2). One of the most important decision-making skills by healthcare teams is to decide which sources of streaming information to devote attention to and what can wait. Where data overload is the rule and the patient's status changes continually, the ability to recognize clinical cues quickly and completely, to detect patterns, and to set aside distracting or unimportant data can be lifesaving. Situation awareness (or situation assessment) is a comprehensive and coherent representation of the (patient's) current state that is continuously updated based on repetitive assessment [31].

Situation awareness appears to be an essential prerequisite for the safe operation of any complex dynamic system. In the case of healthcare, establishing and maintaining a "mental model" of the acute patient and the surrounding environment including facilities, equipment, and personnel are essential elements to effective situational awareness [32]. Successful team situational awareness requires constant communication that enables members to converge around a shared mental model of the situation and a course of action to quickly correct course as needed. Effective teams adapt to changes in task requirements, anticipate each other's actions and needs, monitor the team's ongoing performance, and offer constructive feedback to other team members [33]. When team members share a common mental model of the team's ongoing activities, each may "instinctively" know what each of their teammates will do next (and why) and often communicate their

Table 17.2 Performance shaping factors affecting surgical care[a]

Individual factors	Clinical knowledge, skills, and abilities
	Cognitive biases
	Risk preference
	State of health
	Fatigue (including sleep deprivation, circadian)
Task factors	Task distribution
	Task demands
	Workload
	Job burnout
	Shiftwork
Team/communication	Teamwork/team dynamics
	Interpersonal communication (clinician–clinician/ clinician/patient)
	Interpersonal influence
	Groupthink
Environment of care	Noise
	Lighting
	Temperature and humidity
	Motion and vibration
	Physical constraints (e.g., crowding)
	Distractions
Equipment/tools	Device usability
	Alarms and warnings
	Automation
	Maintenance and obsolescence
	Protective gear
Organizational/cultural	Production pressure
	Culture of safety (vs. efficiency)
	Policies procedures documentation requirements
	Staffing cross coverage
	Hierarchical structure
	Reimbursement policies
	Training programs

[a]Modified from Barach, P., Weinger, M. Trauma Team Performance. In: Trauma: Emergency Resuscitation and Perioperative Anesthesia Management., Vol 1, Wilson, W. C., Grande, C.M. Hoyt, D.B. (Eds.), Marcel Dekker, Inc. 2007, 101–113. NY. ISBN: 10-0-8247-2916-6

intentions and needs nonverbally (sometimes referred to as implicit communication) [34].

Medical Device Features

Medical device alarms are deliberately designed to alert attention [35]. They can make the difference between timely, lifesaving interventions, and serious injury or death. Physiologic monitors, ventilators, infusion pumps, and many other medical devices contain clinical alarms to alert caregivers to critical events and to keep patients safe [36].

Monitoring devices that process complex data streams should produce clinically relevant alarm signals in environments optimized for discernment and attribution and contain user interfaces designed for timely interpretation, prioritization,

and prompt action. Addressing alarm fatigue requires that regulators, manufacturers, and clinical leaders recognize the importance and context of human factors and staff behavior, with design and evaluation of devices accomplished through clinical simulations [37]. In simulations, however, most of the noises are false alarms or don't require action [38]. The ventilator sounds a warning because a patient coughs. The infusion pump beeps after running out of a medication the patient no longer needs. The blood pressure monitor goes off after a nurse adjusts a catheter in the patient's artery.

Excessive numbers of alarms—particularly alarms for events that aren't clinically significant or that could be prevented from occurring in the first place—can lead to fatigue or worse ignoring the alarms as a form of tuning out, an unintended consequence of alarms, and ultimately patient harm [39]. Alarm fatigue, a condition which can occur in any hospital, is usually not caused by a single device but rather to the cacophony of noises and aggregate conditions under which alarms occur [40]. Alarm fatigue results in confusion and stress resulting from loud and conflicting signals which can lead to dangerous, life-threatening decisions, and behaviors [41]. Under these conditions, caregivers can easily become overwhelmed and are unable to respond to any alarm or to distinguish among simultaneously sounding alarms. They can become distracted, with alarms diverting their attention from other important patient care activities. Moreover, caregivers can become desensitized, possibly missing an important alarm because too many previous alarms have "cried wolf" (proved to be insignificant) [42].

In contrast to alarm fatigue, patients can also be at risk if an alarm does not activate when it should, if the alarm signal is not successfully communicated to staff, or if the alarm is ambiguous as to the source or severity of physiologic derangement, that is, does not provide sufficient information about the alarm condition. Additionally, when the caregiver who recognizing a signal as a valid alarm is unable to respond or is unfamiliar with the proper response protocol, patients do not benefit from the value of these technologies [43]. In short, any circumstance that results in the failure of staff (1) to be informed of a valid alarm condition in a timely manner, or (2) to take appropriate action in response to the alarm, can be considered a clinical alarm hazard [44].

Improving the acoustic environments for hospitalized patients can have significant positive effects on patients including decrease rehospitalization rates, improve sympathetic arousal in patients, and raise patient satisfaction as compared with noisy hospital environments [45]. Reduced noise was the most common item reported by hospital executives as a way to improve Patient-Reported Outcomes Measures (PROM) [46]. Almost 90 % of these executives believed that the primary benefit for patients was better sleep to help patients recover faster (75 %) and improve stress/anxiety (67 %).

Source–Path–Receiver Model

A simple approach to analyzing noise in surgical areas is by considering three basic elements: the sound source, the conveying medium, and the receiver (see Fig. 17.1) [47]. The most appropriate solutions then require alteration or modification in any or all of these three components. For instance: (a) to modify the output from source of the noise, (b) to alter or control the sound path to reduce transmission to the recipient, and (c) to provide the receiver with personal protective devices. This cross-disciplinary approach can provide detailed insights into addressing hospital noise and alarm fatigue.

For example: (a) Sources, e.g., planning and specification of paging systems, clinical and monitoring alarm systems; HVAC/ airflow equipment and other building mechanical engineering (MEP) systems; strategic placement of nursing stations and other dedicated areas where unamplified speech occurs; selection of audible monitoring alarm systems optimized for sound pressure levels; informational content, audibility, and their location. (b) Paths, e.g., design and configuration of the physical plant with attention to sound transmission, and specification of sound absorptive surface materials to limit sound mix-

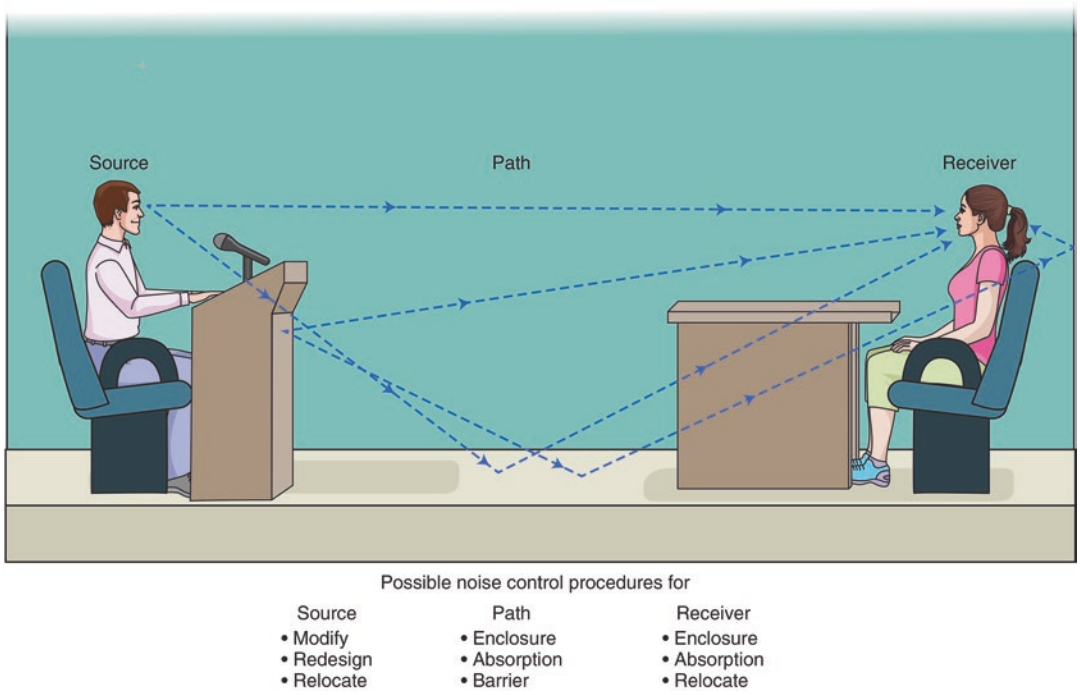

Fig. 17.1 Noise control procedures are applied to source, path, and receiver (Modified from [46])

ing and reverberation. (c) Receivers, e.g., modifying traffic flow and other behaviors through architectural and equipment layouts to ensure that caregivers and patients can hear and respond without being distracted, confused, and fatigued by high levels of ambient noise.

Numerous case studies demonstrate methods for reducing noise levels and improving signal-to-noise ratios through changes to programs, procedures, maintenance, and modifications to the physical environment [48]. Noise reduction measures found to be effective follow these same three parallel components: eliminating or reducing noise sources, for example, by replacing overhead paging with wireless communication devices carried by staff; insulating loud noise sources such as ice machines and pneumatic tubes, and conducting group conversations in an enclosed space; and modifying transmission by installing sound-absorbent surfaces such as high performance ceiling tiles and providing receiver protection such as in single-bed patient rooms [49].

The Role of Alarm Standards and Codes

There are three main standards relating to alarm signals as recognized by the U.S. Food and Drug Administration: (a) IEC/ISO 60601-1-8:2006 Ed.2: medical electrical equipment, part 1–8: general requirements for safety—collateral standard: general requirement, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems; (b) ANSI HE75: 2009, human factors engineering—design of medical devices; and (c) IEC62366, medical devices—application of usability engineering [50].

The current international standards for alarms, IEC 60601-1-8, stipulate that medical device audible alarms should be priority encoded and validated for efficacy. Yet, evidence shows that the melodic alarms described in the standard do not function in situ as intended [51]. Clinical urgency information when patients are in distress needs to be encoded using a human factors paradigm for alarm design via modulation of the

physical characteristics of sounds. New standards should be developed to bring consistency across devices and manufacturers [52].

There is little evidence, however, that the urgency-encoding standards proposed in IEC 60608-1-8 actually works in a complicated and noisy operating room environment where task loads and ambient noise can be significant [53]. An important point stressed in the IEC standard is that any new audible alarm be validated before implementation. However, the suggested melodies and the suggested method for urgency encoding espoused by the standard were never, themselves, validated in clinical real-world—let alone in simulated—clinical settings [54]. Furthermore, the standard does not offer a validation method [55].

Standards and guidelines relating to alarms and ambient noise levels in healthcare facilities can be found in the Guidelines for the Design and Construction of Health Care Facilities (2014) from the Facility Guidelines Institute (FGI) [56] and the Sound & Vibration Design Guidelines 2.0 [57]. These two documents are referenced in the Joint Commission report Planning, Design, and Construction of Health Care Facilities, 2nd Edition [58], and in the U.S. Green Building Council's new LEED Rating System for Health Care [59]. In addition, a new IEC standard is in draft: IEC 80001-2-x: application of risk management for IT networks incorporating medical devices offering guidance on the integration of alarms.

The Role of Medical Device Designers and Manufacturers

Medical devices in the operating room often suffer from fundamental flaws in their interface design and thus impair alarm usability. Manufacturers are required by the FDA to investigate deaths when hospitals report them as monitor related, but almost always attribute the patient deaths to human error, concluding that monitors worked correctly but staff misprogrammed them or didn't respond appropriately [60]. Most current medical device systems, for example, do not relay information in real time. In typical use, data acquired from medical devices goes to a queue that waits for a clinician to validate before it is pushed into the chart. Innovative data mining and ongoing trend analyses could better indicate patient deterioration and facilitate relevant clinical action before full 'rescue' efforts are initiated. This level of interoperable connectivity requires cooperation between vendors. Medical device vendors want to control the mechanisms and alerts associated with their devices to create end-to-end proprietary solutions. Without pressure from clinicians and purchasers, common business concerns will keep device and healthcare IT manufacturers from collaborating on solutions that could help mitigate persistent alarm problems. Healthcare providers can be better technology consumers by advocating for what they need from vendors. Providers should identify the gaps in current alarm notification systems and draft requirements for future purchases. Vendors, expectedly design equipment and interfaces with a "device-centric" perspective at the Point of Care (POC). Meaningful improvements in patient safety require that alarms be clinically significant and are integrated to the sociotechnical environment using a "patient-centric" approach [61].

Advocating for Change to Improve Alarm Management (Fig. 17.2)

Addressing alarm fatigue will require changes in how individuals and teams address noise measures. Any approach must be grounded in team theory, account for individual and team-level performance, processes and outcomes, adhere to standards for reliability and validity, and address barriers to measurement. A 2011 summit addressed alarm fatigue focusing on the pragmatic aspects of training staff and offered a number of recommendations for research in the real clinical setting where alarms must function to help teams deliver safe care [62].

Organizational Environment: The Role of Clinical Microsystems in Addressing Alarms

Noise and alarm management exist within the context of technology, providers, and patients, i.e., a system. A system is a set of interacting, interrelated, or independent elements that work together in a particular environment to perform the functions that are required to achieve a specific aim. A clinical microsystem is a group of clinicians and staff working together with a shared clinical purpose to provide care for a population of patients [63]. The clinical purpose and setting define the essential components of the microsystem, which include clinicians, patients, and support staff; information and alarm technology; and specific care processes and behaviors that are required to provide care. The best microsystems evolve over time, as they respond to the needs of their patients and providers, as well as to external pressures such as regulatory requirements. They often coexist with other microsystems within a larger (macro) organization, such as a hospital [64].

Guiding Principles in Alarm Management

In an April 2013 Sentinel Event Alert, the Joint Commission cited 98 alarm-related events over a three-and-a-half-year period, with 80 of those events resulting in deaths [65]. In June 2013, the Joint Commission announced the creation of a new National Patient Safety Goal (NPSG) focused on clinical alarm safety. This NPSG calls on each hospital to understand its own situation and to develop a systematic, coordinated approach to alarm deaths and permanent loss of function. Addressing clinical alarm hazards requires a comprehensive alarm management program involving stakeholders throughout the organization.

Best practice goals for hospital alarm management programs should include (1) minimizing the number of clinically insignificant or avoidable alarms so that the conditions that truly require attention can better be recognized, and (2) optimizing alarm notification and response protocols so that the patient receives the appropriate care at the time it is needed. Institutions can improve management of cardiac monitor

Fig. 17.2 Alarm management program. (Modified from ECRI [70]).

Table 17.3 Institutional alarm management strategy

• Establish a broad-based multidisciplinary alarm working group
• Understand the recurrent manufacturer alarm defaults
• Extract and evaluate their alarm data
• Observe staff response to alarms, looking for the barriers to timely response
• Identify with clinician stakeholders clinically insignificant alarms
• Remove audible notification for clinically insignificant alarms
• Choose an alarm setting that requires staff response for all clinically significant alarms
• Standardize alarm defaults across patient care units wherever possible
• Empower nursing staff to eliminate false alarms, appropriately adjusting alarm in real time after validation with second registered nurse

Table 17.4 Alarm management guiding principles

• The organizational complexity of healthcare must be recognized
• Patient-centered health services means that the patient's perspective and acoustic well-being must be central to all healthcare policy, planning, and procurement decision making
• Quality healthcare includes all aspects of service delivery: clinical and nonclinical
• Patient safety must be the foundation of acoustic decisions regarding alarm management
• Systems of care, and facilities, as well as individuals, affect the quality of healthcare
• Learning from error, rather than seeking someone to blame, must be the priority of health policy makers in order to improve safety and quality
• Openness and transparency are crucial to the development of trust between health facility procurement and healthcare professionals, patients and consumers, and the wider public

Table 17.5 Focus on alarm parameters

• Implement safety checks on alarm settings
• Revise default alarm parameters in each unit to actionable levels—recognize that settings may vary from one unit to another
• Implement revisions/changes incrementally
• Prioritize and differentiate between actionable alarm signals in each unit, e.g., visual vs. auditory (recognize that settings may not be the same from one unit to another)
• Define alarm condition types, e.g., false, true, nuisance, unactionable, etc., and assure that definitions are understood by unit staff
• Gather quantitative baseline data to evaluate alarm conditions
• Examine logs from the network that track alarm messages from devices in order to capture the quantitative data
• Observe alarm condition patterns and distinguish between alarm conditions
• Compare pre- and postdata to measure changes

alarms without requiring additional resources or technology (Table 17.3).

The environment has a significant impact on the ability of clinicians to build trusting, therapeutic relationships. The physical structure and design of healthcare buildings must support the model of care with appropriate physical, social, and symbolic environments. The design process for healthcare environments needs to be radically changed to address the needs of patients, providers, and the community at large. We are moving from a decade of highly structured top-down programs to local ownership and more transparent community partnerships. Engagement strategies need to include: (1) get clinicians 'moving and experimenting' with their own systems; (2) provide permission, space, and time for clinicians to find purpose and set their own direction in partnership with their patients and consumers; (3) direct attention through hyper transparent measuring, collating, and sharing of data about 'what is happening' at the service delivery level; and (4) facilitate respectful interaction between clinicians and managers (Table 17.4).

Creating an environment where a culture of patient safety can flourish is a daunting challenge [66]. Innovation will not happen if participants in the process are not invited or are unable to think outside the constraints of convention especially if they are unwilling to challenge the risk-averse nature which characterizes the cultural and intellectual development of so many of our professional and commercial institutions. Designing better methods to learn from adverse events that are caused or are part of a larger adverse event is key to changing clinicians' attitudes towards alarm-related events [67]. Designing new training programs and assessing learners in a more holistic and meaningful way will require innovative training and engagement approaches (see Table 17.5).

Table 17.6 Training recommendations

• Undertake risk analysis of patient populations within acute care facilities to develop standards for monitor assignment and continuation
• Examine indicators of patient deterioration such as respiration rate, pulse rate/heart rate, systolic blood pressure, pulse oximetry, to determine which indicators should be monitored
• Design simulation scenarios from reported harm or near misses with trigger events that link alarm fatigue and teamwork skills to training objectives and specific competencies
• Design a parallel set of scenarios that can be used to evaluate the effectiveness of training these specific competencies
• Develop and apply measures of success in alarm management
• Embed training in alarm management into multidisciplinary teams so members train in the context in which they will work

Asking the right questions while focusing on the correct parameters that mean the most to providers can go a long way to gain trust of providers (Table 17.6) [62].

Conclusions

Hospital noise routinely exceeds international, WHO noise acceptable standards and is more than just an annoyance. This failure to provide patients with quiet rooms due to alarms and other ambient noise affects clinical outcomes through several mechanisms, including sleep deprivation, cardiovascular derangements (increased heart rate and blood pressure), poor wound healing, higher incidence of readmissions, patient falls, pain, stress, and dissatisfaction [65]. Moreover, poor acoustic clinical environments are associated with excessive cognitive load on staff, and interference with speech and communication among healthcare professionals, both of which can increase risk of medical errors and patient harm [68]. Improving acoustic environments of hospitalized patients has been shown to decrease rehospitalization rates, improve sympathetic arousal, and raise patient satisfaction as compared with conventional hospital environments [42].

If, however, alarm function is considered to be that of maintaining situational awareness, designers need to engineer monitor devices able to do some or all of the following: distinguish artifact from real state changes, determine the importance of state changes within context, convey alarm source, and allow prioritization when operating attention is directed elsewhere (e.g., during line placement) or when multiple alarms sound. Development of more advanced device algorithms is needed to balance the sensitivity and specificity in triggering alarm signals, to block artifacts, and to produce clinically relevant alarms. Real-time trend analyses must be conveyed so care can be delivered before full patient rescue is required. Hospitals need a system-wide alarm policy and protocols that define the alarm management strategy for alarmed medical equipment, and delineate how caregivers/nurses respond to alarm conditions and signals. These conditions produce an "acoustic feedback loop" in which noise inevitably and rapidly escalates to intolerable levels and interfere with behavior. It is imperative to use a human factors-based approach based around the hospital's culture and engage architects, designers, acoustical engineers, facility engineering, staff, and clinicians to address alarm fatigue and its implications on the physical built environment [69]. Involving patients in the redesign of hospital acoustic environments may also improve patient experiences and satisfaction with their hospital care. There is a compelling role for industry cooperation that will facilitate device linkages to limit alarm redundancy, standardize, and scale alarm signals to convey urgency, develop alternative modalities and sensory channels, and enhance options for central oversight.

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Implementation Science: Translating Research into Practice for Sustained Impact

18

Gregory A. Aarons, Marisa Sklar, and Nick Sevdalis

"…translational research refers to translating research into practice; ie, ensuring that new treatments and research knowledge actually reach the patients or populations for whom they are intended and are implemented correctly."

—Woolf, SH. The meaning of translational research and why it matters. JAMA. 2008; 299(2), 211–213.

What is Implementation Science?

In the past 20 years there has been a growing imperative to bridge the gap between scientific discovery and the development of evidence-based health innovations and practices (EBPs), and the effective and efficient delivery of evidence-based care to those who would most benefit [1, 2]. While there are new and emerging health technologies and efficacious health interventions, there is a gap in the utilization of such interventions in public health and healthcare settings [3–11]. Despite significant taxpayer dollars having been allocated for the basic science discovery and the development of EBPs, the public health impact of these investments has been limited.

For basic scientific discovery and development of EBPs to have greater public impact, people must interact in some way with the results of these research and evaluation efforts. With practitioners' busy schedules and the overwhelming amount of output produced through research, an unawareness of, and/or a lack of easy access to, the latest research findings can act as a barrier to the spread of knowledge. Consequently, there has been a movement in the field of scientific publishing toward open access to research results [12]. There is a huge body of knowledge available for discovery, most of which is published in scientific journals. The open access movement suggests that communication of research findings could be improved through increasing accessibility and readability of scientific journals. The open access movement seeks to make research articles and scientific journals readily available to anyone, any time, free of charge, over the internet.

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Despite open access to research findings, the gap between what we know to be true and effective from research and what is actually dictated in policy and/or applied in practice remains. In 1995, the General Accounting Office proposed that the problem was not in *access* to research and evaluation findings, but that "available information is not organized and communicated effectively" [13]. Many theorists suggest evaluation research and evaluation research reports be designed in a manner which leads to clear communication of findings, easily understood by relevant stakeholders.

The open access movement implies an influence or impact of research and evaluation efforts through passive diffusion. Diffusion is a relatively passive process wherein new knowledge is communicated through certain channels over time among the members of a social system [14]. A growing knowledge of evaluation research implementation has suggested that passive diffusion of innovative research is largely ineffective and unlikely to result in influence [15–19]. Practitioners have continued to express an uncertainty about where and how they should access the best information [20]. Some even suggest that the volume of available information can lead to information overload [21]. Even when practitioners have access to various sources of information, there is still confusion regarding which sources of information are credible, and which ones are most relevant to their work [20]. Some practitioners even express the lack of time to seek out information that is not targeted directly to them [20]. With regard to the research-to-policy gaps, Weiss [22] has noted that policymakers are very busy people, with "little time available for reading," with no "time to study and analyze." These findings suggest that it is simply not enough for researchers to rely on diffusion of evaluation findings. Rather, the more active approach of dissemination and implementation is necessary.

Recognition of the failure to translate research findings to widespread use via passive diffusion has led to research designed to help the dissemination and implementation of knowledge to a widespread audience. These active dissemination and implementation efforts are believed to facilitate the translation of research into policy and practice. The underlying theory is that effective policies and practices are not being applied due to a lack of access to evaluations and evaluation findings and a lack of communication and cooperation between researchers and their intended audiences. If evaluation and research results are in a cumbersome report that is too lengthy for relevant stakeholders or uses scientific jargon, it is unlikely the report will be read, and unlikely the evaluation and research will be influential [23]. Correspondingly, innovation development, implementation, and evaluation are lengthy, costly, endeavors. If practitioners and policymakers fail to recognize evidence for effectiveness from these efforts, they risk creating a cycle of reinventing the wheel, or reinventing something less effective [24]. Furthermore, the research-to-policy and research-to-practice gaps will remain.

Implementation science focuses on decreasing these gaps through the development of and testing of frameworks and strategies for improving the dissemination and implementation of EBPs [2, 6]. Implementation research has been defined as *"…the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services. It includes the study of influences on healthcare professional and organisational behaviour*" [25, p. 1]. The United States National Institutes of Health defines implementation research as *"…the scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare practice and policy. It seeks to understand the behavior of healthcare professionals and support staff, healthcare organizations, healthcare consumers and family members, and policymakers in context as key variables in the adoption, implementation and sustainability of evidence-based interventions and guidelines…*" [26]. Some of this research has focused on the development and testing of implementation frameworks and/or models that identify structures and processes that can impede or enhance EBP implementation efforts.

Implementation Frameworks

A recent review catalogued over 60 implementation frameworks [27]. Many implementation frameworks utilize a multilevel approach to enumerate different components, structures, and processes of the implementation endeavor [28–30]. Implementation frameworks may note that characteristics of the intervention (e.g., direct costs, time demands, specificity, expertise required by the user) and the quality of evidence supporting the EBP are critical [31]. Others have noted that the fit of an innovation with the context for implementation (e.g., hospital, community health clinic, school, public sector health system) is a critical consideration [30, 32–34].

The Exploration, Preparation, Implementation Sustainment (EPIS)

Implementation framework. A number of frameworks approach implementation as a complex, multiphasic process that involves multiple stakeholders in service systems, organizations, and practices [28, 35, 36]. One such framework is the Exploration, Preparation, Implementation, and Sustainment (EPIS) implementation framework. EPIS considers the implementation process in four phases: Exploration (consideration of new approaches to providing services), Preparation (planning for providing a new service), Implementation (provision of this new service), and Sustainment (maintaining this new service over time) [37]. The EPIS model also emphasizes the importance of contextual factors in the outer (policy, system) and inner (organizational, work team) contexts [37]. Thus, EPIS attends to issues both inside the unit providing services (i.e., service organization, surgical team) as well as those in the larger environment in which the service unit operates (e.g., policy and funding, interorganizational networks, relationships with intervention developers and technical assistance providers, certification, and regulatory environment). Figure 18.1 shows the EPIS framework considering outer and inner context, interconnectedness, and EBP fit at the system, organizational, provider, and patient levels. Figure 18.2 shows the multiple phases and levels of the EPIS framework. Note that some factors (e.g., fidelity, provider attitudes, interorganizational networks) are relevant to multiple EPIS phases.

In order to illuminate this complexity, we provide the following hypothetical example: In the exploration phase, a service system, organization, (e.g., hospital, clinic, community-based provider, etc.) or an individual considers what factors might be important in regard to implementing a practice. For a new empirically supported and approved medication, these might include regulatory and reimbursement constraints (e.g., FDA approval, health plan formularies), training and support for physicians and pharmacists in appropriate prescribing, and potential drug interactions. In the preparation phase, changes in formularies would be made and electronic health records would need to be amended to allow for documenting indications and prescribing. Plans would need to be made for physician/pharmacist training including scheduling, procuring space, and follow-up coaching and support, if needed. In the implementation phase, training begins along with assuring that the medication is now available in formularies and available for patients to obtain from pharmacies. In the sustainment phase, ongoing monitoring would involve oversight of quality of care, appropriateness of prescribing practices, patient adherence, and patient outcomes (including new studies or clinical experience) would be utilized to understand and increase the likelihood of positive outcomes. While this example is oversimplified, it illustrates that there are a number of issues to be considered in order to facilitate effective implementation of an EBP in each EPIS phase.

Implementation Outcomes

Another important consideration is that of "implementation outcomes" that differ from clinical outcomes. Implementation outcomes are unique and distinct from either service system outcomes or clinical treatment outcomes

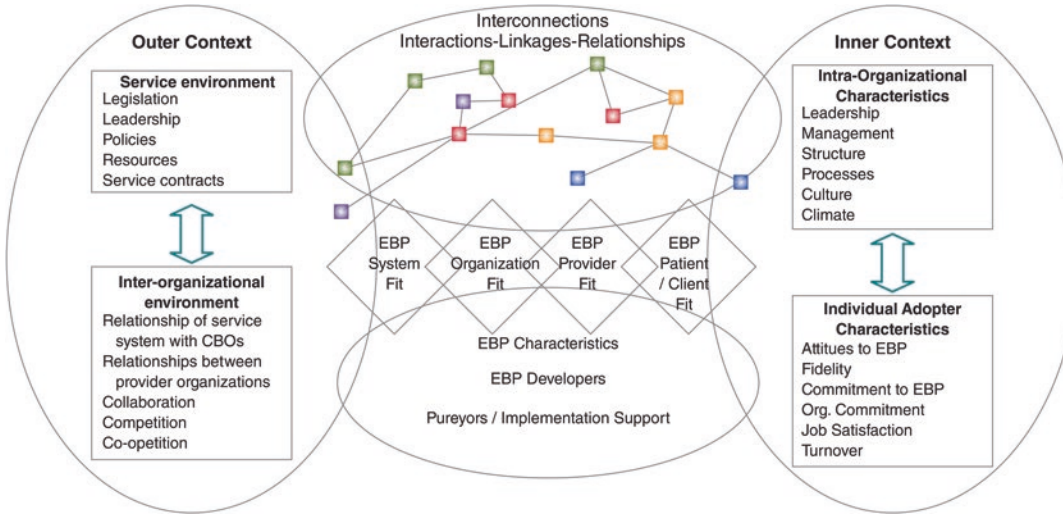

Fig. 18.1 EPIS framework illustrating outer and inner context, linkages, EBP fit, and intervention developer

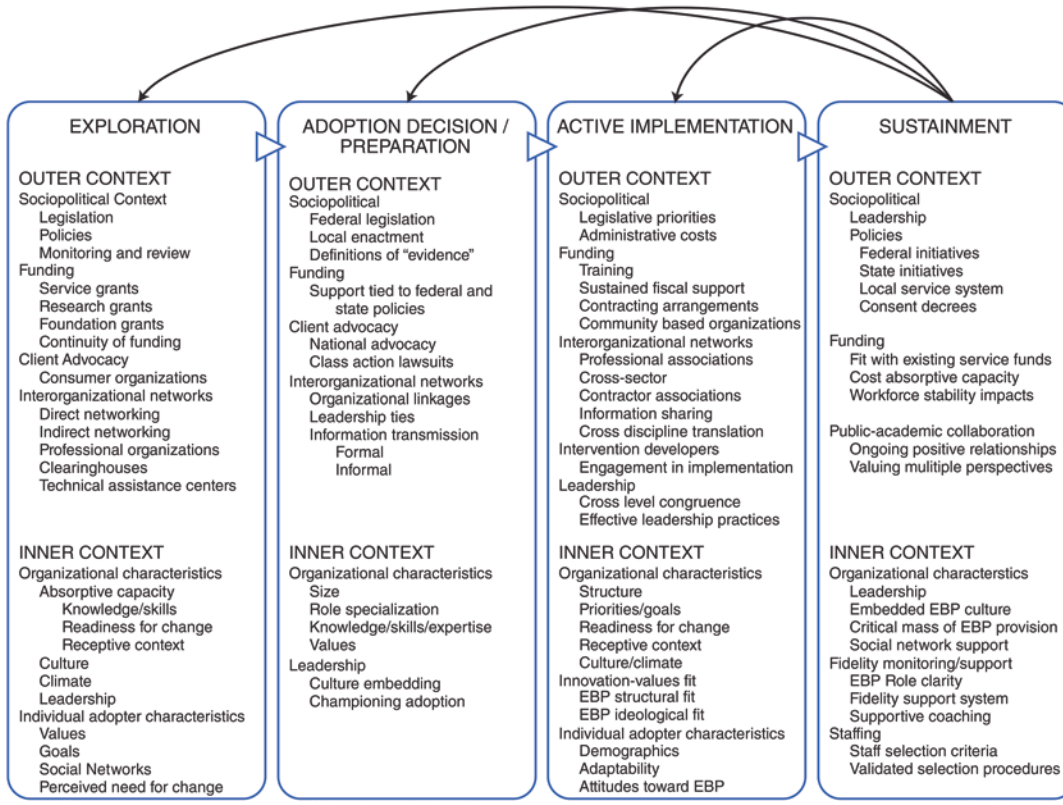

Fig. 18.2 Exploration, Preparation, Implementation, Sustainment (EPIS) Framework illustrating the four implementation phases and outer context and inner context implementation considerations

and have been defined as the "…effects of deliberate and purposive actions to implement new treatments, practices, and services" [38]. Implementation outcomes have multiple functions including serving as indicators of implementation success, representing implementation processes (e.g., mediators/moderators of change), and can be intermediate outcomes in treatment effectiveness and quality-of-care research [38]. Implementation outcomes may include factors such as acceptability, feasibility, reach, fidelity, and costs of implementation including those above and beyond the cost of the clinical intervention [39]. There is often a lack of consideration of the costs of implementation that can, in and of itself, limit implementation effectiveness [38, 40]. Figure 18.3 illustrates this distinction noting implementation outcomes including constructs such as feasibility, organization or provider adoption, penetration (i.e., reach) to providers or patients, and costs. These are distinct from Institute of Medicine Standards of Care (e.g., safety, patient-centeredness, etc.) or patient outcomes (e.g., functioning, symptom reduction, etc.). Because it is assumed that a given EBP will be less effective if it is not well implemented, implementation outcomes are important precursors for attaining changes in clinical practice. It is also critically important to distinguish implementation outcomes from other outcomes in hybrid design studies that examine both implementation along with clinical effectiveness or efficacy within the same study [41].

Consideration of Organizational Context in Implementation

There are a number of common organizational processes likely to be associated with successful implementation [28, 30]. There may be a tendency to focus on processes directly involved in healthcare, including the care recipients (e.g., patients, clients) and care providers (e.g., doctors, nurses, clinicians). However, it is important to consider that healthcare and allied health services (e.g., mental health, social care) are delivered to the public within the larger contexts of work groups, healthcare organizations and wider local or regional health economies, and public health systems of various sizes and scopes [42]. Organizational factors involving stakeholders at multiple levels impact successful organizational change, such as implementation [29, 43, 44]. In fact, it is becoming increasingly clear that organizational and cultural factors are likely to have more impact on successful implementation of EBP compared to individual factors (e.g., clinician age or degree) [45, 46]. Characteristics of implementation settings (e.g., systems, organizations) are critical for effective adoption and use of EBPs and it is often the leaders of systems of organizations who are responsible for developing a context that supports a strategic initiative such as EBP implementation [47].

It follows that evaluating the context within which an EBP will be introduced and embedded is becoming increasingly important. Numerous

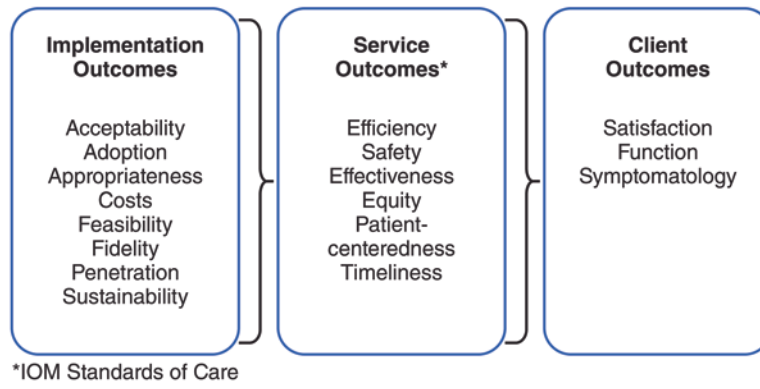

Fig. 18.3 Implementation outcomes as distinct from service outcomes and client outcomes

current efforts focus on developing measures of implementation context to better inform, assess, and facilitate successful EBP implementation. For example, a new measure of implementation leadership identified four distinct leader attributes likely to be important in the implementation process [48]. These include the leader being knowledgeable about the new practice, supportive of team members in implementing the practice, proactive problem-solving implementation issues as they arise, and persevering through the ups and downs of the implementation process [49]. Other measures capture organizational climate that would facilitate EBP implementation and sustainment. Dimensions include providing educational supports and training for EBP, recognition and rewards for excellence in EBP delivery, and selecting team members who are adaptable and have experience with EBPs [50]. Another more general measure of implementation climate assesses the degree to which use of the new practice is expected, supported, and rewarded by the organization [51]. Related to these efforts, there is also interest in, and measures for, assessing organizational readiness for change [52].

Implementation leadership. Connecting these issues, Aarons and colleagues identify how leaders may facilitate the development of organizational climates that support EBP implementation while enumerating important components of the implementation process [28, 30, 32]. An example that highlights literature on organizational climate and implementation climate, and outlines approaches to leadership that can support the development of such climates, involves the implementation of minimally invasive approaches in cardiac surgery teams [53]. Amy Edmondson and colleagues conducted a study of organizational, leadership, and team process among such teams in four different hospitals. They found that leaders who motivated their teams and minimized power differences created a positive psychological safety climate that enabled effective implementation and sustainment of minimally invasive cardiac surgical procedures [54, 55]. This work is consistent with previous work in business settings demonstrating that both management support and organizational context were important in the implementation process [44]. Thus, consistent with generalizability in organizational research, such organizational and leadership approaches to implementation are likely to generalize across health and allied healthcare settings.

Given evidence from observational studies of leadership, novel research is being conducted in the development and testing of implementation strategies to improve leader knowledge, skills, and effectiveness for implementation and sustainment of new innovations. One such approach, the Leadership and Organizational Change for Implementation (LOCI) intervention, combines the training of team leaders in transformational leadership and implementation leadership, while also working with organizations to provide appropriate organizational supports to develop a positive organizational and team climate for implementation [56, 57].

One of the most well-known and most heavily researched approaches to leadership is the full-range leadership model most closely aligned with transformational leadership. This model captures leadership behaviors across the dimensions of individual consideration (understanding the needs of individual team members), intellectual stimulation (engaging team members in problem solving and innovation), inspirational motivation (creating a compelling vision for others to follow), and idealized influence (serving as a role model) [58]. Research has demonstrated that transformational leadership is associated with increased job satisfaction [59, 60]; organizational commitment [61]; and performance for leaders [62, 63], teams [64, 65], and employees [66]. Of specific relevance to this chapter, transformational leadership has been shown to be particularly important for ameliorating the negative impact of organizational stress on work group climate during large-scale behavioral health reform [67] and to support positive attitudes to EBP in statewide system change efforts [68]. Transformational leadership is also associated with successful implementation efforts [69, 70]. New work on implementation leadership has identified four additional leader attributes including knowledgeable leadership (having expertise about the new innovation to be implemented), supportive

leadership (supporting staff in their implementation efforts), proactive leadership (i.e., anticipating and solving problems during the implementation process), and perseverant leadership (i.e., persevering through the ups and downs of the implementation process) [49]. For implementation to be successful, team leaders must be proactive and perseverant in communicating their knowledge of and support for EBP while managing resistance to change and communicating the importance of the change being implemented [49, 71–74].

Although much of the literature on leadership has focused on the organizational and work group levels, healthcare organizations can be strongly influenced by the decisions and policies made or instantiated by leaders at the system level. Decisions and policies at the system level can impact funding, disbursement of resources at state and local levels, and policy making to support EBP implementation [75]. Leaders in the Veteran's Health Administration (VHA) developed The Uniform Mental Health Services Handbook [76] that includes a number of mandates that help create the capacity for medical centers and outpatient clinics to deliver EBPs. The handbook specifies that each VA medical center have an EBP implementation coordinator responsible for educating providers and upper level management about EBP, encouraging providers to attend EBP trainings, working with leaders at the organization and work group levels, and with providers to increase delivery of EBPs in clinical care. Consistent with the EPIS multilevel framework, this approach recognizes that leaders in the outer context (system) can develop policies that impact the inner context (e.g., hospitals, clinics, workgroups, providers).

Leaders at the organization level (e.g., CEOs, presidents, administrators) often are responsible for decisions regarding implementation of new practices and organizational strategies [72, 77]. This level of leadership is often involved in securing funding, which may be related to the decision to implement new practices as funders are increasingly requiring the use of EBPs [8, 78–81]. However, congruence or alignment across levels is an important consideration. The challenge for executive leaders is to involve other levels of leadership and staff to facilitate congruence of mission and process. If not addressed, work group leaders (i.e., those who supervise direct service staff) may not have needed buy-in, organizational support, or an understanding of the rationale behind the decision to implement EBP required to communicate the rationale to their teams [44]. Furthermore, although strategic decisions about implementing EBPs are commonly made by upper level leaders, the effectiveness of implementation efforts is driven by first-level leaders and the providers who deliver the actual services [82–84]. Consequently, the implementation process can be better facilitated if led by "first-level" or team leaders [85].

Although a majority of leadership research has focused on the individual leaders, studies have demonstrated the importance of alignment across multiple levels of leadership [72, 86, 87]. Chreim and colleagues [82] examined system-level factors that influenced implementation processes during the transformation of healthcare service delivery to a new model within one Canadian province. They found that implementation was supported through agreement, participation, commitment, and congruence of support at all levels of leadership. At the work group level, the degree to which providers agree about the strategy or change being implemented predicts implementation success [88]. Similarly, the aggregate of multiple levels of leadership predicts organizational outcomes as a function of strategic implementation efforts [72]. This interplay between different leadership levels has been identified as a key factor in the implementation of a multicenter clinical quality improvement intervention across multiple hospital medical wards in the UK [89]. The intervention consisted of team-based clinical safety briefings, designed to embed proactive risk surveillance within routine, daily ward work. Through a 20-month implementation and evaluation period, the research team reported a shift in focus from the frontline healthcare providers to the middle- and higher level organizational management structures, as these emerged as critical determinants of the implementation effectiveness, and, in turn, its clinical effectiveness on care processes and patient outcomes. We

propose that such congruence and alignment is important because it facilitates a positive implementation climate among stakeholders [47].

Implementation of Surgical Checklists

Many, if not all, elements of implementation research and also practice that we outlined earlier are illustrated in the recent trajectory within hospital-based care of checklists in surgical care. The concept of avoidance or reduction in postoperative complications is likely as old as surgery itself—see for example efforts by Codman [90] in early twentieth century to systematically record and measure surgical outcomes. However, the political and policy drive to improve the safety and quality of surgical care via a range of evidence-based interventions flourished in the past two decades—as it did for all of medicine. Sparked by the influential report by the Institute of Medicine '*To Err is Human*' [91], initial efforts to improve safety concentrated on establishing the epidemiology of errors, lapses, and patient safety incidents, as well as understanding their nature. We now know that, on average, 1 in 10 patients admitted to hospital will suffer at least one adverse event as a result of their care [92]. Although the majority of adverse events are minor, some lead to serious injury or death [93]. Approximately 60 % of them on average occur within surgical care [94]. The importance of teamwork in healthcare is firmly established, with recognition that many high-profile failures were due in large part to substandard teamwork, including in the highly complex operating room environment [95, 96]. In recent years, the focus has shifted from understanding, to intervening and preventing—and this is when aviation-styled checklists were first implemented in surgery.

Early Support for Implementation of Surgical Checklists

The current widespread prevalence and ongoing discussion of surgical checklists is due in large part to a large-scale international study, which evaluated the clinical efficacy of a 19-item checklist developed to address the Second Global Patient Safety Challenge: Safe Surgery Saves Lives, as part of a World Health Organization initiative [97]. The WHO Checklist consists of three parts, the first applied before the patient is anaesthetized ('Sign-In'), the second immediately prior to surgical incision ('Time-Out'), and the final one immediately prior to procedure completion ('Sign-Out'). The subsequent evaluation of this checklist across eight countries worldwide, including both developed and developing world economies, provided startling findings: across study hospitals, the WHO Checklist reduced mortality by almost 50 %, whereas overall complication rate decreased by over a third [98]. The WHO Checklist became an instant success story—within weeks of publication of the study results in the *New England Journal of Medicine*, the National Patient Safety Agency (NPSA) in England mandated use of a slightly modified version of this checklist across all surgical procedures [99]. Subsequent patient safety campaigns in England (e.g., Patient Safety First campaign [100]) and internationally included this checklist almost by default, as a flagship intervention for improvement of surgical care. Widespread dissemination of surgical checklists was indeed intended: a checklist implementation manual was produced by the developer team [97], followed by video-based examples produced by the NPSA in England showing how to do (and not to do) the Checklists in the OR [101].

Fading Evidence for Implementation of Surgical Checklists

A flurry of studies followed, included randomized trials [102]—using this and other checklists in surgical pathways. But the findings were not as unequivocal—reductions in mortality in particular were not found [103]. Explanatory hypotheses that proposed that checklists achieve their clinical efficacy via improved team and safety culture remain controversial, with some studies supporting these hypotheses [104], but others not finding evidence for such links [105]. However, the big-

gest 'upset' in the checklists evidence base to date is the largest implementation evaluation—across the Ontario province in Canada. This remains the largest regional implementation of the WHO Checklist in a study of routine surgical care of over 215,000 patients in Canada, where no reduction in mortality or morbidity indicators was found [106]. Surprise was expressed at these results, which were speculatively attributed to the likely nonuse of the checklist in practice [107]—a likely valid explanation but one that does not address the barriers to change of culture and behaviors [108].

Incomplete Plan for Implementation of Surgical Checklists

What is the catch here? The answer is, at least partly, certainly within incomplete and ineffective methods for implementation of checklists. As in many areas of medicine, efficacy evidence normally stems from research-funded studies, where interventions under scientific scrutiny are given every chance of being efficacious: their implementation is careful, well thought-out, carried out by motivated staff with time dedicated to deploy them. Yet, routine clinical practice typically does not replicate the resource-rich, highly motivated, expert research setting of a trial. Further, what the initial success story of the WHO Checklists may have caused is a sense of simplicity and hope that implementation of an evidently simple intervention such as a checklist is vastly cost effective, as the costs are practically zero. Unfortunately for patients, this view is rather naïve—as it fails to take into account the vagaries of implementing what is, in many ways, a behavior change intervention within a highly complex sociotechnical environment (the OR), rife with professional identities, team dynamics, and often competing organizational pressures (for safety and productivity) [109]. The signs of an overall naïve approach were there from the start. An early analysis of how the WHO checklist had been implemented in England revealed significant variations between teams and ORs [110]. Use of the checklist in this study diminished when the research team withdrew from the clinical areas; further underutilization of the intervention was attributed to cultural, organizational, and practical barriers. Leadership was recognized as a key strategy for improved implementation, both at organizational level but also at the operational level, through checklist 'champions.' Although qualitative implementation analyses such as this one are hard to repeat longitudinally for direct comparison, more recent studies using standardized observational assessments in the OR while the checklist is being carried out have confirmed the same pattern [111, 112].

The problem may in fact have wider implications. Naïve portrayal of checklists in surgery presents them as the 'silver bullet' that can cost effectively improve the way a team communicates and shares information and thus improve basic care processes (including timely administration of antibiotics, appropriate deep vein thrombosis prophylaxis, robust patient identity checks and similar) and ultimately patient outcomes. This may indeed happen in some cases—but it likely will not happen when safety lapses and quality gaps are underlined by deeper team and organizational problems [113, 114]. The narrative for both the effectiveness and also the implementation of checklists in complex clinical environments has thus been oversimplified in a manner that is not conducive to enhancing our understanding of exactly how such interventions actually work when they do, and why they fail to bring about improvement when they do not [115. The comparison of surgery with commercial aviation, where some of the fascination with checklists in healthcare can be traced, has often been accordingly simplistic: aviation did not become safer just because pilots and crews started relying more on checklists in the past few decades. Other factors contributed to safety, in a synchronized manner; these include technological improvement, improved skills training, error and incident reporting structured, and safety data sharing at international level, i.e., safety in aviation progressed at a systemic, industry-wide level [115, 116]. Checklists can certainly enhance safety but likely not as a single isolated safety intervention [117]. With simplistic views of checklists rather prevalent, perhaps not surprisingly detailed

implementation analyses of checklists remain scarce—in the largest and most detailed one to date that we are aware of, of the national implementation of the WHO Checklist across English hospitals, a host of factors were identified [118]. These cover the full range of implementation strategies mentioned in earlier sections of this chapter and reveal interactions between them and significant contextual influences.

Summary and Challenges and Future Directions for Implementation Science Research

Implementation science is playing a crucial role in reducing the research-to-policy and research-to-practice gaps with the ultimate intention of advancing health outcomes. However, significant challenges present when completing implementation science research. Consistent with issues facing implementation science globally, The US National Institutes of Health Fogarty International Center (FIC) [119] has outlined challenges facing the field of implementation science research: (1) implementation science is a new, developing field; (2) effective implementation requires a multidisciplinary, collaborative approach; and (3) implementation strategies requires rethinking scientific rigor and the importance of mixed methodologies. These three challenges are described later. The FIC challenges are followed by a discussion of future directions and global initiatives for the field of implementation science.

1. *New, developing field*. The FIC recognizes the potential for implementation research in improving program quality and performance through the use of scientific methods. However, implementation science as a field is relatively new and still in development. There are many efforts to improve implementation of EBPs that utilize a variety of frameworks, a number of constructs hypothesized to affect successful implementation, and many measures of these constructs. With so many efforts to improve implementation of EBPs, there is little consensus on optimal scientific methodology for implementation science research [120–122]. In fact, there is debate regarding the "best" strategies for successful implementation of EBPs [36]. Recent implementation science research has begun addressing this debate. For example, Brown and colleagues [123] directly compared two strategies for implementing one EBP across two states. This study was also successful through their use of the Stages of Implementation Change (SIC) measure that enabled the measurement of implementation process across multiple stages, multiple milestones, and multiple levels of participants. By using this measure, the authors assessed progress in EBP implementation or lack thereof. The authors introduce plans for future advances toward addressing this debate. Through a recently funded R01, Saldana will adapt the SIC to evaluate common/universal implementation activities that are utilized across EBP implementation strategies, and to examine whether these items are equally important in achieving implementation success, and whether stages of implementation are stable across EBPs despite differences in activities defining SIC stages [124]. As Brown et al. [123] have illustrated, continued coordination and communication of efforts for broader dissemination of results, best practices, and lessons learned are suggested for future implementation science research.
2. *Interdisciplinary—multidisciplinary and collaborative approach*. The FIC highlight the importance of inter/multidisciplinary collaboration for effective implementation. A number of approaches have been utilized including community-based participatory research [125], community-participatory partnered research [126], and collaborative approaches such as the Institute for Healthcare improvement (IHI) Breakthrough Series [127], though there are few established communication channels and forums for such communication. As discussed in this chapter, alignment across levels within and between organizations is crucial for establishing an organizational

climate in support of EBP implementation. There is often a gap between the expectations of researchers who generate and report implementation science results and practitioners who implement results. Congruence between leaders at the organization level (e.g., CEOs, presidents, administrators), frontline providers in the trenches of delivering services, and the implementation science researchers will facilitate successful implementation of EBPs.

3. *Rethinking scientific rigor*. The FIC and the US Office of Behavioral and Social Sciences Research stresses the importance of using mixed methodology (qualitative and quantitative methods) [128], and methods from fields such as economics and business, to guide implementation strategies and evaluate the implementation of health interventions [129]. Scientific rigor has traditionally referred to random assignment in highly controlled laboratory settings. In real-world settings where random assignment is not always possible, and highly controlled laboratory settings do not provide the context targeted through implementation science research, alternative approaches are needed while balancing and maximizing rigor in scientific research. Mixed methodology provides an avenue for conducting rigorous implementation science research that can be done in the context of an RCT or other design. Other quasi-experimental approaches one may consider in the conduct of implementation science research include regression discontinuity designs, interrupted time series designs, multiple imputation techniques, and propensity score analyses. Type I, Type II, and Type II hybrid implementation science research designs that combine implementation and effectiveness questions and outcomes in the same study are increasingly being used while maintaining scientific rigor [41].

Future Directions and Global Initiatives for the Field of Implementation Science

There are several considerations of future directions and global initiatives for the field of implementation science, including (1) identifying and classifying implementation strategies, (2) mapping the similarities and differences between implementation science and quality improvement research, (3) creating a platform for implementation research via the Global Implementation Initiative, (4) providing training for dissemination and implementation research. These are discussed in the following paragraphs.

1. *Implementation strategies*. Recent work on identifying and classifying implementation strategies has helped both researchers and practitioners to consider multiple approaches to consider to support EBP implementation [130, 131]. Beyond a review of implementation strategies, Powell and colleagues have developed and make recommendations regarding methods for identifying, selecting, and tailoring implementation strategies for use in various health and allied health settings [132, 133]. This approach combined with the use of an appropriate implementation framework can provide guidance in the implementation process through progression through the four implementation phases [37].
2. *Implementation and quality improvement*. The literature and the fields of implementation science have held that there is a distinction between the two [134]. Of course this becomes even more complex as there is consideration of how best to implement quality improvement initiatives [135]. However, there are a number of similarities in quality improvement research and implementation science and both should be considered in a comprehensive approach to improve delivery of health interventions [136].
3. *Global implementation initiative*. Several initiatives have commenced with the purpose of accelerating the use and influence of practices and policy with demonstrated effectiveness. One such initiative is the Global Implementation Initiative (GII). The GII was founded in 2012 with the purpose of "promoting 1) *access* to implementation networks, experts and educational and workforce development opportunities, 2) *influence* on researchers, policymakers, and organizational leaders to increase focus on effective implementation

strategies in applied settings, and 3) *impact* on the integration of effective implementation practices in human service settings in order to improve outcomes for children, families, individuals, and communities worldwide [137]." Major initiatives of the GII are the Global Implementation Conference, the Global Implementation Society, and organizing Global Implementation University efforts. The GII initiatives provide a worldwide platform for collaborative approaches promoting effective implementation practice, science, and policy. Since GII inception, other implementation science initiatives and networks have emerged with similar objectives, such as the European Implementation Collaborative, and the current development of the Canadian Implementation Network.

4. *Education and training*. As the field of implementation science is rapidly advancing, training programs for dissemination and implementation research are an important avenue to build the knowledge base and capacity of the field. Several training programs have been developed with the purpose of advancing implementation science. One such program is the National Institute of Health and Veteran's Health Administration collaborative Training in Dissemination and Implementation Research in Health (TIDIRH). The TIDIRH is a five-day program to maximize opportunities for trainees and faculty to interact, and for trainees to gain exposure to curriculum that includes structured large group discussions and interactive small group sessions. Another training program for investigators new to the field of dissemination and implementation research is the Implementation Research Institute (IRI). The IRI was established at Washington University in St. Louis with support from a grant from the National Institute of Mental Health and additional support from the U.S. Department of Veterans Affairs, and the National Institute on Drug Abuse. The IRI is a two-year training program in implementation science wherein fellows attend a 1-week training each year where they receive individualized mentoring and visit active dissemination and implementation research study sites to gain real-world perspectives on the complexities involved when conducting dissemination and implementation research.

Similar programs have started to appear in Europe as well. In the UK, the Center for Implementation Science within King's College London launched an Implementation Science Masterclass in 2014. A 2-day, intensive course on implementation methodologies and metrics, the Masterclass offers state of the art lectures on core implementation topics, followed by small group interactive sessions for participants to hone the implementation strategies and measures of their research or clinical implementation projects. Alongside the Masterclass, the same group launched a Master's program in Implementation and Improvement Science in 2016. This is a 1 or 2 year program including taught modules which bridge implementation and improvement sciences, and a final dissertation project on clinical implementation. Both training programs aim to enhance the implementation capability within healthcare systems internationally. They have been set up through initial funding from England's National Institute for Health Research.

Conclusion

Our goal in this chapter was to introduce the concept of implementation science along with some discussion of frameworks, strategies, and examples of some of the experiences and challenges facing implementation science and those wishing to implement new practices. The authors had to be selective in what to present as each topic could comprise a chapter in and of itself. We encourage the reader to delve more deeply into how an implementation science approach may help to accelerate the introduction and effective use of new medical procedures and technologies so that the time from evidence-based intervention development to effective use in practice can be

reduced. The ultimate goal is to improve patient care and patient outcomes. This goal should always be first and foremost in implementation theory, research, and practice.

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Part III

Perioperative Quality and Patient Safety

19 The Leadership Role: Designing Perioperative Surgical Services for Safety and Efficiency

Victoria M. Steelman and Martha D. Stratton

"Every system is perfectly designed to get the results it gets."

—Paul Batalden, MD

Introduction

Despite continued national and international efforts focusing on improving the quality and safety of healthcare, adverse events and near misses continue to occur at an alarming rate. Recent research using the Institute for Healthcare Improvement's Global Trigger Tool found that one-third of adults and 40 % of pediatric patients admitted to hospitals experience an adverse event [1, 2]. For adults, the most frequently identified events are well known to perioperative clinicians, including medication-related, pressure-related, nosocomial infection, pulmonary emboli/DVT, pressure ulcers, device failures, and falls [1]. Many of these events (32.5–40 %) were found to be preventable [2, 3]. Results of voluntary reporting also support that adverse events continue to occur in perioperative care. In 2014, unintended retention of a foreign body after surgery remained the sentinel event most frequently reported to The Joint Commission. Other frequently reported events include delay in treatment, operative/postoperative complication, and wrong patient/site/procedure [4, 5].

Because of the invasiveness of the procedures, high-tech environment, fast pace, and multidisciplinary work, perioperative care involves a high risk for these serious events. Historically, efficiency has been a primary focus of perioperative services, and quality and safety may not have received the prioritization needed. This focus is changing, in part, because of external pressure surrounding public reporting of harmful events and reimbursement tied to quality. Of the 27 serious reportable events identified by the National Quality Forum, five focus directly on surgery [6]. The Centers for Medicare and Medicaid Services (CMS) will no longer reimburse for the additional patient care required to treat patients who sustain a serious reportable event. CMS also attaches a percentage of reimbursement to performance on quality measures and a penalty to hospital-acquired conditions and preventable patient harm [7]. Clearly, there is an enhanced awareness of the importance of patient safety and financial incentives to support implementation of safety initiatives. The time is right for a concentrated effort to design perioperative services to enhance the safety and quality of patient care.

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Building a Safety Culture

The design or redesign of perioperative services should start with a commitment to the principles of safety and the establishment of a culture of safety throughout the healthcare system. Components of a safety culture focus on leadership, process and human factors elements, and how the interaction of these elements provides a platform for safe patient care. A systematic review of the literature found that the most frequently identified conceptual dimensions of a positive safety culture include:

- Leadership commitment to safety,
- Open communication founded on trust,
- Organizational learning,
- A non-punitive approach to event reporting and analysis,
- Effective teamwork, and
- A shared belief in the importance of safety. [8, p. 340]

Interventions to improve the safety culture are usually multifaceted bundles of interventions or a program that targets more than one dimension. One approach is the Comprehensive Unit-Based Safety Program (CUSP) which was developed by a team at Johns Hopkins [9]. This five-step program is designed for department-by-department implementation throughout an organization, but with the responsibility for execution and program maintenance remaining at the unit level. The five steps of CUSP are:

1. Train staff in the science of safety,
2. Engage staff to identify defects,
3. Partner with senior executive leadership,
4. Learn from defects, and
5. Implement tools for improvement. [9]

Implementation of a unit-based safety program requires a team approach and staff members should have input into the development and ongoing performance of the team [10]. However, it remains incumbent upon the perioperative leadership to assure that appropriate education, assessment, and communication are provided as the program progresses.

Building a culture of safety begins with assessment of the existing viewpoints of staff, departmental leadership, and executive leadership as well as the processes in place to address patient welfare. There are several external comparative benchmarking surveys that can be used to assess safety cultures. Tools that measure both leadership and staff perceptions give a clearer picture of any disparities between policy and practice. The AHRQ Hospital Survey on Patient Safety Culture measures staff perceptions of patient safety culture in their specific work area/unit, as well as perceptions about patient safety culture in the organization as a whole [11]. Comparative database reports are available to perioperative leaders using this survey tool to evaluate progress on the journey to a patient safety culture [12]. This assessment should be conducted before and after restructuring and periodically to evaluate the impact of initiatives to promote safety and quality. It is essential to share the results of these surveys with perioperative personnel to ensure they develop trust in management's goals, and encourage their input into strategies to address opportunities for improvement identified in the results [13].

Designing the Infrastructure for Safety

Once baseline information is gained about the current culture, the next step is to design or redesign the infrastructure to promote safety. This requires a top-down approach, integrating safety and quality into all aspects of perioperative services, including values, human resources management, collaboration, and quality measurement and reporting. Components of an infrastructure for safety are depicted in Fig. 19.1.

The mission of the perioperative care should be developed or revised to emphasize the importance of safety and quality. It is essential that this message be in alignment with the healthcare organization's mission. Engaging practitioners to participate in the development or refinement of the perioperative mission encourages a shared

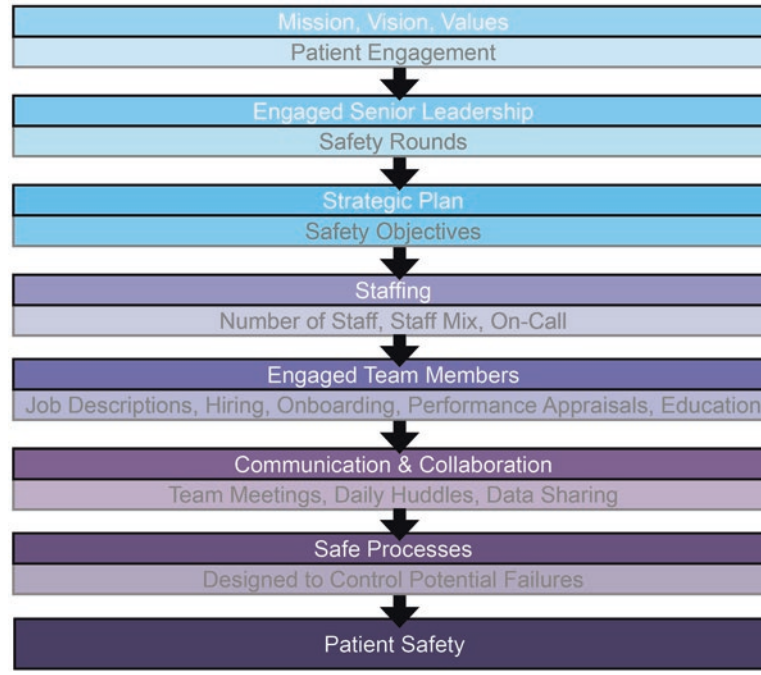

Fig. 19.1 Designing perioperative services for safety. Designing the infrastructure for safety requires integration of safety into all aspects of the organization

mental model of the importance of safety and buy-in into subsequent changes. Displaying the mission on the wall or as a screen saver provides ongoing reinforcement of the importance of safety and quality and sustainability of this as a shared responsibility [14]. Having these signs visible to the public engages patients and may also provide a competitive differentiation, inspiring patients to select the facility with the stronger commitment to safety and quality [15]. Incorporating patient safety and quality into the strategic plan reinforces that this is a priority supported by executive leadership, and facilitates allocation of needed resources.

Hiring for Safety

A study conducted by the Health Research and Educational Trust found that utilization of high performance work practices can improve patient outcomes in both safety and quality parameters [16, 17]. Building these high performance work teams requires having the right people in the right jobs. This begins with having expectations about safety incorporated into job descriptions, which are then used for advertising vacant positions and communicating during the hiring process. Candidate interviews should utilize behavioral-based questions that elicit the applicant's understanding and experience with patient safety scenarios and working within a team environment. During the hiring process, the expectations of working within the organization's safety culture need to be clearly articulated. While a candidate's functional skill set is important, the ability to assimilate successfully into a safety culture is crucial. It is usually easier to learn a functional skill than to learn teamwork and change attitudes. Integration of patient safety and quality expectations into employee or partner contracts prior to hiring or renewal is valuable. Once hired, team members need to thoroughly understand that safety and quality are a priority. Integrating these expectations into the onboarding processes for hospital employees and contracted partners is essential. Video clips from senior executive leadership provide as strong message about the importance of safety and quality.

Promoting Safety Norms

While executive leaders are responsible for establishing safety as an organizational priority, unit-based leaders are pivotal in assuring that patient safety processes are sustained as an integral part of perioperative care. Frontline leaders are strategically positioned to set performance standards and implement team-centered systems that support an overall safety culture and meet safety goals. Providing ongoing reminders during daily huddles, and communicating progress toward goals on a Managing Daily Improvement board integrate safety into daily activities and establish it as a norm. Staff meetings provide a valuable opportunity to discuss challenges and obtain staff input about strategies to overcome these challenges. These meetings should contain a standing agenda item to discuss progress toward safety goals.

Performance appraisals should include key expectations of safety. However, addressing non-compliance in a constructive, timely manner is critical. Principles of a just culture should be used to address inconsistencies between desired behavior and observed behavior. This also provides input into systems changes that promote desired behaviors.

The perioperative team's progress toward goals should be shared with executive leadership. This integrates perioperative safety into the overall quality and safety program and instills a sense of accountability. This communication is often in the form of a scorecard, aligning perioperative safety goals with the overall strategic plan for the organization.

Lastly, developing a safety culture at the surgical microsystem is a journey requiring continuous reinforcement and support [18]. Progress toward goals should be recognized and celebrated. Having healthy competition between perioperative teams can serve as an additional incentive, and may make the journey toward a safety culture more enjoyable.

The Role of the Operating Room Management Committee

In perioperative settings, all levels of providers should be involved in the journey to a safety culture. Due to the complexity of the departments and the episodic nature of interactions, it can be difficult to design a mechanism for meaningful collaborative engagement. Most surgical settings have a multidisciplinary committee charged with overseeing the functioning of the operating room and facilitating communication between perioperative disciplines. Key responsibilities of the OR Management Committee include:

- Ensuring patient safety and high quality of care to optimize patient outcomes
- Ensuring appropriate and timely access to perioperative services
- Maximizing the efficiency of perioperative services
- Utilizing personnel and materials in a safe, cost-effective manner
- Providing a safe work environment that promotes collegiality, mutual respect, and effective teamwork

This committee's meetings provide a venue for tracking the progress of safety initiatives and other key metrics and dedicated time for sharing safety concerns. Balanced scorecards are often used for this purpose. The content of this report is tied to the organization's strategic plan. Although these reports vary between facilities, some elements of a perioperative score care may include:

- The associated strategic objective(s)
- Key process measures (e.g., first case on-time starts, beta blocker at discharge)
- Incidence of adverse events by type or hospital-acquired conditions (e.g., retained surgical item, surgical site infection, readmission)
- Adherence to a safety process goal (e.g., specimens correctly labeled, surgical procedures scheduled correctly)
- Patients perceptions of care (e.g., Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS))
- Employee metrics (e.g., RN turnover rate, employee satisfaction, use of agency personnel)
- Safety culture (staff perceptions of safety culture)
- Financial metrics (e.g., number of procedures, cost of supplies, productivity)

Although membership of the OR Management Committee varies somewhat between types of facilities and networks, the structure usually includes the triad of perioperative nursing director, anesthesia director, and surgeon director. This oversight requires effective collaboration between members of the committee, sharing data to and from their respective departments, discussing initiatives, and addressing issues with their departments. Incorporating the committee members into the ongoing surveillance of safety initiatives helps to underscore the importance of building and maintaining safety initiatives.

Collaborating for Safety

Executive Leadership

The OR Management Committee should not only manage down, but also manage up, partnering with the senior executive leadership. This partnership should include monthly safety rounds by the senior leadership, talking to staff members in each perioperative area. This provides an opportunity for two-way communication. The frontline staff members see the commitment of leadership to safety initiatives, and the executive hears from the frontline what issues staff members face and recommendations for overcoming hurdles. This information is valuable because senior executives have access to resources that can be deployed to address these issues.

Effective perioperative leadership also requires a strong network of collaboration with other departments, including the Information Technology, Quality, Safety, and Risk Management departments.

The Information Technology Department

Provision of data-driven reporting is integral to tracking and trending the actual incidence of adverse events as well as near miss occurrences and progress on other patient safety goals [19]. The Information Technology department plays a vital role in designing data abstraction processes to capture multiple data elements that can be aggregated for a clearer picture of the processes toward a safety culture [20]. By examining harmful and potentially harmful patient safety events and trending these over time can help pinpoint areas that need improvement in safety protocol adherence. Information technology can also be utilized to "improve safety by providing decision support to clinicians during the cares process, assisting providers with missed diagnoses, and improving compliance with evidence-based medicine" [21].

Robust process improvement is essential to a culture of safety and information technology is essential to extract and synthesize data in meaningful ways to provide a basis for examining current practices and identifying areas for further development. Sustainability of a safety culture requires a continuous focus on the process of safety and the resulting outcomes. Keeping relevant safety data highly visible maintains an awareness of where the organization is progressing and where opportunities for further progress toward safety goals exist toward a safe environment of care. It is best to have dedicated IT support assigned to perioperative services to facilitate timely reports and accurate trending.

Quality, Safety, and Risk Management Departments

The role of Quality, Safety, and Risk Management departments is essential in the investigation of adverse events and the trending of these occurrences to determine process failures and opportunities for performance improvement. Engaging these departments in the overall oversight of a safety culture is beneficial in aligning the organization's focus on the outcome of patient care and the resulting cost to the patient and the organization of substandard care [22]. Perioperative leaders should utilize the expertise of these practitioners to enhance the education and communication to their team regarding the efficacy of safe patient care practices.

Other Departments

Building a wide network of collaboration with other organizational departments promotes a

better understanding of the unique characteristics of perioperative patient care and maximizes the resources available to perioperative leaders in the execution and continuation of a safety program. This facilitates improving access to and timeliness of perioperative services, and perioperative efficiencies. For example, collaborating with the Emergency Department is essential to promote timely surgery for trauma and other emergency patients. Collaboration with the Intensive Care Unit minimizes issues with bed access. Collaborating with Material Services supports the availability of needed supplies and implants.

External Partners

Collaboration may also extend to external partners. This can be done through the National Healthcare Safety Network (NHSN), state reporting, Patient Safety Organizations, or collaborative learning networks. Collaboration with other facilities allows the use of aggregate data collected from many facilities to enhance learning and drive changes in safety and quality. By mid-2012, 27 states and the District of Columbia had enacted legislation to establish collective reporting systems for adverse events or errors [23]. The CUSP Learning Network is an example of network-based collaborative learning in action. This network facilitates peer-to-peer learning and coaching [9].

Staffing for Safety

The availability of the perioperative team to manage the daily schedule and acute emergencies is essential for patient safety. Having too few staff for a patient surgery or having personnel who are not competent in the particular aspects of the procedure and patient care requirements increases the risk of harm to the patient.

Planning staffing for an operating room (OR) is considerably different than for an inpatient care unit. While staff working in an inpatient unit care for multiple concurrent patients within a specific medical specialty, OR staff care for patients sequentially for multiple surgical specialties.

Staffing Plan

Providing an appropriate number and mix of staff starts with a staffing plan. The staffing plan should be based on the complexity of patient care, competency of staff, and surgical volume. The plan should set a standard for a minimum safe level of staffing and have enough flexibility to adjust for unforeseen circumstances. This plan should identify number of staff members, staffing mix, and scheduling of personnel to be present in the unit or on call. This staffing plan should be addressed in the perioperative budget [24]. Personnel should not be required to work more than 12 h in a 24 h period or more than 60 h in a work week [24]. The use of 12 h shifts, compared to 8 h shifts, has been found to be associated with an increase in fatigue, patient care errors, and worker injuries [24, 25]. Using these extended shifts should be avoided. The on-call staffing plan should include strategies to minimize extended work hours and provide relief for personnel working beyond 12 h.

OR in-room staffing is calculated based on the number of concurrent rooms at various times of the work day, with additional support staff available. Minimum staffing for one operating room generally consists of one registered nurse circulator and one surgical scrub person per operating room. However, increasing case complexity and patient acuity indicate that this minimum number may not be sufficient for an ever increasing number and types of procedures. In some settings, it's not unusual to have two or three persons in the scrub role due to equipment and technology requirements. It is also common to have two circulators for high patient acuity cases or procedures that require enhanced patient monitoring (e.g., laser or hybrid procedures). The AORN has published guidelines for safe staffing that include a formula for calculating the number of staff needed for an OR suite [24].

Some states have imposed mandatory staffing requirements based on either nurse–patient ratio or a facility committee-led approach, with direct care providers comprising more than half of the members. An alternate approach used by some states is a requirement to disclose staffing levels to an agency or the public. Perioperative leaders must be knowledgeable and compliant with the laws in their states.

Table 19.1 Staffing requirements by level of trauma center designation [67]

	Level I	Level II	Level III
Nursing	OR team must be available within 15 min (e.g., in-house 24 h per day). If the trauma OR is in use, another team must be available	OR team must be available within 15 min (e.g., in-house 24 h per day). If the trauma OR is in use, another team must be available	OR team must be available within 30 min
Anesthesia provider	Available in-house 24 h per day. When anesthesiology senior residents or CRNAs fulfill this requirement, the attending anesthesiologist on call must be available within 30 min at all times, and present for all operations	Available in-house 24 h per day. When anesthesiology senior residents or CRNAs fulfill this requirement, the attending anesthesiologist on call must be available within 30 min at all times, and present for all operations	Anesthesiologist or CRNA must be available within 30 min
General surgeon	General surgeon or appropriate substitute (year 4 or 5 resident) must be in house 24 h a day	Must be available within 15 min, 24 h per day with back-up call	Must be available within 30 min
Neurosurgeon	Immediately available 24 h per day with back-up call	Must be available within 15 min, 24 h per day with back-up call	Not required
Orthopedic surgeon	Must be available within 30 min	Must be available within 30 min	Must be available within 30 min
Other surgical service coverage	Must have a full spectrum of other surgical specialists available (cardiac surgery, thoracic surgery, hand surgery, microvascular surgery, plastic surgery, obstetric and gynecologic surgery, ophthalmology, otolaryngology, and urology)	Must have a full spectrum of other surgical specialists available (thoracic surgery, hand surgery, microvascular surgery, plastic surgery, obstetric and gynecologic surgery, ophthalmology, otolaryngology, and urology). Should provide cardiac surgery	Not required

Perioperative services should also be staffed in a manner to adequately respond to emergent patient needs. The responsiveness depends on the type of care provided. Hospitals designated as Level I trauma centers must have immediate availability to provide a range of services. Hospitals designated as Level II or III have lower requirements (see Table 19.1).

Educating and Training in Patient Safety

Designing perioperative services for safety requires an understanding of the science underpinning safety. Education about safety should be provided for all personnel and contracted partners working in perioperative services. Content from perioperative leadership and executive leadership should be included. This can be done by inserting a video clip into presentations. The content of this education should include:

- Safety is owned by the system
- Basic principles of safe design (standardization of work, independent checks (checklists) for key processes, and learning from mistakes)
- The importance of teamwork in safety [26]

A culture of safety also requires assurance that healthcare personnel have the knowledge and technical skills to make sound clinical decisions, perform tasks needed for their roles, routinely function as a team, effectively work together to

manage emergency situations, and maintain these skills over time. Simulation and spaced education are two strategies to accomplish this [27].

Simulation

Academic and healthcare facilities are rapidly adopting simulation as a way to prepare healthcare professionals for their direct patient care responsibilities, including care of the surgical patient. This educational strategy provides a risk-free environment for individuals to learn how to make clinical decisions and develop technical skills for specific tasks. Systematic reviews of surgical simulation have found that the knowledge gained transferred to performance during surgery [28, 29]. A recent meta-analysis found that simulation also has a positive impact on surgical time [30].

Multidisciplinary simulation has been effectively used to teach teamwork and crew resource management in perioperative patient care [31]. In addition to providing practice for their skills, the multidisciplinary experience teaches personnel what they can expect from other team members [32]. Multidisciplinary simulation has been found to improve communication and teamwork in the operating room [33]. It is also effective for teaching the knowledge and skills required for a variety of emergency situations, such as managing anaphylaxis [34]. It has been used to enhance preparation for cardiac emergencies and response in the operating room to care of a patient with a ruptured aortic aneurysm [35]. A study of a multidisciplinary simulation of an exsanguination emergency and team performance found that the simulation resulted in better understanding of team member roles, activation of the massive transfusion protocol, and an improvement in time spent performing clinically significant tasks [36]. Simulation has enormous potential to improve the safety of perioperative care [37].

Spaced Education

It is also important to assure that perioperative personnel maintain knowledge gained about how to handle unusual events (e.g., surgical fire). This is usually done through annual competency assessment. Traditionally, personnel have been required to attend annual educational programs about a set of expected competencies. This is time consuming, and often dissatisfying to personnel that have attended the training multiple times and believe that they have already mastered the content. For these situations, spaced education (SE) is a valuable alternative. SE is an innovative, evidence-based educational method that is very popular with busy perioperative personnel. SE involves delivering periodic e-mails or text messages containing clinical scenarios and test questions. Immediately after answering the question, the learner receives the correct answer with an explanation of the topic. The question is then placed into a cycle, and repeated in 8–42 days, to reinforce the content. When the learner answers a question correctly twice, the question is retired.

SE is based upon educational psychology theories in which spacing of education and testing enhance learning and retention. In randomized trials, SE has been found to improve knowledge acquisition and boost learning, and improve retention of knowledge for up to 2 years [38–40]. This methodology is especially appealing because it can be done in a few minutes at a convenient time, rather than requiring attendance at a traditional lecture. Qstream (https://app.qstream.com/) has some applications of interest to perioperative leaders. Educators may also create their own courses in Qstream (e.g., fire safety, deep vein thrombosis prophylaxis, perioperative hypothermia, sleep apnea). Although the use of SE in perioperative safety is in its infancy, it has enormous potential, particularly for annual competency assessment for nurses, surgeons, and anesthesia providers.

Designing Processes for Safety

When implementing new programs or processes or redesigning those in place in the perioperative setting, it is important to identify potential failures and, when possible, proactively prevent these from occurring. This strategy is a proactive risk analysis. Unlike a root cause analysis that

retrospectively examines a single failure, a proactive risk analysis involves a "deep dive" examining a process and identifying and correcting potential failures [41]. In this way, the learning is from what could go wrong, rather than what went wrong in single event [27]. Two tools to conduct a proactive risk analysis are: Failure Modes and Effects Analysis and the VA Center for Patient Safety's modification of this tool, a Healthcare Failure Mode and Effect Analysis (see Table 19.2) [42, 43].

Using a proactive risk analysis is ideal when initiating a new type of surgical procedure. For example, an FMEA was used to analyze the processes for intraoperative radiation therapy. Starting with planning for the procedure through completion of the procedure, 57 different failure points were identified. Using the hazard matrix, interventions for preventing failures were prioritized, and included double checking, interlocks, and automation [44].

Using a proactive risk analysis is also valuable for investigating current processes that are high risk or have resulted in an adverse event. An HFMEA of managing surgical sponges to prevent a retained sponge found 57 different potential failure points during the process. Only 14 were associated with final count. The most frequent underlying causes identified were: distraction (21%), multitasking (18%), and time pressure or emergency (18%). These causes are extremely difficult or impossible to control. Because knowledge deficit was not identified as an underlying cause, the authors concluded that education would not be an effective strategy and they recommended considering adjunct technology to assist with prevention of retained sponges [45].

Table 19.2 Steps of a healthcare failure mode and effect analysis (HFMEA)[a]

Step	Key elements
1. Define the HFMEA topic	Verify that the process to be studied is clear
2. Assemble the team	Should be multidisciplinary
	Include representatives from all affected areas
	Include subject matter expert(s) and an advisor
3. Graphically describe the process	Number each step and subprocess
	Create a flow diagram of all subprocesses
	Verify that all processes and subprocesses are included
4. Conduct a hazard analysis	List all potential failure modes for all subprocesses
	Rate the severity of injury should the failure occur, for each failure mode (1–4)
	Rate the probability of occurrence of each failure mode (1–4)
	Calculate a hazard score by multiplying the severity and probability (score 1–16)
	Use the decision tree to determine next steps
5. Actions and outcomes	Determine if the failure is to eliminated, controlled, or accepted
	Identify action to be taken
	Identify desired outcome
	Identify individual responsibility
	Identify whether top management has concurred

[a]Adapted from VA National Center for Patient Safety. The basics of healthcare failure mode and effect analysis. Washington, DC: VA. http://www.patientsafety.va.gov/professionals/onthejob/HFMEA.asp

Presenting a Business Case for Safety

Any new program or initiative to improve quality and safety has an impact on limited resources. This might be in the form of cost savings, cost avoidance, and/or increased costs of supplies, equipment, or labor. Someone will question this financial impact prior to recommending or approving the change. Although financial projections have been used in healthcare for decades, the structure of this information into a business case was first introduced by Leatherman and colleagues in 2003 [46]. Based on modern finance theory, organizations will be more likely to undertake and sustain initiatives that can be shown to generate a positive (or at least neutral) financial return on investment. As healthcare resources have become increasingly restricted,

the use of a business case to depict anticipated costs has gained momentum. It has now become a standard perioperative leadership strategy [47–55].

A benefit–cost analysis is a simplified formula often used as a foundation for presenting a business case. The cost savings and costs avoided (e.g., labor, supplies, length of stay, readmissions, drugs) comprise the numerator and are divided by the cost of the proposed intervention, which serves as the denominator. It is important to assure that the cost savings and costs avoided are as complete as possible.

Sources of Data

Developing a business case requires data from one or more sources: internal facility data, published data, and estimated hidden costs. Examples of data routinely available in facility reports to perioperative leaders are listed in Table 19.3.

Although many of these data are in existing reports, collaboration with the Hospital Information Systems department may be required to create new reports, particularly when data are needed about patient outcomes.

Table 19.3 Sources of data for developing a business case

Facility reports	External data
Cost of equipment/supplies	Operating room time [68]
Types and numbers of procedures performed	Healthcare-acquired conditions [69]
Duration of procedures	Legal defense [70]
Length of stay	Legal settlements [71]
Number, frequency, and cost of readmissions	State penalties for serious adverse events
Cost of labor	
Types and incidence of hospital-acquired conditions	
Types and incidence of adverse events	
Compliance with quality performance measures	
Hospital Consumer Assessment of Healthcare Providers and System (HCAHPS) scores	
Reimbursement	

For calculating some costs, it is useful to use published data sources. Swensen and colleagues used consensus to develop a list of examples of sources of financial data for hospital leaders to consider (e.g., [56]).

The University Healthsystem Consortium (UHC) used a combination of facility and published data to conduct a benefit–cost analysis of an intervention to prevent retained sponges. For this comparison, authors used facility data for duration of surgical procedures and number of retained surgical sponges. They based the cost of a minute of operating room time and the cost of intraoperative radiographs on published data [57].

At times, costs are difficult to measure and remain hidden, such as the time required for certain tasks. An example is the time required to reconcile surgical sponge counts. If reconciled, an event report is not generated. One study measured these hidden costs by collecting the number of minutes required to reconcile the sponge count and estimating the percent of this time that was nonproductive operating room time [58]. When possible, it is best to include an estimate of hidden costs. This may mean collecting data on a small number of events or tasks for inclusion as an estimate in the business case.

Minimizing and Managing Resistance

Changing human behavior is inherently difficult, even in the best facilities with the best teams [59]. An initial step in promoting any patient safety initiative is providing rationale for the need to change. This can be done by presenting either published evidence supporting the need for the practice change or internal data depicting an opportunity for improvement. Unfortunately, education alone is usually inadequate to influence behavior [60, 61]. Although physicians, nurses, and other perioperative personnel want to provide high quality, safe patient care, they also face competing priorities. Unless these priorities

are aligned or realigned with patient safety and quality initiatives, complacency remains a stronger force, passive or active resistance occurs, and the outcome is inadequate adoption of the practice change. Effective leadership in perioperative quality and safety requires an understanding of this tension and implementation of successful strategies for minimizing and managing resistance. A bundle of strategies used together maximize the potential for success [60].

Engage Emotionally

The first strategy to minimize resistance is to assure an emotional connection with the safety initiative. The individuals making decisions that affect patient safety are often not in clinical practice and may be emotionally disengaged from the patient experience. This may also occur in clinicians experience "initiative fatigue" and have become complacent or developed negative attitudes. Presenting data alone does not provide the impact necessary to successfully influence change. Joseph Stalin said, "The death of one man is a tragedy. The death of millions is a statistic." When individuals are emotionally disengaged, the data are only numbers. When this occurs, leaders need to refocus the attention on the individual patient experience. This can be accomplished through storytelling, starting a discussion from the patient experience of an event, depicting the tragedy, before presenting the data. This emotional engagement is a simple yet powerful strategy and increases the sense of urgency for the desired change. A classic example of storytelling is Josie's Story, in which a mother discusses the medical mishaps resulting in her 18-month-old daughter's death in a hospital [62]. This story is more powerful than discussing the number of medical errors that occur annually. Following the patient story with the data extends the impact the single patient experience to other patients, making the data seem that much more compelling. Successful leaders in quality and safety often begin meetings with a patient story, hardwiring this emotional engagement into the culture.

Maximize Efficiency

The second strategy to minimize resistance is to make the desired behavior easier to do than the undesired behavior. When designing a practice change, the processes should be as efficient as possible, minimizing the effort required of busy practitioners. Minimizing the steps required and incorporating the steps into current processes is likely to be more successful than the burden of additional workload. Make the desired behaviors easier and the undesired behaviors more difficult or inconvenient. This can often be accomplished by the location of supplies and equipment. For example, if the goal is to eliminate the use of razors for preoperative hair removal, place hair clippers closer to the point of use, and razors further away. Personnel are less likely to walk the additional distance to obtain a razor and will eventually fall into a pattern of using the clippers instead of razors. If the desired behavior is wearing gowns and gloves when starting central lines, placing these items with the central line catheters encourages the desired behavior. When adding electronic documentation requirements, minimize the number of key strokes required to complete the desired documentation. Consistently involving end users in the location of supplies and design of processes provides valuable insight into how to effectively maximize efficiency.

Leverage Peer Pressure and Support

The third strategy for minimizing resistance is to leverage the use of peer pressure and support. This can be accomplished by engaging opinion leaders to serve as safety champions. The use of opinion leaders has a strong theoretical foundation and is a strategy that has been used for many years for implementation of public health promotion programs. These individuals influence the opinions and motivations of others, change social norms, serve as a communication conduit back to change leaders, and accelerate the rate of behavioral change [63]. A meta-analysis including 19 studies of the effectiveness of using opinion leaders to drive evidence-based

practice changes found that alone or in combination with other interventions, opinion leaders may effectively promote practice changes [64]. The selection of individuals to serve as opinion leaders and safety champions should be based upon their level of influence, with consideration given to their position within the organization, professional expertise, communication skills, and positive can-do attitude. These individuals should represent the multidisciplinary stakeholders involved in the change.

Audit and Feedback

One strategy to encourage compliance with clinical practice changes is audit and feedback [65]. Ivers and colleagues conducted a meta-analysis to assess the effects of audit and feedback on the practice of healthcare professionals and patient outcomes, and to identify factors that explain variation in the effectiveness [66]. Seventy studies were included in the analysis. Audit and feedback increased provider compliance with desired practices and improved patient outcomes. The effectiveness is more significant when baseline performance is low, the feedback is given by a supervisor or colleague, the feedback is given more than once, when this feedback is both verbal and written, and clear targets for improvement are provided in an action plan [66]. Written feedback can be provided through managing daily improvement boards and scorecards. Verbal feedback can be provided during daily huddles or staff or committee meetings. The Association of periOperative Registered Nurses has an electronic audit tool, My AORNGuidelines (http://www.myaornguidelines.com/), that allows data entry at the point of use and real-time reports for feedback. My AORNGuidelines provides an efficient method of comparing practices with evidence-based guidelines. This tool can be used proactively for comparing practices with evidence-based practice guidelines or to evaluate practices when investigating an adverse event. Progress over time can be measured as well as benchmarking with other teams or facilities.

Dealing with Persistent Resistance

It would be naive to think that there won't be some individual(s) who remains resistant to a change even though a bundle of strategies have been implemented to promote adoption of a safety initiative. Managing these individuals should progress in a stepwise manner. First, one-on-one discussions with the individual should be able to determine the cause of the resistance. If the individual does not believe that the practice change is the right thing to do, providing more evidence is helpful. However, if the individual just does not want to do the desired behavior, providing more evidence is likely to escalate the resistance. At this point it is helpful to listen to the individual's rationale, identify any barriers to adoption of the change, and continue the discussion at a later time. The second meeting should include a recap of the rationale for the resistance, any additional actions taken to make the practice change easier, and then a discussion of the expected behavior. If this is not successful, the next step is reporting the issue to the individual's immediate supervisor. Problematic behaviors may also be addressed in contracts with employees or partners upon renewal.

Summary

Patient safety must be the highest priority for perioperative care. Designing perioperative services for safety requires a top-down integration of safety into all aspects of work practices. This starts with senior leadership committed to safety as a priority. Inclusion of safety initiatives in the strategic plan and conducting monthly safety rounds demonstrates this commitment. Team members must also be actively engaged in safety on a consistent basis, placing safety as the highest priority, particularly when faced with pressure for efficiency. A safety culture requires having the right people in the right jobs, and starts with the hiring process. Communication is essential. Discussing safety during huddles and team meetings keeps safety as a priority on a daily basis. Work processes should be proactively designed to minimize the risk of failures, instead of relying solely on root cause analy-

ses after adverse events have occurred. And, providing a business case facilitates integration of safety in a cost-effective manner.

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Operating Room Management, Measures of OR Efficiency, and Cost-Effectiveness

20

Sanjana Vig, Bassam Kadry, and Alex Macario

"First rule of leadership: everything is your fault."

—A Bug's Life

Introduction

Everyone who works in an operating room (OR) suite sees inefficiencies they think should be corrected. When correcting for these inefficiencies, it is important to keep in mind that the goal for any surgical facility is to perform cases safely and expeditiously. Common obstacles in an inefficient OR suite include long turnover times and unanticipated extended case durations. Unfortunately, for these types of OR management dilemmas, there is no one single answer that applies to every facility. Although a quick and effective solution is desired, a detailed diagnostic analysis of a facility's local issues is required. This analysis will lead to corresponding local interventions to improve the issue at that facility. While gathering and analyzing OR efficiency data is important, true success also depends on many unquantifiable variables, such as quality leadership and the effective management of human behaviors.

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OR managers (sometimes referred to as site directors or schedulers) can potentially come from surgery, anesthesiology, or nursing departments and are responsible for making the best possible decision that allows for the most efficient use of OR time and resources. OR decision-making is an active and challenging process that involves block time assignments, staff schedules, case duration predictions, and last-minute fluctuations such as emergencies and add-on cases.

As a method of illustrating the variety of obstacles faced by OR managers, several individuals from different OR environments were asked to describe their day-to-day administrative challenges (Table 20.1).

The goal of this chapter is to address the daily challenges and to summarize key aspects of OR management. Topics of interest include defining basic OR terminology, discussing case duration predictions, addressing OR utilization and staff management, and exploring measures of OR efficiency.

Basic Definitions [1–4]

Since OR managers can come from different departments, it is imperative that communication occurs using precise vocabulary to ensure that there are no misunderstandings. Below is a list of common OR management terms with generally accepted definitions.

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Table 20.1 Examples of administrative challenges for individuals with OR management responsibilities

Job title	Facility type	What is your biggest daily administrative challenge?
OR Scheduler[a]	Academic Medical Center	Predicting future busy caseload days to ramp up physician and nursing staff ahead of time
		Anesthesia staffing for emergent cases outside of the OR
Medical Director Perioperative Services	Academic Medical Center	Managing long e-mail queue, answering to all stakeholders
		Addressing patient safety reports (especially MD problem behaviors)
OR Scheduler[a]	Academic Medical Center	Dealing with last-minute issues getting patients into OR (e.g., after an unexpected early case finish—logistics of getting next case from waiting area to holding to OR expeditiously)
Nurse Patient Care Manager	Academic Medical Center	Filling open salaried assistant nurse manager positions
		Filling open OR nurse positions
OR Data Analyst for Strategic Development	Academic Medical Center	Redistribution of block time to support institutional growth
		Aligning perioperative services to match hospital priorities
		Estimating resource needs to support strategic vision
Senior Resident Scheduler	Ambulatory Surgery Center	Dealing with add-on (nonscheduled) cases
		Adjusting the schedule to accommodate cancellations
Nurse Patient Care Manager	Ambulatory Surgery Center	Training new RNs for high complexity cases
		Having enough high priced equipment (e.g., microscopes) readily available when needed
OR Scheduler[a]	Community Hospital	Allocating OR time to services and making time for new surgeons
		Scheduling inaccuracies: case booked for 90 min but takes 3 h causing the entire schedule to go out of sync
OR Scheduler[a]	Community Hospital	Retention of staff and having appropriate staffing levels
		Ensuring the entire perioperative process goes smoothly (e.g., have every patient go to preoperative clinic)
Medical Director	Freestanding Surgery Center	Reassigning cases based on daily OR efficiency
		Stopping sick patients from being inappropriately scheduled when are better served at a hospital OR

[a]OR scheduler: individual running the OR board for the day

Staffing: The process of calculating the number of OR teams that must be available at each time during the week. For example, there may be staffing for four ORs Monday through Thursday, 7 AM–3 PM, and 7 AM–12 noon on Fridays.

Regular Scheduled Hours: The hours that an OR team member works on the days when not on call (e.g., 7 AM–3 PM).

Master Surgical Schedule: A cyclic timetable that defines how many ORs are available, the hours that the ORs are open, and the specific OR times for individual surgical groups. Many surgical suites use a schedule that repeats every 1 or 2 weeks.

Allocated OR Time: Specific OR time slot that is assigned to a surgical group. For example, a specific group of neurosurgeons may be allocated OR time from 7 AM to 3 PM every Tuesday. This allocation does not mean that additional cases would be turned away if the group could not finish them by 3 PM. Instead, OR time allocation indicates that the regularly scheduled hours planned for the surgeons are between 7 AM and 3 PM.

Block Time: A category of allocated, protected, OR time. Procedures are electively scheduled during a block only if they are predicted to finish within the block.

Open Time: Hours of unreserved OR time during which *any* service/surgeon can schedule cases/procedures.

Released Time: Hours of OR time released from a service/surgeon's block time and converted to open time. This usually occurs when it is known in advance that block time will be unused e.g., due to vacation or meetings.

OR (case) Time: Time span from when a patient *enters* the OR, until he/she *leaves* the OR.

Turnover Time: The time from when one patient *leaves* the OR until the next patient *enters* the OR.

Early Start: When a patient enters an OR *before* scheduled start time.

Late Start: When a patient enters occurs *after* scheduled start time.

Productivity Index: Percent of total elapsed time that a patient is in the OR during prime time (i.e., the first 8 h of the day) shifts.

Raw Utilization: The total hours of elective procedures performed by a surgeon or surgical group during allocated OR time, *excluding* turnover times, divided by the allocated OR time.

Adjusted Utilization: The total hours of elective procedures, *including* the corresponding turnover times, performed within allocated OR time, divided by the allocated OR time. For example, if allocated time is 8 h, case time is 6 h, and turnover is 2 h, then the adjusted utilization is 100 %.

Underutilization: Reflects how early a room finishes and becomes idle. If OR staff are scheduled to work from 8 AM to 5 PM and a room finishes at 2 PM, then there are 3 h of underutilized time. The excess staffing cost would be 33 % (3 h/9 h). Excess staffing cost is one metric for assessing how well a surgery suite is being managed.

Overutilization: The hours that ORs run beyond allocated time. For example, if 11 h of procedures (including turnovers) are performed with staff scheduled to work 9 h, then there are two overutilized hours. Overutilized hours are at least twice as expensive as regular hours because of the additional monetary and morale cost of staff staying late unexpectedly. The excess staffing cost here would equal 44 % (2 h/9 h equals 22 %, then is multiplied by 2 to account for the incremental cost).

Case Duration Predictions

Predicting case durations is a difficult and frustrating task. Even with large amounts of data regarding a surgeon's case performance history, duration predictions for cases that have already begun and for those yet to start are still poorly estimated [5]. In fact, when graphing case duration data, the distribution is not a standard bell curve as might be expected (Figs. 20.1 and 20.2)[1] [6]. Unusually long cases will increase the average case duration estimate and skew the results to the right. This occurs because case distributions do not provide a single point value for how long a scheduled case will last but, rather, provide a probability estimate [6]. Therefore, when questioning how long a case has left, the answer is

[1]Originally printed in "Anesthesia & Analgesia" Vol. 108, Issue 3, Jan 1, 2009.

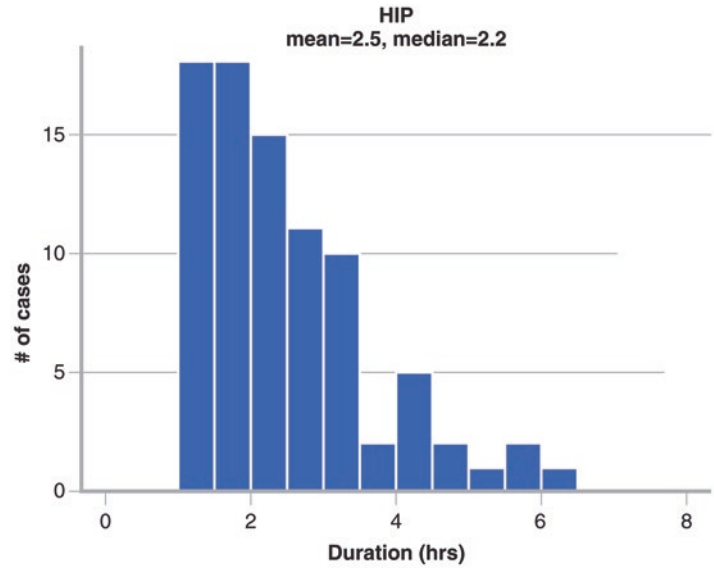


Fig. 20.1 Case duration data have *non*-bell shaped distributions making it difficult to choose a specific number for how long a scheduled case will last. The figure shows differences in duration of scheduled Hip procedures (Originally printed in "Anesthesia & Analgesia" Vol. 108, Issue 3, Jan 1, 2009)

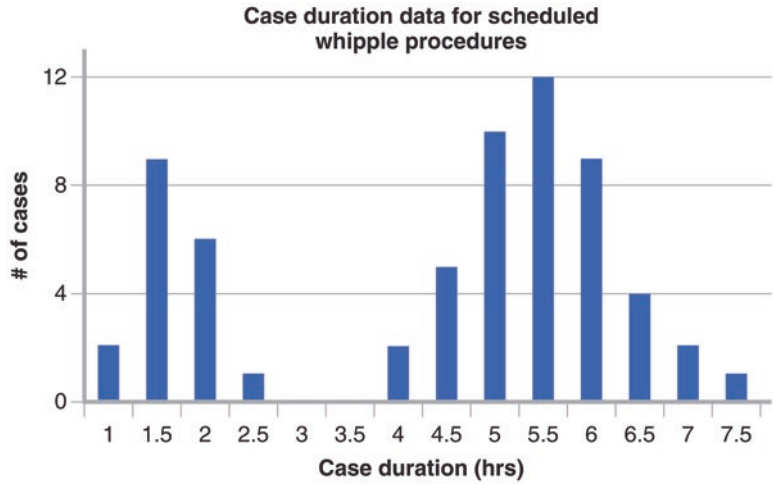


Fig. 20.2 Case duration data have *non*-bell shaped distributions making it difficult to choose a specific number for how long a scheduled case will last. The figure illustrates scheduled Whipple procedures. On the left are cases in which the operation was aborted; on the right are cases that were fully performed (Originally printed in "Anesthesia & Analgesia" Vol. 108, Issue 3, Jan 1, 2009)

better given as a percentage estimate. For example, "There is a 62 % chance that the case in room 6 will take another 30 min."

How to Make Duration Predictions

One method available to determine the duration of a case already under way is through Bayesian analysis. Bayesian analysis refers to the use of previous observations and current information to help determine future events. A computerized scheduling system that employs Bayesian analysis can transform scheduling by creating real-time decision support for the OR manager. Such a system may be able to make recommendations to an OR manager, such as: "Move the last case from OR 3 to OR 10" or "Have the on call team take over in room 8" [6].

Current real-time estimates can be supplemented by maintaining continuous communication with OR staff on the status of ongoing cases [6]. Regular updates are particularly valuable for longer cases and those with few historical comparisons [7, 8]. Approximately 20 % of surgeries in the United States are performed fewer

than 1000 times per year and 36 % are performed less than once a year per surgical facility [6]. Therefore, building a database with enough prior historical case duration data becomes difficult.

Last 5 Case Estimate is a method of predicting durations when there is limited historical data [8]. This procedure-surgeon specific method averages the durations of the last five similar cases performed. For instance, if the surgeon has completed at least five similar cases in the past year, or barring that, if any surgeon has performed the same case, then those estimates are used to make current predictions. Over- or underestimations are closely associated with certain factors, such as if the case is an add-on, is performed after 5 PM, or is an outpatient procedure [8].

Another method of predicting case durations is to ask the surgeon to generate a time estimate [5]. However, their estimate may be biased due to a facility's scheduling policies. For example, at some hospitals, surgeons may think it is necessary to provide shorter case time estimates to ensure that scheduled durations do not exceed the end of the regularly scheduled block time. Conversely, at another institution, a surgeon may be biased to lengthen case estimates to ensure that he/she does not lose block time to another surgeon.

Improving Duration Predictions

One approach to improve inaccurate case duration predictions is to first identify high volume cases with highly variable case duration estimates (e.g., spine surgery or sinus surgery) and compute the percent deviation of actual time from scheduled time. The next step is to define the source of this variability. In other words, determine if the variability occurs due to clinical differences in surgery or if the data is inherently flawed. It is also imperative to investigate how the data is collected. Some electronic systems consider incision time to close time as the case duration, which then leads to future predictions based on that time frame. However, duration estimates should include a patient's room enter to room exit time as well [5]. Defining the nonsurgical time frames, room in to incision and surgical closure to room out, can help improve scheduling accuracy.

Inaccuracies may also result from improper scheduling of the procedure type. Each case is defined not only by the type of procedure and the surgeon, but also by the facility site. This is because case times for the same procedure can differ in an ambulatory center versus an inpatient hospital surgery suite. Therefore, understanding the terminology used (e.g., are there incomplete procedures codes), having an appropriate user interface in computer scheduling programs, and adequately training scheduling personnel is imperative in accurately scheduling cases and producing time estimates.

Improving surgeon time estimates may occur by giving surgeons their own historical summary data and ensuring that they understand the terminology and the appropriate time frame estimates to use [5].

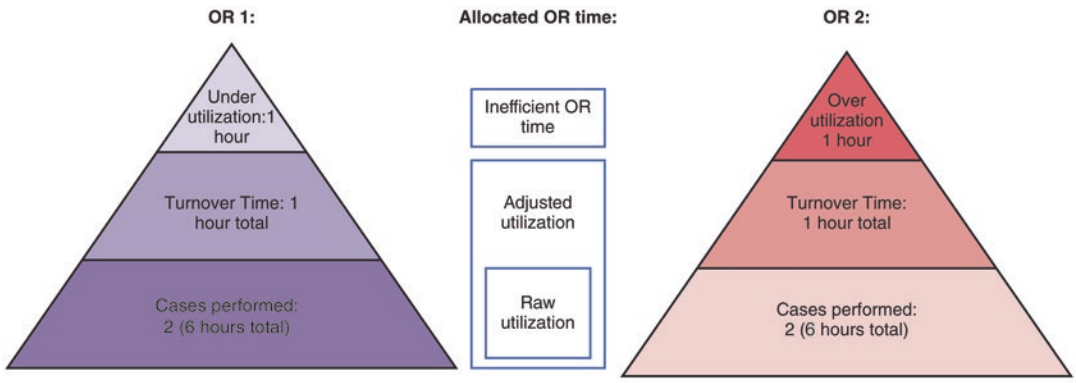
OR Block Time and Utilization

One of the most important OR management decisions is to allocate the right amount of block time to each service on each day of the week. This allocation is based on historical usage by the surgeon and computer analysis of data from similar cases. The goal is to minimize the amount of underutilized time and, the more expensive, overutilized time.

Figure 20.3 illustrates how allocated OR time is broken down by cases performed, turnover times, and resulting utilization patterns. In each OR, allocated time is 8 h. OR 1 has 1 h of underutilized time. In OR 2, the case time and turnover time lead to an hour of overutilization. Determining causes of this inefficient OR time is an important method to evaluate how well a surgical suite is being managed.

Surgeon Block Time

Generally, block times are given out in half or full block intervals that can range between 4 and 12 h [10]. Block lengths of 8–10 h are recommended, though, to allow for more cases to be accommodated and to improve overall efficient use of OR time [11]. Block time can be given to individual surgeons or surgical subspecialties as a whole



Allocated OR Time: Block time allocated to surgeon/service for the day

Raw Utilization: Percent of OR time that is used to perform cases (excludes turnover time)

Adjusted Utilzation: (Raw utilization + Turnover time)/Allocated OR time

Inefficient OR Time: Under and over utilization

Turnover Time: Included in adjusted utilization: time from one patient's exit from OR to another's entrance to OR

Under Utilization: Idle allocated OR time; due to excess time between cases or early finishes

Over Utilization: Time in excess of allocated time; due to long turnover or long case times; multiplied by 2, fudge factor to account for non financial impact of working in excess

Fig. 20.3 Illustration of OR definitions (Modified from [9])

[12]. However, assigning blocks to surgeons instead of whole services can increase efficiency and give surgeons a sense of ownership that encourages them to utilize their assigned time efficiently [11]. Other advantages of surgeon-specific block times include [10]:

- The ability to ensure, in advance, that clinic days do not conflict with OR time.
- Availability of appropriate surgical assistant staffing for given OR block times.
- The ability to book the appropriate number of procedures according to case length and complexity.

Surgeon-specific block time can also be used to promote surgical growth by recruiting new surgeons and offering them dedicated block time. From a hospital's perspective, block times for different surgeons can be spread out during the week to accommodate the use of limited surgical supplies (e.g., if there is only one robot, then surgeons who use it can be given blocks on different days so there is no conflict in use) [10].

Block Time Allocation

Surgeons, or specialties, that underutilize their OR time are typically not given additional OR time. Instead, additional OR time is allotted to those specialties or individuals whose use of OR time exceeds their allotment [10]. It is important to establish a usage threshold at which block time should be taken from one surgeon/service and reassigned to another. The next directive is to determine to whom this freed up block time should be given.

Formulating solutions to these issues requires aligning block times to the OR's strategic vision. The goal is not only to increase efficiency, but also to allow certain specialties or surgeons to grow their practice. Achieving this entails assigning dedicated time, regardless of initial utilization percentages. As a result, there is a potential upstart cost to the facility in the form of hospital and human resource support to get a group or surgeon up and running.

Viewing a facility's OR network as an ecosystem can assist with case scheduling and block

allocation. Specifically, if one facility in a network has underutilized OR time, or not enough case bookings, then it may be prudent to consider diverting cases from another, busier, center in the network to the less busier OR suite. Evenly distributing the workload can offset overutilization in one place and help to fill in underutilized time in another.

Block Time Utilization

Raw utilization is computed by dividing the total hours of elective surgery time by the number of hours allocated for the OR block [13]. For example, if a room finishes after performing cases that totaled 7 h out of 8 h of block time, then utilization is 7/8 or 87.5 %. However, this method penalizes surgeons with many short cases because the turnover times are not included, thus underestimating utilization. To compensate for this, adjusted utilization is used: (raw utilization + turnover) divided by allocated block time.

Optimum utilization rates vary depending on the facility, the types of procedures commonly performed, and the facility's independent management goals [14, 15]. Any analysis that discovers suboptimal utilization in a facility may indicate local issues with ineffective management [11]. Low utilization may also be due to operating more ORs than needed. Identifying and addressing the underlying cause and working closely with OR physicians is necessary for developing effective solutions to maximize utilization.

Case Scheduling

In general, a service or surgeon should not schedule a case that runs into overutilized time if they can place it in another OR without causing overutilization [3, 16]. Additionally, nonelective cases should be performed in a room that is underutilized [3, 16], that is, if it is safe to otherwise wait for one if it is not readily available.

Impact of High Utilization

Improving utilization overall may help free up additional OR time on any given day, which, in turn, increases the flexibility of the daily schedule. This flexibility creates room to accommodate unanticipated scheduling changes and avoid overutilization [11]. However, attempting to increase utilization to 100 % can have a negative impact by removing the ability to schedule cases on short notice. As a result, patient waiting times increase and may affect patient satisfaction. With this in mind, utilization should only be increased up to a certain point, where use of resources and revenue are maximized in tandem and align with a facility's independent goals [1].

Efforts to increase OR utilization by scheduling more inpatient surgery cases may not be possible due to other constraints, such as hospital bed availability. Regular communication between the OR manager and hospital executives must occur to determine which OR cases can be allowed to proceed. This involves looking at the total hospital census, including patients in the emergency room awaiting admission, projected direct hospital admissions and discharges, and the limited available capacity in certain inpatient wards (e.g., ICU or telemetry) [5]. An available countermeasure to optimize OR suite activity is to prioritize outpatients or inpatients needing surgery.

OR Decision-Making

Utilization-Based Decisions

While many will focus on utilization data to make OR allocation decisions, it is important to take into account the individual situation of each healthcare system in question. Based on local factors, different decision conclusions may be necessary. For instance, a facility that achieves and reports high utilization may be performing cases with low contribution margins. As a result, the finances for that facility may be negatively

impacted. On the other hand, a facility with low utilization may still have enough revenue stream to make low utilization acceptable. This highlights the fact that examining utilization data alone cannot accurately drive management decisions. Table 20.2 lists limitations, and corresponding examples, to only using OR utilization metrics for OR management decisions.

Table 20.2 Limitations of using only historical OR utilization data for decision-making [10]

Limitation	Example
Inaccuracies in an individual surgeon's utilization average estimates	Block times are usually assessed every 3–6 months [13]. However, longer intervals are required to obtain a true average [4] e.g., if 3 months average = 65 % utilization, the Confidence Interval (CI) is 38–85 % [10]
Increased underutilization for specialties with longer procedure case times	Once a long procedure (e.g., ENT cancer) is complete, the amount of block time left may not be sufficient to schedule a second case
Some specialties will not be able to have high OR utilization due to the nature of practice	Specialties with many urgent cases (trauma, cardiac) are less likely to have high utilization than specialties with predictable caseloads months ahead of time (e.g., joint replacements)
Increasing utilization may not be possible due to other hospital constraints	Not enough ICU beds can limit performance of certain cases so that OR utilization appears low
High utilization rates can inadvertently reduce overall hospital revenue	If utilization is 90 %, there is room for 10 % increase. Hospital decides to accept new, low reimbursement insurance and adds many new patients. With increased waiting times, new patients may actually replace full payers, thus actually decreasing revenues
Utilization is not an indicator for potential future expansion	Historical utilization does not take into account the future forecast of a surgical subspecialty
High utilization may negatively impact patient waiting time to have surgery	Increasing use of OR time increases wait times for patients needing surgery, decreasing the ability to book cases quickly within a few days when desired
Utilization does not correlate to contribution margin	Contribution margin profitability varies by surgical specialty [12]

Decision-Making Priorities

In regards to OR decision-making, the following priorities can be followed as general rules [1]:

- Patient safety trumps all other issues. Cases should be arranged to maximize OR efficiency without risking patient harm.
- Provide surgeons with access to OR time on any future workday, provided the cases can be done safely. This allows surgical procedures to be performed in a timely manner and promotes flexibility and growth of surgeons' practices.
- Maximize OR efficiency, i.e., reducing overutilization. Service-specific staffing is calculated to maximize expected OR efficiency. OR time is released only when a service has filled its allocated OR time and still has another case to schedule. The case is scheduled into the OR time of the service with the most allocated but underutilized OR time.
- Reduce patient wait time on the day of surgery. Generally, patients are given specific arrival times based on when their surgeries are scheduled. However, updated times may be needed if prior cases are cancelled or delayed.

Staffing

Over 60 % of hospital expenses are fixed costs for salaries and benefits of caregivers and ancillary staff [1, 17]. This factor is one of the most important in driving up hospital spending [5, 13] and also incentivizes OR managers to maximize labor productivity [1, 17]. This means using the least amount of labor staff for the most OR cases pos-

sible, thus decreasing overall cost while increasing overall revenue. As a result, maximizing OR utilization and matching staffing with work caseload becomes a priority [3, 17].

OR allocations for a service, or surgeon, vary by day of the week, and staffing also varies accordingly, e.g., in 8-, 10-, or 12-h blocks [3]. While keeping in mind surgical needs, OR staffing can theoretically be determined based on calculating labor costs. For example, OR staffing costs over a 4-week period, for specific services and day of the week, can be compared for an 8-h block with the cost of a 10-h block. If a surgeon or service has more than one OR day per week, then costs of two block time assignments, e.g., two 8-h allocations or one 8- and one 10-h block allocation, can be calculated and compared.

On the other hand, in some community-based facilities, if utilization is low on a particular day, shifts for full-time staff can be cancelled or the staff can be sent home early. The challenge is doing this fairly. Staff clinical workload and exposure must be taken into account, as it is essential that they are given the opportunity to maintain their clinical skills.

Managing Staff

Successful management of the OR requires not only sound organizational structure, but also strong leadership, and interdisciplinary cooperation [18]. Common problems that arise when attempting to lead physicians and ancillary staff include [18]:

- Reluctance and lack of motivation to assist in change.
- Placement of blame on others; lack of accountability.
- Lack of physician discipline.

Firm institutional policies with clearly defined provider roles allow OR managers to handle disruptive physician behaviors in an objective and rational manner. In addition, staff must be educated on these policies and procedures and be kept up to date on any changes that occur. The overall goal is to maintain patient satisfaction, patient safety, and positive clinical outcomes. Any behavior that disrupts these policies and affects these outcomes must be addressed, and the physicians and staff involved must be held accountable [19]. It is important that everyone takes responsibility for their actions and is aware of the consequences when expectations are not met. Hand-in-hand with this is the need for positive reinforcement for providers. Being rewarded for working harder, or taking on more responsibility, can make implementation of change a much smoother process and also heightens the sense of collaboration in the workplace.

Strong communication and listening skills are also essential. It is not just what is said that is important, but also *how* it is said. Being aware of how one communicates can make a difference in how messages are received and how effectively leadership decisions are carried out [19]. In addition, identifying with the constituents, with their concerns or complaints, can assist an OR manager in effectively handling any issues that arise. This is particularly useful when negotiating the different behaviors and values of nurses, doctors, and ancillary staff from different generational age groups [20].

A driving factor for studying these interactions is the occurrence of human error and the impact of human behavior in the workplace [21]. Human fatigue, workload, poor communication and decision-making skills, ineffective leadership, and inability to work as a team can serve to negatively affect work ethics and overall work satisfaction and motivation [22].

While correcting for human error and honing nonclinical skills is important, it is also imperative to realize that one can only correct for human behavior up to a certain point. The rest of the managerial focus should surround the much more easily controlled design and flow of the OR work environment [22].

OR Efficiency

Calculating Efficiency

When determining how efficient (or inefficient) an OR is on a particular day, under- and overutilized times need to be computed [14].

Taking the example mentioned earlier, if 7 out of 8 h of a block are used, then 1 out of 8, or 12.5 % of the block, is underutilized. At most facilities, OR nurses are full time hourly or salaried. Therefore, the incremental labor cost from 1 h of underutilized OR time is negligible [1]. This is called a "fixed" cost as they are paid for that hour regardless of whether or not they are in a case.

If an OR runs late, for instance by 2 h, then 2/8, or 25 % of the block, is overutilized. This is then multiplied by a fudge factor of "2" to account for staffing costs for those additional 2 h [13]. As a result, inefficient use of OR time is related to overutilized block time, which OR managers should, therefore, strive to minimize [23]. A survey of OR directors showed that moving cases from one OR to another to decrease overutilization was only worthwhile if the time saved was more than 1 h [1].

Goals of Efficiency

Each facility can, and should, have different goals regarding efficiency that are unique to its own circumstances. Each facility has its own unique patient and surgeon population whose characteristics and contributions to a hospital must be balanced with the overall well-being of that facility.

Measures of OR Efficiency

Measures of efficient day-to-day scheduling and OR managing efforts can vary depending upon whom you ask within the hospital infrastructure. For example, administrators concentrate on efficient use of budgets or measured throughput, while surgeons aim for fewer cancellations and more accurate first case start times [23, 24]. Nurse managers may focus more on maintaining the flexibility to move cases around, and having adequate reserve capacity for add-on cases or emergencies. In contrast, risk management may focus on lowering the percentage of patient injuries (e.g., fewer wrong-sided surgeries).

A method to measure OR efficiency and performance is through scorecard rating systems. Table 20.3 is an example of a scorecard that can be used to assess OR efficiency [24]. Suggested parameters include staffing costs, late start times for elective cases, case cancellations, PACU delays, turnover times, and case duration prediction biases. For poorly managed OR suites one would expect a score of 0–5 points (on a 0–16 scale) [24]. High scores of 13–16 are especially achievable with the help of state-of-the-art management systems. Unfortunately, variations in data systems, data fields, and data definitions exist between hospitals, which can make external benchmarking difficult [23].

Table 20.3 Discussion

Case Cancellations

Case cancellation rates include same day cancellations and, depending on the type of facility, must be viewed through different lenses. Surgeons may be more comfortable with cancelling/rescheduling inpatients versus outpatients. Outpatient procedures may be more complicated to cancel because the facility does not expect, nor is prepared to fill in, for any cancellations. In addition, cancelling outpatient procedures can have a large impact on patients themselves. Many take time off from work and ask for special transport assistance. Thus, an outpatient cancellation can mean a frustrating loss of time and money.

Case cancellations can also call into question the value of the preoperative patient assessment. If a patient is cleared by the preoperative clinic, then it is assumed that the anesthesiology team will proceed with the case.

PACU Delays

PACU duration is not associated with quality of care. Attaining accurate metrics requires obtaining measures of when patients are *ready* to be

Table 20.3 An example of a scorecard that can be used to assess OR efficiency (with permission from Macario, Alex, "Are Your Hospital Operating Rooms "Efficient"? A Scoring System with Eight Performance Indicators" *Anesthesiology* Vol. 105, Issue 2, Aug. 1, 2006)

A scoring system for OR efficiency			
	Points		
Metric	0	1	2
Excess staffing costs	>10 %	5–10 %	<5 %
Start time tardiness (mean tardiness per OR per day)	>60 min	45–60 min	<45 min
Case cancellation rate	>10 %	5–10 %	<5 %
PACU admission delays (% of workdays with at least one delay in PACU admission)	>20 %	10–20 %	<10 %
Contribution margin (mean) per OR hour	<$1000/h	$1000–2000/h	>$2000/h
Turnover times (mean setup and cleanup turnover times for all cases)	>40 min	25–40 min	<25 min
Prediction bias (bias in case duration estimates of OR time)	>15 min	5–15 min	<5 min
Prolonged turnovers (% of turnovers that are more than 60 min)	>25 %	10–25 %	<10 %

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discharged from the PACU and not when they actually leave. Delays are often due to nonclinical reasons, including nursing staff and number of physical beds. Another important measure is the PACU bay to OR ratio. This is especially relevant with cases of shorter duration, as they will quickly fill up PACU beds, which can then lead to PACU admission delays from the OR.

OR Summary Data

OR data can be summarized for the decision makers, as seen in Figs. 20.4 and 20.5.

There are multiple factors that determine whether a case will be able to start on time, including room ready time, and preoperative issues such as difficult intravenous access, complex patient histories, and patient arrival delay. Having this kind of report allows differentiation of ownership of the cause of delay, i.e., OR nurses versus patients, surgeons, or anesthesia. Causes due to different groups are presented in different formats to remain relevant based on user archetype.

Conclusion

People involved in the OR suite need to believe the data that is presented by OR managers when change is being proposed or implemented. This requires standardized measurements across the hospital system's OR suites so everyone is using the same data definitions. Often times, data is not enough to drive change as there may be organizational and workplace cultural barriers that need to be addressed. Effective leadership skills are instrumental to motivate and inspire teamwork and ensure cooperation with any new changes or updates to OR management processes. Ultimately, the goal of any OR is to complete its cases in as

MOR
October 10th

First Case Delays

Summary

Status	Target Time	Total	Actual	Percentage
Room Ready	7:10	16	11	69
In Room	7:15	16	9	56
In Room +5min	7:20	16	14	88

Detail

Room	Department	Scheduled In	Actual In	Variance	Delay Reasons	Delay Comments
MOR 15	Neurosurgery	7:15	7:23	8.0	Complex patient management	EKG requested preop
MOR 17	OHNS	7:20	11:18			Patient ate breakfast
MOR 18	Orthopedics	7:15	7:09	-6.0		
MOR 20	Urology	7:15	7:16	1.0		
MOR 21	General	7:15	7:20	5.0	Difficult IV	

Fig. 20.4 This report was created in order to have a simple to understand, automated, timely display of late case starts reported as a percentage relative to total case volume on any given day. Prior reporting occurred in generalized statements, such as "13 % of cases were late on Monday, October 10," which were unsatisfying and did not allow for understanding of the underlying issues. This figure illustrates a detailed service-by-service breakdown, assigning ownership to late groups and allowing further investigation into why any delays were occurring. The "In Room" time correlates with the beginning of OR time allocations, which is a driver for staffing support. "Room ready" represents when the OR nurses communicate with preoperative staff that the room is ready to receive the patient as defined by having the appropriate supplies, equipment, and staff. "In room + 5 min" is the grace period, of which, according to the table, includes 88 % of cases. A grace period helps to differentiate cases that are truly late versus those that have been purposely scheduled to start late, e.g., at 8 AM

Turnovers

Summary

Primary Department	# of Turnovers	Avg turnover (min)
Vascular	2	74
Cardiac Surgery	3	62
Neurosurgery	2	62
Thoracic	3	60
Neurosurgery	4	57
General	6	49
Urology	2	43
Orthopedics	5	39

Detail

Room	Department	Actual In	Actual out	Turnover	Delay reasons	Delay comments
MOR 01	Thoracic	7:09	12:49		Outside department-imaging services	Waiting for X-ray
MOR 01	Thoracic	13:30	14:34	41.0	OR/Procedure room set up. Patient others, Equipment & supplies	Disconnecting and storing Robot from prior case. Missing equipment
MOR 01	Thoracic	15:25	17:52	51.0		Patient arrived late

Fig. 20.5 The idea behind this is to have an overall view of not only how many turnovers are occurring, but also how much time they utilize. As can be seen, turnover times vary greatly amongst different service blocks. It is important to keep these differences in mind when addressing and attempting to solve any issues with prolonged turnovers. Different services have different case requirements, thus, increased turnover time may be necessary, and accepted, to ensure appropriate preparation for surgery

efficient a manner as possible while optimizing use of staff and resources and maintaining positive patient experiences and outcomes.

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The Science of Delivering Safe and Reliable Anesthesia Care

21

Maurice F. Joyce, Holly E. Careskey, Paul Barach, and Ruben J. Azocar

"Patient safety is truly the framework of modern anesthetic practice, and we must redouble efforts to keep it strong and growing."

—Ellison C. (Jeep) Pierce, Jr., M.D.; Founding Leader of the APSF

Abbreviations

AAR	After action review
ABA	American Board of Anesthesiology
AfPP	Association for Perioperative Practice
AIMS	Anesthesia information management systems
AIRS	Anesthesia incident reporting system
AORN	Association of Perioperative Registered Nurses
APSF	Anesthesia Patient Safety Foundation
AQI	Anesthesia Quality Institute
ASA	American Society of Anesthesiologists
CCAP	Closed claims analysis project
CMS	Centers for Medicare and Medicaid Services
CRM	Crisis Resource Management
DISS	Diameter index safety system
EHR	Electronic health records
FDA	Food and Drug Administration
FMEA	Failure mode and effects analysis
ICU	Intensive care unit
MOCA	Maintenance of certification in anesthesiology
MPOG	Multicenter Perioperative Outcomes Group
NACOR	National Anesthesia Clinical Outcomes Registry
NQF	National Quality Forum
OSCE	Objective structured clinical examination
PPAI	Practice performance assessment and improvement
PQRS	Physician quality reporting system
PSH	Perioperative surgical home
QCDR	Qualified Clinical Data Registry
RCA	Root cause analysis
SCIP	Surgical Care Improvement Project
SRE	Serious reportable events

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Introduction

The approach to providing safe perioperative care starts with a common goal. The delivery of anesthesia entails working within several complex, multifaceted systems. An effective and safe system is one that is consistent between patients and effective at identifying and preventing errors. The design and implementation of safe processes

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is essential to prevent mistakes. Anesthesiologists are involved in the care of patients in a myriad of locations from the preoperative assessment to the perioperative and postoperative periods. Additionally, anesthesiologists have a large presence outside of the operating room including in the intensive care unit (ICU), inpatient wards, and outpatient pain clinics. Each of these locations has its own set of standards, protocols, safety measures, and cultures.

The primary goal of anesthesia care is to deliver safe care and avoid process failures which lead to never events [1]. These are events defined as "serious, largely preventable patient safety incidents that should not occur if relevant preventive measures have been put in place" [2]. Secondary goals include providing high quality care in an efficient manner for every patient. To attain these goals there are technical solutions including medical device and medication fail-safe measures as well as process solutions including checklists, crisis resource management protocols, and incident investigation. Establishing and following evidence-based standards and protocols, we can attempt to prevent mistakes made by fallible, albeit well-intentioned, providers. Deviation from an established protocol or standards should be rare and require justification.

Designing and Enabling a Culture and Climate of Safety

The phrase "culture eats strategy for breakfast", a phrase originated by business guru Peter Drucker, is well known by administrators trying to implement change. The term "safety culture" was coined after the Chernobyl incident in the town of Pripyat, in Ukraine in 1987. Although many definitions exist, the definition by Turner et al. is most applicable to healthcare: "the set of belief, norms, attitudes, roles and social and technical practices that are concerned with minimizing the exposure of employees, managers, customers and members of the public to conditions considered dangerous or injurious" [3].

Safety climate, however, refers more to "a summary of molar perceptions that employees share about their work environment" as defined by Zohar [4]. Safety climate is generally the accepted term for the collective view of safety within an organization as manifested by recent or current events. In other words, the safety climate can be considered an immediate antecedent to behavior. An organization's employees are often driven to action, or inaction, based on their perceptions of reality driven by the safety climate. Safety climate is often significantly influenced by recent events. For example, the safety climate of an organization can experience an immediate negative impact if a major workplace event such as a fatality occurs. Although this event may eventually also impact the safety culture, it could have a significant latency and its long-term impact may require years to accurately evaluate [5]. This culture can greatly improve the trust between members and between workers and management, and influence willingness to speak up, collaborate, and work more effectively as surgical team members [5].

A "reporting culture" is at the heart of engendering safety and only really works when workers feel free to report their errors and near misses to management without punishment [6]. The most important organizational value that supports a reporting and learning culture is when employees feel psychologically safe, and if they speak up to report on process or outcome failures, they will not be censured or suffer reprisal [7, 8]. In this environment, errors are not only reported but are also dissected without assigning blame and subsequently steps are taken to prevent them in the future. This type of environment has been described as a learning environment and, in conjunction with concrete learning processes and practices, is the first step towards creating a learning organization [9]. Another key aspect of safety in nonmedical industries is incident reporting systems that focus on near misses. Reporting of near misses offers numerous benefits over adverse events: greater frequency allowing quantitative analysis; fewer barriers to data collection; limited liability; and recovery patterns that can be captured, studied, and used for improvement [10].

The final essential component needed to enable a culture of safety is leadership that

reinforces learning. When leaders actively question and listen to employees, spend time on problem identification, support knowledge transfer, and reflective post-audits, employees feel reassured to offer new ideas and options [11].

Reason in his "Swiss cheese theory" described the negative outcomes that occur when system barriers fail, allowing actions to penetrate the organizational barriers, and thus the holes of the Swiss cheese slices align. Analyzing process and outcome failures in which patients are harmed can be done using a variety of methods including root cause analysis (RCA) sessions, where the organizational, cultural, and technical roots of the failure process are discussed and recommendations for future prevention are generated [12]. Failure mode and effects analysis (FMEA) is another systematic technique that can be utilized to assess a complex clinical socio-technical process such as a liver transplant operation and identify à priori which steps in the clinical process are most likely to fail and lead to harm [13]. Organizational psychologists advocate debriefing all critical or high-stakes events. For example, the U.S. Army After Action Review (AAR) is a structured debriefing process for analyzing what failure happened, why it happened, and how it could have been done better by the participants and those responsible for the project or event [14].

Healthcare organizations continue to have high variation in their patient outcomes and need to make significant progress before they can be regarded as learning and high reliability organizations [15]. Tucker and Edmonson explain that in order to create a trustful environment three factors must be present: (1) Management support (not only in voice but also demonstrated by a presence "in the field," experiencing and witnessing the problems firsthand); (2) Creation of an environment where individuals can provide feedback without fear of embarrassment or punishment; and (3) Follow-through based on employee observations or suggestions, thus allowing individuals to see the organizational reaction to their participation [16]. The barriers to creating a learning organization include physician burnout and even practices that are sometimes considered positive, such as an emphasis on individual vigilance, unit efficiency concerns, and employee empowerment [17]. Limiting the resolution process to individual vigilance alone may lead to solutions for the immediate issue at hand but not address systemic problems. An excessive focus on efficiency may lead to safety problems, thus it must be emphasized that safety trumps efficiency [18]. Clinician empowerment is enabled when the communication from management is authentic and the actions they are asked to undertake make sense to them—we call this clinical sensemaking [19]. Individuals will only feel empowered to maintain open communication with leadership if leadership is fully committed to the process and the staff understands why particular actions and interventions are being supported and deployed [20].

Equipment and Monitoring Advances

The administration of anesthesia is predominantly a complex monitoring task and relies on an integrated anesthesia workstation that has evolved over time through tremendous technological advances [21]. This evolution includes scientific improvements related to anesthetic delivery and patient monitoring as well as the addition of enhanced safety measures. Multiple gases are utilized in the operating room in the delivery of anesthetic and surgical care. It is critical that swapping of agents is prevented. Unintentional swapping of the gas supply can lead to serious harm in the form of delivery of a hypoxic gas mixture to a patient, increased risk of intraoperative fires, and inadvertent expansion of closed chambers. The most common gases required during anesthesia delivery include oxygen, air, and nitrous oxide. Less frequently, additional gases are used including nitric oxide, helium, and xenon. Carbon dioxide is often used for insufflation during laparoscopic surgeries.

The development of several safety measures has made the delivery of an unintended gaseous agent less likely to occur [22]. Foremost among these measures is engineered redundancy including delivery and transport of the correct agent in

color-coded pipelines and cylinders, ventilator gas analyzers, and continued monitoring of agent purity in the central gas supply. Medical gases are delivered to the operating room in two different ways. They are delivered to various locations in a healthcare facility from a central supply through a series of pipelines. These pipelines can be accessed through outlets in each operating room suite. The hoses for each of these pipelines are color coded according to national standards adopted by Bureau of Standards of the US Department of Commerce [23]. Connection of the pipeline hose to the anesthesia machine is achieved with a unique fitting specific to the gas being attached known as the diameter index safety system (DISS). These unique fittings prevent the wrong hose from attaching to the ventilator. A unidirectional valve at the hose terminal prevents the backflow of gases. An opportunity for error exists if gases are interchanged in the central supply source. The second method of gas delivery is through the use of gas storage cylinders [1]. These cylinders, like the pipeline hoses, are color coded according to national standards. The cylinders can be attached to the end delivery device (i.e., ventilator, insufflator) through a specific fitting known as the pin index safety system. The yoke manifold on each cylinder contains a pin connection that fits into corresponding socket in the delivery device. The room for error exists should the pins become damaged or the cylinder becomes filled with the incorrect agent. Overlapping and redundant layers of safety measures is a key theme within anesthesia safety that is repeated time and again.

The ventilator itself contains several mechanisms to ensure proper functioning and prevent inadvertent delivery of hypoxic mixtures. Before each patient encounter, an anesthesia machine checklist must be performed (see Fig. 21.1). This checklist includes a minimum set of standards that are developed and occasionally revised by the U.S. Food and Drug Administration (FDA). The checklist includes verification that there are at least two oxygen sources (usually an emergency-cylinder and pipeline from central supply), calibration of an oxygen sensor, confirmation of functional unidirectional valves and simulated ventilation and leak tests. Each anesthesia machine contains an oxygen pressure sensor that alarms if the oxygen input is below a set threshold. The position of the oxygen control knob is always closest to the breathing circuit. If there is a leak from "upstream" gas inlets, the distal position of oxygen inlet allows for an adequate oxygen supply to reach the patient. Additional safety measures built into the ventilator include minimal oxygen flow, end-tidal gas monitoring, oxygen:nitrous oxide controller, and pressure regulators.

The American Society of Anesthesiologists (ASA) initially published standard monitoring guidelines in 1986. These standards were developed to help providers more readily recognize a decompensating patient as well as provide a minimal universal standard of care. The guidelines have been updated as medical technology has advanced. Today, the guidelines include that an anesthesia provider must be present for the duration of the anesthetic. Monitoring standards are such that during all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature are continually evaluated [24]. Oxygen delivery must be measured using an oxygen analyzer and an alarm for low oxygen concentration must be used (notably, both are present on modern anesthesia machines). Quantitative measurement of oxygenation, most commonly using pulse oximetry, is necessary. Monitoring of ventilation is done through qualitative assessment (for example, chest rise and breath sounds) as well as quantitative assessment of end-tidal carbon dioxide. End-tidal gas monitoring is included in the standards and provides a means of early recognition of esophageal intubation. Circulation is measured with continuous telemetry and through frequent blood pressure measurements (at least every 5 min). Temperature is to be monitored when changes in patient temperature are anticipated. While the guidelines provide a minimal standard, there is freedom to employ additional monitoring methods should providers deem them necessary for patient care.

The development of monitoring guidelines was an early step in automating aspects of care so the provider could be quickly alerted to

TO BE COMPLETED DAILY, OR AFTER A MACHINE IS MOVED OR VAPORIZERS CHANGED		
ITEM TO BE COMPLETED		RESPONSIBLE PARTY
Item #1:	Verify Auxiliary Oxygen Cylinder and Manual Ventilation Device (Ambu Bag) are Available & Functioning.	Provider and Tech
Item #2:	Verify patient suction is adequate to clear the airway.	Provider and Tech
Item #3:	Turn on anesthesia delivery system and confirm that ac power is available.	Provider or Tech
Item #4:	Verify availability of required monitors, including alarms.	Provider or Tech
Item #5:	Verify that pressure is adequate on the spare oxygen cylinder mounted on the anesthesia machine.	Provider and Tech
Item #6:	Verify that the piped gas pressures are ≥ 50 psig.	Provider and Tech
Item #7:	Verify that vaporizers are adequately filled and, if applicable, that the filler ports are tightly closed.	Provider or Tech
Item #8:	Verify that there are no leaks in the gas supply lines between the flowmeters and the common gas outlet.	Provider or Tech
Item #9:	Test scavenging system function.	Provider or Tech
Item #10:	Calibrate, or verify calibration of, the oxygen monitor and check the low oxygen alarm.	Provider or Tech
Item #11:	Verify carbon dioxide absorbent is fresh and not exhausted.	Provider or Tech
Item #12:	Perform breathing system pressure and leak testing.	Provider and Tech
Item #13:	Verify that gas flows properly through the breathing circuit during both inspiration and exhalation.	Provider and Tech
Item #14:	Document completion of checkout procedures.	Provider and Tech
Item #15:	Confirm ventilator settings and evaluate readiness to deliver anesthesia care. (ANESTHESIA TIME OUT)	Provider

Fig. 21.1 APSF Pre-Anesthesia Checkout Guidelines. Apsf.org [Internet]. New Guidelines Available for Pre-Anesthesia Checkout. [cited 01 Feb 2016]. Reprinted with permission from Anesthesia Patient Safety Foundation: http://www.apsf.org/newsletters/html/2008/spring/05_new_guidelines.htm

changes in a patient's condition. Unfortunately the multiple and lack of connected monitoring alarms leads to a phenomenon known as alarm fatigue [25]. This occurs when the provider becomes desensitized to the monitor alarm and ignores new onset alarms. Alarm fatigue has been listed as a top patient safety concern of the Joint Commission as described in the 2014 National Patient Safety Goals which require hospitals to explicitly address alarm fatigue and be held accountable from 2016 [26]. Addressing this challenge will require many steps at different system levels [27]. Monitoring devices that process complex data streams should produce clinically relevant alarm signals, in environments optimized for discernment and attribution, with user interfaces designed for timely interpretation, prioritization, and prompt action. Alarm fatigue solutions require regulators, manufacturers, and clinical leaders to recognize the importance and context of human factors and their effects on staff behavior.

Anesthesia Information Management Systems

The intraoperative electronic medical records that are becoming standard practice throughout the United States are known as anesthesia information management systems, or AIMS. Implementation has been influenced by the adoption of electronic health records (EHR) throughout other aspects of the medical system after passage of the 2009 Health Information Technology for Economy and Clinical Health act. Additionally, governmental incentive programs, namely meaningful use from Medicare and Medicaid, are encouraging providers to participate in meaningful use programs [28]. These computer-based documentation records are taking the place of paper charting of vital signs, procedures, and medication administration in the operating room as well as labor and delivery anesthesia and acute pain documentation

elsewhere in the hospital. A proposed benefit of an AIMS is that it allows the provider to focus more attention on caring for the patient and less on documentation. Additional benefits include the ability to mine data for quality improvement, automated billing, help with compliance measures and research capability [29].

There are certain established concepts that any AIMS product should possess in order to be an effective tool for the anesthetist. These include automatically uploading data from physiologic monitors, the ability to take and store records throughout the continuum of perioperative care including preoperative history and physical exam and postoperative recovery, automatic documentation necessary for billing, and automated reminders for quality assurance measures (for example, antibiotic administration timing). Additional functionality includes clinical decision support, customizable templates, automated alerts, and institutional EHR integration. The ability of electronic records to improve anesthesia safety seems evident when compared to the tedious task of paper charting, though future research should investigate this area as AIMS become increasingly utilized. The system must be optimized with physician workflow in order to be a useful tool and not a barrier to care. Perioperative outcomes research using anesthesia information management systems (AIMS) is an emerging research method that can offer a much better understanding of anesthesia complications [30]. Finally, deploying AIMS offers examples of unintended consequences related to errors and security concerns, and issues related to alerts, workflow, ergonomics, and quality assurance [31].

Medication Safety

The operating room is a unique environment without many of the standard safety protocols that exist elsewhere in the hospital. In fact, medication errors in the operating room have been reported to be as high as one in 20 perioperative medications administered [32]. For example, pharmacy approval and preparation of medication and two person checks prior to medication administration are often not feasible in the operating room. In the operating room, prompt medication delivery is often necessary due to rapidly changing patient condition, thus precluding these safety measures and leading to medication administration errors. Since the same safety measures that are used elsewhere are often unfeasible in this unique environment, there must be novel approaches toward minimizing medication errors.

Nebeker et al. define a medication error as the inappropriate use of a drug that may or may not result in harm [33]. An adverse drug event is defined as harm caused by the inappropriate use of a drug [33]. When a medication is used properly with a subsequent adverse outcome, it is known as an adverse drug reaction [33]. Examples of common medication errors within the operating room include incorrect dosage, incorrect medication, and wrong site administration. These errors are multifactorial in nature and are related to poorly designed medication labels and fonts, vial sizes, and unaddressed human factors including the long history and culture of the anesthetist working in isolation to draw up, dilute, label, and administer all medications involved in an anesthetic delivery with little to no oversight.

In one large, single institution prospective study, the most common medication errors were labeling errors, wrong dose errors, and omitted medication/failure to act errors [32]. The most common medications associated with errors in the operating room were propofol, phenylephrine, and fentanyl. Other studies have shown that neuromuscular blocking agents and opioids are the most common associated agents [34]. Other types of errors include incorrect route of administration (for example, epidural instead of intravenous) or wrong site administration (for example, bolus through a carrier line). In addition to the unique environment of the operating room, anesthesiologists are also at risk of the same medication errors and subsequent adverse drug events that occur throughout the hospital due to poorly designed systems and safeguards. A review of the literature in 2007 concluded that common risk factors for medication errors include the lack of knowledge regarding the medication or the patient history by providers,

errors in the clinical chart or nursing documentation, and decentralized pharmacy services [35]. This review estimated that medication errors occur in about one in 20 episodes of drug administration, which is consistent with the previously referenced intraoperative medication error rate [32]. Anesthesiologists, like all providers, must be especially vigilant with regard to high alert medications. These are medications, which, if administered in error, are more prone to significant or life-threatening adverse drug events. The Institute for Safe Medication Practices publishes a list of these medications and classes [36]. Some common medications included on this list are adrenergic agonists, adrenergic antagonists, anesthetics, antiarrhythmics, anticoagulants, epidural and intrathecal medications, inotropes, insulin, sedation agents, opioids, and neuromuscular blockers.

Preventing Medication Errors

Efforts to improve patient safety, including the prevention of medication-related errors, have been a focus of healthcare improvement since the 1999 Institute of Medicine report *To err is human* [37]. Optimizing care delivery in the operating room in a way that prevents common errors is an ongoing effort. The incorporation of "smart pumps" into practice helps prevent wrong dose or rate of drug administration [38]. However, the ability to override alerts or a limited drug library makes them only part of the solution. The most common type of drug error that the anesthesiologist is likely to encounter is that of labeling mistakes [39]. Several innovations have been created in an attempt to address this problem, including prefilled syringes with standardized packaging, concentration and pharmacy formulation to prevent dilution errors and wrong drug administration. Additionally, distinct labeling including color-coding and high visibility of drug name and concentration (see Fig. 21.2) is quite common now and may help to reduce, but not eliminate, wrong medication errors [39].

Clinical decision support, which is widespread in current computerized physician order entry, has proved to be effective in other areas of medical care [40]. However, until recently, the technology in the operating room has lagged behind electronic medical record innovations in the hospital. Systems can print accurate labels for syringes and also scan those syringes prior to medication administration. There is often verbal readout of medication as well as accurate documentation of administration into the electronic medical record [40]. The anesthesiologist may find himself or herself giving up some of their prior independence in order to improve patient safety. It is prudent to carefully assess the dangers and unintended consequences of highly automated anesthesia systems which can create new obstacles to delivering safe and reliable care.

Closed Claims Analysis and Associated Anesthesia Registries

The Closed Claims Analysis Project (CCAP) is a longitudinal study of malpractice claims filed against anesthesiologists in the United States. In 1984, the ASA President, Ellison C. Pierce, Jr, M.D., spearheaded a number of programs to improve patient safety and prevent anesthetic injury, the most notable being the CCAP [41]. The Closed Claims Project data includes detailed clinical information on events and outcomes allegedly causing anesthesia-related injury from 1970 to the present (excluding injury to teeth), regardless of whether the claim was dropped, settled, or adjudicated [41].

By analyzing the clinical information that lead to harm and malpractice legal suits, regardless if the cases had been settled, dropped, or adjudicated in court, the CCAP aimed to enhance patient safety by learning from each case and assessing causes of significant anesthesia-related poor outcomes. This project was also framed in a time when malpractice insurance premiums for anesthesiologists were rising significantly. At that time, anesthesiologists represented only 3 % of insured physicians, but accounted for 11 % of the total dollars paid for patient injury.

Despite the limitations of this method due to its retrospective nature, the inability to determine a denominator to calculate the risk, and the fact

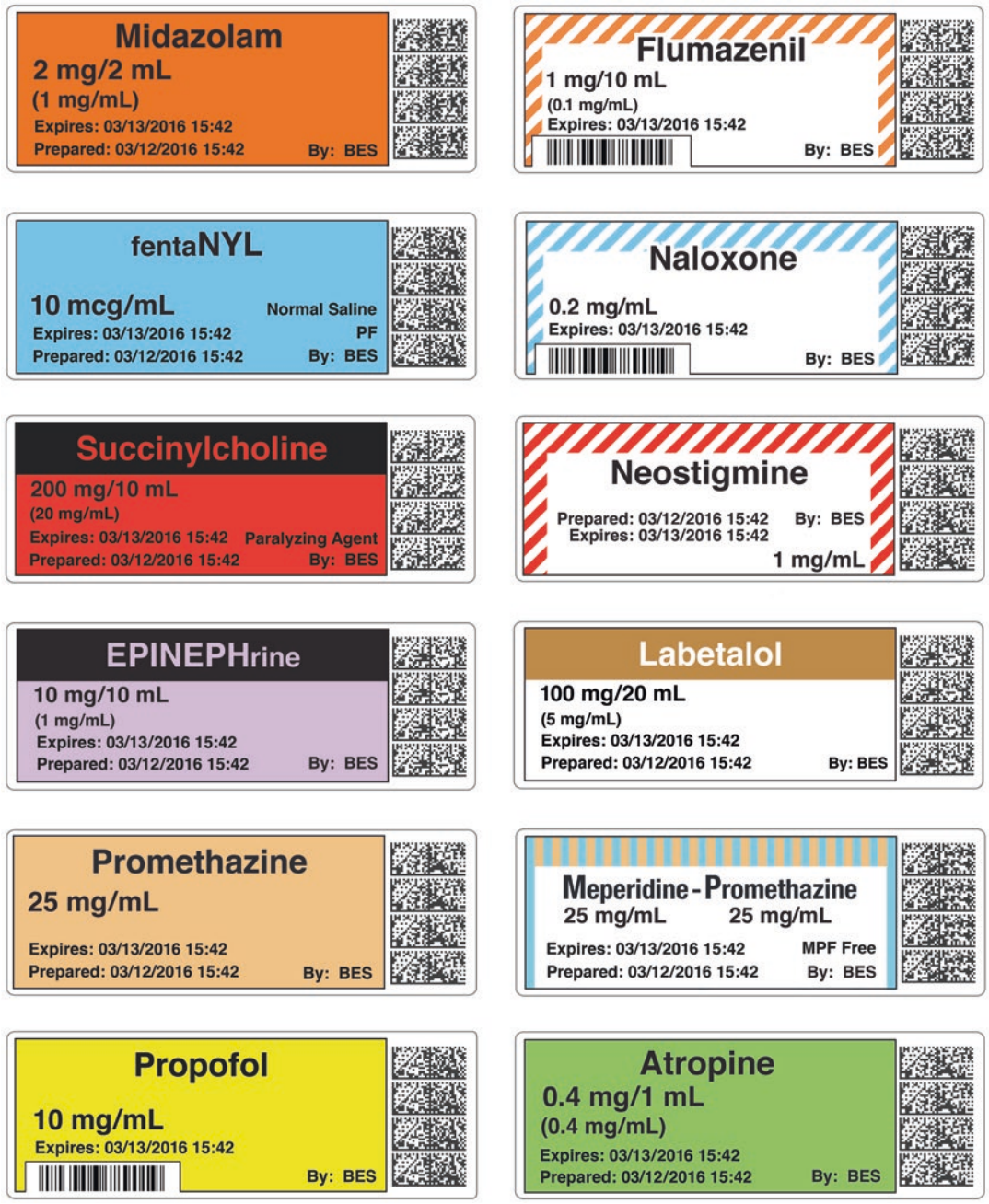

Fig. 21.2 Drug Label Examples. Codonics.com [Internet]. SLS Safe Label System. c2005–2016 [cited 01 Feb 2016]. Reprinted with permission from Codonics: http://www.codonics.com/Products/SLS/

that not all injured patients file claims, the project was incredibly successful by providing a snapshot of anesthesia liability [41]. From 1998 through 2010, there have been 63 newsletter articles and 33 peer-reviewed manuscripts published which have highlighted patient safety and liability issues from the data collected by the CCAP [42]. For example, closed claims findings of major sources of anesthesia-related injury, such as death and brain damage, have led to the creation of standards

requiring the use of pulse oximetry intraoperatively and the use of end-tidal carbon dioxide as verification of tracheal intubation by the ASA Committee on Standards. Similarly, data on difficult intubation led to the development of the ASA Practice Guidelines for Management of the Difficult Airway in 1993. Data pertaining to frequent negative outcomes such as peripheral neuropathies and blindness associated with spine surgery has also been captured by the CCAP and led to the creation of practice advisories in an attempt to prevent such complications.

The CCAP and its registries are strongly aligned with the Anesthesiology Quality Institute (AQI). The institute maintains different registries with case data as the primary resource for anesthesiologists looking to assess and improve patient care [43]. These registries include:

(a) National Anesthesia Clinical Outcomes Registry (NACOR): NACOR is a data warehouse that is planning to capture 40 million of the cases and several million of the pain clinic procedures that are performed each year by anesthesiologists in the United States. This will allow for the development of benchmarks, where practices can compare their outcomes to national data. NACOR has been designated by the Centers for Medicare and Medicaid Services (CMS) as a Qualified Clinical Data Registry (QCDR) for the physician quality reporting system (PQRS). PQRS has significant implications for reimbursement, as those who do not report will be penalized starting in 2016.
(b) Anesthesia Incident Reporting System (AIRS): The first nationwide system for collecting individual adverse events from anesthesia, pain management, and perioperative care. This online reporting tool can be accessed on the AQI website.
(c) The Maintenance of Certification in Anesthesiology (MOCA®) Practice Performance Assessment and Improvement (PPAI): As part of the American Board of Anesthesiology (ABA) recertification process, this tool provides a four-step process whereby diplomats assess their practices and implement changes with the intent of improving patient outcomes.

The Multicenter Perioperative Outcomes Group (MPOG) and the Anesthesia Quality Institute began repositories of anesthetic cases which can be searched by participants to examine rare events and outcomes, but these efforts are still in their infancy and are far from providing robust, broadly generalizable incidence estimates of the type that CCAP provides.

Checklists and Cognitive Aids

Checklists

One of the trickle-down, lasting patient safety accomplishments that resulted from the publication of *To Err is Human: Building a Safer Health System* by the Institute of Medicine is the World Health Organization surgical safety checklist [37, 44]. Implementation of surgical checklists in hospitals throughout the United States and world through the use of a perioperative timeout has resulted in significant reductions in morbidity and mortality. In the inaugural surgical safety checklist implementation study, Haynes et al. found statistically significant decreases in both the rate of death (1.5–0.8 %) and inpatient complications (11.0–7.0 %) after introduction of the checklist in eight diverse hospitals worldwide [44]. de Vries et al. described similar significant reductions in inhospital mortality (1.5–0.8 %) and overall complications (27.3–16.7 per 100 patients) with implementation of the Netherlands' Surgical Patient Safety System [45]. Several other studies have further supported the findings from these inaugural studies [46–48]. Notably, Semel et al. found that the use of the surgical safety checklist not only resulted in improvements in morbidity and mortality but also suggested that it was cost-saving [49]. Utilization of the surgical safety checklist has also been shown to result in improved operating room team communication in addition to improved attitudes regarding patient safety [46, 50–53].

Despite these demonstrated improvements in team communication, attitudes towards patient safety, economic efficiency, and patient morbidity and mortality, use of the surgical safety checklist remains inconsistent and the quality of the perioperative timeout is quite variable. In quantitative analysis of 24 video-recorded perioperative timeouts, Rydenfält et al. found that only 54 % of the total expected checklist items were completed [54]. More specifically, they also found that team introductions, a vital component of the preoperative timeout, were completed in only 50 % of the observed timeouts. They hypothesized that each surgical team member's conception of risk and the perceived importance of individual checklist items greatly influenced checklist compliance. In a study of 671 perioperative timeouts, Sparks et al. found similar problems with checklist compliance [55]. Most notably, they found that the accuracy of checklist completion was poor (54.1 ± 16.9 %). In a recent study by Urbach et al., implementation of a surgical safety checklist did not result in improvement in surgical mortality or complications due to ineffective top-down engagement and inauthentic partnering and engagement with clinicians; however, as Leape questions, this lack of improvement could be related to poor checklist compliance [56, 57]. It is clear that introducing a checklist in an environment characterized by a lack of trust causes clinicians to feel jeopardized professionally and personally, and encourages gaming of clinical metrics and measurements [58]. Effective adoption requires local championship, sustained clinician engagement, and a commitment to teamwork [59, 60].

Moreover, even with consistent use of the checklist, errors still occur, suggesting that there are always underlying human factor issues at play [61–63]. The surgical safety checklist reduces but does not eliminate the harm due to human errors and their associated morbidity and mortality. This limitation is important to recognize as the role of checklists becomes more prominent in the entirety of the perioperative process, including transitions of care and perioperative procedures [64].

Cognitive Aids

Recently, the use of cognitive aids to assist a team that is facing a critical event has been widely endorsed. The aids make responses to such events more amenable to standardization and provide guidance to ensure all possibilities and alternatives are considered. Two recent reviews shed light on the use of cognitive aids. In the first, the authors discuss cognitive aids in healthcare and other high-risk industries, and describe why emergency manuals have a role in improving patient care during critical events [65]. Additionally, they propose four steps for the successful development and implementation of medical emergency manuals: create, familiarize, use, and integrate. In the other review, Marshal describes mixed success with the use of an emergency manual, but suggests that cognitive aids should continue to be developed based around clinical guidelines when such guidelines exist [66]. He also indicates that the implementation of these aids could benefit from extensive simulation-based usability testing before clinical utilization. Arriaga et al. have demonstrated this technique in the development of surgical-crisis checklists showing that checklist utilization improved the management of operating room crises [67]. The advent of handheld devices and apps with cognitive aids may make the use of these tools more common and accepted.

Patient Transitions and Handoffs

Anesthesia providers often participate in patient handoffs several times for each patient under their care. The process of transferring responsibility for care of a patient from one healthcare provider or healthcare team to another is referred to as the "handoff," or "handover," referring to the act of transmitting information about the patient and posed known risks and dangers to patient [68]. Such handoffs occur several times a day between nurses, between attending physicians/nurse practitioners, and between trainees when the patient is admitted to, managed in, and transferred from the OR to the PACU or the

intensive care unit [69]. Clinicians and researchers agree that patient handoffs serve as the basis for transferring responsibility and accountability for the care of patients from outgoing to incoming healthcare teams across shifts, across disciplines, and across care settings [70].

During a handoff, necessary and critical information about a patient is transmitted from one caregiver to the next, or from one team of caregivers to another [71]. Such information allows the health professionals or healthcare team who takes over the patient's care to gain relevant knowledge about the patient, understand the management plan, and ultimately ensure that the patient's care continues in an uninterrupted, error-free manner. The patient handoff between healthcare providers is a vulnerable period in the patient's care journey during which vital information may be lost, distorted, or misinterpreted. Unfortunately, the practice of patient handoff to, within and from, the OR is often suboptimal due to communication barriers and is a major contributor to medical errors and adverse events [72].

In fact, a recent study suggested that more operating room anesthesia handoffs are associated with increased adverse events [73]. Further, the Joint Commission and the World Health Organization have both identified patient handoff communication as a major patient safety initiative [74, 75].

A fundamental reason, however, is the lack of a common ground to enable interpretation of the complete handoff content. *Common ground* refers to the pertinent mutual knowledge, beliefs and assumptions of providers that support interdependent action, and an ongoing process of tailoring, updating, and repairing the mutual understanding and mind-sets [64]. It is constructed by three skills: the ability to share, inform, and request; the ability to jointly share attention and intentions with each other; and the ability to construct common cultural knowledge. According to Cohen and colleagues, true handoffs involve a co-construction by both parties of the oncoming caregiver's understanding of the patient, and not a one-way transmission of information [76].

Poor information storage and retrieval systems that are not user-friendly also contribute to compromised handoffs [77]. For example, even with sophisticated electronic medical records, many operating rooms and post-anesthesia care units continue to use paper forms or parallel electronic databases as repositories of patient information to transmit to incoming colleagues. Other studies demonstrate that distractions during complex patient management tasks and lack of adequate time to complete documentation without interruptions contribute to key information being overlooked, prioritized, or not transferred [78, 79]. Asynchronous communication practices in which the patient's status and management plan are written down or audio-recorded by the outgoing professional and the information is ready or played back by the incoming team later to gain information about the patient can also contribute to errors and omission of key data [80].

Patient handoff management is rarely taught systematically. Though, several groups have demonstrated success with standardized handoff systems such as the I-PASS system [81]. In the interest in patient safety, it is vital that anesthesiologists either adopt or develop both an intraoperative and perioperative standardized handoff system.

The following principles can help to redress this, and should be considered a "starter set" of principles to be customized based on the specific contexts of perioperative settings, teams, and individuals as described above:

- Teach providers to tell a "better story." More effective integration of the quantitative outcomes data with the more qualitative contextual data will enhance the wisdom of health professionals, and capture the complexity of patient stories.
- Provide feedback. Sustain the effort by giving feedback about individual performance and by setting performance expectations.
- Couple inexperienced providers with experienced incoming and outgoing providers. The experienced incoming provider can demonstrate proper inquiries about patient status and issues, and the experienced outgoing provider can demonstrate proper "storytelling" and methods. Capturing the wisdom of a 4–6 h operation is more complex than one might assume.
- Consider the use of videotaped simulated handovers and self-directed videotaping for

reflective learning. Use of these tools can improve handover [82]. They can demonstrate the nature of false assumptions and omissions; the effects of interruptions; good versus poor patient problem descriptions; and the consequences of relying only on written information.
- Educate all staff using interactive methods on the importance of effective handoffs and about the characteristics of good handoff—include communication training using a program such as TeamSTEPPS or other team training programs [83].
- Provide staff with laminated reminder cards listing desirable features of handoffs.
- Use a mnemonic such as IPASS or SIGNOUT [84].
- Provide a quiet private physical space for handoffs to occur.
- Develop standardized written handoff tools and try to import patient information automatically from the electronic medical record into these tools (to avoid transcription errors) [85].

Teams Training, Crisis Resource Management, and the Role of Simulation

In high-stakes situations, such as those in the perioperative environment, success is dependent on high performing and reliable teams. This dictum is particularly true in an environment as complex, and at times uncertain, as the operating room [86]. In this site, there are additional challenges as many times operating room team members change and are frequently determined almost randomly. Further, there are personnel changes throughout the day, and even during a single case due to shifts and breaks. While the operating room personnel are well-intentioned and trained individuals who are able to work in difficult conditions, the evidence demonstrates these characteristics are insufficient, as errors and underlying system issues continue to plague the operating room environment leading to patient harm.

Teams make fewer mistakes than do individuals, especially when all team members know their individual responsibilities as well as those of the other team members. However, simply bringing individuals together to perform a specified task does not automatically ensure that they will function as a team [87]. Perioperative teamwork depends on a willingness of clinicians from diverse backgrounds to cooperate toward a shared goal, to communicate, to work together effectively, and to improve. Each team member must be able to: (1) anticipate the needs of the others; (2) adjust to each other's actions and to the changing environment; (3) monitor each other's activities and distribute workload dynamically; and (4) have a shared understanding of accepted processes, and the knowledge of how events and actions should proceed [88].

Traditionally, medical training has not included team-building skills, but rather, has concentrated on the development of individual skills, thus leading to the challenge of generating more functional teams in the perioperative space. The airline industry, in contrast, was a pioneer in the evolution of the team paradigm, moving away from a pilot-centric approach after major airplane disasters and transitioning to a crew resource management model where emphasis is placed on communication, the use of checklists and ensuring that all members of the team are empowered to provide their opinion [89]. Gaba recognized the parallel between the cognitive profiles of anesthesiologists and airline pilots, in addition to the similarities of the environments in which they work [90]. Gaba and his colleagues created Anesthesia Crisis Resource Management in the early 1990s and were one of the pioneers in reporting the success of this endeavor when integrated with medical simulation [91, 92]. At its core, crisis resource management (CRM) refers to the nontechnical skills required for effective team performance during a crisis as well as the recognition and management of factors that affect performance. These factors are outlined in Table 21.1 with further delineation of each of these principles in Table 21.2.

Assessing team competencies remains challenging and there is a range of reliable methods to assess and give feedback to surgical team members. Structured observation of effective teamwork in the operating room can identify

Table 21.1 Factors that affect individual and team performance

Factor	
Individual (HALTS: hungry, angry late, tired, stressed)	• Fatigue
	• Sleep deprivation
	• Emotional disturbance (e.g., angry, stressed)
	• Ill health
	• Inexperience
	• Lack of knowledge
Team	• Role confusion
	• High power distance/ authority gradient
	• Ineffective communication techniques
Environment	• Interruptions
	• Noise
	• Handovers
	• Production pressure
	• Equipment failure
	• Unfamiliar place and equipment

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substantive deficiencies in the system and conduct of procedures, even in otherwise successful operations [93].

The key principles of CRM include:

- Know your environment
- Anticipate, share, and review the plan
- Ensure leadership, role clarity, and good teamwork
- Communicate effectively
- Call for help early
- Allocate attention wisely—avoid fixation
- Distribute the workload—monitor and support team members

Medical simulation has become ubiquitous in healthcare and the use of this technology in team training and crisis resource management is well described and has extended beyond the walls of the operating room and into all other areas of the hospital [94, 95]. Importantly, simulation is not only useful for team training and CRM, but also can be utilized for the acquisition of clinical skills such as history taking and physical exams (via standardized patient actors) and technical

Table 21.2 CRM principles

Principle	Actions
Know your environment	• Know location and function of equipment, especially for time-critical procedures
	• Logically structured and well-labeled environment
	• Use cognitive aids
	• Regular training
	• Know the role and level of experience of team members
Anticipate, share, and review the plan	• Think ahead and plan for all contingencies
	• Set priorities dynamically
	• Reevaluate periodically
	• Anticipate delays
	• Use checklists
	• Share the plan with others—sharing the mental model facilitates effective action towards a common goal
	• Think out loud and provide periodic briefings to verbalize priorities, goals, and clinical findings as they change
	• Encourage team members to share relevant thoughts and plans
	• Continually review the plan based on observations and response to treatment

(continued)

Table 21.2 (continued)

Principle	Actions
Ensure leadership, role clarity, and good teamwork	• Employ the least confrontational approach consistent with the goal
	• Participative decision-making improves team buy in
	• Use an authoritative approach when necessary (e.g., time-critical situations)
	• Allocate team roles
	• Establish behavioral and performance expectations of team members
	• Establish and maintain the team's shared mental model of what is happening and the team's goals
	• Monitor the external and internal environments of the team to avoid being caught off guard
	• Team members should show good followership and be active—each observes and monitors events and advocates or asserts corrective actions
	• Leader provides debriefing
	• Team members including the Leader need to be able to recognize when they are affected by stress, and develop appropriate self-care behaviors
	• All team members—Leaders and Followers—are equally responsible for ensuring good patient outcomes
Communicate effectively	• Distribute needed information to team members and update the shared mental model
	• Use closed loop communication
	• Be assertive, not aggressive or submissive
	• Avoid personal attacks
	• Resolve conflict
	• Maintain relationships
	• Facilitate collaborative efforts working towards a common goal
	• Double check
Call for help early	• Be aware of barriers to asking for help (e.g., fear of criticism or losing face)
	• Set predefined criteria for asking for help
	• Call for help early
	• Mobilize all available resources
Allocate attention wisely—avoid fixation	• Be aware of "fixation error" that reduces situational awareness
	• Prioritize tasks and focus on the most important task at hand
	• Delegate tasks to others
	• Use all available information
Distribute the workload—monitor and support team members	• Team Leader stands back whenever possible to maintain situational awareness and oversee the team
	• Assign tasks according to the defined roles of the team
	• Team Leader supports team members in their tasks

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skills (airway management, venous access, laparoscopic training, etc.) with task-trainers [96]. Further, simulation allows practitioners to encounter and manage rare events that may never be experienced during training or even during an entire career. Malignant hyperthermia is a prime example of such a rare event.

Finally, many medical and anesthesia educators have considered the use of simulation as an assessment tool for knowledge and skills [97, 98]. In the United States, the ABA introduced a simulation experience requirement as part of its MOCA process. In the next several years, the ABA will administer a "hands-on session" as part of its Part 2 exam. This assessment will likely be similar to an Objective Structured Clinical Examination (OSCE), but details have not yet been finalized.

In sum, for practicing clinicians, simulation is a haven for safety—both for trainees, who can

practice, make errors, and learn without harming anyone, and for patients, who will be cared for by providers with superior technical and nontechnical skills.

Perioperative Safety Organizations

The approach toward ensuring safe care should be organized, sensible, and deliberate. Several organizations have developed a vested interest in ensuring safe perioperative care. The Association for Perioperative Practice (AfPP), a working group within the UK, defines and analyzes so-called "never events" [1]. The National Quality Forum (NQF), a nonprofit organization which aims to improve quality in the United States, has developed a list of Serious Reportable Events (SRE) which are defined as an "unambiguous, largely, if not entirely, preventable, serious, and any of the following: adverse; indicative of a problem in a healthcare setting's safety systems; and important for public credibility or public accountability" [99]. The Joint Commission released the 2015 National Patient Safety Goals for hospitals, including the goal to implement a universal protocol for the prevention of wrong surgeries (wrong patient, wrong site and/or wrong procedure) which continue to occur despite efforts to prevent these adverse events [100, 101]. In 2006, CMS in collaboration with multiple agencies including but not limited to the Joint Commission, American Society Anesthesiologists, American College of Surgeons, and the Center for Disease Control implemented the Surgical Care Improvement Project (SCIP). The SCIP includes multiple quality indicators designed to improve patient outcomes by reducing hospital-acquired infection, perioperative myocardial infarction, perioperative venous thromboembolism, and other perioperative morbidity and mortality and ensure that patients receive standardized care [102]. Patients and patient advocates are becoming more and more interested in seeking high quality care for themselves and their families. CMS has published a website where patients can look at various quality indicators (including patient satisfaction) at a regional and hospital-specific level.

The Anesthesia Patient Safety Foundation (APSF) was established in the mid-1980s in order to organize safety campaigns, promote research and education regarding safety, and serve as a national and international hub for the exchange of information regarding patient safety. The APSF is one of the first specialty-specific organizations to focus on safety. It circulates a free and easy-to-read newsletter which is available on the website (http://www.apsf.org). The APSF has helped create a cadre of experts in addition to a culture and an infrastructure devoted to promoting safety. The most important feature of the APSF effort may be the elevation of patient safety to coequal status with more traditional concerns, such as determining the molecular mechanisms of anesthesia, developing specialized drugs, or managing critically ill patients. An important focus has been around the dangers of conscious sedation given growing evidence of patient harm due to inexperienced providers administrating powerful sedation drugs such as propofol [103]. Designing safe and reliable sedation services for non-anesthesia providers and in nontraditional locations remains huge challenge [104].

In addition to these physician-led patient safety organizations, the Association of periOperative Registered Nurses (AORN) plays a vital role in ensuring safe perioperative care. This organization has a mission to promote safety and optimal outcomes for patients undergoing operative and other invasive procedures by providing practice support and professional development opportunities to perioperative nurses.

Caring for the Provider

A discussion of patient safety would not be complete without mention of the central role that the physical and emotional health of healthcare providers plays in the safe care of patients. While a full discussion of this topic is outside of the scope of this chapter, it is important to briefly discuss several topics which are especially relevant to anesthesiology.

Human Factors and Their Impact on Performance

It is well known that sleep deprivation has significant impacts on mood, cognitive tasks, and motor tasks [105]. Further, shifts of 24 h or more have been shown to result in impairment of psychomotor performance equivalent to or exceeding alcohol intoxication [106]. While trainees and practicing anesthesiologists are educated regarding the effects of fatigue and sleep deprivation on patient care (both from a cognitive and motor standpoint), preventable errors still occur that are directly attributable to these human factors [107]. Several organizations, including the Joint Commission, have recommended further enforcement of work-hour limits for both trainees and attending physicians [107].

Another well-known cause of impairment amongst anesthesiologists and anesthesia trainees is substance abuse. While the rates of alcoholism and other types of impairment are similar to those of other professions, impairment secondary to opioids is particularly problematic for anesthesiologists [108]. Additionally, impairment secondary to highly addictive drugs such as propofol, ketamine, and nitrous oxide has been described. Possible explanations for the high incidence of drug abuse amongst anesthesiologists include proximity to large quantities of highly addictive drugs, the relative ease of diverting particularly small quantities of these agents for personal use, the high stress environment in which anesthesiologists work, and exposure in the workplace that sensitizes the reward pathways in the brain and thus promotes substance abuse [109]. Designing better systems to monitor providers, peer-to-peer support systems, and continued education of providers about the dangers of impairment in addition to early recognition of impaired providers is vital to the safety of both the provider and patients.

The Second Victim

Recently, increased emphasis has been placed on ensuring the emotional well-being of the care team, known as the second victim, following an adverse event [110]. While analysis of adverse events is essential to the future prevention of similar events, it is important to not place blame on any one individual or group, as the root causes are generally multifactorial or systemic in nature [111]. It is vitally important for institutions to support providers after patients have been harmed and recognize at-risk personnel following adverse events and provide appropriate support in an attempt to prevent this second victim phenomenon [112, 113].

The Future: Coordination of Care and the Perioperative Surgical Home

The ASA has proposed the Perioperative Surgical Home (PSH) as a way to achieve better and sustained patient outcomes along the Institute of Healthcare Improvement's "Triple Aim": enhance quality, improve patient satisfaction, and decrease cost. Under this conceptual framework, the PSH can be defined as a patient-centered and physician-led multidisciplinary system that aims to prevent variability and fragmentation of care that could result in negative outcomes from the moment the patient is scheduled for surgery up to 30-days after discharge [114, 115]. This proposal aims to: standardize care; follow best-practice evidence; collect and report quality, safety, and cost data; improve outcomes; and decrease costs. The anesthesiologist is the ideal facilitator for this coordination of care along the perioperative continuum, as they already provide a degree of coordination between patients, other medical staff, and healthcare delivery institutions. Additionally, the specialty has a strong culture of safety and healthcare metrics [116]. The PSH will necessitate an expanded scope of practice for the anesthesiologist, not to replace the surgeon or abandon operating room responsibilities, but rather to be a leader in the perioperative continuum.

There have already been reports of successful implementation of PSH programs, most of them aligned by service lines although robust assessment of long-term impact are still scarce. The University of California at Irvine experience with

total joint replacements is probably the premier example [117]. Further expansion of the concept among anesthesiologists in addition to its integration into training programs is vital to ensure the sustainability of this effort. Changes in residency educational curriculums and even increasing the length of training might be required to transform anesthesiologists into true perioperative physicians [118, 119].

Strategies to make anesthesia care safer included within the PSH model include: adoption of reliability engineering principles, technological advancements in monitoring, setting up robust near miss reporting systems, applying critical event analysis tools such failure mode and effects analysis when adverse incidents occur, wide adoption of simulation and team training, deploying standardized medication, implementing robust handoff protocols, and adherence to the ASA and WFSA practice parameters. There is still considerable work to be done in order to make it practical and sustainable.

Conclusions

Anesthesiologists have been and will continue to be leaders in ensuring safe and reliable patient care. Through technological advancements in monitoring, training and assessment using simulation, and coordination of care via the perioperative surgical home, patient safety will continue to improve and preventable medical errors will be reduced. However, continued vigilance with regard to human factors and focus on systematic rather than personnel issues are vital to this reduction. The development of a safety culture and safety climate amongst all members of the perioperative team will result in medical errors no long being a leading cause of preventable morbidity and mortality.

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Enhanced Recovery After Surgery: ERAS

22

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"If you can't measure it you can't manage it."

—Peter Drucker

Abbreviations

CR	Colorectal
EDA	Epidural anesthesia
ERAS	Enhanced recovery after surgery
GI	Gastrointestinal
GNP	Gross national product
PCA	Patient-controlled analgesia
PD	Pancreaticoduodenectomy
PONV	Postoperative nausea and vomiting
QoL	Quality of life
UGI	Upper gastrointestinal

Background

Prolonged recovery from anesthesia, including longer hospital stay, higher morbidity, and poor outcomes, has plagued surgical recovery. In response, the ERAS—Enhanced Recovery After Surgery—was developed as a collaboration formed by a group of surgeons involved in research of perioperative care in Europe 15 years ago [1]. ERAS is an approach to perioperative care where a complex perioperative protocol consisting of several evidence-based interventions deployed by a multidisciplinary team interacts to enhance recovery after major surgical operations. The ERAS Study group set out to further develop perioperative care from the Fast-Track surgery work, initially described by the Danish surgeon, Professor Henrik Kehlet. Professor Kehlet published a case series of initially eight patients in 1995 [2] and later a larger cohort of patients undergoing open colonic resections, where half the patients were successfully discharged 2 days after the operation [3]. The concept used a multimodal approach to improve recovery [4] using a bundle idea first published in cardiac surgery. At the time (and to this day) [2], this report of such a short stay after major colonic surgery was a sensation as the average length of postoperative stay was much longer and still remains more than a week in many countries worldwide.

The ERAS group developed a perioperative care pathway for colonic and rectal resections based on the available literature on best perioperative care. A consensus paper was published in 2005 [5]. In the paper, 20 perioperative interventions, most with a high level of evidence, were recommended as part of the ERAS pathway. Since perioperative care can vary also within institutions with a traditional approach to perioperative care,

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some of these interventions would be regarded as normal practice in parts of the world but not in others. Some interventions were seldom adhered to such as balanced intravenous infusions or avoiding preoperative fasting by providing a carbohydrate drink [6]. Several joint studies were performed over the last decade including surveys showing that these practices were not being regularly used [7], and studies on how implementation of the ERAS protocol changed clinical practice [8]. The ERAS group formed a common database for these studies that later developed into an interactive audit system (see below). Based on the ERAS protocol, close audit and in collaboration with the CBO Kwaliteitsinstituut in the Netherlands, a series of implementation programs were run with great success. In the Dutch ERAS implementation study, more than 30 hospitals moved from an average compliance with the ideal ERAS protocol of 44–75 % adherence [9]. This change of practice was associated with a significant reduction in recovery time in postoperative length of stay from around 9–10 days to 6–7 days. The basis for this program was not only the ERAS recommendations but also active coaching of the units using new methodology [9]. Another key component was the multidisciplinary team approach involving surgeons, anesthetists, nurses, and also physiotherapists and dietitians. These initial efforts formed the basis of the ERAS Implementation Program run by the ERAS Society (see "Implementation" section).

The English National Health Service decided to support implementation of Enhanced Recovery in colorectal, orthopedic, gynecologic, and urologic major elective surgical practice during 2009–2012 [10]. An audit conducted after this large-scale program of more than 24,000 patients demonstrated that improved compliance with the ERAS pathway was associated with reduced length of stay in colorectal, orthopedic, urologic but not in gynecological surgery [10].

A 2010 meta-analysis demonstrated reduced length of stay and reduced postoperative complications in ERAS vs. traditional care [11]. A more recent meta-analysis showed a reduction in complications of around 40 %, mainly in medical complications in colorectal surgery when using ERAS [12]. Similarly, the length of stay was reduced by 2.3 days, or roughly 25 %.

In 2010, the enhanced recovery after surgery (ERAS®) Society for Perioperative Care (www.erassociety.org) was registered as a nonprofit medical society. Surgical units from a growing number of countries are currently included in a worldwide network of professionals employing and developing the ERAS pathway. The ERAS Society is a multi-professional and multidisciplinary medical society with an aim to develop perioperative care by research and education but also by actively supporting hospitals worldwide to implement ERAS principles. An important part of this program involves helping the units to get full control over their practice by employing an interactive audit tool developed based on the ERAS Society guidelines [13–18]. To date, there are about 30 surgical centers from 16 countries that are leading the development of the ERAS practice. The ERAS Society has so far held three annual world congresses on ERAS. In some countries, national Societies were formed early such as the ERAS UK, Fast-Track Surgery group in Spain, ERAS Canada, and ASER in the USA. Many of these national groups have run events jointly with the ERAS Society.

Part of the success of ERAS relates to the growing evidence of not only major improvements in outcomes for the patients, but also marked savings for the health provider and funders of health care. This is particularly timely given the fast growing and unsustainable increase in health care costs worldwide. Several reports in the last few years indicate major savings when employing the principles of ERAS [19]. This is mainly related to less need for intensive care, reduced complications, reduced costs for pharmacotherapy and parenteral nutrition, and the reduced need for hospital beds [19]. A main mechanism behind the functionality of ERAS is the stress reducing effect of the protocol elements [20]. Many of the ERAS protocols dampen the classical stress reaction with stress hormone release and inflammatory responses thereby reducing the catabolic reactions and insulin resistance, otherwise developing as a response to surgery [21]. By combining several of these elements using a multimodal approach, the ERAS

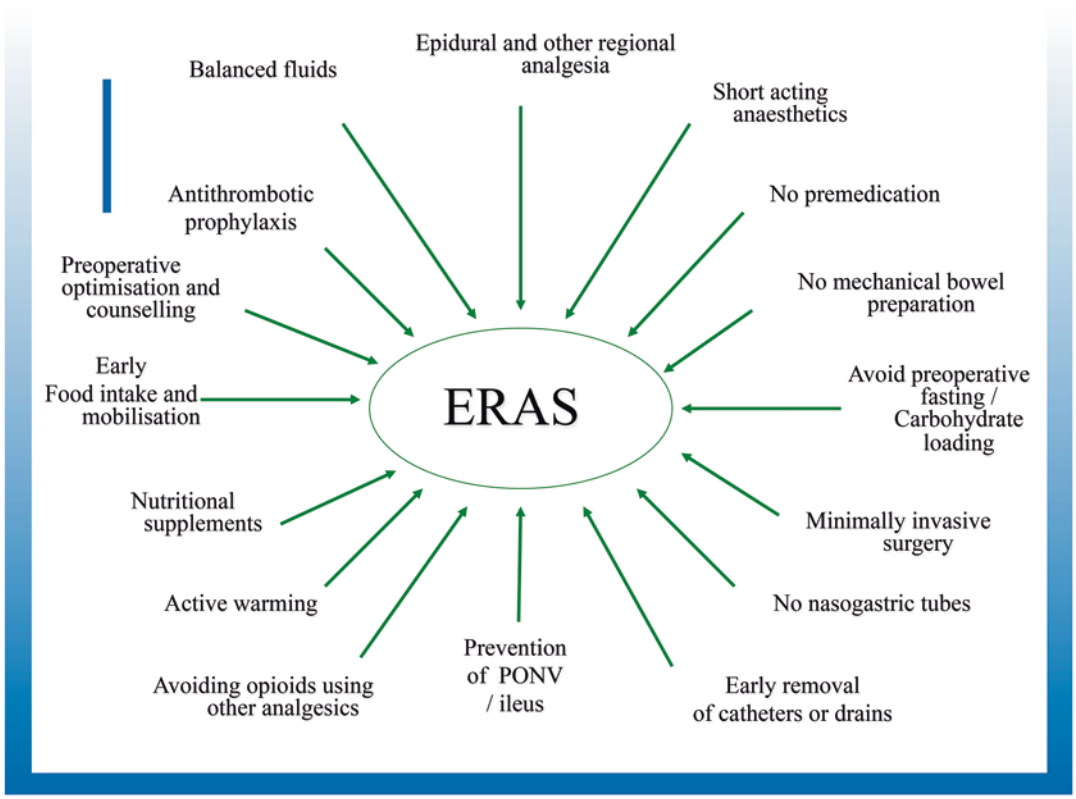

Fig. 22.1 Interventions involved in multimodal ERAS protocol in open colorectal surgery. Adopted from Fearon et al. (2005) [5]

protocol may effectively minimize the stress response (Fig. 22.1). This maintained homeostasis for metabolism and fluid balance support return of organ function and thus complications are avoided. The ERAS protocol has been shown to effectively reduce complications, as well as symptoms that keep the patient in the hospital, such as pain and/or nausea [22].

The ERAS Protocol: Individual Items

Items are summarized in Table 22.1.

Preoperative Optimization

Advances in surgical and anesthesiological care have allowed major surgery to increasingly be offered to the ageing population as well as in subjects with substantial comorbidity. Thus, in order to reduce risk and to improve clinical outcome in this group of patients, a thorough preoperative preparation and optimization is necessary. This includes a detailed assessment of comorbidity and multidisciplinary involvement in the optimal treatment of *hypertension, cardiac and respiratory function* [20, 23]. *Glucose control* should be evaluated using fasting blood glucose or HbA1C levels [20, 23]. Also in nondiabetic individuals, an increased or borderline-increased HcA1C was associated with a threefold increase in postoperative complications after colorectal surgery [24]. In case of *anemia*, the need of iron supplementation should be considered. Malnourished patients have a high risk of postoperative complications and benefit from *preoperative nutritional support*, which in most patients is tolerated using the oral route [15]. There is evidence that pharmaconutrition/immunonutrition (supplements

Table 22.1 Interventions included in ERAS protocol in GI surgery

Preoperative	Preoperative optimization
	Prehabilitation and exercise
	Cessation of smoking and alcohol use
	Preadmission counseling
Intraoperative	No oral bowel preparation
	Preoperative carbohydrate loading
	Antimicrobial prophylaxis and skin preparation
	Avoiding sedative premedication
	Balanced fluid therapy
	Active warming
	Minimally invasive surgery
	No abdominal drains or nasogastric drains
Postoperative	Epidural or other regional anesthesia
	Multimodal analgesia to avoid opioids
	PONV prophylaxis
	Early removal of urinary catheter
	Thromboembolism and antimicrobial prophylaxis
	Early oral feeding and intense mobilization
	Nutritional supplements
	No intravenous infusions
	Support of GI function (laxatives/prokinetics)
	Audit

PONV postoperative nausea and vomiting, *GI* gastrointestinal

containing specific nutrients such as arginine, glutamine, Ω-3 fatty acids, and others) may reduce postoperative infection rates and hospital stay in patients undergoing major abdominal surgery [25]. This intervention may be considered in subjects undergoing procedures associated with a high risk of postoperative infection regardless of preoperative nutritional status.

Prehabilitation and Exercise

Prehabilitation comprises preoperative physical conditioning to improve functional and physiological capacity in order to enable patients to recover sooner after surgical stress [20]. A systematic review evaluated the effects of preoperative exercise therapy on postoperative complications and length of stay in surgery of all types [26]. In patients undergoing cardiac, orthopedic, and abdominal surgery, a meta-analysis indicated that prehabilitation led to a reduced length of stay and improved physical fitness. Although the applicability of these studies to patients undergoing specific colorectal or upper GI surgery procedures is unclear, they may be a promising concept.

Smoking and Alcohol Cessation

Tobacco smoking is associated with an increased risk of postoperative morbidity and mortality, attributed mainly to reduced tissue oxygenation (and consequent wound infections), pulmonary complications, and thromboembolism. A recent Cochrane review concluded that cessation of smoking, preferably at least for 4–8 weeks before surgery, was associated with marked reductions in postoperative complications (Intensive care unit intervention, effects on any postoperative complication: RR 0.42; 95 % CI 0.27–0.65) [27]. In addition, hazardous drinking, defined as intake of three alcohol equivalents (12 g ethanol each) or more per day, has long been identified as a risk factor for postoperative complications. Alcohol abstinence for 1 month has been associated with better outcome after colorectal surgery [28]. Available ERAS guidelines for colorectal and upper GI surgery, therefore, recommend cessation of alcohol for abusers and tobacco use in all patients 4 weeks prior to surgery. In bariatric and other benign major abdominal surgery, even longer periods of alcohol abstinence are usually recommended in patients with history of alcohol abuse.

Preoperative Information, Education, and Counseling

Preoperative information and/or a visit to the surgical ward have been shown to reduce anxiety, and improve compliance with postoperative instructions, postoperative recovery, length of

stay, and long-term outcomes after various types of surgery [15]. Although data from studies specifically evaluating the effect in specific procedures such as in upper gastrointestinal surgery are sparse, preoperative counseling is part of currently published ERAS guidelines.

Intraoperative Care

Mechanical bowel preparation before colorectal surgery has been extensively evaluated, and generally abandoned since it provides no benefit [15]. In patients with a planned diverting loop ileostomy after low anterior resection, mechanical bowel preparation is still recommended to avoid remaining stools in a diverted colon [25].

Preoperative Fasting and Preoperative Treatment with Carbohydrates

Fasting from midnight before elective surgery is not supported by evidence, and therefore, in most guidelines has been replaced with guidance for fluid intake of clear fluids up to 2 h prior to induction of anesthesia [29]. Solids should, however, be withheld until 6 h before operation to prevent risk of aspiration. A preoperative carbohydrate-rich drink given up to 2 h before anesthesia has been shown to reduce preoperative hunger, thirst, and anxiety [30]. In addition, PONV [31] and surgical stress as measured by postoperative insulin resistance and protein catabolism are improved and length of stay is reduced, with the most pronounced effect after major surgery [6]. Avoiding preoperative fasting using carbohydrate loading is therefore recommended in current ERAS guidelines for colorectal surgery, gastrectomy, pancreaticoduodenectomy [14–16], and bariatric surgery [13].

Antimicrobial Prophylaxis and Skin Preparation

Prophylactic antibiotics reduce infectious complications. Patients should receive a single dose orally or intravenously at least 30 min before skin incision [15]. Repeated dosing can be administered depending on the half-life of the drug and the duration of surgery. The skin should be prepared with chlorhexidine–alcohol [15].

Preanesthetic Medication and Anesthetic Management

There is no convincing evidence in the literature of the benefits from long-acting sedatives prior to surgery and their use is therefore not recommended. Short-acting anxiolytics might be used, in particular to facilitate procedures such as insertion of epidural catheters. The data from studies comparing various anesthetic protocols is sparse. However, the use of short-acting induction agents such as propofol and opioids such as sufentanil is usually recommended and included in available ERAS anesthesiological [20], colorectal [15], and upper GI guidelines [20]. In addition, short-acting muscle relaxants are widely used. In particular in laparoscopic surgery, deep neuromuscular block is helpful in order to ensure surgical access. In order to avoid deep sedation, a Bispectral Index (BIS) might be used for titration of anesthetic agents although the evidence for its efficacy is limited.

Perioperative Fluid Balance

Near-zero fluid balance, avoiding salt and water overload, has been shown to result in improved outcomes [20, 23]. Vasopressors should be considered as first choice to treat hypotension to avoid unnecessary fluid overload. Goal-directed fluid therapy is recommended to obtain optimal tissue perfusion and in high-risk patients Doppler-guided techniques might be used in order to improve outcome [32], even though the benefits are unclear in patients already managed within an ERAS pathway.

Avoiding Hypothermia

There is convincing documentation of benefits associated with prevention of hypothermia in

terms of reducing complications as well as improving postanesthetic recovery [33]. This is usually achieved by the use of active cutaneous airborne heating systems (Bair-hugger) or circulating-water garments. Avoidance of hypothermia is of particular importance in surgical procedures with long operating times such as pelvic procedures or pancreaticoduodenectomy, whereas the effects might be less pronounced in, for example, uncomplicated laparoscopic bariatric surgery [34].

Access

Minimally invasive surgery reduced damage to tissues by changes in surgical access [20]. In open surgery, the length and orientation of incision affect pain and may influence surgical outcomes [20]. The extent of the injury to abdominal wall is further reduced using minimally invasive techniques such as laparoscopy which has been evaluated for the treatment of colorectal cancer in randomized trials [35, 36]. The safety and overall value of robotic surgery remains unclear although present evidence suggests higher costs and at least similar rates of complications [37]. We are awaiting results from a large multicenter (RCT: ROLARR, ClinicalTrials.gov. Identifier: NCT01736072). Other minimally invasive options such as Trans-anal TME, SILS, or NOTES are still under evaluation.

In bariatric surgery, laparoscopy has rapidly superseded open surgery due to improved outcome in terms of reduced complications and improved recovery [38]. For distal gastrectomy, there is evidence supporting the use of laparoscopic-assisted surgery in early gastric cancer, whereas more data on long-term survival after laparoscopic compared to open surgery in advanced disease is still awaited [14]. In total gastrectomy, laparoscopic-assisted approach might be used if expertise is available, since it has been shown to reduce complication rates and improve patient recovery [14]. Although laparoscopic resection of the pancreatic head has been shown to be feasible, too little data is available on oncological outcomes after laparoscopic pancreaticoduodenectomy to recommend its routine use.

Nasogastric Tube and Abdominal Drains

A Cochrane meta-analysis concluded that routine nasogastric intubation following open abdominal surgery should be abandoned in favor of selective use [39]. A subgroup analysis of nine RCTs with 1085 patients that underwent gastroduodenal surgery found increased pulmonary complications associated with routine use of postoperative nasogastric tube. In addition, intra-abdominal or pelvic drains have no advantage in colorectal surgery [15] although the evidence in pelvic procedures was based on a small number of patients. However, a large multicenter RCT of prophylactic pelvic drains in low anterior resection (GRECCAR 5, ClinicalTrials.gov Identifier: NCT01269567) was recently completed and preliminary data (Presented by Dr. Denost at ESCP in Dublin, at International Trials Symposium, September 23rd, 2015) show no effect of pelvic drains on the incidence or severity of anastomotic leakage. Perianastomotic drains have not been shown to reduce overall complication rates in pancreatic [40] or gastric cancer surgery [41], and are associated with slower recovery [42]. Similarly, no advantages were shown by the use of abdominal drain after gastric bypass for morbid obesity. Thus, no convincing evidence supports the routine use of postoperative drains after upper gastrointestinal surgery. In contrast, the use of a passive *subcutaneous drain* was associated with a reduction in superficial surgical site infections in a randomized study of 263 patients undergoing open or laparoscopic colorectal surgery [43].

Urinary Catheter

The duration of urinary drainage should be as short as possible, and the catheter can in most cases be removed within 24 h after colorectal surgery without increased incidence of urinary retention [15]. Early removal with intermittent urine drainage as needed has been shown to be safe also in patients with thoracic epidural analgesia [15]. When urinary catheterization of more than 3 days postoperatively is expected (i.e., some pelvic procedures), a

suprapubic catheter seems the better choice [15]. The optimal duration of ureteral stents and transurethral neo-bladder catheter after radical cystectomy is still unknown [18].

Postoperative Care

Postoperative Analgesia

Comprehensive ERAS guidelines for anesthesia practice in gastrointestinal surgery have recently been published [20]. In open abdominal surgery, epidural analgesia (EDA) has been shown to provide superior postoperative pain control compared with opioids as well as patient-controlled intravenous opioid analgesia (PCA). Moreover, the EDA was reported to be associated with fewer episodes of postoperative ileus, pulmonary complications, and improved insulin sensitivity. A thoracic EDA is recommended in ERAS guidelines for open colorectal and major upper GI surgery such as pancreaticoduodenectomy and gastrectomy. Studies evaluating the use of EDA in open liver resections are sparse. The EDA in laparoscopic colorectal procedures where skin incision and abdominal wall injury is kept minimal has been questioned. In addition, there is no consensus regarding the value of EDA in laparoscopic upper abdominal surgery, such as gastric bypass. In situations where an EDA cannot be used, a PCA is the most commonly used alternative after open abdominal surgery although other alternatives, including various techniques for regional anesthesia and intravenous lidocaine infusion, are recommended in ERAS guidelines [20, 23]. After cessation of EDA or PCA, multimodal systemic analgesia should be used including non-opioid analgesics such as paracetamol and NSAIDs. For opioids, when necessary, the enteral routes should be used as soon as possible.

Postoperative Nausea and Vomiting (PONV)

Although mainly extrapolated from studies in colorectal surgery, available data suggest that patients at risk of PONV should be treated with a multimodal approach with the use of antiemetics according to patient risk factors [20, 23]. This includes the use of propofol for induction of anesthesia and avoidance of volatile anesthetics, opioids, and fluid overload. The recommended antiemetics for PONV prophylaxis vary in their efficacy and include 5-hydroxytryptamine receptor antagonists, corticosteroids, butyrophenones, neurokinin-1 receptor antagonists, antihistamines, and anticholinergics [44].

Antithrombotic Prophylaxis

The risk factors for venous thromboembolism (VTE) include major surgery, malignant disease, and obesity. Therefore, patients undergoing major colorectal and upper GI surgery are at risk. Low molecular weight heparin (LMWH) is effective at preventing VTE and advantageous compared to unfractionated heparin due to its once-daily administration. Mechanical methods such as intermittent pneumatic compression or graduated compression stockings may be used as an adjunct in patients who are at moderate or high risk for VTE. LMWH treatment is usually initiated either the evening before, or within 6 h postoperatively and continued at least until patients are fully mobile. After major open surgical procedures 4 weeks treatment is usually recommended, whereas 7 days is usually considered sufficient after laparoscopic surgery. The risk of spinal or epidural hematoma in patients with EDA should be considered and a 12 h interval between LMWH administration and catheter insertion or removal should be adhered to.

Early and Scheduled Mobilization

Major open abdominal surgery is associated with long recovery time even in the absence of complications. Prolonged immobilization/bed rest is associated with several adverse effects and should be avoided although scientific data is lacking [20, 23]. Day-to-day targets for mobilization should be defined and progress monitored

and documented. Satisfactory pain control is mandatory in order to achieve adequate mobilization. In patients undergoing laparoscopic surgery, early mobilization is normally much easier to achieve, and usually possible within a few hours after surgery [20, 23].

Early Oral Intake and Stimulation of Bowel Movement

Early oral intake has been shown to be safe and most often feasible after major colorectal as well as upper gastrointestinal surgery [20, 23] and should therefore be encouraged. However, in the presence of impaired gut function, enteral or parenteral nutritional support might be necessary, in particular if complications occur. Return to oral intake should be aimed for as soon as possible. The need for motility-enhancing drugs is usually not required after upper GI surgery compared with after colorectal surgery. Although commonly used after colorectal surgery, only some fast-track programs for pancreatic surgery include the use of laxatives postoperatively, and there is limited documentation of the effectiveness of such regimens after gastrectomy and hepatic surgery.

Discharge

Patients can generally be discharged when they tolerate adequate oral intake, when they are fully mobilized and when pain can be managed with oral analgesics. Sufficient time should be provided for the patient to independently manage a new stoma. After early discharge, patients should be contacted by a nurse after 2–3 days, to assure that rehabilitation is progressing well. Usually another contact 30 days postoperatively is useful in order to assure a normal postoperative course and to prevent hospital readmissions [45].

Audit

A structured audit on perioperative care and clinical outcome is essential for maintaining a successful ERAS program. Using the International ERAS database facilitates this process through a detailed registration on the perioperative care, and the clinical outcome of the patients in combination with a clique view statistical ad on that provides an easy and immediate feedback and analysis of registered data (http://www.erassociety.org/).

Implementation of an ERAS Program

Given the growing evidence of improved outcomes using the ERAS protocol, it would seem likely that these principles would be adopted without delay. However, implementation of ERAS involves overcoming many barriers to change in care including many routines that may have been in use for a very long time [46]. Many units like to believe that they already practice ERAS while in fact a careful study of their actual perioperative practice might reveal that only some elements of the ERAS protocol are in use and that clinical outcomes are on a level similar to what is found in traditional care. This may also be reflected after review of the average hospital length of stay data. In the UK and Sweden, where most surgical units would claim that they are using ERAS, postoperative stay after resections for colonic cancer is currently averaging eight days (as shown in the national colorectal cancer registries). In France, these figures are similar or even higher. Since minimally invasive techniques are gaining momentum, recovery should be earlier also in traditional practice. In contrast to these national figures, surgical units using a more complete ERAS protocol report postoperative length of stay of around 3–4 days after colonic resections with minimal invasive surgery, and as short as 2–3 days in the most advanced units [47].

It is often stated that medical practice is very slow to change and it may take 15 years for a fully established proven novel care to get in full use. Surgery and anesthesiology are no exceptions to this [7, 48] rule due to barriers to behavior change and adoption of new concepts [49]. A very well-known example is the use of overnight fasting as a way of protecting patients from aspiration. This routine was introduced in the early days of surgery

and has no scientific backing. When the routine was challenged in the 1980s and 1990s, numerous studies demonstrated clearly that patients could be allowed to drink clear fluids up to 2 h before elective surgery [29]. In fact, gastric volumes were lower since intake of clear drinks stimulates gastric emptying. Anesthesia guidelines in the last 20 years have advocated the novel routine of 6 h fasting after intake of solids and 2 h for clear fluids [29]. Nevertheless overnight fasting is still in use in many hospitals worldwide. Similarly, some surgeons still use postoperative drains and nasogastric tubes despite grade A evidence that these are not useful as prophylactic measures after colorectal surgery [50].

Similar to what have previously been raised about surgical checklists, Rapid Response teams, CLABSI, and more, the methodological challenges of evaluating complex social interventions such as the ERAS program are presently been managed within the ERAS community (http://www.erassociety.org/). In planning future surgical care, more advanced collaboration between care providers, medical academia, and clinical institutions will provide further optimization on perioperative care and a more complete appreciation of the organizational culture [51] and evaluation of implementation interventions and their outcomes after major surgery [52].

Although there are currently many units that have implemented ERAS, many hospitals are still practicing perioperative care in a more traditional fashion [7, 48]. The ERAS Society has developed a protocol to introduce and fully implement ERAS. An ERAS Implementation Program may be organized by a national center following a careful identification of the implementation strategies [52]. For each hospital a multidisciplinary team is gathered and trained to work as an ERAS team using robust scientifically validated team training methods [53]. The team is often supervised by a physician, usually a surgeon or anesthetist, but the ERAS coordinating nurse is also a key person in this team. The ERAS nurse coordinates the group activities and the continuous audit. The team should have support from management to get the required resources for successful implementation of ERAS.

The ERAS Society Implementation Program is performed as a series of four workshops over a period of 8–10 months involving several teams for each implementation program. In between the workshops the participants make the changes needed in their practice to improve adherence to the ERAS protocol. This requires careful planning from the team under guidance and coaching from ERAS experts with experience in both the ERAS concepts and implementation issues [54]. The coaching needs to be individualized to meet the specific needs at hand. The ERAS Society has developed a web-based IT system for continuous Interactive Audit. All ERAS teams use the same system and record data on all their consecutive patients into the system. The teams can easily review details of their practice, review changes over time, and make changes in practice accordingly.

Economics of ERAS

Health care is under growing financial and political pressure worldwide. In some countries, the cost for health care has risen to 18 % of the GNP and in most countries they are rising [55]. Obviously this is not sustainable, and major changes to control staggering costs are taking place, not least in the USA. The demand on health care is also rising from a growing elderly population and increasing demands for better results. So the challenge facing health care providers today is to provide better care for an older population at a lower cost.

Several reports demonstrate major cost reductions when employing ERAS [56]. Most of these studies have used calculations from ERAS in colorectal surgery, but other surgical procedures such as esophageal resection, liver and pancreas surgery, as well as major gynecology are showing the same trends of substantial savings. In general, the savings are in the range of 1500–4500 USD depending on where the study is done and how the calculations were made [57]. Most commonly the savings are calculated on the basis of reduction in hospital days or reduced need for ICU stay and sometimes reoperations and readmissions. Data

from a detailed analysis is available from a group in Switzerland [58] where all costs were calculated including the cost of changing from open to laparoscopic surgery, the cost for the ERAS team, the training, etc. This analysis showed that it took 20 patients to cover the cost associated with implementation of the ERAS program. In the first 50 patients the savings were approximately USD2000 per patient. The variation in savings is usually dependent on the effect of the implementation with regard to length of stay and complications. Thus, pancreatic surgery has been reported to be more cost-effective with ERAS than gynecologic surgery. Still, surgery of any magnitude is likely to show cost-effectiveness [59–61].

Research Outcomes and Quality of Life

The overwhelming majority of studies in ERAS have focused on short-term outcomes such as length of stay and complications. However, only a few studies have reported data on outcomes beyond 30 days including quality of life beyond 30 days. These data are urgently needed to help improve quality of care, public reporting and increased value of surgical care [62]. With the proven effects of ERAS in the short term, there is a growing interest in the potential long-term effects (Summary of research issues related to ERAS in Table 22.2). The primary goal for the patient is to be cured from his/her disease and to recover sufficiently to be able to return home. Thereafter the focus shifts to being able to go back to normal function and activity. While it may seem likely that, if early recovery is improved, recovery in the long term would be improved as well, there is no data to confirm this hypothesis. Patient-centered outcomes [63], such as the Patient Quality Recovery System, which is available for research online (www.pqrsonline.org), may provide valuable information on such outcomes. However, these studies still need to be done.

Table 22.2 Research issues related to ERAS

Short term	Recovery
	Hospital stay
	Clinical outcomes
	Cost-effectiveness
Medium term	QoL
	Postdischarge recovery
	Need for assistance at home
	Time off work
	Cost-effectiveness
Long term	QoL
	Long-term functional outcome
	Survival
	Cost-effectiveness

There is also a growing interest in long-term outcomes after ERAS. Reports from large databases in the USA show an association between a complication occurring after surgery and long-term morbidity [64]. Patients with a complication have a much lower life expectancy than patients without complications. This difference remains in patients surviving the first 30 days postoperatively, and the survival curves continue to diverge during a follow-up of 10 years after the operation. There is also a growing interest in the effects of perioperative treatment on long-term cancer survival rates.

There are only a couple of reports showing associations between the ERAS protocol and improved long-term survival. With the introduction of ERAS protocols in hip and knee replacement, the 2-year survival had improved in 1500 consecutive patients compared to 3000 controls before the introduction of ERAS [65]. In a cohort of more than 900 patients undergoing colorectal cancer surgery under the ERAS pathway, a higher compliance with the ERAS protocol was associated with improved 5-year overall and cancer-specific survival [66]. Although these studies may not show cause and effect, they raise important questions about causality and long-term benefits of ERAS.

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The Next Frontier: Ambulatory and Outpatient Surgical Safety and Quality

23

Beverly A. Kirchner

"Knowledge and error flow from the same mental sources, only success can tell the one from the other."

—Mach, 1905, p. 84

Introduction and Overview

The Centers for Medicare and Medicaid Services ("CMS") defines the Ambulatory Surgical Center ("ASC") in the Conditions for Coverage that can be found on their website www.cms.gov. The CMS defines an ASC as "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 h following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B §§ 416.25–416.35 and C §§ 416.40–416.52 of [42 CFR Part 416 of the CMS Federal Register]" [1]. Note the key phrase in the CMS definition "distinct entity that operates exclusively for the purpose of providing surgical services" [1, 3].

ASCs are highly regulated healthcare facilities that are focused on the quadruple aim: improving the patient experience of care (including quality and satisfaction), improving the health of populations, reducing the per capita cost of healthcare and improving the experience of providing care. Therefore, in 2006, healthcare leaders from the ambulatory industry and associations with a focus on healthcare quality and safety formed the ASC Quality Collaboration ("ASC QC"). The ASC QC has worked closely with the National Quality Forum ("NQF") to obtain endorsement of quality indicators that are significant to ASCs. The ASC QC has recently expanded to work with other organizations to continue assisting in the development of quality indicators for specialties such Gastrointestinal, Ophthalmic, Pain Management, Orthopedics, and Anesthesia. To date, CMS has adopted many of the quality indicators the ASC QC has helped to develop and ASCs are required to report results of the quality indicators if the ASC performs 249 or more Medicare cases annually. The measures developed by the ASC QC include both outcome and process measures. An "outcome measure" assesses patients for a specific result of healthcare intervention. A "process measure" evaluates a particular aspect of the care that is delivered to the patient" [2].

The ASC QC has helped develop the following seven outcome measures:

1. Patient fall in the ASC.
2. Patient burn.
3. Hospital transfer/admission.
4. Wrong: site, side, patient, procedure, implant.
5. All cause hospital transfer/admission.
6. Normothermia.

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7. Toxic anterior segment syndrome ("TASS"; a rare and devastating complication of intraocular surgery) [2].

The ASC QC has also helped develop the following two infection control process measures:

1. Appropriate surgical site hair removal.
2. Prophylactic intravenous ("IV") antibiotic timing [3].

The ASC QC does a great job of keeping its website, ascquality.org, current and can be used as a resource for ASCs wishing to perform external benchmarking. The ASC QC also provides guides and other resources to help ASCs successfully accomplish the task of tracking and reporting the quality indicators.

The ASC Quality Reporting program ("ASCQR") was developed to enact safety measures that assessed patient outcomes. In the ASCQR, the ASC is required to report all data collected. Failure to report data results in a reduction of the ASC's Medicare payment amount.

Currently, ASCs are required to track and report on 12 measures (see Table 23.1). Each ASC must track and then compare and report the results to their Governing Board and CMS through Claimed Base Reporting, Quality Net, and the National Healthcare Safety Network ("NHSN"). The ASC leadership team must ensure that the staff member(s) managing the Quality Assessment Performance Improvement program ("QAPI") receives specialized education annually and is given appropriate time and space to work to accomplish the requirements.

ASCs must be proactive in developing a comprehensive, ongoing QAPI program. The program must be data driven and show that the ASC is improving quality of care and providing a safe environment for the patient, visitors, and staff. The quality improvement program evaluates the processes in which tasks are carried out and identifies the potential for future process failures. Every member of the staff should be educated on how to identify a potential process failure and report the problem. In addition, all staff members need to be educated on how to evaluate a process for a potential failure or how to evaluate a process that has failed. The goal of the QAPI program is to be able to identify potential process issues before they actually have caused patient harm. While it is generally accepted that most ASCs are excellent at collecting data, the real change happens when the ASC begins using the data collected to improve processes and decisions. Therefore, the key to a successful QAPI program is knowing how to use the data collected and implementing the correct changes.

Table 23.1 Measures ASCs are required to report in ASC Quality Reporting (ASCQR)

ASC-01	Patient burn
ASC-02	Patient fall
ASC-03	Wrong site, wrong side, wrong patient, wrong procedure, wrong implant
ASC-04	Hospital transfer/admission
ASC-05	Prophylactic IV antibiotic timing
ASC-06	Safe site surgery checklist use
ASC-07	ASC facility volume data on selected ASC surgical procedures
ASC-08	Influenza vaccination coverage among healthcare personnel
ASC-09	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk patients
ASC-10	Endoscopy/polyp surveillance: colonoscopy interval with a patient with a history of adenomatous polyps—avoidance of inappropriate use
ASC-11	[Voluntary reporting] cataracts—improvement of patient's visual function within 90 days following cataract surgery
ASC-12	Facility 7-day risk standardized hospital visit rate after outpatient colonoscopy [21]

Factors That Drive a Culture of Safety in an ASC

Building a culture of safety in an ASC is a team effort. The ASC is an environment where the staff members, physicians, guests, and vendors must all work together to provide safe, quality care for the patient. The ASC leadership team, overseen by the Administrator, runs the day-to-day operations. The Administrator is granted the authority by the Governing Board to oversee day-to-day operations and make decisions that impact quality and safety. CMS states that, "The ASC must have

a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation." The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops and maintains a disaster preparedness plan" [4].

Culture begins at the top and filters down to every employee, surgeon, and anesthesia provider working in the ASC. Lucian L. Leape, MD says, "Management must 'manage' for patient safety just as they manage for efficiency and profit maximization. Safety must become part of what a hospital or healthcare organization prides itself on" [5]. The mission of every ASC should be to encourage the sharing of knowledge freely; thus optimizing patient safety practices. The staff members must be empowered by leadership to speak up and support patient safety.

Typical characteristics found in ASCs that embrace a safety culture:

- The team embraces patient safety goals and processes. They understand how to implement process and procedural changes that support the delivery of patient care [6].
- The ASC team establishes a patient safety program that is well defined and supports communication. Communication should be clear and convey a strong commitment to safety. The ASC safety programs have well-defined objectives. The ASC should have at least one person dedicated to collecting and analyzing safety data. The data and suggested changes are reported through the QAPI Committee to the Medical Executive Committee to the Governing Board. The Governing Board must see and understand that the Quality and Safety program are essential to patient care. The Governing Board must provide the resources needed to maintain the program [6].
- The ASC team willingly discusses patient safety. Team members seek out the means to assure communication is appropriate and enforce the ASC's goals addressing patient safety. Team members feel they are valued and respected when they speak up. Team members actively encourage patients and family members to participant in patient care [6].
- The ASC is transparent and discloses to the patient and family what error(s) was made and the potential consequences of the error. Embracing transparency is woven into the ethical and moral responsibility of the ASC organization. The ASC leadership team communicates to the Governing Board errors and other safety problems. The Governing Board provides support to the team to resolve the problem and provides resources to prevent further errors.
- The organization promotes a blame-free environment.

Typical characteristics found in a blame-free environment:

- The organization embraces the concept that most errors occur as a result of flawed systems or processes, not flawed people.
- The ASC rewards the team for reporting of errors, near misses, and safety concerns.
- The organization educates and reeducates its staff every time a process change is made.
- Prevention of errors is one of the ASC's key focus points.

Typical characteristics found in an ASC that focuses on safety:

- The ASC is proactive in looking for ways to improve safety in every process used in the center.
- The ASC incorporates checklists, protocols, and defined work processes.
- The ASC embraces the process of "hand[ing]-off" a patient from one caregiver to the next caregiver using a specialized handoff checklist.
- The team encourages the patient to participate in the handoff by encouraging the patient to "speak up" if something said is not accurate.

Resolving conflict among caregivers is imperative to the culture of safety. If staff members are not trained to deal with conflict, then the environment has the potential to become toxic with characteristics such as bullying, gossiping, and sabotage becoming the norm. An ASC can be a high-stress area to work. The fast pace of work performed in an ASC creates an environment ripe for potential conflict. The staff needs to be taught how to deal with high-stress levels and to communicate their needs in a respectful manner. Leadership needs to be held accountable for recognizing issues early on and help the team members having a conflict deal with the issues openly and properly [7, 8].

Building a culture of safety takes an entire team and leadership must be actively involved and support the team. Everyone must be held accountable for their actions and decisions without resorting to the "blame game." Policies and procedures must be written clearly and describe the how they will be met by the ASC staff. Safety should not be a topic that is only addressed quarterly when reports are due. Safety needs to be addressed in an ongoing fashion. Reviewing documents and processes, auditing for compliance to policies, and the use of checklists are essential for leadership to be able to identify gaps and address them in a timely before a safety issue actually occurs [9].

Quality Assessment Performance Improvement

A Quality Assessment and Performance Improvement ("QAPI") program is the key to an ASC practicing safely. The Risk Management, Pharmacy, Safety and Infection Prevention committees report to the QAPI committee within an ASC. However, QAPI is only somewhat protected from discovery in case of a potential or actual malpractice suit or other lawsuit as some states do not honor the confidentiality of the QAPI process. Other states, including the federal government, see QAPI as important to improving patient care and solving problems and encourage ASCs to follow the process by allowing organizations to keep the information confidential. Some healthcare leaders feel that if the QAPI process is not held confidential, many healthcare facilities would not fully investigate or report problems. Without the investigation and reporting of problems, the ambulatory industry would be setup to make the same errors over and over again with the potential to harm patients. However, most facilities are afraid to share errors and lessons learned for fear the public would find out and competitors would use the information against them. If the ambulatory industry felt safe to share errors and potential solutions many more errors could be prevented.

CMS says, "The ASC must develop, implement, and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program" [10]. The QAPI program must be proactive. In order to be proactive, the leadership team must provide time for the QAPI Coordinator and the QAPI committee members to meet, review, audit, and follow-up on issues identified. The committee needs to be provided space so that the group can hold confidential conversations, review and analyze data, make recommendations (solutions), and setup studies to test recommendations (solutions) to confirm the validity of the improvement that it provides a safer process.

The ASC's Governing Board must identify QAPI priorities for the center. The priorities must focus on high risk, high volume, and problem-prone areas in the ASC such as the preadmission process where there is such a high volume of interviews performed. Then a preadmission process analysis is completed each month on the effectiveness of the interview process. The QAPI Committee could look at the analysis and see how many patients canceled on the date of service and how many patients were transferred to the hospital after surgery and why. The priorities set by the Governing Board must consider how often the ASC could experience an incident and the severity of the incident if experienced. The Governing Board is obligated to look at the potential patient outcomes, patient safety failure opportunities, and the quality of care the ASC is providing.

The QAPI Committee members need to be educated in conducting comprehensive audits, data analysis, and reviews of errors. If the facility leadership team neglects educating the QAPI committee members on how to be effective committee members, the result is a QAPI program that does not meet the CMS requirements for certification and does not promote patient safety. The key to a successful QAPI program is the committee members being proactive and taking their responsibilities seriously.

The QAPI committee must understand how to perform root cause analyses. When performing a root cause analysis, the committee must avoid treating the "symptoms" of the problem. By using the root cause analysis approach, the committee will focus on the origin of the problem and thereby have the information needed to fix the problem whether it be process or system related. The goal of using the root cause analysis process is to determine what happened, why it happened, and how to reduce the risk of it happening again. What you hope to determine is whether the reason for the error or near miss was physical (i.e., tangible goods failed), human factors, or a system failure; keeping in mind that it could be any combination of the three. The end goal is to discover what factors truly contributed to the specific problem. Keep in mind the root cause analysis could reveal more than one problem that will need to be addressed.

Once the root cause analysis is completed and the information reviewed, the committee must go one step further and determine how to implement the solution(s). A point person should be assigned to be responsible for the implementation, education, and changes required. The committee should determine if there are any risks in implementing the solution. If risks are identified, the committee must review the risk(s) and determine if the solution is the proper path forward. The process used to determine the risk of a solution is called the cause-and-effect process. Using the cause-and-effect process the QAPI committee will be able to plan ahead and resolve problems before they occur, thereby making it safer for the patient.

Other useful tools at the QAPI committee's disposal: Failure Mode Effects Analysis ("FMEA") that helps identify potential areas of failure in a process, rank the failures, and correct them before a failure occurs [11]; Impact Analysis that helps the committee explore the possible consequences of a change; Kaizen that the idea of small changes occurring continuously create a better system and that the people closest to the process should be making the change. The QAPI committee should include a cross-section of the segments of care; thereby assuring people closest to the process are making the changes. All of the committees in an ASC report findings and solutions through the QAPI committee to the Medical Executive committee to the overall Governing Board.

Risk Management

In an ASC, risk management is closely tied to the QAPI process. Risk management's scope includes writing and reviewing incident, occurrence, and variance reports; controlling litigation to protect the ASC's assets; focusing on underlying causes for incidents and working with QAPI committee to reduce potential and actual harm; assisting in improving quality of care and patient safety; and working to determine potential risk for harm.

The risk management process exists to protect the patient, the staff, and the overall organization. A good risk management program is fully integrated into QAPI and oversees regulatory compliance, infection control and prevention, patient safety, and employee safety. The risk management process is designed to identify, analyze, plan, and implement change, monitor and respond to any risk or harm identified. The Risk Manager is also trained to identify risk in the ASC for not being or remaining in compliance with CMS and state licensure or accrediting body requirements. A well-trained Risk Manager can be responsible for billing and coding compliance as well as HIPAA and OSHA. The key to a successful risk management program is education for the Risk Manager.

Environmental and Patient Safety

CMS is very specific about their expectation of a safe and sanitary environment. "The ASC must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients" [12]. An ASC must comply with CMS requirements. In addition, the ASC must meet state and accrediting body conditions.

"The ASC must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, safety from fire, emergency equipment and emergency personnel" [13]. In mid-2016, CMS notified the ASC industry of the Federal Register change where National Fire Protection Association ("NFPA") approved NFPA 101 (2012 Edition) A. NFPA 101, Chapter 6—Occupancy Types NFPA 101, Chapter 8—Fire Protection Requirements and NFPA 99 (2012 Edition) ANSI 170—HVAC System Design. The changes go into effect on July 5, 2016. ASC have 1 year to comply with all changes that were not "grandfathered." Any new ASC being built has to have been permitted and have begun construction by July 5, 2016, or the ASC will have to comply with the change. Many ASCs will struggle with this change since most states have not adopted this change. If the state has not adopted the change made by CMS, the ASC will have to work with the state to determine how to comply with both the state and CMS requirements.

ASCs must have policies and procedures describing how to monitor, track, and assess the ASC's safety plan to confirm the environment is safe for employees and patients. The safety plan includes environmental hazards and emergency preparedness. Safety plans must be approved by the Governing Board. The safety plan must address risk and types of internal and external disasters that could occur based on where the ASC is located. The risk assessment should be completed first so that the high-probability risks identified can be addressed in detail. ASCs must work with the local disaster coordinator/office to determine the role an ASC will play in the event of an external disaster. After the risk analysis is completed and the ASC has written its plan and it has been approved by the leadership team, the Safety Officer will begin to identify how to implement the plan.

Internal emergency preparedness includes, but is not limited to, the crash cart, malignant hyperthermia cart, emergency generator, smoke detectors, and sprinkler systems. Some ASCs like to have an emergency airway cart for lost airways as well as difficult intubations and other centers have Anaphylactic Shock boxes ready for use. The QAPI committee makes recommendations to the Medical Executive committee on the type of emergency carts, supplies, and equipment the center needs. The Medical Executive committee makes recommendations to the Governing Board and then the Governing Board approves or makes recommendations and the decision goes back to the Safety Officer and QAPI committee to implement.

Internal disasters commonly identified are cardiac arrest, respiratory arrest, patient transfer to the hospital due to an error or other medical issue, fire, loss of power, and water. It is the Safety Officer's responsibility to survey using a checklist based on the ASC's potential for internal disaster or a problem with the building causing a hazard to the patient, guest, and staff. Holding mock drills quarterly and reviewing the process using a report card document is required by CMS, accrediting bodies, and some states. The drills must be documented. If gaps are noted in the process during the drill, it is the Safety Officer's responsibility to address the process issue with the QAPI committee and Risk Manager. The QAPI committee, Safety Officer, and Risk Manager will analyze and determine how to eliminate the issue. Communication to the staff is always important. The communication needs to be clear and provide detailed directions on how to perform the task correctly.

Potential external disasters are identified in the risk analysis. The staff must be educated by describing their role during each of the potential external disasters. ASCs are required to hold external disaster drills. The drills need to be held at least once annually to be in compliance with CMS, other accrediting bodies, and state requirements.

Safety Education will be provided at orientation and at least annually thereafter. The program

Table 23.2 General safety standards used for safety education at orientation and, at least, annually at ASCs

• Review of safety policies and procedures	• Hazardous materials communication
• Body mechanics	• SDS/hazardous waste
• Safety risks/ responsibilities	• Equipment safety/ operations manuals
• MSDS/hazardous waste	• Utility systems and electrical safety
• Infection control and prevention	• Reporting of sentinel events, variances in practice, accidents, injuries, and safety concerns
• OSHA	• Fire and life safety
• Security	• Internal and external disaster
• Mock codes	• Equipment safety

will address general safety processes: area-specific safety and job-related hazards. The general orientation includes the general safety standards in Table 23.2.

During orientation and annual follow-ups, the department/job-specific orientation will include specific safety standards related to safe practices and the safe use, inspection, cleaning, and maintenance of specialized equipment. At least annually, the safety in-service education will provide updated information and review concerns with all staff members. A review of all general safety standards must occur at least annually.

The Administrator/Nurse Manager and Safety Officer are responsible for assuring that employees are provided with the safety standards pertaining to their area of job responsibilities. All personnel are responsible for obtaining the information necessary to perform a task in a manner that prevents injury to themselves, patients, and others. A review of the safety policies and procedures is required annually.

Infection Control and Prevention

"The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines" [14]. CMS is very prescriptive in describing how an ASC must maintain an ongoing infection control and prevention program. The infection control and prevention program is integrated into the QAPI Program. An ASC has the following national organizations it can use to develop and maintain its infection control and prevention policies, procedures, protocol, and surveillance checklist: Centers for Disease Control and Prevention ("CDC"), the Association for Professionals in Infection Control and Epidemiology ("APIC"), the Society for Healthcare Epidemiology of America ("SHEA"), and the Association of periOperative Registered Nurses ("AORN") [14].

Infection control and prevention policies and procedures must start with a mission statement followed by scope of practice. The mission statement tells the staff and anyone surveying the center what infection control guidelines are being followed in the center and stresses the mission to have an infection-free environment. The guidelines can include a combination of recommendations from the national organizations. The organizations used should fit with the population and type of cases the facility is performing. The scope of practice further defines the type of patients, cases, and services being performed in the center and must address at least the following: training provided for the Infection Control Preventionist Nurse, staff training, policies and procedures, risk assessment, establish infection prevention goals, employee health program, employee orientation, employee in-service education program, surveillance methods and documentation, monitoring for compliance to policies, procedures, and program requirements, developing and reporting system, evaluation of program, Governing Board's role in the program and compliance with federal, state, and accrediting bodies [15–17].

CMS requires that every center identify with standards for infection control and prevention. Infection prevention and control begins when an ASC provides a clean and sanitary environment. The most important place to begin the infection

prevention and control program is with housekeeping. A well-trained staff who understands why the area must be maintained (i.e., trash in appropriate containers, linen hampers emptied frequently, clutter at a minimum) and all surfaces cleaned properly with the correct product is a staff that helps prevent infections. Training is the key to a clean and sanitary environment. Training begins during Orientation. Staff should be taught how to clean surfaces between patients and after patients use a stretcher, bedside table, or any other item. The ASC staff is taught to be fast and to turn over equipment, areas (i.e., preoperative bays, postanesthesia care unit bays, operating rooms) leaving no downtime between patients. Turning rooms quickly is a good practice so long as being fast does not mean cutting corners. Leadership must also be aware of the time needed to properly clean after each patient based on the type of case and amount of equipment used in the case. For example, it takes minutes to turnover a Bilateral Myringotomy Tube placement because there are no liquids being used and it is a minimally invasive procedure versus turning over a major shoulder case which used at least ten pieces of equipment, has thousands of milliliters of fluids used, and a large number of instrument pans opened and used. Fast is good… but fast cannot compromise patient care or patient safety.

Employee health is addressed under the infection prevention and control policies and procedures. The ASC must obtain the immunization records of all employees, credentialed staff (i.e., physicians, allied health), and vendors. The center must have policies addressing employee infectious diseases and work restrictions based on the disease. All employees, physicians, allied health, and anyone working a day in the ASC must show they have been vaccinated for the flu annually during flu season. If anyone working in the center is not able to take the vaccine for any reason, the center must have a policy on how to address the employee who is not vaccinated for the flu. The ASC must report annually through the National Healthcare Safety Network ("NHSN") the ASC's compliance rate to the flu vaccination program. Infection plan also addresses work injuries and how they are handled [18]. The center must address blood-borne pathogen exposure and develop an exposure control plan. The ASC leadership team must provide education on blood-borne pathogens during orientation and procedures. The ASC needs a comprehensive policy concerning Tuberculosis ("TB") and exposure to TB.

The ASC must address standard infection prevention precautions in the policies and procedures as well as in orientation and at least annually thereafter. The precautions that must be addressed are hand washing, standard universal precautions, employee risk classification, task at risk, personal protective equipment ("PPE"), environmental and engineering controls, safe work practices, management of regulated waste, management of contaminated equipment and handling of laundry (i.e., clean, soiled). Transmission-based precautions are addressed in these policies and procedures. The staff must understand how to identify a patient or guest with a potentially infectious disease and how they are to address the potential infection exposure to staff and other patients and guests. One area of difference between older and newer ASCs is isolation rooms. Many new ASCs are building isolation preoperative and PACU rooms. The staff must be trained on how to educate patients and visitors on ways to reduce the transmission of infections and communicable diseases. Today, many ASCs are providing hand-washing brochures with instructions in the postoperative education patient packets. It has been generally accepted that educating patients and families on good hand hygiene reduces the potential for surgical site infections [19, 20].

Identifying and monitoring infections is a requirement of CMS, state health departments, and accrediting bodies. ASCs must follow up with the surgeon requesting infection information on every patient the surgeon has performed a procedure on in the ASC. The first contact made by the ASC concerning infection is 30 days after the original date of procedure. ASCs strive to obtain 100 % compliance on receiving an infection report on every patient seen in the ASC. The ASC must track patients for infections if they received an implant for 90 days. The infection control information (data) must be reviewed, analyzed, and reported to the QAPI committee,

Medical Executive committee, and Governing Board. If an infection is identified, the Infection Control Preventionist Nurse must investigate the infection and identify the potential source. It will be the Infection Control Preventionist Nurse's responsibility to identify the potential gaps in practice and to educate the staff to eliminate the gaps identified.

Conclusion

The ASC is focused on providing care for patients needing a surgical or procedural intervention. The ASC can be a very safe place for the patient to receive surgical care so long as the Governing Board and leadership team strive to follow the rules, regulations, and standards that govern ASCs. The key to a successful outcome for a patient is a highly trained staff who understands the principles of safe practice. The ASC industry began in the mid-1970s and has grown into an industry of over 4500 freestanding facilities that are licensed and/or accredited and Medicare certified. The industry is expanding its scope of practice taking on more and more complicated cases thanks to advancement in technology and the demands of the public, thus driving the need for ASCs to track patient outcomes and closely assess their practice for quality safe care. The ambulatory industry values quality safe care as proven by the creation of the not-for-profit, self-funded organization that addresses quality and safety, the ASC QC.

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Human Factors and Operating Room Design Challenges

24

Dirk F. de Korne, Huey Peng Loh, and Shanqing Yin

"Reliable human-system interaction will be best achieved by designing interfaces that minimize the potential for control interference and support recovery from errors".

—Charles Vincent and René Amalberti, from Vincent C, Amalberti R. Safer healthcare: strategies for the real world. Springer Open, 2016:55.

Operating Rooms as Socio-technical Environments

Diffusion of Innovation

Operating rooms (ORs) are rich and complex socio-technical environments where technology and human actions are closely interwoven and outcomes are co-dependent on the success of this interaction. Operating rooms are not unique in this regard, and diffusion of innovations from other complex environments (e.g. high-risk industries such as nuclear power, offshore, and aviation) into health care to improve safety has been advocated by many authors [1–12]. According to Rogers [13], an innovation is "an idea, practice, or objective perceived as new by an individual, a group, or an organization", and diffusion is "the process in which an innovation is communicated, through certain channels over time, among the members of a social system". As Greenhalgh et al. [14] indicate, diffusion often is not a passive process but involves negotiating, influencing, and enabling a work staff that can enable change and "help it happen". Examples of recent innovations diffused into health care are the investigative tool of root cause analysis and the surgical checklist [15]. The framework to analyse the diffusion of innovations developed by Greenhalgh et al. [14], see Table 24.1, is a useful tool to focus on the factors that determine actual diffusion. In this chapter, we will use the framework to analyse the applicability of innovations from other industries to improve safety and quality in surgical patient care.

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Risks in the Operating Room

Operating rooms (ORs) are high-risk areas for preventable patient harm [16–18]. Besides wrong-site surgery and medication or instrument-related incidents, surgical site infection (SSI) has been reported to be one of its major categories [16, 17, 19–21]. For example, bacterial air and fomite contamination are generally accepted as the main causal risk factor of SSIs

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Table 24.1 Analysis framework for diffusion of innovations [14]

	System A (e.g. airline)	System B (e.g. hospital)	Feasibility of changing practice, procedures, and context of hospital to match airline
The innovation	Salient features currently used in System A?	Salient features of innovation proposed for use in System B?	Could and should System B adopt the same innovation as is used by System A?
The resources	What resources were used in producing the outcomes (e.g. staff time, money, equipment, space)?	What resources in System B?	Does System B have the resources to emulate the practice of System A?
The people	What are the salient characteristics of the key actors in terms of expertise, experience, commitment?	What are the characteristics of the key actors in System B?	Insofar as there is a mismatch, would it be desirable or feasible to recruit different staff, invest in training, etc.?
Institutional factors	How much were the outcomes dependent on organizational/departmental structure, organizational cultures?	To what extent does the organizational structure and culture of System B determine practice?	Differences? Feasible or desirable to change the institutional structures and cultures in B?
Environmental factors	How much were the outcomes dependent on particular environmental factors (e.g. political, legislative, etc.)?	To what extent is the external environment of System B comparable to System A?	Differences? Change the external environment of System B?
Measures	What baseline, process, outcome, and other measures were used to evaluate success?	Does (or could) System B use the same measures?	Desirable or feasible for System B to change the way it measures and records practice?
Procedures	What was exactly done in System A that led to the outcomes reported?	Does (or could) System B do exactly the same?	Differences? Should System B change what it does?
Outcomes	What were the key outcomes, for whom, at what cost, and what are they attributable to?	What were the key outcomes in System B? Achieve for same actors as A?	To what are the differences attributable? Desirable outcomes that System B is not achieving?

Source: de Korne DF, van Wijngaarden J, Hiddema F, Bleeker FG, Pronovost PJ, Klazinga NS. 2010. Diffusing aviation innovations in a hospital in the Netherlands. Jt Comm J Qual Patient Saf 36(8):339–347

[19, 20, 22, 23]. Proper ventilation in and near the OR coupled with rigorous hand hygiene is key in establishing an environment that stops the spread of infection [24, 25]. Since Lidwell et al. in 1982 demonstrated a correlation between airborne bacteria contamination levels and the incidence of postoperative wound infections, the use of ultraclean ORs with laminar air flow (LAF) ventilation has been recommended for many types of surgery [19, 20, 22]. With LAF, cold, clean air is blown into the OR from a ceiling system and contaminated air is sucked out through ventilation grids in the walls. Different studies have shown the effects of LAF ventilation on the number of contaminations of samples in different OR areas [19, 20, 22].

In the past 30 years, much attention has been given to the proper installation of LAF systems as well as details about its size, position, concentration, efficiency, degree of filter, temperature, and other technicalities [26]. The actual effect of the clean air, however, is largely dependent on the correct positioning of the surgical table and instruments in its flow as well as staff traffic behaviour and patterns (e.g. number of people standing within the flow or against wall vents)

[22, 23, 25–28]. Energy from movement of devices and staff decreases the volume of clean air and both hinder air flow [25, 28].

In most literature on hygiene and infection studies, the focus is on teaching, training, and changing staff behaviour, e.g. appropriate OR dress or hand hygiene discipline [16, 17, 19, 22, 25, 27]). Adhering to infection prevention recommendations like correct positioning of devices within the clean air flow is rarely emphasized, despite infection prevalence being dependent on design characteristics of the OR.

Most safety improvements in high-risk industries first focus on work area design—here defined as 'creating and developing concepts and specifications that optimize the function value and appearance of products and systems for the mutual benefit of both user and manufacturer' [29]—before attempting to change behaviour. Many studies performed in industry have concluded that it is hard to change behaviour; changing design is probably easier [30–34]. On offshore oil vessels, for example, the position of all materials on decks is marked to support safe behaviour [35], as are the positions of airplanes and all surrounding equipment on the airport tarmac [36].

Human factor engineering, concerned with the understanding of interactions among humans and other elements of a system, can help in 'mistake proofing' by changing designs to make processes more reliable and effective [21, 37]. Influencing users' behaviour is challenging and smart design can potentially shape behaviour towards sustainable practices and improve teamwork dynamics and situational awareness [38, 39]. Teamwork has been defined as 'skills for working in a group context, in any role, to ensure effective joint task completion and team member satisfaction' [40]. Situational awareness has been defined for this context as 'developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment, understanding what they mean and thinking ahead what might happen next' [41]. Behaviour steering could be used as a strategy that could be integrated into product design [33, 42], encouraging users to behave in ways prescribed by the designer through embedded affordances and constraints. In operating rooms, human factor engineering and design thinking therefore plays an important role in safety and efficiency improvement. An unacceptable number of avoidable patient safety incidents result from the widening disparity between surgical innovation and the environment in which it is applied [43, 44]. Design that aims to minimize the increasing problem of patient safety must consider the behaviour of staff and patients as well as the complex interrelationships between culture; technology; and achieving reliable, high-quality surgical outcomes [44]. While OR floor marking is increasingly applied in the design of ORs, little is known about its effects on clean air compliance.

Case Study I: Effects of Operating Floor Marking on the Position of Surgical Devices[1]

The application of OR floor marking at the Rotterdam Eye Hospital, The Netherlands (REH) was part of a safety learning programme between surgical staff at the hospital and terminal operators at Amsterdam's Schiphol Airport. While the direct purposes of floor marking are obviously different for airside and OR (prevention of collisions and logistic support in a dynamic environment versus infection prevention and proximity for ease of use in a relatively static environment), the main goal of doing the right things on the right spot is similar. The hospital used a laminar flow system with an inflow of 0.27 m/s, from a ceiling rectangle area of 160 × 220 cm, and with a total content of 124.5 m^3 per OR (See also Fig. 24.1a). The relative humidity was 55 % and the temperature was 19.5 °C. The ventilation rate was calculated at 20.5 per hour. An OR workspace analysis was performed, indicating 42 different items on various positions. The following equipment was routinely used during ophthalmic operations: surgical table, one (mostly) or two (e.g. for more

[1]This case study has been published as de Korne et al. BMJ Qual Saf 2012; 21(9):746–52, ref. [45].

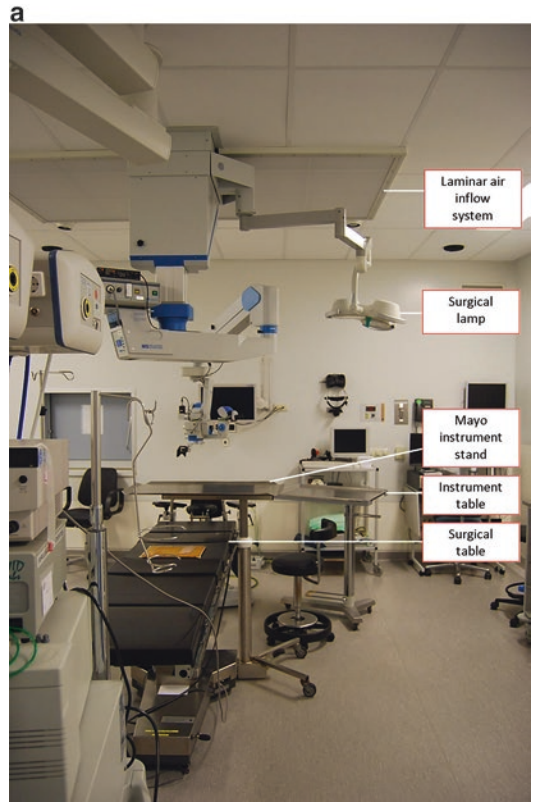
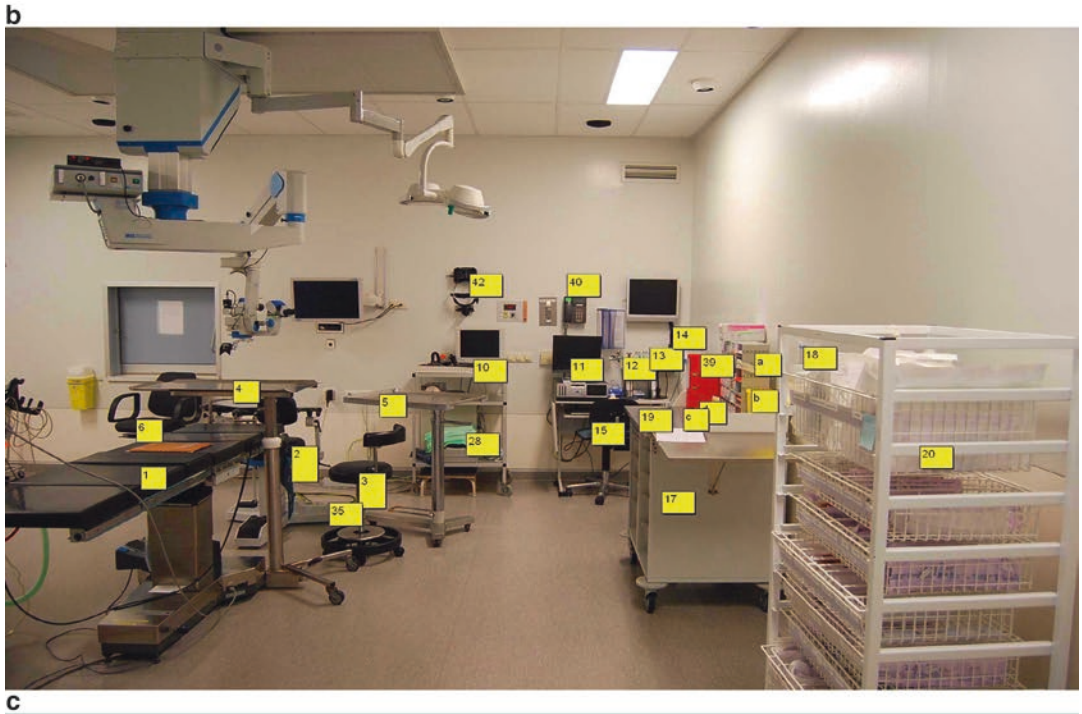


Fig. 24.1 (**a**) Position of surgical devices at the operating room (photo: REH). Source: de Korne DF, van Wijngaarden JD, van Rooij J, Wauben LS, Hiddema F, Klazinga NS. Safety by design: effects of operating floor marking on the position of surgical devices to promote clean air flow compliance and minimize infection risks. BMJ Qual Saf 2012; 21(9):746–52. (**b**) Overview of the OR floor and space analysis (photo: REH). (**c**) Airside marking at Amsterdam Airport Schiphol (Schiphol 2010). Source: de Korne DF, van Wijngaarden JD, van Rooij J, Wauben LS, Hiddema F, Klazinga NS. Safety by design: effects of operating floor marking on the position of surgical devices to promote clean air flow compliance and minimize infection risks. BMJ Qual Saf 2012; 21(9):746–52. (**d**) Provisional surgery floor marking for T1 and T2 (photo: REH). (**e**) Permanent surgery floor marking for T3 (photo: REH)

extensive retina surgery) instrument tables, Mayo instrument stand (e.g. for retina surgery and cataracts with general anaesthesia), surgical lamp (for oculoplastic and strabismus surgery), chair for surgeon, chair for assistant (resident or surgical nurse), medicine and disposable material trolley, anaesthesia instrument, chair for anaesthesiologist, phacoemulsification and vitrectomy machinery for cataract, respectively, vitreoretinal surgery (See Fig. 24.1b).

The REH is a major referral centre, handling approximately 140,000 outpatient visits and 14,000 surgical cases annually. According to Dutch infection prevention guidelines, the ORs of virtually all ophthalmic surgeries are required to have an LAF [46]. We studied the potential relationships between equipment position and endophthalmitis (an internal inflammation of the eye), the most common infection in intraocular surgery, particularly cataract surgery, which can result in loss of vision or the eye itself [47]. A mixed methods study was done including interviewing providers and doing a detailed time series analysis to measure compliance (the position of devices within the clean air flow) 5 months before marking (T0, $n = 180$ surgeries), and at 1 month (T1, $n = 194$ marked, $n = 86$ not marked), 6 months (T2, $n = 166$ marked), and 20

b



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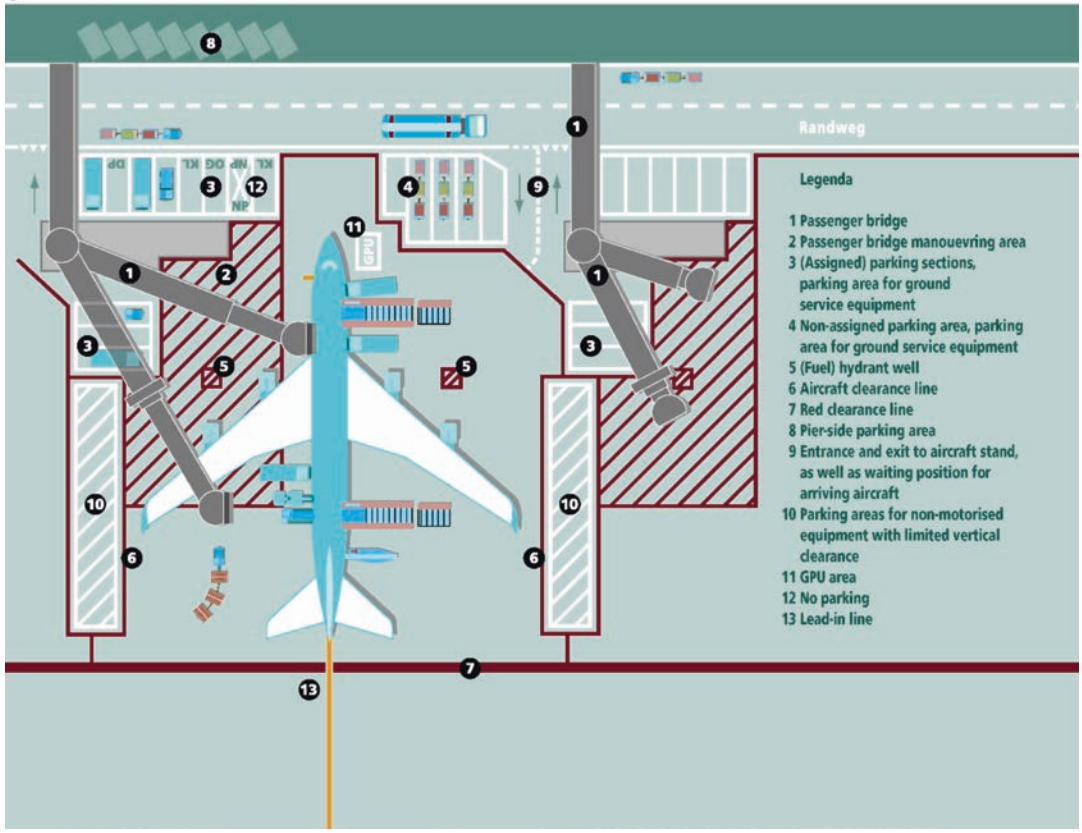


Fig. 24.1 (continued)

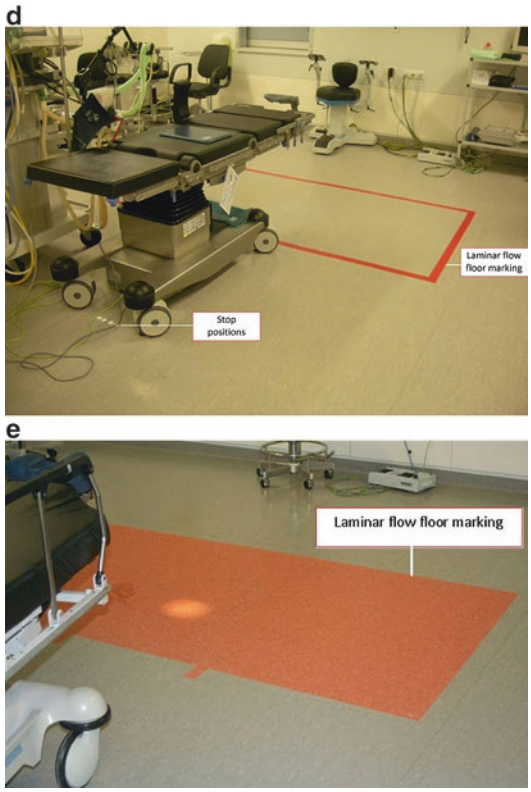


Fig. 24.1 (continued)

months (T3, $n = 199$ marked). The positions of devices, mobile OR table, instrument table, Mayo stand, and surgical lamp were determined by four circulating nurses (Fig. 24.1a).

Floor Marking Effects

The marking project was a co-creation of a multidisciplinary team with hospital surgical staff and tarmac operators from Schiphol airport.[2] Five mutual site visits were included. During three airport sessions, experience in airside marking, position of materials, traffic flows, safety rules and regulations, and incident management were discussed. Different colours and patterns indicate the exact position of approaching and departing planes, fuel and luggage devices, and vehicle and foot traffic (Fig. 24.1c).

During two hospital sessions, OR traffic flows, position of surgical tables and materials, safety management, and incident reporting were discussed. Marking was applied to two of the four ORs. Red tape (width 2.5 cm) was pasted on the contours of the laminar flow area (162 cm × 224 cm) of the OR floor (Fig. 24.1d). The stop positions of the surgical tables were indicated by white tape dots. In a second phase a permanent mark was applied (Fig. 24.1e).

Surgeons, nurses, and other staff were not specifically instructed to change the positioning of the devices. After T0 documentation of positioning, compliance with laminar flow was determined based on device positioning at T1–T3. The results are presented in Table 24.2.

Instrument table. Before marking, the instrument table was positioned completely within the laminar flow in only 6.1 % of the cases. With floor marking, this significantly increased to 36.1 % (T1, $p = 0.000$), 52.1 % (T2, $p = 0.000$), and finally 53.8 % (T3, $p = 0.000$). At T1, only 10.7 % of the instrument tables in the ORs without floor marking was positioned completely within the laminar flow. At T2 and T3, in almost half of the cases, the instrument tables were still positioned (partly) outside of the clean air flow. In interviews, staff indicated that in their view an ergonomically correct position is more important than positioning the instrument table in the clean air flow. For some operations a diagonal position is necessary, requiring more space. The size was also criticized: "*For retinal surgery, you can't position a resident and a scrub tech and all your instruments in the flow area. The field is too small*" (ophthalmic surgeon).

Mayo stand. Mayo stands (above the patient) were increasingly positioned within the laminar flow after marking: from 74.2 % (T0) to 82.8 % (T1), 84.6 % (T2), and 84.7 % (T3). These changes were not statistically significant. The number was expected to approach 100 % because the stand is normally positioned close to the patient. In certain surgeries, however, it was placed at a distance because as one surgeon

[2]Benchmarking with aviation was part of a larger safety focus; for details see de Korne et al. Jt Comm J Qual Patient Saf 2010;36(8):339–347, ref. [48].

Table 24.2 Percentages of surgeries with the instrument table, Mayo instrument stand, and surgical lamp in the laminar

		T0	T1		T2	T3	
		$n=182$	$n=86$	$n=195$	$n=167$	$n=199$	
		Not marked (%)	Not marked (%)	Marked (%)	Marked (%)	Marked (%)	p Value
Instrument table	Completely in	6.1	10.7	36.1	52.1	53.8	0.000[a]
	Partly out	26.7	72.6	37.6	27.0	27.6	
	Largely out	67.2	16.7	26.3	20.9	18.6	
Mayo instrument stand[b]	Completely in	74.2	82.4	82.8	84.6	84.7	0.080[c]
	Partly out	18.2	8.8	8.7	9.0	15.3	
	Largely out	7.6	8.8	8.5	6.4	0.0	
Surgical lamp[d]	Completely in	41.8	35.8	38.7	28.7	48.6	0.000[a]
	Partly out	15.7	22.4	6.5	4.7	0.7	
	Completely out	42.5	41.8	54.8	66.7	50.7	

Source: de Korne DF, van Wijngaarden JD, van Rooij J, Wauben LS, Hiddema F, Klazinga NS. Safety by design: effects of operating floor marking on the position of surgical devices to promote clean air flow compliance and minimize infection risks. BMJ Qual Saf 2012; 21(9):746–52

[a]χ^2 test $T0_{\text{not marked}} - T1_{\text{marked}}$

[b]Includes only cases where the Mayo instrument stand was used (34 %)

[c]χ^2 test $T0_{\text{not marked}} - T3_{\text{marked}}$

[d]Excludes oculoplastic and strabismus cases because the surgical lamp is in use

noted: *"Having sufficient space to move and position your arms is more important for a successful surgery than the position in the flow"*.

Surgical lamp. In many ophthalmic surgeries (with the exceptions of strabismus and oculoplastic surgeries) the microscope light is used instead of the surgical lamp. To maximize clean air flow, the surgical lamp should then be positioned outside the area since its volume and energy disturb clean air flow. In such cases, the surgical lamp was decreasingly positioned in the flow: from 41.8 % (T0) to 38.7 % (T1, $p=0.000$) and 28.7 % (T2, $p=0.000$). However, at T3 (20 months after the marking) in 48.6 % of the cases the lamp was again positioned in the air flow. In interviews, staff indicated that they often forgot to reposition it because, according to them, there is no clear marking.

"*There's an indication of the clear air flow on the floor now, but not in 3D. If we were doing surgery in a real clean air box, all disturbing devices could be eliminated*" (nurse).

In the 2 years after the marking, the incidence of ophthalmic infections (endophthalmitis) was lower than in the 4 years before (Table 24.3). Due to very low incidence (0.078 % in 128,130 cases over previous 11 years), no significant differences could be found. Notably, changes in corneal versus corneoscleral incisions and the use of prophylactic antibiotics probably acted as confounders and it is not sure whether besides this associative relation there is also a causal relation.

According to interviewed staff, discussions and site visits between airside operators and surgical staff resulted in an increased awareness of the specific risk areas in the OR. Due to the exchange sessions, professionals not only focused on the position of the surgical table, but were more aware of the complete air flow area, including the instrument table positions. Therefore, the surgical table's stop position was permanently marked (T3). The surgical team usually focused on the position of the patient in the clean air flow. During discussions about risks, however, the focus was on the total risk surfaces. Since the wound surface in ophthalmic surgery is very small, the materials used appear to play a larger role. For example, surgical staff indicated that they became aware that donor tissue for a corneal transplant was placed outside of the flow:

Table 24.3 Endophthalmitis infection statistics at the case hospital, 2000–2010

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Total surgeries	9701	9955	10,328	10,428	11,199	11,864	12,692	12,610	13,338	13,242	12,773
Postoperative endophthalmitis infections in all surgeries	7 (0.072 %)	9 (0.090 %)	8 (0.077 %)	6 (0.058 %)	12 (0.105 %)	10 (0.084 %)	10 (0.078 %)	14 (0.102 %)	9 (0.067 %)	7 (0.053 %)	8 (0.063 %)
Cataract surgeries	4986	5018	5126	5274	6011	6015	7040	6893	7366	7442	7164
Postoperative endophthalmitis infections in cataract surgery	4 (0.080 %)	5 (0.099 %)	7 (0.136 %)	4 (0.076 %)	11 (0.083 %)	7 (0.116 %)	3 (0.043 %)	8 (0.116 %)	5 (0.068 %)	5 (0.067 %)	3 (0.042 %)

Source: de Korne DF, van Wijngaarden JD, van Rooij J, Wauben LS, Hiddema F, Klazinga NS. Safety by design: effects of operating floor marking on the position of surgical devices to promote clean air flow compliance and minimize infection risks. BMJ Qual Saf 2012; 21(9):746–52

"The donor cornea is prepared in the laminar flow. When the patient arrives at the OR, we reposition the instrument table with the donor tissue. Through the marking, we became aware that the donor cornea is not in the clean air flow during heavy traffic flows (patient arrival, staff entry) at the first part of the surgery" (surgeon).

Some ophthalmic surgeons were sceptical about the marking initiative at the start. Clean air flows were seen as important to prevent infections, but due to low infection rates in ophthalmology it was in their view not worthwhile to use marking and measure compliance. Confronted with the compliance results after the marking, they indicated that marking seemed to increase awareness and good positioning.

"Marking not only encourages staff to position the patient and instruments correctly, it also makes clear that non-sterile visitors have to stay outside the marked area" (surgeon).

The circulating and scrub nurses found that they positioned the instruments increasingly in the laminar flow since the marking project without being aware of any differences. Only when they saw the results were they convinced that positioning had changed. The new design nudges for a compliance improvement without a need for specific instructions or even explicit awareness of the staff involved.

Marking Floors as Improvement Design Intervention

Marking the clean air area on the floor of ORs resulted in significantly increased compliance with the positioning of surgical devices. While the focus was previously on the position of the patient, the marking resulted in a focus on positioning instrument tables within the clean airflow. The change was sustained over time. Drawing a simple line created awareness and resulted in discussions about the required surface and the correct position of devices and staff. At first, the surgical light was more often put in the right position (out of the clean airflow when not needed) but this was not sustained. The marking seemed to have created an initial awareness, but perhaps because the marking on the floor and the lamp hangs on the ceiling, the marking did not help to sustain the behaviour to position the lamp outside the clean air area.

Case Study II: Video Feedback to Improve Sensomotor and Non-technical Skills[3]

Sensomotor and Non-technical Factors in the Operating Room

Over the last decade, ORs have consistently been indicated as high-risk areas for preventable harm, yet the factors contributing to complications and surgical confusion within this context are usually multifactorial and remain poorly understood [43]. Poor surgical outcomes may result from a combination of surgical complications resulting from poor surgical technique, or suboptimal OR support resulting from inadequate communication among the surgical team, or an interplay and combination of the earlier two major aspects of OR safety [50].

Traditional training of surgeons is focused exclusively on developing and training technical (surgical) skills [51]. However, an analysis of the reasons for surgical adverse events revealed that these events stem from behavioural or non-technical aspects of performance (e.g. poor communication among members of the surgical team) [50, 52]. Surgical training of new surgeons within this complex environment is highly dependent on a supervisor–trainee trust and mentorship in a one-to-one training model. Objective assessment and monitoring of surgical skills with the goals of enhancing learning and improving resident outcomes are crucial [53]. However, current training schemes have shown to be subjective with significant intersupervisor variability and significant variation in style and consistency of feedback [54, 55].

[3]Parts of this case study were published as de Korne et al. J Health Organ Manag. 2014;28(6):731–53, ref. [49].

There is therefore a need to explore more objective assessment methodologies to assess surgical expertise [56]. Operating room safety has admittedly improved with measures instituted such as 'Time Out' (to ensure operating on correct side, site, procedure, etc.), education with regard to needle stick injuries/lost or flying needles/missing swabs, ensuring the safety and availability of surgical instruments, and sterile procedure to name a few. Despite numerous costly measures already in place, reportable incidents still occur, some of which are serious [21]. We have therefore explored the application of video recordings.

Video Feedback as Means for Improvement

The hospital initiated a Team Resource Management (TRM) Programme with top management participation. Video feedback was to be used and is recognized as a very useful approach in reviewing and understanding work processes as well as a means for quality improvement [57, 58]. Inspired by aviation, a 'black box' approach was introduced in one of our hospitals. Aviation safety experts videotaped ophthalmic surgeries monthly to give the surgical team feedback on the application of the safety procedures taught during the classroom TRM sessions. Standard operating procedures for the production, use, and distribution of the images were documented. The aviation black box is automated, but for financial constraints the hospital used a handheld video recorder.

Videotaping team activities was not easily accepted and the medical staff was initially hesitant, fearing that recorded unexpected outcomes could be used against them. Only ophthalmologists who participated in the larger TRM Programme consented to having their surgeries videotaped, but with the stipulation that the images be taken with a handycam and used solely for their own training. The chief ophthalmologist, who had declared his willingness in an earlier stage of the programme, consented to make the recordings available to all the hospital's staff, residents, and nurses, stimulating others to get involved in the programme. In the end, 70 % of the ophthalmologists participated in the training.

Awareness of Risks

Awareness of risks was observed via the video analysis. From the staff interviews and observations, it was clear that anticipation of approaching safety threats was a recurrent session topic. Participants talked about a lack of standards and interoperability and requested this be addressed:

> *"There are no strict protocols for what I do and what the surgeon does. Continuous evaluation and risk assessment depends on the surgeon [alone]" (resident).*

As a result of the discussions, multidisciplinary, standard operating procedures were agreed upon, including a pre-operative briefing (with task division) and time out. The importance of situational awareness and the influence of human factors were a recurrent topic in the video feedback items (Table 24.4). The videotapes revealed team-specific differences in performing the time-out procedure and the variation in using the safety communication rules agreed on during the TRM training. The videos also showed that the absence of team members at the pre-operative briefing resulted in less structure and more communication gaps during surgery. As one aviation safety expert said,

> *"It is a new and inspiring experience for ophthalmologists to see their own performance … within their environment. It confirms the notion that surgery is a team activity".*

It was difficult for staff to deny teamwork failures when they were clearly revealed on tape. One video showed how a lack of briefing resulted in indecisive behaviour of a resident and an unexpected movement of a locally anesthetized patient. During the feedback session with staff, most ophthalmologists blamed the resident. The TRM trainer, however, confronted the ophthalmologist rather than the subordinate resident with the situation and focused on a responsible leadership role.

Table 24.4 Examples of video observations and feedback to surgical team

Item	Observation	Feedback
Mental preparation	Before the patient was on the operating table, who (attending or resident) was supposed to perform the surgery had not been agreed on	The performing surgeon is not able to prepare mentally and obtain situational awareness
Briefing	After the patient arrived in the operating room, a resident and student received a medical–technical explanation about the procedure. There was no talk about who would be performing what actions or potential problems. As it turned out, the resident was prepared to do so	A "captain" needs to have situational awareness regarding the competencies of the colleague performing the operation. To prevent such errors, he or she briefs him before on what to expect, so the situational awareness of the "co-pilot" is updated. The co-pilot can ask questions or be asked to jump in during the surgery. This was not made clear to the team
Projection	The ophthalmologist discussed the surgical schedule for the day and indicated that the first surgery in the afternoon was expected to last 2.5 h. He asked the team to plan their lunch time accordingly	This is a good example of correct projection of tasks and managing of resources
Time out	The time out was performed, but there was no check against the information in the medical chart	How can we ensure that the time-out procedure is performed in a standard manner?
New instrument	Halfway during surgery, a scalpel with new tip was on the surgical table. The surgeons did not know why	The fact that surgeons did not know about the new tip can be observed as a "threat" from the organization. Are the communication procedures from the organization to surgeons sufficient, and did the team take responsibility and sufficient measures to prevent errors from such threats?
Communication	The surgeon asks for an intraocular lens (IOL) and the circulating nurse gets one. Before putting it on the table, she says "20" but did not receive a response from the surgeon. After a while, the surgeon asks to see the chart to check the IOL power	When the IOL is unpacked, it was shown to be the wrong one. Why not close the communication loop before unpacking the IOL or implement a check moment before?
Communication	Frequently, a task or some material is required, but is not repeated in a standardized manner to confirm that it is understood	Communication at surgery is limited (e.g. covered face, working hands, not looking at each other), which every team member should be aware of and try to compensate for. Closing the communication loop during handovers (repeating an assignment, saying "check" or "yes") seems useful
Assertiveness	As the ophthalmologist prepared to wash the eye, the circulating nurse asked if the right method and material were used	The circulating nurse's assertiveness was perfect, as was the reaction of the ophthalmologist

Source: de Korne DF, Van Wijngaarden JD, Van Dyck C, Hiddema UF, Klazinga NS. Evaluation of aviation-based safety team training in a hospital in The Netherlands. J Health Organ Manag. 2014;28(6):731–53

Aversion to Error Reporting

Team members were convinced that eye surgery is highly unpredictable and most complications are not preventable. The trainer responded:

> *"You're talking about complications like we did in aviation 30 years ago. Bad weather, for instance, was called a complication. Today we say, no, weather conditions can be anticipated, so don't call it a complication"*.

This seemed to create an awareness and resulted in discussions about the differences between complications, medical errors, and adverse events. The number of reported near

misses increased by about 300 % (from 78 to 409) in the 3 years following the introduction of the video feedback programme. Some surgeons, however, indicated that reporting errors was still difficult.

> *"You know that you're not guilty or being blamed, but it still feels like it"* (ophthalmologist).

Only 18 % of the (near) incident reports over the past 3 years were submitted by ophthalmologists, while the rest was reported by nursing and administrative staff. This low percentage of physician reporting has been showed before [59]. A retrospective analysis of medication incidents reported using an online reporting system showed that 9.1 % were reported by doctors, 37.6 % by nursing staff, and 51.9 % by pharmacists [60].

Considering the one-to-one supervision model in which residents are trained, leading by example turned out to be a crucial factor influencing error reporting. "*Basically you're looking at the work practices of your supervisor and trying to copy that*" (resident). Others indicated that they were highly dependent on the existing leadership culture. "*You have to take the culture for granted; you know it's part of the game when you want to become a specialist*" (resident). During the debriefing sessions, senior ophthalmologists claimed there were no barriers for residents to talk about errors. Residents did not agree: "*I cannot comfortably report errors and concerns to my supervisor*" (resident). As a result of the training, seniors and juniors openly discussed about barriers during the TRM session. Many of them were related to the lack of psychological safety and the role of hierarchy [61].

Social Orientation

During the video feedback programme, the risks of the mono-disciplinary focus (both between ophthalmologists and anaesthesiologists and between physicians and other groups) and their own rules and behaviour were clearly demonstrated. An ophthalmologist spoke about the different worlds of surgery and anaesthesia:

> *"I don't see myself telling anaesthetists that they have to react to beeps of their equipment. That's their responsibility"* (ophthalmologist).

The aviation expert, however, explained that each team member influenced patient outcomes. Staff indicated that the training revealed basic communication (mis)understandings between professionals:

> *"During medical training you only learn how to be a technically good ophthalmologist. You learn from your supervisor. I have never learned anything about team communication, other than from experience" (ophthalmologist).*

Team Resource Management training discusses the mental models that various team members share and has shown to be effectively related to various team skills [62]. It has shown to be effective in changing participants' mental model about errors and risks [63] and thereby can be used as a vehicle to stimulate safety culture.

Automated Versus Handheld Video Feedback

Cataract surgery is one of the most performed surgeries in the world, uses sophisticated equipment and is process fairly uniform. IOL-related confusions have been consistently identified as one of the most common surgical errors. Currently, video recording devices are installed in Singapore National Eye Centre (SNEC) (see Fig. 24.2a) and in many ophthalmic surgical microscopes around the world. All intraocular surgeries are video recorded and reviewed whenever deemed necessary from surgical complication or education perspective. However, the use of the images is often limited to the retrospective ad hoc tracking of interesting cases for teaching or conference and the systematic analysis of data is often lacking due to intensive manual work required in retracing the relevant information.

A handheld video camera in the OR is, however, is still far removed from aviation's black box standard. We developed an ongoing Automatic Digital Operating Room Assistant (ADORA)

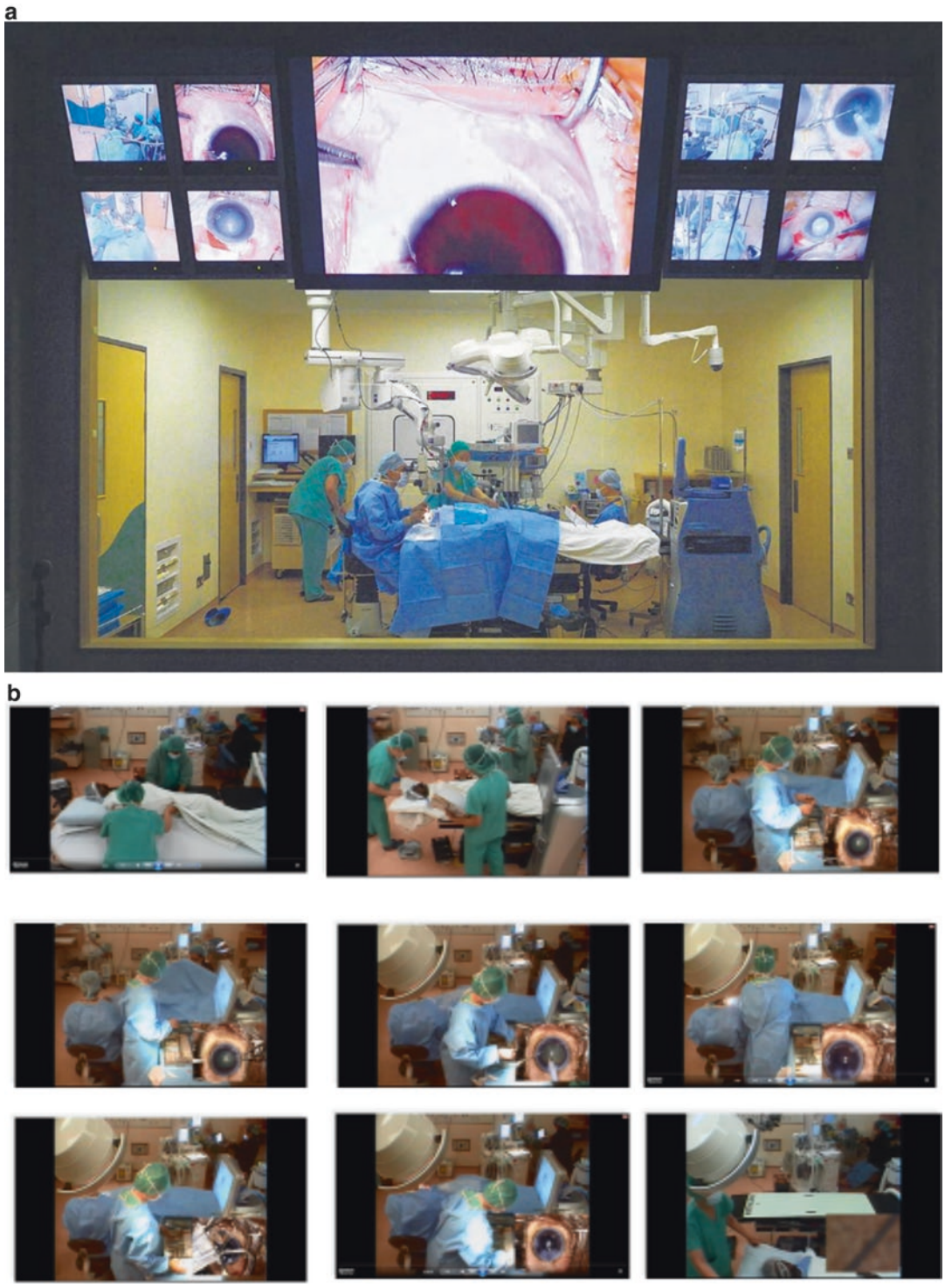


Fig. 24.2 (**a**) Video recording at the operating room of the case hospital (photo: SNEC). (**b**) Integrating picture-in-picture video imaging from microscope and overview (stills: SNEC)

project that targets to develop an integrated device to improve operating room (OR) safety and efficiency. The system uses automated computer-assisted recognition of surgical technical performance based on microscopic video images of cataract surgeries. It does this to assist in objective structured assessment of cataract surgical skills and to assess the relationship with non-technical findings in OR patterns and teamwork based on OR overview video images [64–66].

Video images provide actionable information that can be processed by image-based analysis techniques. Automation of the data extraction process is potentially greatly advantageous because manual work is time consuming and can be affected by human bias [66, 67]. While microscopic video images can be used to assess surgical performance, images from the overview camera in the OR can be used to assess non-technical and efficiency aspects within the OR. See Fig. 24.2b.

Innovative integrated analyses of views of the microscope and the OR overview can support analysis of the relationship between the surgical skills and the non-technical factors in the context of the OR (Fig. 24.3) [53, 67]. Application of these insights will result in better and more efficient training of surgical trainees and optimize the outcomes of all (human) activities in the OR.

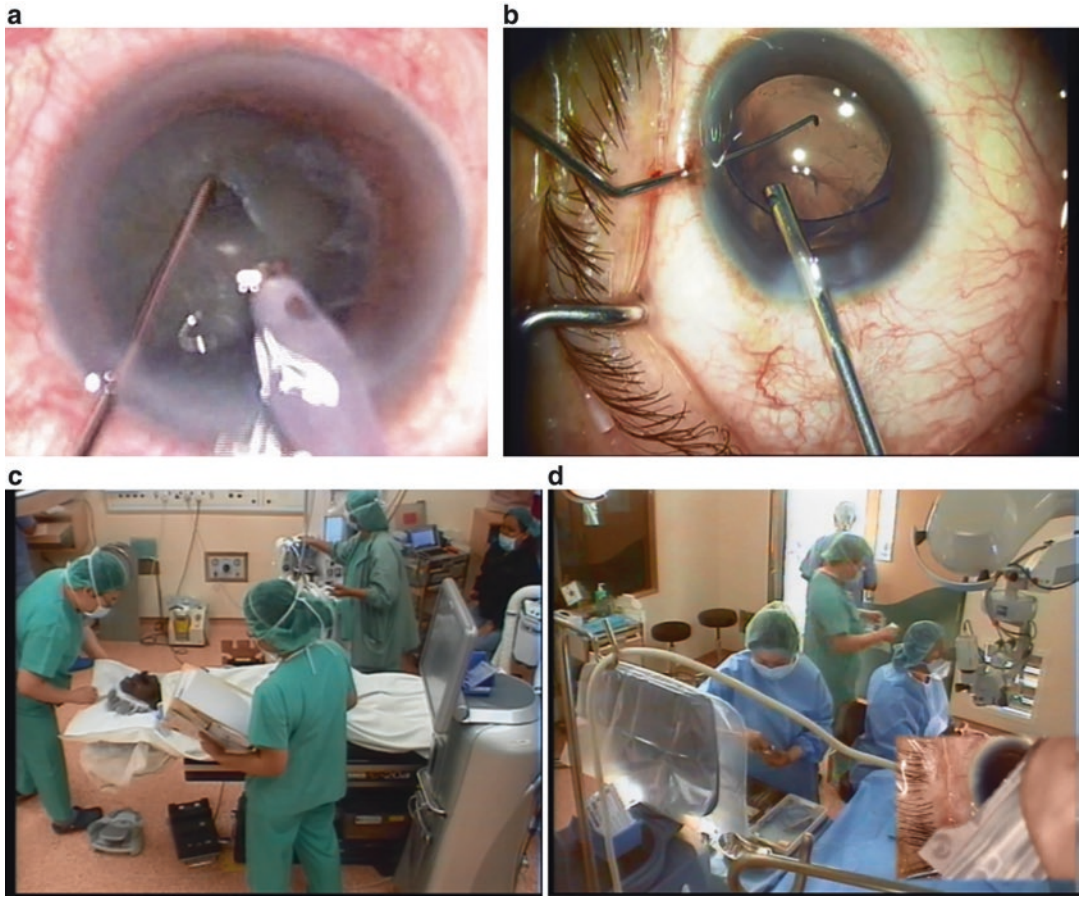
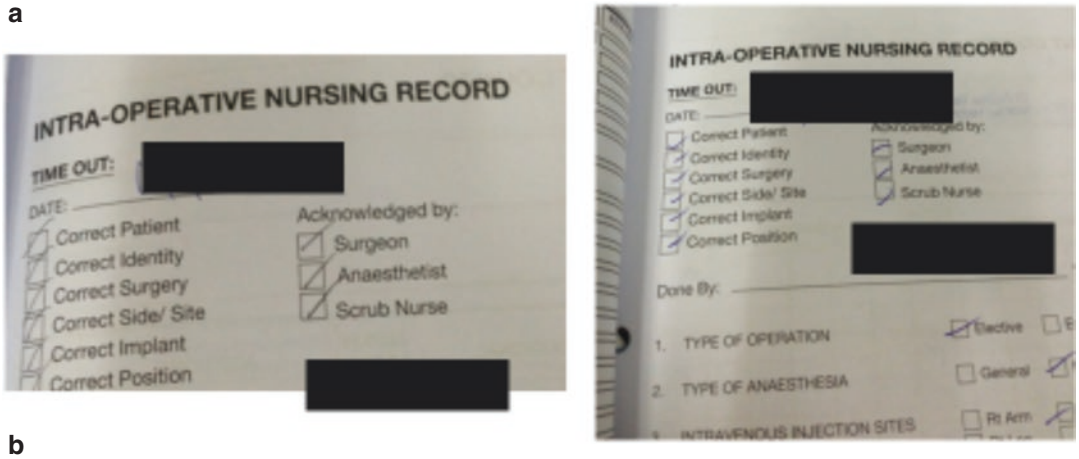


Fig. 24.3 Examples of microscope (A1, A2), OR overview (B1), and integrated video images for automated assessment of cataract surgery performance. (**a**) Phacoemulsification: use and movements during cracking of the nucleus (phase 8–11) (source: SNEC OT). (**b**) Posterior capsule rupture, one of the most occurring complications during cataract surgery (source: SNEC OT). (**c**) Final 'time out' team check on correct patient ID, eye, procedure, and instruments before surgery starts (source: SNEC OT). (**d**) Comparative analysis of two-layer video images from microscope and overview: OT-door opening and staff movement during lens insertion (phase 13) (source: SNEC OT)

Preliminary Results in Cataract Surgery

Preliminary results of our pilot study conducted in fifteen cataract sessions, that combine an overview, a microscopic image and audio data, demonstrated variation wide execution of the surgical time-out procedure as well as in communication between the staff. Audits of checklist in the paper case notes indicate a 100 % time-out involvement and acknowledgement by surgeon, anaesthetist, and scrub nurse (Fig. 24.4a), according to the protocol requirements, while actual observations using the ADORA system show that verbal acknowledgement of the time out by anaesthetist was clear in only 27 % of the cases, for scrub nurse in 53 % of the cases, and for surgeons in 73 % of the cases (Fig. 24.4b).

a



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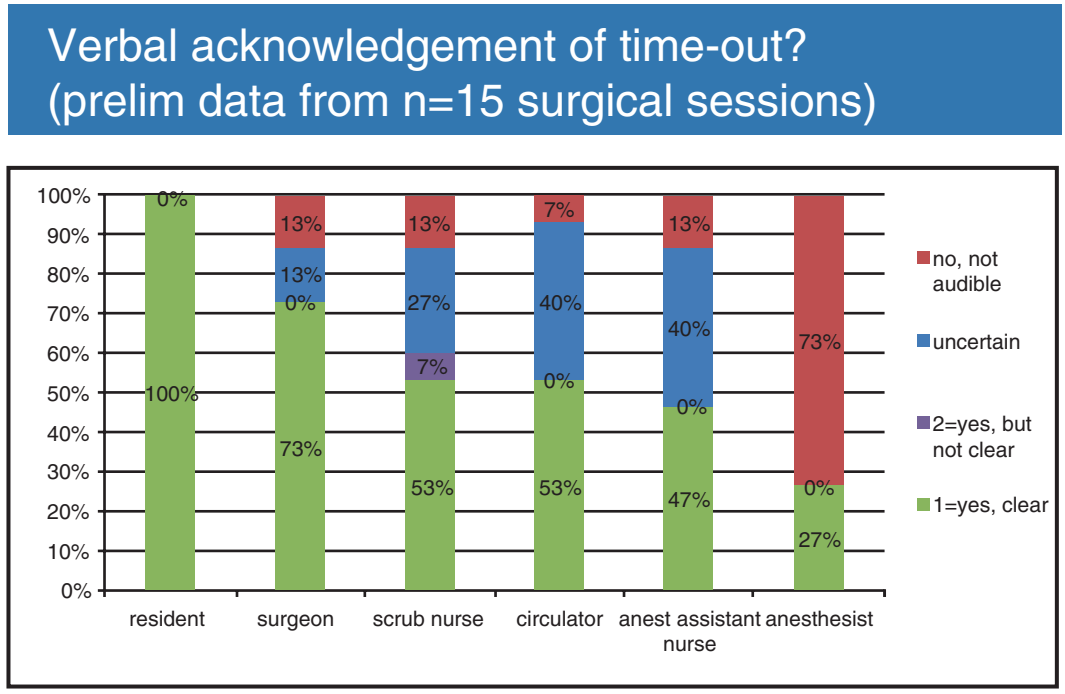

Fig. 24.4 Comparing notes in patient records to ADORA observations. (**a**) Intra-operative nursing records suggest 100 % time-out compliance. (**b**) ADORA observations on verbal acknowledgement of time out

The ADORA stimulated discussion on who initiates the time out, how it is performed, and who should be involved. The video observations showed that in one surgical session the time out was initiated by different circulating nurses as well as the anaesthesia nurse. See Fig. 24.5.

As a result the exact execution was reemphasized and standardized. As a large area of the OT is captured in the ADORA system, we were also able to do a detailed analysis on door openings as earlier literature suggests a close connection between door openings and OR infections [68–70]. During an average 14.5 min of cataract surgical process, the doors were opened seven times, with an average opening time of 19 (±3.5) s (see Fig. 24.6). This suggests that the door is open during 16 % of the surgical (knife in–knife out) time. In one of the observed cases, the ADORA system showed that the new intraocular lens (IOL) was inserted just at the time when the door was open.

As the preliminary findings are promising, we are currently working on the study of a larger set-up that includes analysis of the situational awareness of the OT stakeholders, in particular the scrub nurses. In the longer term, we plan to integrate the findings into algorithms that would be able to automatically identify the human activities and relate them to potential triggers. Besides the time-out compliance and door openings, the system detectors can also be related to noise, temperature, and other technical distractors. Intelligent fusion with the microsurgical views and segmentation of the phase of surgical could lead to a quantifiable score that is computed by the ADORA system.

Computer-Assisted Surgical Systems

Computer-assisted surgical (CAS) systems using video imaging technology are being increasingly developed, aiming at understanding the current situation and possessing the capability of automatically adapting the assistance functions appropriately [71]. Being able to automatically extract information on surgical phases, times

Who initiates for 'time out'?

		Surgical staff			Circulating staff			Anesthesia staff	
Session	Surgery	*surgeon*	*scrubnurse*	*resident*	*circulator1*	*circulator2*	*circulator3*	*anesthetsist*	*anest nurse*
1	1	S1	N1		C1			A1	AN1
am	2	S1	N1		C1	C8		A1	AN1
	3	S1	N2		C1	C2		A1	AN1
	4	S1	N2		C1	C2		A1	AN1
	5	S1	N3		C2	C8		A1	AN1
2	6	S2	N5		C3			A2	AN1
am	7	S2	N6		C4			A2	AN1
	8	S2	N7		C5	C8	C4	A2	AN1
	9	S2	N6		C6	C8	C7	A2	AN1
	10	S2	N7		C5	C8		A2	AN1
3	11	S3	N6	R1	C7			A3	AN1
pm	12	S3	N7	R1	C5			A3	AN1
	13	S3	N6		C7			A3	AN1
	14	S3	N7		C5			A3	AN1
	15	S3	N8		C5	C7		A3	AN1

Fig. 24.5 Overview of different staff types initiating and involved in time out

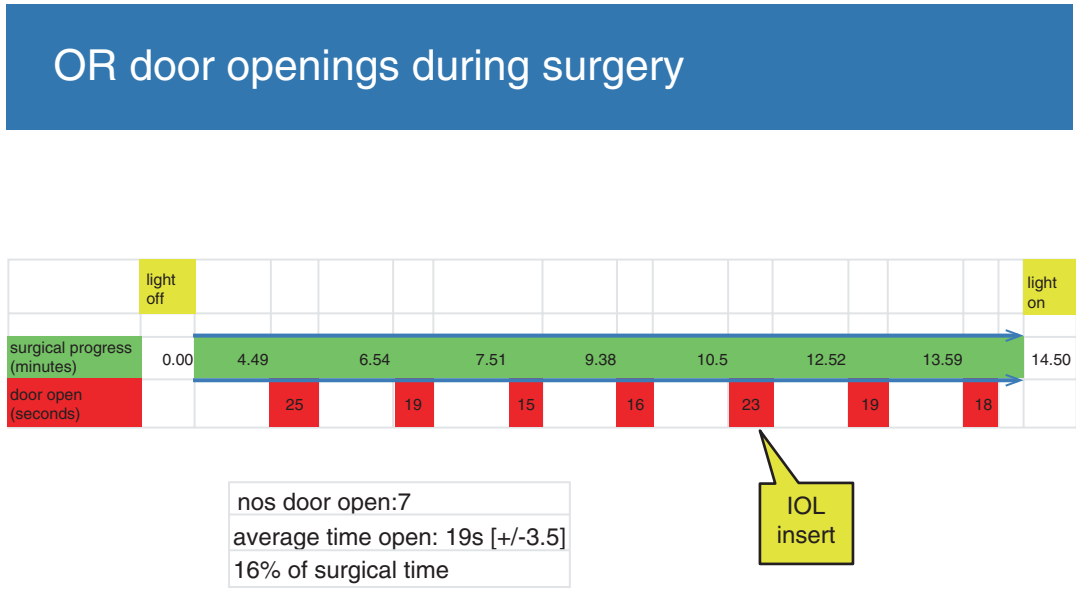

Fig. 24.6 OR door openings during surgery

frames, and events would facilitate proactive management of the OR processes and further enables for a structured evaluation of the (variation in) surgical performance.

There are two video sources for the ADORA system (microscope videos and OR overview videos). See Fig. 24.7. For microscope videos, the first step would be to develop an algorithm to automatically identify the main surgical patterns in a video that are deemed to be inevitably part of the surgical procedure. Once the patterns are identified, they are assigned labels, e.g. draping—surgical field clear of lashes, lens insertion, adjustment of position, etc. These labels are then integrated into a video signature, which is essentially a succinct yet complete representation of the video. The signatures of videos from trainee/new surgeons and expert surgeons are then compared and a measure of similarity is derived to determine the quality of trainee surgeons. These measures could be in the form of some 'distance' between signatures, which could then be translated into a quantifiable score for surgical performance evaluation [72]. For OR overview videos, the earlier similar algorithm would be applied to automatically identify the human activities in the OR, in which teamwork (e.g. explicit vs. implicit, action vs. information coordination behaviour) will be assessed based on operating room overview images. After comparison and analysis of the activities between new surgeons and expert surgeons, a quantifiable score for teamwork evaluation is computed by ADORA system. Finally, the outcomes of surgical performance evaluation and teamwork evaluation will be compared and integrated based on intelligent fusion algorithms. This will enable to determine the relation between technical and non-technical factors that influence surgical performance in the operating room.

Existing systems focus on "live showings" of high-quality images, not on recording and meta-analysis of historic data. We however propose to use real surgical data instead of simulated or otherwise biased. While simulation for new surgeons can be successful, in our approach surgeons do not need to go through time-consuming and expensive simulation sessions. In the proposed project, we will create 'big data' through the recording of all cases and details instead of "sample selection for assessment". The unique marriage of microscope and overview images will create a unique toolbox that is valuable for every hospital. The automatic assessment and recognition of surgical phases is

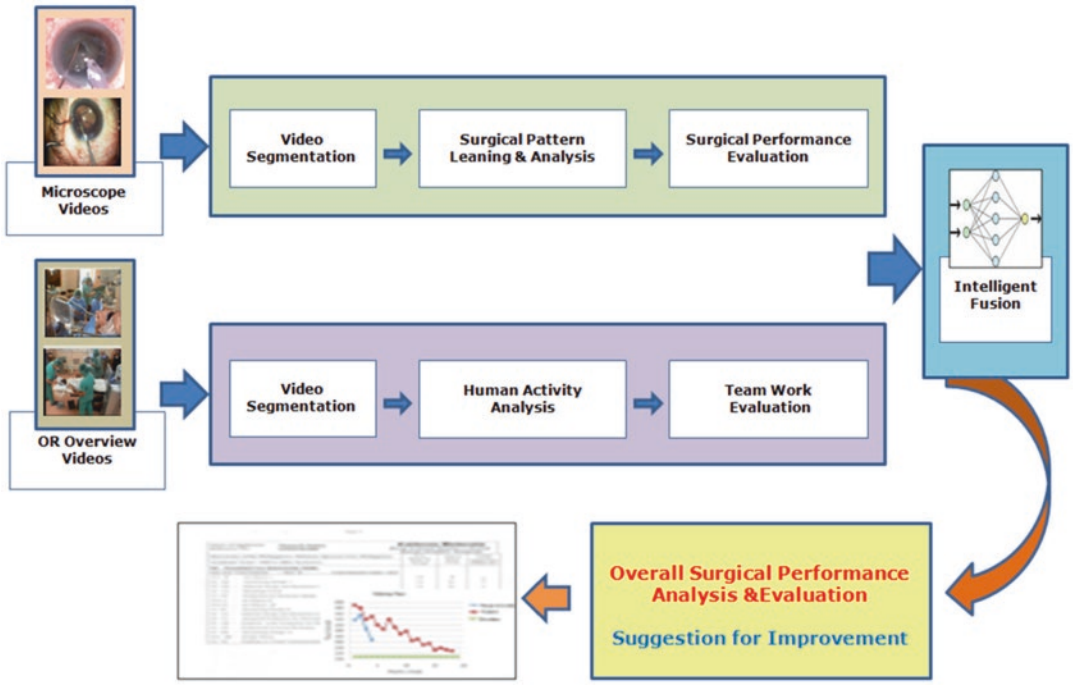

Fig. 24.7 Layout of the Automated Digital Operating Room Assistant (ADORA)

very useful for situational and context awareness of surgeons and surgical staff. The use of (microscope) videos allows automating the surgeons' assistance without altering the surgical routine which will reduce teaching time [73, 74].

These systems might also support intraoperative decision-making by comparing situations with previously recorded or known situations. This would result in a better sequence of activities and improved anticipation of possible adverse events, which would, on the one hand optimize surgery, and on the other hand improve patient safety. These systems have the promise to reduce complications that potentially result in blindness or reduced visual acuity. The regular day-to-day data obtained from the numerous cataract surgeries performed at the SNEC can be categorized into the ideal, good, and unsafe surgery and used by the new software written to assess to what extent each surgical procedure deviates from the ideal or normal safe surgery at the 12 preidentified crucial steps in cataract surgery.

While simulation for new surgeons can be successful, in our approach surgeons might not need to go through time-consuming and expensive simulation sessions as with ADORA we may be able to create 'big data' through the recording of all cases and details instead of "sample selection for assessment" [75]. The unique marriage of microscope and overview images will potentially create a unique toolbox that is valuable for every hospital and supposed to make cataract surgical training more standardized and give resident-surgeons objective feedback on their performance. Ultimately it could proactively identify unexpected variation and thereby improve communication, teamwork, and efficiency in the operating room.

Aviation has not become a safe industry just due to well-willing and transparency oriented pilots. Governmental bodies, like national transportation and safety boards played an important role. Sector-wide systems approaches are needed. If black boxes have proven to be invaluable in

improving safety in aviation, could not black boxes prove to be invaluable to ensuring safety in the operating room?

Recommendations[4]

Safety and Quality Improvement in the Operating Theatre Are Not Single Treatment Interventions But Require Complex Socio-technical Interventions to Succeed in Sustained Improvement

The design and the video feedback case studies demonstrate that many aspects of improvement are related to organizational aspects outside the scope of the team, like the autonomous position of self-employed medical specialists. Catchpole et al. [77] measured the effect of aviation-style team training on three surgical teams from different specialties. They concluded that aviation-style teamwork training can increase compliance and team performance but that "the effect was reduced by significant latent failures in organizational and personal management factors such as the attitude and collaboration of key individuals". Safety training is not always translated into sustained improvement in day-to-day care delivery. Assessing the organizational and social contexts in which interventions are successful, rather than trying to apply strict and artificial controls, is thus important to providing widely generalizable safety and quality improvement [78].

Diffusion and Learning in Professional Organizations

The fact that hospitals are professional organizations seems to have implications for how they diffuse innovations. The diffusion of innovations in hospitals takes often more time, requires a longer term perspective than in other industries, and reveals many different influencing factors. Trisha Greenhalgh et al. [14] have conceptualized these ideas in their model for 'Diffusion of innovations in health service organizations', based on many examples and a large literature review, a model for the spread and sustainability of innovations in service delivery and organization. They showed that diffusion is dependent on the characteristics of the innovation itself (and its resource system) as well as the 'user system' (with system antecedents and readiness for innovation, the adopter, assimilation, the implementation process) and its links to the outer context (socio-political climate, incentives and mandates, interorganizational norm setting and networks).

The 'user system' is one of the most striking differences between industrial settings and hospital care. The most important resources (physicians) are often not a formal part of the organization that acts as a threshold for the diffusion of changes. In our first case study, physicians cooperate in partnership with the hospital, giving it few opportunities to require physician involvement in quality and safety initiatives. The lack of physician involvement and thus ability to make sense of these changes greatly limits uptake, spread, and sustained engagement [79]. The individual, independent physician can have limited affinity with a hospital's 'performance system' perspective. Comparative studies of hospital performance where medical staff are employed by the hospital are, however, scarce [80]. There is no evidence for systematic differences in quality of care between self-employed or hospital-employed physicians [81, 82] but it is known that financial incentives could influence it. Fee-for-service physicians operate at higher volumes than hospital-employed physicians [81, 83, 84]. In Dutch general hospitals, even when all were lump-sum reimbursed, salaried medical specialists spent relatively less time on direct patient care and more time on organizational issues [85]. And a popular European comparison showed that countries where all doctors are hospital- (or government-) employed, such as Denmark and the U.K., have lower performance scores than the Netherlands [86].

[4]Part of these recommendations have been described in ref. [76].

Health Care Teamwork Is Work in Progress

Health care professionals seem to have a different view on teamwork than peers in other industries. Sexton et al. [87] compared safety attitudes in aviation and hospitals, finding differences in team perception. The majority of (resident) surgeons had high scores on cooperation; anaesthesiologists' and (surgical) nurses' views were much lower. Surgical consultants agreed more often than pilots to statements such as "Even when fatigued, I perform effectively during critical times" (60 % vs. 26 %) and "My decision-making ability is as good in medical emergencies as in routine situations" (76 % vs. 64 %). Despite the surgeons' disavowal, stressors can have a negative effect on surgical performance.

How organizational learning takes place in health care is very much influenced by the organizational culture and by the position of the physicians, and the relation between caregivers and others [88]. As shown in the case studies teamwork and integration of the sensomotor and non-technical issues are important for quality and safety improvements in health care; learning should be a collective process. Strong medical competences in combination with non-technical skills and teamwork are highly important for effective work, productive relations, and realizing organizational improvements in high-reliability bodies such as hospitals [89, 90]. Highly educated professionals are usually excellent in individual and single loop learning: they have had to learn to define and solve problems by themselves. Since they are good at their jobs, however, they rarely experience failure and usually react defensively or blame others when something goes wrong [89]. Acknowledging and identifying failures is, however, necessary for 'double-loop learning', which occurs when error is detected and corrected in ways that involve modifying the organization's underlying norms, policies, and objectives [91]. As observed in the case studies, there can be a difference between individual and collective learning in teams.

Learning from Others

The application of quality and safety methods from other industries can stimulate double-loop learning [92]. The results of the video feedback programme demonstrated that ophthalmologists and other hospital staff had become increasingly aware of safety issues. The multidisciplinary approach promoted social (team) orientation and thus learning. Professionals are disposed to focus on their own world. Mirroring other industries stimulates critical views on one's own work and simultaneously catalyses the diffusion of innovations.

We showed that design approaches are relevant to improve safety behaviour in ORs. The findings are also relevant for other hospital units: Birnbach et al. [93] showed in a small but controlled study that the location of the hand rub dispenser (immediately adjacent to the patient and clearly visible to anyone facing the patient's bed) increased compliance with hand washing. Lowe [94] showed the contribution of latent conditions to patient safety in the design of ORs and other hospital areas, finding that 27 % of all medical devices were designed without adequately addressing human factors issues. Grout [29] argues for 'mistake proofing' by changing designs to make processes more reliable and effective. Safety and quality approaches in hospital care, therefore, should include a human factors approach that focuses on system design in addition to teaching clinical and non-technical skills [95].

Conclusions

Human factor engineering and design thinking are useful approaches to improve safety, quality, and value in the operating room. Operating room (OR) design facilitates and stimulates safety awareness and resulted in significantly increased compliance with the safety procedures [96]. We demonstrated that simple and inexpensive changes in design can improve safety and reduce undesirable variation. Safety improvement approaches, therefore, should focus on 'mistake

proof' designs in addition to human factors and skills training. Moreover, team exchange and benchmarking with other high-risk industries is inspiring, facilitates risk awareness, and fosters the identification of practical safety improvements. Video feedback of OR processes and team behaviour can generate strong data to show variation and stimulate for improvement. Advanced technology and computer-assisted systems could be useful to support automated analysis of video streaming and enable proactive managing of the surgical workflow.

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Diagnostic Error in Surgery and Surgical Services

25

Mark L. Graber, Juan A. Sanchez, and Paul Barach

"You're on the Island of Conclusions."
"But how did we get here?" asked Milo.
"You jumped, of course," explained Canby. "That's the way most everyone gets here. It's really quite simple: every time you decide something without having a good reason, you jump to Conclusions whether you like it or not. It's such an easy trip to make that I've been here hundreds of times."
"But this is such an unpleasant looking place," Milo remarked.
"Yes, that's true," admitted Canby; "it does look much better from a distance."

—From *The Phantom Tollbooth*, by Norton Juster

Introduction

The surgical environment contains abundant opportunities for adverse events, and patients under surgical care are at risk for harm. The monitoring of surgical safety has focused almost exclusively on treatment-related concerns, especially on complications of surgery. Diagnostic errors have received little attention. Coincident with the growing awareness about the importance of diagnostic error in general and the recently issued report from the Institute of Medicine on *Improving Diagnosis in Health Care* [1], it is appropriate to consider what is known about diagnostic error in surgery, while acknowledging that the vast majority of knowledge in this domain has evolved from internal medicine and emergency medicine.

There are currently four definitions of diagnostic error (Table 25.1) [5], some of which are based on diagnosis as the noun (the label we give to an illness), some of which are based on diagnosis as the verb (the process of arriving at the label), and the most recent, IOM definition, "The failure to establish an accurate and timely explanation of the patient's health problem(s) or to communicate that explanation to the patient," which involves both. These definitions are complementary, and the choice of which one to use depends on the purpose and the audience being addressed. There are no specific definitions of diagnostic errors in surgery, but in the surgical context the concept of diagnosis extends to all of the decisions and choices made before, during, and after surgery. These all involve clinical reasoning, and will all entail a risk of error.

The IOM report provides a comprehensive review of diagnostic error that summarizes the

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Box 25.1. A case study of diagnostic error in surgery [1]

Pat, a 43-year-old male in good health, experienced progressively severe neck pain, and a scan showed a mass on his cervical spine. While removing the mass, the neurosurgeon sent a tissue sample to a hospital pathologist, who examined the sample and called back to the operating room to report that it was an atypical spindle cell neoplasm. Assuming that this meant a benign mass, the surgical team completed the operation and declared Pat cured. Following the operation, however, the hospital pathologist performed additional stains and examinations of Pat's tissue, eventually determining that the tumor was actually a malignant synovial cell sarcoma. Twenty-one days after the surgery, the pathologist's final report of a malignant tumor was sent to the neurosurgeon's office, but it was somehow lost, misplaced, or filed without the neurosurgeon seeing it. The revised diagnosis of malignancy was not communicated to Pat or to his referring clinician. Six months later, when his neck pain recurred, Pat returned to his neurosurgeon. A scan revealed a recurrent mass that had invaded his spinal column. This mass was removed and diagnosed to be a recurrent invasive malignant synovial cell sarcoma. Despite seven additional operations and numerous rounds of chemotherapy and radiation, Pat died 2 years later at age 45 years with a 4-year-old daughter and a 6-year-old son.

available literature through 2015 and presents a series of eight recommendations for improving diagnostic performance [1]. In addition to providing the new definition of error, the report provides a helpful framework for understanding and discussing the diagnostic process (Fig. 25.1). The power of describing diagnosis as a process,

Table 25.1 Four definitions of diagnostic error

Definitions of diagnostic error	
Author	Definition
Mark Graber	Medical diagnoses that are wrong, missed, or delayed [2]
	A diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information (LABEL)
Hardeep Singh	A breakdown in the diagnostic process and a missed opportunity to have made the diagnosis more accurately or more efficiently…regardless of whether there was patient harm [3] (PROCESS)
Gordon Schiff et al.	Any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis. This could include any failure in timely access to care; elicitation or interpretation of symptoms, signs, or laboratory results; formulation and weighing of differential diagnosis; and timely follow-up and specialty referral or evaluation [4] (PROCESS)
Institute of Medicine	The failure to establish an accurate and timely explanation of the patient's health problem(s) or to communicate that explanation to the patient [1] (LABEL AND PROCESS)

using the structure-process-outcome model of Avedis Donabedian, is that healthcare organizations and departments of surgery are familiar with process improvement, opening the door for applying these same approaches to improving surgical diagnosis and outcomes [6]. Many "surgical" errors involve the very first step—timely access to surgical care. Delays in referring patients who could benefit from surgical evaluation and interventions are common in many conditions, ranging from cataracts to cancer-related surgery to aortic dissection, to name a few. For some conditions, these delays can be catastrophic: in aortic dissection, delays between presentation and diagnosis and, once diagnosed, definitive treatment leads to dramatic increase in adverse outcomes [7].

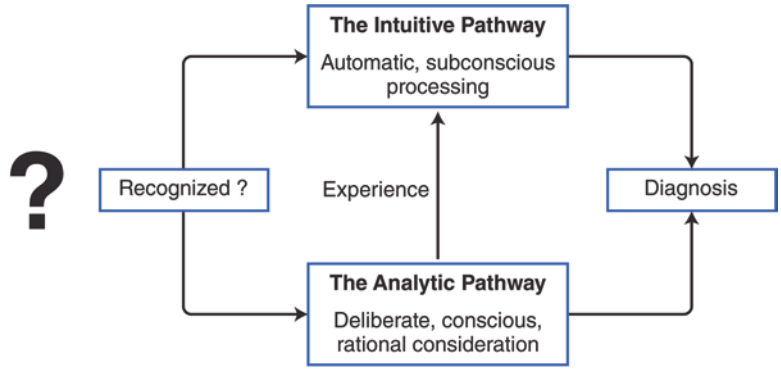

Fig. 25.1 The dual process paradigm of decision-making. Modified from Ref. [1]

The Incidence of Diagnostic Error in Surgery

Diagnostic errors are extremely common; one in every ten diagnoses is probably wrong [8]. Fortunately, the vast majority of diagnostic errors are inconsequential; the original problem resolves, the error is caught in time, the patient is resilient, or the treatment that was provided worked anyway. For some fraction of patients, however, the error results in harm and death. One estimate places the annual toll of diagnostic error in the USA at 40,000–80,000 deaths per year [9]. When timely surgical intervention is critical, misdiagnosing conditions such as spinal cord compression, necrotizing fasciitis, acute myocardial infarction, among many others, is lethal. The decision whether to operate on patients in whom these diagnoses are being considered is also a diagnostic decision, and the pressure and angst inherent in these situations is substantial and undeniable [10].

Data compiled from malpractice claims have clarified the relative incidence of surgical errors and what conditions are most commonly encountered. Diagnostic errors are the number one or two categories of claims in all of these studies. More than half of the diagnostic errors originate in ambulatory settings. In one recent study of 2531 cases of diagnostic error in ambulatory settings, 17% were surgery related, with orthopedics, urology, and general surgery being the leading categories [11]. Most of these cases involved patients with cancer, cardiovascular conditions, and various injuries, especially orthopedic injuries. In another study, of 7438 closed claims from 2007 to 2013, 1877 were attributed to diagnostic error [12]. Of the 3963 claims involving surgeons, 524 were related to issues in diagnosis. The top five claims in each specialty are noted in Table 25.2.

While data from filed claims can help determine the relative distribution of surgery-related cases, the true incidence of diagnostic error in surgery is not known because the number of cases with good outcomes is large and not precisely known. A similar situation is encountered in internal medicine and emergency medicine—the actual incidence of diagnostic error is not known, and at the present time, no organizations report rates of diagnostic errors [13, 14]. This reflects primarily the difficulty in identifying diagnostic errors, but also the challenges physicians encounter in coming to an agreement on what comprises an error, as opposed to the normal evolution of a diagnosis over time, or the normal variability from one physician to another in diagnostic evaluation. Although healthcare has focused on patient safety for almost two decades, diagnostic errors have received relatively little attention. This has reflected cultural attitudes discouraging discussion of misdiagnosis, the challenges in finding and defining these errors, assumptions about the impracticality of potential process or outcome measures of diagnostic quality, and the belief that diagnostic errors are less amenable than

Table 25.2 The most common conditions leading to claims involving diagnostic error [12]

General surgery claims (855)		Gynecological claims (674)	
16 % Diagnosis-related (143)		15 % Diagnosis-related (98)	
15.4 %	Puncture/laceration during procedure	21.4 %	Breast CA
9.8 %	Breast CA	12.2 %	Puncture/laceration during procedure
8.4 %	Post-op infection	9.2 %	Uterine CA
6.3 %	Colorectal CA	7.1 %	Cervical CA
4.2 %	Appendicitis	5.1 %	Ectopic pregnancy
Orthopedic claims (1647)		Obstetrics claims (757)	
13 % Diagnosis-related (215)		9 % Diagnosis-related	
11.2 %	Post-op infections	17.6 %	Ectopic pregnancy
5.6 %	Bone/soft tissue CA	7.4 %	Postpartum hemorrhage
4.2 %	Compartment syndrome	4.4 %	Puncture/laceration during procedure
3.3 %	Fracture malunion	4.4 %	Appendicitis
2.3 %	Pulmonary embolism	2.9 %	Pulmonary embolism

other types of medical errors to systems-level solutions [15, 16].

Although real-time data is lacking, there is a wealth of research data that suggests diagnostic errors are quite common [8]. In internal medicine, one in every ten diagnoses is believed to be wrong, based primarily on studies involving standardized patients with classic presentations in real-world settings. A recent study using chart reviews found that one in every 20 ambulatory care patients will experience a diagnostic error every year [17]. Autopsy studies consistently show major discrepancy rates (discrepancies with a high likelihood to have changed management and treatment) in the range of 10–30 % [18, 19]. In programs providing second opinions, the likely diagnosis changes for one in seven patients, and treatment recommendations change for one in three patients [20]. The surgical specialties differ greatly, however, in how often the second opinion differs from the first. In terms of treatment recommendations, changes are less frequent in surgical oncology (19 %) and urology (28 %), and are more frequent in neurosurgery (42 %) and obstetrics (42 %) [20]. Finally, retrospective collections of cases are available for many conditions, and invariably report either bad or shocking statistics on diagnostic accuracy and timeliness. Several examples relevant to surgical care are listed in Table 25.3.

Table 25.3 Examples of case studies of specific surgical conditions and their findings relating to diagnostic accuracy and timeliness

Appendicitis	Graff et al. (2000) [21]	Retrospective study at 12 hospitals. Of 1026 patients who had surgery for suspected appendicitis, 110 patients had no appendicitis at surgery; Of 916 patients with a diagnosis of appendicitis, the diagnosis was missed or wrong in 170 (18.6 %)
Subarachnoid hemorrhage	Kowalski et al. (2004) [22]	Of 482 patients with subarrachnoid hemorrhage, the diagnosis was initially wrong in 56 (12 %) and 22 of these patients suffered neurological complications before the diagnosis was confirmed
	Edlow (2005) [23]	Review of published studies: approximately 30 % are misdiagnosed at presentation

(continued)

Table 25.3 (continued)

Ruptured aortic aneurysm	von Kodolitsch et al. [24]	In patients presenting with chest pain due to dissections of the proximal aorta, the diagnosis was missed in 35 %
	Lederle et al. (1994) [25]	Review of all cases at a single medical center over a 7-year period. Of 23 abdominal aortic dissections, the diagnosis was initially missed in 14 (61 %)
Gastric cancer	Mikulin and Hardcastle [26]	Of 83 patients with gastric cancer, the median delay in diagnosis was 7 weeks
Oral Cancer	Schnetler [27]	Of 96 cases seen in three oral surgery departments, the referring general practitioner had made the correct diagnosis in only 52 %
Breast cancer	Beam et al. (1996) [28]	50 accredited centers reviewed blinded mammograms of 79 women, 45 of whom had breast cancer. The diagnosis would have been missed in 21 %
Cancer detection	Burton et al. (1998) [29]	Autopsy study at a single hospital: Of 250 malignancies, 111 were either missed or misdiagnosed, and in 57 cases the cause of death was cancer related
Breast cancer	Burgess et al. (1998) [30]	Of 132 patients with breast cancer, referral for definitive management was delayed in 32 (17 %)
Tongue cancer	Kantola et al. (2001) [31]	Of 75 cases, referral to specialty care was delayed in 35 %
Cancer-related spinal cord compression	Levack et al. (2002) [32]	Of 319 patients, the median delay in diagnosis was 18 days
Bone cancer	Goyal et al. (2004) [33]	Of 103 patients with osteosarcoma or Ewing's sarcoma, delayed diagnosis was associated with being seen by a general practitioner (vs. ER physician) and in patients under 12 years of age
Testicular cancer	Vasudev et al. (2004) [34]	Of 180 men with testicular cancer, referral to specialty care was delayed in 60 %

The Etiology of Diagnostic Error in Surgery

Diagnostic errors in surgical patients evolve from the same set of cognitive- and system-related factors as in other clinical settings. A very small fraction of errors derives from patient-related factors, for example patients with Munchausen's syndrome who feign symptoms [35], or patients who choose not to undergo diagnostic tests that were recommended or attend follow-up appointments. Most errors, however, reflect shortcomings of the clinician's cognitive processes, in the face of one or more breakdowns in the systems of care [2].

Cognitive errors involve one of three problems:

1. *A knowledge deficit*. For example, the physician does not know or recognize the disease at hand. There are over 8000 diseases listed in the National Library of Medicine's MESH catalogue, and over 100 new diseases are entered every year.

2. *A problem collecting or interpreting diagnostic data*. For example, the physician fails to appreciate the auscultatory findings of a pneumothorax, or doesn't recognize that a patient's hyperkalemia is from hemolysis, noted at the bottom of the laboratory slip.
3. *An error in "putting it all together," synthesizing the facts at hand* with the physician's knowledge base to arrive at the correct diagnosis or differential diagnosis. This is the process of clinical reasoning.

There is no data on the relative frequency of these error types in surgery, but in internal medicine, the vast majority of cognitive errors are in the third category, which entails synthesizing the available information [2]. The current paradigm of clinical reasoning involves the use of two very different cognitive pathways [36] (Fig. 25.2). Except for early trainees, most new problems are recognized immediately, and using a subconscious, intuitive pathway, the diagnosis is evident within milliseconds. If the problem is not recognized, we resort to deliberate, rational consideration of the situation, a process that takes longer and involves cognitive "work." Humans and probably all animals have evolved to take advantage of the intuitive pathway whenever we can, and indeed almost all everyday actions and thoughts derive from this system. In practice, both systems may come into play in diagnosing a new patient problem, and in theory, the rational system has the opportunity and responsibility to be constantly monitoring intuitive processing. If some discrepancy is noted or something just "doesn't fit," the rational pathway takes over and we sense the need to slow down, or look for additional data or input to affirm our hunches or heuristics. If there are no such flags, we assume our assessment is correct and proceed. Unfortunately, the "feeling of right" in these situations is exactly the same whether our diagnosis is correct or not, until that unpleasant point that we realize that the diagnosis may be wrong [37]. Physicians, like all decision-makers, are generally not accurate in predicting which of our diagnoses are correct or not, a problem of calibration [38–40].

Both systems are error prone but for different reasons. The *rational pathway* for understanding a clinical dilemma in surgery can be degraded by insufficient knowledge or experience, or by flaws in logical thinking, or reasoning. *Intuitive decision-making* can be degraded by a large range of innate cognitive "biases," of which over 150 have been described, (See Wikepedia's ever expanding "List of Cognitive Bias") and commonly encountered examples are shown in

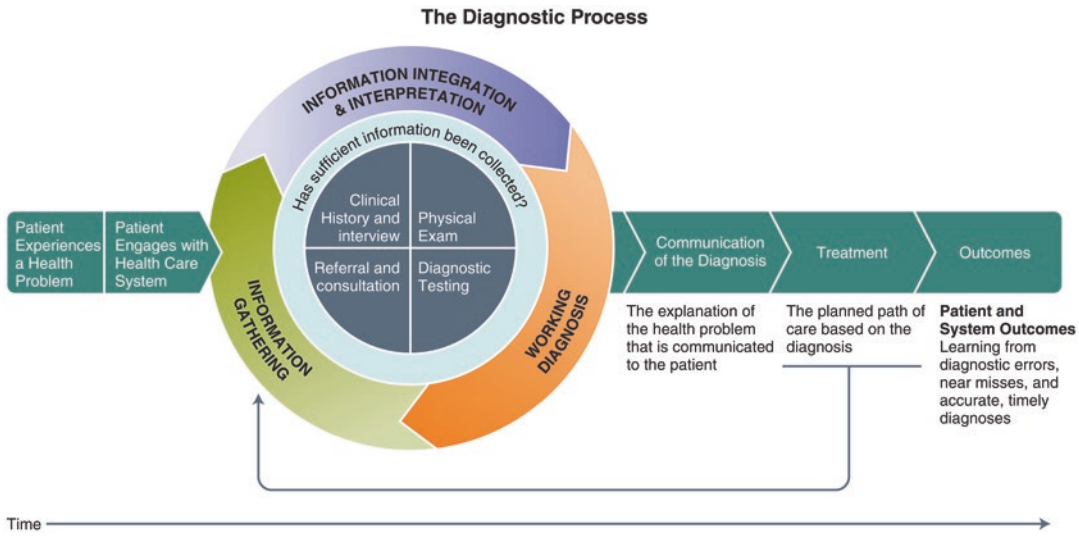

Fig. 25.2 The current dual-process paradigm for "how doctors think"

Table 25.4 Common cognitive biases associated with diagnostic error

Common cognitive biases in medical diagnosis		
Cognitive bias	Definition	Predisposing factors, examples
Premature closure	Accepting a diagnosis that "fits" without considering other possibilities	The physician is rushed; failure to recognize two conditions happening at once (e.g., second or third fractures after identifying the first one)
Representativeness bias	Missing the correct diagnosis because of excessive reliance on the presence/absence of classic characteristics	Atypical presentations: an elderly woman with fatigue and shortness of breath but no chest pain is not worked up for MI
Availability bias	Judging a diagnosis to be more likely if it readily comes to mind, particularly because of recent experience	A patient with vomiting and fever from gangrenous bowel is diagnosed with gastrointestinal flu because it is "going around"
Framing error	Accepting a diagnosis suggested by the patient or another MD	Referrals, handoffs. The consulting surgeon may too easily accept the diagnostic impression of the ER physician who first sees the patient
Context errors	Misunderstanding the true context of the problem at hand, a failure of sense-making	A patient with vomiting and fever is assumed to have a GI problem, but the real issue is sepsis and diabetic ketoacidosis
Affective bias	Negative or positive emotions and feelings that subconsciously detract from optimal decision-making	*Positive*—we fail to consider a more serious diagnosis in someone we are close to or admire or identify with
		Negative—we fail to investigate further in a patient who we subjectively dislike

Table 25.4 [41]. The IOM report emphasized the importance of the environment and the work system in determining the quality and outcome of diagnosis and clinical decisions. The local culture of safety is critical, along with human factors that can influence the immediate situation, such as stress, distractions, fatigue, and team support.

Surgeons face a number of unique cognitive challenges that may predispose to diagnostic errors. First, patients undergoing surgery have typically been seen by a number of physicians leading up to the surgical event, creating the unavoidable assumptions that all of the requisite diagnostic thinking has already been completed, and that the diagnostic conclusions can be trusted (see Box 25.2).

Conversely, patients presenting with conditions that are considered primarily surgical, such as patients with an "acute abdomen," may not be seen by other internists or emergency medicine staff, thus losing the opportunity to be assessed from a different perspective. Secondly, the large amount of task-oriented activities surrounding preoperative preparation and the mental rehearsal a surgeon or anesthesiologist must go through may not leave sufficient cognitive capacity to avoid diagnostic errors or prevent biases [42]. It is generally acknowledged that cognitive overload directs cognition away from the rational, deliberate pathway and toward the more error-prone intuitive approach. Finally, surgeons require a high level of confidence to lead a team through high-risk operations, raising the question of whether this may sometimes engender overconfidence and a tendency to disregard other opinions or novel information. This requires training surgeons on becoming team leaders and being aware of how these factors can shape their actions and the actions and outcomes of others [43].

System-related errors that contribute to diagnostic error include breakdowns in communica-

Box 25.2. Cognitive Challenges of Diagnostic Error in Surgery

A patient is being evaluated for upper GI bleeding in the Emergency Department. The patient has a remote history of an abdominal aortic aneurysm repair and a more recent history of peptic ulcer disease. The diagnosis by the patient's primary care provider, the ED staff, and a consulting gastroenterologist is a bleeding ulcer. When the surgeon is called for persisting bleeding and proceeds with plans for an emergency gastrectomy, the assumption is made that the diagnosis is correct. In the OR, the patient is found to have an aorto-enteric fistula and the patient exsanguinates on the table before a vascular surgeon can be called in to assist.

What factors might have contributed to the cognitive errors in this case?

- Knowledge by the surgeon about the prior history of aortic aneurysm repair
- Deliberation about the speed of the bleeding ulcer diagnosis
- Cognitive challenges of preparing for the technical aspects of the procedure
- Accepting a diagnosis without due consideration of other possibilities leading to assuming the diagnosis is correct

tion or coordinating care, reliably transmitting test results and consults, erroneous laboratory or imaging interpretations, difficulties associated with using an electronic health record, supervising trainees, and a host of other issues [2]. Cognitive load contributions are identified as the lead cause for most cases of diagnostic error [2].

Addressing Diagnostic Error in Surgery

As the old saying goes, the first step in addressing any problem is recognizing that you have one. This is particularly relevant in the case of diagnostic error, because physicians generally believe that they are practicing at a very high level, and tend to attribute diagnostic errors to other clinicians who aren't as experienced or careful. All humans and, perhaps, physicians in particular are overconfident in their abilities and in the correctness of their clinical decisions [44] The cognitive errors made in clinical diagnoses are the same errors people make in their everyday lives; we jump to conclusions, we trust information given to us without verifying it, we accept an assigned diagnosis without rethinking it, and our emotions get in the way of good judgment. All physicians can improve the quality of their practice by accepting the universal predisposition to error, understanding the causes of diagnostic error, and addressing these problems transparently.

Addressing Interpretive Diagnostic Error in Surgical Pathology and Cytology

Optimal surgical diagnosis and care relies heavily on accurate cyto-pathological diagnosis, and errors deriving from the interpretation of cytology, biopsy, or surgical specimens are important to recognize and address. Errors may arise at any point in the "total testing cycle" [45], which begins with specimen acquisition, labeling, and delivery to the laboratory, where the specimen is prepared for the analytic phase. The post-analytic phase begins with a report generation and ends with delivery of the report to the clinician, and the clinician acting on it appropriately. Unlike the other phases of the total testing cycle, the analytic phase is substantially different in surgical pathology and cytology (vs. clinical pathology and automated lab testing) in that it involves visual interpretation and the judgment of the pathologist to arrive at the correct interpretation [33, 46, 47]. Compared to automated lab testing, which operates at error rates in the range of 0.01–0.001 %, the error rate in surgical pathology is orders of magnitude higher, in the range of 2–5 % [34, 48, 49]. Errors in the post-analytical phases of testing are also especially common [50, 51], and many involve failures to

reliably communicate test results [52], as illustrated in the case vignette above.

There are many factors that contribute to an accurate interpretive diagnosis, including: (1) the pathologist's knowledge and experience, (2) clinical correlation, (3) standardized diagnostic criteria and taxonomy, (4) confirmatory ancillary studies when available, and (5) secondary review of cases.

Studies have shown the additive value of clinical correlation, standardization of diagnostic criteria, and taxonomy and confirmatory ancillary testing to the accuracy of surgical pathology and cytology diagnoses [53–55]. Several of these factors contribute to establishing a precise diagnosis, but the pathologist's knowledge and experience remain the essential factors in interpretive diagnosis such as in neuropathology tissue ambiguity. Although numerous studies have shown that second opinions help detect interpretive diagnostic errors [56], there have been only scattered efforts to formalize and adopt this practice as a clinical standard. Targeted case reviews could be an integral component of a quality assurance plan that is aimed proactively at preventing errors before they have a potential adverse impact on patients. The College of American Pathologist has issued a recent guideline on the use of second opinions in surgical pathology [49], (see Table 25.5) and a much more detailed and specific set of guidance on second opinions in cancer diagnosis is available in the 11-part series from Cancer Care Ontario [57].

Table 25.5 Guidelines College of American Pathologists Guidelines for Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology [48]

• Anatomic pathologists should develop procedures for review of pathology cases in order to detect disagreements and potential interpretive errors, and to improve patient care
• Anatomic pathologists should perform case reviews in a timely manner to have a positive impact on patient care
• Anatomic pathologists should have documented case review procedures that are relevant to their practice setting
• Anatomic pathologists should continuously monitor and document the results of case review
• If pathology case reviews show poor agreement within a defined area, anatomic pathologists should take steps to improve agreement

Addressing Cognitive Errors

Experience and meaningful feedback are the cardinal requirements to acquire expertise, and expertise is probably the most important factor in determining the ultimate quality of the diagnostic process. It is generally accepted that experts make the fewest errors, possibly because they've made them all before [58, 59]. Think-aloud verbal protocols, both concurrent and retrospective, have been used to reveal the refined knowledge and reasoning strategies underpinning superior performance [60]. These techniques are useful to identify the domain-specific knowledge that experts utilize to perform the task. For example, Lesgold et al. reported that expert radiologists demonstrate longer reasoning chains with more of their comments being interlinked and interconnected to at least one other chain. These findings highlight how experts store and organize knowledge in a more coherent manner, enabling them to better access and retrieve this information to solve simple tasks [61].

Regardless of one's level of expertise, there are several strategies to improve clinical reasoning that have good potential to reduce the likelihood of cognitive errors [62, 63]:

1. *Practice Reflectively*. Active reflection allows clinicians the rational, deliberate pathway to review intuitive decisions, opening the door to considering alternative ideas or approaches. Although both intuitive and rational cognition are error prone, it is widely believed that most diagnostic errors involve the intuitive pathway, and that these errors can either be avoided, or recognized more reliably by reflective practice and knowing the common biases that arise. "De-biasing" refers to formal training on the common cognitive error types, and has been shown to reduce diagnostic errors in research settings [64–66]. Because the most common cognitive errors are prema-

ture closure (accepting a diagnosis without due consideration of other possibilities) and context-related errors, it is valuable to be as comprehensive as possible in considering different diagnostic possibilities. Always construct a differential diagnosis. In a recent study of diagnostic error, there was no differential diagnosis listed in 80 % of the cases [67]. *"What else can this be?"* is the universal antidote in these situations and that question should be commonly asked by both patients and their surgeons [68].

2. *Work in Teams*. The power of the team to improve decision-making and performance in general is well recognized and amply documented [69, 70]. The Institute of Medicine strongly endorsed the recommendation to work in teams as a strategy to reduce diagnostic error, and specifically called for patients and nurses to be consistently and effectively included and empowered as team members [1]. The patient can act as a safety net to detect diagnostic errors, and as the party most intimately affected has both the knowledge and the incentive to monitor the diagnostic process and its outcomes [71, 72].

   The concept of the surgical team is well established in the operating room, where team behaviors have been shown to correlate with outcomes and complications [73], especially in cases of high complexity [74]. The leadership style of the surgeon has received increasing attention as a determinant of surgical outcomes; surgeons who score poorly in transformational leadership styles have worse outcomes [75], thought to reflect in part a climate in the surgical theater where there is limited psychological safety for others to speak up [76]. The "captain of the ship" approach discourages members of the team from pointing out findings which may be inconsistent with the presumptive diagnosis out of fear of censure [77].

   Surgical team training, such as using TeamSTEPPS, teaches the communication and coordination processes that are required to bring together the individual knowledge, skills, and attitudes of the team members in the service of a common and valued team goal [78]. At its core, TeamSTEPPS™ aims to teach four fundamental competencies that constitute teamwork (leadership, situation monitoring, mutual support, and communication) with the aid of patient scenarios, case studies, multimedia, and simulation [79, 80]. Individual surgical team members are highly specialized and have their own functional task-work (e.g., anesthesia, nursing, surgery, and perfusion), yet come together as a team towards the common goal of treating the patient. Interventions focusing on teamwork have shown a relationship with improved teamwork and safety climate [81]. The "working together" of a clinical microsystem is accomplished by a complex suite of "nontechnical skills" coming together to grow the situational awareness and interconnectedness [82, 83]. Teams that score low on independently observed nontechnical skills make more technical errors and in cases where teams infrequently display team behaviors, patients are more likely to die or experience major complications [84]. There is a significant correlation between subjective assessment of teamwork by team members and postoperative morbidity. Good teamwork (in terms of both quality and quantity) is associated with shorter duration of operations, fewer adverse events, and lower postoperative morbidity [85].

3. *Get Help—Second Opinions*. Second opinions are a particularly effective method of detecting diagnostic errors, and should be encouraged at every opportunity. This should begin by requesting a second review of all important surgical biopsies, whereas, the diagnosis will change in a small but important fraction of these cases [49, 86]. Interdisciplinary case conferences and "tumor boards" are the role model for effective ways to obtain second opinions and learn from others in critical manner [87]. Working in teams is a very effective way to obtain second opinions. Second opinions may be helpful intraoperatively from other surgeons or other types of specialists in ensuring a correct diagnosis or operative decision.

A second key area where second opinions may be helpful is when the decision to proceed with elective surgery is being considered. Second opinions were once required by insurance carriers; of 4555 patients who participated in the Cornell Elective Surgery Second Opinion Program, the second surgeon often disagreed with the need for elective surgery, and disagreement was highest in gynecology and orthopedic cases [88]. Disagreement, of course, does not imply that the initial decision was wrong, as we lack studies with detailed and long-term follow-up of patients.

An interesting variant of this approach involves the addition of a nurse practitioner to a pediatric trauma service to specifically review and follow all cases. Missed injuries in trauma care average 4–5 % [89], and the involvement of this second pair of eyes was effective in uncovering many surgical misdiagnosis cases that would have otherwise been missed [90].

Web-based decision support tools are readily available to assist in differential diagnosis [91–93], but these resources are generally underutilized by clinicians [94]. Although not yet evaluated in surgical settings, these tools can improve the accuracy of medical diagnosis, in addition to being an excellent teaching tool for trainees. Checklists and "time out" procedures have proven to be an important aid in regard to surgical safety, and comparable interventions could be potentially helpful in preventing diagnostic error by surgeons if used to engage surgical providers in meaningful way [95]. The tertiary trauma survey, for example, provides a systematized and reproducible approach to the diagnosis of injuries in these patients, and can reduce diagnostic errors [89].

Addressing System-Related Errors

All system-related errors are considered preventable, and the original IOM report *To Err is Human* concluded that the repair of system-related flaws would be the most effective approach to improving safety in healthcare [96]. A recent systematic review of system-related diagnostic errors identified several opportunities to close the system-loopholes that can become the key factors in producing an error [97]. Communication breakdowns are the most commonly identified problems in cases of diagnostic error, as they are in all other types of adverse events. Surgical care is particularly susceptible to communication challenges, given the large number of players involved in a typical case, involving the patient, family members, the referring physicians or ER staff, the anesthesiologists, the surgical team, and pathologists, just to name a few [98]. Communication breakdowns, for example, are almost always cited in cases of wrong-site surgery [99], and in patient handoffs where vital information is lost or degraded [100].

The electronic medical record can improve communication if used appropriately, by making tests, notes, consults, impressions, and plans readable, and accessible. They can also degrade communication to the extent that the team members no longer interact verbally, as illustrated by the "Texas Ebola" case where the ER triage nurse knew that the febrile patient in the ER had been exposed to Ebola, but the treating clinician failed to read her note in the electronic record [101]. Copy-paste notes seriously degrade the reliability of the medical record [102], as do many features that were designed more for billing than to optimize clinical care [103, 104]. The case study presented in this chapter illustrates a communication breakdown, the failure of an amended pathology report to be effectively communicated to the cancer surgeon in a timely manner.

Other addressable system-related human factors problems include workload stress, fatigue, and the constant distractions that are commonplace in surgical environments [105, 106]. Surgical units should also promote a culture of safety at every opportunity, eliminating blame and focusing on learning from cases of diagnostic error. Encouraging feedback from patients, autopsies, and clinical follow-up on discharged patients back to discharging clinical staff offer enormous learning opportunities both to validate the accuracy of diagnosis and to unmask process deficiencies. Most training programs, both undergraduate and postgraduate, offer little or no training on patient safety in general, or diagnostic

error specifically [107]. Lectures, case studies, and morbidity/mortality conferences are all appropriate vehicles to expose surgical trainees and students to the basic concepts relevant to diagnostic error: Human factors, the cognitive psychology of decision-making, practice-based improvement, communication optimization, teamwork, and many other topics would provide both a foundation and a vocabulary for improving the reliability of clinical reasoning in practice [108].

One of the major recommendations in the IOM report on *Improving Diagnosis in Health Care* was to make the patient an effective partner in the diagnostic process (see Chaps. 4–13). There is growing evidence that engaged patients have better health outcomes [109]. Involving patients in decisions on their elective surgery illustrates that patients welcome being involved in shared decision-making. An instructive example is a patient-focused decision aid regarding hip and knee replacement surgery that reduced the number of operations by 26 and 38 %, respectively [110].

The Future Reliability and Assurance of Surgical Diagnosis

In the long run, the quality and safety of diagnosis in surgery will inevitably improve, thanks to innovations in diagnostic testing. There is no better example than the problem of diagnosing appendicitis, originally based on the careful integration of the clinical story with observations of the patient's abdomen, and inevitably the critical presence or absence of discomfort at McBurney's point. The diagnosis was missed in 20 % of patients, and of those patients who went to surgery, about the same percentage had something else. Abdominal imaging has led to dramatic improvements in diagnostic reliability, with sensitivity and specificity now exceeding 90 % [111]. This represents a real improvement in the reliability of diagnosis, but possibly at the expense of some degradation in the ability of physicians to conduct a thorough and accurate physical examination [112].

The more relevant question is whether we can improve the timeliness and accuracy of diagnosis in the short term. The recent advances in understanding the system-based and cognitive factors that contribute to these errors are important, and they create an opportunity to redesign the training and feedback to surgeons and consider what interventions might be helpful [62, 63, 97]. Surgeons and surgical programs should be encouraged to consider which of these interventions would have the greatest impact on improving diagnostic performance in their own situations and participate in research programs to evaluate the outcomes of these projects. Surgical programs should strive for patient-centered approaches that incorporate the benefits of working in teams, practicing reflectively, taking advantage of second opinions, and efforts to address the many other system-related and cognitive factors that underlie diagnostic errors.

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Preventing Perioperative 'Never Events'

26

Patricia C. Seifert, Paula R. Graling, and Juan A. Sanchez

"Errors will be made, but it is from our mistakes, if we pursue them into the open instead of obscuring them, that we learn the most"

—Harvey Cushing, New England Otological and Laryngological Society, 1920, 156, p. 210.

Introduction

In 2001, Kenneth Kizer, M.D., the former Chief Executive Officer of the National Quality Forum (NQF), introduced the term 'Never Event' to describe an egregious medical error that should never occur (e.g., wrong-site surgery) [1]. The initial list published by the NQF in 2002 identified 27 events. A revision in 2011 regrouped the events into seven categories: surgical, device, patient protection, environmental, care management, radiologic, and criminal [2]. Three important characteristics of never events are as follows:

1. Unambiguous: identifiable and measurable.
2. Serious: results in significant patient disability or death.
3. Usually preventable.

Another consideration that has become increasingly significant in an era of cost consciousness is that adverse events are expensive. For hospitals and physicians, never events such as surgical site infection and other adverse complications can result in a reduction of reimbursement from the Centers for Medicare & Medicaid Services (CMS) and other payers [3–5].

Among the never events that have been identified during the perioperative period by the NQF [1] and CMS [3]—and are discussed in this chapter—are the following:

- Misidentification (wrong patient/procedure/site)
- Medication errors
- Pressure ulcers and related positioning never events
- Surgical site infections
- Electrical and other energy-related never events
- Retained surgical items (formerly known as 'retained foreign bodies')
- Device failures and misuse
- Difficult airway, failed airway, and air embolus
- Surgical specimen errors
- Inadvertent hypothermia
- Instrument care and reprocessing never events

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These adverse events are similar to the top rated safety issues reported in a study [6] of over 3000 perioperative nurses working in both hospitals and ambulatory surgery centers. The consistency of the issues identified as safety risks among the health professions is reflected in the surgical [7–9], medical [10], anesthesia [11, 12], nursing [13–19], and interprofessional [20–22] literature.

The following discussion of never events incorporates information from various professional sources and describes recommendations, strategies, and resources that can be employed to prevent or minimize these adverse events.

Misidentification (Wrong Patient/ Procedure/Site)

Over 2/3 of the respondents (68.6%, $N=2151$) in the study by Steelman and colleagues ([6], p. 407) identified the prevention of wrong site/procedure/patient surgery as the highest priority safety issue in both hospitals and ambulatory surgery centers. Although preventive tools, such as checklists [23] have been promoted since the 1998 publication of The Joint Commission's Sentinel Alert [24], misidentification never events persist [25].

Studies employing checklists have shown reductions in surgical complications and mortality [23, 26]; however, errors and adverse events continue to occur [14]. The World Health Organization's (WHO) original [23, 27] checklist addresses three phases of surgery: (1) before anesthesia induction (briefing), (2) before the skin incision (time-out), and (3) prior to the patient's exit from the operating room (OR) (debriefing). Numerous factors, most notably communication failures, lack of compliance with policies and procedures, and lack of collaboration and teamwork [7, 28] contribute to the challenges associated with avoiding errors during the three phases of surgery.

The WHO checklist has undergone numerous iterations. One notable example developed by the Association of periOperative Registered Nurses [29, 30] (AORN) is a surgical checklist (Fig. 26.1 Checklist) that incorporates the WHO requirements [23] as well as components of The Joint Commission's Universal Protocol™ [31]. The checklist also mirrors many of the guideline statements from the American College of Surgeons' (ACS) Statement on Ensuring Correct Patient, Correct Site, and Correct Procedure Surgery [32] as well as information found on the Anesthesia Patient Safety Foundation's (APSF) website [33].

In particular, interventions to prevent or reduce never events include:

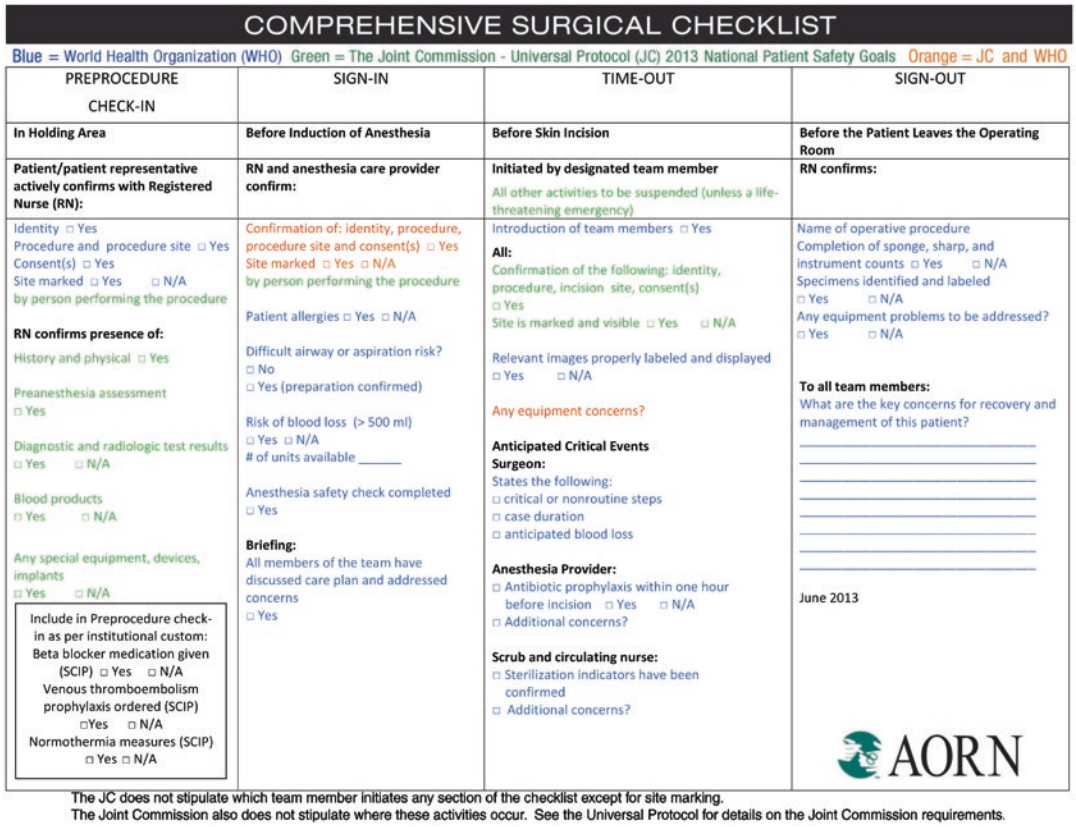
- improving communication (e.g., nurses clarifying scheduled procedures with surgeons' office staff as well as the attending surgeon),
- complying with policies mandating the use of checklists (e.g., team members engaging in time-outs and surgical briefings and debriefings),
- strengthening teamwork (e.g., engaging in simulation exercises to promote interprofessional behaviors), and
- training team members to strengthen nontechnical skills (e.g., situational awareness, flexibility, adaptability, questioning, leadership) [34–37]

Additional strategies for reducing the risk of wrong patient/procedure/site surgery are listed in Table 26.1.

Medication Errors

According to Grissinger and Dabliz [38], Steelman and Graling [19], and others [39, 40], major issues related to medication safety include:

- failure to confirm the identity of the patient with the right medication ordered for that patient
- storage of similar-looking and same-sounding medications in close approximation (e.g., placed next to one another in a medication storage unit)
- absent, incomplete, or inaccurate labeling of medications on the surgical field (including those transferred into metal or plastic basins—such as heparin solutions or normal saline)
- verbal orders (e.g., unclear, inarticulate, incomplete)



COMPREHENSIVE SURGICAL CHECKLIST

Blue = World Health Organization (WHO) Green = The Joint Commission - Universal Protocol (JC) 2013 National Patient Safety Goals Orange = JC and WHO

PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
In Holding Area	**Before Induction of Anesthesia**	**Before Skin Incision**	**Before the Patient Leaves the Operating Room**
Patient/patient representative actively confirms with Registered Nurse (RN):	**RN and anesthesia care provider confirm:**	**Initiated by designated team member** All other activities to be suspended (unless a life-threatening emergency)	**RN confirms:**
Identity □ Yes Procedure and procedure site □ Yes Consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure **RN confirms presence of:** History and physical □ Yes Preanesthesia assessment □ Yes Diagnostic and radiologic test results □ Yes □ N/A Blood products □ Yes □ N/A Any special equipment, devices, implants □ Yes □ N/A Include in Preprocedure check-in as per institutional custom: Beta blocker medication given (SCIP) □ Yes □ N/A Venous thromboembolism prophylaxis ordered (SCIP) □Yes □ N/A Normothermia measures (SCIP) □ Yes □ N/A	Confirmation of: identity, procedure, procedure site and consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure Patient allergies □ Yes □ N/A Difficult airway or aspiration risk? □ No □ Yes (preparation confirmed) Risk of blood loss (> 500 ml) □ Yes □ N/A # of units available _____ Anesthesia safety check completed □ Yes **Briefing:** All members of the team have discussed care plan and addressed concerns □ Yes	Introduction of team members □ Yes **All:** Confirmation of the following: identity, procedure, incision site, consent(s) □ Yes Site is marked and visible □ Yes □ N/A Relevant images properly labeled and displayed □ Yes □ N/A Any equipment concerns? **Anticipated Critical Events** **Surgeon:** States the following: □ critical or nonroutine steps □ case duration □ anticipated blood loss **Anesthesia Provider:** □ Antibiotic prophylaxis within one hour before incision □ Yes □ N/A □ Additional concerns? **Scrub and circulating nurse:** □ Sterilization indicators have been confirmed □ Additional concerns?	Name of operative procedure Completion of sponge, sharp, and instrument counts □ Yes □ N/A Specimens identified and labeled □ Yes □ N/A Any equipment problems to be addressed? □ Yes □ N/A **To all team members:** What are the key concerns for recovery and management of this patient? _____ _____ _____ _____ _____ _____ _____ _____ June 2013 AORN

The JC does not stipulate which team member initiates any section of the checklist except for site marking.
The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.

Fig. 26.1 Comprehensive Surgical Checklist. Reprinted with permission from AORN.org. Copyright © 2016, AORN, Inc.: Denver, CO. All rights reserved

- lack of standardization (e.g., drug doses, names, routes)
- excessive variability in available doses of medications
- lack of unequivocal differentiation between medications (e.g., geriatric/adult/pediatric/neonatal; look alike/sound alike; packaging design, coloration)
- lack of clear, direct communication about (e.g.) drug name/strength/amount between medication preparer (e.g., scrub person) and user (e.g., surgeon)
- failure to fully read medication labels
- acceptance of nonapproved medication abbreviations
- inconsistent processes to remove outdated medications
- reliance on use of surgeon's procedure or preference card for drug preparation and use
- staff fatigue

Ambulatory Surgery Centers (ASCs) have additional challenges as they may lack pharmaceutical resources compared to tertiary care settings [19, 38]. One comprehensive review of ambulatory surgery facility-related medication errors in the State of Pennsylvania ([38], p. 89) found that of 502 events, the predominant medication error types were as follows:

- Drug omission (26.7 %)
- Wrong drug (22.3)
- Monitoring error/administering drug to patient with documented allergy (17.1 %)
- Extra dose (4.2 %)
- Wrong dose/overdose (3.6 %)
- Wrong dose/underdose (2.2 %)
- Other (14.1 %)

Of the classes of medications cited in the study ([38], p. 89), antibiotics were most often

Table 26.1 Strategies to prevent wrong patient/procedure/site surgery never events

• Employ checklists not only for the OR, but also for OR schedulers and for Physician office personnel to ensure accuracy, consistency, opportunities for clarification ("possible" mini, endoscopic, etc.); see sample forms from Pennsylvania Patient Safety Authority[a]
• Do not start procedure until all questions, concerns, and/or confusion about patient/site/procedure are clarified and resolved
• Ensure all necessary documents (e.g., consents, H&Ps) are available
• Minimize interruptions during time-out (e.g., music, unrelated chatter, inattention, telephones/pagers)
• Enact policies developed by an interprofessional team that are evidence based and applicable to every member of the surgical team; administrative executives and other nonclinical leaders must support such policies and foster a culture of responsibility among all team members and professional groups
• Engage nurses as active and equal participants in strategic and cost decisions related to the use of technologies and tools that can reduce the risk of errors related to misidentification

Source: Steelman and Graling [19]

[a]Pennsylvania Patient Safety Authority. Educational tools. For surgeons' offices: what can you do to prevent wrong-site surgery? http://patientsafetyauthority.org/EDUCATIONALTOOLS/PATIENTSAFETYTOOLS/PWSS/Pages/home.aspx. Accessed 3 May 2016

cited—33.9% of reported errors. Ambulatory facilities that do not have an onsite pharmacy or pharmacist should have a process for communicating with pharmaceutical professionals for clarification, information, and education for all staff. It is especially imperative that anesthesia providers, surgeons, and nursing staff have clear, direct, and unambiguous policies and communication processes that reduce the risk of error—particularly those related to miscommunication (or lack of effective communication).

Medication safety applies to all healthcare settings—inpatient and ambulatory as well as clinics and physicians' offices [41, 42]. Perioperative clinicians should consider safety considerations in the many expanding arenas of practice, notably the interventional suites where an increasing number of procedures are performed jointly by perioperative/surgical professionals and interventional clinicians (e.g., radiology, cardiac catheterization, electrophysiology, and gastrointestinal interventional suites). Grissinger and Dabliz [38] reported on deaths caused by the injection of the wrong medication. One event that was discussed occurred in an interventional suite where basins containing clear, but different, solutions were not labeled. The patient was accidentally injected with a topical antiseptic solution rather than the correct contrast material. These types of never events can occur in any setting and constant vigilance by all staff is as important as any one staff member feeling free to question (e.g.) which medication is in what container.

Medication errors can take place in a wide variety of settings and clinicians must not limit themselves to preconceived notions of where or what can happen [43]. Although the focus of medication errors tends to be on drugs, clinicians should use caution in relation to infusions of blood and blood products. Oxygen delivery (e.g., via nasal cannula) is another related consideration, particularly in patients who may be restricted in their oxygen use (e.g., patients with chronic obstructive pulmonary disease). Strategies for the prevention of medication error never events are presented in Table 26.2.

Pressure Ulcers and Related Positioning Never Events

Pressure ulcers occur as a result of skin compression, which impedes blood flow and damages underlying tissue; prolonged pressure can cause tissue decay. Although pressure ulcers are commonly associated with long-term care, extended periods of uninterrupted pressure and friction during surgical procedures put patients at risk for these injuries [44–46]. Table 26.3 lists the four stages of pressure ulcers according to the degree of tissue damage.

The Braden Scale [44] is the most common tool used for assessing risks for acquiring pressure ulcers; however, the Braden Scale does not capture all the critical risk factors for the development of injury in surgical patients [45]. The Munro [46] scale was created by a perioperative nurse to capture factors specific to surgical patients and has demonstrated promise for predicting patients at risk during surgery.

Table 26.2 Strategies to prevent medication error never events

Promote an interprofessional approach to medication safety
• Support a medication safety committee that includes surgeons, anesthesia personnel, nurses, and pharmacists, as well as risk managers, purchasing personnel, information technology (IT) members, and administrative champions
• Include patients and community members in medication safety initiatives
Procure and store medications and related supplies in a safe and efficient manner
• Have a contingency plan for 'back-ordered' medications
• Ensure that out dates are monitored and out dated drugs are removed
• Monitor temperature and humidity levels of areas where medications are stored
• Consider automated drug dispensing storage systems to restrict and document access
• Promote use of single- versus multidose vials of medications
• Standardize medication carts and separate look-alike and sound-alike drugs
Medication orders should be clear, accurate, and unambiguous
• Limit verbal medication orders; when used, read back, and record
• Computerized-provider order entry (CPOE) systems should be used whenever possible
Actively engage pharmacists in perioperative medication ordering and dispensing
• Have pharmacists review medication orders
• Include pharmacists in grand rounds
Clinicians should review the patient's health record before medication administration
• Before administering a medication, confirm patient's identity, metric weight, medication history, current medication history, and allergies
• Involve the patient (or surrogate), when possible, to identify current medications, allergies, and preferences (when applicable)
Administer medications in a safe manner
• Verify correct patient, drug, route, amount/dose, time, indications, and contraindications
• Avoid interruptions during medication preparation
• Have available weight-based conversion charts and other tools to ensure correct calculations
• Encourage clarification of all medication orders
• Label all medication containers (e.g., syringes, metal basins, plastic medication cups)
• Make use of safety devices (e.g., infusion pumps, safety needles, sterile transfer devices)
• Collaborate with IT to develop 'prompts' in the electronic health record for (e.g.) prophylactic antibiotic administration
Monitor the patient for intended or unintended reactions to medications
• Document reactions to medications
• Collaborate with surgical colleagues to manage medication-related crises emergencies

Source: Grissinger and Dabliz [38]; Steelman and Graling [19]; Smetzer et al. [39]; AORN [41, 42]
ISMP Guidelines. http://www.ismp.org/Tools/guidelines/default.asp. Accessed 3 May 2016

Primiano and fellow researchers [47] studied the prevalence of, and risk factors for, pressure ulcer development during general, orthopedic, neurological, cardiothoracic, gynecologic, and vascular procedures lasting longer than 3 h. They and others [48–50] found several risks for the development of pressure injuries:

- Male sex—twice as many males develop pressure ulcers
- Positioned on thin (1.5″–2″) foam OR bed pads
- Major skin abrasions
- Older age (less elastic, smaller, more calcified blood vessels)

Table 26.3 Four stages of pressure ulcers according to the degree of tissue damage

Stage I: Observable pressure-related alteration of intact skin when compared to adjacent tissue and may include one or more of the following: skin temperature (warm or cool), tissue consistency (firm or boggy), and sensation (pain or itching). Most pressure ulcers that develop during a surgical procedure are stage I cases
Stage II: Partial skin loss of the epidermis and dermis. The skin is eroded or blistered or has shallow craters
Stage III: Full skin loss, possibly down to, but not through, the fascial layer, causing deep craters
Stage IV: Extensive tissue loss. Muscle, bone, and supporting structures show

National Pressure Ulcer Advisory Panel. Pressure ulcer category/staging. Text and illustrations. http://www.npuap.org/resources/educational-and-clinical-resources/pressure-injury-staging-illustrations/. Accessed 3 May 2016

- Obesity (more weight and pressure on bony prominences); morbidly obese patients (body mass index/BMI of 30 and above) are particularly at risk [50].
- Malnourishment (increases the risk and can retard healing; albumin levels under 3.0 [normal albumin = 3.5–4.5 mg/dL] pose a risk for pressure injuries)
- Diabetes mellitus or hypertension
- Length of surgery (susceptible patients can develop ulcers during procedures that last only one half-hour to 1 h)
- Moisture (e.g., pooling of prep solutions; staff not allowing prepping solutions to dry completely)
- Shearing and friction (when outer layer of skin slides across a surface and the underlying tissues shift or move; can also occur if the patient is pulled or moved without being lifted)
- Warming blankets (the risk of burns should be considered. For example, a warming blanket under the patient warms the tissue, therefore less blood travels to the warmed area, depriving the tissue of oxygen)

Guidelines for patient positioning in the OR from the National Pressure Ulcer Advisory Panel [51] and the European Pressure Ulcer Advisory Panel [52–54] recommend using a pressure redistributing mattress on the OR bed. Some organizations report insufficient evidence to recommend a specific pressure redistribution intervention or product [55, 56], but a randomized controlled trial [57] did demonstrate that viscoelastic polymer pads reduced the incidence of pressure ulcer formation (compared to the standard OR bed mattresses). Recommendations for the prevention of pressure ulcer never events are listed in Table 26.4.

Although pressure injuries are often related to adverse events associated with positioning, another serious adverse event can occur when a patient falls during transfer from the gurney to the OR bed, during positioning on the OR bed, during Trendelenburg or reverse Trendelenburg positions, or when the patient becomes agitated, e.g., during induction or local anesthetic procedures. It is important to ensure that patients are secured with safety straps and that there are staff members on either side of the patient as well as the head and the feet during transfers and position changes [54]. Additional positioning considerations are listed in Table 26.5.

Surgical Site Infections

Surgical site infection (SSI) is an infection occurring in an incisional wound within 30 days of a surgical procedure, according to the Centers for Disease Control and Prevention (CDC) [58]. The occurrence of a surgical site infection during the postoperative period may significantly affect patient recovery and hospital resources leading to longer length of stay, readmission, and possible delay in resumption of normal daily activities and return to employment. This surgical complication can be devastating to the patient and family, as well as to healthcare institutions that can be penalized financially for SSI readmissions through decreased reimbursement and other financial penalties. There is no single factor which

Table 26.4 Recommendations for preventing pressure ulcer never events

1. Assess the patient's skin continuously. Before positioning, assess the patient's overall skin condition. Immunocompromised patients (e.g., diabetics, patients undergoing steroid, chemotherapy, or radiation treatments) are especially at risk
2. Use a pressure ulcer assessment scale to measure the patient's risk. The Braden Scale, the most widely used assessment tool (available at http://www.bradenscale.com/images/bradenscale.pdf) is made up of six subscales scored from 1 to 4 that measure a patient's sensory perception, skin moisture, degree of physical activity, ability to change and control body position, usual food intake pattern, and amount of assistance they require for moving. Lower scores (less than 20) indicate higher risks of pressure ulcer development. Reassess these patients in PACU/ICU to ensure problem areas did not develop or preexisting skin conditions were not exacerbated during surgery
A perioperative pressure ulcer scale has been developed by Munro [46] who identified a need for an OR-specific assessment tool
3. Anticipate the patient's position. The circulating nurse should confirm the patient's surgical position with the surgeon and have necessary positioning supplies and devices
4. Use thick gel pads. Thirty percent of patients in one study [47] who were positioned on thin foam table pads (1.5″–2″) developed pressure ulcers. Surface pads should be 3″–4″ thick to maintain skin integrity
5. Keep OR bed sheets smooth. Wrinkles in sheets can cause skin breakdown; smooth OR bed mattress covers before placing patients on them
6. Pad bony prominences with cushioning devices. Use appropriate cushioning devices/pads that maintain normal capillary pressure of 32 mmHg or less, are durable, resist moisture and microorganisms, are fire resistant, are nonallergenic, and are easy to clean and disinfect
7. Keep pressure off heels. Use the foam heel protectors or place a pillow or positioning under patients' heels to keep off the OR bed surface
8. Avoid elevating patients' ankles (this can actually increase pressure ulcer development risks). Brief periods of heel/ankle elevation may be required for prepping in certain procedures (e.g., saphenous vein removal during coronary artery bypass surgery)
9. Apply sacral padding for patients undergoing prolonged procedures (e.g., greater than 2 or more hours) in the supine position
10. Avoid leaning on patients during surgery. Surgical team members of the surgical team may inadvertently lean on the patient during surgery in order to improve the view of the surgical site or reach for needed instruments
11. Move portions of the patient's body when possible. This is challenging for prolonged cases (e.g., cardiac or other surgeries of 4–5 h or more) but there may be some opportunities to enhance perfusion to certain areas. For example, a staff person may reach underneath the drapes to gently shift a patient's extremities several times throughout a procedure. Anesthesia providers may be able to briefly lift the patient's head. It does not take long for circulation to return to potential problem areas and slight movements can reduce the risk of developing pressure ulcers
12. Document the skin the pre-op and post-op skin condition. Additionally, document the positioning devices used as well as the protective devices. Observed injuries should be documented per institutional policy

Source: AORN [54]; Braden and Bergstrom [44]; European Pressure Ulcer Advisory Panel [52]; Munro [46]; National Pressure Ulcer Advisory Panel. Pressure ulcer category/staging. Text and illustrations. http://www.npuap.org/resources/educational-and-clinical-resources/pressure-injury-staging-illustrations/. Accessed 3 May 2016; Primiano et al. [47]; Sullivan and Schoelles [49]

Table 26.5 Positioning considerations to reduce the risk of pressure ulcers and falls

• Supine Position. In the supine position pressure sores most commonly occur on the heels, sacrum and ischium, the back of the skull, and the shoulder blades. These areas should be protected with cushioning pads, and heels should be kept off the OR bed. Avoid elevating the patients' ankles as this can actually increase pressure ulcer development risks
• Lateral Position. Cushion the ear, shoulder, thigh, knee, ankle, and foot of patients in the lateral position; place pillows between legs; secure body with a safety strap
• Prone Position. Place padding under the face, chest, and feet to prevent wounds on the nose, forehead, chest, feet, and toes
• Lithotomy Position. Pad the lateral or posterior knees and ankles to prevent pressure injuries

Source: AORN [54]

predicts whether a patient may develop a surgical site infection and plans developed to reduce SSIs should embrace a variety of factors along the patient's continuum of care.

Individual patient characteristics may be associated with improved surgical outcomes. Four preoperative specific factors have been identified by the Strong for Surgery team in Washington State: adequate nutrition, glycemic control, smoking cessation, and appropriate medications [59–61]. Strong for Surgery provides a presurgery checklist to doctor's offices to help with education, communication, and standardization of best practices, and hence to improved clinical outcomes. Other preoperative patient factors related to surgical site infection include specific medication use, such as steroids or immunotherapy which may naturally compromise wound healing, and colonization with *Staphylococcus aureus*, increasing chances of developing methicillin-resistant *Staphylococcus aureus* (MRSA) [62].

Bacteria are becoming increasingly resistant to antibiotics making SSI prevention even more challenging. The use of intranasal mupirocin ointment for *Staphylococcus aureus* decolonization has resulted in statistically significant reduction of *S. aureus* SSIs [63]. *Staphylococcus* decolonization is routinely used prior to cardiac surgery and total joint arthroplasty and is becoming more common in other procedures. Bundles comprised of decolonization, preoperative showers, and antibiotic prophylaxis should be considered [64]. Several protocols have specifically targeted decolonization of methicillin-sensitive *S. aureus* (MSSA) and methicillin-resistant *S. aureus* (MRSA) using intranasal mupirocin and chlorhexidine washes and demonstrate [65, 66] effectiveness for reducing MRSA/MSSA colonization.

Skin is a major potential source of microbial contamination in the surgical environment. When implementing a program to reduce SSI, one must look at the patient and the provider to manage reduction of skin flora. Evidence suggests that preoperative antiseptic showers reduce bacterial colonization and may be effective at preventing SSIs [67]. No one antiseptic has been found to be better than another for preventing SSI. A 2010 study by Edmiston et al. [68] provided clear evidence for using chlorhexidine gluconate (CHG) preoperatively to reduce the risk of surgical site infection. In a 2013 study, Graling and Vasaly [69] found that 4 % CHG delivered preoperatively by cloth bath reduced surgical site infections in general and vascular surgery. A recent study by Edmiston et al. [70] provides evidence for a standardized showering regimen to achieve maximal skin surface concentrations of CHG 4 % in surgical patients preoperatively.

The optimal use of preoperative antibiotics has been a focus in a number of major projects looking to reduce complications of healthcare. These include the Prevention of Surgical Site Infection, Institute for Healthcare Improvement, 5 Million lives campaign [71], and The Joint Commission's Surgical Care Improvement Project (SCIP) [72].

The Centers for Disease Control and Prevention's (CDC) classic 1999 Guidelines for Prevention of Surgical Site Infection [73] provide category IA evidence for preoperative antibiotic prophylaxis. Prophylactic antimicrobial agents should be administered only when indicated and should be selected based on the efficacy against the most common pathogens causing SSI for a specific operation and published recommendations. Appropriate and timely administration of preoperative antibiotics for routine surgical cases is also a perioperative patient quality measure defined by The Surgical Care Improvement Project (SCIP), a national program aimed at reducing perioperative complications and is a quality benchmark metric for Centers for Medicare and Medicaid Services [72].

Antibiotics should be administered by the intravenous (IV) route and the initial preoperative dose timed to establish optimal tissue and serum concentrations prior to incision. Therapeutic levels of the antibiotic agent should be maintained in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. Team members should standardize protocols using national guidelines, using preprinted or computerized standing orders, verify administration during time-out processes, and have the preoperative

Table 26.6 Recommendations for reducing surgical site infection never events

Preoperatively
Patient actions
Perform preoperative antiseptic showers with prescribed cleanser
Staff actions
Assess patient predisposing factors; optimize risk reduction strategies for elective surgical procedures
• Nutrition
• Glycemic control
• Smoking cessation
• Steroid and/or immunotherapy
• MRSA colonization
Perform frequent hand hygiene
Optimize incision site preparation with limited to no hair removal, preferably in preoperative area; use clippers if hair removal required
Administer preoperative antibiotics within time frame to maximize tissue perfusion
Intraoperatively
Maintain optimal surgical environment (temperature, humidity)
Use EPA-approved hospital disinfectant to clean surfaces and equipment; inspect surfaces, equipment prior to room setup
Minimize operating room traffic (enter/exit through sterile core)
Sterilize instruments according to manufacturer's instructions
Minimize the use of immediate use steam sterilization
Don clean OR attire and personal protective equipment
Cleanse (prep) skin with appropriate surgical antiseptic
Adhere to standard principles of operating room asepsis and surgical technique (e.g., handle tissue carefully, eradicate dead space when closing incisions)
Maintain normothermia
Classify wound at end of case (i.e., clean, clean contaminated, contaminated, infected)
Postoperatively
Incision care
Remove drains and catheters as soon as possible
Provide adequate nutrition for wound healing

Source: AORN [67, 74]; Edmiston et al. [70]

nurse or anesthesia professional assign dosing responsibilities [63]. Team members play important roles throughout the perioperative period; Table 26.6 identifies actions by patients and staff in the perioperative, intraoperative, and postoperative periods.

Another safety measure is hand hygiene, which has been recognized as a primary method of decreasing healthcare-acquired infections [75]. Hand hygiene, handwashing, and surgical hand scrubs are the most effective way to prevent and control infections and represent the least expensive means of achieving both [76]. Despite this, studies have showed remarkably low hand hygiene rates by surgical providers as they enter in the OR to prepare their equipment, insert intravenous lines and catheters, etc. [77].

Preparation of the surgical incision site may include hair removal and application of a surgical skin antiseptic. Hair removal should only be performed when necessary. When hair removal is performed, *clipping* hair lowers the risk of SSI development rather than *shaving* hair with a razor [67]. The effectiveness of any skin antiseptic used for the surgical skin prep can be affected by a number of factors. The effectiveness of each solution depends on concentration, temperature, particular germ or virus, and contact time. Following manufacturers' recommendations for use optimizes results. Skin antiseptics should be

chosen for the individual patient based on patient assessment, the procedure type, and a review of the manufacturer's instructions for use and contraindications [78].

Preparation of the surgical site is one factor in creating a safe environment. The physical environment within a surgical suite should support patient care to reduce the risk of developing a surgical site infection. The AORN Guidelines for a safe environment of care provide guidance for the design and maintenance of building structures to accommodate a perioperative procedure as well as guidelines for hazardous waste and storage conditions [79–81].

Another environmental concern is the movement of people and supplies. Traffic patterns should facilitate movement of patients, personnel, supplies, and equipment through the OR suite, with restriction levels intended to provide the cleanest environment possible. The number and movement of individuals during an operative procedure should be kept to a minimum. Evidence suggests that bacterial shedding increases with activity and that air currents may pick up contaminated particles shed from patients, personnel, and drapes and distribute them to sterile areas [82]. Additionally, an optimal surgical environment maintains temperature and humidity to deter microbial growth. Perioperative personnel should use an Environmental Protective Agency-registered disinfectant to clean surfaces and equipment, and physically inspect surfaces and equipment prior to preparing the OR for surgery [74].

There are several practices that reduce the spread of transmissible infections when preparing for surgery or working in the OR [83]. Perioperative personnel should don clean scrub attire and wear personal protective equipment (PPE) to protect both the patient and provider from microbial contamination and blood borne pathogen exposure. To deter passage of microorganisms, particulates, and fluids between sterile and unsterile areas, PPE should be resistant to tears, punctures, and abrasions [83]. Sterile drapes provide a barrier that minimizes the passage of microorganisms from unsterile to sterile areas and reduces the risk of healthcare-associated infections [73]. All surgical instruments should be sterilized according to published guidelines and manufacturers' instructions. Instruments should be prepared using immediate use steam sterilization (formerly called "Flash" sterilization) only if they are required for immediate use and not for convenience, or to avoid purchasing additional instruments, or to save time. Implementing sterile techniques when preparing, performing, or assisting with surgical procedures is the cornerstone of maintaining sterility and preventing microbial contamination. Studies looking at colorectal surgery have shown that isolation techniques and the use of closing trays discourage the seeding of enteric contents to the incision site has been reported to reduce the incidence of SSI [83, 84].

Additional clinical trials have shown that hypothermia increases the incidence of serious adverse consequences including surgical site infections [85]. Several recent studies have shown the use of evidence-based surgical care bundles in patients undergoing colorectal surgery significantly reduced the risk of SSI; included in these bundles is maintaining normothermia [61, 84, 86]. Perioperative personnel should evaluate a patient's risk for unplanned, inadvertent hypothermia and implement strategies such as temperature monitoring and patient warming in order to adjust environmental conditions according to patient needs [87].

Postoperative care considerations should be reviewed at the conclusion of the procedure by the surgical team using a debriefing process [23]. Additionally, determining the surgical wound class assists clinicians in gauging the risk for infection. Surgical wound classification is determined using the wound classification scheme from the CDC. The CDC recommends four surgical wound classifications:

1. Clean,
2. Clean-contaminated,
3. Contaminated, and
4. Dirty or infected wounds [73].

This classification scheme reflects the probability of infection and should be determined by the surgeon at the end of the surgical procedure. AORN has developed the Surgical Wound Classification Decision Tree (Fig. 26.2) to assist in decision making for surgical wound classification [88].

Wound classification is subject to change; therefore, it should be assigned in consultation with the surgeon at the end of the procedure and documented in the perioperative record ([89], p. 491–511). Postoperative incision care is a significant factor in reducing SSIs; practices include sterile dressing changes as needed and removal of drains (e.g., chest tubes) and catheters (e.g., urinary drainage catheters) as soon as possible [90].

Electrical and Other Energy-Related Never Events

A variety of energy sources and modalities are employed during surgery. Considerable information is available about energy modalities, their mechanism of action, their unique characteristics, and their safety risks. Ball [91] offers an extensive description (with illustrations) of the many modalities employed in the perioperative setting. Additionally, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) created the Fundamental Use of Surgical Energy™ (FUSE) curriculum in 2010 to address the safe use of endoscopic energy sources [92–94]. Table 26.7 (Surgical Energies and Considerations) lists various types of energy sources and considerations for their safe use. These energy sources may be employed in the traditional 'open' surgical manner as well as the video-assisted, endoscopic, and interventional routes. Although there are extensive available information and initiatives developed by professional organizations such as SAGES [92] and AORN [96, 97], energy-related patient injuries continue to occur [98].

One of the oldest and most common sources of energy is electrosurgery, which directs the flow of electrons from an electrosurgical unit (ESU) through a delivery device (i.e., the electrocautery pencil) to the patient's tissue, where the tissue is either 'cut' or coagulated. Two modes can be employed:

- Monopolar, wherein electricity flows from the source of energy through the ESU pencil to a specific area on or in the patient where heat is generated, producing coagulation or cutting. The electrical energy then passes through the patient to a dispersive electrode (i.e., the 'Bovie' pad) where the energy is returned to the generator and the electrical circuit is completed.
- Bipolar, wherein electricity flows between one tip of an electrical device that looks like a pair of forceps, into the patient's tissue, and returns to the other tip of the device, thereby completing the electrical circuit; a dispersive pad is not required because the electrical energy returns directly to the generator from the electrosurgical device itself [91].

It is not unusual to employ both monopolar and bipolar devices during one surgery—for example, performing simultaneous endoscopic vein harvesting with a bipolar device while dissecting the mammary artery with a monopolar device during coronary bypass grafting. Patients undergoing a procedure that employs monopolar energy would require the application of a dispersive pad, regardless whether other, bipolar, devices are also employed. When applying a dispersive pad, commonly performed by the circulating nurse, the clinician should place the pad on clean, dry skin overlying healthy muscular tissue (which conducts electricity better than adipose tissue), and as near as possible to the surgical site. Areas on the patient's skin with excessive hair, scar tissue, tattoos, or over bony prominences or distal to a tourniquet should be avoided for pad placement because hair, scar, bone, or poorly vascularized (e.g., distal to the tourniquet) can increase impedance of electrical energy flow, create heat, and potentially burn tissue [96, 99]. If needed, hair can be clipped to access a suitable site for the pad. Surgery performed on more than one site may require the use of two dispersive pads.

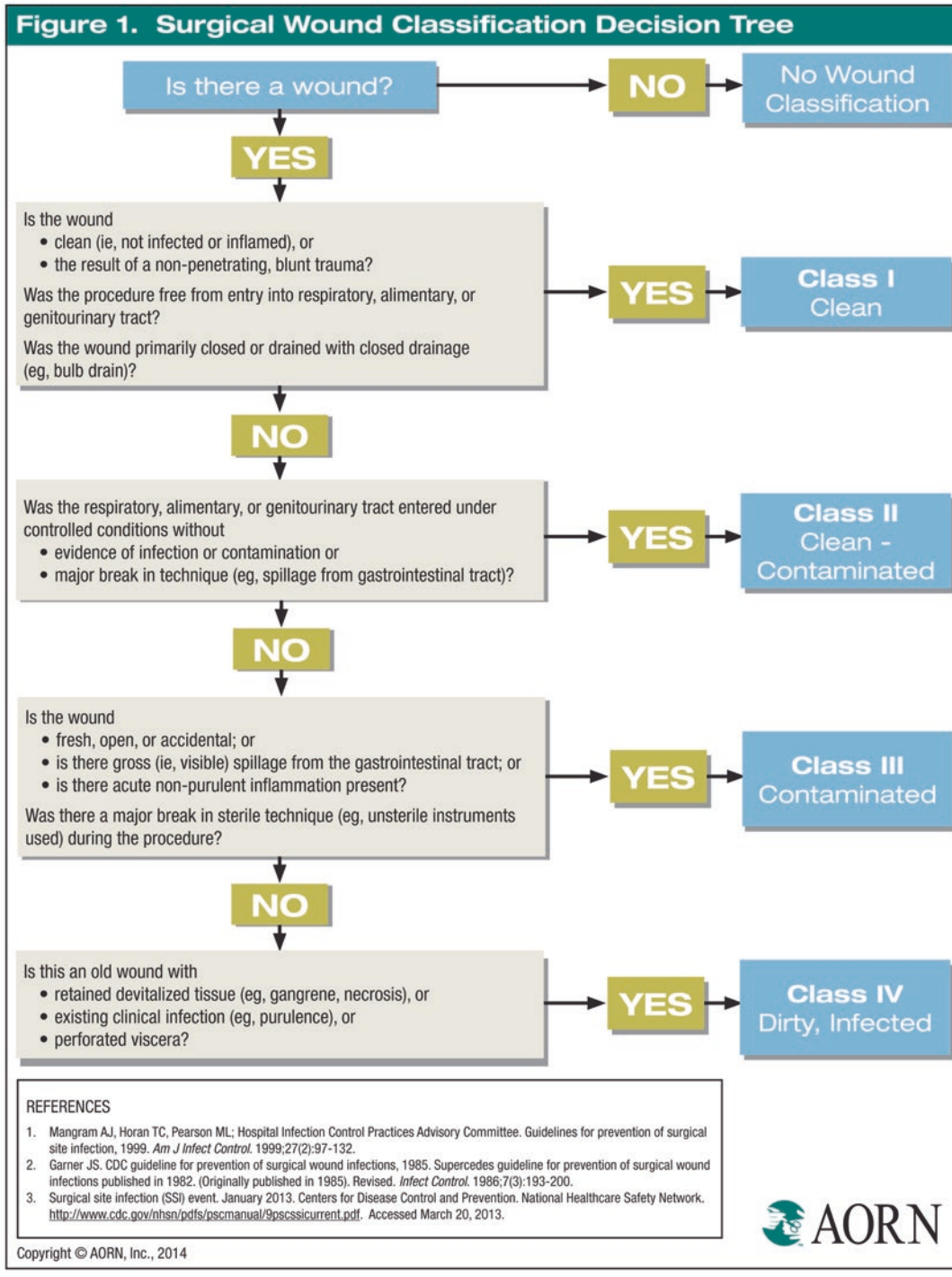


Fig. 26.2 Surgical Wound Classification Decision Tree. Reprinted with permission from AORN.org. Copyright © 2016, AORN, Inc.: Denver, CO. All rights reserved

Table 26.7 Surgical energies and safety considerations

Energy type	Safety considerations
General considerations: all energies	• Confirm that energy source is in proper working order
	• Have backups available if there is energy failure
	• Employ the appropriate energy for its intended effect
	• Be aware of energy-specific risks to patients and staff (e.g., ESU—burns; cryo—cold injury)
	• Never silence alarms
	• Maintain in good working order with regular scheduled checkups
	• Know how to trouble shoot problems, or, whom to contact
	• Remove from service when not functioning; send for repair promptly
Electrosurgery	• Conduct risk assessment for fire triangle (i.e., fuel, oxidizer, ignition source) elements
	• Attach appropriate size dispersive pad; avoid placing pad over metallic implants (e.g., prosthetic hip replacement, pacemaker generator)
	• Unless certain that only bipolar energy to be employed, apply a dispersive pad onto the patient's skin
	• Check instruments for insulation integrity
	• Ensure flammable prepping agents are completely dry before draping
	• During head and neck surgery, ensure that moist sponges can be made available promptly to surgical team members (including anesthesia personnel)
	• Holster active electrode (ESU pencil) when not in use
	• Do not wrap cords around metal towel clips or clamps
	• Keep electrode tip clean and free of eschar
	• Ensure that appropriate personnel are available to reprogram implanted devices (e.g., ICDs, pacemakers) as needed
	• Evacuate plume
Argon beam coagulator	• All ESU precautions
	• Vent laparoscopic entry sites
	• Monitor intraabdominal pressure
	• Be alert for gas embolism
LASER (light amplification by stimulated emission of radiation)	• Ensure eye protection for surgical team members (including patient)
	• Place moist towels around surgical field
	• Place laser on standby mode when not in use
	• Place 'laser alert' signs (on OR door) when in use
	• Evacuate plume
Cryo energy	• Specify activation time
	• Have saline available to facilitate release of freezing probe to tissue
Radiofrequency ablation (RFA)	• Need multiple dispersive electrodes; 90° angle to current flow
	• Manage patient temperature
Endoscopy with monopolar devices (snare, hot biopsy forceps, sphincterotome, argon plasma probe)	• Assess bowel prep; want ↓methane gas
	• Remove jewelry
	• Assess presence of CIED
	• Concern for perforation and bleeding
	• Use standby mode when not in use
	• Ensure proper cleaning and sterilization of endoscopic devices and instruments
Endoscopy with bipolar (MPEC gold probe)	• May use needle for sclerosing agent
	• Ensure proper cleaning and sterilization of endoscopic devices and instruments
	• Avoid placing cables with light activated on patient drapes

(continued)

Table 26.7 (continued)

Energy type	Safety considerations
RF array for GERD	• Need dispersive electrode required
Ultrasonic energy	• No dispersive pad needed
	• Handle blade carefully, holds residual heat
	• Do not place on drapes
Microwave	• Often used with ultrasound guidance
	• No dispersive electrode required
	• Monitor patient temperature
Pediatric considerations	• Choose pads according to weight
	• Place pad as close to surgical field as possible
	• Neonate pads often placed on back
	• Always protect pad from fluid exposure
Electromagnetic interference (EMI) (most commonly comes from a CIED)	• Have defibrillation and pacing equipment available
	• Use bipolar or ultrasonic over monopolar sources if possible
	• Place pad nearest surgical site, do not cross CIED
	• ECG lead placement does not affect EMI
	• Pacer dependent patients most at risk
	• May use magnet to go asynchronous
	• Interrogate for proper function postprocedure

Source: Ball [91]; Feldman et al. [93, 94]; Lindsey et al. [95]; Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) [92]; Strong for Surgery [59]
CIED Cardiovascular Implantable Electronic Device, *ECG* electrocardiogram, *EMI* electromagnetic interference, *ESU* electrosurgical unit, *GERD* gastroesophageal reflux disease, *ICD* Implantable cardioverter Defibrillator, *MPEC* multipolar electrocoagulation, *RF* radiofrequency, *RFA* radiofrequency ablation

A common site that allows the placement of two pads is the buttocks; a pad on each thigh may also be feasible when performing surgery on both legs [96].

Electrical devices can cause burn injuries to both patients and staff. Patients undergoing head and neck surgery (where there may be accumulated oxygen under the patient's drapes) are at especial risk for upper body and airway burns that can be triggered by the electrical energy device [100]. Electrical and other energy sources can also lead to fires that can threaten not only the immediate surgical team but also surrounding units. The subject of fire is only briefly mentioned in this section; the topic is more fully discussed by Bruley (see Bruley, Chap. 10).

Electrosurgical energy also presents nonthermal risks to patients. For example, the use of electrosurgical energy can interfere with a patient's electrocardiogram (ECG) and potentially adversely affect the performance of a pacemaker or implantable cardioverter defibrillator (ICD); reprogramming of the device(s) may be required and the perioperative staff should have contact information for the device manufacturer's representative. Shortly after surgery, the pacemaker and/or ICD function should be evaluated by the responsible implanting physician (or surrogate) and the manufacturer's representative. A bipolar, or a battery-powered, cautery device may be feasible if more extensive cautery is not needed. Precautions related to interference with device function are applicable to many additional implanted electronic devices [101] (e.g.):

- Deep brain stimulators
- Spinal cord stimulators
- Bone growth stimulators
- Other nerve stimulators
- Cochlear implants
- Ventricular assist device

Ultrasonic devices employ mechanical vibration of high-frequency sound waves (greater

than 20,000 Hz) that enable the user to cut and coagulate tissue. The tip of the hand piece comes in various shapes: blade, ball, and hook [91]. Some of the advantages of ultrasonic devices are as follows:

- Adjacent tissue is damaged less than it might be with laser or electrosurgical energy
- Nerve or muscle stimulation does not occur (due to the absence of electrical current in the tissue)
- Absence of surgical smoke (plume)

Surgical smoke has become increasingly scrutinized for the hazards found within the plume—viruses; toxic gases; cellular (living and dead) contaminants; and vapors such as benzene, formaldehyde, and hydrogen cyanide [95, 96, 102]. Evacuation of surgical smoke increasingly is seen as a safety practice [91].

Another form of energy, radiation, is generally employed as a diagnostic imaging modality but is increasingly used as an integral component of therapeutic interventions performed in hybrid ORs and endovascular suites for repair of aneurysms and other cardiac and vascular abnormalities.

Radiologic energy/fluoroscopy is employed in a growing array of imaging-based procedures that carry their own inherent risks but also as a diagnostic tool to look for, and identify, possible retained surgical items. Radiation safety remains an important component of these newer, innovative technologies. Tracking and documenting radiation exposure levels as well as ensuring that surgical team members protect themselves (and the patient's body parts not requiring radiation exposure) with lead barriers, glasses, and coverings (e.g., tops, skirts, gloves, and thyroid shields) is an important safety consideration [103]. Perioperative colleagues should also be considered by posting signs on the OR door(s) alerting staff members that radiologic procedures are being performed [104].

Although the various energies themselves (e.g., electricity, laser, microwave, radiofrequency) pose their own inherent safety risks, the surgical route and technique may create additional safety challenges. For example video-assisted laparoscopic and other endoscopic procedures differ from traditional 'open' surgeries in a number of ways. One is that when emergencies occur—e.g., sudden hemorrhage—there needs to be a prompt and efficient transition in technique and access in order to control the bleeding; this may require a new incision, a new set of instruments, and different mechanisms for controlling bleeding (e.g., placing a hand on the bleeding site cannot be achieved laparoscopically).

Additional considerations include the use of fluids or gases to distend the abdomen via the laparoscopic route and the potential risks to the patient that an overdistended abdomen may pose. These potential complications may not themselves constitute a never event but one's awareness of risks and preparation for contingency planning to address complications is consistent with Kizer and Stegun's [1] definition of an event that should never occur.

Retained Surgical Items

The study by Gawande and colleagues published in 2003 [105] was one of the first to illustrate the serious consequences of retained surgical items (RSI, formerly called retained foreign bodies); these included infection, prolonged hospital stay, reoperation, fistula, and death. The study authors reviewed medical-malpractice claims by patients with retained surgical sponges or instruments to identify the following major risk factors for RSI:

- Emergency surgery
- Procedures with unplanned changes, and
- Patients with higher body mass index (BMI)

Interestingly, the patient's sex, changes in nursing personnel, the presence of multiple teams, and the amount of blood loss were not associated in this study with an increased risk of RSI.

Lincourt et al. [106] and Wang et al. [107] confirmed the study's [105] findings of significant increased risk for RSI in:

- Procedures performed on an emergency basis
- Procedures with unexpected changes during the surgery

Increased BMI was not a significant finding in the Lincourt [106] and Wang [107] studies, and Rowlands [108] actually found an inverse relationship between increased BMI and risk of RSI. Rowlands also found that complex procedures, an increased number of personnel, and a greater number of specialty teams posed higher risks for RSI. None of these findings is surprising to clinicians who have participated in a trauma or emergency procedures—and it would not be surprising if a blood-soaked, compressed sponge was not visualized in the retroperitoneum or pleural cavity of a patient with a small or large BMI—if surgical team members failed to follow policies or guidelines, or, if behavioral or environmental factors adversely affect team function.

Three behavioral and environmental categories were designated by Rowlands and Steeves [109], who reviewed the perioperative stories of perioperative registered nurses (RNs) and surgical technologists (STs) relating the counting procedures during surgery. These general areas and examples included:

1. Bad behavior
   (a) Lack of respect
   (b) Sloppiness (e.g., sponges in disarray, counted items thrown into trash, inattention)
   (c) Inconsistent practice
2. General chaos
   (a) Loud noise
   (b) Lack of preparation
   (c) Assignment changes
   (d) A fast pace
3. Communication difficulties
   (a) Idle chit-chat
   (b) Lack of proper equipment
   (c) Resistance to sharing information
   (d) Difficulty working together ([109], p. 413)

Related causes of failure to prevent RSI were the focus of a healthcare failure mode and effect analysis by Steelman and Cullen [110]. They identified the following as the most frequently cited reasons:

- Distraction
- Multitasking
- Noncompliance with the facility's 'count' policy
- Time pressure ([110], p. 682)

Several recommendations address the underlying issues and risks:

- Members of the perioperative surgical team should participate in team training that promotes active communication and collaborative practice [111–114].
- All members of the surgical team have a responsibility for preventing RSIs [111–113, 115].
- When an RSI event occurs, an investigation should be carried out that reflects human factors considerations, e.g., communication failures, lack of situational awareness, mental fatigue [8].
- Distractions should be minimized and team members alerted that the count is about to commence; interrupted counts should be restarted [19, 111–113].
- Team members should verbally verify the final count as part of a checklist [111–113].
- The RN circulator should record the count immediately after each item is counted (e.g., blades, cautery tips, sutures), on a surface (e.g., 'white board' placed on the wall in the OR) visible to all team members [111–113]; if the count occurs away from the 'board' (i.e., next to the surgical table where the countable items are located), then the Circulator should document the count on paper and transcribe the numbers onto the white board. It is important for the counted items to be fully visualized when counting.
- Create a no-interruption zone that prohibits nonessential conversation when counting [113].

Additional recommendations are listed in Table 26.8.

Table 26.8 Recommendations for preventing retained surgical items

All surgical team members
• When possible, limit soft (e.g., cloth, plastic) items used to those that are radiopaque; items that are not radiopaque should be counted and documented
• When counting, separate items (e.g., sponges) and visualize each item
• When counting, verbalize that the count is starting
• When performing 'closing' counts, avoid counting in a loud voice, but ensure that every counted item has been visualized
• The process of selecting and purchasing products developed to prevent RSIs should include all members of the surgical team
• Employ adjunct technologies (e.g., RF devices) per manufacturer's instructions
Surgeons and assistants
• Be aware of items employed
• Before the closing count begins, explore the wound methodically and completely
• Notify team members when items that remained within the wound (e.g., for hemostasis) at the start of the final count have been removed and returned to the scrub person
• If a suture needle or instrument breaks during use, retrieve broken parts and pass to the scrub person
• Inform patients that a 'never event' occurred
Scrub personnel (RN or ST)
• Perform a baseline count
• Be aware of items employed by surgeon and assistant
• Whenever possible, engage in 'exchange' (e.g., hand new suture to surgeon after receiving used suture)
• Arrange items on the field and back table, mayo tray near end of procedure in order to facilitate more efficient count
• In situations where there is persistent, copious bleeding, initiate a count in order to be aware of the number of sponges used and remaining
• Avoid altering counted items
• Count the components of instruments with multiple pieces (e.g., retractors)
• Upon verification of all counts being correct, clearly verbalize to the surgeon and team that there is a 'correct count'
Circulating RN
• Perform a baseline count
• Maintain an awareness of the stage of the procedure and be alert to possible needs for (e.g.) extra sponges (with persistent bleeding); suture (for repairs or suture reinforcement
• Avoid loud music
• Request that pagers or other communication devices are off, on silent mode, or on standby
• Provide dressing sponges only after the final count
• Keep up with sponges that have been passed off the field; do not allow an excessive number of sponges to accumulate (prolonging the final count)
• Employ sponge bags or other mechanism for separating and visualizing sponges
Anesthesia personnel
• Do not hesitate to speak up if there is uncertainty about removal of sponges or other items
• Maintain 'situational awareness'
• Do not use counted items for (e.g.) line insertions or other anesthesia procedures
Other staff (e.g.)
• Cardiovascular Technologists: may assist with insertion of monitoring lines. Should not use "countable" sponges and should keep these and other items separate from counted items
• Radiologists: if required to have an x-ray for RSI, inform the radiologist and/or technologist of the item to be identified, the surgical site, and the best position; provide radiology protection for staff and patient during x-ray; provide a sample of the item being looked for (e.g., "pill" sponge)

Source: AORN [111, 112]; AORN. RP summary: recommended practices for prevention of retained surgical items. AORN J. 2012;95(2):220–21; Goldberg and Feldman [115]
RN Registered Nurse, *ST* Surgical Technologist', *RF* radiofrequency

Device Failures and Misuse

Surgery requires the use of numerous supplies, instruments, and devices. According to the Food and Drug Administration (FDA), a 'device' is defined as, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" [116].

The FDA distinguishes between chemical (i.e., pharmacologic) devices and those that alter the structure or function of the body. It is this latter category that is discussed in this section.

Medical devices used in surgery are classified by the FDA according to the potential injury that may occur as a result of their use or misuse [117, 118]. Table 26.9 lists the FDA's three classifications with examples of devices within each category.

Given the wide array of devices—some with associated energies (discussed earlier)—it is not difficult to see the associated risks, hazards, and dangers. The ECRI Institute publishes the 'Top Ten Health Technology Hazards' on an annual basis; the hazards published for 2015 [119] address endoscope reprocessing, ventilator misconnections, and insufficient training in robotics surgery. Other hazards include alarms, missing data in electronic health records, insufficient data security, and insufficient attention to updating software.

Table 26.9 Food and Drug Administration (FDA) classification of medical devices with examples. According to the FDA, device classification depends on the intended use of the device and also upon indications for use[a]

CLASS I: low-risk devices
• Tongue depressors
• Bandages
• Handheld surgical instruments
CLASS II: intermediate risk devices
• Computed tomographic scanners
• Intravenous infusion pumps
CLASS III: high risk devices
• Pacemaker leads and generators
• Internal cardioverter defibrillator leads and generators
• Joint implants (e.g., hip, knee)
• Heart valves
• Coronary artery stents
• Ablation catheters (e.g., radiofrequency, cryothermia)
• Robots
• Endoscopic instruments

Source: Jin [117]; Food and Drug Administration (FDA) [116]; Food and Drug Administration (FDA). Device product classification (search database). 2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm. Accessed 3 May 2016

[a]Food and Drug Administration (FDA). Classify your medical device. 2014. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/. Accessed 3 May 2016

Although these hazards are seemingly 'soft' (and relate to software) they play an important role in the proper function of many devices (hardware) that increasingly rely on electronic accuracy, maintenance, and safety [119]. Some specific considerations for different devices are listed in Table 26.10, Preventing Device-Related Never Events.

It is not within the scope of this chapter to present information on all the possible devices used in an OR, interventional suite, or other location where operative and invasive procedures are performed, but there are general guidelines that apply to most, if not all situations.

Part of the challenge clinicians face daily is the ever-changing technology. The key requirements for the prevention of never events are to support and strengthen a culture that embraces continual

Table 26.10 Recommendations for preventing device-related never events

Device/risks	Safety considerations
General recommendations for all devices	• Adequate training of clinicians in OR technologies to reduce risk of harm (ECRI 2016)
	• Confirm that device is in proper working order
	• Have backups available if there is device failure
	• Employ the device for its intended purpose
	• Use only FDA-approved devices
	• Never silence device alarms
	• Maintain in good working order with regular scheduled biomedical engineering maintenance checks
	• Know how to trouble shoot problems, or, whom to contact
	• Remove from service when not functioning; send for repair or replacement promptly
	• Provide education material to patients and family members
	• Install manufacturer's software updates promptly and verify that most current update is installed
	• For implants stocked on consignment (and may not be documented in the purchase history), ensure that they can be identified if there is a product recall
Light sources (endoscopic):	
• Burns	• Connect light cable before activating light (applies also to surgical head lights)
	• Use standby mode when not in use
	• Avoid placing cables with light activated on patient drapes
Endoscopic instruments	
• Infection	• Keep scopes wiped free of gross blood and body fluid during surgery (inner and outer surfaces)
	• Ensure initial cleaning in the OR suite
	• Ensure adequate reprocessing
	• Communicate actively and clearly with reprocessing staff about the precise steps required for cleaning and reprocessing
Defibrillator	
• Failure to discharge (e.g., due to depleted battery power)	• Ensure adequate 1) battery or 2) in-line power. If defibrilating, ensure that the device is NOT in the synchronous mode (device will look for a nonexistent QRS and will not discharge); if cardioverting, ensure that the ECG waveform is in the synchronous mode (will not discharge without linking to a QRS waveform)
• Joules setting too high or too low	• Confirm defibrillation setting depending on whether internal (e.g., 10–20 Joules) or external (e.g., 400 Joules), and times of discharge
• Failure to defibrillate due to external pad misplacement (e.g., energy does not cross heart)	• Apply defibrillation external patches so that energy crosses the heart (e.g., one padplaced on upper right chest above clavicle, and second pad placed on lower left chest in mid-axilary line)
Implantable Cardioverter-Defibrillator	
• Inadvertent shocks	• Check leads, generator, and accessories for integrity of the components (e.g., no insulation tears or fractures, tight connections)
• Malfunction or cessation of function	• Coordinate use of electrosurgery with pacer testing
	• Be prepared to defibrillate with external defibrillator (apply external defibrillator pads to chest preoperatively)
• Fractured leads or broken insulation	• Avoid injuring devices with surgical instruments (e.g., knives, forceps)

(continued)

Table 26.10 (continued)

Device/risks	Safety considerations
Pacemaker	
• Interference or injury from ESU	• Check leads, generator, and accessories for integrity of the components (e.g., no insulation tears or fractures, tight connections)
	• Coordinate use of electrosurgery with pacer testing
• Fractured leads or broken insulation	• Avoid injuring devices with surgical instruments (e.g., knives, forceps)
Prosthetic Implants (e.g., joint prostheses, heart valves, ophthalmic implants, cosmetic [e.g., breast], other)	
General recommendations for all prosthetic implants	• Store in conditions approved by manufacturer
	• Verbally confirm type, size, model, and other specific identification aspects of implant requested before opening product
	• If implant/prosthesis is in storagesolution (e.g., glutaraldehyde), rinse solution and prepare prosthesis according to manufacturer's instructions
	• Document device lot number, size, type, and other information required per policy
Robots	
• ESU burns	• Collaborate with biomedical engineering to ensure regular maintenance checks of the robot
• RSI	• Engage in training simulations to develop practices to avoid RSI
• Organ puncture	• Be aware of the possibility of injury occurring outside the field of vision; scan the entire field often
Infection	• Collaborate with sterile processing personnel to ensure proper cleaning of robot and accessories
General recommendations	• Surgeons, nurses, anesthesia personnel, and other team members should receive interprofessional and collaborative education and training
	• Employ simulation technologies forinitial training
Saws (bone)	• Ensure that saw blade is inserted properly and securely; test to confirm
	• After inserting blade, place battery powered saw in 'safety' mode and confirm mode with another member of sterile team; if another kind of power source (e.g., electrical) is used, ensure that saw is in safety mode
	• When handing saw to surgeon, verbalize whether saw is "on" or in "safety" mode
	• Have backup saw available
Tourniquet	• Pad tourniquet site
	• Document and track time that tourniquet is employed
	• Verbalize predetermined time periods elapsed under the tourniquet to surgeon
X-Ray machines	
• Excessive radiation	• Monitor and document radiation exposure
	• Use lead shields during procedures employing radiation
	• Have qualified staff members use radiation devices (e.g., C-arms, portable X-ray machines)

Source: AORN [101]; Hauser [118]; ECRI Institute. Top 10 Health Technology Hazards for 2015. A Report from Health Devices. 2014. (The 'Hazards' for more current years are also available at the website). https://www.ecri.org/Pages/SearchResults.aspx?k=top%20technology%20hazards%202015&Page=1&PageSize=20&Sort=relevance&mo=false. Accessed 3 May 2016 (available for free; registration required); ECRI Institute. Top 10 Health Technology Hazards for 2016. A Report from Health Devices. 2015. (The 'Hazards' for more current years are also available at the website). https://www.ecri.org/Pages/2016-Hazards.aspx. Accessed 6 May 2016 (available for free; registration required)
ESU electrosurgical unit, *FDA* Food and Drug Administration

learning, active communication (including solicitation of probable questions related to knowledge deficits about new devices), and team training. A study by Pisano, Bohmer, and Edmondson published in 2001 [120] showed that the successful introduction of that new technology (with significantly new and different devices) relied not only on cumulative experience (i.e., the volume/number of cases performed), but also on organizational, collective learning. The amount of experience was necessary but it was not sufficient. Other factors played a key role. Successful innovators in the study illustrated the attributes of team cohesion, the importance of previous positive interactions among team members, a high degree of communication and cooperation among departments before and during the learning period, frequent and robust communication and explanation of the surgery and the techniques by the surgeon as well as by other team members, and standardization of the terms to be used during surgery [120]. These actions served not only to educate the staff about the specific technology, but also to provide a clear framework for discussion and clarification, and a strong foundation for creating a cohesive team.

Initiating new techniques employing new devices is challenging, but device safety is applicable also to the more mundane daily aspects of surgery. Not to be underappreciated is the importance of ensuring, for example, that the tips of forceps ('pick-ups') meet, that scissors cut cleanly, and that needle holders hold needles securely. The scrub person plays a vital role in checking the working order of instruments. One need not assume that dull scissors will go unnoticed by the surgeon; the value of the scrub person's scrutiny of instruments cannot be overstated.

Confirming that devices such as laparoscopic insufflators, electrosurgical units (ESU), defibrillators, and saws are working properly is one of the crucial safety roles of the circulating RN as well as the scrub person. Nonworking ESUs (and instruments) are important examples of device-related events that are unlikely to occur with proper examination of these devices.

Other types of devices include implants. Prosthetic implants (e.g., joints, cardiac valves, or blood vessels) often have implant-specific accessories and instrumentation that cannot be exchanged with other device accessories. Selecting the appropriate sizing obturators, gauges, or other measuring instruments for the surgeon to use in determining the most appropriate implant is not only a crucial safety factor but also an important factor in the successful outcome of the procedure for the patient. The proper function of the device is the responsibility of the entire surgical team—not just the surgeon performing the procedure and using the device.

Difficult Airway, Failed Airway, Air Embolus

Adverse events affecting the airway are not only of primary concern to anesthesia personnel, but to all members of the surgical team [121–126]. Events that affect the patient's airway and gas exchange were among the top ten priority safety issues identified by perioperative nurses [6, 19] and were cited among the most critical crises by Arriaga et al. [121] in their series of operating room crises. Some specific considerations for airway difficulties and air embolus are listed in Table 26.11, Recommendations for Reducing Difficult Airway and Failed Airway Never Events.

Airway difficulties may be especially challenging in small hospitals, ambulatory surgery centers (ASCs), and physicians' offices where there are fewer resources (e.g., emergency airway supplies and devices, medications, personnel) [19]. Unfortunately, not all airway difficulties can be anticipated and are not treated appropriately in the absence of a coordinated response, specialized airway equipment, and clinical expertise. Additionally, there may be an assumption that 'ambulatory' patients are otherwise healthy and low-risk surgical candidates [19]; such a presumption may prevent adequate contingency planning and preparation for an adverse event.

Table 26.11 Recommendations for reducing difficult airway and failed airway never events

• Identify potential risks for difficult or failed airway
• Assessment patient preoperatively for potential airway-related risks: (e.g., short, thick neck; large tongue; patient unable to extend neck; shape of palate; inability to visualize palate or uvula; past airway issues)
• Review emergency policies and procedures, including a failed airway protocol
• Create Difficult Airway Cart or other mobile storage container
• Provide imaging resources (e.g., video laryngoscopy, bronchoscopy, echocardiography)
• Identify personnel to support perioperative teams
• Practice emergency scenarios that include all members of the surgical team
• Develop annual (or more frequent) hands-on displays for all team members of emergency airway devices, imaging equipment, techniques of emergency airway management, and related activities

Source: American Society of Anesthesiologists [124]; Mort [127]; Wadlund and Seifert [128]

In addition to specific interventions described later, it is important to promote collaborative practices, develop specific procedural interventions and policies, and have necessary equipment and supplies available—ideally in a 'difficult airway cart' or tool case. Adverse outcomes include death, neurologic injury, and cardiac arrest, as well as trauma to the airway, damage to the teeth, and the creation of an unnecessary surgical airway [126].

Difficult Airway

There is no standard definition of a 'difficult airway' according to the American Society of Anesthesiologists (ASA). However, difficulty with facemask ventilation of the upper airway or difficulties intubating a patient—with resulting inadequate oxygenation—are defining components of a 'difficult airway,' according to the ASA [126]. Early considerations include determining if there is an inadequate facemask seal or excessive resistance to gas flow (in or out) in the patient, being unable to visualize the vocal cords during multiple attempted laryngoscopies, and being unable to intubate the trachea after multiple attempts. Additional interventions may include repositioning the patient, checking the equipment (e.g., confirming the integrity of the anesthesia circuit), changing laryngoscopic blades, performing nasal intubation, or using additional intubating devices (e.g., stylet, light wand, video laryngoscopy) [122, 123, 126]. If, after these maneuvers and attempting to employ a supraglottic airway device, [126–128] the patient's oxygenation status remains abnormal, the anesthesiologist can consider the following actions:

- Awaken the patient to resume spontaneous breathing.
- Create a surgical airway.

Failed Airway

Preparing to create a surgical airway indicates there is a failed airway. This situation may be reflected by the following anesthetic considerations [123]:

- Unable to intubate on three attempts by a skilled and experienced provider.
- Unable to maintain SaO_2>90 % with bag ventilating mask (BVM) after failure to achieve oral intubation.
- "Can't intubate, can't oxygenate" situation.

At this point (or earlier) there would likely have been a call to the surgeon as well as a call for additional help; emergency airway supplies and instruments would have been brought into the OR. While the tracheostomy instrument set is opened, the circulating nurse (or resident or other available staff member) would cleanse the neck and upper chest while the surgeon scrubbed and gowned in preparation for performing the tracheostomy.

After resolution of the patient's emergency, it can be useful to engage in a debriefing conference, a formal root cause analysis, or some other standardized method of reviewing what occurred, the patient's outcome, what could

have been improved (or not), and what recommended changes result from close scrutiny of the event. Emergencies cannot always be prevented; each team member's duty is to prepare to respond to emergencies in a competent, collaborative, and proactive manner, which can reduce the number of potential subsequent never events. Table 26.11 describes additional recommendations related to difficult airway and failed airway events.

Air Embolus

Airway emergencies affect oxygenation. Air emboli—venous or arterial—also risk adequate oxygenation via the introduction of atmospheric air or surgical gases (e.g., carbon dioxide/CO_2, nitrous oxide, nitrogen, helium) into the circulatory system where the embolus becomes wedged in an artery or vein, thereby obstructing distal flow [129].

Signs and symptoms of air embolus, which may include decreased end-tidal CO_2 and reduced oxygen saturation are commonly first noted by anesthesia professionals. Additional signs and symptoms include shortness of breath; pain in the chest, back, or shoulders; mental status changes; seizures; hypotension; acute pulmonary shunting producing hypoxemia and hypercarbia; tachy- or bradyarrhythmias; and cardiac arrest [129, 130].

After recognizing the early signs of an air embolus (e.g., decreased end-tidal CO_2 and lower oxygen saturation), the anesthesiologist would call for assistance: personnel and emergency supplies and equipment. Transesophageal echocardiography (TEE) and precordial Doppler ultrasound may be used also to detect air emboli. Restoring hemodynamic stability and restoring normal oxygen saturation is the goal and the anesthesia provider will increase the FiO_2 to 100 % and stop nitrous oxide anesthetic (if used) [130].

Venous Air Embolus

A venous air embolus (VAE) is produced when gas enters the venous circulation, commonly via an intravenous (IV) line or a central venous pressure (CVP) line, or during laparoscopic insufflation [129–131]. Conditions required for this to occur include (1) an open pathway between the source of air and the venous system, and (2) a pressure gradient of higher atmospheric pressure favoring the passage of air into the lower pressure venous circulation [129]. Of special concern is during neurosurgery when the venous anatomy poses some risk for VAE because the major cerebral venous sinuses, for example, do not collapse and may remain 'open,' thus creating a pathway for air movement down the pressure gradient.

A VAE also can migrate to the right ventricle and into the pulmonary circulation increasing pulmonary artery (PA) pressure; this can produce pulmonary outflow tract obstruction. Subsequently, pulmonary venous return is reduced to the left side of the heart, resulting in reduced cardiac output [130, 131]. In patients with suspected air emboli originating from an IV or CVP line, anesthesia personnel, surgeon, and/or circulating nurse would check the intravascular catheter(s) for possible entry sites of air and close off the entry point. Aspiration of air from a CVP line may be attempted; closing the source of air entry may require filling the surgical site with irrigation. The scrub person can provide irrigation to the surgeon for sealing off the entry point of air within the surgical wound [131–134].

Placing the patient with the left side down and in slight Trendelenburg will allow air to collect in the apex of the right ventricle where it can be aspirated if the chest is open (e.g., during cardiac surgery). Another action is to increase venous pressure with IV volume, thereby reducing the air pressure gradient favoring air entry. Lowering the surgical site below the level of the heart also has been used to prevent further air entry.

Arterial Air Embolus

An arterial air embolus (AAE) can occur during cardiac surgery when air bubbles remain in the arterial inflow line or the cardiac chambers after the heart resumes contractions, or, as a result of chest trauma when air from, for example, the bronchial veins can enter the left atrium. An AAE can also occur when venous air passes through a

cardiac defect such as a patent foramen ovale and enter the arterial circulation; this can occur when right atrial pressure is higher than left atrial pressure, producing a right-to-left shunt [129, 130, 132, 133]. Arterial air emboli going to the functional end arteries of the coronary circulation or the brain can be especially dangerous because these organs are highly susceptible to injury after only brief periods of hypoxia [130, 132].

Administering 100 % oxygen can improve oxygen saturation and increase the partial pressure of oxygen and nitrogen within the blood, causing the nitrogen to separate from the embolus and move into the bloodstream. It is important to minimize the nitrogen content in the blood because nitrogen can increase the size of the air bubbles; turning off a nitrous oxide anesthetic (if used) is an important component of treatment [131]. Infusing vasopressors (e.g., dobutamine, norepinephrine) to strengthen myocardial contractility and performing chest compressions (even when the patient is not in cardiac arrest) can break up large blocks of air and facilitate their dispersal. Hyperbaric oxygen therapy may be provided in more severe cases once the patient is stabilized [135, 136]. A plan for transferring a patient to a hyperbaric chamber should be part of any emergency protocol.

The most effective way to avoid arterial (or any) air embolus is to be observant of entry sites into the vascular system and prevent the introduction of air. This is an obvious but important recommendation that should be emphasized often. For example, the scrub person and surgical assistant(s) participating in establishing cardiopulmonary bypass play an important role in observing for air bubbles when arterial tubing connections are made, or, when clearing air bubbles from any line before infusing fluids into the arterial system.

Surgical Specimen Never Events

Errors in the management of surgical specimens are important never events because they can lead to delays in care due to inaccurate or incomplete diagnosis, require reoperation to retrieve a new specimen to replace one that has been lost, and lead to a possible failure to receive appropriate therapy. Ultimately these errors may create a lack of confidence in the quality of the facility and in the providers who are delivering care [19].

One of the challenges in developing improvement strategies is that there is currently no national database for evidence about incidence of specimen error. Makary and colleagues [137] reviewed surgical patient encounters in a large east coast academic hospital and identified 91 surgical specimen errors in a 6-month period. Surgical specimen identification errors were defined as specimens not labeled; empty specimen container(s); no patient name; missing tissue site; and incorrect or missing documentation of laterality, tissue site, or patient identification.

In 2013, Steelman, Graling, and Perkhounkova [6] surveyed AORN members to identify high priority patient safety issues. Of the over 3000 respondents, 35 % rated specimen errors as high priority. Percentages were similar across settings and hospital type but higher in larger hospitals (over 100 beds); these findings may reflect the complexity of surgery and number of specimens per procedure in tertiary care centers.

Accurate specimen management requires effective multidisciplinary communication, minimizing distractions, and an awareness of opportunities and risks for error. Barriers to optimal specimen management include communication issues, time pressure, interruptions, and using preprinted labels from another patient (e.g., left in the OR from a previous patient) for the patient currently undergoing surgery. Although specific steps for handling various types of specimens may differ, the management process is similar and the basic requirements (correct identification of patient and specimen site) are essentially the same ([138], p. 560).

Although there are few national guidelines and other resources to help prevent specimen errors, one exception is AORN's Guideline for Specimen Management [139], which provides a number of robust resources. The guideline addresses the following critical specimen processes:

- Conducting a needs assessment
- Site identification

Table 26.12 Recommendations for reducing specimen never events

• Ensure communication, assess need for obtaining specimen, utilize processes such as check back for confirmation (e.g., Teamstepps)
• Eliminate distractions and multitasking during receipt, description, and confirmation of specimen
• Label specimens accurately; use two unique identifiers (e.g., patient's name, medical record number, and/or date of birth)
• If using a preprinted label, verify accuracy of information as it is used; ensure unused labels are removed at end of procedure
• Utilize debriefing or Sign-Out time before patient leaves the OR for identifying specimens with surgeon, confirming specimen is correctly labeled, with correct patient's name, and—if required—in appropriate fixative ([23], p. 492)
• Before removing specimens from the OR, two people should identify the label and contents
• Follow facility policies for documentation (e.g., surgeon confirms specimen list, signs specimen request form)

Source: Haynes et al. [23]; Steelman and Graling [19]; TeamSTEPPS. Agency for Healthcare Research and Quality. http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/index.html. Accessed 3 May 2016; Van Wicklin [138]

– Collection and handling
– Transfer from the sterile field
– Containment
– Specimen identification and labeling
– Preservation
– Transport
– Disposition of the specimen
– Documentation

The guideline also addresses special care and management (e.g., optimizing fixation and preservation) of specific specimens: breast cancer specimens, forensic specimens, radioactive specimens, and orthopedic hardware. Some specific recommendations for reducing specimen never events are listed in Table 26.12.

Hypothermia

Numerous studies have shown that hypothermia (less than 36.00 °C; normal, 37.00 °C) increases the incidence of complications: surgical site infection, coagulopathy, and possible cardiac injury related to preoperative shivering (in patients with heart disease) which increases myocardial oxygen demand [85, 140]. Additionally, hypothermia has been associated with altered drug metabolism, prolonged recovery after surgery, and general discomfort [141–143]. Complications related to hypothermia cannot only cause suffering and severe complications but also extend length of stay and increase costs [144].

The use of surgical care bundles in certain patient groups (e.g., undergoing colorectal surgery) [145] that include measures to maintain normothermia has shown a significantly reduced risk of SSI. Perioperative personnel should evaluate patients at risk for unplanned hypothermia and implement strategies such as temperature monitoring and patient warming to adjust environmental conditions according to patient needs [87].

A growing number of evidence-based resources are available to clinicians. These include AORN's Guideline for Prevention of Unplanned Perioperative Hypothermia [87] and a recently developed 'Tool Kit' [146, 147] that contains templates for electronic medical record documentation and Healthcare Failure Mode Effect Analysis (HFMEA), an educational slide show on 'best practices,' a 10-Step implementation plan, references, and other components. Recommendations include 'prewarming' the patient before the start of surgery; Vanni and colleagues' work [148] demonstrated benefits of both prewarming (before surgery) as well as warming during surgery. In an editorial discussing perioperative temperature management, the author [149] cited studies [150, 151] as well as personal experience supporting the efficacy of preoperative warming.

The mechanism of warming (e.g., passive or active warm air) and the delivery method (e.g., mattress, air tube) has been studied more intensively with the increasing ability to exert more control over body temperature and the increased scrutiny given to temperature thermally related complications. Bender et al. [152] compared newer methods of passive warming to traditional methods. Use of the newer devices, which employ nylon and polypropylene material that is wrapped

around the patient's extremities and support the head and body, showed improved maintenance of core body temperature. The authors showed that the newer passive devices complemented active warming devices [152].

It is important to understand how and why perioperative hypothermia can occur. Steelman and Graling [19] stress that the goal is to focus on patient outcomes; although compliance with process measures and metrics is not unimportant, the primary concern is the result of the patient's surgical experience. Additional recommendations for maintaining perioperative normothermia are presented in Table 26.13.

Table 26.13 Recommendations for reducing hypothermia-related never events

General considerations
• Educate staff about the pathophysiology of inadvertent hypothermia
• Differentiate (e.g., indications, methods of promotion or prevention, techniques) between the need for intentional hypothermia (associated with cardiac surgery) and avoidance of unintentional hypothermia
• Make patient outcome metrics an integral part of the quality improvement program
• To prevent burns, use extreme caution with forced warm air devices; ensure that temperature of the air is within acceptable limits
Preoperatively
• Employ active prewarming procedures (for at least 30 min)
• Do not rely on warm blankets to prevent hypothermia (but do not deny a patient's request for a "warm blanket")
Intraoperatively
• Prewarm fluids (e.g., intravenous, irrigating); exception: during cardiac surgery, if irrigating during period of induced cardiac arrest, ensure that temperature of irrigating fluid is cold; when patient's temperature is normothermic, use warm irrigation.
• Employ active prewarming procedures (before induction of anesthesia)
• When employing forced air warming (FAW) through a hose, ensure that air is going into the FAW blanket and not directly onto the patient's skin in order to prevent patient burns
Postoperatively
• Maintain active warming procedures
• Do not rely on warm blankets to prevent hypothermia (but do not deny a patient's request for a "warm blanket")

Source: Steelman and Graling [19]; AORN [87]; AORN. Prevention of perioperative hypothermia (PPH) tool kit. AORN. https://www.aorn.org/aorn-org/guidelines/clinical-resources/tool-kits/prevention-of-perioperative-hypothermia-pph-tool-kit. Accessed 3 May 2016

Instrument Care and Reprocessing Never Events

The complexity of current instruments and devices challenges the most scrupulous clinicians and sterile processing professionals. The design of many instruments—especially those with multiple lumens—makes thorough cleaning even more difficult. In facilities with fewer human resources, there are additional challenges. The Top 10 Health Technology Hazards for 2015, published by ECRI ([119], p. 2), lists "inadequate reprocessing of endoscopes and surgical instruments" as the number #4 hazard.

Greater public awareness of reprocessing difficulties and shortcomings has encouraged greater oversight by a number of organizations, most notably the Association for the Advancement of Medical Instrumentation (AAMI) [153], the Centers for Disease Control and Prevention (CDC) [154], the Association for Professionals in Infection Control and Epidemiology (APIC) [155], and AORN [156–158].

There is also a greater incentive for perioperative clinicians to actively partner not only with their sterile processing colleagues, but also with Infection Preventionists and Risk Management personnel. Perioperative staff who may have been hesitant in the past to invite Infection Prevention colleagues into the OR setting, can benefit by collaborating to solve issues jointly and effectively.

Recommendations for the care, cleaning, and reprocessing of endoscopes and other instruments and devices are available from many sources: ECRI [119], CDC [154], AORN [156–158], and individual experts [159]. Effective strategies for preventing reprocessing never events are listed in Table 26.14.

There are multiple resources available for information and guidance related to never events; these

Table 26.14 Strategies for preventing reprocessing never events

Before surgery starts (setup)
• Scrub person confirms sterility of instruments sets, individually sterilized instruments, and supplies
• Scrub person checks instrument lumens, teeth, box locks, security of screws, and freely moving parts to ensure no bio burden or other material on/in instruments
During surgery
• Scrub person keeps instruments clean (e.g., with moistened sponge); bioburden and debris that is allowed to dry may be very difficult to remove; sterile H_2O is recommended for cleaning instruments (scrub person must ensure that container with water is labeled)
• Assistant may use moist sponge to keep personal forceps and suture scissors clean and free of debris
At the completion of surgery
• Perform initial cleaning of instruments before leaving OR
• 'Tag' and remove damaged and/or nonworking instruments
• Presoaking with appropriate product is recommended
After surgery
• Use only approved cleaning solutions (do not place instruments in chlorine bleach!)
• Rearrange instruments in order on stringers
• Protect delicate instruments
Sterile processing
• Instruments that are not 'clean' cannot be disinfected or sterilized
• Follow manufacturer's instructions for cleaning, disinfecting, and sterilizing
• Have tools appropriate for cleaning (e.g., lumens, jaws, teeth)
• Reorganize instruments and prepare for sterilization with care to avoid injury to instruments
• Have instrument cleaning accessories recommended by the manufacturer
• Protect delicate instruments

Source: ECRI Institute. Top 10 Health Technology Hazards for 2015. A Report from Health Devices. 2014. (The 'Hazards' for more current years are also available at the website). https://www.ecri.org/Pages/SearchResults.aspx?k=top%20technology%20hazards%202015&Page=1&PageSize=20&Sort=relevance&mo=false. Accessed 3 May 2016; ECRI Institute. Top 10 health technology hazards for 2016. https://www.ecri.org/Pages/2016-Hazards.aspx. Accessed 3 May 2016; ECRI Institute. Top 10 patient safety concerns for 2016. https://www.ecri.org/Pages/Top-10-Patient-Safety-Concerns.aspx. Accessed 3 May 2016; AAMI [153]; APIC [155]; AORN [156, 158]; Cowperthwaite and Holm [157]; Seavey [159]

are listed in Table 26.15. These resources reflect organizations as well as specific publications related to never events in particular and safe, effective care in general.

Conclusions

A recent systematic review [9] looking at three never events occurring during surgery—wrong-site surgery, retained surgical items, surgical fires—found limited evidence of effective intervention other than improved communication. The results may seem disconcerting to those wishing for a magic 'silver bullet' that will prevent never events, but clinicians should appreciate even more the importance of sharing information, helping others to succeed, and always looking for better ways to improve and to measure—in other words engaging in effective communication.

Although the Institute of Medicine's report, To Err is Human [10], became a landmark publication that focused the public's attention on the prevention of error and the promotion of safety, there were earlier, notable attempts to identify errors and initiate methods to prevent repeating those errors. Almost 100 years ago, Harvey Cushing, MD, Johns Hopkins neurosurgeon, catalogued and analyzed his mistakes in one of the earliest examples of documenting, reporting,

Table 26.15 Resources to address perioperative never events

Resources to address the highest priority perioperative patient safety issues	
Safety issue	Resources
1. Patient misidentification: preventing wrong site/procedure/ patient surgery	1. AORN, http://www.aorn.org
	• Correct Site Surgery Tool Kit, http://www.aorn.org/guidelines/clinical-resources/tool-kits/correct-site-surgery-tool-kit
	• Position statement on preventing wrong-patient, wrong-site, wrong-procedure events, https://www.aorn.org/aorn-org/guidelines/clinical-resources/position-statements
	• Webinars, https://www.aorn.org/search#q=webinars
	2. Joint Commission, http://www.jointcommission.org/
	3. World Health Organization, http://www.who.int/en/
	4. Institute for Healthcare Improvement, http://www.ihi.org/Pages/default.aspx
	5. Agency for Healthcare Research and Quality, https://psnet.ahrq.gov/
	6. National Guideline Clearinghouse, http://www.guideline.gov/
	7. National Quality Forum, http://www.qualityforum.org/Home.aspx
2. Preventing medication errors	1. AORN, http://www.aorn.org
	• Guideline for medication safety. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:289–328
	• Clinical FAQs, http://www.aorn.org/aorn-org/guidelines/clinical-resources/clinical-faqs
	• Webinars, https://www.aorn.org/search#q=webinars
	2. Joint Commission, http://www.jointcommission.org/
	3. Institute for Healthcare Improvement, http://www.ihi.org/Pages/default.aspx
	4. Agency for Healthcare Research and Quality, https://psnet.ahrq.gov/
	5. National Quality Forum, http://www.qualityforum.org/Home.aspx
	6. Anesthesia Patient Safety Foundation, http://www.apsf.org/
	7. Institute for Safe Medication Practices, http://www.ismp.org/
	8. US Food and Drug Administration, http://www.fda.gov/
	9. US Pharmacopeia, http://www.uspharmacopeia.com/
3. Preventing pressure injuries	1. AORN, http://www.aorn.org
	• Guideline for positioning the patient. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.; 2016:649–668
	• AORN Tool Kit. Safe patient handling and movement in the perioperative setting. https://www.aorn.org/aorn-org/guidelines/clinical-resources/tool-kits/safe-patient-handling-tool-kit
	2. American College of Surgeons (ACS), Statement on older adult falls and falls prevention, https://www.facs.org/about-acs/statements/73-older-falls
	3. National Guideline Clearinghouse, http://www.guideline.gov/
	4. National Quality Forum, http://www.qualityforum.org/Home.aspx
	5. Wound Ostomy and Continence Nurses Society, http://www.wocn.org/#
4. Preventing surgical site infection	1. AORN, http://www.aorn.org
	• Guideline for environmental cleaning. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.; 2016:7–28
	• Guideline for hand hygiene. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:29–40
	• Guideline for preoperative patient skin antisepsis. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:41–64
	• Guideline for sterile technique. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:65–94
	2. National Guideline Clearinghouse, http://www.guideline.gov/
	3. National Quality Forum, http://www.qualityforum.org/Home.aspx
	4. Association for Professionals in Infection Control and Epidemiology (APIC), http://www.apic.org/
	5. Surgical Care Improvement Project (SCIP), http://www.jointcommission.org/surgical_care_improvement_project/

(continued)

Table 26.15 (continued)

Resources to address the highest priority perioperative patient safety issues	
Safety issue	Resources
5. Preventing electrical and other energy-related injuries	1. AORN, http://www.aorn.org
	• AORN Guideline for environment of care, Part 1. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:237–262
	• AORN. Guideline for electrosurgery. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:119–136
	• AORN. Guideline for laser safety. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:137–150
	• AORN. Guideline for minimally invasive surgery. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:589–616
	• Ball KA. Surgical modalities. In Rothrock JC, editor. Alexander's care of the patient in surgery. 15th ed. St Louis: Elsevier Mosby; 2013. p. 211–252
	• Seifert PC, Peterson E, Graham K. Crisis management of fire in the OR. AORN J. 2015;101(2):250–263
	• Fire Safety Tool Kit, https://www.aorn.org/aorn-org/guidelines/clinical-resources/tool-kits/fire-safety-tool-kit
	• Webinars, https://www.aorn.org/search#q=webinars
	2. Anesthesia Patient Safety Foundation, http://www.apsf.org/
	3. ECRI Institute, https://www.ecri.org/
	4. National Guideline Clearinghouse, http://www.guideline.gov/
	5. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Fundamental use of surgical energy (FUSE). (Registration [free] required). http://www.fusedidactic.org/. Accessed 2 May 2016
6. Preventing retained surgical items	1. AORN, http://www.aorn.org
	• Guideline for prevention of retained surgical items. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:369–415
	• Goldberg JL, Feldman DL. Implementing AORN recommended practices for prevention of retained surgical items. AORN J. 2012;95(2):205–216
	• Steelman VM, Cullen JJ. Designing a safer process to prevent retained surgical sponges: a healthcare failure mode and effect analysis. AORN J. 2011;94(2):132–141
	2. Joint Commission, http://www.jointcommission.org/
	3. Agency for Healthcare Research and Quality, https://psnet.ahrq.gov/
	4. National Quality Forum, http://www.qualityforum.org/Home.aspx
7. Preventing device failures and misuse	1. AORN, http://www.aorn.org
	• Guideline for environment of care, Part 1. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:237–262
	• Guideline for electrosurgery. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:119–136
	• Guideline for laser safety. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:137–150
	2. National Quality Forum, http://www.qualityforum.org
	3. ECRI Institute, https://www.ecri.org
	4. Individual manufacturer's instructions
	5. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Fundamental use of surgical energy (FUSE). (Registration [free] required). http://www.fusedidactic.org/

(continued)

Table 26.15 (continued)

Resources to address the highest priority perioperative patient safety issues	
Safety issue	Resources
8. Responding to difficult intubation/airway emergencies, air embolus	1. AORN, http://www.aorn.org
	• Wadlund DL, Seifert PC. Crisis management of failed airway in the OR. AORN J. (2015);102(4):413–423
	• Seifert PC, Yang Z, Munoz R. Crisis management of air embolism in the OR. AORN J. (2015);101(4):471–481
	2. American Society of Anesthesiologists, http://www.asahq.org/
	3. American Association of Nurse Anesthetists, http://www.aana.com
	4. Anesthesia Patient Safety Foundation, http://www.apsf.org/
	5. National Guideline Clearinghouse, http://www.guideline.gov/
9. Preventing specimen management never events	1. AORN, http://aorn.org
	• Guideline for specimen management. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:441–470
	2. Department of Veterans Affairs, National Center for Patient Safety, Healthcare Failure Mode and Effect Analysis (HFMEA)
	• The Basics of Healthcare Failure Mode and Effect Analysis. Washington, DC: Veterans Health Administration; 2001. http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp
10. Preventing perioperative hypothermia	1. AORN, http://www.aorn.org
	• Guideline for prevention of unplanned perioperative hypothermia. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:531–554
	• Prevention of Perioperative Hypothermia Tool Kit https://www.aorn.org/aorn-org/guidelines/clinical-resources/tool-kits/prevention-of-perioperative-hypothermia-pph-tool-kit
	• Webinars, https://www.aorn.org/search#q=webinars
	• Clinical FAQs, http://www.aorn.org/clinicalfaqs
	2. Anesthesia Patient Safety Foundation, http://www.apsf.org
	3. American Society of PeriAnesthesia Nurses, http://www.aspan.org/
	• Hooper VD, Chard R, Clifford T, et al. ASPAN's evidence-based clinical practice guideline for the promotion of perioperative normothermia: second edition. J Perianesth Nurs. 2010;25(6):346–365
	4. National Quality Forum, http://www.qualityforum.org
	5. National Guideline Clearinghouse, http://www.guideline.gov/
	6. Surgical Care Improvement Project (SCIP), http://www.jointcommission.org/surgical_care_improvement_project/
11. Preventing failures in instrument care and reprocessing	1. AAMI, http://www.aami.org
	• FDA beefs up reprocessing guidance. September 2015. http://www.aami.org/productspublications/articledetail.aspx?ItemNumber=2735
	2. AORN, http://www.aorn.org
	• Guideline for cleaning flexible endoscopes and endoscope accessories. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:675–758
	• Guideline for high-level disinfection. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:759–772
	• Guideline for instrument cleaning. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.; 2016:773–808
	• Sterile processing webinar series for ambulatory surgery centers, presented in partnership with International Association of Healthcare Central Service Material Management. https://www.aorn.org/Member_Apps/Product/Detail?productID=9452
	• Clinical FAQs, http://www.aorn.org/aorn-org/guidelines/clinical-resources/clinical-faqs

(continued)

Table 26.15 (continued)

Resources to address the highest priority perioperative patient safety issues	
Safety issue	Resources
	3. Joint Commission, http://www.jointcommission.org/
	4. National Guideline Clearinghouse, http://www.guideline.gov/
	5. ECRI Institute, https://www.ecri.org
	6. Association for Professionals in Infection Control and Epidemiology (APIC), http://www.apic.org/
	7. Individual manufacturer's instructions

Source: Steelman et al. [6]; Steelman and Graling [19]
All websites accessed 3 May 2016

improving, and innovating one's practice by recognizing a human tendency to err and to learn from those very errors [160]. In an address to the New England Otological and Laryngological Society in 1920, Cushing stated that "Errors will be made, but it is from our mistakes, if we pursue them into the open instead of obscuring them, that we learn the most" ([161], p. 210). Cushing's advice is as pertinent today as it was in 1920.

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Healthcare-Associated Infections in Surgical Practice

27

Scott J. Ellner and Affan Umer

"One sometimes finds what one is not looking for."

—Sir Alexander Fleming

Introduction

Healthcare-associated infections (HAIs) pose a significant burden to healthcare delivery systems, representing an active inefficiency in healthcare today. HAIs can be acquired during treatment within any healthcare setting, be it acute care hospitals or post-acute rehabilitation centers (http://health.gov/hcq/prevent-hai.asp). The Center for Disease Control (CDC) 2011 surveillance data reports that 1 in 25 hospitalized patients will acquire a HAI (http://www.cdc.gov/HAI/surveillance/#progress). To put this in perspective, it amounts to an estimated 722,000 HAIs in US acute care hospitals (http://www.cdc.gov/HAI/surveillance/#progress) [1]. Not only does this have a significant economic impact, amounting to billions of dollars, it also represents one of the leading causes of preventable morbidity and mortality [2].

HAIs were historically perceived as an inevitable consequence of patient care. This belief is no longer compatible with modern medical practice. Federal institutions have tracked HAI data through the National Nosocomial Infections Surveillance (NNIS) System since 1970, later succeeded by the National Healthcare Safety Network (NHSN) [3]. Their impact on the sustainability of our healthcare delivery model has brought our practice under considerable scrutiny. In response, the Center for Medicare and Medicaid Services (CMS), starting October 1, 2008, pushed stringent measures to enforce its vision of quality in healthcare. This shift in policy meant that hospitals would claim limited reimbursement on HAIs such as catheter-associated urinary tract infections (CAUTIs), catheter-related bloodstream infections (CRBSIs), ventilator-associated pneumonia (VAPs), and surgical site infections (SSIs), etc. As a result, institutions have been circuitously pressured into prioritizing reduction in HAIs. Over the last few years, hospitals have aligned all tiers of healthcare delivery to the value-based model by adopting evidence-based guidelines from the CDC, for HAI reduction (http://www.cdc.gov/HAI/prevent/prevent_pubs.html; http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html), and the results have been encouraging. Recent data from the Agency for Healthcare Research and Quality (AHRQ) led by the US Department of Health and Human Services (HHS) demonstrate a 17 % reduction in hospital-acquired conditions (HAC), including HAIs (https://psnet.ahrq.gov/primers/primer/7).

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Quality is the new dictum in all specialties of healthcare. The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is in the forefront in its efforts to prevent postsurgical complications, including HAIs. Although ACS-NSQIP reported data is confidential and available only to participating institutions, there is increasing advocacy for public reporting of HAIs. The effect of measures such as public reporting remains unknown [4] but some evidence suggests that it helps increase implementation of preventive protocols [5, 6]. Therefore, the future will most likely mandate greater transparency and could be critical to patient autonomy in choosing their healthcare providers. To hospitals, this may sound counterintuitive, but there is a strong belief among focus groups, payers, and policymakers that accountability in outcomes will accelerate improvement processes, as well as serve as an impetus for their continuance.

Surgeons, who historically have been most resistant to change, are rapidly embracing patient safety. They are aggressively addressing postoperative HAIs, thus decreasing both hospital length of stay and hospitalization costs. Most HAIs can be addressed through relatively inexpensive process improvement measures. Further innovation in Electronic Health Records (EHR) systems, modification of nursing protocols, and patient education will assist preventive strategies already in place. The responsibility lies with all healthcare providers to develop a patient centric culture in our dominion, meeting all benchmarks of quality.

Catheter-Associated Urinary Tract Infection (CAUTI)

Urinary tract infection (UTI) is the second most common type of HAIs. Approximately 80 % of UTIs are related to an indwelling urinary catheter or instrumentation [7, 8]. After the first 48 h, the risk of bacterial colonization increases by 5 % with each continuous day of catheterization. Subsequent infection rates can reach as high as 25 % in those who are colonized [9]. CAUTIs cause unnecessary discomfort in patients, prolong hospital length of stay, and can be fatal, especially in the setting of urosepsis or systemic bacteremia. Although CAUTIs are a relatively inexpensive adverse event, with an average cost of $758 per infection [10], its high frequency of occurrence translates into a cumulative cost of millions of healthcare dollars [11]. Reduction in CAUTIs is a top priority for federal and state regulatory bodies, but despite a nationwide effort, there has been a 6 % increase in CAUTI rates between 2009 and 2013 (http://www.cdc.gov/HAI/surveillance/#progress). Per NHSN data, CAUTI rates are highest in general surgery and trauma ICU patients. Not surprisingly, these figures are congruent with high-indwelling urinary catheter usage rates in surgical units (http://www.cdc.gov/nhsn/PDFs/dataStat/2010NHSNReport.pdf). The best preventive strategies, therefore, are based around modifying catheter usage.

Risk factors for CAUTI include older age, female sex, malnutrition, diabetes mellitus, renal insufficiency, ureteral stents, and inappropriate management of catheter draining system [7, 12]. The microbiology of uncomplicated CAUTI consists of gram-negative bacteria such as *Escherichia coli* (most common), *Klebsiella pneumoniae*, and *Proteus mirabilis* [13]. A recent analysis of HAIs found *Enterococcus* species as the third most common cause of UTI [1]. Other prevalent organisms causing CAUTI include *Pseudomonas* and various fungi; both found more commonly in postsurgical patients [14]. Only 10 % of patient with a CAUTI will have symptoms, thereby making CAUTI diagnosis difficult [15]. Bacteriuria is often present with indwelling catheter use, though it may not necessarily mean an infection is present. The CDC defined criteria for CAUTI diagnosis is shown in Table 27.1. Once a diagnosis is established, treatment revolves around targeted antibiotic therapy and catheter removal. If the catheter cannot be removed, it should be changed. However, with ongoing catheterization, a longer course of antimicrobial therapy will be required and infections will likely recur despite adequate treatment [16].

Table 27.1 Hospital-acquired infection (*HAI*) criteria

Hospital-acquired infections (HAIs)	Criterion
Catheter-associated urinary tract infection (*CAUTI*) (requires 1, 2, and 3)	1. Patient has a urinary catheter in place for >48 h and was either; • Present for any duration on the day of infection *OR* • Removed the day before the date of event 2. Patient has at least *one* symptom or sign of UTI[a] 3. A positive urine culture (with no more than two species) of $>10^5$ colony forming units (CFU)
Catheter-related blood stream infection (CRBSI)	1. A positive blood culture with the same organism cultured from the catheter tip *OR* Culture of the same organism from at least two blood samples (one from a catheter hub and the other from a peripheral vein or second lumen) meeting criteria for quantitative blood cultures or differential time to positivity 2. Central line-associated bloodstream infection (*CLABSI*) is defined separately as a laboratory-confirmed bloodstream infection in a patient with a central line within a 48-h period
Surgical site infection (*SSI*)	• Infection occurs within 30 days (90 days for organ space infection) after the operation • Diagnosis is made by the surgeon (attending physician) • Sign and symptoms of infection should be present on physical[b], radiological, or histopathologic (positive culture) examination • *Superficial*: only *one* is required 1. Purulent drainage, with or without laboratory confirmation, from the superficial incision 2. Organism is isolated from an aseptically obtained culture of fluid or tissue from the superficial incision 3. Incision is deliberately opened by surgeon, unless incision is culture negative • *Deep*: only *one* is required 1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site 2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon • *Organ space*: only *one* is required 1. Purulent drainage from a drain that is placed into the organ/space 2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space 3. An abscess or other evidence of infection involving the organ/space that is found
Pneumonia	• Hospital-acquired (or nosocomial) pneumonia (*HAP*) is pneumonia that occurs 48 h or more after admission and did not appear to be incubating at the time of admission • Ventilator-associated pneumonia (*VAP*) is a type of HAP that develops more than 48–72 h after endotracheal intubation • Healthcare-associated pneumonia (*HCAP*) is defined as pneumonia that occurs in a nonhospitalized patient with extensive healthcare contact • Diagnosis requires appropriate clinical (fever, leukocytosis or leukopenia, or altered mentation), radiological (chest X-ray or CT), and histopathological (blood, pleural fluid, or bronchoalveolar lavage cultures) signs and symptoms
Clostridium difficile infection (*CDI*)	1. The presence of diarrhea, defined as passage of 3 or more unformed stools in 24 or fewer consecutive hours *AND/OR* 2. A stool test result positive for the presence of toxigenic *C. difficile* or its toxins or colonoscopic or histopathologic findings demonstrating pseudomembranous colitis

[a]Fever (>38.0 °C), suprapubic tenderness, costovertebral angle pain or tenderness, urinary urgency, urinary frequency, and dysuria

[b]Pain or tenderness, localized swelling, redness, heat or fever (>38 °C), localized pain, or tenderness

Prevention

Effective CAUTI reducing strategies are focused on minimizing catheter usage. This involves staff education and training, so urinary catheters in operative candidates are used only when necessary. It also includes aseptic insertion techniques and vigilant assessment of necessity and removal of indwelling catheter [17–19]. Additionally, there is strong evidence in favor of maintaining closed drainage systems

and intermittent catheterization in non-ICU patients to minimize CAUTI risk [20]. However, measures such as antibiotic prophylaxis during prolonged catheterization, bladder irrigation, or external catheterization (in males) have shown little benefit in reducing CAUTI, if none at all [4]. Variable success has been reported with silver-coated or medicated catheters, and routine use is not recommended at the moment.

With over 30 % of catheters inserted for wrong indications, CAUTI reduction is still an uphill battle. Unfortunately, very often the females, elderly, and disabled, who are all more likely to develop an infection, are victims of this oversight. Preliminary 2014 data from the CDC shows improvement in CAUTI incidence. Hopefully, a detailed look will shed light on what measures were effective and enable infection stewards to focus efforts in the proper direction.

Catheter-Related Bloodstream Infection

Approximately 3–16 % of intravascular catheterization, depending on site of intervention and type of catheter, can result in CRBSI [21]. These infections can cause increased morbidity, excess hospitalization, and can be potentially fatal [22, 23]. The CDC data estimates 15 million central venous catheter (CVC) days annually in US intensive care units, 250,000 CRBSI (92,000 central line-associated bloodstream infections—CLABSI) resulting in 62,000 deaths. The estimated cost of treating a CRBSI ranges from $3000–$56,000 [24]. Bloodstream infections, especially those associated with CVC, are the costliest among HAIs; hence, a lot of quality improvement work has been directed toward their reduction.

Risk for CRBSI and CLABSI can be multifactorial depending on the operator, host, and device, Table 27.2. Majority of CRBSI are caused by gram-positive organisms (*Staphylococcus* spp., *Enterococcus* spp.) followed by gram-negative bacilli and fungi (*Candida* spp.) [24–26]. Recent trends have showed lower rates of gram-positive CRBSI owing to the commonly used chlorhexidine skin preparations [24]. The diagnosis of CRBSI requires a positive blood culture with the same organism isolated from the catheter tip (gold standard) or a differential period of 2 h between the initial positive blood culture and the subsequent CVC culture which grew the same organism (http://www.apic.org/Resource_/EliminationGuideForm/259c0594-17b0-459d-b395-fb143321414a/File/APIC-CRBSI-Elimination-Guide.pdf). CLABSI is defined separately as a laboratory-confirmed bloodstream infection in a patient with a central line within a 48-h period. Additional details regarding diagnosis criteria are listed in Table 27.1.

Table 27.2 Risk factors for catheter-related bloodstream infection (*CRBSI*)

Operator	Insertion circumstances and site, operator experience, appropriate barrier precautions, skin antisepsis, duration of catheter use, appropriate catheter maintenance
Host	Age, comorbidities, malnutrition
Device	Multi-lumen CVCs, multiple CVCs, tunneled catheters
Other	Parenteral nutrition, prolonged hospitalization, use of blood products, cardiac surgery

It is important to note, as quality measures are being adopted with greater frequency especially in ICUs, majority of the CRBSI/CLABSIs are occurring outside the ICU setting [27, 28]. However, treatment remains the same. Systemic antibiotics and catheter removal are the key elements in the management of CRBSI. Vancomycin is the recommended antibiotic for empiric therapy [29]. This can be further tailored depending on blood culture speciation. Femoral catheters in critically ill patients should receive empiric treatment for gram-negative bacilli and fungi as well [30]. The duration of treatment varies depending on severity and pathogen. Uncomplicated infections generally require 5–14 days of antibiotics, while treatment for complicated CRBSI can stretch to as much as 8 weeks. Multidrug-resistant organisms remain a serious issue; until recently 50 % of all *S. aureus* isolates in ICUs were methicillin resistant.

Catheter removal should always be the priority in CRBSI unless unusual circumstances occur, and an alternative site is not available [31]. Short-term catheters should be removed in CRBSI due to the presence of *Staphylococcus aureus*, *Enterococci*, gram-negative bacilli, and fungi. Long-term catheters should be removed in the setting of severe sepsis, endocarditis, suppurative thrombophlebitis, or persistent infection after 72 h of antimicrobial therapy [31].

Prevention

Among all the HAIs, measures to reduce CRBSI have shown the most promise. Successful implementation of catheter management protocol in both the Michigan Keystone ICU Project and the Pittsburgh Regional Health Initiative has shown a decrease of up to 70 % in CLABSI rates. Most of these protocols adhere to best practice guidelines and are cost-effective, sustainable, and replicable. Generally, preventive algorithms are geared toward staff education for insertion and maintenance of catheters. The emphasis is on using maximum barrier precautions [32], chlorhexidine skin preparation [33], weekly dressing changes for central lines, and daily inspections for signs of infection. Scheduled simulation-based training and educational modules are paramount to reiterating these practices among healthcare personnel. In addition, checklists and electronic health record system hard stops can aid in compliance. Recent data suggests promising results with antimicrobial lock solutions [34, 35], antimicrobial impregnated catheters [36], and chlorhexidine dressings [37]. Use of antimicrobial ointments, frequent catheter manipulation, and replacement increase colonization at the insertion site and are best avoided.

The most important intervention is to assess the need for intravascular access daily and remove the catheter as soon as its purpose is served.

CLABSIs have decreased by 56 % between 2001 and 2009 and another 46 % by 2013. The gains have been remarkable, but the goal is to get to zero. The debate among healthcare professionals continues regarding whether a benchmark of 0 % is realistic or sustainable. A multidisciplinary approach is favored with a focus on minimizing variability, zero tolerance for noncompliance, and a commitment to internal accountability.

Surgical Site Infections (SSI)

According to a recent surveillance survey, surgical site infections are tied with pneumonia as the most common HAI [1]. Despite over a decade of effort to reduce surgical site infections, they still remain a common occurrence. Approximately 40 million surgical procedures take place in the United States annually and SSIs are expected to occur in 2–5 % of postsurgical patients [38]. SSIs constitute 14 % of the total burden of HAIs and 38 % of HAIs in surgical patients [39]. These infections result in excess morbidity, hospital length of stay, and increased risk of readmission, and unlike CRBSI, their occurrence has a well-established link to increased mortality [40–42]. The risk of death is 2–11 times higher in infected patients as compared to those who are not infected. The cost of an average SSI is estimated to cost between $6000 and $10,000 [43]. The total cost of hospitalization can be up to 70 % higher in an admission with an SSI depending on its severity [44].

The CDC has standardized definitions for SSIs, which vary depending on the depth of the infection. They are further classified into superficial incisional, deep incisional, and organ space SSI. Details of each are available in Table 27.1. Multiple risk factors exist which can be host dependent (extremes of age, obesity, diabetes mellitus, malnutrition, MRSA carriers, cigarette smoking, steroid use, and remote site infection) [45–52] or operation dependent (heavily dependent upon the inherent risk of infection determined by the class of wounds). Clean wounds have an SSI rate of 2 %, while dirty wounds can have infection rates as high as 40 % [53]. Additional risk factors, depending on operative choices, include preoperative shaving, chlorhexidine skin preparation, preoperative showering, antibiotic prophylaxis, maintaining sterility,

operative room ventilation, intraoperative transfusions, and ultimately on the type and duration of surgery [53–64]. Postoperative wound care provides additional opportunity to prevent infections. Various risk stratification models for SSI exist, such as the SENIC index predicted SSI risk and the NNIS basic risk index, but their actual use in surgical practice has been limited.

The majority of SSIs are secondary to endogenous flora occupying the surgical site. *Staphylococcus aureus* is still the most common organism overall, followed by *K. pneumoniae*, *E. coli*, and *Enterococcus* [1]. Variations may exist depending on the type of surgery. Immunocompromised patients can have SSIs from a variety of less common organisms, including fungi. Treatment focuses around meticulous wound care and antimicrobial therapy. Some superficial and deep SSIs can be successfully treated with suture removal, draining any collections, debriding the fibrinous exudate, and frequent dressing changes. Deeper infections, especially those associated with cellulitis, will require oral or systemic antibiotics and a strategy to heal by secondary intention if the wound is opened. Negative pressure dressings or daily wound care with moist saline gauze will aid in wound maintenance and accelerate healing. In some cases, flap coverage may be necessary to close the infected site. Normothermia and euglycemia are equally important in mitigating risk of infection both pre- and postoperatively.

Prevention

In 1999, the CDC released comprehensive guidelines, focusing on pre-, during and postoperative phases of surgical wound care, for SSI reduction, Table 27.3. Although strong evidence exists to suggest effectiveness of these strategies, compliance has been less than ideal [65, 66]. A parallel initiative by CMS, the Surgical Care Improvement Project (SCIP), was implemented nearly a decade ago. Despite increasing adherence, there has not been a remarkable improvement in SSI rates [67]. This brings into question our understanding of effective strategies and surveillance programs in place. For example, a popular opinion that hand washing, by its own, can reduce MRSA SSI rates outside the operating room has been refuted [68] and needs to be coupled with decolonization strategies in order to be effective. We need to standardize and bundle our efforts in a similar fashion, as they are most effective when used in conjunction.

Table 27.3 Preventive measures to reduce surgical site infections (*SSI*)

Preoperative	Tight glycemic control, treat remote infections, optimize nutrition, shorter preoperative hospital stay, preoperative antiseptic showering
Intraoperative	Antimicrobial prophylaxis, maintain normothermia, optimize tissue oxygenation, use of alcohol-based skin preparation, plastic wound protectors for biliary and GI surgery, use of surgical checklist, avoid blood transfusions, asepsis, meticulous surgical technique, proper instrument sterilization
Postoperative	Proper incision care, appropriate discharge planning, patient education

Best practice bundling through Comprehensive Unit Safety Program (CUSP) has been an extremely effective strategy in curbing various HAIs. The AHRQ plans to reinvigorate efforts for SSI reduction by implementing the Comprehensive Unit Safety Program in operating rooms called Surgical Unit-Based Safety Program (SUSP). In addition to prevention, proper surveillance is vital to the efforts. Multiplicity of platforms such as the ACS-NSQIP and NHSN collect and report SSI data. Depending on the veracity of data, 16–84 % of SSI's will occur after discharge [69]. The ACS-NSQIP quality assessment improvement tool attempts to follow complications, such as SSI, in the post-acute phase. Accurate data collection will be critical to improving quality of care provided to surgical patients.

Pneumonia

Pneumonia can be defined as community acquired or nosocomial. Nosocomial or hospital-acquired pneumonias (HAPs) can be further subdivided

into ventilator-associated pneumonias (VAPs). Definitions vary in literature, but in general, HAP occurs 48 h after admission and is not present at admission [70]. VAP occurs 48–72 h after endotracheal intubation. Healthcare-associated pneumonia (HCAP) is another entity, which includes nonhospitalized patients with extensive healthcare contact preceding the infection [70]. Pneumonia is the most frequently encountered HAI [1]. Mortality associated with HAP is estimated between 27 and 50 % [70]. Higher mortality rates are considered attributable to VAP, though this remains controversial [71]. The NHSN reports VAP rates of 0.0–4.4 per 1000 ventilator days [72]. Incidence is among highest in surgical, burn, and trauma units.

Risk factors for HAP include extremes of age, underlying respiratory condition (COPD, ARDS, etc.), impaired consciousness, aspiration, and mechanical ventilation [73]. Surgery [74] and trauma [75] are independent risk factors for developing VAP. Mechanical ventilation is the most important risk factor; the risk of developing pneumonia increases with each day of intubation [73, 76]. Almost every diagnostic criterion relies on a combination of clinical, radiological, and microbiological evidence. Fever, leukocytosis, hypoxemia, or purulent sputum needs to be associated with a new infiltrate viewed on a chest radiograph. The diagnostic accuracy increases when these signs are coupled with a positive gram stain and positive sputum culture (sensitivity: 69 %, specificity: 75 %) [77]. The diagnostic approach for VAP is similar but may be strengthened with sampling of respiratory secretion with bronchoalveolar lavage. Bacteria are the most commonly isolated pathogens. Viruses and fungi are more likely to be isolated from immunocompromised hosts (lung transplant, steroid use, neutropenic patients). In a recent multipoint survey, *Staphylococcus aureus* was the most common bacterial organism, followed by *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* [1]. Traditional gram-negative bacilli account for the majority of the infections.

Therapeutic algorithms for pneumonia depend on prompt but judicious antibiotic use, pulmonary support and surgical intervention where necessary. Antibiotic therapy should be of adequate dosage, covering the causative agent, and be tailored or de-escalated once cultures and sensitivities are available to avoid multidrug resistance. Inadequate therapy is associated with higher mortality in VAP [78]. Along with adequate antimicrobial therapy, complications of pneumonia (abscess, empyema or effusions) can require tube thoracostomy or decortication for adequate treatment.

Prevention

Standard measures for preventing HAP include hand hygiene, aerosol and contact precautions, and other infection control measures. More specific interventions focus on avoiding or minimizing endotracheal intubation. Noninvasive positive pressure ventilation can be a suitable alternative in select patients. If mechanical ventilation is necessary, risk can be minimized through sedation breaks, daily assessment for extubation, early mobility, and use of secretion ports for subglottic drainage. Oropharyngeal and digestive decontamination have shown to minimize VAP risk. Similarly, use of prophylactic antibiotics has shown promise in ventilated patients. No concrete evidence for VAP reduction exists for head-of-bed elevation and stress ulcer prophylaxis, but these measures are readily employed in the ICU setting.

In addition to employing these best practices, any success in preventing HAP is hostage to the same principles that have been discussed in other HAIs. These include bundling of processes (e.g., CUSP), monitoring, regular surveillance, compliance, and ultimately, internal and external accountability. Multidisciplinary teams led by quality champions are critical to sustaining a dynamic safety culture. These not only include physicians and hospitals but also managers and administrators in nursing homes, post-acute facilities, and rehabilitation centers. Finally, engaging and educating patients regarding HAP and HCAP will further catalyze decline in rates.

Clostridium difficile Infection

Nosocomial gastrointestinal infections are garnering increased public health focus. Chiefly among these is *Clostridium difficile* infection (CDI) which contributes to as many as 70.9 % of all gastrointestinal illnesses. *Clostridium difficile*-associated diarrhea or CDAD is an emerging problem in healthcare due to improper antibiotic use and the spread of hyper-virulent strains. Incidence of CDAD has grown steadily since 2000, plateauing only recently [79]. In 2011, 453,000 cases were reported in the United States, out of which 65.8 % were healthcare associated [80]. A recent epidemiological report found *C. difficile* to be the most prevalent causative organism for HAIs [1]. With the potential to cause severe disease, prolonged hospitalization, and death [81], reduction in CDIs has been a top priority for state and federal healthcare regulatory and oversight bodies.

Clostridium difficile is a spore-forming, gram-positive, strict anaerobic bacillus that is part of the normal intestinal flora. Spores are spread routinely through the fecal-oral route. Both patients and healthcare personnel are frequently colonized, acting as reservoirs for transmission [82]. Colonization is not synonymous with infection; hospitalized patients who are colonized are offered some immunity from developing CDAD [83, 84]. Bacterial overgrowth and toxin production by colonized strains will lead to diarrhea and any subsequent systemic consequences.

Risk factors for infection include extremes of age (tenfold higher in age >65) [85], prolonged hospitalization, and antibiotic use. Secondary risk factors include comorbidities (obesity, diabetes), factors that affect gastrointestinal integrity (inflammatory bowel disease, gastric acid suppression, enteral feeding), or cause immunosuppression (HIV, malnutrition, stem cell transplantation, chemotherapy) [86]. Clinical manifestations of CDIs vary widely. Most patients are asymptomatic carriers. Others may develop CDAD, colitis (with or without the presence of pseudomembrane), or fulminant disease [87]. Mild disease will usually present with abdominal pain and cramping, frequent passage of unformed stool. More severe CDAD may include fever, leukocytosis, dehydration associated with progression to septic shock, and multisystem organ failure.

Diagnosis of CDI should be suspected in patients with more than three episodes of diarrhea within 24 h or ileus in the setting of appropriate risk factors (recent antibiotic use, prolonged hospitalization). Confirmation of diagnosis requires demonstration of the *C. difficile* organism or its toxin in the sample. Stool culture, although being most sensitive, is rarely preferred over PCR. Radiographic imaging and endoscopy are adjunctive to diagnosis. Treatment with antimicrobials is not warranted for asymptomatic carriers. Accordingly, the inciting antibiotic should be discontinued. Symptomatic disease will require oral or intravenous antibiotic therapy or both depending on the severity of illness. Recurrent disease can be treated with combination therapy which includes vancomycin, fidaxomicin, and fecal transplantation [86]. Surgical treatment involving total abdominal colectomy with end ileostomy is reserved for progressive disease not responding to medical therapy.

Prevention

Clostridium difficile infection in US surgical patients, especially those undergoing intestinal resections, is a major problem [88]. CDIs are an independent predictor for increased hospital length of stay, cost, and mortality in surgical patients [88]. Reporting of CDI events is mandatory as part of CMS vision to improve quality in healthcare since 2013. This initiative is reinforced by active surveillance programs (NHSN and Emerging Infection Program) managed by the CDC to monitor our progress in prevention. The National Action Plan for prevention of HAIs has targeted a 30 % reduction in healthcare-associated CDIs by 2015.

Reducing CDI rates require strategies that prevent horizontal transmission, minimize exposure, and decrease risk factors for those exposed, as detailed by the Society for Healthcare Epidemiology of America (SHEA) (http://www.cdc.gov/HAI/pdfs/cdiff/Cohen-IDSA-SHEA-CDI-guidelines-2010.pdf). Appropriate hand

hygiene, contact precautions, early detection and isolation of patients, dedicated equipment, and environmental disinfection will minimize transmission and exposure [89, 90]. Antibiotic stewardship is essential. Stricter hospital policies regarding the type and duration of antibiotic use can mitigate risk in exposed individuals [90]. Restricting use of clindamycin and fluoroquinolones is directly related to fewer outbreaks of *C. difficile*. Analogous themes such as multidisciplinary involvement at hospital level, staff and patient education, and internal reporting including measuring compliance are synergistic to preventive efforts. Statewide collaborates from Illinois, Massachusetts, and New York report 15–25 % reduction in CDI rates by implementing aforementioned approaches.

Since majority of CDIs occur outside the hospital setting, CDC is actively working to bring these facilities into its surveillance network. Engaging these facilities and understanding their role in the problem is critical to elimination of CDIs. Emerging opportunities involve promising results with *C. difficile* vaccination and fecal bacteriotherapy.

Conclusions

Healthcare facilities, especially hospitals, are under great pressure to provide quality care, often with limited resources. HAIs are detrimental to this goal. The stagnancy in our attitude toward HAI reduction has been steadily purged, fueled by a universal focus on value. In addition, with growing demand for transparency, HAIs translate to suboptimal care. This is simply poor business.

Surgical patients have a notoriously high rate of HAIs, so any meaningful, lasting changes needed to come from within. The ACS-NSQIP embodies our commitment to reduction in HAIs. In addition to providing the framework for such efforts, ACS-NSQIP strives to induce a cultural transformation. Best practices, in this way, become the workplace norm. This is the best way to sustain compliance. However, high compliance does not guarantee complete elimination of HAIs (as this might be an unrealistic benchmark).

With over 60 % of operations taking place in ambulatory surgery centers, quality measures need to be extended outside the traditional hospital setting. Similarly, invasive and critical medical therapies are now routinely being administered in nursing homes, dialysis centers, etc. There is growing concern that attention to infection control maybe lacking [91, 92] in centers outside of the hospital. Aggressive infection control in outside centers needs to be addressed.

Further research and innovation in the field will help us understand the problem, minimize variability in our approach, and accurately measure our successes.

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Safer Medication Administration Through Design and Ergonomics

28

Sheldon S. Sones and Paul Barach

"Do the right thing. It will gratify some people and astonish the rest."

—Mark Twain

Part I: Introduction

Since the early 1990s, adverse drug events have received significant attention from researchers in quality and patient safety [1]. Nationally recognized quality experts have identified adverse drug events as a top safety priority [2] because these events are the most common type of iatrogenic injury [3]. Studies have indicated that adverse drug events occur almost daily in medium-sized hospitals and outpatient, ambulatory clinics [4–6]. However, despite the high morbidity and mortality, physicians often do not recognize or appropriately treat instances of drug-related harm [7, 8].

We believe that inadequate recognition and treatment of drug-related harm are, in part, a result of what has been called a Tower of Babel of terminology [1]. Terms originally developed in the narrow context of drug effects in a clinical and regulatory setting are now being applied in the broader context of quality improvement in healthcare delivery systems [9]. As might be expected, the expanding role of these terms has been coupled with their use in contradictory ways, even within the same discipline [4, 7, 10–14]. In this chapter, we use a case of an actual patient as a framework to explain the recognition, treatment, documentation, and reporting of drug-related harm.

In the rapidly evolving shift from hospital-based surgery to ambulatory surgery centers (ASC), the management of medications in both a safe and efficient manner is a key focus of overseers from federal, state, and accrediting organizations. It continues to be, year after year, an enunciated national patient safety goal of the Joint Commission. Clearly, an effective program is a complex challenge that calls for proactive efforts on the part of the facility's staff, leadership, and, importantly, support from the medical staff. Additionally, the role of the pharmacist and medication management oversight programs in these facilities are key factors in the overall success of achieving these goals. In this chapter, we review some basic elements of performance (EOP) for medication management safety and regulatory compliance.

Patient Story

A 15-year-old boy underwent elective right knee arthroscopy and debridement under general anes-

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thesia with a laryngeal mask airway (LMA). He was otherwise healthy with no allergies to medications. After uneventful induction of anesthesia, the surgeons requested antibiotic prophylaxis with cefazolin 1 g, which the anesthesiology team administered. Just before the surgical incision was made, 50 mcg of fentanyl was administered. About 2 min later, spontaneous respirations slowed, and the patient became apneic. The surgeon and anesthesiologist assumed the patient's apnea was due to opiate sensitivity and assisted ventilation by hand for 30 min. However, despite a rise in the end-tidal CO_2 to 70 mmHg, spontaneous respirations did not return.

Case Commentary

When to Suspect Wrong Drug Administration in the Operating Room

The patient experienced an adverse event while under anesthesia care. Apnea during anesthesia has several etiologies, including anesthetic agents themselves, as well as opiates, barbiturates, or benzodiazepines, and hypocarbia-induced respiratory depression. Prolonged apnea occurs more often in hyperventilated patients; neonates; elderly patients; patients with compromised renal, pulmonary, or hepatic function; hypothermic and acidotic patients; patients receiving neuromuscular blockade, aminoglycosides, or intravenous magnesium; and patients with neurological impairment or injury. Assuming this patient is healthy, normothermic, and not acidotic or hypocarbic and assuming he did not receive neuroaxial anesthetic blockade (such as spinal or epidural regional anesthesia), clinicians should be concerned that the patient received an unplanned drug due to a syringe or an ampule "swap" (see Table 28.1).

While maintaining cardiovascular and respiratory functions, clinicians should attempt to ascertain whether a wrong drug was administered and, if so, which drug (see Table 28.2).

Table 28.1 When to suspect wrong drug administration in the operating room

(a)	Unusual response or lack of response to drug administration: pounding heart, mental status changes, apnea, muscle weakness and visual disturbances
(b)	Extreme or unexpected increase or decrease in blood pressure or heart rate
(c)	Unexpected or persistent muscle relaxation
(d)	Unexpected change, or lack of change, in level of consciousness
(e)	Incorrect ampule found to be open in work area

Table 28.2 Checklist: steps to determine drug administered

(a)	Check the syringes and ampules used during the case
(b)	Check to see if low volume unexpectedly remains in syringe
(c)	Inspect open ampules
(d)	Impound the "sharps" container to allow inspection of ampules and syringes at later time
(e)	Consider drawing blood levels to ascertain drug given

Clinical Management of Apnea

The most common drugs that may lead to apnea in the operating room include muscle relaxants or highly potent opiates (such as sufentanil, which is ten times as potent as fentanyl). Alternatively, the patient may have a previously unrecognized metabolic disorder such as a neuromuscular disease (i.e., myasthenia gravis) or a structural abnormality (i.e., stroke or embolism) that needs to be evaluated. Treatment of medication-induced respiratory depression adverse event varies by cause (see Table 28.3). When respiration is depressed by opiates, as evidenced by miotic, unresponsive pupils, naloxone (Narcan) in 0.04 mg increments may be titrated to reverse the condition. In the case of persistent peripheral muscle blockade, typically due to residual muscle relaxants, reversal with neostigmine is initiated. Other interventions include discontinuation

Table 28.3 Clinical management of apnea

(a)	Ensure adequate oxygenation and ventilation
(b)	If the error in drug administration is recognized immediately after injection: a. Stop the IV carrying the drug b. Attempt to aspirate or drain the IV tubing to point of injection c. If there is blood pressure cuff on the arm of IV, inflate to slow down entry of drug to central circulation
(c)	Maintain normocarbia or slight hypercarbia
(d)	Increase O_2 flow to breathing circuit to enhance elimination of inhalation anesthetics
(e)	Check neuromuscular function with nerve stimulator
(f)	If residual blockade is present: a. Give reversal medication to max of neostigmine dose of 70 mcg/kg along with glycopyrrolate up to 1 mg to reverse blockade b. Reassure the patient and continue short-acting sedation c. Consider potential synergistic effects of muscle relaxants and aminoglycosides—if so give 1 g calcium chloride to promote reversal of neuromuscular blockade
(g)	Review the doses of medication administered and check for syringe or ampule swap of opiates, hypnotics, muscle relaxants, anticholinergics
(h)	Consider reversal of specific drugs such as opiates (check the pupils), benzodiazepines, anticholinergics
(i)	Send blood samples for ABG and serum electrolyte levels
(j)	Conduct a neurological examination to exclude focal CNS injury as cause of failure to breathe

of anesthetics, determination of arterial blood gases, and appropriate adjustment of ventilation.

Because the apneic episode lasted longer than 30 min, the anesthesia team began to question their initial assumption that the apnea was due to opiate sensitivity. They had obtained the cefazolin from the medication drawer of the anesthesia cart. The anesthesia team examined the drawer and found vials of cefazolin and vecuronium (a long-acting paralytic agent) in adjacent medication slots. The vials were of the same size and shape, with similar red plastic caps (see Fig. 28.1). The team realized that the patient had received vecuronium 10 mg, not cefazolin 1 g, and that the observed apnea was therefore due to unrecognized muscle relaxation.

There are few accurate measures of the morbidity and mortality associated with anesthesia [15]. It has been estimated that between 2000 and 10,000 patients die each year from causes at least partially related to anesthesia, but those estimates are based on circumstantial data and include all patients regardless of age or physical status [16]. A recent study in the United Kingdom found that only one patient in 185,000 died solely as result of anesthesia, although 1 in 1351 deaths was in part related to anesthesia [17]. An estimated 44,000–98,000 Americans die in hospitals each year as a result of preventable medical errors [18]. Bates and colleagues have shown that medication errors were the number one cause of adverse and preventable patient events that 6.5 % of admitted patients suffered an adverse drug event, and they lead to more than 7000 deaths annually [19]. Of these events, 28 % were due to errors, and an additional 5.5 % involved near misses caught due to interception of the error. In the Harvard Medical Practice Study, adverse drug events accounted for 19.4 % of all disabling adverse events, 45 % of those events were caused by errors [20]. In a large insurer's study, injuries due to drugs were the most frequent cause of procedure-related malpractice claims [21]. The prevalence of medication errors in the operating room is not accurately known. A recent study demonstrated that about half of all surgeries involve some kind of medication error or unintended drug side effects, a rate calculated by researchers who observed 277 procedures and found that 1 in 20 perioperative medication administrations included a drug error and/or an adverse drug event [22]. Perioperative areas are among the only remaining patient care areas that have not had rigorous assessments of medical errors to guide proposed solutions. Reductions in MEs in other patient care areas, including inpatient units and outpatient clinics, have occurred because error rates were measured, errors were categorized to determine their root causes and potential for harm, solutions were designed and implemented, and error rates were then systematically measured again to show a reduction. This process has occurred with solutions such as computerized

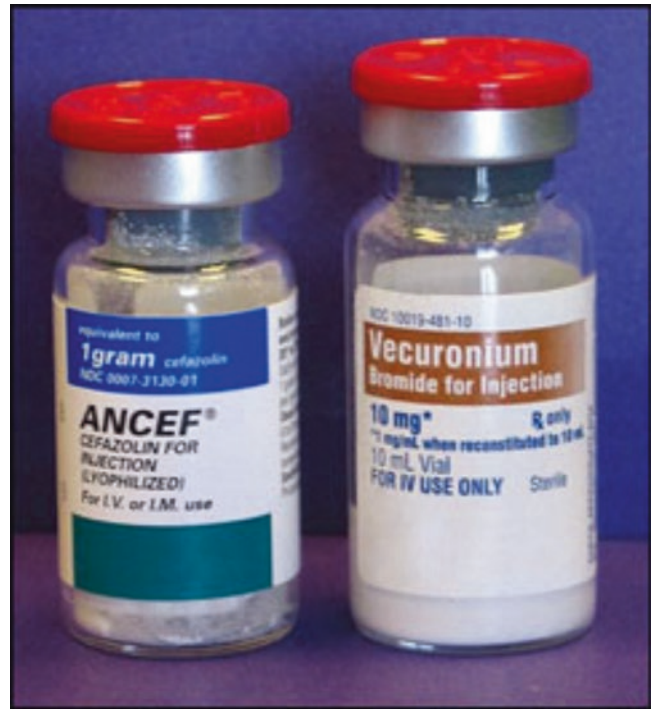

Fig. 28.1 Look-alike drug vials

physician order entry systems, bar-code scanning systems for medication administration in hospital pharmacies, and outpatient electronic prescribing systems [4, 23–25].

Wrong medication administration in the operating room is due to failure to label syringes, incorrect matching of labels on syringes and drug ampules, failure to read the label on the vial/ampule, misuse of decimal points and zeroes, and inappropriate abbreviations. What happened to this patient illustrates an example of faulty drug identity checking, where two drugs were packaged in similar vials, so that one was easily mistaken for the other. Poor system design also makes errors difficult to intercept before injury occurs. Leape and colleagues discovered that failures at the system level were the real culprits in more than three-fourths of adverse drug events [26]. Reason and colleagues suggested that some complex healthcare systems are more vulnerable and therefore more likely to experience adverse events [27].

Medication Errors in Operating Room

Documenting errors at the administration stage is difficult, because it requires direct observations and reliable, robust near-miss and adverse-event reporting systems. Currie and colleagues found 144 incidents related to drugs, of which 58 were related to syringe or drug swaps [28], among the first 2000 incidents of the Australian Incident Monitoring System. Of those 58 events, 71 % involved muscle relaxants. Implementing a red syringe color change for all succinylcholine drug administration in Australia has helped to reduce drug and syringe swap by 70 % [29]. A large, retrospective study of anesthesiologists' self-reported incidents found that of a total of 1089 incidents, 71 were related to either syringe or drug ampule swap (7 %) [30]. Leape and colleagues found that 40 of 334 errors (12 %) at the stage of drug ordering and delivery were due to imperfect dose and identify checking [26]. Studies in intensive care units have produced similar results [31].

Administrative medication errors in the operating room and intensive care unit are believed to be more common in unfamiliar settings, when drug packaging or ampules have changed, when similarly appearing ampules are stored close together in the medication carts, when syringes are prepared by other personnel, when handwritten labels are used, and when lighting conditions are poor [32]. There is an exponential relationship between the number of drugs administered to a patient and the prevalence of adverse drug events [33].

System Theory and System Checks to Prevent Wrong Drug Administration

Although there is no excuse for failing to read medication and syringe labels, the occasional failure to do so represents an expected "slip," more likely to occur with fatigue, distraction, or other causes of momentary lapses in concentration and failures in automatic behaviors [34, 35]. Not until recently did the pharmaceutical industry realize the importance of packaging medications to easily facilitate rapid identification of and discrimination between potent drugs used in operating rooms. For years muscle relaxants such as pancuronium vials were very similar to those of heparin. Some manufacturers continue to package ephedrine in ampules similar to those of oxytocin and epinephrine. This problem also occurs with different doses of the same drug—the vials for at least three concentrations of atropine sulfate from one manufacturer are similar. This results in inadvertent over- and underdosing.

Any medication drawn into a syringe for later use should be labeled immediately. Unlabeled and incorrectly labeled syringes invite errors in drug administration and dosing and should be discarded. Routine use of approved, commercial color-coded labels may reduce these errors. The labels should conform to the standards of the American Society for Testing and Materials (ASTM) [36].

A cluttered and disorganized workspace also predisposes to medication errors and searches that can delay administration of emergency medications. All anesthesia and resuscitation medication carts should be standardized (see Fig. 28.2), by applying a systematic method for stocking new and discarding outdated medications.

To understand the causes of errors, we must examine what happened, what was the root cause,

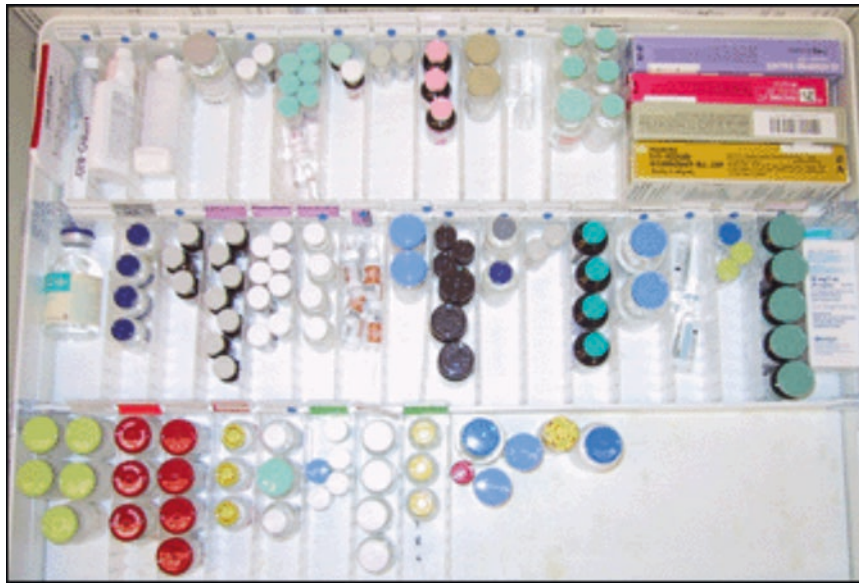

Fig. 28.2 A well-organized anesthesia cart that keeps similar-looking and/or similar-sounding drugs well separated

Table 28.4 System checks to prevent wrong drug administration

(a)	Check for correct patient, drug name, concentration, dose, route, time
(b)	Use drug labels that conform to ASTM standards
(c)	Label syringes carefully—use preprinted color-coded adhesive labels
(d)	For emergency drugs, use "ready-to-use" syringes that are prepared according to ASTM standards
(e)	Standardize location of medications
(f)	Discard unlabeled vials, syringes

and what were the underlying system failures. In a system analysis, people are viewed as an important safety resource, not only a source of errors. Designing robust transparent systems, with built in feedback control strategies, is important given human flexibility and fallibility. This was a case of unintentional administration of a paralytic agent in place of an antibiotic due to similar packaging. System checks that could be implemented here to avoid inadvertent drug swaps include color-coded labeling and reorganization of the anesthesia cart (see Table 28.4).

Training all healthcare professions in the six rights—patient, drug, dose, route, time, and concentration—is critical to effective and safe medication administration. Recognizing environmental factors that predispose and distract clinicians is paramount. These include noise, interruptions, fatigue and lack of adequate rest, poor lighting, and poor information systems.

Part II: Organizational Medication Safety Management and Procurement

Formulary Management

While the hospital setting historically has a formal pharmacy and therapeutic committee that oversees the approved drugs endorsed by the medical staff, such structure usually does not exist in the ambulatory surgery centers (ASC). This function is traditionally incorporated into the responsibilities of the "Medical Executive Committee" or similarly named committee. The charge to this committee should be to assure that the medications utilized in the facility are FDA approved, are appropriate for the size and scope of the facility, and will be safely managed using required equipment where necessary (such as calibrated pumps) and that the nursing staff has a pathway to assure safe handling of these medications.

Specifically, in addition, the committee should endorse the contents of the emergency "code cart" as well as, where applicable, the drugs required for reversal such as the malignant hyperthermia requirements and reversal agents availability, such as naloxone and flumazenil. It is in the purview of this committee to assure that the list is reviewed annually, as is the entire formulary, to assure continuing appropriateness with an eye toward contemporary and published guidelines and standards. Not only identified drugs, but the quantities of the agents in the "code cart" should be memorialized in the minutes of the meetings.

Controlled Drug Management

Perhaps the most focused area to review is the status of controlled drug management in the hospital or ASC. The management of controlled drugs represents significant challenges. The system has to afford easy access for both the nursing and anesthesia staff, be in compliance with state and federal laws and regulations, as well as being managed in such a way as to limit unauthorized access.

There are several interested parties who may present themselves with inquiry into the management of controlled drugs. The external parties might include the Department of Health, Board of Medicine, Centers for Medicare and Medicaid Services (CMS), accrediting bodies such as The Joint Commission or DNV GL (Det Norske Veritas), the federal Drug Enforcement Administration (DEA), the Accreditation Association for Ambulatory Health Care (AAAHC) which oversees a majority of ASCs, as well as sections of the state government, which may have responsibilities on the state level for medication compliance.

Controlled drug records should reveal, in detail, basic documentation of drug, dose, and time administered, who administered, and, importantly, attestation of drug discard of partial doses. It is this latter require-

ment that is most vulnerable to review and, if not done properly, subject to inquiry as to the authenticity of the discarding providers' procedures. Controlled drug discards should be done in *real time* and not at the end of the workday. Drugs should be rendered "non-recoverable," which by definition, and may vary from state to state. Facilities could avail themselves of commercial products for such purpose, or, if allowable by individual states, discard to absorbable products and then to traditional waste systems.

One of the challenges in controlled drug management is to meet the needs of the anesthesia providers and, at the same time, assure that they are in step with the facility's overall responsibility of documentation and safe medication management. Regarding the latter, it is imperative that single-dose products be preferentially utilized as indicated and not for multiple patients. This extends to other products, which at this writing are not "controlled" except in a few states, such as propofol, but are clearly designated as single patient use only.

The recording of retention of control drugs may vary from state to state, but it is recommended that a three-year retention be a minimal standard practice in hospitals and ASC.

Finally, as facilities move toward computerized medical records, as well as automated drug dispensing systems, the maintenance of control drug records will be less of a challenge. We will address automatic drug dispensing systems in another section of this chapter.

Safe Medication Management Education

One of the contemporary expectations of the pharmacist as well as the medical staff leadership is to assure that the nursing, surgical, and anesthesia staffs have access to drug information as well as presentations that are stipulated in accreditation standards. In fact, one such stipulation is in the area of malignant hyperthermia preparedness. It is imperative that the staff be well acquainted with the management of this sudden and life-threatening challenge. Further complicating this initiative is that the dantrolene sodium used for reversal tends to be difficult to manage under a time-dependent scenario that could have negative outcomes if drug management falls short. Likewise, incorrect administration could cause serious adverse outcomes including central nervous system side effects, speech and visual disturbances, mental depression and confusion, respiratory depression, and sedation [37]. While in the case of MH preparedness, an annual presentation is expected/required; the facility must also train new employees who have joined the facility after such a presentation.

When new drugs enter into the formulary, the physician who has asked for inclusion as well as the consultant pharmacist should be prepared to present to the staff the guidelines on the management of the new entity as well as their untoward effects. This is an important part of the formulary management system, to assure that not only safe and effective drugs are accepted into the formulary, but importantly, they are safely managed. Safe medication management education can be provided through appropriate textbooks, videos, and access to the Internet.

Drug Procurement

The selection of a vendor for supply of medications is important part of the medication system that must be relied on for a seamless continuum of medication supply. Drug shortages and recalls over recent years have complicated the challenge to assure adequate resources on a day-to-day basis for the facility, for key drugs such as propofol.

Traditionally, facilities have aligned with a single vendor, which is either selected by the facility or orchestrated by the purchasing section of larger multi-facility companies. In either case, we have seen drug wholesalers fall short in meeting the demands of their clients. This points, therefore, to the need to have several wholesalers engaged as suppliers to the facility.

Wholesale providers should have the ability to assume responsibility for prompt notification of drug recalls as enunciated either on the FDA website and/or directly from the manufacturer.

The economics of medication supply, as well as all supplies, cannot be overstated in this present climate. Prudent purchasing practices require "benchmarking" cost experience for high-volume and/or high-cost drugs. This is enabled when the consulting pharmacist has established a system that draws information from the facili-

ties they serve. Drug costs which fall outside of the normal experience are highlighted on this form for the facility to review with their provider. Finally, it is suggested that the wholesaler establishes a representative who can communicate routinely and effectively with the facility to resolve issues as well as opportunities for effective/cost-containing initiatives.

Injection Practices

The literature is replete with guidelines and position statements on safe injection practices (http://www.cdc.gov/injectionsafety/). The Association for Professionals in Infection Control and Epidemiology (APIC) has led the way in providing educational outreach, materials, and standards, which also reflect positions defined by the Centers for Disease Control. These are presented as an addendum to this chapter.

It is always a challenge to move practitioners away from habits of the past, which in their minds have been successful. However, contemporary healthcare providers should acknowledge the clear evidence that safe injection practices are a mandatory element of performance that can significantly improve outcomes and minimize untoward effects. Additionally, the proper labeling of drawn syringes, handling of multiple-dose vials, restriction of single-dose vials for single use only, handling of IV solutions, and prudent due diligence in selecting a compounding pharmacy for the facility are all mandatory steps, which the facility should not waiver from in assuring the entire spectrum of safe injection practice expectations.

Compounding Pharmacy Selection[1]

Tragic events over the past several years in places such as in Massachusetts and elsewhere reflect deficits in compounding pharmacy practices, which provided subpar or, even worse, inattention to current Good Manufacturing Practices (cGMP). This newly uncovered gap in oversight has prompted states and regulators on a federal level to focus on monitoring and regulating compounding pharmacies to a degree heretofore unprecedented.[2] In selecting a compounding pharmacy as a provider, the facility must be explicit in drawing attestations from proposed providers to best assure insulation from poor or mediocre practice. The consultant pharmacist should be relied on to help navigate this very important decision and help orchestrate the decisions based on a number of elements.

While it would be ideal for on-site visits of the compounding pharmacy to be conducted by the facility and its leadership, this is not always feasible nor can all visitations be conducted by individuals with the knowledge base of this complex specialty. Accordingly, it would be prudent to employ some tools such as the "contractor assessment tool" produced by the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation. Another resource is generated by the International Academy of Compounding Pharmacists (IACP) with their "Compounding Pharmacy Assessment Questionnaire" (CPAQ®).

Both of these instruments afford the pharmacy the ability to issue a signed "attestation" regarding their commitments to established standards. This is an important part of the due diligence process. While each state will have its own guidelines and regulations regarding sterile compounding pharmacies, most facilities engage a Food and Drug Administration (FDA)-registered 503B human drug outsourcing facility. These facilities are registered with the FDA, enlist their awareness of potential FDA inspection, and adhere to such standards. Facilities should also be vigilant on FDA recalls related to compounding pharmacies.[3]

[1] Adapted from APIC Position Paper: Safe Injection, Infusion, and Medication Vial Practices in Heathcare.

[2] http://theincidentaleconomist.com/wordpress/new-massachusetts-law-on-compounding-pharmacies/

[3] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

Drug Recalls

It is imperative that when drugs are recalled by the manufacturer or FDA that it be promptly sequestered by the facility to eliminate the possibility of administration to patients. It is an implicit expectation that suppliers promptly notify facilities when they have determined that the facility has received lot numbers of recalled items. While this obviously applies to all products, certainly, the recall takes on a higher level of importance when it pertains to contaminated, sub- or superpotency, or other manufacturing deviations. The facility should have a recall system that affords easy access, such as facsimile or other electronic means, to assure recall alertness. Proper documentation of action taken by the facility is a reasonable expectation of overseers.

Drug Defect Reporting

An ethical and regulatory obligation to our patients is a prompt communication to regulatory depots regarding suspected drug defects. The mechanism in place is to complete the "MedWatch" forms and submit them for further investigation where warranted. MedWatch is the FDA's Safety Information and Adverse Event Program.[4]

Clarity of the Medical Record

While electronic medical records may well mitigate current concerns regarding the clarity of the patient record/medical record, currently, most facilities still maintain what we would refer to as a "manual record." Regardless of the status of the facility's movement toward the electronic medical record (EMR), it is imperative that all stakeholders have access to the detail contained in this document. That would include physician, nursing, and financial information that is pertinent to the care and administrative management for the patient. Within the medical record, there are several elements of probable regulatory performance review and, more importantly, should be readily accessible to the facility's own staff including medication reconciliation documents, physician order sets both preoperatively and post procedure, medication documentation forms, discharge instructions, and the anesthesia record.

The anesthesia record should be explicit as to which drugs were administered, when they were administered, and in what dosage. It continues to be a routine challenge when the anesthesia record is maintained manually and how to decipher the required elements given illegible handwritten records.

Of particular interest is the ongoing assessment of antibiotic administration times in relation to the start of the procedure/incision. Reference is routinely made to the standard of the start of administration of the antibiotic within 60 min of surgical incision or procedure start [38]. Correct administration of antibiotics has drawn the attention of both the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of Gastroenterology Nurses and Associates (SGNA). In 2007, the Centers for Medicare and Medicaid Services (CMS) listed antibiotics administered for prophylactic purposes prior to surgery/procedure as part of its quality reporting program. For 2013, it became a "G-Code" entry. The measure indicated was "within 1 h prior to surgery" [39]. The *Medical Letter* [2] called for "60 min or less prior to incision."

Role of the Pharmacy Consultant

Each facility should secure the services of qualified pharmacy consultant. Hospitals have a continuum of service from their own pharmacy department; surgical centers have to draw on outside consultants to oversee pharmacy systems in general and medication management in specific. Each state has either very specific requirements or duties enlisted in regulation or are vague or mute regarding this role. It is interesting to note that accrediting agencies allow for a qualified physician to oversee the services. However, this often tends to fall short and does little to provide substantial input and guidance to medication safety and will most likely not provide the proper

[4] http://www.fda.gov/Safety/MedWatch/

guidance to avoid medication misadventures and/or regulatory criticism.

The duties of the consultant pharmacist should include a physical inspection of the facility on the frequency based on the scope and size of the facility, educational outreach, easy accessibility to respond to questions as they arise, controlled drug system development and monitoring, and clinical review of the medical record and should be followed by signed dated reports. These reports should be problem-oriented with suggestions for improvement and should be validated as resolved on the consultant's next scheduled visit. A signed contract, which delineates the responsibilities of the consultant as well as that of the facility, is provided as an example, at the end of this chapter (see Appendix 1).

Pharmacy and Medication Safety Committees

Three important committees, which oversee medication management or make decisions that affect medication management in the facility, are usually part of the administrative oversight and ambulatory surgical center.

The pharmacy and therapeutics committee (P&T), or a similarly named group, is responsible for the policies and procedures that are staged to assure safe medication management. In addition to policies and procedures, this committee is responsible for the organization and management and ongoing focus of the facility formulary. This document is a formal endorsement of various drugs used in the facility and considers drugs for addition or deletion as appropriate. Physicians who want to support the addition or deletion of a drug should present the facility with detailed information, through this committee, regarding its use, contraindications, financial impact, and distinctive features of the proposed drug that warrants consideration for adoption. Conversely, when drugs fall out of use in the practice setting, due to replacement with a newer agent, or concerns about its continued appropriateness or safety, proposals for removal of the drug from the formulary are similarly considered by this committee. The committee is usually made of the executive group of the medical staff and has the pharmacist as a member in addition to nursing leadership. As noted earlier in this chapter, most ambulatory surgical facilities move this committee's function to the Medical Executive Committee (MEC).

The *infection control committee* is a committee that considers strategies to minimize exposure of patients, and/or staff, to infection-prone practices or other professional missteps. In addition to the medical and nursing staff of the facility, the infection control prevention asked, as well as the pharmacist, who are key members of this committee.

The third committee is the *quality assurance committee*. The broad mission of this committee is to assure that proper mechanisms are in place to assess and respond to quality assurance compliance. The committee should also evaluate untoward events when they relate to medication management, infection prevention, or other exposures to unwanted and unexpected occurrences.

Emergency Preparedness

The facility, depending on the scope and mission of the facility, and its area of specialty must assure all of the stakeholders that they are adequately prepared for unanticipated natural or human-made disasters and events [40]. Implicit in this preparedness is adequate educational training for the staff that is ongoing and part of the new employee orientation. All employees should be aware of the tools and resources that are available within the facility to respond appropriately to a medical event, negative outcomes from administered drugs, or a combination of both [41]. The expectations are that the facility has adequate resuscitation and cardio conversion equipment, and as mentioned above, there is a high level of workable knowledge among the staff to employ these resources [42, 43].

The "code cart" and its appropriate contents of both drugs and equipment is a basic requirement in all facilities. Regarding the drugs, the contents should be listed based on the size and scope of the facility and include as a minimum, all medications required in ACLS protocols. Routinely, code cart contents are staged beyond the ACLS group of drugs and will include drugs for ATLS and PALS protocols. Reversal agents, appropriate intravenous

fluids, antihistamines, corticosteroids, as well as the full battery of cardiac drugs are rather standard contents. Of major concern, as previously mentioned, is the facility level of capability to treat malignant hyperthermia (MH). For codes in general, as well as MH-specific protocol, the facility should conduct routine mock drills usually directed by an anesthesiologist in conjunction with the pharmacy consultant. The contents of the cart should be reviewed regularly by the medical staff committee. This committee needs to assure that the contents reflect contemporary practice standards and that appropriate educational processes are in place on an ongoing basis.

Additional Resources

There are several resources which facilities are encouraged to pursue to provide a continuum of information and strategic steps to maximize the effectiveness and safety of the medication management program in hospitals and ambulatory surgical centers.

One of the valuable services that pharmacists can provide is to enable the facility to compare, or benchmark, their performance to other similar facilities. Quality measures or metrics, when properly applied, can afford the facility insight into opportunities for improvement or, conversely, validate excellent trending. Since most consulting pharmacists serve a variety of facilities and within those clients, a variety of specialties, they are well positioned to gather and bring forth comparative performance measures. We call this a "VBP" or value-based program. Benchmarking has been done for ophthalmology (i.e., vitrectomies), gastroenterology (i.e., perforation and adenoma detection rates), antibiotic administration (i.e., conformance with the 1 h guideline), orthopedics, patient satisfaction, hospital transfers, slips and falls, and importantly the pharmacoeconomics of surgical care. Regarding the latter, there are benchmarks for high-cost and/or high-volume drugs and have been immensely successful in significantly decreasing costs once the facility is aware of the benchmark of specific drug acquisition.

Details beyond the scope of this chapter are available by the Institute for Safe Medication Practices (ISMP) of Horsham, PA, and include newsletters, alerts, research, and educational and consulting services. Valuable guidelines and charts such as drugs with confusing names, high-alert drugs, as well as numerous other resources are provided through their exceptional staff.

Conclusions

Erroneous medication orders continue to maim and harm thousands of Americans annually and millions of people around the world. Medication management is a high priority of all of the stakeholders and those who oversee the facility with regulatory responsibilities. Medication management touches every physician, every nurse, and every patient, and all of these participants who share the mission of safe effective outcomes must remain vigilant on both preparedness, as well as on the part of the patients, assuring reasonable compliance.

Adverse drug reactions are injuries caused by drugs administered at usual doses; they are the primary focus of regulatory agencies and post-marketing surveillance. Medication errors are the number one cause of preventable adverse events, including death. Causes of wrong drug administration include failure to label medications, mislabeling of syringe or ampules, or failure to confirm identification of the medication by reading label carefully. To reduce drug administration errors in the OR, label syringes carefully with color-coded, preprinted labels that conform to ASTM standards; use "ready-to-use" easily identified syringes to administer emergency drugs; standardize location of medications on the anesthesia cart; and always review the six rights (patient, drug, dose, route, time, concentration). System checks should be designed into the medication administration process to prevent or reduce chances of inadvertent drug/vial swap. While putting pharmacists in hospitals, in all patient care areas, and ensuring there is pharmacy expertise, overseeing all medication administration is central to delivering reliable and safe patient care [44]. In the ASC, however, collaboration of the entire surgical team, including the consulting pharmacist, is essential to delivering high-quality and safe care.

Appendix 1: Contract Pharmacy and Medication Management Consultation Services

CONTRACT

PHARMACY AND MEDICATION MANAGEMENT CONSULTATION SERVICES

This agreement between (Consultant Pharmacist Name) hereafter referred to as the "Consultant Pharmacist", and _____SURGERY CENTER, (Location), referred to as the "Facility", wherein for good and valuable consideration, it is hereby agreed that the Consultant Pharmacist, agrees to provide services to the Facility according to the terms and conditions set forth below.

I. The Consultant Pharmacist shall be responsible for the general supervision of the Facility's pharmaceutical services. More specifically, these services shall include:

1. General supervision of the Facility's procedures for the control and accountability of all drugs and biologicals throughout the Facility and that such drugs and biologicals shall be approved and dispensed in compliance with federal and state laws and the Facility's own policies and procedures.

2. Supervision of the records of receipt and disposition of all controlled drugs and the maintenance of such records in sufficient detail so as to allow an accurate reconciliation

3. Quarterly review of the facility to determine compliance with the established practice standards for pharmacy services to and at ambulatory surgical centers. In addition, a random audit of medication documentation practices will be performed during each review. All findings shall be submitted to the Facility in a confidential written report. The Facility recognizes that all facilities will be benchmarked quantitatively; however this will be done in a blinded format.

4. Supervision of the labeling of drugs and biologicals to insure that such labeling is based on currently-accepted professional principles and includes the appropriate accessory and cautionary instructions as well as the expiration dates and lot numbers.

_____SURGERY CENTER
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5] Recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are provided to, and retained by, the Director of Nursing and/or Administrator, for follow-up action and evaluation of performance.

6] Being present at appropriate committee meetings as feasible and at the request of the Facility

7] All other responsibilities required of a Consultant Pharmacist as set forth in any federal or state laws, statutes, or regulations, as enacted or, as may be enacted or amended during the term of this Agreement.

II.

The Consultant Pharmacist agrees that it shall be his responsibility to provide continuous services to the Facility, during the term of this Agreement, and in accordance therewith, it is further understood that either (Consultant Pharmacist Name) , or his designee, with the approval of the facility, will provide services as outlined in this Agreement.

III.

The Consultant Pharmacist agrees that it shall be his responsibility to be covered by adequate professional liability insurance and malpractice insurance. The Consultant Pharmacist is stipulated to be an independent contractor and is not an agent of the Facility. The Facility acknowledges that it is responsible, and not the consultant pharmacist, for acts of its employees and selected vendors and agencies supplying or administering medications within the facility. In accordance therewith, the Consultant Pharmacist shall not be responsible to the Facility for any losses or liabilities sustained as a result of other provider's independent malfeasance or negligence.

_____ SURGERY CENTER
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IV.

The facility acknowledges that it is aware that the Consultant Pharmacist serves other licensed centers. In drafting policies and procedures for one facility, this Agreement shall not limit the drafting and application of similar policies and procedures for another facility served by the Consultant Pharmacist, where and when applicable.

V.

The Consultant Pharmacist shall devote a sufficient number of hours, based on the needs of the Facility, to carry out the stipulated responsibilities as otherwise defined in this Agreement. The Consultant Pharmacist further agrees to document hours spent performing said duties on the quarterly statement.

VI.

In consideration of the services rendered, the Facility will compensate the Consultant Pharmacist at the rate of _____ Dollars ($_____.00) per annum, all inclusive. This will be paid on a quarterly basis of $_____.00 within thirty (30) days of submission of the visits report. The compensation will increase by 4% in each year following the conclusion of the initial one year term ending (Date)

VII.

The consultant pharmacist will provide a maximum of two in-services per year, at the request of the Administrator/ Director of Nursing, at no additional costs

VIII.

This Agreement shall be in force commencing (Date) and shall continue in force until cancelled by either party for cause or no cause, and it shall automatically renew at the pleasure of the Consultant and the Facility. The contract may be terminated by either party, with or without cause, with thirty (30) days prior written notice after an initial two year term.

_____ SURGERY CENTER

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IX.

The Consultant Pharmacist represents and warrants that he has not been convicted of a criminal offense related to health care, or been listed as debarred, excluded or otherwise ineligible for participation in a State or Federal health care program. The Consultant Pharmacist further agrees to immediately notify the Facility should he become subject to an investigation or inquiry involving items or services reimbursable under a Federal or State health care program, or is listed as ineligible for participation in such program. At the time of such notification, the Facility may terminate this Agreement immediately.

X . In performing its obligations pursuant to this Agreement, each party may have access to, and receive certain non-public information about the other and its affiliates, including, but not limited to, patient information, which is considered confidential and/or proprietary to the disclosing party. This section is not intended to grant the parties' rights to confidential information to circumscribe the use, which the parties may make of any information to which they have access.

Each party hereto agrees and shall maintain the confidentiality of all confidential and proprietary information and shall not disclose the same to any third party, except as may be required by law or court order, and shall not use such confidential and/or proprietary information for any reason other than the fulfillment of its obligations hereunder, for the term of this Agreement and thereafter. Upon termination of the Agreement, each party shall return all confidential information together will all copies thereof, to the other party, regardless of the medium in which such confidential information is stored.

Each party shall retain the ownership rights to its confidential and proprietary information. Each party recognizes that any breach or violation of this section may result in irreparable harm to the non-breaching party; each party agrees that, in addition to any and all remedies available, the non-breaching party shall be n injunction restraining the breaching party and any related persons from violating this section.

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XI.

This Agreement constitutes the entire Agreement between the parties, and may not be modified without the written consent of the parties.

_____ SURGERY CENTER

BY:_____ Date:_____

Its_____

_____ Date:_____
Consultant Pharmacist

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29 Preventing Venous Thromboembolism Across the Surgical Care Continuum

Lisa M. Kodadek and Elliott R. Haut

"The disconnect between evidence and execution as it relates to DVT prevention amounts to a public health crisis."

—American Public Health Association

Abbreviations

AAOS	The American Academy of Orthopedic Surgeons
ACCP	The American College of Chest Physicians
AHRQ	The Agency for Healthcare Research and Quality
APHA	The American Public Health Association
CDS	Clinical decision support
CPOE	Computerized provider order entry
DVT	Deep vein thrombosis
EAST	The Eastern Association for the Surgery of Trauma
INR	International normalized ratio
IVC	Inferior vena cava
LMWH	Low molecular weight heparin
PCORI	Patient-Centered Outcomes Research Institute
PE	Pulmonary embolism
SC	Subcutaneous
SCDS	Sequential compression devices
TEDS	Thromboembolic deterrent stockings
US	United States
V/Q	Ventilation/perfusion scan
VTE	Venous thromboembolism

Background

Prevention of venous thromboembolism (VTE) is a critical patient safety practice as well as an important measure of healthcare quality. VTE refers to deep vein thrombosis (DVT), pulmonary embolism (PE), or the presence of both. As many as 350,000–900,000 people each year in the United States (US) will be harmed by VTE, and over 100,000 people will die from VTE each year [1]. National annual expenditures for treatment of VTE may be as high as $10 billion [2]. While high-quality evidence-based guidelines for VTE prevention are available and strongly encouraged for adoption, studies continue to show that hospitalized patients are not routinely provided with risk-appropriate VTE prophylaxis [3, 4]. One study has demonstrated that only 42 % of patients diagnosed with DVT during hospitalization had received VTE prophylaxis [5]. Another showed

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that <60 % of surgical patients worldwide received appropriate prophylaxis [4].

Numerous groups have recognized VTE as a public health and safety problem. The American Public Health Association (APHA) issued a White Paper in 2003 stating, "The disconnect between evidence and execution as it relates to DVT prevention amounts to a public health crisis" [6]. The US Surgeon General recognized VTE as "a major public health problem" and issued "A Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism" in 2008 [1]. The Agency for Healthcare Research and Quality (AHRQ) has identified VTE prophylaxis as "the number one patient safety practice" to prevent in-hospital death [7–9]. Most recently, AHRQ has placed "Strategies to increase appropriate prophylaxis for VTE" on the list of top 10 "Strongly Encouraged Patient Safety Practices" [3, 10]. The collective attention from these groups has raised awareness that passive strategies to improve VTE prophylaxis are not as likely to be impactful as active strategies, especially since well-done evidence-based guidelines for VTE prophylaxis are widely disseminated and available [11].

Closer evaluation of the VTE example reveals that the outcome measure of interest (decreased incidence of VTE) is best improved by critically evaluating the system of care and improving the component process measures involved in prevention of VTE [12]. For example, risk-appropriate VTE prophylaxis is a process including assessment and prescription by a provider, administration by a nurse, and acceptance by the patient. Active strategies, including a reminder to providers to assess individual patient risk for VTE and prescribe prophylaxis as part of a standard electronic order set, are more likely to improve outcomes than passive dissemination of guidelines [10, 13–15]. Similarly, active attempts to understand nursing practices and beliefs can identify barriers to the administration of prescribed prophylaxis [16]. Finally, since many patients are not aware of VTE or its potential consequences, patients may not recognize the importance of accepting prescribed prophylactic medications [6]. A cohesive approach to decreasing the incidence of VTE must address all aspects of the system of care.

As public reporting and pay-for-performance initiatives have developed as effective tools to improve the quality of healthcare, it is prudent to recognize that even when patients are prescribed and administered VTE prophylaxis according to guidelines, VTE may still not be preventable in as many as 50 % of cases [17]. VTE prevention is quite effective but cannot drive the event rate to zero without undue risk of bleeding [17–19]. National bodies, including the Centers for Medicare and Medicaid Services, impose financial penalties when hospitalized patients develop VTE, despite the fact that many of these VTE events are truly not preventable with current best-practice prophylaxis [19]. Policy changes at the regional and national level should focus on a more impactful approach. A true benchmark of patient safety and quality care should not focus on the incidence of VTE (outcome measure), without considering how frequently patients are prescribed and administered VTE prophylaxis according to best-practice guidelines (process measure). Rather than measuring incidence of VTE alone, some experts argue for a pure process measure approach or combined process and outcome measure instead [12, 13, 20, 21].

Definitions

DVT is the partial or complete occlusion of the venous system from formation of venous thrombi, typically in the lower extremities. A proximal DVT involves thrombosis at the popliteal vein or above, while a distal DVT is confined to the deep veins of the calf. The "superficial femoral vein" is part of the deep venous system, and any thrombus identified within this vein must be treated as a deep, true DVT. PE refers to occlusion of the pulmonary vasculature and is thought to result from embolism secondary to DVT. More recent data suggest that primary thrombosis of the pulmonary vasculature may be the cause of some PE events [22]. The severity of PE determines mortality risk and is typically stratified according to hemodynamics and assessment of right ventricular cardiac function. Massive or high-risk PE is associated with hypotension, signs of cardiogenic

shock, and/or cardiac arrest. Submassive or intermediate-risk PE is associated with preserved hemodynamics but evidence of right ventricular dysfunction or myocardial necrosis. These immediately life-threatening PE events mandate immediate intervention to salvage life.

Incidence and Cost

Each year in the USA, there may be as many as 350,000–900,000 cases of VTE [1]. More than 100,000 people will die from VTE, making VTE the most common cause of death from cardiovascular disease after heart attack and stroke [23]. Over one third of patients with DVT will experience PE [24]. Autopsy studies have identified PE in 7–27 % of patients postmortem, and in most of these cases, there was no clinical suspicion of PE before death [25]. A single DVT or PE event has been estimated to cost an additional $7700–$10,800 or $9500–$16,600, respectively, for treatment in the hospital setting during the initial event [9, 26]. As many as 5–14 % of these patients with VTE will require readmission to the hospital, the readmission cost may vary from $11,000 to $16,000 [26]. Post-thrombotic syndrome, the most common long-term complication affecting patients with DVT, has been estimated to cost at least $200 million annually in the USA [27]. National annual expenditures for treatment of VTE in total may be as high as $10 billion [2]. While the costs of VTE are high and in many cases represent preventable expenditures, the true cost of VTE to patients and society is considerably higher when considering the harm to patients.

Harm to Patients

Post-thrombotic syndrome, chronic thromboembolic pulmonary hypertension, recurrent VTE, and risks of anticoagulation treatment are only some of the harms associated with VTE [9, 28, 29]. Post-thrombotic syndrome may affect as many as 23–60 % of patients with DVT [27]. Symptoms include chronic calf swelling and skin changes and in 5–10 % of cases skin ulcerations and chronic wounds [29]. Chronic thromboembolic pulmonary hypertension may occur in 2–4 % of patients after acute PE and can result in dyspnea both at rest and with exertion [23]. Some of these patients will ultimately succumb to right heart cardiac ventricular failure and/or sudden cardiac death. One group has recognized the need to provide rehabilitation services to patients after PE to improve dyspnea and functional capacity [30]. Risk of recurrent VTE is highest during the first 6–12 months after the initial episode, but the cumulative risk of recurrence at 10 years may be as high as 30 % [31, 32].

Anticoagulation remains the mainstay of treatment for VTE to prevent recurrence and associated sequelae, but clinically relevant or major bleeding can occur with any anticoagulant, especially at the beginning of treatment. Furthermore, VTE may recur even with appropriate anticoagulation treatment. The RIETE Registry, a prospective, ongoing, multicenter international registry, documents consecutive patients with confirmed symptomatic acute VTE [33]. In this series of over 19,000 patients with VTE, 2.4 % had major bleeding after anticoagulation was started, and one of every three cases of major bleeding proved fatal.

Risk Factors

Virchow described the basic etiology of venous thromboembolism as vascular endothelial injury, venous stasis, and hypercoagulability. This classic framework can be used to understand the etiology of risk factors that predispose patients to VTE. Vascular endothelial injury may be iatrogenic (e.g., central venous catheter, surgery) or traumatic. Venous stasis results from factors causing immobilization such as bed rest, prolonged sitting, stroke, immobilization (i.e., long-bone stabilization for trauma), pharmacologic paralysis, or traumatic paralysis (e.g., spinal cord injury). Hypercoagulability may be inherited (e.g., factor V Leiden) or acquired (e.g., malignancy, hormone/contraceptive use). Specific major and minor risk factors are listed in

Table 29.1 Risk factors for venous thromboembolism

Major VTE risk factors
• Malignancy • Personal history of previous VTE • Family history of VTE • Prolonged surgical procedure (>2 h) • Major general surgery • Major traumatic injury • Hip or leg fracture • Hip or knee replacement • Acute spinal fracture • Acute spinal cord injury (<1 month) • Acute stroke (<1 month) • Pregnancy/postpartum (up to 6 weeks) • Known thrombophilia (e.g., factor V Leiden, lupus anticoagulant, anticardiolipin antibodies, antithrombin deficiency, protein C or S deficiency, etc.) • Central venous catheter • Respiratory failure/mechanical ventilation
Minor VTE risk factors
• Older age • Bed rest • Immobility from prolonged sitting (e.g., airplane travel or prolonged car travel) • Laparoscopic surgery • Inflammatory bowel disease • Obesity • Pregnancy/antepartum • Acute infection • Varicose veins • Arteriovenous malformations • Tobacco use • Estrogen/selective estrogen receptor modulators (e.g., tamoxifen) • Contraceptives

VTE venous thromboembolism

Table 29.1. The AHRQ recently published an updated report "Preventing Hospital-Acquired Venous Thromboembolism - A Guide for Effective Quality Improvement" which promotes accepted approaches for VTE prevention in hospitalized patients [9]. This report summarizes numerous risk assessment models that have been created to stratify patient risk for acquiring VTE during hospitalization. University of California (UC) San Diego and Johns Hopkins employ a bucket model, while others use a point allocation system (e.g., Caprini, Padua, Rogers, IMPROVE) [14, 34–38]. The Caprini model is a complex scoring system but has been validated in surgical patients [35]. The Padua model is somewhat less complex but is derived from a relatively small study in a single Italian hospital [36].

Prevention

Pharmacologic Prophylaxis

Guidelines for VTE prophylaxis are available and widely disseminated. The guidelines from the American College of Chest Physicians (ACCP) are often considered the definitive resource [11]. This group has specific recommendations for prophylaxis in non-orthopedic surgery patients [39]. Guidelines for specific populations at risk, such as trauma patients and orthopedic surgical patients, are available from specialty societies such as the Eastern Association for the Surgery of Trauma (EAST) and the American Academy of Orthopedic Surgeons (AAOS), respectively [40, 41].

Most protocols use subcutaneous (SC) injection of unfractionated heparin or low molecular weight heparins (LWMH) such as enoxaparin, dalteparin, or fondaparinux for VTE prophylaxis. Trauma and orthopedic literature typically supports the use of LMWH over unfractionated heparin [40]. Patients with unstable renal function or creatinine clearance less than 30 mL/min should receive unfractionated heparin instead of LMWH due to risks associated with bioaccumulation of some LMWHs in patients with reduced renal clearance. Newer oral anticoagulants are being promoted for VTE prevention, although at this time, the only well-studied indication is for patients undergoing hip or knee replacement surgery.

VTE prophylaxis should generally be provided throughout the inpatient hospitalization, but some literature also supports extending prophylaxis to the outpatient setting for a limited duration after discharge from the hospital. This may be of particular use in patients at high risk for perioperative VTE including orthopedic surgery patients, or those with major abdominopelvic oncologic resections. Dosing of unfractionated heparin is typically 5000 units SC every 8 h for many patients, while less frequent dosing (5000 units SC every 12 h) may be appropriate for some patients at lower risk. Dosing for a common

LMWH, enoxaparin, is typically once daily with 40 mg SC for most surgical patients yet should be 30 mg twice daily for trauma patients [42]. VTE prophylaxis is typically administered 1–2 h before any major surgical procedure and resumed 12–24 h postoperatively. Contraindications to pharmacologic prophylaxis include active bleeding, high risk of bleeding, systemic anticoagulation, coagulopathy with international normalized ratio (INR) ≥1.5, or thrombocytopenia (platelet count <50,000).

Mechanical Prophylaxis

Mechanical prophylaxis may include sequential compression devices (SCDS) and thromboembolic deterrent stockings (TEDS). SCDS are preferred over TEDS alone, and TEDS may be associated with ulcers or skin breakdown, especially in patients with stroke, peripheral vascular disease, or chronic lower extremity wounds [43]. Compliance with these devices in surgical patients is poor even without any specific contraindications, and efforts to improve compliance by addressing misconceptions will be discussed later in the chapter. Although very little data support its use, ambulation has been suggested as an effective adjunct to VTE prophylaxis when feasible [44]. However, this should not be considered an acceptable replacement to pharmacologic and/or mechanical prophylaxis in hospitalized patients at risk for VTE.

Prophylactic Inferior Vena Cava Filters

Inferior vena cava (IVC) filters have been used as prophylaxis in certain high-risk patients without VTE who are unable to receive pharmacologic prophylaxis. The strongest data for this indication come from the trauma literature [45]. EAST offers a level III recommendation (based on retrospective data and/or expert opinion) that a prophylactic IVC filter may be considered in very high-risk trauma patients who are unable to receive pharmacologic VTE prophylaxis [40]. This recommendation may apply to patients with both increased bleeding risk and an injury pattern rendering them immobile for a prolonged period (e.g., severe closed-head injury, spinal cord injury with paraplegia or quadriplegia, or multiple long-bone fractures). However, there is considerable disagreement on this topic, and the ACCP states that "for major trauma patients, we suggest that an IVC filter should not be used for primary VTE prevention (Grade 2C)" [39].

While the trauma literature has identified a potential benefit, IVC filters may also be associated with increased morbidity and mortality in other patient populations. In the bariatric surgery literature, prophylactic IVC filters are associated with higher mortality and higher risk of DVT [46]. Further research is needed to truly understand the implications and safety considerations for IVC filter use in different patient populations.

If a retrievable IVC filter is used, it is important to remove the IVC filter as soon as the patient's acute risk of VTE decreases. In many cases, patients do not return for IVC filter removal. One study of 446 trauma patients who received retrievable IVC filters demonstrated that only 22 % actually had their IVC filter removed [47]. Filter endothelialization may occur as soon as 3 weeks after placement, yet many can still be recovered years later. Patients may experience complications from prolonged indwelling IVC filters, including perforation of the IVC noted on subsequent CT imaging and strut fracture and embolization [48, 49].

Numerous efforts are underway to identify strategies to ensure better rates of filter retrieval. One group has applied the DMAIC (Define, Measure, Analyze, Improve, Control) methodology of the Six Sigma paradigm and increased filter retrieval rates from a baseline of 8 to 52 % by employing automated clinic visit scheduling for 4 weeks after IVC filter placement [50]. A group in New Zealand implemented an "IVC filter pathway" and increased retrieval rates from 63 to 100 % [51]. Focused efforts to improve poor IVC filter removal rates in trauma have been successful and increased rates to 59 % at one US hospital and 87 % at a Canadian trauma center [52, 53].

Systems of Care to Improve Prevention

While guidelines for VTE prevention are widely available, VTE prophylaxis remains underutilized in a significant proportion of hospitalized patients [11, 40, 41]. One study included over 68,000 hospitalized patients at risk for VTE in 32 countries and determined that only 59 % of surgical patients and 40 % of medical patients received guideline-recommended VTE prophylaxis [4]. As with most quality improvement interventions, improved outcomes are best achieved by evaluating the system of care and identifying the component process measures. By improving specific process measures, better outcomes may follow. VTE presents an important example of how to improve healthcare quality and patient safety through active interventions targeting specific aspects of the system of care. A basic framework for the VTE prophylaxis system of care includes risk assessment and prescription of appropriate prophylaxis by a provider, administration of all prescribed prophylaxis doses by a nurse, and acceptance of all doses by the patient (Fig. 29.1).

VTE Risk Assessment and Prescription of Prophylaxis

One approach to improve documentation of VTE risk status and compliance with evidence-based guidelines is to utilize a mandatory computerized provider order entry (CPOE) clinical decision support (CDS) tool, as suggested by the AHRQ [8, 9]. Computer order entry system requires the prescribing provider to complete a checklist of VTE risk factors and contraindications specific for the patient. Based on this checklist, the patient is risk stratified, and the appropriate prophylaxis, according to current guidelines, is determined. The provider is then prompted to order the appropriate prophylaxis regimen. This approach has demonstrated dramatic improvements in both prescription of risk-appropriate VTE prophylaxis for medical and surgical patients and an associated decrease in the rate of preventable harm from VTE [14, 15]. When this strategy was implemented at the Johns Hopkins Hospital, compliance with guideline-appropriate prophylaxis in trauma patients increased from 66.2 to 84.4 % ($p < 0.001$), and the rate of preventable harm from VTE decreased from 1.0 to 0.17 % ($p = 0.04$).

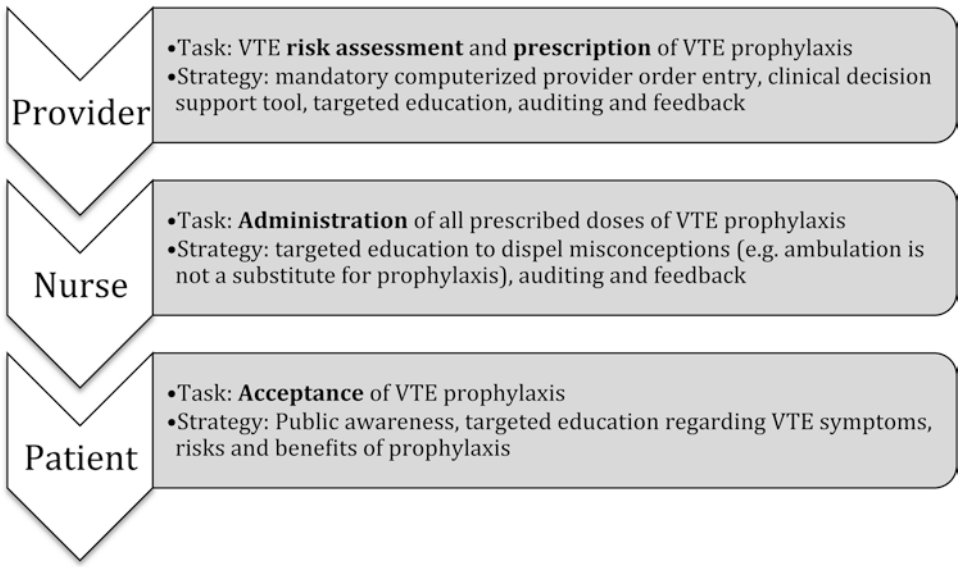

Fig. 29.1 VTE prophylaxis system of care and strategies for improvement (*VTE*, venous thromboembolism)

It is important to ensure that interventions designed to improve prescription of VTE prophylaxis are targeted at the appropriate individuals. At many academic institutions, quality measures attributed to attending physicians (e.g., rate of compliance with appropriate VTE prophylaxis) may actually reflect the average performance of both highly compliant and noncompliant residents. One study compared the proportion of risk-appropriate VTE prophylaxis orders written by each resident and attributed to attending physicians [54]. While there was no difference in proportion of risk-appropriate VTE prophylaxis when attributed to attending physicians, there was a significant difference among residents. Over half of the residents prescribed optimal prophylaxis for every patient they admitted, but there was a minority of residents (9.3 %) who failed to prescribe optimal prophylaxis for *any* of the patients they admitted. This study demonstrates the importance of targeting the providers actually responsible for entering the prophylaxis orders. Furthermore, this suggests that an educational intervention with the limited number of residents not prescribing appropriate prophylaxis might be most effective. Accordingly, a system designed to audit resident compliance with VTE prophylaxis and provide individualized performance feedback was implemented and has been shown to significantly improve compliance with guidelines, reduce incidence of VTE, and improve residents' satisfaction with their education [55].

Administration of VTE Prophylaxis

Once risk-appropriate VTE prophylaxis is ordered, it does not necessarily mean that all ordered doses of prophylaxis will actually be administered. Even missing one dose of VTE prophylaxis is associated with VTE events as demonstrated by a 2014 analysis of 202 trauma and general surgery patients [56]. This study showed an overall incidence of DVT of 15.8 %, and 58.9 % of patients had missed at least one dose of prescribed VTE prophylaxis. DVT occurred in 23.5 % of patients who missed at least one dose of prophylaxis and in 4.8 % of patients who missed no doses of prophylaxis ($p < 0.01$). A 2015 study examined 128 medical and surgical patients with hospital-acquired VTE and determined that 72 % (92 patients) of these VTE events were potentially preventable [17]. The VTE events that were not preventable were attributed to the presence of a central venous catheter [57]. Of the 92 patients who experienced potentially preventable VTE events, 79 (86 %) were prescribed optimal prophylaxis, yet only 43 (47 %) received defect-free care. Of the 49 patients (53 %) who were noted to have defects in their care, 13 (27 %) were not prescribed risk-appropriate VTE prophylaxis, and 36 (73 %) missed at least one dose of appropriately prescribed prophylaxis. A retrospective review examined the medication administration record for patients prescribed VTE prophylaxis over a 7-month period at one academic medical center [58]. Over 100,000 doses of VTE prophylaxis were ordered, but 12 % of these doses were not actually administered to patients. Patient refusal was the most commonly documented reason for nonadministration in about 60 % of cases. This study also demonstrated that a small group of patients (approximately 20 %) constituted the majority (80 %) of all nonadministered doses. Heterogeneity in terms of administration of VTE prophylaxis across nursing floors was noted which suggests that targeting interventions to specific nursing floors, individual nurses, or individual patients may be effective.

Patient Engagement and Education

Many patients are not aware of VTE or its potential consequences, which may lead some patients to refuse VTE prophylaxis without a clear understanding of the risks and benefits of this decision. An APHA telephone survey established that fewer than one in ten Americans know about DVT and are familiar with its symptoms or risk factors [6]. Recently, for World Thrombosis Day (October 13, 2014), Wendelboe surveyed 7233 participants in nine countries to determine the awareness of VTE. They found awareness to be lowest for DVT (44 %) and PE (54 %) compared

to other common conditions such as breast cancer (85 %), stroke (85 %), prostate cancer (82 %), and heart attack (88 %) [59]. Initiatives to increase awareness among patients and the public are also important to decrease the incidence of VTE. For example, US Congress has designated the month of March as DVT Awareness Month to help highlight the symptoms of this common disease. Ongoing efforts must incorporate patient-centered interventions to ensure that patients understand the importance of VTE prophylaxis and the inherent risks associated with refusal of prophylaxis. Recently, our group has been funded to address this problem by the Patient-Centered Outcomes Research Institute (PCORI) for a project titled "Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology" [60]. Patient educational materials are readily available in both paper (http://www.Hopkinsmedicine.org/Armstrong/bloodclots) and video (http://bit.ly/bloodclots) formats, which can be used for this purpose.

Overcoming Hospital Culture Obstacles

Efforts to improve VTE prophylaxis in accordance with best-practice guidelines may require addressing obstacles attributed to hospital culture [61]. For example, mechanical VTE prophylaxis with SCDS is often prescribed but commonly underutilized in about 50 % of patients [62]. Noncompliance may be largely related to patient discomfort and the ease with which these devices may be removed by the patient. Another well-known contributing factor is lack of available SCD equipment at the time of patient admission. Some hospitals have addressed this issue by assigning SCD equipment to each hospital bed, ensuring that the patient will be provided with clean SCD equipment at the time the bed is made available. There may be a tendency for multidisciplinary staff members to remove SCDS to help a patient out of bed without reapplying the SCDS when returning the patient to bed. This problem requires education of a broader multidisciplinary group including nursing assistants, physical therapists, occupational therapists, and transport teams. A common misconception held by some hospital staff and contributing to noncompliance is that SCDS may cause patient falls. A retrospective study examined the incidence of SCD-related falls and determined that only 0.45 % of falls in the hospital are related to SCDS and SCD-related falls are not more harmful than other types of falls [63].

Active attempts to understand nursing practices and beliefs identified barriers to administration of prescribed VTE prophylaxis in a mixed methods study published in 2014 [16]. The study revealed a nursing belief that nurses are responsible for assessing individual patient risks and benefits of prescribed pharmacological VTE prophylaxis before administering the medication to the patient. One nurse who participated in a focus group during this study stated "We make the clinical decision all the time as to whether a patient needs VTE prophylaxis every day, based on how much the patient is ambulating." This study was able to identify misconceptions held by many nurses and introduced an opportunity to provide additional education to this group.

Public Reporting of VTE Outcomes

Public reporting and pay-for-performance initiatives are effective tools to improve the quality of healthcare [64, 65]. National bodies, including the Centers for Medicare and Medicaid Services, impose financial penalties when hospitalized patients develop VTE, despite the fact that many of these VTE events are truly not preventable with current best-practice prophylaxis [19]. Furthermore, the incidence of VTE is related to screening practices and therefore subject to surveillance bias [66]. Providers who screen more aggressively by performing more Duplex ultrasounds on asymptomatic patients at risk for VTE may identify more cases of VTE and will appear to provide lower-quality care than providers who do not screen or order fewer screening tests.

Screening of Asymptomatic Patients and Surveillance Bias

There is no consensus regarding DVT screening of high-risk asymptomatic patients, and practices among surgeons may vary significantly [66]. ACCP does not recommend routine screening for DVT in critically ill patients [11]. EAST recognizes that some patients at high risk may benefit from routine screening for DVT [40]. However, the clinical importance of asymptomatic DVT detected by routine screening remains unclear. Supporters of routine screening see benefit in performing a relatively inexpensive and noninvasive test (Duplex ultrasonography), in order to diagnose and treat asymptomatic DVT before it progresses to symptomatic or fatal PE. Others feel that increased medical testing, associated costs, and treatment of asymptomatic DVT (which may never have come to clinical attention otherwise) incur not only the risk associated with anticoagulation but also unnecessary costs.

Surveillance bias ("the more you look, the more you find") is a common concern when screening asymptomatic patients for VTE. Studies have clearly shown that increasing screening is associated with increasing rates of VTE, primarily in trauma patients [20, 67, 68]. However, this phenomenon has also been shown in a large sample of nearly one million Medicare patients undergoing a wide range of surgical procedures [69]. While national and regional bodies recognize low incidence of VTE as a marker of quality, this is a biased measurement since hospitals that less commonly screen patients for VTE are going to identify fewer VTE events regardless of associated healthcare quality.

Linking Process Measures and Outcome Measures

The standard of patient safety and quality care should not only focus on the incidence of VTE (outcome measure) alone but also consider how frequently patients are prescribed and administered VTE prophylaxis according to best-practice guidelines (process measure). Rather than measuring incidence of VTE alone, some experts argue for a pure process measure approach or combined process and outcome measure instead [12, 13, 20, 21]. Outcome measures are of considerable interest and have been commonly used to determine the quality of care [70]. However, poor outcomes provide no information about how to actually address the underlying problem. Interventions to improve the quality of care must be directed at the process of care [71]. Using the VTE and Outcome Measures example, linking the process measures (prescription and administration of risk-appropriate VTE prophylaxis) and the outcome measure (incidence of VTE) estimates one of the most valuable markers of patient safety and excellent care: the true rate of preventable harm [20, 21].

Quality and Safety Aspects of Diagnosis and Treatment

DVT was historically diagnosed with invasive contrast venography, but in current practice, DVT is almost exclusively diagnosed with Duplex ultrasonography. Duplex ultrasound is safe, noninvasive, and relatively inexpensive. Similarly, invasive pulmonary angiography via right heart catheterization was historically employed to diagnose PE. This invasive, risky, and costly procedure has been replaced with contrast-enhanced computed tomography (CT) angiography for the diagnosis of PE. Current multidetector helical CT angiography allows highly accurate diagnosis of PE [72]. Furthermore, improvements in imaging modalities allow visualization of segmental and subsegmental pulmonary arteries, although the clinical importance of treating peripheral pulmonary emboli is not certain.

Other modalities utilized in the diagnosis of PE may include ventilation/perfusion scan (V/Q scan) or D-dimer assay. V/Q scan is a nuclear medicine test sometimes used to diagnosis PE in patients who are unable to undergo contrast-enhanced CT secondary to renal insufficiency or severe contrast allergy. D-dimer assay is commonly used in emergency department patients and outpatients to rule out VTE due to its high sensitivity. Fibrin D-dimer

measures the final product of the plasmin-mediated degradation of fibrin and is often elevated in patients with acute VTE. However, D-dimer is also common in many other conditions associated with fibrin production including malignancy, trauma, infection, inflammation, and the postoperative state. A negative D-dimer can help rule out the diagnosis, but a positive test is certainly not confirmatory for VTE, especially in hospitalized surgical patients. Both V/Q scan and D-dimer assay must be utilized in conjunction with a pretest probability assessment such as the Wells score or the Geneva score to be clinically useful.

The Choosing Wisely campaign from the American Board of Internal Medicine aims to decrease unnecessary healthcare expenditures and improve patient care [73]. Various medical societies identify the top five tests or treatments that are often ordered inappropriately or too frequently. The ACCP, in conjunction with the American Thoracic Society, has encouraged providers to "choose wisely" when ordering CT angiography to screen for PE. They caution: "Do not perform chest CT angiography to evaluate for possible pulmonary embolism in patients with low clinical probability and negative results of a highly sensitive D-dimer assay" [74].

Conclusions

VTE prevention provides a salient example for targeted interventions to improve healthcare quality and patient safety. VTE is associated with significant morbidity and mortality and in many, although not all, cases is preventable. Strategies to improve VTE prophylaxis must target the system of care to optimize risk assessment and prescription, administration, and acceptance of prophylaxis.

Key Points

- *VTE prevention* is a critical *patient safety practice* for all hospitalized patients.
- As many as 350,000–900,000 people each year in the USA will be harmed by VTE, and over *100,000 people will die* from VTE each year.
- National *annual expenditures* for treatment of VTE may be as high as *$10 billion*.
- *Post-thrombotic syndrome* is the most common long-term morbidity associated with VTE and may affect *over half* of patients with VTE.
- *Evidence-based guidelines for VTE prophylaxis* using pharmacologic and/or mechanical prophylaxis are available and widely disseminated.
- *Not all VTE events are preventable*, even with optimal prescription and administration of risk-appropriate prophylaxis.
- Improved *VTE prophylaxis decreases preventable harm* to patients.
- A true *benchmark of patient safety and quality care* should not focus on the incidence of VTE alone, without considering how frequently patients are prescribed and administered VTE prophylaxis according to best-practice guidelines.

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30 Preventing Perioperative Positioning and Equipment Injuries

Lisa Spruce

"Injuries may be forgiven, but not forgotten."

—Aesop Fables

Introduction

Positioning the patient for surgery is an important aspect of patient care, and proper positioning keeps patients safe. New types of surgery and innovative technologies continue to grow; in particular, robotic procedures and minimally invasive surgery pose unique challenges to safe positioning practices. Research has shown that perioperative personnel can be implicated in patient injury cases when a breach of the standard of care is determined to be a causative factor [1]. The Centers for Medicare and Medicaid Services (CMS) considers pressure ulcers to be a hospital acquired condition (HAC) and will not reimburse the facility's related costs.

Prevention of injury requires anticipating the needs of the patient along with the planned operative or invasive procedure and application of the principles of body mechanics, knowledge of anatomy and physiology, and assessment of the patient's body systems. Positioning requires the skills and knowledge of every team member and teamwork to prevent patient harm. The main objectives for positioning patients are to:

- Provide optimal exposure for the surgeon
- Minimize patient risk
- Provide optimal physiologic monitoring and IV access
- Keep patients safe and secure, avoiding injury
- Maintaining patient dignity
- Allowing for optimal ventilation and circulation

Many factors come into play when deciding what position to place the patient in; the surgeon preference is one such factor, and other factors may depend on the patient's preexisting conditions such as arthritis, or joint problems, previous surgery, decreased range of motion, fractures, or patient height, weight, and age [2]. These conditions should be identified prior to the commencement of the surgical procedure. Positioning requires precision and attention to detail as the possibility of patient injury exists at any time during the surgical procedure.

Anatomy and Physiology

Many patients undergoing surgery require general anesthesia. General anesthesia and the use of anesthetic gases depress the autonomic nervous system causing some degree of vasodilation which reduces the mean arterial pressure [3]. All of the volatile anesthetic agents cause a dose-dependent decrease in blood pressure [4]. The decrease in

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blood pressure with halothane and enflurane is mainly due to a decrease in stroke volume and cardiac output, while the anesthetic agent's isoflurane, desflurane, and sevoflurane decrease systemic vascular resistance but maintain cardiac output [4]. Other factors such as diuretic and antihypertensive medication use, the use of bowel preps, nausea, vomiting, and a poor nutritional state can further impact the drop in blood pressure [2]. These physiological effects leave the patient vulnerable to pressure effects. Pressure is exerted on the body by the patient's weight against the bed surface and is exerted on the bone, muscle, soft tissue, and skin [3].

Anesthesia has a profound effect on positioning, and the anesthesia care provider will play an important role in positioning the patient [5]. Anesthesia, no matter the type, general, regional, or local, blocks the patient's response to pressure and pain [2]. Careful questioning and examination of the patient are required to implement a comprehensive plan of care for the patient, and the patient should have an understanding of the impact of pressure on his or her body [2]. Patients with chronic conditions such as cardiac disorders, diabetes, cancer, neurological disorders, respiratory disease, and peripheral vascular disease are particularly vulnerable to positioning injury and will need extra caution. Older patients whose skin is less elastic, thin with less muscle and fatty tissue are also more susceptible to pressure, bruising, skin tears, and infections. These patients need careful assessment by anesthesia care providers and nursing team members to provide adequate protection from these injuries [2].

Risk Factors

One of the most significant risk factors that impact patients who are positioned for surgery is the amount of time they spend on the operating room (OR) bed. Pressure and time are inversely related. Patients can tolerate a large amount of pressure for a very short period of time or a low amount of pressure for a longer period of time [6]. External pressure that is consistently exerted on patient tissue at capillary pressures greater than 32 mm Hg will result in an occlusion of blood flow, thereby inhibiting tissue perfusion with resultant ischemia to the tissue [7]. Patients are immobile during surgery and are not able to shift or change position and cannot voice discomfort therefore cannot play a role in prevention of injury and depend on perioperative nurses and team members to be their advocates. Patients are most often not positioned in such a way that their body weight is evenly distributed, and an increased risk of tissue damage is present [8]. Areas of skin over bony prominences are particularly vulnerable to injury and are enhanced in those patients who are thin or underweight.

Patients must be positioned in such a way that diaphragmatic movement and airway are not compromised. When lying supine, the anteroposterior diameter of the chest and abdomen decreases, and the tidal volume and residual capacity of the lungs are decreased, thus there should be no constricting devices around the chest or neck [6].

Pressure injuries (see also Chap. 18) are the most common cause of injury to patients followed by nerve injury. Most nerve injuries occur at the ulnar nerve and the plexus brachialis nerve [8]. Other nerves that can be injured include the radial, perineal, and facial nerves which can all be stretched or compressed against bone or components of the OR bed. Caution and awareness must be taken when positioning body parts in various holders or when manipulating them.

Positioning Equipment

Positioning equipment should be designed for that purpose and should protect, support, and maintain the patient's position in surgery. Additional padding is used to protect bony prominences. Tape should never be used to secure a patient in surgery; tape is not approved as a positioning device and using it in such as way could compromise the patient's safety and place the healthcare team at risk for liability should an injury occurs.

Operating room mattresses provide a support surface (Fig. 30.1); these surfaces should be designed in alignment with the recommenda-

Fig. 30.1 Operating room mattress. Reprinted with permission from Hill-Rom Services, Inc

tions from the National Pressure Ulcer Advisory Panel which states that "support surfaces should be specialized devices for pressure redistribution and design to manage tissue loads, microclimate and other therapeutic functions" [9]. Decisions on purchasing mattresses should be made by individual organizations based on the healthcare population of patients, current research, and equipment design and safety features. The primary safety feature is that the surface should redistribute pressure, especially at the patient's bony prominences [10]. A systematic review done by Reddy looked at mattresses or mattress overlays such as air, water, gel, foam, or a combination of these or dynamic support surfaces (those that mechanically vary the pressure under the patient) and found the dynamic support surfaces decreased the incidence of pressure ulcer development [11]. A study done by Kirkland-Walsh et al. compared pressure mapping of four OR surfaces. The best surfaces are those that provide not only efficient pressure redistribution but should also have low-peak interface pressure (pressure at the skin surface), low-average interface pressure, and the highest skin contact area. The researchers determined that the air-inflated static seat cushion had the best pressure redistribution properties in the sacral region, compared to standard three-layer viscoelastic memory foam, with two layers consisting of a top layer of non-powered self-contouring copolymer gel and a bottom layer of high-density foam and a fluid immersion simulation surgical surface [12].

Perioperative team members should always follow equipment manufacturer's instructions for use including weight limits for beds and equipment. There should be advanced preparation for overweight and obese patients so there will be no delay in the planned procedure.

When planning care for patients, perioperative team members should review the patient's plan of care and anticipate the positioning equipment that will be required for each patient. This will be determined by the procedure, surgeon's preference, and the condition of the patient. Optimum positioning will allow exposure to the surgical site and access to all IV lines and monitoring devices. The room should be set up appropriately before the patient arrives, and the correct patient position and equipment should be verified during the time-out process [10].

Perioperative team members should select surfaces that will minimize pressure over patient's bony prominences [10]:

- Rolled sheets and towels should not be used beneath the procedure mattress or overlay. They do not reduce pressure and can in fact contribute to friction injuries.
- Pillows, blankets, and molded foam devices may only provide a minimum amount of

pressure relief and are less effective for longer procedures.
- Foam may be effective when not heavily compressed.

Equipment and Positioning Injuries

Often equipment injuries happen because perioperative team members fail to read the manufacturer's instructions for use [13]. In a classic study by Reason, it was determined that there are 12 common contributing factors to a mistake; the most common was misjudgment, followed by [13]:

- Failure to check equipment preoperatively
- Faulty technique
- Other human factors
- Other problems with equipment
- Inattention
- Haste
- Inexperience
- Communication problems
- Inadequate assessment preoperatively
- Problem with a monitor
- Inadequate preoperative preparation

Most mistakes are usually organizational in nature (i.e., the origin of the mistake can be traced to a decision made before the mistake happened). Therefore, it is up to individual institutions to understand the behaviors and risk reduction strategies that can be implemented in each unique situation [13]. Facilities can focus on teamwork and communication, issues with equipment and maintenance, and coordination and planning among perioperative team members [14] (for detailed discussion, refer to other chapters on teamwork, communication, or human error).

Preoperative Assessment

A comprehensive preoperative assessment should take place prior to the patient being sedated. The process should involve the patient and family members present and should consist of a thorough interview, a review of records, and a head-to-toe assessment. Preexisting conditions should be identified as well as joint issues or implants, decreased range of motion, current or previous fractures, neck or back problems, and any issues with numbness in the hands or arms [2]. The perioperative nurse should have a thorough discussion with the patient and family if any of these conditions are present and how positioning may impact those conditions and discuss how measures will be taken to minimize impact on those conditions [2]. The preoperative assessment checklist is listed in Table 30.1 [10].

Table 30.1 Preoperative assessment

Preoperative assessment checklist
Age
Weight
Height
Body mass index
Nutritional status (decreased muscle mass, dehydration, albumin level)
Blood pressure
Range of motion or physical limitations
Presence of internal or implanted devices such as artificial joints or pacemakers
Presence of external devices such as a colostomy bag or urinary catheter
Presence of jewelry or piercings (remove before surgery)
Medical history including history of a previous injury or pressure ulcer
Results of lab and diagnostic tests
Psychological and or cultural issues

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Skin Assessment

A skin assessment should be part of the routine assessment of all patients; additional precautions should be taken to decrease the risk of pressure ulcers in patients who [10]:

- Are more than 70 years of age
- Require a procedure lasting longer than 4 h or undergoing a vascular procedure

- Are thin, of small stature, or who have poor nutrition
- Have vascular disease or are diabetic

When assessing the skin, assess for the following [9]:

- Skin temperature
- Edema
- Change in tissue consistency in relation to the surrounding tissue
- Redness
- Pain

Document any areas that meet the conditions above and take additional steps as needed such as placement of extra padding and other pressure-relieving devices and try not to position patients on areas of redness if possible.

Surgical Positions: Safety Considerations

With any position, perioperative team members should provide the patient with privacy and dignity while transporting, transferring, and positioning. The entire team is responsible for patient safety and privacy. Safety and privacy considerations by team members are listed in Table 30.2.

The entire perioperative team should be involved in moving and positioning the patient. Care should be taken not to slide or pull the patient which can result in shearing forces or friction on the patient's skin. Shearing can happen when the patient's skin stays stationary and the underlying tissues shift or move which can happen if a patient is dragged or pulled without support or if using a drawsheet. Friction occurs when skin surfaces rub over stationary surfaces [10]. The team should be communicating at all times throughout the process, and patient needs should be identified. Tubes, drains, catheters, and other devices should be secured prior to transferring or positioning the patient. Make sure the patient's body is maintained in alignment and is supported at the extremities and joints and the patient's airway is maintained. Make sure there are enough people present to transfer and position the patient safely [10].

In all positions, padding should be used to protect the patient's bony prominences, and the limbs should be positioned to protect them from nerve damage. Most injuries to the nerves are caused by improper patient positioning [15]. There are different types of nerve injuries and they are listed in Table 30.3 [15].

One of the most common positioning injuries is to the brachial plexus (Fig. 30.2) and can occur from several etiologies. The use of a shoulder brace can cause this type of injury when a patient is placed in steep Trendelenburg. If the shoulder brace is placed too lateral, a stretch injury can occur. If placed too proximal, a compression injury can occur due to the shoulder brace pressing the brachial plexus against the first rib. Therefore, the use of a shoulder brace is not recommended [15]. There has not been any proven method of preventing this type of injury when a patient is placed in steep Trendelenburg. A systematic review done by Codd et al. stated that stretching was the principal mechanism of injury, and minimizing the amount of time that a patient remained in the position may help reduce the risk of injury to the brachial plexus. If necessary, returning the OR table to the neutral position when head down may help to reduce the pressure on the nerve [16]. Improper positioning of the upper extremities on arm boards can also cause this type of injury. There is risk of a compression or stretch injury because the brachial plexus runs posterior to the humeral head. If the arm is abducted greater than 90°, then a stretch injury can occur. Patients experiencing this type of injury can experience numbness and tingling or a complete inability to move the arm; wrist drop may also occur [15].

Another common injury that can occur is an injury to the ulnar nerve (Fig. 30.3). The ulnar nerve is located in the olecranon groove as it crosses the elbow. The groove is located posteriorly between the medial condyle of the humerus and the olecranon process of the ulna. The ulnar nerve is covered by soft tissue leaving it vulnerable to injury. An ulnar injury can occur when the arms are tucked at the patient's side. If the arms are not correctly positioned and secured, the arm can migrate down and press against the edge of the table causing the nerve to be compressed.

Table 30.2 Safety considerations by team member

Circulator	Surgeon	Anesthetist
Restrict access to patient care areas to designated personnel only	Expose only the areas of the patient's body that are necessary to access the surgical site or provide care	Airway is positioned correctly and is patent; patient is ventilating adequately
Keep doors closed	Provide care without prejudice	Monitors are in place, and IV lines are patent
Limit traffic in and out of the procedure room	Communicate with team when a position change is necessary	Patient's eyes are closed and protected
Provide care without prejudice	Participate in moving and positioning the patient	Tubes, lines, and catheters are secure
Keep conversation to a minimum	Verify position and placement of extremities	Conversation is kept to a minimum
Assess position and function of all equipment		Provide care without prejudice
Implement precautions to decrease the risk of pressure ulcers		Assure adequate staff is present before moving or positioning the patient
Make sure safety straps are secure but not too tight		

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Knight D, Mahajan R. Patient positioning in anaesthesia. Continuing Education in Anaesthesia, Critical Care & Pain. 2004;4(5):160–163

Table 30.3 Types of nerve injuries

Neurapraxia	Axonotmesis	Neurotmesis
A mild injury which may cause a conduction block across a small area of the nerve and is caused by external compression to the nerve	A more severe injury that damages the axon of the nerve and is caused by profound compression or traction on the nerve	The most severe injury caused by a transection or ligation of the nerve and is a complete interruption of the nerve and supporting structures

Bradshaw A, Advincula A. Postoperative Neuropathy in Gynecologic Surgery. Obstetrics and Gynecology Clinics of North America. 2010;37(3):451–459

Before tucking a patient's arms, the forearm should be pronated so that the olecranon groove is rotated both outward and lateral which will protect the nerve from compression. Placing extra padding at the elbow before the arms are tucked will add additional protection [15]. Additionally when placing the patient's arms on arm boards, the forearm should be supinated to prevent compression of the ulnar nerve, and extra padding can be applied to the elbow.

Other safety considerations are presented in Table 30.4.

Injury to a patient's eyes is of particular concern; direct pressure on the eye should be avoided to reduce the risk of central retinal artery occlusion and other damage to the eye such as a corneal abrasion. Patients who are at increased risk for developing postoperative visual loss are those that are undergoing prolonged procedures greater than 6.5 h and those who experience a blood loss greater than 44.7 % of estimated blood volume or those who are positioned prone [10].

Patients at risk for this injury should be positioned with their heads level with or higher than their hearts, and the head should be maintained in a neutral forward position without significant flexion, rotation, or extension. The use of a horseshoe headrest may increase the risk of injury [10].

To reduce the risk of injuries to the extremities, the safety precautions that should be followed [10] are shown in Table 30.5.

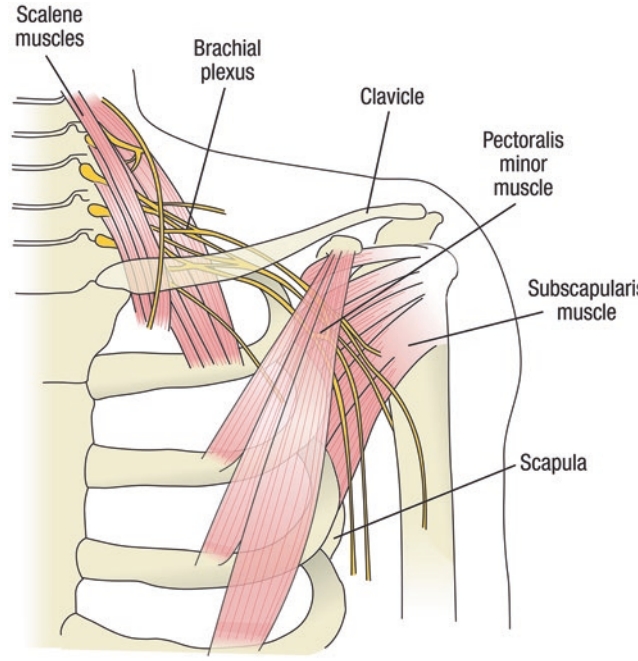

Fig. 30.2 Brachial plexus nerve

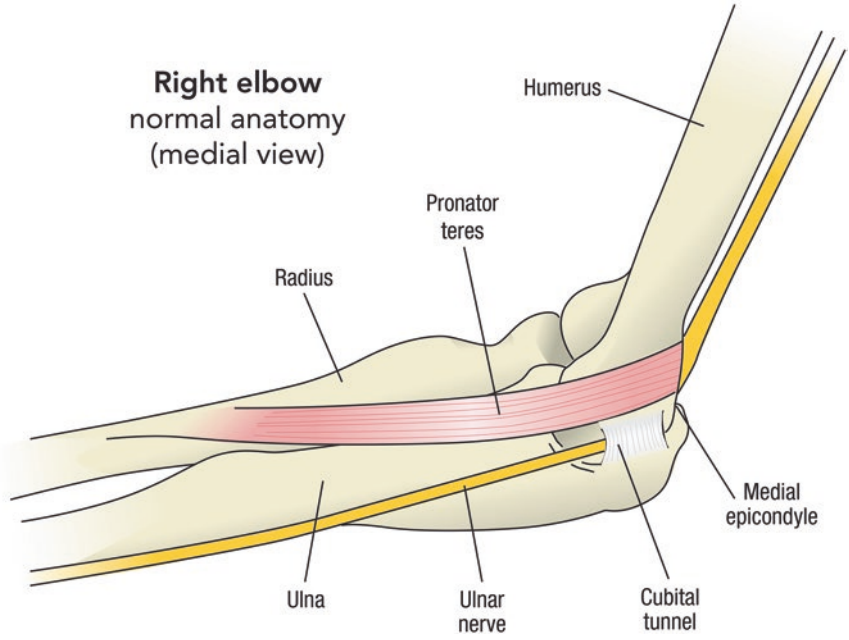

Fig. 30.3 Ulnar nerve

Supine Position

The supine position is the most commonly used surgical position (Fig. 30.4). Almost every patient is initially placed in the supine position for induction and then repositioned as necessary. Many surgeries performed in this position are general surgery; reconstructive or plastic surgery; proce-

Table 30.4 Safety considerations

There is a risk of injury to the patient's fingers, and therefore the location of them should always be confirmed before repositioning the bed or raising and lowering the feet
Safety restraints should be applied in such a way so there is not compression or interference with blood flow
Make sure the patient does not come into contact with metal on the OR bed
Make sure the patient's heels are elevated and are not touching the underlying surface of the bed
Align the patient's head and upper body with the hips; legs should be parallel and not crossed at the ankles
Position the head in a neutral position on a head rest; a pillow may be placed under the patient's knees to relieve pressure on the low back
Pregnant patients should have a wedge inserted under the right side to displace the uterus to the left and prevent compression of the aorta and vena cava causing supine hypotensive syndrome

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Table 30.5 Safety precautions for the extremities

Padded arm boards should be used and attached to the bed at less than a 90° angle for patients who are positioned supine
Place the patient's palms facing up with the fingers extended when on arm boards
When the arms are placed at the sides, they should be in a neutral position with the elbows slightly flexed, wrists neutral, and palms facing inward
Keep shoulders neutral and avoid abduction or lateral rotation
Prevent extremities from dropping below the bed
Adequate padding should be provided when a patient is positioned laterally or in lithotomy to prevent injury to the saphenous, sciatic, and perineal nerves
When a patient is positioned on a fracture table, a well-padded perineal post should be placed against the perineum between the genitalia and the uninjured leg

dures involving the anterior chest, pelvis, or epigastrium; orthopedic procedures on the knees, feet, hands, and forearms; and some neurosurgical procedures such as anterior cervical or cranial procedures [2]. When a patient walks back to the procedure room and then lies down in the supine position, they experience a decrease in vascular resistance, heart rate, functional residual capacity, and total lung capacity. There is an advantage to patients positioning themselves in the supine position as they can verbalize any discomfort, and adjustments can be made as needed such as placing a pillow under the knees. As noted previously, there is an increased pressure on the elbows, heels, and sacrum. The ligaments of the spinal column relax with induction agents and can result in back pain. Additionally, the back of the head is under pressure, and patients can experience pressure alopecia [2].

If patients do not walk back to the procedure room but are transported on a stretcher, a lateral transfer will be performed. Use a lateral transfer device such as a slider board or air-assisted transfer device (Figs. 30.5, 30.6, and 30.7). The following recommendations should be followed regarding team members required to safely transfer patients [10]:

Patients up to 52 lbs: one perioperative team member and one anesthesia care provider
Patients up to 104 lbs: two perioperative team members and one anesthesia care provider
Patients up to 157 lbs: three perioperative team members and one anesthesia care provider

Patients who weigh more than 157 lbs: three perioperative team members and one anesthesia care provider and use a mechanical lifting device such as a mechanical lift with a supine sling (Fig. 30.8), mechanical lateral transfer device, or air-assisted lateral transfer device.

When moving a patient in and out of a sitting or modified-sitting position (Fig. 30.9), three healthcare providers should work together to move a patient up to 67 lbs and use a mechanical lifting device with three team members if a patient weighs 68 lbs or more [10].

The areas prone to pressure (Fig. 30.10) should be adequately padded, and the patient's arms should either be extended on arm boards or secured at the patient's sides. When tucking the arms close to the body, the palms should face the body, and the drawsheet is brought up over the arms and tucked smoothly under the patient's

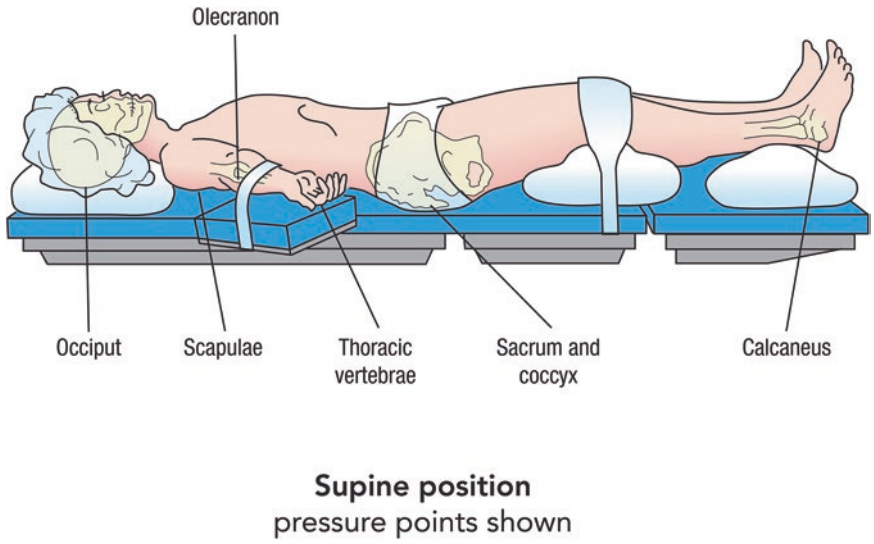


Fig. 30.4 Supine position

Fig. 30.5 Slider board. Reprinted with permission from Hill-Rom Services, Inc

body not the mattress (Fig. 30.11). This method helps to prevent the patient's arms from falling down outside the mattress. Arms are tucked in this manner because the combined weight of the mattress and the patient's body could impair circulation and cause nerve torsion and increase the risk for compartment syndrome. Compartment syndrome is caused from excessive pressure inside an enclosed space in the body. Blood flow is impeded and causes damage to the underlying tissues which may require surgery and could result in permanent damage (Fig. 30.12).

If the arms are placed on arm boards, they should be extended no more than 90° to prevent an injury to the brachial plexus (Fig. 30.13). Arm boards should be padded, and the pad level should be equal to the OR bed. Palms should be facing up to prevent pressure on the ulnar nerve. Wrist restraints should be used to secure the arms but should be padded and loosely applied. The safety strap should be placed across the thighs approximately two inches above the knees with a blanket or sheet between the strap and the patient's skin. The patient's heels should be ele-

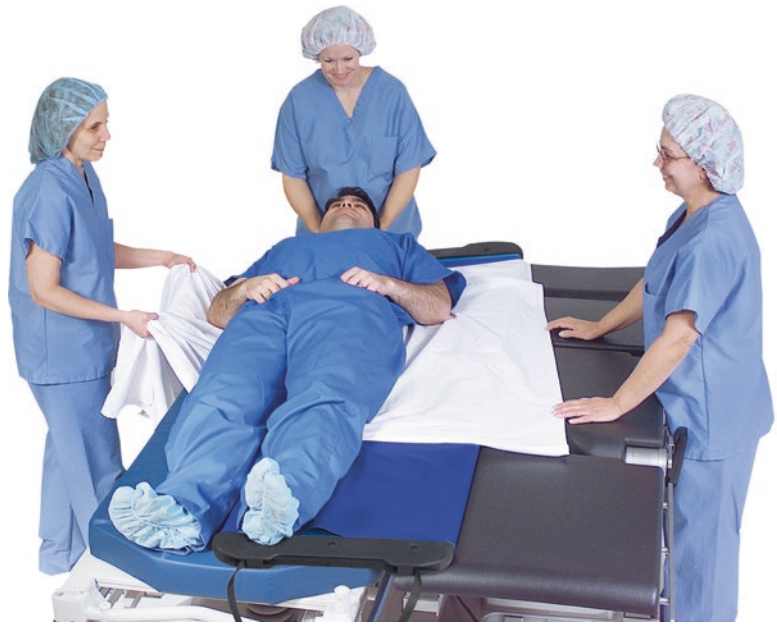


Fig. 30.6 Slider board in use. Reprinted with permission from Hill-Rom Services, Inc

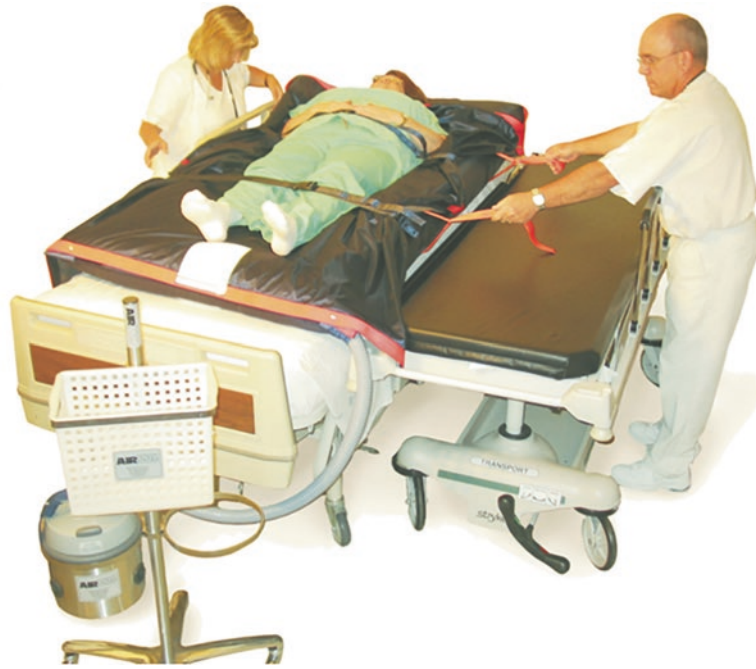


Fig. 30.7 Air-assisted transfer device. Reprinted with permission from Hill-Rom Services, Inc

vated. From the supine position, patients can be positioned into the lawn or beach chair position which is oftentimes used with shoulder procedures because it allows anterior and posterior access to the shoulder joint (Fig. 30.14). When transitioning patients into different positions from the supine position, changes should be made slowly to allow for hemodynamic compensation to prevent hypotension. Additionally, after every patient movement, reposition, or changing positional devices, the perioperative team should reassess the patient, making sure that there is still

Fig. 30.8 Mechanical lift with supine sling. Reprinted with permission from Hill-Rom Services, Inc

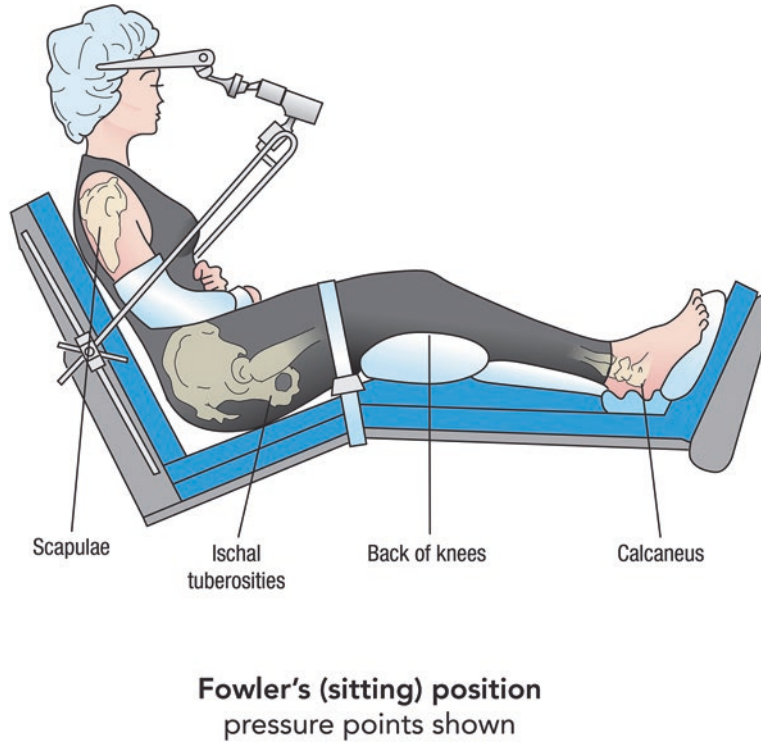


Fig. 30.9 Sitting position

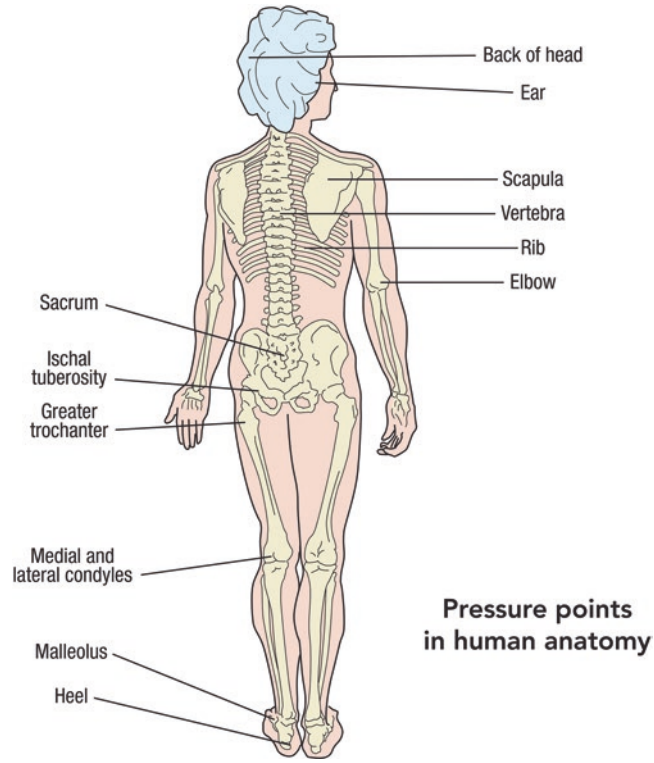


Fig. 30.10 Areas prone to pressure

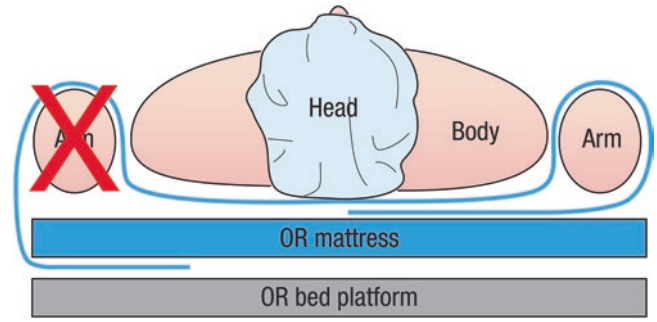


Fig. 30.11 Tucking the arms

good body alignment and a recheck of all pressure points [17].

Trendelenburg Position

This position can be defined as one where patients are positioned with the head down 15°–30° or 30°–40° in steep Trendelenburg and feet down in reverse Trendelenburg (Figs. 30.15 and 30.16). The position is named after a German surgeon Friedrich Trendelenburg who in the mid-1800s began placing patients in this position because it allowed better access to the organs of the pelvis. Today the position is used often in robotic surgery during gynecological, urogynecological, and gynecology-oncology procedures. Patients placed in this position are at risk for injuries involving the eyes, nerves, and extremities (i.e., compartment syndrome and rhabdomyolysis (the breakdown of muscle tissue that leads to muscle fiber contents being released into the bloodstream)). One study found that there is a low incidence of complications related to this posi-

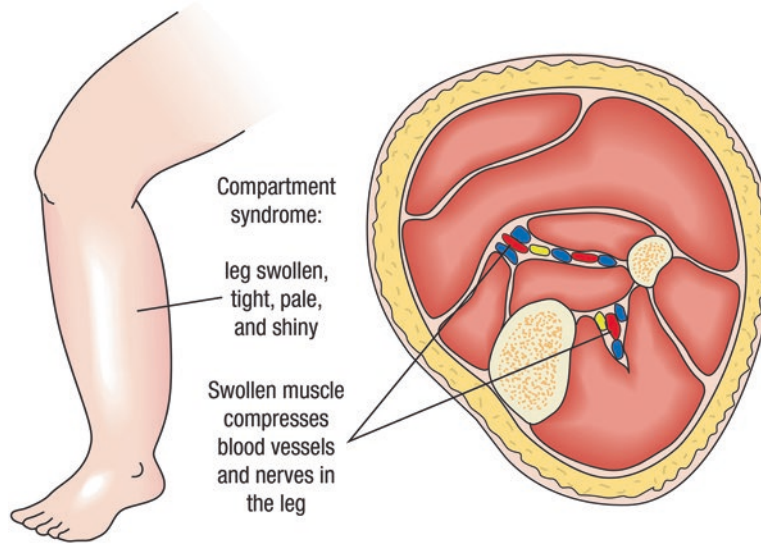


Fig. 30.12 Compartment syndrome

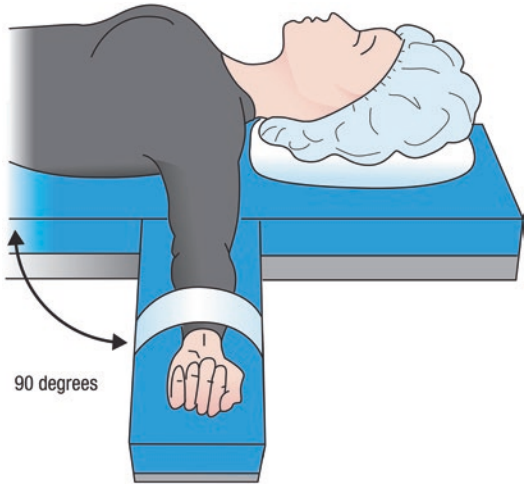
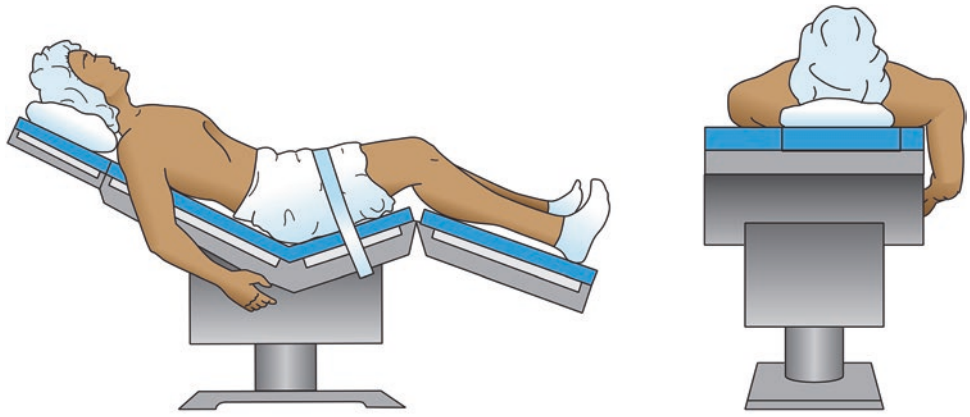


Fig. 30.13 90° arm placement

tion; however, when complications do arise, they place a huge burden on facilities as well as increase the patient's length of stay [18].

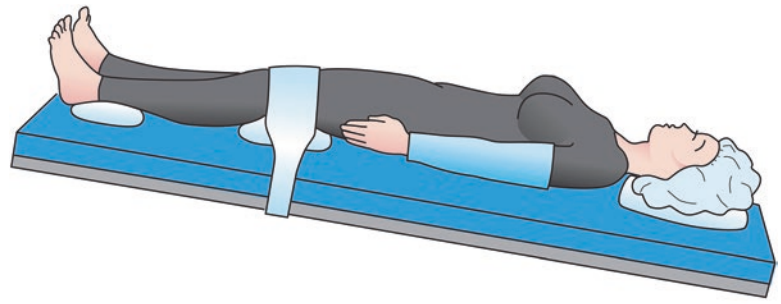
Oftentimes, patients are placed in steep Trendelenburg as well as the lithotomy position and also have the induction of a pneumoperitoneum for prolonged periods. Changes in both the sympathetic and parasympathetic nervous systems occur immediately following placing the patient in the steep Trendelenburg position. The body's initial response is that there is an instant shift in fluids into the thoracic cavity with an increase in central venous pressure; [19] this is quickly followed by an increase in stroke volume and cardiac output and results in a decrease in heart rate and blood pressure. The addition of a pneumoperitoneum can cause other circulatory problems such as decreased venous return, increased systemic vascular resistance, and increased mean arterial pressure. These may have an adverse effect on patients who are elderly or have preexisting cardiac disease [19].

Positioning injuries can occur due to various mechanisms such as neural-mediated injuries and vascular mechanisms of injury. As discussed above, peripheral nerve injuries range from mild to severe and are caused by stretching, compression, or ischemia. Upper extremity injuries can occur due to high body mass index (BMI) and tucking of the arms. Oftentimes, if a robot is being used, the view of the patient can be blocked, and the robotic arms may compress the patient or the patient may slip down. Bean bag devices are sometimes used to prevent slippage, but there is controversy over whether using this type of device increases or decreases the risk of nerve damage [20]. There are products on the market to prevent patient slippage, and facilities should evaluate them on the risk and benefit to determine which product to use (Fig. 30.17). Shoulder braces should not be used because they contrib-



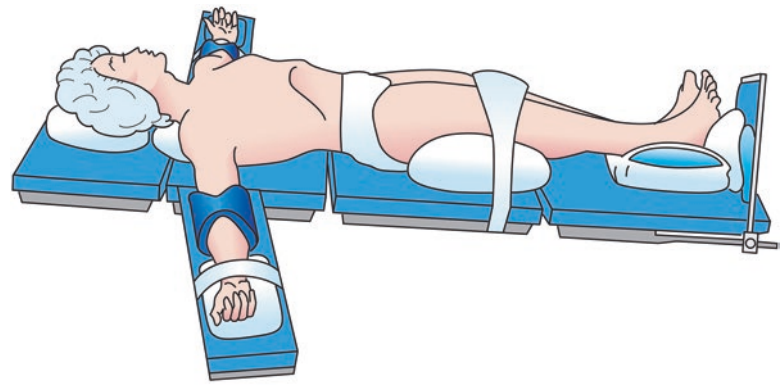
Beach chair position

Fig. 30.14 Lawn or beach chair position



Trendelenburg's position

Fig. 30.15 Trendelenburg's position



Reverse Trendelenburg's position

Fig. 30.16 Reverse Trendelenburg's position with foot rest

Fig. 30.17 Products used to prevent slipping. Reprinted with permission from Hill-Rom Services, Inc

ute to stretching of the brachial plexus and median nerves. Pressure from shoulder braces increases the mechanical loading on the brachial plexus and can cause injury [20].

Compartment syndrome is a vascular-mediated injury that can be seen in this position. Due to the extreme positioning and a decrease in blood pressure, tissues may become hypoperfused. Ischemic conditions can occur such as when the calves are compressed in stirrups. Pressure increases on the calves, and blood flow is decreased causing muscle and nerve damage. As the dying muscle cells release particles, more water is attracted into the area increasing the pressure even more. Once the area is reperfused, toxic intracellular contents are released into the patient's bloodstream causing rhabdomyolysis which can lead to renal failure [20].

Postoperative vision loss can also occur related to steep Trendelenburg and in prone positioning [21]. The gravitational forces encountered in the steep head down position may cause venous stasis, facial edema, and increased intraocular pressure leading to ischemic optic neuropathy which can result in permanent vision loss [20].

Modifiable Risk Factors and Prevention

Patient Factors

Elevated BMI is one risk factor for all types of injuries. If time allows, patients should be instructed to lose weight prior to undergoing surgery. Optimal medical management should also be in place for patients who are diabetic or have peripheral vascular disease as these patients are at increased risk of nerve damage [20].

Padding

Adequate padding of all pressure points as discussed previously applies to this position as well. Patients with a high BMI can have their arms padded using a well-padded arm sled. Avoidance of extreme extension, flexion, or abduction should also be a high priority. Padding the occiput such as with a gel donut will help to avoid ischemic necrosis of the scalp and subsequent hair loss.

Positioning Devices

Use padded arm boards and limit arm abduction to 90°, or arms should be tucked. A padded foot board should be used in the reverse trendelenburg position (Fig. 30.17). Using a non-sliding mattress under the patient should help to prevent movement. One study found that the degree of slope could be decreased to an average of 16° versus 30°–40° and was sufficient to provide adequate surgical exposure [22].

Team Communication

Communicating with all members of the team is a high priority [23]. Patients who are at increased risk for positioning injuries oftentimes have mild to severe systemic illness and all team members should be aware of the patient's underlying medical condition. Patients who have severe illness should be in the steep Trendelenburg position the shortest time possible and should be frequently rechecked to make sure their position has not been compromised. Anesthesia providers should make sure these patients have optimal fluid management [22].

During robotic procedures, a robotic time-out and checklist can be completed after the robot has been docked but prior to the start of the procedure. This will allow the team to assure that standard positioning requirements are met such as position of the extremities, type and location of padding and restraints, any planned position changes during the procedure, and the proximity of the robotic arms to the patient. A checklist such as this may aid the team to recognize risk factors and prevent injury [20]. Song and colleagues conducted a literature review to determine complications associated with extended robotic operations that required prolonged time in the OR. The study team developed a checklist for a second time-out that included nursing, anesthesia, surgeon, and patient factors [24]. The second time-out takes place after about 3–4 h and is beneficial to the surgeon who is not at the bedside and who may become unaware of operative time and what is happening at the bedside. This time-out gives the entire team a chance to evaluate the progression of the surgery, identify potential risk to the patient, and understand what factors are contributing to the extended OR time. Team considerations are presented in Fig. 30.18.

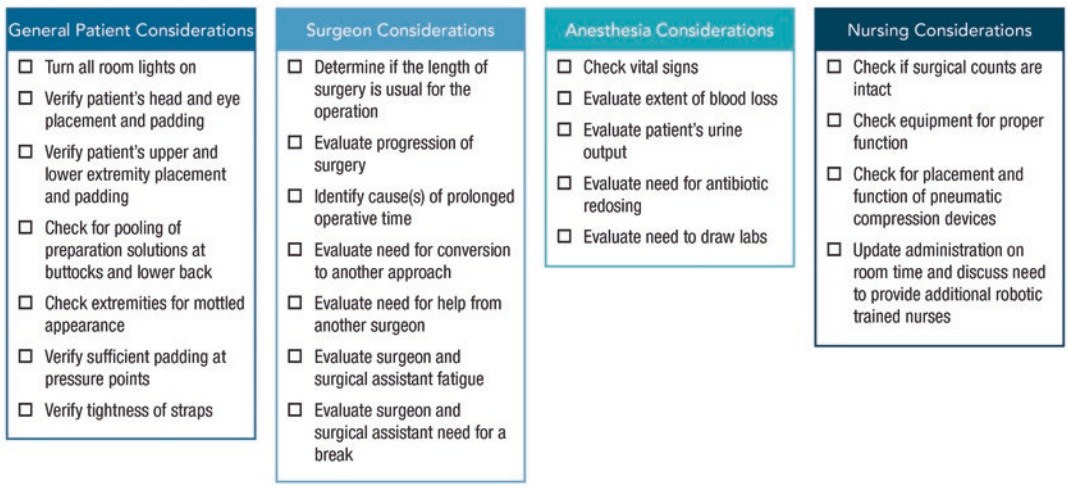


Fig. 30.18 Surgical safety checklist

Prone Position

The prone position is required for many surgeries such as laminectomy in the prone position, or surgeries that require access to the back or rectal area. Sometimes, these patients are placed into a form of the prone position called the jackknife or Kraske's position (Figs. 30.19 and 30.20). Positioning a patient prone has many safety considerations. One of the most devastating injuries that can occur in these patients is postoperative vision loss (POVL) [21]. Patients can experience brachial plexus and cervical spine injuries as well. The main mechanism of injury for POVL is the effect of hemodynamic changes on intraocular perfusion pressure (IOPP) [25]. Agah et al. conducted a study that measured the intraocular pressure under general anesthesia and in the prone position and found that there was a linear relationship between IOP rise and the duration of the prone position [25].

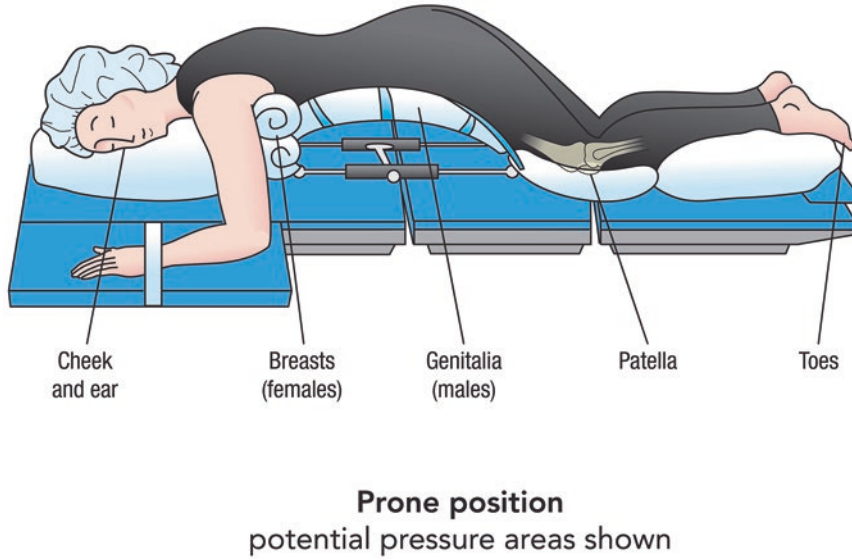


Fig. 30.19 Prone position with pressure points

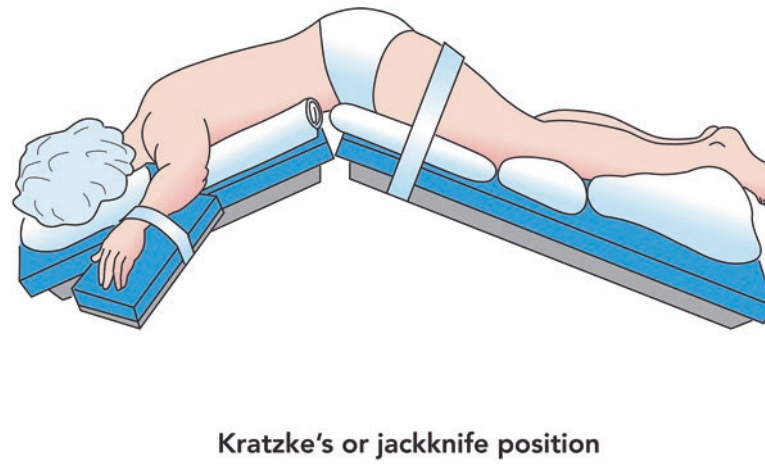


Fig. 30.20 Jackknife or Kraske's position

To prevent injury in the prone position, the perioperative team should make sure that the patient's eyes are protected, avoiding pressure on the eyes and avoiding the use of a horseshoe headrest. The patient's eyes should be assessed on a regular basis. Risk factors associated with eye injuries include being in the prone position, the length of the procedure, and significant blood loss during the procedure [26]. To reduce the risk of injury, the following precautions should be taken [26]:

- Place a headrest under the patient's head to provide access to the airway and prevent eye, forehead, and chin injury by decreasing excessive pressure.
- Cervical alignment should be maintained by keeping the head in a neutral forward position without significant neck flexion, extension, or rotation.
- Place two large chest rolls from the patient's clavicle to the iliac crest. This raises the weight of the body off of the thorax and abdomen and allows for free expansion of the lungs.
- Female breasts should be protected by applying soft ventral supports on the lateral sides of the breasts diverting them toward the midline.
- Male genitalia should be protected by making sure they are free from pressure.
- Pendulous skin folds should be checked to assure they are not trapped under the patient.
- Pad the knees.
- The patient's toes should be elevated off of the bed by placing padding under the shins.
- Place the arms at the patient's sides or on arm boards placed at less than 90° at the shoulder with elbows flexed and palms facing down.
- Hands and wrists should be kept in normal alignment.
- Avoid placing the patient's arms above the head.
- A stretcher or cart should be immediately available in case emergency repositioning to the supine position is required such as with cardiopulmonary resuscitation.

Lithotomy Position

The lithotomy position is most often used for procedures of the pelvis and genitourinary tract and for combined abdominal and perineal procedures (Fig. 30.21). There are varying degrees of

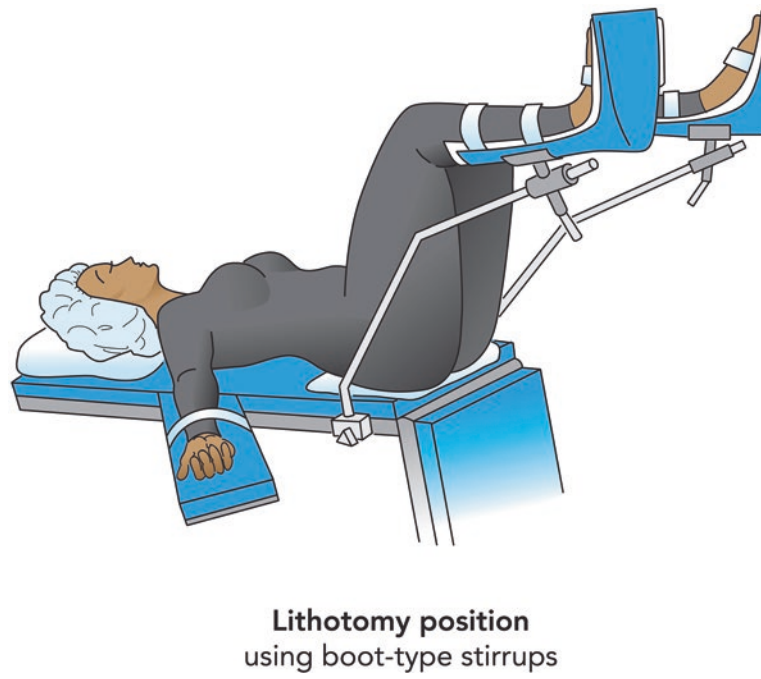
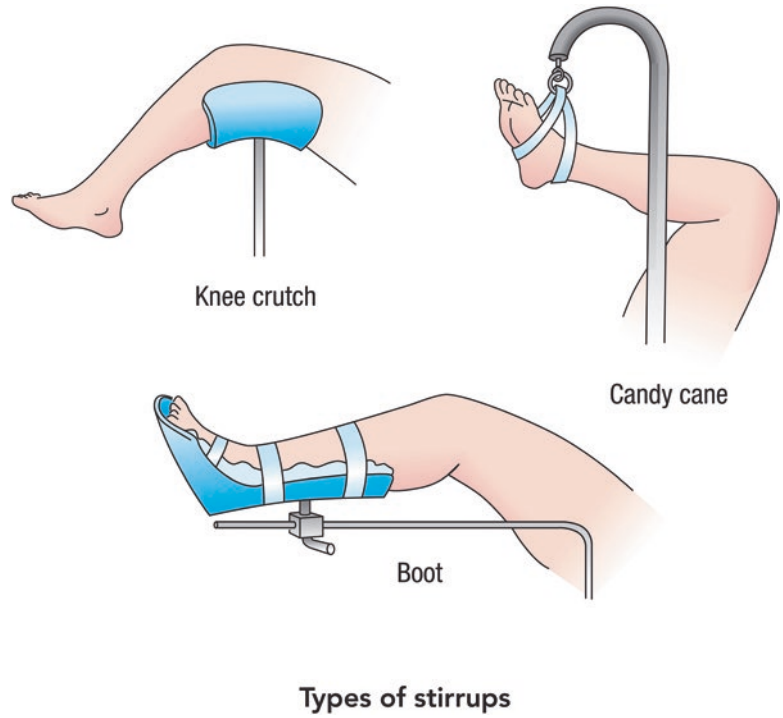


Fig. 30.21 Lithotomy position

Fig. 30.22 Types of stirrups



lithotomy (low, standard, and exaggerated) and different stirrup types, depending on type of procedure and surgeon preference (Fig. 30.22). All degrees of this position require repositioning of the legs. When the legs are raised above the heart, blood will be directed to the central circulation which will result in an increase in cardiac output and venous return. Intra-abdominal pressure will be increased limiting the movement of the diaphragm resulting in decreased lung volumes [2]. Because of this, when the patient's legs are raised, move them slowly and simultaneously to allow the body to physiologically adjust to the sudden shift in circulatory volume. The nerves at risk for injury are the femoral, saphenous, obturator, and perineal nerves (Fig. 30.23). Candy cane stirrups can cause injuries to the femoral nerve due to excessive hip flexion or extreme abduction and external rotation of the thighs (Fig. 30.24). The femoral nerve may become angulated and compressed against the inguinal ligament causing injury [15]. Another mechanism of injury to the femoral nerve is when surgical assistants have leaned on the patient's inner thighs during the procedure. Perioperative team members must be diligent in positioning patients correctly in stirrups, making sure that the thighs are not overly abducted or rotated so the hips are not hyperflexed beyond 80° or 90°. Assistants must also be educated about the danger of leaning against the patient's lower extremities [15].

The perineal nerve crosses laterally over the knee joint and then wraps around the fibular head as it enters the lower leg. Compression of the nerve can occur from incorrect positioning. If a patient's knees or lower legs are allowed to press against a hard surface such as the candy cane stirrups, the nerve can press against the fibular head and be compressed. It is important to inspect the lower legs when the patient is placed in the stirrup and pad the knee to prevent an injury [15].

When patients are placed in the exaggerated lithotomy position, the pelvis is elevated and the legs extend higher than the body. This position puts stress on the lumbar spine and can cause the ligaments and muscles of the lower back to stretch. The legs and feet have a dramatic decrease in perfusion as well as an increase in pressure in the abdomen. Careful and controlled intubation and ventilation are required [2].

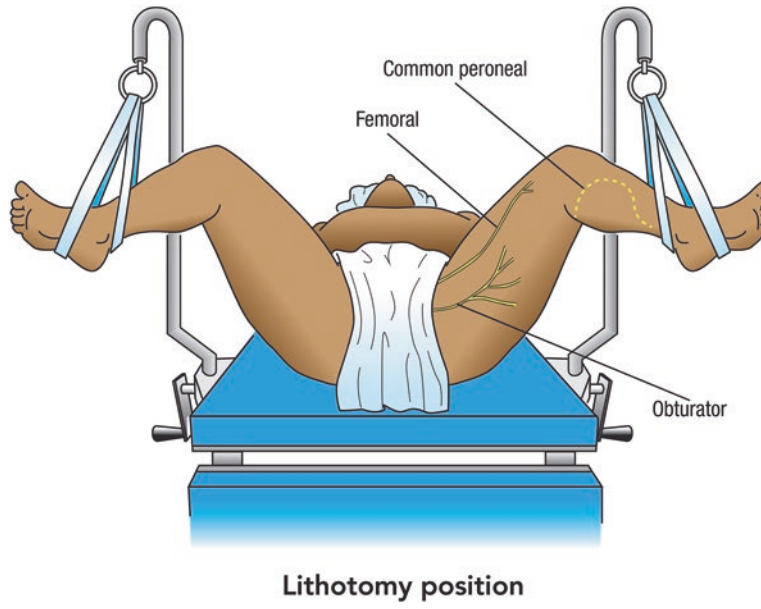


Fig. 30.23 Nerves at risk for injury

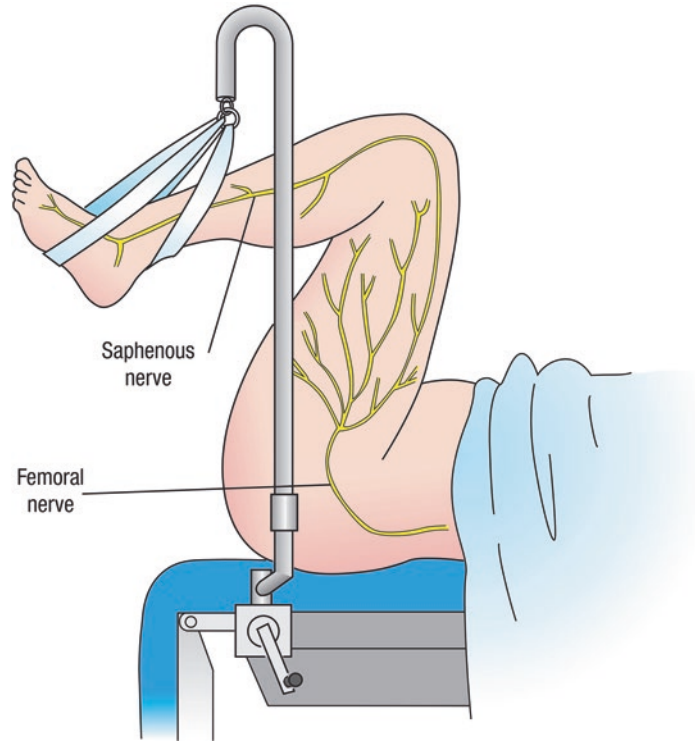


Fig. 30.24 Candy cane stirrups

Procedures lasting a long time put the patient at risk for compartment syndrome of the legs.

The arms may be positioned as noted above on either arm boards or tucked. If tucking the arms, careful protection of the fingers is required. The fingers can migrate over the edge of the bed, and there is a significant risk of trauma to them as the foot of the bed is raised. Protecting the hands and

Fig. 30.25 Mechanical device with support sling

fingers can be achieved by using a foam heel protector to prevent the fingers from slipping out [2].

Other safety considerations for this position [10]:

- Place stirrups at even height.
- Position the patient's buttocks at the lower break in the procedure bed that securely supports the sacrum. Confirm this position prior to starting the procedure.
- Position the patient's heels in the lowest position possible.
- Support should be over the largest surface area of the patient's legs.
- The legs should not rest against the posts of the stirrups.
- Exercise care to avoid shearing when repositioning the patient.
- A minimum of two caregivers should be used to lift the legs. If needed, use mechanical devices such as support slings to assist with lifting (Fig. 30.25).

Lateral Position

The lateral position is most often used for orthopedic procedures that involve the hip and the modified lateral position for the kidney and thorax (Fig. 30.26). After anesthesia induction, the patient is carefully turned so that the operative side is facing up. The patient is at risk for injury of the spine due to misalignment as well as pressure injury to the ears, acromion process, lateral knee, iliac crest, greater trochanter, and malleolus (Fig. 30.27) [10]. Three caregivers should help with turning the patient to avoid injury to the suprascapular nerve. The anesthesia provider and one caregiver should support the head and neck and maintain the airway during lateral positioning [10]. Place a small roll below the axilla so that the chest is lifted and there is adequate blood flow to the arm and the axillary nerves are not compressed [2]. A pillow placed under the patient's head will help to keep the thoracic and cervical vertebrae aligned, make sure the ear is not folded and is well padded. The eyes must also be free from pressure and protected [2]. The lower leg should be flexed with a foam pad placed under the fibular head to protect the perineal nerve; the upper leg is extended and a pillow should be placed between the legs [2]. The lower knee, ankle, and foot should be padded. The arms can be placed on either one or two arm boards. If two are used, the lower arm should be placed palm up, and the upper arm should be on the same plane as the shoulder with the wrist and forearm in a neutral

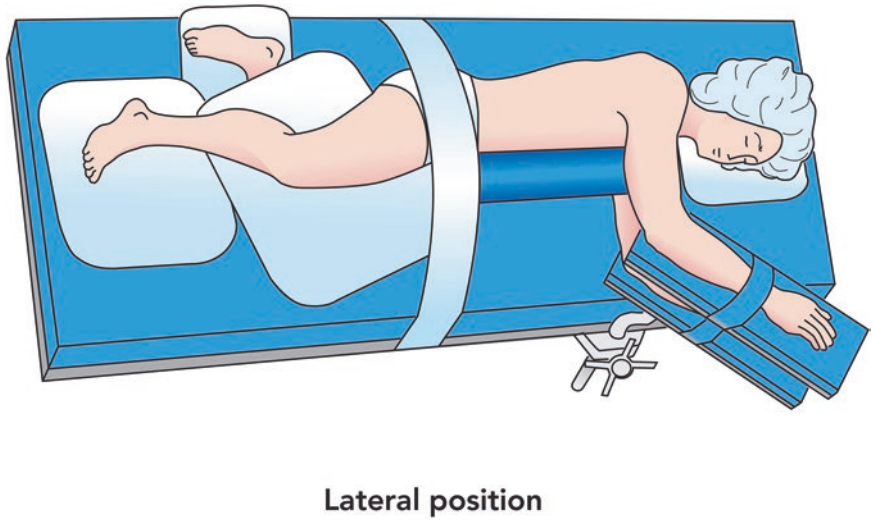


Fig. 30.26 Lateral position

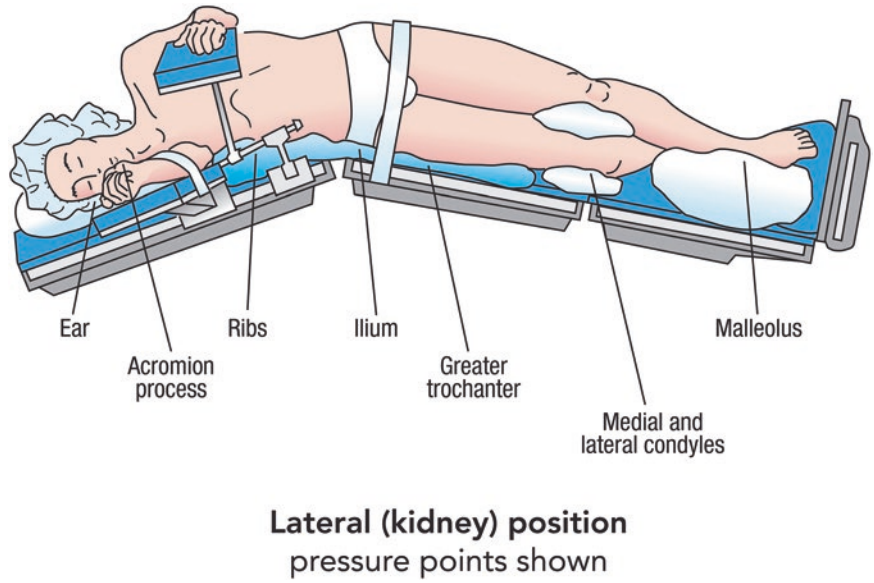


Fig. 30.27 Lateral position with pressure points

position. If one lower arm board is used, a pillow should be placed between the arms to keep them aligned [2]. When transferring the anesthetized patient into and out of the lateral position, three caregivers plus the anesthesia care provider can safely position a patient weighing 115 lbs; if more than 115 lbs, lateral positioning devices should be used [10]. When patients are positioned in a modified lateral position such as when exposure to the thorax or kidneys is required, the following safety strategies should be followed [2]:

- Stabilize the torso with padded braces.
- Flex the lower part of the bed to expose the thoracic area.

- For kidney exposure, the upper and lower parts of the bed are flexed, and the kidney rest is raised.
- Position the patient so the kidney rest is under the dependent iliac crest. If the kidney rest is under the patient's flank, the lower lung will be severely compromised.
- Use compression stockings to minimize the systemic effect of the lowering of the lower extremities below the heart.

Positioning the Obese Patient

The Centers for Disease Control and Prevention (CDC) defines obesity as weight that is considered higher than a healthy weight with a body mass index of greater than 30 kg/m^2 [27]. Obesity has been increasing in incidence, and it is now estimated that more than one third of US adults are obese [27]. Morbidly obese patients typically have comorbid conditions such as diabetes type II, hypertension, and arthritis of weight-bearing joints, sleep apnea, atherosclerosis, alveolar hypoventilation, gastroesophageal reflux disease, and urinary stress incontinence [10]. Obese patients have been shown to have higher complication rates and longer hospital stays following surgeries than normal weight patients [28].

Obese patients require a careful preoperative assessment to identify issues that may adversely affect them such as the inability to tolerate certain positions, joint or range of motion issues, and conditions of the skin or circulatory system [29]. Perioperative team members should establish a plan when caring for this population; additional staff members will need to be available to help move and position the patient and ensure that all equipment necessary is available and checked for safety [29, 30].

Obese patients have special issues that need to be considered when positioning them, these include [10]:

- Airway may be compromised due to a short, thick neck.
- Possibility of a difficult intubation.
- Increased intra-abdominal pressure on the diaphragm.
- Increased risk of aspiration and hypoxia.
- Increased risk of compression of the vena cava.
- Increased pulmonary artery pressure and cardiac output.

Safety Considerations

In addition to all of the precautions noted thus far, there are additional safety considerations for the obese patient. First and foremost is the operating or procedure bed. The beds should be capable of supporting and moving obese patients. Beds should be capable of managing patients weighing up to 800–1000 lbs. Specialized hydraulics should be available and capable of lifting these patients (Figs. 30.28 and 30.29). Mattresses should provide sufficient padding and support, and extra wide and long safety straps should be used to secure the patient. Two safety straps can be used if necessary, one placed across the thighs and the other across the lower legs (Fig. 30.30) [31]. When placing the patient's arms on arm boards, it may be difficult to determine if they are positioned at less than 90°, therefore padded arm sleds or toboggans may be used to allow the patient's arms to be secured at the side of the body. Precaution should be taken to make sure these devices do not cause excessive pressure on the patient's arms. Safety considerations for obese patients based on position are noted in Table 30.6.

Fig. 30.28 Bariatric assist device

Fig. 30.29 Bariatric assist device

Fig. 30.30 The use of two safety straps

Table 30.6 Safety considerations for obese patients

Supine position	Prone position	Trendelenburg	Reverse trendelenburg	Lithotomy
It may be difficult for obese patients to tolerate this position due to additional weight on the respiratory and circulatory systems, and patients may have to be repositioned into a sitting or lateral position	Support the upper chest and pelvis to free the abdominal viscera to reduce the pressure on the inferior vena cava and the diaphragm	Avoid if possible because the abdominal contents press against the diaphragm and can cause respiratory compromise	Patient's feet should be placed on a foot board	Stirrups may be used and should be designed for the obese patient
Placing patients laterally allows the panniculus to be displaced off of the abdomen		Increased blood flow from the lower extremities to the pulmonary and central circulation causes vascular congestion	Care should be taken to make sure the feet are flat against the board and maintained in alignment to prevent rotation and increased ankle pressure	Several staff members should be available to lift the patient's legs into stirrups. A single team member should not attempt to lift the legs alone
If placed supine, a roll or wedge should be placed under the right flank to decrease compression on the vena cava				Leg holders may be used to hold patient legs while prepping or doing other activities. See image

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Conclusion

Positioning and equipment injuries can occur in perioperative patients, and it is the responsibility of all perioperative team members to minimize risk to patients. Surgical positions and equipment pose specific challenges that should be prepared for prior to the procedure. Good team communication and preparation as well as following safety principles are key to providing the safest patient care possible and to preventing the risk of injury.

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Challenges in Preventing Electrical, Thermal, and Radiation Injuries

31

Mark E. Bruley

"When you have eliminated all which is impossible, then whatever remains, however improbable, must be the truth."

—Arthur Conan Doyle

Introduction

Patients continue to suffer inadvertent skin and tissue injuries in the perioperative setting from mundane (such as from heated solution bags used for positioning) to highly advance therapeutic and monitoring technologies (electrosurgery; fluoroscopy) that employ electricity, heat, or radiation. This occurs despite a great deal of care and concern for patient safety by surgeons, anesthesia professionals, nurses, and clinical engineering personnel. Such injuries can prolong morbidity and extend hospitalization, appreciably increasing medical costs to the patient and hospital. The healthcare facility and surgical team may also face associated costs if litigation ensues.

Therapeutic and monitoring technologies and medical devices that employ electricity, heat, or radiation present a multitude of hazards that can injure skin or tissues if adequate attention is not paid to their safe use. With these devices various forms of energy are necessarily applied to surgical patients in the perioperative setting. Surgical fires on (or in) the patient, although rare, can also cause potentially devastating tissue injuries. Each type of energy—electricity, heat, and radiation (including light, x-rays, and intense MRI magnetic fields)—presents risks of injury if those risks are not recognized and care not taken to prevent harm.

This chapter addresses the etiologies of intraoperative skin and tissue injuries from medical technologies that are the source of electrical, thermal, and radiation energy. A procedure for investigating such injuries is presented along with guidance on their prevention. Additional guidance on incident investigation techniques is presented in Chaps. 27 and 28.

Preventive recommendations that target various potentials for patient skin and tissue injury, including prevention of surgical fires, are not intended as standards, guidelines, or absolute requirements. Adoption, modification, or rejection of the recommendations may be considered based on clinical assessment of individual patient needs and are not presented with the intent of replacing local institutional policies.

Background

Medical technologies and devices used for perioperative treatment or monitoring of patients have tremendously advanced our practice of surgery since the 1920s with the introduction of the first electrosurgical unit (ESU) by William Bovie, MD [1, 2]. In addition to electrosurgical devices, there have been advances in other technologies

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Table 31.1 Technology in which significant advances have vastly improved surgical patient care

1. Monitoring (e.g., ECG, capnometry, pulse oximetry, nerve monitoring)
2. Patient warming and cooling
3. Surgical drills
4. Lasers
5. MR imaging
6. Fluoroscopy
7. Fiberoptic light sources.
8. Monitoring (e.g., ECG, capnometry, pulse oximetry, nerve monitoring)
9. Patient warming and cooling
10. Surgical drills
11. Lasers

deployed during surgery have vastly improved our ability to provide care (see Table 31.1).

The discussions of intraoperative tissue injury mechanisms from such electrical, thermal, or radiation emitting surgical devices highlight and point to the types of information that should be collected and considered during an investigation. Historically, the dissemination of innovation in healthcare has been a slow process [3]. Patient safety initiatives, as a facet of the process of healthcare delivery, also suffer from a slow pace of adoption, especially related to the safe use of medical technologies. For electrical, thermal, or radiation based surgical technologies, the reality is that the recommendations for safe application of the technologies have been in the medical literature and equipment user manuals, for decades in many cases, but the understanding and adoption of those safe practices by members of the surgical team has lagged [4–6]. Clinical residencies serve critical purposes for the surgical team members to become proficient in the use of technology. However, such didactic training rarely stresses the need for users to read the device's user instructions or to understand how the device functions. This is remarkably different than industry safety standards. Understandably, time available for medical and nursing training is limited. However, safety of the surgical patient related to the technologies applied to them is enhanced by clinicians having an understanding of how a device functions along with the associated warnings and precautions.

Keeping the surgical patient safe from perioperative skin and tissue injury caused by electrical, thermal, or radiation emitting medical technologies is enhanced by surgical team members understanding potential etiologies of skin and tissue injury related to the involved technologies, knowing how to investigate such adverse events in order to develop and employ measures to prevent some of the more common causes of such injuries.

Etiologies of Intraoperative Tissue Injury

There are many potential etiologies of accidental injury to skin and tissues during surgery. Intraoperative injuries that are suspected of having been caused by a medical device and its related energy may, however, not be related to a technology. In many cases, the injury may be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of device use and performance. Alternatively, the injury may be due to pressure necrosis, tissue chemical sensitivity, an adverse drug reaction, or a disease process that happens to develop in the area where a device was applied. The causes and prevention of tissue and nerve injuries related to pressure and patient positioning [7–12] are addressed in Chap. 17 in broader detail. In this regard, alternative etiologies beyond those of energy emitting technologies need to be recognized and considered to determine the nature of the injury, appropriate treatment, and develop recommendations for preventing recurrence. While these may appear obvious in particular cases, the seemingly obvious explanation for a skin injury is often *not* the correct one.

Although certain medical procedures (e.g., electrosurgical procedures) are known to present the risk of causing device-related burns or other accidental tissue injuries, it is important to not rush to judgment about the nature or cause of such injuries. Over a period of 45 years of investigating patient injuries and deaths from errors and accidents involving healthcare technology, instruments, devices, and systems, ECRI Institute has observed that perioperative skin and tissue injuries are usually much more complex than what they seem [4, 13–16]. Table 31.2 lists the

Table 31.2 Etiologies of *suspected* energy-related perioperative tissue injuries [17]

- *Electrical*
  - Radiofrequency (RF): electrosurgical units (ESUs), RF prostate heating probes, intrauterine ablation probes.
  - Direct Current (DC): nerve and muscle stimulators, pacemakers, batteries, ESU circuit continuity monitors
  - AC (60 Hz line voltage): OR table, general electro-medical equipment in the OR.
- *Thermal*
  - Direct contact: heating pads, cooling pads, electrocautery, diathermy, heated irrigation solution bag, heated cotton blanket, powered surgical handpieces (drills, saws) unlubricated, flash-sterilized surgical instruments, heated prostate or intrauterine probes
  - Irradiant: (radiant warmers, exam and operating lights, fiberoptic light cables, lasers, high intensity aiming lights in mobile X-ray heads)
- *Chemical*
  - Povidone-iodine prep solutions (problems with lot-specific formulations; solution pooled under a patient that reacts with other solutions or with residual laundry chemicals in linens; mixing with alcohol or hydrogen peroxide)
  - Ethylene oxide (EtO; improper aeration of EtO-sterilized devices)
  - Improper electrode (ECG) plating components reacting with conductive paste
- *Mechanical*
  - Constant high pressure in excess of two to three hours (e.g., positioning contours, supports, straps, worn OR table mattresses pinching); time may be shorter with very high pressure
  - Pneumatic tourniquets
  - Tenacious electrode adhesive
- *Radiation*
  - Diagnostic imaging
  - Therapeutic treatment
- *Pharmacologic Adverse Reactions*
  - Warfarin therapy (e.g., Coumadin)
  - Intra-arterial injection of Bicillin (penicillin G)
  - Drug infiltration at a catheterization site
  - High-dose injected barbiturates injection in subcutaneous or fat layer
- *Physiologic/Medical/Disease*
  - Allergic reaction (e.g., to adhesives, electrode gel, ointment, and skin prep solution)
  - Aplasia cutis (neonates)
  - Chronic chilblain (pernio)
  - Ecthyma gangrenosum
  - Disseminated intravascular coagulopathy (DIC)
  - Lesions secondary to lupus erythematosus or Hodgkin's disease
  - Lichen sclerosus et atrophicus
  - Livedo reticularis
  - Livedo reticularis (including idiopathica)
  - Purpura fulminans
  - Necrotizing fasciitis ("flesh eating bacteria")
  - Ischemic lesions resulting from:
    - Peripheral vascular disease
    - Venous stasis
    - Diabetes mellitus
    - Cryoglobulinemia
    - Arterial emboli of atherosclerotic plaque (blue-toe syndrome)—iatrogenic, intraoperative, or otherwise
    - Anterior-compartment syndrome

potential etiologies to consider when presented with a skin or tissue injury that is suspected of having been caused by a medical technology or device. The major etiologies include electrical, thermal, radiation, chemical, mechanical, pharmacologic adverse or allergic reactions, and physiologic/medical (including diseases). Within these categories are listed the subordinate mechanisms of injury and the more common involved devices.

Medical devices are frequently blamed for perioperative accidental skin and tissue injuries, particularly for those that have the appearance of a full- or partial-thickness burn. However, thermal or electrical sources are not always involved. It is therefore misleading—and in many cases inaccurate—to refer to such an injury as a "burn." For these injuries, "lesion" is a more appropriate term because it enables a more deliberate discussion about the consideration of other causes when analyzing the root causes of the lesion [18].

Histology and Etiology

Histologic examination of specimens from the injured tissue can potentially be revealing as to the type of energy insult that caused the injury, including differentiating between an electrosurgical injury and a thermal injury. Guidance for undertaking histologic analysis has been published specific to electrosurgical injuries [19, 20] and is available in a well-known pathology reference text [21]. The pathology and pathogenesis of cutaneous thermal burns is addressed in the seminal works on the study of thermal injury in humans [22, 23].

If tissue specimens can be obtained without stress to the patient, such analysis can go a long way in understanding the root cause of injury, including the devices truly involved in the cause, and aid in understanding how to prevent recurrence. It can also prevent rancorous debate between departmental clinical staff and prevent legal challenges. Unfortunately, tissue specimens are not typically available for histologic analysis. Nevertheless, awareness of the ability of histologic examination to assist in differentiating between an electrosurgical insult and a thermal insult should be part of the investigative approach.

Investigation Guidelines for Perioperative Skin and Tissue Injuries

When an accidental injury is suspected to have occurred during surgery, healthcare facilities typically initiate an investigation to determine both the nature of the injury and the cause. While these may appear obvious in particular cases, the seemingly obvious explanation for a skin injury is not always the correct one [17, 24]. The guidelines presented here will help healthcare personnel organize and conduct a thorough skin injury investigation to identify the cause of an accidental skin injury. The questionnaire in Appendix 1 facilitates the investigation process (see page 538).

When approaching the problem of tissue injury, the questions listed in Table 31.3 need to be addressed in addition to the questions contained in Appendix 1.

An understanding of the possible causes and effects of perioperative skin and tissue injury, combined with an effective investigation procedure, enables investigators to identify the actual cause of a particular injury and recommend precautions, thereby helping to minimize future risks to patients and to healthcare facilities.

Table 31.3 Questions to consider when investigating perioperative skin and tissue injuries suspected of having been caused by a medical technology

1.	What are the various kinds of skin and tissue injury, and where in the hospital do they occur?
2.	What procedures should be followed immediately after discovery of an injury?
3.	Who should be involved in an investigation?
4.	What information should be gathered?
5.	What measures should be implemented to prevent future occurrences?
6.	How and when should the hospital communicate with the manufacturer of implicated devices?
7.	What are the various kinds of skin and tissue injury, and where in the hospital do they occur?
8.	What procedures should be followed immediately after discovery of an injury?
9.	Who should be involved in an investigation?
10.	What information should be gathered?
11.	What measures should be implemented to prevent future occurrences?

Injury Prevention and Management: Pre- and Post-Operative Considerations

Perioperative Steps:

A few routine clinical steps and recorded information, listed in Table 31.4, will facilitate the investigation of any skin injury that develops afterward.

Finding an Injury

If an injury is found or suspected, the steps detailed in Table 31.5 will help in determining the cause:

Incident Report Documentation

Completion of an incident report and record of immediate observations of all involved personnel is indicated. To avoid premature or inaccurate conclusions, the incident report should include only facts, not speculation or supposition. For example:

- *Incorrec*t: "Patient received electrosurgical burns on right buttock and heel."
- *Correct*: "Postoperative skin check revealed lesions on the patient's right buttock and heel."

Table 31.4 Clinical steps and recorded information that facilitate the investigation

Skin condition	Before a procedure, surgical nursing and/or medical personnel should thoroughly examine the patient's skin. A description of the general skin condition, as well as any unusual conditions—rashes, reddened or discolored areas, contusions, cuts, abrasions, or other abnormalities—should be recorded in the patient history, perioperative record, or surgical notes. Information obtained during a preoperative skin check will allow staff to identify changes that might have occurred during or after the procedure
Perform a postoperative skin check	As soon as possible following a surgical procedure, personnel should examine the patient's skin and record any observed changes or abnormalities. In some cases, the patient's physical condition may not permit an immediate and thorough postoperative skin check, but accessible areas (e.g., buttocks, heels, thighs, elbows, head, electrode sites) should be checked. The nursing staff should check other areas as soon as possible. Pictures should be taken immediately and in regular intervals to follow the progressing of the skin injury
Medical technology information	The surgical notes for each patient should also include information on the manufacturer, lot numbers, and expiration (or "use before") dates of prepping solutions, electrodes, and electrode gels, as well as information on manufacturers, models, hospital control numbers, and serial numbers of equipment. However, because it is impractical to expect operating room personnel to record all this information, the available information should be collected at the first sign of an injury by the investigative team

Table 31.5 Clinical steps and recorded information that facilitate the investigation

Evidence preservation	Preserve and document the evidence. When a suspected device-related lesion is discovered, personnel should preserve and thoroughly document the evidence, especially all disposables and packaging. Contaminated disposables or other instruments should be stored in appropriate biohazard containers
Delayed injury onset	Be aware that injury to internal organs, e.g., bowel, from electrosurgical current may not manifest until several days post-op. Nevertheless, upon discovery, efforts need to be made to obtain relevant information on the electrosurgical devices and instruments used
Photographs of injury	In collaboration with risk management personnel, and if practical, take color photos of the injury immediately after discovery and 24 and 48 h afterward (permission from the patient or family may be necessary). Photographs should provide some indication of the scale of the lesion (e.g., using a coin or ruler)
Medical equipment handling	If possible, surgical and medical personnel should not move or disconnect the equipment, except as necessary to care for the patient or to prevent further injury or equipment damage. When it is not possible to preserve the physical setup of the involved equipment and devices, personnel should record the scene with photographs or sketches. Color photographs should be taken before inspection of devices that may be damaged when examined, such as a disposable electrosurgical dispersive electrode used with an ESU
Maintaining evidence possession	Ensure that no involved materials or devices are released to the manufacturer or other outside parties until completion of the internal incident investigation or until approval has been given by risk management or administration

Patient and Family Discussion

Institutional policy will guide the discussion with the patient and family. The discussion with the patient and family about the injury should be honest with full disclosure while being cautiously diplomatic [17, 25]. The *actual* cause of the injury probably will not be known before the incident is discussed with the patient and their family. As such, offering specific theories can be misleading and provoke litigation. For example, if a patient develops a palm-sized lesion over the sacrum on the day following a lengthy cardiovascular surgical procedure, pressure necrosis is the probable cause with many potential underlying co-morbidly factors that contributed to the lesion development. Unfortunately, in many such cases, the nursing, medical, or surgical staff has told the patient, "The electrosurgical machine accidentally burned you during the surgery." A more productive and factual approach is to tell the patient that there is "an injury" or "an area of skin breakdown" and that it will be treated. In some cases, it may be suitable to mention that the cause is being investigated in open and transparent matter [26].

Components of a Thorough Investigation

Skin or tissue injuries sustained—or suspected of having been sustained—by patients in the operating room are often initially mistaken for thermal or electrical burns, with medical devices immediately blamed as the cause. However, such a hasty conclusion can overlook the actual cause of the injury (see Table 31.1 for the list of potential etiologies) and delay the implementation of measures to prevent future occurrences. Below is a thorough investigation process to help clinical investigators uncover the real cause of an accidental skin injury.

The Investigation Process

An investigation need not be a threatening experience for anyone. The goal of the investigation is to determine what happened and recommend appropriate preventive measures—not to assign blame. This should be explained to all personnel involved in the incident. To aid the patient safety process during investigation of a perioperative skin or tissue, the questionnaire in Appendix 1 can be used by investigators to collect information during staff interviews and to summarize needed baseline patient and equipment data.

The Investigation Team

The investigation team should include staff members who are familiar with the equipment used and the environment in which the incident occurred. The team might include a clinical engineer, a surgical or critical care nurse, a physician, an equipment technician, and the risk manager. The risk manager will help ensure that proper steps are taken to preserve confidentiality and maintain legal compliance. The chosen coordinator should understand the various mechanisms of skin injury, the surgical setting, and the investigative process. To ensure objectivity, no one who had primary responsibility for the patient before or after the injury should be included in the team. Also, the team must be careful to fairly represent different interpretations of the incident: what one person calls operator error may be interpreted by someone else as inadequate equipment design or a device failure [27].

It may be beneficial to deploy qualified, independent external investigators in some cases including experts in human factors and accident investigation in the healthcare setting [28]. For example, the hospital may lack the in-house expertise to investigate the incident; also, the potential for bias or concealment exists in any in-house investigation. External investigators can be helpful in exploring both technical and legal issues, especially when litigation is likely. External investigators are usually objective and cooperative, rather than defensive or adversarial. With in-house investigators, there may also be the risk of damaging long-term working relationships.

Identifying the Cause

When trying to ascertain the cause of any accident involving healthcare technology, instruments, devices, and systems, the investigation should consider the five broad categories listed below [13, 29]. Within each of these categories are listed the relevant subcategories that may need to be considered when investigating suspected perioperative device-related skin or tissue injuries or burns. To ensure thoroughness and accuracy, each of the factors and issues listed in Table 31.6 must be considered in any investigation.

It helps to remember that a patient may have specific physiologic sensitivities, abnormalities, or diseases. As such, a patient's suspected "burn" or tissue injury may ultimately be determined to be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of use and performance for that device. It may also be determined a technology was not at all involved.

Time is also a significant factor in starting an investigation. The longer it takes to mount and complete an investigation, the greater the probability that the cause will grow elusive as evidence is lost, memories dim, defensive rationalizations crystallize, and speculation clouds the process.

Table 31.6 Causal factors to consider in the investigation

Device factors	Device failure
	Design or labeling error
	Manufacturing error
	Packaging error
	Software deficiency
	Random component failure
	Failure of an accessory
	Device interactions
	Improper maintenance, testing, repair, or lack or failure of pre-use incoming inspection
	Improper modification
External factors	Power supply failure
	Medical gas/vacuum systems
	Electromagnetic or radiofrequency interference (EMI or RFI)
	Environmental conditions: temperature, humidity, light
	Water supply (especially temperature)
Tampering/ sabotage	Family member
	Patient
	Healthcare worker: doctor, nurse, aide
	Enemy
	Random act
	Supplier
Support system failure	Poor device evaluation during trial process
	Lack or failure of incoming and pre-use inspections
	Using inappropriate devices
	Improper storage
	Failure to train and credential
	Poor incident/recall reporting system
	Lack of competent accident investigation
	Failure to sequester incident devices
	Error in hospital policy
User or use error	Abuse of the device
	Accidental misconnections
	Improper ("bad quality") connection
	Device misassembly
	Failure to monitor
	Labeling ignored
	Inappropriate reliance on an automated feature
	Incorrect clinical use
	Incorrect control settings
	Maintenance or incoming inspection error
	Pre-use inspection not performed

The Investigation Format

A thorough investigation of accidental skin injury should include the following:

- Consideration of the incident report and collected evidence, such as photographs
- Collection of baseline patient and equipment information
- Documentation and assessment of the lesion's appearance and progression
- Inspection and testing of equipment used
- Interviews with involved personnel.

Before performing equipment inspections and interviews the investigation team should review and be familiar with the clinical and surgical

procedures and conditions surrounding the incident as well as understand the lesion's clinical appearance and collect the baseline information.

Lesion Assessment

Details about a lesion's clinical appearance and progression are important to determining its cause. A guide for collecting critical information about the lesion can be remembered by the mnemonic OPALSS—Onset, Progression, Appearance, Location, Shape, and Size. These six descriptive criteria are central to assessing the cause of a lesion and the potential involvement of a medical device. For example, pressure necrosis injuries (decubitus ulcers) from intraoperative pressure may show up several days after the insulting event, whereas electrosurgical burns are visible immediately at the end of surgery and do not suddenly appear days later.

The following list illustrates how the OPALSS criteria can be applied to obtain needed details about a lesion. The list is not intended to be all-inclusive, but rather to stimulate thinking during the investigation (Table 31.7).

Baseline Information

Baseline information should be collected from both the patient and the equipment as required for the investigation. Much of the patient baseline information will come from the patient's chart. Before conducting any interviews, the patient's chart should be thoroughly reviewed because it will indicate the hospital personnel most appropriate to be interviewed. The investigation team should make sure that equipment information is recorded for all devices involved in the incident, including disposables. For devices that are routinely inspected, the date of the "last" inspection and the "due" date must be recorded. If available, equipment inspection, preventive maintenance, and repair history records should also be reviewed.

Table 31.7 Criteria for lesion or skin injury assessment

Onset	When was the lesion discovered? Get the precise time and date
	When did surgery occur?
	How long was the patient immobile in the recovery room or intensive care unit after surgery?
	At what time was the last heat therapy device or heated product used on the patient and how long was it applied?
	Where was discovery made and by whom?
Progression	After discovery, did lesion get larger, deeper?
	Did blister(s) form? When?
	Did an eschar form?
Appearance	What did the lesion look like upon discovery and as it progressed?
	Note the color and texture of both the central area and the surrounding areas
Cation	Where was lesion on the body?
	Record the lesion location in relation to electrodes, high pressure areas of contact, positioning devices
	Is there a clearly definable electrical current path through the area of injury?
	Specify the validity of the alleged electrical current path in collaboration with engineering staff
Shape	Note the geometry of the lesion
	Are there patterns of devices or electrodes within the lesion?
	Does the shape correspond to heat therapy devices or electrodes?
Size	Measure the injury dimensions
	What is the area of the injury, including ALL affected tissue area (e.g., perimeter halos)?
	If there are multiple lesions, what is the combined area?

Lesion Assessment

Characteristics of the lesion itself are frequently the best indicators of its cause. They include the following:

- Time of lesion discovery in relation to the patient's surgery or application of a suspect device (the actual elapsed time is very important).

Lesions from thermal or electrical sources (e.g., ESUs) typically show up right away. Lesions due to chemical exposure or pressure necrosis will take longer to appear, often hours or days after a procedure.
- Shape and dimensions at the time of discovery.
- Color and texture at discovery.
- Location on the body and relation to placement of suspect devices.
- Injury depth estimation upon discovery (i.e., first, second, or third degree).

Changes in any of these characteristics should be noted as the injury progresses. Color photographs are the best way to document changes in the condition of the injury. The time, date, and scale should be recorded for each photograph. The use of the same lighting conditions should be maintained when taking photographs.

Equipment Inspection

After discovery of a suspected device-related skin or tissue injury, all equipment that may be involved, including disposables should be sequestered until it has been inspected. While rarely possible, due to the need for use of equipment and instruments that were obviously not involved in an accident, it may also be helpful to cordon off the operating room or physical location in which the adverse event happened to reduce change of contaminating the accident location and preventing advertent or inadvertent tampering. Most equipment can be immediately returned to service because it will be obvious that it played no role in the injury. However, no suspect device should be returned to service until it has been eliminated as a possible cause of patient injury.

The manufacturer should not be permitted to remove equipment or disposables from the hospital because the hospital then loses ready access to them. The hospital should not send such devices to their manufacturers or distributors, nor should vendors be permitted unwitnessed access to the devices for inspection or repair. In many cases, evidence that might protect the hospital is lost or compromised.

No one who ordinarily maintains suspect equipment should inspect it following an incident, as he or she may not recognize past errors or may even try to conceal them. If alternate technical personnel are not available, an outside, independent examination of equipment may be most effective. The manufacturer may want to witness equipment inspections, and it is usually in everyone's best interest that this be permitted. Inspections are best undertaken by the hospital's risk manager and clinical engineer, an outside investigator, and the manufacturer simultaneously. Consider videotaping these investigations to avoid further confusion and legal challenges.

Using the Investigation Questionnaire

The questionnaire in Appendix 1 is a guide for collecting information during interviews, as well as for summarizing baseline patient data and recording necessary details about each device involved in the investigation [13]. Although it is designed for skin injuries that occur in the OR, the questionnaire may also be used to investigate skin injuries that occur in the recovery room and special care areas or skin injuries noticed on any patient exposed to heating and illumination devices, tenacious tape or electrode adhesives, or prepping and degreasing agents. The completed questionnaire should be filed with the incident report and not with the patient's record. Most information can be recorded directly on the questionnaire form. Lengthy answers to questions and device identification details should be recorded on a separate sheet of paper with the numbers corresponding to the questions.

The questionnaire is divided into five main sections:

A. Baseline Patient Information
B. Baseline Equipment Information
C. The Surgical Procedure
D. The Injury
E. The Equipment

These sections are discussed below. Additional sections for the interviewer's and the interviewee's summary comments are also provided.

Instructions

- Record the baseline patient and equipment information (Lists A and B).
- Make a separate copy of the partially completed questionnaire for each person who is to be interviewed.

Note: Each person involved in the incident should be interviewed. Relevant questions should be directed to all appropriate people because multiple responses will help corroborate data on the time and sequence of events. Although it is unlikely that any one person will be able to answer all the questions, everyone can provide useful information based on his or her general observations and discussions with other personnel involved in the incident.

- Record the interviewee's answers to all relevant questions in Lists C through E.

Note: Most information can be recorded directly on the questionnaire form. If needed, lengthy answers to questions or device identification details can be recorded on a separate sheet of paper with the numbers corresponding to the questions. Be sure to record the interviewee's name and your name on all attached sheets.

- File the completed questionnaires with the incident report. The questionnaires should *not* be filed with the patient's record.

A. Baseline Patient

The need for baseline information is self-evident.

B. Equipment Information

Information about each involved device, including disposables, will also be needed for a thorough investigation to be conducted.

C. The Surgical Procedure

Patient surgical and medical records typically provide information that is only marginally useful in determining the cause of a device-related injury. The investigation team must interview all surgical, medical, and nursing staff involved in the procedure and postoperative care of the patient. It may also be necessary to question technicians and other personnel responsible for cleaning, sterilizing, inspecting, and maintaining the equipment and supplies used for the injured patient.

Investigators should pay special attention to information concerning any unusual occurrences during the procedure. For example, they should ask about occurrences such as those listed in Table 31.8.

Investigators must also determine how solutions, degreasers, and prepping agents were applied during the procedure. During routine surgery, there is usually enough time to apply these substances carefully. During emergency surgery, however, sometimes not enough care is taken and too much prepping agent is applied. This can result in pooling beneath the patient. After exposure for several hours to these substances, a sensitive patient may develop skin lesions. A patient may be sensitive to the prepping agent itself, and the application of heat from a hyperthermia blanket, for instance, may increase that sensitivity. Even the wetness alone can compromise skin tone and make it more susceptible to developing pressure necrosis.

D. The Injury

The anatomical drawing on the questionnaire enables interviewers to locate lesions in

Table 31.8 Unusual occurrences to ask about during interviews

Changes in device performance
Unattended devices
Peculiar sounds, monitor displays, smells, or alarms
Sudden changes in the patient's condition or physical position

relation to the incision site, dispersive electrosurgical electrodes ("grounding pads"), stimulation electrodes, ECG electrodes, and all associated cables. Any contact between the patient and metal (e.g., drape supports on the side of the operating table, mechanical supporting instruments such as retractors) should also be recorded.

Lesion patterns can help identify the causes. When an ESU is used, incomplete contact of an electrosurgical dispersive electrode with the patient may produce a lesion identical to a section of the electrode's perimeter. Or when a hypo/hyperthermia blanket is used, lesions that conform to the blanket's ridges or internal connectors may appear on the sacral areas, while no other area of the skin that was touching the blanket shows any injury. In such a case, the blanket was probably not hot enough to cause thermal injury from simple contact. As such a possible cause to consider is pressure necrosis (perhaps in combination with mild heat).

The investigation team should pay attention to when the injury was discovered and any subsequent changes. While a lesion on the patient's back or sacral area may have been discovered several hours postoperatively in the recovery room or intensive care area, it may have actually occurred in the OR, but was aggravated by the patient's position during postoperative care. The patient's treatment and medication and other comments regarding the progression and prognosis of the lesion should also be recorded.

As previously mentioned, determining the etiology of an injury may be aided by histological examination of skin or tissue pathology specimens [16, 19, 20]. Such specimens may have been taken during debridement. Pathology findings may be able to reveal whether the injury was caused by a disease, electrosurgical current, or thermal injury.

E. The Equipment

Following are discussions specific to the injury mechanisms from electrical, thermal, and radiation emitting surgical devices used during surgery. These technology-specific discussions will aid in determining whether the suspect device truly caused the patient injury.

Electrosurgical and Electrocautery Technology

Electrosurgery vs. Electrocautery: Untangling the Terminology

Electrosurgery and electrocautery are similar in that both apply electric current for therapeutic purposes, but they are distinct technologies with some fundamental differences. The most significant of these is that electrosurgery incorporates the patient as part of the electrical circuit, whereas electrocautery does not. Although staff may sometimes use the terms "electrosurgery" and "electrocautery" interchangeably, the terms are not synonymous, and the distinction between the two is important. For example, the use of the incorrect term can hinder efforts to investigate and address adverse surgical incidents.

Both technologies are inherently hazardous—they are intended to cut, coagulate, or destroy human tissue and can do so not only at the target operative site, but also in alternate sites if care is not taken during equipment and accessory setup and use. However, electrosurgical units are much more likely than electrocautery to cause injuries based on the physics of the technology [13, 30–38].

Electrosurgery is used for a wide variety of applications, from removing skin lesions to performing thoracic, abdominal, orthopedic, and brain surgery. The technology concentrates a high-density, radiofrequency electric current at the tip of an active electrode, enabling the active electrode to cut and/or coagulate tissue [39]. The therapeutic current for electrosurgery is generated by an ESU and then conducted through a completed electrical circuit that comprises the following: the ESU itself, insulated cables, an active electrode (which delivers the electrosurgical current to the target tissue), the patient, and one or more dispersive return electrodes (which collect

the current from the patient and return it to the ESU). The dispersive return electrode is frequently called by the colloquial term of "grounding pad," although they are no longer grounded with modern ESUs. Thus, the current generated by the ESU passes through the patient's body. ESUs operate only on AC line power.

Electrocautery is typically used for minor surgical procedures in dermatology, ophthalmology, and gynecology. The technology uses electric current to heat a high-resistance wire or scalpel blade at the tip of the electrode. However, unlike with electrosurgery, the technology does not pass current through the patient's body. Electrocautery units, which are available in reusable or disposable versions, can operate either with DC (i.e., battery) or AC line power.

Electrosurgical Units (ESUs) and Accessories: Overview

Information obtained from interviews about the performance and control settings of the ESU, its electrodes, and cables should be compared with the results from equipment inspections. If the ESU unit itself meets proper performance specifications (e.g., the manufacturer's), it can be returned to service. In most cases of skin injury involving ESUs, the cause of the injury is related to the electrodes, cables, or other accessories, rather than improper functioning of the unit itself. Insufficient contact, improper electrode placement or size, an inadequate amount of gel, pressure on the pad, or a defective electrode can contribute to lesions beneath the dispersive electrode. Defective cables and connectors may cause electrosurgical currents to seek alternate return pathways through the patient, resulting in injuries at locations other than the incision or return electrode sites.

The type of ESU can be a factor in the cause of alternate-site burns. Typically, ground-referenced ESUs will more likely be associated with an alternate-site burn than isolated-output units, although very few units of such design are in use in North America. However, the investigator should be aware that isolation can fail and that, under certain operating conditions (e.g., open-circuit activation), a properly operating isolated-output unit could cause an alternate-site burn from current originating at the return electrode. Alternate-site burns have been reported with the use of needle electrodes used for EEG or ECG monitoring and at the site of an esophageal temperature probe [40, 41]. The current pathway for alternate-site burns can be complicated to determine: outside assistance is frequently needed in reviewing such cases.

Poor electrical continuity in either the return electrode or cables usually results in a request by the surgeon for more power (higher dial settings) because the desired surgical effect is not achieved. However, increasing the power setting under conditions of poor continuity usually does not result in the expected increase in ESU performance, and the surgeon may again request more power. Staff education and the use of a return electrode contact-quality monitor can minimize the risk of injury from a partially detached return electrode.

If a lesion is found beneath the electrosurgical dispersive electrode, surgical personnel should inspect the electrode immediately for discoloration, obvious damage, wetness of the gel, evidence of contact with fluids, and those other characteristics listed in the questionnaire. Comparison with a new electrode is helpful in determining subtle differences in the suspect electrode. The investigator should also observe whether the entire conductive or capacitively coupled surface had been in contact with the patient's skin. It should also be noted whether straps were placed over the electrode or whether a member of the surgical team leaned on it or stepped on its cable and caused partial dislodgment. Pressure on a disposable return electrode or partial dislodgment may cause localized high current densities, which can cause burns. Later inspections should be performed to determine if there are any discontinuities or separations of the connector and/or of the conductive substrate (usually made of foil) or whether a part of the electrode is missing.

Hand-switched active electrodes ("pencils"), both disposable and reusable, must also be inspected. A defective switching mechanism of a hand-switched active electrode can cause inadvertent activation of the ESU and result in burns. Insulation failure can also cause a burn where the

section of the electrode with missing or poor insulation contacted the patient. Determining where the active electrode was placed between uses is essential to discover the mechanism of injury. Injury from inadvertent activation would be more likely if the electrode was not placed in a well-insulated safety holster.

Burns at the dispersive return electrode site have historically been related to due to poor electrode site preparation or pad dislodgement [33, 42, 43]. More recently, the increased use of electrosurgical devices and techniques that apply high currents to the patient for long periods of time has led to an increased risk of skin burns at the return-electrode site [44–47]. To protect patients, clinicians and other personnel need to be alert to the situations that are most likely to lead to such injuries during surgical procedures that may demand greater activation times of the ESU. Patient injuries have resulted from damage to active electrosurgical instruments and chords [43] as well as from performance or design limitations of specific makes and models of electrosurgical active electrodes [48–50].

Misconnecting a bipolar electrosurgical forceps to the monopolar sockets has caused inadvertent activation of the ESU and burns to non-target tissues [51]. The plugs for many third-party bipolar forceps can be readily plugged into the monopolar sockets. More recently, dedicated molded plug designs on bipolar electrodes prevent such misconnection.

The Clinical Knowledge Base About Electrosurgery

Surgeons are typically *expert users* of electrosurgical technologies, but may have much less understanding about how it actually works, how it can cause accidental skin or internal organ injury, or how to investigate an injury suspected of having been caused by electrosurgery. Recently published research has shown that surgeons, regardless of their years of experience, have knowledge gaps regarding the safe use and effective use of electrosurgical technology [6, 52]. Of note in the attempts to address the knowledge gaps related to surgical patient safety and the use of energy emitting medical devices the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has created an educational initiative called the Fundamental Use of Surgical Energy (FUSE) program (www.fuseprogram.org) [52]. The FUSE program was established to ensure that surgeons and others in the perioperative setting who handle energy-based devices have a more comprehensive understanding of how to use them safely. It focuses on providing education about devices that apply energy to tissues in many different ways, including electric current at radiofrequency wavelength (e.g., electrosurgery), ultrasonic energy, and microwave-based, water jet-based, and plasma-based energy. The program is designed to certify that successful candidate licensed physicians, nurses, and surgical technicians have demonstrated knowledge fundamental to the safe use of surgical energy-based devices in the operating room, endoscopic suite, and other procedural areas.

The FUSE program attempts to bridge a gap in patient safety as it relates to best practice in the use of surgical and endoscopic energy devices by addressing the most common types of energy emitting devices, their impact on surgical fire prevention, the safety of implantable electronic devices, and safe use of such devices within the operative field.

Nerve Monitoring Units and Electrosurgery

Burns from electrosurgical current interacting with nerve monitoring equipment may result in skin or tissue injuries. Needle electrodes used with such monitors have a very small surface area and, therefore, a potentially high current concentration if electrosurgical current passes through them. One manufacturer, Medtronic, provides the warnings on their website to prevent such injuries [8]. For example, warnings for the Medtronic NIM 3.0 nerve monitor the websites state that:

"To avoid patient burns:

- Do not activate the electrosurgical instruments while stimulator is in contact with tissue.

- Do not leave stimulating electrodes or probes in surgical field.
- Do not store stimulating electrodes or probes in electrosurgical instrument holder.
- Do not allow a second surgeon to use electrosurgical instruments while stimulator is in use."

Direct Current Injury

Low voltage (3–14 V) of direct current (DC) can cause surprisingly serious lesions to the patient if the offending current is in contact with the skin or tissue for sufficient time [53]. An application of DC to the tissues results in an electrochemical lesion due to electrolysis. The errant DC may come from overly aggressive application of the therapeutic current levels, a device malfunction, or from interaction with another technology. Nerve stimulators/locators and nerve monitors, as well as at least one pacemaker, have been associated with such lesions [54–58]. The investigation of a suspected DC lesion must consider interactions between the suspect DC device and electrosurgical equipment. Testing to determine if a device is performing according to specification is typically insufficient to assess the potential involvement of a device in the cause of an injury.

Pulse oximeters have been reported to cause a DC burn due to exposed conductors in the sensor [59]. Disposable adhesive oximeter sensors are potentially more prone to damage during use such that the conductors can become exposed. The conductors carry DC and contact the skin directly. The long duration of application of pulse oximeter probes on the patient sensing site (e.g., finger, ear lobe, foot, toe) can result in an electrochemical DC burn despite the low DC current levels present.

Handling Electrodes During Investigations

Care should be taken when handling electrodes (e.g., electrosurgical, nerve stimulation, and EEG electrodes) used during a procedure in which an injury may have been sustained. Suspect electrodes with adhesive borders or conductive adhesive should not be folded over on themselves. Rather, they should be applied to a nonstick material, such as the backing material with which the electrode was packaged. If necessary, a new electrode can be opened and its nonstick backing can be applied to the suspect electrode. Doing so will help prevent the electrode from drying out and makes subsequent testing easier and more likely to produce useful results.

Endoscopes and Laparoscopes

Endoscopes, laparoscopes and their accessories, trocars and sleeves are frequently used in combination with electrosurgery and have the potential to be a pathway for stray electrosurgical currents to cause injury to internal organs [34, 44, 60, 61]. The investigation team should be familiar with the basics of the safe use of laparoscopes and their instruments, as well as any special connectors that are required, before investigating an incident in which these devices were involved. Errors made in the setup and operation of endoscopes and their accessories may not be evident when the equipment is examined later. However, deficiencies in their insulation may be revealed during an inspection. Endoscopes are exposed to repeated sterilization by steam or EtO or by cold sterilizing or disinfecting chemicals. This exposure can result in insulation breakdown on the active electrode or on components of the endoscope itself. If this type of deterioration is observed, the possibility of alternate electrosurgical current pathways as a cause of the injury should be considered. Under certain conditions, internal burns can occur without observable damage to insulation. The risks of patient injury resulting from capacitive coupling of electrosurgical energy to endoscopic accessories should be thoroughly understood by the investigators.

Thermal Injuries

Experimental research into the temperature and duration of application of heat to cause cutaneous burns in humans from contact or a radiant heat source has been published in only a few studies

[22, 23, 62–65]. Since human physiology and the pathophysiology of burned skin has not changed, these seminal studies remain valid for assessing the time and temperature required to cause a thermal injury from contact with a hot object or heating from an irradiant source. Investigators of a perioperative injury suspected of being thermal in origin are directed to these references to gain a functional understanding of the time and temperature relationships that may impact on determining whether a specific surgical device may have been hot enough for long enough to cause a thermal injury.

Hypo/Hyperthermia Units

Hyperthermia Pads

In most cases of intraoperative skin injury attributed to hyperthermia warming blankets, the unit proves to be operating properly: other causative mechanisms must then be considered (e.g., pressure necrosis) or misuse [17, 24, 66]. With both of these devices, it is important to inspect the units in all possible operating modes, both with and without the actual temperature probe used on the patient plugged into the machine. Primary and redundant thermostat failure, misadjustment, or faulty calibration may not be discovered except under very specific, abnormal operating conditions.

In addition to general information on the use of the equipment, the investigation team should review cleaning and sterilization procedures for the hypo/hyperthermia blanket if it was reusable. Latent cleaning and disinfecting chemicals may be the cause of what appears to be a thermal burn. Also reviewed should be the placement of the temperature probe on the patient. Manipulation or repositioning of the patient after insertion or placement of the temperature probe (rectal, esophageal, or skin) can dislodge the probe. Depending on the operating mode, this may cause a hypo/hyperthermia unit to heat even though it was set to cool the patient.

Hypothermia Pads

Cooling patients during surgery to slow body and especially brain metabolism, such as during surgeries involving cardiopulmonary bypass, involves withdrawing energy from the patient. If the investigation of a postoperative skin lesion on a patient's back, for example, finds that the machine is performing to specification, systemic physiologic conditions or diseases need to be considered as the cause, but as they may be related to the cool temperatures applied to the skin. An initial perspective may be that the patient suffered frostbite, which occurs from freezing of the skin. However, human skin does not freeze until at least 30.7 °F (–0.53 °C), which is below the freezing point of water at 32 °F (0 °C) [67]. Further, the hypothermia cooling pads cannot deliver water at that freezing temperature: they operate by circulating chilled water through a blanket at a temperature of approximately 36 °F (3 °C). Nevertheless, at the temperatures around 36 °F (3 °C), skin lesions can occur from condition of cryoglobulinemia [17, 24]—a reaction to systemic infections that released cryolobulin into the blood stream—wherein the cold compromises venous blood flow by solidifying the cryolobulin at leading to venous stasis lesions. Cryoglobulin precipitates at 50 °F (10 °C). Similarly, patients with pernio [17, 24], an inflammatory skin condition presenting after exposure to cold that can lead to skin lesions, may present postoperatively with lesions that mirror the geometry of the cooling pad.

Forced Air Hyperthermia Blankets

Patient burns have occurred from use of forced air warming blanket systems [68–70]. Although these systems are intended for surgical use, incorrect use can cause the heated air delivered to the table and the blanket to be inadequately distributed resulting in localized heating to the extent of causing burns to the surgical patient. Specifically, using the units by placing the hose under the surgical drapes without using the associated air distribution blanket can cause injury [68].

Phacoemulsifiers

Scleral and corneal burns have been reported during phacoemulsification—a delicate and complex surgical ophthalmic procedure performed to remove cataracts. During extended use of the probe, the rapid oscillation of the ultrasonic probe tip and the friction generated can cause excessive heating. The thermal injuries can occur at the location where the probe entered the eye and are caused by overheating of the probe tip. Such injuries are less common today, but the potential is still present. The cause of the heating is multifaceted, relating primarily to insufficient irrigation and aspiration flow, the use of more aggressive techniques, and the use of smaller incisions and smaller diameter probe tips [71].

Pulse Oximeters

Thermal burns and other skin injuries have been associated with the use of pulse oximeters, which are used during most surgical procedures (i.e., during electrosurgery) [59, 72]. Pulse oximeter probes have provided alternate path—ways for electrosurgical currents. Also, skin injuries have occurred at pulse oximeter probe sites from pressure necrosis, and mismatching of pulse oximeter probes and monitors has resulted in excessive heating of the probe LEDs. Burns involving the leads from pulse oximeters have also occurred during MRI procedures [72–74]. If pulse oximeter involvement is suspected, carefully inspect the probe and its cabling, note the location of the probe and how the cable was draped, and note whether the probe site was changed during the procedure. Because pulse oximeter and probe compatibility is a potential cause of injury, note whether the probe was used with the appropriate pulse oximeter monitor and compatible cable.

Irradiant and Other Heat Sources

A variety of surgical technologies have resulted in perioperative thermal burn injuries, including those listed in Table 31.9.

Table 31.9 Surgical technologies that have caused thermal burns during surgery

High intensity surgical light sources, including fiberoptics [75–80]
Hot surgical instruments due to flash sterilization [62, 81–83]
Laryngoscope bulbs [84] or heating from battery failure [84]
Overhead surgical lights [85]
Infant radiant warmers [86]
Surgical drills [87, 88]
Surgical microscopes [79]
Transilluminators [89, 90]
Bags of solution or irrigation fluids from solution warming cabinets [91–94]
Blankets from blanket warming cabinets [92–95].

Of these, infant radiant warmers and warming cabinets are discussed in greater detail below

Radiant Warmers

Surgery on neonates is being performed more frequently in the neonatal intensive care unit with the patient in the infant radiant warmer bassinet. These procedures include, among others, repair of patent ductus arteriosus and pyloric stenosis, and virtually all of which involve the use of electrosurgery. Neonatal skin is highly vulnerable to heat and a postoperative skin lesion on a neonate may be suspected of having been caused by the ESU or the radiant warmer. Lesions resulting from exposure to radiant warmers are commonly caused by operator error, device malfunction, or poor device design [86]. As with hyperthermia pads, a dislodged probe on a radiant warmer can cause it to constantly heat, even if it was set to cycle on and off. Differentiating between ESU versus radiant heat as the cause of the injury especially requires defining the onset, progression, appearance, location, shape, and size of the lesion as described earlier.

Blanket and Solution Warming Cabinets

Burns have occurred to surgical patients from overheated blankets removed from warming cabinets set to excessive temperatures, as well from

heated solution bags used as positioning aids. The ECRI Institute recommends that temperature settings on blanket warming cabinets be limited to 130 °F (54 °C) and that solution warming cabinets be limited to 110 °F [92–95]. Warming cabinets are used to heat blankets and solutions (e.g., for surgical irrigation and intravenous infusions) for patient comfort. Warmed blankets are often placed on patients to make them feel more comfortable in cool ambient temperatures or when sedation or anesthesia has disturbed the body's thermal regulation. Warmed solutions are used to prevent hypothermia caused by infusion of lower-temperature liquids into a patient's body. Most warming cabinets have separate compartments and temperature settings for blankets and solutions. In response to customer demands, suppliers have designed some cabinets so that they can be set to a wide range of temperatures. Unfortunately, this allows the cabinets to heat blankets and solutions to temperatures that can cause contact burns to patients' skin.

Surgical patients have received burns during surgery because warmed blankets or solutions were too hot. Such thermal injuries typically occur with patients who are unconscious or who have been given regional (e.g., spinal) anesthesia and are therefore insensate to temperature. Most incidents have involved solution containers (e.g., IV bags) that have been heated to unsafe temperatures and then used inappropriately as positioning aids during surgery or as "hot water bottles" to provide local heat. In other incidents, overheated solutions have been used for surgical irrigation, causing severe internal injury. Also, blankets that have been excessively heated and placed on or under the patient have caused burns; in some cases, the blankets were folded in layers.

Fluoroscopy

The use of interventional radiological imaging has been reported to cause radiation burns [20, 96, 97]. Investigators of suspected perioperative radiation burns are advised to seek assistance in their inquires from medical radiation physicists, in addition to reviewing the citations provided. Many of these lesions appear similar to conventional radiation injuries and require expert support to manage the acute and potentially lasting injuries to tissue [98].

MR Imaging

Patient burns during MR imaging, along with recommendations for preventing them, have been reported for many years [72–74, 99–104]. Perioperative MR imaging is a growing field. Although burns in this setting have yet to be reported, investigators should be cognizant of the possibility.

Thermal Injury from Surgical Fires

The risk of a fire on or within a surgical patient continues to be present in modern surgery [5, 10, 14, 75, 78, 105–129]. Surgical fires were ranked among the top ten health technology hazards from 2007–2012 by the ECRI Institute [130–136]. Fires can result in severely disfiguring or fatal skin, tissue, or lung injuries—*and* take an emotional toll on surgical team members. The current recommendations in the perioperative setting make virtually all surgical fires preventable. Unfortunately, the sensitivity of surgical, anesthesia, and operating room (OR) nursing staff members to these fire hazards has waned since the cessation of the use of flammable anesthetic agents in the late 1970s [5, 11, 20, 118, 137]. It is encouraging, however, that during the last ten years, the surgical, anesthesia, and nursing communities have experienced the beginnings of a resurgence in the awareness of this continuing risk as well as an understanding of the need for a surgical team approach to the prevention of surgical fires. Preventive measures to minimize the risk of a surgical fire have existed for decades, but only in recent years have they begun to diffuse across professional boundaries and to be put into wider practice.

Aiding in this diffusion have been initiatives by a variety of medical professional societies and health care organizations including the American College of Surgeons [10, 105], the American Society of Anesthesiologists [10, 135], the Anesthesia Patient Safety Foundation [10, 138], the Association of periOperative Registered Nurses [9, 108, 125, 128, 129, 135, 139, 140], the Pennsylvania Patient Safety Authority [120–122], and The Joint Commission [110, 127] which now hosts the surgical fire prevention and education Internet resources compiled by the US Food and Drug Administration (FDA) between 2011 and June 2015.

Fire requires three things: The principal contributing factor to surgical fires has historically been the use of open oxygen supplied at 100 % concentration from an anesthesia machine or wall oxygen outlet to a disposable mask or nasal cannula on the face during surgery of the head, neck, and upper chest with monitored anesthesia care [4, 10, 14, 24, 75, 108, 137, 139]. Oxygen-enriched atmospheres account for approximately 70 % of surgical fires [75, 114] with oxygen enrichment as a major contributing factor to surgical fires [105, 119, 126, 141]. Administration of supplemental oxygen has typically been performed without consideration of the true need of the patient for such a high concentration. Enrichment of the facial hair, including the fine vellus hair on the face, nose, cheeks, and forehead of both men and women, and of the surgical towels and drapes results in an easily ignitable condition. Alcohol-based surgical skin prep have had a resurgence in use over the past 20 years and have also contributed to the incidence of surgical fires [75, 114, 122, 142, 143].

The estimated number of surgical fires has ranged from 550 to 650 per year in 2007 [75, 139] to a more recent estimate incidence of 200–240 [113] based on this chapter's author's scaling of newer data from the Pennsylvania Patient Safety Authority [109] to the US population. ECRI receives reports from healthcare institutions and other sources on about 100 fires per year in the USA, but it cites the Pennsylvania data as being the most accurate estimate of the incidence of surgical fires currently available. About 70 % of surgical fires involve electrosurgical equipment as the ignition source with another 10 % involving surgical lasers [75]. A variety of other ignition sources account for the remainder of fires, including:

- Electrocautery (hot wire cauterization), either battery operated or line powered
- Fiberoptic light sources
- High-speed burs (which can produce sparks), but only if an oxygen-enriched atmosphere is present.

Most laser ignited fires occur during tracheal or bronchoscopic surgery where the beam or laser fiber is in extremely close proximity to the endotracheal tube or bronchoscope when fired [123, 124]. Laser safe, ignition resistant endotracheal tubes are available, but must be selected specifically for the wavelength of the laser being used. However, the bronchoscopes are not protected against ignition—if the laser is fired while inside the scope or if the energy strikes the outside of the scope it can ignite, especially if there is oxygen enrichment present in the pulmonary tree.

Over the past decade, refined recommended techniques for prevention of surgical fires have been begun to change practice and are freely available on the Internet, including posters, and videos [10, 75, 107, 120, 138]. Appendix 2 reproduces the free posters from ECRI Institute that summarize the still current recommendations for minimizing the potential for a surgical fire and for extinguishing a surgical fire burning on or in a patient [144–146].

The key points promoted in these initiatives include a major change in the recommendations regarding the control of oxygen delivery during surgery of the head, face, neck, and upper chest [10, 75, 107, 138]. This recommendation, with certain limited exceptions, is

that the traditional practice of open delivery of 100 % oxygen should be discontinued for these surgeries. If supplemental oxygen is needed to maintain the patient's blood oxygen saturation, the airway should be secured through intubation or the use of a laryngeal mask airway to prevent oxygen-enriched gases from venting under the surgical drapes. The need to assess the range of human factors [147] that contribute to surgical fire risks as a component of the preoperative "time-out" is an innovative addition to the present standard [10, 75, 109, 138]. Tools for assessing the surgical fire risks during the "time-out" were first published in 2006 [148] and are available at www.christianacare.org/FireRiskAssessment.

Summary

The hazard of electrical, thermal (including surgical fires), and radiation related perioperative skin and tissue injuries to patients continue to present risks of injury to patients. Care must be taken by clinical staff to understand the mechanisms of potential injury from the healthcare technologies they use in surgery, including understanding the warnings and precautions presented in the user manuals. Following careful forensic guidelines for conducting an effective investigation of a patient injury will help ensure effective determination of the etiology of the injury, appropriate treatment, and help develop preventive recommendations.

Perioperative injuries that are suspected of having been caused by a medical device and its related energy may *not* be related to a technology: consideration of all possible device and/or solution interactions is essential. In many cases, the injury may be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of device use and performance.

While it is easy to assume that a certain medical device caused the injury simply because it was used, such assumptions are often incorrect and may preclude considerations of other possibilities. Hasty conclusions that a device or operator was at fault may bias the investigation, cause ineffective treatment of the injury, delay development of effective preventive recommendations, mislead the patient into bringing suit, and unjustly impugn personnel, equipment, service organizations, or manufacturers.

Development of effective preventive recommendations is promoted and surgical patient safety enhanced when all possibilities of an injury are explored and everyone involved in the incident has provided input to the investigation.

Appendix 1: Questionnaire for Investigating Accidental Perioperative Skin or Tissue Injury [51]

Page ___ of ___

Accidental Skin Injury Investigation Questionnaire

Date of Interview: _____

Interviewee:

Name _____

Title/department _____

Job function during incident _____

Interviewer:

Name _____

Department _____

A. Baseline Patient Information

1. Name _____
2. Hospital ID No. _____
3. Sex _____
4. Age _____
5. Race _____
6. Skin color and skin description (e.g., mottled)

_____

_____

_____

7. Weight _____
8. Diagnosis _____

_____

_____

9. Known allergies _____

_____

10. Known circulatory problems _____

_____

Instructions

Record the baseline patient information (Section A) and baseline equipment information (Section B). Note that Section B will need to be completed for each involved device, including disposables; thus, it may be necessary to make multiple copies of that page.

Make a separate copy of the partially completed questionnaire for each person who is to be interviewed.

Record the answers to all relevant questions in the remaining sections. Attach additional sheets, if needed; be sure to record the interviewee's name and your name on all attached sheets.

File the completed questionnaires with the incident report. The questionnaires should not be filed with the patient's record.

Source. This form was developed by ECRI. A detailed discussion of how to use this questionnaire is included in the December 2005 issue of ECRI's monthly journal *Health Devices.* ◆

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

B. Baseline Equipment Information

Copy this page and record the following information for each involved device (including disposables). Attach all completed copies to the questionnaire.

Device ___ of ___

1. Device type _____
2. Manufacturer _____
3. Model _____
4. Serial and/or Lot No. _____
5. Hospital Equipment Control No. _____
6. Expiration date or "use before" date _____
   _____
7. "Last" and "due" inspection dates _____
   _____
8. Any outstanding recalls or Action Items regarding this device* _____
   _____
9. If reusable, method of sterilization or cleaning _____
10. For endoscopes and endoscopic instruments, also record the following:
    a. Generic type (e.g., laparoscope or laparoscopic forceps, resectoscope, colonoscope) _____
    b. Endoscope type
       i. Operating or diagnostic (circle one)
       ii. Direct viewing or video (circle one or both)
    c. Trocar sleeve type—metal, plastic, other _____
       _____
    d. Light source and fiberoptic cable used _____
       _____
    e. Special connectors or adapters _____
       _____

Device ___ of ___

1. Device type _____
2. Manufacturer _____
3. Model _____
4. Serial and/or Lot No. _____
5. Hospital Equipment Control No. _____
6. Expiration date or "use before" date _____
   _____
7. "Last" and "due" inspection dates _____
   _____
8. Any outstanding recalls or Action Items regarding this device* _____
   _____
9. If reusable, method of sterilization or cleaning _____
10. For endoscopes and endoscopic instruments, also record the following:
    a. Generic type (e.g., laparoscope or laparoscopic forceps, resectoscope, colonoscope) _____
    b. Endoscope type
       i. Operating or diagnostic (circle one)
       ii. Direct viewing or video (circle one or both)
    c. Trocar sleeve type—metal, plastic, other _____
       _____
    d. Light source and fiberoptic cable used _____
       _____
    e. Special connectors or adapters _____
       _____

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

C. The Surgical Procedure

1. Procedure _____
2. Date performed and OR No. _____
3. Time duration _____
4. How many procedures of this type are performed per month? _____
5. Was this an elective or emergency procedure? _____
   _____
6. Who was present during the procedure? _____
   _____
7. Who performed the following tasks? When?
   a. Applied degreasing and prepping agents _____
   b. Applied ESU dispersive electrode _____
   c. Applied surgical drapes _____
   d. Inserted hypo/hyperthermia temperature probe _____
   e. Set up ESU and connected cables _____
   f. Set up endoscope and accessories _____
   g. Applied any other electrodes, temperature probes, etc. _____
8. Was a skin check performed before the procedure? By whom? Results? _____
   _____
9. Was the patient wearing jewelry or any other items during the procedure? _____
10. What degreasers, prepping agents, and ointments were used? _____
    _____
11. How were they applied to the patient? Were they poured onto the skin? _____
    _____
12. Was there pooling of fluids beneath the patient? _____
13. Were prepping agents dry before draping? _____
14. What was the patient's initial position on the operating table? For how long? _____
    _____
15. In what position(s) was the patient placed for surgery? For recovery? _____
    _____
16. Were any changes made in the patient's position during surgery? Describe. _____
    _____

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

17. What types of restraint straps or positioning pads were used to position the patient? Describe their location. _____

_____

18. What, if anything, occurred during the procedure that was out of the ordinary? Any alarms or unusual noises?

_____

_____

19. How well does the user understand the equipment controls, functions, and safety features? _____

_____

D. The Injury

1. Mark on the anatomical drawing the position and shape of the following items:

   a. Skin injuries

   b. ESU dispersive electrode

   c. ECG electrodes and cables

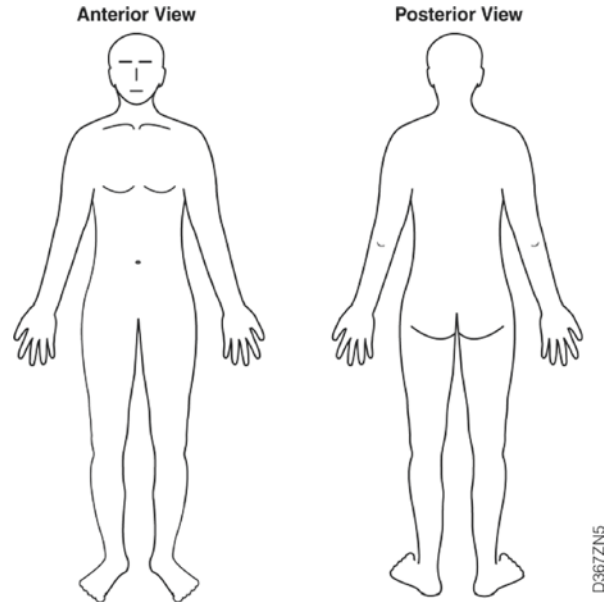
   d. Extent of prepping

   e. Incision (or site of active electrode)

   f. Restraint straps

   g. Patient/metal contacts

   h. Conductive masks and tubing



2. When and where was the lesion noticed (e.g., during surgery, postop, or recovery; in the patient's room)? By whom? _____

_____

_____

_____

3. Did the lesion correspond to the position of an electrode, a cable, or patient/metal contacts?_____

_____

4. Does the patient have any metal implants (e.g., hip, knee)? _____

5. Sketch the shape of the lesion in the space provided.

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

6. Give the dimensions. _____
7. Extent: Full or partial thickness? First degree? Second? Third? _____
8. Describe lesion tissue color, texture, size, and location when first noticed and as healing progressed. _____
   _____
9. Were photographs taken? Record the dates and times, and note the scale. _____
   _____
10. Were skin or tissue specimens from the injury retained? Pathology findings? _____
    _____
    _____
11. Describe the treatment and medication applied to the injury. _____
    _____
    _____
12. Did infection of the lesion occur? How soon? _____
    _____
13. Comments by patient regarding the level of pain at the injury site. _____
    _____

E. The Equipment

1. Sketch the positions of equipment, cables, and leads relative to the patient. Do this for operative, recovery room, and general care settings, as appropriate. Use separate sheets if needed, and attach them to the questionnaire. If known, indicate where equipment was plugged in and the relative distance from the patient and other equipment.

2. Describe the condition of all cables, leads, and connectors. _____
   _____
   _____
3. Document all switch, control, and indicator settings on all devices used. Were these settings typical for the procedure? _____
   _____
4. If a device that was EtO sterilized was touching the lesion, how was the device aerated? _____
   _____
5. Who had contact with the suspect equipment after the incident? _____
   _____
6. Were any inspections or repairs performed? Results? _____
   _____

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

7. Have there been any recent malfunctions of devices used in this procedure or similar procedures? Does the injury possibly relate to device malfunctions recently experienced? Were there any malfunctions during the procedure? (Review equipment service records for possible information.) _____
   _____
   _____
8. Was the packaging from suspect disposables saved? _____
9. **Electrosurgery**
   a. Determine the following:
      i. What was the mode of operation (cut, coag, blend, bipolar)? _____
      ii. What were the control settings for each mode? _____
      _____
      iii. What electrode adapters were used? _____
      _____
      iv. Does the ESU have a ground-referenced or isolated output? _____
      v. Does the ESU have a return-electrode contact-quality monitor (e.g., return electrode monitor)? If so, was it used? _____
      _____
   b. Was the condition of the ESU cables and connectors checked before surgery? _____
   c. Was electrosurgery effective at normal settings? _____
   d. Were ESU settings changed during the procedure? To what? When? Why? By whom? _____
   _____
   e. Describe the condition of dispersive and active ESU electrodes after the procedure. Discolored? Charred? Evidence of fluid contact? _____
   _____
10. **ESU Dispersive Electrode**
   a. Describe the gel condition before and after use. Dry to touch? Viscous or runny? Color? Odor? _____
   _____
   b. When was the dispersive electrode package opened? _____
   c. At the time of removal, was the entire electrode surface in contact with the patient? _____
   _____
   d. Were there separations or discontinuities in the foil substrate? _____
   _____
   e. Was the electrode checked for proper placement after patient repositioning or checked at any other time during the procedure? _____
   _____
   f. Did anyone lean on the dispersive electrode or put tension on the associated cable during the procedure? _____
   _____
   g. If injury occurred beneath the dispersive electrode, was the electrode saved? _____

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

11. **ESU Active Electrode**
    a. Where was the active electrode placed when not in use during the procedure? Was it placed in a safety holster? _____
    _____
    b. Was the active cable draped next to any other cables, leads, or conductive tubing or across the patient? Was it clamped to the drapes? How? _____
    _____
12. **Hypo/Hyperthermia Units and Radiant Warmers**
    a. Record the following:
        i. Placement of temperature probes (rectal, esophageal, skin) _____
        _____
        ii. Times unit was turned on and off _____
        _____
        iii. Set temperatures and times _____
        _____
        iv. Mode of operation (manual, automatic, warm-up) _____
    b. Was the temperature of the unit routinely checked? How? Results? _____
    _____
    c. Was the patient's temperature routinely checked? How? Results? _____
    _____
    d. Describe the cleaning/sterilization procedure for the hypo/hyperthermia blanket. _____
    _____
13. **Blanket and Solution Warming Cabinets**
    a. Were blankets that were warmed in a warming cabinet placed on the patient? Where were they placed? ____
    _____
    b. Were irrigation solution bags taken from a warming cabinet and placed on or under the patient? Where were they placed? _____
    _____
    c. What was the set temperature on the warming cabinet for both the blanket and the solution chambers? Was it above 110°F? _____
14. **Endoscopes and Accessories**
    a. Is there visible damage to or deterioration of the insulation of the electrosurgical handpiece? _____
    _____
    b. Describe the method of cleaning and sterilization of the endoscope and its accessories. _____
    _____
    c. Is the fiberoptic cable appropriately matched to the light source? _____
    d. Are there damaged fibers within the fiberoptic cable? _____
    e. Was the fiberoptic cable or endoscope removed while the light source was still powered on? _____
    _____
    f. Note the placement of the light source and fiberoptic cable in relation to the patient. _____
    _____

Investigation Questionnaire: Accidental Skin Injury **Page ___ of ___**

15. **Pulse Oximeters**
    a. Describe the condition of the pulse oximeter probe and cable. _____
    _____
    b. Was the probe used with the correct pulse oximeter? _____
    c. Was the probe moved during the procedure? _____
16. **Other Equipment**
    a. Could other equipment have contributed to the problem? Describe. _____
    _____
    b. Were difficulties experienced with other devices used? Describe. _____
    _____

F. Summary (Interviewee)

1. Other comments?

_____
_____
_____
_____
_____

2. Given your observations, how do you think the injury occurred?

_____
_____
_____
_____
_____

G. Summary (Interviewer)

1. Highlight salient points gained from the interview.

_____
_____
_____
_____
_____
_____
_____
_____
_____

Note: *For a detailed discussion of how to use this questionnaire*, *refer to the text in Chap. 19 above*.

Do not file the completed questionnaires with the patient's medical records.

When beginning the investigation of a perioperative skin or tissue injury, record the baseline patient and equipment information first. Then, copy the partially completed questionnaire, and record answers to the remaining questions during each interview. Complete one questionnaire for each person interviewed. If needed, attach additional sheets to answer questions. Be sure to record the interviewee's name and your name on all attached sheets.

To ensure objectivity, no one who had primary responsibility for the patient before or after the injury should be included on the team investigating the incident, but they may well contribute to the investigation during the interview process. Similarly, engineering or other staff who had responsibility for the most recent performance inspection, repair, or calibration of the medical devices suspected of having been involved in the cause of the injury should not be included on the team.

Appendix 2: Posters—Preventing Surgical Fires and Extinguishing Fires Burning On or In a Patient [41, 42]

ONLY *YOU* CAN PREVENT SURGICAL FIRES

Surgical Team Communication Is Essential

The applicability of these recommendations must be considered individually for each patient.

At the Start of Each Surgery:

- Enriched O_2 and N_2O atmospheres can vastly increase flammability of drapes, plastics, and hair. Be aware of possible O_2 enrichment under the drapes near the surgical site and in the fenestration, especially during head/face/neck/upper-chest surgery.
- Do not apply drapes until all flammable preps have fully dried; soak up spilled or pooled agent.
- Fiberoptic light sources can start fires: Complete all cable connections before activating the source. Place the source in standby mode when disconnecting cables.
- Moisten sponges to make them ignition resistant in oropharyngeal and pulmonary surgery.

During Head, Face, Neck, and Upper-Chest Surgery:

- Use only air for open delivery to the face if the patient can maintain a safe blood O_2 saturation without supplemental O_2.
- If the patient cannot maintain a safe blood O_2 saturation without extra O_2, secure the airway with a laryngeal mask airway or tracheal tube.

  Exceptions: Where patient verbal responses may be required during surgery (e.g., carotid artery surgery, neurosurgery, pacemaker insertion) and where open O_2 delivery is required to keep the patient safe:

  - At all times, deliver the minimum O_2 concentration necessary for adequate oxygenation.
  - Begin with a 30% delivered O_2 concentration and increase as necessary.
  - For unavoidable open O_2 delivery above 30%, deliver 5 to 10 L/min of air under drapes to wash out excess O_2.
  - Stop supplemental O_2 at least one minute before and during use of electrosurgery, electrocautery, or laser, if possible. Surgical team communication is essential for this recommendation.
  - Use an adherent incise drape, if possible, to help isolate the incision from possible O_2-enriched atmospheres beneath the drapes.
  - Keep fenestration towel edges as far from the incision as possible.
  - Arrange drapes to minimize O_2 buildup underneath.
  - Coat head hair and facial hair (e.g., eyebrows, beard, moustache) within the fenestration with water-soluble surgical lubricating jelly to make it nonflammable.
  - For coagulation, use bipolar electrosurgery, not monopolar electrosurgery.

During Oropharyngeal Surgery (e.g., tonsillectomy):

- Scavenge deep within the oropharynx with a metal suction cannula to catch leaking O_2 and N_2O.
- Moisten gauze or sponges and keep them moist, including those used with uncuffed tracheal tubes.

During Tracheostomy:

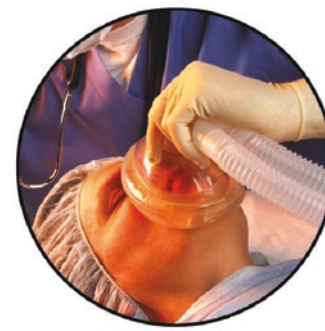
- Do not use electrosurgery to cut into the trachea.

During Bronchoscopic Surgery:

- If the patient requires supplemental O_2, keep the delivered O_2 below 30%. Use inhalation/exhalation gas monitoring (e.g., with an O_2 analyzer) to confirm the proper concentration.

When Using Electrosurgery, Electrocautery, or Laser:

- The surgeon should be made aware of open O_2 use. Surgical team discussion about preventive measures before use of electrosurgery, electrocautery, and laser is indicated.
- Activate the unit only when the active tip is in view (especially if looking through a microscope or endoscope).
- Deactivate the unit before the tip leaves the surgical site.
- Place electrosurgical electrodes in a holster or another location off the patient when not in active use (i.e., when not needed within the next few moments).
- Place lasers in standby mode when not in active use.
- Do not place rubber catheter sleeves over electrosurgical electrodes.



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MS0944S_2

Source: New Clinical Guide to Surgical Fire Prevention. *Health Devices* 2009 Oct;38(10):319.
More information on surgical fire prevention, including a downloadable copy of this poster, is available at www.ecri.org/surgical_fires

EMERGENCY PROCEDURE
EXTINGUISHING A SURGICAL FIRE

Fighting Fires ON the Surgical Patient
Review before every surgical procedure.

In the Event of Fire on the Patient:

1. **Stop the flow of all airway gases to the patient.**
2. **Immediately remove the burning materials** and have another team member extinguish them. If needed, use a CO_2 fire extinguisher to put out a fire on the patient.
3. **Care for the patient:**
   - —Resume patient ventilation.
   - —Control bleeding.
   - —Evacuate the patient if the room is dangerous from smoke or fire.
   - —Examine the patient for injuries and treat accordingly.
4. **If the fire is not quickly controlled:**
   - —Notify other operating room staff and the fire department that a fire has occurred.
   - —Isolate the room to contain smoke and fire.

Save involved materials and devices for later investigation.

Extinguishing Airway Fires
Review before every surgical intubation.

At the First Sign of an Airway or Breathing Circuit Fire, Immediately and Rapidly:

1. **Remove the tracheal tube,** and have another team member extinguish it. Remove cuff-protective devices and any segments of burned tube that may remain smoldering in the airway.
2. **Stop the flow of all gases to the airway.**
3. **Pour saline or water into the airway.**
4. **Care for the patient:**
   - —Reestablish the airway, and resume ventilating with air until you are certain that nothing is left burning in the airway, then switch to 100% oxygen.
   - —Examine the airway to determine the extent of damage, and treat the patient accordingly.

Save involved materials and devices for later investigation.

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MS09445_1

Source: New Clinical Guide to Surgical Fire Prevention. *Health Devices* 2009 Oct;38(10):330.
More information on surgical fire prevention, including a downloadable copy of this poster, is available at www.ecri.org/surgical_fires

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Downloadable copies of these posters on prevention and extinguishment of surgical fires are available online at www.ecri.org/surgical_fires.

For all fires, save involved materials and devices for later investigation.

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Improving Clinical Performance by Analyzing Surgical Skills and Operative Errors

32

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"Every time a human being touches something it's likely to go wrong."

—James Reason

Introduction

Operative errors play a major role in the safety and quality for surgical patients. In 1999, the Institute of Medicine (IOM) released a report estimating that between 44,000 and 98,000 patients die each year in US hospitals as a result of preventable medical errors [1]. This report lead to several recommendations surrounding patient safety including understanding the reasons for errors and how to prevent them. While most of the errors noted were attributed to poor communication and team skills, it remains clear that individual errors still play a role and need to be addressed. For example, a recent study by Birkmeyer et al. [2] revealed that the technical skills of bariatric surgeons were variable and surgeons with the poorest skills had the highest number of complications. This study and others support the use of technical skills assessment as this may be the first step to identifying and learning from errors and making a difference in the safety and quality of surgical care. This chapter reviews the current skills assessment methods in surgery, error analysis frameworks, and how we can improve patient safety through the assessment of technical skills and increasing our understanding of errors.

Surgical Assessment

Surgical trainees are required to master a variety of technical skills upon certification [3, 4]. Numerous methods of formal skills assessments have been developed in order to demonstrate those competencies. Technical skill was once evaluated through subjective assessment by senior surgeons but has transitioned along with

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the rise of technology to task-specific checklists and global rating scales [5]. These methods examine surgical performance to evaluate surgeons' consistency and patient outcomes. Currently, the two most prominent techniques are through observation and technology-based performance measures [6, 7].

Observation-Based Methods

Objective Structured Assessment of Technical Skills

Observation-based methods are most frequently used to assess surgical technical skills, with the Objective Structured Assessment of Technical Skills (OSATS) at its cornerstone [5]. OSATS merges task-specific checklists with global rating scales and generic pass/fail judgments to provide stronger validity and reliability than the previous Objective Structured Clinical Examination (OSCE) [8, 9]. During an OSATS evaluation, a participant attempts a number of standardized surgical procedures while being observed by an expert. The expert evaluator uses a checklist to address specific surgical techniques fundamental to the procedure, and the global rating scale typically focuses on broader surgical behaviors, such as economy of motion and use of assistants.

The OSATS (1997) has received mixed reviews, as validity evidence is variable. General surgery residents were evaluated across eight stations, with OSATS scores improving with each postgraduate year [10]. In another study, gynecology residents and faculty performed open and laparoscopic tasks for OSATS evaluation and showed increasing scores on a majority of tasks as surgical experience progressed from resident to faculty [11]. On the remaining tasks, there was no significant difference between resident and faculty scores, with junior residents outscoring faculty on one task. Another evaluation of gynecology residents in the United Kingdom demonstrated that senior house officers scored lower on OSATS skills than specialist registrars and consultants; however there was no difference in scores between the higher-level specialist registrars and consultants [12]. These studies bring into question the ability for the OSATS to differentiate performance on some operative tasks and between higher-level performers. Moreover, our previous research with general surgery chief residents showed variable performance as measured by task-specific checklists on three procedures—laparoscopic ventral hernia repair, hand-sewn bowel anastomosis, and pancreaticojejunostomy—despite relatively high mean OSATS ratings across procedures [13]. In addition, resident OSATS scores were considerably high in contrast to low completion rates (range, 25–100 %), suggesting that individual OSATS global rating scale items may not be sensitive to variant performance across different procedures. Some also question the objectivity of the tool [12–14], which suggests multiple assessment methods and further characterization of errors may be needed during certain types of performance assessment.

Checklists

Task- and procedure-specific checklists are also commonly used to assess surgical skills. A majority of the published performance checklists focus on laparoscopic procedures [11, 15–20]. Eubanks et al. (1999) created a checklist for the laparoscopic cholecystectomy procedure that incorporates a raw performance score with an error score to provide a more accurate assessment of performance [15]. While it produced reliable and valid data, the checklist was inferior to the generic and modified OSATS global rating scales when Aggarwal et al. (2008) compared the assessment tools on a benchmark laparoscopic cholecystectomy procedure [19]. The use of checklists in isolation has been criticized as there is a tendency to reward thoroughness and not necessarily competence [9].

Global Rating Scales

Global rating scales are another tool used to evaluate technical skill [21, 22]. While checklists are specific to a procedure or task, global rating scales address general surgical skills and translate easily across procedures. Most scales involve using the Global Operative Assessment of Laparoscopic Skills (GOALS) consists of a five-item global rating scale that focuses on depth

perception, dexterity, efficiency, tissue handling, and autonomy [22]. Doyle et al. (2007) created the Global Rating Index for Technical Skills (GRITS) with nine items focusing on respect for tissue, time and motion, instrument handling/knowledge, flow of operation, knowledge of specific procedure, use of assistants, communication skills, depth perception, and bimanual dexterity [21]. The seven-item Global Rating Scale (GRS), initially created for OSATS, though, has received the most attention because ACGME gave GRS an overall Class 1 grade [5, 23]—deeming it a core component for evaluation—and has been assessed across multiple studies [19].

Technology-Based Performance Measures

Compared to observer-based assessments, technology-based performance measures may provide more objective methods for assessing hands on surgical skill [24]. The integration of technology during assessment allows for measures of motion, visual attention, and physiologic stress during the performance of surgical tasks [24]. These measures may provide information integral to evaluating surgical performance that cannot be captured through traditional observer-based measures.

Motion Analysis

Motion analysis relies on electronic sensors or optical systems to capture the movement of surgeons' hands or surgical instruments [16, 24, 25]. Surgical efficiency relates to the conservation of time and motion during an operation. Tracking the motion of surgeons' hands or instruments provides multiple motion parameters related to surgical efficiency: time taken to complete the procedure [26] or subtask [27], the number of movements made by each hand [26], the path length of each hand [25, 28, 29], and the three-dimensional working volume of each hand [30]. These studies [26, 28, 29, 31–33] have demonstrated the ability of motion metrics to differentiate performance based on expert versus novice differences both in the simulation laboratory [31, 34] and the operating room [28]. Additional validity evidence comes from correlations between motion metrics and global rating scales [26, 35] and outcome variables [31].

Of interest is how these motion metrics can identify errors in technical performance or even decision-making. Recently, our laboratory has been using motion-tracking technology to investigate what occurs when surgeons' hands are not moving [29]. We theorize that periods when surgeons' hands are not moving, termed idle time, may represent phases of decision-making or operative planning. Recent work demonstrated that participants of all experience levels had greater idle time when suturing on more friable tissue [29]. Additionally, surgical experience played a significant role in the distribution of idle times during the suturing task. Attending surgeons had fewer idle periods during the portion of the task related to placing the needle through the simulated tissue and greater idle periods while tightening the knot on the suture [29]. This combination of video and motion-based assessment can provide information regarding surgical skill that may demonstrate differences in technical errors not clearly evident with observation alone. The further development and use of optical and magnetic motion-tracking technology may afford the increased applicability of this assessment method in the skills lab and the operating room.

Attention Monitoring Technology

Attention monitoring takes into consideration the amount of information that can be processed at a given time. Related to cognitive load theory, attention levels and characteristics have been considered a fundamental limit for human performance because it influences the amount of information that can be processed at a given time [36]. Eye tracking technology allows for evaluation of where surgeons are placing their visual focus and attention during a task [37]. Recent work by Tien et al. [38] found differences in expert and novices visual focus during open inguinal hernia repairs performed in the operating room. Experienced surgeons had greater fixation frequency (rate of fixed steady eye gaze on an object) and dwell

time (total duration of fixations and saccades on an object) on the operative site during particular portions of the procedure than less experienced surgeons [38]. This follows from prior work that has demonstrated expert-novice differences in visual focus during laparoscopic surgery [39]. In the future it is possible that this technology could be integrated into error-based assessments by providing information regarding visual focus and attention during specific procedural steps or when errors are occurring. This type of data may enhance our ability to study a wide variety of errors and error types including attention. As attention serves as a limit to our ability to perform information processing including perception, working memory, decision, and action [36], further work in this area is necessary.

Physiologic Stress Monitoring

Physiologic stress or arousal can contribute to increased performance up until a certain point at which stress becomes excessive, and performance decreases [40]. The operating room is a high-stakes environment, and the impact of physiologic stress on performance is critical to assessing operative errors. Physiologic stress can be monitored with contact sensors (measuring heart rate, respirator rate, sweat gland activation) or thermal imaging (measuring blood flow, sweat gland activation, and breathing) [24]. During a suturing task using perinasal thermal imaging, Pavlidis et al. [41] found that novices demonstrated multiple elevations of thermo-physiological stress with an increased number of operative task errors and task attempts. In contrast, experienced surgeons had a low and unchanging thermo-physiological stress levels and higher performance. Ongoing work in this field is investigating the role of thermo-physiological stress in surgical performance assessment [42]. This technology may prove to be a valuable adjunct for assessing performance both in the simulation laboratory and the operating room with a particular focus on the contribution of stress to technical errors.

The performance assessments discussed in the previous sections focused on various methods of surgical skill evaluation. Surgical skills typically include following procedural steps, dexterity, and instrument and tissue manipulation. The methods addressed the consistency and outcomes of a surgical performance. We also discussed the weaknesses inherent in the current assessment methods, such as assessing completeness rather than competence. Surgical skill and surgical error, though, differ. Incorporating error analysis into surgical skill assessment may provide rigor that current methods lack and identify additional areas for improvement. The following section will detail how error analysis has been utilized in other fields.

Error Analysis in Other Fields

Errors occur across all fields and can have varying impact based on the risk level of the area. High-risk fields such as aviation, mining, and anesthesia have previously investigated the nature of errors because they are considered high-risk fields. They operate in dynamic environments at some level of uncertainty with the loss of human life as the ultimate consequence of failure. Understanding how error assessment has been performed in these fields will shed light on the importance of including similar methods into the previously discussed surgical performance assessments. This section will highlight how errors have been investigated, identified, and characterized in these fields.

Aviation

In many ways, aviation is seen as the field to first promulgate the notion of error and its role in accidents. One of the more widely known analysis methods, the Human Factors Analysis and Classification System (HFACS) [43], comprehensively categorizes human failure based on the "Swiss cheese" model of human error [44]. Reason (1990) identified four levels of failure: (1) organizational influences can bring about events of (2) unsafe supervision that set in motion any (3) preconditions of unsafe acts that may result in the (4) unsafe acts of operators [44].

While HFACS includes all levels of Reason's model and presents a systems perspective on error and accidents, the last level pertaining to unsafe acts is most relevant to our discussion.

Unsafe acts of operators are considered errors or violations [43]. Where violations require the willful disregard of the rules, errors occur when an individual's mental or physical activities fail to achieve the intended outcome [44]. In the HFACS taxonomy, an individual can commit three fundamental error types: decision, skill-based, and perceptual errors.

Decision errors can occur for various reasons. Aviation is highly proceduralized, with explicit processes for nearly all aspects of flight [45]. Procedures can be misapplied or inappropriately used in certain circumstances, and sometimes situations do not have associated procedures. During these instances, experience, time, and external pressures can influence decision-making and lead to error. Skill-based errors typically occur when a pilot's attention or memory failures impact basic flight skills. Perceptual errors happen during "visually impoverished conditions," such as night flying or inclement weather, where the pilot responds incorrectly to the disorienting conditions [45].

HFACS has been used in commercial and general aviation [45–48] and abroad [49–51]. Multiple causal factors for aviation accidents in China were identified with perceptual, skilled-based, and decision errors present in 22.2, 43.2, and 42.6 % of events, respectively [51]. An investigation into civil aircraft accidents in India also identified skill-based and decision errors as the most frequent in unsafe acts [50]. US investigations also support this finding, with skill-based errors associated with 79.2 % of general aviation accidents [45].

Cognitive failure analysis presents another perspective to analyze aviation errors [52, 53]. The Cognitive Error Taxonomy (CET), modified from Rasmussen (1982), describes six steps in information processing: (1) opportunity for intervention, (2) detection of cues from change in system state, (3) diagnosis of system state, (4) setting of an appropriate goal, (5) selection of suitable strategy, (6) adoption of a suitable procedure, and (7) execution of procedure as intended. The CET provides more in-depth analysis on the previously described unsafe acts identified in the HFACS taxonomy. O'Hare and colleagues (1994) were able to code 261 of 373 aviation mishaps, with procedure errors (26 %) and strategy errors (19 %) occurring most frequently. A more recent study on military mishaps found action errors (30 %) were most common [52].

By identifying underlying causes of errors, trends in errors can be analyzed to help provide insight into interventions and mitigation strategy development. O'Hare et al. (1994) studied aviation accidents that involved intermediate-level pilots and found goal-setting errors were committed more frequently than procedure or action errors [53]. Wiggins [54] suggests this is due to the culture of aviation. The experience necessary to evolve from an intermediate-level to expert is not obtained from instructional systems, but rather from repeated exposure; in gaining experience, novel situations will occur that require knowledge intermediate pilots do not yet possess. Wiegmann and Shappell [55] identified additional trends using multiple cognitive models to analyze over 4000 aircraft accidents. Minor trends were associated with procedural and execution errors, while errors surrounding decision-making, setting goals, and choosing strategies were linked with major accidents. For licensed pilots with over 2000 h of flight time, reported accidents associated with goal selection were most common at 27 %, while information errors were most prevalent (28 %), partially supporting the previous claim [56].

Mining

The mining industry remains one of the highest-risk professions [57]. Despite significant improvements in safety, human error still plays a role in 85 % of mining accidents [58]. Using incident and accidents reports, an analysis on the causal factors of the events was performed using HFACS-MI, a modified HFACS framework for the mining industry (MI) [59]. Unsafe acts were prevalent and identified in almost all cases, with

skill-based and decision errors occurring more frequently than perceptual errors. Skill-based errors identified included omitting operations or inadvertently including operations and errors in technique. Decision errors that occurred frequently involved misapplying procedures for a given task and identifying hazards and taking appropriate measures. Interestingly, decision errors varied significantly by mine type ($p < 0.05$), suggesting that the setting influenced the information available or knowledge necessary to make correct decisions [59].

Anesthesia

In medicine, the field of anesthesia has also sought to address the issues surrounding human error. Similarly to aviation, understanding error in anesthesia has been analyzed with multiple approaches. Anesthesiologists described mistakes previously committed or observed and identified many events, including issues in equipment, unintentional overdose of drugs due to technical or judgment errors, and misuse of monitoring equipment [60, 61]. By identifying these critical incidents, it provides context to where errors occur.

Others have looked into the role of decision-making and cognition in error [62] because of the high cognitive demands placed on anesthesiologists. A framework based on the work of Rasmussen (1982) and Reason (1990) recognizes four levels of work performed by an anesthesiologist: (1) sensory/motor, (2) procedural, (3) abstract, and (4) supervisory control [44, 63, 64]. The first three levels map onto Rasmussen's skills-rules-knowledge framework (1982), while the supervisory control level addresses coordinating between the anesthesiologist and others and appropriating attention between different problems [63].

At the supervisory level, anesthesiologists tackle multiple streams of data, including the patient, surgical field, multiple monitors, and any conversations or alerts, in order to identify and assess any problems that arise. These data streams increase the possibility of faulty perception and incorrect observations [63]. Anesthesiologists must also prioritize problems based on severity and urgency and consistently reevaluate the current environment. Prior to taking any action, they must weigh the options against preexisting patient conditions, side effects, efficacy, and reversibility. All of these decisions have the potential for error.

The procedural level in anesthesia consists of observation, verification, and problem recognition. Incorrectly assessing or misdiagnosing abnormalities is a common error at this level [65], as well as leaving out steps. At the sensory/motor level, anesthesiologists choose and perform actions skillfully and with intention. Skill-related errors can occur at this level when technique is poor or an action is unintentionally performed.

Each field experiences unique issues pertaining to their area, but the methods of analysis and types of errors can carry over across domains. The next section will address how errors are currently assessed and analyzed in the field of surgery.

Errors in Surgery

As a surgeon, performance in the operating room (OR) requires the balance of an already complex environment. The elements of the OR—staff, procedural complexity, equipment, environment, and the patient—are interconnected [66], each with their own level of uncertainty or unpredictability. On top of it all, the life of the patient imparts a high level of risk that affects each element in its own way. Making mistakes or committing errors in everyday life can sometimes have significant negative consequences; in the OR, that likelihood is tenfold. The following sections discuss the identification and understanding of errors in surgery.

Malpractice Claims Studies

One of the initial methods to understanding the operative errors began with malpractice claims

investigations. In a major study investigating technical errors across surgical specialties, general and gastrointestinal surgeries were most commonly associated with error (31 %) [67]. The study considered technical errors as failures in execution (i.e., manual performance) or planning (i.e., decision-making and judgment), with execution errors occurring most frequently (91 %). The most common execution errors included incidental injuries to internal anatomy, breakdowns of the repair, and hemorrhage, while recurrent planning errors included delay or error in intraoperative diagnosis/management. Like the above studies mentioned, Regenbogen et al. [67] also recognized the interplay between execution and planning errors and found 26 % of errors were characterized by both execution and planning issues. Numerous errors occurred in routine operations (84 %) by experienced surgeons (73 %) but also involved complicating factors such as patient complexity or systems issues (69 %), suggesting even the most experienced surgeons are still susceptible to error. Others investigated trainees and their role in surgical error. One study identified similar cognitive errors between surgical trainees and non-trainees, with flaws and failures in judgment as one of the most prevalent contributing factor to errors [68]. In another study, residents self-reported complications and the potential for errors, identifying up to five error types per complication [69]. Residents reported errors of technique most frequently (63.5 %) while cognitive errors in judgment (29.6 %), inattention to detail (29.3 %), and incomplete understanding (22.7 %) were still commonly reported.

Observational Studies

Observational studies can provide a different perspective in characterizing surgical error by including the visual layer sometimes necessary to truly understand the context and underlying etiology of errors. A majority of studies focused on minimal access surgery because laparoscopy involves the additional challenge of remote visualization and limited tactile feedback during surgery.

Joice et al. [70] used human reliability assessment (HRA) to evaluate task performance on video-recorded laparoscopic cholecystectomies, demonstrating the feasibility of this type of analysis in the surgical domain. Error modes, describing the different ways in which an error could occur, were identified in the procedure along with any consequences. Errors were later separated into errors of procedure or execution. Procedural errors involved performing a step correctly with step(s) reordered or omitted, while execution errors were considered when the step(s) was physically performed incorrectly. Approximately 190 errors were identified in 20 procedures, with a majority of them identified as execution errors. Gallbladder perforation was the most common consequence, occurring in 15 of the 20 procedures.

The HRA method was later developed into a larger system called Observational Clinical Human Reliability Assessment (OCHRA). Tang et al. [71] used OCHRA to understand errors in laparoscopic cholecystectomy procedures based on whether the error's impact was consequential or not. Consequential errors were considered events that required corrective measures, while inconsequential errors only increased the possibility of undesirable consequences. Of 20 procedures observed, 30 % of the errors identified were with consequence, with diathermy burns to the liver and perforation of the gallbladder classified most frequently. Inconsequential errors usually involved inappropriate tissue grasping, overshooting instrument movement, and not visualizing an instrument's tip during dissection. While a majority of the surgeons were first-year residents, the study shows propensity to commit errors varies widely.

Lien et al. [72] used a different approach to error analysis. Recognizing a high incident rate of common bile duct (CBD) injury during LC procedures, videos were retrospectively analyzed to understand the events that led to a CBD injury [72]. Surgeons frequently committed errors by omitting or incorrectly performing procedure steps, such as not fully exposing Calot's triangle—a critical step in performing LCs—causing surgeon's to misidentify anatomical structures. The study also broadened beyond the surgeon's

technical performance and identified two additional factors that contribute to the injury—the patient, such as concomitant diseases, and environmental factors of the OR and surgical field, such as poor lighting or inexperience of assistants. Once these factors were identified, a checkpoint system was developed to encourage reviewing performance at critical procedure steps in order to prevent these errors leading to a significant reduction of CBDs in the second half of their study.

Utilizing video-recorded procedures for error analysis was popular in the literature with few assessing surgical performance in the OR. Mishra et al. [73] observed laparoscopic cholecystectomies to understand the relationship between nontechnical teamwork skills and technical error. The HRA and error modes described previously were used in the study [70]. Technical errors were identified approximately three times per procedure on average and were strongly negatively correlated to the surgical team and surgeon's subteam situational awareness [73]. These findings highlight the important role cognitive skills play in surgical errors.

Simulation provides additional opportunity for error analysis without risk to patient mortality. Using an error-enabled laparoscopic ventral hernia (LVH) simulator [74], senior general surgery residents were assessed on their surgical performance using a scored sheet created based on Rasmussen's skills, rules, and knowledge framework [64, 75]. Residents received feedback and returned the following day to reattempt a non-equivalent simulated LVH procedure. On the first day, 75% of residents failed to complete the LVH procedure successfully. Common errors involved improper visualization of the suture passer, preparing the mesh incorrectly prior to insertion, and omitting anchoring sutures. After receiving feedback, residents committed fewer decision-making errors during port placement and mesh preparation on the following day, which enabled them to progress and complete the procedure. This suggests incorrect decision-making and judgment can be highly impactful to progressing through a surgical procedure, as all residents completed the procedure successfully on the following day with fewer decision-making errors.

Our laboratory further investigated the surgical performance of the senior residents and categorized errors committed using video recordings of each procedure [76]. A cognitive error taxonomy [53, 64] identified error levels and omission-commission categories characterized each error. Combining classifications further clarified the understanding on the residents' performance, by identifying how a resident failed to understand the environment or make incorrect diagnosis or strategies (cognitive errors), or failed to include procedural steps or performed them incorrectly (technical errors). Procedure steps were also identified and used to compare error types and levels across the entire LVH repair procedure (see Fig. 32.1). Residents struggled on the first day during the mesh preparation steps and made more cognitive errors in mesh sizing, mesh suture placement, and mesh insertion. On the following day, error-type prevalence changed, as resident remembered or learned to include more steps of the procedure and committed more commission (86%) than omission (14%) errors (see Table 32.1). Our findings show that our error assessment method was able to detect changes in performance after receiving feedback and additional training, even at the level of a novice. Additionally, our findings support the previously discussed studies showing current assessment methods, and the more broadly understood surgical performance, should be expanded to evaluate intraoperative knowledge and skill.

The studies previously discussed demonstrate how broadly errors and surgical performance have been understood. Using multiple methods of investigation (malpractice claims, video-recorded surgical procedures, and simulation), these studies defined errors as incidents in physical skill and technique, failures in procedural understanding, and higher-level issues in judgment and decision-making. The following section will address what these findings mean for the future understanding of surgical performance and surgical assessment as a whole.

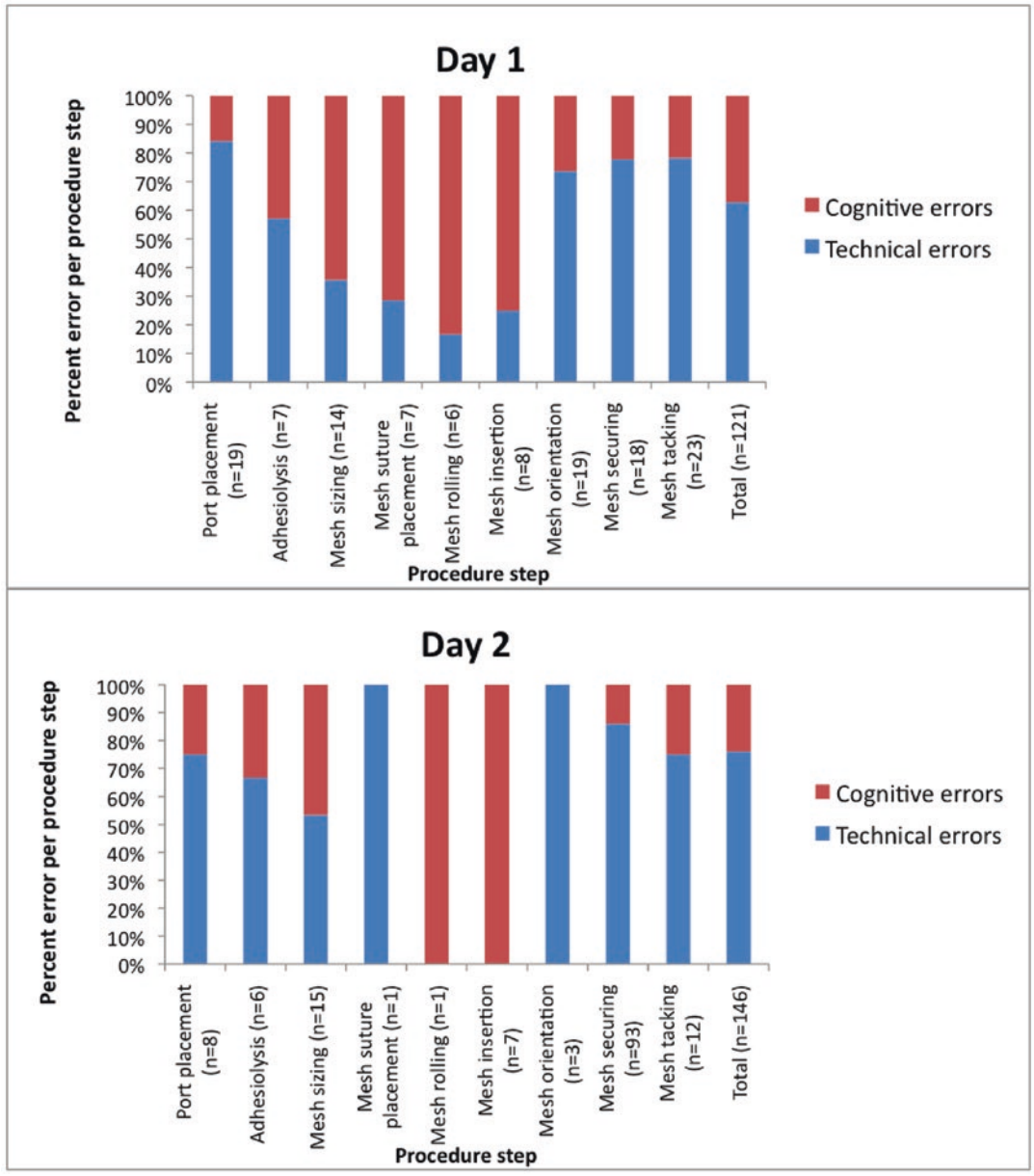

Fig. 32.1 Proportion of cognitive versus technical errors during each step of the procedure

Future Directions

Defining "Error" and Understanding Error Management

Humans, across all fields, regardless of their expertise are fallible, yet there is not one consistent definition of surgical errors across the studies discussed. In order to move forward, an error nomenclature needs to be further developed. Evaluating the applicability of errors assessments employed in other fields provides a broad framework for assessing errors in surgery. This will allow for easier methods of comparing across studies and identifying areas of improvement not only for senior surgeons but residents as well.

Table 32.1 Details of intraoperative errors on Day 1 and Day 2

	Day 1	Day 2	*p*-value
Total LVH completion			
No. (%) of residents with complete repairs	1/7 (14 %)	7/7 (100 %)	0.001
Total number of errors	121	146	
Mean (SD) participant errors	17.3 (4.3)	20.9 (5.8)	0.26
Error type			
No. (%) of *omission* errors	40 (33 %)	20 (14 %)	<0.001
No. (%) of *commission* errors	81 (67 %)	126 (86 %)	
Error level			
No. (%) of *cognitive* errors	45 (37 %)	35 (24 %)	0.019
No. (%) of *technical* errors	76 (63 %)	111 (76 %)	

Studies have shown that surgical performance and patient outcomes are related [2, 77–80] and also that the operative environments in which surgeons work impact surgical performance in decision-making and technique [81–83]. By developing a more concise definition of surgical error, understanding the relationships between errors and patient outcomes and the surgical environment could improve and aid in intervention development to reduce possible disruptions.

While these studies focused on understanding and defining surgical errors, there was little discussion in how residents and senior surgeons compensated for their actions or decisions once an error was committed. Aviation, nuclear power, and various other industries have identified error management as an important, if not critical, skill to have. While the traditional method of surgical education pushes error avoidance, studies have demonstrated that those trained in error management fair better [84]. Incorporating this skill set into future resident training and continuing education for established surgeons may not eliminate the errors committed intraoperatively, but possibly improve their consequences and more importantly patient outcomes [85, 86].

The current assessment methods described previously primarily focus on procedure time and both subjective and objective measures of technical skill. These methods, however, fail to provide a more thorough understanding of the underlying causes and characteristics of surgical performance failures [76, 87]. Incorporating error analysis into future assessment methods may highlight areas for improvement so that surgeons can identify their weaker surgical skills, whether that be in technique or judgment and decision-making, and address them through intentional and deliberate practice [88, 89].

Integrating Technology and Observation-Based Methods

There is promise in some of the newer technologies that are currently in development. Sensor technology has been applied to multiple clinical exams, including the pelvic and breast exams, to assess the role of palpation in performance. Sensor technology demonstrated that differences in palpation force and the technique used plays a role in exam accuracy and proficiency [24, 90]. Pixel-based motion tracking is another promising area that could be used to identify trouble areas or skills for improvement. Pirsiavash and colleagues (2005) have used this method in combination with video-recorded performances to predict performance scores for Olympic athletes [91]. A similar approach could be used in surgery to predict patient outcomes based on surgical performance. Additionally, progress is currently being made to automate the understanding of human behavior [92]. Using methods such as cognitive task analysis, similar research could be performed to automate the understanding of surgical behavior and identification of surgical error. Ultimately, using technology-based assessment methods in complement with observational methods can provide additional understanding in surgical performance that has not yet been addressed.

Regardless of how surgical errors may be defined or what methods we use to assess and analyze performance, without a shift in the culture of the surgical community, we will fail to provide valuable and much needed error-based assessment knowledge to the medical community.

In addition, HIPPA laws and regulations must be revisited to allow for non-discoverable use of surgical videos for training and quality assessment. Currently, the evaluation culture within the medical field is marked by a punitive tone, which may continue to prevent broad interest in using assessment technology in the operating room. In medicine and surgery, most of the widely used, standardized assessments such as the licensing and board examinations are competency based. This translates to the use of performance analysis and measurement to identify the minimum standard for which one can practice medicine or perform surgery. In contrast, athletes rely on performance analysis and measurement to set criterion for mastery that in turn drives a positive competitive culture and the desire for optimal performance. If medicine and surgery embarked on a paradigm shift and began to use performance analysis and measurement to drive a positive competitive culture, this would greatly facilitate the attainment of gold standard levels of success, quality, and safety other fields have achieved.

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Part IV

Approaches to Managing Risks

33 Perioperative Risk and Management of Surgical Patients

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"The major difference between a thing that might go wrong and a thing that cannot possibly go wrong is that when a thing that cannot possibly go wrong goes wrong, it usually turns out to be impossible to get at or *repair."*

—Douglas Adams

Overview of Risk Management

Clinical Case

A busy orthopedic surgeon scheduled two cases for knee replacement surgery on the same day. His office later added a third knee replacement case to the middle of the string rather than at the end of the string as is customary when additional cases are added in this setting. Patients 2 and 3 had different laterality and were not in the same order on the surgeon's schedule compared with the planned operating room (OR) and anesthesia schedules. The surgeon's schedule from the office listed patients in the order 1,3,2, while the anesthesia and OR schedules listed the patients as 1,2,3. On the day of surgery, the patients were admitted to the pre-op area of the hospital and the registered nurse (RN) completed a verification process between the surgical consent and consult notes from the physician. Patients 2 and 3 were in rooms next to one another. The pre-operative area contains a white board and the RN places a check by the surgeon's name and anesthesiologist's name when they each see the patients. After finishing surgery on patient 1, the surgeon saw his next patient, patient 3, on his schedule, and informed the nurse that he had seen and marked his next patient. The RN then placed a

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check mark by patient 2's name (when the surgeon had actually seen patient 3). The OR circulator checked the board, determined that both the anesthesiologist and surgeon had seen the patient, and proceeded to interview patient 2. The circulator noticed that the patient had not been marked and informed the supervisor who went to the lounge to talk to the surgeon. The surgeon informed the supervisor that he is sure he had just marked the patient and instructed the nurse to have the patient taken to the OR. The nurse followed this directive and the patient was taken to the OR where anesthesia was induced and the patient was intubated. The surgeon scrubbed, entered the room and noticed that the patent was not marked. He then broke scrub, called his office to obtain an imaging study, reviewed the chart, noted the name discrepancy, reviewed the radiology report, and verified the patient's name with anesthesia. The circulator then asked the charge RN to verify the site with the family, and the surgeon proceeded with the knee replacement on the correct side.

This case study illustrates a near miss and raises important questions about risk and how one thinks about it in the surgical setting [1]. The order of the cases was not the same on the surgeon's schedule as it was on the OR and anesthesia schedules which led to a series of miscommunications that were only discovered because enough safeguards were in place to eventually correct the error. It is clearly important to have a system with standardized policies and procedures, trained personnel, and a culture of communication among all caregivers [2].

Joseph Juran, one of the quality gurus of the twentieth century, is quoted as saying: "*A principal finding has been that…quality problems are planned that way, which means that the quality problems are largely traceable to deficiencies in the methods used to plan for quality.* Those deficiencies are still in place. To get rid of those deficiencies we must revise the quality planning process and then learn how to acquire mastery over that revised process." [3]

Juran made the point that planning for quality is a necessity for any organization, and although this has many facets, risk and safety planning are certainly at a high level of importance for any healthcare organization. While risk has been defined in many ways, the definitions usually contain the following elements:

- Risk involves potential harm or loss
- Risk can be costly
- Risk can be traumatic
- Risk must be identified before it can be minimized/prevented [4, 5]

In the surgical setting, risk is a fact of life and must be considered in everything that touches and interacts with a patient. All policies, procedures, and processes must be designed and developed with the idea of identifying risk and minimizing it when feasible. This means that measures must be adopted to standardize workflow, order sets, and procedures as much as possible [6]. Success depends upon many factors, but the development of and experience gained by a surgical team that works together, learns from its experiences, and supports team members is probably most important [7]. Communication among team members is of course critical in any perioperative environment and is greatly facilitated by a culture of transparency and safety, as well as structural elements such as checklists and a governing council [8].

Individual Risk

The calculation of individual risk relies upon assessment of inherent procedure difficulty, comorbidities, urgency, and the experience of the OR team, anesthesiologist, and surgeon. The structure or setting may also contribute to risk in the sense that an outpatient facility may not be appropriate to handle cases that would normally be performed in a hospital operating room.

The actual measurement of risk is not usually a simple proposition, and for the individual patient, several risk calculators have been developed to assist surgeons and anesthesiologists in assessing risk. In 2013, the American College of Surgeons and its National Surgical Quality Improvement Program (NSQIP) developed a web-based surgical risk calculator that is designed to take those individual data and calculate the surgical risk for complications and possible death [9]. This tool was compiled from statistical data collected from 1.5 million patients, allowing the surgeon to adjust the risk factors for each patient utilizing 21 preoperative factors. The tool contains a feature where the surgeon, based on the surgeon's experience and evaluation of the patient, can adjust the score for a patient. There are similar surgery risk calculators developed by other healthcare organizations [10].

These include risk calculators for large bowel obstructions, lymph node harvesting, colorectal laparoscopic conversion, ileal pouch failure, cardiothoracic surgery (Society of Thoracic Surgeons risk calculator), and several others. Practitioners can find information on surgical risk calculators on the internet [11, 12].

Process Risk

Process risk can be thought of as the inherent risk of the procedure or the risk of a particular process in a phase of perioperative care [13]. It has to do with the complexity and difficulty of the surgery, but also includes the following types of variables that can affect the outcome either directly or indirectly [14]. Examples of process risk are listed in Table 33.1.

We consider the inherent risk of the process for the "average" patient, and then compare this risk to the risk for the patient under consideration with various comorbidities. In this way, we are able to determine if there are specific steps or processes within the overall care experience that are particularly risky *for this patient* and that should be noted by the providers caring for the patient.

Risk Engineering in the Perioperative Environment

There are many ways to think about risk in the perioperative setting, and we have summarized the general concepts in the section below entitled, *Other Factors in Managing Patient Safety Risk*. In this section we discuss a methodology to quantify risk using analyses based on the phases of care. An overriding theme is the importance of culture both within the perioperative environment and throughout the organization. This is discussed in detail in Chap. 6 within the section entitled, *Overview of Enterprise Risk Management.*

Phases of Care

Patients move through different care settings or phases of care within the perioperative environment and the goal is to quantify risk at the process level for each of these phases of care. The methodology described in this section may not be practical for patients in all care settings, but it provides a framework in which to think about providing care for each patient in a way that minimizes risk. Having a system allows all providers to communicate and share information within the clinical setting at the point of care. Although risk factors can produce complications in any care setting, it is often unclear how these risk factors are linked to specific care processes. Each setting is associated with processes that are common to the care setting and others that are unique to the particular disease or diagnosis. Examples of common processes include:

- Hemodynamic management process
- Imaging/testing process
- Medication process
- Nutrition process
- Ventilation process

These common processes could involve virtually all areas (phases of care) the patient progresses through during an episode of illness. The phases of care are listed in Table 33.2.

Table 33.1 Examples of process risk

Communication complexity/dissemination
IT/information needs
Program management
Resource management
Service structure
Service area issues
Team size and makeup
Team skill and stability

Table 33.2 Phases of care

Initial visit/consult
Preoperative work-up and testing, imaging, consults
Preoperative day of surgery
Intraoperative
Immediate postoperative in PACU or ICU
Postoperative in hospital
Discharge planning
Follow-up post-discharge

Each phase of care may contain a few steps/processes or many, and each step may present a risk if it is not executed properly. Something as simple as placing an order for laboratory tests has inherent risk since the wrong test may be ordered, review of the test result may not happen, or the test may be ordered on the wrong "Mr. Smith." The system described in the following subsection is a methodology for quantifying risk for each process and at each process step if desired. It is based upon making a judgment about how often something goes wrong, how bad the outcome may be when it does, and how easy it is to detect or predict the adverse event or mistake. While many steps in many processes may indeed be the same for most patients, some steps have risks that are higher for some patients than others, and the increased risks are usually due to comorbidities. After looking at the processes and steps, we determine which aspects of this episode of care are particularly important/risky for *this* patient.

Another way of looking at the issue of risk is to understand that there is an inherent risk for any procedure—the *process risk* or "*being in the hospital*" *risk*. Additional risks are produced by comorbidities and risk factors associated with an individual patient, their care providers, and the hospital or environment of care [15, 16].

The questions listed in Table 33.3 may be used to assess these risks.

Table 33.3 Questions to assess process risk

How is the process/phase of care evaluated for risk and safety issues?
How do these relate to the individual patient?
Does an individual patient have specific, unique risk factors that need to be taken into account?
Which care processes/steps are affected by the risk factors?
If risk is identified, how is it quantified in order to determine if it's significant or not?
How is the information reported and communicated to the care team?
Is decision support provided by the system?

Quantifying Risk in the Care Setting

The next step is to quantify risk in each phase of care by mapping the overall process and identifying each step in the phase of care. The risk may then be quantified using the tool Failure Mode Effects Analysis (FMEA). A FMEA is a well-described and proven methodology used by industrial engineers and quality managers. It can be adapted to the surgical setting in order to assess and quantify patient risk. The FMEA utilizes three parameters to calculate a Risk Priority Number (RPN) for each risk that has been identified (Figs. 33.1 and 33.2). The three factors are: frequency of occurrence, severity, and likelihood of detection. Each of the three factors is usually given a scale range of 1–10 with the RPN being the product of the three factors, ranging from 1 to 1000. Risk factors that are low frequency or low severity or have a high likelihood of detection would be assigned low numbers, while higher numbers would be assigned to risk factors with high frequency, or high severity, or a low likelihood of detection. We prefer this methodology in the clinical setting since the ability to detect or predict the risk is important from a safety standpoint. Most organizations with formal enterprise risk management (ERM) systems utilize a simpler version with only the parameters of frequency (likelihood) and severity (impact) to derive a risk score in the range of 1–100 (in the case of a scale of 1–5 rather than 1–10 for each factor, the range would be 1–25). For both RPN and risk score numbers, the scales of 1–5 for each parameter are easier to use and to make decisions, while the scales of 1–10 afford more precision and are preferred in engineering work.

The FMEA methodology may be utilized to assess risk for each process/step in each phase of care for an individual patient. This is done by comparing the risk of an average patient to the risk of the specific patient being treated. It is important to keep in mind that the numbers assigned to each risk factor are estimates derived by the team performing the assessment, data from registries, databases, or published journal articles

Fig. 33.1 Risk Priority Number (RPN)

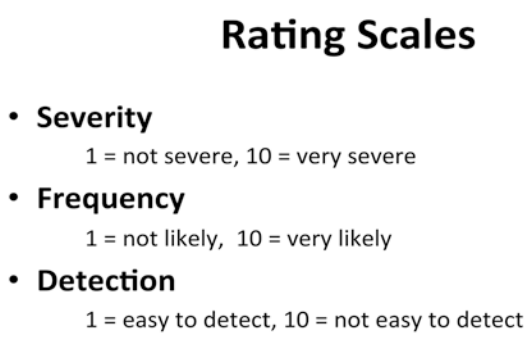

Fig. 33.2 Risk rating scales for calculating RPN

utilized to assist in making the estimates. Although the risk is the same most of the time in the pre-op phases of care, it could certainly be increased for a patient with complex problems who requires dialysis and imaging studies for staging prior to lung resection. Planning each step in the pre-op time period would be very important for the patient, and knowing where to look for potential problems is the value of this methodology.

Another example is the intraoperative phase of care in an obese patient with an albumin 1.9 g/dL undergoing an exploratory laparotomy for small bowel obstruction. The RPN for the wound closure process is calculated twice:

- **Exploratory laparotomy for bowel obstruction: Wound closure process**
  - Disease entity: Small bowel obstruction
  - Complication: Wound dehiscence
  - Risk factors: Obesity, albumin <3.5 g/dL
  - Care setting: Operating room
  - Process: Wound closure
  - **RPN**:
    Not obese, albumin >3.5 g/dL (S × F × D)
    5 × 3 × 1 = 15
    Obese, albumin <3.5 g/dL 7 × 5 × 1= 35

In this example, we estimated that without obesity, the severity (S) of wound dehiscence would rate 5 on a scale of 1–10, the frequency (F) would rate 3, and the detectability (D) would rate 1, amounting to an RPN value of 15. For the obese patient with a low albumin, the severity rate is 7, frequency 5, and detectability 1, leading to an RPN of 35. The risk for this patient having a wound dehiscence is therefore over twice as high as the average patient, so using retention sutures might be a good idea.

A second example involves a morbidly obese patient undergoing a colon resection:

- **Colon resection: Instrument, needle, sponge count**
  - Disease entity: Colon resection for cancer
  - Complication: Retained sponge
  - Risk factor: Morbid obesity
  - Care setting: Operating room
  - Process: Instrument, needle, and sponge count
  - **RPN**:
    Not obese (S × F × D) 2 × 3 × 2 = 12
    Obese 3 × 5 × 4 = 60

The obesity in this case increases the frequency of a retained sponge as well as reducing the detectability, so that the RPN is 5× higher in the obese patient.

A third example involves mapping out the key processes in a coronary artery bypass operation (CABG) during the intraoperative phase [17, 18]. The 15 processes listed in Table 33.4 each include several different steps.

Table 33.4 Key processes in a coronary artery bypass operation

Anesthesia process
Non-anesthesia medications process
Chest-opening process
Conduit preparation process
Cannulation process
Cardiopulmonary bypass (CPB) process
Myocardial protection process
Distal/proximal anastomosis process
Weaning CPB process
Decannulation process
Checking conduit process
Hemostasis process
Drainage process
Sternal closure process
Transfer process

One could list all steps in each of these processes and develop a RPN number for each step. In this example, we choose to evaluate protamine administration to reverse heparin that is part of the hemostasis process. Giving protamine can produce a reaction resulting in acute pulmonary hypertension and right ventricular failure in patients with risk factors including insulin-dependent diabetes mellitus, history of previous cardiac surgery, previous vasectomy, and/or fish or seafood allergy. The calculations would be as follows:

- **Cardiac surgery using cardiopulmonary bypass: Protamine administration process**
  - Disease entity: Coronary artery disease
  - Complication: Protamine reaction
  - Risk factor: Insulin-dependent diabetes
  - Care setting: Operating room
  - Process: Protamine administration
  - **RPN**:
    No diabetes (S × F × D) 6 × 4 × 1 = 24
    Insulin-dependent diabetes 9 × 7 × 1 = 63

The history of insulin-dependent diabetes in this patient increases the RPN by a factor of 2.6, thereby alerting the team to be cautious in giving protamine and not removing the cannulae until later in the process of giving the protamine.

Table 33.5 Summary of using FMEA methodology in the perioperative setting

Determine which care settings or phases of care are of interest or concern
Map process steps within each care setting and calculate the RPN for each key step for the average patient without known risk factors or comorbidities
List risk factors/comorbidities for an individual patient
Determine which care processes/steps are affected by the risk factors FMEA analysis of each process step FMEA combined with known risk factors and comorbidities Determination of most important and risky process steps based on RPNs with differences between patient being treated and average RPN Assess RPN values based upon Absolute values of RPN Percent changes in RPN after risk factor adjustment Number of RPN values affected by risk factors
Provide decision support to care team within each care setting
Effect of combining risk factor analysis with FMEA Quantify processes Quantify risk Understand ***system of care*** Information available at point of care Improve patient safety and prevent errors

Practical Applications of the FMEA Methodology

The FMEA methodology is a powerful tool to use in assessing risks, and it can result in improved patient safety and fewer errors. The recommended method is summarized in Table 33.5.

Other Factors in Managing Patient Safety Risk

The risks to patient safety in surgical care come from individual practitioners, equipment failures, lack of having correct supplies, and many other factors. All organizations that provide surgical services should conduct a patient safety risk assessment at least annually to identify opportunities for improvement. Once these opportunities are identified, an action plan must be developed and implemented, and the results must be sustained.

Process

The high complexity of performing surgery and the increasing need for complicated device technology increase the potential for medical errors and adverse events to occur. Safety systems must be in place to help reduce the chance of these errors occurring [19]. One method to determine the current state of patient safety in the surgical arena is through a patient safety culture assessment. There are some assessment tools developed explicitly for surgery, and there are tools developed that include the surgical area of care [20]. Two of the best-known tools were created by the Agency for Healthcare Research and Quality (AHRQ) [21]. The safety culture survey is given to the staff to complete and is then analyzed with the facility receiving a report benchmarking it with similar facilities. The data in the report may be utilized to make improvements in the patient safety culture of the organization.

Unfortunately, it is not possible to predict and prevent errors in the surgical arena, but there are many educational and process changes that can help to reduce the likelihood of harm occurring [22]. There has been a movement in healthcare to put processes in place which will provide redundant checks prior to and during a surgical procedure. The Joint Commission (TJC) developed the Universal Protocol for use in all surgical settings in facilities that they accredit [23]. The Universal Protocol includes verification of information when the patient arrives for the procedure through the start of the procedure, the marking of the operative site, and a time-out before the procedure begins to assure that all the necessary information, equipment, and supplies are ready in the operative area. Surgical checklists have been developed from TJC Universal Protocol, or from the World Health Organization (WHO), for all areas where procedures are performed [24]. Although these checklists have been in place for many years, they are not always utilized in the correct manner [25]. A study by Araujo and Oliveria [26] concluded that 38 % of the articles reviewed showed a relationship between the use of the surgical checklist and a reduction in surgical morbidity and complications, while 46 % of the articles suggested a need for surgical safety improvement. Urbach et al. showed clearly that without engagement of the surgical team, the benefits of the surgical checklist are greatly diminished [27] and despite great efforts, only minimal gains are achieved [28].

Another potential risk in the surgical arena is the risk of fire (see Chap. 20). Seifert et al. [29] state that the surgical team must be aware of the potential for fires and complete an assessment to determine that the three elements of fire—fuel, oxygen, and ignition source—are controlled. The Association of periOperative Registered Nurses (AORN) has developed a five question perioperative fire risk assessment that can be utilized to evaluate the location of the surgery, types of anesthesia, antiseptic cleansers, and energy sources which could lead to a fire [30]. Seifert et al. also stress that education of the surgical team is essential in not only knowing how to prevent a fire but also in knowing the role of each team member should a fire occur.

These examples include a large element of human factors that greatly influence the risks that are present in the surgical environment [31]. Adverse events in surgery commonly occur due to a lack of communication, a delay in diagnosis or failure to diagnose, or a delay in treatment [32]. The entire team must adopt a culture of safety and be ever vigilant prior to, during, and after the procedure. Everyone must work as a team and be willing to speak up should a team member determine that something is not as it should be [33]. If the culture of the organization is not a patient safety culture, members of the team may not feel comfortable speaking up if a person of perceived power is about to make a mistake. The patient safety culture in the surgical arena is characterized by the elements listed in Table 33.6.

Table 33.6 Characteristics of a patient safety culture

Reporting culture without fear of reprisal
Learning culture where team members learn from their successes and failures
Flexible culture that changes and adapts to meet new demands
Engaged culture where everyone does their part
Just culture where every team member is treated fairly

Dangers of Technology

Advances in healthcare technology have improved the accuracy and minimized the risk to patients through the use of new technology. However, the introduction of new technically advanced equipment also comes with added or different risks. For example, there is currently concern about the adequate cleaning of endoscopic retrograde cholangiopancreatography (ERCP) endoscopes, based on reports of a fatal drug-resistant pathogen and inadequate sterilization of these scopes [34]. Endoscopes are frequently utilized throughout the United States, with an estimated 15,000 operations performed a year with contaminated ERCP scopes [35]. Ineffective cleaning and sterilization is more than a personnel competency issue. Manufacturing design of equipment has parts that are inaccessible for cleaning and allow for the retention of tissue and other debris from the operation. If such problems are attributed to personnel competency issues, they are often related to not following the standardized or recommended procedure for cleaning the equipment. Furthermore, developing an ongoing system for assessing technical competency of invasive procures using rehearsal and warm up is valuable [36].

Many procedures have been standardized, and other technology is utilized to minimize the potential for errors to occur. The use of electronic health records (EHR) has increased the standardization of documentation, including order sets for patient conditions and treatment. The EHR has provided an electronic interconnectedness among practitioners who can now readily review the documentation of other practitioners. However, as the recent MedStar data-hacking event suggests, there are inherent dangers with HIT interconnectedness. Through the use of the EHR and other electronic communication devices, practitioners can select hyperlinks and in some cases QR codes that will lead them to more information concerning any topic. A QR code (abbreviated from Quick Response code) is the trademark for a type of matrix barcode, made up of black square dots arranged in a square grid on a white background. Any imaging device, such as a scanner, camera, or smartphone, can read the QR code and open or link to information or connect to a database. The barcode idea has also been utilized in the administration of medications, where every medication has a barcode that is scanned in conjunction with a barcode for the patient who is to receive the medication. This use was intended to eliminate medication errors and has been very successful. However, none of these technological systems are infallible, with common "work-arounds," which negate the purpose of the safety system [37]. Identification of work-arounds to determine why current policies and procedures fail to work is therefore an essential element of safety [38].

Supply Issues

The operating room contains a large quantity of supplies, stock, and instruments needed to perform the surgical procedures. However, there are several issues with surgical supplies that are challenging. One of the largest supply issues is the use of the wrong implant or equipment during the procedure [39]. Procedures are delayed if the correct supplies are not available, or if a surgical instrument is dropped or is missing from the surgical pack. Such problems can potentially cause harm to the patient [40]. Another issue is that in some cases the supplies being utilized are expired, a situation in violation of the Food and Drug Administration requirement that all drugs and medical materials administered to humans be used within their expiration date [41].

Another issue is the use of counterfeit medical supplies. The Veterans Administration (VA) received counterfeit surgical devices and supplies

when they started utilizing reverse auctions where sellers compete to provide goods or services at the lowest price to fulfill their contracts [42]. This resulted in unauthorized distributers utilizing counterfeit supplies, some of which may have been stolen from other hospitals. These products may not have been stored at proper temperatures, maintained in appropriate packaging, and so forth.

Governance

Reducing risks in the perioperative environment requires management and leadership from hospital administration, surgeons, and anesthesiologists. An effective way of providing structure for this goal is to establish a perioperative governing council comprised of leaders from all three areas. The goals of the council are to build trust among the medical staff, keep physicians abreast of perioperative initiatives, identify opportunities to increase physician satisfaction and ease of practice, and support initiatives to improve the efficiency and effectiveness of the operating room. The governing council should establish a set of bylaws and written policies and procedures dealing with the kinds of perioperative issues listed in Table 33.7.

In many institutions, other committees such as a surgical executive committee, an operations committee, and a quality committee complement the governing council. Surgeons, nurses, anesthesiologists, and administrators are represented on each of these committees so that all points of view are represented and communication with peers and other staff is optimized.

Table 33.7 Issues addressed by the perioperative governing council

Add-on classification
Behavior issues
Block scheduling
Capital requests
Care coordination with physician offices
Credentialing in difficult areas such as robotics
Expensive implants
On-time starts
Quality oversight and reporting
Staffing, workforce issues
Surgical products and vendors
Throughput
Time-outs

Scope of Practice Issues

The surgical team must work together with trust and good communication skills to ensure that all the team members are competent within their roles and are willing to speak up when something is wrong or suboptimal. An important part of this trust is the competency of each practitioner and team member, which must be established by the organization where they are practicing. The size and type of healthcare organization is a very important variable in the topic of scope of practice issues. Each of the care settings may have different types of procedures and different types of practitioners on their surgical rosters. The settings where the surgical procedures are conducted will have different support services available, depending upon the particular type of healthcare organization. Thus, an acute care hospital is capable of performing more complex surgeries than an ambulatory surgery center while the ambulatory surgery center is capable of performing more complex procedures than a physician's office.

Credentialing and Privileging

Every team member must have his/her credentials verified at the time of employment and on an ongoing basis. For Licensed Independent Practitioners (LIPs), which includes physicians, advanced practice nurses, physician assistants, and dentists, the credentialing is completed at the time of initial hiring/approval to work at an organization. Recredentialing normally occurs every 2 years. The LIP may also be granted additional privileges that are based on the practitioner's education and experience with the privilege. The criteria to grant privileges are determined by the medical staff, and there are many guidelines developed by medical professional organizations that can be used to identify

the required competency. An example is the *Guidelines for Laparoscopic Ventral Hernia Repair*, established by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in 2014 [43]. At the time of reappointment, the practitioner must produce evidence of having performed a minimum number of ventral hernia repairs over the past 2 years without harm to patients.

Professionals make errors, but a pattern or trend of errors may indicate an unsafe practitioner, an issue that must be examined at the time of reappointment. If a LIP currently on staff wishes to add a new privilege, the LIP must demonstrate the education and experience level determined by the medical staff before the LIP is awarded the privilege. For example, when bariatric surgery was first introduced, physicians were asked to take didactic and clinical courses to learn how to perform the procedure. The medical staff determines the number of cases the practitioner has to perform and whether or not proctoring by a senior practitioner is required before the privilege will be awarded to the practitioner.

Robotic surgery is a major technological advancement. As one might imagine, this technology represents a complicated piece of machinery and there is a risk of malfunction during the procedure as well as several unintended consequences. The da Vinci Surgical System was approved for use by the FDA in 2000, and was rapidly adopted and widely used in hospitals within a few years [44]. In this system, the surgeon controls the robotic arms while sitting at a computer console. Although the robotic system enhances flexibility, precision, and control during the procedure, the system is not without its inherent problems and issues. For surgeons to have clinical privileges to use the robotic system, they must have specific training with the use of the particular system and model [45]. The different units available for robotic surgery are controlled in different ways by robotic arms working from a predetermined program to the point of complete control of the robotic instruments by the surgeon. The surgeon must have education and experience with the type of robotic system in use at a facility and not just a general robotic proficiency. The surgeon must also have the ability to intervene if something goes wrong with the robot during the procedure. In 2013, the FDA conducted a survey of physicians who utilize robotic systems, examining the problems encountered with using these devices [46]. Among their findings was a patient whose colon was punctured during prostate surgery with the da Vinci robot, a robotic arm that would not let go of tissue grasped during colorectal surgery, and one woman who was hit in the face by the robot during a hysterectomy. Alemzadeh, Iyer, Kalbarczyk, Leveson, and Raman reported in 2015 the results of a retrospective study of 14 years of FDA data. The authors examined 10,624 robotic system adverse events and found that over 8061 events (75.9 %) were caused by device malfunctions [47].

The lawsuits resulting from these types of errors have found the surgeon liable for some of the errors. It is therefore important for the credentialing committee and medical staff at all facilities using robotics to carefully determine the requirements for an individual to receive robotic privileges. Privileges may be granted for specific procedures rather than across the board, and many institutions have established a robotic committee to oversee robotic practices and the credentialing process.

Once a LIP is granted clinical privileges, the list of those privileges should be sent to the surgical department and to the schedulers who post the cases. Ideally, both the surgical department and the schedulers should be checking the privilege list of all practitioners who schedule a procedure to ensure that the practitioner has privileges to perform the procedure. If the LIP does not have privileges, the case should not be scheduled and the practitioner notified of the reason.

Staff Competency

When members of the surgical team are first employed by the healthcare organization, they go through an orientation period which includes a

competency checklist. The skills on the competency checklist are determined by the individual's role on the surgical team. For example, the circulating nurse does not have to possess the skills of the surgical technician assisting the physician, unless that nurse may also assist the physician in a role similar to the technician. The timeframe for this orientation varies based on the type of facility and the types of procedures performed, as well as the experience level of the team member.

Association of periOperative Registered Nurses

The Association of periOperative Registered Nurses (AORN) has established various practices for the nurses within the surgical environment, Guidelines for Perioperative Practice [48]. This document contains revised and new evidence-based guidelines for perioperative nurses and other team members in an effort to standardize practice and promote patient and worker safety. The AORN has also developed a Perioperative Patient Focused Model to be utilized in surgical settings to help RNs document and describe perioperative patient care [49]. This model puts the patient at the center of the framework with all practice designed to meet the needs of the patient and family. The model, similar to the clinical microsystem model [50], is an outcomes-driven model focusing on perioperative nursing practices as they relate to patient outcomes. The model has four domains: safety, physiologic responses, behavioral responses (family and individual), and health system. The first three domains are patient focused and the last domain, health system, refers to administrative, operational, and structural data. The model addresses 74 nursing diagnoses, 153 nursing interventions, and 38 nurse-sensitive patient outcomes.

Nontechnical Skills

Nontechnical skills such as situational awareness and effective interpersonal relationships are critical for the surgical team. If the surgical team does not communicate well with one another, a medical error is more likely to occur [51]. Situational awareness refers to an individual's ability to maintain attention and to be able to respond to changes in the environment and changes in a patient's condition [52]. This awareness may in some cases require the individual to speak up or stop the line and prevent the procedure from continuing [53]. As the surgical team goes about their job during a procedure, they are concentrating on what they are doing and may become less aware of what is actually happening in the room around them. It is at these times that a sponge can be left in the patient or the procedure can be initiated at the wrong site. All team members must be able and willing to speak up and stop the procedure to prevent an error from occurring [54]. It is critical that the culture of the organization support this type of communication and team approach to surgical procedures.

Surgical Setting

The healthcare physical setting where the surgical procedure is performed also has a high impact on the scope of practice of the surgical team [32, 55]. Many of the outpatient service sites, other than an outpatient surgery center, for example, do not have the capability to perform advanced life support on patients in extremis. There is not always a crash cart with emergency supplies present in many office settings used for surgical procedures. The only way to get assistance is to dial 911 and perform cardiopulmonary resuscitation (CPR) until the paramedics arrive with emergency equipment. The surgical team members in an outpatient facility may not have experience and training with rare, but potentially fatal events, and they could lack support personnel. Additionally, office-based surgery, such as cosmetic surgery, is often performed under monitored anesthesia or conscious sedation care, which is different than general anesthesia [56] and requires careful planning for safe and reliable sedation [56].

In 2010, almost 70 % of all cosmetic surgery was performed in doctors' offices [57]. A concern in performing office surgery is the lack of regulatory oversight. Office-based procedures, such as liposuction, have been found to be severalfold more risky than when done in hospital setting [58]. The facility must be accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, the Joint Commission on Accreditation of Healthcare Organizations, a state-recognized entity such as the Institute for Medical Quality, or Medicare certified under Title XVIII.

Equipment

The facility should be outfitted with the appropriate medical equipment, materials, and drugs necessary to provide anesthesia, recovery ministration, cardiopulmonary resuscitation, and provisions for potential emergencies. Furthermore, the operating facility should have the basic patient safety devices, such as "humidifiers, oximeters, capnography, warming blankets, and pneumatic/compression leg garments." It must also have appropriate "fire-fighting equipment, signage, emergency power capabilities, and lighting." All operative equipment should be inspected, maintained, and tested on a regular basis as recommended by the manufacturer. The personnel, equipment, and procedures must be adequate to handle potential medical and other emergencies [59]. Table 33.8 lists emergency equipment for sedation and analgesia recommended by the American Society of Anesthesiologists [56, 60].

In some cases, there is a limit to the amount of equipment and support services available, and most likely no anesthesiologist is available to provide assistance if needed. In these cases, the surgical team must be extra vigilant to ensure that the equipment is working properly and that there are backup supplies and surgical instruments. The entire surgical team must be well prepared for any situation that may arise during or after the procedure.

Table 33.8 Emergency equipment for sedation and analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated
Intravenous equipment
Gloves
Tourniquets
Alcohol wipes
Sterile gauze pads
Intravenous catheters (24–22 gauge)
Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
Intravenous fluid
Assorted needles for drug aspiration, intramuscular injection (intraosseous bone marrow needle)
Appropriately sized syringes (1-ml syringes)
Tape
Basic airway management equipment
Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
Source of suction
Suction catheters (pediatric suction catheters)
Yankauer-type suction
Face masks (infant/child)
Self-inflating breathing bag-valve set (pediatric)
Oral and nasal airways (infant/child sized)
Lubricant
Advanced airway management equipment (for practitioners with intubation skills)
Laryngeal mask airways (pediatric)
Laryngoscope handles (tested)
Laryngoscope blades (pediatric)
Endotracheal tubes
Cuffed 6.0, 7.0, 8.0 mm ID (Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID) stylet (appropriately sized for endotracheal tubes)
Pharmacologic antagonists
Naloxone
Flumazenil
Emergency medications
Epinephrine
Ephedrine
Vasopressin
Atropine
Nitroglycerin (tablets or spray)

(continued)

Table 33.8 (continued)

Amiodarone
Lidocaine
Glucose, 50 % (10 or 25 %)
Diphenhydramine
Hydrocortisone, methylprednisolone, or dexamethasone
Diazepam or midazolam

From the American Society of Anesthesiologists' "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" (Anesthesiology 96: 1004, 2002)

Another practice issue is the use of equipment and implants that have not been approved by the FDA for the intended use. The Code of Federal Regulations (CFR) Title 21 Parts 800–898 establishes approved uses for all devices, drugs, nutrition, and biologicals. The law states that FDA-approved equipment is not to be utilized for non-approved use [61]. Utilizing approved devices for unapproved use can result in harm to the patient and/or others in the surgical area [62]. In a transplant hospital that is part of a seven-hospital system, a female patient went to surgery to receive a kidney transplant from a family member. The donor suffered a massive hemorrhage that resulted in her death. This sentinel event was investigated with a root cause analysis, and it was discovered that the FDA did not approve a clamp that was used in the surgery. The clamp was not the cause of the bleeding, but because the facility was not in FDA compliance, they were found at fault for the death.

The Second Victim

This chapter would not be complete without addressing the role of error disclosure and the second victim of a medical mistake or untoward outcome not caused by a mistake—the practitioner. In the year 2000, Dr. Albert Wu wrote about a difficult period during his residency, when a resident's failure to diagnose led not only to the patient's deterioration, but also to condemnation by his peers [63]. Dr. Wu described this resident as the second victim of the error. In his article, Dr. Wu sets forth the basic elements of the second victim scenario, ranging from the unduly high expectation of the physician to the reaction of peers about the feelings of the practitioner:

> … technological wonders, the apparent precision of laboratory tests, and innovations that present tangible images of illness have in fact created an expectation of perfection. Patients, who have an understandable need to consider their doctors infallible, have colluded with doctors to deny the existence of error. Hospitals react to every error as an anomaly, for which the solution is to ferret out and blame an individual, with a promise that 'it will never happen again.'

Paradoxically, this approach has diverted attention from the kind of systematic improvements that could bring a more systems awareness and help to decrease harm [64]. Many errors are built into existing routines and devices, setting up the unwitting physician and patient for disaster. Although patients are the first and obvious victims of medical mistakes, doctors are wounded by the same errors—they are the second victims [65].

Wu elaborates by noting that there are no formal mechanisms for providing support to the provider for the emotional impact of serious patient harm. In many instances the physician feels guilty and technically incompetent. These feelings are then combined with the fear of discovery, all of which can lead to an atypical reaction to the family, ranging from being overly attentive to distress over disclosure [66].

Scott in 2009 applied a consensus definition developed by the University of Missouri Health Care (UMHC) in a study performed by their Office of Clinical Effectiveness (OCE) [67]:

> Second victims are healthcare providers who are involved in an unanticipated adverse patient event, in a medical error and/or a patient-related injury and become victimized in the sense that the provider is traumatized by the event. Frequently, these individuals feel personally responsible for the patient outcome. Many feel as though they have failed the patient, second guessing their clinical skills and knowledge base.

The following case studies serve to illustrate and expand the concept of the second victim.

Case #1: The Almost Event

The telephone rings in the cabin in Central Texas at 2 a.m. Sunday. Answering it, I hear a female who cannot talk above a whisper. "Are you the risk manager?" "Yes," I reply, thinking that she must not work for our main hospital or she would know that. "I'm Sally Field, a nurse at Disney Hospital, a newly affiliated hospital. I almost took the wrong patient to surgery" "Almost? Did the wrong patient have surgery?" "Oh no, it was caught by the nurse in holding." "That's good, isn't it?" "Yes, it is but I'm so upset. So embarrassed. Now people will know what I did." The nurse is not new to the job, she is not inexperienced, and she knows the procedures. So why did she call? She is worried that it will happen again. She is mortified. We debrief the event. The patients had similar names and were on the same floor. She is used to doing her tasks without any aids—no notes, nothing to assist her memory—but at age 55 she finds that her system isn't working anymore. Being that age myself, we discuss simple tools such as a small spiral pad for note-taking. The procedures worked properly and tomorrow we will debrief again to see if any steps done on the unit could have prevented this near miss.

In the UMHC study, six stages were identified that occur in response to a serious mistake [67]. These stages included:

- Chaos and accident response
- Intrusive reflections
- Restoring personal integrity
- Enduring the inquisition
- Obtaining emotional first aid
- Moving on

The sixth stage, moving on, led to one of three outcomes: dropping out, surviving, or thriving. At the time of the event, the physician may be having two types of thoughts: how to care for the patient combined with an immediate reaction to the event as an error. In many cases clinicians are able to describe almost complete recall of the event, which could be triggered by outside stimuli, with continual self-questioning. On their website, K.U. Leuven *Second Victims in Health Care* summarizes the impact as follows [68]:

- The healthcare professional can experience a *professional impact*, such as:
  - Different attitude within the team
  - Insecure feeling in the presence of the team
  - Different attitude in the presence of patients and their families
  - Uncertainty, which elevates the chance in making other mistakes
  - Burnout
- The healthcare professional can also experience a *personal impact*, such as:
  - Post-traumatic stress
  - General stress symptoms
  - Anger
  - Insomnia
  - Nervousness
  - Effect on family life
  - Depression

Case #2: The Angry Physician

A physician is angry. Really angry. Yelling at me angry. Standing in the hallway smoking a cigarette, absolutely livid. The physician review committee has considered a surgical case that may possibly become a claim and found her care appropriate. The physician feels totally blindsided—that the review was a whitewash. A highly respected physician, she believes the committee failed to note treatment options that could have led to a different outcome out of deference to her. This person is a detail-oriented practitioner. She is, like many physicians, someone who came to medicine through science. She doesn't want to repeat the event. She doesn't want to defend an indefensible case. Most of all, she wants to know why this happened. That's what science teaches—if you do this, that will happen. If this, then that. If we cannot assist her to determine why the case had a poor outcome, she is doomed to repeat it, and this is her biggest fear.

One liability review chairman taught that we have all killed a patient. We have all faced this awful experience. But what did we learn? How

did we handle it? How may we help our fellow physicians in the future? Another liability review chairman taught that no one comes to work to hurt a patient. Everyone wants to leave work with a smile on his face, jangling his keys, happy about the day. But what happened? And even more important: If we can determine what happened, we can establish a routine to prevent it.

Case # 3: A Different Type of Impairment

A physician appears in the office and sits down. "I think I killed that woman." A physician appears in the office and sits down. "I think I misdiagnosed that child." A physician appears in the office and sits down. "I missed an abnormal lab." A physician appears in the office and sits down. "I operated on the wrong side. What do I tell the patient? How do I meet the family? How do I go back to work? How do I face my peers?"

Practitioners in these situations call the risk manager for help. Certainly, many call because the risk manager is the liaison to their malpractice company or because they were mandated to call. Others call because it is the route to an unbiased peer review process. Some will not call the risk manager and will only call a peer. A common concern is whether they can return to practice. Some physicians called to report but could not come to the office. Their voices spoke of fear and stress.

Risk management requires neutrality. Rule number one for the risk manager—be fair. Physicians, nurses, and allied health practitioners—anyone who could cause harm—called the office and were offered a chance to tell their story and to be informed about the procedures. For many, the risk management office is a safe place to report an event and hear the worst. For others, it carries potential censure.

Physicians often express gratitude that someone else shared their burden, would point the way, would provide and arrange support, and would help them return to practice. Nevertheless, risk management is not the employee assistance program (EAP). For nursing this can mean a referral to an established nursing support team. For physicians, this means a referral to EAP; however, many physicians refuse to go and turn to their peers. They meet with the liability review committee chairman. For this reason a provider support group may be needed to provide counseling, support, and in some cases mentoring and proctoring.

Just as organizations face risk on a daily basis, the day-to-day life of a healthcare practitioner also involves risk. Virtually all activities of a physician involve risk. An unexpected outcome produces personal and professional fears for the practitioner and legal, regulatory, and reputation fears for both the practitioner and the institution. How the institution supports the practitioner sets the stage for an environment of trust and is a signal to other practitioners about the true culture of the institution.

Fear of litigation is as paralyzing as the fear of repeating the (possible) mistake or damaging one's reputation. The laws and regulations under the Patient Safety and Quality Improvement Act of 2005 established the creation of Patient Safety Organizations (PSOs) that should allow for a patient safety review process without fear of legal discovery [69].

Several elements are essential in providing support for the second victim:

- The physician often wishes a formal peer review of the event in order to determine the adequacy of the care rendered to the patient and ways of preventing the type of event in the future.
- The physician often requires personal support from a peer, through formal or informal channels. Note this is not a onetime meeting but ongoing as the clinician travels through various emotional stages of grief.
- The physician may request a monitoring period for support and feedback during similar circumstances.
- The physician may wish to or be directed to meet with the patient and family for purposes of disclosure.

There is tension between the fact-finding investigative mission, the legal defense considerations, and the physician support teams. The trajectory of these three paths requires a clear policy and

procedure, with the facility culture as the underlying tenet [66]. Establishing a peer support team, with specific training and immediate availability, is essential and has been implemented at a number of facilities including at Johns Hopkins Hospital, the University of Maryland Medical Center, and the Greater Boston Medical Center [70].

Summary

Surgical risk management is an important and complicated aspect of the perioperative environment. Factors that must be considered and carefully studied include measurement and assessment of risk, culture, governance, credentialing, training and competency, scope of practice, equipment availability, and the effects of errors on both patients and the provider staff.

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Managing the Complex High-Risk Surgical Patient

34

Kevin W. Lobdell, B. Todd Heniford, and Juan A. Sanchez

"Risk comes from not knowing what you're doing."

—Warren Buffett-Business Magnate and Investor

Risk and Risk Registries

Risk, hazards or threats that an outcome might be different than expected, implies that choice rather than fate is involved. The word risk is thought to have evolved from Italian, circa 1600s, where "risicare" meant "to dare" has evolved to suggest that, in accepting risk in the hope of a favorable outcome, a different result may occur. Risk has various modern definitions that include, but are not limited to: (1) the possibility of injury or loss; (2) a person or thing that creates a hazard; and (3) the financial chances of loss, whether in insurance or investing. Additionally, to risk is to (1) expose injury or loss, and (2) incur the danger of injury or loss. A practical example of risk would be the flip of a coin, in which the potential outcomes and probability are known. In contradistinction to a coin flip, the uncertainty of surgical risk does not allow us to know all possible outcomes or the probability of occurrence of each outcome.

The evolution of risk, and risk management programs parallels progress in mathematics. It is noteworthy that developments in mathematics related to risk include Pascal and Fermat's theory of probability in 1654 resulting from a challenge to divide the stakes of an unfinished game between two players when one player was ahead. By 1725, mathematicians devised life expectancy tables for the English government which became the genesis for annuities. Bernoulli described the "Law of Large Numbers" in 1703 and subsequent, noteworthy concepts were developed by de Moivre, who described the Law of Averages in 1730, Galton who related Regression to the Mean in 1875, and Markowitz who advanced the concept of "diversification" in 1952.

The computer era has accelerated data management, analysis, and risk-modeling. Governments, military, and financial institutions utilize information technology advancements to communicate, optimize efficiency, and improve the efficacy of resource allocation, all central to mitigating risk. Similarly, data has accumulated in healthcare leading to the development of modeling techniques and simulation models, allowing comparison of process compliance, death, complications, length of stay, readmissions, and cost per case for various procedures and maladies.

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The Society of Thoracic Surgeons National Cardiac Database (STS-NCD) and its risk models, first established in 1989, is the archetype of a risk-adjusted clinical registry [1]. Similarly, the American College of Surgeons has developed the National Surgical Quality Improvement Program (NSQIP) and aims to improve quality in breast disease, cancer, pediatric surgery, trauma, as well as via a surgeon specific reporting (SSR) program [2]. Additionally, the United States' Medicare program has developed Hospital Compare (https://www.medicare.gov/hospitalcompare/search.html) with the aim of allowing the program's subscribers and the general public to compare the quality and value of health care delivery institutions.

The "volume-to-value" evolution in healthcare with its inherent reward and granular definitions of quality is generally expected to result in improved measures of clinical and financial outcome as well as enhanced level of patient satisfaction. Domains of quality and value in healthcare converge in Medicare's Value-Based Purchasing program. Proprietary datasets, such as Premier, Truven, US News & World Report, utilize administrative data and their own methodologies to rate health care facilities. Although this plethora of information should assist individuals, employers, and payers to make wiser informed choices, the result is confusing and unhelpful to many consumers of healthcare as a result of major differences between these sources of information and their analyses. As such, the natural evolution of efforts to derive actionable information with regard to clinical risk resides in programs, such as NSQIP and STS. These types of registries provide for concurrent data abstraction by clinicians as well as transparent, continuously adjusted risk models to assess patient-specific risk as well as meaningful comparisons of clinical outcomes between providers.

High-Risk Surgery

The Global Burden of Surgery (GBS) comprises 11–28 % of the Global Burden of Disease (GBD) and the worldwide estimate is 234 million operations per year. Overall surgical mortality is estimated to be 0.4 % and morbidity 3–17 % [3–11]. Surgical and anesthesia perioperative complications can be categorized as local/specific or general either by providers or by patients [12]. Temporal categorization of outcomes can be early, intermediate, and late. The rate of complications correlates well to clinical risk. For example, the NSQIP analysis of over 105,000 patients suggests that the occurrence of any one of the 22 complications reduced the median life expectancy by 69 % [13]. This risk of death and morbidity is always borne by the patient; however, other participants in the healthcare system (surgeon, facility, and payer) bear other types of risks including reputational, regulatory, and financial [14].

Although statistical models for death and complications are useful, the statistician George E. P. Box reminds us that "all models are wrong, some are useful." The American College of Surgeons National Surgical Quality Improvement Program calculator (available at https://www.facs.org/quality-programs/acs-nsqip) is one example of an accessible, simple to use, and validated surgery risk assessment tool that applies to numerous procedures and can assist the patient's and clinician's decision making (https://www.facs.org/quality-programs/acs-nsqip/about/businesscase). Computerized risk models have also been validated by comparing results with experienced surgeons [15]. Risk scoring systems can be used as a snapshot of a patient's risk at a point in time prior to operative intervention or be more dynamic where the risks evolve with a patient's clinical course in general or organ specific terms, associated with specific phases of care (e.g., perioperative or critical care phase). Table 34.1 shows examples of surgical risk models which can be disease or specialty-specific (http://www.riskprediction.org.uk/; http://riskcalc.sts.org/stswebriskcalc/#/; http://www.euroscore.org/) [16–22]. Risk-model characteristics include, but are not limited to, calibration-observed and expected rate of agreement, discrimination-ability to separate high and low risk or those that have event or disease from those that do not, accuracy, precision, etc. [19] (http://riskcalc.sts.org/stswebriskcalc/#/).

High-risk surgery (HRS) is generally defined as mortality greater than two standard deviations

Table 34.1 Surgical and organ dysfunction risk models [16–22]

Acute physiology and chronic health evaluation (APACHE)
American society of anesthesia (ASA)
Charlson co-morbidity index (CCI)
EuroScore 1 and 2
Lee revised cardiac risk (RCRI)
Mortality probability model (MPM)
Multiple organ dysfunction score (MODS)
Physiologic and operative severity score for the enumeration of mortality and morbidity (POSSUM, P-POSSUM)
Sequential organ failure assessment (SOFA)
Simplified acute physiology score (SAPS)
Society of thoracic surgeons (STS-NCD)
Surgical risk outcome tool (SORT)
Vascular study group cardiac risk index (VSG-CRI)

Table 34.2 Examples of low, intermediate, and high-risk procedures

High risk	Open aortic and major vascular, urgent intra-thoracic, or intra-abdominal surgery
Intermediate risk	Elective abdominal, carotid, endovascular, major neurosurgical procedures, arthroplasty, pulmonary resections, and major urological operations
Low risk	Breast, dental, thyroid, ophthalmic, plastic, and minor gynecologic, orthopedic, and urologic surgery

from the mean mortality for a procedure as determined by analyses using accurate, statistically acceptable datasets [23]. Similarly, a projected mortality over 5 % may be defined as high risk and greater than 20 % very high risk. The physiologic assessment of risk is an increasingly useful method of risk analysis including anaerobic threshold quantification, functional capacity and frailty, and biomarkers (e.g., BNP for heart failure or TIMP-2 and IGFBP-7 for acute kidney injury). Examples of procedures with different levels of risk are shown in Table 34.2.

Economics of High-Risk Surgery

In the USA, health care consumes approximately 18 % of the Gross Domestic Product (http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS). Global waste in healthcare is estimated to be $4.27 trillion annually, making it the least efficient and unsustainable system in the world. This staggering inefficiency, with questionable efficacy in many areas, impedes meaningful impact and progress in relieving the Global Burden of Disease (GBD). Surgical care has evolved from a focus on technical proficiency in anesthetic and procedural refinement, to a "360°" view that includes patient and family perceptions of service, teamwork and communication, long term morbidity, patient report of morbidity (PROM), etc. Additionally, cost-containment measures such as lengths of stay, readmissions, cost per case, for example, are increasingly used measures to gauge the effectiveness and value of care. Numerous investigations have evaluated and correlated risk with cost (http://www.ahic.nihi.ca/ahic/docs/IBV%20Study%20Redefining%20the%20Value%20of%20Healthcare.pdf) [24–26]. Studies have linked lower quality and complications with additional costs [27]. For example, Dimick et al. evaluated the economic impact of complications in high-risk surgical procedures (935 hepatic and esophageal operations) [28]. The observed mortality was 6.1 %, while 38.4 % patients had complications, and the median cost increase for patients with complications was 31 % when compared to patients with no complications. Acute renal failure (ARF) was associated with an incremental increase in cost of $25,219, septicemia $18,852, and myocardial infarction $9573. Because of variation in the incidence of complications, the attributable fraction of total resource costs was highest in ARF (19 %), septicemia (16 %), and surgical complications (16 %). Speir and colleagues report from the Virginia Cardiac Surgery Quality Initiative (VCSQI) elegantly quantified the additive costs of complications associated with 14,780 coronary artery bypass operations between 2004 and 2007 [29]. These costs ranged from $62,773 for mediastinitis (240 % greater costs than without this complication), $49,128 with renal failure, $40,704 with prolonged ventilation, $34,144

with postoperative stroke, $20,000 for reoperation for hemorrhage, and $2744 (10.3%) for atrial fibrillation. The average length of stay (LOS) of 7.4 days was also significantly impacted costs and ranged from 37.8 days for mediastinitis to 9.6 days for isolated atrial fibrillation. Additional large cardiac surgery studies have also demonstrated a strong correlation between poor quality and increased cost [30–32].

Birkmeyer and colleagues found that federal payments for kidney transplantation to low-quality centers exceed that of high-quality centers [33]. A 2012 investigation demonstrated that centers in the highest quintile for complications versus the lowest quintile required greater cost payments for coronary artery bypass surgery ($5353), colectomy ($2719), abdominal aortic aneurysm repair ($5279), and hip replacement ($2436) [34]. The utility of incorporating risk models in determining provider reimbursement for a variety of alternative payment models is often the source of contentious and bipartisan debate [35].

Host Risk Factors

A systematic and disciplined approach to mitigating modifiable risk across the health system is the goal of risk management systems [36]. Each patient's evaluation should include a history, physical exam, review of medical records, appropriate testing and specialty consultation as indicated, and all available information used in the assessment of specific risks [37, 38]. A keen understanding of the response to injury and surgical trauma is fundamental to caring for surgical patients especially in high-risk patients and procedures [39]. Risk is increased in high-physiologic demand procedures, low physiologic reserve patients, and when a mismatch occurs between the physiologic demand and the patient's reserves. Cardiopulmonary exercise testing (CPET) can provide valuable insight into a patient's reserve but is not commonly utilized due to patient limitations, resource utilization, and the inability to consistently predict outcomes [40].

Cuthbertson is credited with early insights into the "stress response" characterized by fever, increased metabolic rate, oxygen consumption, and muscle loss [41]. Many researchers have further elucidated and characterized the physiology of the stress response to include neuroendocrine changes, catabolic degradation of muscle proteins, the release of a multitude of inflammatory mediators, alteration in intravascular, intracellular, and extracellular fluids (commonly described as "third-spacing"), coagulopathy, etc. [42]. Modulation of the stress response has been intensely investigated with the aim of mitigating the associated risks. Common examples include anabolic agents such as growth hormone and testosterone and anti-catabolic agents such as amino acids like glutamine, arginine, and branched chain amino acids [43]. Beta-blockade has been demonstrated to reverse the catabolic effects of burns [40] and has also been studied in various conditions demonstrating a reduction in mortality and cardiovascular morbidity [44, 45]. A better understanding is needed about the manifold effects of these commonly utilized agents as well as the more recent additions to our pharmacologic armamentarium such as lipid lowering agents [46]. Neuraxial anesthesia, deep opioid anesthesia, peri-procedural sedation, and other anesthetic techniques have also been proposed to reduce risk and improve outcomes due to their mitigating effects on the stress response [47, 48].

Thermoregulation

Thermoregulation is commonly disturbed as a result of low ambient temperatures in the operating room as well as the effects of anesthesia. Thermoregulation is important in maintaining hemostasis by reducing coagulopathy and the amount of surgical blood loss, thereby avoiding the risk of blood transfusions and products. Hypothermia is associated with lower metabolic rates, immunologic changes that increase the risk of surgical site infections, delays in recovery, and separation from mechanical ventilation [49–51]. The incidence of hypothermia can be reduced with accurate temperature measurement and assiduous attention to ambient room temperature, patient draping, warming intravenous solutions

and blood products, warming ventilator circuits, and the use of warming blankets.

Age

Age is an independent risk factor for poor outcomes and knowledge of age-specific risks creates an opportunity to anticipate and mitigate these risks (https://www.facs.org/~/media/files/quality%20programs/geriatric/acs%20nsqip%20geriatric%202016%20guidelines.ashx). Postoperative delirium is an example of a frequent, insidious complication which is observed in 30–50 % of patients after major surgery and as high as 75 % in patients over age of 70. It is commonly seen in the older age group and is associated with short and long term increased mortality, morbidity, and LOS. Mitigation strategies include vigilant monitoring, careful analgesia, vision and hearing aids, mobility, quiet and reassuring surroundings, and an active effort to maintain circadian day–night schedules where possible. Adding a clock to patient's rooms has been shown to reduce delirium and confusion. Jung determined that the incidence of delirium in frail cardiac surgery patients was 3–8-fold higher [52]. Additionally, increased risks in the elderly include falls, infection, and pulmonary complications accounting for 40 % of postoperative complications and 20 % of potentially preventable deaths [53].

Mass and BMI

Lower than normal body mass index (BMI) consistently confers a surgical risk, while overweight patients may have an increase in wound complications and deep venous thrombosis. These patients, however, are not at increased risks of death and other major complications. In fact, some higher and BMI patient populations appear to exhibit fewer perioperative complications, operative mortality, and better long term survival. This phenomenon is often referred to as the "obesity paradox." Mullen et al. reviewed 118,707 non-bariatric general surgical patients using the NSQIP database and observed that BMI's influence on mortality exhibited a reverse J-shaped relationship, with the highest rate of death in underweight and extremely morbidly obese patients while the overweight and moderately obese had the lowest mortality rates [54]. These observations are in contrast to mortality in the "general medical" population in which obesity reduces longevity, hence the "paradox." The study also demonstrated a direct correlation between BMI and complications particularly surgical site infections (SSI). The authors also demonstrated that obesity is not a risk factor for postoperative mortality or major complications after major intra-abdominal cancer surgery while underweight patients experienced a fivefold increased risk of postoperative mortality [55]. Ramsey and Martin have suggested that elevated BMI increases operative complexity in pancreatectomy but that the increased risks associated with BMI may be reduced with modifications in techniques and meticulous perioperative care [56]. Underweight and extremely high BMI patients experience greater risk while mild obesity wasn't found to be a risk factor for 30-day outcomes after vascular surgery and actually appeared to confer an advantage [57]. Studies examining the influence of BMI on spine surgery outcomes have produced mixed results. There appears to be an increased risk in high BMI patients undergoing revision spine surgery but not cervical fusion [58, 59]. Cardiac surgery patients are similarly impacted by weight, where low BMI and extremely high BMI confer an increased risk. Although an increased BMI may adversely alter some recovery processes while simultaneously reducing hemorrhage and transfusions [60]. Stamou demonstrated that overweight cardiac surgery patients have lower operative mortality and a better 5-year survival than patients with a normal BMI supporting the "obesity paradox" phenomenon [61]. Johnson et al. corroborated these findings in 78,762 cardiac surgery patients where overweight and mildly obese patients had better outcomes than the underweight and the morbidly obese did [62].

Neurologic System

A history of a stroke, seizure, movement disorders, and other neurological conditions confer additional risks and can adversely affect outcomes in surgical patients. The ability to assess pain accurately is important in providing patient comfort, preventing immobility and atelectasis. Several useful pain scoring systems may be utilized [63–65]. The use of neuraxial and opioid anesthesia has been shown to reduce operative mortality by 30 % in a meta-analysis comparing neuraxial blockade with general anesthesia [47, 48].

Pulmonary System

A history or evidence of chronic respiratory insufficiency or other respiratory conditions can impact perioperative care and elevate operative risks [66]. It is essential that we develop and agree on common definitions across different disciplines treating the patient [67]. Spirometry and formal pulmonary function testing, arterial blood gases, and chest radiography should be obtained in the evaluation of these high-risk patients particularly in patients undergoing thoracic and abdominal procedures. Smoking cessation 30 days prior to operation is strongly recommended and is often coupled with counseling and nicotine replacement; however, smoking cessation of seven or less days can actually increase pulmonary secretions and pulmonary complications [68, 69]. Pulmonary rehabilitation appears to be beneficial in reducing pulmonary risk although its impact needs more intensive study [70–72].

Postoperative respiratory complications occur in approximately 3–6 % of surgical patients and most risk models commonly include respiratory data such as active smoker status, chronic obstructive pulmonary disease, dyspnea, and active pneumonia. In addition, assessing functional status, ASA class, renal insufficiency, and other cardiopulmonary conditions are important elements of a comprehensive evaluation in patients undergoing major surgery [73–76]. As an example, ARISCAT provides preoperative pulmonary-specific risk assessment which takes into consideration age, oxygen saturation, and other clinical factors as well as the location of the surgical incision, the duration of surgery among other elements [74]. ARISCAT categorizes risk as follows: 0–25 points low risk and is associated with a 1.6 % pulmonary complication rate, 26–44 points intermediate risk, and a 13.3 % pulmonary complication rate, while 45–123 points suggests high risk and is associated with a 42.1 % pulmonary complication rate (http://www.uptodate.com/contents/calculator-ariscat-canet-preoperative-pulmonary-risk-index?source=search_result&search=risk+calculator&selectedTitle=7~150).

Mechanical ventilation can be a contributory factor in the development of postoperative acute lung injury and acute respiratory distress syndrome (ARDS) [76]. It is associated with mechanical ventilation, inspired oxygen fraction, the administration of crystalloid volume intravenously, as well as transfusion of homologous blood components [77]. In contradistinction to pulmonary barotrauma in which pulmonary damage is the result of excessive airway pressures, the mechanism of injury from volutrauma is likely to over distention of alveoli from excessive excessively high tidal volume settings and injury to the alveoli epithelium. Early extubation after surgery, particularly in patients with pre-existing lung disease, may reduce the incidence of both barotrauma and volutrauma and has been correlated with improved outcomes [78, 79]. Intraoperative alveolar recruitment using PEEP, maintenance of tidal volumes of 6–7 ml/kg, and postoperative utilization of non-invasive positive pressure ventilation are protective ventilator strategies known to reduce the incidence of postoperative respiratory complications [80, 81]. Hypercapnia is another lung protective strategy that has been proven meritorious [82, 83].

In thoracic surgery, dependent, bedridden living correlates with 7–8-fold increased risk of mortality, nine fold prolonged ventilation rate, and three fold more likely to require reintubation [84]. The predicted postoperative lung function after lung resection is typically greater than what is witnessed clinically by at least 30 % and is most disparate on the first postop-

erative day with subsequent progressive improvement [85, 86].

The Thoracoscore, a convenient and useful risk scoring system in thoracic surgery, was the result of an in-depth analysis of 15,183 thoracic surgery patients where in-hospital mortality correlated with ASA classification, age, gender, dyspnea score, performance status, priority of surgery, diagnosis group, procedure class, and comorbid disease. Modifiable risk factors to reduce the risk of complications include weight loss, smoking cessation, and a multidisciplinary approach towards optimizing lung functions including exercise, patient education, as well as the treatment of bronchorrhea and bronchospasm [87, 88].

Cardiovascular System

The preoperative evaluation of the high-risk patient with cardiovascular disease should focus on assessing the risk of perioperative myocardial ischemia and infarction and the identification of significant cerebrovascular disease, congestive heart failure and ventricular dysfunction, rhythm abnormalities, and pulmonary hypertension [89]. Lab testing may include biomarkers such as BNP. Treadmill exercise testing is readily available and well-studied [90]. Additional imaging can include many variations of echocardiography, nuclear testing, computerized axial tomography, coronary artery calcium (CAC) score, magnetic resonance imaging (MRI), and coronary angiography with or without ventriculography and, more recently, fractional flow reserve-FFR, as indicated.

In 1977, Goldman developed the eponymous cardiac risk scoring systems for patients undergoing non-cardiac surgery which was revised by Lee et al. (RCRI) in 1999 making it simpler and more predictive [91]. The risk factors are tallied and are correlated with the risk of major cardiac complications. Zero risk factors has a 0.4 % risk of death, 1.0 % with one risk factor, 2.4 % with two risk factors, three or more risk factors carry a risk of 5.4 % [16].

The Vascular Study Group of New England (VSGNE) studied the vascular surgery population's risk of adverse cardiac events and has developed the Vascular Study Group Cardiac Risk Index (VSG-CRI) [17]. Additional investigations utilizing the American College of Surgeons' NSQIP database reinforces the importance of surgery type, ASA classification, functional status, age, as well as renal dysfunction [92]. CAC score improves preoperative assessment and is able to assign patients to various risk categories in order to modify processes and care plans accordingly [93].

The impact of drugs to mitigate cardiovascular risk has been well-studied, albeit controversial, and continues to evolve. For example, the PeriOperative ISchemic Evaluation (POISE) trial evaluated metoprolol in patients at increased risk for perioperative cardiovascular events (death, myocardial infarction, and nonfatal cardiac arrest) [94]. While significantly fewer cardiovascular events were noted in the treatment group, metoprolol was associated with an increased risk of death and stroke potentially related to the observed perioperative hypotension. Clonidine has also demonstrated similar hypotensive effects and nonfatal cardiac arrest and failed to reduce the risk of death or myocardial infarction [95]. Aspirin has been shown to have no beneficial impact on a composite measure which includes death and myocardial infarction and increases the risk of bleeding [96]. Combinations of these strategies have been reported including the use of neuraxial blocks with general anesthesia which wasn't associated with an increase in adverse cardiovascular outcomes in the POISE-2 study [97].

Valvular heart disease is increasingly recognized in our aging patient population. The effects of volume loading on left ventricular function occurring in mitral regurgitation as well as the pressure load in aortic stenosis, particularly in the setting of depressed myocardial contractility, carry considerable risk. These conditions must be recognized during the preoperative evaluation and anesthetic as well as surgical techniques modified to optimize outcomes [98]. Atrial fibrillation

Table 34.3 Stroke risk using the CHA2DS2-VASc score

0 points	0.2 % per year
1 point	0.6 % per year
2 points	2.2 % per year
3 points	3.2 % per year
4 points	4.8 % per year
5 points	7.2 % per year
6 points	9.7 % per year
7 points	11.2 % per year
8 points	10.8 % per year
9 points	12.2 % per year

commonly accompanies valvular heart disease although non-valvular atrial fibrillation (AF) is more common. Regardless of its underlying cause AF can affect cardiac performance especially with a poorly controlled heart rate and pose thromboembolic risk. The CHA2DS2-VASc (Congestive heart failure, Hypertension, Age >75, Diabetes, prior Stroke/transient ischemic attack, VAScular disease) risk stratification score for estimating stroke risk in non-valvular AF ranges from 0 to 9 points as shown in Table 34.3 (http://www.uptodate.com/contents/calculator-cha2ds2-vasc-risk-stratification-score-for-estimation-of-stroke-risk-for-nonvalvular-atrial-fibrillation?source=search_result&search=risk+calculator&selectedTitle=5~150). Appropriate perioperative anticoagulation strategies can mitigate the risk of atrial fibrillation associated emboli.

Aortic surgery and other major vascular procedures are frequently associated with a high risk for adverse cardiac events and mortality. Investigation of this subset of patients highlights importance of ASA class, age, and preoperative organ dysfunction as essential elements of risk assessment and mitigation strategies [99]. In patients undergoing left ventricular assist device (LVAD) implantation postoperative right ventricular dysfunction can be a vexing problem. A right ventricular failure risk score (RVFRS) has been developed which attributes points to preoperative vasopressor requirements as well as to elevated serum levels of aspartate aminotransferase, bilirubin, and creatinine to predict the need for postoperative inhaled nitric oxide, inotropic support, and mechanical support of the right heart [100].

Splanchnic System

The history and physical exam should be focused (looking for jaundice, signs of portosystemic shunting, ascites, encephalopathy, etc.) to elucidate liver dysfunction as well as altered bowel and pancreatic dysfunction. A patient with advanced hepatic cirrhosis is simple to identify, but less pronounced degrees and other hepatic disorders may be overlooked with considerable consequence(s). It is vital to elucidate the amount and limits of the functional reserve. Timing of operation and avoiding hepatic insults (pharmacologic and hemodynamic) are central to successful anesthesia and perioperative care.

The Model for End-Stage Liver Disease (MELD) is clinically valuable and relevant, categorizing patients via bilirubin, creatinine, International Normalized Ratio (INR), and the etiology of underlying liver dysfunction [101]. MELD scoring has also been compared favorably with others systems, such as the Child-Turcotte-Pugh classification [102]. Common problems in patients with liver dysfunction include coagulopathy 2–28 % and hemorrhage, immunoincompetence and sepsis 9–58 %, malnutrition, cardiomyopathy with systolic dysfunction and/or diastolic dysfunction, and peripheral vasodilation, pulmonary dysfunction 6–29 %, and renal dysfunction 5–79 % [103].

Liver dysfunction increases mortality of patients undergoing cardiac surgery, where coagulopathy and hemorrhage are commonplace, and progressively increases with the severity of liver dysfunction. The MELD score has proven useful for risk assessment and planning in the cardiac surgery population [104]. Liver resection also poses a discrete and identifiable risk to patients with liver dysfunction. Four independent risk predictors include ASA class, aspartate aminotransferase level, extent of liver resection (>3 vs <3 segments), and the need for an additional hepaticojejunostomy or colon resection [105].

Intestinal and pancreatic exocrine deficiency may emanate from a variety of diseases, have a myriad of signs and symptoms, but the greatest functional risk relates to malnutrition. Gastrointestinal, colon, and rectal surgery are common procedures, where ASA class, age,

BMI, prolonged and open procedures (vs. laparoscopic techniques), active smoking, chronic obstructive pulmonary disease (COPD), kidney dysfunction, corticosteroid use, and sepsis have been correlated with increased risk [106]. Pancreaticoduodenectomy is a high-risk procedure and significant predictors of morbidity include functional status, increased age, obesity, COPD, kidney disease, corticosteroid use, hypoalbuminemia, hemorrhagic diathesis, and leukocytosis. Significant predictors of 30-day mortality included COPD, hypertension, neoadjuvant radiation therapy, elevated serum creatinine, and hypoalbuminemia [107].

Perioperative bowel prep regimens can be beneficial with recent studies suggesting that mechanical bowel prep should be accompanied with oral antibiotics in colon and rectal surgery to reduce the risk of surgical site infections, anastomotic leak, and ileus. The use of mechanical bowel prep and oral antibiotics may also reduce length of stay and readmissions [108–110]. The use of H2-blockers and proton pump inhibitors can markedly reduce the risk of stress induced gastrointestinal hemorrhage, but may increase the risk of hospital acquired pneumonia [111].

Renal System

The targeted history and physical, searching of renal dysfunction is commonly accompanied by urinalysis, serum creatinine, and calculation of glomerular filtration rate. Imaging is less commonly utilized than for cardiac and pulmonary evaluations, but ultrasonography, radiography, and endoscopy may be useful in certain circumstances.

Perioperative renal dysfunction is common and often unrecognized [112]. Patients may suffer various degrees of acute kidney injury (AKI), without the need for dialysis, and incur increase short and long term risk. Ableha et al. reported on 1597 patients and found ASA classification, emergency and high-risk surgery, age, ischemic and congestive heart disease, and RCRI score significant predictors for the development of AKI, in patients needing intensive care after surgery [113]. AKI is linked with increased risk of mortality and longer LOS and these risks are documented extensively in adult cardiac surgery [114–118]. Various risk models have been developed and commonly include age, BMI, hypertension, peripheral vascular disease, chronic pulmonary disease, serum creatinine concentration, anemia, previous cardiac surgery, emergency operation, and operation type [119–121] (http://riskcalc.sts.org/stswebriskcalc/#/calculate). AKI risk mitigation strategies include avoidance of nephrotoxic drugs—e.g., aminoglycosides, amphotericin B, and ionic contrast. Pretreatment with sodium bicarbonate and fenoldopam haven't stood the test of time. Delay after ionic contrast administration appears important, though many details remain to be understood. More recently, high-chloride intravenous fluids are thought to be associated with a significantly higher risk of acute kidney injury [122].

Goal directed therapy (GDT), also known as goal directed hemodynamic management, is well studied and maintains considerable promise as a modifiable risk in AKI and renal failure [123–125]. A prospective study is underway to further define the utility of this strategy [126].

Endocrine System

The targeted history and physical should elucidate risks which include thyroid dysfunction, adrenal insufficiency, and pancreatic endocrine abnormalities, most commonly diabetes mellitus, which also adds considerable, additional risk. Considerable controversy exists, despite extensive research, in the management and risk mitigation of perioperative hyperglycemia. Hyperglycemia is linked with death, surgical site infection, and atrial fibrillation in the cardiac surgery patient and various protocols have been developed to provide glycemic control [127].

Skin and Wounds

The history and physical must elucidate risks (malnutrition, vitamin, and trace mineral deficiency central to wound healing, diabetes mellitus, immunosuppression, infection, peripheral

occlusive vascular disease, immobility, genetic defects, radiation therapy and chemotherapy, smoking, etc.) which can impair recovery, either through development of problems such as pressure sores/ulcers or non-healing wounds. Tests such as ankle-brachial indices, transcutaneous oxygen saturations, and quantitative wound cultures may augment expert evaluation and decision making.

Proper planning, positioning, and padding are imperative during operative procedures to prevent pressure sores. Considerable investigation has been devoted to wound closure and includes type of suture, monofilament vs. braided, permanent vs. absorbable, skin closure with sutures and staples, and a multitude of dressings. In cardiac surgery, various techniques for sternal closure after median sternotomy have been investigated and the role of "rigid sternal fixation" to prevent dehiscence and/or infection is currently unresolved. Skin cleansing, wound closure, and support have been vigorously marketed, but evidence for value is scarce. A complete review of adjuncts, such as wound healing factors and hyperbaric oxygen, is beyond the scope of this text.

Comprehensive, postoperative care will include attention to skin, dressings, mobility, nutrition, etc., in order to reduce the risk of pressure sores and wound problems. Skin can be assessed in combination with the Braden Scale, with special attention to sensory perception, moisture, activity, mobility, nutrition, and friction or shear. Glucose control is thought to be important in preventing sternal wound infections after sternotomy and various other surgical site infections as well. Wound evaluation should also be included in the comprehensive, postoperative routine (http://www.uptodate.com/contents/calculator-pressure-ulcer-risk-stratification-braden-score?source=search_result&search=risk+calculator&selectedTitle=8~150130; http://www.uptodate.com/contents/wound-healing-and-risk-factors-for-non-healing?source=search_result&search=wound+closure&selectedTitle=9~95).

Negative pressure wound therapy has a long history, is well studied, and commonly utilized. The use of "wound vacs" has simplified wound care, makes management of open and infected wounds more comfortable for patients, and accelerates wound healing. The archetype for this growing use and experience is the infected sternal wound, where topical negative pressure is commonly thought to be superior to traditional methods of irrigation and packing [128, 129]. "Wound vacs" are also commonly utilized to assist in preventing wound infections associated with delayed sternal closure.

Metabolism and Nutrition

The comprehensive history and physical will include special attention to metabolic and nutritional signs and symptoms that increase the risk of recovery. Wound healing may be impaired with various metabolic maladies and commonly with malnutrition—where attention should focus on weight loss, loss of muscle and subcutaneous fat, and edema. Laboratory tests to be considered include electrolytes, BUN, Cr, etc. Markers of protein status (albumin, transferrin, and pre-albumin) may be valuable in select patients. Malnutrition can increase the risk of infection related to impairment of cellular and humoral immunity, poor wound healing, pressure ulcers, etc. Nutritional intervention has been shown to be valuable in various areas. Enteral, parenteral, and targeted repletion of vitamins and trace metals have been studied and should be considered when appropriate to mitigate surgical and perioperative risk [130, 131].

Hematologic and Immune System

The history and physical must elucidate risks associated with anemia, coagulopathy, infections, and related factors that would suggest increased risk of intraoperative and postoperative problems. Anemia is commonly associated with surgical patients and will often lead to increased use of blood products although with unclear benefits. In fact, according to the STS-NCD in 2014, 43.2% of coronary artery surgery patients received blood transfusions. Much has been written about the considerable, negative impact (death and complications as well as cost) of this

phenomenon. Consideration should be given to preoperative diagnosis and correction of anemia with iron, vitamin B12, folate supplementation, or administration of recombinant human erythropoietin [132]. Investigations continue to refine our understanding of the risks of anemia and transfusion and aim to optimize our management of these common and vexing issues [133].

Coagulopathy is important, albeit less commonly recognized than anemia. Hypercoagulable states can lead to deep venous thrombosis (DVT), which has a lower clinically recognized incidence than when imaging is routinely utilized for screening. DVT is associated with pulmonary thromboembolism, which is low incidence, but potentially catastrophic. The DVT Geneva risk scoring system suggests the following risks: heart failure, respiratory failure, stroke, MI, infection, rheumatic disease, cancer or myeloproliferative disorder, nephrotic syndrome, prior thromboembolic disorder, hypercoagulable state, immobility, travel, age, increased BMI, venous insufficiency, pregnancy, hormonal therapy, and dehydration. Points attributed to the presence of each risk correlate with incidence: 0–2 lower risk—0.8 % 30-day risk of symptomatic VTE or VTE-related mortality, 3–30 points higher risk—3.5 % 30-day risk of VTE or VTE-related mortality (http://www.uptodate.com/contents/calculator-geneva-risk-score-for-venous-thromboembolism-in-hospitalized-medical-patients?source=search_result&search=risk+calculator&selectedTitle=6~150). Caprini has investigated postoperative venous thromboembolism and also categorized patient's risk with 20 variables: low (0–1, 34.5 %), moderate (2–4, 48.5 %), or high-risk (more than 4, 17.2 %) categories. DVT prophylaxis wasn't utilized as commonly as guidelines would recommend and mechanical prophylaxis with sequential compression devices was utilized more frequently than chemoprophylaxis [126, 134–135].

Hemorrhagic diathesis is less common than anemia and DVT. Hemophilia and platelet disorders must be elucidated and an appropriate plan for safe intraoperative management and postoperative care coordinated with a hematologist and anesthesiologist. Increasingly, genetically engineered coagulation factors and concentrates are available, limiting the risk associated with blood product transfusion. Acquired coagulopathy is increasing with the use of various anticoagulants for atrial fibrillation, coronary and cerebrovascular disease, as well as side effects of non-traditional medical remedies. The HAS-BLED bleeding risk score is useful and includes age, liver dysfunction, renal dysfunction, bleeding tendency, warfarin and antiplatelet drug use, and alcohol excess [136]. The risk is tallied with 0–9 points and bleeds range from 1.13 per 100 patient-years to 8.7 bleeds per 100 patient-years with four points, with greater than or equal to three points suggesting high risk. Insufficient data for 5–9 points precludes forecasting, but the risk remains high (http://www.uptodate.com/contents/calculator-clinical-characteristics-comprising-the-has-bled-bleeding-risk-score?source=search_result&search=risk+calculator&selectedTitle=10~150; http://www.uptodate.com/contents/perioperative-management-of-patients-receiving-anticoagulants?source=search_result&search=perioperative+anticoagulation&selectedTitle=1~150).

A complete review of pharmacologic agents that impair coagulation is beyond the scope of this text, but the clinician should be familiar with characteristics of common drugs, including half-life of effect, bridging and reversal strategies, etc. This includes warfarin, direct thrombin inhibitors, antiplatelet agents, and also the use of antifibrinolytics which are valuable and recommended in cardiac surgery guidelines and also in trauma patients at high risk of hemorrhagic shock [137].

Immunologic disorders may contribute to surgical risk. Clinicians should seek relevant information about congenital and acquired immune deficiencies and mitigate risks as they associate with perioperative infections (and also wound healing).

Non-host Factors

Surgeon Factors

Karamichalis et al. and Nathan et al. have extensively investigated the operative phase of care in congenital cardiac surgery and developed a technical performance score. The final technical performance

score has the strongest association with patient outcomes [138–143]. Additional work with this technical performance concept should be developed in other technical, high-risk procedures to identify risk, learn, improve, and mitigate risk [143].

Team Factors

Growing evidence from TeamSTEPPS and other training programs suggest that surgical teams that train together, develop surgical leadership skills, and use briefing and debriefing can produce better outcomes [144, 145]. Neily et al. reviewed 182,409 surgical cases from 108 VHA facilities, using the VHA Surgical Quality Improvement Program (VASQIP) in years 2006–2008, and showed that briefings and debriefings in the operating room, surgical checklists and quarterly coaching interviews, led to a remarkable 18 % reduction in mortality compared with the year before and with non-training sites [146]. Furthermore, observation and feedback to surgical teams of effective teamwork in the operating room can identify substantive deficiencies in the system and conduct of procedures, even in otherwise successful operations, and lead to improvements in surgical team performance [147].

Collaboratives and Quality Improvement Programs

Many efforts have improved the quality, safety, and value of healthcare, thereby mitigating risk. Cardiac surgery mortality was reduced by 24 % by the prototypical learning collaborative, the New England Cardiovascular collaborative, and by 20 % in the Michigan surgical collaborative [148, 149]. Stamou et al. pioneered the use of a Quality Improvement Program (QIP) in cardiac surgery and witnessed a 40 % reduction in mortality, improved morbidity and process compliance, as well in leading key performance indicators such as early extubation [78, 79, 150–152]. Culig et al. utilized the Toyota Production System in a new program and found the risk-adjusted mortality was 61 % less than expected and the cost per case was also decreased by $3497 [153].

The Michigan Keystone Project collaboration targeted the critically ill, where Pronovost et al. demonstrated decreased catheter related bloodstream surgical infections (CLABSI) by 66 % [154, 155]. Others like Dixon-Woods have demonstrated greatly reduced benefits of CLABSI efforts when clinicians are not actively championing and privy to all change efforts [156]. Additional investigation in this area is aimed at understanding how to sustain the gains achieved and diffuse them across other clinical units [157]. More recent, US government sponsored efforts include Hospital Engagement Networks (HEN) and the Partnership for Patients (PfP) (https://innovation.cms.gov/Files/reports/PFPEvalProgRpt.pdf.). Both HEN and PfP have demonstrated success in reducing some complications and cost savings although some question remains whether this approach actually improves care on the whole [158].

Geographic regionalization efforts in high risk, low incidence procedures such as head and neck surgery, cancer surgery, and pediatric cardiac surgery are noteworthy [159–161]. In Maryland, mortality from pancreaticoduodenectomy, LOS, and costs all appeared to be favorably impacted by regionalization [162, 163]. Birkmeyer et al. have studied the impact of volume on quality and suggest that in the USA, operative mortality with high-risk surgery has decreased [164]. Furthermore, market concentration increased and hospital volume have contributed to declining mortality with some high-risk cancer operations (pancreatectomy, cystectomy, and esophagectomy), but mortality reduction with other procedures (carotid endarterectomy, abdominal aortic aneurysm repair, coronary artery bypass, and aortic valve replacement) are largely attributable to other factors.

Failure to Rescue

"Failure to rescue" (FTR) from complications, another form of risk to patients, was endorsed by NQF as a core quality measure in 2012 and is quantified for acute care facilities (https://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Surgical_Measures.aspx). The study of FTR has elucidated

a 2.5 fold difference, variation in institutional procedural mortality, and strong correlation with FTR (range 6.8–16.7 %) [165]. Ferraris et al. utilized NSQIP data for nearly 2,000,000 patients and found that 20 % of the high-risk patients account for 90 % of FTR and two thirds of the FTR patients had multiple complications [166]. Elderly patients are at significant risk of FTR from pulmonary and infectious complications and differences are also witnessed between facilities competence in rescuing the elderly [167]. Considerable variation in FTR rates appear to be prominent in the highest risk patients, pointing to the need to identify high-risk patients [168]. Additional insight will accrue from the related pursuit of failure to arrest complications (FTAC), by not limiting our analyses to deaths, but important complications.

Prager et al. demonstrated that the FTR rate in cardiac surgery was significantly better in the low mortality facilities for the majority of complications (11 of 17) with the most significant findings for cardiac arrest, dialysis, prolonged ventilation, and pneumonia. Furthermore, low mortality hospitals are found to have lower FTR rates [169]. Novick et al. also investigated FTR in the cardiac surgery population and found a 3.6 % mortality rate, complications in 16.8 % of patients, and 19.8 % FTR. FTR in patients with acute renal failure was 48.4 % while septicemia was 42.6 %. They recommend that FTR should be monitored as a quality-of-care metric, in addition to mortality and complication rates, and utilized to identify opportunities to improve quality and value [170]. FTR rates in lung surgery have also been found to be higher at high mortality hospitals [171].

Readmission Risk Factors

A 10-year review of Medicare data, including 9,440,503 patients undergoing one of 12 major operations determined that the readmission to the index hospital was associated with 26 % lower 90-day mortality than when a patient was readmitted to a non-index facility [172]. Additionally, the effect was significant for all procedures, but most pronounced for hospital readmissions after pancreatectomy and aortobifemoral bypass [173]. This finding reinforces the risk mitigation potential for centralization of high-risk procedures.

Pharmacology

The archetype risk prevention drug efficacy and safety is aprotinin. While utilized for years in cardiac surgery, and markedly reducing the risk of hemorrhage and transfusion, various studies ultimately led to discontinuation of its use [174]. Aprotinin has been linked with risk of myocardial infarction, cardiac arrest, heart failure, renal dysfunction, stroke, encephalopathy, and even long term survival [175]. A complete review of the risks and benefits of various pharmacologic agents is beyond the scope of this text, but each has a therapeutic index, small or wide, as well as favorable characteristics and various risks. Antibiotics are another example, having markedly reduced the risk of various infections, but increased use and abuse has led to the proliferation of drug resistant infections and maladies such as C. difficile colitis and Carbapenem-Resistant-Enterobacteriaceae.

Blood Management

Intraoperative transfusion of red blood cells and other blood products increases the risk of mortality and several types of morbidities in surgical patients [176]. This risk has been described in cancer surgery, cardiac surgery, and surgical critical care affecting both short and long term outcomes [177]. An NSQIP database interrogation related risk to a single unit appears after adjustment for transfusion propensity [177].

Systems of Care

Peri-Surgical Home

Early patient and family engagement has been utilized and incorporated into care for many years. For example, Ergina et al. believed in the merit of engagement and published the seminal investigation on preoperative patients with COPD [178]. They promoted appropriate perioperative

strategies to mitigate risk, which included smoking cessation, education, exercise training, and weight reduction. Jones et al. demonstrated the value of education in joint replacement via improvement in LOS (without changing complications) [179]. Additional studies at proactive risk mitigation strategies include exercise and inspiratory muscle training [180–182]. Arora and colleagues have investigated the positive merits of combating the risk of frailty with 8 weeks of "prehabilitation" on 3 and 12 month outcomes [183, 184].

More expansive programs include surgical preparedness aimed at the continuum of care, or the "surgical home," and detailed pathways developed to promote early recovery after surgery (ERAS). ERAS protocols have been developed for gastrectomy, cystectomy, colonic and rectal surgery, and pancreaticoduodenectomy (http://www.erassociety.org/). ERAS protocols are proactive, including counseling, neuraxial anesthesia, avoidance of hypothermia, non-opioid oral analgesics, early mobilization, removal of urinary catheters, and challenge entrenched practices such as nasogastric tubes (See Chap. 23). The American Society of Anesthesiologists maintains standards, guidelines, and practice parameters for pre-anesthesia care, post-anesthesia, and perioperative care (http://www.asahq.org/quality-and-practice-management/standards-and-guidelines).

Organizational Structure

Porter suggested altering the traditional structure of care into the integrated practice unit (IPU). The IPU is a dedicated team comprised of both clinical and nonclinical personnel providing the full care cycle for the patient's condition (https://hbr.org/2013/10/the-strategy-that-will-fix-healthcare). This model is similar to the clinical microsystem. Microsystems, based on work of intelligent enterprises by Quinn, apply systems thinking to organizational design and represent the smallest replicable organizational unit of change [185]. Microsystems are key to implementing effective strategy, leveraging information technology, and embedding other performance-enhancing practices into the service delivery process [186]. The evolving redesign of healthcare delivery around service lines mirrors that of "focus factories" (smaller number of offerings of high-quality products) in other industries [187]. This trend in value creation represents a migration away from "solution shops" (viz. traditional hospitals) creating considerable opportunities to optimize quality improvement activities.

Process

Various methods have been used to promote the sharing mental of models, mitigating risk, and improving patient care. Most noteworthy are goal sheets, shown by Pronovost et al. to correlate with improved communication of goals and resulting in shorter ICU LOS [188]. Gawande et al. have shown reduced mortality and morbidity with checklist utilization [5, 189]. Patient hand-off tools have been utilized and been shown to reduce complications and readmissions to surgical ICU's and back to hospitals [173, 190] and Quality Function Development (QFD) has been used to reduce waste and improved clinical support Managed Care Organizations [191].

Multidisciplinary rounds have been shown to engage the team providers and patients and may mitigate the risk of death for critically ill patients and provide value and efficacy, despite some inefficiency [192–194]. Organizational staffing of critical care units with "closed" management by dedicated critical care trained providers vs "open" model of non-critical trained providers has been shown to reduce risk (lower mortality, morbidity, and LOS) [195], as have the use of tele-ICU technology [196, 197]. Similarly, operational risk can be assessed and mitigated with the insight gathered from improved data management and analysis paired with computer decision support. For example, high acuity, an increased number of admissions, inexperienced teams, and staffing ratios can present various opportunities for risk mitigation [198]. Weick and Sutcliffe

have studied complex industries and found that they share an extraordinary capacity to discover and manage unexpected events resulting in exceptional safety and consistent levels of performance despite a fast-changing external environment [199]. These high reliability organizations (HROs) have characteristics that parallel many features of the surgical environment, including the use of complex technologies, a fast-paced tempo of operations, and a high level of risk, yet they manifest spectacularly low error rates [200].

Goal directed therapy (GDT) is a process where a variety of physiological goals and actions are utilized to mitigate risk in high-risk patients (e.g., trauma, sepsis, cardiac surgery, etc.) [201]. Shoemaker is commonly recognized as the investigator who perceived the merit of GDT, studied its use, and demonstrated its value [202, 203]. While controversy persists around specific parameters, goals, and associated therapeutic strategies, representative positive effects have been demonstrated in femoral fractures and cardiac surgery [204, 205].

Various other epidemiological modifiable risk factors for processes of care have been emerged such as late in day cardiac operations have been correlated with adverse outcomes [206]. The day of week may correlate with risk with 36% increased mortality risk for non-emergency, major operations on Friday to Sunday vs. rest of the week [207] as well as the month of year may affect patient outcomes [208] and weekend patient admissions of cervical spine fractures have worse outcomes than those admitted on weekdays [209]. Outpatient disc surgery had been correlated with better outcomes than inpatient discectomy [210]. Discharge location may also be a risk factor according to Gozalo et al. who assessed 512,967 elderly patients who underwent hip fracture repair who were discharged to 15,439 skilled nursing facilities (SNF), and found that SNF volume correlated strongly with patient's successful return to the community [211].

> *"The future is already here—it's just not evenly distributed"*
> *William Gibson in* The Economist, December 4, 2003

Conclusions

The global burden of surgery, staggering costs, and inefficiencies coupled with an exponential improvement in data management, analytics, and decision support create an epic opportunity to revolutionize healthcare. Systematic and meticulous risk assessment and mitigation of modifiable risks should be incorporated into all aspects of surgical care. Future risk assessment and mitigation will certainly be built on a foundation of improved bid data minding including data management, analytic capability, computer decision support, and the widespread utilization by clinicians and insurers.

Parallel improvements in technology and communication will burnish multidisciplinary teamwork and accelerate the transformation of networked, decentralized surgical care. Wearable biosensors are evolving rapidly and will provide health care with data across the continuum. These biosensors and the "Internet of Things" will facilitate the development proactive strategies and increasingly provide early warning systems to mitigate risk. Parallel changes in the processes of care will also occur as will learning by clinicians and compliance with protocols and pathways. IBM's Watson is an example of massive data mining project aimed at harnessing healthcare data and revolutionizing healthcare data management, analytics, and decision making (http://www.ibm.com/smarterplanet/us/en/ibmwatson/watson-oncology.html).

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Geriatric Surgical Quality and Wellness

35

Daniel J. Galante, JoAnn Coleman, and Mark R. Katlic

"It's a poor memory that only works backwards"

—White Queen to Alice; Lewis Carroll, 1980

Introduction

The surgical treatment of the geriatric patient does not require special training, but rather caring for the older adult patient demands and mandates following six simple, and common sense, principles. While *the Principles* are quite basic, there are many aspects of geriatric care that they affect, and failure to recognize their importance not only puts older patients at risk for preventable harms but also does not provide these patients with the highest quality of care possible.

First described by Katlic [1], *the Principles* are:

I. The *clinical presentation* of surgical problems in the elderly may be subtle or somewhat different from that in the general population. This may lead to delay in diagnosis.
II. The elderly handle stress satisfactorily but handle severe stress poorly because of *lack of organ system reserve*.
III. Optimal *preoperative preparation* is essential, because of Principle II. When preparation is suboptimal, the perioperative risk increases.
IV. The results of elective surgery in the elderly are excellent in some centers; the results of emergency surgery are poor though still better than nonoperative treatment for most conditions. The risk of *emergency surgery* may be many times that of similar to elective surgery because of Principles II and III.
V. Scrupulous *attention to detail* intraoperatively and perioperatively yields great benefit, as the elderly tolerate complications poorly (because of Principle II).
VI. A patient's age should be treated as a *scientific fact*, *not with prejudice*. No particular chronologic age, of itself, is a contraindication to operation (because of Principle IV).

The Principles concisely describe how older surgical patients differ from their younger counterparts. Here we present ten common geriatric syndromes and relate them to *the Principles*. While there are many more syndromes and

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problems that affect surgical patients, these are the most common, with the greatest incidence. Much like the *Principles*, the syndromes are not singular problems. Rather, they typically occur in concert with each other. By relating them to *the Principles*, the surgeon is provided with a common sense guide for caring for all patients, but in particular the older surgical patient.

Frailty

Frailty is a syndrome that is associated with falls, increased risk for disability, and ultimately increased mortality. The work of Fried and colleagues has defined frailty as a syndrome with multiple components and varying levels of severity. Unintentional weight loss, poor self-reported endurance, decreased walking speed, and low levels of physical activity are included in the determination of a patient's degree of frailty. Patients with at least three of the criteria are considered "frail" and are considered to be at increased risk for falls, decreasing/worsening mobility, ability to perform activities of daily living, hospitalization, and death. Patients with one or two of the frailty criteria are considered at "intermediate risk" and were also at increased risk of becoming frail over the next 3–4 years [2].

The "frailty phenotype" has been applied to older patients around the world, with reproducible results. Frailty has been identified as an independent predictor of postoperative events, increased length of stay, and likelihood of discharge to a skilled nursing or assisted-living facility. While frailty has been associated with worse outcomes following large surgical procedures to a greater extent than smaller ones, the fact remains that frail patients do not do as well postoperatively. By identifying those patients who are "frail" and "intermediate frail" or "pre-frail," further work to decrease the level of frailty can be accomplished [3].

When examining frailty using *the Principles*, it can be noted that the topic arises in all. A patient's frailty may mask or delay the clinical presentation of a condition (Principle I). Additionally, due to a frail state, elderly patients may have decreased organ system reserve, and be unable to handle the severe physical stress of a major procedure or complication (Principle II). In order to counteract the effects of frailty on patients, preoperative preparation, or "prehabilitation," is a developing field. This may allow patients to both reduce their frailty, and thus their potential for complications and adverse outcomes, and increase their system reserves to counter severe stressors (Principle III).

Unfortunately, frailty, if not identified and investigated, may not become apparent until it is too late. Patients may tolerate elective procedures due to compensation mechanisms and "prehabilitation" programs, but when an emergency arises, the lack of reserve and preparation can leave elderly patients at increased risk for complications and adverse outcomes (Principle IV). In order for patients to appropriately handle complications and major stressors, scrupulous attention to detail in the perioperative setting is required (Principle V).

Ultimately, frailty is a factor that must be taken into account to provide the highest quality care to patients, regardless of their age (Principle VI). Some patients who are well above the elderly cutoff will fare far better than those many years below.

Problems with Cognition

As patients increase in age, their risk for developing problems with cognition increases. Cognitive impairment affects a large percentage of the population, to a greater extent than dementia. The Aging, Demographics, and Memory Study (ADAMS) [4] reported that over 20 % of the population older than 71 years of age suffered from some degree of cognitive impairment without dementia. The presence of preoperative cognitive impairment is correlated with postoperative delirium, which is further associated with poor surgical outcomes, longer length of stay, and increased risk for perioperative morbidity and mortality [4].

An easy method for assessing cognitive impairment is the Mini-Cog assessment. This simple assessment consists of providing three words to remember, instructions to draw a clock

face with a set time, and repeating the three-item recall. Patients are scored on the number of correct words recalled and the clock face. If all words are recalled and the clock is normal, the patient receives five points. An abnormal clock scores zero points and each recalled word scores one point. Zero to two points is indicative of impaired cognition and three to five points suggests there is no cognitive impairment [5]. It is recommended that those patients whose scores are suggestive of cognitive impairment be referred for evaluation by a specialist. Studies have shown that abbreviated testing, like drawing the clock face in the Mini-Cog, are more effective at detecting dementia than other, more complicated tests. This speaks to the ability of many patients to compensate and mask their symptoms, be they mental or physical (Principles I, II, III, V, VI) [6].

While this is just one method of assessing cognition, there is no "best test" to be used. Other validated tools are just as efficacious in the assessment of a patient's cognition [7].

Problems with postoperative delirium are also extremely common in the older surgical patient and have been associated with increased morbidity. Defined as an acute decline in a patient's cognitive function and attention, anywhere from 5 % to 50 % of patients older than 65 will experience postoperative delirium, with an estimated cost of $150 billion. The American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults, in its 2015 Best Practices Statement, gives evidence-based recommendations for both the diagnosis and treatment of postoperative delirium. While there are many risk factors for postoperative delirium (Table 35.1) (6), ultimately having as few as two risk factors places a patient at a significantly increased risk of developing postoperative delirium.

In the treatment of delirium, the consensus of the AGS is that healthcare providers (physicians, nurses, therapists, etc.) be properly trained in the evaluation and diagnosis of delirium, in an effort to create multidisciplinary, multicomponent programs to combat delirium and increase cognitive function. Avoidance of polypharmacy and psychoactive medications, environmental modifications, and rapid and consistent diagnosis is vital to the prevention of delirium and maintenance of cognitive function [8].

Table 35.1 Risk factors for delirium (modified from optimal perioperative management of the geriatric surgical patient, ACS NSQIP/AGS best practices guideline, 2016)

Preoperative risk factors	Intraoperative and postoperative risk factors
• Age greater than 65	• Infection
• Visual or hearing impairment	• Surgical stress
• Preexisting cognitive impairment	• Cardiopulmonary complications
• Severe illness	• Procedure complications
• Presence of infection	• Inadequate pain control
• Depression	• Sleep deprivation
• Alcohol abuse	• Hospital-acquired conditions
• Current hip fracture	• Medication toxicity/ sensitivity
• Renal insufficiency	• New pressure ulcers
• Anemia	• Malnutrition
• Poor nutrition	• Use of physical restraints
• Poor functional status	• Greater than 3 new medications added
• Limited mobility	• Inappropriate medications (per Beers Criteria)
• Unintentional injury (falls)	• Indwelling bladder catheter
• Polypharmacy	
• Aortic procedures	
• Frailty	

Polypharmacy

A complete medication reconciliation should be completed for every patient undergoing a surgical procedure, regardless of age. As patients age, the potential for medication interactions increases. In order for the surgeon to adequately prepare a patient for a surgical procedure, a full list of medications, including over-the-counter and herbal supplements should be reviewed (Principle V).

The American Geriatrics Society and American College of Surgeons recommend all

nonessential medications that may increase surgical risk be discontinued prior to surgery, as well as medications that pose the potential to interact with anesthetics. Herbal medications should be stopped at least 7 days prior to any procedure, due to the unstudied (or understudied) nature of their interactions with anesthetics and other medications administered in the perioperative period.

The AGS/ACS also relies on the use of the Beers Criteria for Potentially Inappropriate Medications to identify medications that may cause issues in the perioperative period. The Beers Criteria is the product of a systematic review that examines medication-related events and adverse reactions in the United States and creates a list of medications to completely avoid in older adults, medications to avoid when patients have particular syndromes or disease states, and medications to use with caution in older patients. New to the 2015 update, the Beers Criteria now also provide a list of drug-drug interactions that are associated with medications other than anti-infectives, as well as non-anti-infective medications that should be avoided or dose reduced due to kidney function (creatinine clearance) [9].

Decreased Mobility/Falls

Approximately 30 % of the population over the age of 65 falls each year. Multiple studies have investigated different interventions to prevent falls, particularly in the postoperative population. The programs investigated with both home- and group-based exercise programs, as well as home safety interventions and modifications aimed at decreasing falls. Guidelines from the American and British Geriatric Societies recommend an exercise component fall prevention programs [10].

Whenever possible, environmental modifications should be performed as part of a fall risk assessment [11]. These modifications should be made to allow patients to safely perform their activities of daily living (Principles III and V). In addition, visual impairment should be addressed to both prevent falls and promote the completion of daily activities. Two studies showed that patients undergoing immediate cataract surgery experienced a lower rate of falls, compared to those undergoing delayed surgery. However, other studies that included vision correction in their programs experienced mixed results, including one study showing an increased risk of falling with vision correction interventions. Ultimately, vision problems should be formally addressed, but the data supporting the various available interventions is mixed [12].

A thorough medication reconciliation and review should be performed to help eliminate medication-related fall risk. Elimination of certain classes of medications has been shown to have a significant effect on fall risk reduction. Specifically, the removal of psychotropic medications from a patient's regimen has been shown to have a positive effect on fall risk reduction. Additionally, if a medication cannot be completely eliminated, reduction in dose should be considered.

Nutrition

Malnutrition is one of the most common conditions to affect the older population [13]. A sad truth is that a malnourished state may exist in an individual for a significant period of time before physical manifestations appear. Despite the multitude of screening tools available to the clinician, the Mini Nutritional Assessment (MNA) was developed for assessing older patients and is the recommended assessment as part of the comprehensive geriatric assessment [13]. In a multinational retrospective study of older patients, the MNA was able to identify that more than two-thirds of the 4507 patients identified were either malnourished or at risk for malnutrition. Additionally, the study showed that a patient's nutritional state declines as their need for care increases [13].

The European Society for Parenteral and Enteral Nutrition (ESPEN), in their guideline statement for enteral nutrition in geriatric patients, recommends a complete nutritional assessment of all geriatric patients. Additionally,

a nutritional plan should be developed that provides adequate supplementation of necessary nutrients. Generally speaking, patients require 1 g/kg/day of protein and approximately 30 kcal/kg/day of energy (calories from carbohydrate and fat) daily. Micronutrient deficiencies should be supplemented appropriately, based on individual needs and deficiencies (Principles II, III) [14].

Patients should be evaluated for their ability to tolerate oral intake. Some patients, while they can eat and drink, are at increased risk for aspiration. Patients with coughing or choking, difficulty initiating swallowing, a globus sensation (perception of something being stuck in the throat), drooling or inability to handle oral secretions, noted regurgitation, or any other problem should be formally evaluated for their ability to take oral nutrition. Some older patients may be in a physical state that simply does not permit adequate independent oral intake. Current guidelines recommend against initiating supplementary enteral nutrition via a nasogastric or gastrostomy tube purely due to financial or time-saving means. If enteral nutrition is appropriate for a patient, but they are unable to tolerate oral intake, percutaneous access is superior to nasogastric feeding. In an analysis by the Cochrane group, it was shown that while enteral feeding and supplementation (via any means) is superior regarding increasing energy and nutritional intake, due to formulations, taste alterations, and other side effects (nausea, diarrhea, cost), percutaneous feeding tubes have greater compliance and tolerability [14].

Ultimately, if a patient is competent to make their own medical decisions (see: goals of life/care), there should be a thorough discussion regarding nutritional status and how it affects the disease process, surgical treatment and healing, and possible placement of a feeding tube.

Function (Activities of Daily Living)

Patients are at an increased risk for decline in function and disability following a hospitalization. Prospective data has shown that older patients are at risk for suffering both a decline in their ability to perform their activities of daily living (dressing, eating, bathing, toileting, transferring) and developing new deficits while hospitalized. A study of 2293 patients, all 70 years and older, showed that 35 % of the cohort experienced a decline in functional status over the course of a hospitalization. Of this group, 23 % failed to recover back to their baseline function [15].

Patients who are at increased risk for functional decline are those of advanced age, deemed "frail," suffering from cognitive impairment, of poor mobility or suffer a functional impairment, suffer from depression, or suffer –from another "geriatric syndrome" (e.g., falls, pressure ulcers, malnutrition, etc.) (Principle II). Hospitals and extended care facilities have implemented programs to help prevent functional decline in older patients. Special nursing and rehabilitation units have been developed particularly for older patients. The Nurses Improving Care of Health System Elders (NICHE) program [16] has been developed to provide tools that allow for specialized care of elderly patients. These tools help address specific problems that affect the patient experience and patient outcomes. Families are engaged to help prevent a further decline in function and ultimately help provide the best care possible to patients.

As part of a geriatric preoperative evaluation, determination of functional status is important. This helps track, and prevent, a loss of function. The Karnofsky performance score (KPS) is a 100-point scale that allows quantification of a patient's functional status. The continuum spans from a score of 100 (totally independent, no care needs) to 0 (dead). In addition to grading a patient's functional status, the score is also helpful in identifying those patients who are at risk of loss of functional status (Principles I, II, III, V, VI) [17].

A similar scale that is used to evaluate a patient's functional status has been developed by the Eastern Cooperative Oncology Group (ECOG). Used in many research trials, the ECOG score is a 0–5 scale that, similar to the Karnofsky performance score, ranges from 0 (fully active, at pre-disease performance status) to 5 (dead) (Table 35.2) [18]. Studies have shown that the two scores are similar in their utility, assessment, and prognosis [19]; however, the ECOG score has been shown to better evaluate a patient's general prognosis [20].

Table 35.2 Comparison of ECOG and Karnofsky performance status scores

ECOG performance status	Karnofsky performance status
0—Fully active; able to carry on all pre-disease performance without restriction	100—Normal, no complaints; no evidence of disease 90—Able to carry on normal activity; minor signs or symptoms of disease
1—Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work	80—Normal activity with effort; some signs or symptoms of disease 70—Cares for self but unable to carry on normal activity or to do active work
2—Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50 % of waking hours	60—Requires occasional assistance but is able to care for most of personal needs 50—Requires considerable assistance and frequent medical care
3—Capable of only limited self-care; confined to bed or chair more than 50 % of waking hours	40—Disabled; requires special care and assistance 30—Severely disabled; hospitalization is indicated although death not imminent
4—Completely disabled; cannot carry on any self-care; totally confined to bed or chair	20—Very ill; hospitalization and active supportive care necessary 10—Moribund
5—Dead	0—Dead

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Zubrod C, et al. Appraisal of methods for the study of chemotherapy in man: comparative therapeutic trial of nitrogen mustard and thiophosphoramide. *Journal of Chronic Diseases*; 1960;11:7–33

Goals of Life/Care

Components of surgical care of the older patient seldom discussed are goals of care and end-of-life wishes. While many may feel that this is a morbid topic to discuss, it is a topic that, post hoc, is seen as a necessary discussion. Surgeons must incorporate the conversation into their preoperative planning, including not only the quantity of life desired but also the quality of life. This conversation should include patients, as well as their families/significant others. Conflicting opinions should be discussed and reconciled (Principles IV and VI).

There are many tools to help document these conversations, and some of these documents and tools are widely accepted across the country. In the state of Maryland, the Maryland Orders for Life-Sustaining Treatment (MOLST) is a variant of the Physician Orders for Life-Sustaining Treatment (POLST) [21]. These tools are not "Do Not Resuscitate" (DNR) forms, but rather they concisely state the extent to which medical providers should attempt life-sustaining and resuscitating efforts. There is an element of choice in completing these orders, where the patient may select the entire spectrum, from DNR to "full code" to any combination of treatments in between.

An additional tool that is widely used around the country is the "Five Wishes" living will tool kit. This document allows patients to clearly state who is to make medical decisions for them in the event the patient cannot, the types of medical treatments they want and do not want, the level of comfort they wish to maintain, how the patient wishes to be treated, and what the patient's family is to be told or informed of. The ultimate goal of this tool is to remove any ambiguity or confusion when a patient is unable to speak for him- or herself or found to be in extremis and requires medical care.

The ultimate goal of any of these tools is to stimulate an honest and frank discussion between the physician, the patient, and the patient's family about the quality and quantity of remaining life desired. It is important for the physician to be honest with the patient and their family regarding diagnosis and prognosis. It is acceptable for the surgeon to recommend against a procedure. However, a patient's age should not be the only factor taken into account (Principle VI).

The utilization of vetted risk stratification tools, like the ACS/NSQIP risk calculator [22], is helpful in removing subjective bias from the conversation (Principles II, IV, VI). Once the

perceived risk that is associated with age is removed, and these tools are implemented, a true conversation can be held between the surgeon and the patient.

Depression/Seclusion

Depression in the older population is seen mainly in those patients who suffer from chronic medical problems and those with cognitive impairment. Depression can lead to suffering, family problems and increased levels of disability and may worsen a patient's morbidity and ultimately cause mortality. There is documented evidence that medical illness is associated with depression, and the greater the medical burden a patient suffers, the greater the risk for depression. Depression may be associated with dementia or cognitive decline, as well as a risk factor for dementia later in life [23].

Low socioeconomic status, poor physical condition, disability, isolation, and seclusion are all linked to depressed mood and may cause worsening depression. Of extreme concern is the risk for suicide. Depression is present in nearly 80 % of elderly patients who commit suicide, and depression has been identified as a major risk factor for suicide attempts. Not just major depressive disorder but also minor depression, dysthymic disorder, psychotic disorder, and anxiety disorders all raise the risk for suicide. Those patients who suffer from seclusion and broken social bonds are at risk for suicide outside of a diagnosis of depression [23].

Social isolation is associated with the maintenance of health and a deterrent to cognitive decline (Principles I and II). Studies have shown that those patients who do not maintain social ties are at increased risk for cognitive decline over time [24]. Additionally, a robust social network has been shown to have protective effects against dementia and cognitive decline [25]. Patients who are socially engaged have been shown to have an improved subjective quality of life when compared to their age-adjusted counterparts [26].

The Geriatric Depression Scale (GDS) was developed as a screening tool for older patients or persons. The tool contains 30 questions that are aimed at assessing a patient's gestalt level of depression. This is a well-validated and vetted tool that allows clinicians to assess a patient's overall mood and (depressed) state. The 30 questions are binomial (yes/no), and the number of yes/no answers is tallied and converted to a "level" of depression—from normal to severe depression [27].

If the GDS is too complicated for regular use, the Patient Health Questionnaire (PHQ)-2 tool is a significantly shorter screening tool. While this is not intended to diagnose or monitor depression and its severity, it is an initial step in evaluating patients for depression. Those patients who screen "positive" on the PHQ-2 should then be further evaluated for major depressive disorder. The PHQ-2 asks two questions on a 0–3 scale. The questions are based off the same root but relate to 1,anhedonia, and 2, mood (Table 35.3) [28]. Patients with a score of 3 or greater had an 83 % sensitivity and 92 % specificity for major depression The PHQ-2 tool has also been shown to relate to a decline in functional status; as scores increase, functional status decreases [29].

Comorbid Conditions

Part of the preoperative assessment of any patient is consideration of underlying comorbid conditions as they relate to a patient's overall outcome. This is necessary for any patient, regardless of their age, but it is of particular importance in older patients. Older patients may not be able to handle severe stress as well as younger patients; therefore, optimal preoperative preparation is essential, and attention to detail intra- and perioperatively is essential to reduce risk (Principles I, II, III, IV, V). There are many tools to evaluate the affect that comorbid conditions have on surgical risk and outcomes, and risk calculators are essential to take these conditions into account.

One such tool is the Charlson Comorbidity Index. While this scoring system was originally developed for women being treated for breast

Table 35.3 Patient Health Questionnaire-2: initial screening test for depression

Over the past two weeks, how often have you been bothered by any of the following problems?	Not at all	Several Days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Total Point Score: _____				
Score Interpretation				
PHQ-2 Score	Probability of major depressive disorder (%)	Probability of any depressive disorder (%)		
1	15.4	36.9		
2	21.1	48.3		
3	38.4	75		
4	45.5	81.2		
5	56.4	84.6		
6	78.6	92.9		

If a patient has a positive response to either question, then further evaluation is needed. For older adults consider the Patient Health Questionnaire-9 or the Geriatric Depression Scale. A negative response to both questions is considered negative for depression

Modified from Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care 2003; 41:1284–92

cancer, many studies have shown validity and applicability to both genders and many different medical and surgical conditions [30].

The Charlson Comorbidity Index takes the following conditions into account: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular accidents, hemiplegia, pulmonary disease (asthma, COPD, chronic bronchitis), diabetes, organ damage from diabetes, moderate to severe renal disease, liver disease, ulcer disease, cancer, metastatic disease, dementia, rheumatic disease, and HIV/AIDS. Each condition/situation is given a value (1, 2, 3, or 6). The sum of the score is then calculated. In the initial studies, patients with a score of 0 showed a 12 % rate of mortality within 1 year; 1–2, 26 %; 3–4, 52 %; and ≥5, 85 %. In their 10-year follow-up, the mortality had changed to 0, 8 %; 1, 25 %; 2, 48 %; and ≥3, 59 % [30]. More recently, studies have linked a higher Charlson Comorbidity Index score with hospitalization and age-related mortality [31]. Table 35.4 lists the components of the Charlson Comorbidity Index and the scores for each condition.

Ultimately, it is the sum of a patient's comorbid conditions that affect their overall health and well-being. Surgeons must take all comorbidities into account when planning a procedure. As *the Principles* state, scrupulous attention to details pre-, intra-, and postoperatively will help prevent complications.

Caregiver Burden

As patients age and they become more reliant on others to help with both simple and complex tasks, there comes a second (or third) party into the conversation regarding care and planning of surgical procedures. A patient's caregiver (if applicable and appropriate) must be taken into consideration. The Zarit Caregiver Burden

Table 35.4 Charlson comorbidity index conditions

Condition	Assigned score/ value
• Myocardial infarction • Congestive heart failure • Peripheral vascular disease • Dementia • Chronic pulmonary disease • Connective tissue disease • Ulcer disease • Mild liver disease • Diabetes	1
• Hemiplegia • Moderate or severe renal disease • Diabetes with end-organ damage • Any tumor • Leukemia/lymphoma	2
• Moderate or severe liver disease	3
• Metastatic solid tumor • AIDS	6

Modified from: Charlson ME et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chron Dis. 1987;40(5):373–83

Interview is a questionnaire that may be useful. It is scored on a (0–4) scale and helps assess the emotional and physical stress that is placed upon a caregiver.

Originally developed for those taking care of patients suffering from dementia, it has been applied to other medical diagnoses with consistent validity. While there is no definitive outcome from the Zarit Caregiver Burden Interview, it is useful to identify caregivers that are at risk for fatigue, collapse, or an unwillingness to care for the patient. When performing a geriatric preoperative assessment, and a patient's caregiver scores high on the Zarit interview, a discussion should be initiated to help the caregiver seek assistance. This could mean assistance with caregiver tasks, relocation of the patient, or even relieving the caregiver from his or her caregiving duties [32, 33]. Involving social work or case managers preoperatively may also prevent delay in discharge if the caregiver is unwilling to care for or take the older surgical patient home.

Conclusion

All are capable of providing high-quality care. While the care of the older surgical patient does not require any particularly novel or different skills, it does require attention to the *Principles*. By taking these seemingly commonsense concepts and integrating them into daily practice, patients will benefit from the highest quality and safest care available.

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Patient Transitions and Handovers Across the Continuum of Surgical Care

36

Donna M. Woods and Lisa M. McElroy

"Life is pleasant. Death is peaceful. It's the transition that's troublesome."
—Isaac Asimov

Introduction

Transitions Overall and Their Risks

The goal of surgery is total recovery—for the surgical patient to come out better than before. One key challenge to safe and effective surgery are the numerous and complex transitions of care involved in the process of providing surgical care to a patient. The effective transfer of responsibility for the care of the patient from one healthcare provider to another is crucial to providing safe, high-quality patient care. Ineffective transition processes lead to fragmented communication and clinical understanding and can result in delays, errors, and substantial patient harm. Overall, care transitions and clinical communication have emerged as the root cause of 75–89 % of sentinel events in 2014–2015, the most serious high-harm events, reported to The Joint Commission [1]. Care transitions and communication are also a contributing factor to 91 % of medical errors reported by residents [2]. In surgical care, events related to surgical care transitions represent 24 % of malpractice claims [3], 29 % of physician reported adverse events (http://www.ahrq.gov/professionals/prevention-chronic care/improve/coordination/index.html. Accessed 26 Sept 2015), and 46 % of surgical care-related sentinel events [4]. Care transitions, while not a technical aspect of surgical care, are clearly an important contributor to positive and negative patient outcomes [5].

Care transitions in healthcare are defined "as the movement of a patient from one healthcare provider or setting to another" (http://www.jointcommission.org/assets/1/6/toc_hot_topics.pdf. Accessed 26 Sept 2015). These transitions can occur (1) within a setting (e.g., hand-offs at shift changes), (2) between settings (e.g., OR to ICU, hospital to home or skill nursing facility), and (3) between types of providers (e.g., primary care to a specialist or surgeon). Care transitions are a set of actions designed to ensure coordination and continuity of patient care. There are key identified transitions in the care of the surgical patients that include (1) preoperative transitions into the operating room (OR) (a) surgery is scheduled, (b) sign in, time-out, sign out, (2) postoperative transitions (a) OR to intensive care unit (ICU) or postanesthesia care unit (PACU), (b) ICU or PACU to the floor), and (3) (a) discharge transitions and (b) outpatient follow-up (see Fig. 36.1). Clinician shift and service changes also play a role in each of these environments.

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Fig. 36.1 Transitions across surgical care. Figure reprinted with permission from the American Society of Anesthesiologists (asahq.org/psh)

Each transition of care, from one phase in the surgical pathway to another, presents an opportunity for medical error. For surgical patients, the process from diagnosis to surgery involves numerous transitions in care. From the time of diagnosis, the patient encounters a variety of clinicians, from primary care to diagnostic specialists. The surgical referral and scheduling process may be arduous and can occur over weeks to months. Following surgery, care may be provided in many different settings, including the PACU, the ICU, rehabilitation, long-term care facilities, and finally the patient's home. There are often numerous caregivers helping with recovery, but the care teams are frequently not well integrated [6].

This chapter will discuss recent advances and remaining challenges in improving the quality of surgical care transitions to ensure patient safety during the major phases of surgical care, from surgical scheduling to discharge and in the period of recuperation and recovery following discharge.

The Transition into the Operating Room

The Surgery Is Scheduled

Whether initially encountered in the hospital or clinic, one of the first hurdles encountered is accurate translation of surgical diagnostic and planning information to the scheduling of surgery. Errors in surgical case scheduling result in incorrect room and equipment preparation, as well as inappropriate planning on the part of the surgeon and surgical team. Although some variability between scheduled and actual procedures due to progression of disease or unexpected intraoperative findings cannot be avoided, accurate case scheduling is integral to OR efficiency, and errors have the potential to lead to increases in OR time, wasted supplies, and opened but unused surgical instruments, ultimately diminishing patient and staff satisfaction and increasing costs [7, 8].

A recent study by Pariser et al. analyzed the delays in start time and changes in total case time associated with incorrectly scheduled surgical cases [9]. The authors analyzed 14,970 surgical cases, 3.3 % of which were found to be incorrectly scheduled. Incorrectly scheduled cases were shown to lead to OR delays, longer turnover times, and cases going beyond scheduled length (mean 26 min). For those surgeons who have high heterogeneity of practice, the implementation of a more robust, multilayered scheduling process allows more detail to be conveyed in the OR scheduling system and increases scheduling reliability [9].

One of the most significant consequences of incorrectly scheduled cases is their connection to

surgical errors, such as wrong-site surgery. Several studies have linked the surgical scheduling process to the downstream occurrence of wrong-site surgery [10–14]. Wu et al. looked at over 17,000 scheduled surgeries and found that wrong-side errors were the most common (N = 55, 36 %). In plastic surgery wrong-side errors were most common, whereas general surgery had mostly wrong-approach booking errors (N = 16, 43 %). Most surgical booking errors were caught in the holding area or the OR (N = 122, 81 %). The remaining errors were caught in the admitting or assessment areas (N = 28, 18 %) [10]. Abecassis et al. [11] performed a systematic review of the literature reporting root causes of wrong-site surgery, and surgical scheduling was found to be the most vulnerable aspect of the process with reports of 39 % of wrong-site surgeries attributable to errors in surgical scheduling [15].

Despite these challenges, many of the surgical scheduling processes are amenable to operational interventions to reduce communications errors and improve surgical scheduling accuracy [16]. Effective application of lean processes and root cause analyses have been shown to assist with the identification of key drivers in the process and in the implementation of interventions to reduce surgical listing errors and improve the accuracy of scheduled operative times, such as centralized scheduling [5, 16–18]. Simon describes the transition from paper to electronic surgical scheduling for orthopedic procedures. The development and implementation of the new scheduling system was guided by lean problem-solving and facilitated by a multidisciplinary work group [19]. The new system saw a reduction in lag time between surgical planning and the patient notification that surgery would be needed from three days to less than one day. Site/side discrepancies went from 4 % for clinic procedures and 2 % for operative procedures to zero for each [19]. Patient satisfaction also increased, with Press Ganey scores increasing by 20 %. Even with an electronic system, several checks need to be in place to prevent surgeons or office staff from clicking or selecting the wrong surgery [19].

Sign In/Time-Out/Sign Out

The WHO Surgical Safety Checklist

According to The Joint Commission, wrong-site surgery was the most common sentinel event reported between 2004 and 2010 [15]. The Joint Commission has been working for decades to standardize and implement guidelines known as the Universal Protocol as a verification step to ensure the accuracy of all patient information at the transition to the OR prior to the start of the procedure [15]. The World Health Organization (WHO) developed and implemented a surgical safety checklist that contains three components, the sign in, time-out, and sign out, which apply to three phases of surgery, respectively: before induction of anesthesia, before skin incision, and after the completion of surgery before the patient leaves the OR. Each phase involves a verification process with all members of the surgical team, who must be in agreement with one another before the procedure can continue. Use of the WHO surgical safety checklist has been linked to improvements in patient outcomes, compliance with standard processes of care, and the quality of teamwork in the OR [20, 21]. Although the WHO provides informational materials on how to conduct the safety checklists, OR teams are frequently not provided with this information in a structured educational format. Instead, individual centers and surgical specialties decide for themselves how to use the checklists, including who will lead them, when they are initiated, and what measures are in place to ensure compliance [22].

The result is wide variability. Observational studies of surgical time-outs and sign outs in the United States, United Kingdom, and Australia have demonstrated that the sign in, time-out, and sign out are often abbreviated, with absent or non-participating team members. Time-out checks are often completed after commencement of the procedure or are skipped entirely [23–25]. Additionally, current approaches to ensuring compliance with the WHO checklists are often executed in a yes/no manner, and team members rarely actively participate checklists in completion of the process [26].

Adherence to a presurgical checklist, along with the time-out, has been shown to reduce morbidity and mortality [20, 27]. Though effective when performed correctly, in our studies, we conducted a multi-site study of video observations of the use of the surgical safety checklist in the OR prior to donor hepatectomies [28] and found that sign-in was performed 83 % of the time and the complete sign-in protocol was performed for only 20 % of the procedures. The elements most frequently omitted were antibiotics given (75 %) followed by team introduced (50 %) and procedure to be performed (50 %). The full team was focused on the sign-in 80 % of the time. The time-out occurred in 100 % of the videoed procedures; however adherence to the institutional protocol occurred 38 % of the time. The most frequently omitted were procedural equipment (62 %) and patient positioning 50 % followed by site marked (32 %). The full team was focused on the time-out for 75 % of the procedures [28]. Other studies have demonstrated use in only 70 % of procedures and large variation in their use [29]. The result is the surgical team having incomplete patient information and surgical errors leading to harm in surgical patients. Dixon Woods et al. have shown that unless surgical team members are engaged in the surgical checklist process, little to no gain may be achieved with surgical checklists [30].

Postoperative Transitions

The transfer of care after surgery to the PACU or ICU presents special challenges to providers on both the delivering and receiving teams. The OR anesthesia and surgical team must physically transport the patient, along with any monitoring equipment from the surgical procedure. The physical transition occurs, while team members also simultaneously provide continuous monitoring, perform additional therapeutic tasks, and avoid potential pitfalls such as physical hallway obstructions [31]. Upon arrival at the receiving unit, the technology and support are transferred to stationary equipment, while knowledge of the patient is transmitted, in an environment that is often chaotic and busy, and to a team largely unfamiliar with the patient. This knowledge transfer involves cross-disciplinary staff with varied experience; the delivering team members with their diverse yet important perspectives of the course of surgery; and the receiving team concurrently stabilizing, assessing, and making care plans for the patient [32]. It is not surprising, under these circumstances, that postoperative transitions are plagued by technical and communication errors with deleterious effects on patient outcomes [33–38].

Transitions involving the ICU lead to more errors and adverse events when compared to other hospital units, and a significant percentage of these adverse events occurring in the ICU are potentially life threatening to the patient [39].

Our group investigated risks of patient harm during OR-to-ICU handoffs, using liver transplant recipients as a model for a failure modes, effects, and criticality analysis (FMECA). We identified 37 individual steps in the OR-to-ICU handoff process. In total, 81 process failures were identified, 22 of which were determined to be critical and 36 of which relied on weak safeguards, such as informal human verification. Process failures with the greatest risk of harm were lack of preliminary OR-to-ICU communication, team member absence during handoff communication, and transport equipment malfunction [40]. Post hoc analysis revealed the need for early OR-to-ICU communication, the challenge of the competing demands and relative prioritization of clinical care versus participation in handoff communication, and the role of interpersonal relationships within and between OR and ICU teams. The limited common ground reduced the likelihood of correct interpretation of important handover information, which may contribute to adverse events [6]. Institutional culture and interdepartmental relationships were also reported to greatly influence behavior during this transition [41]. Members of the OR and ICU teams described different priorities for a high-quality handoff process, including the optimal timing and content of handoff communication, as well as whether handoff communication should take priority over initiation of clinical care in the ICU. The varied opinions among participants demonstrate the potential success of

interventions that clarify roles, responsibilities, and expectations [42]. This study also determined attributes of high-quality OR-to-ICU transitions to include the following:

- Communication from the OR to the ICU of the start time of the surgery.
- Communication of the start time of closing by the anesthesia resident following first instance of counts.
- The ICU charge nurse calls the ICU resident and charge respiratory therapist.
- The charge respiratory therapist assigns the respiratory therapist to bring the vent to the ICU.
- The primary surgeon, fellow, anesthesiologist, and resident conduct a huddle.
- The OR nurse communicates to the ICU that the procedure has ended and that they are preparing to transfer to the ICU.
- The surgical and ICU teams perform the verbal transfer.
- The surgical fellow completes the surgical/ICU transition note [43].

Finally, interpersonal dynamics between team members were reported to affect care transition quality, and there was a general recognition that even a single "difficult" team member could compromise patient safety by discouraging open communication [43].

Postanesthesia Care Unit (PACU)

ICU and PACU have different challenges in safely transitioning care of a surgical patient. The PACU is the standard location for the initial recovery of the postoperative patient. The concept of the PACU was first introduced in 1923, yet far less research has been done examining transfers to the PACU than transfers to the ICU. Postoperative patients are at higher risk for complications or death when their surgical teams exhibited less briefing and information sharing during the transition [44]. Studies of postoperative transitions to the PACU have repeatedly demonstrated that the process is largely informal, unstructured, and incomplete. This involves the risk of losing relevant information and may result in increased rates of complications. A recent prospective analysis of PACU transfers found that critical aspects of care such as fluid and pain management were transferred in less than 20 % of the transitions [44, 45]. The shortest handover lasted only 1 s. Although it is difficult to define exactly what constitutes adequate length of time for a handover, the longest was only 300 s.

The Transition of the Postoperative Patient from the ICU or PACU to the General Floor

An ICU-to-ward patient transfer consists of several steps, beginning with a consult request for patient transfer from the ICU service and with the initial patient assessment by the receiving physician(s) following the patient's arrival on the ward. During the transfer process, there is often conflict between the need to physically settle the patient and the need to receive information, and the perceived needs of the postoperative patient may supersede the need for information exchange [46, 47]. There is also frequently confusion as to who is responsible for receiving which specific information. Physician-to-physician and nurse-to-nurse communications occur at different phases of the transition, with respective groups communicating different aspects of the care plan, and the overall transition process, whether from the ICU or PACU to the general floor or from the hospital to home, may take several hours, further contributing to fragmented care [48].

Li et al. conducted a prospective observational study of physician handoff for 112 ICU-to-ward patient transfers and showed a significant deficiency in physician-to-physician communication despite overall satisfaction with the handoff process by involved providers and patient families [49]. Helling et al. recently examined incidents of unexpected clinical deterioration in surgical patients on standard nursing units. Of 111 of these, 90 % had been recently discharged from an ICU or PACU, overall mortality was 27 %, demonstrating the potential severity of these issues [50].

While ICU staff typically notified and explained to patients and families that a transfer to the general ward was pending, there was a general lack of interactive physician communication during the patient transfers, and physician-to-physician communication was largely unstandardized. In addition, during transfers there was ambiguity with regards to physician responsibility for patient care. Finally, 35.7 % of these transfers took place during night and weekend shifts, despite an increased incidence of physician cross coverage duties and reduced numbers of residents and ancillary staff. Important information that was often missing in handoff documents included pending investigations, recommendations arising from specialist consultations, and changes of important medications [49].

The length of time that a patient stays in the PACU is variable. While it is common practice for PACU discharge policies to stipulate a minimum length of stay, beyond that, a surgical patient's readiness for discharge traditionally relies upon a nursing assessment of the appropriateness of physiological parameters. Recently, guidelines for the management of patients in the PACU and assessing their readiness for transfer have been proposed. Twenty-four essential criteria were identified through expert consensus [51]. In Canada, criteria considered essential for assessing when a patient is clinically stable and ready for transition from PACU included those related to (1) cardiac and respiratory function, such as blood pressure, pulse, respiratory rate, oxygen saturation, end-tidal CO_2, arrhythmia, shortness of breath, respiratory stability, and tachycardia; (2) mental status, such as alertness, level of consciousness, sedation level, and coordination; and (3) postsurgical factors, such as pain, surgical bleeding, temperature, postoperative urinary retention, urine output, nausea and vomiting, and functional status. No corollary has been proposed in the United States, and there are currently no widely accepted professional guidelines for PACU transition [51].

Critical care transition program (CCTP) is an overarching term which includes rapid response teams, medical emergency teams, critical care outreach teams, or ICU nurse liaison programs that provide follow-up for patients discharged from the ICU. CCTPs appear to reduce the risk of ICU readmission in patients discharged from ICU to a general hospital ward. A meta-analysis of studies on CCTP demonstrated a reduced risk of ICU readmission (risk ratio, 0.87 [95 % CI, 0.76–0.99]; p = 0.03; I2 = 0 %); however, no significant reduction in hospital mortality (risk ratio, 0.84 [95 % CI, 0.66–1.05]; p = 0.1; I2 = 16 %) is associated with a CCTP. The rarity of the outcome (unexpected mortality) may have resulted in insufficient power to detect a significant difference. The risk of ICU readmission was similar whether the transition program was included within an outreach team or a nurse liaison program and did not depend on the presence of an intensivist [52].

Shift and Service Handoff Transitions

Communication, teamwork, and shift and service change transitions are a major challenge in healthcare and require a mention in the context of care transitions [53]. Transitions in patient care also involve the transfer of responsibility between work shifts in the contexts of the ICU, PACU, and the general floor. These interactions are particularly error prone due to a multitude of factors [54, 55]. Incomplete information exchange, nonstandardized formats, time pressures and other human factors, fragmented teams, and environmental distractions and conditions contribute to the overall failures of communication at the root of the problem. Missing, incorrect, or incomplete patient care information exchange is common in handoffs and includes medications, labs and tests to be performed and results, information regarding diagnoses, and the patient's plan of care. Physicians, nurses, and other care providers report direct patient harm due to handoffs and cite competing demands, frequent interruptions, and the lack of transfer of critical information as contributing factors [54–56].

The Discharge Transition

The Discharge Transition Process: What Is Involved?

Patients who have undergone surgical procedures often have self-care concerns and information needs in the preparation for the discharge transition from the hospital. The most common concerns are related to the incision/wound care, pain management, activity level, monitoring for complications, symptom management, elimination, medications, and quality of life. Because of their clinical knowledge of the perioperative experience, advanced practice nurses have a critical role in the development of discharge-educational programs for postoperative patients and caregivers. Because unmet discharge needs can contribute to poor patient outcomes and readmission, it is critical that clinical staff nurses and social workers accurately identify patients' informational needs and find ways to meet these needs, especially with aging populations, new/advanced surgical procedures, vulnerability/poverty, and literacy and health literacy levels of patients [57, 58]. Patient understanding of and adherence to discharge instructions and appropriate follow-up care are critical to successful discharge transition and recovery [59]. However, there are key challenges in the postoperative discharge transition including, coordination with others of the patient's care providers and ensuring the restoration of any home medications that may have been discontinued during the surgical admission.

Risks Associated with the Postoperative Discharge Transition

There is no universally accepted definition of recovery after surgery, and it is well accepted that the recovery process is variable and dependent on many patient and operative procedural factors. While this variation is acceptable for long-term recovery after surgery, short-term recovery is often marked by discharge from the hospital and is an important benchmark of postoperative care quality. The surgical discharge is a critical transition of care, as effective discharge failure often results in an emergency room visit or readmission, both of which are care quality concerns.

A recent Cochrane review investigated the effectiveness of planning the discharge of individual patients from the hospital [60]. They found that although discharge planning may lead to increased satisfaction with healthcare for patients and professionals, a discharge plan brings only a small reduction in hospital length of stay or risk of readmission at 3 months follow-up, for older people with a medical condition. This difference in risk has not been shown in surgical patients, and there is little evidence that discharge planning reduces costs to the health service. Care coordination that provides more than just discharge planning appears to be needed.

Care coordination as defined on the AHRQ website "involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient" [61].

In a survey study of the impact of patient and provider coordination across the continuum of care on outcomes for surgical patients, knee-replacement surgery patients were asked about the coordination of their discharge care. Patients identified serious communication breakdowns between providers, as well as between providers and patients. Measured 6 weeks postsurgery, coordination of care problems were associated with adverse health outcomes—greater joint pain, lower functioning, and reduced satisfaction. The average patient reported problems on 42 % of the indicators related to coordination of discharge. Widespread problems included not being told what problems related to surgery to watch for (46 %) and not being informed about medication side effects. More than a third (39 %) said it was not easy to find someone to talk to about their concerns [62].

Strategies to Improve the Postoperative Discharge Transition

Care coordination is a key component of a safe and effective postoperative discharge transition. As readmission rates after surgery become a more prominent metric of quality, increased attention has been paid to the quality of the discharge transition and coordination of care after surgery [63]. A few care models have been advanced: the Transitional Care Model, the RE-Engineered Discharge Model, and specifically for surgery the Care Coordination for Care Improvement Initiative [41].

The Care Coordination for Care Improvement Initiative was developed to improve the quality of patient care while easing the transitions that happen before, during, and after surgery. The initiative is designed to follow patients through their continuum of care, from surgical decision through 90 days after discharge. This initiative involves the use of a nurse navigator, that is assigned at the time of the decision that surgery is necessary who will provide ongoing care coordination through the entire surgical episode (https://www.sosbones.com/services/care-coordination-for-care-improvement-initiative/).

Enhanced Recovery After Surgery (ERAS)

Kehlet, a renowned colorectal surgeon from Copenhagen University Hospital in Denmark, was the first to describe the concept of ERAS in the 1990s [64, 65]. The ERAS protocol is a wide-reaching collection of about 20 specific clinical practices aimed at reducing length of stay after surgery. These include reduced preoperative fasting, preoperative carbohydrate loading, avoidance of premedication, and others. When originally introduced, the ERAS protocol was used specifically for patients undergoing colorectal surgery, but subsequently the use of this protocol has expanded to other surgical subspecialties [66–68]. To date, ERAS protocols have been embraced in several European and Canadian institutions and have already been tested in multiple large-scale healthcare systems such as the National Health Services in the United Kingdom for colorectal surgery [69]. ERAS has been shown to decrease the incidence of postoperative complications and decrease the LOS in the hospital, without the use of new equipment [70].

Perioperative Surgical Medical Home

Similar but distinct from ERAS protocols is the perioperative surgical home (PSH) [71]. The PSH is a much larger conceptual framework that includes coordination of care from the minute the decision to operate was made until 30 days after discharge. PSH assures continuity of care and treats the entire perioperative episode of care as one continuum rather than discrete preoperative, intraoperative, postoperative, and post-discharge episodes (see Fig. 36.2).

In this model the interdisciplinary team is headed by anesthesiologists, who manage all aspects of care across this continuum. The PSH involves the following components of care: the importance of preoperative nutrition and hydration, focus on pain control with minimal opioid use, aggressive postoperative ambulation, as well as the prominent role the patient plays in their recovery. A nurse coordinator can be added to the team as well. In one study, this model resulted in reduction of 30 readmission from 17.3% to 9.2%, surgical site infections from 21% to 7%, and UTIs from 3% to 0, satisfaction with pain control was increased from 43rd to 98th percentile on the Press Ganey survey, and "the extent that the patient felt ready for discharge" increased from 41st to 99th percentile (https://www.google.com/?gws_rd=ssl#q=Perioperative+Surgical+home+University+of+Virginia. Accessed 16 Jan 2016). PSH protocols will vary significantly across institutions, as they will depend on the surgical services, the local perioperative environment, and active participation of all stakeholders. Although both ERAS and PSH have the same goals of better outcomes, better service, and lower cost, the route that these two methodologies are taking to achieve these goals may be different but complementary [72]. Widespread use of the

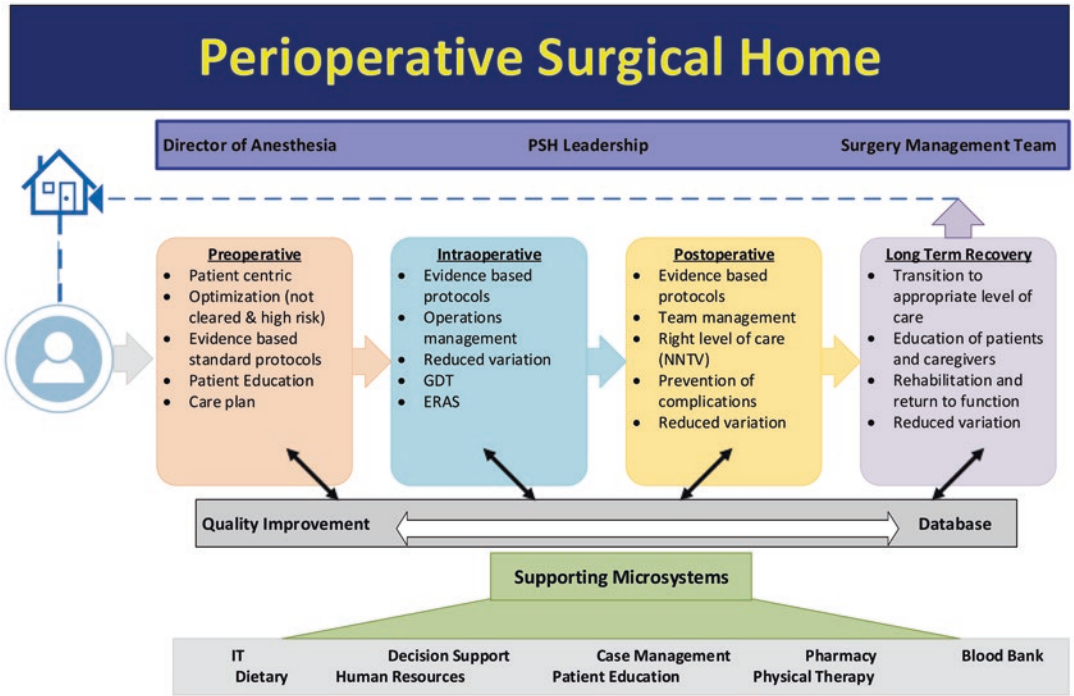

Fig. 36.2 Perioperative surgical home. Figure reprinted with permission from the American Society of Anesthesiologists (asahq.org/psh)

ERAS protocols and PSH will depend on further demonstration of their effectiveness, both in improving patient outcomes and containing costs. Future studies investigating the effectiveness of these interventions should focus on higher-level outcomes, such as functional status, which encompass the multidimensional nature of recovery, as well as on the validation of instruments and measures for these outcomes [73].

Conclusions and Implications

Prior research has identified specific causes of medical error and harm in the context of transitions of care. Literature review and consensus panels have been used to elucidate essential elements of the challenges and methods for reliable, improved patient transitions across the surgical care continuum. A recent systematic review has taken the implications of transition of care quality one step further, by assessing the empirical evidence for the relationships between the characteristics of a transition of care and outcomes [74]. The authors found that care transition research is highly diverse and as such presents a serious challenge to researchers and practitioners. Because it is unclear what they can gain with certainty from previous studies to use when designing future research and improvement initiatives. Even interventions that have been shown to improve surgical care and outcomes and reduce adverse events (e.g., surgical safety checklist) are inconsistently performed. Even when interventions are well defined, they are idiosyncratically and unreliably implemented. It can be hard to copmpare results and detrmine the generalizable impact of the results. Additionally, given variability of protocols and inconsistent implementation for many of the interventions that are recommended in the literature to improve outcomes, makes the effect of any one or a combination of best practices on outcomes, their replicability, and broad implementation a challenge [75].

New more comprehensive models involving multimodal interventions (e.g., ERAS, PSH, CCTP)

are emerging that will redefine the way surgical care is delivered. These are largely focused on improving the many patient care transitions across the continuum of surgical care and will require a more comprehensive approach to the improvement of surgical services [76]. Therefore, to be successful in the deployment of these models and interventions, a culture that encourages reliable performance of these care models that have demonstrated improved patient safety and outcomes must be cultivated.

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Failure to Rescue and Failure to Perceive Patients in Crisis

37

Christian Peter Subbe and Paul Barach

"Failure isn't fatal, but failure to change might be."

—John Wooden

Failure to Rescue and the Context of Surgical Patient Management

Definition

The hallmark of a safe and reliable hospital is the ability to identify, address, and prevent a complication from leading to lasting patient harm and suffering with safety defined as "freedom from accidental injury" [1]. Failure to rescue surgical patients is defined as mortality after a complication occurring in patients who are hospitalized after a surgical procedure or with surgical disease. Initially limited to surgical patients the term has subsequently been used more broadly in the context of patients who suffer avoidable complications despite visible and early warning signs. The original work on failure to rescue focused on coded complications following surgical complications and subsequent mortality and morbidity [2].

Failure to rescue is an important metric from the point of view of patients, health care professionals, and health care organizations. Efforts have been focused on reducing complications of surgical procedures by improving the awareness and performance of the surgical microsystem while optimizing infection risk through better hygiene and preventative measures and optimizing team related processes through usage of checklists [3] and changes in the team culture [4]. At the same time variability in patients, surgical performance, human errors, unpredictable and preventable technical faults, and simple bad luck may mean that a percentage of patients will suffer complications even in a vastly improved system [5]. In these circumstances patients need to be reassured that every effort is being made to detect the complication, treat it and restore them to their full health [6]. Health care professionals would like to be reassured that their errors do not result in fatal outcomes or impact on the chronic health of their patients, both for their own peace of mind and their standing amongst their peers [7]. Healthcare organizations need to reassure themselves that a single error or mishap does not lead to long-term cost implications and legal and professional consequences.

The management of failure to rescue has been seen as the hallmark of the best performing health systems. A 2009 analysis of US Medicare data from the 20 % hospitals with the best adjusted mortality rates and the 20 % hospitals with the worst mortality

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rates demonstrates that the corresponding complication rates in major surgical cases between these two hospital groups seems to be much less different than one would expect [8]. While the difference in mortality was 3% vs. 8% (i.e., a factor of nearly 3) the small differences in coded complications was only 3.7% (32.7% vs. 36.4%). While the quality assurance of the coding was not part of the study's objectives it is reasonable to assume that the best hospitals also code better and therefore capture more of their complications, and that the real difference might be even smaller. The difference in failure to rescue rates was, however, 6.8% vs. 16.7%, with an odds ratio of 2.43 (O.R.=2.30–2.58). This difference persisted for different types of patients and complications such as pneumonia, post-operative myocardial infarction, and surgical site infections.

Epidemiology

The seminal report "To Err is Human" is seen as the document that empowered healthcare professionals to open up about the preventable flaws of their work and was key in addressing the importance of creating a culture of safety [1]. The acknowledgement that in hospital patients come to harm as often as 10% of all admissions is evident from studies in many developed health care systems. The Health Foundation's literature review on "Levels of harm" demonstrated this prevalence [9]. The authors concluded that "people receive only half of the appropriate care for their condition." Unsurprisingly, the highest rates of adverse events are being experienced by older patients, patient with mental health issues, and in those requiring a longer hospital stay. The latter might be simply due to the fact that their exposure time to risk is longer and that there are therefore more opportunities to "get things wrong."

Impact of Culture and Climate of Care

Failure to rescue has been measured in a number of studies from the USA [1], Canada [10], New Zealand [11, 12], Netherlands [13], and the UK [14]. Organizational culture and the working relationships of those caring together might be a key ingredient for improved rate of failure to rescue. Failure to rescue is more common in organizations with steep hierarchical gradients perhaps due to the lack of psychological safety and the inability to assuredly speak up about concerns [15]. Even within healthcare systems and between different procedures significant differences in the rate of failures exist [8, 16]. Variation in failure to rescue in a detailed study from New South Wales, Australia, was largest in hip replacement, knee replacement, and cholecystectomy patients [17]. Larger organizations fared worse in this study in contrast to other previously published work on single disease groups [18–20]. How might the hospital or unit size affect the ability to identify, address, and recover from system failures?

Surgical Clinical Microsystem and Implications for Rapid Response Success and Impact

Several models of care delivery have emerged as health care institutions face challenges in providing safe, reliable, and effective health care in a complex regulatory and financially burdened environment [21]. Microsystems, small team of providers, based on work of intelligent enterprises by Quinn applies systems thinking to organizational design and represent the smallest replicable organizational unit of change and can be applied to assessing Rapid Response Team (RRT) impact and uptake [22].

The goals of the microsystem are as follows:

The five essential goals (5 Ps) of the microsystem[a]
1. Purpose. What is the purpose of the clinical microsystem and how does that purpose fit within the overall vision?
2. Patients. Who are the people served by the microsystem?
3. Professionals. Who are the staff who work together in the microsystem?
4. Processes. What are the care-giving and support processes the microsystem uses to provide care and services?
5. Patterns. What are the patterns that characterize microsystem functioning?

[a]From Barach P, Johnson JK. Understanding the complexity of redesigning care around clinical microsystem. Qual Saf Health Care 2006;15(Suppl 1);10–6; with permission

Quinn studied companies that achieved consistent growth, high quality, and high margins

as well as exceptional reputations with their customers. He found that these smallest replicable units were the key to implementing effective strategy, engendering loyalty, leveraging information technology, and embedding other performance-enhancing practices into the service delivery process. Health care microsystems consist of a small group of people who provide care to a defined set of patients and for a particular purpose, such as the peri-operative care continuum. Microsystems have both clinical and business aims, tightly coupled processes, and a shared information platform. Clinical, service, and financial outcomes are measured systematically and with a view toward continuous improvement [23].

A microsystem's developmental journey toward maturation and improved performance entails five stages of growth [24] (Box 37.1).

The clinical microsystem approach emphasizes identifying and promoting the strengths of both the team and individuals. It maintains a focus on continuous improvement rather than externally imposed targets and initiatives that members think do not directly have an impact on their work. In addition, the microsystem incorporates the experience and perceptions of patients and their families in the strategic development to deliver the most desirable service from the end user's point of views. A surgical microsystem can involve, for example, a pediatric cardiac surgical team that includes the corresponding critical care team, wards, or perhaps a large surgical critical care unit providing services in a defined geographic space [25]. The microsystem includes patients and their family members given the need for real co-production convergence between patients and providers to achieve a patient's full recovery [26–28].

Characteristics of high-performing microsystems applied to assessing RRT teams include—leadership, organizational support, staff focus, education and training, interdependence, patient focus, community and market focus, performance results, process improvement, and information and information technology—and can be linked to specific design concepts, actions and impact, to enhance patient safety in microsystems (Box 37.2).

Rapid Response Systems

Rapid Response Systems (RRS) were introduced in order to reduce the failure to rescue when patients had a cardio-pulmonary arrests and preventable admissions to critical care units [29]. Much of the literature on failure to rescue has been published in the context of these clinical conditions. A short introduction is therefore necessary.

RRS consist of several parts [30]: The afferent limb of the system records physiological abnormalities and escalates care when significant pre-defined abnormalities in a patient's vital signs are evident. The efferent limb responds to calls from the afferent part. The third part, the system is usually supplemented by an administrative limb and structures supporting education (Fig. 37.1).

The afferent limb relies on assessments of vital signs such as blood pressure, heart rate, respiratory rate, oxygen saturations, temperature, and level of consciousness. Alerts triggered by abnormalities in some of all of these parameters are complemented by alerts related to "nurse concerns" acknowledging the fact that not all deterioration is proceeded by measurable abnormalities and the intuition, experience, and "gut feeling" is hugely important, and can supplement the quantifiable abnormalities.

The efferent limb responds to calls for help from the afferent part. The efferent limb can take different forms in different health systems. In Australia, this consisted mainly of a team of doctors from intensive care and general wards supported by nurses with critical care skills (Medical Emergency Team (MET) [29]). In the UK, however, critical care trained nurses would respond (Critical Care Outreach [31]), and while in the USA, a teams of doctors, nurses, and respiratory therapists might respond (RRT [30]). This diversity and heterogeneity creates immense challenges in making meaningful comparisons

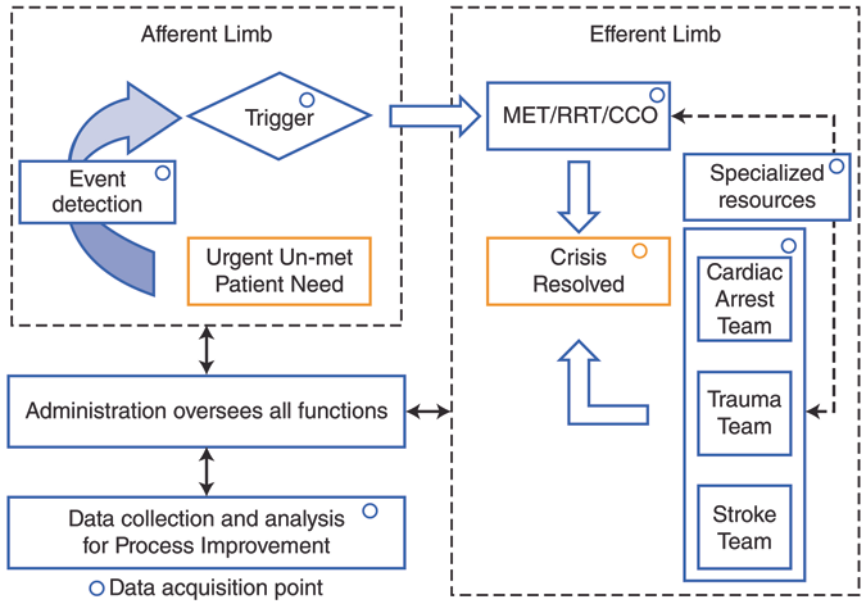

Fig. 37.1 Structure for a Rapid Response System

about the relative effectiveness of each of these staffing models.

Hospitals analyze complications as a means to reduce failure to rescue and improve their patient outcomes [32]. The resulting discussions led quickly to changes in health policy in several countries with RRS becoming a new standard of care, despite many remaining questions about how best to deploy RRS and their effectiveness. In the USA, the 100,000 Lives Campaign chose RRTs in 2005 as one of five interventions to reduce preventable mortality in hospitals. The campaign run by the Institute for Healthcare Improvement (IHI) resulted in some measurable changes in hospital mortality; however, some controversy remains regarding its generalizability and lasting impact [33, 34]. Subsequent spread to the UK (supported by the IHI) resulted in initial pilot projects in small groups of hospitals (Safer Patients Initiative I and II) that followed the pattern of the US campaign. Published results came to mixed conclusions [35, 36]. While there was clear evidence of improvement in processes of care and clinical outcomes in the participating units, these improvements were in line with other organizations that did not take part in the initiative. The UK's Intensive Care Society and the Modernisation Agency published recommendations on the make up of services and funding from the Department of Health following the report "Comprehensive Critical Care" that lead to rapid spread prior to detailed evaluation [37].

The largest interventional trial, a cluster randomized study of 23 hospitals created massive interest and the majority of Australian hospitals adopted METs with limited follow-up. This further impacted objective assessment [38]. The patient safety movements inspired by the IHI have led to spread of national programs through Denmark and the Netherlands. Interestingly these have been often without attempted standardization of the tools used to assess patients at risk or the format of the responding team structure, leading to further confusion as to the effectiveness of these interventions.

Chain of Survival

Principles of Reliable and Safe Care

Failure to rescue patients in hospital is often due to a systems failure and breakdown in care at a number of levels which we have described as a

Box 37.1: Clinical Microsystems: Five Stages of Growth

1. Awareness as an interdependent group with the capacity to make changes
2. Connecting routine daily work to the high purpose of benefiting patients
3. Responding successfully to strategic challenges
4. Measuring performance as a system
5. Juggling improvements while taking care of patients

Box 37.2: Questions to Ask When Assessing an RRT Team's Performance [39]

- Is the team the right size and composition?
- Are there adequate levels of complementary skills?
- Is there a shared goal for the team?
- Does everyone understand the team goals?
- Has a set of performance goals been agreed on?
- Do the team members hold one another accountable for the group's results?
- Are there shared protocols and performance ground rules?
- Is there mutual respect and trust between team members?
- Do team members communicate effectively?
- Do team members know and appreciate each other's roles and responsibilities?
- When one team member is absent or not able to perform the assigned tasks, are other team members able to pitch in or help appropriately?

"chain of survival" [40]. Safe care of deteriorating patients depends on robust and reliable recording of vital signs, recognition of abnormalities, reporting of patient deterioration as soon as detected, an appropriate and timely response, and more often than not a repeat cycle to check whether interventions have had the desired effects (Fig. 37.2). All elements of the chain need to function seamlessly in order to provide reliable and safe care [41]. The following sections will describe the elements of the chain of survival, the reasons for failure and possible mediating mechanisms.

Failure to Record

Deterioration of patients is often clear in hindsight from the characteristic changes in vital signs [42, 43] or pathology results [44]. The majority of patients admitted to Intensive Care Units or suffering cardio-pulmonary arrests demonstrate signs of deterioration for a minimum of 6 h prior to the "event" [45]. In the majority of patients failure to rescue is therefore not due to a failure to record vital signs but failure *to recognize* the trend in the patient status. It is unclear how many patients have cardiac arrests without physiological abnormalities purely due to the fact that no observations or no complete set of observations were recorded in the hours prior to the event. In general terms, a full set of vital signs could comprise respiratory rate, oxygen saturations, blood pressure, heart rate, temperature, level of consciousness, and possibly urine output. The most powerful parameter predicting patient deterioration, and at the same time the most often missed vital sign, is the respiratory rate [46]. Respiratory rate (RR) changes with thoracic cage and lung conditions, metabolic acidosis, infection, fever, etc. RR is measured manually and not electronically like other key measured parameters and is more time consuming. The optimal frequency of observations for acutely unwell patients is not clear from the literature. A report about "Standardising the assessment of acute-illness severity in the NHS" by the Royal College of Physicians [47] recommended at least 4 h vital signs on general wards. In Dutch hospitals the frequency is often less [48]. In many other systems vital signs might only be assessed by healthcare providers once or twice per day and consist of blood pressure, heart rate, and temperature only, thus potentially

Fig. 37.2 The chain of survival for the deteriorating patient on a general ward

missing opportunities to capture deterioration through a full set of vital signs.

Standardization of vital sign recordings might improve the number of opportunities for intervention. Standardization of vital sign recordings and analysis of abnormality is described in the literature as Medical Emergency Criteria [49] (Table 37.1. Medical Emergency Team criteria) and as Early Warning Scores [50] (Table 37.2. Modified Early Warning Score). Triggers of abnormal physiological signs are complemented by nurse concerns as an important safety net for those patients who do not or not yet exhibit gross abnormalities [51].

Validation of Early Warning Scores has been undertaken predominantly in acutely unwell medical patients [47] and to a lesser extent in surgical patients [52]. Standardization can be anchored in clinical teams through training using a common model to describe severity of illness [48]. Automated monitoring can also improve monitoring of post-surgical patients [53–55].

Failure to Recognize Pathophysiological Changes

Perception of "illness" and mental models of providers about the disease severity can have a major influence on behavior and decisions of healthcare professionals. In the words of Peter Senge [56]: "Mental models are deeply held internal images of how the world works, images that limit us to familiar ways of thinking and acting. Very often, we are not consciously aware of our mental models or the effects they have on our behavior." Mental models are subtle but powerful. Subtle, because we usually are unaware of their effect. Powerful, because they determine what we pay attention to, and therefore what we do. For example, if a young patient *"looks well"* with red cheeks and a smile despite a systolic blood pressure of 70 mg than the nursing staff is much less likely to trip the alarm than in an elderly patient who has been unwell for several days with the same vital signs. The perception that young patients are usually well and can't really be that ill remains an ongoing recognized risk and a form of normalized deviance [57]. Recognition of physiological abnormalities is often in the context of what is expected: it is easier to spot "abnormal" in a patient in whom staff expect this abnormality. For example, in a post-operative patient hypotension might be expected; a patient with chronic obstructive pulmonary disease might post-operatively be more short of breath because of metabolic acidosis or volume overload but his or her respiratory rate will be interpreted in the context of their previous condition. Furthermore, we know that elderly patients' physiological response to acute illness is attenuated [58]. This might make it more difficult for staff to classify changes in vital signs as "critical" and requiring further action. Age might, however, not be the defining factor for prognosis. Crucial to the understanding of acute physiology is the underlying degree of frailty. Frailty is a syndrome with measurable metrics [59] based on pathophysiological modeling and epidemiological data from large cohorts of aging patients (Fig. 37.3).

Increased levels of frailty are associated with higher mortality, higher levels of complications after surgery, and higher mortality after admission

Table 37.1 Modified Early Warning Score

	3	2	1	0	1	2	3
Systolic blood pressure (mmHg)	<70	71–80	81–100	101–199		≥200	
Heart rate (bpm)		<40	41–50	51–100	101–110	111–129	≥130
Respiratory rate (bpm)		<9		9–14	15–20	21–29	≥30
Temperature (°C)		<35		35–38.4		≥38.5	
AVPU score				**A**lert	Reacting to **V**oice	Reacting to **P**ain	**U**nresponsive

Table 37.2 The Medical Emergency Team is activated according to the following criteria

Acute physiology change in
• Airway Threatened
• Breathing All respiratory arrests
• Respiratory rate ≤5
• Respiratory rate ≥36
• Circulation All cardiac arrests
• Pulse rate ≤40
• Pulse rate ≥140
• Systolic blood pressure ≤90 mmHg
• Neurology Sudden fall in level of consciousness
• Fall in GCS
• ≥2 points
• Repeated or prolonged seizures
• Other Any patient who you are seriously worried about that does not fit into the above criteria

to ICU. The majority of patients with physiological deterioration and those experiencing failure to rescue are frail [60] (Fig. 37.4).

Failure to Report

Reporting on patient abnormalities or staff concerns are an important function of communication between professional groups. Real or perceived hierarchy plays a major role in acting on available warning signs [61]. Professionals might hesitate to discuss abnormalities if they fear and lack psychological safety or have a non-supportive recipient of the information. In the context of activation of RRS nurses might be hesitant to call a physician if they fear that the physician will not take their concerns seriously or will be short on the phone because of real or perceived pressures of work. The failure to report can be "simple forgetfulness" when workflow pressures and conflicting priorities over-ride the need to escalate care. It can be a conscientious decision that the reporting of abnormalities is not a priority for the patient or workflow. Nursing staff might judge abnormalities to be within the expected range for a given patient or hope that they are transient and resolve without further intervention.

Failure to Treat

Failure to treat can be the consequence of a failure to record or recognize or equally a failure despite recording and recognizing. Correct treatment will depend on the clinical competencies (i.e., knowledge, skills, and attitudes) of the treating clinician and their mental model of the patient's disease and situation [62]. Reliability of treatment can be enhanced by using "care bundles" [63] and by making available a RRT with critical care skills [64].

Complications from surgery fall into a small number of distinct groups which have been labeled MET syndromes [65]. Common complications of surgical care are sepsis, acute kidney injury, and hypovolemic shock. Sepsis is the combination of suspected or confirmed infection and Systemic Inflammatory Response Syndrome [66]. Reliability of sepsis treatment can be enhanced using a "sepsis-bundle" that combines key elements of diagnostics (cultures and serum lactate level) with key treatments (fluids, antibiotics) and monitoring (urine output) [67] (Table 37.3. "Sepsis six" response bundle).

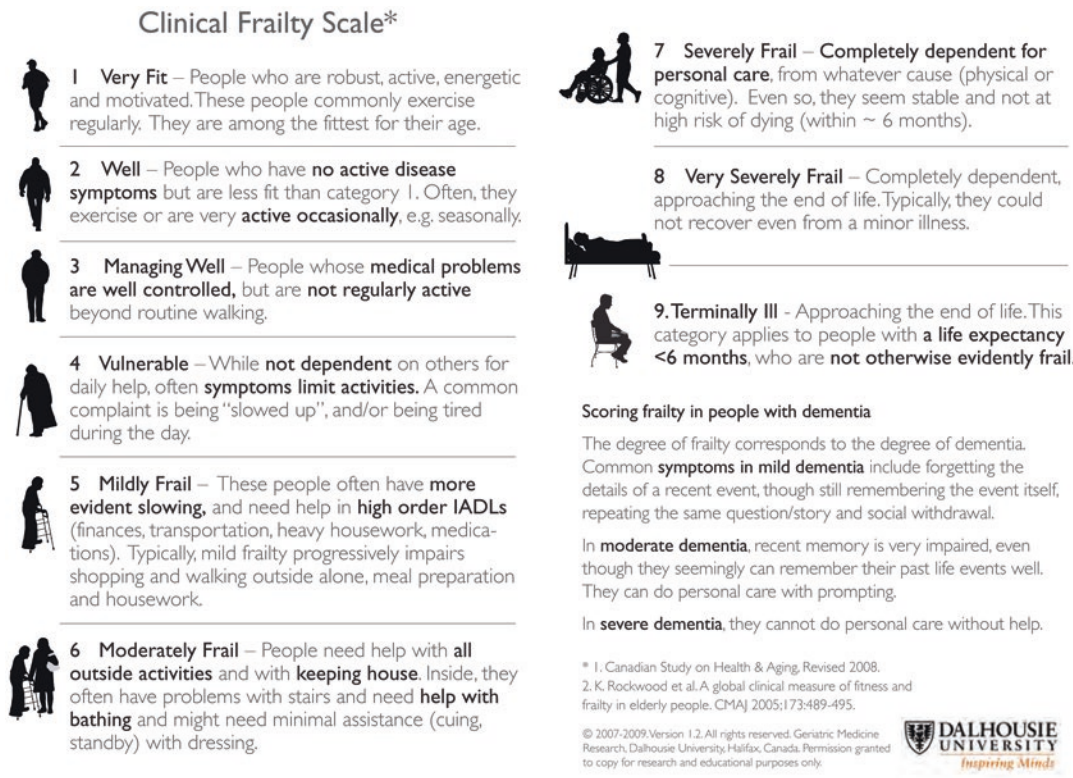

Fig. 37.3 Clinical frailty scale (reprinted with permission from CFS©)

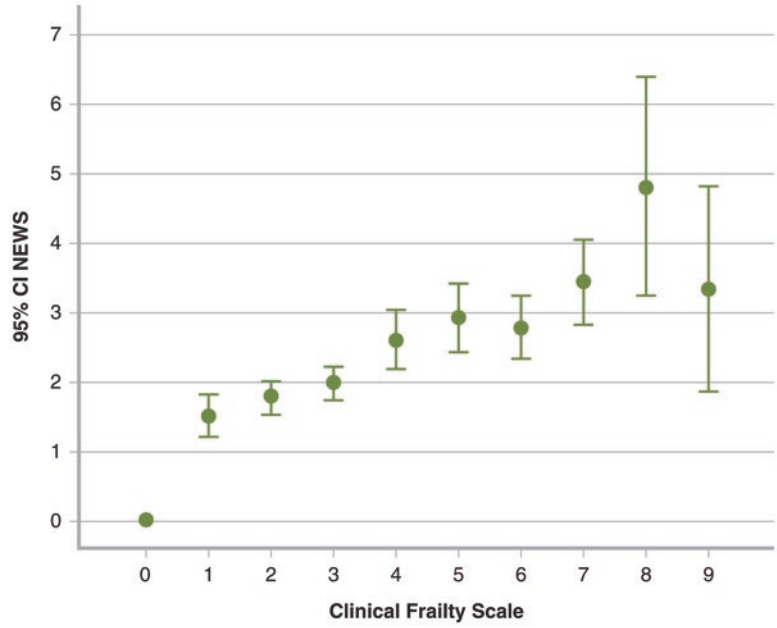

Fig. 37.4 Breakdown of patients who trigger a National Early Warning Score by degree of frailty

Table 37.3 "Sepsis six" response bundle according to [68]

The sepsis six to be delivered within 1 h
1. Deliver high-flow oxygen
2. Take blood cultures
3. Administer empiric intravenous antibiotics
4. Measure serum lactate and send full blood count
5. Start intravenous fluid resuscitation
6. Commence accurate urine output measurement

Implementing these tools facilitates education and improves clinical results [68].

Checklists have been widely accepted for peri-operative care. Similarly check lists could be used for antibiotic choice [69]. The World Health Organization (WHO) checklists represent a "normal checklist" [3]: "Normal" checklists in aviation are performed as routine procedures to anticipate complications. Peri-operative checklists can anticipate complications and improve mortality and peri-operative morbidity. The impact of surgical checklists is likely to be mediated through engaging the staff's attention and changes in their safety culture: Improved communication, flattening of hierarchies, and better social functioning within teams rather than the mechanical ticking of boxes [70]. The absence of these social changes in short term studies might explain why some trials have found little to no improvement in clinical outcomes despite checklist usage [71].

Adaptive lists can be further used for the majority of surgical patients [72]. Crisis checklists are "emergency checklists" that are only applied during an expected impending catastrophe. Experience is currently limited to complications in the operating room [73, 74]. The concept can be further developed to improve standardization or harmonization of care for patients experiencing "MET syndromes" in general wards.

Evidence for Impact of Rapid Response Teams in Surgical Patients

The impact of RRTs on outcomes in surgical patients has been largely part of generic evaluation of RRS [75]. A meta-analysis of published literature suggests a reduction in cardio-pulmonary arrests and a trend toward improved mortality in units utilizing RRS [64]. However, it is not clear whether certain sub-groups of patients or certain hospital specialties benefitted more or less from the RRS interventions.

Properties of track-and-trigger systems in surgical patients have been described: The Modified Early Warning Score (MEWS) was originally created for deteriorating surgical patients [76]. In a cohort of patients from a UK university hospital the reliability of an Early Warning Score for identifying patients at risk on surgical wards is comparable to that described in medical cohorts [52]. The United Kingdom's National Early Warning Score [47] was found to have similar sensitivity and specificity in surgical and medical patients (G. Smith, personal communication).

Two studies have reported data on the effect of these interventions: The impact of implementing an Early Warning Score coupled to an RRT and a call-out algorithm has been evaluated in a 6-month before and after study [77]: An RRT saw 273 patients on four surgical wards. The author reports a reduction in the proportion of emergency admissions to intensive care from 58 % to 43 % with a reduction of mortality in this patient group from 29 % to 24 % during the study period. However, detailed data about the patient cohort and inclusion criteria was not reported.

A second interventional study of surgical patients comes from Australia: A single center 4 months control and intervention period with just over 1000 patients each were compared [78]. A reduction in both mortality and a broad range of complications including myocardial infarction, stroke, and acute renal failure were reported. The rational for the reduction in complications is not clear. Better renal outcomes might be due to more pro-active peri-operative fluid therapy, and this would be expected to be associated with an increased rate of pulmonary edema and possibly myocardial infarction which was not observed. The complication rate decreased from 1 in 3–1 in ten patients. It would be unusual to associate all of these with abnormal MET triggers. It is therefore possible to hypothesize that the presence of a Rapid Response practitioner might have triggered discussions about management of non-crisis patients with improvements in complications.

Failure to Repeat

Failure to rescue in clinical practice often occurs after an initial successful activation of the chain of survival and a transient improvement in patient status. Notably, in patients with complex surgical pathology sustained monitoring and re-evaluation is required. Electronic systems might provide more reliable ways to remind clinicians of unstable patients. There is some indication that this might lead to a safer patient environment [79–81].

Failure to System Design

The design and human factors of systems in hospitals frequently do not follow principles of safe design [82, 83]. High reliability industries rely on the fact that safety critical steps rely on redundant systems [84]. In case one component or a system (or a member of a team) commits an error other components are able to fully compensate for this error and thus prevent catastrophe [83]. Most high reliability industries employ systems that have in-built redundancy: safety critical interventions always exist in duplicate or triplicate [84]. Important parts of procedures are being performed by a least two operators following a scripted process of call and re-call [39]. The principle of redundancy can be introduced into hospitals on a number of levels. Computerized alerts for abnormal laboratory tests and vital signs in electronic patient records can alert staff to deteriorating patients that were missed by the primary care team [85].

Failure to Measure

Establishing safe systems requires defining what safety "looks like." The literature on RRS has often focused on reduction of cardio-pulmonary arrests (CPA). These have been significantly reduced over the last decade. While a reduction of admissions to intensive care has also been attempted it is less clear whether this is achievable given the variation in judgment on what is an appropriate, bed availability, and timely intensive care admission. In VITAL I [79] the admission to ICU increased in US units and fell in Australian units when employing the seemingly same intervention. Decisions to admit to an intensive care unit are variable [86] and might depend on the numbers of intensive care beds and providers available [87] and on the availability to provide high levels of care such as ventilation and inotropic support outside intensive care. On the other hand, it is comparatively easy to time processes from first physiological deterioration to clinical outcomes such as admission to critical care ("Score-to-Door time" [88]) and this can be used as a marker of functional processes [89]. The financial cost of failure to rescue is often difficult to measure for individual patients and might only be evident in the comparison of systems with different levels of adverse events.

There are some limitations to the metrics of failure to rescue: cardio-pulmonary arrests might not be relevant outcomes for the majority of patients. Failure to rescue in patients with advanced cancer or those nearing the expected end of life might take different priorities that are less easy to measure. It is therefore essential that patients at risk of catastrophic deterioration receive a robust assessment by an experienced clinician and a frank and open discussions of likely outcomes of the range of available interventions.

In this chapter we have focused on the detection and prevention of deterioration by analysis of abnormal vital signs. These are more difficult to gauge in patients with chronic conditions such as chronic obstructive pulmonary disease or congestive cardiac failure. These patients will often suffer with abnormal vital signs even in times of being well. As a consequence reliable care is more difficult to define and might require more complex monitoring interventions. In patients with multiple conditions the correct course of treatment is also often not immediately obvious. The failure to identify protocols for conditions such as sepsis that work in randomized controlled trials illustrate the importance of clinical decision makers in deciding which treatments might be beneficial for a given patient. Consultation with colleagues might reduce the risk to administer treatments that are harmful.

Conclusions

Failure to rescue is a key phenomenon at the heart of patient safety. Its resolution requires understanding of the physiology of deteriorating patients as well as the sociology of hospitals and the psychology of individuals. Serious social science, confirmed by statistical analysis and experiment indicates that vital signs will pinpoint the majority of patients at risk and needs to be supplemented by regular and recurring assessments of physiological reserve. RRS are a means to drive safer care across organizations. In order to thrive they require a change in the underlying safety culture with an acceptance that the individual clinician is always fallible and requires redundancy for safety critical steps.

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A Quiet Revolution: Communicating and Resolving Patient Harm

38

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"Truth never damages a cause that is just."

—Mahatma Gandhi

Imagine falling ill or being injured, but with a curable condition. You are referred to a successful, confident, and experienced surgeon. He presents a clear, compelling plan of treatment, which you gratefully accept. Imagine entering the hospital for your operation: the majestic facility, the cutting-edge technology, and the skilled, compassionate personnel there to care for you. Afterwards, however, things are not as you had been led to expect. But what went wrong, why it happened, or how to make things better again are withheld from you. There are whispers but no answers. Some people don't look you in the eye; others have simply vanished. Now imagine the same thing happening to your parent, spouse, or child.

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Fortunately, serious injuries from errors in surgical care are uncommon. Unfortunately, they happen more often than should be the case for an industry that aspires to high reliability in safeguarding patients' lives and health [1–3]. Inexcusably, their occurrence not infrequently leads to the nightmarish scenario of abandonment described above, a through-the-looking-glass experience reminiscent of buying cheap consumer goods or taking fraudulent investment advice far removed from how health professionals see themselves and their work. Surveys of physicians confirm that many medical errors, even those causing significant injuries, are not disclosed to patients [4–6]. But that is finally changing—a significant trend in medical practice and professional ethics that this chapter describes, explains, and celebrates.

Consider the following not-so-hypothetical cases:

Case #1 A right hepatic lobectomy for hepatocellular carcinoma. The OR shift change occurs during the uneventful, 3-h case, and a new scrub tech and circulating nurse relieve the original team. Once the specimen is removed and hemostasis achieved, the attending surgeon scrubs out to start another case while the surgical fellow closes. Sponge and instrument counts are performed and documented as correct. However, a

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chest x-ray obtained as part of a fever work-up 4 days later reveals a retained laparotomy sponge.

Case #2 A surgical consultation for a patient complaining of intermittent right upper quadrant pain. The history and exam are consistent with biliary colic. The patient brings an ultrasound that was ordered by her primary care physician; the accompanying report documents cholelithiasis. A laparoscopic cholecystectomy is recommended and performed, but the pathology report reveals a normal gallbladder without evidence of gallstones. Upon investigation, it is discovered that the ultrasound had been mislabeled and in fact was that of another patient.

Case #3 Operative fixation of a right ankle fracture 4 days after admission following a highway-speed motor vehicle accident. The case had been delayed to allow resolution of pulmonary contusions noted on an admission CT scan. Near the completion of the case, the patient becomes profoundly hypotensive with a significant rise in peak airway pressure. An emergent transthoracic echocardiogram reveals a dilated right ventricle. Despite resuscitative efforts the patient dies in the OR, and autopsy shows a saddle pulmonary embolus as the cause. Peer review determines that DVT prophylaxis with low molecular weight heparin had not been started on post-injury day one as specified in the institution's guidelines.

Although they differ in terms of cause, fault, and perceptibility by patients and families, these cases all involve serious preventable harm. They also all merit prompt investigation and full explanation to the individuals affected by them [7]. How this communication occurs should reflect a deliberate organizational strategy—informed by research—regarding what patients and families need and want, what supports the members of the health-care team, and what keeps patients safe in the future.

The need for a team approach to resolving errors is particularly pressing for modern surgery, which captures perhaps better than any other specialty the importance of centering health care on both individuals and systems, and of delivering services that are timely, compassionate, and effective [8]. After a long and seemingly inexplicable lapse in addressing these issues, clinical leaders, safety experts, and patient advocates began roughly 20 years ago to change practice norms to prioritize honesty and transparency following medical error and are now developing standards and procedures for comprehensive strategies of patient and professional engagement called Communication and Resolution Programs (CRPs). In late 2014, the American College of Surgeons adopted a statement on medical liability reform concluding that "on balance, disclosure and offer programs, otherwise known as communication and resolution programs, show the most promise for promoting a culture of safety, quality, and accountability; restoring financial stability to the liability system; and requiring the least political capital for implementation" [9].

Public Policy Underpinnings of CRPs

The overarching goal of CRPs is to provide good patient care, both by reducing the frequency of unanticipated, adverse outcomes and by remediating preventable harm that has already occurred. Patients and families should be treated no worse—clinically, emotionally, and financially—after a medical error than before it. Plausibly, they should be treated better. Physicians, nurses, and other health professionals also require support and guidance when things go wrong. Improving safety cannot and will not occur unless all concerned—whether technical experts, ancillary personnel, or laypeople—have confidence that the organizations in which they provide or receive care are capable of dealing humanely with error.

Saving money is not a fundamental objective for CRPs. CRPs are designed to be proactive when injuries occur and therefore may end up compensating a larger number of patients than has been the case historically. The analytic and communication functions of CRPs must happen quickly and must be performed correctly, which often requires a substantial investment of personnel and other resources. On the other hand, cost savings can be a welcome by-product of CRPs, particularly for organizations that self-insure their liability risk, because compensation payments tend to be smaller

and more predictable and because total administrative costs tend to be lower.

CRPs respond to three major changes in the public policy context for accountability in health care. First, policymakers understand patient safety very differently now than two decades ago. Research on medical errors conducted mainly in the 1980s and 1990s was brought to the attention of the broader public in the Institute of Medicine's seminal reports, *To Err Is Human* and *Crossing the Quality Chasm*. In addition to exposing significant lapses in safety and quality, the IOM reports asserted the centrality of systems thinking and the need for human factors engineering, which substantially reoriented the established, individually oriented paradigm for medical quality assurance even if it did not wholly supersede it. CRPs embody this commitment to safety redesign, including gathering information, analyzing it, and feeding it back to those who can use it to improve care.

Second, informational accountability has proliferated not only in health care but also generally as a regulatory strategy for government [10]. In medicine, ethical and legal requirements of information disclosure respond to asymmetries that have long skewed treatment relationships to favor health-care providers and health insurers and that often have compromised both patient autonomy and consumer sovereignty. Information-based regulation is even more common today because the Internet and mobile communications have so dramatically expanded and democratized information and because our increasingly partisan political process regards disclosure as a palatable compromise between an unrestrained market and direct government control. We therefore rely more on informed consent to empower individuals in their treatment decisions, impose more obligations for providers and insurers to report information to regulators, and enact broader mandates for direct disclosure to the consuming and voting public—all under the umbrella term "transparency." CRPs honor this movement by offering patients and families information that dignifies their personhood and facilitates their decision-making, while building a knowledge base of professional and institutional experience that can be conveyed to regulators and the public in the form of validated processes and measurable outcomes.

Third, the structure and financing of health care have moved rapidly to an industrial model in which physicians are increasingly employees or close affiliates of hospitals, large practice groups, HMOs, or emerging organizational forms such as accountable care organizations (ACOs). This shift has been characterized by both integration of complementary components of production into coordinated units and consolidation of small producers into larger entities. Correspondingly, payment systems in health care are changing to reward "value" based on cost, performance metrics, and improvements in population health. CRPs are consistent with this move toward organized systems of care, many of which emphasize interprofessional practice and shared accountability, and the more innovative of which offer bundled treatment at a unit price, sometimes with a warranty against additional costs should unanticipated problems arise.

Communication-and-Resolution Essentials

Designing and implementing a successful CRP requires a committed institution, actively engaged health-care professions, and a suitable legal and regulatory environment. There are seven core commitments for organizations and their clinicians [11]:

- Being transparent with patients around risks and adverse events
- Analyzing adverse events using human factors principles
- Supporting the emotional needs of the patient, family, and care team
- Proactively and promptly offering financial and nonfinancial redress when care was unreasonable
- Educating patients about their right to seek legal representation
- Working collaboratively with other providers and liability insurers when adverse events involve multiple parties
- Assessing continuously the effectiveness of the CRP program

Assuming these commitments are in place, one can specify a basic sequence of steps that are necessary to the resolution of medical injury [11].

The CRP process begins with an *initial response* to the patient (or family) and the caregiver when an unanticipated outcome of care occurs. This includes reporting the event to the organization and meeting each party's immediate medical and emotional needs. The initial response is followed by *early collaboration* among the health professionals and institutional representatives to access and organize the available information and to formulate a plan for discussing the situation with the patient and family [12].

These two steps lead promptly to an *initial communication* with the patient and family regarding what is already known, what is not yet known, what their emerging needs are and how they might be met, and what the next steps in the process will be. Apologies of sympathy or of responsibility may be offered, as appropriate; however, compensation for injury may or may not be discussed. Overall, the conversation should be factual, sensitive to patients' and families' circumstances, and customized to match their preferences [13]. Patients and families need time to process news of the harm, reflect with one another, and deal with feelings of loss. Depending on the severity of the harm, patients and families may be angry or disbelieving and may feel particularly vulnerable if they are still receiving care from the organization where the harm occurred [14, 15]. Nonetheless, patients and families want to have open conversations with their clinicians, usually with multiple interactions.

Having initiated the CRP, the next phase consists of *event review*, employing the investigative and analytic tools of the organization but also maintaining active communication with the patient and family, eliciting their perspectives, and incorporating their ideas into the patient safety workflow. Event review should lead directly into *quality and safety improvement* actions to be taken both by the individual professionals who were involved and by the system of care. After this has been done, the timing may be right for a *resolution conversation* with the patient and family, usually represented by counsel, to discuss the overall experience, finalize compensation where appropriate, and discuss safety improvements that have been instituted or that are anticipated. The final step in successful CRP engagement is to obtain *feedback about the process* from all of the individuals who were involved in it.

Involving Patients and Families in Safety Improvement

Patients and families who experience preventable harm generally have a desire to partner with their clinicians and the health-care organization in understanding what happened and preventing recurrences [16, 17]. However, they are often left out of the process [18].

Eliciting patient and family perspectives on the harm supports the CRP process in three ways: (1) by helping identify causes that only the patient and family may know, (2) by offering recommendations to improve patient-centered quality of care, and (3) by promoting their emotional healing. In surveys, patients and families who suffered harm reported that knowing that their narrative would be acknowledged in the event analysis and would help guide preventative efforts made them feel valued [19–22]. They described interaction with the hospital as fundamental to emotional healing, post-event support, and maintaining confidence in their medical care [23].

The CRP process can be designed to align patient and family communication with formal safety analysis of the harmful event (Fig. 38.1). When the patient and family are initially given the news that harm occurred, they can be invited to think about what transpired. Eliciting patient and family input on multiple occasions and by multiple persons lets them know that the desire to obtain their feedback is real. Because patients and families may not remember the specific things said to them during the emotion of the initial disclosure conversation, repeated attempts for follow-up should be made unless they ask not to be approached, and they should always have

current information about whom to contact in the health-care organization if they wish.

Patients and families can be interviewed informally, be sent a written survey about the events they experienced, be included in the formal root cause analysis, be invited to discuss their experiences during patient safety training programs, or be asked to join a patient and family advisory council on quality improvement. Institutions with strong patient and family engagement programs may make several of these options available and have patients and family members choose among them.

An interview is preferable to a written survey because it allows an exchange of information and ideas. In developing a set of structured questions for patients and families, institutions should choose a format that allows them to tell their stories, identify specific causative factors they observed that might be prevented, and share recommendations they may have for improving health care in the institution. Beginning with

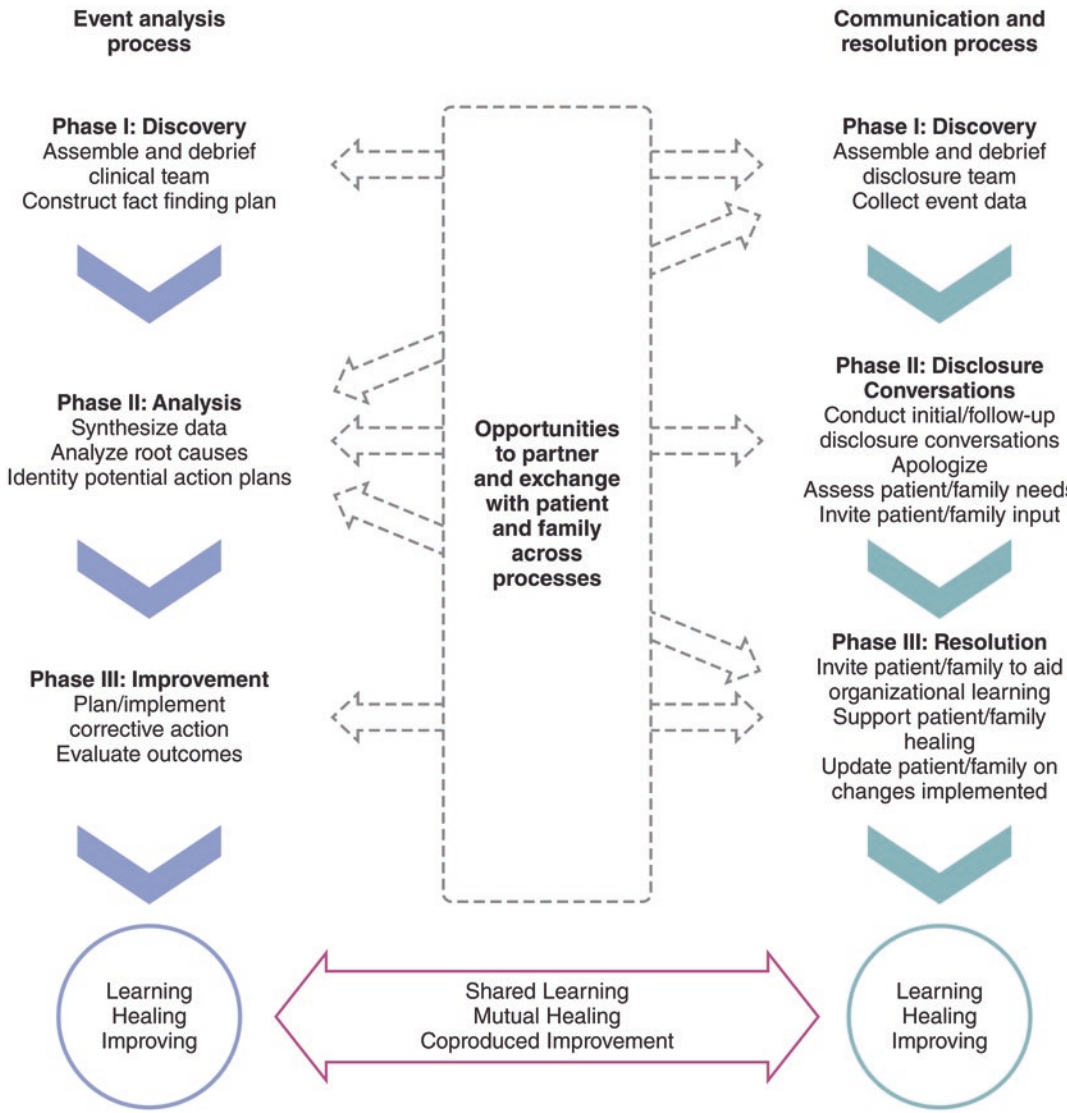

Fig. 38.1 Opportunities for patient and family engagement after a harmful event

open-ended questions gives patients permission to share the things most impactful to them. Following up with more focused questions helps patients remember other issues they may have identified, such as staff attitudes or handwashing practices.

The best person to carry out the interview depends on the situation. An objective facilitator who is trusted by the patient and family is often advisable. If the harm was serious, such as a patient's death, this role may be best filled by a mental health professional trained in critical incident management or in the support of persons experiencing such events. Interviewers should be aware that patients and families may not be ready to tell their full story during a first interview, may need to stop or take a break, and may need to have someone with them for emotional support.

The Long Shadow of Medical Malpractice Liability

CRPs represent a significant advance over current practice with respect to medical injury, which is seldom timely, compassionate, transparent, or preventative. The United States expends over $3 trillion annually on health care, far more per capita than any other nation, and the high status and economic prosperity of American physicians reflect their careful selection, intense training, and ethical commitment. Why this massive investment has yielded so few dividends in terms of effectively responding to avoidable injury is an important question, which could also be asked about the safety, quality, and value of US health care more generally. If the goals are self-evident, and the methods for reaching them relatively clear, why have we not already achieved greater success?

Surprisingly often, the answer to such apparent paradoxes is that a century-long accumulation of legal and regulatory constraints that originally were intended to reinforce physician professionalism has ended up frustrating sound policy design as health care became more technically sophisticated and necessarily more industrialized and costly [24]. The legal domain principally responsible for erecting barriers to effectively communicating and resolving medical errors is medical malpractice law, which continues to influence physician perception and behavior to a far greater extent than an unbiased observer would predict given its actual frequency, outcomes, or expense [25].

An overtly adversarial system that targets individual physicians and thrives on secrecy, expense, and delay, medical malpractice litigation does none of the things that CRPs seek to accomplish [26]. Civil liability for medical negligence has always represented an imperfect solution to the problem described years ago by Gold of "holding experts accountable to non-experts" [27]. In an unmeasured world of professional judgment and discretion, contextual decisions by local judges and juries based on a "standard of care" that was determined by professional custom and introduced into evidence by the testimony of other physicians seemed reasonable. Almost from the outset, however, this approach evoked visceral opposition from the medical profession because the setting and language suggested a criminal proceeding, monetary damages with a hefty cut paid to plaintiffs' lawyers smacked of blackmail, both patients and their testifying experts seemed to be engaged in acts of betrayal, and final decisions on clinical matters rendered by laypeople lacked legitimacy in physicians' eyes.

As medicine grew in sophistication and expense, malpractice lawsuits became a greater threat to physicians and a more formidable obstacle to honesty about error [28, 29]. Fragmentation of care delivery among professional and institutional providers led plaintiffs' lawyers in search of defendants with deep pockets, to which potential defendants responded with concealment or finger-pointing. As "captains of the ship," physicians were forced to bear considerably greater financial responsibility for health system failings than their earnings could reasonably support. The solution, third-party liability insurance, in many ways compounded the failings of the malpractice system by regarding patients as both strangers and adversaries, as well as by creating a new political interest group to question the veracity of malpractice plain-

tiffs and lobby for legislative restrictions ("tort reform") whenever insurance premiums rose.

Protecting and managing personal information has always been a central aspect of preserving reputation [30]. Because allegations of medical malpractice were so entwined with physicians' professional and personal reputations, publicity about possible errors (which often took the form of malicious gossip rather than objective proof) was fraught with peril. Silence when error was unsuspected by patients, and quiet settlement when error was self-evident, therefore became the *modus operandi* of many malpractice defendants. This resistance to sharing information about medical errors has carried over to the modern era of clinical practice in several ways, each of which CRPs must confront and overcome if they are to succeed.

First is the increased diversity of parties in whose good graces physicians must remain, which used to be limited to colleagues who referred them patients, malpractice insurers, and state licensing boards. Relevant constituencies now include hospitals, health insurance networks, and various other contracting partners, as well as Internet-based rating systems which patients and competitors can manipulate instantly and costlessly to harm physicians' reputations. Second is the paradoxical way in which some physician groups and malpractice insurers have responded to new knowledge about the frequency of medical errors. After decades hearing such groups assert that lawsuits should be curtailed because few physicians committed errors, one might have expected revelations that errors are in fact common to cause some backpedaling. To the contrary, many of these stakeholders redoubled their efforts to secure tort reform, arguing that only if physicians are protected from litigation and its associated publicity will they report problems internally and work collectively to improve patient safety. When Pennsylvania in 2003 became the first state to mandate disclosure of serious adverse events, for example, many health-care providers and malpractice insurers dismissed it as a trick of the trial lawyers designed to gin up additional business.

Third is informed consent, which is well accepted by recent generations of physicians as an ethical and legal obligation in advance of surgery or other procedures. If physicians are obligated to tell patients about bad things that *might* happen, how can physicians conceal information about bad things that *did* happen? Yet informed consent is not generally understood to encompass error disclosure. Even worse, some physicians incorrectly believe that informing a patient about a potential complication absolves them from fault if that complication occurs, regardless of whether the particular occurrence was preventable. Fourth is confidentiality in the settlement of malpractice lawsuits. Settlement was only in physicians' reputational interest if it was done quietly (something that the National Practitioner Data Bank and mandatory reporting to state licensing boards has made more difficult). As a result, settlement agreements typically prohibit claimants and their lawyers not only from publicizing the amounts received or disparaging the physicians involved but also from discussing the circumstances of the care received—a bitter pill for patients and family members seeking validation of their experiences and protection for future patients [31].

On the other hand, the dark cloud that hangs over effective communication and resolution of errors because of medical malpractice contains a few silver linings for CRPs. Physicians fear malpractice suits in part because they feel unable to control them; tort reform, for example, requires sustained political engagement and costly campaign contributions and can be undone by state constitutional courts even if legislatures and governors remain sympathetic. By contrast, the decision to be honest with a patient, and quite possibly to defuse a potential lawsuit, is fully within each physician's individual control. Transparency coupled with early resolution has even greater advantages relative to conventional litigation: less anxiety and hostility, less time away from one's medical practice, quicker analysis with greater opportunity to implement safety improvements, and perhaps the chance to avoid mandatory reporting of a settlement to a licensing board or the national data bank, with its associated blemish on one's professional reputation.

From Error Disclosure to CRPs

The move toward CRPs began voluntarily in a few institutions as early as the 1980s, expanded and acquired support from professional associations and regulatory bodies in the early 2000s, and became more systematic following the enactment of the ACA in 2010. Leaders in early settlement models include the Veterans Health System, several self-insured academic institutions (Michigan, Illinois, Harvard, Stanford), and some nonprofit hospital groups (Catholic Healthcare West, Ascension Health), while noncaptive liability insurers (COPIC, Coverys, West Virginia Mutual) have pioneered limited compensation models not requiring release of legal claims or reporting to the National Practitioner Data Bank [32–34]. Patient advocacy groups also embraced transparency following error, notably the SorryWorks! Coalition, which urged hospitals to be honest with patients as a compassionate obligation and a sound customer relations strategy more than for litigation risk management or patient safety. With leadership from the federal Agency for Healthcare Research and Quality (AHRQ), which began funding demonstration projects and developing consensus standards in 2010, the focus shifted from simple disclosure of error, often with apology, to a structured process of patient engagement, compensation, and safety improvement.

Pioneers and Early Adopters

Disclosure and Apology: Veterans Health System

In 1987, the Veterans Affairs Medical Center in Lexington, Kentucky, in response to losing two malpractice judgments totaling more than $1.5 million, instituted a radical policy of apologizing to patients as soon as possible after the occurrence of a medical error, giving a full explanation of the cause and the steps taken to prevent future harm and, when appropriate, offering a fair settlement. Between 1990 and 1996, 88 malpractice suits were filed of which only one proceeded to trial (and was won by the government). A total of $1,330,790 was paid out over the 7-year period (averaging $190,113 per year), and the average payment per claim was $15,622. Compared to 35 similar VA hospitals, disclosure and apology suggested a financial advantage for full disclosure [35]. A follow-on study with 12 years of data showed an average of 14 settlements per year totaling $215,000 – averaging roughly $15,000 per settlement, compared to the mean VA system settlement in 2000 of $98,000 [36].

Based largely on the Lexington VA experience, the Department of Veterans Affairs adopted in 1995 a policy requiring all its medical centers to inform patients or their families when medical errors result in injury, to offer appropriate medical treatment, and to advise them of their right to file a claim. In 2005, the Veterans Health System issued a national directive titled "Disclosure of Adverse Events to Patients." This policy has been renewed and improved several times [12, 37]. The Veterans Health System has important advantages in its CRP operations, including employed physicians, "enterprise liability" for malpractice defined and limited by federal statute, exemption from many state laws, and the ability to enter into memoranda of understanding with other federal agencies and to define its own legal standards for evaluating the cause of patient injuries and reporting individual but not system-based settlements to the National Practitioner Data Bank [37].

Early Resolution: University of Michigan and University of Illinois – Chicago

In 2002, the University of Michigan Health System (UMHS) launched a comprehensive claims management model with disclosure as its centerpiece. Its core principles, articulated by system counsel Richard Boothman, were as follows: "We will provide effective and honest communication to patients and families following adverse patient events; we will apologize and compensate quickly and fairly when inappropriate medical care causes injury; we will defend medically appropriate care vigorously; and we will reduce patient injuries and claims by learning from the past." The model, which applies an expert construct of "reasonable" care rather than a legal standard of negligence, was associated with a sharp decline in the number of new claims against UMHS from 121 in 2001 to

61 in 2006 [38, 39]. The model also reduced the average claim processing time from 20.3 months to roughly 8 months. This had the effect of decreasing the number of open claims from 262 in 2001 to 83 in 2007, dropping required insurance reserves by two thirds and more than halving litigation expenses.

Drawing on the Michigan approach, the University of Illinois Medical Center at Chicago (UIMCC) in 2004 began to implement a comprehensive process for responding to patient safety incidents with "seven pillars":

> Report incidents that could harm patients; investigate those cases and fix problems before an error happens; communicate when an error occurs, even if no harm was done; apologize and 'make it right' by waiving hospital and doctors' fees; fix gaps in the system that can cause things to go wrong; track data from patient safety reports and see if changes make things safer; and educate and train staff how to make care safer. [40]

UIMCC emphasized teaching young physicians to report and analyze unsafe conditions and providing "care for the caregiver" when injuries occur. In the first 2 years, the process doubled the number of safety incidents reported, prompted more than 100 investigations with root cause analysis, generated nearly 200 system improvements, and served as the foundation of 106 disclosure conversations and 20 full disclosures of inappropriate or unreasonable care causing harm to patients. A 2012 UIMCC communication to AHRQ updating the program's results showed a continued increase in patient safety reporting to 7500 incidents per year, with a 50 % decrease in new claims filed by patients and a reduction in median resolution time from 55 months prior to program implementation to 12 months afterwards [32]. A later article noted that the initiative seemed to have significantly slowed the practice of defensive medicine, reducing the rate of growth in clinical lab orders by 24 % and radiology orders by 18 % [41].

Limited Compensation: COPIC

In 2000, the physician-owned medical professional liability insurer in Colorado, COPIC Insurance Company, launched a post-incident risk management program called the 3Rs Program ("Recognize, Respond, Resolve") [42]. Within 72 h of a complication or injury to a patient, the 3Rs Program enables the physician and patient to engage in open, honest, empathic conversation. In cases in which no lawyer is involved and which are unlikely to incur large damages, COPIC offers patients immediate, unconditional compensation for out-of-pocket losses, which are capped at $50,000. Within 5 years, 65 % of COPIC-insured physicians in procedurally based specialties and 28 % of other physicians were enrolled in the program. As of October 2006, 2853 Colorado physicians had enrolled, and the program had handled 3200 events involving disclosure of medical errors. Of these events, 25 % of patients received payments at an average of $5400 per case. Of the cases in which compensation was paid (roughly 800 cases), seven cases proceeded to litigation with two resulting in tort compensation. Of the cases without compensation paid (roughly 2400 cases), 16 proceeded to litigation with six resulting in tort compensation.

Broadening Consensus

Self-Regulatory and Professional Bodies

Organizations directly concerned with the quality of medical care became supportive of error communication early in the 2000s. In 2001, The Joint Commission adopted a standard requiring a limited form of error disclosure, involving "unanticipated outcomes of care," as a condition of facility accreditation. The Institute of Medicine offered liability reform based on CRP principles as a "Rapid Advance" recommendation to the Department of Health and Human Services in 2002 [43]. The Joint Commission's Tort Resolution and Injury Prevention Roundtable issued a white paper endorsing transparency in conjunction with a CRP-type approach to compensation and safety improvement [44]. In 2006, the National Quality Forum included full disclosure of "serious unanticipated outcomes" among its 30 "safe practices" for health care and promulgated disclosure standards as guidance for physicians and hospitals [45].

Medical professional associations were somewhat slower to follow because of the difficulty disentangling commitments to honesty and improvement from concerns over malpractice liability, particularly during the liability insurance crisis of that time. In 2003, the AMA's Council on Ethical and Judicial Affairs issued a report explaining physicians' ethical obligations to study and prevent error and harm [46]. Opinion 8.21 of the AMA's Code of Medical Ethics reads:

> Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.

The American College of Surgeons has not included error disclosure in its code of ethics but stated in a recent report on medical liability reform and safety improvement that "Adverse events should be approached with open communication and recognition that an unfortunate outcome is not synonymous with negligence. Compensation for injured patients, monetary or otherwise, should be fair and timely without the unnecessary delay commonly associated with the current tort process" [9]. Similarly, the Institute of Medicine has renewed its endorsement of error disclosure and specifically recommends that states encourage the development of CRPs [47].

State Laws

State laws requiring disclosure to patients of medical errors were a novel and important part of the legislative response to surging malpractice insurance premiums nationally in the early 2000s, not long after the IOM reports thrust patient safety onto the national health policy agenda. In 2002, Pennsylvania enacted a heavily negotiated set of malpractice reforms, including the first state law duty on hospitals to notify the patient or patient's family in writing within 7 days of a "serious event," which the statute defines as "(a)n event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient" (Pennsylvania MCARE Act, 2002 40 P.S. § 1303).

The Pennsylvania statute triggered efforts by the state medical society and hospital association to provide communication guidance to their members, as well as a substantial research effort funded by the Pew Charitable Trusts. The researchers recommended four measures to create a culture that supports candor, the free exchange of information, fair outcomes for patients and physicians, and improved patient safety—all mainstays of CRPs today [48]. These were to provide communication skills training to physicians and other health-care professionals to prepare them for disclosure conversations, to create a consult service of expert communicators among the hospital's professional staff who can help plan and conduct disclosure conversations with patients and families and provide debriefing and emotional support to the health-care providers involved, to apologize when appropriate and attend to the form of apology (sympathy versus responsibility) most likely to be helpful in restoring trust between the patient and physician, and to use facilitative mediation techniques to resolve claims promptly, possibly before a lawsuit is filed [49, 50].

Simultaneously with the Pennsylvania law, Tennessee required disclosure to patients of "unusual events" that were made reportable to the state department of health. Shortly thereafter, Nevada, New Jersey, and Florida imposed requirements that patients be notified in person (rather than in writing) by the medical facility after any event that causes serious injury [51]. The Florida statute specified that notification of adverse incidents did not constitute an admission of liability and could not be introduced as evidence (Fla. Stat. § 395.1051, Nev. Rev. Stat. § 439.835, N.J. Stat. § 26:2H-12.25). Over the next few years, laws mandating error disclosure were also enacted in Oregon, Vermont, California, and Washington, while South Carolina, Connecticut,

and Maryland instituted limited disclosure obligations by administrative rule. A significantly larger number of states shield medical apologies from being used in court as evidence of fault, although the scope and impact of these laws vary.

Recent Developments

AHRQ Demonstration Projects

Policy proposals advocating disclosure as a key element of patient safety and dispute resolution moved into the national political arena slowly [52]. Early in the Obama administration, the President announced in a speech to Congress intended to generate bipartisan support for health reform that the Department of Health and Human Services would fund the liability demonstration projects that the IOM had recommended to the Bush administration in 2002 [53]. As a result, AHRQ awarded $23.2 million in 2010 for nine large efforts to combine patient safety improvement with innovations to reduce liability costs, five of which involved CRPs, and for two smaller planning grants [54, 55]. The AHRQ demonstrations partner leading academic researchers with other stakeholders in order to expand CRPs to broader community settings, encourage public-private collaborations, and engage patients in safety improvement.

Launched in a volatile malpractice environment, the New York State Patient Safety and Medical Liability Reform Project works with the state's Office of Court Administration (OCA) and five New York City hospitals to provide communication training, establish a CRP for general surgery, and implement a judge-directed settlement program for all malpractice lawsuits [56]. In the Washington State "HealthPact" project, a liability insurer and 11 health-care institutions are attempting to implement CRP models statewide, working with plaintiff attorneys, patient advocates, and regulators such as the state medical licensing board. The Project on Patients as Partners in Learning from Unexpected Events is being conducted in the University of Texas System, which consists of six health campuses and about 2000 caregivers, in a malpractice climate that is relatively favorable to health-care providers [13].

Ascension Health System's Excellence in Obstetrics Project has enrolled more than 23,000 mothers and infants at five demonstration project sites to test the effects on clinical outcomes and liability claims of improved obstetrician and nursing teamwork, a standardized electronic fetal monitoring curriculum, a shoulder dystocia best practice "bundle," and a coordinated open communication and resolution process known as CORE [57]. University of Illinois Hospital's Improving Communication with Patients Project entails further refinement of the "seven pillars" approach along with implementation of the program at ten private Chicago-area hospitals with open medical staffs and multiple liability carriers, also in a challenging malpractice climate. Building on earlier work at the Harvard hospitals, the Massachusetts Alliance for Communication and Resolution Following Medical Injury (MACRMI) created a road map for transforming the state's medical liability system, established a statewide model known as the Communication and Resolution (CARe) Program, and launched CRPs in eight Massachusetts hospitals that have handled more than 850 patient safety cases [58, 59].

CandOR Toolkit and Collaborative for Accountability and Improvement

Although empirical results from the AHRQ demonstration projects are still forthcoming, AHRQ decided to build on the positive momentum by awarding a $3 million contract to the American Hospital Association's educational arm, HRET, to develop a CRP toolkit akin to the toolkits it has developed in other quality and safety areas such as TeamSTEPPS. The toolkit, named Communication and Optimal Resolution (CandOR), was piloted at 14 hospitals in three large health systems (MedSTAR, Dignity Health, and Christiana Care). As with the demonstration projects, implementation and evaluation proved challenging given the short time frame. The toolkit was released to the public in the spring of 2016.

After 2 years of planning, the Collaborative for Accountability and Improvement was launched in December 2015. The Collaborative brings together pioneering CRP institutions and key stakeholders such as liability insurers, patient advocates, and researchers to pursue three primary goals: to accelerate the adoption of CRPs nationally and internationally by identifying and disseminating best practices, to foster a supportive state and federal policy environment, and to create a shared space for learning and innovation. The Collaborative applies a "Just Culture" framework to CRP design, integrating multiple principles from ethics, management, and safety science to create a framework and algorithms that link institutional response to the level of clinician responsibility for adverse events. Just Culture is based on the core human factors observation from high-reliability industries that the first principle of safety improvement is driving out fear [60, 61]. Although the application of Just Culture requires complex, value-laden judgments, the preferred response to human error is to console and the preferred response to at-risk behavior to coach, leaving punishment only for behavior that is deliberate or reckless.

Individual, Institutional, and Environmental Optimization

CRPs operate successfully in many geographic locations, organizational settings, and clinical situations, but implementing a CRP is not easy. Experience to date suggests important lessons for health-care institutions, individual health professionals, and state and federal policymakers, attention to which can help CRPs accomplish their goals [62].

Institutions

Because many health-care organizations are large bureaucracies with habituated practices, overcoming inertia requires dislodging long-held assumptions and prejudices regarding medical injury and its aftermath, and backsliding is an omnipresent risk. Therefore, leadership is the key attribute of successful CRPs from an institutional perspective—operational leadership from the general counsel or chief quality/safety officer and unequivocal endorsement by the chief executive, deans/department chairs, and board of trustees. Strong leadership is also necessary to assure sufficient resources. In conventional litigation, risk management, fact-finding, analysis, outreach, reconciliation, and improvement are either done slowly or not done at all. CRPs must perform these functions not only well but also quickly, which requires a substantial investment in personnel and support services.

Institutions that self-insure malpractice risk or use a captive liability insurer are better positioned to launch a CRP, as are institutions that provide coverage to their employed and affiliated physicians, because they can more easily present a unified response to injury, integrate patient care and legal functions, and capture savings directly within clinical departments. Even in these organizations, however, it is important for risk management and billing practices to be coordinated with the CRP process. For example, patients may need encouragement and assistance finding legal counsel to represent them, which seems counterintuitive but benefits CRPs in the long run. Settlement should be consistent with the goals and ethics of CRPs, with confidentiality provisions limited to the parties' legitimate interests in avoiding disparagement and not attracting meritless claims [31]. In addition, institutions should develop systems that ensure that all medical bills from care that resulted in injury are waived or held pending resolution; ideally, these efforts should extend to bills from unaffiliated physicians who were not at fault.

Individual Professionals

Physicians, nurses, and other professionals must have sufficient confidence in an organization's commitment to Just Culture to overcome their fears of reprisal and reputational damage. Indeed, causing harm to one's patient is a traumatic event for every health-care professional, and "care for

the caregiver" is a core function of any successful CRP. As with the patient and family, these interventions should begin promptly but may be needed over a protracted period. Health professionals should recognize that CRP engagement is a process, not a single, discrete event.

Having individual physicians participate fully in communication and resolution activities encompasses four key responsibilities, which can serve as indicators of a smooth transition from conventional approaches to a CRP. First, physicians in a CRP should promptly and fully report to their organizations any unanticipated clinical events that may occur (both injuries and near misses). Second, physicians should proactively access available training in how to communicate with patients and families should the need arise, as well as regarding other aspects of the CRP [63]. Third, physicians who find themselves in a situation requiring communication should seek assistance from the CRP's disclosure support team before engaging patients or families in detailed conversation. Finally, once the CRP has assumed primary responsibility for resolving a patient's situation, the physicians involved in the event should not disengage, but should remain part of the settlement process.

Legal and Regulatory Environment

In addition to institutional and individual attributes, the legal and regulatory environment is a significant predictor of CPR success [64]. The legal and regulatory environment relevant to CRPs has three parts: the civil justice system, which sets the rules for private accountability; the professional disciplinary system, which sets the rules for public oversight; and the payment system, which sets the financial incentives.

CRPs have been implemented successfully in states with a range of litigation environments, although both extremes can be challenging. In Texas, with strict tort reform, it is harder to interest health-care providers in trying CRPs because the background risk of litigation is low. In New York, with virtually no tort reform, health-care providers tend to be cautious about which cases to refer to CRPs because they are admitting fault. Because safety improvement is a critical aspect of CRPs, an important issue in all jurisdictions is whether information gathered and shared by CRPs receives legal protection from discovery and use in litigation—either because of immunities granted patient safety organization under federal law or because of state-specific legal standards.

The professional disciplinary response from state licensing boards is the most important source of potential regulatory incompatibility for CRPs. Physicians and nurses involved in avoidable injuries and even near misses worry that licensing boards will take a punitive approach to cases resolved by CRPs rather than adhering to Just Culture principles. Mandatory reporting of settlement payments, both to state boards (some of which make information publicly available) and to the National Practitioner Data Bank (access to which is limited to government entities), also raises concerns among physicians. Some CRPs assert that their payments are not based on individual fault and therefore need not be reported, but legal authority for that position is questionable. In terms of payment rules, increasingly stringent standards and complicated processes allowing Medicare to recoup care costs relating to malpractice settlements can alter the economics of CRPs for both patients and providers, as might the continued expansion of insurer nonpayment policies for care associated with harm.

Several states have changed their laws to facilitate CRP implementation. The AHRQ demonstration project in Massachusetts spearheaded the adoption in 2012 of CRP-enabling legislation that established a 6-month pre-litigation notification requirement, with sharing of all pertinent medical records, enhanced apology protections, and set guidelines for disclosure of unanticipated outcomes. Iowa passed comprehensive CandOR legislation that took effect July 1, 2015, conferring extensive protections on CRP processes and declaring payments made through the CRP exempt from reporting to the Iowa Board of Medicine. In Washington, the Medical Quality Commission issued guidelines affirming Just

Culture principles and endorsing a certification program that would enable CRP resolutions to be regarded favorably by the licensing board [65, 66]. Perhaps the most important statewide initiative has occurred in Oregon, which launched a statewide early disclosure and resolution program in 2014 [67]. On the other hand, the National Practitioner Data Bank recently reaffirmed its established position that all settlements, including in CRPs, that involve a written demand for payment are reportable and failed to clarify whether attribution of an event to system rather than individual failure would alter its reportability [68].

Conclusion

Communication and Resolution Programs represent a significant advance over malpractice litigation to address the causes and consequences of medical error. Closer to the bedside, farther from the courtroom, and based on teams and institutions, they are more relevant to ongoing care, more focused on system improvement, more compassionate, less adversarial, and typically less costly than litigation. Over the past 20 years, CRPs have moved into the medical-legal mainstream and are now being implemented by hospitals, liability insurers, and public-private partnerships in much of the country. Still, there is an urgent need to expand and improve the research base for CRPs, with better data on long-term outcomes such as safety, adequacy of compensation, patient and provider satisfaction, and cost.

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39 It's My Fault: Understanding the Role of Personal Accountability, Mental Models and Systems in Managing Sentinel Events

Elizabeth A. Duthie

"Accountability for decisions without understanding the context is a form of blame."

Introduction

The Institute of Medicine (IOM), in 2000, advocated shifting the focus from the individual to the system when managing adverse events [1]. Healthcare's embrace of a systems approach for managing human error has proven a heavy lift for a multitude of reasons. One of those reasons is physicians and nurses strongly value individual autonomy and accountability [2, 3]. Personal responsibility and the emphasis on error-free care (first do no harm) are deeply embedded in the educational preparation for both professions. Experts have noted that professionals, with expectations of nothing less than perfection in their own performance, are prone to self-assign blame when patient harm occurs [2–5]. Long after the IOM's pronouncement, these entrenched beliefs are contributing to an ongoing struggle to find the right balance between system redesign and individual accountability [6–9].

Within a decade of the IOM report, patient safety experts began asking if a system focus was degrading patient safety by inappropriately ignoring individual accountability [6–9]. They propose that answering the question "is it the system or the individual?" as essential to ensuring individual accountability is appropriately invoked [10]. The prevailing wisdom is that if the individual's actions are the source of the adverse event, individual accountability or sanctions are warranted. If the system is at fault, focusing on the individual's performance isn't necessary and may be counterproductive [9]. The focus for this chapter is on understanding the impact of systems on decision-making and the role of root cause analyses in achieving sustainable safety and reliable progress. The following composite case is presented to illuminate the issues.

The First Story: What Happened

On Tuesday the ORs start an hour later than usual to allow time for learning from grand rounds. But for the staff in OR 3M at The Continually Improving Medical Center (TCIMC), there would be no learning. The risk management team had summoned them to a root cause analysis (RCA) meeting. Dr. Kelly Stone had never attended one of these sessions before but he knew they had a bad reputation. The RCA was frequently referred to as root canal without anesthesia. He had been the anesthesiologist in OR 3M when catastrophe had struck. It was now being called a sentinel event. The OR 3M team was living in the land of

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uncertainty as hope that the patient would recover still loomed large. But Kelly was less hopeful. It had been 18 min between Evelyn's own breath and the one supplied through the surgical airway. The surgeon, surgical resident, scrub technician, circulating nurse, the nurse manager, the resuscitation team physician, and the otolaryngology resident joined Kelly in the small windowless conference room. The risk manager, Catherine Parker, arrived with the surgical critical care intensivist, the designated expert, and the team leader. There weren't enough chairs so Catherine stood at the front of the room. She announced the meeting goal was to create a time line of what had happened to the patient. The follow-up meetings would ascertain why, despite everyone's best efforts, things had gone so terribly wrong. Catherine said: "The focus isn't on any one individual, but rather the systems that allowed the event to transpire. There will be no blame. The starting place is in the telling of the story."

Evelyn Couch was a 43-year-old mother of two adolescent sons, scheduled for a robotic-assisted hysterectomy. At 5′10″ and 319 lbs (145 kg), she had a body mass index (BMI) of 45.8. Evelyn had no medical history, but this might be attributed to the fact that the last time she had seen a physician was 13 years prior, after the birth of her youngest son. Evelyn only sought out her gynecologist after months of persistent vaginal bleeding. The dysfunctional uterine bleeding was associated with a large fibroid and the gynecologist recommended a hysterectomy. Evelyn was found to be hypertensive (189/98) and diabetic (Hgb A1C 12.4) during her preoperative assessment. The newly assigned internist delayed surgery for 6 weeks, while he brought both conditions under control. Evelyn's only other noteworthy medical issue was a history of snoring. She had never been sent for a sleep study. The screening anesthesiologist in the preadmission testing center designated her at risk for obstructive sleep apnea and a difficult 3 of 4 intubation level. She was scheduled for the minimally invasive surgical suite (MISS) where gyneco-urological procedures were performed. The MISS was connected to the main hospital through two blocks of internal corridors. Kelly successfully intubated Evelyn but only on the third attempt using a glide scope. The surgical procedure was uneventful and the surgeon left the OR to speak with Evelyn's husband, while the resident completed the case.

When Kelly extubated Evelyn, she immediately started thrashing around, grasping her throat while attempting to sit up. Kelly struggled unsuccessfully to assist her. He told the nurse to get a stretcher. It arrived in an instant from the corridor immediately outside of the OR door. Evelyn followed the directions to move onto it, inadvertently disconnecting the monitoring leads. Sitting upright did nothing to relieve her distress. In less than a minute Evelyn stopped breathing and lost consciousness. Kelly instructed the staff to summon the resuscitation team. He couldn't reach Evelyn to intubate her as the robot blocked his way. He asked everyone to help return her to the OR table. The four of them couldn't move Evelyn's body off the stretcher. To get more help, the circulating nurse hit the blue panic button; a blaring sound outside in the corridor announced disaster. Staff came charging into OR 3M. It took six people to move Evelyn to the OR table. Reconnecting the monitoring equipment revealed asystole. Manual chest compressions were initiated and medications to restart her heart were administered. Bag mask ventilation was attempted and abandoned in the absence of the reassuring rise of her chest. Kelly unsuccessfully attempted intubation. The screeching monitoring alarms created an audible reminder of the dire circumstances and sharpened the team's edgy apprehension. The resuscitation team arrived breathless from running, 8 min after the call went out, as Kelly was preparing for a percutaneous airway insertion. The responding anesthesiologist and Kelly worked together to insert the percutaneous tracheostomy tube, but the internal swelling and external adipose tissue made it impossible. They called for a tracheostomy set and Otolaryngology stat. For the first time, luck worked in their favor as the on-call ENT resident was in an adjacent suite. He arrived at the same time as the trach set and successfully established a surgical airway. It was 18 min since the resuscitation team had been

summoned and within another 3 min Evelyn's heart began beating on its own. Evelyn was taken to the surgical intensive care unit late on that Friday afternoon to start brain cooling.

The entire event unfolded over 21 min but the retelling and responding to questions required 55 min of the RCA time. Catherine informed the team that they had all the details they needed for today. They would continue meeting to identify the root causes and develop plans for correction. At the next meeting, she would present the time line. Kelly knew what the root cause was and he didn't need another meeting or an official time line. He spoke up—"Before we go, I think you need to know I recognize this event occurred as a result of my judgment. I removed the tube and failed to immediately establish an airway. We lost valuable time placing her on a stretcher and then back onto the OR table. Everyone pulled together as a team to support me after that bad decision. I don't think we need another meeting to establish that this was my fault. Time lines and meetings won't change what we all know to be true." The overcrowded, poorly ventilated meeting room was now oppressively hot. The adrenalin fueled retelling of the event had been replaced with an overwhelming exhaustion. Kelly's pronouncement sucked what little oxygen was left, out of the room. Everyone averted their eyes as silence descended upon them; no one knew what to say. It filled the team with admiration for his courage and sadness for a wonderful professional. And then there was the fear. If this could happen to someone as good as Dr. Stone it could happen to anyone. What would this mean for his career? After all, they knew he spoke the truth. Catherine finally broke the silence saying "We appreciate your honesty and insights Dr. Stone. We will review all the information from today's meeting and let the team know the next steps within a few days. We thank everyone for coming to the meeting and for your cooperation. The honest, forthright explanations are critical to understanding what needs to be done to prevent this type of event in the future."

Catherine wrote up the report identifying human error as the root cause. Her corrective action recommended monitoring Kelly's performance for a year to determine if the event represented a pattern of substandard performance. And with that pronouncement, his blameless 12 years of dedicated service slid into oblivion. The RCA team approved the report. Catherine informed them there was no need for more meetings. The report would be sent to the mandated committees and regulatory agencies. A newly appointed Chief Medical Officer (CMO) reviewed the RCAs prior to presentation at the Quality Committee. He rejected it as he said human error was unacceptable. When human error is the root cause, the only thing to fix is the human. James Reason, the father of human error theory, tells us "we can't change the human condition we can only change the conditions under which humans work" [11, p. 73]. The failure to identify the systems meant no organizational learning. Catherine felt strongly that the RCA team had determined there were no systems issues and reconvening them would be futile. The team had approved the report, it should be accepted. The CMO instructed the Patient Safety Manager, Megan Carter, to meet with Dr. Stone to ascertain the systems issues.

Megan had been at the hospital for more than two decades in varied administrative nursing positions and 3 weeks as the Patient Safety Manager. Through intensive study, she had gained a respectable knowledge about patient safety. She had never led an RCA. Megan knew that reading about RCAs didn't necessarily make you ready to do one, leaving her anxious about how to proceed. She called Dr. Stone and he was unpleasantly surprised to hear a request for further discussion. He had been notified that the report was complete. The facts were clearly laid out and he had admitted it was his fault. What else did they expect to find? Megan explained that while they appreciated his acceptance of responsibility, it would be useful to know if there was anything the hospital could do better to prevent future cases. Kelly reluctantly agreed to meet with her, largely as he felt he had no choice.

Megan knew that if you asked the question five times, you would arrive at the root cause in need of remediation [12]. That approach was a huge failure. Every time Megan asked about why

something happened, or why Kelly had performed a certain action, it led to a dead end. He would say that it was his judgment or he just shrugged. And Megan didn't disagree with him. Even as she was asking him why he extubated the patient she was thinking in her head "because I thought she was ready to be extubated." And in fact that was the answer she got. It all seemed so lame. She didn't even bother to ask the next "why did you think she was ready to be extubated?" as it seemed insulting and challenging to his judgment. Maybe the risk manager was right; sometimes it's just human error. Or maybe Megan just didn't know how to ask "why" questions correctly. The entire process took less than 5 min and Megan had learned nothing new. The atmosphere was tense and awkward and Megan wanted to bring it to a close. She decided to ask one final question and call it a day.

"What would have happened if you had left her intubated?" Kelly looked up in surprise and gave a rapid-fire response. "Are you kidding me? We can't leave patients intubated in the MISS. It would have taken the OR out of service as the nurses in the MISS post-anesthesia care unit (PACU) aren't trained to care for ventilated patients. Every minute the OR is delayed is analyzed and charged to someone's budget. If we are obtaining a patient consent while the OR is ready, that would be charged as lost time to the Anesthesiology budget, and I would be personally assessed. If we need to send a patient to the main PACU we have to beg the nursing manager to help us. I would have had to recover the patient in the OR until they found us space. In the old days when we took a patient to the main PACU, the waiting times were outrageous. There are no respiratory therapists covering the MISS as our patients are all low-risk and shouldn't need coverage. If I have to transport an intubated patient to the main PACU, I need to talk to the respiratory therapy supervisor for a special authorization and then wait for a therapist to be deployed. This all came down on a Friday afternoon. If I had left her intubated we could have been in that OR well beyond the scheduled OR closure time of 1700. Now in addition to the lost OR time there would have been nursing overtime. Do you know how popular that would have made me with the nursing staff on a Friday afternoon? There would have been hell to pay. Afterwards, I would have had to justify my decision about why a low-risk patient was being left intubated." Megan responded "well you just described about half a dozen system issues that need to be fixed so that no one else needs to face the same hard decision you had to make." Kelly looked startled. Before he could respond, Megan asked a clarifying question. "You mentioned low-risk patients are treated in MISS. Was Evelyn low risk?" Kelly said "actually no, she was an ASA 3. Come to think of it she didn't meet our criteria for a MISS case. There must have been a scheduling error. She should have been done in the main OR." Megan confirmed that this was another systems issue for investigation. The RCA team had agreed the event was attributable to personal accountability. The follow-up interview suggested organizational systems in need of investigation. A workgroup of clinicians not involved in the event was convened to better understand why the adverse outcome occurred.

The Second Story: Why It Happened

What happened is called the first story and why it happened is the second story [13, 14]. The time line (Fig. 39.1) summarizes what happened based on the group RCA meeting (many of the times assigned to the event are based on participant guesses about how long between events and may not be technically accurate).

The second meeting to ascertain why the event occurred never happened as Kelly's self-assignment of blame was accepted as the root cause. Table 39.1 lists the systems issues identified by the RCA team in the group meeting as compared to Kelly's interview.

The change to the operative location for high-risk patients uniquely contributed to the event. The hospital had one robot for urology and one for gynecology. The MISS performed robotic procedures for low-risk patients and the main OR performed the higher-risk patients (i.e., ASA class 3–4 patients). The robots were moved between MISS and the main OR to accommodate the cases. Transporting this expensive equipment two blocks on and off elevators resulted in damage with costly repairs and equipment downtime. Cases were reassigned to a non-robotic approach

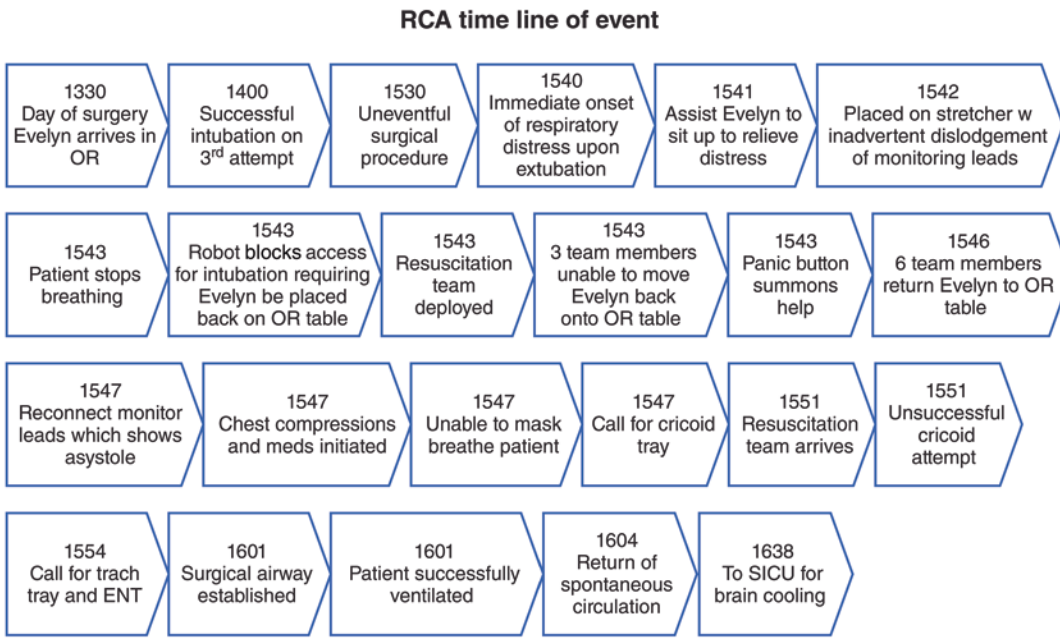

Fig. 39.1 RCA time line of event

as the equipment malfunctioned or was found damaged at the start of the case. The surgeons submitted a request to the Resource Analysis Committee (RAC) for more robots to eliminate the need for cross campus relocation. The committee was comprised of financial and administrative staff that reviewed the fiscal implications for new programs, expensive equipment purchases, processes that met outlier criteria for higher-than-expected costs and any other high-cost problems referred for review. There were no clinicians on the committee as the focus was financial rather than clinical. The resource committee referred the request for the purchase of the two additional robots to the capital strategic planning committee which meets annually to align the purchase of expensive technology with programmatic mission. The strategic capital committee wouldn't be considering the purchase for several months and if approved, it would be several more months before it arrived.

In the interim, the resource committee recommended that the equipment be permanently located in the MISS where all cases would be performed. This would reduce the costs associated with repairs, lost equipment time, and rescheduled procedures. In theory, the resource committee made recommendations for the clinicians' consideration. In reality, the power brokers who sat on the committee viewed challenges to their decisions as a lack of commitment to the organization's fiscal viability. The word on the street was to comply rather than engage in a futile argument. The two surgical chairs from urology and gynecology notified the affected surgeons that going forward all robotic urology and gynecology cases would be performed in the MISS. The anesthesiologists weren't included in this communication. The anesthesiologist who screened Evelyn in preadmission testing indicated on the form that the procedure was to be performed in the main OR, unaware that the OR assignment would be ignored.

The Role of Mental Models

It was 2 weeks from decision to impact. The screening anesthesiologist had refined the MISS triage criteria to accurately identify low-risk patients with exquisite precision. In post-event reviews no one could recall the last time a patient was sent to the main PACU for extended ventilation or other problems. Kelly's knowl-

Table 39.1 Comparison of factors from RCA and the clinician interview

Contributing factors identified during RCA	Factors identified from clinician interview
Inadequate space in the ORs with robots	Financial decision changes operative location for high-risk patients
Patient is moved off OR table in acute distress	Anesthesiologists aren't informed of the change for high-risk patients
Inadequate resources for moving obese patients	Forms for assignment of patient's operative location aren't changed
No established process for patients that can't be ventilated or intubated	Intubated patients in MISS PACU are recovered in OR
Distance for hospital resuscitation team to reach the MISS is excessively long	Lack of respiratory therapy support for MISS patients
Cricoid insertion fails when excessive neck adipose tissue and internal swelling are present	Lack of access to main PACU level of care
	Need to justify clinical decisions which impact financial outcomes
	Charges assigned to individuals for lost productivity
	Production pressures

edge that only low-risk patients had surgery in MISS supported his mental model in care delivery to Evelyn. Mental models are formed by the individuals' professional knowledge, the experience, and the systems in which they work (i.e., group dynamics, organizational rules, managerial implementation of work practices, and institutional culture) [2, 15–19]. They constitute a person's beliefs about how to respond in a given situation, converting organizational policies and procedures into a functional reality. Mental models are incomplete, unstable, dynamic, and evolving and contain gaps as clinicians cope with the messy, uncertain complexities of clinical practice [2, 15–19]. Components of Kelly's mental model included the organization's emphasis on efficient throughput, the lack of resources to manage patients on a ventilator, the screening process that ensured only low-risk patients had surgery in the MISS, production pressures with punitive enforcement, and an organizational culture that valued financial priorities. His mental model was deeply entrenched in his subconscious and gave rise to a pre-compiled response [20].

A pre-compiled response has been described as "recognition-primed decision-making" acquired through personal experience [21]. In other words, our prior interactions build patterned responses in similar situations. Pre-compiled responses are quick, intuitive, carry a low cognitive burden and are highly effective in familiar situations [21]. Evelyn was successfully intubated and her procedure was uneventful. Kelly reflexively extubated her just as he had in hundreds of patients before. His recognition-primed decision-making was for low-risk patients seen every day in MISS, unaware that Evelyn didn't fit this picture. When Evelyn struggled to sit up Kelly's response was to assist her. Because Evelyn's distress was so immediate, he had no time to process a change to his mental model. Once the new, unexpected reality of the situation registered however, critical thinking kicked in. He deployed the resuscitation team and summoned help. Given the limitations of the MISS environment, his management of Evelyn's distress was appropriate. To achieve a different outcome, Evelyn should have remained intubated until her airway swelling resolved, or clinicians skilled in surgical airway procedures should have been present during her extubation. This would have required an awareness of Evelyn's risk status and collaborative preplanning prior to her surgery. This form of system redesign is intended to create a new mental model. Successful system redesign requires detecting the contributory faulty systems and thinking about how the new system will confer a different metal model on the providers.

Discovering Flawed Systems

Systems are the foundations of our mental models dictating how clinicians respond in a given situation [2, 15–19, 21]. Organizational learning about how to prevent future harm emerges from

the discovery of how individuals transform systems "from work as imagined to work as actually performed" (i.e., their mental models) [21]. Uncovering how clinicians navigate the systems that the organization designed requires a nonjudgmental approach [2, 13, 14, 22, 23]. While organizations articulate that they are seeking systems and avoid blaming individuals, frequently they miss the mark sending subtle signals of liability and implied censure under the guise of accountability. An unintended consequence of accountability is to drive blame underground making it more difficult to recognize and avoid. A physician who served on the serious adverse event reporting committee at his hospital commented in 2015 that "we've really made progress with our RCAs. We now ask why five times until we find who did it." When serious harm has transpired, self-blame and fear are inevitable [2–5]. The investigator's approach to clinicians will determine if these feelings are intensified or abated. Using non-blaming language and clarifying the goal are intended to reduce the anxiety of the interview process [24]. Designating it as an event debrief, rather than incident investigation, may be less threatening [25]. Articulating that the investigation is seeking flawed systems transfers the focus from the individual to the organization. One researcher has suggested that renaming the individuals investigating adverse events as organizational learning specialists may reduce fear and improve information sharing [26].

Uncovering system flaws starts with understanding the perceptions of the participants and why they responded as they did. Reliance on the clinicians' acknowledgment of responsibility or explanation of the event is an error-prone approach as the involved practitioners frequently don't understand or misremember what happened [13, 14, 27–33]. Research has shown that 40 % of all decisions are habits that occur without conscious input [30]. Workers constantly make decisions, frequently unaware that they are responding to the systems in which they themselves are embedded [21, 23, 25, 30–36]. The context of the surrounding events matter, but the involved individual may not recognize their relevance [2, 11, 14, 23, 26, 34, 35]. When decisions are lost to the subconscious, clinicians can't tell you why they performed an action [29–34, 36], rendering the "five why questions" mostly ineffective. A better approach is to reconstruct the real world with its competing demands and barriers that conspired to derail success [13, 14, 23]. Seeking to determine what went wrong by challenging clinicians as to why they didn't follow the correct course of action transforms the investigation into a blaming event and clinicians recoil in defense [13, 14, 23]. Information sharing quickly shuts down which may shape future behaviors for clinicians, especially trainees [31]. Instead patient safety practitioners should consider guiding the frontline clinicians through a detailed story telling while avoiding drawing conclusions. These investigators tirelessly pursue, in exhaustive detail, the circumstances surrounding the incident in order to understand why the clinicians acted as they did [13, 14, 23].

The real challenge is to reconstruct the reality of the world at the time of the event without introducing the new post-event reality [32]. This form of incident investigation seeks the perspective of the clinicians by looking forward through their eyes, reconstructing the assumptions and thought processes before disaster struck, instead of looking backward from the error [13, 14, 23].

The flawed systems reside in the mental models that made so much sense before life fell apart. Seeking one absolute version of the event forces a decision about who is lying and who is telling the truth when in reality this determination is not only rarely possible, but creates more fear and silence. Mental models are imperfect and are designed to be more functional than technically accurate [15, 18, 19, 21]. In addition, they may differ between individuals, creating inconsistent viewpoints of what transpired. Discrepant stories can be a rich source of organizational learning as they frequently represent goal conflicts experienced during the unfolding event. Varied accounts, like a Rashomon-like investigation, should be viewed as clues that can advance understanding and learning [13, 14, 23].

The Story Continues

Evelyn never regained cognitive function. She was weaned off the ventilator and able to breathe on her own. Tube feedings sustained her life. After 3 months in an acute care setting, she was sent to a traumatic brain injury unit to enhance cognitive recovery. After 9 months with no appreciable change, she was sent to a nursing home. The hospital negotiated a multimillion dollar settlement. Evelyn's heartbroken family remained devoted to her and at the time of settlement continued to harbor tremendous anger. The event triggered the purchase of two new robots that arrived within 3 months. High-risk patients were scheduled only in the main OR and the robots remained in MISS. There was a hiatus of high-risk robotic cases while awaiting the arrival of the new equipment. A new senior leadership team, knowledgeable about patient safety concepts, arrived just a few months prior to Evelyn's surgery. They began changing the organizational culture. The resource allocation committee was disbanded and a new patient safety finance committee was convened. It consisted of financial, clinical, and administrative senior leaders as well as board members from the quality and finance committees. Clinicians were invited to make presentations and financial decisions became patient centered and collaborative. The monitoring of clinicians for wasted OR time was suspended pending reassessment. It was reinstated after 6 months with a focus on organizational systems (i.e., barriers clinicians encountered that interfered with meeting productivity targets). Monitoring to identify outlier performers resumed but financial charges to individuals and departments did not. Kelly Stone continued his distinguished career in anesthesiology.

Clinical practice lagged behind the other organizational changes. Evelyn's weight was the harbinger of an emerging era in healthcare that went unappreciated. The organization attributed her extreme obesity as a "one off" and processes to manage it weren't developed. It would be another 5 years before the anesthesiology's guidelines for obstructive sleep apnea would be published. It would be closer to a decade before the need to manage patients who can't be intubated and can't be ventilated would move to the forefront of care. Evelyn's case is yet another example of clinical practice changing faster than the science to support it. And yet, the clinicians on the front lines are expected to perform within the highest standards that will ensure a positive outcome. Only years later was the significance of Evelyn's case recognized and practice guidelines developed.

Accountability

Does this case study illustrate that if the systems are at fault that individual accountability doesn't matter? That depends. Accountability is about how rule breaking is perceived and managed. To answer this question requires an understanding of the beliefs and values surrounding rule breaking. In the wake of an adverse event, it is common to identify a missed step in the process or a broken rule as the cause. Invoking sanctions for omissions or rule breaking is seen as holding individuals accountable. Rule enforcement effectively communicates high standards when an individual purposely disregards a good rule [9, 29, 37]. When the rule breaking is unintentional, the same process is a blaming behavior [29, 37]. If only Kelly had been more careful in following the basic rules of airway management, Evelyn might not have sustained brain damage. Holding him accountable for following a rule he never intended to break is punishing human error.

A strongly held belief supporting sanctions is the myth of personal control [27–29]. This view sees the individual's actions as separate from and independent of the surrounding environment. It is consistent with the traditional view of the practitioner as solely responsible for the care and outcomes of the patient [2, 38–42]. Responsibility for decision-making is seen as a personal choice [2, 23, 25–28], and there is a lack of appreciation that practitioners are responding to the context in which they work [2, 11, 13, 14, 16, 19, 22, 27, 28, 42]. The myth of personal control is a form of denial that deflects the responsibility away from the organization, thereby limiting learning [2, 11, 13, 14, 27, 28]. If the RCA had ended with the

monitoring of Kelly's performance, many key systems for this adverse event would have been missed including the inadequate number of robots, the role of the resource allocation committee in decision-making about clinical care, and the emphasis on financial priorities. These flawed systems might never have been identified and corrected. When the story begins and ends with the person, there is nothing to be learned or improved.

But doesn't this support that it is always the system and never the person? The answer is no in a just culture. A just culture is an open and fair approach to human error that supports learning after an adverse event [27–29, 37]. Sanctions are rarely invoked in healthcare as workers almost never break rules with malevolent intent. Intentional rule breaking is commonplace to accommodate variation in care delivery [43].

For example, dual identifiers using the patient identification bracelet are mandated at the time of medication administration. Anesthesiologists during operative procedures, and resuscitation teams during a cardiac arrest, omit patient identification as the risk of misidentification is eliminated when caring for one patient. This intentional rule breaking is intended to save time by eliminating a non-value-added activity. Clinicians that save time by omitting the intravenous line port disinfection are exposing patients to a possible blood stream infection. In this situation, the intentional rule breaking isn't intended to improve patient care and sanctions will communicate organizational value for this activity. The worker, who forgets to sanitize his hands and does so in response to a colleague's prompt, shouldn't be punished. Clinicians, who refuse to perform hand hygiene in response to a prompt, should be sanctioned. Intentionality matters and is integral to determining when punishment is appropriate. In a just culture, human error (i.e., unintentional rule breaking) isn't punished but egregious rule breaking is.

Two separate surgeons left the operating room when the sponge count was wrong and the film was still pending. The resident misread the X-ray, the retained sponge went undetected and both patients had a second procedure to remove it. The rule is that the attending must remain in the OR until the count has been reconciled. Since the surgeons left the OR in violation of the rule, should they be punished? The answer requires understanding the context of their decision. In one case, the attending left the OR to assist in rescuing a patient with a vascular injury during robotic surgery. His prompt response saved the other patient's life. In the second case, the surgeon left for the airport to meet his family for vacation. When the procedure ran later than anticipated, he failed to arrange coverage with a colleague. In a just culture the first surgeon shouldn't be sanctioned, but the second surgeon should be. The first surgeon's rule breaking was intended to improve care while the second surgeon's was not. In both instances changing the system to ensure an attending radiologist reviews the film when the attending surgeon is unavailable would ensure timely detection of the retained sponge. Even when rule breaking occurs, systems should be assessed for improvement opportunities.

Root Cause Analysis

Is the RCA process capable of transforming the tragedy of Evelyn's harm into system redesign that would save the next patient? Understanding what the research has to say about the strengths and weakness of the RCA process informs the answer. The RCA process begins with the notification about the event and the interviews of participants [12, 44, 45]. It has been noted that "You only have 24 hours to uncover the naked truth. After that, it will be all dressed up and ready for the party that is about to begin" [46, p. 3]. Stories evolve with repetitive telling [23].

As the horror of the event unravels within the caregivers' minds, their perceptions are altered and reshaped [47]. Interviewing staff as close to the event as possible, is crucial to the discovery of the mental models in play at that time [23, 45]. In addition, TCIMC often did group interviews such as the one where Kelly accepted responsibility for the adverse outcome. The goal was to understand the shared mental models during the event. After the group interview, the involved

clinicians were invited to participate in the RCA to identity the systems issues and develop corrective action plans. Attendance was optional and a clinician's decision to participate or not was respected. The group interview was very helpful in clarifying issues and completing gaps in the individual interviews. There were no records of attendance at the RCAs so it isn't possible to know how often the clinicians accepted the invitation to participate. Those who did participate said that they attended in the hopes that something good could come out of the event so that it would never happen again. Anecdotally, these clinicians reported that action plans were very important to them.

The current literature recommends excluding clinicians who were involved in the adverse outcome from participating in the RCA to avoid introducing those clinicians' biases into the process [45, 48]. Evidence supporting improved outcomes from this recommendation and discussion about unintended consequences could not be located. There are several adverse consequences to this recommendation, including that the shared mental models of the team and the accompanying systems may not be fully understood without the input of the individuals making the decisions that led to the adverse event. More importantly, deciding to proceed with RCA without active and continuous input and participation from involved clinicians can lead to further fear, obstruction and lack of trust [49].

The opportunity to clarify the issues during the RCA is lost. Ensuring that the depth and breadth of the interviews are adequate becomes even more crucial to ensure that the RCA teams are equipped with complete and accurate information. Kelly didn't know that the location for the high-risk patients had been changed but the surgeon did. If the two are sharing information during a group interview, the discrepant knowledge might be discovered in a timely manner. Without this vital information, the ability to reconstruct the mental models is lost or misunderstood, and the accompanying flawed systems may not be recognized. RCA teams, which are unaware of mental models and the connection to faulty systems, will focus instead on what happened.

Once the RCA team is satisfied they understand what happened, their next mission is to find problems to fix. How RCA teams successfully achieve this mission is drawn from this author's experience in close to two decades of working with RCAs across a broad range of organizations. RCA teams seek out problems by searching the time lines for failure points. In Evelyn's case the clinicians determined placing her on a stretcher in response to her respiratory distress was a fixable problem. The corrective action plan was to develop a protocol with an algorithm to guide the anesthesiologist's response. The protocol is a short-term solution that allowed TCIMC to submit an achievable plan within the regulatory deadline of 30–45 days. Quickly developing a practical solution communicates to the public and regulators that organizations are concerned and take the event seriously [26]. It also creates a sense of closure for clinicians and that normalcy has been restored. The downside of an aggressive deadline is that it only allows time to remediate simple problems rather than the broader systems changes that take months to accomplish and that underlie the mental models.

RCA teams are usually comprised of frontline clinicians without training in systems theory [48, 50–52]. When developing solutions they most typically employ strategies with which they have familiarity, such as writing new procedures or protocols [26] instead of trying to understand the events that transpired using concepts from human factors engineering [53]. The solutions frequently address what went wrong (e.g., moving Evelyn off the OR table) instead of why the adverse event occurred (i.e., Kelly's mental model). Consequently they fail to detect that their proposed solution is ineffective. Kelly's decision to move Evelyn into a sitting position wasn't driven by a lack of knowledge about how to clinically manage her care. His pre-compiled response was to manage Evelyn as he did every other MISS patient. A second time line (see Fig. 39.2), from Kelly's interview after the group meeting, makes it apparent that effective solutions would need to correct factors beyond what happened in MISS that day.

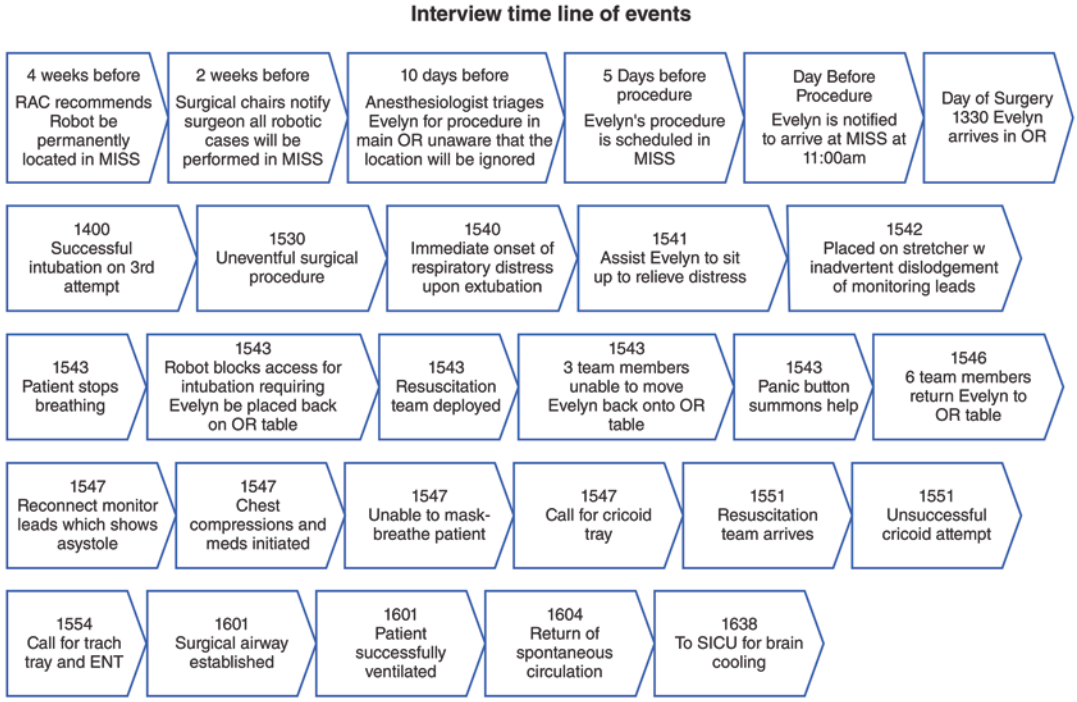

Fig. 39.2 Interview time line of events

Research has shown that RCA teams pursue fixes within their reach [26, 54, 55]. The productivity issues were politically charged and outside of their scope. The CMO presented the information from Kelly's interview to the newly appointed senior leadership team. They changed the financial decision-making process and eliminated punitive productivity targets. Their decisions would have far-reaching positive implications for patient safety across the organization but were too late to help Evelyn. But realistically would an RCA team be capable of such system redesign? The realities of regulatory mandates and the pressure to reassure the public create the mental models where RCA teams avoid system-level fixes outside of their reach [26, 45]. But durable, meaningful improvements reside in system-level change [2, 11, 13, 14, 27, 28, 42, 56]. This means RCA teams need more information than what is available from the time line depicting the event. Table 39.2 lists the omitted contributing factors from both of the time lines.

The contributory factors in Tables 39.1 and 39.2 are the building blocks of the mental models in play that day. They comprise the systems that collided in the OR resulting in patient harm. Flawed systems will not be found in time lines. To improve detection of faulty systems, experts recommend using a causal tree to visually display antecedent events (i.e., the why answers) [57]. There are many different versions of causal trees and all involve time-consuming analysis. To meet mandated deadlines, RCA teams avoid the in-depth analysis required to understand why an adverse outcome occurred. Instead they focus on responding to what went wrong which represents a more achievable workload burden.

Writing a protocol for the management of patients who can't be intubated is designed to manage the complication (i.e., reactive). Preventing the complication (i.e., proactive) involves creating a shared mental model [58] for the entire team at the start of Evelyn's surgery. A handoff from the screening anesthesiologist about her risk for obstructive sleep apnea and difficult intubation could generate a revised and improved mental model and include a conversation about equipment selection to maximize a

Table 39.2 Factors omitted in time lines

Anesthesiologists aren't notified of a change in the operative location for high-risk patients
Forms for assignment of patient's operative location aren't changed
Intubated patients in MISS PACU are recovered in OR
Lack of respiratory therapy support for MISS patients
Lack of access to main PACU level of care
Focus on financial concerns over clinical issues
Lack of clinical input into financial decision-making
Production pressures
Charges assigned to individuals for lost productivity
Need to justify clinical decisions which impact financial outcomes

successful intubation on the first attempt. If multiple attempts at intubation occur, proactively planning for a prolonged intubation, finding a monitored ICU-like bed, or a surgical airway at the time of extubation would be considered [59]. Had Evelyn's procedure been performed in the main OR, the decision to leave her intubated would have been easier as the barriers present in the MISS didn't exist. But without the preplanning conversations, the mental models remain unchanged and the potential of the same event occurring in the main OR is very high. Unless the unexpected is explicated, mental models won't be reset [58]. Changing mental models to build resilience for coping with the unexpected has begun to emerge in healthcare.

Simulation for hard-to-intubate patients is an example of a program intended to build clinical expertise for rare and unpredictable events [60]. When clinicians participate in drills for rarely occurring events where reaction time is critical, they are building pre-compiled responses that will maximize performance under difficult circumstances. Well-intentioned RCA teams seek to control the unexpected with more rigid and prescriptive procedures. They erroneously believe that if they spell out how to respond in a given situation, that clinicians won't err. A well-written procedure supports practice in routine, predictable situations. But when the unpredictable occurs that isn't covered by the procedure, trouble arrives. The goal should be to build resilience that allows clinicians to respond to the unexpected by creating agility in their reasoning [2, 13, 14, 16–19, 21, 22, 27, 28, 42, 58]. TCIMC created stronger systems for financial decision-making but not for clinical processes. The RCA team did the best they could, given the state of the patient safety science at the time. Looking back we can see a better way and this has implications for managing RCAs.

The retro-scope provides a clear vision of how events could have been better managed. When the retro-scope is applied to a single adverse event, it may introduce hindsight bias which superimposes knowledge about the outcome to assign blame and identify how clinicians got it wrong. When the retro-scope is applied to multiple RCAs for aggregate analysis, it can provide a rich source of information about common organizational themes [25]. Patient safety experts are questioning the wisdom of creating system redesign based on a single event [26]. Instead aggregate analysis is being advocated to identify flawed processes involved in multiple RCAs [54, 61]. Effective system redesign remediates the faulty systems creating the potential for a new ending in Evelyn's story.

Writing a New Story

The lessons learned from any adverse event are useful only if they allow a new narrative to be written. Creating a new story begins with understanding the behaviors during the adverse events and the two factors shaping them. The first factor consists of core values and beliefs. The second is the clinician's response to the systems in which they work (i.e., the mental models). Mental models have been explored in this chapter but to fully understand how the organization responded to the event requires an examination of the beliefs and values.

Kelly's acceptance of responsibility for his decision was based upon deeply held professional values. If his excellent work ethos was attributable to him, when things went wrong, he needed to own that as well. His acknowledgement of responsibility during the group RCA meeting was courageous, ethical, completely

understandable, and yet totally misguided. Drawing on his education and professional experience, he believed he was solely responsible for the outcome. Megan, the patient safety manager, drew on his professional altruism to reset his mental model. Introducing the idea he could prevent his colleagues from traveling the same path he had, she persuaded Kelly that making changes beyond his own practice would be valuable. But the other RCA team members shared his viewpoint and changing their belief systems would need to occur as well.

Catherine Parker, the risk manager, admired Kelly's courage and supported his perspective as it was consistent with her own personal values. She frequently spoke about how the systems approach was protecting staff from punishment and would ultimately lead to careless practitioners and lower standards. As human error involves rule breaking [11, 27], she passionately believed that the answer to errors was for workers to follow the rules. She viewed her perspective as holding individuals accountable and not a blaming approach. Catherine's blame-based mental model never changed and had implications for her and the organization. She guided RCA teams to add more rules, educate clinicians to follow the existing rules or enforce rules (see Table 39.3).

Yet Her system fixes were a subtle form of blame that went unrecognized. When Catherine's fixes are compared against system redesign (Table 39.3), it becomes evident that she sought to enlist staff in doing a better job instead of seeking how systems could support clinical practice. The hallmark of a well-designed system is that it makes life faster, easier, and safer for the staff [27]. Catherine's mental model of focusing on human performance didn't include system improvements. She believed finding fault with the system meant individual accountability didn't matter. Her values reflect the fears expressed in the literature [7–9] and underscore why the systems and individuals must be considered as integrally connected. Sidney Dekker eloquently explains the concept in Chap. 2 and below:

> Systems are not enough. Of course we should look at the system in which people work and improve it to the best of our ability. But safety critical work is ultimately channeled through relationships between human beings (such as in medicine), or through direct contact of some people with risky technology. At this sharp end, there is almost always a discretionary space into which no system improvement can completely reach. Rather than individuals versus the systems, we should begin to understand the relationship and roles of individuals in systems. [29, pp. 131–132].

Closing Thoughts After 20 Years

Finding the balance between systems and individual performance continues to be an ongoing challenge 20 years after the Joint Commission's sentinel event guidelines. The concern that individual accountability may get lost is valid. I have taught new nurses systems theory with the goal of emphasizing the importance of event reporting for the identification of flawed systems for remediation to improve safety. When interviewing a new nurse about a medication error, she reported that it was a result of a bad system design. I remember thinking "I've died and gone to heaven, at last, here is someone who gets the importance of systems issues." When I asked what the flawed systems were in need of fixing, she responded, "I have no idea. I went to a class on medication errors and they told me that errors aren't my fault, it's from bad systems." And at that moment, I went from heaven to the seventh circle of hell. The lack of accountability and insight was appalling. In the course of the investigation, it became clear that she was a scattered, disorganized practitioner frequently overwhelmed by her patient care assignment. Although the interview with this young nurse did reveal the flawed systems, she wrongly assumed she had no responsibility whatsoever. The systems were redesigned and the nurse manager and educator intervened with the nurse to improve her performance. Both outstanding and incompetent clinicians may be involved in adverse events and their beliefs matter.

In addition the beliefs and values of the senior leaders are important. The resource allocation committee believed that ensuring fiscal viability for the organization was the most important goal.

Table 39.3 Approaches to system redesign

Comparison of rule-based and system redesign fixes			
Event	Analysis of error	Rule-based system fixes	Redesigned systems
RN administers a tenfold overdose of oral methadone when she draws up 20 mL from multidose bottle instead of 2 mL (10 mg/mL)	Cognitive flip confusing mg with mL (dose was 20 mg)	Implement an independent dose calculation by a second clinician (add more steps to intercept the error)	Unit dose dispense the volume in an oral syringe eliminating the need to calculate and draw up medication (eliminates the cognitive flip)
Anesthesiologist delays intubating a patient in acute distress	Mental model expects low-risk patient who will not need re-intubation	Write a procedure to ensure a prompt response (add more rules to guide practice)	Proactively identify at risk patients & engage the team in developing a plan during a pre-procedure briefing (reset the mental model)
Patient sustains fatal cardiac arrest from fluid overload associated with 10 L (+) fluid balance over 3 days. RNs are not completing the totals for fluid balance sheets and physicians aren't checking it	The 24 h fluid balance sheets are to be completed in the final hour of the night RN's shift when there isn't adequate time. The timing is after morning rounds so physicians don't see the totals	Educate RNs about the importance of fluid balance sheets and monitor compliance with completion (rule enforcement)	Change the 24 h time to midnight providing a 5 h window to complete the totals before rounds (redesigns workflow to a more convenient time) Computerize the fluid balance sheet w an auto-add feature (automate the task)
Physicians inserting CVLs forget some items necessitating the RN leave the bedside to retrieve missing items during the procedure	The items for the line insertion are stored in different locations on every nursing unit requiring physicians to rely on memory for the required items and the location	Require physicians to use a checklist for selecting the supplies prior to the procedure (add an additional step to reduce reliance on memory)	Provide a kit that contains all of the items except for the size-specific items (e.g., sterile gloves and catheter) and store the size-specific items adjacent to the kits (eliminates need for recall and a checklist)

The razor-thin margins, clinically important programs that were underfunded, and reduced reimbursements shaped their mental models. Removed from clinical care, they didn't understand the impact of their decisions and didn't hear about adverse events. This was the first time a financial decision had been connected directly to an adverse outcome, but in informal conversations with clinicians, many will draw a direct line between adverse events and financial decisions to cut clinical services. The resource committee's response was to hold the clinicians accountable. They correctly asserted that they weren't qualified to make clinical judgments and the clinicians needed to inform them if the recommendations were inadvisable. Yet they clearly communicated they were right and the clinicians were wrong. The message that they weren't receptive to being challenged went unspoken. The new leadership team recognized the futility of trying to change the process with the current members. They disbanded the committee in favor of a collaborative structure to better align senior leaders with front-line clinicians. Academic medical centers that place patient care first in the tripod mission of education, research, and patient care have better safety profiles than hospitals that value education or research above patient care [61]. TCIMC used Evelyn's story to place patient safety at the top of their agenda.

The path from a flawed financial decision to a delayed intubation is arduous, exhausting, and politically charged. To achieve a different outcome the resource committee members needed to change their beliefs about decision-making. The new leadership team had suffered the conse-

quences of poor fiscal decisions, motivating them to restructure the decision-making process. System redesign requires thoughtful consideration of the political ramifications. Presenting information that reflects negatively on the organization requires extraordinary diplomacy. Chances of success are enhanced when the patient safety practitioner sits at the table with senior leaders and has a profound knowledge of the organizational culture. Challenging the culture when you are an accepted and valued member of the leadership team improves the chances of success. Patient safety practitioners are educated about human error theory, systems engineering, root cause analysis, and failure modes and effects analysis, but courses in diplomacy and organizational politics are lacking. An organizational mentor is invaluable for patient safety practitioners navigating the dangerous, uncertain political waters. If organizational politics had supported the RAC decision-making model, the risk of recurrent patient harm would have persisted, illustrating how values may negatively impact the patient safety mission. So how do we effectively advance patient safety?

Learning from adverse events can transform knowledge into meaningful safety advancements but is extraordinarily difficult. Kelly viewed the adverse event as a result of his clinical judgment. He was an expert clinician but lacked familiarity with mental models and their influence on decision-making. The risk manager attributed the event to human error despite limited knowledge about human error theory. The frontline staff implemented a system fix despite a lack of understanding about systems theory. The patient safety manager had a broad knowledge of human error and systems theory but was politically inept. The original leadership team believed in patient safety but had limited knowledge about how to make it happen. The resource allocation committee truly believed they were saving the organization from financial ruin and that their decisions didn't affect clinical outcomes. These knowledge deficits may explain the glacial progress in patient safety.

Advancing patient safety requires skilled individuals with knowledge about systems theory that can guide the frontline clinicians in recognizing their mental models, the systems driving them, and the science behind system redesign. Clinicians, frontline workers, patient safety practitioners, and organizational power brokers need to form a shared mental model of how to manage rule breaking and how to transform the tragedy of patient harm into durable patient safety advancements. To develop a shared mental model means learning, not just about the adverse event and how clinicians navigate faulty systems, but what it communicates about organizational values. Because competing goals are both valued, balancing them is difficult. Production pressures are tremendous in operative settings as inefficiency represents waste in the system that can impact the bottom line. Lost OR time is easy to measure and assign to individuals who can make improvements. Many believe that the impact of productivity pressures on patient safety is significant and yet hard to definitively measure. Competing priorities may contribute to adverse outcomes [2, 11, 27]. They are all too common in healthcare and present a serious conundrum for patient safety practitioners trying to improve patient safety.

In closing, if we are to rewrite Evelyn's and Kelly's life stories, we would need to rewrite the approach to adverse events. Instead of seeking problems to be fixed, we should seek to understand why life unfolded as it did. Understanding why Kelly couldn't leave Evelyn intubated generated a wealth of knowledge. Helping her onto a stretcher makes sense. The faulty systems reside in the mental models and sense-making capabilities of the clinicians. Skilled and humble investigators are required who have the patience to elicit them during interviews. Simulating interviews is one approach for ensuring competent investigators. From the mental models, the faulty systems emerge. Individuals skilled in systems or human factors engineering training are critical in effectively remediating these systems to truly prevent the patient harm from recurring. Leaders across all levels need to understand the organizational patient safety values, recognize the difference between blame and accountability, and have a rudimentary understanding of systems theory. Seeking to understand their own values and what

role they play when an adverse event occurs acknowledges they have shared ownership of the systems and are partners with the frontline staff. This values a collaborative approach toward achieving durable safety advancements, so that the harm doesn't revisit the organization on another day, disguised as a different problem. Only then will the story have a different ending, one that doesn't involve patient harm.

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Capturing, Reporting, and Learning from Adverse Events

40

Juan A. Sanchez and Paul Barach

"… The value of history lies in the fact that we learn by it from the mistakes of others, as opposed to learning from our own which is a slow process."

—W. Stanley Sykes, 1894–1961

Introduction

Efforts to reduce rates of errors and adverse events have not yielded the results desired in part as a result of the complex nature of healthcare [1, 2]. Unsafe patient care, however, continues to be widespread and recurrence of the same errors and harm are common. Each preventable "defect" in care, whether causing harm or not, is an opportunity to learn and redesign processes of care in order to create a safer system. For every major incident that causes a patient actual harm, there are many other events such as "near misses," unsafe acts, and precursor events, from which learning and adaptation can occur [3]. The ability to capture and examine both harmful and "non-harm" incidents can provide enormous opportunities to understand how the process failed and how to improve the delivery of care.

The increasing emphasis on value, outcomes, and quality should motivate organizations to focus attention on preventable events as a strategy with the highest priority. In one study, the majority of consumers surveyed indicated an expectation that all healthcare workers should report all errors [4]. However, while incident reporting systems are being increasingly used, there is a tendency to focus on reporting rather than on learning and on effectively responding to the events detected. The healthcare system has an obligation to the public to learn from process failures and adverse events. The failure to learn from mistakes is, unfortunately, a common characteristic of the complex healthcare environment. Mishaps and errors, even when reported, often do not lead to the changes necessary to prevent their recurrence and often miss the deep-seated systems issues that enabled the adverse event to happen. Furthermore, when learning occurs as a result of an investigation, it is often not shared within the institution or externally [3]. Root cause analyses are often done in secrecy, and even those involved in the incident being investigated are not privy to all the documents and learnings [5]. As a result, the same mistakes recur and patients continue to be harmed by preventable errors. Providers become more jaded and cynical and learning opportunities can be missed.

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Incident reporting systems (IRS) have been developed and used effectively in many other high-risk, safety-critical industries (see below). The Institute of Medicine, in its report on patient safety, To Err is Human, called for the widespread adoption of voluntary reporting systems throughout healthcare in order to capture adverse events, near misses, and unsafe acts to improve quality and safety [6]. A robust IRS is an essential component of any patient safety program. It allows organizations to identify and learn from failures and share learning with others. The ultimate goal, however, is to actually improve care, and collecting information without affecting change is itself an unsafe act for an organization. The main purpose of any reporting system is to learn from experience and ensure process and outcome failures do not recur [7]. To be sustainable, all IRS must trigger visible, useful responses to events. Reporting incidents are only of value if useful information is obtained and if the findings are able to be generalized in order to prevent similar harms in the future. Moreover, findings should be analyzed in aggregate for sensemaking to occur and to guide smart resource allocation decisions [8]. Identifying areas of concern, commonalities in causation, and following trends can help expand opportunities to redesign operational processes, workflows, and organizational structure. From this learning, a wide range of possible solutions can emerge to mitigate or eliminate hazards and prevent the recurrence of incidents [2].

Types and Definitions of Incident Reporting Systems

The technology enhancements afforded by web-based information systems make it an ideal platform for incident reporting. A number of different types of electronic systems have been designed which take advantage of the ubiquitous nature of the internet and of systems that interface with each other in order to share data [9]. The goals and objectives of a patient safety program determine the design of a specific reporting system. Factors such as whether reporting is voluntary or mandatory and whether anonymous reporting is allowed are crucially important. Another design consideration is to what degree the information collected is structured, which facilitates the analysis of aggregate data, versus a narrative-based approach which provides more contextual and granular information but more difficult to aggregate data [10].

In this emerging field of study, many definitions are used and a common terminology has yet to emerge. For example, iatrogenic injury originates from or caused by a physician (*iatros*, Greek for "physician") [11]. However, the term has come to have a broader meaning and is now generally considered to include unintended or unnecessary harm or suffering arising from any aspect of healthcare management. Problems arising from acts of omission as well as from acts of commission are included. One of the more difficult problems in discussing patient or medication safety is imprecise taxonomy, since the choice of terms has implications for how the problems related to patient safety are addressed [12]. This makes the comparison of different studies and reports problematic. The lack of standardized nomenclature and a universal taxonomy for medical errors complicates the development of a response to the issues outlined in the IOM report.

The National Research Council defines a safety "incident" as an event that, under slightly different circumstances, could have been an accident. The word "accident" is intertwined with the notion that human error is responsible for most injuries [13]. This notion can be challenging since judgments about human behavior retrospectively are strongly influenced by hindsight bias. As such, the ability to classify events into a safety framework requires a standard set of definitions to facilitate the analysis of events and the aggregation of data [14–17]. There remain major variations in nomenclature with no fixed and universally accepted definitions [18]. The International Classification for Patient Safety, developed by the World Health Organization's World Alliance for Patient Safety, offers definitions and concepts consisting of ten major levels which are listed in Table 40.1. Such a classification system facilitates learning across disciplines and organizations and should be more widely adopted.

Reporting systems may extend beyond the boundaries of a single hospital or organization.

Table 40.1 Definitions

Safety	Freedom from accidental injuries
Error	The failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). Errors may be errors of commission or omission and usually reflect deficiencies in the systems of care
Adverse event	An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable
Preventable adverse event	An adverse event caused by an error or other types of systems or equipment failure
"Near miss" or "close call"	Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event
Adverse drug event	A medication-related adverse event
Hazard	Any threat to safety, e.g., unsafe practices, conduct, equipment, labels, names
System	A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim
Event	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards (see also incident)
Incident (or adverse incident)	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards
Potential adverse event	A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted (also called "near miss" or "close call")
Latent error (or latent failure)	A defect in the design, organization, training, or maintenance in a system that leads to operator errors and whose effects are typically delayed

Multicenter specialized systems have been developed for settings such as critical care units and those which capture surgical and anesthesia-related errors [19–21]. Some systems are limited to certain types of events such as the one from the Institute for Safe Medication Practices and may restrict access to certain types of clinical or administrative personnel. Nationwide systems including the Sentinel Event system of the Joint Commission in the USA and the National Reporting and Learning System in the UK aim to improve patient safety using a population-based approach.

Ideal Characteristics of Hospital-Based Reporting Systems

Successful reporting and learning systems which enhance patient safety have the characteristics outlined in Table 40.2 [22]. A "reporting culture" is one which creates the psychological safety for individuals to timely report any incident without fear of reprisal and maintains the confidentiality of patients and staff to the greatest extent possible. Individuals who report must be aware that their reporting makes a difference. As events are reported and validated, a response should be initiated even if reporting is anonymous. It is possible to learn from even seemingly insignificant incidents and all events should be reported. The awareness that reports are taken seriously by the organization promotes an environment in which frontline workers are more likely to increase the level of surveillance and reporting [23].

The analysis of reported events provides insight into how all factors causing the event converge so that steps can be taken to make the system safer. Granular clinical information regarding events, particularly using a combination of narrative and structured data, provides fertile ground for identifying major categories of defects in the system. Additionally, the reporting system must be capable of disseminating its findings in a comprehensive and understandable way and make recommendations for change by addressing the systems issues rather than targeting on individual or group performance [24].

Table 40.2 Characteristics of successful incident reporting and learning systems whether national or institutional (Leape)

Nonpunitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting
Confidential	The identities of the patient, reporter, and institution are never revealed
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes
Timely	Reports are analyzed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified
Systems oriented	Recommendations focus on changes in systems, processes, or products rather than being targeted at individual performance
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible
Resourcing	Expertise and adequate financial resources are available to allow for meaningful analysis of reports
Legal protection	When deidentified information is reported to a national incident reporting system, it is important to ensure that the information be given legal protection
Data entry interface	The need to optimize ease of use and ensure relevant and adequate data submission

To get the maximum benefit, events must be evaluated, categorized, and analyzed by individuals with expertise who understand both clinical context and are additionally trained to recognize underlying systemic issues. Clinical personnel with additional training in human factors, systems engineering, patient safety, and other related fields are excellent candidates for these activities. Legal protection for reporting should also be an essential component of a patient safety program [25, 26]. The absence of such protection may stifle the desire to report, even if reporting is anonymous.

In addition to the attributes noted in Table 40.1, good hospital-based reporting systems allow reporting by anyone in the organization, including patients. Multiple sources of reporting provide richer, more granular contextual information as opposed to a single source. Good systems particularly value the important role patients and their family members play in improving safety. These systems also gain invaluable information regarding a patient's experience and the needs of the community directly from the "voice of the customer" perspective [25–27].

Fostering a Reporting Culture

As noted, there is pervasive underreporting of adverse events and near misses thereby perpetuating the risk to patients and missing opportunities to learn. In a completely open and just culture, incidents and failures are honestly discussed by all staff, patients, and families enabling the causes of serious events to be established and lessons to be learned. Organizations with the best reporting culture go to great lengths to ensure that reports and investigations carry no blame or liability. Top management in these healthcare systems vigorously promotes the message of a "blame-free and nonpunitive" reporting environment [28]. Additionally, feedback is given to individuals who report on the outcome of an investigation and what measures have been taken.

High reporting rates in organizations with a strong reporting culture do not necessarily indicate inferior quality but, rather, an environment that encourages the reporting of errors and adverse events. This "reporting paradox" gives the appearance that the incidence of safety events is higher in these organizations. On the contrary, higher levels of reporting allow an institution to integrate the learnings derived into quality and safety improvement efforts, focusing on system-level changes leading to a safer healthcare environment [29].

It is essential to introduce norms in professional schools and graduate training programs

that inculcate learning and nonpunitive safety reporting to have a sustainable impact on the future workforce so that a reporting culture becomes second nature. In addition, heightened expectations from consumers, patient advocacy groups, regulators, and accreditors that errors and near misses are to be reported as a professional obligation will contribute to the necessary culture change.

Integrating Reporting Systems with Other Patient Safety Surveillance

No single approach to address patient safety will detect all adverse events. Incident reporting systems are one of many ways to monitor and collect information. Each approach by itself may not be sufficient to create significant change. As such, the ability to integrate the entire set of patient safety activities in an organization allows for a more robust, safety-focused approach. For example, the abstraction of clinical data for purposes of generating insurance claims may be also used to identify adverse events and possibly near misses which can then be investigated. Analysis of these data may allow an organization to monitor and view events across different dimensions using AHRQ Patient Safety Indicators (PSI) and with the addition of ICD-10 hospital discharge codes specific to medical errors [30].

An organization's patient safety portfolio may include such activities as direct observation through routine "patient safety walk-rounds," medical record audits and focused reviews, workforce safety attitude surveys, failure modes and effects analysis (FMEA), and the use of the Global Medication Trigger Tool [30]. Additionally, a periodic review of an institution's malpractice claims, although subject to selection bias, may be useful in focusing attention on specific areas of concern.

Barriers to Reporting

How can we transform the current culture of blame and resistance to one of learning and increasing safety? Understanding the balance of barriers and incentives to reporting is the first step (Fig. 40.1) [31]. Each healthcare organization has its own unique set of characteristics, values, practices, and culture, all of which contribute to the degree by which its workforce is willing to report safety-related events [32]. As noted earlier, fear of punishment or retribution is a particularly strong factor, especially in rigidly hierarchical organizations. Reluctance to report may be bred at the clinical microsystem, mesosystem, and even macrosystem level depending on the group dynamics and culture of an organization as well as its leadership structure [33].

The high-paced, high-tempo, and intense nature of delivering high-quality healthcare creates limitations in time as well as physical and emotional energy. Time constraints, pervasive in healthcare, are compounded by an absence of communication with staff when safety issues are reported and by a general lack of acknowledgement, encouragement, and positive feedback ultimately demotivating frontline providers from reporting. In one study, most respondents believed that lack of feedback was the greatest deterrent to reporting [31]. At a minimum, feedback based on the findings from investigations and analysis should occur. Ideally, it also should include recommendations for changes which are developed in collaboration with great input from the staff. This approach emphasizes the importance of open, honest, and timely communication and feedback [34].

The main reasons for not reporting events are related to fear of collegial reputation and blame, a high workload, and a lack of clarity as to whether an event should be reported [35]. Measures to increase the reliability of reporting include providing clear definitions of incidents (Table 40.1), simplifying the ease of reporting, and providing ongoing education and feedback. In general, different types of IRS have inherent conflicts and trade-offs (Table 40.3) which should be understood in order to make the best use of the information obtained.

Reporting is only of value if it leads to meaningful change. Failure to do anything about events instills a sense of futility and discourages workers at all levels from reporting. Safety awareness becomes integral to providers' work when an

	Individual	Organisational	Society
Legal			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, costs, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality, and multi-institutional databases
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, inforce reporting statutes
Cultural (values, attitudes, beliefs)			
Barriers	Dependent on profession, code of silence, fear of colleagues in trouble, scepticism, extra work	Dependent on organisation, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicised medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values: philanthropic, integrity, educational, cathartic	Become a leader in safety and quality; good for business	Enhanced community relations, build trust, improve health care, transparency
Regulatory			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, licence suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intense
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
Financial			
Barrier	Loss of reputation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in healthcare system

Fig. 40.1 Barriers and incentives to reporting. Modified from Ref. [20]

organization is visibly willing to make fundamental changes in response to reported events [36]. On the other hand, delays or a lack of response from supervisors and hospital leaders will discourage an already beleaguered workforce from reporting events, particularly near misses [37].

Meaningful analysis, learning, and dissemination of lessons learned require expertise in safety systems, accident investigation, and human factors. Faulty, incomplete, or lax analysis and interpretation and the application of ineffective, misguided, or potentially unsafe processes may result in reluctance by frontline workers to report in the future particularly when ineffective fixes add burdensome administrative tasks which detract from clinical responsibilities and do not make patients safer. Additionally, inabilities to access the reporting system either by physical access, cumbersome computer program rules and incompatibilities, or simply poor usability of the software interface also serve as impediments to reporting [38].

Participation Bias

The rate of reporting and the types of error reported vary depending on job function. While nurses report a large proportion of all events, these tend to focus predominantly on nursing processes. Physicians are much less likely to

Table 40.3 Common conflicts in reporting systems [20]

• *Sacrificing accountability for information*—Negotiating moral hazards in choosing between good of society compared with needs of individuals
• *Near-miss data compared with accident data*—Near-miss data plentiful, minimizes hindsight bias, proactive, less costly, no indemnity
• *A change in focus from errors and adverse events to recovery processes*—Recovery equals resilience; emphasis on successful recovery, which offers learning opportunity
• *Trade-offs between large aggregate national databases and regional systems*—National offers longer denominators, capture of rare events; regional offers potentially more specific feedback and local effectiveness
• *Finding right mix of barriers and incentives*—Supporting needs of all stakeholders; ecological model
• *Safety has up-front*, *direct costs*; *payback is indirect*—Spending "hard" money to save larger sums and reduce quality waste
• *Safety and respect for reporters as well as patients*—A just culture that acknowledges pervasiveness of hindsight bias and balances accountability needs of society
• *The need for continuous timely feedback that reporters find relevant*; *changing bureaucratic culture*—Critical to sustain effort of ongoing reporting

report except in cases of serious events [31]. Interestingly, a survey by Wilson et al. demonstrated that, although nearly all physicians believed that reporting should occur when a patient gets the wrong treatment, only about half thought that a report should be generated when a patient does not receive necessary treatment. This difference is concerning since acts of omission are twice as common as acts of commission in medical errors [39]. The contrast in reporting rates between nurses and physicians may indicate different perceptions of what is an adverse event as well as differing mental models and attitudes regarding their professional roles and responsibilities as part of a healthcare system.

Other categories of healthcare workers may be also unwilling to participate in incident reporting depending on their level of involvement in direct patient care and where they stand in the hierarchy of the organization. Therefore, given the wide variation of participation in reporting by job function, it is important to recognize that aggregate data and trends generated from IRS may provide only a selective view depending on which type of healthcare workers actually report. For incident reporting to be useful, it must collect a representative account of all errors from a broad range of healthcare workers regardless of role or status. This approach is more likely to result in more accurate information and effective learning [40].

Anonymity Versus Confidentiality

Anonymously reported data may be less reliable and potentially less useful than its counterparts due to the limited ability to obtain more information and to ask specific questions of the reporter. This lack of accountability and transparency in anonymous reporting, however, may be a necessary trade-off during the early phases of instituting a reporting system in an organization until trust is established and reporting becomes habitual. Unless staff feel safe to report, it is likely that reporting of adverse event will only capture a small number of process and adverse events. Confidential reporting, on the other hand, where the reporter is identified but protected from any reprisals, can yield more valuable information for analysis at the expense of underreporting by those individuals who have not reached sufficient levels of trust to report. Ideally, all reporting should be confidential and not anonymous, but this depends greatly on organizational culture, safety attitudes, and the risk of being blamed for reporting. Whether an anonymous or a confidential approach to reporting is employed, the success of a reporting schema ultimately depends on obtaining sufficient information to conduct a full investigation in order to effect change [41].

The Importance of Near Misses for Learning and Recovery

Most accidents are preceded by warnings or events that forewarn of an impending system failure resulting in patient harm [42]. However, because many responses to safety events are reactive and not proactive, it is not uncommon for

organizations to wait for events to occur before taking steps to prevent a recurrence.

Near misses and other precursor events occur much more frequently than actual harm and, as such, offer ample opportunities for learning. We define a near miss as any event that could have had adverse consequences but did not and was indistinguishable from fully fledged adverse events in all but outcome. There exists a continuous cascade of adverse events from apparently trivial incidents and near misses to full-blown adverse events [43]. The same etiological patterns and relationships exist which precede both adverse events and near misses [44]. Only the presence or absence of recovery or blocking mechanisms determines the actual outcome. It could be argued that focusing on near-miss data can add significantly more value to quality improvement than a sole focus on adverse events [45, 46].

Near misses are ripe learning opportunities and reporting them can have a considerable impact on the safety of patients. Although near-miss events are often ignored, reporting incidents not resulting in harm may be easier to report from a psychological perspective if the learning opportunities are recognized. Reporting these types of events also helps to promote an open reporting culture whereby everyone shares and contributes information to enhance patient safety.

Aviation Near-Miss Reporting Systems

The decade-long aviation effort to improve safety through system monitoring and feedback holds many important lessons for healthcare [47]. Public accident investigation and confidential near-miss analyses have been complementary elements in the remarkably successful effort to improve air safety [48]. After three decades, over 500,000 confidential near-miss reports (currently over 30,000 reports annually) have been logged by the Aviation Safety Reporting System (ASRS) [49]. Eligibility for limited immunity for non-criminal offenses is a powerful incentive to report. Cracks in the framework of trust among aviation stakeholders have been associated with marked decreases in reporting [50]. Billings, a physician who led the effort to create the ASRS in 1976, stresses the value of learning with minimal indemnity [51].

Risk management in aviation illustrates how organizations learn by applying near-miss information to augment the sparse history of crashes and injuries. Data from IRS have been used effectively to redesign aircraft, air traffic control systems, airports, and pilot training programs reducing human error. An overarching lesson from 35 years of aviation experience is that the data collection methods and structures can be used to simultaneously maximize confidentiality and optimize bidirectional information flow [52].

Schemes for reporting near misses, close calls, or sentinel (i.e., "warning") events have been institutionalized in aviation, nuclear power, petrochemicals, steel production, and military operations [51, 53–55]. In healthcare, efforts are now being made to create medical near-miss incident reporting systems to supplement the limited data available through mandatory reporting systems focused on preventable deaths and serious injuries.

Nuclear Power Safety Systems

In the highly charged political, financially accountable, and legal environment of the nuclear power industry, no penalties are associated with reporting non-consequential events, or "close calls," to the Human Performance Enhancement System. In the nuclear power industry, near misses are referred to as "accident precursors" [56]. Feedback from the Accident Precursor Program is felt to greatly contribute to a strong safety record for the nuclear industry over past 25 years [57]. This has been achieved by mapping events on fault trees using probabilistic risk assessment analysis (PRA) [58, 59].

The Three Mile Island disaster led to the emergence of industry-wide norms which supported a communitarian approach to regulation [60, 61]. The dread of even a single potential catastrophe and its implications for all industry members outweighed any objection to

IRS. Backed by public and communal pressures, local proactive safety methods were institutionalized and put into effect across the industry. The intensified approach to process improvement through a focus on safety led to financial gains as a result of better power production (i.e., fewer power outages, shutdowns, and reductions in capacity) [61]. As in aviation, nuclear power incident reporting has evolved to capture the subtlest information using a nested systems approach with confidentiality and other protections increasing in proportion to the sensitivity, value, and difficulty of obtaining necessary information.

Near-miss analyses follow the same procedures as actual harm investigations and should be subjected to the same rigorous root cause analysis methodology in order to identify the system and human factors which contribute to events. It is important to note that, since they occur much more frequently, reporting and thus investigating these types of events may overwhelm the capacity of an organization to respond fully. Reporting these incidents without having the capacity to respond is a waste of an organization's time and resources.

Analysis of near misses over adverse events offers advantages: (1) near misses occur three to three hundred times more frequently enabling quantitative analysis; (2) fewer barriers exist to data collection allowing the in-depth analysis of interrelationships in small failures; (3) recovery strategies can be studied to enhance proactive interventions and to de-emphasize the culture of blame; and (4) hindsight bias is more effectively reduced. Near-miss events offer powerful reminders of system hazards and retard the process of forgetting to be afraid and reinforce a continuous preoccupation with failure [31, 45].

Costs Versus Benefits of IRS

Many high-risk fields such as nuclear power technology, aviation, and petrochemical processing have shown that implementing incident reporting systems for near misses is essential because they benefit their organizations much more than they cost. The system developed for petrochemical processing, for example, uses seven quality indicators to assess the effectiveness of reporting systems while also highlighting the fairness, the revenue optimization, and the cost-effectiveness of the program [62, 63]. Reporting system leaders believe that these systems not only reduce waste but are highly cost effective [64]. This is similar to the implementation of new worker safety climate laws where companies required to embrace the safety rules of the occupational safety health administration have discovered the profits which accompany a healthy workforce [65].

Evidence-based medicine and improvement in outcomes are accelerating the translation of lessons learned in other domains to the healthcare field over the past decades. Studies of IRS from nonmedical domains hold promise for catalyzing a shift in the healthcare culture from a punitive to a collaborative mindset that seeks to identify the underlying system failures [66, 67].

Conclusions

The systematic identification of defects in processes of care that lead to medical harm and their systematic evaluation allow healthcare systems to understand and develop corrective strategies for reducing harm. Incident reporting systems that capture these events and allow an understanding of the root causes of errors, particularly if they include "near misses," are the hallmarks of successful patient safety programs and key to meaningfully improving safety. Nonpunitive, protected, voluntary incident reporting systems in high-risk nonmedical domains have grown to produce large amounts of essential process information unobtainable by other means. Reporting systems across industries have evolved over the past three decades to emphasize identification and analysis of near misses in addition to adverse events. They encourage confidentiality over anonymity and a move beyond traditional linear thinking about human error toward a multiple causation understanding at the level of systems. These programs offer important and timely lessons for healthcare.

For healthcare reporting systems to function well, incentives must exist which promote voluntary reporting—completely, confidentially, and objectively. Reporting should be the right, easy, and safe policy for all healthcare professionals regardless of outcome. To maximize the usefulness of IRS, there will be a need to balance accountability, system transparency, and protections for reporters. To ease implementation, all stakeholders in the healthcare community must be involved in system oversight, support, and advocacy. The top priority must be to design systems geared to preventing, detecting, and minimizing the effects of undesirable combinations of physical design, organizational performance, and circumstances.

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How Not to Run an Incident Investigation

41

Bryce R. Cassin and Paul Barach

"If you don't inquire in a way that respects the intelligence of the other person, you probably won't find many insights."

—Gary Klein, Seeing What Others Don't, 2013

Don't Let the Investigation Get in the Way of Learning from People

Incident investigation is an integral feature of perioperative surgical safety programs and is likely to be fundamental in directing future initiatives. Advances in clinical practice and biomedical technology make the challenge of doing effective incident investigation more complex and nuanced. There is a palpable distance between the stable incident investigation activities of quality and safety departments and the continually evolving scope of surgical practice necessitating increasingly risky and complex procedures, requiring clear communication across clinical disciplines, and ongoing adjustment to the subtle changes in workplace conditions.

Incident investigation should not be a remote activity of senior management disconnected from everyday practice in the perioperative setting but a functional tool for discovering fresh insights about the challenging aspects of the local clinical workplace in context [1]. Local experience and expertise are important factors in shaping a culture of good clinical judgment and decision-making [2]. However, clinicians remain ambivalent about incident investigation processes and tend to find more value in the informal debriefing conversations that start up after an adverse event across the organization. Perhaps the establishment of local review meetings and departmental debriefings is the most vital aspect of any incident investigation process. A good and timely debrief shifts the conversation from a retrospective search for isolated causes to a prospective exploration of patterns and cues in the local clinical workplace that emerge from everyday activity over time [3–6].

Nonetheless, it is commonplace for hospitals and health service providers to use structured methods for the analysis of adverse events, the determination of contributing factors, and the implementation of corrective actions to improve the safety and performance of clinical systems (e.g., root cause analysis in combination with human factors engineering). Incident investigation typically involves a broad range of techniques for gathering and arranging the facts that relate to adverse events into a report that categorizes areas of breakdown and vulnerability in the interactions within a clinical micro-system [7, 8]. Investigation methods have become systematized

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and organized over time around a predetermined set of procedures to produce the required data [9]. However, it does not follow that incidents need to be investigated according to a fixed scheme. Above all, clinicians need to have the authority and inclination to shape the investigation process to achieve the ends that they most value in their particular workplace [10, 11].

A Surgical Trauma Case

The insights drawn from the experience of facilitating nearly 200 incident investigations in a medium sized health service in the outer suburbs of a large urban center in Australia underpin the observations presented in this chapter [10, 11]. One particularly illuminating investigation demonstrates how the ideas and setting for an incident investigation evolved from a top-down to a bottom-up process.

The case concerned a 25 year-old male brought into the emergency department by ambulance following a high speed motorbike accident. The patient was assessed by the trauma team on arrival to be in profoundly shock with a bleeding wound to the left upper thigh and chest. Chest tubes were inserted and intravenous fluids commenced. The patient was transferred to the operating room for surgical management of internal injuries and pelvic vascular injuries. During surgery the patient deteriorated and required resuscitation, which was unsuccessful, and the patient expired. The case involved clinicians across disciplines and departments from various specialties. The initial response, preparation for surgery, and overall management were discussed at a multi-department Trauma Meeting. The case was referred for a root cause analysis (RCA) investigation. The investigation team included a trauma surgeon, general surgeon, intensive care specialist, orthopedic surgeon, a perioperative nurse, and trauma nurse. The trauma physician led the team and the patient safety manager facilitated the investigation. What makes the case interesting is the broad representation of clinicians from the perioperative setting, and the leadership from the trauma physician who used the opportunity to get clinicians around the table to talk about the lessons *they* learned from the case and will apply going forward. Notably, the trauma physician was more interested in improving the quality of insights generated from the local conversations between respected clinicians about the case than the investigation process and its detailed methods and regulatory requirements.

In retrospect, the measure of each investigation at the facility was the personal qualities and approach of the investigation team and the collective wisdom of the local clinicians. Over the last two decades various techniques and methods for incident investigation have been tested in the acute clinical settings of surgical departments (e.g., root cause analysis, common cause analysis, cognitive human factors, failure modes and effect analysis, critical incident review, risk analysis, and review of morbidity data). None should be viewed as a prescription or a system, but a set of tools to be adapted, updated and revised with each new adverse event by well-informed clinicians. Perhaps the best advice to a prospective investigation team is not to see the adverse event in isolation but a group of clinicians busily going about their work as they would on *any given day*. This is the art of incident investigation, no matter the method selected to analyze the event [12].

The experience of working with different incident investigation teams highlights the importance of good governance, transparency and authentic leadership within the surgical department and hospital. This will enable a department to move away from the zealous insistence on a particular system for investigation and direct attention to the thoughtful and timely triage of events, the selection of an appropriate team, and combination of methods, according to the goals and needs determined by the local conditions and context. Validation of the incident investigation will be demonstrated by the relevance of the findings to local clinicians and managers (What Weick refers to as their "clinical sensemaking" [13, 14]). For the investigation of an adverse event to be rendered meaningful the findings need to relate to a concrete situation where patterns of action are recognizable [1]. This is crucial for the construction of a legitimate explanation that has integrity in the local workplace.

An investigation report that makes sense to people in context is more likely to stimulate further conversation and action over time [1].

The dynamic conditions of the surgical environment and the human factors related to the performance of surgical teams warrant specific attention. Incident investigation tools and methods need to be assessed and constantly adjusted for their fit and applicability to local conditions. The skill of commissioning an investigation is a matter of clear perception of the character of the people selected for the investigation team, and an appreciation of the available resources given the organizational climate. It requires a developed capacity for understanding the human predicament of clinical work, and an ability to assess an unexpected event on a continuum, as a set of circumstances in the ongoing flow of activity in the clinical workplace [15]. Even though the situation was not personally encountered, a senior clinician who knows their department and staff will seek to understand the challenges the situation presented to the people involved, when tasked with commissioning an investigation team. He will first and foremost work to establish trust in the process and create a sense of safe space that allows open and uninhibited conversations about how best to learn from the adverse event [16].

Define Your Purpose

The investigation of adverse events should be organized around the surgical workplace culture, the organization of surgical space and schedules, the impact of perioperative work on human performance, and the potential for learning from the adaptations that surgical teams and perioperative staff make in order to recover from unexpected events [15, 17]. The extent to which local adaptation and the fitness of the selected investigation method impact on the meaningfulness of the inquiry for making sense of surgical adverse events should not be under-estimated [10, 11, 14]. Living with uncertainty and ambiguity contrasts the demand from administrators to account for the facts related to an adverse event with a plausible explanation [15]. The misguided bureaucratic search for *the* root causes or a single explanation has the tendency to give investigation teams and health care administrators the impression that a description of specific causative factors must and can reliably be applied to the health system as a whole (e.g., the establishment of classification systems and taxonomies of serious adverse events; [18]). The contrasting reality is that the safety and performance of a perioperative environment is the product of the continuous flow of small everyday adaptations and course corrections from multiple people within the surgical workplace in response to the ongoing technological pressures, transformations and system level developments, such as introduction of new electronic medical record systems, that shape the level of complexity and inherent patient risks [6, 19].

There is an acute need to move away from the Newtonian assumption that the investigation of a past event will arrive at a stable explanation, or that the perioperative environment operates in a stable state according to an automated set of rules [8]. Commonly used investigation techniques such as root cause analysis may create an appearance of order, but the findings of a single investigation are rarely, if ever, indicative of safety and performance at a systems level [8]. This is due to the properties of system complexity and the difficulty of reconstructing events post hoc in the clinical setting using the standardized language of incident investigation models. Organizational life is continually being shaped by unintended, unexpected and unknown factors that result in *both* positive and negative outcomes [14]. A comparison of the common assumptions behind the US Veterans Affairs National Centre for Patient Safety (NCPS) RCA process [20, 21] and the human factors approach described by Dekker [8] highlights the impact that contrasting mental models can have on event perception (see Table 41.1).

Developing insight into the way complex human systems interact and making connections within perioperative environments requires a shift in mindset about the knowledge generated from incident investigations [19]. Techniques like root cause analysis originate from industrial

Table 41.1 The level of event reconstruction possible in the local work context can vary somewhat from the assumptions made in formal incident investigation models

Common assumptions in RCA	The local reality
The investigation team displays a thorough understanding of the event through the rational presentation of information	The information gathered by the investigation team is partial and incomplete
The purpose of an investigation is to establish a reliable account of what happened and why it happened	There is no single authoritative account of an event as the analysis of what happened is influenced by the emerging mental models of the people involved and interpreted through the collective wisdom of the investigation team
The investigation team's task is to demonstrate cause and effect relationships and develop corrective actions that address each root cause or contributing factor	The findings of an investigation team are tentative and recommendations need to be confirmed in the local setting because it is not possible to capture all possible consequences of an event or anticipate all future possible situations where a similar event may occur
The incident investigation system takes into consideration the concerns of frontline personnel and is a tool for learning through the dissemination of positive actions that reduce or eliminate vulnerabilities identified	The consequences of an event are related to subjective factors that operate deep within the workplace independent of rational statements in incident investigation reports. Therefore, all conclusions remain open to review and require ongoing dialogue in the workplace

settings where, typically, the contributory factors to a defect in a stable system can be attributed to a limited number of physical causes. The nature of clinical adverse events is such that it is near impossible or exceedingly rare to frame an investigation around a single procedure or device. Human error is even more problematic as it is hard to link individual actions to discrete properties of a broken system [6, 8]. Rather than argue for a best method of incident investigation, the chapter presents a number of related propositions that can be used to make decisions about the most appropriate combination of tools that will help make sense of an adverse event. In contrast to the assumptions of Newtonian rationality about the universal application of methods, the guiding premise is that an investigation team needs to understand an event *within the context* of the operating environment and adapt the selection of tools and techniques accordingly [22]. The approach represents a shift away from assuming that there are broken properties to fix, to shaping a perspective of the event that best fits the nature of the problematic situation, and directs sparse organizational attention and resources towards the methods of inquiry that will provide a useful explanation.

A Cautionary Word About Methods of Inquiry

Most of the frustration with adverse event data and the slow progress with making changes in response to incident investigations can be related to either relying too heavily on a particular investigation technique to draw conclusions, or to making incorrect assumptions about the purpose of an inquiry. The trajectory of a serious adverse event is unique and unlikely to occur again in exactly the same pattern. Meta-analyses of RCA report data make the assumption that common factors can be categorized and aggregated across multiple (often high risk) clinical adverse events without due regard for the contextual factors that were particular to individual cases on a given day in a specific perioperative setting with a particular surgical team [23]. Aggregated RCA data, consequently, has little predictive value for future adverse events. This is challenging for regulators, risk managers, and the public to appreciate. Separated from the original context of action, system level aggregations of event data become a "cumulative mess" through the multiplication of known causes and effects [18].

When external governing bodies make these assumptions they tend to work from a basic set of definitions for the purpose of systematically organizing the consequences of multiple adverse events into categories within a measurable body of knowledge (e.g., incident management and reporting systems). At a universal level, the questions posed by regulators relate to what can be *known* generally about adverse events and clinician's performance.

In contrast, clinicians deal with everyday interactions in context and relate knowledge construction to the dynamic of particular situations [5]. In order to address what is *known* or *unknown* about the risks and vulnerabilities in the perioperative setting methods are needed that enable the discovery of previously unrecognized problems (e.g., failure modes effect analysis, fault tree analysis, and probabilistic risk assessment) [24]. Questions at a contextual level relate to gaining a better understanding of operational matters across a department. When making sense of an adverse event it is important to find out what was *known* about the particular problematic situation *by the people involved*. An incident investigation draws on the experience of people working on the frontline in the clinical setting in order to reconstruct the event.

In summary, the three different ways of knowing represent three basic approaches to constructing knowledge about adverse events:

1. *Knowledge as transferring data*. Policy makers and regulators look for what is known generally, from aggregated reports,
2. *Knowledge as learning about systems*. Perioperative suite quality and safety programs seek to discover what is unknown or better understand known risks, and
3. *Knowledge as an ongoing dynamic*. Local incident investigation teams work with what is knowable about an event from the circulating information about everyday clinical actions.

The points of intersection in the diagram (Fig. 41.1) represent the current state of knowledge about actual or potential problems. In practice, knowledge varies from situation to situation, is highly context dependent, and mediated through a process of translation by multiple people at different levels across the organization (For a thorough analysis of knowledge transfer, see [25]. Cook and Woods [19], discuss the impact of resources and constraints on knowledge at the point of care delivery in complex systems).

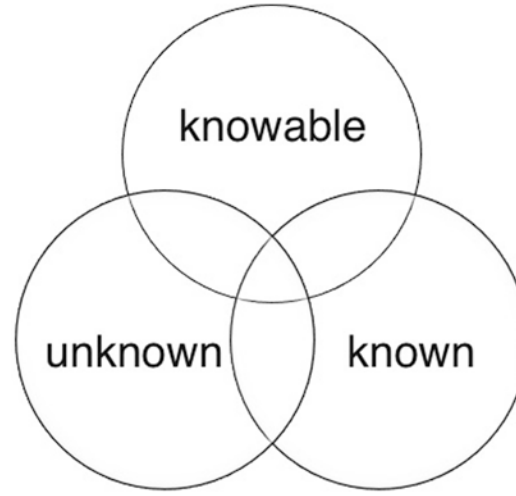

Fig. 41.1 Different inquiry methods produce different types of knowledge

Building a Body of Knowledge About Adverse Events

Although root cause analysis was introduced into health care for the investigation of serious clinical adverse events, it uses causal reasoning from stable categories to deduce what happened (i.e., root cause analysis works from categories of what is generally *known* to break an event into *knowable* parts). The view of the system is drawn from a process of deduction from known factors. Curiously, the root cause analysis checklist of questions used by the US Veteran's Administration (and adopted by other countries such as Australia) is labeled as a set of human factors questions, but the method is unlike most human factors investigations due to a focus on identifying specific causation and applying fixed categories in relation to multiple aggregated events [23, 26]. Without knowing the consequences for the local clinical workplace, and

how the people involved defined the situation, there can be no meaningful understanding of the event and the depth of analysis is limited [18, 19].

In terms of the way knowledge is produced, most adverse event investigations fit between two antithetical positions: either there is a specific "root" cause to find and sort into causal statements for corrective action according to a standardized hierarchy imported from other industries [9], or they opt for the alternative, that a clinical adverse event is the outcome of multiple contributory factors that are open to explanation from different perspectives particular to the complexity and context of the situation [15]. The separation of human factors in an event from system issues, under the label of "human error" is arbitrary, reflecting a misguided commitment to investigation methods adopted from engineering without regard for the interplay between expertise and situational constraints in complex clinical environments [4, 6, 9, 19]. The selection of method often says more about the purposes and philosophy of the investigation team and the sponsor of the investigation than the event itself [26]. The choice of response to an adverse event will to a large extent determine whether the investigation team seeks to replace broken components of a system, identify a barrier to prevent recurrence, consider the redesign of particular tasks, or to optimize workplace systems by developing a better understanding of what people do at the local level [27].

An Overreliance on Rational Analysis Paralyzes Local Knowledge

Top-down quality and safety processes have been implemented in all major health care systems for the management of adverse events. The situation in health care a decade ago was that decision makers needed to be mobilized to turn the idea of the patient safety movement into an organizational reality [28]. There is a growing body of literature that documents the implementation of the resultant processes such as root cause analysis (RCA) for the investigation of serious adverse events [5]. However, the assumptions about using retrospective approaches to locate patterns of error within health care systems need to be challenged due to an over reliance on rational analysis as a basis for understanding breakdowns in care delivery [29]. The initial implementation of safety improvement programs introduced structured processes for thinking about the causes and contributing factors to adverse events. As health departments and jurisdictions accumulated data about findings from RCAs assumptions were made about the transferability of what was known about past events from generalized data aggregated from multiple RCA reports [23]. Informal corridor conversations about care lack the apparent rigor of rational management sanctioned incident investigations. The inherent risk in the pursuit of more reliable adverse event data is the paralysis of knowledge transfer at the local level which is the most important level for developing an understanding of how people manage constraints and regain control of unexpected events [6, 30]. A philosophical commitment to the prevention of adverse events feeds into a belief that systems are generally consistent and reliable. The reality is rather different in complex clinical systems. Accepting that good people sometimes make poor judgments and decisions is more likely to lead to an understanding of the inconsistencies that are common in everyday human interaction with complex clinical and organizational systems [30].

In order to manage this dilemma it is necessary to consciously reflect on the models that the perioperative department selects to guide incident investigation [26]. If the department is primarily concerned with external reporting there is likely to be a focus on identifying the organizational factors related to adverse events. A limitation of this risk averse approach is that perioperative care directly depends on what humans do each day in the operating room environment where only the indirect impact of organizational decisions are seen. Health care is quite different to other industries and trying to identify a rational explanation for interaction in human systems can be problematic and over reaching. Clinical work involves a level of complexity not encountered in stable closed systems where incident investigation heuristics such as the "Swiss

cheese model" originate [26, 31]. It is a constant challenge to resist the management imperative to produce normative incident investigation data about what happens in the operating room. A contrasting focus on the original concerns that guided local clinicians to initiate an inquiry into an adverse event will enable the development of measures that are the most meaningful and most likely to gain the trust of clinicians in the findings [26]. Incident investigation models that aim to develop insights about an adverse event that inform the local clinical operating system look at all aspects of human and technological interaction with the perioperative suite. Asking how local systems fit together and the nature of local constraints on perioperative care will provide a more dynamic and contextually sensitive approach to guiding incident investigation [26]. A systemic model of investigation shifts attention from what is already generally *known* to identifying what is *knowable* within the organization at the time of the event [27]. This is a hugely important distinction that is often lost on regulators.

The selection of an incident investigation model will inform how the organization chooses the types of incidents to be investigated, makes decisions about the process for engaging staff and providing feedback, and how to support the clinicians involved in the adverse event. It will also shape the type of information gathered from investigation reports. These factors are important in shaping the debriefing session format with local perioperative staff following the adverse event and its investigation. Questions should relate to a specific context where particular cues and patterns make sense and are recognizable [2, 26]. This approach will help guide future decision-making and judgments when faced with similar situations and also engender trust in present and future deliberations by management.

How to Run a Local Investigation

The decisions about the process and techniques for analyzing adverse events are best made at the local level where investigation teams reflect the workplace culture of the surgical center, its human resources, and the mix of perioperative activities [32]. Many health facilities and their surgical centers will have established structures for clinical governance and processes for the

Table 41.2 Triage questions and key decision points to consider when setting up an investigation that will facilitate and support the team process within the facility

Triage questions	Key decision making points
What is the political landscape for inquiry?	Evaluate the existing process for the investigation of adverse events, and the track record at the facility
Is the inquiry within the scope of your facility?	Select techniques from the available toolkit at the facility and for which there is local expertise and experience
Who will commission a team?	Establish a core group of experienced investigators/senior clinicians to appoint a team leader and the advise team
Who will lead the team?	Identify a senior clinician with clinical currency in the facility who is not involved in the event under review
Who needs to be on the team?	Appoint an investigation team with the requisite knowledge of the clinical area, balancing representation across disciplines and clinical specialties, from staff not involved in the event under review
Who is responsible and accountable for which actions during the investigation?	Determine the number of investigation team meetings required and the available time for each meeting Define the internal and external team reporting requirements, including who signs off on the final report Identify who will endorse the investigation team findings, allocate resources and support the implementation of the team recommendations across the organization Set a timeframe to evaluate the effectiveness and impact of any proposed changes to practice Organize debriefing sessions with different groups of staff at regular intervals to provide timely feedback

investigation of clinical adverse events. A particular method of inquiry (e.g., root cause analysis) is not prescribed here. Table 41.2 describes a commonplace approach (based on ref. [26]) that could be adapted as a triage tool for use in a range of settings to investigate different events:

Risk Assessment and Triage

Standard incident risk matrices rate an event in terms of the severity of injury to the patient and the likelihood of recurrence of the event type. There is a need for some level of triage beyond the risk assessment stage where experienced local senior clinicians not involved in the event determine what aspects of the situation warrant the most attention. The emphasis when making the decision is the knowledge of previous and current relevant challenges in the perioperative environment. In the trauma case above this was particularly relevant. The trauma physician at the facility had the foresight to convene an investigation team with the necessary senior expertise and experience to evaluate the trauma call system, the escalation process for medical review, the roles and responsibilities of the trauma team once the patient arrived in the operating room, and highlighted the importance of the trauma team leader in setting care priorities [33].

Framing the Investigation Process

The investigation needs to be flexible with the amount of time allocated tailored to the complexity of the event, recognizing if similar events have been investigated in the past. This may shorten the current inquiry. Key tasks include establishing a timeline or chronology, analyzing contributing factors to the event, and taking existing and related care delivery problems in the facility into account. It is not always possible to identify specific causal factors. The team needs to consider where the greatest benefit might be obtained in making recommendations. This was evident in the trauma case, where the trauma physician leading the investigation team had the foresight to recognize that there would be considerable benefit in having the senior clinicians on the investigation team interviewing local staff and reflecting with their peers on recent practices.

Asking Questions and Gathering Information

Beyond establishing a basic chronology of an event it is useful to identify what activities people were engaged in at the time of the event (see Table 41.3). It is essential to gather information directly from people involved in the event close to

Table 41.3 Asking key questions that help to analyze the constraints on normal operations at the time of the event helps to situate the actions of people in a specific and naturalistic context

Constraint	Questions to unfold everyday thinking
Expectations	What was the expected outcome of the clinical intervention or activity for the patient in the perioperative environment?
Professional standards	What were the normal parameters or standards that clinicians were expected to follow?
Expertise and experience	What were the reasonable limits on human performance at the time? Were people working outside of their usual roles?
Work environment	How did the people who were involved in the event identify cues and make sense of their work environment?
Protocols and procedures	Were there any obvious adaptations of the normative care protocols that were deemed necessary at the time?
Teamwork	Were people working independently or did the activity require some level of teamwork and cooperation?
Attention	Where did people focus their attention and what was pointedly ignored by people in the situation? What competing demands did people need to negotiate in order to participate in the activity?
Perception	What perception did people have of evolving changes in the immediate physical setting as the event unfolded?

the time of the event as this will increase the opportunity to capture the immediate perceptions of what happened and what operational constraints needed to be negotiated [26]. The delivery of perioperative care is increasingly complex and contingent on the interaction between multiple team members and departments that make many adjustments to routine everyday activity and continually adapt to less than optimal conditions in order to provide safe and quality care.

A more nuanced and tacit understanding of what the people involved were thinking at time can be obtained by asking them to retrace their actions while speaking out loud their assumptions and their perceptions of the situation as it developed [34]. This "think aloud" approach enables people to talk about things they usually would not verbalize (e.g., thoughts, feelings, reasoning, and expectations) [35]. Thinking out loud can provide useful information about how people interpret their environment and the constraints operating in the workplace at a specific point in time. Moreover, it situates events back into the messy flow of workplace activity [6].

Facilitating Team Meetings

The investigation team will need to consider how information will be shared in face-to-face meetings as well as online in a secure manner. Clinician demands need to be weighed carefully when determining where and how often the teams need to meet and for how long. The team meeting ideally will have a facilitator of the investigation process and a senior clinical team leader to guide the clinical conversation. The individual team members each bring their own set of experiences and levels of expertise to the investigation. Rather than the team engage in a retrospective flow charting process that is prone to hindsight bias due to knowledge of the outcome of the event, it is more productive for the investigation team to put the available information from people involved in the adverse event back into the context of the unfolding situation as it was experienced [6, 8, 26]. This approach directs the inquiry toward capturing the complexities and uncertainties of why actions made sense at the time of an event. Making assumptions based on a standardized checklist of trigger questions [9, 21] runs the risk of not allowing the team to capture the nuanced perceptions of people and the variety of valid perspectives that can be derived directly from contextual information about the unfolding unexpected situation [14].

Notably, during the trauma case, the senior clinicians on the team considered that the task of categorizing the relevant factors was the remit of the patient safety manager facilitating the process. The majority of the team conversation was dedicated to a detailed analysis of local systems and the development of insights based on comparison with the team's broad experience with similar problematic trauma presentations.

Identifying Contributing Factors

Consulting senior management at the facility early and often in the investigation process and developing a formative picture of what type of practical recommendations could realistically be implemented as an outcome of the investigation increases the likelihood that recommended changes will be taken seriously and implemented. Talking with management also reduces the risk that an adverse event might be investigated in isolation from other safety improvement activity in the department or across the hospital. If controls and corrective actions were put in place for a similar event, this is vital information for the investigation team. Arbitrary systems for deciding whether a risk is to be mitigated or removed are too disconnected from the complex and continually changing nature of the perioperative clinical setting. It is a false and dangerous assumption that risks in health care can be removed or errors completely prevented [29]. The nature of working in human systems is such that this level of predictability does not exist in a reliable form.

Recommendations that result from an incident investigation must be tested and trialed in the clinical setting [36]. This can be via formative feedback from the frontline clinicians or through simulation prior to implementation, depending

on the level of complexity of the activity [37]. Simulation is an incredibly useful and visual form of event analysis. Whether using desktop, task trainer or a high fidelity surgery simulator, it can highlight the breakdowns in human performance and errors in the use of technology during the event [38, 39]. The simulation helps ensure all members of the investigation team as well as management understands what actually occurred during the event and how the team performed [40].

The Investigation Report

The team report describes the process and outcomes of the event, contributing factors, recommendations, and strategies for implementation, with timeframes for review and evaluation. It should be acknowledged that the team's view is a limited perspective based on the *available* information at the time of the investigation [41]. A meeting to debrief and discuss the team's findings with local staff across discipline and department boundaries is the single most important step. In the example of the trauma case above, there was significant email conversation between clinicians about drafting recommendations outside of the scheduled team meetings. The investigation reporting process became a vehicle for the articulation of patterns and the identification of potential solutions to the issues raised by the discussion of the case. Constructing the investigation report provided the team with a medium for inter-professional dialogue and debate that did not previously exist in the perioperative culture of the facility.

Staff Debriefings

Translating investigation reports into meaningful actions is a challenging task. In fact, in our 35 years of combined experience in being part of over 400 adverse event investigations, the investigation process is largely disconnected from everyday clinical practice and thus imposes a huge administrative burden on individuals who have ongoing operational responsibility as well as investigating the process failures that led to the adverse event. Feedback following an investigation and the implementation of strategies to implement change is not well managed [5]. Providing ongoing feedback to staff in a completely transparent manner with an interest in the event at strategic points during the investigation and debriefing after the completion of the investigation is essential if the analysis is to penetrate the local clinical workplace culture and lead to entrusting future communications [15, 17, 42]. It is additionally important to evaluate the process followed by the investigation team and to measure how effective the recommendations made by the investigation team were in addressing the challenges related to the original situation. The debriefing needs to focus on the aspects of the problematic situation that warrant the most attention in order to reduce the interference of competing agendas. An adverse event will involve many potential problems that could potentially consume large amounts of time and resource. It is useful for debriefing sessions to look beyond the event and consider the patterns and trends from similar events within the context of the facility.

In the trauma case above, after the investigation was completed, members of the investigation team participated in an open interdepartmental Trauma Meeting where people involved in the adverse event and their clinical peers were able to make sense of the investigation team's findings through the debriefing process. The debriefing brought together in one room key people who were loosely connected with the case. If the larger feedback meeting had not been held, there was a risk that opinion and rumor would impede the impact of the investigation. The Trauma Meeting proved an effective forum to produce insight, synthesize bits of information, and conceptualize improvements in perioperative care delivery. Intelligently, the trauma physician had recognized that routine organizational networks were not able to resolve the workplace tensions related to the case due to the impact of a death in the operating room. A different mode of thinking was required that would be a "springboard into action" for the local clinicians [14]. The coordi-

nated response to the case piqued the interest of staff and helped to embed the Trauma Meeting as a respected clinical forum. Attention to how staff conceived the adverse event in the perioperative setting in retrospect was a key feature of the coordinated response to the case.

Reflection on the outcomes of incident investigation requires careful handling and this applies directly to the way the investigation report and its recommendations are disseminated and shared in the local clinical environment. The report needs to be seen as part of an ongoing process of making sense of clinical work and not a fixed definitive statement. Socializing the report (and the ongoing place of the adverse event in the local workplace culture) is a collective thinking task that requires a coordinated response, with due regard for differing standpoints, acknowledgement of hindsight biases, recognition of familiar cues, an emphasis on plausible explanation rather than root causes, and provision for people to adjust to the impact and changes that result from the investigation [6, 14].

How to Interpret an Investigation Report

The nature of an investigation report will depend to a large extent on the selection of methods and techniques for the investigation of an adverse event and the leadership style of the person in charge of the investigation [41]. Regardless of the particular method of inquiry chosen, the investigation report should contain deductions from the known facts about the event and a set of proposed recommendations or corrective actions that address the problematic situation surrounding the adverse event in a particular time and place. It is important to note how the experience and expertise of the investigation team is positioned relative to the perioperative workplace. The stance adopted by the investigation team, its demeanor and credibility, and the selection of methods of inquiry directly shape the strength of the statements made in the report and the range of possible conclusions that readers of the report can make as they interpret the report.

The analysis conducted by the investigation team usually consists of a combination of propositions about characteristics of the event based on standardized language contained in checklists of human factors categories [9]. Interpretation is drawn from what is knowable about the event and the report should provide a reader with a clear picture of what was happening at the time of the adverse event. The investigation team report goes beyond the experience of people involved in the event and includes statements drawn from the collective knowledge of the team, use of electronic medical records about similar events in the perioperative setting, as well as global experience with similar events. This is the process of understanding at work. Investigation teams are not able to present an objective interpretation, as both authors and readers of an investigation report, bring with them subjective perspectives based on their own experiences and understanding of the clinical workplace [30]. However, if the characteristics of the event described in the report are not recognizable the readers are likely to dismiss the report as unrepresentative of the event as experienced or a simple white wash of the events by management [43].

What Is in a Name?

It is appropriate to mention the role of the word "event" at this point in understanding the investigation report process. A word like "event" is an approximation of something that has happened in the clinical setting for the purpose of making it knowable [6, 18]. The adverse event described by the investigation team is not the same as the experience of that event by the people involved. While this may seem self-evident it is an important distinction about the process of interpretation. Clinical operations in the perioperative environment are a dynamic ongoing activity. When an investigation report speaks of an event it represents a moment in time when something changed [6]. An event does not come packaged as an organic whole. The beginning and end of the event described in the investigation report chronology is a convenience. Put simply, the

investigation team sets up the conditions for interpretation. If it is not made clear to the readers of the report that the event is an approximation of what happened, the risk is run that people will feel that what they personally know has been left out of the picture or erroneously modified.

The reporting process, therefore, is concerned with making the adverse event knowable. There is considerable potential for the investigation report to be interfered with by distracting factors and the final version may be altered due to the introduction of different perspectives to those captured by the investigation team [41]. Unwittingly, clinical leaders, senior management and health facility administrators may impede the interpretation of the event due to their concerns about the wider implications within the organization and beyond if and when the report is shared with external stakeholders. The investigation report is not intended to cover all related clinical situations and possibilities. The investigation team report deals with a specific problematic situation in a particular perioperative workplace setting such as an operating room at the time of the event. It is important to clarify that the investigation report must be understood within these parameters.

The testing of what is recommended in the investigation report will follow. It is important that senior management can make decisions about what changes to implement based on a clear picture of what was knowable from the event based on the characteristics of what was happening at the time of the adverse event [26]. The description of the event in the investigation report provides a structure or framework for interpretation by different audiences. The report needs to contain information that will enable readers to construct a meaningful picture of the event that relates to the reality of everyday experience [14].

Care must be taken when reducing an event to essential or abstract terms in an investigation report (e.g., human factors categories, incident classification systems, and risk management controls). The selection of investigation methods directly impacts the way a report is written and interpreted [18]. The guiding principle when reading a report should be determining local operational utility more than satisfying the demands of external administrative control [44]. The investigation report is a vital part of the process by which local staff in the perioperative suite deal with the experiences and outcomes of an adverse event. A report needs to be written in an accessible form in order for different readers to find ways to discriminate what they know from the knowledge gathered by the investigation team. It may be helpful to consider three types of report formats: a one page executive summary, a three page summary, and a more detailed report with all the key investigation findings. The report is not a final statement but a transition document that identifies the problems that require ongoing attention in the perioperative setting. Report findings are more likely to be made known when they relate to how the perioperative workplace is experienced.

New knowledge about an event takes on meaning when it is considered in the context of the familiar circumstances and conditions in the local environment where problems are experienced and managed. Finding points of identification with the report will enable resolution of the issues raised by the adverse event. People with local knowledge need to come together and talk often several times about the report in order to make progress beyond the approximations of the investigation team. This is rather different from essential explanations that reduce an adverse event to an allocation of root causes. What moves an event forward is when a cogent narrative is conceived in terms of a specific perioperative setting where new knowledge about the operational problems can be differentiated from existing knowledge and corrective steps can be implemented [41].

Engaging Staff in Learning Through Feedback and Debriefing

Studies of investigation reports and the implementation of investigation team findings following surgical adverse events commonly report that the team has “no power to enforce any recommendation or ensure compliance” and that learning is limited to the clinical unit involved in the event

[45, 46]. Publishing aggregated RCA data may improve the dissemination of knowledge, but it does not follow that this is an effective strategy to engage staff in meaningful learning at the level of the perioperative suite in individual facilities [47]. Despite a sustained response in the literature to the category of "wrong surgery" and the implementation of checklists and time-out protocols by surgical teams, meta-analyses of RCA reports are limited to confirming that incorrect surgeries continue to occur at a rate not much dissimilar to before checklists were required [48]. Aggregating data from multiple RCA reports does not make the clinical workplace environment more predictable; rather it creates a false impression of an ordered world waiting for its causal links to be identified [6]. The reality is that adverse events take place within a flow of dynamic activity not isolated in discrete and context-free repeatable actions. The meta-analysis of wrong surgery events suggests that "errors upstream and downstream" to the implementation of universal checking protocols in the perioperative suite require attention [48, 49]. However, what might be happening upstream in one perioperative setting may well be rather different to other surgical departments. Activity downstream today in a given facility may be due to rather contrary factors tomorrow.

The metaphor of the stream of activity is a step in the right direction [6]. However, to effectively engage staff in making sense of adverse events in the continuous flow of clinical experience, a strategy for workplace learning is required that can be tailored to the dynamic conditions of local clinical culture [15]. This process is important for making sense of investigation team findings in everyday operations [10, 11].

Building an Adaptive Workplace Culture

There are activities that can augment or even replace the need for an incident investigation by focusing attention on the analysis of the clinical workplace. Considerable attention has been given to near miss reporting and clinical risk assessment in health care over the last decade [50]. Incident management systems and adverse event investigations work hand-in-hand. However, despite improvements in reporting and data collection, progress with changes in the reliability of clinical operations as an outcome of adverse event investigations has been less convincing in the literature [51]. This is because reliability is a local dynamic property within clinical microsystems (i.e., in this case, the perioperative setting) and not a stable property of the health system [52]. Tools and techniques that test the reliability of local clinical systems and the efficacy of local system design provide a useful adjunct to incident investigation. Indeed, they may be integral to the testing and evaluation of recommendations arising from adverse event investigation reports.

Applying Probabilistic Risk Assessment (PRA)

The national and international professional standards for the regulation of perioperative environments provide a useful guide to the boundaries of safe operation in the operation room. In contrast to perioperative risk assessment with a clear focus on the patient and procedural risk for different patient groups, PRA is concerned with assessing and evaluating the safety of the operating room environment [53]. Adverse event investigation identifies problems in the current system and regulatory standards indicate optimal operating room practices. In anesthesiology in particular there are checking procedures for multiple items of equipment and the related processes. It is routine to run safety drills and simulations to identify how best to recover from conditions that threaten patient safety in the operating room. Individual investigations of adverse events include some level of commentary on the chronology of actions, or sequence of events that were precursors to the event. Identifying these factors can help inform where redundancies need to be built into clinical practices to promote surgical safety [54]. In the root cause analysis methodology, for example, this is referred to as

barriers and controls. In order to determine which interventions are critical for perioperative safety, a process such as probabilistic risk assessment (PRA) can be applied to measure specific thresholds of safe operating practice within the boundaries of the relevant professional standards [45]. Considerable attention to safety in the surgical environment has identified a need to balance effective utilization of perioperative resources and operating room time with strategies and techniques to reduce risk and promote patient safety. An adverse event investigation can highlight areas needing attention in the current design of operational systems, the configuration of equipment, or the physical layout of the perioperative space. In determining priorities, a PRA will provide an estimation (based on current operations) of the safety measures that reduce the frequency and likelihood of future adverse events at different levels of utilization for the particular operation, operating room and the dedicated surgical procedures within a perioperative facility.

The limitation of PRA is that it is less able to predict future risks that may produce unexpected events and the uncertainties that a change in procedures may introduce [55]. Maintaining real time activity within the perioperative setting within the boundaries of safe practice is mostly dependent on clinician expertise and experience in observation and interpretation of the available information on a given day. Local adverse event data, however, can be used to inform ongoing risk assessment. PRA when used in combination with and adverse event investigation report provides information about problem identification and resolution within the boundaries of safe operation [24]. Clinicians and managers must make the decisions about how the investment in resources, changes to operating room schedules, and introduction of new procedures will impact current levels of system safety in the perioperative suite. One method available to determine the duration of a cases or how changes already under way might impact current safety is through Bayesian analysis. Bayesian analysis refers to the use of previous observations and current information to help determine future events [56].

Applying Failure Modes and Effects Analysis (FMEA)

FMEA is a useful tool to analyze workflows through the perioperative suite following an adverse event. An investigation may identify that an aspect of operations within the perioperative suite is not performing as intended. Investigation teams can also use FMEA to develop and evaluate recommendations for corrective action in a final report. The analysis of the failure modes and effects involves identifying the elements and their sequence in the procedure under review, the conditions that could result in failure at each step, the effects of each failure on the performance of the procedure, the likelihood that the failure could occur under local conditions, the impact of the failure on patient safety, and, what remedial action could reduce the risk of failure [27, 57].

Measurable activities in the perioperative setting include standardized processes with multiple steps performed in sequence. As an adjunct to an adverse event investigation it useful to break a procedure or protocol into separate steps using a process mapping methodology, and consider the stages where something unexpected happened or there is potential for the sequence to break down. Rather than look at the prevailing conditions in the perioperative suite, the FMEA looks specifically at human interaction with technology or equipment and the potential for procedural failure at a systems level [27].

An example of an adverse event where the consequences of a procedural failure needed to be mapped out involved a patient who had a spinal fusion performed at the incorrect level [58]. The local neurosurgical practice for sighting and marking of spinal levels was a contributing factor to the adverse event. FMEA identified that the timing of access to radiological images was critical as was the ability of the members of the surgical team to visualize and confirm the spinal level with the radiology team. A key finding was that the position of the surgeon relative to the patient and the position of the assisting surgeon on the opposite side of the operating table could give the perception of different spinal levels depending

on the viewing angle. Visualization of the radiological image was not always completed at the same time by each surgeon due to movement within the operating room relative to the position of the viewing box. In the adverse event, this was compounded by the fact that the two surgeons did not provide clear verbal confirmation to each other or to others on the team in the room about the spinal level. An experienced neurosurgeon not involved in the adverse event used the information available to the investigation team to analyze the practice for spinal marking at the facility and developed specific insights to reduce the chances of similar events. The high probability of recurrence suggested by the FMEA led to a change in the local procedure whereby both surgeons had to provide clear verbal confirmation citing specific anatomical markers and read-back their interpretation of the radiology image to the entire OR team. The agreed position was recorded by a third person prior to the marking of the spinal level for the surgery. Before the investigation, the neurosurgeons at the facility had varying individual practice for sighting and marking spinal levels. The FMEA provided an opportunity to develop a consistent and reliable practice.

Looking Beyond the Investigation Phase

Following the incident investigation there is the interpretation phase. Different groups will interpret the findings of an investigation team, and therefore, there is a need to create opportunities for making sense of the event back in the clinical setting of the perioperative workplace [6, 14]. Adverse events have a context around which various arguments are constructed and perceptions are shaped by different groups of people. The discussion of a particular event must become sensitive to operations in the local clinical setting, taking into account the impact of the relative distance of the event in time and space. The treatment of individual adverse events in terms of how they are experienced by different groups facilitates discrimination of what is relevant from a range of possible explanations (that might apply to other perioperative settings). The retrospectively constructed chronology of an adverse event needs to make sense in terms of everyday operations, as they are currently experienced, not at some imagined point in the past. When it comes to interpretation, it is important to acknowledge that all arguments about adverse events cannot be separated from the current experience of the clinicians doing the interpreting. The determination of the beginning and end of an adverse event is constructed through the process of an adverse event investigation, as it is easier for the investigation team to deal with a finite bounded set of circumstances. How an event is then put back into the continuous flow of perioperative activity is a separate but crucial task to the actual investigation [6].

An adverse event is but one moment in the continuous flow of activity in the perioperative setting. This flow of action is essentially local, making it necessary that the event be examined and interpreted via a range of thinking processes that enable the construction of a composite picture that can be translated by local clinicians and managers into everyday operations where there are ongoing interrelated problems in motion that relate to and continue to inform the interpretation of the adverse event and the resolution of problems raised at different levels of operations within the perioperative clinical micro-system [7]. The various processes recommended that might help to manage what might be distorted or limited in defining and discussing the event from the particular preferred perspectives of dominant clinicians in the clinical workplace culture.

Translate Insights into Everyday Operations

Translating knowledge involves more than the formal feedback of the findings by the investigation team in the form of a report. What is involved, in *knowing* even what the investigation team discovered, is more than what is now known about the adverse event, there is also the *knowledge* that each discipline and practitioners of differing levels of expertise seek and how various people

make sense of the event according to their particular set of relations within the perioperative setting [25]. It is important to acknowledge *who wants to know* about an adverse event, how it has impacted different people psychologically, and what variations on the story have accumulated in the workplace about the event. Translation, in contrast to unilateral forms of feedback following an adverse event, seeks to integrate and take into consideration these various perspectives [25]. The everyday operations at the local perioperative workplace are the basic setting for translating event analysis into different levels of organizational knowledge. It is the place where the explanation for an adverse event is grounded and the process of sense making is translated into genuine insights.

This does not mean that inquiry is reduced to the level of opinion. Rather, in selecting appropriate methods, the subjective is viewed as guiding the human factors analysis. The selection of an appropriate means whereby an investigation team's findings can be translated into the functioning of the local workplace should be supplied. The process of translation involves activities such as simulating and testing knowledge and skills, analyzing the components of a task, reviewing communication channels, and evaluating resource constraints and utilization [25]. Suitable methods for the translation of the investigation team findings include but are not limited to process mapping [7], common cause analysis [59], implementation mapping [60], probabilistic risk assessment (PRA) and failure modes effect analysis (FMEA) as discussed previously. These devices need not be applied in isolation from everyday activity, but facilitate ongoing discussion and meaning construction. The analysis of any adverse event should not be viewed in isolation from the particular nuances of the workplace environment and the people who do the perioperative work. The findings of the investigation team are basic working hypotheses or approximations that require testing in real situations where they can be made meaningful to the people who use the workplace.

Actively Explore the Problematic Situation with the People Involved

Formal feedback following an adverse event investigation is often limited to summary statements of the investigative team's findings and recommendations. This is not adequate for frontline clinicians and risks undermining the credibility of the investigative team on this and future investigations. The outcome of the team's event analysis and the proposed solutions to the original problematic situation need to make sense in relation to what is already *known* about the perioperative setting, for the different groups of people who *want to know* about the adverse event, incorporating the current state of *knowledge* about the variety of actions and human factors the investigation team identified as pertinent to the adverse event under review (outlined in Table 41.4).

Safe practice and adverse events exist on a continuum and learning comes from seeing the tension between interruptions to normal perioperative activity and routine activity in the same organizational space [18]. In order to extract the most value from the investigation of an adverse event the local managers and clinicians need to step back and look at the event in the wider context of the continuous flow of perioperative activity while constantly evaluating the impact of the proposed policy or service interventions [61].

Test Alternative Actions and Hypotheses in the Perioperative Setting

How do the various recommendations made by the investigation team fit together? The dynamic nature of activity in the perioperative setting needs to be taken into consideration when evaluating the applicability of the investigation team's recommendations. The formalized standard language of investigation techniques such as RCA (e.g., mitigating actions and quantifiable outcome measures) can give an impression that the recommended actions that result from the investigation

Table 41.4 The problems that investigation teams identify bring the (human) factors related to different types of knowledge together around a variety of human actions

Types of knowledge	Variety of human actions
The experiences of individual people involved in the adverse event	What is pertinent to the perioperative setting that was not evident prior to the interpretation of the adverse event? And conversely, what aspects of the event are relevant to prior experience in the local workplace? What do people pay attention to and what do they ignore?
The habits and routines of the organization	In some accident models these problems are referred to as "latent" or "system" level issues. Activity in the clinical workplace is determined by local systems as defined by the particular perspectives of people working at the time
User perspectives on technology and work	Techniques such as PRA and FMEA can assist in identifying local definitions and perceptions of human–machine interfaces in particular situations and practices. Simulation and thinking aloud can be very useful here in stepping through the use of technology by the people involved in the event, and any proposed changes to the application of technology following the investigation
The varying bodies of knowledge among the clinical disciplines	A clinical workplace problem concerns not only interdisciplinary and intradisciplinary communication about clinical work but the beliefs and practices at different levels of expertise within each clinical discipline

are stable and reliable and ready to be implemented [9]. This could not be further from the truth. The recommendations presented in an investigation team report are vulnerable to many distortions and intrusions and as such require careful interpretation before being considered for implementation [41]. It is well reported that recommendations from RCA investigations have an uneven record of effective implementation [5, 46, 62, 63]. This may in part be due to a lack of processes to test the viability and feasibility of proposed changes to action in the clinical workplace. The different groups that constitute the perioperative workforce have varied levels and awareness of knowing about surgical work and its processes, and differing experiences of working in the perioperative setting (e.g., the perspective of the surgeon will vary to that of the circulating nurse on the team in the same operating theater on a given day).

The recommendations made in the investigation report need to be tested with surgical teams at different levels engaged in everyday workplace activity, or simulations of that activity where real time testing would either be unethical or not feasible [37]. The perspectives of all perioperative team members on the surgical processes are needed in order to facilitate practical testing. Well-designed team based simulations enable the necessary actions that underpin any surgical situation to be better understood and respected. Knowing how normal work is done will make the interventions of the investigation team less arbitrary and more trustworthy.

Develop Effective Strategies for Insight into Local Systems

The investigation team's stable recommendations need to be distinguished from the ambiguity of everyday operations in the perioperative setting. The distinction involves identifying the differing frames of reference that are an integral part of working relations and the arguments people express in support of certain recommendations over other changes proposed by the investigation team. There is no objective stance apart from the world of experience. Experiences bring together those who want to know and what is known about an adverse event. The insights that are produced as a result of an investigation process make sense to people as the new knowledge enters into circulation within the workplace [25].

Statements about zero tolerance for error in health care and preventing harm are at best wishful thinking and at worst create cynicism, anger, distrust and contribute to clinician burnout (Compare [29] with [64]). Turning error management into a bureaucratic activity stifles local attempts to take risks and develop insights [16]. For example, it is common to label the causes of adverse events as

STABLE SYSTEM	SYSTEM INSIGHT	SYSTEM FAILURE
Perioperative suite schedule	Unsheduled surgery	No operating room available
Formal Communications	Corridor Conversations	Missed Communications
Aggregated Event Data	Unexpected clinical events	Adverse Events
Policy, Protocols & Procedures	Drills & Simulations	Unsafe practice
Safety & Quality Activities	Real time adaptations	Human errors

Fig. 41.2 The desire to pursue system stability is compelling in health care organizations (*arrow* #1). What can be known about the perioperative suite exists on a continuum between stable predictions about the system on the left and significant breakdowns in the system on the right

"communication failure," but this practice simply generates another cycle of event classification rather than exploring the systemic vulnerabilities in the local clinical context [19, 65]. Likewise, and importantly for the present discussion, adverse event investigations are a quality and safety activity and *a product of system stability* that often constitute the immediate response to *system failures* (Fig. 41.2). In contrast to the stable activities produced by the left hand side of the diagram, rich information about perioperative communication pathways generated through everyday clinical work provides an opportunity for robust local discussion and interpretation (middle column of the diagram). Real insight comes from exploring ambiguous and novel situations (arrow #2). Unlocking *system insight* involves building a local workplace culture for learning from experiences in a supportive environment where clinicians and managers feel safe to experiment with new ways of doing things [3, 15, 66]. Developing system insight is an ongoing process of negotiation. Articulating what needs to be done in the aftermath of an adverse event in organizations with a healthy workplace culture is recognizable by the level of participation in negotiation, discussion and learning about the work [67].

Progress in perioperative system safety will largely come from strategies to better understand how people and processes operate when they are in the middle zone of the diagram. Paradoxically, this involves turning attention away from formal quality and safety activities (e.g., retrospective investigations that produce hypothetical recommendations to reduce errors) and looking at what people *actually do* to recover from a breakdown in care delivery (by strengthening informal opportunities for local conversations about perioperative team experiences using qualitative methods such as interviews, focus groups, observations and more) [68]. Both systems are necessary but they require different approaches, in order to continue general strategies that reduce errors and to also develop strategies that enable local system insights to be brought to light [3]. These systems help to create resilience that allows people to conduct hundreds of operations a week with few to no adverse events.

The evaluations of incident investigation processes such as RCA consistently identify that health care organizations need to prioritize time and offer some productivity slack for clinicians and managers to reflect on their learning, share information and insights about everyday care delivery problems [5, 31, 46, 63]. Existing review meetings within the perioperative workplace environment could profitably be redesigned to meet regularly to explore and discuss the lessons learned and patterns identified from incident investigations. A single incident investigation is simply not adequate to capture the insights that a complex problematic situation entails. Shifting the emphasis from stable system processes to thinking about the ambiguous and unexpected opens the team up to a variety of responses and sets up the conditions for mindfulness in the local perioperative workplace culture [15].

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42 Multi-institutional Learning and Collaboration to Improve Quality and Safety

Julie K. Johnson, Christina A. Minami, Allison R. Dahlke, and Karl Y. Bilimoria

"If you want to go fast, go alone. If you want to go far, go together."

—African Proverb

Introduction

A quality improvement collaborative (QIC) is a broad-based approach to identifying and adopting best practices and implementing rapid organizational change [1, 2]. The term is now commonly used to describe different multifaceted interventions that focus on accelerating better outcomes for a targeted topic [2] and, while focused in a number of areas, are understood to use similar methods for clinician engagement as well as a relentless focus on continuous quality improvement.

Clinical outcomes attributed to QICs include reduced inpatient mortality rates associated with coronary artery bypass graft procedures, decreased neonatal infection rates, decreased C-section rates, less costly prescription practices, improved patient safety, decreased emergency department waiting times, and improved management of people with chronic illness [3]. Along with reports of measurable success, several authors question whether the QIC model is an effective mechanism for improving patient care [4]. Others argue that the methods of evaluation are lacking and have failed to capture the unique complexity of improving care in complex organizational settings [5].

This chapter outlines the history of quality improvement collaboratives and describes the role of the collaborative model in improving surgical quality of care. We discuss core structural components of a collaborative and research identifying key success factors. Finally we consider the challenges in evaluating the effectiveness of a collaborative. Research on teamwork, leadership, and communities of practice can inform the development of future collaboratives.

History of the Quality Improvement Collaborative

A quality improvement collaborative is simply defined as multidisciplinary teams from various health care departments or organizations that join forces for a period of time to work in an agreed upon structured way to improve care or a defined population of patients [4, 6]. In essence a quality improvement collaborative acts as a "temporary learning organization" [7] with the goal of sharing and spreading of ideas.

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In his work on social learning systems, Wenger recognized the potential power of "communities of practice" within and across organizations that resulted in not only the sharing of information but also the generation of information through their interactions. A community of practice is "a group of people who share a concern, a set of problems or a passion about a particular topic, and who deepen their understanding and knowledge of this area by interacting on an ongoing basis." [8]. Communities of practice are characterized by the domain (an identity defined by shared interest, commitment, and shared competence), the community (joint activities and discussions to help members of the community and to share information), and the practice (the shared repertoire of resources, experiences, stories, and tools). The combination of these three elements, as well as the development of these elements in parallel, creates the community of practice.

According to Wenger and colleagues, a community of practice can be distinguished from formal departments and project teams along the following five dimensions [8]:

1. Purpose: to create, expand, and exchange knowledge, and to develop individual capabilities;
2. Membership: self-selection based on expertise or passion for the topic;
3. Boundaries: Communities of practice have fuzzy boundaries (in contrast to a business or organization with distinct boundaries);
4. What holds them together: passion, commitment, and identification with the group and its expertise; and,
5. Life cycle: communities of practice evolve and end organically; they last as long as there is relevance to the topic and interest in learning together.

A community of practice is an umbrella term for a number of different organizational groupings that are characterized by the support for formal and informal interaction between novices and experts, the emphasis on learning and sharing knowledge, and the investment to foster a sense of belonging among members [9]. Wenger suggests seven principles for cultivating a community of practice which are relevant for QIC: (1) design for evolution, (2) open a dialogue between inside and outside perspectives, (3) invite different levels of participation, (4) develop both public and private community spaces, (5) focus on value, (6) combine familiarity and excitement, and (7) create a rhythm for the community [8].

Thus, a QIC is a community of practice. Introduced initially in the USA in the mid-1980s, QICs are now used in many countries with varying health care financing systems, including Canada, Australia, and European countries, where several national health authorities support nationwide quality improvement programs based on this strategy. A similar approach has been used in the UK through its National Health Service Modernization Agency; it is call the Beacon Model and focuses on transfer of best practices, derived from Beacon organizations "that have achieved a high standard of service delivery and are regarded as centers of best practice" [6].

The earliest well-documented QICs are those of the Northern New England Cardiovascular Disease Study Group, established in 1986, and the Vermont Oxford Network, established in 1988. Another well-known approach is the Breakthrough Series developed by the Institute of Healthcare Improvement in 1995 [10]. Participants share a commitment to making small, rapid tests of change that can be expanded to produce breakthrough results in a specific clinical or operational area [11]. There is evidence of effectiveness in improving targeted topics [10] together with evidence of positive spill-over effects on participating teams in other areas of care and enthusiasm for improvement [12, 13].

Improving Surgical Quality via the Collaborative Model

QICs have become particularly prevalent in surgical care, especially at the state-level [14–17].

Michigan Perioperative Transformation Network, Tennessee Surgical Quality Collaborative, Washington State's Surgical Care and Outcomes Assessment Program, and the Illinois Surgical

Quality Improvement Collaborative are described in the following paragraphs.

The Michigan Perioperative Transformation Network (MPTN) is unique in that it is a collection of collaboratives. It includes the Michigan Surgical Quality Collaborative (MSQC), which focuses on improving surgical quality, the Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE), which incorporates anesthesiology to improve perioperative care as a whole, and the Michigan Value Collaborative, which seeks to optimize the cost-efficiency of surgical episodes. As one of the "value partnerships" that Blue Cross Blue Shield of Michigan created with physicians, organizations, and hospitals in order to accelerate quality improvement, MSQC was one of the first surgical quality collaboratives in the nation and exemplifies a successful partnership between payer and hospitals. MPTN emphasizes (1) culture change, (2) data sharing, and (3) best practice implementation. Culture change is addressed at quarterly meetings, where performance, data assessment, and implementation of best practices are discussed. Data sharing not only includes a focus on driving change guided by hospital-specific reports, but also includes sharing information regarding collaborative learning and details specific to hospitals' areas of exceptional performance. Best practices are identified from high-performing hospitals from the collaborative registry and shared after being modified for local contexts. For instance, one hospital that had markedly low blood transfusion rates, shared their protocol, which was then modified and adopted by the network hospitals. This resulted in a collaborative-wide 22 % drop in perioperative transfusions [18].

The Tennessee Surgical Quality Collaborative (TSQC) was established in 2008 and, similar to MSQC, was born of a partnership between Blue Cross Blue Shield of Tennessee and local hospitals. In addition, the collaborative was supported by the Tennessee chapter of the American College of Surgeons (ACS) and the Tennessee Hospital Association. The Tennessee collaborative emphasizes data-driven change and TSQC was the first known collaborative to use their data to do surgeon specific reporting. A central website, managed by the Tennessee Center for Patient Safety, allows data to be shared between all participating hospitals. In turn, lessons in applying this data to quality improvement efforts are shared at in-person meetings. Because the Tennessee ACS chapter was heavily involved in the initiation of the collaborative, there was a preexisting camaraderie between the participating surgeons that facilitated open discussions regarding surgical quality early in the collaborative. Since the inception of the collaborative, post-operative complication rates have markedly declined throughout participating hospitals: postoperative acute renal failure has been reduced by 25 % and surgical site infection by 19 % [18].

Washington state's Surgical Care and Outcomes Program (SCOAP) was started in 2005 after significant variability in surgical outcomes were noted by the University of Washington's Surgical Outcomes Research Center. Funded in part by a grant from Washington state's Life Science Discover Fund, SCOAP is also supported by hospital-paid subscription fees. With 50 participating hospitals, SCOAP is a large state-collaborative that has, like Tennessee, leveraged the state chapter of the ACS to enhance participation and support. SCOAP generates quarterly risk-adjusted hospital-specific data and creates a community that shares best practices in a transparent fashion. This collaborative has notably achieved broad adoption of collaborative-wide instruments; a modified surgical checklist, which included process metrics on which Washington was underperforming (e.g., glycemic control in diabetic patients), and a checklist initiative to reduce preoperative risk (known as Strong for Surgery), have been successfully deployed in recent years [18].

The newcomer to the field of surgical collaboratives is The Illinois Surgical Quality Improvement Collaborative (ISQIC) which was developed in late 2014. ISQIC is a payer-funded initiative and includes 57 diverse Illinois hospitals that agreed to adopt the widely recognized American College of Surgeon's National Surgical Quality Improvement Program (ACS NSQIP) as

the common data sharing platform. In addition, ISQIC includes 21 components to facilitate quality improvement that target the hospital, the surgical QI team, and the perioperative microsystem. The components were developed from available evidence, a detailed needs assessment of the hospitals, reviewing experiences from prior surgical and nonsurgical QICs, and interviews with quality improvement (QI) experts. The components comprise five domains: guided implementation (e.g., mentors, coaches, statewide QI projects), education (e.g., process improvement curriculum), hospital- and surgeon-level comparative performance reports (e.g., process, outcomes, costs), networking (e.g., forums to share QI experiences and best practices), and funding (e.g., for the overall program, pilot grants, and bonus payments for improvement) [19–22].

Figure 42.1 illustrates the conceptual model that we developed to guide the implementation and evaluation of ISQIC. The overarching influence of the collaborative (purple) is depicted as operating on the Hospital, Surgical QI Team, and Perioperative Microsystem levels of surgical QI [23].

The Nuts and Bolts of a Quality Improvement Collaborative

The common characteristics of QI Collaboratives have been well described [2, 10] and emphasize collaborative learning, support, and exchange of insights among different health care organizations [11]. Ayers and colleagues identified guidelines for developing a successful learning collaborative, based on qualitative interviews with key informants from ten established learning collaboratives [1]. Table 42.1 outlines their findings which could be used as structural guidelines for developing a successful learning collaborative.

In the simplest terms, the ultimate goal of a collaborative is learning. Beyond the structural components outlined in Table 42.1, Gauthier [24] suggests several conditions for successful collaborative learning across organizational boundaries:

- Participants should have similar maturity level on the learning continuum (e.g., with some experience of quality improvement techniques and vision building);

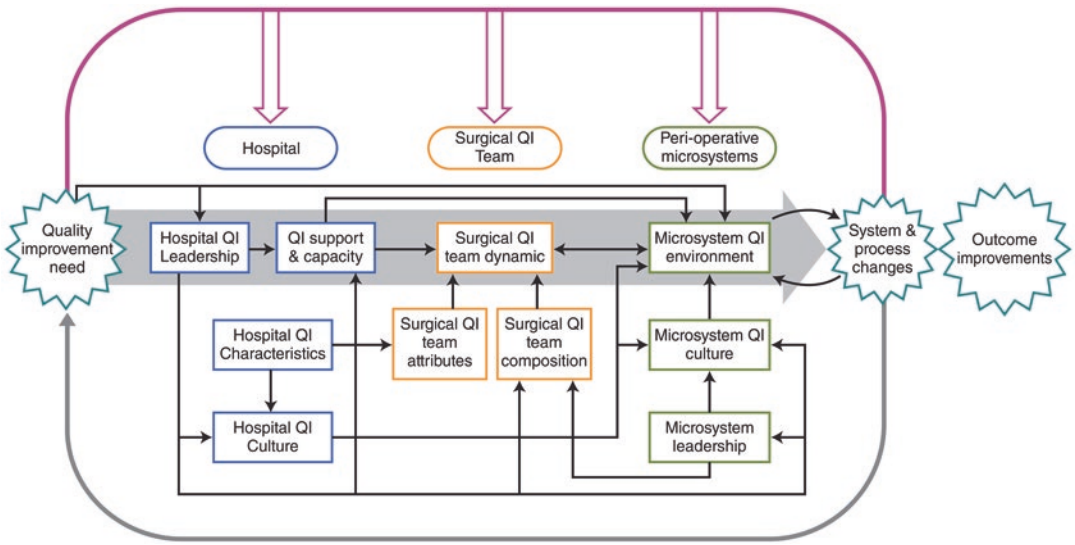

Fig. 42.1 ISQIC conceptual model

- Senior executives and line managers need to commit to a multiyear program and to involve themselves personally in the learning sessions;
- Participants agree to a noncompetitive environment to create a safe setting for sharing all relevant experiences;
- A core team of facilitators combining general and specialized skills should be involved in and between the meetings to help structure a cumulative learning experience and increasingly involve the participants in designing and co-leading the sessions;
- There must be a willingness to experiment in content and format from session to session, and a commitment to dialogue and collaboration;
- Participants should be encouraged to take time for exchanges between the learning sessions (social networking, site visits, etc.)
- A focus on personal development and on challenging one's mental models should be adopted from the beginning and sustained throughout the multiyear program.

Similarly, [25] describes four general categories of collaborative success factors: topics chosen for improvement, participant and team characteristics, skills of facilitator and expert advisors, and ensuring ways to maximize spread of ideas. Greenhalgh et al. elaborate that these success factors result from:

1. Clearly focused important topics that address clear gaps between current and best practice.
2. Highly motivated participants who clearly understand individual and corporate goals in a supportive organizational culture.
3. Effective teams and team leadership whose goals are in alignment with those of the organization.
4. Facilitation by credible expert, who provide adequate support outside as well as through the learning events.
5. Maximizing the spread of ideas through networking between teams and other mechanisms ([6], p. 167).

Once the collaborative is established, there is a general process of that guides the flow of collaborative work in which participants agree to work together over a number of months to share ideas and knowledge. They set specific goals and measure progress toward meeting those goals. Through facilitated sessions, participants share techniques for creating organizational change and implementing rapid-cycle, iterative tests of change at the microsystem level [6, 26].

The functioning of a QIC can be tied to an effective team structure and strong leadership. For example, in describing the successful application of a QIC using the IHI Breakthrough series in 40 US hospitals to reduce adverse drug events Leape et al. (2000) identified strong leadership and team work among their most important success factors: "Success in making significant changes was associated with strong leadership, effective processes and appropriate choice of intervention. Successful teams were able to define, clearly state and relentlessly pursue their aims, and then chose practical interventions and moved early into changing a process" [27]. As the leader of the collaborative team, the Champion has a unique role in the QIC. Champions persistently support new ideas; and have persistence to fight both resistance and/or indifference to promote the acceptance of a new idea or to achieve project goals [6]. A different type of leader—the boundary spanner—have influence across organizational and other boundaries, acting as bridges to connect people and ideas [6, 28].

Evaluation

Intuitively, the collaborative model seems to be an effective way to learn and engage front line clinicians in designing and implementing change. What's the catch? Mainly, creating and running a collaborative is expensive and difficult to measure using traditional epidemiological methods. Mittman and others note that QICs are arguably the most important response yet to the health "quality chasm," and call for rigorous mixed-method evaluation to identify factors which determine their success [29].

The evaluation of QI collaboratives poses substantial challenges given the multitude of changes occurring simultaneously and the existence of

Table 42.1 Key components of a successful learning collaborative

Component	Description
Mission and target population	Clear and achievable mission Tangible goals
Membership	Strategies for membership (application, invitation, etc.)
Defined roles	• Clinical Leader or "Champion" (e.g., knowledgeable of improvement processes, ability to integrate spirit of collaborative learning with everyday practice, willingness to share) • Project Manager (e.g., coordinates communication, organizes and facilitates meetings, project expertise) • Data Analyst (e.g., transforms data into useful information)
Technology	Develop data management and communication systems across member organizations to enable collection, aggregation, and analysis of the data
Funding	Identify and select sources (e.g., membership dues, private organizations, research institutions)
Governance	Establish multidisciplinary decision-making body to guide Collaborative process
Contractual issues	Establish and articulate policies addressing confidentiality, data ownership by organization submitting data, publication/presentation process and rights, and participant responsibilities
Meetings	Convene regular, formal face-to-face meetings

Modified from Ayers LR, Beyea SC, Godfrey MM, Harper DC, Nelson EC, Batalden PB. Quality improvement learning collaboratives. Qual Manag Health Care. 2005;14:234–47

concurrent external and internal stimuli to improve care [30]. Further knowledge of the basic components of effectiveness, cost effectiveness, and success factors is crucial to determine the value of quality improvement collaboratives [10].

Comprehensive evaluation of a QIC requires using mixing qualitative and quantitative data and methods to gain insight into the specific processes and mechanisms by which the QIC method and its individual components operate and to gain insights into the situational factors that facilitate or impede its acceptance, implementation, and effects including what service interventions end points to choose [29, 31]. The Consolidated Framework for Implementation Research (CFIR) offers one potential method for evaluating a QIC [32]. CFIR was recommended by the 2014 NIH-sponsored Conference on the Science of Dissemination and Implementation [33] and addresses the question of "Under what conditions does the intervention work?" [34] CFIR, validated in 51 studies, is a meta-theoretical framework comprising 19 other theories and frameworks [34]. According to CFIR, there are five major domains (the intervention, inner setting, outer setting, the individuals involved, and the process by which implementation is completed) which influence implementation effectiveness and interact in complex ways [32].

Conclusion

Working across institutions to improve quality and safety will be an important strategy for the future as we continue to improve quality of patient care at the front lines as well as at the system level. An effective collaborative requires acceptance of shared goals among all stakeholders, measurement of processes and outcomes, and sharing of best practices. The success and widespread adoption of the collaborative methodology is directly related to the growing trust in transparent data sharing among like-minded health care professionals. This trust leads to meaningful exchanges and insights among experts and peers who then apply best practices to improve their care.

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Lessons Learned from Anesthesia Registries About Surgical Safety and Reliability

43

Richard P. Dutton

"A point of view can be a dangerous luxury when substituted for insight and understanding"

—Marshall McLuhan, Canadian Communications Professor

Introduction

The Information Age has created the opportunity for new advances in surgical quality improvement, based on the ability to aggregate large quantities of clinical and administrative data. Anesthesiology, with a long history of self-inquiry to promote quality, has embraced the development of multi-institutional registries. Participation in these efforts enables anesthesiologists to improve business efficiency, meet federal regulatory requirements, benchmark local outcomes to national norms, and conduct observational and comparative effectiveness research spanning millions of anesthetics.

This chapter reviews the development of anesthesia registries over the past three decades, focusing on the accelerated growth of recent years, and describe the data captured, the feedback provided and the lessons learned. Use of registry data to meet "pay for performance" requirements is described, along with the scientific potential of registries in the years to come. Anesthesia registries have evolved differently from other registries in perioperative care, emphasizing automatic rather than manual collection of data and broad rather than focused patient and case populations. This history leads to different strengths and weaknesses when compared to surgical registries organized around narrow populations, something that is explored below in detail. Finally, the chapter prognosticates on the future of anesthesia registries, the potential for interaction with surgical registries and learning plaforms and what will become possible with the continued development of information technology.

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The Regulatory Environment

Since the 1999 publication of *To Err is Human* by the Institute of Medicine, there has been increasing public scrutiny about the quality of health care [1]. Federal programs have increasingly focused on "pay for performance" as an incentive to measure outcomes and continuously improve. The Physician Quality Reporting System (PQRS) was launched by the US government as an incentive program in 2005 [2]. Providers billing Medicare could report additional codes for eligible cases, demonstrating compliance with evidence-based best practices. In the early years, good performers were rewarded with additional payment on their Medicare claims; today, any physician not successfully reporting on at least nine measures is penalized −2 % on future Medicare payments. The physician's practice group will be penalized

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an additional −4 % under the Value Modifier system if fewer than half of the group are successful in PQRS. The Merit-based Incentive Payment System (MIPS) authorized by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 replaces PQRS in 2019 with penalties ranging up to 10 % of all Medicare income for low-performing groups [3]. Rather than continuing to reward volume of services regardless of the quality of care delivered, the goal of the Department of Health and Human Services is to increase the proportion of Medicare value-based purchasing from 30 % by the end of 2016 to 50 % by the end of 2018.

The evolution of the regulatory environment has been rapid enough that few physicians or health care administrators have a clear understanding of the rules and implications. Table 43.1 shows the changes in pay for performance systems over the past few years, with a projection into the future. One safe assumption is the necessity to gather and report data is not going away but will likely increase significantly given growing awareness to the escalating costs and continued evidence of variable value and patient harm. [4, 5] This is a major driver for registry development in anesthesia—as it has been in other domains of health care. Recognizing this, quality improvement professionals not only embrace the collection and aggregation of data, but work behind the scenes to make regulatory requirements for reporting complimentary to the data desired for practice improvement and scientific advance. The American Society of Anesthesiologists (ASA) has successfully advocated for development of the Qualified Clinical Data Registry (QCDR) mechanism for group reporting of PQRS and specialty-specific measures, with the intention of advancing multiple safety, value and academic agendas under the same umbrella [6]. Table 43.2 lists the currently approved PQRS and non-PQRS measures for anesthesiologists under this system.

Table 43.1 Evolution of American federal Pay for Performance programs affecting anesthesiologists

1999	Publication of *To Err is Human* by the Institute of Medicine
2005	Medicare Physician Group Practice incentive program launched as a 3-year demonstration project
2006	Physician Quality Reporting System (PQRS) launches, providing incentives to those reporting on quality events
2008	Medicare eliminates hospital payments for care resulting from “never events”
2011	Affordable Care Act modifies PQRS, and calls for transition from incentives to penalties
2013	Value Modifier system phase-in begins; applied to groups of providers
2014	Medicare endorses the first Qualified Clinical Data Registries
2015	PQRS incentives all replaced by penalties; PQRS antibiotic measure retired; anesthesia practice participation in QCDRs begins; first announcement of Merit-based Incentive Payment System to take effect in 2019
2016	Most claims-based reporting mechanisms for anesthesia quality eliminated in favor of registry-based reporting

Table 43.2 PQRS and non-PQRS Measures supported by the National Anesthesia Clinical Outcomes Registry (NACOR)

PQRS measures	Non-PQRS measures
Beta-blockers for cardiac surgery patients	Transfer of care checklist: OR to ICU
Use of a bundle of sterile techniques for central venous catheterization	Prevention of postoperative nausea and vomiting (adult)
Assessment of pain in osteoarthritis patients	Prevention of postoperative nausea and vomiting (pediatric)
Medication reconciliation	Transfer of care checklist: OR to PACU
Pain assessment and follow-up	Composite anesthesia safety
Perioperative temperature management	Perioperative cardiac arrest rate
Tobacco cessation counseling	Perioperative mortality
Pain management in palliative care	PACU reintubation rate
Patient-centered surgical risk communication	Postoperative pain management
	Central line placement safety

(continued)

Table 43.2 (continued)

PQRS measures	Non-PQRS measures
	Measurement of patient experience
	Timely administration of antibiotics
	New perioperative temperature management
	Aspirin for patients with cardiac stents
	Use of a surgical safety checklist
	Smoking abstinence before surgery
	Perioperative corneal injury
	Timely extubation after cardiac surgery
	Stroke after cardiac surgery
	Renal failure after cardiac surgery
	Stroke or death after carotid stenting
	Stroke or death after carotid surgery
	Mortality after aortic aneurysm stenting
	Venous thrombosis prophylaxis after total knee replacement
	Antibiotics prior to tourniquet during total knee replacement
	Unplanned hospital admission after a surgical procedure
	Rate of surgical site infection

OR operating room, *ICU* intensive care unit, *PACU* post-anesthesia care unit

The History of Anesthesia Registries

Anesthesia is a data-rich medical discipline, with a history of systematic capture of vital signs, medications and fluids that goes back to the early days of surgery. Harvey Cushing and E.A Codman famously competed as medical students in 1895 to see who could produce the smoothest anesthetic; this rivalry depended on recording and comparing the details of care [7]. In the 1930s pioneering anesthesiologist Emery Rovenstine recorded each of his cases on a punch card, for tabulation by the precursor of a modern computer [8]. Beecher and Todd in 1954 published a landmark paper on surgical outcomes calling out the risks of anesthesia, based on the aggregation of case records from a consortium of university hospitals [9]. The earliest automated record keeping systems were developed in the 1970s, but the real acceleration of these efforts began in about 1990 with widespread deployment of microprocessors. This coincided with a series of breakthroughs in monitoring, leading to the present day capture in electronic anesthesia records of simultaneous output from more than a dozen different measures of patient status, including heart rate and rhythm, blood pressure, oxygen saturation, temperature, inspired and expired gas concentrations and even cerebral function [10]. A single anesthetic can thus generate thousands of data points per hour of intraoperative care.

Before the tools of the Information Age made the collection and manipulation of big data feasible there were a number of anesthesia data collection projects based on understanding specific populations of patients. The most useful of these was without doubt the ASA Closed Claims Project [11]. This repository was based on the manual abstraction of data by expert anesthesiologists from the medical and legal records of patients who filed malpractice claims following adverse outcomes. The Closed Claims researchers worked behind the scenes with malpractice insurance providers to confidentially review a sample of records from cases which have been resolved in the legal system. The reviewers captured dozens of objective data elements such as the surgical case, the type of anesthesia, the patient age and the outcome of the legal proceedings, and combine this information with a narrative describing the course of the case and the complication. The Closed Claims review began in the mid-1980s and has continued to the present, with more than 10,000 total records in the repository. The project has generated two to five papers a year in the anesthesia literature

since 1990, and has provided an excellent and ongoing description of the most serious anesthesia complications, beginning with an overview of morbidity and mortality related to anesthesia (dominated in the 1980s and 1990s by failed airway management) [12]. Recent topics have included unintended awareness under anesthesia [13], injuries in the course of chronic pain management [14] and malpractice related to acute hemorrhage [15]. While not quantitative—Closed Claims reports cannot provide the true incidence of complications because the denominator is not usually known—these papers provide guidance for how to change and evolve present practice and what are key risk areas in present practices. The Closed Claims reports have been highly influential in changing the practice of care in these areas.

The Closed Claims Project is limited by the expense involved in expert review of charts, by the inability to measure the risk of the complications seen (because the denominator information—the number of patients at risk—is unknown), and by the time lag between the occurrence of the adverse event and the complete resolution of the malpractice case. This last limitation means that Closed Claims information lags current clinical practice by 3–5 years. The Anesthesia Quality Institute (AQI) launched the Anesthesia Incident Reporting System (AIRS) in 2011 to address these limitations. The AIRS enables any anesthesia provider, anywhere in the world, to submit confidential case reports regarding unsafe conditions, near misses or anesthetic complications [16]. Each case report captures similar objective information to the Closed Claims reports, as well as a narrative from the provider themselves. While AIRS reports are more variable in quality than those generated by the small pool of closed claims experts, they benefit from much greater proximity of the reporter to the actual event. The AQI AIRS Steering Committee actively reviews all collected reports. Emerging trends in patient safety are examined—e.g., complications related to robotic surgery—and exemplary cases are "fictionalized" and then presented as teaching exercises in the *ASA Monitor,* for the education of the specialty. More information regarding AIRS, including the library of published case reports, can be found at https://www.aqihq.org/airsIntro.aspx.

Wake Up Safe

A similar, but more focused, effort was launched in about 2000 by the Society for Pediatric Anesthesia (SPA). Wake Up Safe (WUS) is a registry of case reports from adverse events occurring during pediatric anesthesia [17]. Participating institutions commit to recording each event from a mutually agreed list of serious complications, using a standardized data capture form which draws heavily on objective information from the medical record. Forms are then sent to a central clearinghouse for entry into the registry, analyzed by a SPA workgroup, and translation into public knowledge through informal and formal academic channels. Each institution also provides the registry with background information on the numbers and types of pediatric anesthesia performed, enabling estimation of risk rates for common complications. For the represented demographic segment—children having major surgery in specialty hospitals—WUS is an important source of information on the safety of pediatric anesthesia [18].

Pediatric Regional Anesthesia Network (*PRAN*)

The Pediatric Regional Anesthesia Network (PRAN), captures data on all regional anesthesia cases completed in 22 participating facilities [19]. A standard case report form is filled out for every case, usually by the anesthesiologist. The registry is maintained by the Colorado Children's Hospital, in collaboration with the University of Washington. This registry now includes more than 110,000 cases, and has been used for a number of descriptive papers and comparative effectiveness studies in the subspecialty of pediatric anesthesia [20].

The MPOG Registry

The Multicenter Perioperative Outcomes Group (MPOG) is a consortium of anesthesia departments working to aggregate clinical anesthesia data for research and quality improvement [21]. Each participating institution uses an Anesthesia Information Management System (AIMS) to digitally capture electronic anesthesia records. Idiosyncratic local data are translated into a common registry format that permits uniform aggregation of records from multiple information technology (IT) platforms. While setting up and maintaining the IT mapping can be a challenge, the end result is the ability to automatically transfer information on every case to the registry, without the need for additional human abstraction but maintaining common definitions of important variables. MPOG began as a collaboration of academics but has recently received funding to promote anesthesia quality improvement in the state of Michigan, which it has used to begin data collection from community hospitals. To facilitate regulatory reporting for participants, MPOG has created a QCDR based on measures of intraoperative anesthesia process which can be automatically calculated from the registry data. Table 43.3 shows the publication dates and topics of scholarly papers based on MPOG data.

Table 43.3 Papers published using data from the Multicenter Perioperative Outcomes Group (MPOG)

- Bender SP, Paganelli WC, Gerety LP, Tharp WG, Shanks AM, Housey M, Blank RS, Colquhoun DA, Fernandez-Bustamente A, Jameson LC, Kheterpal S. Intraoperative lung-protection ventilation trends and practice patterns: a report from the multicenter perioperative outcomes group. *Anesth Analg*. 2015
- Kheterpal S, Healy D, Aziz M, Shanks A, Freundlich RE, Linton F, Martin LD, Linton J, Epps JL, Fernandez-Bustamante A, Jameson LC, Tremper T, Tremper KK. Incidence, predictors, and outcomes of difficult mask ventilation combined with difficult laryngoscopy: a report from the Multicenter Perioperative Outcomes Group. *Anesthesiology*. 2013
- Bateman BT, Mhyre JM, Ehrenfeld J, Kheterpal S, Abbey KR, Argalious M, Berman MF, Jacques PS, Levy W, Loeb RG, Paganelli W, Smith KW, Wethington KL, Wax D, Pace NL, Tremper KK, Sandberg WS. The risk and outcomes of epidural hematomas after perioperative and obstetric epidural catheterization: a report from the Multicenter Perioperative Outcomes Group research consortium. *Anesth Analg*. 2012
- Freundlich E, Kheterpal S. Perioperative effectiveness of research using large databases. *Best Pract Res Clin Anaesthesiol*. 2011
- Kheterpal S. Clinical research using an information system: the multicenter perioperative outcomes group. *Anesthesiol Clin*. 2011
- Aziz MF, Healy D, Kheterpal S, Fu RF, Dillman D, Brambrink AM. Routine clinical practice effectiveness of the Glidescope in difficult airway management: an analysis of 2004 Glidescope intubation, complications, and failures from two institutions. *Anesthesiology*. 2011

The National Anesthesia Clinical Outcomes Registry (NACOR)

The Anesthesia Quality Institute (AQI) was created by action of the ASA House of Delegates in 2008, to "become the primary source for quality improvement in the clinical practice of anesthesiology." The specific mission of the AQI was to create and maintain a registry of anesthesia cases and outcomes, using modern information technology [22]. NACOR was announced in 2009, with the early participation of six pioneering anesthesia practices, and case data collection began on January 1, 2010. Since that time, growth and penetration of NACOR has been rapid (Fig. 43.1). NACOR was created on a model of automated harvest of existing electronic records. The easiest of these to obtain—and the starting point for any participating practice—are the group's "administrative data," or billing records. Far from being too simple to be useful, anesthesia billing records include about 20 consistently defined data points for every anesthetic. These data provide an important source of truth about the demographics of the practice, and anesthesia nationally. This layer of information in NACOR provides a backdrop for subsequent assessment of outcomes—gathered by about 25 % of participating practices—by providing the denominator needed for calculation of risk and occurrence rates. Definitions of administrative data elements are generally quite uniform, although gathered

Fig. 43.1 Growth of the National Anesthesia Clinical Outcomes Registry (NACOR) from 2010 to 2014. *Top panel* = growth in cases in the registry; *Bottom panel* = growth in number of participating practices

through dozens of different billing companies each with its own proprietary software system. Fortunately, the needs of the end-users of this data—Medicare and private insurance companies—force consistency in defining otherwise complex elements such as surgical case type, facility type, and mode of anesthesia.

Once an automated reporting routine has been created to harvest a group's administrative data, the quest for outcome information begins. More than half of all practices in the USA have mechanisms in place to digitally record the short-term outcomes of each case, and case-by-case reports can be automatically transmitted to NACOR on a regular basis [22]. Many of these systems are targeted directly at the data needed for PQRS reporting (e.g., the time of antibiotic administration) but many admirably exceed this baseline by capturing the occurrence of anesthetic complications such as postoperative pain, nausea and vomiting, corneal abrasion, or serious safety issues such as intraoperative cardiac arrest, pneumothorax after central line placement, major medication error, and anaphylaxis. Anesthesia quality capture systems are generally limited to the time of direct contact with the patient, from preoperative assessment through PACU discharge. This feature necessarily limits the outcomes which can be transmitted to NACOR to those which are readily observed in this time frame: data on intraoperative cardiac arrest are likely complete and accurate, whereas capture of myocardial

infarction—typically diagnosed 3–5 days postoperatively—is not realistic. A second limitation is that events are self-reported and thus unverified. While the clinician involved is obviously the best situated to record a complication, doing so requires time and energy. Further, as pay for performance systems advance there may be significant financial incentives to *avoid* reporting serious adverse events due to fear of loess of income and professional prestige [23]. In practice, the accuracy of self-reported outcomes varies with the culture of safety in the group, and these data must be taken with a grain of salt by users of registry data [24].

A third level of participation in NACOR is achieved by the groups able to transmit clinical information from their AIMS. (Fig. 43.2 shows the relative quantities of data available at each level.) Electronic anesthesia records are used in 30–50 % of cases nationwide, supported by a dozen different software platforms. These vary from modules of enterprise-wide electronic health care records (EHRs) such as Epic and Cerner to stand-alone products designed by anesthesiologists themselves. Larger facilities tend to follow the first model, but with a steady rise in outpatient anesthesia there are now cloud-based stand-alone AIMS customized specifically for use in offices, surgery centers and other remote locations [25]. As anesthesia practice groups become larger, many find themselves working with different software in different locations, making aggregation of case information for practice-wide quality improvement a significant challenge.

Although only 6 years old, NACOR has already inspired a number of investigators studying both narrow and broad topics in American anesthesia. Table 43.4 shows a sample of publications based on NACOR data.

NACOR vs. Surgical Registries

The model for data aggregation followed by NACOR is substantially different from that followed by the Society for Thoracic Surgeons

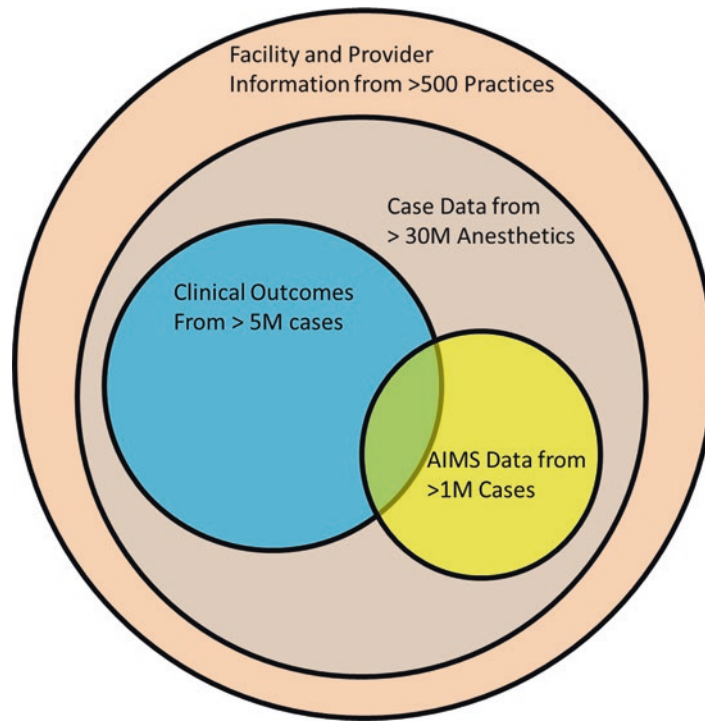

Fig. 43.2 Quantities of data of different types in NACOR, as of April 1, 2015

Table 43.4 Papers published using data from the National Anesthesia Clinical Outcomes Registry (NACOR)

• Whitlock EL, Feiner JR, Chen LL. Perioperative mortality, 2010 to 2014: a retrospective cohort study using the National Anesthesia Clinical Outcomes Registry. *Anesthesiology.* 2015
• Pollak KA, Stephens LS, Posner KL, Rathmell JP, Fitzgibbon DR, Dutton RP, Michna E, Domino KB. Trends in pain medicine liability. *Anesthesiology.* 2015
• Schonberger RB, Dutton RP, Dai F. Is there evidence for systematic upcoding of ASA physical status coincident with payer incentives? A regression discontinuity analysis of the National Anesthesia Clinical Outcomes Registry. *Anesth Analg.* 2015
• Flood P, Dexter F, Ledolter J, Dutton RP. Large heterogenuity in mean durations of labor analgesia among hospitals reporting to the American Society of Anesthesiologists' Anesthesia Quality Institute. *Anesth Analg.* 2015
• Gabriel RA, Lemay A, Beutler SS, Dutton RP, Urman RD. Practice Variations for carotid endarterectomies and associated outcomes. *J Cardiothorac Vasc Anesth.* 2015
• Chang B, Kaye AD, Diaz JH, Westlake B, Dutton RP, Urman RD. Complications of non-operating room procedures: outcomes from the National Anesthesia Clinical Outcomes Registry. *J Patient Saf.* 2015
• Dexter F, Dutton RP, Kordylewski H, Epstein RH. Anesthesia workload nationally during regular workdays and weekends. *Anesth Analg.* 2015
• Nunnally ME, O'Connor MF, Kordylewski H, Westlake B, Dutton RP. The incidence and risk factors for perioperative cardiac arrest observed in the National Anesthesia Clinical Outcomes Registry. *Anesth Analg.* 2015
• Dutton R, Lee L, Stephens L, Posner K, Davies J, Domino, K. (2014, September). Massive hemorrhage: a report from the anesthesia closed claims project. *Anesthesiology.* 2014
• Shapiro FE, Jani SR, Liu X, Dutton RP, Urman RD. (2014, June). Initial results from the National Anesthesia Clinical Outcomes Registry and overview of office-based anesthesia. *Anesthesiol Clin.* 2014
• Deiner, S., Westlake, B., Dutton, RP. Patterns of surgical care and complications in elderly adults. *J Am Geriatr Soc*. 2014
• Fleischut PM, Eskreis-Winkler JM, Gaber-Baylis LK, Giambrone GP, Faggiani SL, Dutton RP, Memtsoudis SG. Variability in anesthetic care for total knee arthroplasty: an analysis from the Anesthesia Quality Institute. *Am J Med Qual*. 2014
• Wanderer, J. Infographics in anesthesiology: resident anesthetic case types: what types of cases do anesthesiology residents spend their time performing? *Anesthesiology*. 2014

(STS) registry of cardiac surgery cases [26] or the National Surgical Quality Improvement Project (NSQIP) of the American College of Surgeons [27]. These surgical registries obtain data through the efforts of an army of abstractors—usually experienced nurses—who comb through medical records to find the data elements desired by the registry. This model results in greater completeness and consistency of records, especially when the abstractors can be centrally trained and supported, but comes at a substantial cost. The estimated "throughput" of a nurse abstractor is from 300 to 1000 cases per year, depending on the number of fields in each record, at a cost of about $100,000 per abstractor per year. Most large hospitals require two to three abstractors to meet the load of cases. While STS, focused on the low-volume but high importance domain of cardiac surgery, can abstract every case in every participating facility, NSQIP is forced to sample both surgical case types (only certain operations are included) and patients (only the first few in any month are included). Considering that any single type of surgical procedure, e.g., total knee replacement, represents at most 3 % of the volume of anesthetics for a practice for a year, the use of hand abstraction would be prohibitively expensive if any kind of a comprehensive view of anesthesia care was desired. Indeed, one of the limitations of NSQIP data may be a relative bias towards cases performed in large, academic institutions which can afford the costs of participation.

In practice, the data aggregation models of NACOR (accepting everything available in electronic form) and NSQIP (specifically abstract the desired fields) are converging. NSQIP is seeking ways to reduce the manual abstraction

burden by importation of data directly from the medical record, while NACOR is seeking greater consistency and completeness of data submission supported by the increased penetration and complexity of AIMS. Over time, more university and large private hospital systems are creating their own "data warehouses" to integrate clinical and administrative records from across the enterprise, for the purpose of generating reports to multiple stakeholders, including clinical registries [28].

The Digital Future

One way in which clinical registries can advance is by ongoing visualization of the desired future state. This is especially productive in the IT arena because, in general, what is actually being accomplished in health care lags behind what is possible in other industries. Future registries will be built on a common language of medical terminology that stretches across all specialties and disciplines, meaning that "myocardial infarction" in one registry will have the same definition in all others. Initiatives such as SNoMed (Standard Nomenclature in Medicine) and RxNorm are efforts in this direction, and the recent implementation in the United States of International Classification of Diseases, version 10 (ICD-10) coding of patient conditions and procedures will help. In perioperative care the International Organization for Terminology in Anesthesia (IOTA) meets on a regular basis to develop the fundamental linguistic building blocks for all terminology [29]. These terms can be assembled to describe any condition or procedure required, at a degree of specificity that can be shared across different facilities, software systems and national borders.

Macro political forces including government reimbursement programs and regulatory agencies are adding pressure from above. The rise of Pay for Performance in the USA is creating an industry in the development of rational, validated clinical measures. When these appear, and are linked to payment incentives, they will create standardization and uniformity of data across facilities and vendors that might otherwise be tempted to promote parochial outcome definitions [5]. Harmonization of common definitions for perioperative antibiotic dosing, for example, is a development priority of the National Quality Forum because of the need for multiple specialties to collect and report this information to CMS (National Quality Forum, personal communication).

The need for a universal patient identifier—currently unavailable because of patient privacy concerns in the USA, but standard practice in many progressive health care systems. Australia, UK and Norway have been doing this for over a decade. With the mobility of the US consumer, not to mention the shifting landscape of hospital and surgery center affiliations, the clinical need to link today's record with the patient's past and future care has never been greater. The ability to link patients and encounters across multiple registries will unlock a trove of new scientific advances. For example, linking anesthesia process data from NACOR to surgical outcomes from NSQIP would allow us to understand the role of pain management in hospital length of stay or link the type and quantity of fluid resuscitation to the potential for adverse cardiac events a week later.

The registries of the future will benefit from collaborative design and implementation. One example is the Maternal Quality Improvement Project (MQIP), jointly sponsored by the ASA and the American Congress of Obstetricians and Gynecologists (ACOG) [30]. This new registry project (currently enrolling a first wave of pilot sites) is based on the implementation of common clinical documentation software templates across multiple sites, such that routine documentation of care by doctors and nurses is easy to translate directly into the data fields in the national registry. This will enable collection of homogeneous data across sites, without the expense of abstractors reviewing every record.

Linkage of registries will lead naturally to collaborative registry projects, like MQIP. These will support the next important quality improvement initiative in health care: the idea of shared accountability with hypertransparency. Any health care experience, even a simple outpatient

surgery, involves complex coordination of multiple professionals, from surgeons to anesthesiologists to nurses and therapists and technicians delivered by the surgical microsystem [31]. Attempting to measure the performance of any single individual in this effort misses the fact that the patient's outcome will be driven more by their ability to coordinate as a team than by the individual efforts of any of them [32]. In a performance measurement system driven by shared accountability, the patient's outcome (e.g., mortality after cardiac surgery) would be "owned" by all of the participants in the patient's care, including the surgical team, the anesthesia team and the hospital [33]. The ASA has made an early effort in this direction by listing measures developed by surgical societies (e.g., wound infection after total knee replacement, time to extubation after coronary artery bypass) as reportable by anesthesiologists participating in the NACOR QCDR (see Table 43.5). The logical next step—working directly with the surgical societies to develop shared measures—has not yet occurred. Potential targets for collaboration might be the incidence of metastasis after cancer surgery (influenced by both surgical technique and anesthetic modification of the inflammatory response) and long-term cognitive function after pediatric cardiac surgery [34].

Table 43.5 Core anesthesia data collected for every case in the National Anesthesia Clinical Outcomes Registry (NACOR)

• Case identifier
• Facility (supported by metadata: facility type, location, size)
• Patient sex
• Patient age
• Patient ZIP code (can be linked to median family income and other descriptors)
• ASA Physical Status
• Date of procedure
• Start time of procedure
• Stop time of procedure
• Surgical procedure(s) (expressed as CPT code)
• Anesthetic procedure(s) (expressed as CPT code)
• Anesthesia type
• Anesthesia provider(s) (supported by metadata: provider age, training, board certification status)

ASA American Society of Anesthesiologists, *CPT* Current Procedural Terminology

Clinical Data Warehouses and Large Group Practices

The future of data-driven quality improvement in the USA may soon shift from the traditional university systems and national organizations to a new entity: the large group practice. These are umbrella corporations incorporating multiple anesthesia practices, created to bring economies of scale to the increasingly complex business of surgical care. The largest of these now include thousands of providers, care for patients in hundreds of hospitals—often over wide geographic areas—and perform in excess of a million cases a year. One of the efficiencies delivered by these businesses is a unified billing and practice management approach that inevitably unites large amounts of clinical data in a common format. Further, leveraging this data for ongoing quality improvement is a competitive advantage that large group practices use to win hospital contracts, negotiate better rates from payers and attract groups for acquisition or partnership.

Many large group practices, like the most-technologically savvy university systems, currently support their own clinical data warehouses. While the primary purpose of these registries is to support billing and collections, they are also the ideal destination for process and outcome data elements used for regulatory reporting (PQRS) and internal quality improvement. These registries are used by the most progressive practices to benchmark providers, develop hospital quality dashboards and support scientific research. Large group warehouses suffer from the same information technology challenges as national registries, including the cost of building interfaces, the need for homogeneous data definitions, the lack of methodological expertise, and the willingness of hospitals and providers to contribute [35]. However, large group practices have strong financial incentives for success, central control of data formats, the resources to hire information technology professionals and the agility to make and

execute decisions quickly. The future of anesthesia quality improvement may well be driven more by these organizations than by specialty-society sponsored registries.

One area in which the private sector is clearly outpacing public organizations is in the collection, analysis and utilization of patient experience data. "Patient centered outcomes" are a national goal advanced in the USA by the Affordable Care Act and promoted by the Patient Centered Outcomes Research Institute (PCORI), a new—and well-funded—federal agency [36]. While CMS, the American Medical Association and to some degree the specialty societies have been locked into the Healthcare Consumer Assessment of Hospitals and Provider Survey (HCAHPS) and the monopolistic private company which runs it [37], large group practices have had the agility to leap a technical generation ahead, deploying anesthesia-specific patient satisfaction surveys—sometimes within hours of the anesthetic in question—that interact with the patient through smartphone and internet based technology [38]. In contrast, HCAHPS surveys are administered by phone, 60–90 days after discharge, and do not include detailed questions regarding the patient's experience with anesthesia. Large group practices that have deployed their own surveys, and provided the results as periodic feedback to their providers, have seen substantial improvement in patient satisfaction (US Anesthesia Partners, personal communication). This trend, in turn, has been advantageous in winning hospital contracts and favorable insurance contracts. Patient centered outcomes, because of their holistic nature and high face validity, fit naturally into the concept of shared accountability described above. They will also be one key measure of another emerging trend in perioperative care: the concept of enhanced recovery (ERAS—see Chap. 22 above) and the perioperative surgical home (PSH—see Chap. 46 above). This idea, strongly advanced by the ASA, espouses close coordination of the entire surgical episode under one team [39]. The intent is to design and manage the flow of routine perioperative care to enable effective and efficient delivery, consistent with a near-future payment model that assigns the health care system (including both facilities and physicians) a single global bundle payment for a given procedure, rather than the current fragmented fee-for-service collections. The PSH experiments are being deployed in hundreds of sites across the USA, in service lines ranging from total joint replacement and coronary artery bypass grafting (the most common) to colorectal surgery, urology, and even pediatric spinal procedures. Overall patient outcome, e.g., rate of return to work or school within 30 days of knee replacement, will be one of the metrics by which the success of these experiments is judged, but gathering and analyzing these data will require the creation of new, collaborative registries in the perioperative arena.

Other National Anesthesia Registry Projects

Most of this chapter has focused on US registries, and the influences of America's unique reimbursement and incentive environment. Anesthesia registry efforts are also underway in many other countries, and include both focused collections of adverse events and comprehensive census registries capturing data from routine care.

The Scandinavian countries, with a long history of organized national health care, have the most general experience with health care registries, facilitated by national level patient identifiers that enable tracking of individuals across different hospitals. Denmark and Sweden have notable national surgical registries described in numerous publications, yet neither has a national-level registry focused specifically on anesthesia care. Anesthesiologists in Sweden are working to create such a system now, building on the existing surgical project, and will likely have centralized data within a few years [40].

The Japanese Society of Anesthesiologists is just beginning work on a national census registry, based on automated data extraction from electronic records [41]. Beginning with those institutions—largely urban university hospitals—that currently have AIMS, the Japanese Registry has been growing rapidly as the enabling health care

information technology penetrates into every hospital.

The Swiss maintain the Critical Incident Reporting System (CIRS), which is open to all European nations as a central repository of adverse events and unusual complications in anesthesia [42]. Reporting is through the internet, using a standard form that is completed by the anesthesia provider. This system has been used to generate a number of reports and alerts regarding complications in anesthesia.

The British conduct National Anesthesia Practice Survey (NAPS) audits on a regular basis focused on particular high risk topics as part of a national requirement of clinical audit and quality improvement [43]. All hospitals in the National Health Service complete reports of total cases (denominator) and the occurrence of the complication (numerator) for defined audit periods. Data are gathered and analyzed centrally, and findings are published and widely distributed to affected providers. Recent efforts have examined difficult airway management (NAPS 4) [44] and the occurrence of unintended awareness during anesthesia (NAPS 5) [45].

The Australian Anesthesia Incident Monitoring Study began in the early 1990s as a project similar to the ASA's Closed Claims Project or AIRS, but became a rapidly adopted standard for collecting complications of anesthesia care [46]. In the 2000s, this registry was expanded to all medical specialties, but an unintended consequence of this loss of focus was reduction in reports from anesthesia. A specialty-specific project, now based on electronic reporting, has recently been restarted for all anesthesia providers in Australia and New Zealand. One interesting feature of this system is awarding continuing medical education credits to physicians who enter case reports (Martin Culwick, personal communication).

A cautionary tale of the difficulty of creating a national anesthesia registry comes from the ZAPOD project in Germany. Beginning with motivated investigators from a consortium of university hospitals, a registry of anesthesia cases was developed and launched across a few dozen pilot sites. Despite substantial effort devoted to maintaining the security and confidentiality of the data collected, the registry's existence was challenged on the premise that data about a particular surgery occurring on a particular day could be easily reassociated with a particular patient. The German federal high court, in keeping with a strong public culture protecting patient confidentiality, ordered the registry closed and the existing 18 months of data destroyed. It remains to be seen if this same argument will compromise other anesthesia registries maintained in the European Union.

Summary

Anesthesiology, as a specialty, is as data intensive as any other in the house of medicine. It is not surprising, therefore, that registry efforts in anesthesia are flourishing in the Information Age. Anesthesia registries are already providing a greatly expanded understanding of the scope and scale of anesthesia care today. Whether this understanding will lead to improvements in patient care remains to be clearly demonstrated; collecting data is easy, but transforming it into clinical knowledge is the hardest challenge of all. Many methodological questions about validity and reliability of the day including how generalizable are the data remain to be worked out.

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Use of Data from Surgical Registries to Improve Outcomes

44

Jeffrey P. Jacobs

"So I am called eccentric for saying in public that hospitals, if they wish to be sure of improvement:

- *must find out what their results are*
- *must analyze their results …*
- *must compare their results with those of other hospitals*
- *must welcome publicity not only for their successes, but for their errors*

Such opinions will not be eccentric a few years hence."

—Ernest Amory Codman, Surgeon. Massachusetts General Hospital, 1917

Introduction

The art and science of outcomes analysis, quality improvement, and patient safety continue to evolve at an increasingly rapid pace, and surgery leads many of these advances (Fig. 44.1) [1, 2]. The American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®) [3] and The Society of Thoracic Surgeons (STS) National Database [4] exemplify this leading role, as they each provide a platform for the generation of important new knowledge in all of these domains.

In order to better care for patients and to be successful in today's rapidly evolving healthcare environment, understanding these topics is an essential professional responsibility of all surgeons. According to the Merriam-Webster dictionary, quality is defined as "how good or bad something is" [5]. In 1966, Avedis Donabedian (7 January 1919 to 9 November 2000) published the theory that three domains of quality exist in medicine: Structure, Process, and Outcome [6], and this conceptual model became known as Donabedian's Triad (Fig. 44.2). In 2010, Michael E. Porter, Ph.D. defined value in healthcare as "health outcomes achieved per dollar spent" [7]. Although this definition is often quoted as: "value = quality/cost" (Fig. 44.3), the original manuscript written by Porter published in *The New England Journal of Medicine* describes the following equation: "value = outcome/cost," perhaps demonstrating that the key component of Donabedian's Triad is outcome!

This chapter is titled: "Use of Data from Surgical Registries to Improve Outcomes." In reality, most surgical registries and databases serve multiple purposes: the analysis of outcomes, the improvement of quality, and research (Fig. 44.4). And it is a fact that the border separating the domains of quality and research may be blurred and vary across institutions and Institutional Review Boards (IRBs) [8]. Nevertheless, in order to perform meaningful multi-institutional analyses of outcomes, any database should strive to incorporate the following seven essential elements [1, 2, 9, 10]:

1. Use of a common language and nomenclature,
2. An established uniform core dataset for collection of information,
3. Incorporation of a mechanism to evaluate and account for case complexity,

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Fig. 44.1 This figure depicts the intersecting domains of outcomes, quality, and safety

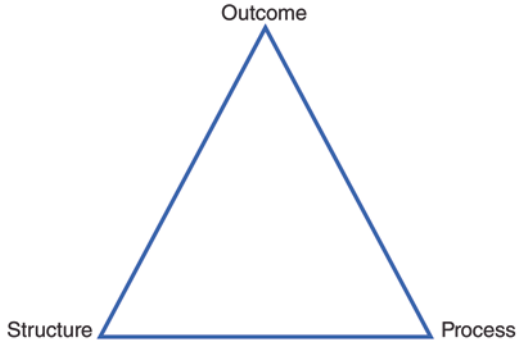

Fig. 44.2 In 1966, Avedis Donabedian (7 January 1919 to 9 November 2000) published the theory that three domains of quality exist in medicine: Structure, Process, and Outcome [6], and this conceptual model became known as Donabedian's Triad

The Healthcare Value Equation

$$\text{Value} = \frac{\text{Quality}}{\text{Cost}}$$

Fig. 44.3 In 2010, Michael E. Porter, Ph.D. defined value in healthcare as "health outcomes achieved per dollar spent" [7]. Although this definition is often quoted as: "value = quality/cost", the original manuscript written by Porter and published in The New England Journal of Medicine describes the following equation: "value = outcome/cost", perhaps demonstrating that the key component of Donabedian's Triad is outcome!

Fig. 44.4 This figure depicts three goals of surgical registries: the intersecting domains of outcomes, quality, and research

4. Availability of a mechanism to assure and verify the completeness and accuracy of the data collected,
5. Collaboration between medical and surgical subspecialties,
6. Standardization of protocols for lifelong follow-up, and
7. Incorporation of strategies for quality assessment and quality improvement.

This chapter briefly describes two of the leading surgical databases in the world: ACS NSQIP and the STS National Database. This chapter then examines the seven elements described above, using ACS NSQIP and the STS National Database to exemplify important principles.

Examples of Surgical Databases

The American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®)

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®) is the only nationally benchmarked, clinical, risk-adjusted, outcomes based program

in the USA that is designed to measure and improve care across the surgical specialties [3, 11]. ACS NSQIP is a nationally benchmarked, peer-controlled database that allows hospitals to compare 30-day patient outcomes to hospitals of all sizes and types across the country. ACS NSQIP uses data that are:

- From the patient's medical chart, not insurance claims
- Risk-adjusted
- Case-mix-adjusted
- Based on 30-day patient outcomes

The Society of Thoracic Surgeons National Database

The STS National Database was established in 1989 as an initiative to enhance the quality and safety of cardiothoracic surgery and to provide an accurate and valid basis for measuring performance in our specialty [4, 12, 13]. The STS National Database has thus far had five chairs: Richard E. Clark (1989–1997), Frederick L. Grover (1997–2004), Fred H. Edwards (2004–2010), David M. Shahian (2010–2015), and Jeffrey P. Jacobs (2015–). The STS National Database has three major component databases, each focusing on a different area of cardiothoracic surgery: the STS Adult Cardiac Surgery Database (ACSD), the STS Congenital Heart Surgery Database (CHSD), and the STS General Thoracic Surgery Database (GTSD) (Fig. 44.5) [4, 12, 13]. Table 44.1 documents the size and penetration of the three major component databases of the STS National Database. STS-ACDS is the largest adult cardiac surgical database in the world and contains data from over 90 % of the hospitals that perform adult cardiac surgery in the USA. STS-CHSD is the largest pediatric cardiac surgical database in the world and contains data from over 95 % of the hospitals that perform pediatric cardiac surgery in the USA. STS-GTSD is the largest clinical registry of general thoracic operations in the world. All three component database of STS National Database function as platforms for outcomes analysis, quality improvement, and research.

Key Components of Surgical Databases

Use of a Common Language and Nomenclature

The first step in creating a surgical registry is developing a standardized nomenclature so that all diagnoses and procedures are coded uniformly across centers. Ample data exists demonstrating the limitations of administrative systems of nomenclature that were designed for billing and not for the analysis of outcomes [14–18]. A universal clinical system of nomenclature is the foundation of any surgical registry.

An Established Uniform Core Dataset for Collection of Information

Once a system of nomenclature is established, the next step is creating a platform of data collection with a shared minimal dataset and standardized definitions for fields of data.

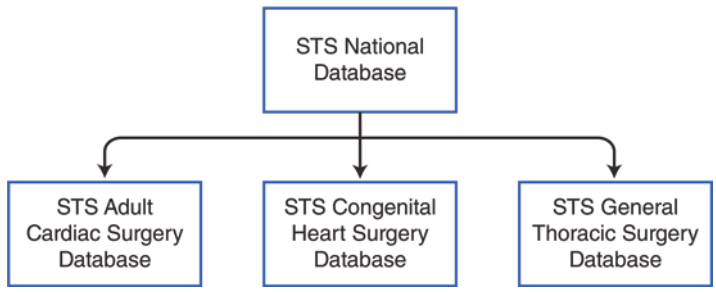

Fig. 44.5 The STS National Database has three major component databases, each focusing on a different area of cardiothoracic surgery: the STS Adult Cardiac Surgery Database (ACSD), the STS Congenital Heart Surgery Database (CHSD), and the STS General Thoracic Surgery Database (GTSD)

Table 44.1 Society of Thoracic Surgeons (STS) National Database participation [12]

Society of Thoracic Surgeons (STS) National Database Participation[a]				
	STS Adult Cardiac Surgery Database[a]	STS Congenital Heart Surgery Database[a]	STS Congenital Cardiac Anesthesia Module[a,b]	STS General Thoracic Database[a]
Participants[c] in USA	1113	116	50	301
Hospitals[d] in USA	1105	127	59	353
Surgeons in USA	2937	361	441 (anesthesiologists)	883
Operations[e] in USA	5,142,262	345,108	64,506	416,984
States in USA	50	39	27	43
Estimated penetrance at the Hospital level in USA[f,g,h]	>90–95 % of hospitals that perform adult heart surgery[f]	>95 % of hospitals that perform pediatric heart surgery[g]	31.2%[g]	?[h]
Percentage of Programs in USA that voluntarily publicly report	44 %	33 %	Public reporting is not available	Public reporting is not yet available. Voluntary public reporting with GTSD is planned for 2017
Total countries (including USA)[i]	9	5	1	4
Participants outside USA	13	6	0	3
Hospitals[d] outside USA	18	6	0	3
Surgeons outside USA	39	15	0	9
Operations[e] outside USA	5594	10,655	0	0
Total Participants	1126	122	50	304
Total Hospitals[d]	1123	132	59	356
Total Surgeons	2976	376	441	892
Total Operations[e]	5,741,489	355,763	64,506	416,984

[a]Data updated on September 25, 2015

[b]The STS Congenital Cardiac Anesthesia Module was developed jointly by STS and Congenital Cardiac Anesthesia Society (CCAS)

[c]An STS Database Participant is either a "practice group of cardiothoracic surgeons" or, uncommonly, an individual cardiothoracic surgeon. In the majority of instances, an STS Database Participant is a hospital cardiac or thoracic surgery program

[d]In most situations, one STS Database Participant is linked to one hospital; however, in some instances, one STS Database Participant is linked to more than one hospital or one hospital is linked to more than one STS Database Participant. Therefore, the number of STS Database Participant and the number of hospitals is slightly different

[e]Total number of operations refers to the total number of operations in each database since the databases began storing data at Duke Clinical Research Institute (DCRI) in 1998. DCRI is the data warehouse and analytic center for ACSD, CHSD, and GTSD

[f]Center-level penetration (number of CMS sites with at least one matched STS participant divided by the total number of CMS CABG sites) increased from 45 % in 2000 to 90 % in 2012. In 2012, 973 of 1081 CMS CABG sites (90 %) were linked to an STS site. Patient-level penetration (number of CMS CABG hospitalizations done at STS sites divided by the total number of CMS CABG hospitalizations) increased from 51 % in 2000 to 94 % in 2012. In 2012, 71,634 of 76,072 CMS CABG hospitalizations (94 %) occurred at an STS site. Completeness of case inclusion at STS sites (number of CMS CABG cases at STS sites linked to STS records divided by the total number of CMS CABG cases at STS sites) increased from 88 % in 2000 to 98 % in 2012. In 2012, 69,213 of 70,932 CMS CABG hospitalizations at STS sites (97 %) were linked to an STS record. (Reference: *Jacobs JP*, Shahian DM, He X, O'Brien SM, Badhwar V, Cleveland JC Jr, Furnary AP, Magee MJ, Kurlansky PA, Rankin JS, Welke KF, Filardo G, Dokholyan RS, Peterson ED, Brennan JM, Han JM, McDonald D, Schmitz D, Edwards FH, Prager RL, Grover FL. Penetration, Completeness, and

(continued)

Table 44.1 (continued)

Representativeness of The Society of Thoracic Surgeons Adult Cardiac Surgery Database. Ann Thorac Surg. 2016 Jan;101(1):33–41. doi: 10.1016/j.athoracsur.2015.08.055. Epub 2015 Nov 3. PMID: 26542437.)

[g]The 2010 Society of Thoracic Surgeons Congenital Heart Surgery Practice and Manpower Survey estimates that 125 hospitals perform pediatric cardiac surgery in the USA and eight Hospitals perform pediatric cardiac surgery in Canada (Jacobs ML, Daniel M, Mavroudis C, Morales DLS, Jacobs JP, Fraser CD, Turek JW, Mayer JE, Tchervenkov C, Conte JV. Report of the 2010 Society of Thoracic Surgeons Congenital Heart Surgery Practice and Manpower Survey. Ann Thorac Surg. 2011 Aug; 92:762–9.).

[h]The penetration of the STS General Thoracic Surgery Database cannot be calculated because the number of General Thoracic surgical programs in the USA (the denominator of penetration) is not known. (Reference [13] provides graphs documenting the number of participants [the numerator of penetration] and surgeons in the STS General Thoracic Surgery Database.)

[i]Countries participating in the STS Adult Cardiac Surgery Database are: USA (50 states), Australia, Brazil, Canada, India, Israel, Italy, Turkey, and United Arab Emirates. Countries participating in the STS Congenital Heart Surgery Database are: USA (39 states), Canada (3 Canadian Provinces), Columbia, Turkey, and Saudi Arabia. Countries participating in the STS General Thoracic Database are: USA (43 states), Saudi Arabia, Singapore, and United Arab Emirates

In ACS NSQIP [3], each hospital assigns a trained Surgical Clinical Reviewer (SCR) to collect preoperative data through 30-day postoperative data on randomly assigned patients. The number and types of variables collected differs from hospital to hospital, depending on the size of the hospital and the population of its patients, and its quality improvement focus. The ACS provides SCR training, ongoing educational opportunities, and auditing, to ensure data reliability. Data are entered online in a HIPAA-compliant, secure, Web-based platform that can be accessed 24 h a day. A surgeon champion assigned by each hospital leads and oversees program implementation and quality initiatives. Blinded, risk-adjusted information is shared with all hospitals, allowing them to nationally benchmark their rates of complications and surgical outcomes. ACS also provides monthly conference calls, best practice guidelines, and many other resources to help hospitals target problem areas and improve surgical outcomes.

In each of the three STS National Databases [4], data are collected regarding patient demographics, preoperative factors that may impact the outcomes of surgery, details of the specific disease process that led to the surgery (e.g., degree of coronary artery stenosis in each vessel [19], etiology and severity of valvar lesions, type of thoracic aortic pathology, stage of lung cancer, or esophageal cancer, type of congenital cardiac lesion); technical details of the conduct of the operation that was performed; detailed clinical outcomes; and disposition of the patient (e.g., home, rehabilitation facility, or dead). Data from the STS National Database are reported back to participants in Feedback Reports that include the types of procedures performed; demographics and risk factors of the patients; details about the conduct of the surgical procedure; and outcomes. In each database, individual institutional outcomes are benchmarked against aggregate data from all programs in the given database. Data in each of the STS National Database are either entered by a trained abstractor (database managers) or entered by caregivers and carefully reviewed by the database manager. These database managers work with surgeons, physician assistants, nurse practitioners, and others to ensure that that data entered into the STS National Database adhere to the definitions established by STS and that they are supported by documentation in the patient's medical record. These data managers have many resources available to them including:

- the detailed written database specifications
- a teaching manual that expands upon the formal specifications and often includes clinical examples
- advice of colleagues in regional collaboratives around the nation
- bi-weekly telephone calls with leaders of the STS National Database and Duke Clinical Research Institute (DCRI), the data warehouse and analytic center for all STS databases
- e-mail alerts
- newsletters and
- a four-day annual national meeting attended by hundreds of data managers from around the

country (at which data managers and surgeon leaders present educational sessions on challenging coding issues and new developments in data specifications).

Standardization of definitions of all fields in the database is essential [19]. For example, Operative Mortality is defined in all STS databases as (1) all deaths, regardless of cause, occurring during the hospitalization in which the operation was performed, even if after 30 days (including patients transferred to other acute care facilities); and (2) all deaths, regardless of cause, occurring after discharge from the hospital, but before the end of the 30th postoperative day [20, 21].

Incorporation of a Mechanism to Evaluate and Account for Case Complexity

After standardizing nomenclature and establishing a database with defined fields of data, the next step is the incorporation of a mechanism to evaluate and account for case complexity. Case mix can vary between surgeons and hospitals. Risk adjustment is essential when assessing and comparing healthcare performance among programs and surgeons, as this adjusts for differences in the complexity and severity of patients they treat. Reliably accounting for the risk of adverse outcomes mitigates the possibility that providers caring for sicker patients will be unfairly penalized because their unadjusted results may be worse simply because of case mix. A variety of strategies exist to adjust for variations in case mix [22]. Risk models can adjust for variations in the preoperative status of patients and the overall case mix of a given provider.

Three fundamental issues in health care performance measurement must be addressed when comparing the performance of providers and hospitals: selection of a homogeneous target population, risk adjustment, and assignment of quality rating categories [22]. Differences in provider classification may result from these methodologic decisions [22–25]. Multi-domain composite performance metrics may be utilized that combine the outcome domains of mortality and morbidity [26]; this strategy is important because of progressively decreasing mortality rates and because survival is only one measure of the quality of care. For example, consider two patients who undergo the same surgical repair of an abdominal aortic aneurysm. Patient one recovers with no complications. Patient two survives but has a postoperative stroke, develops dialysis dependent renal failure, and needs a gastrostomy because of an inability to swallow after the stroke. These two patients will both count as survivors in a model that only measures mortality; however, a multi-domain composite that includes postoperative morbidity will differentiate the outcomes of these two patents. Such composite measures provide more end points and also a much more comprehensive assessment of quality of care, because such composites include both risk-adjusted mortality and risk-adjusted morbidity.

Availability of a Mechanism to Assure and Verify the Completeness and Accuracy of the Data Collected

Once one has a developed a standardized nomenclature, a core database, and a system to adjust for variations in case mix, the next step is to assure the completeness and the accuracy of the data. Three potential strategies may ultimately allow for optimal verification of data:

1. Intrinsic data verification (designed to rectify inconsistencies of data and missing elements of data)
2. Site visits with “Source Data Verification” (in other words, verification of the data at the primary source of the data)
3. External verification of the data from independent databases or registries (such as governmental death registries).

Data quality in all STS databases is evaluated through intrinsic data verification by DCRI

(including identification and correction of missing/out of range values and inconsistencies across fields). In addition to intrinsic data verification by DCRI, each year, approximately 10 % of participants in all STS databases are randomly selected for audits of their center. The audit is designed to complement the internal quality controls, with an overall objective of maximizing the integrity of the data in all STS databases by examining the completeness and accuracy of the data. STS has selected Telligen (http://www.telligen.com/) to perform these independent, external audits. As the state of Iowa's Medicare Quality Improvement Organization (QIO), Telligen partners with health care professionals to assure high quality, cost effective health care. As a QIO, Telligen is HIPAA compliant and performs audits adhering to strict security policies.

Collaboration Between Medical and Surgical Subspecialties

It is often stated that caring for surgical patients is a "team endeavor," bringing together a variety of professionals to maximize the outcomes [27, 28]. The harmonization of nomenclature and database standards between medical and surgical databases can enhance the science of outcomes analysis and quality improvement and benefit our patients [29]. Medical and surgical databases can be linked through a variety of strategies including linkage based on indirect identifiers using probabilistic matching [8, 30, 31] and linkage with direct identifiers using deterministic matching [8, 32, 33].

Standardization of Protocols for Lifelong Follow-up

One weakness of most surgical registries is their inability to provide longitudinal outcomes. The transformation of a surgical registry into a platform for longitudinal follow-up will ultimately result in higher quality of care for all surgical patients by facilitating longitudinal comparative effectiveness research. Several potential strategies will allow longitudinal follow-up with the surgical registries, including the development of clinical longitudinal follow-up modules within the surgical registry itself, and linking the surgical registry to other clinical registries, administrative databases, and national death registries:

1. Using probabilistic matching with shared indirect identifiers, surgical registries can be linked to administrative claims databases (such as the CMS Medicare Database [8, 30] and the Pediatric Health Information System [PHIS] database [31]) and become a valuable source of information about long-term mortality, rates of rehospitalization, long-term morbidity, and cost [34].
2. Using deterministic matching with shared unique direct identifiers, surgical registries can be linked to national death registries like the Social Security Death Master File (SSDMF) [32, 33] and the National Death Index (NDI) in order to verify life-status over time.
3. As described in the preceding section, through either probabilistic matching or deterministic matching, surgical registries can link to multiple other clinical registries, such as the National Cardiovascular Data Registry (NCDR) of the American College of Cardiology (ACC), in order to provide enhanced clinical follow-up.
4. Surgical registries can develop clinical longitudinal follow-up modules of their own to provide detailed clinical follow-up.

Incorporation of Strategies for Quality Assessment and Quality Improvement

A major goal of all surgical registries is to function as a platform for quality improvement. The simple act of benchmarking individual institutional data to national aggregate data can facilitate quality improvement. Multi-institutional registries can identify high performing outliers

and low performing outliers. Quality improvement initiatives can be initiated in "low performing centers" and best practices can be identified by studying structure and processes of care at "high performing centers."

The National Quality Forum (NQF) [http://www.qualityforum.org/Home.aspx] is a multi-stakeholder, nonprofit, membership-based organization that aims to improve the quality of healthcare through the preferential use of only the most valid performance measures. NQF endorsement is the gold standard for health care quality measures, and NQF-endorsed measures are recognized by the national healthcare community as "best in class," evidence-based, and valid. Both ACS and STS (Table 44.2) have developed quality measures that are endorsed by NQF (Table 44.2), and both specialty based-medical professional organizations are stewards for more NQF-endorsed measures than any other professional surgical society (Table 44.3).

Table 44.2 NQF endorsed measures of STS [12]

	NQF #	Measure title	Domain
1	0113	Participation in a systematic database for cardiac surgery	Adult
2	0114	Risk-adjusted postoperative renal failure	Adult
3	0115	Risk-adjusted surgical re-exploration	Adult
4	0116	Anti-platelet medication at discharge	Adult
5	0117	Beta blockade at discharge	Adult
6	0118	Anti-lipid treatment discharge	Adult
7	0119	Risk-adjusted operative mortality for CABG	Adult
8	0120	Risk-adjusted operative mortality for aortic valve replacement (AVR)	Adult
9	0121	Risk-adjusted operative mortality for mitral valve (MV) Replacement	Adult
10	0122	Risk-adjusted operative mortality for mitral valve (MV) Replacement + CABG Surgery	Adult
11	0123	Risk-adjusted operative mortality for aortic valve replacement (AVR) + CABG surgery	Adult
12	0126	Selection of antibiotic prophylaxis for cardiac surgery patients	Adult
13	0127	Preoperative beta blockade	Adult
14	0128	Duration of antibiotic prophylaxis for cardiac surgery patients	Adult
15	0129	Risk-adjusted postoperative prolonged intubation (Ventilation)	Adult
16	0130	Risk-adjusted deep sternal wound infection	Adult
17	0131	Risk-adjusted stroke/cerebrovascular accident	Adult
18	0134	Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG)	Adult

(continued)

Table 44.2 (continued)

	NQF #	Measure title	Domain
19	0455	Recording of clinical stage prior to surgery for lung cancer or esophageal cancer resection	Thoracic
20	0456	Participation in a systematic national database for general thoracic surgery	Thoracic
21	0457	Recording of performance status prior to lung or esophageal cancer resection	Thoracic
22	0459	Risk-adjusted morbidity: length of stay >14 days after elective lobectomy for lung cancer	Thoracic
23	0460	Risk-adjusted morbidity and mortality for esophagectomy for cancer	Thoracic
24	0696	STS CABG composite score	Adult
25	0732	Surgical volume for pediatric and congenital heart surgery: total programmatic volume and programmatic volume stratified by the 5 STAT Mortality Categories	Congenital
26	0733	Operative mortality stratified by the 5 STAT Mortality Categories	Congenital
27	0734	Participation in a national database for pediatric and congenital heart surgery	Congenital
28	1501	Risk-adjusted operative mortality for mitral valve (MV) repair	Adult
29	1502	Risk-adjusted operative mortality for mitral valve (MV) repair + CABG surgery	Adult
30	1790	Risk-adjusted morbidity and mortality for lung resection for lung cancer	Thoracic
31	2514	Risk-adjusted coronary artery bypass graft (CABG) readmission rate	Adult
32	2561	STS aortic valve replacement (AVR) composite score	Adult
33	2563	STS aortic valve replacement (AVR) + coronary artery bypass graft (CABG) composite score	Adult
34	2683	Risk-adjusted operative mortality for pediatric and congenital heart surgery	Congenital

Graphical Depiction of Outcomes Data

Thoughtful graphical depiction of clinical data will serve multiple purposes and enhance communication [35]. Such enhanced communication is important on multiple levels including communication amongst health care professionals and communication between health care professionals and our patients [36–40].

Multiple examples of thoughtful graphical depiction of clinical data can be seen in The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®) and The STS National Database. Figures 44.6 and 44.7 are caterpillar plots derived from NSQIP® (Fig. 44.6) [41] and The STS National Database (Fig. 44.7) [24]. Figure 44.8 is a funnel plot [42] derived from The STS National Database [43].

Table 44.3 Stewards of NQF endorsed measures [12]

	Steward	# NQF endorsed measures
1	Centers for Medicare & Medicaid Services	118
2	National Committee for Quality Assurance	81
3	Agency for Healthcare Research and Quality (AHRQ)	55
4	American Medical Association (AMA)-convened Physician Consortium for Performance Improvement (PCPI)	37
5	*The Society of Thoracic Surgeons*	*34*
6	The Joint Commission	32
7	American College of Cardiology	26
8	The Child and Adolescent Health Measurement Initiative	18
9	Centers for Disease Control and Prevention	14
10	American Society of Clinical Oncology	13
11	*American College of Surgeons*	*11*
12	MN Community Measurement	9
13	American Dental Association on behalf of the Dental Quality Alliance	7
14	American Gastroenterological Association	7
15	American Medical Association	7
16	Focus on Therapeutic Outcomes, Inc.	7
17	RAND Corporation	7
18	University of Minnesota Rural Health Research Center	7
19	American Academy of Neurology	6
20	American College of Rheumatology	6
21	Society for Vascular Surgery	6
22	American College of Emergency Physicians	5
23	College of American Pathologists	5
24	University of North Carolina-Chapel Hill	5
25	American Academy of Ophthalmology	4
26	American Nurses Association	4
27	Health Resources and Services Administration—HIV/AIDS Bureau	4
28	Pharmacy Quality Alliance	4
29	American Society of Hematology	4
30	Ambulatory Surgical Centers Quality Collaborative	3
31	American Health Care Association	3
32	American Urogynecologic Society	3
33	Boston Children's Hospital	3
34	Bridges To Excellence	3
35	Leapfrog Group	3
36	Oregon Health & Science University	3
37	Virtual PICU Systems, LLC	3

(continued)

Table 44.3 (continued)

	Steward	# NQF endorsed measures
38	Renal Physicians Association	3
39	American Academy of Dermatology	2
40	American Association of Cardiovascular Pulmonary Rehabilitation	2
41	American Medical Directors Association	2
42	American Podiatric Medical Association	2
43	American Society of Anesthesiologists (ASA)	2
44	ASC Quality Collaboration	2
45	California Maternal Quality Care Collaborative	2
46	CREcare	2
47	Department of Health Policy, The George Washington University	2
48	HealthPartners	2
49	Kidney Care Quality Alliance	2
50	Massachusetts General Hospital	2
51	National Hospice and Palliative Care Organization	2
52	Optum	2
53	Philip R. Lee Institute for Health Policy Studies	2
54	American Thoracic Society	2
55	The Children's Hospital of Philadelphia	2
56	Vermont Oxford Network	2
57	Center of Excellence for Pediatric Quality Measurement	2
58	Heart Rhythm Society	2
59	American Heart Association/American Stroke Association	1
60	American Society for Radiation Oncology	1
61	American Urological Association	1
62	Brigham and Women's Hospital	1
63	Christiana Care Health System	1
64	City of New York Department of Health and Mental Hygiene	1
65	Deyta, LLC	1
66	Health Benchmarks-IMS Health	1
67	Henry Ford Hospital	1
68	Hospital Corporation of America	1
69	National Assoc. of State Mental Health Program Directors Research Instit., Inc. (NRI)	1
70	American Society of Addiction Medicine	1
71	Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. and its successor in interest, UDSMR, LLC	1
72	University of Colorado Denver Anschutz Medical Campus	1
73	Department of Veterans Affairs/Hospice and Palliative Care	1
74	University of Pennsylvania, Center for Health Outcomes and Policy Research	1
	Total	*626*

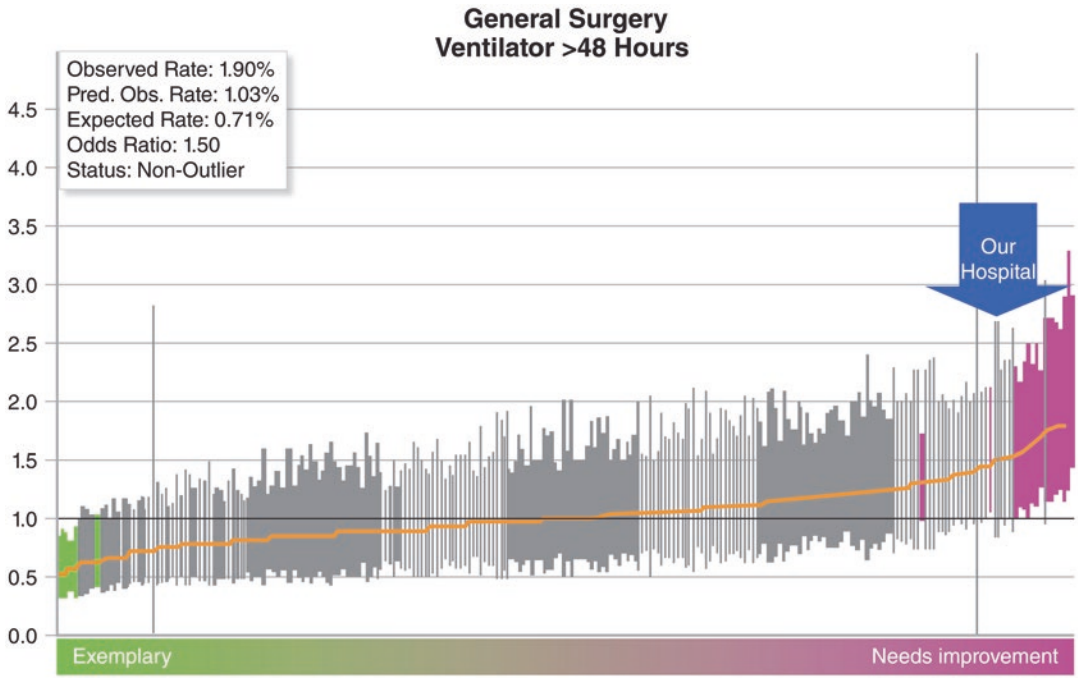

Fig. 44.6 This caterpillar plot demonstrates programmatic observed-to-expected (O/E) ratios for prolonged ventilation greater than 48 h for general surgical patients. The *bold arrow* indicates a hypothetical program that is interested in comparing its performance to aggregate data. For this hypothetical institution, the O/E ratio is 1.5. (*Each vertical line* corresponds to the result of one particular hospital, with the *orange dot* representing the point estimate and the vertical bar representing the 95 % confidence interval. More successful performers lie to the *left*. Better than expected outliers have Confidence Interval [CI] entirely below the mean [*horizontal black line*]. Worse than expected outliers have Confidence Interval [CI] entirely above the mean [*horizontal black line*]. *Shaded green and pink* are outliers [41]

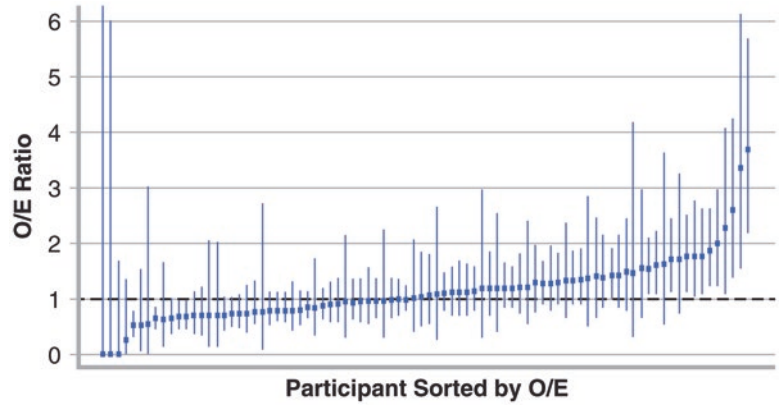

Fig. 44.7 This caterpillar plot demonstrates programmatic observed-to-expected (O/E) ratios for risk adjusted Operative Mortality using the STS Congenital Heart Surgery Database Mortality Risk Model. (*Each vertical line* corresponds to the result of one particular hospital, with the *dot* representing the point estimate and the *vertical bar* representing the 95 % confidence interval. Outliers with lower than expected Operative Mortality have Confidence Interval [CI] entirely below the mean [*horizontal dashed line*]. Outliers with higher than expected Operative Mortality have Confidence Interval [CI] entirely above the mean [*horizontal dashed line*] [24]

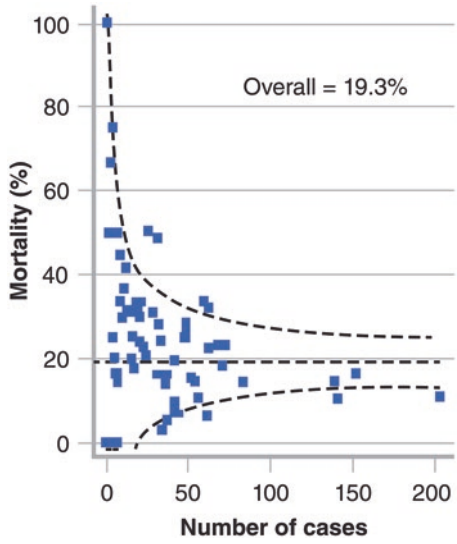

Fig. 44.8 This funnel plot of discharge mortality after the Norwood (Stage 1) Operation demonstrates participant-specific mortality rates that are depicted graphically in relation to the participant's number of eligible cases (i.e., the participant's sample size). The *horizontal dashed line* depicts aggregate STS rate of mortality after the Norwood (Stage 1) Operation before hospital discharge. *Dashed lines* depicting exact 95 % binomial prediction limits were overlaid to make a funnel plot [42]. *Squares* represent the number of cases and mortality before discharge for individual STS Congenital Heart Surgery Database participants (centers). For each participant, the probability of observing a mortality rate that falls outside the plotted prediction limits is less than 5 % if the participant's true mortality rate is equal to the overall aggregate mortality rate of all STS participants in the analysis [43]

Conclusion

Surgical registries are valuable tools to improve the outcomes of our patients and advance the art and science of outcomes analysis, quality improvement, and patient safety. As public reporting of surgical outcomes evolves, surgical registries will also be important platforms for transparency [36–39]. Patients and their families have the right to know the outcomes of the treatments that they will receive, and it our professional responsibility to share this information with them in a format that they can understand [44]. In the final analyses, surgical registries should allow surgical teams to provide better care for our patients.

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Part V

Regulation, Policy, and the Future of Surgical Care

How Regulators Assess and Accredit Safety and Quality in Surgical Services

45

Stephen Leyshon, Tita Listyowarodojo Bach, Eva Turk, Aileen Orr, Bobbie N. Ray-Sannerud, and Paul Barach

"The spectacles of experience; through them you will see clearly a second time."

—Henrik Ibsen

Background

Systems Thinking and Surgical Safety

With an estimated annual 234 million surgeries performed worldwide, surgery has become an inherent part of health care [1], corresponding to one operation for every 25 people alive [2]. Performing surgical procedures is risky [3]. For example, in industrialized countries, major complications are estimated to occur in 3–16 % inpatient surgical procedures. It is estimated that 0.4–0.8 % of these major complications result in permanent disability or death [2].

Despite research and global safety initiatives over the past decade demonstrating that surgical complications can be preventable, reports suggest that adverse events continue to occur at alarming rates [4]. In an attempt to mitigate risk, there is an increased global recognition on the need to develop standards, requirements, and recommendations within surgical centers. The World Health Organization (WHO) launched the Safe Surgery Saves Lives campaign in January 2007 to improve consistency of surgical care and adherence to safety practices. The Surgical Safety Checklist was created through an international consultative process. The checklist is a 2-min tool, much like the checklist a pilot uses before takeoff, and is designed to help operating room staff improve teamwork and ensure the consistent use of safety processes [5]. In the U.S., as an example, national regulatory groups have been established to focus on integrating and advocating a quality standard for health care. These regulatory groups include for example DNV GL, Joint Commission on Accreditation of Health Care Organizations, the National Quality Forum, the Agency for Healthcare Research and Quality, the National Committee on Quality Assurance, and the Leapfrog Group [2, 6]. More recently in 2014, the Surgical Never Events Taskforce developed a

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series of recommendations for new standards and systems to further develop and improve the safety of surgery in UK hospitals [7].

Quality of Care in Surgery Settings

The ideal way to ensure quality of care is to have internal quality assurance processes within each individual setting, and to have an external means of measuring quality of care across settings, for similar procedures. If each provider is vigilant in benchmarking/tracking quality indicators and is engaged in continuous efforts to improve patient outcomes, patient health and safety will be better protected [8]. State licensing, federal certification, and accreditation standards all require some level of internal quality assurance.

However, from an external perspective, quality of care is most often measured through determining compliance with minimum state, federal, or accreditation standards. Compliance is determined through periodic surveys or complaint investigations. Data on compliance trends is collected by the state and federal government and accreditation organizations, but there is very little data or analysis that is routinely made available to the public about the quality of care in surgery settings. Further, the data collected by external entities varies greatly in its rigor and requirements, and quality comparisons across all setting categories for the same procedures are not possible at the current time.

Other mechanisms for measuring quality may include research studies or quality indicators. However, there have been very few published studies, articles, or analysis about the quality of care in surgery and especially outpatient settings readily available to the public. A growing public concern relates to the question of how increased volumes of specific procedures can minimize negative patient outcomes. This is consistent with other studies and practices for other types of surgical procedures. Indeed, some state and federal standards require minimum numbers of procedure as a condition of qualifying to perform those procedures.

While each of these methods of measuring quality of care has benefits, they are often under the oversight authority of different agencies or organizations (both public and private). The available information maintained or collected by these agencies differs greatly. Therefore, it is difficult to reach overall conclusions about the relative quality of care provided across all categories of outpatient and inpatient surgical settings, for general surgery or for subspeciality procedures.

Comparison of Current Assurance Schemes in Surgical Safety: National and International

Many clinicians and hospital administrators wonder how regulators assess safety and quality in surgical services. Accreditation is a process of review that health care organizations participate in to demonstrate their ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. The health care organization or ambulatory surgery center pays a fee to the accreditation organization (AO) for the costs related to oversight of the setting.

A quality assurance scheme of surgical services can be in the form of a mechanism to ensure that the end-users are going through a safe and the least risky journey within the health care organization, pursuing an outcome acceptable by certain standards (http://www.asianhhm.com/surgical-speciality/quality-assurance). To date, there are very few assurance schemes targeting surgical safety. In Table 45.1, we document examples of assurance schemes related to surgical safety. These examples show that surgical assurance schemes are still patchy and vary highly from one practice to another, and from one country to another. The examples are categorized into the following types [9]: (1) national or international, (2) Statutory regulation and institutional licensing, (3) or voluntary system (e.g., peer review and health care accreditation).

The advantage of statutory regulations and institutional licensing as forms of assurance schemes is their visibility in that they mandate health care providers to change the way surgery is organized and practiced. For example, the surgical checklists introduced by the World Health Organization (WHO), which were designed and implemented throughout the globe to help reduce surgical mortality and complications, have been

Table 45.1 Overview of international regulatory and quality assurance schemes

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 7151:1988	1988		Surgical instruments—Non-cutting, articulated instruments—General requirements and test methods
Internationally	Voluntary system		ISO	ISO 7153-1:1991	1991	Contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and specific instruments for orthopedic surgery. It takes into account steel grades and chemical compositions	Surgical instruments—Metallic materials—Part 1: Stainless steel
Internationally	Voluntary system		ISO	ISO/DIS 7153-1	Under development	Standardization in the field of surgical instruments such as forceps, scissors, scalpels and retractors	Surgical instruments—Materials—Part 1: Metals
Internationally	Voluntary system		ISO	ISO 7153-1:1991/ Amd 1:1999	1999		
Internationally	Voluntary system		ISO	ISO 7740:1985	1985	Lays down the dimensions of two sizes of fitting features for detacheable scalpel blades and the handles with which they are used. It secures a good fitting and interchangeability of detachable blades for scalpels manufactured in different countries or by different manufacturers. The transitional period for a gradual adaption of the fitting dimensions specified in this standard should end with the year 1990	Instruments for surgery—Scalpels with detachable blades—Fitting dimensions

(continued)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 7741:1986	1986	This standard deals with materials, heat treatment and hardness of component parts, corrosion resistance, workmanship and cutting ability of scissors and shears used in the surgery and defines the test methods	Instruments for surgery—Scissors and shears—General requirements and test methods
Internationally	Voluntary system		ISO	ISO 13402:1995	1995	Describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure	Surgical and dental hand instruments—Determination of resistance against autoclaving, corrosion and thermal exposure
Internationally	Voluntary system		ISO	ISO 8828:2014	2014	ISO 8828:2014 specifies the recommended procedures for handling orthopedic implants, hereafter referred to as implants, from receipt at the hospital until they are implanted or discarded. This guidance applies to implants (such as currently used metal, ceramic, or polymeric implants) and also to acrylic resin and other bone cements. This guidance does not apply to the implant manufacturer. However, it contains references to the stocking of implants that can be useful for manufacturers and especially for third-party suppliers	Orthopedic implants

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 12891-1:2015	2015	ISO 12891-1:2015 specifies the method to be followed for the retrieval and handling of surgical implants and associated tissues and fluids. In particular, it specifies the essential steps to be followed for the safe and proper obtaining of the clinical history, pre-explantation checks and examinations, collection, labelling, cleaning, decontamination, documentation, packing and shipping. It also provides guidance on infection control. *Note* National or other regulations, which can be more stringent, can apply. ISO 12891-1:2015 does not apply in cases of explantation where there is no intention to collect retrieval data. However, many clauses give useful information which can apply in these cases also. ISO 12891-1:2015 specifies the method to be followed for the retrieval and handling of surgical implants and associated tissues and fluids. In particular, it specifies the essential steps to be followed for the safe and proper obtaining of the clinical history, pre-explantation checks and examinations, collection, labelling, cleaning, decontamination, documentation, packing and shipping. It also provides guidance on infection control. *Note* National or other regulations, which can be more stringent, can apply. ISO 12891-1:2015 does not apply in cases of explantation where there is no intention to collect retrieval data. However, many clauses give useful information which can apply in these cases also	Retrieval and analysis of surgical implants—part 1: retrieval and handling

(continued)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 12891-2:2014		ISO 12891-2:2014 specifies methods for the analysis of retrieved surgical implants. ISO 12891-2:2014 describes the analysis of retrieved metallic, polymeric and ceramic implants. The analysis is divided into three stages which are increasingly destructive. ISO 12891-2:2014 can also be applied to other materials, e.g. animal tissue implants. ISO 12891-2:2014 can be applied in accordance with national regulations or legal requirements regarding the handling and analysis of retrieved implants and tissues and associated biological material	Retrieval and analysis of surgical implants—part 2: analysis of retrieved surgical implants
Internationally	Voluntary system		ISO	ISO/TR 14283:2004		ISO/TR 14283 provides fundamental principles for the design and manufacture of active or non-active implants in order to achieve the intended purpose	Active or non-active implants
Internationally	Voluntary system		ISO	ISO/CD TR 14283	Under development		Implants for surgery
Internationally	Voluntary system		ISO	ISO 14607:2007	2007	ISO 14607:2007 specifies particular requirements for mammary implants for clinical practice. With regard to safety, ISO 14607:2007 specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer	Non-active surgical implants—mammary implants
Internationally	Voluntary system		ISO	ISO/WD 14607	Under development		Non-active surgical implants—mammary implants

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 14630:2012	2012	ISO 14630:2012 specifies general requirements for non-active surgical implants. ISO 14630:2012 is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue. With regard to safety, ISO 14630:2012 specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements	Non-active surgical implants
Internationally	Voluntary system		ISO	ISO 16054:2000	2000	Minimum data sets for surgical implants	Implants for surgery
Internationally	Voluntary system		ISO	ISO 16061:2015	2015	ISO 16061:2015 specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment. This International Standard also applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves. With regard to safety, this International Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the manufacturer. This International Standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants, and ophthalmic implants	Instrumentation for use in association with non-active surgical implants

(continued)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO/WD 17327	Under development		Non-active surgical implants—implant coating
Internationally	Voluntary system		ISO	ISO/CD 19227	Under development		Cleaning of orthopedic implants—general requirements
Internationally	Voluntary system		ISO	ISO 10282:2014	2014	ISO 10282:2014 specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove. ISO 10282:2014 is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging, and storage procedures are outside the scope of ISO 10282:2014	Single-use sterile rubber surgical gloves
Internationally	Voluntary system		ISO	ISO 10334:1994	1994	Specifies the dimensions and mechanical properties and gives test methods. The mechanical properties specified are tensile strength, elongation, and resistance to damage in bending and in torsion. Surface finish is not covered	Implants for surgery—malleable wires for use as sutures and other surgical applications

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	The UK	Association of Breast Surgery (ABS) at BASO	Quality assurance guidelines for surgeons in breast cancer screening	1992 (first publication), updated in 1996, 2003, 2009	The guidelines are addressed principally to surgeons working in the screening program for breast cancer, who will use the guidelines in a personal capacity to audit their own activity	Breast cancer screening program
National	Voluntary system	Australia	Queensland Health, Governmental organization	VLAD system		VLAD charts provide an effective, easily visualized display of surgical performance and can be applied to pediatric cardiac surgery. Early detection of change, whether improvement or deterioration, is important for ongoing quality assurance within a cardiac surgery program	
National	Voluntary system	The UK		Quality assurance program (QAP)		The implementation of a QAP improved quality of care in terms of consistency of patient selection and outcomes of surgery during a period of major reorganization of cancer services in London. The QAP framework presented could be adopted by other organizations providing complex surgical care across a large network of referring hospitals	
International	Voluntary system		WHO	Surgical safety checklists:		The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anesthesia (“sign in”), before the incision of the skin (“time out”) and before the patient leaves the operating room (“sign out”). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation	

(continued)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	USA	Accreditation Association for Ambulatory Health Care (AAAHC)	Handbook for small office-based surgery practices			
National	Statutory regulation and institutional licensing	The UK	Care Quality Commission (CQC)			CQC inspection is based on the following questions: (1) are services safe, (2) are services effective, (3) are services caring, (4) are services responsive to people's needs, (5) are servies well-led	In general clinics but include surgical practices
International	Voluntary system	EU	European Union	European guidelines for quality assurance in breast cancer screening and diagnosis			
National	Voluntary system	USA	American College of Surgeon	American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®)		Various surgical quality assurance programs within surgery, using four key principles required to measurably improve quality of care and increase value: (1) Standards, (2) Right Infrastructure, (3) Rigorous data, (4) Verification	Various surgical services e.g. National Accreditation Program for Breast Centers (NAPBC), Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBASAQIP)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	UK	The Association for Periope-rative Practice (AfPP)			Guidance on a number of perioperative issues e.g. best practice for safe handling of surgical sharps, PCC perioperative support worker, safer surgery checklist, etc.	Perioperative
National	Voluntary system	UK	The Royal College of Surgeons of England			Develop a range of guidance aimed to provide a robust framework for promoting good practice in surgery, professional development and effective delivery of surgical services e.g. guidance for individual surgeons and for the surgical team on professinalism and good practice, guidance on day-to-day working practices that facilitate and promote the delivery of effective services, and guidance and tools on appraisals and revalidation	
National	Voluntary system	UK	The Royal College of Surgeons of Edinburgh (RCSEd)			RCSEd develops a range of guidance aimed to provide a robust framework for promoting good practice in surgery, professional development and effective delivery of surgical services	
National	Statutory regulation and institutional licensing	Canada	Accreditation Canada			Accreditation Canada's sector and service-based standards help organizations assess quality at the point of service delivery. They are based upon five key elements of service excellence: clinical leadership, people, process, information, and performance. These standards contain the following sections: Investing in surgical care services. Engaging prepared and proactive staff. Providing safe and appropriate services. Maintaining accessible and efficient clinical information systems. Monitoring quality and achieving positive outcomes	

(continued)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Statutory regulation and institutional licensing	France	The Haute Autorité de santé (HAS)—or French National Authority for Health			Provides practice guidelines in general that also include surgery services	
International	Voluntary system	EU	*The European Union of Medical Specialists* (Union Européenne des Médecins Spécialistes—UEMS)			*The main activities of the EUMS can be summarized in four headings*: Surgical training Standard of the Certificate of Completion of Specialist Training (CCST) Continuing Medical Education in Surgery (Continuing Professional Development) Surgical Quality Control	
National	Statutory regulation and institutional licensing	USA	Centers for medicare and medicaid services (CMS)			*Include conditions of participation for hospitals with surgical services, for example*: (1) If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. (2) Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC	

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	USA	Joint Commission (JC)			Include standards on Surgical Site Infection (SSI)	Hospital acquired infections
National	Voluntary system	USA	Joint Commission (JC)			Include Surgical Care Improvement Project (SCIP)	National quality partnership of organizations interested in improving surgical care by significantly reducing surgical complications
National	Voluntary system	USA	Joint Commission (JC)			*Office-based surgery accreditation*	Smaller surgical practices
International	Voluntary system		Joint Commission International (JCI)			None found specific related to surgical services	
International	Voluntary system		Accreditation Canada International			None found specific related to surgical services	
National	Voluntary system	Canada	Accreditation Canada			Accreditation Canada's sector and service-based standards are based upon five key elements of service excellence: clinical leadership, people, process, information, and performance	
National	Voluntary system	Canada	Royal College of Physicians and Surgeons of Canada			Among their core functions is to accredit medical education under two broad categories: (1) the residency programs sponsored by Canada's 17 medical schools, (2) and the learning activities pursued by physicians who engage in continuing professional development	Residency programs and learning activities pursued by physicians for professional development

part of many national regulations in the USA and Australia [10, 11]. Since 2012, the US Centers for Medicare & Medicaid Services (CMS) requires ambulatory surgery centers (ASC) to conduct quality reporting that includes the use of surgery checklists for all, not only Medicare, patients [12, 13].

Within voluntary schemes, it is worth noting that non-governmental, private sector regulators are rapidly gaining their influence in the way that surgery is practiced, billed and supervised [6]. For example, the Leapfrog Group [13] has become one of the most powerful forces in the private regulatory sector and provides excellent evidence on the impact of this sector on surgical care. Furthermore, specialty colleges or board and professional licensing bodies are key players in developing assurance schemes based on consensus into more uniform, regulated schemes. For example, there is a global trend in developing and implementing a scheme for physicians' continuous professional development such as schemes to maintain physicians' competence [14]. In Australia, as an example, the Royal Australasian College of Surgeons requires surgeons to maintain their skills, knowledge and competence by self-directed learning, teaching, researching, publishing scientific articles, and attending educational gatherings such as scientific meetings, workshops, and seminars. In most of western countries, surgeons must retain records to verify their competence and professional development [14].

The specialty colleges or boards can also potentially be the champions in closing the gap in the areas in need of regulations such as robotic surgery. Technology advancements in surgery are growing rapidly, for example, the scale and spread of 3-D organ and prosthetic printing. This growth creates an urgent need for assurance schemes to ensure the quality and safety of patients not being harmed from the technology. Currently, there are no standards, nationally or internationally, for assuring patients are not harmed during the use of robotic surgery. However, there is a growing consensus in this field, such as a consensus document produced by The Society of American Gastrointestinal and Endoscopic Surgeons [15, 16]. This consensus document provides guidance to surgeons wishing to perform robotic surgery to fulfill specific training prior to performing it.

Most surgical assurance schemes have a focus mainly on prescriptive, rather than performance-based frameworks. Whereas health care practitioners need assurance schemes that are performance-based to help them put systems thinking into practice. This is crucial to ensure that end-users receive the necessary treatment with the desired outcome. There remains an evidence gap forcing regulators to be ever vigilant about the safety and reliability of surgical services [9].

Outpatient/Ambulatory Surgery

National and international professional associations have published information about the quality of care provided in outpatient settings for their own specialties, there have been very few published studies, articles, or analyses about the overall quality of care in outpatient surgery settings. In addition, there is little information about the relative quality and safety of specific outpatient surgical procedures across the range of settings in which these surgeries are performed.

Quality of care is most often measured by internal facility quality assurance processes, and by information collected by oversight agencies through determining compliance with minimum state, federal, or accreditation standards. Data may be collected by the state and federal government, accreditation organizations, and internal facility quality assurance processes, but this data is not analyzed in such a way as to reach a determination about the quality of care, nor is this information readily available to the public.

In order to protect public health and safety, and to provide more information about health care being provided in outpatient surgery settings, a fresh look at the oversight, transparency, and quality of care across all settings is warranted. Some of the opportunities will require additional analysis and stakeholder involvement to develop and will take more time than others.

Future Challenges in the Assessment and Regulation of Surgical Safety and Quality

The Surgical Never Events Taskforce standards provide an overarching framework with high level descriptions of what should constitute standard practice for peri-operative procedures that can be developed locally to create standardized practices within organizations [7]. For surgical centers that are required to meet specific standards or requirements that promote quality assurance and improve the processes by which their services are held accountable to the public, accreditation and/or regulation models provide the means of ensuring the correct environment for clinical practice has developed into a form of public regulation [17]. In brief, the regulatory model is driven by the government in which standards are set and the inspection of health care organizations within these standards produce verification for continued operation, often a condition for receiving public funding. Accreditation is often characterized by a model driven by self-regulation or voluntary participation, where the compliance of standards are both defined and assessed by an independent body [18]. This external validation of standards in safe practices can provide the patient and relevant stakeholders with information about surgical center's commitment and progress toward quality improvement and safety, with benchmarking performance against other accredited facilities. An organization's motivation for accreditation can stem from a number of different areas, all of which are subject to the model adopted. As a result, these local standards and their oversight are highly dictated by local country specific policies.

Developing and Applying Surgical Standards

The growing interest in the development and application of standards for surgical centers is due to the presumption that accreditation may provide surgical centers the advantage of improving outcomes of surgical practices. However, given the only recent growth of regulation and accreditation in surgical centers, there is little research to empirically support this claim. Recently two studies were published that examined the impact of accreditation in bariatric and ambulatory surgical centers [19, 20]. The outcomes of bariatric surgery performed compared between those done at accredited versus non-accredited centers using a nationally representative database evaluated a total of 277,068 bariatric operations performed within a 3-year period. Results of the study indicated that accreditation in bariatric surgery was associated with more than a threefold reduction in risk-adjusted in-hospital mortality [19]. The results, however, were not as favorable toward accreditation in a study that examined the impact of accreditation in ambulatory surgical centers (ASC) suggesting no systematic differences in the quality of care between ASCs that were accredited or and those that were not accredited. This aligns with the most comprehensive meta-analysis of accreditation and certification studies and which demonstrated little to no evidence supporting any lasting positive outcomes of these efforts given the way accreditation is presently conducted [21].

In light of the limited evidence comparing the safety and outcomes of accredited and non-accredited surgical centers, a very important contribution to accreditation is the process of assessment and regulation that allows for organizations to understand the range of risks that are present, their ability to control them, the probability of occurrence and its potential impact—Fig. 45.1. If risks are properly assessed and managed then it stands to reason that, with appropriate controls in place, the safety and quality of surgical outcomes can be increased. As surgical centers are moving towards a greater emphasis on establishing standards and requirements that mitigate and potentially eliminate risks to the patient, accreditation systems have the potential to address the reliability of this process. Fortes and colleagues [22] describe the development of accreditation as a tool "to evaluate the risks that occurred in the hospital environment, with the objective of protecting the professional that worked at these units." These good intentions, however, come with various challenges for accreditation surveyors related to implementing approaches that

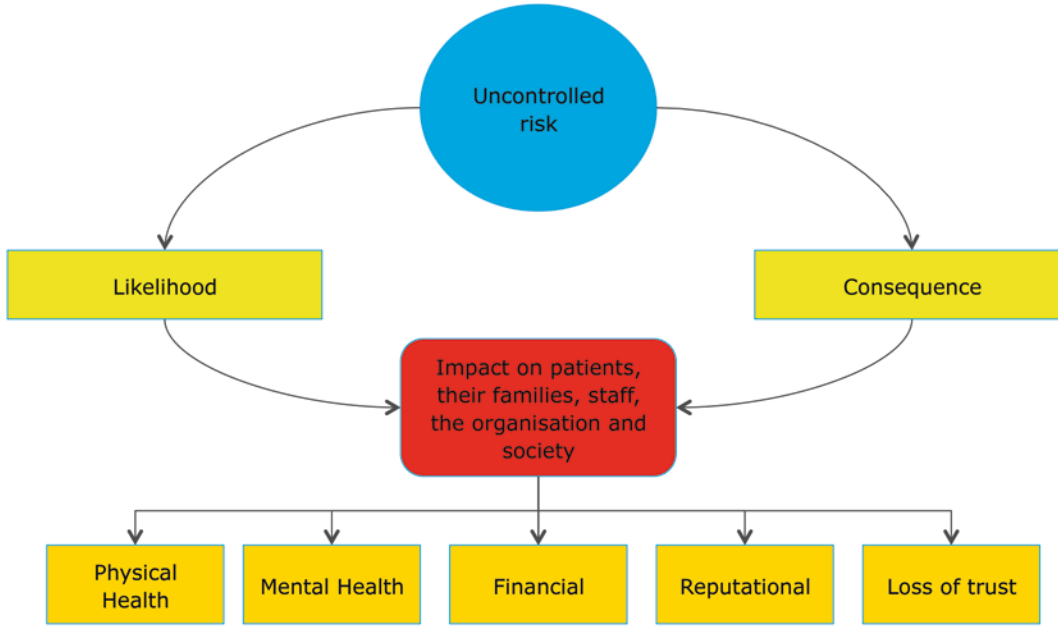

Fig. 45.1 Enterprise Risk Management approach and its impacts on patients, families, providers, managers and society

accurately assure that the surgery center policies and procedures designed to aid clinical practice are reflected in safe patient outcomes and are internalized by the providers doing the surgery.

Specifically, the activities related to the assessment of surgical safety centers, which are often characterized as having dynamic and complex infrastructures, can be a daunting process for external accreditors. This is especially the case when properly identifying the unique risks specific to the center being assessed. This is mostly due to a process that is dependent on the willingness of the organization to report and disclose past, current, and anticipatory errors. Unfortunately, the culture of fear of punishment and litigation leads hospital personnel to avoid disclosing or to shading this information [23]. As a result, in order to gain an accurate understanding of the center's adherence and performance to mitigating risk, the assessor must rely on a deep knowledge of the domain, have the skills to tactfully navigate the political challenges, using nimble risk management approaches and tools. Assessors must additionally use their time and resources wisely to provide a wider assessment of the factors that may be relevant to surgical safety outcomes in capturing all the salient features of surgical operation [24]. Vincent et al. [24] suggests including factors such as equipment design and use, communication, team coordination, human factors affecting individual performance, and the working environment [25, 26]. Others who have conducted and analyzed over 100 surgical RCA point to the need to better understand what the employees and staff feel is important and relevant to the investigation [27]. The broad competencies expected by assessors can be difficult to achieve and presents a challenge in both recruiting and training surveyors, and in providing an objective evaluation by third party agencies.

Building Safety Through Accreditation and Risk-Thinking: Responsibility and Accountability

Researchers are identifying strategies in auditing that ensure risks are being accurately assessed. For a successful adaptation strategy, this demands a more dynamic approach that focuses on the

system as a whole by including all levels of the organization from top leadership to workers at the coal face [28]. Yet for decades, auditing and safety improvements have been driven by the retrospective review of incident reports, errors, and violations. The problem with these approaches is that they mean a negative event has already occurred. A more proactive approach is to assess the likelihood and consequence of something going wrong within a process and the system in which it takes place and to put in place controls to prevent or mitigate the negative event [29]. Such a risk-based approach underpins the nature of accreditation.

Designated individuals should be responsible for the clinical and financial outcome of patient pathways and accountable to senior management. All information should be distilled as it flows upwards, to keep leaders informed but not overwhelmed with data, with appropriate levels of detail for each audience. In some of the best examples, quality and safety are built into the strategic goals and become a central part of all board meetings, supported by robust internal audits to verify the established high standards of governance, as with financial audits, are consistently applied [30].

Optimizing and Standardizing Clinical and Organizational Processes

Doctors have typically been deeply resistant to standardization, believing that every patient is unique. However, such an individual-by-individual approach actually increases the likelihood of errors. Leading providers have achieved dramatic results by implementing standard guidelines and operating procedures, increasing patient survival rates and cutting the cost of care significantly. The path to standardization can, however, be slow and painful, with staff at all levels reluctant to change behavior, resulting in a frustrating lack of compliance. Clinical leaders must be relentlessly vigilant in checking and double-checking adherence to protocol, making those on the front line directly accountable and stressing that guideline adherence is not a loss of professional autonomy, merely a replacement of pure *individual* autonomy by more *collective* autonomy [31]. Results should be fed back to the pathway owners, whose task is to continuously improve the performance and thus the quality of care. Information technology (IT) plays a vital role in measuring outcomes and improving processes. However, some of the most impressive breakthroughs have occurred in organizations where the IT infrastructure was still unsophisticated, so technological limitations are no reason for inactivity [32].

A Culture Devoted to Quality and Reliability

Health care can be thought of as hypercomplex, involving interacting processes, systems and people (Table 45.2). Risk based approaches offer a way to tackle the way in which people and socio-environmental factors interact. Risk thinking encompasses cyclical, continuous and dynamic processes of assessing hazards and selecting, implementing and evaluating controls to reduce the potential of those hazards from becoming harm [33]. It offers a means to create safer, high quality care by addressing in structured, scientific ways human, technical and organizational issues, i.e. the nexus of factors and circumstances where preventable harm most often arises [8]. In doing so, it supports the spread and sustainability of good practice, by enabling people to understand their local context; the nature of any innovation; and its planned cause and effect (including foreseeable positives and negatives).

Learning from other high risk sectors supports this [34]. Responding to major disasters such as Flixborough and Piper Alpha [35], other sectors have made great strides in improving safety at a system level by using risk based approaches [36]. They have been able to think ahead about what the obstacles and hazards might be; how those obstacles and hazards might prevent improvements or become harmful outcomes; and how systems can then best be designed to prevent or mitigate unintended results [34].

Table 45.2 Dimensions and attributes of the hyper complex nature of health care

Dimensions	Attributes
Vulnerability and involvement of "end user"	• Unwell, fearful, impaired communication • Variable knowledge—information asymmetry and vulnerability to quackery and fraudulent information • End user is also a component but non-standardized (genetics, social circumstances, choices = life course) • Most processing is "off plant"
Leadership and culture	• High degree of professional autonomy and power • Silo working with emphasis on specialization • Ambiguous and ambivalent relationship to management • Poor history of safety education and culture—implicit rather than explicit
Highly politicized	• Constant wholesale change • Evolution rather than system design • Conflicting goals • Regulatory tensions—centralism vs. localism • Ideological toy • Almost daily media coverage
Activity patterns	• Large numbers • Difficult to impossible to shut down • Lots of predictability but episodes of uncertainty (new diseases, major incidents)—not just emergencies but immediate sustained changing needs
Technical/competence	• Differentiated workforce with varying education and competence—from no post-compulsory education to post-doctoral • Research to practice gap—information overload and varying competence in critique and application • Tendency towards pseudo-invention and pseudo-understanding • Guidance/guideline multiplicity and (in)coherency • Diversity of providers and equipment—lack of standardization and evolutionary introduction/adoption
Geography	• System orbiting and overlap in patient pathways • Patient movement within and across systems and organizations (primary, secondary, tertiary health care; social care; voluntary sector) • Regulation behind the curve—often different for primary, secondary, tertiary health care; social care; voluntary sector—reflected by being "under" different government departments

Accreditation provides a framework for organizations to put risk thinking into practice and address the hypercomplexity of health care. It is a program of activity in which trained external peer reviewers evaluate an organization's compliance with preestablished standards [37, 38], that can be applied to specific areas (such as managing infection risk or wrong site surgery [39]) or across an organization's services. The iterative processes build on risk thinking by helping an organization to drive best practices in risk management (Table 45.3).

Table 45.3 Iterative best practices in risk management

Step 1:	Map processes (including how processes connect within and between organizations)
Step 2:	Identify and assess risks to human, technological and organizational safety and performance
Step 3:	Establish prevention and mitigation controls to deliver safe and reliable results
Step 4:	Continuously monitor to evaluate the efficacy of those controls

The risk thinking inherent in accreditation supports wider models of improvement, such as the Baldrige Model [13]—Fig. 45.2. By supporting organizations to identify, prioritize, and manage risks accreditation tackles the key dimensions of quality.

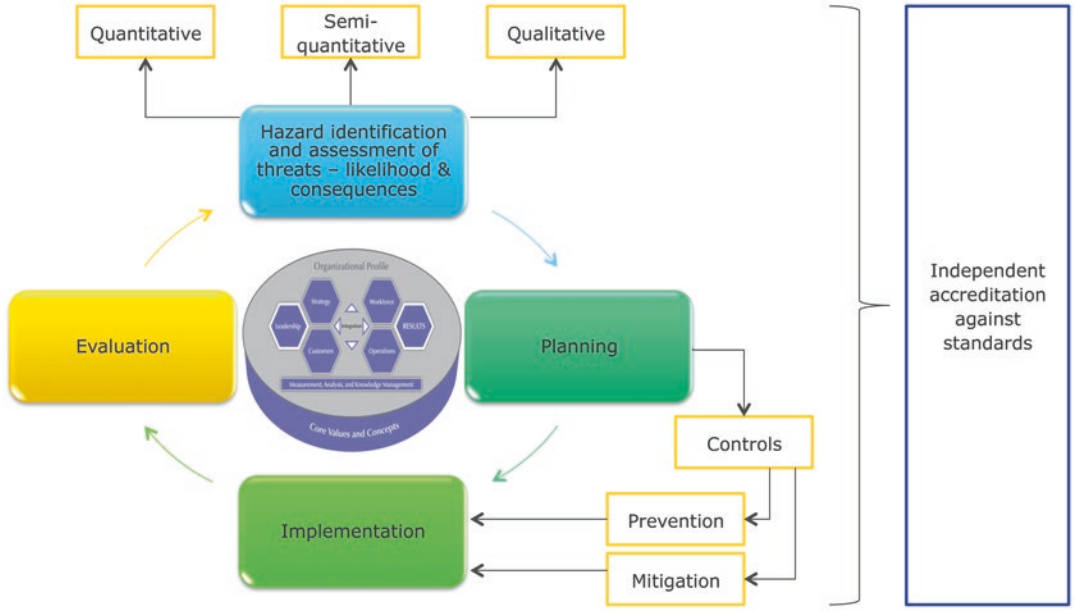

Fig. 45.2 Risk-based thinking underpinning accreditation and other quality improvement models, such as the Malcolm Baldrige National Quality Award

Wrong-Site Surgery: A Dynamic Risk Management Model

One way to bring accreditation to life is to use an example of how the risk thinking that underpins it can be applied to practice. The problem of wrong-site surgery is a useful illustration. Wrong-site surgery includes operations performed on the wrong side or site of the body, the wrong procedure performed, and surgery performed on the wrong patient [40]. Wrong-site surgery is classified as a never-event [13] because it is both preventable and can be devastating for patients and professionals alike.

Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse (WSPE) events, although rare, are more common than health care providers and patients appreciate [41]. Wrong-site surgery is associated with failures in communication (70 percent), procedural noncompliance (64 percent), and leadership (46 percent) [42]. Other system and process causes are listed in Table 45.4. Risk factors associated with wrong-site surgery are emergency cases, multiple surgeons, multiple procedures, obesity, deformities, time pressures, and unusual equipment or setup, and room changes. Prevention of WSPEs requires new and innovative technologies, reporting of case occurrence, and learning from successful safety initiatives (such as in transfusion medicine and other high-risk nonmedical industries), while reducing the shame associated with these events.

Organizations that want to deliver highly reliable and patient centered outcomes based around the model in Fig. 45.3 can assure regulators and accreditors that they are managing their risks, constantly vigilant at what could go wrong, assessing the likelihood and consequences, and developing robust yet proportional controls at each stage of the surgical patient pathway [44].

Learning from Experience: The Accreditation Process and How to Ensure Effective Implementation

Accreditation programs vary extensively as do the organizations that carry out accreditation visits. There is however one constant across all accreditation programs and that is the need for organizations to undertake a deep and authentic

Table 45.4 Causes of wrong-site surgery [43]

System factors	Process factors
• Lack of institutional controls/formal system to verify the correct site of surgery • Lack of a checklist to make sure every check was performed • Exclusion of certain surgical team members • Reliance solely on the surgeon for determining the correct surgical site • Unusual time pressures (e.g., unplanned emergencies or large volume of procedures) • Pressures to reduce preoperative preparation time • Procedures requiring unusual equipment or patient positioning • Team competency and credentialing • Lack of complete information • Organizational culture • Orientation and training • Staffing • Environmental safety/security • Continuum of care • Patient characteristics, such as obesity or unusual anatomy, that require alterations in the usual positioning of the patient	• Inadequate patient assessment • Inadequate care planning • Inadequate medical record review • Miscommunication among members of the surgical team and the patient • More than one surgeon involved in the procedure • Multiple procedures on multiple parts of a patient performed during a single operation • Failure to include the patient and family or significant others when identifying the correct site • Failure to mark or clearly mark the correct operation site • Incomplete or inaccurate communication among members of the surgical team • Noncompliance with procedures • Failure to recheck patient information before starting the operation

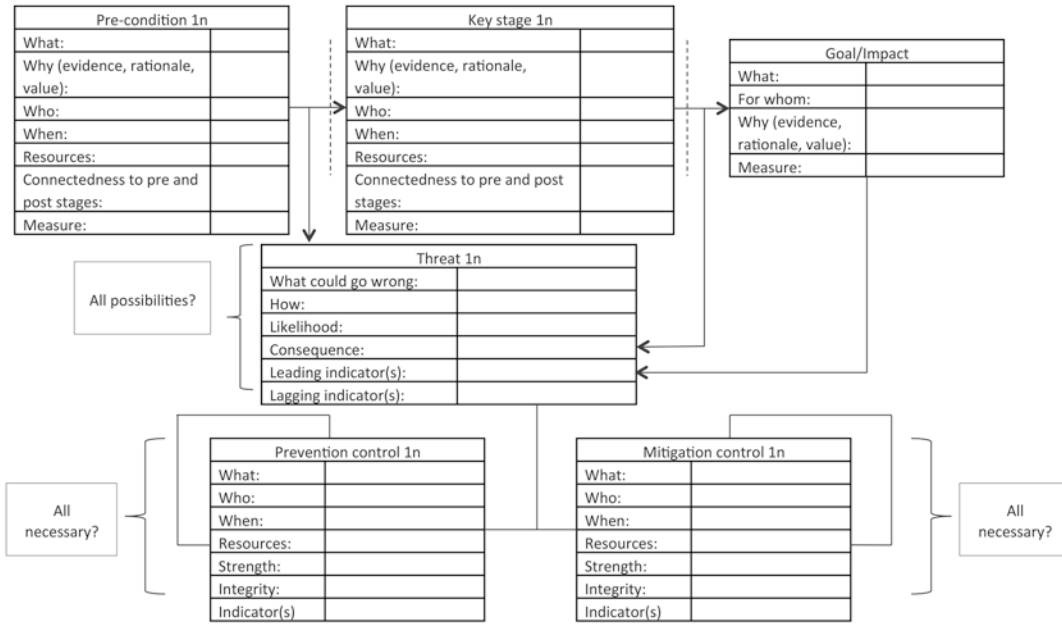

Fig. 45.3 Risk-based process mapping

reflection process to learn from their experiences. By undergoing accreditation, organizations have multiple opportunities to learn from experience and influence positive change; the challenge is identifying these learning opportunities and ensuring their effective implementation.

Accreditation is not and should never be a one-off process that organizations only engage with in the run up to and during the actual accreditation visit. The evidence shows that these types of accreditation approaches rarely if ever lead to lasting change in quality, outcomes or value [21]. Accreditation must be viewed as a continual learning process taking place at every level of the organization and supported by the accreditation journey. All accreditation programs have two key stages: preparation and accreditation. The first covers the key actions that an organization should undertake before an accreditation visit—Table 45.5.

The second stage, the accreditation process itself, varies from program to program, and normally includes the requirement for an on-site visit. This will be followed by either an accreditation award or the need to implement improvement actions prior to accreditation being awarded. Organizations that achieve accredited status may then be required to undergo periodic visits prior to a full re-accreditation visit. The nature and timing of these visits again varies extensively between programs but all will require a full re-accreditation visit 2, 3 or even 4 years after the initial visit.

A good accreditation program will not require an organization to develop systems that are not already required by law, professional guidelines, etc. They serve rather as a framework within which organizations can guide, co-ordinate and implement their quality and safety improvement activities. Unfortunately, in the years between initial and re-accreditation visits, many organizations focus on other priorities and let their attention drift from the accreditation requirements. By drifting from the accreditation program organizations also find that their quality and safety improvement activities also drift and have highly variable outcomes.

Table 45.5 Actions to undertake prior to an accreditation visit

Key actions:
• Understanding the accreditation program and standards/requirements;
• Establishing governance arrangements for the accreditation;
• Pulling together and briefing a team;
• Identifying what help is available from the accreditation body;
• Conducting a self-assessment;
• Producing an action plan with clear roles and responsibilities;
• Implementing the action plan and reviewing progress.

So how do organizations ensure continual buy-in to an accreditation program and use it as an on-going performance improvement tool?

There are several key factors to be considered:

1. *Selection of the right accreditation program* is crucial. Accrediting organizations must have a clear remit and that must be understood by the organization being accredited. The accreditation program itself should include a requirement for self-assessment and on-site visits. The length of these visits should be proportional to the size of the organization to allow adequate time to understand the organization's processes. The accreditation program must be cyclical and must be used to drive *continuous improvement* and therefore the structure and content of any program should drive this.
2. Accreditation programs *must allow for improvement action* to be taken when a problem is identified. There is much merit in having an improvement process to enable organizations with identified problems the opportunity to put into place improvement actions. The process should not end with the production of the action plan but must involve review of plan implementation and follow up by the accreditation agency. Reports on accreditation outcomes must be shared with staff and the organizations so that they have a clear action plan to work from.
3. The team sent to audit an organization must have experience and deep domain knowledge the organization's field. They needs to understand how clinical teams work, how to assess

and capture optimal team performance designed around surgical microsystem system properties [45, 46]. This will help to ensure understanding of the organization and buy-in from those that they are auditing. The provision of support in the form of education and guidance is essential for organizations going through accreditation. Accreditation programs need to be conceptual with guidance on practical implementation.

4. Senior managers must however ensure that the mark of success of any accreditation program is not merely the achievement of an award, but the *learning and improvement opportunities associated with accreditation*. The way in which senior managers engage with clinicians and hospital staff and promote the accreditation program will have a direct effect on the program and quality improvement. Without senior management buy in and support it is unlikely that staff will wholly commit to, and engage with the process and opportunities for improvement may be lost [47]. Senior managers who react positively to the accreditation process and proactively respond to improvement recommendations will demonstrate to staff that accreditation can be used as a learning opportunity rather than as a "stick to beat" the organization [48].
5. *Authentic communication* within organizations and the establishment of multidisciplinary teams, in which clinicians actively participate, are also essential. Clinicians may be reluctant to participate in accreditation programs if the lack of transparency and their lack of awareness of what the program is trying to achieve or if they have little or no input to the preparation process [49]. Gaining their input to resultant quality improvement activities will therefore be challenging. Nominating clinical leads, developing communication plans and sharing knowledge within teams will all help with learning.
6. Finally, it is vital that organizations *set realistic expectations*. Accreditation milestones and deliverables should be established at the outset and actively discussed and agreed upon. These should not impose unrealistic expectations on staff and should allow time for improvement actions. Any improvement work should be based on standard quality improvement methodology such as "Plan, Do, Study, Act" to ensure that improvement actions are embedded within the organization [50].

Does Accreditation and Certification Make a Difference?

Accreditation and certification have been proposed as interventions to support patient safety and high quality health care. Guidelines recommend accreditation but are cautious about the evidence, judged as inconclusive. The push for accreditation continues despite sparse evidence to support its efficiency or effectiveness. Greenfield and Braithwaite identified the effects of accreditation on promoting change and professional development, indicating that the effects were probably due to accreditation and certification, but lacking firm evidence [51]. A systematic review by Nicklin et al. [52] found several positive benefits of accreditation; however, the study lacked rigor to support their conclusions. Shaw et al. [53] found evidence for positive effects between accreditation, certification and clinical leadership, systems for patient safety and clinical review, but was fell short of endorsing accreditation, and concluded with recommending further analysis to explore the association of accreditation and certification with clinical outcomes. Furthermore, Ho et al. [54] have demonstrated an unintended negative impact on the learning environment of medical students and trainees, including decreased clinical learning opportunities, increased non-clinical workload, and violation of professional integrity in preparation and during accreditation and certification.

A recent extensive meta-analysis literature review [21] uncovered three systematic reviews and one randomized controlled trial. The lone study assessed the effects of accreditation on hospital outcomes and reported inconsistent results from one controlled study, the randomized trial from South Africa from 2003. The study [55], however, is weak scientifically, and does not address morbidity or patient safety

measures well enough to support any conclusions across a wide range of safety systems examined.

The methodological challenges of measuring the effects of accreditation/certification are increased by the complexity of the hospital organizations and their heterogeneous components. Lessons can be learned from non-controlled studies such as cross-sectional studies [56]. Comparison between accredited and non-accredited hospitals yields important information about potential differences between these hospitals, but cannot provide information about the observed variations, and whether the results are transferable to other settings.

The review by Brubakk et al. [21] provides a comprehensive overview of the effects of accreditation and/or certification of hospitals on quality and patient safety outcomes and concludes that due to scant evidence, no conclusions could be reached to support its effectiveness. Accreditation programs require substantial financial and labor investments, and distract health care teams from their primary clinical goals. Accordingly further research about the clinical impact of these programs is needed, and it is important to weigh the transactional opportunity and financial costs of accreditation against other financial investments in quality improvement interventions.

Before planning further studies to evaluate impact of accreditation and certification efforts, a more thorough and nuanced analysis of the available evidence about which components of accreditation/certification seem to be most effective in enabling patient centered, high quality and safer outcomes should be performed [57]. These conclusions need to be considered given the impact of how accreditation is managed and executed, and the varied political, financial and organizational macro- and meso-health care constraints [58].

How Best to Prepare for Accreditation Visit?

Accreditation typically occurs over a 3-year cycle—Fig. 45.4. During the accreditation assessment, assessors are looking for evidence of effective risk assessment and controls. Where these are absent or inadequate the assessors will identify them as non-conformities to enable the organization to take corrective actions prior to reassessment. It should not be seen as a one-off event or as an end in itself. Rather it is a continuous process that provides a structure for organizations to manage their risks, improve the quality of their services and to realize the benefits outlined in Table 45.6. A health care organization can prepare for an accreditation visit be following the steps in Table 45.7. Ideally and learning from other high risk domains, healthcare accreditation will be a continuous process of assessment and learning akin to high reliable nuclear power, aviation and maritime industries [36, 59].

Conclusions

Accreditation continues to grow internationally despite inconclusive evidence to support its effectiveness. The surgical space, by nature, is a high-risk hypercomplex environment where hazards lurk around every corner and for every patient. Health care institutions continue to face challenges in providing safe patient care in increasingly complex and demanding technical, organizational, and regulatory environments. Real, sustainable change comes from the organizations and hardworking staff that deliver care to patients. It is odd that something so important and personal as health care does not have widely acknowledged or adopted "industry standards" of inspection, reporting, and improvement.

Both high reliability theory and systems theory provide conceptual and practical frameworks for supporting accreditation driven approaches towards delivering safe and reliable care. Although many ambiguities and conflicts arise from the implementation of these theoretic constructs, they should guide the development of work processes and stimulate innovation in designing ways to provide safe and effective care within health care systems. Organizing surgical care around the pursuit of safety and reliability as an overarching priority is a professional obligation for all members of the health care team. This goal can be accomplished by organizing around and shaping a culture focused on reliable performance but requires substantial investments in human capital.

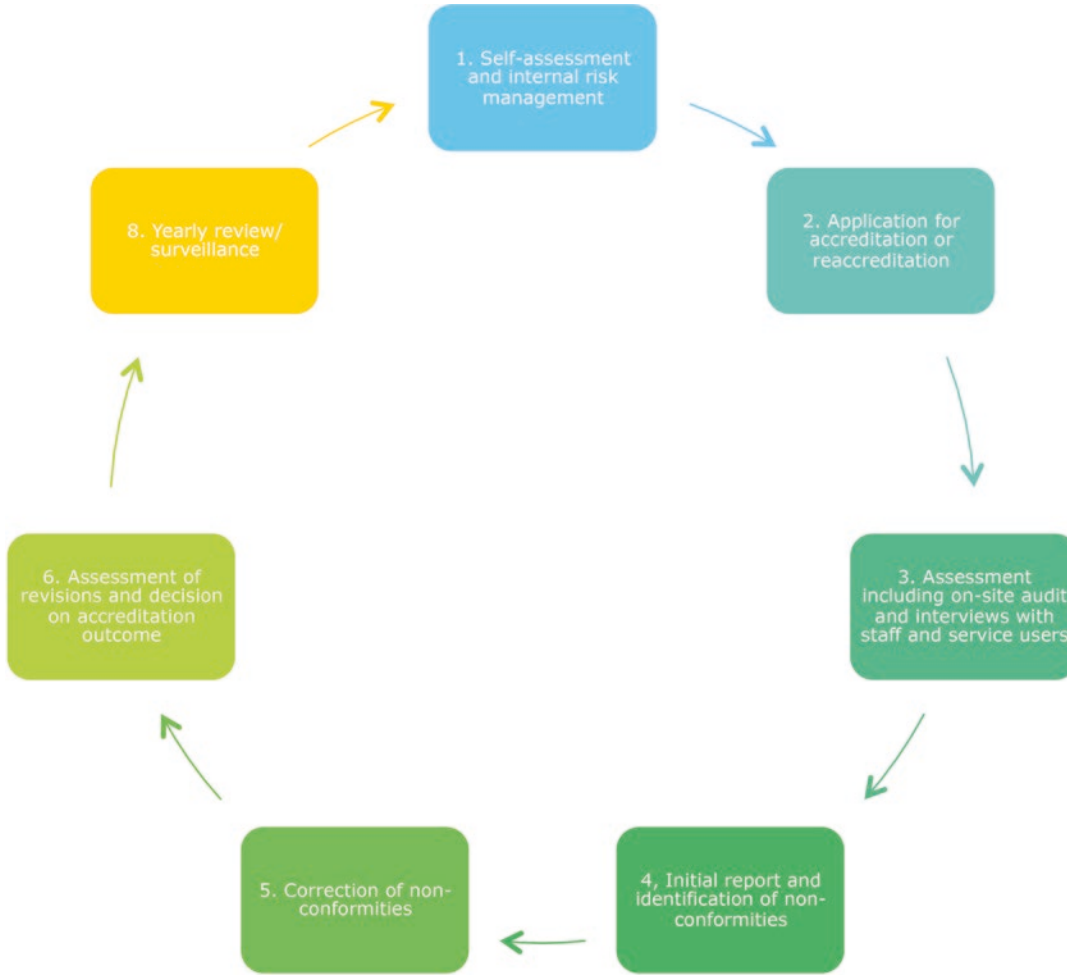

Fig. 45.4 Virtuous and continuous accreditation cycle

Table 45.6 The benefits of accreditation for an organization

Positive impact	Evidence
Improved organization and coordination	?????
More systematic management practice	????
Improved professional practice and compliance with expected standards of care	???
Compliance with QI mechanisms and achievement of other quality indicators	?
Perception amongst health professionals	?

Greenfield D, Braithwaite J. Health sector accreditation research: a systematic review. Int J Qual Health Care. 2008;20(3):172–83

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Table 45.7 Steps to prepare for an accreditation visit

1. Form team	(a) Designate responsibilities for ensuring that preparatory work is addressed and that all staff within the organization understand and own the accreditation process
2. Review previous survey results where they exist	(a) Ensure previous requirements/non-conformities have been addressed and action plans implemented
3. Complete a self-assessment within units and across the organization	(a) Survey or interview key stakeholders (leadership/management staff, clinicians, support and ancillary staff, patients and carers, representatives from organizations that connect along care pathways) (b) Observe practice—use tracer methodologies to follow patients along pathways and processes to identify if appropriate controls are in place and working (Fig. 46.3)
4. Identify areas for improvement	(a) Based on the self assessment identify and share strengths and weaknesses (b) In DNV GL's Standards, areas for improvement are categorized as: 1. Non-conformities Category 1 (Major): i. An absence of one or more required system elements or a situation which raises significant doubt that the services will meet specified requirements ii. A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to a requirement of the standard iii. A category 2 non-conformity that is persistent (or not corrected as agreed by the hospital) shall be up-graded to category 1 iv. A situation that on the basis of available objective evidence may directly lead to unacceptable risk of patient harm or does not meet minimum standards of care 2. Non-conformities Category 2 (Minor): i. The hospital has a lapse of either discipline or control during the implementation of system/procedural requirements but which does not indicate a system breakdown or raise doubt that services will meet requirements 3. Observations: i. An observation is not a non-conformity, but something that could lead to a non-conformity if allowed to continue uncorrected 4. Opportunities for improvement: i. An opportunity for improvement relates to areas and/or processes of the hospital which may meet the minimum requirements for accreditation but which could be improved to reach best practice
5. Develop action plans to address areas for improvement	(a) Engage stakeholders for each area of improvement and create a specific, measurable, achievable, relevant and time-bounded action plan that should address: 1. What needs to be changed 2. Why 3. How it will be changed (the steps to be taken) 4. Who will be responsible 5. When the change should be completed 6. The measures that will be used to show that the change has been implemented, is having the desired effect (or not) and that the change can be sustained over time
6. Implement action plans to deliver necessary improvements	(a) Use the Plan, Do, Study, Act cycle of improvement to implement, revise and sustain change

(continued)

Table 45.7 (continued)

7. Prepare for the site visit by the accreditation audit team	(a) Keep in mind that the value of accreditation is in helping your organization to improve by providing an independent, structured, constructively critical review of your pathways and processes. It will only deliver this value if you and the staff within your organization are committed to accreditation as a learning opportunity and are honest with the accrediting body as to your strengths and weaknesses. To this end, organizations should have in place mechanisms to ensure that staff and service users are able to share openly their experiences of what works and what does not. (b) The emphasis of the accreditation visit will be on observing practice in real-time—how patients are treated and processes put into practice. To support this, the auditors will need access to supporting documentation that shows how the hospital is organized, how care is delivered and how care ought to be delivered according to the hospital's own polices and procedures. You should typically expect to provide the audit team with: 1. Organizational charts for the organization as a whole and broken down by service areas 2. A map showing the locations of patient care and treatment and other services 3. A list of current in-patients with room number, age, diagnosis, attending physician, primary nurse, admission date and any other significant information 4. Patient census for the last 12 months including patient acuity/case mix 5. Current surgical schedule where applicable 6. Most recent accreditation and/or ISO certification where applicable 7. Bylaws of the Governing Body 8. Minutes of the Government Body 9. Medical staffing bylaws, rules and regulations 10. Minutes of the Medical Executive Committee 11. Organizational plan for patient care/scope of service for each department and patient care unit 12. Terms of reference for the Quality Oversight/Management Review Committee 13. Minutes of the Quality Oversight/Management Review Committee—including performance improvement data for the last 12 months, complaints data for the last 12 months (showing complaints received and response), incident data for the last 12 months (showing incidents reported and response), root cause analysis for the last 12 months 14. Minutes from Environment of Care/Safety Committee 15. Risk management policy and procedures 16. Risk assessment—organizational wide and unit specific as applicable including risk management plan 17. Management plans for the physical environment and annual evaluations 18. List of contracted services, companies and individuals—surveyors will select a sample for review 19. List of other organizations with whom you share care for patients (including organizations that refer patients and accept patients on discharge)—surveyors will select a sample to contact for feedback 20. Nursing service plan of administrative authority/delineation of responsibilities for delivery of patient care 21. Infection Control Plan with risk assessment/hazard vulnerability analysis 22. List of employees including name, title, unit, and hire date 23. Skill mix of staff 24. List of current patients who have had restraint (chemical or physical) or seclusion used during hospitalization 25. List of patients discharged with the past 6 months who had restraint (chemical or physical) or seclusion used violent or self-destructive behavior during their hospitalization 26. Policies and Procedures, typically including but not necessarily limited to: i. Autopsies ii. Blood and Blood Product Administration iii. History and Physical Examination iv. Informed Consent v. Medication Security vi. Moderate Sedation

8. Site visit by audit team	vii. Patient Assessment (Nursing, respiratory, nutritional services, etc.) viii. Pain Management ix. Patient Care Planning/Interdisciplinary Treatment Plan x. Patient Grievance xi. Procedural Verification Process (Practices ensuring the correct patient, site & procedure) xii. Restraint or Seclusion xiii. Verbal/Telephone Orders (a) The audit team will focus on reviewing how care and other processes are delivered in real-time. To do this, you will need to: 1. Receive the audit team and show them around the premises 2. Provide the audit team with a dedicated room that they can use for the duration of their visit 3. Present a summary of your services and be prepared to answer questions on recent, current and foreseen threats to quality 4. Provide the audit team with access to the resources outlined in step 7 as well as access to patient records to enable them to use the tracer methodology in following patients through their care pathways 5. Provide the audit team with access to staff and, through clinical staff, access to patients and their families to interview and follow 6. Provide the audit team with access to telephone numbers and contact details so that they can follow-up with contractors, partner organizations and former patients and their families
9. After the site visit	(a) Review the audit report, which will outline the findings including whether or not the organization has reached the necessary standard for accreditation or if corrective actions are needed before additional assessment (b) Where a corrective action plan is needed your organization will typically have 30 days from receipt of the audit report to submit their action plan to the accrediting body for review (c) The corrective action plan should address: 1. Each of the specific unmet elements in turn 2. A full explanation of the actions take to address the unmet elements 3. When the actions were completed 4. The impact of the actions including how they will be maintained 5. Measurement criteria and methods that are in place to monitor the elements (d) Moving forward, your organization should use the standards you are assessed against as a way to make risk management and quality improvement a continuous process. The standards reflect best practice in health care quality and patient safety and should be part of every employees day to day work—incorporated into their unit and personal objectives

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The Perioperative Surgical Home: The New Frontier

46

Juhan Paiste, Daniel I. Chu, and Thomas R. Vetter

"First comes thought; then organization of that thought, into ideas and plans; then transformation of those plans into reality. The beginning, as you will observe, is in your imagination."

—Napoleon Hill, 1883–1970

Introduction

The Perioperative Surgical Home has been promoted as a novel, clinician-championed yet institution-supported, well-coordinated and very patient-centered, interdisciplinary model of care. The highly *collaborative* Perioperative Surgical Home more consistently and effectively guides the patient through the entire surgical continuum, from the initial decision to undergo surgery to the post-hospital discharge and rehabilitation phase [1, 2].

Berwick, Nolan, and Whittington, along with the Institute for Healthcare Improvement (IHI), have promulgated the "Triple Aim" of health care reform, which is comprised of three interdependent goals: (1) improving the individual experience of care, (2) improving the health of populations, and (3) reducing per capita costs of health care [3, 4]. The Perioperative Surgical Home, using rigorous standardization and integration of care, can achieve the IHI Triple Aim for the *surgical population*, by optimizing quality, safety, and satisfaction while decreasing costs—thereby adding measurable *value* to the highest cost segment of health care [5].

Because of its intentionally broad initial definition, and its equally broad array of stakeholders, there will undoubtedly be multiple effective variants of the Perioperative Surgical Home, based upon institutional infrastructure and resources, as well as internal and external economic and political forces [6]. The Perioperative Surgical Home can also be conceptualized as an umbrella, under which its variants or components are positioned. These include service line or procedure-specific integrated care pathways, Enhanced Recovery After Surgery protocols (see Chap. 23), and Perioperative Risk Optimization and Planning Tools (Fig. 46.1).

Integrated care pathways are rigorously standardized, task-orientated care plans that detail *all* the essential steps or elements in the care of *all* patients undergoing a *specific* surgical procedure [7]. Integrated care pathways (for coronary artery bypass graft surgery, chest pain, etc.) link evidence to practice to optimize clinical outcomes while maximizing clinical efficiency [8, 9].

Enhanced Recovery After Surgery (ERAS®) is an evidence-based, fast-track approach to surgery (e.g., colorectal), which relies upon perioperative

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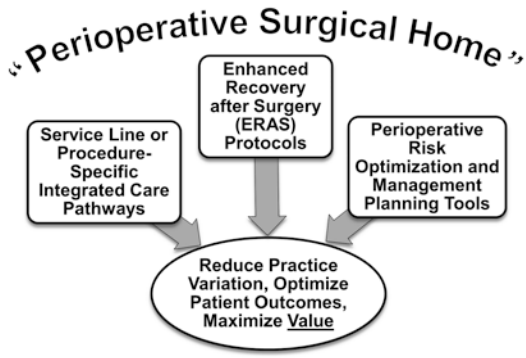

Fig. 46.1 The Perioperative Surgical Home conceptualized as an umbrella, under which its variants or components are positioned

care protocols designed to attenuate the stress response during the entire perioperative period, so as to facilitate the maintenance of bodily composition and organ function, and in doing so to achieve *early recovery* [10–12].

A Perioperative Risk Optimization and Planning Tool (PROMPT™) amalgamates the evolving published evidence with equally valued local clinicians' expertise, to arrive at consensus, thereby increasing the applicability and acceptance of the resulting condition-specific, *decision support tool* [5]. A PROMPT™ is not a static document but instead is subject to an iterative series of Plan-Do-Study-Act (PDSA) cycles, which incorporate newly published evidence, concurrent institutional-level outcomes data, and continued local clinician innovations and feedback [5, 13, 14].

Globally, increasing health care costs are consuming a larger and disproportionate share of national budgets [15]. This has resulted in strategies being implemented to control health care delivery costs, through the more efficient use of health care resources, not only in the USA but also in Canada, England, France, and Germany [15]. In England, recent reductions in health care expenditure (i.e., budget cuts) have also included decreasing the rate of certain surgical procedures, deemed to be ineffective, overused, or inappropriate [16]. Efforts are likewise underway in the USA and several other member countries of the Organization for Economic Cooperation and Development (OECD) to implement value-based cost sharing, whereby patients are encouraged to use providers, health care services and delivery systems, and medications, which offer better value than other available options [17].

The chapter first frames the Perioperative Surgical Home as a value-based proposition. After providing a definition and an inventory of the drivers of health care value, specifically in the USA as a representative developed country, this discussion focuses on the fundamental determinants of value, namely, appropriate care and quality, safety, satisfaction, and cost. It concludes with a brief review of the literature supporting the effectiveness and implementation of a Perioperative Surgical Home model [18].

The Perioperative Surgical Home as a Value-Based Proposition

Expanded health insurance coverage under the 2010 Patient Protection and Affordable Care Act, more robust economic growth, and an aging population (the "Silver Tsunami") are expected to result in a continued greater demand for health care goods and services in the USA. Thus by 2023, a projected 19.3 % of the USA gross domestic product will be spent on health care [19]. Furthermore, surgical care currently accounts for an estimated 52 % of hospital admission expenses in the USA [20]. Fragmentation and inefficiency in surgical care delivery, defensive medicine, discordant incentives between stakeholders who deliver versus those who pay for this care, and a lack of emphasis on *value* are contributing to excessive surgical harm and expenditures [21, 22].

Leading health economist, Michael Porter, has asked the fundamental question, "What is value in health care?"—defined it as the ratio of health outcomes achieved per dollar spent [23, 24]. However, Porter observed that value in health care remains largely unmeasured and misunderstood, partly because its "stakeholders have myriad, often conflicting goals, including access to services, profitability, high quality, cost containment, safety, convenience, patient-centeredness, and satisfaction" [23]. Therefore, despite the current contentious

health care environment, all stakeholders must embrace a *value-based* framework, given its unifying primary goal of improving outcomes while doing so as efficiently as possible [25].

Like the Patient-Centered Medical Home [26], upon which it was patterned [2], the Perioperative Surgical Home essentially seeks "to improve value for patients, where value is [specifically] defined as *patient outcomes* achieved relative to the amount of money spent" [27]. This basic quotient translates into a health care value equation (Fig. 46.2) that is applicable to the Perioperative Surgical Home, whose numerator includes perioperative quality, safety, and satisfaction and whose denominator is the total costs of perioperative care [13].

Rather than continuing to reward the volume regardless of quality of care delivered, the goal of the Department of Health and Human Services is to increase the proportion of Medicare value-based purchasing from 30% by the end of 2016 and to 50% by the end 2018 [28, 29]. The Health Care Transformation Task Force, a new coalition of the country's largest health care systems and commercial insurers, is similarly committed to transitioning the way providers and hospitals are paid from the traditional volume-based, fee-for-service contracts to one predominately linked to the patient centered value of care. This task force is committed to shifting 75% of non-governmental health care payments to value-based arrangements by 2020 [30].

There are a number of drivers of health care value, which collectively represent a "burning platform" that will necessitate a fundamental change—a "New Frontier"—in perioperative care delivery and payment models in the USA, all being closely watched by many health care systems internationally (Fig. 46.3) [13]. Likely the most pressing of these drivers of perioperative health care value is the Bundled Payment Initiative for Care Improvement (BPCI) [13]. The BPCI has been introduced by the Centers for Medicare and Medicaid Services (CMS) to break existing health care system silos down and to improve patient care through innovated payment models that promote coordination of care and quality through a more patient-centered approach [31, 32]. Under the initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care.

In Model 4 (final phase of its BPCI), "CMS makes a single, prospectively determined bundled payment to the hospital that encompasses all services furnished by the hospital, physicians, and other practitioners during the episode of care, which lasts the entire inpatient stay. Physicians and other practitioners submit "no-pay" claims to Medicare and are paid by the hospital out of the bundled payment" [32, 33]. On April 1st, 2016 CMS started the Comprehensive Care for Joint Replacement (CJR) model, which will hold hospitals accountable for the quality of care they deliver to Medicare fee-for-service beneficiaries for hip and knee replacements. Through this payment model, hospitals in 67 geographic areas will receive additional payments if quality and spending performance are strong or, if not, potentially have to repay Medicare for a portion of the spending for care surrounding a lower extremity joint replacement procedure.

The Perioperative Surgical Home care model can respond successfully to such bundled payments where historically, hospitals, surgeons and other physicians, and post-acute care providers have been paid separately for services occurring during and after hospital admissions.

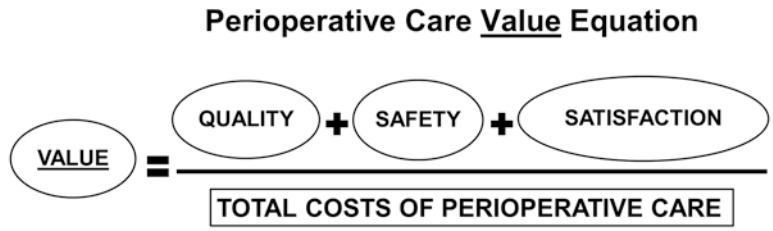

Fig. 46.2 The health care value equation applicable to the Perioperative Surgical Home

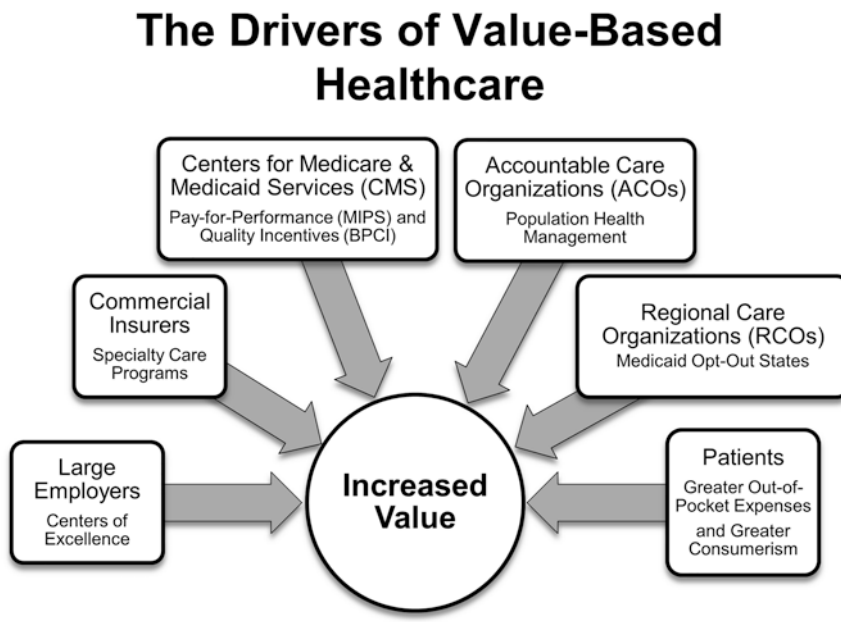

Fig. 46.3 The drivers of health care value necessitating a fundamental change—a "New Frontier"—in perioperative care delivery and payment models in the USA

Quality

Quality in health care describes the extent to which health services provided to individual patients and patient populations improve desired health outcomes and are consistent with the current body of knowledge [34]. In 2001, the Institute of Medicine (IOM) defined quality health care as "safe, effective, patient-centered, timely, efficient and equitable" [35]. The Agency for Healthcare Research and Quality (AHRQ) defined quality simply "as doing the right thing for the right patient, at the right time, in the right way to achieve the best possible results" [36]. While significant strides in quality have been made in the last century, "doing the right thing" is no longer expected to just improve traditional metrics, such as mortality, but to also improve patient-centered metrics such as health-related quality of life and patient-reported outcomes. These new challenges of the modern era necessitate more resourceful approaches for continued improvement in health care. As a more comprehensive yet integrated, value-based, and patient-centered model, the Perioperative Surgical Home is *anticipated* to provide a modern framework to achieve these goals.

Many of the continued challenges in achieving high quality care arise from the underuse, misuse, and overuse of health services, including surgery [37, 38]. Variations in these practice patterns can lead to undesired measures of quality, including increased mortality, morbidities, lengths-of-stay, readmissions, and cost [39, 40]. Modern efforts in quality improvement (QI) focus on minimizing variations in care by using best-available evidence to standardize care pathways for patients. Successful results from standardizations of care have been repeatedly demonstrated in disciplines ranging from cancer care [41] and geriatrics [42] to obstetrics [43] and outpatient ambulatory medicine [44]. Surgical patients are particularly amenable to QI efforts as these patients require complex care in a surgical microsystem defined by multiple providers in varying environments, and attendant quality metrics are readily measurable [45]. A deliberate method in standardizing the continuum of care for the surgical population and reliably measuring its outcomes has the potential to achieve significant, far-reaching gains in quality of care and health outcomes [46].

The Perioperative Surgical Home aims to improve quality by standardizing patient care in every phase of the perioperative continuum. While the Perioperative Surgical Home is a relatively new concept and direct practical examples are limited, evidence from the Patient-Centered Medical Home [47] and Enhanced Recovery After Surgery (ERAS) pathways [48, 49] demonstrate that standardization of care can positively impact quality with significant reductions in length-of-stay, readmissions, morbidities, and cost. Standardization studies have also demonstrated significant gains in less-traditional, but equally if not more important, quality metrics including short-term quality-of-life [50], reduced patient readmission [51] and other health-related quality measures [52]. These studies suggest that high-quality care in the modern era is best achieved not by the lone practitioner at a single patient encounter but by a cross-disciplinary, collaborative, and consistent delivery of care by all stakeholders across the entire patient experience [53].

The development and implementation of the Perioperative Surgical Home is gaining momentum, and studies of individual elements of the Perioperative Surgical Home show promising results in supporting their effectiveness in improving many measures of quality [54]. The organization of these elements under one comprehensive system produces a powerful construct that may gain more in quality than any one component by itself. Recently, the Perioperative Surgical Home has been successfully implemented in the Veteran Health Administration (VHA) with positive, collaborative effects on health care delivery at a single institution [55]. These results parallel the well-recognized effects of the Patient-Centered Medical Home on quality improvement in both patient and provider-centered measures of quality [47].

While the definitions and measures of quality will undoubtedly continue to grow, the Perioperative Surgical Home *appears* well-positioned to facilitate patient engagement through preoperative risk optimization of chronic diseases management, patient education and post-acute care coordination—all *anticipated* to improve outcomes and overall quality of care.

Importantly, this engagement provides a unique and meaningful opportunity for stakeholders to address other top priority issues in health care such as health-related disparities and patient safety. Disparities, as an example, are caused by a confluence of patient, provider, and systemic factors [56] and the ability to detect, understand and reduce health-related disparities requires a comprehensive approach. Factors such as poor health literacy and inconsistent patient–provider communication [57] contribute to disparities and could be better targeted with more patient-centered, standardized delivery of care as championed by the Perioperative Surgical Home. While future studies will begin validating its positive effects on traditional quality metrics, the Perioperative Surgical Home is positioned to make its most groundbreaking impact on adjoining, quality-associated frontiers such as health-related disparities and patient–provider communication.

Patient Safety

Patient safety is the foundation upon which quality care is based [35], and both concepts are inextricably linked when building a trustworthy health care delivery system. While the definition of patient safety is constantly evolving, the World Health Organization (WHO) defines patient safety as the "prevention of errors and adverse effects to patients associated with health care" [58]. The Institute of Medicine (IOM) considers patient safety "indistinguishable from the delivery of quality health care" [59]. Effecting changes in quality therefore has repercussions on patient safety. The Perioperative Surgical Home aims to provide not only the highest quality of care but also the greatest level of patient safety by comprehensively standardizing perioperative processes based on the best clinical care and safety practices.

Improving patient safety is an international priority. The landmark 1999 IOM report "To Err is Human" estimated that as many as 98,000 people die every year from preventable medical errors that occur in hospitals [60]. These examples include wrong-site surgeries, hospital-acquired

infections, and adverse drug events [61]. The 1999 IOM report sparked a remarkable series of events, including Senate bill 580 (Healthcare Research and Quality Act of 1999) that renamed the Agency for Health Care Policy and Research to the Agency for Healthcare Research and Quality (AHRQ). In 2004, the Institute for Healthcare Improvement (IHI) implemented the "100,000 Lives Campaign" with the goal of saving 100,000 lives by challenging hospitals to improve health care quality and patient safety through six goals: develop rapid response teams, provide evidence-based care for acute myocardial infarctions, prevent adverse drug events, administer appropriate perioperative antibiotics, and use central line and ventilator bundles [62]. While this campaign succeeded in catalyzing institutions to focus on patient safety, significant variations in institutional effort and heterogeneous results suggested that there was a need for more comprehensive, reproducible, and effective safety strategies that targeted how best to implement these solutions while addressing the barriers to uptake and behavior change.

The complex nature of modern health care invites errors to occur, and efforts to mitigate these risks require innovative approaches. The 2007 Joint Commission's Annual Report on Quality and Safety identified significant determinants of errors and reported that inadequate communication was the most common root cause of sentinel events from 1995 to 2005 [63]. Additional causes of medical errors included inadequacies in patient assessments, organizational culture, care planning, continuum of care, and training. Few would refute that better communication and coordination of care can improve patient safety and resultant health outcomes. While the direct effects of the Perioperative Surgical Home on patient safety have yet to be fully validated or realized, studies have consistently demonstrated that standardization of care, from patient hand-offs [64] and preoperative surgical checklists [65] to insulin regimens [66, 67], leads to higher levels of patient safety [68]. Models like ERAS and the Patient-Centered Medical Home have also suggested that the delivery of consistent care and communication across the entire care continuum improves both safety and quality [47–49]. Reducing variability in health care structures and processes, which is a principle goal of the Perioperative Surgical Home, may therefore provide the greatest gain in patient safety and related quality.

As the discipline of safety science continues to evolve, our ability to identify, understand and reduce harm necessitates innovative strategies [69]. The Perioperative Surgical Home provides the platform to engage and target key determinants of patient safety at all points of care from the preoperative assessment to the postoperative debriefing and hospital stay. The Perioperative Surgical Home is furthermore aligned with the central tenet of patient safety which posits that systemic change is far more productive in reducing medical harm than targeting individuals. Exacting these changes in the perioperative continuum alters habits and expectations for all stakeholders, from patients to providers, and allows the Perioperative Surgical Home to change not only our perspective towards safety but also the culture in providing the safest and reliable care for all surgical patients.

Patient Satisfaction

Patient satisfaction has garnered greater attention as a metric of health care provider performance and an important dimension of value-based health care. While defined in a number of ways, patient satisfaction is now publicly reported to help patients choose more discernibly among available providers [13, 70].

There are numerous demonstrated benefits to keeping patients satisfied [71]. Satisfied patients are more likely to adhere to prescribed treatment plans, to maintain an ongoing relationship with a health care provider, and to realize subsequent benefits related to health care outcomes [72]. Providers' interests are also well served by satisfied patients, as they may realize increased patient volume, an enhanced community reputation, reduced malpractice claims, more satisfied staff, decreased staff turnover, and improved efficiency [72].

Patient satisfaction is widely recognized to be multidimensional and highly personalized, but at

its core is based upon delivering patient-centered care [73]. Research shows that how patients perceive their health care experience reflects sociodemographic characteristics, such as education level, age, race/ethnicity, income, and health status [74]. Studies have observed that patients with younger age, better health, higher income, and greater education tend to be less satisfied as compared to the older patients and those who are sicker or have a lower socioeconomic status [75–77]. However, it is no longer enough for patients to be merely satisfied with their health care [78]. Patients' expectations and perceptions of their experience may vary widely, but ultimately, they seek health care that is patient-centered and yields the outcomes that they value and thus expect most [79].

Although patient-centered care and patient satisfaction have been the central focus, there has been inadequate attention paid to surgeon and other providers satisfaction [80]. It is well known that surgical services (the operating rooms) drive hospital financial performance. The contribution margins per hour of OR time, although rather variable, can reach up to $2500.00 [81, 82]. Due to this significant financial impact, effective and efficient operating room utilization is paramount not only to surgeons but to all stakeholders.

The Perioperative Surgical Home supports multispecialty teams that design and implement patient-centered, data-driven, surgical service-specific workflow processes, starting from when the decision for surgery is made. These processes include comprehensive preoperative patient preparation, intraoperative management, and postoperative care. Surgical service-specific teams develop standardized care and workflow plans to address (a) all components of the preoperative assessment and optimization; (b) all intraoperative elements of the "day of surgery" patient encounter and experience; and (c) all postoperative care, starting with minimizing postoperative nausea and vomiting and pain in post-anesthesia care unit (PACU) and ending with long-term plans for rehabilitation. Standardized care plans are based on evidence-based-medicine, but take into consideration institutional and surgical procedure, and local surgical team-specific variations.

The Perioperative Surgical Home seeks to improve patient satisfaction, by promoting shared decision-making, earlier and greater engagement in patient education and preoperative optimization, standardized and thus likely better pain and postoperative nausea/vomiting management, shortened stay in hospital and ultimately, improved outcomes and experience with the total care episode [83]. From the surgeon's prospective, the Perioperative Surgical Home seeks to improve satisfaction by creating more efficient operating room scheduling and patient throughput. The sustained success of these operational changes must be based upon data (e.g., key performance indicators) and preferably confirmed using "Six Sigma" or "Lean" methodologies. Appropriate patient preoperative optimization decreases delays and cancellations on the day of surgery, assuring that surgeons are able to use their operating room (OR) block time with maximum efficiency. Finally, patients satisfied with their care are less likely to initiate malpractice claims and are the best advocates to endorse their physicians [54].

Cost

The health care value equation for the Perioperative Surgical Home cannot be defined without including the costs associated with the optimal care in the equation. The Healthcare Cost and Utilization Project estimates that about 15 million hospital stays each year involve an operating room (OR) procedure and these hospital stays are 2.5 times more expensive than admissions without an OR procedure [84]. The OR is a significant cost center and revenue generator for the hospital. The majority of costs associated with surgery are incurred on the day of surgery. The economic definition of cost is the value of opportunity forgone as a result of engaging resources in an activity. From the health care providers' prospective, there are four basic reasons to measure costs: (a) to make economic decisions for resource allocation; (b) as justification for reimbursement; (c) to encourage or discourage use of services; and, (d) for income and asset measurement for external parties [85]. However, the reality in health care is that measurement of these economic variables has been

extraordinarily challenging and controversial. Lead health economists have observed, "an almost complete lack of understanding of how much it costs to deliver patient care" [86].

From payers' perspective, the "unit" of cost is the price paid for each unit of service multiplied by the frequency of services. The mix of services, and the variation in price per unit paid to different providers, makes it difficult to assemble the reasonable cost of providing care for an individual plan member for a specific procedure. All above makes it difficult for consumers, employers, and health plans to understand and agree on the total price paid for an episode of care and to transparently compare that price paid from one provider to another [87].

Deming wrote that you can only improve a process that you measure [88]. Information enables decision-making and, ultimately, empowers change. However, with the paradigm shifting from "fee for service" (FFS) and "Diagnoses-Related Group" (DRG) to the "accountable care organization" (ACO) model, hospital systems are faced inevitably with major adjustments to their payment system.

Hospital cost accounting software systems integration with multiple hospital information systems has enabled a bottom-up cost method otherwise known as Activity-Based Cost Accounting [85]. This method aims to establish the actual of specific resources consumed to provide each service and is presently used to price surgical services by measuring expense at the patient care level and working upward. Activity Based Costing (ABC) method maps all surgical procedure related activities, calculates the cost associated with each activity and the unit cost for each procedure. Although this approach appears to be the most accurate, it is still complex and requires tremendous resources for implementation. As cost basis is the integral component of any accountable care organization, hospital administrators are recognizing the importance of correct and timely cost accounting practices as a prerequisite to the institution financial success [89].

Health care's various stakeholders are on a quest to achieve value—which is defined as the relationship between outcome and cost or, more specifically, the health outcome per dollar expended. Our existing Fee-For-Service and DRG-based payment model does not focus on value—and for that reason is arguably unsustainable. The Perioperative Surgical Home can offer significant cost reductions by improving care coordination, minimizing unnecessary testing, consistently applying standardized best practice surgical and anesthesia care pathways, decreasing length of stay in the hospital and ultimately improving patient outcomes and satisfaction with care [54].

Evidence to Support the Perioperative Surgical Home

In an effort to analyze the evolution of the elements of the Perioperative Surgical Home and similar care models, in the USA and other countries, researchers from Texas A&M University and the American Society of Anesthesiologists performed a comprehensive systematic review of 152 studies published between 1980 and 2013 [54]. They summarized the published findings related to (a) clinical outcomes and (b) cost and efficiency, in a variety of preoperative, intraoperative, or postoperative settings. The studies predominantly reported positive quality and cost outcomes across the perioperative continuum (Table 46.1). These authors concluded: "The potential for … cost savings and quality improvement is apparent across the perioperative continuum of care, especially for integrated care organizations, bundled payment, and value-based purchasing" [54].

It should be noted while the majority of these 152 identified studies reported a significant effect of a given perioperative intervention on a measured outcome, one should not equate (a) such observed statistical significance with substantial association, (b) such observed simple association with definitive causation (causality), and (c) statistical precision (i.e., small *P*-values and narrow confidence intervals) with scientific validity [90].

Table 46.1 Summary of the results of a comprehensive systematic review of 152 perioperative care-related studies that were published between 1980 and 2013 [41]

	Significantly positive clinical outcomes	Significantly positive cost and efficiency
Phase of perioperative care	Results were reported	Results were reported
Preoperative initiatives	82 %	82 %
Intraoperative Initiatives	86 %	77 %
Postoperative Initiatives	87 %	75 %

Identifying and Overcoming Barriers to Implementation

The implementation of a PSH model will be predicated on successful, often large-scale change management [13]. We have noted at our institution that an early implementation barrier can be a lack of engagement and buy-in necessary for the project's success [91]. The perspectives of the key stakeholders—surgeons, anesthesiologist, nursing, and hospital administration—are likely not innately and initially aligned. Furthermore, critical but often initially limited resources are available to collect and to report real-time data that demonstrate meaningful improvements in clinical outcomes, efficiency, safety, and patient satisfaction, thereby fostering greater buy-in and larger scale education and implementation activities [92]. Lastly, another prerequisite yet potential barrier for successful PSH implementation is development of an institutional funding mechanism to compensate providers for the value-added services rendered that will not be directly reimbursed by payers.

Engagement of every stakeholder in the change management process is paramount for success if the above and other implementation barriers are to be overcome. ERAS pathways can represent one component of an institutional PSH model. Studies of ERAS have identified many barriers to successful implementation, including the above noted resistance to change among personnel, time restrictions, limited hospital resources, lack of data, and organizational environment [93, 94]. Overcoming these barriers requires a coordinated, sustained and multipronged approach. This includes starting the focused project with one or two physician champions, working with smaller groups of highly engaged participants, in a controlled setting, seeking to secure demonstrable "early wins [80]." Many of the possible strategies are derived from other business sectors and include frameworks such as Knowledge-to-Action (KTA) and Plan-Do-Check-Act (PDCA). The KTA framework, in particular, has been used to successfully implement ERAS by McLeod et al. [93].

Using a "ground-up" approach, McLeod et al. [93] implemented ERAS in 15 provincial hospitals and found that the path to success started with the involvement of ground-level providers from the very beginning of program development (knowledge). Constant feedback and wide inclusion of stakeholders from all disciplines during program rollout (action) ensured continued buy-in and momentum in overcoming barriers. Implementation of PSH will likely face similar barriers at the patient, provider and hospital-level, but experience with ERAS suggests that with the right people, these barriers are surmountable.

Conclusions

Health care in the USA is rapidly evolving from being a volume-based to a value-based proposition. There are a number of major drivers of increased health care value, including for the surgical patient, which collectively represent a "burning platform" that will necessitate a fundamental change—a "New Frontier"—in perioperative care delivery and payment models in the USA. The highly collaborative Perioperative Surgical Home model represents a new approach to surgical patient care, which can increase quality, safety and satisfaction, while decreasing costs, thereby maximizing perioperative value for all stakeholders.

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47 Surgical Graduate Medical Education Program Accreditation and the Clinical Learning Environment: Patient Safety and Health Care Quality

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"As to diseases, make a habit of two things — to help, or at least, to do no harm."

—Hippocrates, Epidemics, 460 BC–377 BC

Introduction

The Accreditation Council for Graduate Medical Education (ACGME) was established in 1981 as a "council" in the American Medical Association (AMA) [1]. In 2000, ACGME became an independent organization. As of 2014–2015, ACGME was accrediting 692 sponsoring institutions (SI) and 9645 residency and fellowship programs, who are training 121,599 residents and fellows [2]. It is the largest private regulatory organization over graduate medical education (GME) in the USA.

Its mission is to "*improve health care and population health by assessing and advancing the quality of resident physicians' education through accreditation*." [3].

Its principle program is that of accreditation. However it also has a major education program serving the GME community. More recently it has established two new programs: the GME resident milestones and the Clinical Learning Environment Review Program (CLER).

The ACGME has increasingly emphasized patient safety and quality improvement in its requirements. This chapter reviews the main evolution of the ACGME standards in patient safety and health care quality and presents an overview of the CLER program. The focus of this chapter is how these standards and the CLER program seek to impact the quality of GME for surgical training.

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Patient Safety, Health Care Quality, and Accreditation of Surgical Training

The ACGME sets it standards in three levels of detail. These include requirements specific to each specialty and subspecialty, the requirements that are common to all residency and fellowship training (Common Program Requirements), and standards that are at the level of the institution that sponsors one or more ACGME accredited training programs (Institutional Requirements).

Specialty, Subspecialty, and Common Program Requirements

The earliest ACGME requirements held that, "Resident physicians are expected to participate in safe, effective and compassionate patient care under supervision, commensurate with their level of advancement and responsibility." They also called for hospitals participating in resident education to be accredited by The Joint Commission (or an equivalent external regulator) and that the program director and faculty members be appropriately certified and licensed. Initially there was a most rudimentary requirement regarding quality improvement that all deaths be reviewed and that autopsies be performed in sufficient number to enhance the quality of patient care [4].

Requirements regarding patient safety and quality assurance advanced only slowly over the next two decades. The 1992 Requirements stated that, "Institutions … must conduct formal quality assurance programs and review complications and deaths. Residents must be informed of the institution's organization for, and methods of, providing quality assurance. They should participate in the quality assurance activities of the clinical services to which they are assigned" [5].

In 1995, the requirement was added that, "Institutions must provide residents with an opportunity to participate in institutional committees and councils, especially those that relate to patient care review activities and to develop an understanding [of] how to apply cost containment measures in the provision of care" [6]. The last requirements of the ACGME as a council of the AMA added specificity regarding quality assurance. "Institutions … must conduct formal quality-assurance programs and review complications and deaths. All residents should receive instruction in quality-assurance/performance improvement. [Residents] should participate in appropriate components of the institution's performance improvement program" [7]. *In 2001, the ACGME became independent of the AMA. Closely following that important structural change, the ACGME promulgated six "General Competencies" to be demonstrated by residents* (Table 47.1) [8].

Largely in response to concerns for patient safety, the ACGME implemented duty hour restrictions in all programs in 2003. These generally limited resident duty hours to 80 per week (although minor exceptions for sound education purposes could be granted to individual programs) [9]. In addition, the standards called for residents to be provided 1 day in seven free from all educational responsibilities, in-house call no more frequently than every third night, continuous duty not to exceed 24 h, plus 6 additional h, "to participate in didactic activities, maintain continuity of medical and surgical care, transfer care of patients, or conduct outpatient continuity clinics." Importantly, the 2003 standards also clearly stated that, "All patient care must be supervised by qualified faculty. The pro-

Table 47.1 ACGME/ABMS general competencies for specialty-based graduate medical education

• *Patient care* that is compassionate, appropriate, and effective
• *Medical knowledge* of biomedical, epidemiologic, and socio-behavioral sciences as applied to patient care
• *Practice-based learning and improvement* that involves investigation and evaluation of their own patient care, appraisal and assimilation of scientific evidence, and improvements in patient care
• *Interpersonal and communications skills* that result in effective information exchange and collaboration with patients, their families, and other health professionals
• *Professionalism* as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse population
• *Systems-based practice* as manifested by actions that demonstrate an awareness of and response to the larger context and system of health care and effectively call on system resources to provide optimal care

gram director must ensure, direct, and document adequate supervision of residents at all times" [10].

The next major revision of the ACGME Requirements occurred in 2007 [11]. That change further refined some of the requirements regarding patient safety and introduced the term "quality improvement" into ACGME requirements. They stated that residents are expected to, "systematically analyze practice using quality improvement methods, and introduce changes with the goal of practice improvement," "work effectively as a member or leader of a health care team or other professional group," be accountable "to patients, society and the profession," "coordinate patient care within the health care system relevant to their clinical specialty, advocate for quality patient care and optimal patient care systems, work in interprofessional teams to enhance patient safety and improve patient care quality and participate in identifying system errors and implementing potential systems solutions."

In 2009, the ACGME convened a "Duty Hours Task Force" to reexamine ACGME resident duty hour requirements [12], partly in response to the 2009 Institute of Medicine report on resident duty hours [13]. Based on Task Force recommendations, the ACGME added several requirements regarding resident duty hours to those in place since 2003. Notably, PGY-1 residents were limited to 16 h of continuous duty and a minimum of 8 h between scheduled on-duty periods. Other residents were limited to 24 continuous h plus 4 h for transitions in care. Intermediate-level residents were given a minimum of 8 h between scheduled duty periods and at least 14 h free of duty after 24 h of in-house duty. Residents in the final years of education were allowed somewhat more flexibility within the context of the 80-h per week limit. Strategic napping was encouraged. Finally, the 2011 requirements mandated that all moonlighting be counted toward the maximum weekly hour limit of 80 [14].

What began as a Duty Hours Task Force expanded its mission to encompass quality care and professionalism. Their recommendations in these areas are also reflected in the 2011 Requirements [14]. An entire section was added titled, "Professionalism, Personal Responsibility, and Patient Safety," which emphasized the need for physicians to appear for duty appropriately rested, the need of the [residency] program to be both committed to and responsible for promoting patient safety and the active participation of residents in interdisciplinary clinical quality improvement and patient safety programs. The program director and the institution were charged with ensuring a culture of professionalism that supports patient safety and personal responsibility. This requires the residents and the faculty members to demonstrate an understanding and acceptance of their roles in assuring patient safety, provision of patient-centered care, and their fitness for duty. It requires their management of their time during, but equally importantly, before and after clinical assignments, recognition of impairment from any cause in themselves and their colleagues and monitoring of their patient care performance improvement indicators. It also emphasizes the need for residents and faculty members to demonstrate responsiveness to patient needs that supersedes self-interest.

A new section on "Transitions of Care" was also added. It emphasized the need to minimize the number of transitions, resident competency in the handover process and the need for programs and institutions to ensure and monitor hand-over process that facilitate both continuity of care and patient safety [15]. A third section was added titled, "Alertness Management/Fatigue Mitigation." It underscored the importance of educating faculty members and residents regarding signs of fatigue and sleep deprivation, alertness management and fatigue mitigation strategies. It also required programs to have processes to ensure continuity of patient care in the event that a resident was unable to perform his/her duties. Prior to 2011, the ACGME Requirements said only that the [training] program must ensure that qualified faculty provide appropriate supervision of residents in patient care activities [11]. The 2011 Requirements "Supervision of Residents" contains nearly two pages of specific requirements. Among other things, these requirements address the need for the patient to be informed of the role of the resident, codify the levels of supervision that residents should have based on their abilities, and call for programs to set guidelines regarding circumstances under which the attending

physician must be informed of a patient's condition [16]. They also set specific limits on the degree of autonomy granted to PGY-1 residents.

Patient Safety and Quality for Institutions Seeking to Sponsor ACGME-Accredited GME (Institutional Requirements)

Beyond the Common Program Requirements, the recommendations of the 2009 ACGME Duty Hours Task Force were also manifested in the ACGME Institutional Requirements and in the ACGME Policies and Procedures. Notable additions to the Institutional Requirements included requirements that the Sponsoring Institution and its ACGME-accredited programs to assign residents only to sites that facilitate patient safety and health care quality; that residents have access to systems for reporting errors, adverse events, unsafe conditions and near misses in a protected manner; and that residents have opportunities to contribute to root cause analysis or other risk-reduction processes [17]. Quality improvement was also emphasized by requiring that residents have access to data to improve systems of care, reduce health care disparities and improve patient outcomes and opportunities to participate in quality improvement initiatives [18]. Also added were requirements that Sponsoring Institutions must facilitate professional development for faculty members and residents regarding effective transitions of care and ensure that residents utilize standardized transitions of care consistent with the setting and type of care. The revised Institutional Requirements also required the addition of a quality improvement/safety officer to the Graduate Medical Education Committee which oversees the quality of the GME learning and working environment [14]. Like the ACGME Institutional Requirements, the first major revision to the ACGME Policies and Procedures following the report of the Task Force became effective 1 July 2013. That document provided the policy structure for the Clinical Learning Environment Review (CLER) [19] (Fig. 47.1).

The Clinical Learning Environment (CLE)

The previous section highlighted the evolution that ACGME has taken to increasingly address the issues of patient safety and quality improvement through its regulatory function, specifically its accreditation process for sponsoring institutions and residency and fellowship programs. As noted at the beginning of this chapter, the ACMGE has recently added a new program, CLER, to further address the issues of patient safety and health care quality in the graduate medical education community.

The program was an additional outcome of the 2009 ACGME-convened "Duty Hours Task Force" to reexamine ACGME resident duty hour requirements [10]. This new program has a direct link to the accreditation process; specifically that each ACGME-accredited sponsoring institution must complete a CLER site visit every 18–24 months. Failure to meet that single requirement places the sponsoring institution and all of its residency and fellowship programs at risk for an adverse accreditation decision, including withdrawal of ACGME accreditation. It is important to note that as a formative learning activity each CLER visit concludes with a summary report of findings specific to that CLE and not a summative judgment that influences accreditation decisions. The findings are confidential, shared only with the leadership of the sponsoring institution and the CLE that was visited. In designing the CLER program, the assessment assumes that the basic issues at that sponsoring institution and its training programs are compliant with ACGME standards. ACGME standards set the basis for patient safety and quality improvement, whereas the CLER program seeks to drive continual learning and systems improvement.

A full description of the CLER program is beyond the scope of this chapter and can be found elsewhere [20]. In short, each CLER visit consists of 2–3 days that include structured group interviews with CLE and GME leadership, quality and patient safety leadership, residents and fellows, faculty members, and program directors.

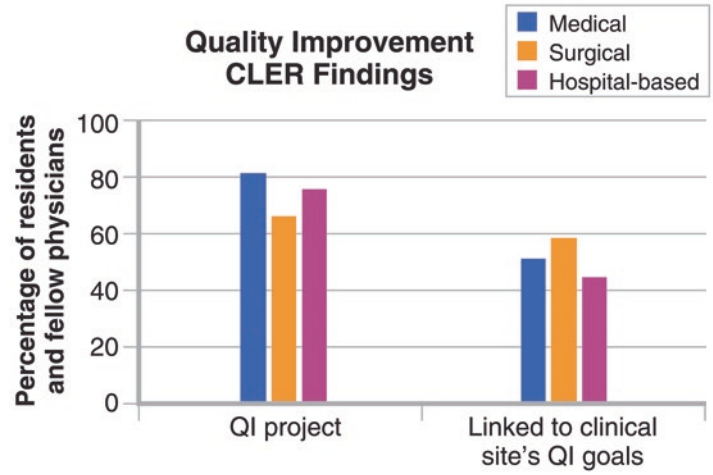

Fig. 47.1 Quality improvement CLER findings

Also a series of walking rounds through the clinical areas that are managed by the site visitors in an effort to have a series of interviews with other, non-physician, members of the clinical teams. Each visit ends with an exit interview where a summary of the findings is presented and that is followed up in approximately 8 weeks with a written summary of the visit.

Currently the CLER program does not have a set of published guidance or recommendations on the clinical learning environment specifically designed for the surgical community. It is first worth considering why ACGME establishes a program that examines the clinical learning environment.

Why Is the CLE Important in the Training of Residents and Fellows?

The clinical learning environment (CLE) represents the structural space in which knowledge and skills are transferred by experiential learning in the course of patient care. The CLE also represents the community of colleagues in which learners are exposed to attitudes and behaviors related to teamwork [21], communication, and professional interactions. Two recent studies underscore the importance of the clinical learning environments and their impact on the resident experience and life-long patterns of care. A study by Asch and colleagues assessing obstetrics residency programs and their graduates demonstrated that women treated by obstetricians trained in residency programs in the bottom quintile for risk-standardized major maternal complication rates had an adjusted complication rate approximately one-third higher than that for women treated by obstetricians from programs in the top quintile [22]. Similarly a study by Chen, et al, compared the regions of residency training and found that the way trainees were trained correlated with subsequent expenditures for care provided by practicing physician spending patterns associated with Medicare expenditures [23].

Why the Current Need for Attention to the Clinical Learning Environment for Surgeons in Training?

The Surgical Health Care Environment

The rapidly evolving needs of the US health care system, the current skills of surgical faculty, and expectations of surgical residents all are important reasons to examine the clinical learning environment. The health care environment is undergoing significant evolution, and factors outside of the surgical CLE are presenting surgeons and surgical training with new challenges. Clinicians face the

need to manage a rapidly changing body of knowledge and dramatically changing technologies as well as integration of the electronic health record in daily practice. There are also changing technologies for learning, such as increased use of simulation for training and assessment and just-in-time audiovisual learning (e.g., watching a video on a new or unfamiliar procedure is replacing the former practice of reading about the procedure in a textbook).

The health care environment calls for clinicians to have leadership skills that include team dynamics management to a greater extent than ever before [24]. Clinicians are also increasingly expected to focus on clinical efficiency and Lean [25] production methods, which at times may seem to physicians to be in conflict with time for patients and for teaching. There is a heightened emphasis on clinical accountability and transparency. Expectations for public reporting of patient care quality and outcomes continues to grow and is increasingly accompanied by changes in the reimbursement model to one based on value—i.e., quality and safety metrics—that are attributed to the surgeon of record and the health care system in which surgical care was delivered [26].

Surgical Faculty: Teaching Clinicians, Clinical Educators

Historically, surgical training has focused on the quality of care of individual patients; and very few faculty were formally trained in population-based care management and health systems design and performance [27]. While working hard to maintain proficiency or expertise in the knowledge and skills of their own surgical specialty, surgeon educators are also challenged to have or gain mastery in systems thinking and design, by which to improve patient flow, information flow, and surgical team productivity [28]. Additionally, there is a need to manage team dynamics effectively. For example, new team management techniques, such as crew resource management [29], were not likely part of the training of most of the surgical faculty. High functioning teams require a change from the traditional hierarchical model of surgeon as leader to a flatter, more horizontal culture of teamwork [30], with deference to expertise and an environment that encourages all on the team to speak up and contribute fully to the team's approach to patient safety and quality [31].

Surgical Learners

The young surgeon learners are also different—inquisitive, yet very oriented toward instant communication, and with greater expectations for attention to their learning, as well as to work–life balance and wellness [32, 33]. Young surgical learners are also coming into surgical training as natives to computers and gaming skills. In the advancing implementation of the electronic health record, it is frequently seen that the students and trainees are quick to identify the issues with functionality and connectivity across health care settings, and they are also quick to contribute to problem-solving and improving design [34]. Their comfort with gaming skills puts them at a significant advantage for rapid adaptability to new technologies in health care—such as minimally invasive, robotic, and catheter-based procedures—and often with faster and more adept acquisition of skills than those who are responsible for training them.

Challenges and Barriers for Surgeons

It is relatively easy and straightforward for clinicians to be strongly in favor of patient safety, high quality health care, and professionalism. However simply identifying these and other focus areas in the clinical environment, then implementing policies, staff roles, and didactic curriculum does not guarantee a quality CLE [35]. There are numerous challenges and barriers to improving the clinical learning environment [36], a few of which are noted here.

One challenge for surgeon faculty in their assessment of the CLE is to separate themselves and their reputation from the way surgeons have traditionally viewed their own educational processes. Surgical faculty may consider that their many years of hard work and lost sleep invested in education and training is the principal link to the quality of work that each delivers on behalf of his

or her patients. Thus, any critique of this model for training surgeons cannot help but be taken personally and interpreted as an attack on the individuals themselves. Rites of passage and longstanding traditions that view the ability to power irrespective of patient complexities, competing obligations, and extreme exhaustion are deserving of reexamination in light of increasing literature in the fields of quality improvement and patient safety.

Another challenge or barrier to improved surgical training has been the often times absent or inconsistent availability of relevant measures with meaningful definitions of quality of surgical care for both processes and outcomes. If surgeons do not find the measures relevant to delivery of quality care or the definitions reflecting meaningful activity of the surgical team, then it is difficult to engage surgeons in contributing to improving the metrics [37]. If the data sources are not perceived by the practicing surgeon as valid and reliable, then the data that are provided will not be trusted, much less acted upon, except under mandate or duress.

The use of data for improvement has advanced with use of data registries such as the National Surgical Quality Improvement Project (NSQIP) [38], or data shared among members of the University Health System Consortium [39]. Trauma registries and tumor registries have added data and information for improving practice. There are some surgical specialty societies (such as the Society of Thoracic Surgeons) that have demonstrated the value in use of such national databases to improve patient care outcomes at the local, regional and national levels [40, 41].

Surgeons who regularly review data on their patient care processes and their patients' clinical outcomes and demonstrate use of data to better understand the patient population served and to improve their processes of care, model important attitudes and behaviors that residents and fellows will begin to incorporate into their practice. This is particularly true of efforts to reduce health care disparities—i.e., if the efforts to provide access to care regardless of ability to pay or other population characteristics are not analyzed for the impact on outcomes, then the surgeon and his/her team are working hard, but not learning how to make a meaningful impact on the health of the population served [42–44].

Focus Areas and Key Questions

The ACGME Board of Directors recognized in developing the CLER program, the necessity of signaling the need for improvement that would lead to higher quality and reliability of care. For this new effort they chose to employ a formative learning effort rather than a summative, regulatory assessment built on requirements. In establishing what would become the CLER program, the Board identified six areas within the CLE that at the time they thought were of highest priority to assess. These focus areas included: patient safety, health care quality and quality improvement, transitions of care, supervision, fatigue management and mitigation, and professionalism. Within health care quality and quality improvement, there is an opportunity to consider vulnerable populations and the risk for and improvement of health care disparities [45]. These focus areas are not unique to surgical specialties, but within the surgical learning environment, there are specific and/or special characteristics and functions to be called out for practical application. Also, these six areas may evolve overtime as the ACGME Board of Directors identifies new priorities within CLEs to target for improvement.

The CLER program has been built on a framework of both the six focus areas as well as five key questions related to each clinical learning environment for GME, as shown in Fig. 47.2.

These focus areas and questions help assess the CLE to provide formative feedback to teaching medical centers and hospitals across the USA, as they consider how their strategies and priorities translate to patient care at the bedside. This approach may help the GME community begin to learn and apply what innovative surgeon educators and health care organizations are doing to integrate the surgical learners and faculty into the system approach to patient safety and health care quality and quality improvement. As patterns and practices are

Central questions for the CLER evaluation

Key questions	Clarifying questions
Who and what form the infrastructure of a Sponsoring Institution's (SI) clinical learning environment (CLE)?	What organizational structures and administrative and clinical processes do the SI and its major participating sites have in place to support GME learning in each of the six focus areas?
How integrated is the GME leadership and faculty within the SI's current CLE infrastructure?	What is the role of GME leadership and faculty to support resident and fellow learning in each of the six areas?
How engaged are the residents and fellows in using the SI's current CLE infrastructure?	How comprehesive is the involvement of residents and fellows in using these structures and processes to support their learning in each of the six areas?
How does the SI determine the success of its efforts to integrate GME into the quality infrastructure?	From the perspective of the SI and its major participating sites, what are the measures of success in using this infrastructure and what was the level of success?
What areas has the SI identified as opportunities for improvement?	From the perspective of the SI and its major participating sites (if different), what are seen as the opportunities for improving the quality and value of the current CLE infrastruture to support the six focus areas?

Fig. 47.2 Central questions for the CLER evaluation. Modified from the AGME CLER executive summary, 6/10/2012

identified to improve both patient care outcomes and GME outcomes, such assessments will begin to influence and inform the accreditation standards for GME institutions and their clinical sites.

Early CLER Findings

The first cycle of ACGME clinical learning environment review (CLER) site visits in 2012–2015 visited the primary clinical participating site for each of 297 sponsoring institutions that sponsored three or more core programs. These CLER visits included group interviews with 111,482 resident and fellow physician representatives, of which 21.8 % were in surgical specialty programs, 57.4 % in medical specialty programs, and 20.8 % in hospital-based specialty programs. These visits also included interviews with hundreds of CEOs, executive leadership teams from the hospitals and medical centers, as well as hundreds of other clinical staff, primarily nursing. A full report of the findings from this first cycle of visits can be found elsewhere [46]. The next section explores some of the findings in light of how surgical residents and fellows experience their CLE as compared with those residents and fellows in medical specialties or other hospital-based specialties.

When asked if they, as residents or fellows, experienced a patient safety event in the past year while training at the hospital or medical center; 71 % of surgical learners reported such an experience, compared to 68 % of medical learners and 64 % of hospital-based learners ($p < 0.0001$). Forty-six percent of the surgical residents and fellows reported that they reported an adverse event through their hospital or medical centers patient safety system. This was less frequent than medical specialty learners with 51 % ($p < 0.0001$).

Patient safety is enhanced when providers and systems learn from near misses, rather than focusing only on the post hoc learning when the patient has already suffered harmed and in morbidity and mortality conferences [47]. Of the physician learners interviewed, surgical residents and fellows who had reported a near miss event was 19 %, compared to 22 % for medical specialty

learners and 17% for hospital-based specialties ($p<0.0001$).

Beyond the reporting of patient safety events to help the system learn and improve, the percentage of PGY3 and above resident and fellow physicians who reported participating in a hospital- or medical center-led patient safety investigation, such as a formal root cause analysis, varies by specialty group, with surgical learners reporting greater participation—45, 40, and 37% for surgical, medical, and hospital-based specialty learners, respectively ($p<0.0001$). In discussions, these activities were primarily through departmental morbidity and mortality conferences with infrequent interprofessional participation and variable system-based problem solving [18].

Surgical learners report lower participation in a quality improvement (QI) project, either of their own design or one designed by their program or department—66% as compared with 81% and 73%, for surgical, medical, and hospital-based specialty learners, respectively ($p<0.0001$). A higher percentage (59%) of surgical learners, versus 52% of medical learners and 45% of hospital-based learners, believed their project linked to one or more of the clinical site's QI goals ($p<0.0001$).

Ninety percent of medical and surgical specialty group learners reported following a standardized process for handling transitions of care during handoffs between shifts, compared with 80% of hospital-based specialty learners ($p<0.0001$). Of those who reported following a standardized process, 84% of medical learners, 76% of surgical learners, and 63% of hospital-based learners reported using a standardized written template for communication during change-of-shift handoffs ($p<0.0001$). Of note, the use of a standardized handoff process at change-of-shift was not currently maintained by surgical residents as they progressed through training: 92.7% for PGY2s, 91.7% of PGY3s, and 87.5% for those PGY4 and above ($p<0.01$).

Twenty percent of surgical learners reported that they had been placed in a situation or witnessed one of their peers placed in situations where they believed there was inadequate supervision (e.g., the attending physician was not available). Thirty-four percent of surgical resident and fellow physicians reported that they would power through to handoff, rather than notify someone and be taken off duty, if placed in a situation in which they are maximally fatigued and impaired in spite of caffeine and a nap.

Forty-two percent of the surgical specialty learners reported having documented a history or physical finding in a patient chart that they did not personally elicit—e.g., copying and pasting from another note without attribution—compared to 40% of medical learners and 39% of hospital-based learners ($p=$NS). Though not found to show a statistically significant difference between surgical specialty learners and the other specialty groups, 16% of the surgical resident and fellow physicians reported to have been pressured to compromise their honesty or integrity to satisfy an authority figure during training at the clinical site.

Practical Approach to the Surgical CLE Focus Areas

In 2014, the CLER evaluation committee, which provides oversight for the CLER program development and then published the *CLER Pathways to Excellence: a set of expectations for an optimal clinical learning environment* [48]. The document was based primarily on the observations from the approximately first hundred CLER site visits, along with the clinical experts on the evaluation committee and what little published information existed on CLEs in the literature. That document describes in each of the six focus areas a series of paths by which a clinical learning environment might seek self-improvement based on the findings from the CLER visit.

This next section of the chapter provides some informal, select thoughts of the authors on where improvement strategies might be gain perched in clinical learning environments for the surgical community.

Patient Safety

Physician leaders, along with practice and organization leaders, serve as role models by the way in which they recognize patient safety events

(adverse events, near misses, unsafe conditions), and use the reporting systems of the hospitals and medical centers that serve as a their CLE.

The full range of reportable events includes near misses, events without harm, unsafe conditions, unexpected deteriorations, delays in diagnosis and care, and procedural complications, as well as events with harm [49, 50]. Common understanding among all members of the team and organization about what constitutes a reportable event provides an important context for situational awareness while delivering patient care and for system improvements. Patient event reporting should drive the follow-up system for event investigation and identification of cause, with focus on reporting events and processes, rather than reporting as a means of retaliation or assigning blame to people. The patient safety reporting system will be most likely used if it is perceived as adding value to patient care. If a hospital or medical center's leadership is not aware if its physicians are reporting patient safety events, there is the risk of having a significant component of the health care workforce not seeing the reporting of patient safety concerns as a valuable contribution to system improvement.

Surgeons have long been mindful of the importance of tracking and trending patient outcomes. To create a culture of safety means that a CLE exists where all members of the clinical team are equally willing to speak up and report patient safety concerns without fear of retaliation. Meaningful discussion and analysis of patient deaths and complications is essential to learning and improvement. Such discussions usually take place in a venue known as a morbidity and mortality (M&M) conference. There are differing views across US teaching medical centers as to whether morbidities and mortalities as presented in M&M conferences should be reported and analyzed as patient safety events. From the patient's perspective, a morbidity or mortality would very likely be considered a patient safety concern, with great desire that the clinicians also do their due diligence in assessing for both individual error due to inadequate knowledge, judgment or skill and system errors and processes in need of improvement [51–53].

The structure and process for conduct of patient safety investigations generally has five components: review by an interprofessional team (physicians, nurses, pharmacists, administrators, etc.), detailed analysis of systems and processes, identification of potential systems changes, implementation of an action plan, and follow-up evaluation of the actions [54]. There are several methodologies that may be used for systematic analysis of patient safety events—the five whys method, Ishikawa or fishbone diagramming, flow mapping, and cause-and-effect diagramming, to name a few [55]. There are numerous resources for assisting physicians as they conduct and lead a patient safety event investigation, but it is just as important to include and involve the interprofessional team and to be sure that action plans and follow-up are outcomes of the investigation [50].

It is imperative to disseminate the lessons learned in order to maximize the shared learning across the organization or practice for transparency and shared learning. This must, and can, be done without HIPAA-violating patient details—the focus is on the lessons learned and actions applied.

Another aspect of transparency that is vital to patient safety is disclosure of patient safety events to patients and families. As Dr. Donald Berwick, former Administrator of the Centers for Medicare and Medicaid Services, and former CEO of the Institute for Healthcare Improvement, has put forward the useful guiding phrase to help clinicians remember the patient's perspective, "Nothing about me, without me" [56].

While the specific process for disclosure in a practice or organization is in large part dictated by the pertinent state laws, the team is well served to understand the process that applies locally, and to support one another in consistent application of that process. Preparing surgeon learners to apply these tools and methodologies in their daily practice as part of their professional commitment to their patients will benefit their patients throughout their career [57] (Fig. 47.3).

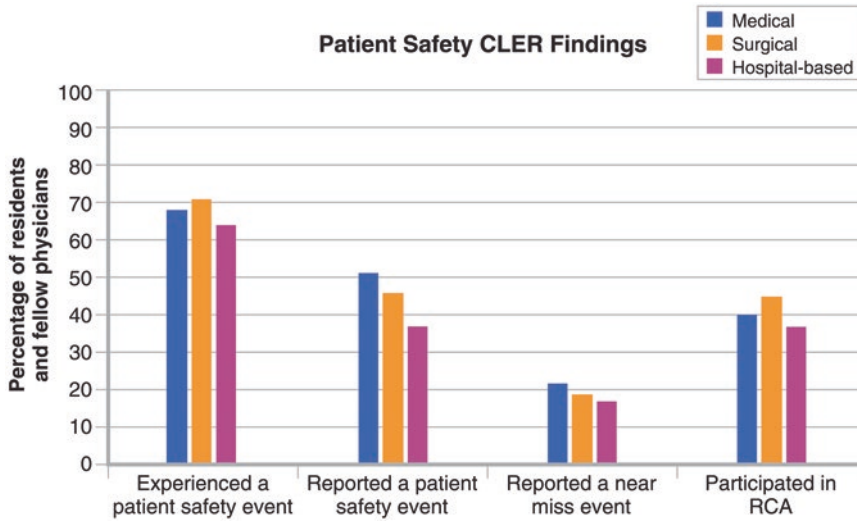

Fig. 47.3 Patient safety CLER findings

Health Care Quality and Quality Improvement

Patient safety and quality improvement are part of a continuous spectrum of interrelated clinical activities. Efforts to improve patient safety require knowledge and skills in quality improvement tools and methodologies. Essential to learning quality improvement is to encounter it as experiential learning through practice and application. Just as physicians learning surgical skills in the operating room need practice with the instruments and technical skills of the specialty, they need practice in applying the tools and skills of designing, leading and facilitating quality improvement [58]. These include the ability to construct a well-defined, measurable aim, identify a balanced set of measures by which to identify that patient care is actually improved (clinical and functional outcomes, costs, and satisfaction), and apply a systematic approach to serial cycles of change that include evaluation of follow-up action for progressive or continuous quality improvement [59, 60].

Clinical teams and their leaders are well served to be familiar with and practiced in systems thinking, particularly about their surgical microsystem(s) of care [61], to consider the impact of a change in the system and its processes that may have a ripple effect far beyond that immediately apparent. Microsystems of surgical care involve interprofessional teams working together in a coordinated way to deliver and improve care. That means that quality improvement initiatives involve multiple interprofessional stakeholders [27].

Clinicians who are immersed in a quality improvement culture are supported by ready access to data for regular review as well as for ad hoc queries in order to better understand their clinical effectiveness. Hospital and practice quality improvement leaders are generally immersed in data and performance measures, particularly as required for externally required reporting. However, it is important for surgical faculty and their clinical teams to have regular access to valid and reliable data, presented in a manner that provides relevant information in order to measure, monitor and improve processes and outcomes. Significant surgical faculty development may be required to know how to make good use of the data provided to identify information for improvement and to lead by example.

Quality improvement is often applied to underuse of evidence-based care, such as efforts to increase hand hygiene, cancer screening, and medication adherence [62]. Opportunity also lies in addressing overuse and misuse of evidence-based care that includes excess or unnecessary use, such

as decreasing excess imaging, unnecessary surgery, and inappropriate antibiotic usage. Many surgeons and clinical sites are familiar with addressing underuse through efforts such as increasing preoperative use of beta blockade for cardiac patients and improving intraoperative glucose control and normothermia [63, 64]. Surgeons and clinical sites are also likely to be familiar with efforts to address overuse and misuse, such as current examples of limiting the course of prophylactic antibiotics [63] and the overuse of urinary catheters. This area of improving evidence-based care continues to be an important foundation for other endeavors using surgical databases and improvement practices.

Another important use of quality improvement tools and skills is through a systematic approach to identifying variability in the care provided or the clinical outcomes of the patients cared for in the surgeon's department or practice, particularly for patients known to be vulnerable to having poorer clinical outcomes due to their social or economic background. But by review of aggregate data, especially outcomes data, with a breakdown by population characteristics (such as age, gender, race, ethnicity, socioeconomic status, etc.) for physicians and their clinical teams, there is an opportunity to better understand the health and needs of the community served and the impact of efforts to provide equitable access and care.

Transitions of Care

Communication breakdowns have long been recognized as a root cause in approximately two-thirds of sentinel events and are critical to the patient's experience with transitions (handoffs or handovers) across the continuum of care [65, 66]. While handoffs of patients and their information has often been viewed by physicians as an opportunity for information to be lost, inaccurate, or incomplete. However, a handoff can also be an opportunity for fresh eyes and ears to catch something that may have been overlooked or underappreciated prior to the handoff [67].

There are numerous types of transitions of care for a patient in the course of the experience with the surgical team, including in and out of the operating room, change of duty, team to team, service to service (including consultations), unit to unit, admissions (outpatient to inpatient), and discharges (inpatient to outpatient or transfer to another facility or level of care). It is helpful to identify which transitions pose the greatest risk or vulnerability for patient safety issues, and particularly those that present the greatest risk of patient transition with incomplete or inaccurate information, to identify key opportunities for quality improvement in care transitions [68].

A common language and systematic approach within the handoff process that is most helpful to the team members—with inclusion of key information, if/then plans, opportunity for clarifying questions, and read-back to check for understanding. Verbal communication can be enhanced and facilitated by use of a written tool, printed or electronic, and access to a single electronic health record (EHR) across the outpatient and inpatient continuum is ideal.

In that care transitions are team efforts, it is also worthwhile to consider how to make handoffs as interprofessional as possible. This helps assure inclusion of the information handoff from other key members of the team, as available, such as nursing, anesthesiology, critical care, and pharmacy. It also helps to make sure that team members have a consistently understood plan of care. It is also important to consider inclusion of the patient and/or family in key transition points [69].

Supervision

As educators, surgeons must extend their skills beyond the competency to perform the procedures of their surgical specialty. In the task of supervising they must exercise the very different skill set of teaching competency and assessing competency while staying at an appropriate distance to allow learners to process patient information and develop a treatment plan. But in the tactile world of surgery, supervision in surgical training also means assuring that the patient is safe and appropriate decisions are made while the supervisor's hands are not holding the instruments—i.e., from the other side of the table. That

fine art of providing guidance to someone else's eyes and hands requires trust in one's own abilities and judgment as well as progressive trust in the skills and judgment of the surgical learner. Such guidance comes in the form of a systematic approach to the diagnostics, the procedure itself, and to the treatment plan for recovery following a procedure. Increasingly, simulation education offers a valuable resource for conveying a structured approach to teaching and learning skills, judgment, and interprofessional teamwork for the learner, while ensuring patient safety [70].

The next aspect beyond the teaching of skills and judgment is the assessment of learning and competency. This can be very difficult for surgeons at times, in that while appreciating the preference for objective assessment tools and methods, surgical skills assessment often is described as subjective judgment or "I know it when I see it."

Meaningful assessment of competency therefore requires that surgeon educators be willing and able to deconstruct their good judgment into component parts, identifying what he/she is looking and listening for, and in what sequence and to what degree the process is complete. The Entrustable Professional Competencies (EPA) approach offers one approach for establishing objective, observable performance criteria. This approach to supervision can then be turned into an objective assessment tool and applied in serial fashion to progressive responsibility with feedback, as well as used to test for proficiency and provide documentation of competency [71]. In addition, a systematic methodology for assessment of competency can be useful for evaluating maintenance of skills after achieving proficiency, as well as providing utility in the credentialing and privileging process [16]. It should be noted that simulation is an effective tool for conducting assessment and providing feedback.

Fatigue Management and Mitigation, and Fitness for Duty

The duty hours in residency and fellowship were introduced to begin to address the impact of fatigue on physician learners and the safety of their patients. Yet there has been an ongoing debate that patients are no safer and surgical training has been compromised because of duty hours limitations [72–74]. Studies continue to evolve in this area, including a recent non-blinded cluster-randomized trial to better study this important issue [75].

It therefore it is important faculty, residents, and fellows, and other members of the health care team, become familiar with the signs of fatigue, and then to have sensible mechanisms to assist the fatigued individual to protect them and their patients. For surgical faculty it would benefit the program to continually scan the environment for situations in the clinical setting that pose greatest risk for fatigue and impairment, especially related to patient safety vulnerabilities. Beyond fatigue recognition training, it is beneficial for surgeons within a practice group or clinical site to be familiar with the available resources and strategies at that site for fatigue management and mitigation. This is particularly helpful, as it is worth noting that there are additional reasons to be fatigued beyond the number of hours on duty as a clinician. For example, personal or family illness or financial stressors, and other obligations can drive acute and chronic fatigue, as well as burnout, in both learners and faculty [76–79].

Another aspect of physician wellness worthy of attention is physician burnout, which has been noted to affect learners and physicians of all levels and specialties [80–82]. Distinct from fatigue, burnout may be characterized as emotional exhaustion—losing enthusiasm for work, depersonalization—treating people as if they were objects, and/or a sense of low personal accomplishment—having a sense that work is no longer meaningful [83]. Rather than waiting until the painful signs of burnout in hindsight after a crisis—or worse, following physician death by suicide—surgeons have an important opportunity to identify situations of greater risk for burnout, be more attentive to and less willing to explain away signs of burnout in self and others, and to think proactively about and model wellness behaviors.

Professionalism

When considering what it means to be a professional, the descriptors and definitions center on values, attitudes, and behaviors. As the ACGME considers professionalism in the CLE, it is difficult to be comprehensive, so special attention is placed on honesty, integrity (including scientific integrity), and professional interactions—how professionals treat each other and their patients and families.

Significant professionalism issues arise that require training and/or remediation during the course of residency and/or fellowship, and in practice. One might like to assume that honesty, integrity and respectful treatment of others are present in all who would seek to apply to medical school. But if that is not a safe assumption, how might a more appropriate filter and assessment be applied to those who seek to enter the profession, and how are high standards of professionalism kept as the norm among those who have attained positions of influence and accomplishment?

Practical consideration for what honesty looks like in a surgical practice includes truthful reporting of data and outcomes in surgical registries and databases, in accurate clinical documentation, and reporting on duty hours. Scientific integrity may include whether an individual (regardless of level of training or rank) has fulfilled a role sufficient and appropriate for inclusion in manuscript authorship, or whether the study materials utilized in preparation for in-training or board certification exams are of legitimate sources.

As to interpersonal interactions, there are those who have do not feel the need to manage their emotions such that their temper flares when upset with a situation, and in the extreme, individuals who gain a reputation for "toughness." Chronic or persistent disruptive behavior can likely influence the willingness and timeliness of physician learners and/or nursing staff to contact the surgeon or call for assistance, which may result in a delay in care or otherwise impact patient safety. Dismissive or disrespectful behavior also likely has an impact on members of the care team, causing them to be less willing to speak up if they see something unsafe or have a concern or question about the patient's care plan [84].

One practical way to improve teamwork, especially under stress, is to consider the importance of interprofessional team training. If we work as we drill, then appropriate training in and reinforcement of communication skills for all in the organization (leaders, staff, physicians, learners) is worthy of drills that reinforce cohesive team functioning with respect and a shared mental model, which enhances patient safety [34]. This is particularly important for the often ad hoc teams that are present in emergency departments and operating suites [24]. It may also be beneficial to practice de-escalation and conflict management training to improve and promote respectful interpersonal interactions, thus providing constructive means for managing situational stresses and enhancing skills for working out differences of opinion without compromising integrity [85].

Summary and Future Considerations

So what does the surgical learning environment of the future look like? Practicing surgeons and surgeon educators are urged to consider the assessment suggested by Marshall Goldsmith's book title, "what got you here won't get you there" [86]. Health care leaders for the future of health care are best served by understanding how to lead a *learning* organization. Surgeon leadership involves caring about what matters to staff and to patients, and being willing to work on system design for care that is both evidence-based and patient-centered. Moreover, surgeon educators have a special opportunity to be leaders not only in the advancement of surgery, but also in the advancement of surgical education, through data-driven, outcomes-focused care of individuals and of the various population groups within the community served.

The culture and motivations of a surgical team or practice are critical to determining how the team functions. Appreciating, studying, and applying aspects of an effective organizational culture in optimizing the health care delivery and learning

environment that include: a heightened situational awareness of the opportunity for error (rather than assume that errors are rare and should be punished); emphasis on interprofessional respect and value; interprofessional team communication and improvement; openness and transparency for reporting errors, near misses, and unsafe conditions, with emphasis on shared learning; motivation from what matters to the patients and families; and empowerment to make local improvements that align with organizational goals.

Rethinking the learning environment compels surgeons to deconstruct and critically analyze and enhance the good judgment that helps them assess competency in a more objective manner. Surgical system redesign can take greater advantage of data and outcomes measurement to better understand and optimize processes for improving patient flow and information flow, and assess for health care disparities. Finally, rethinking the surgeon stereotype involves critically considering the professional behavior and the how best to socialize surgeons in training to model and build appropriate expectations from practicing surgeons and surgical learners alike.

Disclaimer The views and opinions expressed in this chapter are those of the authors and do not necessarily reflect the official policy or position of the ACGME.

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48 Affordable Care Act, Public Legislation, and Professional Self-Regulation: Implications for Public Policy

Stephen J. Lahey

"America's health care system is neither healthy, caring, nor a system."

—Walter Cronkite

Introduction

A manufacturing expansion, unlike anything seen before, was required to keep pace with demands of the US war effort. Following the war, the sudden manufacturing boom would look to the thousands of returning GIs to provide the workforce necessary to fuel the largest industrial revolution in the history of the world. These emerging companies saw health insurance as an enticement to attract and keep loyal employees. Literally overnight, the manufacturing industry entered and became a dominant figure in US health care.

Two decades later, a new question became evident: what was to become of the worker who left the ranks of the employed and was entering the ever-growing demographic niche of the retired American? No longer would these citizens have health insurance. Responding to this looming health care crisis, President Lyndon Johnson signed into law the Social Security Act of 1965. As part of this remarkably progressive legislation, the US Government created Medicare (and its companion agency: Medicaid for low income individuals and the disabled) as a government-financed health care insurance plan to be overseen by the Health Care Financing Administration (HCFA) later to become the Centers for Medicare and Medicaid Services (CMS). The retired American would now have the means to maintain access to health care for the remainder of his/her life. In this newly created health care system, physicians would be reimbursed by the federal government for every encounter with a patient, be it an interpretation of a laboratory value or performing major surgery. More importantly, there was no limit to the number of times that a physician could submit a claim for services provided, for which the federal government, through Medicare, dutifully reimbursed the clinician. The so-called "Fee for Service" reimbursement system took root. Although not appreciated at that time, the seeds were sown for the current US health care crisis.

The World War II returning GIs not only provided the manpower for this modern manufacturing revolution, they also created a new societal demographic: the "Baby Boomers." Through the late 1960s, 1970s, and 1980s, health care costs to the federal government expanded at an alarming rate (Fig. 48.1). The Medicare beneficiaries were becoming older, sicker and their health care more costly. With no limits on the Fee for Service system and with the specter of the largest demographic population, i.e., Baby Boomers, looming on the economic horizon, it became evident to

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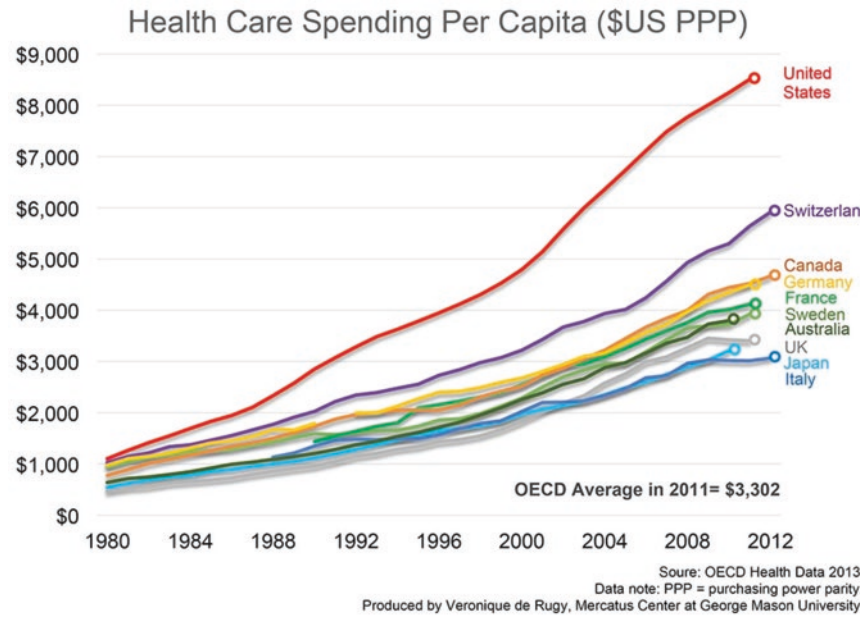

Fig. 48.1 Per Capital Health Care Spending since 1980 by country [1]

health planners and strategists, that the current reimbursement methodology was not sustainable by the US economy. The staggering economic burden of an 11.4% annual increase in Medicare spending from $36.4 billion in 1980 to $120.2 billion in 1991 [2], pushed HCFA, Congress and the entire federal government to appreciate the critical need for health care cost containment. Legislation soon followed that attempted to cap hospital reimbursements and codify all short-term, acute care hospital Medicare reimbursements under an In-patient Prospective Payment System (IPPS), which fundamentally changed the method by which hospitals were reimbursed. Previously, hospital reimbursement was retrospective, based on hospital costs in a fee-for-service manner. The IPPS ushered in a reimbursement methodology that was prospective and based on known costs associated with a series of Diagnostic Related Group (DRG) classifications. These DRG payments allowed Medicare to reimburse hospitals not according to costs incurred but rather based on patient diagnosis and comorbidities. Not surprisingly, an attempt to contain the enormous increase in physician reimbursement was initiated with the publication of the Medicare Fee Schedule (MFS) in the early 1990s.

As the harsh realities of financial catastrophe associated with out-of-control health care costs/spending became accepted as inevitable by forward-thinking health care strategists in the late 1980s, several isolated "demonstration projects" appeared on the health care landscape. The rationale behind the development of these projects was that hospital and physician reimbursement could be effectively contained by a system of "bundled" payments. These projects tended to be focused on surgical procedures with one of the most notable early projects started by Dr. Denton Cooley at the Texas Heart Institute in 1984. At the core of their claim of success was that they were able to reduce costs without compromising their traditional high quality [3].

Perhaps the most ambitious, early project was conducted by HCFA in 1991. Out of a possible 209 pre-applications for participation in this study, four US hospitals were chosen to take part in a demonstration of the feasibility of bundled Medicare payments for both the hospital (Part A) and the physicians (Part B) at a predetermined,

negotiated rate. The demonstration project was later extended to three additional hospitals in 1993. A final report of the project findings were published in 1998 [4] in which HCFA realized a savings of $42.3 million on coronary artery bypass surgeries, which was approximately 10 % of the $438 million that had been expected as Medicare payouts. Several other interesting findings were gleaned from this study:

- The seven demonstration hospitals were found to have significantly lower in-patient mortality rates than what was seen in risk factor controlled rates in Medicare participating but non-demonstration hospitals.
- Multivariate analysis also demonstrated a significant reduction in complication (e.g., post operative renal failure) rates and lengths of stay.

It should be noted that Medicare, as a federal agency, whose original charge was to devise a method of health care cost containment, was now very much interested in quality outcomes and process of care. It was apparent that control of health care costs would not only require some form of bundled payment arrangement with hospitals and physicians but, also, would be permanently linked to clinical outcomes.

One other important notion becomes apparent when reviewing the findings of this early demonstration project: HCFA was keenly aware of the "asymmetry of financial incentives faced by hospital managers versus physicians." The physician bears absolutely no financial down-side risk. The fact that a patient requires an intensive care unit for 2 days or 20, is irrelevant to the physician. In addition, the pre-procedure negotiated payment to surgeons increases with the complexity of the operation. These more complex surgeries may be associated with a higher cost of care, which is essentially borne by the hospital. This has proven to be a rather vexing problem to this day.

As US health care, in particular, and the US economy, in general, limped into the twenty first century, a consistent theme began to emerge: The enemy of cost containment efforts and simultaneous maintenance of high quality of care was the Fee-For-Service model of reimbursement that began with the Social Security Act of 1965. What started as a reasonable method of assuring appropriate physician and hospital reimbursement while guaranteeing full access to medical care for Medicare beneficiaries had, now, become the very mechanism responsible for out-of-control health care spending and a serious drag on the entire US economy. In addition, the Fee-For-Service method of reimbursement fostered fragmentation of care, poor coordination amongst caregivers, and no incentive to limit resource utilization. The impending US health care crisis was becoming likely and the financial ramifications of rising health care costs were starting to be appreciated as threat to the entire national economy. For the first time, the matter of financial solvency of the entire Medicare program began to enter the national health care dialogue. The current trend in health care spending by the federal government would not be sustainable and the USA began to look for ways stop, or at least, abate this serious downward economic spiral. A new direction in governmental health care policy began to emerge as the realization that costs and quality were irrevocably linked. Policy makers understood that the pillars needed to strategically support this effort would be based on (see Fig. 48.2)

1. Clinical data and subsequent reliance on evidence-based decision making
2. Improvement in patient safety and quality outcomes
3. Congressional legislation that would ensure the viability of the Medicare program

Evidence-Based Decision Making

Accurate, reliable clinical data must be the bedrock of any legitimate effort to contain costs through better clinical outcomes. Substandard care is extraordinarily expensive. Early efforts in the 1990s to introduce "Fast Track" cardiac surgery brought to light an interesting revelation: the ability to reduce hospital lengths of stay in a "Fast Track" program was predicated on improved processes of care [5]. For example, limiting amounts of intraoperative intravenous fluid in the operating room translated into shorter times to extubation, shorter

Fig. 48.2 Factors impacting quality and costs

ICU lengths of stay and shorter overall hospital lengths of stay. Better care meant reduced costs.

Efforts to boldly change the processes of care in cardiac surgery require: (a) the total commitment of organizations to submit and share their own clinical data with that of other institutions, (b) the organizational structure to provide robust statistical analysis, and (c) a method of consistent feedback to the participation institutions so as to encourage data-driven changes in the care delivered. The effectiveness of this exercise is directly related to the accuracy, completeness and transparency of data submitted. This truly innovative approach to cardiac surgery (and medicine, in general) began with the pioneering efforts of organizations such as the Northern New England Cardiovascular Disease Study Group (the "NNE"), the New York State Cardiac Surgery Reporting System, and the Society of Thoracic Surgeons National Database. All three organizations have provided valuable insights into concepts such as the existence of significant variability in clinical outcomes, procedural volume statistics as a surrogate for quality in highly complex surgeries, and the linkage between process and outcome. The "NNE" represents the voluntary cooperation of several institutions in the northern New England region, which routinely collect, analyze and collectively share clinical results. It is a remarkable example of institutional transparency and cooperation and, as such, has had an enormous effect on health policy for many years.

The link between health care costs and quality of care was coming into sharp focus as a matter of government public policy. Academic research in health policy, numerous private health care consulting firms, and government-sponsored demonstration projects began to become commonplace in the American health care environment. One of the most interesting and revolutionary projects, The Virginia Cardiac Surgery Quality Initiative (VCSQI) introduced many cardiac surgeons to the phrase "Pay-For-Performance" which started in 1994. These true health care innovators, led by Dr. Jeffrey Rich, dedicated themselves to the notion that improved outcomes and quality of care would necessarily evolve from a state-wide system of clinical outcome analysis, data sharing amongst its members and subsequent process of care change and improvement. The VCSQI, in effect, created a global pricing model based on rewards for superior performance and, more importantly, physician and hospital incentives were aligned by a series of common objectives. Much later (2013), in his testimony to The House Committee on Energy and Commerce, Subcommittee on

Health, Dr. Rich stated that VCSQI collaborators "point out that a road map of short-term next steps is needed to create an adaptive payment system tied to the national agenda for reforming the delivery system. VCSQI has demonstrated that improving quality reduces cost. For example, using evidence-based guidelines, VCSQI has generated more than $43 million in savings through blood product conservation efforts and more than $20 million by providing the best treatment to patients with atrial fibrillation at the right time" [6].

In the state of New York, the Cardiac Surgery Reporting System was created in 1989 and to this day is an extremely active arm of the New York Department of Health. Unlike many other clinical databases, the NY CSRS is a statewide data registry for cardiac surgery and percutaneous coronary interventions. Participation by all New York institutions performing cardiac surgery is mandatory. Risk adjusted mortality data, at the institutional and surgeon-specific levels, is publically reported. These data are reviewed quarterly and alert letters are routinely sent out to institutions should they be found trending towards statistically significant increases in mortality rates. Those institutions that are demonstrating significantly worse outcomes have in-depth review of individual mortalities by CSRS staff. The institutions are required to provide clinical summaries of cases under review and action plans for process improvement. Occasionally site visits by CSRS staff and consultants are required. These efforts have resulted in dramatic improvements in risk adjusted mortality rates in the hospitals of New York State. Through robust efforts at academic literature production, the New York State CSRS has contributed significantly to both the fund of knowledge in outcomes research, but has, also, demonstrated the power of public policy as an effective agent of improving clinical outcomes and patient safety. Currently, approximately one-third of state governments in the USA require mandatory reporting of clinical data [7].

The Society of Thoracic Surgeons was established in 1964 and currently is an international, nonprofit organization representing over 6600 surgeons, researchers and allied health professionals. In 1989, the STS National Database was created to collect clinical data on every cardiac case performed at participating institutions (currently in excess of 90 % of US cardiac surgery hospitals), provide robust risk-adjustment based on pooled national data, and to provide critical data analysis feedback to participating hospitals (see Chap. 44). This remarkably powerful data registry has allowed for the creation of accurate risk predicting models that are used throughout the world [8]. The obvious importance of these risk models to shape public health care policy by agencies such as Medicare cannot be overstated.

Numerous other clinical data registries have emerged across the country. Data analysis from all of these databases has become increasingly more sophisticated and has allowed for more accuracy in risk modeling. The importance of data registries is evident when considering the critical utility of the STS database in activities such as setting reimbursement rates within the Resource Based Relative Value Scale (RBRVS) for cardiothoracic surgical procedures (as defined by Current Procedural Terminology codes) at the American Medical Association/Specialty Society Relative Value Scale Update Committee meeting (RUC). Data from the STS database has allowed the STS to offer an accurate assessment of physician work based on time and intensity of each procedure as part of the relative value unit (RVU) valuation by the RUC. These values are then forwarded to CMS for consideration, as mandated by Congress.

Congressional agencies have noted the power of the STS data registry and CMS has designated it as a Quality Clinical Data Registry (QCDR). Clinical data submission to the STS National Database satisfies the requirement of CMS that eligible professionals must participate in a Physician Quality Reporting System to avoid negative payment adjustments in the future. There is also general acceptance that the STS Database is, perhaps, one of the oldest, most mature and accurate of extant databases. The future of cost containment measures and alternative payment methods may rely heavily on similarly constructed specialty society databases.

Improved Patient Safety and Quality Outcomes

As efforts to create powerful clinical databases to guide process improvement projects and more favorable clinical outcomes intensified, CMS and other government agencies began to focus on initiatives that addressed growing concerns over patient safety. In 1999, the United States Institute of Medicine (IOM) issued a report entitled "To Err is Human. Building a Safer Health System." This landmark publication estimated that as many as 98,000 patients suffer entirely preventable deaths in American hospitals each year as a result of medical errors. As shocking as this sobering statistic was, it was not lost on health policy experts that the additional costs associated with these errors reached the staggering amount of $17 to $29 billion dollars per year in hospitals nationwide. One of the reasons posited by the report to account for this epidemic of devastating medical errors was a health care delivery system (such as it is) that was hopelessly fragmented with no coordination of care by the multiple caregivers for any given patient [9]. To make matters worse, a health care system based on a Fee-for-Service method of reimbursement provides no incentive for caregivers to centralize and coordinate care—in essence, clinicians are perversely rewarded for their mistakes because every patient encounter is billable.

With the gauntlet (the IOM Report) thrown down, the government's response by both the Clinton Administration and Congressional committees with medical jurisdiction, began to hold hearings on this patient safety crisis. The government and CMS clearly understood the critical implications of this game-changing report and needed to address the issue definitively and quickly. One year later, in 2000, $50 million dollars was appropriated for the Agency for Healthcare Research and Quality (AHRQ) to investigate new technologies to reduce medical errors, conduct large scale demonstration projects to address error reduction and patient safety, and fund research to develop provider education tools to help mitigate medical error rates [10].

One of the most effective methods employed by process improvement experts in any field is the development of performance protocols. In medicine, clinical protocols aim specifically at reducing variability of care delivered. Variability has long been known to negatively impact clinical outcomes and make systems of care more prone to medical errors. Government sponsored clinical protocols and practice guidelines became a major focus of US health policy in the 1990s. Between 1992 and 1996, the Agency for Health Care Policy and Research (now known as AHRQ) developed multiple clinical practice guidelines ranging from topics such as "urinary incontinence in adults" to "management of heart failure." Because of the disturbing results of the "To Err is Human" report, health care policy makers understood that evidence-based decision making and protocol driven care would be major factors in reducing the dangerous variability thought to be a primary contributor to unnecessary deaths and complications. Today, these protocols and many more have been updated and expanded and are available for download through the Department of Health and Human Services website: www.ahrq.gov.

Congressional Legislation

The single-most important health care-related legislation passed in the twenty first century was the Patient Protection and Affordable Care Act (ACA). This sweeping health care reform bill has dominated public policy discussion since its stunning passage by Congress in 2010. At its core, the ACA, together with Health Care and Education Reconciliation Act amendment, attempt to drastically reduce the ranks of the under- and uninsured in the USA and to dramatically expand access to health care to as many Americans as possible. However, if full implementation of ACA is ever to be realized, policy makers cannot disregard the fact that health care, as we know it, must undergo radical change to derail the "freight train" that is out-of-control health care costs. In its current form, US health care is not financially sustainable and threatens the solvency of critical entitlement programs such as Medicare and Social Security.

With this sobering fact as a backdrop, health care policy in this country has attempted to focus efforts to promote care coordination, decrease resource overutilization, and encourage evidence-based medical decision-making through data registries and clinical protocols. This is being accomplished through a series of CMS mandates and health care legislation to gradually shift health care away from traditional Fee-for-Service methods to alternative models of reimbursement in which incentives of the many clinicians and hospitals, participating in a particular episode of patient care, are all aligned. It would follow, then, that this can only happen if (1) all stakeholders have the ability to share in financial gains achieved by cost efficient care and (2) all stakeholders share in the down-side financial risk if the cost of care exceeds the predetermined and pre-negotiated, "lump sum" reimbursement rate for the given episode of care. Through public policy and national dialogue, Medicare and governmental health strategists have attempted to force a shift away from Fee-for-Service which encourages more and more volume with little incentive to reduce unnecessary clinical testing, complications, or readmissions, to one of bundled costs with bundled payments. To understand the rationale and logistics of such an enormous shift in health care policy, one must understand five key concepts:

1. Sustainable Growth Rate (SGR)
2. Merit-Based Incentive Payment System (MIPS)
3. Medicare Access and CHIP Reauthorization Act (MACRA)
4. Alternative Payment Models
5. Hospital Value-Based Purchasing

Sustainable Growth Rate

In 1997, the US Congress passed the Balanced Budget Act within which was an amendment known as the Medicare Sustainable Growth Rate. This was a method used by Medicare to contain yearly health care costs by mandating that Medicare costs per beneficiary were tied to, and could not exceed, growth of the national Gross Domestic Product (GDP). Each year, CMS would provide the Medicare Payment Advisory Commission (MedPAC) a budget report consisting of total physician reimbursement expenditure versus the previous year's target expenditure estimation. A conversion factor was used to adjust the proposed expenditure budget for the following year up or down based on the previous year's performance. If expenditures exceeded estimates, reimbursement for the next year would be scaled down to account for the loss. However, with no significant reduction in physician reimbursement and Medicare spending, it very quickly became evident that Medicare would be operating at a significant deficit each year and, more importantly, that this deficit was, by formula, cumulative and had to be reconciled. The total dollar amount, incurred by physician reimbursement overages each year was projected to reach staggering proportions. What ensued was several pieces of Congressional legislation (the so-called "Doc Fix") aimed at delaying implementation of these mandated cuts. In Washington, D.C. parlance, this amounted to "kicking the can down the road" since it allowed Congress to avoid a very unpopular mandate (for yet another year) and, in so doing, failed to address the fundamental issue that the accumulating SGR debt was something that would eventually have to be paid but who was going to pay it and where was the money going to come from. The price tag was in the hundreds of billions of dollars at a time when other important financial burdens such as the US Department of Defense budget was also growing at an alarming rate with active conflicts in Iraq and Afghanistan. Relief from the steadily increasing SGR debt finally came in the form of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which, among other things, summarily repealed the SGR formula.

Medicare Access and CHIP Reauthorization Act (MACRA)

Signed into law by President Barack Obama in 2015, MACRA was created to repeal the physician reimbursement methodology of SGR and

allow physicians to choose one of two distinct pathways to future reimbursement:

1. Merit-Based Incentive Payment System (MIPS)
2. Alternative Payment Models (APM)

Merit-Based Incentive Payment System (MIPS)

The MIPS program offers clinicians a schedule of reimbursement that is a less radical change to what they have traditionally been accustomed since it represents a modification of the Fee-for-Service model. The program allows for bonus payments to eligible physicians who can be measured on certain domains of performance:

- *Quality*—similar to the Physician Quality Reporting System (PQRS) previously in use. Eligible physicians can choose six quality measures to report to CMS (one of which must be an outcome measure or a high value measure).
- *Advanced Care Information*—eligible physicians will document use of key measures of information technology interoperability and information exchange.
- *Demonstration of Clinical Practice Improvement Activities*, e.g., population management, care coordination, care plans/shared patient decision making, and patient safety checklists. Clinicians can choose from a list of 90 proposed activities.
- *Cost*—This will be a measure efficiency of resource utilization and will replace the Value-based Modifier program. This will be calculated by CMS and will be based on claims data. Unlike the previous three domains that require physician data input, the Cost domain will be provided to the physician entirely by CMS.

Based on the performance score achieved in each of these four performance categories, a MIPS Composite Performance Score (CPS) will be calculated.

Each of the performance categories are not equally weighted in calculating the overall MIPS Composite Performance Score (CPS):

- Quality = 50 %
- Advanced Care Information = 25 %
- Clinical Practice Improvement Activities = 15 %
- Cost = 10 %

Beginning in 2019, physicians failing to meet predetermined performance thresholds established by CMS, will be subject to a negative 4 % Medicare reimbursement penalty. In the 3 succeeding years, this penalty for performance failure increases to negative 5, 7, and 9 %. Success in meeting the performance thresholds will be associated with a 4 % bonus in 2019, and 5, 7, and 9 % positive bonus in the subsequent 3 years.

Alternative Payment Models (APM)

A second pathway to physician reimbursement is the voluntary participation of clinicians or groups of clinicians in APMs. At present, an APM can accommodate a fee-for-service construct with participants willingly accepting "down side" financial risk with the hopes of realizing significant positive revenue through gain sharing if care is efficient, coordinated, patient-centered, and linked to quality. However, in the future in its simplest form, CMS would agree to pay out one "lump sum" payment to a group of participating caregivers for a given episode of care. It would be the participants themselves who would determine distribution of reimbursed revenue and, in so doing, enhance transparency of care delivered. It is believed that this method of reimbursement would strongly encourage coordination of care and curtail resource over utilization. Some notable examples of APMs are Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes. A separate category of APM, the "Advanced Alternative Payment Model" also exists. This expanded form of APM is intended to be more rigorous in its requirements for eligibility. In addition to the MIPS-type performance measures that are required, the Advanced APM requires that participants utilize Certified Electronic Health Record technology, receive payments based on the MIPS quality measures and, finally, that participants either construct their APM in the form of a

Medical Home or agree to accept "more than a nominal amount of financial risk." As can be expected, the financial bonuses awarded to successful Advanced APMs will be greater than that which will be paid out to the conventional APM. As yet, it has not been determined what constitutes "nominal" risk.

Physician and hospital organization across the country are actively attempting to create efficient and high quality APMs that can manage the challenge of providing the highest quality care possible while assuming both the up-side financial risks (i.e., bonuses) and the down-side financial risks (i.e., penalties). This is proving to be a surprisingly difficult task [11]. Several specific, important impediments to creation of these APMs are emerging:

- How do APM participants deal with issues affecting outcome that are beyond their control and are not specific to the episode of care for which the patient is being treated? For example, dialysis dependent renal failure in a patient admitted for coronary artery bypass surgery.
- Who determines what constitutes an episode of care? For example, a patient admitted to the hospital for the DRG: Mitral Insufficiency. The treatment, resource use, and overall work of treating a patient with mitral insufficiency are completely different depending on the etiology. A patient with "floppy mitral valve syndrome" causing insufficiency is usually healthy and the surgery is relatively uncomplicated. On the other hand, a patient with mitral insufficiency from a massively dilated, low ejection fraction left ventricle is extraordinarily difficult to treat with very different resource use and quality outcome expectations.
- How are issues of medical malpractice liability to be adjudicated? Will all members of the APM be liable for the failure of one participating consultant who fails to recognize a critical laboratory test value?
- How will newly formed APMs pay for conversion to an acceptable electronic health information technology that will be extraordinarily expensive? Should this cost be partially or completely borne by CMS and the federal government?
- Alternative Payment Models, as envisioned by the federal government, appear to be ideally suited for population health and primary care services. How can subspecialty practitioners effectively participate in APMs of the future?

Intense efforts are currently underway between CMS contracted consulting firms, medical specialty societies, and numerous health care organizations to assess feasibility, practicality and organizational structure of the "ideal" Alternative Payment Model. Clearly, the challenges facing a medical home proposed APM, which has, as its major focus, primary care and preventative medicine, are quite different for APMs, which would include subspecialty surgical practices.

Hospital Value-Based Purchasing

While much of the focus has been on methods of physician reimbursement, CMS has also instituted the Hospital Value-Based Purchasing (HVBP) program, which attempts to link reimbursements to the hospitals for in-patient services to the overall quality of care delivered rather than volume of care delivered. In this methodology, a certain percentage of Medicare reimbursement to the hospital is withheld and used as incentive to provide the highest quality care possible. The HVBP program has established 20 quality measures whose performance enables CMS to estimate quality of care. The hospital is scored on either achievement of the quality measures or demonstration of improvement from the previous year. Adjustments in Medicare reimbursement to hospitals, relative to historical payouts for individual Diagnosis-Related Group codes, can be made and are based on score achieved.

Conclusion

The history of US government public policy as it relates to health care in America is one of remarkable evolution from the simple concept of

governmental agencies created to assure all citizens access to consistent health care for life to complex strategies to contain out-of-control health care costs while maintaining the highest quality care delivered. The sheer enormity of medical spending in the twenty first century has made health care a major political factor as it began to assume larger and larger percentages of the national Gross Domestic Product. This fact can no longer be ignored by any of the stakeholders: physicians, hospitals, patients, medical industry (including device and pharmaceutical industries), politicians, and the US Government through its many medical agencies and legislative bodies. We are in the midst of a seismic shift in US health care—how it is delivered and how it is paid for. Health care in this country is extraordinarily complex and so are the many strategies proposed to make it better, more cost effective and safer. Going from where health care was 50 years ago to where it will ultimately end up, will be an arduous, (at times) painful journey that will require the collective wisdom and cooperation of many but there will be no going back.

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Surgical Quality and Patient Safety in Rural Settings

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Amy L. Halverson and Julie K. Johnson

"A physician is obligated to consider more than a diseased organ, more even than the whole man – he must view the man in his world."

—Harvey Cushing, MD

Access to surgical services is an essential component of medical care and is indispensable as part of a functioning health care system [1]. In a 2011 article in the World Health Organization Bulletin, Bae and coauthors discussed the failure of international organizations to recognize surgery as a fundamental component of global health [2]. The authors explained that failure to embrace surgery, a public health intervention, is due in part to the misconception that surgery treats only a small portion of the burden of disease. The shift of the burden of disease is from communicable diseases to noncommunicable conditions and injuries, with injuries accounting for approximately 10 % of deaths globally. Noncommunicable diseases and injuries require more surgical interventions. A second misconception is that surgical care is disproportionately expensive, yet surgical and obstetric care are comparable to the cost effectiveness of other public health interventions, such as vitamin A distribution, detection and home treatment of acute lower respiratory tract infection and measles immunization. The authors also emphasized the importance of developing sustainable infrastructures for surgical care rather than focusing efforts on short-term medical missions [2].

The report from an international symposium held in November 2014, the "Amsterdam Declaration on Essential Surgical Care," states that surgical diseases kill more individuals worldwide than HIV, tuberculosis, and malaria combined [3]. Essential surgical care is defined as "Basic surgical procedures that save lives and prevent permanent disability or life-threatening complications. Such surgery should be of appropriate quality and safety, accessible at all times and affordable to the community." At the 2015 World Health Assembly, the World Health Organization (WHO) detailed the need for surgical and anesthetic services in low-resource areas of the world, and passed a resolution to strengthen emergency and essential surgical care and anesthesia as a component of universal health coverage.

There has been much needed attention regarding access to surgical care in resource-poor countries; however, there are also millions of individuals in the USA who lack access to surgical services. Twenty to 25 % of US citizens reside in rural areas but only 10–15 % of physicians practice in these areas [4]. Thompson and coauthors calculated the ratio of surgeons in rural areas to be 4.67 general surgeons per population of 100,000 compared to 6.53 per population of 100,000 in urban areas [5].

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Nakayama and Hughes cite data that 18% of federally designated hospital service areas have no surgeon of any specialty and 30% of the service areas have fewer than three general surgeons per 100,000 [6]. The relative lack of surgeons in rural areas is expected to worsen over the next decade. Many surgeons currently practicing in rural areas are older and there is concern that as they retire, it will be difficult to recruit younger surgeons to take their place. Furthermore, rural surgeons, compared to their urban colleagues, face unique challenges including professional isolation and lack of access to professional development activities.

This chapter discusses the implications of surgical programs in rural USA, how rural hospitals and Critical Access Hospitals are defined, challenges facing rural surgeons, and how patients living in rural communities make decisions about seeking surgical care. We discuss rural hospitals as a system, including issues facing rural hospitals concerning regionalization of surgical programs and measures of quality and value. We conclude with a series of potential research questions that could help us better understand the role, vitality, and context of rural surgical health care.

Definition of a Rural Hospital

Rurality may be defined by the population of a community and the distance of that community from a metropolitan area. In addition to geographical distance, the remoteness of a community is a function of the functional relationship of a community, as measured by working commuting flows with larger cities and towns. For example, a small community that has limited economic development and is 50 miles from an urban center via a two-lane highway is much different from a community of similar size that is connected to a larger city via interstate highways with high speed limits and a large number of citizens who commute to the larger city on a daily basis.

In a collaborative effort, the Office of Rural Health Policy, the United States Department of Agriculture Economic Research Service and the Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) Rural Health Research Center and the University of Washington developed the Rural Urban Commuting Areas codes (RUCAs) to classify the rural nature of a community. The classification system was initially developed in 1999 and subsequently revised to include data on travel time and distance to more urban areas in addition to the population of a community [7]. Critical access hospitals (CAH) are a subset of rural hospitals that meet specific criteria. In 1997, the US Congress established the Medicare Rural Hospital Flexibility Program. The goals of this program were to support states in establishing rural health care networks. This program designated certain hospitals as "Critical Access Hospitals." Hospitals seeking designation of a CAH must meet several criteria: (1) be located in rural areas and be at least 35 miles from any other hospital (exceptions may apply); (2) have no more than 25 acute care beds; (3) offer 24-h emergency services, and (4) not exceed an average annual length-of-stay of 96 h [8]. The size and length of stay limitations were established to encourage treatment of common conditions and outpatient care while referring patients with other, more complex conditions to larger hospitals. As of March 2016, there were 1331 CAHs in 45 of the 50 United States (see Fig. 49.1). CAH have limited financial and human resources and are paid by the Centers for Medicare and Medicaid (CMS) on a hospital cost basis rather than the diagnostic related group based payment that is used for inpatient care covered by CMS at other hospitals. This reimbursement system was instituted to prevent the closure of small hospitals that were losing money. Despite this effort, many small rural hospitals, including CAH continue to close [10]. States that chose to not expand Medicaid as part of the Affordable Care Act feel the most financial pressure. Since 2010 more than 70 rural hospitals have closed. (Source=http://www.ivantageindex.com/vulnerability-index/)

The Rural Surgeon: Challenges and Solutions to Practicing in a Rural Setting

Rural surgeons often serve several clinical and administrative roles within the hospital. Their responsibilities may include medical director of the operating room, managing trauma systems and overseeing critical care. In the majority of

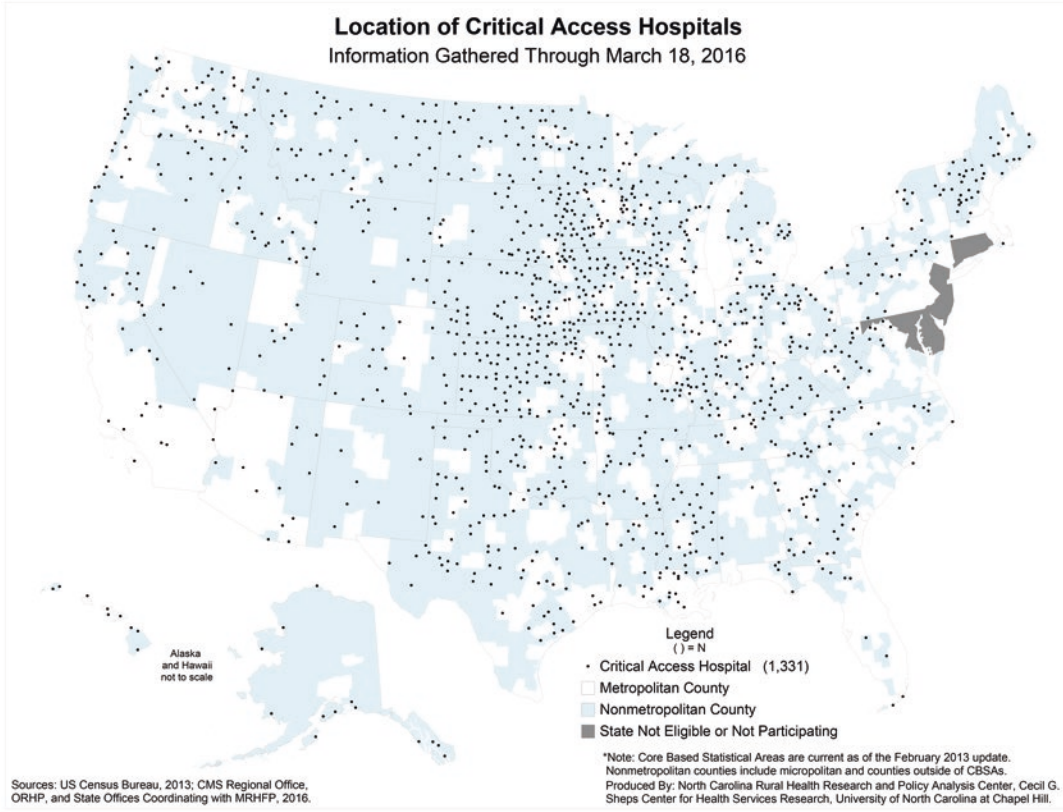

Fig. 49.1 Location of Critical Access Hospitals. Permission to reprint confirmed from location of critical access hospitals. Flex Monitoring Team. http://www.flexmonitoring.org/wp-content/uploads/2013/06/CAH_031816.pdf. Updated 2016. Accessed 03/24, 2016 [9]

rural hospitals, anesthesia is provided by nurse anesthetists and the surgeon is the supervising physician depending on individual state laws. Several studies have suggested this greatly increased the overall risk of anesthesia care. Silber et al., found 2.5 excess deaths within 30 days of admission and 6.9 excess failures-to-rescue (deaths) per thousand cases when an anesthesiologist was not involved [11]. Clinically rural surgeons have a broader scope of practice than their urban counterparts. In addition to cases commonly under the domain of general surgery, such as cholecystectomy, appendectomy, colectomy and hernia repair, rural surgeons may perform other oncologic, otolaryngology, vascular, urologic and orthopedic procedures. In some communities rural surgeons also perform gynecologic procedures and cesarean sections. A significant portion of the rural surgeon's practice consists of upper and lower endoscopy, including both diagnostic and therapeutic procedures [12–15].

Many rural surgeons are in solo practice. Without partners, rural surgeons have frequent, if not continuous, call responsibilities, lack of highly skilled assistance for difficult cases, and lack of coverage for time away. Professional isolation has been singled out as the most important challenge faced by surgeons in rural practice [16]. Often rural surgeons are in solo practice and therefore have limited opportunities to discuss surgical problems with colleagues. Another commonly cited challenge is a relative lack of access to continuing medical education that matches the scope of practice of the rural surgeon and specifically addresses problems in the context of a rural practice [17]. These barriers exacerbate the ability of rural hospitals to attract and retain surgeons.

Various solutions to address the problem of work burden and professional isolation have been described in recent literature, including forming group practices of two to three surgeons to provide dependable coverage [16]. The Gunderson Lutheran system in LaCrosse, Wisconsin has created a model consisting of 25 regional sites that are supported by an academic, full-service tertiary care center. All regional sites in the system share a single integrated electronic medical record. All surgeons in the system are members of a single Department of Surgery within the Gunderson Health System and the surgeons at regional centers participate in patient-focused conferences and educational courses. The regional surgeons have developed a coverage system based on geographical locations of the regional practices.

Another unique approach is the University of North Dakota's rural surgery support program. A full-time faculty member of the medical school's Department of Surgery provides coverage to regional hospitals in 2-week increments. The billing for all services provided by the covering surgeons is the responsibility of the regional health care facility. In addition to coverage, the University offers continuing education and consultation services.

Recently the problem of professional isolation has been addressed through creating an electronic listserv, developed by Dr. Tyler Hughes, for rural surgeons to communicate about various topics related to rural life and surgical practice. Rural surgeons have an opportunity to present clinical scenarios in order to obtain the advice, and sometimes just empathy, of their surgeon colleagues. The overwhelming success of the listserv prompted the American College of Surgeons to establish "Communities" for various interest groups among its members [18].

To address the rural surgeons' lack of access to continuing medical education that matches their learning needs, the American College of Surgeons established the course, "Advanced Skills Training for Rural Surgeons." A team consisting of rural surgeons, academic surgeons, and individuals with expertise in adult education developed the course to be offered as part of the Nora Institute for Surgical Patient Safety. The initial planning for the course involved numerous discussions with rural surgeons, both one-on-one and in groups, to brainstorm potential topics for course content. The initial discussions were followed by conducting a needs assessment of rural surgeons as well as a literature review and review of rural surgeons' case logs [19]. In a flipped classroom approach, course faculty provide participants with Web-based learning materials to review prior to attending the in-person session to maximize the time spent in hands-on, mentored skills practice. Each course module is developed with and taught by content experts. The course is held annually. The curriculum consists of 12 modules that rotate year-to-year [20] (Table 49.1).

Table 49.1 Rural surgery learning modules

Leadership and communication
Advanced endoscopy
Emergency gynecology
Emergency urology
Facial plastic surgery—lesion excision
Facial plastic surgery—laceration repair
Breast ultrasound
Ultrasound for central line insertion
Management of fingertip amputation
Laparoscopic common bile duct exploration
Anesthesia skills Vascular surgery skills

The Rural Hospital in the Context of a Care System

A successful rural health care network relies on rural hospitals to provide readily accessible, high-quality care. Additionally, there must be established, formal relationships between small rural hospitals and regional hospitals to facilitate the transfer of patients when they require a higher level of care [21]. Considering the effectiveness of a health network raises this issue of how to measure quality, safety, and value of surgical care provided at rural hospitals. A second consideration is determining which clinical conditions warrant transfer to a regional center based on the facilities and professional resources of the local hospital. A third, often neglected component to consider is the patient's resources and preferences in obtaining care at a regional versus a local hospital.

Measuring Quality in Rural Hospitals

Casey and coauthors reported the efforts of an expert panel to identify quality measures relevant to critical access hospitals [22]. The panel evaluated CMS inpatient and outpatient quality reporting and electronic health record meaningful use measures as well as the Joint Commission and other National Quality Foundation endorsed measures. Surgical quality measures that were identified as potentially useful and cost effective included perioperative antibiotic prophylaxis, venous thromboembolism, measures to reduce UTI and perioperative temperature control. Additionally, the panel supported the reporting of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data. The expert opinion panel recommended that future surgical quality measure developments include a surgical checklist measure and additional measures focused on high-volume outpatient procedures such as gastrointestinal endoscopy [22].

Prior studies have shown disparities in the quality of medical care in rural vs. urban hospitals. Joynt and coauthors evaluated quality process measures for Medicare beneficiaries admitted between 2002 and 2010 with pneumonia, acute MI and congestive heart failure in 1268 CAHs [23]. In 2002 the mortality rates for these conditions at critical access hospitals were similar to noncritical access hospitals. However, over the study interval, the mortality rates increased in critical access hospitals resulting in a significant gap for all three conditions compared to noncritical access hospitals. Even when compared to other rural noncritical access hospitals of similar size, increased mortality rates were again observed at the critical access hospitals. The authors compared critical access hospitals that improved over the study interval (414/857 (48 %)) to critical access hospitals that did not improve. The only observed difference was a slightly higher median resident income in the critical access hospitals that had a decreased mortality rate. The authors proposed several possible explanations for why mortality rates worsened at the majority of critical access hospitals aside from smaller sample sizes making results difficult to interpret. The first is that CAHs were not required to report the same quality measures as other hospitals. Second, payment systems for CAH may take away a financial incentive to improve quality and efficiency. Third, CAH have not kept pace with improved technologies that improve patient outcome. Finally, patients at CAHs have higher comorbidities and a higher burden of social and financial problems.

In contrast to a gap in outcomes for medical admissions, subsequent studies have found no such difference in outcomes for surgical admissions in CAH and non-CAHs. Gadzinski and coauthors utilized data from the American Hospital Administration and the National Inpatient Sample (NIS) to compare CAH and non-CAHs in terms of surgical outcomes [24]. Although CAHs comprised 26.2 % of patients included in the study, only 1.3 % of the operations were performed at CAHs. Patients admitted for surgery at CAHs were generally younger and had fewer measured comorbidities compared to patients at non-CAH facilities. The authors found that operative caseload at CAHs consists of mostly general surgery, OB/GYN, and orthopedic procedures. These classes of procedures comprised nearly 96 % of procedures in CAHs, compared with 77 % of non CAHs. The most common procedures performed included appendectomy cholecystectomy, colectomy, cesarean section, hysterectomy, hip fracture repair, hip replacement and knee replacement. Mortality rates for these procedures were similar for CAHs and non-CAHs. The exception was hip fracture repair. The mortality risk for this procedure was higher compared with non CAHs in patients with Medicare as the primary payer (adjusted odds ratio [AOR] = 1.37; 95 % CI, 1.01–1.87) and for patients with elective admissions (AOR = 2.65; 95 % CI, 1.20–5.82). The authors opine that increased mortality for hip fracture repair may reflect the urgent treatment of older patients with more comorbidities. An additional finding was that despite shorter lengths of stay, ($p < .001$ for four procedures), costs at CAHs were 9.9–30.1 % higher ($p < .001$ for all eight procedures).

Natafgi and coauthors also found similar rates of complications in CAHs compared to other small

(fewer than 50 beds) hospitals without critical access designation. The authors evaluated hospitals on six patient safety indicators: death, postoperative hemorrhage and hematoma, respiratory failure, deep venous thrombosis or pulmonary embolism, sepsis and postoperative wound dehiscence. After adjusting for patient and hospital characteristics, the authors found that critical access hospitals performed the same or better than the small community hospitals in all indicators [25].

A recent study by Ibrahim and coauthors add more evidence that critical access hospitals provide high quality and cost effective care. The authors conducted a retrospective review of more than one million Medicare beneficiary admissions for one of four common surgical procedures including appendectomy, cholecystectomy, colectomy and hernia repair. The authors found that critical access hospitals had mortality and morbidity rates that were comparable to noncritical access hospitals. Critical access hospitals had significantly lower rates of serious complications (6.4 % vs. 13.9 %; OR, 0.35; 95 % CI, 0.32–0.39; $p < 0.001$). Furthermore, Medicare expenditures adjusted for patient factors and procedure type were lower at critical access hospitals than noncritical access hospitals. ($14,450 vs. 15.845, $p < 0.001$).

In addition to outcome measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores provide another measure of quality of care. A 2011 report showed that 41 % of CAHs reported HCAHPS scores. These results from these hospitals demonstrated significantly higher HCAHPS scores compared to all other hospitals [8, 22].

The majority of studies of quality in rural hospitals are based on large administrative databases. There is a paucity of studies utilizing risk-adjusted, abstracted data such as that used in professional databases, e.g., the National Surgical Quality Improvement Program (NSQIP). Many rural hospitals operate on a narrow financial margin and do not have the financial resources to cover the cost of participation in these programs. Additionally, hospitals may lack personnel to abstract data and to develop and implement quality improvement programs. Just as the rural surgeon play several roles in the hospital, a hospital quality leader may also have several other clinical and administrative responsibilities to compete for their time and attention. A third challenge is the low volume of surgical procedures performed at rural hospitals which makes it difficult for a single hospital to track meaningful outcome measures [26].

Regionalization of Care

A well-functioning rural health network depends upon a predictable and reliable interaction between rural hospitals and larger regional hospitals. The role of the rural hospital in a health network is to provide local care for basic procedures. Patients with conditions requiring more complex treatment will be transferred to regional centers. With this approach, it is important to determine what cases are appropriate for local care and which patients should be transferred. Hospitals may determine a priori that certain conditions necessitating complex surgery should be managed at a larger hospital with appropriate resources. Challenges to developing and maintaining the smooth functioning of such a system for surgical patients include managing patients with acute conditions that warrant emergent intervention and managing patients with routine surgical problems who have significant medical comorbidities. Rural residents have higher rates of diabetes, cardiac failure, mental health, tobacco use and obesity. Additionally, an increasing proportion of rural patients are elderly [27].

There is the argument that regionalization of care equals better care. However, regionalization may unduly restrict the surgeons providing care. This is a complex issue that must take into account many factors, including the complexity of a procedure, the surgeon's annual volume and the surgeon's cumulative experience. In a systematic review of the effect of volume and experience on outcome, Marruthappu and coauthors found that the relationship between volume and outcome is not consistent. Also, determining adequate volume to reach a level of mastery varies widely among surgeons and procedures studied.

The authors found that experience as measured by years in practice and annual case volume correlate to health outcome and are not related to specific procedures [28].

Procedures most commonly performed in rural hospitals include endoscopic procedures, cholecystectomy, breast procedures, hernia repair and colectomy. Complex operations such as pancreaticoduodenectomy and esophagectomy are not being performed at small rural hospitals. Markin and colleagues studied 20 oncologic procedures performed in rural hospitals from 1998 to 2009 and showed that throughout the study period, the most common oncologic procedures performed at rural hospitals were resections of the colon, rectum, breast, or uterus. The proportion of oncologic procedures performed at rural hospitals decreased from 12 % in 1998 to 6 % in 2009. Multivariate analysis showed that, overall, undergoing an oncologic procedure at a rural hospital did not confer an increased risk for postoperative mortality (OR of mortality, 0.93; $p=0.08$). However, surgery at rural hospital increased the risk of mortality following complex operations including resection of lung, pancreas, esophagus or bladder compared to other gastrointestinal procedures, (mortality following complex procedure compared to gastrointestinal procedure in rural hospital OR 2.10 (1.67–2.64), in non rural hospital OR 1.49 (1.40–1.59)) [29].

More recently, Chow and colleagues compared colon cancer treatment in rural and urban hospitals using a California state-wide database. The authors assessed four quality indicators: stage at diagnosis, number of lymph nodes harvested, receipt of chemotherapy for stage III disease and mortality. Patients living in rural areas were more likely to be diagnosed with stage III and IV disease (OR 1.037, 95 % CI 1.001–1.075, $p=0.043$). Rural patients with stage I to III disease were less likely to have ≥12 lymph nodes evaluated compared with their urban counterparts (OR 0.808, 95 % CI 0.777–0.840, $p<0.001$). Rural patients were less likely to receive adjuvant chemotherapy (OR 0.863, 95 % CI 0.799–0.932, $p<0.001$). Additionally patients living in rural areas had a 4 % higher risk of death from their cancer compared with patients living in urban areas (HR 1.038, 95 % CI, 1.007–1.071; $p=0.016$) even after adjustment for stage and other patient, tumor, and treatment factors. Given the limitations of their database, the authors could not adjust for hospital factors or surgeon factors such as hospital case volume, surgeon specialty, or surgeon case volume [30].

While regionalization may be important in providing care in sicker patients and those patients needing complex procedures, regionalization has the potential to limit access to care for some patients. For example, Dr. Arnold Hill commented on the efforts of the Republic of Ireland to regionalize cancer treatment. In 2006 Ireland introduced a program to consolidate cancer treatment from 32 hospitals throughout the country to eight designated cancer centers. This system left patients in some areas having to travel increased distances for care. In response to the new system, surgeons at non-cancer center hospitals either retired or transitioned a portion of their practice to the cancer center hospitals or moved their practice entirely. There did not seem to be a reciprocity on the part of the cancer center hospital surgeons to transfer out patients with uncomplicated, benign conditions requiring surgery. There was a resulting disincentive for surgeons to practice outside of the eight designated cancer centers.

In summary, a system of regionalization should be built upon solid relationships between rural hospitals and regional centers. The role of the regional center should be to provide support to the smaller outlying hospital and their surgeons. This relationship may be facilitated by surgeons at different hospitals agreeing on which types of operative cases and patient conditions are appropriate for transfer to a higher level of care. The agreed upon patterns of care should weigh the burden of travel for the patient with the clinical benefit of more specialized care. The system should allow routine operative procedures to remain at the outlying hospitals to maintain job satisfaction for the surgeons. Additional support for the outlying surgeons may be providing the opportunity for the outlying surgeons to participate in multidisciplinary conferences related to cancer care.

Patient Preferences and Resources

Studies addressing the regionalization of care have primarily focused on process measures and clinical outcomes. Relatively few studies have considered the patient's values when weighing the benefits of regionalization of care. Studies that evaluate patient preferences for care consistently demonstrate that patients prefer to seek care at a more local facility. In 1999 Finlayson and coauthors conducted a study in which 100 patients were given a hypothetical scenario of undergoing a Whipple procedure locally or at a hospital 4 h away by car. The patients were asked where they preferred receiving care if the operative mortality risk was equivalent at both hospitals. Through an iterative process, patients were then asked whether their preference changed with increasing mortality risk at the local hospital. All patients indicated that they would prefer to have surgery at the local institution if operative mortality risk were 3 % at both the local and regional hospitals. If operative mortality risk at the local hospital was doubled, 45 of 100 patients would still prefer to undergo surgery locally. If local risk were 9 percentage points higher (four times the regional risk), 23 of 100 patients would prefer to undergo surgery locally. If local risk were 15 percentage points higher (6 times the regional risk), 18 of 100 patients would still prefer local surgery [31].

In a qualitative study, Nostedt and colleagues interviewed patients from rural areas undergoing surgical treatment at regional center in Winnipeg [32]. Factors that affected patient's decision to seek care at an urban center were categorized according to three main themes. First, patients have varying levels of input regarding the decision of where to seek surgical care. Some patients do not perceive that they have a choice in determining treatment location and they follow recommendations by primary care doctors, gastroenterologists, oncologists or other surgeons without discussion treatment options. Second, patients consider treatment factors, including surgeon factors and hospital factors when considering treatment location. Surgeon factors that contribute to a patient's decision about where to have surgery include a surgeon's technical skills and experience, professional reputation and interpersonal skills. Participants often expressed establishing a good rapport with their surgeons helped them feel more comfortable about the surgery and perioperative care plan. Hospital factors that influenced where participants chose to have surgery included the hospital's reputation, the expertise of other specialist and hospital resources. A third theme affecting patient's choice of treatment location was personal factors such as finances, employment issues, and social support. While these were not the primary deciding factors, the personal issues contributed to the burden that the care entailed. Many patients travel several hours for treatment. They had to contend with the cost of transportation, the necessary time away from work and the cost of accommodations to have surgery in a location where they did not have existing social support mechanisms [32].

Tai and colleagues used administrative Medicare data to show that among Medicare enrollees residing in rural areas, 56 % of hospitalizations were at the patient's closest rural hospital. Patients with complex medical conditions, surgical and psychiatric diagnoses were more likely to bypass the closest rural hospital to seek treatment. Additionally those with greater economic resources were more likely to bypass nearby hospitals. Patients with a local primary care physician and those older than 85 years of age were less likely to bypass the closest hospital [33]. The findings of this study are consistent with prior studies that showed travelling long distances is a deterrent to hospital choice and individuals with a greater complexity of illness tended to choose larger rural and urban hospitals over smaller rural hospitals [34].

A more recent study done by BCBS of Tennessee found that 69.9 % of patient stays were not at the member's closest geographic facility. After eliminating procedures that were not offered at a closer facility, still, 43.4 % of patient visits were at a more distant facility. Patients traveled on average 23 miles farther than the closest facility. The authors opine that patients are more likely to travel for health care due to mobility

including helicopter transfer, technology—regional centers have technology that the smaller hospitals cannot afford, and capacity or regional hospitals to accept more patients Distance from a facility did not affect adherence for mammograms or whether individuals with back pain had surgery. This study does not apply to the uninsured or those with Medicaid or Medicare [35].

Conclusion

This chapter addresses three essential components to providing quality surgical care in rural areas: the patient, the hospital in the context of a health care system and the surgeon. Further research on quality improvement in rural surgical health care may address one of these three domains. A patient centered framework focuses on the needs of the patient, which include the clinical care that the patient's condition warrants as well as the socioeconomic factors that may affect the patient's health care choices and access to care. Additionally, in the rural setting, the hospital does not simply take care of individual patients, but serves as a cornerstone to the health of the rural community. A surgical practice supports the financial viability of the hospital and provides economic support to the community directly in terms of employment and indirectly as access to quality health care is an important factor for business and individuals considering staying in or relocating to rural community [36]. A second component of quality surgical care is the hospital in the context of a regional health system. A rural hospital needs established relationships with larger hospitals that will accept the transfer of patients whose clinical needs exceed the capacity of the rural facility. Hospitals should provide the ancillary staff and equipment to meet care standards for the range of procedures they perform. Third, the hospital and the health care system should consider the needs of the rural surgeon, including coverage for call, for vacation and to allow participation in continuing professional development activities. Thus, the following questions may be considered for future research:

1. What are the financial and social burdens to patients when they are referred outside their community for surgical care and in what ways can portions of their care such as preoperative optimization and postoperative follow-up care be kept within the local community?
2. How can rural and regional hospitals improve collaboration and how can communication optimize the coordination of care for patients?
3. How do we best support rural hospitals in quality improvement efforts?
4. What strategies can be employed to support surgeons in rural practice and recruit new surgeons to impede the growing shortage of surgeons in rural areas?

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Global Surgery: Progress and Challenges in Surgical Quality and Patient Safety

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Christopher Pettengell, Stephen Williams, and Ara Darzi

"Of all the forms of inequality, injustice in health care is the most shocking and inhumane."

—Dr. Martin Luther King, Jr.

Introduction

A provision of care for surgical disease should be a prerequisite for all health systems in all countries, worldwide. The delivery of this surgical care should be high quality and safe. The international recognition and propagation of landmark works, such as *To Err is Human* [1], and involvement in quality reporting databases (e.g. the *American College of Surgeons National Surgical Quality Improvement Program*, ACS NSQIP) [2] has brought the topics of quality and safety to the fore in the minds of health leaders and policy makers.

While there is an ever growing body of peer-reviewed literature on both patient safety and surgical quality, neither holds a uniform definition, presenting something of a dichotomy, since we must firmly establish what we mean by "*quality*" and "*safety*" before if we are to consider these attributes in a robust manner across diverse health contexts. The World Health Organisation (WHO), define patient safety as

> … the absence of preventable harm to a patient during the process of healthcare. The discipline of patient safety is the coordinated effort to prevent harm, caused by the process of healthcare itself, from occurring to patients [3].

We consider health care quality in terms of three core areas: clinical effectiveness, patient experience, and patient safety [4]. Hence, there are extensive links between a health system that is considered safe and one that is considered of high quality—as we discuss further below.

In this chapter we discuss surgical care provision globally, making reference to the limited progress that has been made to date in the fields of quality and safety, while isolating the ongoing challenges we all must look to address in the future.

The Donabedian Model

In 1988, Donabedian published a model that conceptualizes quality in health care as three interrelated components, namely "structure," "process," and "outcome" [5]. While a plethora of other quality of care frameworks have been proposed over the subsequent years, Donabedian's work remains the dominant paradigm over a quarter of a century later.

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While quality and safety have two distinct definitions, there are considerable overlaps when applied to health care. It has been stated "*high-quality systems are safe systems*" and indeed, the two concepts should not be considered mutually exclusive [6]. These similarities are echoed in the work of Provonost, and others, who have developed models for patient safety that use Donabedian's original quality paradigm as a skeleton structure [7–9]. In a similar vein, we consider the facets of quality and patient safety under the headings of Donabedian.

Structure

The term "structure" is better phrased as "infrastructure" as it comprises all the physical equipment, levels of staffing, training and, obviously, the financial situation of a health care system. Since it measures finite, definite things, it is easily quantifiable and is seen as the base upon which other components of quality build. It is also something that, we, as practicing surgeons in high-income countries (HICs), take for granted.

Globally, the greatest burden of surgical disease is found in low-income and middle-income countries (LMICs), yet these countries are exactly those whose infrastructure is often severely limited. This is borne out when considering that while more than 200 million operations are performed across the globe each year, only 3.5 % are for the poorest third of the world's population and therefore accessing surgical care remains a major challenge [10]. Indeed, it has previously been estimated that approximately two billion people lack access to an adequate level of surgical care [11].

The Lancet Commission on Global Surgery [12] defines access to surgery in any country as the existence of four components, capacity in terms of staff and infrastructure and ability to access it in a timely, safe and affordable way. By applying this stepwise model to the global population it is possible to estimate the probability that an individual has access to surgical care. Unbelievably the Commission found at least 4.8 billion people do not have access to surgery worldwide, a figure that represents almost 95 % of the population of many LMICs [13]. By comparison only 14.9 % of the population of HICs lack access. This estimate is over double previous reports [14] but is important when thinking about the challenges facing LMICs in supplying safe and effective surgical care as it recognizes that access is about more than capacity alone. It is the lack of timely, safe and affordable access that results in the majority of the world's population having to forego appropriate surgical care.

A major hurdle then is that of national infrastructure to enable patients to reach the hospital in a timely manner. We know that where appropriate surgical and intensive care facilities exist these can prevent morbidity and mortality in the sickest patients however, these patients are often presenting late to hospital resulting in poor outcomes [15]. The reasons for this are complex and multifaceted since not only are health care facilities in LMICs often vast distances away from where patients require them but those that are able to reach the door of the hospital can find lengthy queues ahead of them owing to overcrowding, poor facilities, and a lack of adequately trained staff [16, 17]. In the face of limited resources and huge demand, providing high-quality care is extremely challenging [18].

Patients are often also discouraged from seeking surgical care due to the direct and indirect costs associated with it. The World Bank estimates three billion people earn less than US $2.5 per day which makes even modest hospital fees of US $133 unaffordable [16] added to this in some places the lack of hospital supplies requires patients to provide their own [19].

For those that do access appropriate care it has long been recognized that outcomes are influenced by the complex interplay of multidisciplinary teams and the systems that they work within [20]. At its simplest level this can be broken down into four parts: the staff, the equipment, the buildings they use and the systems that allow the staff and equipment to effectively work together in the shared space [13]. Access to all of these components is limited in resource-poor settings and will therefore impact on a nation's ability to provide effective surgical care to its population.

In many LMICs the equipment and space to work is woefully inadequate. An analysis of the number of operating theaters available in 792 hos-

pitals participating in the WHO's safe surgery saves lives campaign showed gross disparities [14]. Low-income countries, which accounted for over 2.2 billion people, had on average less than two theaters per 100,000 people and in the worst affected, such as west sub-Saharan Africa, only one operating theater per 100,000. Compare this with the global average of 14 or 25.1 per 100,000 in Eastern Europe and you get an idea of the scale of the problem. Even if a patient is fortunate enough to have access to an operating theater around 77,700 of these worldwide do not have access to basic equipment necessary to provide safe surgical care such as pulse oximetry [14].

Basic infrastructure gaps such as unreliable electricity and water supplies will further hamper efforts and impact on outcomes [15]. In 12 sub-Saharan countries reliable electricity was fully available in only 35 % of health facilities [21]. In Sierra Leone the situation is even direr with a lack of electricity, running water, oxygen and fuel at the government run hospitals, only 20 % had running water [19].

The final barrier limiting access to surgical care is a drastic shortage of trained surgical providers, with general surgeon density ranging from 0.13 to 1.57 per 100,000 population in LMICs [22], contrasting with an equivalent figure of 5.8 per 100,000 population in the USA [23].

Recent estimates suggest that, by 2030, an additional 806,352 surgical providers will be required in LMICs [24]. This is an ever worsening surgical workforce crisis and somewhat crucially, the question remains as to how this can be solved. Current approaches have broadly been either short term humanitarian based projects or "*missions*" (where international surgeons from HIC provide work in LMICs) or, more challenging, longer term projects focused on increasing levels of training for both existing and new practitioners.

HIC Surgeons Practicing in LMICs

An estimated 55 % of all surgical care in LMICs is delivered through international charitable organizations and, for the years 2008–2013, this required funding to the tune of $3.3billion [25]. Not only does this require considerable financing it also requires a large body of willing volunteers—though surveys confirm that there are increasing numbers of surgeons and surgical trainees from HICs, especially those from Europe and North America, expressing a desire to provide such services in LMICs [26].

Many of the international organizations providing surgical care in LMICs do so in response to acute health care crises: as a result of natural disasters, conflict, famine, or sudden disease outbreaks. This generates considerable overlap between the "routine" work these organizations provide and more wide-ranging acute humanitarian relief projects. It is difficult to fully appraise the burden of surgical disease treated by such mission work as there is little by way of data reporting outside of their organizations [27]. However, a recent survey across 99 such organizations showed provision of care across the entire breadth of surgical specialties though it also revealed considerable variation as to the scale of care provided—with a third of organizations performing less than 200 operations a year and only five performing more than 1000 surgeries [28].

One of the largest of these international organizations is Médecins Sans Frontières (*Doctors without borders*, MSF) which, despite being a French-based organization, recruit surgeons internationally and coordinate projects both in response to emergency crises and in other areas of desperate need [29]. Over four decades, MSF have provided surgical care in Afghanistan, Angola, Cambodia, Chad, Ethiopia, Haiti Libya, Sierra Leone, Somalia, and Sudan to name but a few, and in 2006 alone they performed over 64,000 procedures across 20 countries worldwide [30].

While the efforts of HIC surgeons on these short-term missions have undoubtedly improved the lives of countless individuals in LMICs, their ability to confer any long term effects on the actual infrastructure within these countries is somewhat more limited [31, 32]. Some authors have also expressed concerns that, as the cost of health care worldwide continues to increase, that the funding needed by these charitable organizations will increase concurrently and that there is therefore an acute need to move towards sustainable health care in LMICs—without such a reliance on international aid [33].

Enhanced Training for LMIC Surgeons

The majority of long-term projects have taken a particular interest in workforce initiatives to expand surgical and perioperative training for surgical providers in LMICs. Much progress on this front has been made since it has been adopted by the World Health Organization (WHO), though there are some who have chastised the WHO for not recognizing the inadequacies of surgical care in LMICs until this point [34].

In 2004, the WHO launched the Emergency and Essential Care Programme. This program provides a basic training package for surgical providers in LMICs based around the *Integrated Management of Emergency and Essential Surgical Care* toolkit and the text "*Surgical Care at the District Hospital*" [35, 36]. A key facet of this project is a strong emphasis on "Training the trainers" courses, where local staff are empowered to propagate this training program elsewhere, leading to large scale dissemination. While the availability of longer term data is limited by the implementation date of the programme in individual settings, Henry et al. reported its impact within Mongolia over a 6-year period, noting its adoption in over half of all health care centers during this time and a conferred 74% increase in the number of emergency procedures performed [37].

The WHO is also able to lead on aims to improve infrastructure through its influence on global health policymakers and the coordination and integration of stakeholders at multiple levels within LMICs, including the relevant Ministry of Health, international partners and non-government organizations [34]. The clearest path to long-term solutions is through sustained dialogue and collaboration within each country.

Those in HICs can also have an effect on the number of trained surgeons in LMICs through international recruitment strategies. Indeed, the net shortage of 4.3 million health professionals across 57 LMICs prompted the WHO to issue a formal code of practice for the responsible recruitment of health care workers by HICs [38].

What health care organizations in HICs must rather do is establish links with their counterparts in LMICs for the exchange of training and experience [39]. Collaborations such as these would also increase opportunities for surgeons working in LMICs, further increasing workforce retention and going against the clinician "*brain drain*" currently seen all too frequently within these countries [40, 41].

It has been suggested that if the WHO publish surgical workforce data (in the way it already does for other specialities within health care), to allow recognition of the global shortfalls in surgical personnel as only by delineating the problem can we begin to plan and direct targeted initiatives in the future [22].

Unfortunately, the dearth of qualified surgeons and anesthesists is not the only problem faced globally. Another neglected issue is the lack of equipment to permit surgical practice in many LMICs. Simply increasing the funding for health care in these settings is not a viable option in most circumstances and so we must approach this problem more creatively to find more innovative solutions. This is what provides the catalyst for frugal innovation.

Frugal Innovation

Increasingly, there is a recognition that the dissemination, or "flow," of ideas does not have to be one-way traffic from HICs to LMICs. The concept of *reverse* of *frugal* innovation is a relatively new one within the sphere of health care, where we often tend to focus on the refinement of established practices in developed countries with a trickle-down effect to the developing world, but it has been an accepted phenomenon within other fields for some time [42].

LMICs are continually seeking to expand and improve the quality of health care for their populations but they do so under considerable restraints in terms of physical and financial resources. The coupling of these limited resources with their, often acute, health needs drives innovation at levels not seen in HICs. Furthermore, often working from a blank slate, without an established health care framework, they can be considered freer to experiment and innovate [43].

There are countless occasions one can recall where surgical equipment we now see as commonplace was conceived by colleagues working under

the confined of restricted resources. For example, the use of a polyethylene urine bag to temporarily cover large laparostomy wounds was first employed by Borraez in 1984, while working in a hospital in a deprived area of Bogotá, Columbia [44]. The use of the "Bogotá bag" for abdominal wall closure is now a recommended technique and is considerably cheaper than alternate methods [45].

The city of Bogotá was also the birthplace of another frugal surgical innovation in the creation of the first unidirectional valve for the drainage of cerebrospinal fluid in patients with normal-pressure hydrocephalus by Hakim [46]. As with the Bogotá bag, this device can also be produced at low cost and, indeed, the Indian company Surgiwear produces the Chhabra Micro Precision ventriculo-peritoneal shunt system, based on the original Hakim mechanism, for only $35 [47].

Ilizarov developed his eponymous frame for the external fixation of a fracture while working as an orthopedic surgeon in a remote part of western Siberia in the 1950s with very limited resources [48]. It was only some 25 years later, when Ilizarov present his work at a conference in Italy, that his frame began to be adopted by surgeons globally and it continues to be utilized in operative fracture management today [49, 50].

These are but three of the innovations conceived and developed in the context of suboptimal resources. Each was designed to meet a specific need and by the simplest, and so cheapest, way possible. Not only are such frugal innovation low cost but also they are often more suited to their environment, utilizing the materials or resources that are present. More work is needed to make sure that frugal innovations can be recognized and their benefit shared among the health care providers that need them the most. A current project, based in the USA and supported by the Commonwealth Fund is attempting to advance this very issue and we await its results eagerly [51].

Process

"Process" refers to the actions of health care delivery itself, including not only all diagnostics and treatment but also every conceivable event or action that a patient could be exposed to during their health care episode, including unsafe care.

Surgical Quality Improvement in LMICs

Changes in these processes, usually referred to as exercises in quality improvement, should confer downstream beneficial changes in measured outcomes. It is important that we define processes in terms of their associated outcomes as they are what allow us to quantify the effect of a given improvement initiative. Quality improvement (QI) itself is a term becoming increasingly commonplace in health care parlance. One of the best definitions of QI was phrased by Batalden and Davidoff who state QI is the:

> … combined and unceasing efforts of everyone—healthcare professionals, patient and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [52].

This, and in essence all definitions of QI, views health care as a series of processes within a system. The isolation and fine-tuning of these processes is what QI is principally concerned with.

QI has long been accepted as a vital part of the manufacturing industry and a number of specific methodologies have been developed in this sector to reduce variation and error while increasing reliability, thus improving not only quality for the customer but reducing cost for the manufacturer [53]. Many of these methodologies have been adopted by the health care sector including:

- *Plan-Do-Study-Act* (*PDSA*) *cycles*, which consist of four stages in an iterative cycle.

  In the "plan" stage the change for improvement is determined, the "do" stage comprises the testing of this change, the "study" stage examines the effects of the change, in comparison to what was before, and the "act" stage analyses these difference to inform a further cycle of improvement [54, 55]. PDSA cycles have been used successfully in endovascular surgery to reduce atrial closure complications in the UK [56], and in trauma surgery in a large

study to reduce operative waiting times in Finland [57].

- *Six Sigma* (*SS*) was developed by the Motorola Corporation in the USA in 1986 and aims to generate QI through the identification and correction of errors at source—to reduce the rate of errors to a six sigma level of 3.4 defects per million opportunities. SS methodology has been used to reduce morbidity in rectal cancer surgery in India [58], to reduce infection in the surgical ICU in the USA [59] and to improve efficiency in theater in both the Netherlands and the USA [60, 61].
- *Lean* methodology evolved from the Toyota Production system in 1988 and is a continual QI process where all sources of waste from a process are systematically eliminate, leaving only the steps which confer value [62].

  Published studies successfully utilizing Lean methodology in surgery include a significant reduction in mortality in patients with fractured neck of femur following introduction of Lean academy meeting and the standardization of care with dedicated daily theater slots [63].

It should be noted that, despite numerous success stories of QI methodologies from the manufacturing industry conferring benefit when applied to processes in surgery, the results of each are context dependent and so it is not possible to make definitive evidence-based recommendations. Recent systematic reviews exploring the impact of PDSA, SS and Lean methodology make reference to the striking heterogeneity between different interventions preventing any kind of meta-analysis of data [64, 65].

While there is considerable evidence to support the use of QI methodology in health care, we should recall that the initial step in any QI project is a full and thorough determination of the processes and systems already in place locally [66]. Thereafter any innovation, no matter its strategy should, ideally, be configured specifically for the setting in which it will be implemented [67]. The limitations encountered when reviewing reports of QI in the peer-reviewed literature have been noted previously and it is hoped that future reports conform to standardized reporting frameworks, such as *Standards for QUality Improvement Reporting Excellence* (SQUIRE) which will permit more rigorous assessment [68].

As discussed above, the principal issue affecting quality in many LMICs is a lack of access to adequate surgical care and other problems relating to the existing health care infrastructure. This does not, however, mean that improving the processes within the health care system in LMICs is not an ongoing challenge.

There is evidence that a raft of QI projects take place within LMICs, especially within the topic of trauma care, but there is a recognized need to strengthen system improvements in these settings [69].

Qualitative research, carried out among surgeons practicing in LMICs, has suggested that that the first priority should be to move towards standardized outcome data collection, to establish current quality baselines and thereby allow the impact of subsequent QI initiatives to be assessed [70, 71].

Given that many health care professionals in LMICs have differences in exposure to the field of QI and development [69], we must also look to increase training in this field and promote awareness of QI, especially among hospital leadership levels [70, 71].

To further advance this cause, the establishment of formalized working-groups, such as the *Asia-Pacific Trauma Quality Improvement Network* (APTQIN), can only further elevate the QI on the agenda within LMICs [70].

Implementing Surgical Safety Processes in LMICs

The challenges to reducing adverse events in LMICs are substantial. They face all of the difficulties found in HICs, where there has been only limited improvement and avoidable adverse events remain a persistent problem [72]. In addition LMICs lack essential resources and have disproportionately low levels of funding for health services research, which further exacerbates financial difficulties. There is an assumption that access to care and basic public health issues remain the most pressing needs of low-income countries. This explains why over the decade between 1998 and 2007 the Bill and Melinda

Gates foundation awarded 36.5 % of its total funding to basic science research and 24.1 % on health care delivery but only 4.7 % on health services research [73]. While lack of access is of course a priority and will cause significant harm the safety of the care being offered must not be overlooked.

To address this ongoing issue the WHO have launched several campaigns focused on patient safety. The most well known of these is the "Safe Surgery Saves Lives" which not only assessed the global volume of surgery and issues with access, but developed the Surgical Safety Checklist (SSC) [74]. This came from an understanding that merely implementing protocols from high-income countries was unlikely to improve patient safety and so was devised by a group of clinicians from around the world, representing the full range of environments in which surgery is practiced.

This team, led by Dr. Atul Gawande, was faced with the challenge of how to devise a low-cost, universally applicable intervention to reduce the harm associated with surgery. Taking inspiration from other industries such as aviation [75] and construction they developed a checklist to prompt routine checks at three critical stages in the operation: before the induction of anesthesia (sign in), before the skin incision (time out) and before the patient leaves the operating room (sign out). The checklist was trialed in eight hospitals around the world and reduced errors and consequently improved outcomes. Mortality overall fell from 1.5 to 0.8 % and complications fell from 11 to 7 % following implementation of the SSC [76]. These figures included both HIC and LMIC and the effect was even greater when low-income sites were looked at in isolation [76], which would suggest that the SCC is particularly useful and relevant to LMIC where it has the greatest impact. Unlike HIC where operative lists are limited and surgeons subspecialize; in LMIC surgeons may have to perform higher numbers of operations that are not in their areas of expertise. In these settings it is perhaps not surprising that simple steps are forgotten given the increased workload and lack of familiarity.

Despite the remarkable success of the WHO SSC its usage worldwide remains as low as 12 % in some studies [77] and there is clearly room to improve compliance. Studies in LMIC have identified challenges to implementing the checklist in these settings including infrastructure, resources, safety culture, and social norms. For example, in Thailand, lack of equipment affects the use of pulse oximeters and surgical site marking [78]. This is also impacted by the societal norm that you should not make a mark on another person. Similarly, in Thai culture people only introduce themselves upon first meeting and are reluctant to do so subsequently which impacts on surgical team members introducing themselves during the timeout period [78].

When tackling these local issues, particularly in LMICs, it is important to develop focused solutions, which may require the modification of the SSC, training and feedback, all while taking cultural variations into account. A team in Uganda was able to increase the compliance rate from 29.5 to 85 % with relatively simple interventions of a stepwise incremental change and standardizations of practice to address societal and cultural norms [79]. PDSA cycles informed regular structured feedback to generate improvement in health care through changing the local behaviors. They were able to do this with minimal external input and instead relied on strong local leadership and staff engagement with the project. Understaffing and lack of equipment remain challenges and areas where external input by way of training programs and funding would be beneficial.

A recent interview study with surgeons from both HICs and LMICs (within an international collaborative of surgeons working in LMICs) suggested that, while the majority of surgeons expressed an emphasis on cultural sensitivity and respect for local traditions, they also highlighted a need to change the existing surgical culture within LMICs [80]. Proposed changes included increased personal accountability and responsibility, greater advocacy for patients and the introduction of mortality and morbidity meetings to foster an environment of healthy reflection and learning [80].

Fostering a healthy culture within a health care system has been described as "*the key to quality improvement*" [81], but discussions around *health care culture* and *organizational health* can be challenging since both are abstract constructs which can be complex to define, before one even considers their measurement with any degree of

certainty. That being said, the need to forge a healthy and productive organizational culture has long been recognized in the world of business and can be found in the management literature as far back as 1958 [82]. Healthy organizations have a culture promoting trust, openness and engagement and enabling continuous learning and improvement [83]. The link between healthy organizational culture and health care quality and patient safety is being increasingly recognized and it is something that all health care providers, globally, can look to in the future to imprint long term high-level care [84].

Outcomes

"Outcome" relates to the downstream effect of health care delivery and so can be considered a more intuitive indicator of quality and safety. Unfortunately, within LMICs the challenges are not just related to access to surgical care but also *unsafe* care—where patients are harmed by the care they receive—is a major cause of poor patient outcome. This also generates waste in an already poorly resourced setting and will affect patient confidence in the system. In these settings it is suggested that patients may even opt out of formal health care systems, thus creating a further barrier to accessing surgical care. For these reasons patient safety is not just an issue for HIC although the degree to which unsafe medical care is a problem for developing countries is not well known.

The WHO has estimated the global burden of unsafe care for both high and low-income countries using disability adjusted life-years (DALYs). This provides a standard metric with which to compare how much suffering is caused by a specific disease or other public health danger such as road traffic accidents. The global burden of disease (GBD) can be used by policy makers at all levels to direct funding and resources. The WHO's estimates suggest that there are approximately 12.7 adverse events for every 100 hospitalizations in low-income countries which is 25.9 million per year. This equates to 15.5 million DALYs lost per year in these countries, the majority of which were due to premature death [85]. These estimates, however, are limited by the lack of availability of high-quality data such that the research was only able to look at seven different adverse events despite having previously identified 20 topics of importance to patient safety. They were unable to include clinically important and common adverse events related to surgery due to the paucity of data available. The GBD from just these seven adverse events ranked unsafe medical care as the 20th leading cause of DALY loss worldwide. Furthermore, when including estimates for unsafe injection practices the resultant GBD would be placed as 14th, comparable to tuberculosis or malaria [85]. Thus preventable adverse events are a leading cause of morbidity and mortality worldwide.

While measuring the outcomes of surgery can be straightforward as an exercise, being able to establish causality between specific processes and outcomes can often prove fraught with difficulties, requiring large sample sizes and considerable time periods of observation [86]. Indeed, the recognition of a need for outcome monitoring has increased dramatically over the last few decades. We have come a long way since the turn of the twentieth century when Ernest Codman, a surgeon then based at Massachusetts General Hospital, vocalized his ideas around the collection of patient outcomes for quality improvement purposes [87]. While his ideas were originally shunned, now, a century later, those of us practicing in HICs find ourselves inundated with an incredible range of datasets on surgical quality and safety. Determining the value, and indeed limitations, of specific datasets and the extrapolations that can than can be made from each can remain a daunting task.

The challenge now is to develop methods of data collection that will identify the different needs and priorities that LMICs have when trying to improve patient safety. Simply adopting best practice from HICs is unlikely to address the underlying causes and may even cause harm. Given that resources are lacking, these methods need to be inexpensive and therefore should be independently assessed for their cost-effectiveness.

Since the Harvard Medical Practice Study in 1991 [88] unsafe care has been extensively studied in high-income countries. This was based on a retrospective case note review and identified the incidence of adverse events in New York State hospitals. An adverse event is defined as an unin-

tended injury or complication caused by health care management, rather than the disease process, leading to prolonged admission, disability at discharge or death [88]. An error is the failure of a planned action to be completed or the use of a wrong plan to achieve an aim and may be errors of commission or omission [89]. These need not necessarily cause harm and are therefore distinct to adverse events. Some literature refers to these as potential adverse events [90].

Measuring these events is challenging and even Codman was subject to criticism for his methods, predominantly as his data did not account for variation in case-mix. Data collection requires a robust infrastructure and well-defined metrics to measure outcomes. Although retrospective case note review has been the most widely used methodology for assessing harm in HICs there are many other methods including incident reporting or clinical surveillance, routine administrative data, malpractice claims and national or regional audits.

LMICs do not routinely have access to much of the data required for these methods because of the variation in the detail and quality of the case notes. Furthermore current strategies employed in HIC such as clinical surveillance, observation of patient care and retrospective chart review are expensive and require trained observers [91]. A lack of trained personnel affects not just access and ability to deliver safe surgical care but also a health care system's ability to adequately assess outcomes. Alternatives including administrative data analysis and electronic medical records are equally unfeasible because of high implementation costs and rudimentary medical record systems. Finally strategies such as malpractice claims analysis and national or regional audits do not have equivalents in LMICs.

To address this, the WHO have studied whether standard retrospective case note review was feasible in LMICs and found that while it is possible it is only useful in the main flagship hospitals of these countries. Elsewhere, the cost, organization, and limited information contained in the notes made the methodology unsuitable. Having identified a need for new methodologies they developed modified tools for research into unsafe care in hospitals with low resources and variable data quality [92]. They tested retrospective case note review, current inpatient case note review, staff interviews, nominal group meetings and direct observations across 13 different countries. The key was to assess how relevant, feasible, acceptable, and valid the tools were. Following this they produced a "Methodological Guide for Data Poor Hospitals" to allow institutions to choose which method is most suitable to meet their individual needs including the availability of good quality medical records and to facilitate its use and understanding [92].

Conclusions

Many global health improvement efforts in LMICs focus on infectious disease, maternal and neonatal disease and nutrition [93]. However, access to safe, affordable surgical care is essential for a "*functional*, *responsive and resilient health care system*" [12]. Furthermore surgical care is now accepted to be cost-effective relative to other medical interventions when it can be applied safely and effectively [77]. Unfortunately accessing surgical care in LMICs remains a major challenge due to severe limitation in infrastructure at multiple levels. Further challenges exist around issues of appropriate staffing, and a lack of funding which remains the largest hurdle for the majority LMICs. The engagement and involvement of a number of international organizations has been a welcome boost for many patients in LMICs but long-term sustainable strategies are required to meet spiralling health needs.

The ability of LMICs to implement international, well-validated programs given these challenges is not clear but studies have not been optimistic. It is suggested that less that 2 % of providers in Africa have the resources available to implement some international health care guidelines [94]. There are clearly severe shortages in all aspects of access for the populations of LMICs and these will not be filled with generic efforts or guidelines. In these resource-poor settings targeted or modified solutions need to be devised to achieve safe and affordable surgical care when needed. There are a number of success stories we make reference to in this chapter, and their progress should not go unmentioned, but without the coordinated efforts of all invested

parties to improve capacity, infrastructure, and ability to access it in a timely, safe, and affordable way the patient safety and surgical care in LMICs will remain on the brink of crisis.

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International Perspectives on Safety, Quality, and Reliability of Surgical Care

51

Sertaç Çiçek and Hişam Alahdab

"Surgeons can cut out everything except cause."

—Herbert M. Shelton

Background

It is universally accepted that safety and quality are critical dimensions in the provision of surgical care. Evidence shows that services that are unsafe and are of low quality lead to diminished health outcomes, increased cost and more importantly harm to the patient. Surgical interventions have continued to be the gold standard treatment for many disease processes. It has been estimated that one operation is being performed on every 25 person alive and over 234 million operations are performed annually worldwide [1]. Although millions of lives are being saved by surgery, surgical outcomes vary widely across hospitals, surgeons, and countries [2]. Up to 30% of patients undergoing surgery have been reported to have either minor or major complications ending with unwanted outcomes [3, 4].

Patients who experience surgical complications have increased hospital length of stay, readmission, morbidity and mortality rates. Dimick et al. [5] have demonstrated that the increased cost for complications was $1398, $7789, $52, 466, and $1810 for infectious, cardiovascular, respiratory, and thromboembolic complications, respectively. More importantly, Khuri and colleagues demonstrated that, independent of preoperative patient risk, the occurrence of a complication 30 days in duration reduced the median patient survival by 69% [6]. Among the most common complications after surgery are surgical site infections (SSI), postoperative sepsis, respiratory, cardiovascular, and thromboembolic complications. It is evident that most of these complications are preventable in nature by applying safety science and the well-established standards of care [3, 4, 7]. Considering the over 200 million surgical procedures performed each year globally, even small improvements would be associated with substantial savings at the population level. Although clear data regarding surgical complication rates are available in industrialized countries, this is not the situation for developing countries and there might be a lot of room for improvement that could save lives with only simple measures. Many quality improvement projects have been launched worldwide aimed at reducing surgical complications and providing safe surgery. In 2008, the World Health Organization (WHO) created an initiative and published guidelines identifying multiple recommended practices to ensure the safety of surgical patients worldwide [8]. This broad-based initiative defines ten essential objectives for safe surgery (Table 51.1).

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Table 51.1 Essential objectives of safe surgery

• Correct patient, correct site operation
• Avoiding harm related to anesthesia while controlling pain
• Recognition and effective preparation for life-threatening loss of airway or respiratory function
• Recognition and effective preparation for risk of high blood loss
• Avoidance of known allergic and adverse drug reactions
• Minimizing the risk for surgical site infection
• Prevention of foreign body retention in surgical wounds
• Accurate identification of all surgical specimens
• Effective communication of critical information necessary to conduct a safe surgery
• Routine surveillance of surgical capacity, volume and results by hospitals and public health systems

Health quality improvement programs focused on these ten simple and easily attainable objectives may be an effective strategy for improving patient care and reducing cost globally. This chapter aims to address surgery related safety and quality issues from the international perspective and shed light on the best practices for prevention and mitigation of surgical risks.

How Safe Is Surgical Care?

Despite major advances in surgery, anesthesia and improvements in perioperative care, patients continue to have variations in their surgical outcomes [5]. The incidence of postoperative complications ranges from ~6 % for patients undergoing noncardiac surgery to >30 % for patients undergoing high-risk surgery [9, 10]. When surgeons are asked, if they practice safe surgery, the unanimous answer will be "yes"; however, the definition of "safe" surgery will most likely vary for each, and it is out of scope of this chapter to address the whole range of surgical safety and quality issues. We focus on four broad areas as suggested by the surgical care improvement project (SCIP): prevention of SSIs, prevention of adverse cardiovascular events, prevention of venous thromboembolism, and prevention of respiratory complications. The incidence and cost of complications in surgery is high and there are significant opportunities for prevention [11].

Surgical site infections (SSI) continue to represent a significant portion of health care-associated infections. The SSI rate in developed countries is around 1–3 % for elective clean surgery [12]. However, some limited data available from developing countries shows a SSI rate ranging from 1.2 to 23.6 % and higher [12, 13]. Patients with SSI infections have a higher mortality and an increased length of stay in the hospital and in the ICU and higher risk of hospital readmissions. The impact on morbidity, mortality, and the cost of care has resulted in SSI reduction being identified as a top priority worldwide. The majority of SSIs are largely preventable and evidence-based strategies have been available and implemented in many hospitals, as recognized by the SCIP and Society for Healthcare Epidemiology of America (SHEA) in the US. Worldwide attention to safer surgery including the prevention of SSI led to the development of the WHO Surgical Safety Checklist demonstrating the importance of teamwork and communication in addition to evidence-based care for preventing SSI. With the SSIs becoming an integral issue of patient safety not only in the operating room, but also up to hospital discharge and beyond; multimodal, multicenter or global preventive intervention programs based on guidelines, bundles or safety checklists are gaining momentum on a global scale [13]. Table 51.2 lists the WHO recommendations to prevent SSIs. Some other recommendations include effective hand hygiene throughout the care period, smoking cessation 30 days before surgery, optimal glycemic control of diabetic patients during the perioperative period and active surveillance for SSIs. Growing evidence demonstrated that surgical hand hygiene upon coming to the operating room ranges from 3 to 10 % [14]. These interventions do not require new and sophisticated technology. An improved adherence to established basic principles such as surgical hand preparation, skin antisepsis, adequate antibiotic prophylaxis, less traumatic, less invasive and shorter surgery duration, improved hemostasis and avoidance of hypothermia or hyperglycemia will remain cornerstones for SSI prevention. Raising awareness at different levels, including local/national authorities and

Table 51.2 WHO recommendations to prevent SSIs

• Prophylactic antibiotic usage
• Robust sterilization process for surgical instruments
• Redosing of prophylactic antibiotics when needed
• Discontinuation of prophylactic antibiotics after 24 h
• Avoiding hair removal unless it interferes with the operation technique. If needed clipping rather than shaving should be practiced
• Meeting the individual requirements of oxygen for each patient during the perioperative period
• Maintaining normothermia through the perioperative period
• Skin preparation with appropriate antiseptic solutions before incision
• Surgical hand antisepsis by scrubbing the hands and forearms for 2–5 min using antiseptic soap and water
• Covering the hair of the operating team and wearing sterile gowns and gloves

especially inviting the public to assist, may trigger efforts for reporting SSIs and international benchmarking, and possibly contribute towards a further decrease of current infection rates. This goal requires multidisciplinary, multifaceted commitment, dedicated infection control teams and efforts, and institutional and behavioral elements, all of which could be achievable with education, determination and minimal cost. Active and direct feedback is at least equally as effective in reducing SSIs without even further precautions. In 1985, the Study on the Efficacy of Nosocomial Infection Control (SENIC) demonstrated that the presence of a dedicated infection control team, together with surveillance and feedback of observed data to the team, resulted in a 38% decrease of SSIs among participating hospitals [15]. However, this required not only implementing a structural mechanism but as also a behavioral and cultural change package of interventions which were deployed gradually and after deep consultation. Another speculative issue is will public/mandatory reporting of outcomes and transparency initiatives influence SSI incidence [16]. The supporting data for such public reporting benefits are scarce and a recent review could not identify any studies showing public reporting benefits that investigated SSI reduction as an outcome, as well as compared associated costs [17].

Venous thromboembolism (VTE) occurs in ~25% of all major operations if appropriate prophylaxis has not been started and almost a one-fourth end up with pulmonary embolism which appears as sudden death [18]. Cohen et al. found that nearly three quarters of VTE-related deaths were from hospital acquired thrombosis, but only seven percent were diagnosed ante-mortem; 34% were caused by sudden fatal PE, and 59% were undiagnosed pulmonary embolism [19]. In a recent report, VTE associated with hospitalization, in addition to increased hospital costs, was the leading cause of disability-adjusted life-years in low-income and middle-income countries, and the second most common cause in high-income countries [20]. Surgical procedures associated with a high risk of VTE include neurosurgery, major orthopedic surgery of the leg, renal transplantation, cardiovascular surgery, and thoracic, abdominal, or pelvic surgery for cancer. Obesity and poor physical status according to American Society of Anesthesiology criteria are risk factors for VTE after total hip arthroplasty [21]. Observational studies continue to report underuse of prophylaxis for postoperative pulmonary embolism/deep vein thrombosis despite the long-standing evidence-based guidelines [22]. The Institute of Medicine considers failure to provide appropriate VTE prophylaxis to hospitalized at risk patients a medical error, and yet the use of prophylaxis is nonuniform and often varies by physician within a given institution, leading to variability in types and complication rates. A VTE prophylaxis protocol was implemented at Anadolu Medical Center in 2011 to decrease VTE complications, based on standardized electronic physician orders that specify early postoperative mobilization and mandatory VTE risk stratification for every patient, using the "Caprini" grading system [18]. The derived scores dictate the nature and duration of VTE prophylaxis. Both mechanical (pneumatic compression boots) and pharmacologic prophylaxis (unfractionated or low molecular weight heparin) are used, as indicated by risk level. Data has been analyzed every 3 months, feedback was given to physicians individually and adherence rate to VTE prophylaxis protocol was defined as a performance criteria. The adherence rates to VTE

prophylaxis protocol for low, medium, high, and very high risk groups were 51, 67, 47, and 41 %, respectively, for 2011 and 79, 81, 71, and 87 %, respectively, for 2012. The total adherence rate to protocol increased from 48 % in 2011 to 76 % in 2012 and reached to a record breaking 98 % in 2015. With the increasing number of sicker patients and more complex procedures augmenting the risk of postoperative VTE, there is a clear need to establish and implement risk assessment tools and thromboprophylaxis guidelines in an effort to curb rising rates of postoperative VTE.

Ventilator associated pneumonia (VAP) is among the most common health care infections occurring in 9–27 % of all intubated patients and is associated with significant morbidity and mortality [23]. It has been reported that between 10 and 20 % of patients receiving >48 h of mechanical ventilation will develop VAP; critically ill patients who develop VAP appear to be twice as likely to die compared with similar patients without VAP and patients who develop VAP incur ≥ $10,019 in additional hospital costs [23]. Considering the huge economic and clinical burden and preventable nature, lowering the incidence of VAP would be an important goal to achieve patient safety. The National Quality Forum [24], and the Institute for Healthcare Improvement 100,000 Lives Campaign [25] were among the firsts to include VAP prevention as a quality indicator. They used a so-called ventilator bundle consisting of four key components: elevation of the head of the bed to 30–45°, daily "sedation vacation," peptic ulcer prophylaxis, and deep venous thrombosis prophylaxis. The bundle was an all-or-nothing measurement (process indicator). However, difficulties remain in reporting and benchmarking VAP rates due to very heterogeneous patient case mix, and variability in diagnosis and surveillance protocols.

Adverse cardiac events such as myocardial infarction and cardiac death are common complications of surgery occurring in 1–5 % of patients undergoing noncardiac surgery, and in as many as 30 % of patients undergoing vascular surgery [26]. These events are associated with increased mortality as high as 60 % per event, and result in longer hospitalizations and high costs of treatment [27]. The prevalence and high mortality associated with these events make prevention an important priority and has been the subject of many quality improvement projects [28]. Many recent studies suggest that perioperative use of beta blockers may reduce risk of adverse cardiovascular events in patients undergoing surgery [27–29]. Evidence from these papers has led to initiatives for cardiovascular adverse event prevention becoming a priority.

Delivering surgical care is complex, complicated and requires multidisciplinary collaboration, and interdisciplinary action. Complicated procedures and advanced technology increases complexity; concomitantly, sophisticated organizational structures emerge. All these factors make team-based approach a necessity [30]. Many years of psychological research in organizational behavior has shown that individuals possessing high levels of expertise, technical knowledge and resources might easily fail unless a teamwork environment is created and maintained [31]. The essence of a multidisciplinary team (MDT) is a common commitment, which in medical practice, amounts to the provision of optimal care by as many specialists as the individual case requires, who not only are experts in their field, but communicate effectively among themselves as well [32]. A team-based approach has become the standard of practice in fields such as oncology and organ transplantation, where it has been observed that decisions made by MDTs are more likely to conform to evidence-based guidelines than those made by individual clinicians [33–35]. These teams were established after evidence showed better outcomes and less variability in survival among participating hospitals. Kesson et al. recently reported that introduction of teams providing multidisciplinary care for the treatment of breast cancer was associated with 18 % lower mortality at 5 years, compared with the outcomes in neighboring areas, where similar patients were treated over the same period of time [36]. In "Crossing the Quality Chasm: A New Health System for the 21st Century," teamwork is recognized as an integral part of medical practice, cited as essential in caring for patients with complex problems, and strongly recommended as a practice that must be created and maintained [37]. These and numerous similar examples provide convincing evidence that

MDTs strengthen the ability to provide higher quality and more efficient care. Although a multidisciplinary heart team is considered a standard practice in many countries, access to such care still shows high variability among neighboring institutions [38]. Such variability can definitely be reduced, if not prevented altogether, by reinforcing a variety of measures such as implementing joint learning and debriefing arrangements, linked reimbursement or bundle strategies, administrative policies, quality and transparency reporting guidelines [39]. The Public Hospitals Association (KHB) of Turkey recently implemented an obligatory heart team decision for any elective myocardial revascularization procedure. Concurrently, the Ministry of Health (MOH) started an appropriateness control program, in which all myocardial revascularization data are sent to a group of surgeons and cardiologists who are blinded as to the data source with feedback provided to the participating centers. The final goal is linking of reimbursement to the appropriateness of the procedure. Although the program is still in its infancy, it is well received and is being closely monitored. One very important factor to facilitate implementation of a multidisciplinary approach is to educate patients and accept them as members of the team during the decision making process. This approach, in which the patient is at the center of the clinical microsystem has been shown to create many benefits and suggested improved outcomes [40, 41].

Challenges in International Practice

Lack of Education

Abundant data suggests wide variation in the training, oversight, assessment, and success of surgical training in different countries. Until recently most of the medical education and training programs lacked the necessary education to enable patient safety and clinical quality of care. There have been many efforts in the recent years to incorporate such education in the medical curricula, but the vast majority of practicing physicians have not undergone formal safety and quality education [42]. There is an urgent need to incorporate best practices and evidence based standards into medical schools and resident/fellow training program curricula [43, 44].

Cultural Barriers

Health care providers come from different cultural and educational backgrounds and try to mix up and work as one team for the best of patients. The difference in cultures might lead to problems related to communication during the care process [45]. It is not uncommon to hear surgeons say "I've been doing it like that for years," "this is how we do it over here," underscoring the deep set challenges to culture change and the challenges leaders face in these organizations [46]. The importance of standardized communication tools, care plans and written communication tools cannot be over emphasized [47]. Moreover, the diversity of cultural backgrounds of patients and their careers can have a significant impact on their needs, understanding and compliance with medical and surgical care team instructions [52]. The social, cultural and psychological evaluation of each patient is essential to achieve optimal patient centered care [48].

Language/Communication Barriers

Health care is highly influenced by widespread globalization, migration and increased international travel. Minorities with language barriers live in many places and care providers should be equipped to meet the language needs and address the communication barriers of such patients who are particularly vulnerable for handover problems [49]. Interpreters should be widely available either in person or by phone to prevent misunderstandings [50].

Patient and Family Involvement

Evidence has shown that involving patients and their families in the decision making and all other critical steps helps to improve outcomes and

reduce adverse events and medical errors [51]. Tools have been developed to be used in shared decision-making [52]. Educated patients can improve hand hygiene, correct any errors during handoffs and participate actively in their own identification and site markings [41].

Health Tourism and Travelling

The number of travelling patients seeking health care in different parts of the globe is increasing. Health care providers have to cope seamlessly with a versatile group of patients with different needs, cultures, and languages. The system should be ready to meet the needs and communicate well with them. Within this segment of the market, the focus of patient safety is upon the institution or physician who is carrying out the treatment. Although majority of institutions providing care continuously is making efforts to meet highest quality and patient care standards; lack of oversight and transparency is an important challenge.

Problems with Benchmarking and Data Reliability

The main drawback in comparing and benchmarking data in health care is the difficulty of validation. Involving third parties in data collection and validation increases the reliability of data. Another challenge is the difficulty to homogenize the cases. Every organization has different case-mixes and it is difficult to compare those doing surgery for highly complicated patients to those doing the same surgeries for relatively stable ones. On the other hand with the development of electronic systems and the support of information technologies, data is being collected easily, but a pernicious twist: an obsession with numbers arise. With the increasing trend of metrics linked and value-based reimbursements, the risk of the organizations working on improving their "numbers," in effect gaming the system, rather than actually measuring and improving their real performance has dramatically increased [39]. For instance, surgeons might prefer to operate on low risk patients to not worsen their performance numbers, leading to problems with access to care for complicated patients.

Status Hierarchy Barriers

Surgical teams have inevitable hierarchical composition and this is much more marked in practices outside the USA. This can easily lead to undesired outcomes. People might easily "fear" to speak up with overbearing surgeons and when something goes wrong will stay quiet due to concerns about being censured [53]. The safety culture should be established so as to encourage team members to speak up and if need me become "whistleblowers" and raise the flag and stop the operations when they feel there is something missing or wrong [54]. This can be an effective antidote the pervasive normalized deviance in surgical care [55]. This culture needs strong leadership support and a commitment from the C-suite and board to a transparent culture of safety and high reliability principles [7].

Culture of Safety

A safety culture is an essential platform and currently for safe and reliable practice. The main principle of culture of safety is a just and fair culture that transparently explores and discusses the warts and challenges along with celebrating the successes [56]. There is a need for a nonpunitive approach where fingers are not pointed at people but the system is held responsible for creating conditions for mistakes and efforts are made to continuously improve the system to prevent harm.

Conclusions

Health care institutions continue to face challenges in providing safe patient care in increasingly complex and demanding technical, organizational, and regulatory environments. Both high reliability theory and clinical microsystems provide conceptual and practical frameworks for approaching the delivery of safe care. This chapter explores the

applicability of high reliability and microsystems theories to the surgical environment. Safety is a fundamental property of both. It might be argued that improving safety in surgical systems does not require an entire restructuring of organizations and workflow; however, despite intense attention to this subject over the past decade, incremental improvement in safety has not been forthcoming with the existing models of care. Moreover, current systems have failed to address the patients' overall needs.

Organizing surgical care around the pursuit of safety as an overarching priority is a professional obligation for all members of the health care team. This goal can be accomplished by organizing around and shaping a culture focused on reliable performance but requires substantial investments in human capital. Readily accessible communication and information sharing are essential components for creating high reliability. A clinical microsystem concept involving surgical personnel can be an effective vehicle for achieving these goals.

It is impossible to establish a culture of safety without leadership support and commitment. Leadership should protect and support "speak up" attitudes where people stop the practice when they believe something wrong is going on. The leadership should adopt a nonpunitive approach and provide the resources to improve the system. The challenge in getting the leadership on board is to involve them in the practice of safety and provide them with evidence and data about quality and safety. Linking payment to patient safety and clinical quality metrics will help draw leadership attention to the issue.

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Surgical Safety in Developing Countries: Middle East, North Africa, and Gulf Countries

52

Abdulelah Alhawsawi and Paul Barach

"A known mistake is better than an unknown truth."

—Arabic Proverb

Health-Care Systems in MENA Region

The World Health Organization (WHO) has categorized the countries of the Eastern Mediterranean Region (EMR) into three groups based on population health outcomes, health system performance, and level of health expenditure. Group 1 comprises the Gulf Cooperation Council (GCC) countries—namely, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates—will face an unparalleled and unprecedented rise in demand for health care over the course of the next two decades. It is estimated that total health-care spending in the region will reach US$60 billion in 2025, up from US$12 billion today. No other region in the world faces such rapid growth in demand with the simultaneous need to realign its health-care systems to be able to treat the disorders of affluence. These countries have seen considerable socioeconomic and health development in the region over the past decades.

Group 2 consists mainly of middle-income countries which have developed extensive public health infrastructure but continue to face resource constraints. Group 2 countries include the following list: Egypt, Islamic Republic of Iran, Iraq, Jordan, Lebanon, Syria, Palestine, Libya, Tunisia, and Morocco. Group 3 consists of countries which face constraints in improving population health outcomes as a result of lack of resources, political instability, and other complex development challenges. Group 3 countries include the following: Afghanistan, Pakistan, Yemen, Djibouti, Somalia, and Sudan [1].

Recently, many countries in the Eastern Mediterranean Region have recognized Quality Improvement (QI) and Patient Safety as a priority in their national health policy agendas. For example, patient safety has been selected as a priority by 14 out of 22 EMR countries for the operational planning 2016–2017.

Between 2006 to 2008, a region-wide patient safety study was carried out in which a number of hospitals from six EMR countries participated. The aim of the study was to assess the magnitude and the scope of adverse events in Hospital settings in the region [2]. The objective of the study was not to compare countries or regions. Instead, it was to obtain broad-based data on the magnitude of patient harm, the most frequent harmful

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incidents and their severity, when they had occurred, what their causes were, and their preventability and contributing factors.

The study showed that: on average, health care-related harmful incidents affected eight in 100 patients in the region. According to the study, four out of five incidents were preventable. This speaks to the considerable human and financial costs that could have been averted. Added to these costs are the erosion of trust among patients and the unnecessary surcharge on the health-care system, which may lower the overall quality of care (Table 52.1).

The study also showed that rate of adverse events increased with increased length of stay. Rates of adverse events went up from 4 to 25% within hospital stays of 30 days. Length of stay is shown as average for index admission in sample record per hospital (Fig. 52.1).

In addition, the study also showed which procedures and areas of activity are most likely to lead to adverse outcomes: For example, 34% of the observed incidents resulted from therapeutic errors. Other causes of adverse events were as follows: diagnostic errors, surgical mistakes, obstetrics causes, neonatal procedures, drug-related incidents, fractures, anesthesia causes, and falls (Fig. 52.2).

In response to the health-care quality and patient safety challenges in the region, WHO—EMRO (Eastern Mediterranean Regional Office) have suggested several improvement initiatives for the regional governments:

Table 52.1 Frequency of adverse events (AEs), % of preventable adverse events, and % of admissions associated with adverse events that resulted in death in six EMR countries

Country	AEs rate/100 admissions (CI 95%)	% preventability (CI 95%)	% admissions resulting in death
Egypt	6.0 (4.7–7.3)	72.5 (62.8–82.2)	1.25
Jordan	2.5 (2.0–2.9)	83.3 (75.7–90.9)	0.61
Morocco	14.8 (12.6–17.0)	85.6 (79.9–91.3)	3.58
Sudan	8.2 (6.4–10.0)	55.1 (43.9–66.3)	0.75
Tunisia	8.3 (6.5–10.1)	85.7 (77.9–93.5)	1.29
Yemen	18.4 (16.5–20.3)	92.8 (89.9–95.7)	4.28
Total	*8.2*	*83.0*	*1.85*

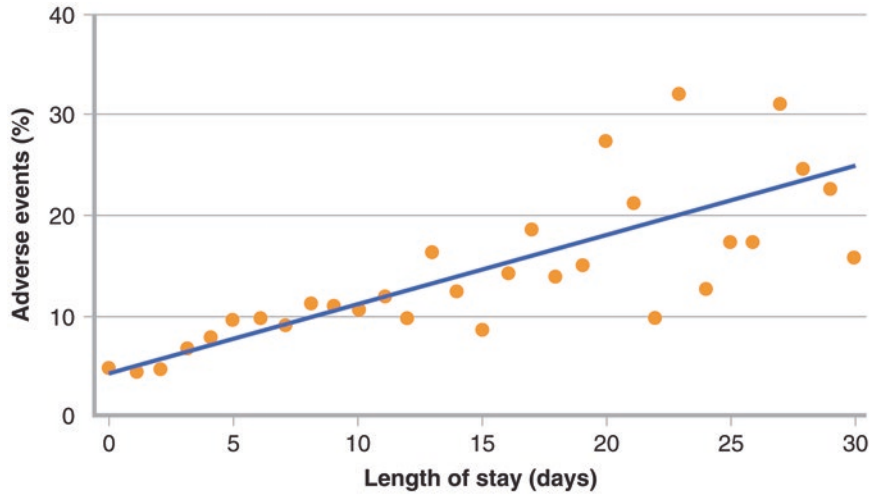

Fig. 52.1 Rate of adverse events by length of stay, indicated as average for index admission in sampled records, per hospital. Modified from Wilson RM et al. BMJ. 2012;344:BMJ.e832

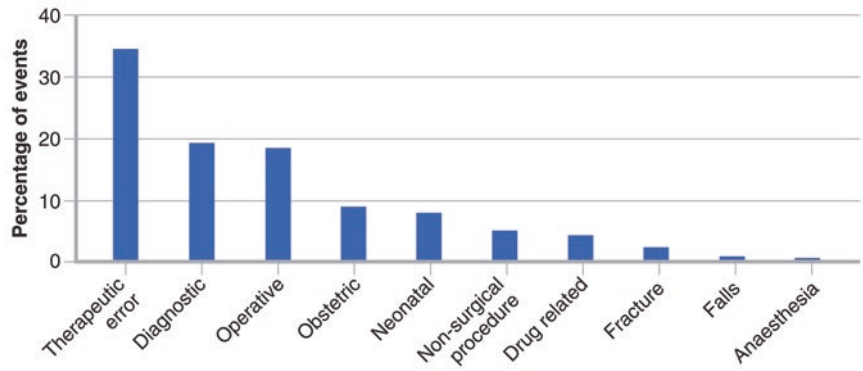

Fig. 52.2 Type of error related to occurrence of adverse event shown as percentage of 890 adverse events with codes for this classification. Modified from Wilson RM et al. BMJ. 2012

The clean care safer care initiative: The goal of Clean Care is Safer Care is to ensure that infection control is acknowledged universally as a solid and essential basis towards patient safety in the region. Such initiative also helps support the reduction of health care-associated infections (HAI) including the importance of hand hygiene and the consequences when providers dont attend to prevention steps [3]. In EMR, the number of registered health care facilities through the "Clean Care Safer Care" website is only 1317 hospital (out of 9000 hospitals in EMRO). By comparison with the other WHO regions, almost every EMRO country has representation but efforts should continue to increase the number of registered health care facilities and improve commitment to promote prevention and control of HAI.

The safe surgery saves lives initiative: The goal of the "Safe Surgery Saves Lives Initiative" is to improve the safety of perioperative care around the world by ensuring adherence to proven standards of care in all countries. The WHO Surgical Safety Checklist has improved compliance with standards and decreased complications from surgery in eight pilot hospitals where it was evaluated. Only three countries from the EMR out of 26 countries worldwide have mobilized resources to implement the WHO Surgical Safety Checklist on a national scale. Globally 4132 hospitals were registered for the "safe surgery saves lives" challenges; out of them 1790 are actively using the checklist. The number of health-care facilities are using the checklist is around 450 [4].

Patient safety education: The World Health Organization (WHO) developed the Multi-professional Patient Safety Curriculum Guide to accelerate the incorporation of patient safety teaching into higher educational curricula. Many recent studies have highlighted that patient safety education needs to be more explicit and better integrated into health care curricula [5, 6]. Taking advantage of the global trends opening up for educational reforms, and the need to introduce patient safety into health-care professionals' curricula, the WHO Multi-professional Patient Safety Curriculum Guide uses a health system-focused, team-dependent approach, which impacts health-care professionals and students learning in an integrated way how to operate within a culture of safety [7].

The patient safety-friendly hospital initiative (*PSFHI*): The objective of the PSFHI is to enhance patient safety by developing universal standards to which hospitals adhere to and by encouraging the participation of hospital executives, clinicians and patients to collaborate in such effort. Furthermore, this initiative encourages national health authorities and medical and nursing schools to participate in the process of safe health-care delivery to complement national, regional, and global health-care accreditation programs [8].

Recognizing the need to develop a valid and reliable instrument for the assessment of patient safety adapted to developing countries, WHO

EMRO embarked on a process of developing a patient safety assessment manual. The development of the assessment manual was followed by its implementation in representative hospitals in seven countries (namely Egypt, Sudan, Pakistan, Morocco, Jordan, Tunisia, and Yemen) in mid-2009. See Fig. 52.3. This served two purposes—first, to assess the adequacy of the patient safety program; and second, to pilot and further refine the PSFHI before rolling out to other countries [9].

The safe birth checklist: Considering the importance of both maternal and Child health, WHO has developed the Pilot Edition of the Safe Childbirth Checklist, to support the delivery of essential maternal and perinatal care practices [10]. The WHO Safe Childbirth Checklist contains 29 items addressing the major causes of maternal death in low and middle-income countries. It is expected that many health care facilities will be using the Safe Birth Checklist during its pilot implementation in various settings, before the release of the clinical trial that is being conducted in India to assess its impact [11].

National accreditation programs in EMR: Currently, Saudi Arabia and Jordan are the only two countries in EMR that have functioning national accreditation organizations, namely: Central Board for Accreditation of Healthcare Institutions (CBAHI) in Saudi Arabia, and Health Care Accreditation Council (HCAC) in Jordan. Tunisia has recently established a national accreditation organization but is still working on building the infrastructure (policies and procedures, quality standards, surveyors training, etc.) to become operational.

International accreditation programs in EMR: There are mainly three international accreditation bodies assessing the quality of EMR. These are: (1) Joint Commission International (JCI), (2) Accreditation Canada International (ACI), and (3) Australian Council on Healthcare Standards (ACHS). The JCI is the most widely known international accreditation organization in the region, with the majority of its activities taking place in group 1 EMR countries.

Since the establishment of the Ministry of Health in 1950, the Saudi government has achieved some important milestones in its journey towards reducing medical harm and improving patient safety situation in the Kingdom. In 1992, the Saudi Commission for Healthcare Specialties (SCFHS) was established as the body that regulates the licensure of health-care professionals. In 2001, national health accreditation started by the creation of Makkah Region Quality Program (MRQP), which

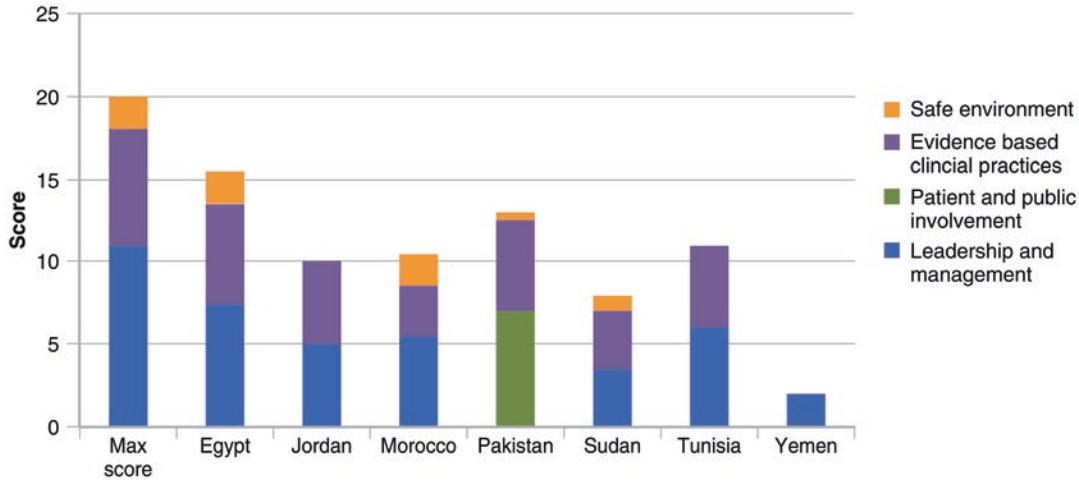

Fig. 52.3 Achievement of critical standards across domains of patient safety. Modified from Siddiqi S et al. Int J Qual Health Care. 2012;24:144–51

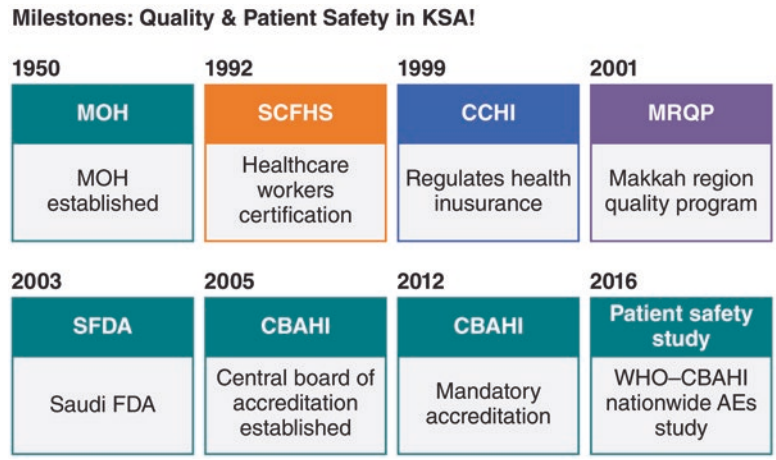

Fig. 52.4 Patient safety milestones in Saudi Arabia

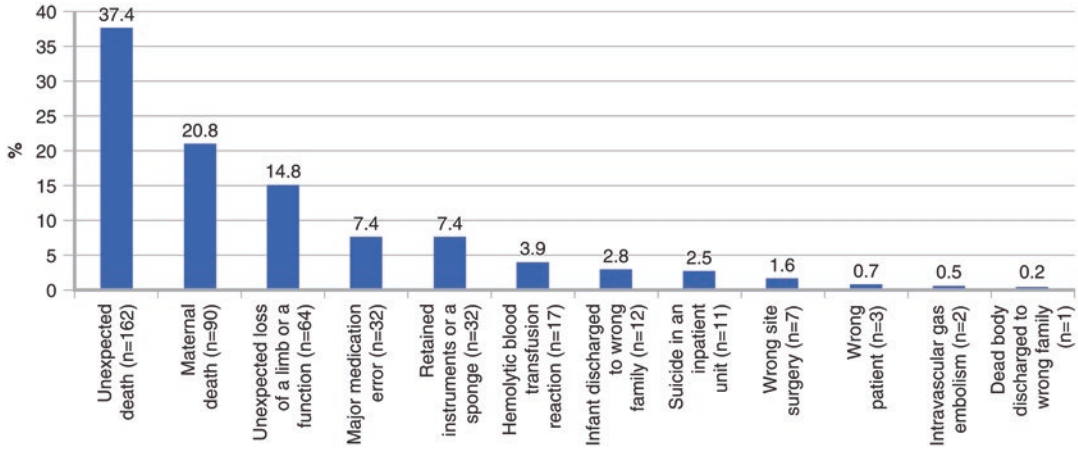

Fig. 52.5 Nation-wide sentinel events (2010–2014) based on the MOH reporting system, Saudi Arabia

later was expanded to include all the regions in the Kingdom resulting in the creation of the Central Board of Accreditation for Healthcare Institutions (CBAHI) in 2005. In 2003, the Saudi FDA was established as the main regulator for Food, Drugs, and Medical Equipment (Fig. 52.4).

All the abovementioned activities have shown the Saudi government's commitment to improving the patient safety situation in the country, which culminated this year by announcing the establishment of the Saudi Patient Safety Center (SPSC). This center will play a pivotal role in promoting patient safety by coordinating with all stakeholders (Regulators, Providers, and Public) to minimize preventable harm to patients.

Epidemiology of Harm in Saudi Arabia

Adverse events are not infrequent in the Saudi health-care system, but the exact magnitude of the problem have yet to be determined because only a few studies in Saudi Arabia have addressed medical errors. Currently, CBAHI is conducting a study with the WHO to assess the country's nationwide prevalence of adverse events. The preliminary results of this study should be available by December, 2016.

The ministry of health has a reporting system for sentinel events where hospitals, both ministry of health (MOH) and private hospitals are required to report on a list of sentinel events within 48 h of

their occurrence (Fig. 52.5). Despite the problems with underreporting, this program provides value by drafting corrective action plans and strategies to minimize harm and promote safety. The MOH requires that each hospital that suffers a sentinel event (SE) submits a Root Cause Analysis (RCA) within a week from the incident (Fig. 52.6).

Quality Standards

Today, GCC and to a certain extent, MENA patients make their private health-care decisions based on word-of-mouth, advertising, and the physical external appearance of the institution. Quality standards of providers are neither transparent nor understood by patients, thus high-quality providers can struggle to distinguish themselves in the market. Even worse, patient safety can be compromised by the lack of effective regulation of the health-care sector.

Policymakers will have to undertake comprehensive regulatory reform in order to weed out low-quality providers and protect patients. Currently, to the extent that standards exist, they, for the most part, apply to the private sector only and are not applied to public health-care institutions. Moreover, the content of the standards and their enforcement, tends to be weak and haphazard.

In order to raise the quality level of the health-care sector and to allow competent private players to thrive, policymakers must create regulatory bodies that will define a set of comprehensive operational quality and facility standards for all public and private providers. This body would be responsible for licensing, inspecting, and enforcing these standards. Because this regulatory body must equally apply and enforce standards to public and private health-care institutions, it should ideally be independent of the ministry of health. In addition, this regulatory body would also be responsible for the licensing and renewal of medical professionals such as doctors, nurses, and allied staff.

Although processes do exist today in GCC countries for this function, they tend to suffer from two problems. First, they can be very bureaucratic and take a long time, resulting in providers losing their ability to attract clinical staff from overseas. Second, the criteria for licensure and renewal can be weak when compared with international best practice, resulting in substandard professionals practicing medicine.

In the small GCC states, regulatory bodies may also choose to guide the strategic capital investments of providers regardless of ownership. Because a critical threshold of patient volume is required for specialty services in order to maintain quality, it is important that investment in these specialties is carefully monitored to prevent excess supply relative to case volume (and, therefore, a decline in quality). A regulator has the unique ability to manage capacity in these services by deciding whether to grant a provider a license [12]. Conversely, it can encourage providers to offer services in areas with the greatest unmet needs, such as the management of primary-care facilities and hospitals, long-term care, home healthcare, *rehabilitation*, and dialysis.

Saudi Arabia Major Health Reform

The Saudi government has undertaken many initiatives to improve the quality of the health-care services in the Kingdom. One of the main quality improvement strategies the Saudi government has introduced is accreditation.

Health-care accreditation in Saudi Arabia dates back two decades. In 1994, Saudi Aramco established the Saudi Medical Services Organization Standards. These standards worked as a quality assurance for health-care providers accepted by Aramco for its employees. Private and governmental hospitals had to meet Aramco standards to be accepted as a referral health-care institution for Aramco's employees.

In 2001, Makkah Region Quality Program (MRQP) was established. MRQP was a voluntary health-care accreditation program for health-care providers in the Makkah region.

This program involved written standards to be met by governmental and private hospitals working in the Makkah region (57 hospitals). These standards were based on The Joint Commission and ARAMCO standards. In October 2005, the minister of health, in his capacity as the chairman of the former Health Service Council (currently the Saudi Health Council), established the Central Board for Accreditation of Healthcare Institutions (CBAHI) in Saudi Arabia. International accreditation bodies have been participating in quality improvement activities in the Kingdom since early 2000. Those include organizations like the Joint Commission International (JCI), Accreditation Canada, and The Australian Council on Healthcare Standards (ACHS).

Health-care accreditation, both national and international, has definitely helped raise the awareness about the subject of quality improvement amongst health-care professionals in the Kingdom. But despite variable and fragmented individual successes here and there, the nationwide overall impact of accreditation on patient safety has yet to be determined.

There's a unique challenge that countries like Saudi Arabia and GCC face in providing health care, the multiethnicity and multilingualism of health-care workers. Knowing the central role nurses play in the quality and safety of patient care, it is very important that health-care workers, especially nurses, are both culturally and linguistically competent to be able to address the patients' daily needs. Nurses in the Kingdom come from several countries and speak different languages [13]. The English language is the language used for communication amongst health-care workers and knowing that English is not the native language for the majority of the health-care workforce poses an added communication challenge in the Saudi health-care facilities. Many nurses don't speak Arabic very well, which makes it more challenging for safe and effective communication between nurses and their patients. Also, patient safety is very much dependent on advocacy from health-care workers and having some nurses not speak up for their patients' rights because of cultural reasons (e.g., excessive respect for superiors, fear of losing their job, etc.) could compromise patient safety [14].

When it comes to perioperative patient safety, the Saudi health-care system has introduced several structures and processes to try to guarantee safety but the outcome of these measures remain variable depending on the setting. The Saudi Commission for Healthcare Specialties (SCFHS) is the regulatory body for health-care professionals and helps improve perioperative patient safety by two main mechanisms: (1) Certification of Surgeons, Anesthesiologists, Nurses and Anesthesia Technicians, and (2) Accreditation and oversight of residency and fellowship training programs in surgery and anesthesia [12]. Despite these efforts, many patients continue to face potential perioperative harm for a variety of reasons. Some of these causes include:

(a) Unqualified OR staff (surgeons, anesthesiologists, and/or nurses). This issue is a real problem in smaller towns where many hospitals are suffering from chronic shortages in quantity and quality of human resources.
(b) Lack of standardization: e.g., Surgical Safety Checklists, Time Out, Perioperative Normothermia, VTE, and Antibiotic prophylaxis.

The MOH has introduced a reporting system for SE but it is still far from perfect and many adverse events go unreported (Fig. 52.6). To understand the magnitude of the medical errors in the country, CBAHI, in partnership with the WHO, will conduct the first nationwide study of its kind in the Kingdom to assess the prevalence and types of adverse events in a representative sample of hospitals. This will kick off in early 2016 and should take around 1 year to finish. The results of this study will help support the patient safety efforts in Saudi Arabia.

Recently, the Saudi government under King Salman's directives has announced a big strategic initiative called Vision 2030. This represents Saudi Arabia's vision for the coming 15 years. The Council of Economic and Development

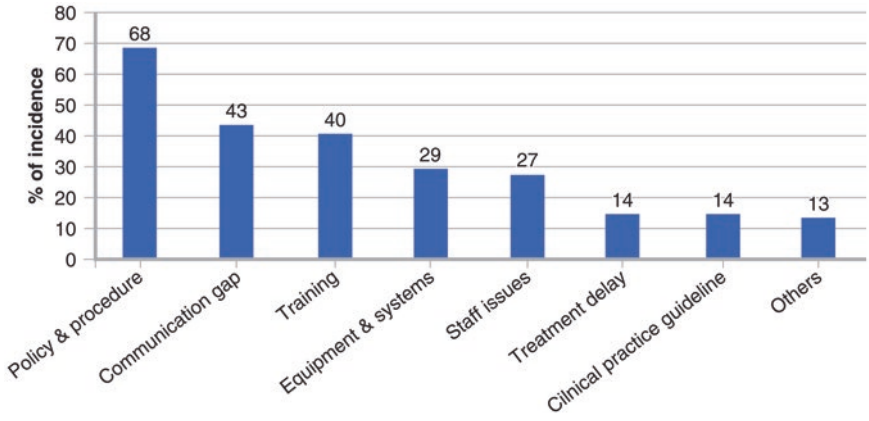

Fig. 52.6 Root causes of the sentinel events between 2012 to 2015, MOH, Saudi Arabia

Affairs (CEDA) announced this strategic national transformation plan to accelerate economic growth and diversification in the Kingdom.

This initiative entails proposals by all government sectors. Each ministry has a component to play in shaping the outlook of this major initiative. As a consequence, the Saudi health-care market will see major changes in areas like health-care finance reform and a bigger role for the private sector in service delivery. Time will tell if such initiative will have a positive impact on the Saudi health-care sector, specifically in the area of quality and patient safety.

In April, of 2016, the MOH announced the establishment of the Saudi Patient Safety Center (SPSC). This SPSC's vision is to eliminate preventable harm in health-care facilities in the kingdom. The Center will focus on building the patient safety improvement capacity through training, research, and collaboration with all stakeholders including regulators, providers and patients and their families.

Health Services During the Pilgrimage (Hajj) Season

One of the main challenges that Saudi Arabia has to deal with on an annual basis is the Hajj season (Pilgrimage) as it embraces the two holiest cities of Islam, Mecca and Medina. Every year, between two and three million pilgrims from all over the world travel to the Kingdom to perform the *hajj*. During the 2009 season, there were 2.3 million pilgrims, 69.8 % of whom came from foreign countries [15].

Hosting such an event annually is a major logistical challenge that requires a planned and organized effort across numerous government agencies and departments to ensure the fulfillment of adequate essential services such as housing, transport, safety and health care [16].

Conclusions

Health care demand and spending are rising sharply in the GCC and MENA countries. The public is expecting more transparency, better services, and more health care service accountability. Policymakers want the private sector to play a bigger role in their health-care systems, in both the provision and the financing of care. The GCC/MENA governments must make major regulatory and policy changes—above all, using public funds to reimburse nationals for the private health-care services they consume, and defining and enforcing a single set of quality standards for both public and private providers. Recent increases in awareness of surgical morbidity in developing countries has placed greater emphasis on strategies to improve surgical safety in resource-limited settings. The implementation of surgical safety checklists in

GCC and MENA countries has specific barriers related to resources and culture. By establishing strong regulatory bodies to define and firmly enforce higher-quality standards for health-care providers and medical professionals, policy-makers will build the confidence of patients in the surgical quality of health care, no matter who provides it.

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Future Directions of Surgical Safety

53

Timothy D. Browder and Paul M. Maggio

"The most important question a modern professional can ask is not 'What do I do?' but 'What am I part of?'"

—Donald Berwick, from Berwick D. Era 3 for Medicine and Health Care. JAMA. 2016;315(13):1329–30

Introduction

In 1999, the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* concluded that 44,000–98,000 Americans die each year as a result of preventable medical errors [1]. This was followed in 2001 by the IOM report *Crossing the Quality Chas*m [2]. *Crossing the Quality Chas*m focused more broadly on the health care system and provided a practical framework for improving the delivery of care. In the report, six dimensions of quality care were defined as care that is safe, effective, patient-centered, timely, efficient, and equitable. Although the IOM reports led to dramatic policy recommendations, in the 15 years since their publication, there have been only limited improvements in patient safety, quality, and value. Patients continue to experience preventable harm through errors that result in significant morbidity and mortality, while the delivery of care remains costly and inefficient [3–5]. Medical errors have recently been identified as the third leading cause of death in the USA [6], and health care spending continues to outpace growth in the US Gross Domestic Product (GDP). As a share of GDP, it is expected to rise from 17.4 % in 2013 to 19.6 % by 2024. This rate of growth is unsustainable [7].

Surgical care is complex, driven by advances in medical science and new technologies, multidisciplinary care teams, and care that must be coordinated through health care systems. Not surprisingly, the majority of adverse events in surgical care are not related to technical errors that occur in the operating room, but from errors that occur throughout the perioperative course [8, 9]. As a result, quality improvement efforts in surgery have focused less on the surgeon and more on the health care delivery system [10]. Today organizations such as The Joint Commission and the Agency for Healthcare Research and Quality (AHRQ) promote the use of systems tools and methods to improve quality and safety and national global initiatives such as the Surgical Care Improvement Project (SCIP), the Universal Protocol, and the WHO surgical safety checklist focus on processes and coordination of care [11–14]. For surgeons this has led to greater emphasis on their nontechnical skills that facilitate performance within a complex system [15]. Nontechnical skills encompass behaviors such as situational awareness, decision-making, communication and teamwork, and leadership [8]. Unfortunately, these skills have not been part of a traditional medical training, and it is failures in these areas that frequently contribute to adverse events. Donald Berwick, prior President and

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Chief Executive Officer of the Institute for Healthcare Improvement, stated it is more important for care providers today not to ask "What do I do?" but "What am I part of?" [16].

Important advances have been made to improve quality and safety in surgery, but the improvements have been largely driven by incentives established by external organizations. They have been established by various payers, governmental organizations, and consumer groups; not by surgeons. As a result, the outcomes from these efforts have been limited. There has been a lack of significant physician engagement and support, and physicians have not invested in understanding and applying improvement science to their practice [16]. Most physicians today do not know how to interpret a statistical process control chart (SPC) or perform rapid tests of change using a plan-do-study-act (PDSA) cycle [17]. For this to change, surgeons must learn to be effective leaders in providing collaborative patient care; a surgeon's nontechnical skills, such as communication and teamwork, will be as equally important as their technical skills. Only by embracing systems-based improvement methods and supporting a culture of safety will surgeons transform and improve the delivery of surgical care [18].

Measuring Health Care Quality

During the second half of the twentieth century, quality in American health care was largely focused on quality assurance (QA). Outcomes such as morbidity and mortality were studied as a means to monitor and eliminate errors, and were supported by the development of thresholds of acceptability by organizations such as The Joint Commission on Accreditation of Hospitals (now The Joint Commission) and Medicare [19, 20]. This approach tends to be reactive, retrospective, and frequently viewed as punitive. It was not until Avedis Donabedian and other care providers championed a systems-based approach to measuring quality that the science of health care improvement advanced dramatically. In a 1966 article, *Evaluating the Quality of Medical Care*, Donabedian argued that quality should not be measured solely by the consequences of care (Outcomes); quality must also take into consideration who provides the care and where (Structure), and how the care is provided (Process) [21]. Although each component can be measured individually, Donabedian emphasized that integration of all three components of the triad are essential in assessing the delivery of care. Today, Donabedian's Structure–Process–Outcome model continues to serve as the prevailing framework for assessing the quality of health care (Fig. 53.1).

Which measures best assess surgical quality continues to be debated, but in general they can be categorized into one of Donabedian's three domains. Examples of structural measures include a hospital's procedural volume and status of its ICUs. Better patient outcomes have been reported for certain complex procedures when performed at high-volume centers, and organizations such as the Leapfrog Group have encouraged patients to seek care at centers with high procedural volumes and closed ICUs. Process measures are a focus of The Surgical Care

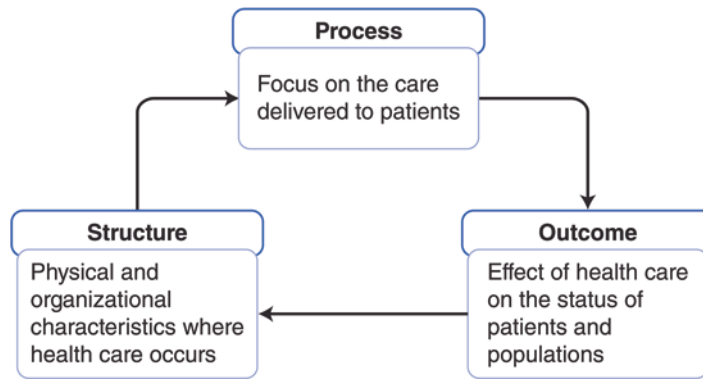


Fig. 53.1 The Donabedian Quality Triad. Donabedian theorized that the integration of all three elements of the triad is essential in assessing the delivery of care [21]

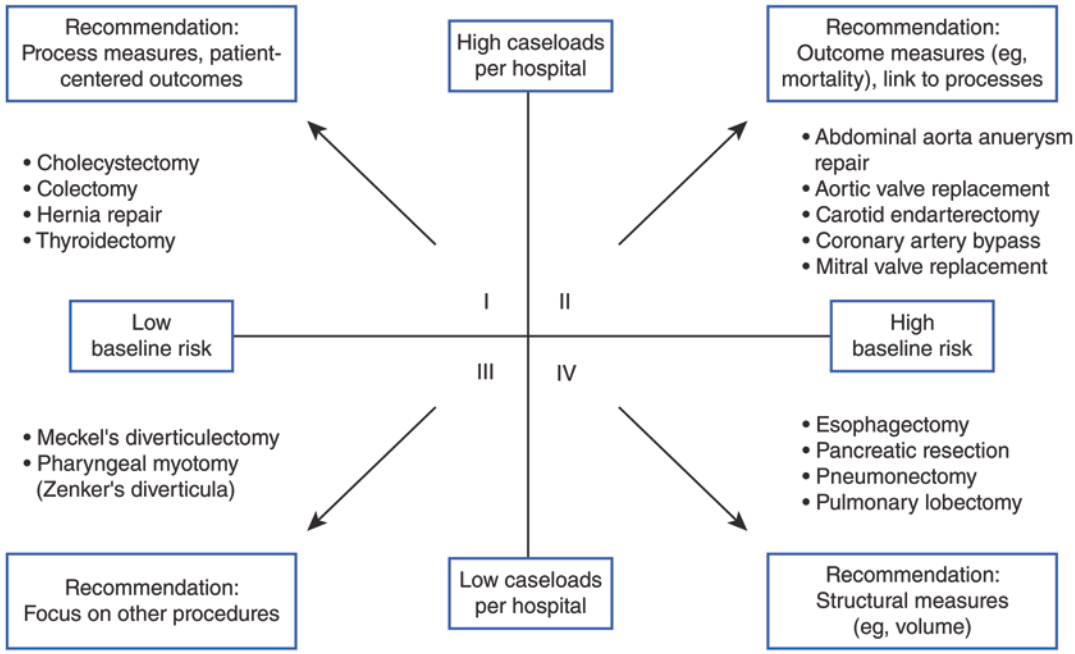


Fig. 53.2 Recommendations for when to focus on structure, process, or outcome metrics. Modified from Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: structure, process, or outcomes? J Am Coll Surg. 2004;198(4):626–32

Improvement Project (SCIP). SCIP is a collaboration initiated in 2003 by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC) to decrease surgical complications through adherence to certain perioperative processes. Outcome measures are exemplified by the risk adjusted surgical outcomes provided by the ACS National Surgical Quality Improvement Program (NSQIP). NSQIP is the most widely recognized data collection, analysis, and reporting program for noncardiac surgery. Participating hospitals are provided surgical outcomes data that are expressed relative to other hospitals as observed to expected (O/E) ratios. An ACS NSQIP Surgical Risk Calculator has also been developed as a clinical decision support tool based on multi-institutional clinical data. By estimating the risks of most operations, surgeons and patients can participate in the shared decision making process [22].

Each measurement domain with the Donabedian framework has its strengths and weaknesses. Recommendations for choosing the best measure based on the procedure have been provided by Birkmeyer et al. [23] (Fig. 53.2).

Although quality improvement efforts have focused on perioperative care, there has been recent interest in assessing the surgeon's performance in the operating room. Historically this has been difficult to measure, and surrogate measures such as procedural volume have been used as proxies. Work by Birkmeyer et al. using intraoperative video have demonstrated that greater surgical skill is associated with fewer postoperative complications and lower rates of reoperation, readmission, and visits to the emergency department [24, 25]. How measures of surgical skill relate to measures of perioperative care and surgical outcomes requires further study, but there is little doubt that surgical skill in addition to measures of the delivery system will influence future quality improvement efforts.

Health Care Systems Engineering

> *Safety does not reside in a person, device or department, but emerges from the interactions of components of a system*
> (Institute of Medicine, 1999 *To Err is Human: Building a Safer Health System*) [1]

Systems engineering is a comprehensive approach to analyze, design, and manage complex systems. It incorporates a broad range of methods and tools to integrate and coordinate personnel, information, materials, and financial resources [4, 26]. The origins of systems engineering date back to quality improvement initiatives at Bell Laboratories during the 1930s and 1940s and the work of Walter Shewhart and W. Edwards Deming. Shewhart is regarded as the father of statistical process control and developed the first statistical process control (SPC) chart. W. Edwards Deming promoted Shewhart's work and was later known for the Deming Plan-Do-Study-Act (PDSA) Cycle. During the post-World War II period systems engineering methodologies became widely adopted in industries outside of health care, where it has been used to successfully improve quality, efficiency, safety, and customer satisfaction [27, 28]. Only recently have systems engineering tools and models for quality improvement been applied to health care. Commonly used management models include Total Quality Improvement, Lean, and Six Sigma. Where Lean identifies and eliminates waste (non-value added processes), Six Sigma identifies and eliminates sources of variability. Frequently used tools adopted from systems engineering include statistical process controls, queuing theory, root cause analysis (RCA), failure-mode effects analysis (FMEA), and human-factors engineering [4, 10] (Fig. 53.3).

The application of systems engineering tools to improve health care has been advocated by several organizations. In 2005, collaboration between the National Academy of Engineering (NAE) and the Institute of Medicine promoted a framework for a systems approach in their landmark publication, *Building a Better Delivery System: A New Engineering/Health Care Partnership* [26]. This was later followed in 2009 by a report from the Agency for Healthcare Research and Quality (AHRQ) entitled *Industrial and Systems Engineering and Health Care: Critical Areas of Research,* and in 2014 by a report to the President of the USA from the Council of Advisors on Science and Technology entitled *Better health Care and Lower Costs: Accelerating Improvement through Systems Engineering* [4, 11]. The report to the President called for systems-engineering know how to be propagated throughout all levels of health care delivery and recommended that the USA build a health care workforce equipped with systems engineering competencies to enable system redesign. Despite these efforts and data suggesting that systems engineering techniques have been associated with significant improvements in health care quality and efficiency, these tools remain underutilized. Their adoption has been hindered by multiple barriers, including inadequate access to relevant data and analytics, health professionals not trained to think analytically about the delivery of health care, and industrial and systems engineers without sufficient knowledge of the health care industry. Most significant is a fee-for-service payment system. A fee-for-service system rewards the performance of procedures and not quality. It favors volume over value and does not provide an incentive for efficient or coordinated care [29].

In recognition of the shortcomings of a fee-for-service payment system, the Patient Protection and Affordable Care Act, commonly known as the Affordable Care Act (ACA) was passed in 2010. The ACA called for the creation of a pilot program to improve the coordination, quality, and efficiency of services by restructuring Medicare reimbursements from a fee-for-service model to bundled payments. Under a bundled-payment system hospitals and providers will no longer be reimbursed for individual services (pay for volume). Instead, a single payment is divided among hospitals and care providers for each episode of care (pay for value). An episode of care is based on a specific condition and typically includes the initial inpatient stay plus the post-acute care and all related services up to 90 days after hospital discharge. The Medicare Bundled Payments for Care Improvement (BPCI) pilot program began in 2013 [30], and it is anticipated that 50 % of Medicare payments will be tied to alternative payment models by the end of 2018. Alternative payment models include Accountable Care Organizations (ACOs) or bundled payment arrangements.

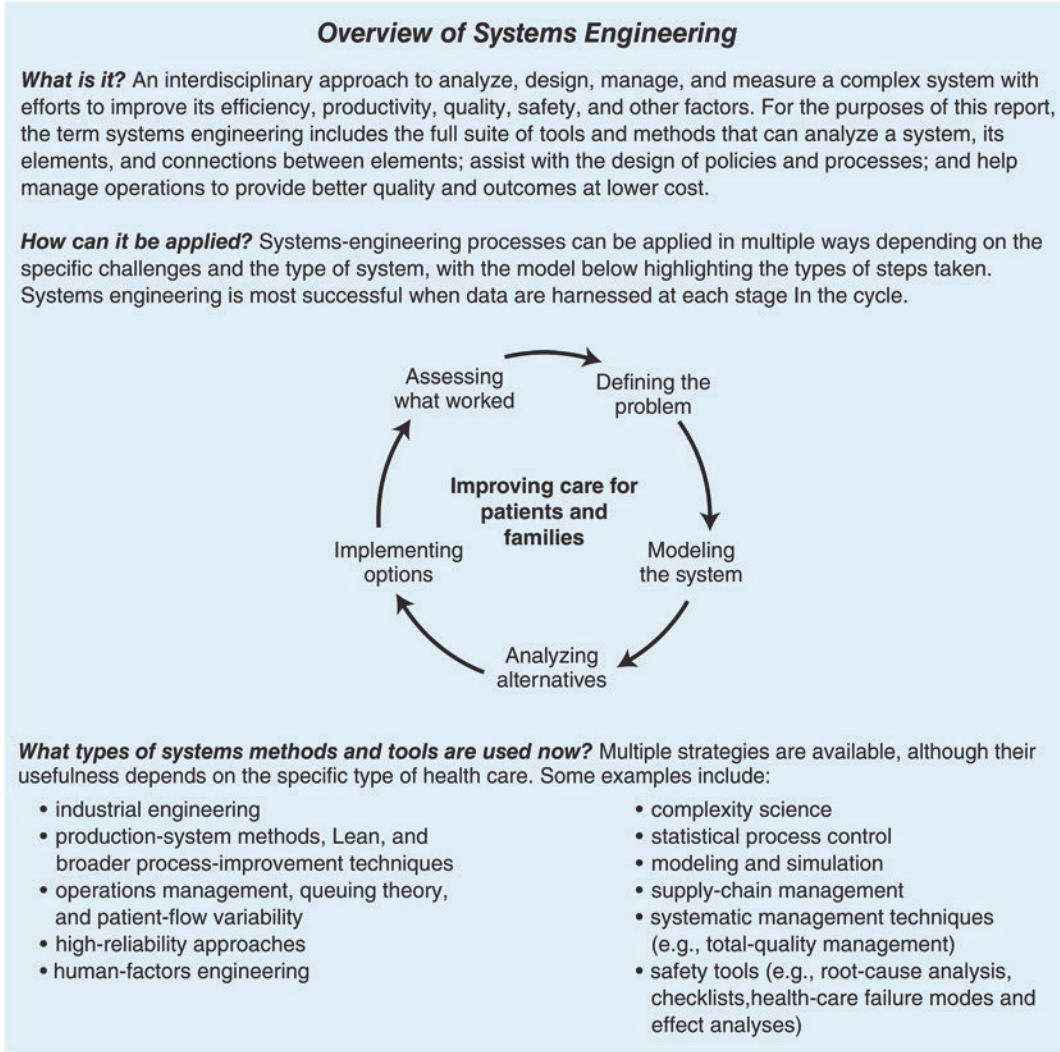


Fig. 53.3 Overview of systems engineering. Better health care and lower costs: accelerating improvement through systems engineering. Modified from Technology PsCoAoSa. *Better health care and lower costs: accelerating improvement through systems engineering.* Washington, DC; 2014

The implementation of new payment models that focus on episodic care is just beginning to drive hospitals and providers to develop a more coordinated care model. Increasingly, health care organizations are incentivized to focus on value by providing higher quality care at lower cost. Health systems will need to deliver care more efficiently and effectively through the evidence-based and standardized processes. Costly complications, such as length of stay and readmissions, will need to be avoided in order for health care organizations to maintain their financial viability. In surgery, this has led to the development of models for perioperative care such as Enhanced Recovery After Surgery (ERAS®) protocols and the Perioperative Surgical Home (PSH) [31–33]. ERAS is an evidence-based care protocol with recommendations for patient care throughout the perioperative care pathway. Approximately 20 elements have been shown to influence outcomes such as length of stay, morbidity, and complication rates. Key components include:

- Preadmission information and counseling
- Nutrition: limited fasting, reduced use of nasogastric tubes, early oral nutrition
- Multimodal pain management: spinal or epidural anesthesia/analgesia, NSAIDs, minimal narcotic use
- Antibiotic and venous thromboembolism (VTE) prophylaxis
- Avoidance of salt and water overload, goal-directed therapy
- Early removal of lines, drains, and urinary catheters
- Early mobilization

The Perioperative Surgical Home represents a fully integrated perioperative care model. It applies a patient-centered approach and promotes standardization, coordination, transition, and value of care throughout the perioperative period (preoperative, intraoperative, immediately postoperative, and post-hospital discharge) [34]. While the PSH incorporates certain components of ERAS, it is a broader concept that uses systems engineering methods and management strategies (Lean and Six Sigma) to optimize care [32]. Although the PSH remains in its operational nascence, there is little doubt there will be multiple future iterations of this concept. At this time published outcomes are sparse and data-based documenting and reporting of institutional experiences will be critical in shaping future efforts (Fig. 53.4).

Culture of Safety

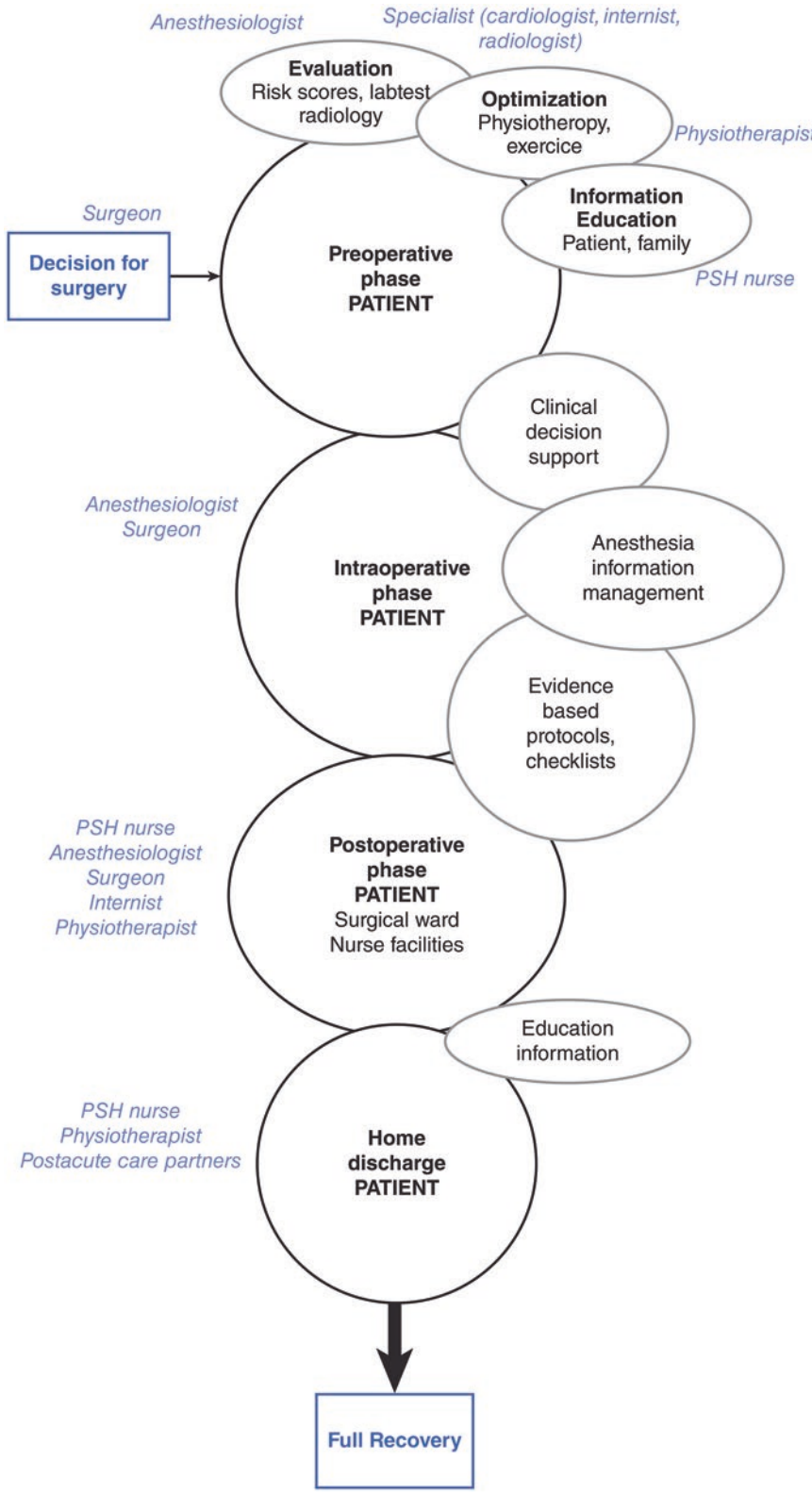
A culture of safety is an essential part of preventing or reducing errors and improving quality. As defined by The Joint Commission, a culture of safety within health care represents "the summary of knowledge, attitudes, behaviors and beliefs that staff share about the primary importance of the well-being and care of the patients they serve, supported by systems and structures that reinforce the focus on patient safety" [35]. Four key features of a safety culture provided by the AHRQ Patient Safety Network include:

- Acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations
- A blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources to address safety concerns [36].

Trust, reporting, and improvement are three mutually reinforcing imperatives for achieving and maintaining a culture of safety [20]. Trust among staff can only be achieved within a blame-free environment where behaviors that prohibit error reporting have been removed [37]. Staff will then be empowered to report risks, errors, and near misses in order to learn and drive improvement. Ideally, within a culture of safety early reporting identifies problems before serious harm has occurred. Unfortunately, this has not been the case in health care. In health care unsafe conditions and adverse events are typically not reported until after harm has occurred. A recent study [38] identified five key challenges for why incident reporting in health care has not reached its full potential:

- *Reports were inadequately processed*. This is largely a result of inadequate resources to manage the volume of reports. As a result, reports are inadequately triaged, analyzed, or acted upon.
- *Lack of adequate medical engagement*. The most successful improvements in patient safety are accomplished with physician input. Without

Fig. 53.4 The perioperative surgical home. A fully integrated perioperative care model that applies a patient-centered approach and promotes standardization, coordination, transition, and value of care throughout the perioperative period. Modified from Desebbe O, Lanz T, Kain Z, Cannesson M. The perioperative surgical home: an innovative, patient-centred and cost-effective perioperative care model. Anaesth Crit Care Pain Med. 2016;35(1):59–66


Anesthesiologist
Specialist (cardiologist, internist, radiologist)
Evaluation
Risk scores, labtest radiology
Optimization
Physiotheropy, exercice
Physiotherapist
Information Education
Patient, family
PSH nurse
Surgeon
Decision for surgery
Preoperative phase PATIENT
Clinical decision support
Anesthesiologist
Surgeon
Intraoperative phase PATIENT
Anesthesia information management
Evidence based protocols, checklists
PSH nurse
Anesthesiologist
Surgeon
Internist
Physiotherapist
Postoperative phase PATIENT
Surgical ward
Nurse facilities
Education information
PSH nurse
Physiotherapist
Postacute care partners
Home discharge PATIENT
Full Recovery

physicians submitting adverse events, the majority of events are reported by nursing staff.
- *Insufficient visible action after an adverse event was reported*. Lack of feedback from the analysis to the reporters and relevant people in the organization negatively influences frontline workers in reporting adverse events [39].
- *Inadequate funding and institutional support*.
- *Failure to capture evolving health information technology developments*. Organizations do not take full advantage of the electronic health record to support auditing and dissemination of adverse event information.

Although a great deal of attention has been focused on the technical aspects of incident reporting in health care such as data collection, online reporting systems, and analytic tools, future efforts need to focus on engaging frontline workers in the process. Physicians, in particular, must feel safe reporting errors and should be encouraged to be as proactive in reporting risks and near misses as they are for sentinel events [40]. Reports must be handled in a transparent process and appropriate feedback provided to the reporters and relevant people within the organization [41]. Additional strategies to improve the culture of safety outside of the operating room include executive walk rounds and unit-based safety teams. During executive walk rounds senior leaders can informally discuss safety issues and demonstrate the organization's commitment to building a culture of safety. Unit-based safety teams frontline staff, physicians, managers, and senior leaders affiliated with one unit to provide sustained engagement and consistent follow through in driving quality and safety [42, 43].

Operating rooms are complex systems, and communication and teamwork are essential to establish and maintain a reliable culture of safety [44]. Patients are cared for by multiple providers in different locations, the procedures are invasive and often technologically complex, and the patients are sedated or anesthetized so they cannot participate in the procedure. As a result, nearly 50 % of hospital errors occur in the OR, and failures in communication represent the most common cause for these errors [45]. Recent studies of OR clinicians and staff suggest that communication and teamwork in the OR are suboptimal [46]. This is based on perceptions of teamwork that vary widely among members of the OR teams. Surgeons believe their style of leadership is collaborative and respectful, and that teamwork in the operating room is good [47]. This is in contrast to other members of the OR team who perceive the surgeon's style of leadership as autocratic, and view the communication and teamwork in the OR less favorably [48, 49]. The largest discrepancy among members of the OR team was the establishment of a shared understanding of the procedure. For complex operations, a shared understanding by all participating team members is essential for optimal team performance, patient safety, and outcomes [50].

Team Training

Based on evidence that better teamwork is associated with fewer errors in the operating room, methodologies such as Crew Resource Management (CRM) and Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) have been adopted to facilitate team communication and teamwork [51]. Originally developed in the aviation industry, CRM focuses on interpersonal communication, leadership, and decision-making [52]. TeamSTEPPS was formed in 2006 from the collaborative efforts of AHRQ and the Department of Defense and provides an evidence-based framework to optimize team performance that is specifically designed for health care professionals. It is based on five principles: team structure, communication, leadership, situation monitoring, and mutual support [53]. Improved operating room efficiency and diminished patient safety events have recently been shown to be associated with implementation of the TeamSTEPPS program [54].

Checklists and Team Briefings

Two tools used to sustain a culture of safety are checklists and team briefings. In 2009, the World

Health Organization (WHO) published the Surgical Safety Checklist. Adapted from the aviation industry, use of the Surgical Safety Checklist has been associated with decreased morbidity and mortality [13, 14]. How checklists improve outcomes is less clear, but evidence suggests that in addition to ensuring that critical tasks are addressed they also improve communication and teamwork [39]. Checklists are frequently used to encourage and direct preoperative briefings. Briefings involve the entire operating team and promote a shared understanding of the procedure. The use of briefings has been associated with decreased mortality in a recent Veteran Affairs study [55].

High Reliability Organizations

High reliability organizations (HROs) are industries that operate under hazardous conditions and are exceptionally consistent in accomplishing their goals and avoiding potentially catastrophic errors [56]. Recent studies of HROs such as the nuclear power industry, the Federal Aviation Administration's Air Traffic Control system, and aircraft carriers have provided insight into how industries outside of health care have been able to achieve and sustain high levels of safety. High reliability science has only recently been applied to health care, but it offers the prospect that similar levels of quality and safety, comparable to other HROs, can be achieved. Work by Weick and Sutcliffe [57] identified five attributes of HROs:

- *Preoccupations with failure*. Regarding minor errors or near misses as a symptom that something is wrong.
- *Sensitivity to operations*. Paying attention to what is happening on the front lines.
- *Reluctance to simplify interpretations*. Avoid overly simple explanations and encourage diversity in experience, perspective, and opinion.
- *Commitment to resilience*. Training and preparation to respond when system failures occur.
- *Deference to expertise*. Decision making down to the people with the most expertise and related knowledge.

Together, these principles produce a collective state of mindfulness. To be mindful is to have an enhanced alertness and awareness to details so errors can be discovered and corrected before they escalate into a crisis [42]. The first three principles maintain high levels of safety through *anticipation*, while the last two principles address *containment* once an unexpected event has occurred [44].

High reliability science has not yet been widely adopted in health care, and future studies will be required to understand the best framework for its successful adoption. In the interim, a model proposed by Chassin and Loeb [58] for the Joint Commission involves a series of incremental changes in three essential areas: leadership, safety culture, and process improvement. In order to progress towards a high reliability health care organization, leadership must be committed and support the ultimate goal of zero patient harm, a culture of safety must be maintained throughout the organization, and robust process improvement tools such as lean, six sigma, and change management must be widely adopted.

Resilience Engineering

Resilience is the ability of a system to adjust its operations before, during, or following a disturbance; a resilient system is able to sustain safe and efficient operations in both expected and unexpected conditions. As described by Hollnagel [59], a resilient system is characterized by four qualities:

- Ability to *monitor* conditions and performance
- Ability to *respond* to both expected and unexpected condition in an effective and flexible manner
- Ability to *anticipate* future events and conditions
- Ability to *learn* from failures and successes

Resilience engineering (RE) is a relatively new discipline to identify and value behaviors and resources that contribute to a system's ability to

respond to the unexpected [60, 61]. Whereas traditional approaches to safety focus on identifying factors that contribute to adverse outcomes, RE focuses on a systems ability to succeed in the event of an adverse outcome [39]. In contrast to root cause analyses where the focus is on contributors to what went wrong, in RE the focus is on contributors to what went well.

Resilience engineering is an important consideration when carrying out performance improvement in health care. As we focus on improving efficiency and eliminating waste, we must take care not to undervalue and eliminate factors that contribute to resilience. Resources that at first appear to be unnecessary under normal operating circumstances may have value that is recognized only during a crisis [60]. How to assess the latent value of resources that contribute to resilience under normal operating conditions has yet to be determined, but will certainly be a valuable contribution to future efforts in quality and safety.

Improvement Science

Improvement science is a relatively new term that has yet to be entirely defined. Influenced by the Institute of Healthcare Improvement (IHI), for many it applies to the application of improvement tools and methods such as rapid testing (PDSA cycles) that trace back to the work of W. Edwards Deming [62]. Marshal et al. [63] have promoted a broader definition that focuses on theories of how change occurs. It supports the design, study, and implementation of improvement work, and adopts the scientific rigor used in other areas of academic research. In doing so, improvement science will generate knowledge that is both generalizable and transferable.

The science of improvement is new to health care, and many of the studies done today rely on non-standardized approaches that call into question their effectiveness. Many quality improvement and patient safety initiatives are supported and incentivized by governmental policies and consumer groups, yet research to determine which improvement strategies are most effective is lacking. Integrating scientific research methodologies with improvement efforts has great potential to drive and shape future quality and safety improvements in health care.

Conclusions

Health care in the USA is complex, and its outcomes are less dependent on the individual provider and more dependent on the entire delivery system. It has been over 10 years since the NAE and the IOM called for a systems approach to improve the delivery of health care, yet systems-based improvement strategies have not been widely adopted. This is likely to change as CMS begins to implement alternative payment strategies such as bundled payments; there will be a greater incentive to provide coordinated, safe, and efficient care. Surgeons are a natural fit to lead these efforts, but in order to do so they must embrace systems-based improvement strategies. Frameworks such as systems engineering have been successfully applied in industries outside of health care to improve quality and safety. In health care, they offer the promise to transform and improve the delivery of care.

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Epilogue

"It always seems impossible until it's done."

—Nelson Mandela

Despite spectacular progress in the diagnosis and treatment of surgical diseases over the past century, real-world surgical care remains suboptimal and is characterized by considerable variation in outcomes, persistent disparities, and too often, preventable defects causing harm to patients. The complexity, cultural, and system design issues of contemporary healthcare delivery result in care that is often fragmented, unnecessarily costly, and often not based on evidence. Additionally, it is clear that patients are exposed to preventable harm as a result of poor coordination and communication, inconsistent processes and practices, and poorly designed systems. In addition, surgical team members—surgeons, anesthesiologists, nurses, technicians, and other healthcare professionals—are increasingly disappointed with healthcare reform and are uncertain about the future of their professions. In order to achieve high reliability in surgical care, the existing paradigm must shift toward a systems-based and transparent approach that engages providers every step of the way and delivers reliable healthcare services across the entire spectrum of care. Moreover, credible clinical data must be used to continuously measure and improve outcomes in a manner that nurtures trust and cohesiveness among all stakeholders, not the least of which is the patient and their caregivers.

This book brings together a wide array of experts on quality, patient safety, systems, health policy, and process improvement with the overarching goal of creating a vital resource for all individuals involved, directly or indirectly, in providing surgical care. By outlining the cognitive, social, technical, and operational elements which contribute to variable outcomes, the Editors hope that frontline practitioners, healthcare leaders, and all who design and manage surgical tools, implements, and workflow systems can re-engineer the surgical environment to optimize outcomes, improve patient and workforce satisfaction, and reduce costs. From concepts and models of safety and reliability to practical chapters on preventing perioperative injuries, and a focus on global challenges in surgical care, these pages provide a vast source of information for all stakeholders in the surgical space to improve quality and value in surgery. They introduce organizational and cultural determinants of quality and safety using a human factors lens and advance contemporary thought on managing workforce wellness, designing more supportive and nurturing culture, capturing and reporting adverse events, as well as considering the physical design of surgical devices and facilities in order to achieve consistent and optimal outcomes.

Surgical care can be a model for healthcare reform because of its many successes in fostering cross-disciplinary and multidisciplinary collaboration. In fact, surgery pioneered the collection

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and sharing of risk-adjusted data over 100 years ago when Ernest Codman, a forerunner in the modern search for medical excellence, challenged his surgical colleagues to share their outcomes with their colleagues and patients in 1916.[1] Codman "walked the walk" as well as "talked the talk." He openly admitted his errors in public and in print. In fact, he paid to publish reports so that patients could judge for themselves the quality of his care. He sent copies of his annual reports to major hospitals throughout the country, challenging them to do the same. From 1911 to 1916, he described 337 patients who were discharged from his hospital. He reported 123 errors. He measured the end results for all. Codman passionately promoted transparency in order to raise standards. Codman said, "Let us remember that the object of having standards is to raise them." However, perhaps owing to his insistent nature, he often irritated his colleagues. One of them, Dr. Edward Martin, wrote to Codman in 1914:

"Dear Codman:

God bless you! I suppose I should hate you if I lived in the same town, but my feeling, being remote, is quite other. Indeed the very enemies who lurk in second story windows with muffled rifles are waiting your passing, are the ones who take off their hats in deepest respect as your cold, but beautiful, corpse is carried away."[2]

Codman was obsessed with quality and believed it was at the heart of surgical professionalism. "The idea was simple, "The common sense notion that *every* hospital should follow *every* patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, 'If not, why not?' with a view to preventing similar failures in the future" (italics from Codman). While today not a very controversial position, it is obvious few hospitals or medical practices follow their patients as he advocated. In Codman's day, the suggestion was particularly inflammatory since he proposed that outcomes rather than seniority should determine whether surgeons should be promoted.[3]

Major changes are needed in the current model of surgical care delivery. In order to thrive, healthcare institutions must focus on the quality of the care they provide, including cost-efficiency, through innovations that align the incentives of payers, patients, and providers. Engaging clinical staff in a forthright manner is critical to accomplishing this realignment. With the changes in medical care delivery and the focus on population health has come an uneasy and increased scrutiny and public oversight of surgical practice and outcomes. Should we pay huge amounts of money for surgical procedures if they fail to improve quality of life? Improving the reliability of care will require accepting this forced transparency and embracing the opportunities inherent in these new models of care. In 2016, the thirst of the public for transparency, coupled with payers and regulators seeking safer and higher value care, has led the UK, the USA, Australia, Norway, and the Netherlands, for example, to broadly expand programs of public reporting of surgical data about outcomes. The release of such data is only the beginning of a major international revolution in public policy to make outcomes data on patients and populations as well as cost publically available.

At the heart of a sustainable, generative, and continuously improving organizational culture of healthcare is a system with three interlinked aims centered around trust and transparency that can lead to[4]:

[1] Codman EA. *A Study in Hospital Efficiency*. Reprinted by the Joint Commission on Accreditation of Healthcare Organizations Press, 1 Renaissance Blvd, Oakbrook Terrace, Illinois 60181, 1996

[2] Mallon B. Ernest Amory Codman: The End Result of a Life in Medicine. Philadelphia, PA: WB Saunders; 2000.

[3] Brand R Ernest Amory Codman, MD, 1869–1940. Clin Orthop Relat Res. 2009 Nov; 467(11): 2763–2765. Published online 2009 Aug 19. doi: 10.1007/s11999-009-1047-8, PMCID: PMC2758958

[4] West E. Organisational sources of safety and danger: sociological contributions to the study of adverse events. Qual Health Care. 2000;9(2):120–6.

- better outcomes (e.g., for individuals and populations),
- better performance of the system (e.g., higher quality, safety, value), and
- better professional development (e.g., improved work-related competence, joy, and pride).

How does the present punitive and secretive culture and style of management of hospitals and other healthcare environments which provide surgical care support these three interlinked aims? Organizations and communities, including those in healthcare, respond to positive and affirmative thoughts and information: "Energy flows where attention goes."

Real quality improvement requires bringing together multiple systems of knowledge. If done effectively, this combination could guide other fields in healthcare down a bold path on "how to" think differently, be transparent, and emotionally and intellectually engage all stakeholders. Surgery can lead the way for the house of medicine using the same innovative and forward-looking leadership and passion that has made surgical care a modern marvel.

Mistrust in healthcare systems and providers has contributed to cynicism and disengagement by clinicians with rates as high as 45 % of providers reporting symptoms of classical burnout and depression. The growing pressures of an expensive and laborious system of medical liability can ultimately harm patients. This system focuses on blame and shame and drives defensive and sometimes perverse actions by providers and institutions. Meaningful change through learning happens at the level of discourse, through education, management, and training, and not through courts of law. The best clues to changing the culture of healthcare come from listening to how clinicians and staff talk about their work, their organizations, their colleagues, and their future.

Trust must be built around efforts to *ensure hierarchical and organizational transparency*. When clinicians feel unsupported and threatened or do not feel safe, they will not speak up about ongoing and emerging consequences that undermine safe practices.[5] Avoiding difficult conversations keeps us from becoming more reliable. Without trust, clinicians tend to resist intentional change, partly because competing commitments and assumptions effectively keep the "status quo" in place. Moreover, the inability to implement change can be exacerbated by patterns of behavior that incorporate "normalized deviance," in which some processes of care have evolved over time to fit established work flow and systems even when these practices are "unsafe" and not permitted.[6] A culture of fear contributes to normalized deviance and keeps clinicians from doing the right thing. The cognitive dissonance that clinicians and executives feel when confronted by organizational opaqueness is predictable and can lead to a lack of sharing of information, lack of learning, and ultimately disruptive behaviors, frustration, burnout, and high "churn" rates.[7]

Additionally, important strategic decisions must be made to accelerate the scale-up of surgical services in low-resource settings both in developed countries and in others. A robust accounting framework that disaggregates health expenditure by intervention, such as surgery, may be necessary for systematic, safe, and efficient scale-up of surgical interventions. Increasing dialogue between surgical providers and political leaders can increase the power of stakeholders to advocate for cost-effective and safe surgical care. Greater emphasis on the importance of surgical care in achieving national health goals can strengthen internal and external framing of these issues. Increasing and improved tracking and public reporting of peer-reviewed, vetted surgical

[5] Edmonson A. 1999. Psychological safety and learning behavior in work teams. Administrative Science Quarterly. 1999;44(2):350–83.

[6] Vaughan D. 1999. The dark side of organizations: mistake, misconduct, and disaster. Annu Rev Sociol. 1999;25:271–305.

[7] Amalberti R, Auroy Y, Berwick DM, Barach P. Five system barriers to achieving ultrasafe health care. Ann Intern Med. 2005;142(9):756–64.

indicators could increase the priority given to surgery internationally.

This book is the product of a long-standing friendship and *camaraderie* fueled by a desire by the Editors, seasoned clinicians, and health services researchers, to bring together the most current quality improvement science and innovative ideas with a specific focus on improving perioperative care and coproducing with patients the best possible outcomes. In doing so, the contributing authors have provided a framework as well as practical knowledge from a patient-centered, systems perspective which includes the view that patients and their families can also contribute to safe, reliable, and exceptional surgical outcomes.

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