Making the Operating Room of the Future Safer

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ABSTRACT

There is an increasing demand for interventions to improve patient safety, but there are limited data to guide such reform. In particular, because much of the existing research is outcome-driven, we have a limited understanding of the factors and process variations that influence safety in the operating room. In this article, we start with an overview of safety terminology, suggesting a model that emphasizes “safety” rather than “error” and that can encompass the spectrum of events occurring in the operating room. Next, we provide an introduction to techniques that can be used to understand safety at the point of care and review the data that exists relating such studies to improved outcomes. Future work in this area will need to proactively study the processes and factors that impact patient safety and vulnerability in the operating room.

Since the Institute of Medicine (IOM) published its report, To Err is Human, in 1999, patient safety has received increased attention in both the medical literature and the lay press.¹ The epidemiology of patient safety and medical error has been well-documented. The Harvard Medical Malpractice Study suggests that 3.7% of hospitalizations involve an adverse event and a study from Colorado and Utah found a similar rate of 2.9%.²,³ Based on these numbers, the IOM extrapolated that 44,000 to 98,000 inpatients die each year from medical errors. Based on these data, the public, healthcare purchasers, and providers alike are calling for change. A recent Sounding Board in the New England Journal of Medicine suggests that “hospitals that do not take specific actions to improve safety should be viewed as negligent and be subject to malpractice lawsuits when a violation of the right to safety results in injury.”⁴ But what exactly should those specific actions be? In surgery, in particular, there are little data to help us in prioritizing our interventions.

There are a number of difficulties related to studying surgical safety, particularly safety in the operating room. First, the traditional medical approach to research is limited in its ability to gather data about the process by which care is delivered. The importance of issues such as communication, workload and team performance has been recognized, but such areas are difficult to study. Most of the research that does exist relies on retrospective analyses of these factors as they relate to adverse events. Other advances in patient safety have come through quality improvement or operational redesign efforts, which have been focused on interventions with less attention to gaining a fundamental understanding of safety in the operating room. Such insight requires scientifically rigorous research focused on the actual point of care. We need to broaden our research methodologies and include more qualitative techniques to continue to advance our understanding of operating safety. Much can be learned by borrowing techniques from human factors engineering and collaborating with researchers who have studied other high risk work environments.

Traditional Thinking and Where It Falls Short

A recent observational field study conducted by the authors provided valuable insight into patient safety issues in the operating room.⁵ A variety of events were observed that clearly compromised patient safety but were not easily described within the current framework available to understand adverse events. In addition, we were able to identify features of the system that influenced safety (positively and negatively) independent of these “safety-compromising events.” These observations suggested that the traditional study of patient safety may be too discrete and outcome-driven in its approach: an adverse event occurs or it does not and if it does not, there is nothing to study. Our observations highlighted the importance of studying the times when patient safety is compromised.
or potentially compromised, but may not result in a measurable negative outcome. To do this, one needs to augment the current terminology, models and methodologies used to investigate patient safety so as to more accurately capture the multiple sources and wide spectrum of risk that arise in complex care delivery settings.

When an operative intervention is proposed, estimated risk is weighed against expected outcome. Assessments of operative risk have traditionally incorporated such characteristics as patient attributes (anatomy, disease process and co-morbidity), procedural complexity, provider experience, and institutional reputation. Little attention has been given to more subtle properties of care such as resource availability, staffing, quality of communication and information flow, and teamwork. Moreover, safety is traditionally assessed almost exclusively in terms of outcome. A good outcome or a lack of an overt, identifiable error or adverse event is often felt to reflect a safe hospital course. This offers little opportunity to uncover and correct latent contributors to risk before they result in measurable harm to patients. Our observations suggest that the design and execution of the processes of care throughout the per operative period more accurately reflect the overall safety of the system, independent of the outcome in any particular instance.

Traditional patient safety research and investigation has been largely outcome-driven and retrospective in design. Instru mental investigations such as root cause analyses and research efforts such as the Harvard Medical Practice Study identify patients based on unexpected or adverse outcomes and rely on postevent reconstruction and analysis. Such analyses often lack the necessary information about the processes of care that resulted in the outcome, or the context in which a specific event occurred. Furthermore, these analyses offer no opportunity to study the compensatory factors that healthcare workers employ when things start to go awry.

Definition of Error and Its Relevance to Patient Safety

The IOM report defines error as “the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning).”1 This IOM definition fails to describe the full range of phenomena surrounding adverse medical events and patient safety. The implication is that the phenomenon to which the label error has been applied is a discrete action committed by a single agent. Given the complex interplay between detection, decision-making, planning and intervention in medicine, this is an oversimplification.8

A classification of error that emerged from industrial safety research and is relevant to the medical domain is the important distinction made by Reason between active and latent types of errors.9 Active errors produce effects that are felt almost immediately, while latent errors lie dormant within the system for long periods before combining with other factors to breach a system’s defenses and produce measurable effects.9 In medicine, an active error would produce an immediate, measurable change in a patient’s clinical status. Latent errors are features of the patient care environment, decisions or plans that do not immediately become manifest, but establish the conditions for a future change in patient’s status. Examples include chronic understaffing of a high-acuity intensive care unit or use of an infusion pump that requires complex dosage calculations and no internal consistency checks. These decisions do not produce an immediate change in patient status, but establish the necessary conditions for such events to occur. A primary goal of safety research should be the identification of these dormant system features before they lead to patient harm.

In medicine, we have traditionally focused almost exclusively on the active type of error. In surgery, in particular, we have become very adept at identifying these events, focusing intently on discrete actions committed by a single agent. This is precisely the goal of the Morbidity and Mortality conference: to stand up and take responsibility for what went wrong and the role we as practitioners played. This approach fails to identify the faults or features of the system that provide the necessary conditions for active errors. Although it is imperative that we, as providers, continue to take responsibility for what happens to our patients, we must shift our energy from trying to be more careful to a proactive redesign of the system for safer patient care.

We assert that error should not be the focus of patient safety research. First, despite the suggestion by some that use of the term will bring the quite-normal imperfections of human behavior into light (after all, to err is human), the use of the term error in medicine will perpetuate the culture of blame that we are trying to discourage. Because of our traditional focus on the active type, error implies a discrete, identifiable, single fault. The human aspect is only one of several components in a complex and vulnerable healthcare system. In fact, it has been said that human error is a symptom of problems deep within a system rather than the problem itself.10,11 In fact, practitioners are often a source of resilience in maintaining safety in the face of an imperfect system. The hidden faults or system features that permit evolution or progression of an event should be the focus of analysis and intervention. In an effort to provide a useful approach to patient safety and adverse events, particularly in terms of process variations and targets for intervention and improvements, the remainder of this article describes an approach that focuses on safety rather than error.

Defining an Adverse Event

In the current patient safety paradigm, there are two types of events that are available for analysis: an adverse event and a near miss. The IOM report To Err is Human defines an adverse event as “an injury that is caused by medical management rather than by the underlying disease or condition of the patient.”11 A near miss is an event or error that does not harm a patient but, occurring again, could easily lead to patient injury.15 A recent study from Australia, recognizing that not all adverse events can be considered an injury, offers a broader definition of an adverse event: “unintended injury or complication which
results in disability, death or prolonged hospital stay and is caused by health care management and not patient disease."\textsuperscript{14} We suggest that the definition needs to be broadened even further: an adverse event is “a deviation from the expected course of care that results in disability, death, or measurable negative change in patient status and is caused by healthcare management or delivery rather than the underlying disease.”

The desire to broaden the definition to include “negative change in patient status” and not just “prolonged hospital stay” is based on our observations in the operating room. To illustrate our point, consider the following hypothetical example that is similar to several events we observed. The gastrojejunostomy is being completed in a patient undergoing a Whipple procedure. While performing a gastrojejunostomy, a misfiring of the stapling device results in a disruption of the anastomosis, requiring a limited resection of the damaged jejunum and reanastomosis. In this case, it is difficult to identify a measurable change in patient outcome because it is unlikely that this incident will even prolong the hospital stay. It will however lead to a prolongation of anesthesia time, increased resource utilization, and an additional suture line. While this event would not meet the criteria of disability, death, or prolongation of hospital stay, it does fall outside of the expected course of care for that patient and causes a negative change in patient status. Such a generalized definition allows the term “adverse event” to encompass all incidents in which a patient is unintentionally harmed by medical treatment, a broad definition suggested by Charles Vincent.\textsuperscript{15} Regardless of how it is classified, events such as this warrant investigation if we are to improve operating room safety.

A second example illustrates the value in identifying deviations from the expected course of care in the absence of measurable changes in patient status. In this case, a patient is given a preoperative antibiotic in an understaffed preoperative holding area just prior to a shift change, and the administration is not documented. The anesthesiologist for the case receives a handoff from the nurse who just took over care for the patient and is not told about the antibiotics. The anesthesiologist then administers a second dose just after induction, assuming the first had not been given. Despite the fact that the second dose will not harm the patient, there is still much to be learned from studying such a case because the factors that contributed to the over-dosage—the understaffed preoperative holding area and the medication documentation deficiencies—represent process issues whose safety impact could be significant in other instances. The difficulty lies in identifying such events so they can be analyzed.

The System View in Patient Safety

Let us start by defining the operating room and everything that occurs within it as our system. At the beginning of a case, there is an expected course based on a preoperative assessment and such variables as the attributes of the patient, surgeon, and other team members and other specifics of the procedure. System vulnerability reflects the opportunity for events and factors to make the system less safe or more prone to adverse events. Throughout the case there will be unanticipated events and factors that can either have a positive, negative, or neutral effect on the vulnerability of the system. A safety-compromising event is an event that significantly increases the vulnerability of the system and has the potential to lead to an adverse event. A safety-compromising event can be what has been traditionally referred to as an error, but not necessarily. There is a large range of severity for safety-compromising events—from minor events (ones that have no consequence in the current case but that could have consequences under different circumstances) to life-threatening events. Many investigators have struggled with how to characterize this wide variation in severity. For example, a human factors study in pediatric cardiac surgery made the important distinction between major and minor events—those with serious consequences for patient safety and those that disrupt surgical flow—but emphasized the impact of both.\textsuperscript{16,17} At the more severe end of the spectrum, a threshold will be crossed where there is a measurable negative change in patient status. At this point, one would say an adverse event has occurred. However, it is possible that compensation can take place before that threshold is reached and the system returns to safe practice (Figure 1).

A safety-compromising event can have one of three outcomes. First, it can go without recognition and without consequence. In other words, there is an increase in vulnerability, but it is not noticed. For example, if a surgeon contaminates his glove and no one notices, the patient will be at increased risk for, but not necessarily develop, a wound infection. Second, it can be recognized and compensation can take place before it can cause harm to the patient. Compensation can be an active intervention or because of chance. This includes events that are traditionally thought of as a “near-miss” in medicine. The blood bank mistakenly sends a unit of mismatched blood to the floor. In checking the blood type against the patient’s blood type, the floor nurse catches the mistake and it is corrected before the patient is harmed. Third, the safety-compromising event can progress to an actual adverse event, as described above. By definition, only the latter two instances can be detected by traditional methods (e.g., self-reporting systems or retrospective root cause analyses) and therefore be analyzed to identify patient safety concerns. In addition, we found that providers are less likely to report events that do not lead to an adverse outcome, representing a form of reporting bias. It is unclear whether this is from a lack of recognition or recall. Methodologies, such as observational field studies, allow for the investigation of events that may not be recognized or reported by the caregivers.

The vulnerability of the system is influenced by safety influencing factors (This is similar to performance shaping factors in the human factors literature). A factor is a property or condition of the system. There are many factors, including those related to the team, individuals, equipment, and the patient. A hierarchical classification of safety influencing factors is particularly useful, allowing general categories to be sub-classified into specific factors. Vincent offered the first such framework
Figure 1. Possible sequelae from safety-compromising events.

During a course of clinical care, one or more events may occur that deviate from the accepted or tolerable range of safe care. There can be several different sequelae. The solid line represents progression to patient injury or significant unexpected change in status. The dotted lines represent three representative patterns of “recovery” or “compensation.” A wider range of possible patterns exist. Pattern 1: Clinical care has deviated outside the bounds of standard or accepted ranges of care, but there is prompt recognition and recovery to the accepted and tolerable (“safe”). Pattern 2: Safety-compromising events progress to a point where the patient is at significant increased risk of an unfavorable outcome, but compensation by provider(s) leads to recovery and no detectable change in clinical outcome. Pattern 3: Safety-compromising events progress to a point where the patient is injured or there is a significant change in clinical outcome. After this initial injury, there may be recovery or compensation, or the injury may be permanent.

in 1998.\textsuperscript{15} These factors can either increase or decrease the vulnerability of the system to the occurrence of an adverse event. \textit{Contributing factors} refer to conditions or properties that increase the vulnerability of the system, increasing the risk of an adverse event. Examples of contributing factors include environmental limitations (such as poor lighting), equipment failures, poor communication between team members, or poor decision-making. Compensatory factors, on the other hand, are conditions or properties that decrease the vulnerability of the system or decrease the chance of an adverse event. Examples of compensatory factors include checks and verifications, continuous status updates to the team, and optimizing the preoperative condition of the patient. A compensatory factor can be an action that is taken to reduce the severity of a safety-compromising event and drive the system back toward the baseline. Table 1 summarizes the terminology defined in the last two sections.

### Direct Field Observational Technique as a New Methodology in Patient Safety

As mentioned above, traditional quantitative research methodologies and quality improvement initiatives such as self-reporting and root cause analyses often fall short in their ability to identify the process elements that led to a particular poor outcome. A thorough understanding of these measures requires an unconventional approach to clinical research. There are a number of related, but different techniques and disciplines that can be employed for investigating the practices and processes of surgical care, particularly operative care. A systems analysis is a study of the organization, interactions, and interdependencies of people, information, resources, equipment and procedures as they work toward a common goal.\textsuperscript{19} Human factors engineering is a discipline devoted to the design and re-design of systems to ensure safer, more effective and more efficient use by humans.\textsuperscript{20-22} Human factors experts are responsible for many safety improvements in other high-risk industries such as transportation and nuclear power control rooms. Human factors and systems analyses both frequently include observational field studies to understand the targeted system.\textsuperscript{23-26} The technique of observational field study has been developed and validated in other high-risk industries, and is increasingly being adapted to healthcare.

There are a number of requirements that must be met for qualitative research, including observational field studies, to be rigorous.\textsuperscript{27, 28} The first step is to identify the environment or system to be investigated. Next, an explicit sampling strategy must be designed and followed, which does not allow for bias in case selection. One must develop an explicit coding process for recording the sampled data. The encoded data must be systematically analyzed. This analysis should lead to explanatory models for what is observed. A necessary part of qualitative research is objectivity and a willingness to consider alternate

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<th>Table 1. Terminology for Studying Adverse Events</th>
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<td><strong>Vulnerability</strong></td>
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<td><strong>Safety-compromising event</strong></td>
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explanations. The ultimate goal is to identify targets for intervention and controlled study based on what is observed. It is important to study the effect of any intervention, since interventions do not always lead to the anticipated result. For observational field studies, there are additional issues related to the selection and training of observers, and the development and validation of intake forms.

There have been several prospective observational analyses in surgery that have provided insight into the prevalence of adverse events and their contributing factors. One study prospectively followed surgical patients for the development of an adverse event (using traditional definitions based on postoperative outcome and reported adverse event rates that are higher (30% to 45% total events, with approximately 13% being “major”) than those identified in the 1999 Institute of Medicine report. This study only identified events that were evident postoperatively. A second study, relying on observations on clinical rounds where cases and events were discussed by practitioners, found an even higher rate of serious adverse events, 17.7%. An advantage to this observational study was its ability to identify some of the contributing factors for these events based on observations and discussions with caregivers. Other studies have observed directly at the point of care—in many ways, the optimal design—mostly, in the intensive care unit and emergency room. For example, a human factors analysis in the intensive care setting found cross-disciplinary communication to be a recurring contributing factor in adverse events.

A recent observational field study of the operating room in a major academic medical center was conducted by Christian et al using systems analysis and human factors techniques. On average, more than one event per case was identified that compromised patient safety and could be analyzed to understand operating room safety. Using both qualitative and quantitative analyses, the quality of communication and information flow and the coordination of workload and multiple competing tasks were found to be the most important safety influencing factors. These safety influencing factors can now be the target of future studies and quality improvement initiatives.

Once an intervention is identified and implemented, it is important to examine the effects of the intervention. Such investigations can include randomized controlled trials, further field observation studies, focus groups, or surveys. The data generated are crucial since any intervention can have unintended consequences on the system in which it is introduced. The only way to recognize these effects before wide-spread implementation is through controlled study and evaluation. For example, an intervention that has been the subject of much interest in human factors engineering is the bar-coding of medications. Through pre- and postintervention field observations, human factors researchers were able to identify five unanticipated side effects of the bar-coded technology on the healthcare system. These included such issues as degraded coordination between physicians and nurses, increased workload, and decreased flexibility when required medications deviated from the standard format. The risk of such unintended side effects must be anticipated and recognized as we move forward with the study and improvement of surgical safety.

Other Approaches to Studying Safety at the Point of Care

Some investigators have advocated video as an alternative to direct field observations. Videotapes have obvious potential medico-legal ramifications that make many healthcare providers wary. This may at explain why video is often perceived to be more intrusive than direct field observations. With direct field observation, the data captured is necessarily limited to what can be recorded by the observer. Since this is not the case with video, such methods are often even more labor-intensive than direct observations. The advantage to video relates to its permanence. Qualitative research is often an exploratory iterative process, greatly enhanced by the opportunity to re-review cases as patterns develop. Additionally, video facilitates audit and review by multiple observers away from the point of care. This is important in the operating room, where more than one observer may disrupt case flow. Multiple observers are necessary for training exercises as well as assessments of inter-rater reliability.

As with any work environment, one of the richest sources of information about safety in the operating room is the frontline personnel. Techniques that utilize the experience of frontline providers in understanding safety include structured interviews, focus groups, or surveys. Such techniques can be used alone or to complement field observations in the study of complex work environments. Following our observational study, we held open forums where we presented our conclusions to the operating room staff. All three disciplines (surgery, anesthesia, and nursing) validated our findings and agreed with our assessment of the major factors influencing safety in their operating room. In 2003, Gawande interviewed 38 surgeons on 146 surgical adverse events. He was able to identify several recurring contributing factors to surgical safety, including inexperience or lack of competence, communication breakdown and fatigue or excessive workload. Investigators at the Johns Hopkins Hospital published another recent example of using front line staff to study surgical safety. They introduced the Safety Attitudes Questionnaire as a potential tool for understanding safety in the operating room. This survey assesses the attitudes and perceptions of OR personnel as a means of measuring the safety of that system. Assessments of the operating room safety climate varied widely across hospitals, but not across providers within an institution, documenting the validity of this instrument as a measure of OR safety. The Safety Attitudes Questionnaire offers a potential means to measure the impact of patient safety initiatives.

Improving Outcomes

The ultimate goal of a study of safety is to improve surgical outcomes by mitigating the risk imposed by the medical system. Data are beginning to emerge that human factors such as
communication and teamwork do correlate with outcomes. The first such study was performed by a multi-disciplinary team of human factors experts and cardiothoracic practitioners studying the Arterial Switch Operation in England. They were able to demonstrate a significant relationship between both major and minor intraoperative errors and mortality rate using multivariable regression modeling to control for patient and procedural factors. More recently, through a number of interventions aimed at improving team performance, the Concord hospital was able to demonstrate an improved observed to expected mortality ratio. Finally, a recently completed study at Kaiser Permanente is investigating the relationship between team performance and 30-day risk-adjusted mortality rates (S. Graham, Kaiser Permanente, personal communication, May 18, 2006). These studies provide a crucial next step in our evolving understanding of the role human factors play in surgical safety. A link between human factors and better outcomes will provide increasing interest and motivation to study and improve this important aspect of care.

Conclusion

This article highlights the current issues in studying safety in the operating room. The traditional models and terminology of patient safety research have led to great advances, but may be inadequate to fully describe the spectrum of events and factors that are encountered in the operating room. Furthermore, traditional research techniques are outcome-driven and limited in their ability to understand process variation and system vulnerability. A focus on safety rather than error will help to advance the cultural changes that are required as we move forward. Investigators are beginning to employ techniques developed in other high risk work environments to healthcare. These newer techniques such as observational field studies and survey analyses offer promising new approaches to study surgical safety at the point of care. Although this article has focused on safety in the operating room, the techniques and ideas can be applied to improve surgical safety throughout the course of patient care.

References