Crossing to safety: Transforming healthcare organizations for patient safety

Ralston JD, Larson EB

ABSTRACT

The current healthcare system is not designed to ensure better patient safety. In addition, healthcare is simultaneously becoming increasingly complex and increasingly fragmented. Medical knowledge and technology are expanding at an incredible rate, making it difficult for the healthcare providers to keep pace with advancing knowledge. Patients’ needs are changing too: shifting from the diagnosis and treatment of a single, acute problem to the long-term management of multiple, interrelated chronic conditions. Our systems of care are not keeping up with these changes and, consequently, patients are experiencing unnecessary risk. Improving patient safety requires a transformation in how we currently care for patients. Healthcare organizations must adopt a new paradigm of care that holds patient safety as a core value and practice. To achieve this aim, healthcare organizations should build and maintain a culture of patient safety, provide leadership for patient safety that establishes a blame-free environment, proactively survey and monitor for adverse events, continually engineer patient safety into healthcare processes, and provide information and communication technologies to support patient safety.

KEY WORDS: Safety, Patient Care, Organizational Culture

The challenge of patient safety

The 1998 Institute of Medicine report “To Err is Human” exposed the magnitude of the serious problems related to patient safety in healthcare systems. This report showed that, despite our best intentions, we are unnecessarily harming patients. It is estimated that each year in the United States, between 44,000 and 98,000 individuals die from potentially preventable injuries associated with medical care in hospitals.1 When preventable adverse events in the ambulatory setting are added to this, the amount of unnecessary death and morbidity is considerably higher.2, 3 The current healthcare system is not designed to ensure better patient safety. Increasing complexity and fragmentation of care, rapidly expanding medical knowledge, increasing use of technology and shifting healthcare needs from diagnosis and treatment of single, acute problems to the long-term management of multiple, interrelated chronic conditions are posing new challenges for the healthcare system to cope with. Consequently, patients are experiencing unnecessary risk.

Improving patient safety requires a transformation in how we currently care for patients. Healthcare organizations must adopt a new paradigm of care that holds patient safety as a core value and practice. To achieve this aim, we propose five key elements for healthcare organizations to pursue:

1) Build and maintain a culture of patient safety
2) Provide leadership for patient safety that establishes a blame-free environment
3) Proactively survey and monitor for adverse events
4) Continually engineer patient safety into healthcare processes
5) Provide information and communication technologies to support patient safety.

All of these elements should be addressed continuously and in concert.

What is patient safety?

Patient safety is freedom from accidental injury. At first glance, this may seem easy to pin down and manage. In the complex world of healthcare, though, patient safety is a moving target. It is a continuously emerging property of a complex system, a complex system involving people, processes, patients, families, and the technology that makes up the system.4, 5 In order to understand how to guide an organization towards improving patient safety we must take into account this dynamic property of patient safety. It means that organizations must be in a continuous state of alert for patient safety.

Taxonomy for patient safety

Medicine continues to make efforts to move away from viewing medical error as an individual’s responsibility and towards recognizing safety as a system property. Discussions about the taxonomy of patient safety and medical error reflect this change. We outline taxonomy of patient safety below that represents our current thinking about the principles of patient safety:

Patient Safety: freedom from accidental injury.
Adverse Event: an event or omission arising during clinical care and causing physical or psychological injury to a patient. 6 Preventable Adverse Event: a subset of adverse events that are judged to be preventable if appropriate and reasonable steps had been taken.7 Error: an act of commission or omission that, based on currently available information, substantially increases the risk of an adverse event.8,9 A Near Miss: A health care near miss is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient.6 Adverse events and near misses are the fundamental outcomes of patient safety. Adverse events, though, are only the visible tip of the iceberg in patient safety. The cause or causes of preventable adverse events almost always lie with failures that are deeper within a system of care that includes technical, organizational and human factors.

We prefer to limit the use of the term “error”. Error can inappropriately focus attention on a single source or individual as the cause of an adverse event.10 Practitioner decisions or healthcare processes closest to the occurrence of an adverse event are typically only one visible step in a much larger and more influential system of care. Safety programs that focus on error may miss the system constraints that are the real opportunities to improve patient safety.

Build a culture of patient safety

The cultural change required to improve patient safety probably constitute the most difficult step for organizations, but it is also the most important one. The tradition of physician autonomy and the “craft model” of healthcare are strong barriers to improving safety. For about a century of years, physicians and other healthcare personnel have been trained and licensed and often then left alone to pursue practice. Hospitals were viewed primarily as places where independent physicians could practice. Physicians, correspondingly, have viewed themselves as independent of hospital and organizational structure. The strong traditional physician values of professional autonomy and personal accountability reflect the independence engendered by this craft model. In healthcare, this model worked adequately when most care was uncomplicated.11 In today’s increasingly complex healthcare environment, though, this fragmentation of care, the same model puts patients at risk. Much of the healthcare today has gotten too complex for any one physician to be able to oversee without the assistance of a robust organizational infrastructure and a hence a shift towards a team approach to care is inevitable.

Changing physician attitudes towards healthcare organizations can be a substantial undertaking. However, it must be conceded that physicians value the health and safety of their patients the most. Hence, as in our experience, once the physicians recognize that their patients’ safety can be improved through organizational change and process, they are engaged and eager to participate in any program devised to enhance patient safety. Recognizing these long-standing cultural and professional barriers to improving patient safety is only the first step. To cross over to a culture of safety, healthcare organizations should focus on: 1) an organizational self assessment of safety, values and beliefs; 2) establishing a blame-free environment surrounding patient safety; 3) building incentives for patient safety processes; 4) never accepting that harm cannot be reduced; 5) orienting care around effective teamwork; and 6) establishing new norms for patient safety in medical training programs.

Organizational Self-Assessment

The concept of a culture of safety has been adopted from airline and other industries. A culture of safety can be divided into three domains: 1) norms and rules for dealing with risk; 2) safety attitudes and 3) the capacity to reflect on safety practices.12,13 Variation in these domains occurs not just between organizations, but also within different parts of an individual organization. Understanding these variations in culture and care-related beliefs within the organization is key to being able to successfully address reform.14 Tools to help organizations through this self-assessment processes are now being developed and tested.15

Blame-free environment

The tradition of physician training and practice enforces a culture of personal accountability that, taken to the extreme, runs counter to an effective organizational approach to patient safety. The profession demands that physicians and other personnel do not make mistakes.16 But mistakes do occur. And in the current professional culture of autonomy and litigation, mistakes are particularly personal. The sense of shame can be profound and extremely difficult for a practitioner to see beyond.17 This environment lends itself not only to underreporting of adverse events, but also to not seeing preventable adverse events altogether. When adverse events do occur, practitioners are prone to chalking them up to the inevitable risks associated with a procedure or a drug. To improve patient safety, organizations must help practitioners shed the tradition of blame and shame and to clearly value safety as a property of the system, not solely the responsibility of an individual.4,17 Furthermore, we need to help expand the vision of patient safety to those outside the medical profession. Patients and the public should recognize that patient safety is largely dependent on the design and performance of healthcare systems rather than the isolated actions or inactions of a physician.

Never accept that harm cannot be reduced

“Primum non nocere”, or “first, do no harm”, is a basic tenet of medical care. Despite this precept in healthcare, a certain risk of harm to patients is usually accepted as unavoidable. Acknowledging that an adverse event did not have to occur may be associated with substantial shame and perhaps punishment. The current environment and rising malpractice costs further encourages practitioners to see some level of harm as unavoidable. This attitude blocks our ability to move ahead with safety. Accepting harm as inevitable or irreducible can become a self-fulfilling prophecy. Safety is a system property. And systems, along with individual performance, can always
be improved.

**Aligning incentives**
The values surrounding patient safety must be aligned with appropriate incentives to promote monitoring and prevent adverse events. Leaders and administrators need to identify both the factors and the champions that can create a business case for patient safety and align incentives within their organizations. There are direct financial as well as medico-legal, ethical, and human resource- and market share-related reasons for promoting patients’ safety within organizations. Organizations aspiring to continuous improvement in patient safety can build creative and appropriate incentives for reporting adverse events and near misses. At Baylor Medical Center in Texas, for example, reporting of adverse events and near misses has increased ten fold by encouraging staff to “plant a flag” when coming across a safety “pothole in the road”. The staff is rewarded for posting these safety flags in a variety of ways, ranging from a free cookie in the cafeteria to coupons for movie tickets. The hospital also sets up competitions between departments to see who can report the most safety flags, rewarding those who win with a pizza party. Other programs for enhancing reporting include the University of Colorado’s Applied Strategies for Improving Patient Safety (ASIPS), where participating healthcare clinics were given local flexibility in how best to use incentive dollars. These types of creative incentives for improving the reporting of adverse events are critical in creating an environment where patient safety is ever present in the mind of each member of the healthcare team.

**Orienting care around effective teamwork**
Effective teamwork is critical for improving patient safety. Organizations should shift away from care based solely around individual physicians and towards care that brings together physicians, nurses, pharmacists, therapists and other providers into teams formed around the needs of patients. To be effective, healthcare teams should foster an environment of open communication and transparency. Team members must feel encouraged to both recognize and learn from mistakes.

**Training to a new norm of patient safety**
The norms of patient safety must permeate our training programs for healthcare practitioners and administrators. In order to provide a sustainable culture of patient safety, our training institutions must train physicians, nurses and other members of the healthcare team in a manner that instills this new norm. Training should first acknowledge human fallibility. Once fallibility is acknowledged, trainees can recognize that safety is a property of the system, rather than just the individual. We should train students and resident doctors to understand the role of systems and human factors in the delivery of safe patient care.

**Provide leadership**
Leaders in organizations play a critical role in improving patient safety. Leaders should be clear that patient safety is a priority objective. They should provide the resources necessary for improvements in safety including both staff and technical infrastructure, be visibly active in the patient safety improvement process — including activities within their own institution, as well as executive safety rounds — be particularly vigilant for patient safety concerns in times organizational change and construction, redefine accountability for patient safety, making it both non-punitive and everyone’s responsibility, establish an environment of team work and collaboration, and make clear assignments for and expectation of patient safety oversight, promote people who have a strong commitment to patient safety, and make improving patient safety a requirement for promotion. In some institutions this has meant creating a devoted patient safety officer and team. Ideally, safety should be a clearly recognized priority and, as such, incorporated in business plans. It should not to be abandoned or considered optional because of competing business interests.

**Proactively monitor and analyze adverse events**
Healthcare organizations should be proactive in surveying and monitoring for adverse events. Preventable adverse events and near misses can only be found if they are sought out. Adverse events often occur without being immediately visible. Decisions and processes that occur in a clinic visit may be associated with an adverse event or near miss that presents itself downstream in an emergency room, in the hospital or in patient’s home. These events are often never tracked back through the system. To facilitate a systematic accounting of adverse events and near misses, organizations should engage in at least three types of surveillance: internal surveillance, event reporting, external surveillance.

**Internal surveillance**
Internal surveillance is actively looking for adverse events and near misses within a healthcare organization. The appropriate mechanism of surveillance should be specific to the task. In some instances this may be an automated search of electronic medical records. In other instances it may involve talking directly with staff and practitioners.

Internal surveillance should be proactive. This can be accomplished in many ways. In one example at the University of Washington Medical Center, it involved the simple device of having a check box on a form to indicate the presence or absence of a variation, an adverse event, or an outcome on every anesthesia record at the Medical Center. Providers mark either a “Y” or “N” in the box, with “Y” signifying that there has been a variation or possible adverse event or outcome. The billing coordinator calls the provider if this box is not filled in, which guarantees 100% surveillance. Data from this single surveillance system are reviewed weekly by a small team and provide the basis for analysis and subsequent efforts to reduce or eliminate risk. This system has been used to “engineer out” scores of adverse events. Much of internal surveillance has been reactive and accomplished through review of the paper chart. This can be quite costly and underestimates the actual adverse event rate by about 20 to one. The recent development of electronic medi-
nal records makes internal surveillance of the record of care less costly and more efficient. As electronic medical records collect more and more comprehensive clinical data, the ability to monitor for adverse events will improve. Despite the promise of information technology to enhance internal surveillance, there is often no substitute for other methods of surveillance such as safety rounds and talking directly to patients and staff. When organization leaders are visibly engaged in internal surveillance, such as executive safety rounds with the CEO and Medical Director, it can also communicate leadership’s commitment to patient safety.

Event reporting
Event reporting involves the description of an adverse event or near miss in healthcare. Efficient and consistent systems for event reporting should be put in place. In the absence of a reporting system, few of the adverse events in healthcare are reported, largely due to fear of blame or legal recourse. Healthcare organizations should put in place processes such as anonymous reporting that help facilitate better reporting rates. Web-based event reporting holds promise as an efficient, convenient and anonymous mechanism. If there is threat of punishment or shame associated with reporting events, they are far less likely to be reported.

External surveillance
External surveillance is also important to improving patient safety. It offers a unique opportunity to evaluate risk in an organization before an adverse event occurs. At its most basic, external surveillance occurs when the media reports on an incident such as a wrong-sided surgery and an organization asks itself, “Could that happen here”? If the answer is “yes”, then it is a great opportunity to improve the system and ideally eliminate this risk. If the answer is “no” then an organization can take pride in the safe design of their system surrounding this risk. Organizations aspiring to improve patient safety can and should evaluate themselves against more recognized standards of patient safety, such as the Patient Safety Indicators (PSIs) developed by the Agency for Healthcare Research and Quality. These PSIs are a set of indicators that look at complications and adverse events following surgeries, procedures and childbirth.

External surveillance has become more systemized thought the Essential Events Policy and Reporting System put in place by the Joint Commission on Accreditation for Healthcare Organizations. In the first five years of the policy going into effect, 1,200 sentinel-event reports were submitted. This reporting system may have already had an impact on improving patient safety. For instance, when there were 11 reports of patients being harmed by the administration of high doses of potassium chloride (KCl) associated with storage of concentrated solutions on the patient wards, there was a sentinel event alert put out to organizations by the JCAHO in February of 1998. In the subsequent five years, there were only two adverse events associated with KCl with one of these being an overdose of oral KCl. This provides a growing, albeit incomplete, database that provides all organizations an opportunity to self reflect and improve on patient safety in their own institution.

The JCAHO’s process of accreditation of healthcare organizations in the United States is also changing in a way that should help facilitate the value and maintenance of patient safety. Instead of announced visits to institutions, the JCAHO will begin unannounced visits. The concern is that with announced visits, organizations may focus their patient safety efforts around the periodic JCAHO visit rather than on continually improving patient safety and the quality of care. Unannounced visits will provide a more representative picture of how safely an organization operates on a daily basis. This change is not meant to be punitive, and, in fact, is intended to level the playing field for all organizations. It is meant to direct focus away from the actual JCAHO visit and towards a state of continual safety readiness, which patients can enjoy at all times.

Reports on patient safety practices elsewhere can also help inform and prioritize safety improvement efforts. In many instances, safety priorities will be determined by the factors specific to the environment of the institution. However, healthcare organizations share many common areas where patient safety can be substantially improved. The Agency for Healthcare Research and Quality and others around the world have developed reports of best practices for patient safety. The list in sidebar 1 shows eleven practices supported by strong evidence for improving patient safety through their broad implementation. These reports can serve as valuable ongoing resource for organizations to develop their patient safety efforts.

Analyzing adverse events
Root cause analysis, a process for identifying the most basic or causal factors or factors that underlie variation in performance, including the occurrence of an adverse sentinel event has contributed substantially to enhancing patient safety. Modifications of root cause analysis can help further delineate the relative contributions of the different factors involved in an adverse event. In order to prevent a recurrence of the adverse

Sidebar 1:
1. Appropriate prophylaxis for venous thrombo-embolism in at-risk patients.
2. Appropriate use of β-blockers to prevent peri-operative morbidity and mortality.
3. Maximum sterile barrier use during central intravenous catheter placement to prevent infections.
4. Appropriate antibiotic prophylaxis to prevent peri-operative infections.
5. Having patients recall and restate information given them during the informed consent process.
6. Continuous aspiration of sub-glottic secretions to prevent ventilator-associated pneumonia.
7. Pressure ulcer prevention with bedding material that relieves pressure.
8. Central line insertion with real-time ultrasound guidance to prevent complications.
9. Warfarin for appropriate outpatient anticoagulation and prevention of complications.
10. Appropriate nutrition with particular emphasis on early enteral nutrition for critically ill and surgical patients.
event, we must understand the organizational, human and
technical factors of the system involved. The success of oth-
ners who have used this approach, such as the aviation industry,
is a testament to its value.

**Continually engineer patient safety into healthcare processes**

Health care organizations should continually engineer out adverse events. According to the Institute of Medicine, three elements are key in engineering for patient safety: design systems to prevent adverse events; make system errors visible when they occur; and design procedures that minimize harm when adverse events occur.

**Design systems to prevent adverse events**

Respect for human factors in healthcare processes is crucial to achieve this aim. People have limited capabilities, especially in very complex environments such as healthcare. In order to be safe, healthcare processes must take into account uniform human limitations such as fatigue and memory lapses. Healthcare is notoriously behind other industries in this area. Pilots, for example, have strictly limited flying hours and have standard checklists with verbal reinforcement to ensure minimal reliance on memory. Simplification and standardization are desirable design principles, since they can also contribute significantly to the prevention of adverse events.

**Design systems that make system errors visible when they occur**

Ideally systems should be designed to make system failures visible before they result in an adverse event. For example, if a dangerous drug is ordered for a patient, alerts should be generated at the point of care, in the pharmacy and in the information on the drug that is given to the patient.

**Design procedures that minimize harm when adverse events occur**

Examples of this include keeping antidotes on hand (such as digibind) and ensuring that equipment defaults to the least harmful mode in an emergency. Simulation of adverse events can also be useful. The airline industry uses this method regularly to reduce risk. The skills learned during these simulations also spill over into emergencies that are not directly related to the simulated event.

**Provide information and communication technologies to support patient safety**

Information technology will likely be crucial for improving patient safety. Although the current focus in the United States is on large integrated clinical information systems, we have already seen that use of some basic information technology substantially reduces the risks to patient safety. At Group Health Cooperative, our pharmacy system for checking drug-drug interactions and medication allergies has been in place since the 1970s and has regularly helped ensure safe medication prescribing. Computerized management of warfarin dosing is another example where stand-alone information tech-
nology applications have improved patient safety. These stand-alone applications, unfortunately, do not often work well together in the healthcare system. Their different interfaces and data requirements limit their utility and contribute, in some cases, to increased fragmentation of care.

In all probability, the integrated clinical information systems will be necessary to substantially move patient safety forward. These newer information systems have the potential to improve patient safety in three areas, as described by Bates: surveillance, prevention, and response.

**Surveillance**

Searching by hand for adverse medical events and sentinel events is inefficient and costly. Information technologies are much better suited to this task and open up new possibilities in the detection of adverse events. Several recent studies have shown the efficacy of using automated surveillance of clinical records to find and track adverse events within a healthcare institution. As more clinical data become standardized and structured within clinical information systems, the opportunities for surveillance of adverse events and near misses will markedly improve. Web-based reporting systems are also offering an opportunity for enhanced capture of adverse events and near misses.

**Prevention**

Large integrated clinical information systems require that we attempt to simplify, standardize and support care. These systems provide a uniform source for clinical information, enhance communication with providers and patients, and assist both patients and providers with healthcare decisions.

Computer physician order entry (CPOE) may be an essential component of these systems and holds great promise in reducing the number of adverse events. Studies have repeatedly identified medication prescriptions as the most common cause of preventable adverse events. Adverse events with medication occur at multiple stages, including illegible or misread handwriting, inappropriate dosing, drug-drug interactions and drug-allergy interactions. CPOE can target all of these areas and thus provide a powerful tool to assist in making care safer and more effective. To date, clinical information systems with CPOE have been evaluated mainly in a couple of academic settings with “home grown” systems. These trials of CPOE systems have shown reduced numbers of errors in prescribing, but have been found to be underpowered in determining whether this translates into the most relevant outcome of reduced adverse events. Although there is already a substantial national movement in the United States endorsing CPOE and integrated clinical information systems to improve the safety of patient care, we await larger trials in community settings to establish the effectiveness of these systems.

**Response**

When adverse events or near misses do occur, information technology can help mitigate the consequences through facilitating rapid response. Automated surveillance of electronic medical records is an area of particular promise. For example,
ware can monitor an electronic medical record for events of drug toxicity or overdose and alert providers to the need for early treatment or an antidote. If a near miss is caught early through automated surveillance, measures can be taken quickly to eliminate the risk of a future adverse event. Other information technology applications, such as Web-based event reporting and secure electronic mail, can also help facilitate quick response to adverse events and near misses.

Cautionary Notes on Information Technology and Patient Safety

Patient safety is only one incentive in implementing these large clinical information systems. Care must be taken to taken ensure that other incentives for the use of these systems do not adversely affect the goals of patient safety. Financial incentives are chief among these other influences behind clinical information systems. Clinical information systems can enhance charge capture, reduce costs of transcription and decrease redundancy in medical testing. Some of these non-safety incentives to implement information technologies in healthcare are aligned with patient safety. For example, reducing adverse events associated with improper prescribing is important both for patient safety and at reducing liability and cost. Organizations, however, need to be clear about seeing patient safety as a mission unto itself. This should drive the development of appropriate information technology, rather than allowing the development of patient safety technology to ride on the coattails of other systems designed for billing or other healthcare processes.6

Organizations also need to be vigilant for new sources of error when implementing clinical information systems. Information technology will likely improve patient safety, but will also inevitably bring about new sources of adverse events. CPOE is an excellent example of this. These systems change the process of care in a manner that bring about benefit as well as unintended harm.1, 10, 16 For instance, one of us recently reported a case of a life-threatening adverse medical event due to medications prescribed for the wrong patient from an outpatient CPOE system.57 Others have reported similar unique safety challenges with CPOE. Transitions from paper-based record systems to electronic based record systems are particularly important periods for heightened awareness of safety issues. During these times, neither record may be complete or always available. Furthermore, the technical and organizational infrastructure required for well functioning electronic medical record system can take time and resources.38 In our experience at Group Health Cooperative, around half of our new clinical information system budget was devoted to the human resources and infrastructure required for well functioning electronic medical record system can take time and resources.38

In our experience at Group Health Cooperative, around half of our new clinical information system budget was devoted to the human resources necessary to integrate the technology safely and effectively into the system and process of care.

Safety as the foundation for quality

Quality is a natural extension of patient safety and vice versa. Safety is, perhaps, the most visible element of quality. The attitudes, processes and technology that support safe patient care can and should be extended into quality initiatives.39 Woolf argues that safety is a relatively small part of quality and that devoting resources to safety may divert resources away from important quality programs.40 We believe that the processes and culture for patient safety that are built within an organization are the necessary foundation for extending an organization’s ability to address quality. Patients certainly expect that harm should not occur from care designed to help them.

Future Areas

Future work in patient safety should focus on areas such as: the hand off of patients between providers and healthcare teams, ambulatory care safety, the role of patient engagement and activation in safety, new sources of error associated with the implementation of information technologies, and developing a clear nomenclature and standards for error surveillance and reporting.41

Conclusions

We are still in the early stages of understanding and improving patient safety. Healthcare is increasingly complex, fragmented and unsafe. It is almost certainly more complex than other areas, such as aviation, which are often cited for their ability to improve safety. To tackle the challenge of patient safety, organizations should develop an integrated plan that, foremost, involves change in the paradigm of care and the culture of medicine. Leadership should play a key role in ensuring a blame-free environment where patient safety is everyone’s responsibility. Surveillance should help identify adverse and sentinel events for organizations to target for analysis and subsequent redesign. Information technologies should play an increasing role in ensuring safe patient care experiences, but must be implemented carefully and systematically into organizations. With these efforts organizations should be able to cross the quality chasm to an environment where patients at last experience safer healthcare.

Patient safety can be an energizing force for morale within healthcare. Delivering safe patient care is at the core of why most persons go into healthcare. Organizations that can help fulfill this fundamental value will see pride and cohesion among their professionals and staff.

References

10. McNutt RA, Abrams R, Arons DC. Patient safety efforts should focus on medical...
11. Merry MD. Healthcare’s need for revolutionary change. Quality Progress 2003;31-5.
21. ASIPS News. Vol 1: Department of Family Medicine, University of Colorado Health Sciences Center; 2002.