Leadership Guide
to Patient Safety

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INSTITUTE FOR HEALTHCARE IMPROVEMENT

Leadership Guide to Patient Safety

Authors:

Laura Botwinick: *Vice President, Joint Commission Resources and Co-Director, Joint Commission International Center for Patient Safety; IHI George W. Merck Fellow 2004–2005*
Maureen Bisognano: *Executive Vice President and Chief Operating Officer, IHI*
Carol Haraden, PhD: *Vice President, IHI*

"I know you didn't mean to hurt me."
– Elizabeth, eight years old, paralyzed from the waist down after a recurrence of cancer was missed
(excerpted from R. Gibson, "Wall of Silence")

"Our systems are too complex to expect merely extraordinary people to perform perfectly 100 percent of the time. We as leaders have a responsibility to put in place systems to support safe practice."
– James Conway, IHI Senior Fellow; former Executive Vice President and Chief Operating Officer, Dana-Farber Cancer Institute

Introduction

The numbers are now widely known: 44,000 to 98,000 Americans die each year as a result of medical errors. Since these staggering figures were published by the Institute of Medicine (IOM) in the 1999 report, *To Err Is Human,*[1] much pioneering and innovative work has been done to reduce adverse medical events and eliminate the harm they cause. This paper shares the experience of senior leaders who have decided to address patient safety and quality as a strategic imperative within their organizations. It presents what can be done to make the dramatic changes that are necessary to ensure that patients are not harmed by the very care systems they trust will heal them.

The Unique Role of Boards and Senior Leaders in Patient Safety

Leadership is the critical element in a successful patient safety program and is non-delegable. Only senior leaders can productively direct efforts in their health care organizations to foster the culture and commitment required to address the underlying systems causes of medical errors and harm to patients. For the purposes of this paper, senior leaders are defined as CEOs and the executives who report to them, senior clinical leaders, and Board members. The unique role of leadership is to establish the value system in the organization; set strategic goals for activities to be undertaken; align efforts within the organization to achieve those goals; provide resources for the creation, spread, and sustainability of effective systems; remove obstacles to improvements for clinicians and staff; and require adherence to known practices that will promote patient safety. When leaders begin to change their responses to mistakes and failure, asking *what happened* instead of *who made the error*, the culture within their health care institutions will begin to change.

A Personal Connection to the Issue

Although it is now widely accepted that serious medical errors and harm occur in health care organizations, many leaders hold the view that "it couldn't happen here." Organization leaders are encouraged to seek out the stories about harm to patients that has occurred in their own institutions, understand how the harm occurred, and use the stories to drive improvement. Here is one patient's story:[2]

When eight-year-old Elizabeth told her parents that her kidney cancer, which had been in remission, was back, her parents believed her. She was experiencing severe pain in her legs that only morphine could relieve. But the little girl's doctors dismissed her complaints as psychological, stemming from her fear of the cancer recurring. Though Elizabeth had been scheduled for an MRI, the test was canceled because the doctors thought it wasn't necessary… Leila [Elizabeth's mother] did everything she could not to reinforce Elizabeth's complaints about pain, believing the doctors' view that all was well and that her daughter's cancer phobia needed to be overcome, not encouraged...

Over the next three months, Elizabeth's symptoms worsened and she lost almost 20 pounds, going from 58 to 40 pounds. Her mom called the doctors about 20 more times, and they continued to assure her that her daughter's troubles were in her head…

With the instinct that only a parent has, Leila called her own mother and said, "Her soul is dying. There is no life in her eyes." She was right. No one knew — not yet — that Elizabeth's brain was swelling because a tumor had metastasized to her spine and was in her brain, pressing on it…

Later that day she had a seizure. Her doctors ordered an MRI, which proved what Elizabeth had known in her heart all along: the cancer had spread to her spine and brain. Nine months of chemotherapy and a stem cell transplant saved Elizabeth's life, but the delay in diagnosis resulted in permanent paralysis from the waist down…

Using her daughter's story as a learning opportunity for future doctors, [Elizabeth's mother] participated in a course in the medical school near where she lives. "I want to see physicians and nurses heal," she explains, and her daughter understands this, too. She recalls how Elizabeth was sitting on the front porch one day and said, "I feel sorry for those doctors. You have to know they must feel bad about what happened." Her mom goes on to say, "The doctors missed the chance to hear Elizabeth say, 'I know you didn't mean to hurt me. I forgive you.' There is so much richness in these words, but the doctors missed it. And they know deep down they screwed up, and it must be so painful."

Understanding Medical Errors

Approximately 80 percent of medical errors are system-derived.[3] Good people simply working harder will be insufficient to overcome the complexities inherent in today's systems of care to prevent errors and harm to patients. Errors will occur; the key is to design the care delivery systems so that harm does not reach the patient.

Medical errors, also called "adverse events," include missed and delayed diagnoses, mistakes during treatment, medication mistakes, delayed reporting of results, miscommunications during transfers and transitions in care, inadequate postoperative care, and mistaken identity.[4,5] Patient safety also

encompasses the concept of "reliability." Reliability in health care is defined as patients getting the intended tests, medications, information, and procedures at the appropriate time and in accordance with their values and preferences.[6] As will be discussed later in more detail, systems of care delivery must be redesigned to incorporate the characteristics of high reliability from other high-risk/high-hazard industries, such as aviation and the nuclear power field.

Many excellent resources are now available that discuss the causes of medical errors and harm, and mechanisms to address them. One type of error is an error of commission, the act of doing something incorrectly. Under normal circumstances that do not include stress and time pressures, errors of commission, such as misreading a label, occur 3 times out of 1,000. Errors of omission, on the other hand, are those in which something that should have been done was not done. Errors of omission in the absence of reminders occur 1 time in 100.[7] These are simply the facts. Human beings make errors.

Another way to understand medical errors is to consider a process with multiple steps, such as the process for fulfilling a physician's order for medication for a patient. This process has been estimated to have 40 to 60 steps. Table 1 depicts the probability of success at each step in the process. The table shows that in a 50-step process, if each of the 50 steps has a 1 in 100 chance of error (i.e., the probability of success is 0.99), then the expected rate of success for all 50 steps is 0.61. Stated another way, the process will be completed perfectly only 61 percent of the time. In reality, the rate of success for each step of the process will vary and the potential impact of a defect will vary substantially. To improve the likelihood of success, the number of steps must be decreased or the reliability of each step increased or both. System changes can increase the reliability of each step and thus increase the overall chance of success for the process and streamline it (removing wasteful or unnecessary steps).

Table 1. Probability of Performing Perfectly

Number of Steps	Probability of Success for Each Step in the Process			
	0.95	0.990	0.999	0.999999
1	0.95	0.990	0.999	0.9999
25	0.28	0.78	0.98	0.998
50	0.08	0.61	0.95	0.995
100	0.006	0.37	0.90	0.990

Medical errors are often not the result of a single individual forgetting to carry out a step in the process. Injury and death also occur because today's technology and complexity in care outdistance past practices of care delivery. Care delivery methods are simply inadequate to ensure reliability in delivery of even the best-intended care.

The Cost of Poor Quality

Improvements in patient safety represent not only a professional and moral imperative, but also a tangible impact on the financial bottom line for a health care organization. The IOM estimated that medical errors resulting in injury cost $17 to $29 billion each year, over half of which reflects health care costs.[8] The impact of medication errors on an individual health care organization was identified in a study by David Bates and his colleagues. They found that preventable adverse drug events in two teaching hospitals caused an increase in length of stay of 4.6 days, at a cost of $4,685 each. They also reported that the overall rate of adverse drug events was 6.5 per 100 admissions, of which 28 percent were judged to be preventable—almost 2 of every 100 admissions.[9]

Another example of the cost of poor quality relates to nosocomial bloodstream infections. Nosocomial bloodstream infections prolong a patient's hospitalization by a mean of 7 days. Estimates of attributable cost per bloodstream infection range between $3,700 and $29,000.[10]

Hackensack Hospital in New Jersey relates its low voluntary turnover rate of Registered Nurses (6.3 percent) to the excellent practice environment for nurses. This translates into savings of $45,000 to $68,000 in recruitment and training expenses for each nurse.[11] A low turnover rate is associated with a culture that supports patient safety, according to Linda Aiken, PhD, RN, Director of the Center for Health Outcomes and Policy Research at the University of Pennsylvania. She has completed research showing that the nursing practice environment is critical to patient safety, quality of care, and nurse retention.[12]

The Keystone ICU project, a two-year initiative partnering safety experts from Johns Hopkins University with the Michigan Health and Hospital Association and funded by the Agency for Healthcare Research and Quality, provides another example of the cost of poor quality. A 2005 article about the project states: "Representing approximately 30 percent of acute costs or $180 billion annually, intensive care is one of the largest and most expensive components of US health care. More than five million people are admitted to ICUs annually, and studies suggest that nearly every one of those patients admitted to an ICU suffers a potentially life-threatening adverse event."[13] Seventy-two hospitals participated in the Keystone project to implement five evidence-based interventions in the ICU to reduce the risk of medical errors and enhance patient safety.

Steps to Achieving Patient Safety and High Reliability

The concepts presented below are based on the experience the Institute for Healthcare Improvement (IHI) has gained through years of guiding organizations in improving patient safety. The focus of this paper is on the acute care setting; however, most of the concepts apply to other settings of care as well. It is understood that organizations will be at different stages of development, and thus will move at different paces through the improvement process. An organization with significant experience in improvement methodology and a successful portfolio of previous safety work will be able to make progress at a faster pace than an organization that has yet to build the infrastructure and commitment to safety at all levels. In addition, based on management style or organization preference, leaders may take on the activities below in Table 2 in a different order.

Table 2 provides a high-level overview of the eight steps that are recommended for leaders to follow to achieve patient safety and high reliability in their organizations. Each step and its component parts are described in detail in the sections that follow, and resources for more information are provided where available.

Table 2. Steps to Achieving Patient Safety and High Reliability

Step One:	Address Strategic Priorities, Culture, and Infrastructure
Step Two:	Engage Key Stakeholders
Step Three:	Communicate and Build Awareness
Step Four:	Establish, Oversee, and Communicate System-Level Aims
Step Five:	Track/Measure Performance Over Time, Strengthen Analysis
Step Six:	Support Staff and Patients/Families Impacted by Medical Errors
Step Seven:	Align System-Wide Activities and Incentives
Step Eight:	Redesign Systems and Improve Reliability

Step One: Address Strategic Priorities, Culture, and Infrastructure

A. Establish Patient Safety as a Strategic Priority

B. Assess Organization Culture

C. Establish a Culture That Supports Patient Safety

D. Address Organization Infrastructure

E. Learn About Patient Safety and Methods for Improvement

A. Establish Patient Safety as a Strategic Priority

Senior leaders have both the responsibility and the authority to position safety as a strategic priority in the organization. If safety is to be seen as a strategic priority for all staff, then leadership must make it a key focus of their attention. According to Jim Conway, IHI Senior Fellow and former Executive Vice President and COO of Dana-Farber Cancer Institute, "Leaders play an extraordinary role in patient safety." First and foremost, he explains, leaders must "provide focus, make patient safety not just another 'program de jour' but a priority corporate objective. You must make everyone in the institution understand that safety is part of his or her job description."[14]

Leaders must make the case for patient safety. Discussing adverse events that have occurred in the institution is one way to make the case. Leaders also can do this by highlighting the gap in the organization's performance between where it is and where it needs to be. Step Five will address this issue in more detail by providing tools to assess organization performance and measure it over time.

Many leaders believe that they are positioning safety as a top strategic priority. The following simple checklist may be helpful to leaders to assess the priority of safety on the strategic agenda:

1. *Review agendas of the last four meetings of the senior leadership team for the following:*

   • Are patient and/or staff safety issues on the agenda?

   • Where is the placement of these issues on the agenda—first, middle, last?

   • Is data from patient and staff safety indicators routinely reviewed and discussed?

   • Are safety agenda items followed by action plans with an assigned senior leader accountable for follow-up?

   • What percentage of time does the team spend on discussion of patient care issues, including safety and other operational matters?

2. *Repeat this exercise with other high-level operational meetings and with the Board minutes.*

The prominent placement of patient safety issues has both symbolic and practical value for all hospital leaders and staff. Below are several concrete steps that the CEO and leadership team can take to demonstrate that patient safety is a priority in the organization:

1. *Place safety issues prominently on senior staff and Board meeting agendas.*

2. *Spend time visiting with staff and asking about safety issues.*

3. *Assign executives to safety performance improvement teams and review outcomes regularly.*

4. *Include patient safety in staff orientation sessions or require separate patient safety orientations for staff.*

5. *Regularly schedule brief presentations from staff working on key projects relating to safety, and ask how the senior staff could be helpful in supporting this work.*

6. *When successful safety projects are presented, develop a plan to spread this work throughout the organization.*

7. *Routinely monitor the spread of important safety changes through the use of an organized spread timetable and work plan.*

8. *Connect executive performance and compensation to improvements in patient safety.*

9. *Refocus hiring and promotional practices to reflect patient safety as a priority.*

B. Assess Organization Culture

One of the early steps in the patient safety journey is to assess the current state of the organization's culture. Several tools are now available to perform an organizational assessment. An organization should use one of these tools to obtain an initial measure of the culture of safety, then obtain additional measures at six-month intervals until the measure is stable at the desired state, and then yearly thereafter. Excellent tools are available to assess and begin to change the culture in health care organizations, all of which are available on IHI.org.

(For more information on these tools, go to http://www.ihi.org/IHI/Topics/PatientSafety/)

For example, a survey for assessing patient safety culture in hospitals was released in November 2004 by the Agency for Healthcare Research and Quality (AHRQ). The AHRQ Hospital Survey on Patient Safety Culture includes guidance on sampling, setting up the survey for web-based completion, and analyzing the data. The survey is specifically designed for use in the hospital setting and was thoroughly tested for reliability prior to its release.

(For more information on the AHRQ survey, go to http://www.ihi.org/IHI/Topics/PatientSafety/ SafetyGeneral/Resources/AHRQHospitalSurveyonPatientSafetyCulture.htm)

C. Establish a Culture That Supports Patient Safety

Organizations that are in the early phases of their improvement journey must focus on establishing a culture that supports and advances patient safety. Significant barriers to a "just" culture are embedded in the traditional practice of medicine. A just culture, as defined by James Reason, is one that supports the discussion of errors so that lessons can be learned from them.[15] The culture in most health care organizations today is still defined by a tradition of seeking out, blaming, and punishing the staff member(s) involved in the event, autonomy among clinicians, lack of teamwork, lack of transparency about medical errors, and poor communication—factors contributing to an environment that puts patients in harm's way. Leaders can facilitate a culture of trust that encourages communication across clinical disciplines about such issues as the causes of medical errors and non-punitive approaches to reporting.

A just culture must be experienced by staff in order to sustain self-disclosure of adverse events. One effective way to reinforce this supportive environment is to reward middle managers for increasing the filing of occurrence reports (incident reports). The just culture can also be reinforced by sharing the analysis of the reports with staff. A just culture also holds managers and staff accountable for establishing reliable processes and adhering to them. The Massachusetts Coalition for the Prevention of Medical Errors is currently undertaking excellent work to further explore this issue of accountability to assist health care organizations in making these difficult distinctions. Additional discussion of accountability appears in Step 5.

(For more information about the Coalition's work on accountability, go to http://www.macoalition.org/ Initiatives/Accountability.shtml)

An excellent tool is available to help hospital executives lead their own institutions on the journey toward a culture of safety. The tool is called "Strategies for Leadership: Hospital Executives and Their Role in Patient Safety" and was developed with the support of several organizations, including the Massachusetts Coalition for the Prevention of Medical Errors, the Massachusetts Hospital Association, and the American Hospital Association. The tool reflects the insights and lessons Jim Conway and his colleagues at Dana-Farber Cancer Institute learned during their intensive years of focus on enhancing safety after the death of Betsy Lehman from a medical error. It covers topics such as the design of safe medication systems, interdisciplinary practice, and making patients and families true partners in care design and delivery.

(For more information on the tool, go to http://www.ihi.org/IHI/Topics/PatientSafety/Medication Systems/Tools/StrategiesforLeadershipHospitalExecutivesandTheirRoleinPatientSafety.htm)

A wonderful tool for managers who are learning to make decisions about accountability of staff with regard to an error or harmful event is the Incident Decision Tree.

(For more information about this tool, go to http://www.npsa.nhs.uk/health/resources/incident_decision_tree)

D. Address Organization Infrastructure

The Patient Safety Officer (PSO) is the senior leaders' partner in promoting patient safety. The PSO should report to the CEO, COO, Chief Medical Officer, or another C-level executive. The Board should be actively engaged in the patient safety effort and regularly track progress in meeting patient safety goals and closing demonstrated safety gaps. The PSO should have the authority to work across all areas of the organization and carry the full support of the CEO in matters relating to patient safety. Giving the PSO a prominent role in safety efforts, one with a wide scope of control to assess and improve safety across the organization, and establishing an effective reporting relationship demonstrates the primacy and importance of safety within the organization.

Senior leaders should visibly demonstrate support for the PSO, and remove obstacles for the PSO and the organization's improvement teams. Leaders should align and, if possible, integrate risk management, quality assurance, quality improvement, credentialing, and other focused resources with the shared strategic aim of patient safety. It is particularly important to create an environment in which staff trained in quality improvement work side-by-side with staff responsible for safety activities, since improvement expertise will be needed to address gaps in patient safety proactively. In addition, measurement expertise should be readily available to both safety and improvement leadership and teams since it is difficult to gauge the impact of safety and improvement efforts without well-designed measures that are tracked over time.

The PSO is someone who understands patient safety and has knowledge of effective tools and improvement methodologies. The PSO imports new ideas and best practices and oversees their local application. He or she is an emissary to teach, mentor, and reinforce good practices within the organization. The PSO also considers and recommends organizational policies to advance patient safety.

(For more information about designating a Patient Safety Officer, go to http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Changes/IndividualChanges/Designate%20a%20Patient%20Safety%20Officer)

It is also important to have an active Patient Safety Committee that meets regularly. An effective committee is a comprehensive leadership-level action committee that reviews all safety issues across the organization. When all safety issues are reviewed by a single body, that body can more readily recognize patterns and trends and can better assign priorities and resources.

The senior leader assigns members of the senior staff, including the CFO, responsibility for addressing key quality and safety issues. In the process of overseeing those improvements, they will work with front-line staff and gain an understanding of and personal commitment to quality. As a result, senior staff will be more willing to remove barriers to patient safety, support investments in the training and development of staff relative to patient safety, and support the hiring of people with expertise in improving health care quality and safety.

Many organizations have established Safety Action Teams. These are small cross-functional groups of people within units who meet periodically (perhaps monthly) to discuss safety issues. These teams can discuss information from the safety reporting system to identify solutions on the front line. They can also provide direct feedback to senior leaders about the impact of their changes.[16]

E. Learn About Patient Safety and Methods for Improvement

An important step in the senior leader's personal patient safety journey is to become educated on the science of patient safety and the process for quality improvement. To learn about safety, senior leaders can begin by reading through this paper carefully and exploring the key documents we cite and link to.

With respect to improvement methodology, IHI utilizes a model called the Model for Improvement, developed by Associates in Process Improvement. The model is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. The Model for Improvement provides the ability to test many ideas from front-line staff, the flexibility to change course when an idea does not work or needs refinement, and guidance to obtain buy-in by many key stakeholders prior to broad implementation. This model has been used successfully by hundreds of health care organizations in many countries to improve a variety of different health care processes and outcomes. The model has two parts:

- Three fundamental questions, which can be addressed in any order:

  - What are we trying to accomplish?

  - How will we know a change is an improvement?

  - What changes can we make that will result in improvement?

- The Plan-Do-Study-Act (PDSA) cycle to test and implement changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement.

(For more information on the Model for Improvement, go to http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/HowToImprove/)

Step Two: Engage Key Stakeholders

A. Engage the Board of Trustees

B. Engage Physicians

C. Engage Staff

D. Engage Patients and Families

A. Engage the Board of Trustees

The Board is a critical driver in moving the organization to higher levels of safety and effectiveness. Increasingly, the role of the governing body in quality and patient safety oversight is being viewed as a fiduciary responsibility at least equal to its financial oversight role, such as in the context of system-wide improvement initiatives like the IHI's 100,000 Lives Campaign.[17]

(For more information on IHI's 100,000 Lives Campaign, go to: http://www.ihi.org/IHI/Programs/Campaign/)

The Board's work relating to patient safety takes many forms: setting goals for organizational improvement; building the business case for patient safety in which patient safety goals are integrated with the organization's strategic goals and business plan; reviewing data related to key organizational metrics; reviewing adverse event reports and root cause analyses; providing resources for improved infrastructure, education, and staffing; and holding management accountable for addressing patient safety issues.

One way to capture the Board's attention is to feature cases from your own hospital. Jim Conway, IHI Senior Fellow and former Executive Vice President and COO of the Dana-Farber Cancer Institute, said, "I'm a big believer in run charts, Pareto charts, and statistics, but there is nothing that engages a Board in safety issues as effectively as a patient's story."[18]

If the trustees are not yet engaged in the patient safety journey, here are a few steps leaders can take:

1. *Educate the Board to their responsibility for the quality of care provided in the hospital.*

2. *Structure the Board agenda so that quality and safety are given the same amount of attention as financial issues.*

3. *Engage the Board in discussions regarding the patient safety measures to be included on the Balanced Scorecard or Dashboard reviewed at each meeting.*

4. *Discuss the organization's performance in relation to national best practices.*

    5. Provide education to Board members to increase their literacy relating to quality of care and patient safety.

    6. Strengthen aspects of the organization's strategic plan that relate to quality of care and patient safety.

The Leapfrog Group Hospital Quality and Safety Survey enables hospitals to voluntarily self-report their status relative to implementing the 30 safe practices recommended in the National Quality Forum "Safer Practices for Better Healthcare" consensus report. Data from the annual survey is then shared with consumers and purchasers of health care to help them make informed health care choices and promote transparency within health care.

(For more information on The Leapfrog Group Hospital Quality and Safety Survey, go to http://www.leapfroggroup.org/for_hospitals)

In 2004, the National Quality Forum convened a meeting to identify key aspects of the hospital trustee role in monitoring and supporting quality improvement and safety initiatives. The recommendations from this meeting were published in the report "Hospital Governing Boards and Quality of Care: A Call to Responsibility" (available online at http://www.qualityforum.org/txcalltoresponsibilityFINAL-WEB02-15-05.pdf).

(For more information about building the business case for patient safety, go to http://www.ihi.org/IHI/Topics/LeadingSystemImprovement/Leadership/Tools/BuildingaBusinessCaseforPatientSafety.htm)

(For more information on the Board's role in ensuring quality of care, go to http://www.ihi.org/IHI/Topics/LeadingSystemImprovement/Leadership/Literature/HospitalGoverningBoardsandQualityofCareACalltoResponsibility.htm)

(For more information on Board-building tools, including sample governance policies, trustee assessment tools, and sample measurement dashboards, go to http://www.greatboards.org/)

B. Engage Physicians

Nurses, pharmacists, and allied health professionals play a critical role in patient safety; however, getting physicians involved is often particularly challenging. Physicians are highly trained individuals; they have been trained to act independently, to treat each patient as unique, and to tailor their decisions accordingly. Consequently, physicians often resist standardization and opt-out protocols.[19] The culture in health care has historically been one in which physicians practice with autonomy. A safe environment requires teamwork and good communication, two skills that traditionally have not been emphasized in physicians' professional training.

To begin engaging physicians in safety efforts, senior leaders should focus first on improvement projects that are important to the medical staff. Rather than focusing on compelling physicians to engage in the improvement work, identify and support "physician champions," especially those who have knowledge of and experience with improvement methodologies. Assure physicians that they will have the option to opt out of predefined protocols if they explain why the patient's condition requires an exemption. Assign department chiefs with responsibility for key department-level and system-level quality performance measures. McLeod Regional Health Center in Florence, South Carolina, was successful in engaging its medical staff by implementing initiatives that are physician-led, and changes that are evidence-based and data-driven. According to Donna Isgett, Vice President for Clinical Effectiveness at McLeod Health in Florence, South Carolina, "Over half of our medical staff has been actively engaged in the performance improvement. They've led it from the actual knowledge base side, we've been the support system to help them get there, and our CEO and some of those physicians have had that vision of where we need to go."

(For more information on engaging physicians in quality and safety, go to: http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Tools/PhysicianEngagementinQualityandSafety.htm)

C. Engage Staff

Improving quality and safety is everyone's job, including clinicians, front-line staff, managers, and administrators. Senior leaders play a critical role in promoting and supporting teamwork and collaboration. Good teamwork enhances coordination of care. An excellent discussion of mechanisms to engage staff in promoting quality and safety is presented in the book, *Achieving Safe and Reliable Healthcare: Strategies and Solutions.*[20] Studies have shown that organizations that foster teamwork by using the techniques described in this book can help improve the safety and care of patients.[21] Importantly, organizations with environments that foster teamwork and good communication also have higher rates of staff retention.

St. John's Mercy Medical Center in St. Louis, Missouri, created an institution-wide policy regarding non-punitive reporting, as well as a brochure entitled "Living a Culture of Patient Safety" that was developed by its Culture of Safety Subcommittee, signed by the medical center president, and mailed to all co-worker homes. The brochure reinforces the non-punitive reporting policy and encourages all co-workers to report errors.

(For more information on the brochure, go to http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/LivingaCultureofPatientSafety.htm)

Several excellent resources are being used successfully at staff orientation and education sessions to generate discussion about safety issues:

  • A video depicting the death of 18-month-old Josie King, as told by her mother Sorrell King,

which can be ordered through the Texas Medical Institute of Technology at
http://www.safetyleaders.org/content_page2.jsp?ID=1580.

- A three-video series called "First, Do No Harm," which portrays a composite of three cases and is available through the Partnership for Patient Safety at http://fdnh.com/interactive_videos.asp.

- Rosemary Gibson's book, *Wall of Silence*,[22] includes many individual stories that may be used as sources for discussion.

D. Engage Patients and Families

Patients and their families are a critical part of the care team and they play a pivotal role in the prevention of medical errors. To be effective partners in their own care, patients need better, sometimes non-traditional, access to information and health care providers. Patients and their family members should be invited to collaborate with care providers in making clinical decisions. Patient-centered care puts responsibility for important aspects of self-care and monitoring in patients' hands — along with the tools and support they need to carry out that responsibility.

IHI offers the following "Reflections of Patient and Family Voices," first presented at the IHI National Forum in December 2005. Consider these reflections as a challenge to organizations to improve patient care:

- To be listened to, taken seriously, and respected as a care partner
  - To have my family/caregiver treated the same way
  - To participate in decision making at the level I choose

- To always be told the truth
  - To have things explained to me fully and clearly
  - To receive an explanation and apology if things go wrong

- To have information communicated to the entire care team
  - To have my care timely and impeccably documented
  - To have these records made available to me if requested

- To have coordination among all members of the health care team across settings

- To be supported emotionally as well as physically

- To receive high-quality, safe care

(For more information, see "Partnering with Patients and Families to Design a Patient- and Family-Centered Health Care System: A Roadmap for the Future. A Work in Progress." available at http://www.ihi.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral/Literature/PartneringwithPatientsandFamilies.htm)

Issues related to health literacy and cultural and ethnic disparities are important aspects of patient-centered care. Effective communication and demonstrated understanding between patient and caregiver are both crucial for delivering high-quality care; failure to establish both contributes to poor outcomes. Furthermore, nearly all patients struggle with "health literacy," regardless of their ability to read and write. The complexity of health care, in general, and the reliance on using medical jargon and terminology create problems for *all* patients when trying to understand care instructions.

With respect to health literacy, it is important to ensure that patients understand care instructions, medications, and treatment regimens or adverse events are likely to occur. Similarly, an appreciation for each patient's cultural and ethnic identity is an important factor in ensuring safe and reliable care.

The *Joint Commission 2006 Requirements Related to the Provision of Culturally and Linguistically Appropriate Health Care* are specific about the responsibility of caregivers to communicate with each patient and help him or her understand medical information and instructions based on individual needs and abilities.

Tools such as "Teach Back" and "Ask Me 3" are effective mechanisms for improving patient-caregiver communication and patient understanding. With the "Teach Back" concept, the caregiver communicates care instructions to the patient who, in turn, "teaches back" this information. Particularly important elements for "Teach Back" are self-care on return home, how/who to contact for help, and medication uses and doses. "Ask Me 3" uses three simple questions that cover the three crucial elements of understanding care: 1) What is my main problem? (diagnosis); 2) What do I need to do? (treatment); and 3) Why is it important for me to do this? (context). The idea is that the caregiver communicates with the patient based on the anticipation that these three questions will be asked, without the patient actually having to ask them.

(For more information on health literacy, see the US Department of Health and Human Services "Quick Guide to Health Literacy" available at http://www.health.gov/communication/literacy/quickguide/healthinfo.htm

and Pfizer Clear Health Communication at http://www.pfizerhealthliteracy.com/

and http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Literature/HealthandLiteracyWorkingTogether.htm)

(For the forthcoming public policy white paper on health literacy to be published by the Joint Commission in Fall 2006, go to http://www.jointcommission.org/PublicPolicy/health_literacy.htm)

(For more information on cultural and ethnic disparities, go to http://www.ihi.org/IHI/Topics/ Improvement/ImprovementMethods/Resources/CompendiumofCulturalCompetenceInitiatives.htm and http://www.jointcommission.org/HLC/)

Step Three: Communicate and Build Awareness

A. Begin Patient Safety Leadership WalkRounds™

B. Implement Safety Briefings

C. Improve Communication Using SBAR

D. Implement Crew Resource Management Strategies

A. Begin Patient Safety Leadership WalkRounds™

There is perhaps no other action a senior leader can take that carries as much symbolism as *regularly spending time with staff talking about the safety issues* that concern them—and then following up to address those issues of concern. For organizations at any stage of development, senior leaders are encouraged to use weekly Patient Safety Leadership WalkRounds™ to demonstrate their organization's commitment to building a culture of safety. WalkRounds™ are conducted in patient care departments (such as the emergency department, operating rooms, and radiology), nursing units, the pharmacy, and laboratories. They provide an informal method for leaders to talk with front-line staff about safety issues in the organization and show their support for staff-reported errors. Leaders who focus solely on safety during WalkRounds™ are more successful at creating a culture of safety than those who use them as an opportunity to discuss a variety of topics such as budgets and patient satisfaction.

(The key elements for successful implementation of WalkRounds™, sample formats, and questions to ask staff are available on IHI's website at http://www.ihi.org/IHI/Topics/PatientSafety/ SafetyGeneral/Tools/Patient+Safety+Leadership+WalkRounds™+%28IHI+Tool%29.htm)

B. Implement Safety Briefings

Safety Briefings are another way that health care organizations help increase staff awareness of patient safety issues, create an environment in which staff share information without fear of reprisal, and integrate the reporting of medication safety issues into daily work. Over time, Safety Briefings help organizations create a culture of safety, reduce the risk of medication errors, and improve quality of care. The senior leader does not participate in all of these briefings, but does empower the

managers and other staff to conduct them. Many organizations that have conducted WalkRounds™ in conjunction with Safety Briefings have achieved greater success in changing the culture than organizations that use either tool alone.

Safety Briefings are used in hospital inpatient units, other hospital departments such as pharmacies and post-anesthesia care units, and other health care settings such as home health care and long-term care facilities. They can be used for review of any safety-related topic, including unsafe conditions for medication use, falls, and devices or equipment. Safety Briefings can also be used prior to procedures to ensure that all the correct elements (equipment, staff, patient, etc.) are in place.

(A Safety Briefing tool, including step-by-step instructions, a data collection form, and a pre- and post-survey to evaluate the effectiveness of the tool, is available on IHI's website at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Safety+Briefings+%28IHI+Tool%29.htm)

C. Improve Communication Using SBAR

SBAR is a communication tool used to standardize discussions among caregivers to ensure that critical information about a patient's status is communicated effectively. An acronym for *Situation-Background-Assessment-Recommendation*, SBAR is a mechanism for framing any conversation, especially critical ones, requiring a clinician's immediate attention and action.[23] Staff and physicians should undergo training on how to use SBAR to maximize its benefit. Below is an example demonstrating how this framework would be used in the health care setting:

Situation	"I'm calling about Mr. Smith, who is short of breath."
Background	"He's a patient with chronic lung disease, his condition has been deteriorating, and he's now acutely worse."
Assessment	"He has decreased breath sounds on the right side. I think he probably has a collapsed a lung."
Recommendation	"I think he probably needs a chest tube. I need you to see him now."

(For more information on the SBAR technique, go to http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.htm)

D. Implement Crew Resource Management Strategies

Another strategy for improving communication is implementation of crew resource management (CRM) techniques used in the aviation industry. CRM is a communication methodology based on team-centered decision making systems. Elements of crew resource management can be incorporated into the training and practice of health care professionals.[24] Effective communication must be considered a necessary skill, and collaboration a conscious, learned behavior.

A crew resource management approach enhances the usual day-to-day work relationships in that it is a structured approach to support staff working in today's complex health care environment, where talented people assemble to accomplish a task but may not come together exactly the same way again. Like a crew in an airplane cockpit, roles, responsibilities, and protocols are systematized and not dependent on the individual serving in that role.

Step Four: Establish, Oversee, and Communicate System-Level Aims

A. Establish Aims Beyond Benchmarks

B. Oversee and Communicate System-Level Aims

A. Establish Aims Beyond Benchmarks

As noted earlier, a key role of the senior leader is to establish quality and safety goals for the organization. Paul O'Neill, former Secretary of the Treasury and co-founder of the Pittsburgh Regional Health Initiative (PRHI), has encouraged leaders not to focus on benchmarks for quality and safety but instead on performing at the highest levels possible. This philosophy is embedded in the PRHI statement of purpose, which commits to "perfecting health care delivery" and to improving "American health care in ways formerly thought unachievable." Leaders must designate responsibility within the organization for learning what is possible and then establish aims that challenge the staff to meet these levels of performance.

An example of how this philosophy translates into practice relates to ventilator-associated pneumonia (VAP). VAP occurs in up to 15 percent of patients receiving mechanical ventilation.[25] IHI developed the Ventilator Bundle—several evidence-based practices that, when implemented together for all patients on mechanical ventilation, result in dramatic reductions in the incidence of VAP. Preventing in-hospital deaths from VAP is one intervention in IHI's 100,000 Lives Campaign that was launched in December 2004. Of the more than 3,000 hospitals that have enrolled in the Campaign, about 67 percent are implementing the Ventilator Bundle to reduce VAP. In June 2006 at IHI's 2nd Annual International Summit on Redesigning Hospital Care, Don Berwick, President

and CEO of IHI, reported that at least 26 of these hospitals had achieved zero VAPs for one year.[26] Now that this knowledge exists, every leader can set the goal for their organizations to reduce rates of VAP to near zero.

(For more information on the Ventilator Bundle, including the Campaign How-to Guide for Preventing VAP, go to http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Changes/ ImplementtheVentilatorBundle.htm)

B. Oversee and Communicate System-Level Aims

Several tools for measuring adverse events are available to advance the effort to create a safer health care organization. These tools, described in detail in Step Five, enable leaders to measure and track system performance and to establish, oversee, and communicate *system-level* aims for improvement. Leaders can use these tools to establish solid measures of system-level performance that can be tracked monthly (if not more frequently), establish aims for breakthrough improvement of those measures, and establish oversight of those aims at the highest levels of governance and leadership.

(For more information on the role of leaders and setting system-level aims, see IHI's white paper, "Seven Leadership Leverage Points for Organization-Level Improvement in Health Care," available at http://www.ihi.org/IHI/Results/WhitePapers/SevenLeadershipLeveragePointsWhitePaper.htm)

Step Five: Track/Measure Performance Over Time, Strengthen Analysis

A. Measure Harm Over Time as a System-Level Measure

B. Improve Analysis of Adverse Events

C. Strengthen Incident Reporting Mechanisms

A. Measure Harm Over Time as a System-Level Measure

1. Hospital Mortality Review

Move Your Dot™ is an effort to help hospitals know more about their organizational performance as it relates to mortality. Sir Brian Jarman, MD, Senior Fellow at IHI and Emeritus Professor of Primary Health Care at Imperial College School of Medicine (London, UK), has developed a statistical methodology to standardize hospital mortality rates in order to compare them fairly.

IHI provides interested US hospitals and hospital systems with information that helps them analyze their mortality rate—view their "dot" on a scatterplot of mortality rates for US hospitals—and understand the factors that contribute to it. This analysis can lead to targeted quality improvement projects that can "move their dot"—that is, reduce hospital deaths.

(For more information on Move Your Dot, see IHI's two white papers, "Move Your Dot™: Measuring, Evaluating, and Reducing Hospital Mortality Rates (Part 1)" available at http://www.ihi.org/IHI/Results/WhitePapers/MoveYourDotMeasuringEvaluatingandReducingHospitalMortalityRates.htm and "Reducing Hospital Mortality Rates (Part 2)" available at http://www.ihi.org/IHI/Results/WhitePapers/ReducingHospitalMortalityRatesPart2.htm)

2. Global Trigger Tool

Identifying "triggers" of adverse events during a manual chart review has been used extensively to measure the overall level of harm in a health care organization. The IHI developed the Global Trigger Tool for Measuring Adverse Events, intended to be used to identify all categories of adverse events including, but not limited to, those related to medications.

Adverse drug events present the single greatest risk of harm to patients in hospitals. Traditional efforts to detect adverse drug events have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients.[27] Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

The Global Trigger Tool for Measuring Adverse Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible medical errors. This tool includes a list of known adverse event triggers and instructions for measuring the number and degree of harmful events. The tool provides instructions and forms for collecting the data needed to measure Adverse Events per 1,000 Patient Days and Percent of Admissions with an Adverse Event.

(For more information on the Global Trigger Tool, go to http://www.ihi.org/IHI/Topics/Patient Safety/SafetyGeneral/Tools/GlobalTriggerToolforMeasuringAEs.htm)

3. Additional Tools Related to Medication Safety

The Institute for Safe Medication Practices (ISMP) "Pathways for Medication Safety: Leading a Strategic Planning Effort" tool (available at http://www.ismp.org/PDF/PathwaySection1.pdf) can assist senior leaders in assessing the current status of medication safety in their organizations and to develop a strategic plan for moving forward. The "2004 ISMP Medication Safety Self-Assessment for Hospitals" (available at http://www.ismp.org/selfassessments/Hospital/2004Hospsm.pdf) examines key elements in the hospital that influence safe medication use. The key elements in the self-assessment tool include patient information, drug information (including communication, labeling, storage and distribution, and standardization), medication devices, environmental factors, education (staff and patient), quality processes, and risk management.

(For comprehensive information and resources for addressing medication administration errors, go to http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/)

B. Improve Analysis of Adverse Events

Assessing what went wrong when an adverse event occurs is a routine part of practice in health care organizations today. The key is to understand the underlying system properties that led to the error, and then to redesign the system so the error cannot happen again. Three tools can assist organizations in strengthening this important analysis and learning function. Knowing how to use these tools is a key staff competency.

1. Root Cause Analysis (RCA)

A critical component of establishing an environment that supports patient safety is to routinely conduct a root cause analysis (RCA) of adverse events to answer three questions: *What happened? Why? What can be done to prevent it in the future?* RCA assists in identifying systems problems that contribute to the adverse event. The following tools for conducting a root cause analysis are available on the IHI and Joint Commission websites:

- Systems Analysis of Clinical Incidents: The London Protocol (available at http://www.ihi.org/ IHI/Topics/PatientSafety/SafetyGeneral/Tools/SystemsAnalysisofClinicalIncidentsTheLondon Protocol.htm)

- A Framework for Conducting a Root Cause Analysis (available at http://www.jointcommission .org/NR/rdonlyres/C8CE68F6-85D7-4EA4-B3E0-895FC1075EE6/0/rcawordframework.doc)

- Tool to Assist Organizations in the Completion of the Framework for Conducting a Root Cause Analysis (available at http://www.jointcommission.org/NR/rdonlyres/60BC7080-0142-4DF4-99D8-2DA64A9D196E/0/rca_assisttool.doc)

2. Failure Modes and Effects Analysis (FMEA)

One of the hallmarks of a safe organization is that it consistently and routinely monitors its own environment to assess what could go wrong. Indeed, a safe organization is characterized by a preoccupation with failure, great systems to identify failures and potential weaknesses, and the ability to address them. Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change. FMEA includes review of the following:

- Steps in the process

- Failure modes (What could go wrong?)

- Failure causes (Why would the failure happen?)

- Failure effects (What would be the consequences of each failure?)

Organizations use the FMEA Tool to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting after failures have occurred. The FMEA Tool is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

(For more information on the Interactive FMEA Tool, go to http://www.ihi.org/IHI/Workspace/ Tools/FMEA/)

3. Agency for Healthcare Research and Quality Patient Safety Indicators

The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) help hospitals identify potential in-hospital complications and adverse events following surgeries,

procedures, and childbirth. The PSIs were developed after a comprehensive literature review, analysis of ICD-9-CM codes, review by a clinician panel, implementation of risk adjustment, and empirical analyses. AHRQ provides a free PSI software tool that uses available hospital inpatient administrative data to identify potential adverse events that might need further study.

(For more information on the PSIs, go to http://www.qualityindicators.ahrq.gov/psi_overview.htm)

C. Strengthen Incident Reporting Mechanisms

An effective reporting system should have leadership support and be easy to access. Often referred to as incident reports, these descriptions of harm to patients and "near misses" are critical to ongoing learning about how to prevent errors within the institution. Julianne Morath, RN, MS, Chief Operating Officer for Children's Hospitals and Clinics of Minnesota, encourages the use of a new nomenclature for these reports—"safety learning reports." Action must be taken as a result of the reports, and feedback must be given to all employees about the actions taken. Information supplied to a reporting system should be aggregated so that trends can be identified.[28] Tools such as the RCA and FMEA (see above) can be used to further analyze the issues identified.

The importance of including near misses in the incident reporting systems cannot be overemphasized. Excellent information can be learned from analysis of near misses. Often, employees are more willing to report near misses, so safety programs that incorporate this component will make greater strides.

Assigning appropriate accountability for errors is another important aspect of an effective incident reporting system. In the book, *Managing the Risks of Organizational Accidents*, author James Reason provides a decision tree for determining culpability for unsafe acts.[29] This decision tree is particularly helpful when working toward a non-punitive approach in your organization. Allan Frankel, MD, Director of Patient Safety, Partners Healthcare System in Boston, Massachusetts, has adapted the decision tree specifically for adverse drug events.

(For more information on the decision tree, go to http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Decision+Tree+for+Unsafe+Acts+Culpability.htm)

(For more information on defining accountability in patient safety, go to http://www.macoalition.org/Initiatives/Accountability.shtml)

Step Six: Support Staff and Patients/Families Impacted by Medical Errors and Harm

A. Provide Support to Staff and Patients or Families Impacted by Medical Errors and Harm

B. Ensure the Safety of Staff

A. Provide Support to Staff and Patients or Families Involved in Errors and Harm

When a complication due to a medical error harms a patient, the emotional toll can be extreme for the patient, the family, and the caregiver. A health care organization with a strong patient safety program will have mechanisms to provide support to patients as well as to physicians and staff involved in the medical error. Appropriate disclosure of the event and an apology are increasingly being recognized as an important part of the care of a patient who has been harmed by error, essential to the healing process. There is also evidence that patients and families are less likely to take legal action if they are provided with information about what happened to them or their loved ones, along with an appropriate apology.[30]

(For more information on how to respond to adverse events, see "When Things Go Wrong: Responding to Adverse Events," a consensus statement of the Harvard Hospitals, available at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Literature/WhenThingsGoWrong RespondingtoAdverseEvents.htm)

In addition, a valuable resource for supporting patients who have been harmed and caregivers involved in the event is the Massachusetts-based Medically Induced Trauma Support Services, an organization established as a result of a serious medical error that impacted the life of a woman and her anesthesiologist. (For more information, see www.mitss.org)

B. Ensure the Safety of Staff

Former CEO Paul O'Neill began his now famous journey at Alcoa by requiring that all employee injuries be reported to him within 24 hours.[31] This commitment to having effectively functioning systems led to the production of high-quality products and increased profits. O'Neill demonstrated that a leader's commitment to employee safety results in a better-functioning organization overall. Similarly, an important element of a hospital's patient safety program is a commitment on the part of the senior leaders to the safety of staff. This includes provision of personal protective gear, needle-less systems, and support devices such as wheelchairs, carts, beds, bedrails, and alarm systems. When these issues are not addressed, time is wasted, trust erodes, and staff members become demoralized. Staff will not believe a leader's commitment to patient safety if they are working in conditions of unmitigated risk. The creation of safe environments for staff should be considered essential to creating safe environments for patients.

Step Seven: Align System-Wide Activities and Incentives

A. Align System Measures, Strategy, and Projects

B. Align Incentives

A. Align System Measures, Strategy, and Projects

Leadership should create alignment between organizational strategy, measures, and improvement projects. Leaders should think about "Moving the Big Dots," that is, starting with the system-wide aims identified in Step Four, and developing a plan for how to achieve the aim. Leaders should unify Quality Improvement Plans, Strategic Plans, and Financial Plans within the organization. Leaders should ensure that the daily work of employees is organized to support deployment of strategies and improvement projects chosen because of their direct impact on system-level measures or direct support of strategic objectives. Leaders should then implement, monitor, and revise the strategy as needed if the desired changes are not occurring.

Consider aligning the organization's strategy, measures, and improvement projects with major national initiatives that are launched by leading organizations involved with quality and patient safety. One major initiative is IHI's 100,000 Lives Campaign, which identified six interventions that will save lives. Another major national initiative is the Joint Commission's National Patient Safety Goals, issued each year, that are applicable to hospitals and other health care settings.

(For more information on Joint Commission's National Patient Safety Goals, go to http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/)

(For information on the IHI's 100,000 Lives Campaign, go to http://www.ihi.org/IHI/Programs/Campaign/)

B. Align Incentives

Just as safety and quality should be incorporated into the organization's strategic plan, they should also be incorporated into the compensation plan for organization leaders and employees. At Sentara Healthcare, a not-for-profit provider in southeastern Virginia and northeastern North Carolina, 25 percent of a senior leader's compensation is linked to meeting goals related to clinical performance improvement. Sentara also has an employee incentive plan that adds an additional 5 percent of gross wages if the organization meets two pre-established quality and safety goals.[32]

Step Eight: Redesign Systems and Improve Reliability

A. Redesign Care Processes to Increase Reliability

B. Implement Rapid Response Teams

C. Introduce Simulation

D. Implement a Computerized Physician Order Entry System

A. Redesign Care Processes to Increase Reliability

This final step describes the concept of reliability and then presents three effective mechanisms for redesigning systems and improving reliability and patient safety.

Work process redesign is a powerful component of the effort to improve patient safety. Its goal is to deploy known science in a reliable way. Important lessons are being learned from high-reliability organizations in other industries such as aviation and nuclear power. Karl Weick and Kathleen Sutcliffe's work provides an important analysis of the process for improving reliability in complex organizations.[33] In addition, new concepts in work redesign have been introduced by the philosophy of "lean thinking" that was implemented first by Toyota and translated for American industry by Jim Womack, Chairman and CEO of the Lean Enterprise Institute, and colleagues while Womack was at the Massachusetts Institute of Technology (MIT).[34]

(For more information about the application of Toyota Production System principles to a health care setting, go to http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Literature/LearningtoleadatToyota.htm)

(For more information about lean thinking in health care, go to http://www.ihi.org/IHI/Results/WhitePapers/GoingLeaninHealthCare.htm)

Efforts are underway in hospitals around the world to design care processes that increase standardization, include redundancies, and take advantage of human factors engineering (i.e., understanding the interactions of people and equipment), all key principles in creating safer systems. Carol Haraden and Pat Rutherford of IHI describe the redesign effort in the following way:[35]

- Make the right thing the easy thing

- Standardize to reduce variation

- Enhance teamwork

- Trust staff

- Design tasks around people's strengths and professional skills

Reliability in engineering relates to the capability of parts, components, equipment, products, and systems to perform their required functions for desired periods of time without failure, in specified environments. Reliability in health care is defined as patients getting the intended tests, medications, information, and procedures at the appropriate time and in accordance with their values and preferences.

Reliability is measured in "defects" per ten (10^{-1}), per one hundred (10^{-2}), per one thousand (10^{-3}), etc. Almost all studies that investigate the rate of failure to apply the appropriate clinical evidence in "production" conclude that our current health care system is delivering care at the level of 10^{-1}.[36] For example, an organization that delivers beta-blockers to acute myocardial infarction patients on arrival at the hospital 85 percent of the time is functioning at 10^{-1}. An organization that carries out that function 65 percent of the time is in a "chaotic" state. There is no standardized system of care; instead, there is significant variation in how things get done. The following demonstrates how reliability is measured:[37]

- "Chaotic" process: Failure in greater than 20 percent of opportunities

- 10^{-1}: 1 or 2 failures out of 10 opportunities (80 or 90 percent success)

- 10^{-2}: 5 failures or less out of 100 opportunities

- 10^{-3}: 5 failures or less out of 1,000 opportunities

- 10^{-4}: 5 failures or less out of 10,000 opportunities

Organizations that wish to move from a "chaotic" state to 10^{-1} must commit to standardizing protocols for the usual circumstances for *entire populations*, and must commit to evidence-based medicine or expert consensus-based practices in the absence of scientific evidence. Organizations that wish to move from 10^{-1} to 10^{-2} must implement protocols and contingencies for exceptions, place a strong emphasis on teams and interdependence, build in decision aids and reminders, make the desired actions the defaults (based on evidence), and recognize and harness patterns of work (i.e., use human factors engineering concepts).

(For more information on reliability in health care, go to http://www.ihi.org/IHI/Results/White Papers/ImprovingtheReliabilityofHealthCare.htm)

B. Implement Rapid Response Teams

A groundbreaking improvement relating to the coordination of care is the Rapid Response Team. Hospitals around the world are creating Rapid Response Teams, sometimes also called Medical Emergency Teams. "The idea is to catch patients before they start this terrible downward spiral," says Kathy Duncan, former director of nursing for critical care services at Baptist Memphis Hospital

in Memphis, Tennessee, and IHI's content expert for Rapid Response Teams. After setting up a team approach, Baptist Memphis found that the number of cardiac arrests dropped by 26 percent, and survival rates almost doubled, from 13 percent to 24 percent.[38]

Testing the Rapid Response Team on a population of more than 1,000 post-surgery patients, researchers found successful changes that directly reduced the level of complications in surgical and medical patients. In addition to significantly reducing rates for mortality and cardiac arrest, the team reduced relative risks as follows:[39]

- 79 percent for respiratory failure

- 78 percent for stroke

- 74 percent for severe sepsis

- 88 percent for acute renal failure

(For more information on Rapid Response Teams, see the Annotated Bibliography and the How-to Guide available on the Campaign Materials section on IHI.org at http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=2)

C. Introduce Simulation

Many other industries, particularly aviation, use simulation to teach people to recognize problems and understand the effects of their responses. The technique is particularly helpful in preparing people for error-prone, high-risk, or unusual situations. Simulations can be as simple as practicing wheeling a patient bed from one patient care unit to the ICU, and as complicated as visiting a dedicated patient safety lab used as a simulation theater. Simulation addresses not only the technical performance of individuals, but also important elements of teamwork such as listening, communicating, respect, and role clarity. Knowing how to conduct simulations is an important staff competency. Simulation has many applications in health care; an organization's investment of staff time in simulation or in a patient safety laboratory demonstrates the leadership's commitment to a safety culture.

(For more information on simulating possible adverse events, go to http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Changes/IndividualChanges/Simulate+Possible+Adverse+Events.htm)

D. Implement a Computerized Physician Order Entry System

As noted previously, the most common type of medical error relates to the administration of medications. Forty percent of medication errors are caused by cognitive mistakes by the prescribing physician and 25 percent are related to illegible handwriting.[40] A Computerized Physician Order

Entry (CPOE) system is an improvement to organizational infrastructure that can reduce medication errors by approximately 55 percent.[41] A more recent study suggests that a CPOE system may be able to reduce medication errors by as much as 88 percent.[42]

CPOE systems are expensive and often complex to implement. Selecting a system is a costly, resource intensive and long-term project in which clinicians must be involved. Selection is just the beginning: installation and integration of the system require a great deal of technical support and training for users, as well as evaluation, adjustments, and improvements. Only 2 to 5 percent of hospitals have purchased such systems.[43] At the very least, however, CPOE systems can eliminate errors related to poor handwriting, but to be of most value these systems should include a decision support function.[44]

(For more information about CPOE systems, go to http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Literature/ImplementingComputerPrescriberOrderEntry.htm)

(For more information on research and resources for evaluating and implementing CPOE systems provided by The Leapfrog Group, go to http://www.leapfroggroup.org/for_hospitals/leapfrog_safety_practices/cpoe)

Conclusion

Harm caused by medical errors is devastating to patients, families, and health care providers alike. There is a growing realization that without the commitment of organization leaders, the changes needed within health care institutions to improve patient safety will not be made. By focusing on creating systems that support both quality and safety, senior leaders will transform the health care system and improve the lives of the patients and communities they serve. This paper has presented several of the key concepts and tools that are available to assist senior leaders on their journey toward a safer health care system.

The landscape of improving safety in health care is changing rapidly, and this Guide presents only some of the resources and information currently available. For more updated information, please visit IHI's website (see the Patient Safety and Leading System Improvement sections, in particular) and the many other additional resources mentioned in this paper.

Glossary

Adverse Drug Event (ADE): Adverse drug events present the single greatest risk of harm to patients in hospitals. Traditional efforts to detect ADEs have focused on voluntary reporting and tracking of errors. IHI recommends tracking ADEs per 1,000 Medication Doses over time.

Aim: A written, measurable, time-sensitive statement of the expected results of an improvement process.

Crew Resource Management (CRM): CRM is a communication methodology derived from the aviation industry that is based on team-centered decision making systems.

Failure Modes and Effects Analysis (FMEA): A systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.

Global Trigger Tool for Measuring Adverse Events: This tool includes a list of known adverse event triggers and instructions for measuring the number and degree of harmful events. The tool provides instructions and forms for collecting the data needed to measure Adverse Events per 1,000 Patient Days and Percent of Admissions with an Adverse Event.

Lean Production: A business system for organizing and managing product development, operations, suppliers, and customer relations that requires less human effort, less space, less capital, and less time to make products with fewer defects to precise customer desires, compared with the previous system of mass production. Lean production was pioneered by Toyota after World War II. The term was coined by John Krafcik, a research assistant at MIT in the late 1980s.

Measure: An indicator of change. Key measures should be focused, clarify the improvement team's aim, and be reportable. A measure is used to track the delivery of proven interventions to patients and to monitor progress over time.

Move Your Dot: Move Your Dot™ is an effort to help hospitals know more about their organizational performance as it relates to mortality. Sir Brian Jarman, MD, IHI Senior Fellow and Emeritus Professor of Primary Health Care at Imperial College School of Medicine (London, UK), has developed a new statistical methodology to standardize hospital mortality rates in order to fairly compare them. "Moving the Big Dots" may also refer to other key system-wide measures such as ADEs per 1,000 Doses.

Model for Improvement: An approach to process improvement, developed by Associates in Process Improvement, that helps teams accelerate the adoption of proven and effective changes.

Patient Safety Leadership WalkRounds: WalkRounds™ provide an informal method for leaders to talk with front-line staff about safety issues in the organization and show their support for staff-reported errors.

Patient Safety Officer (PSO): The Leapfrog Group defines a Patient Safety Officer as "personnel whose sole duty is to understand, manage and optimize all activities relating to quality of patient and provider care within the hospital, reports to a C-level executive within the organization and is part of briefing board members and trustee." (For more information, go to https://leapfrog.medstat .com/pdf/Glossary.pdf)

Although the Joint Commission does not require the creation of new structures or a patient safety "office" in the hospital, it does require that one or more qualified individuals or an interdisciplinary group is assigned to manage the organization-wide safety program (standard LD.4.40).

Plan-Do-Study-Act (PDSA): Another name for a cycle (structured trial) of a change that includes four phases: Plan-Do-Study-Act. Sometimes known as Plan-Do-Check-Act (PDCA). Plan—a specific planning phase; Do—a time to try the change and observe what happens; Study—an analysis of the results of the trial; Act—devising next steps based on the analysis.

Reliability: Reliability is defined as failure-free operation over time. Reliability in health care is defined as patients getting the intended tests, medications, information, and procedures at the appropriate time and in accordance with their values and preferences.

Root Cause Analysis (RCA): RCA assists in identifying systems problems that contribute to the adverse event.

Rapid Response Team: A Rapid Response Team is similar to a cardiac arrest (code) team. However, unlike a code team, it may be summoned at any time by anyone in the hospital to assist in the care of a patient who appears acutely ill, before the patient has a cardiac arrest or other adverse event. Sometimes known as Medical Emergency Teams (METs) or Medical Response Teams (MRTs).

Safety Briefings: Safety Briefings in patient care units are tools to share information about potential safety problems, increase safety awareness among front-line staff, and foster a culture of safety.

SBAR: An acronym for *Situation-Background-Assessment-Recommendation*, SBAR is a communication tool used to standardize discussions among caregivers to ensure that critical information about a patient's status is communicated effectively.

Spread: The intentional and methodical expansion of the number and type of people, units, or organizations using the improvements.

Toyota Production System (TPS): The production system developed by Toyota Motor Corporation to provide the best quality, lowest cost, and shortest lead time through the elimination of waste. Widespread recognition of TPS grew with the publication in 1990 of *The Machine That Changed the World* by James Womack, PhD, and colleagues.

Selected Patient Safety Website Resources

Agency for Healthcare Research and Quality

http://www.ahcpr.gov/qual/

The Agency for Healthcare Research and Quality (AHRQ) website has extensive resources in its
"Quality and Patient Safety Section." The AHRQ website also provides access to the Patient Safety
Indicators (PSIs), a tool to help health system leaders identify potential in-hospital complications
and adverse events following surgeries, procedures, and childbirth. (For more information on the
PSIs, see http://www.qualityindicators.ahrq.gov/psi_overview.htm)

Institute for Safe Medication Practices

http://www.ismp.org/

The Institute for Safe Medication Practices (ISMP) "Pathways for Medication Safety: Leading a
Strategic Planning Effort" tool can assist senior leaders in assessing the current status of medication
safety in their organizations and to develop a strategic plan for moving forward (see http://www.ismp.org/
PDF/PathwaySection1.pdf). The "2004 ISMP Medication Safety Self-Assessment for Hospitals" is
a self-assessment tool that examines key elements in the hospital that influence safe medication use
(see http://www.ismp.org/selfassessments/Hospital/2004Hospsm.pdf).

Joint Commission International Center for Patient Safety

http://www.jcipatientsafety.org/

This website provides resources and information about patient safety for patients and their families,
as well as health care professionals, including physicians, nurses, pharmacists, and other allied
professionals. The Joint Commission's National Patient Safety Goals can be accessed via the website,
along with the timely Sentinel Event Alerts.

The Leapfrog Group

http://www.leapfroggroup.org/for_hospitals

The Leapfrog Group is a voluntary initiative in which organizations that buy health care are
working together to initiate breakthrough improvements in the safety, quality, and affordability
of health care for Americans. The Leapfrog Group has several patient safety resources for hospitals,
including research and selected references on Computerized Physician Order Entry (CPOE) systems.

National Patient Safety Agency (UK)

http://www.npsa.nhs.uk/

The National Patient Safety Agency (NPSA) is a Special Health Authority created in July 2001
to coordinate the efforts of the entire United Kingdom to report, and more importantly to learn
from, patient safety incidents occurring in the National Health Service in the UK. There are several
resources for both providers and consumers available on their website.

National Patient Safety Foundation

http://www.npsf.org/

The National Patient Safety Foundation (NPSF) strives to raise awareness and communication about safety, as well as to create a body of knowledge for improving health care safety. The website has an extensive library of patient safety resources for both providers and consumers, including fact sheets, publications, literature alert newsletters, and programs and conferences.

National Quality Forum

http://www.qualityforum.org/

The National Quality Forum (NQF) is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. In 2003 NQF published "Safe Practices for Better Healthcare," a consensus report that identified 30 health care safe practices and recommended that all applicable health care settings implement these practices to reduce the risk of harm to patients. (For more information on the report, see http://www.quality forum.org/txsafeexecsumm+order6-8-03PUBLIC.pdf)

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INSTITUTE FOR HEALTHCARE IMPROVEMENT

20 University Road, 7th Floor

Cambridge, MA 02138

(617) 301-4800

www.ihi.org