Implementing High Reliability for Patient Safety

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When data in the National Healthcare Safety Network database showed higher rates of infections in Connecticut than in other states, the Connecticut Hospital Association (CHA) launched the first-of-its-kind statewide initiative in 2010 to improve patient safety by eliminating all-cause preventable patient harm using high-reliability science. In 2015, after 2 years of planning and 3 years of training, hospitals and other health care organizations across the state adopted high reliability as part of their safety culture and as a result have decreased the incidence of preventable harm. This article reviews the current state of patient safety, explains high reliability, and discusses key factors CHA used to assess readiness and prepare health care organizations for implementation.

Keywords: High reliability in health care, preventable harm, safety culture

The documented frequency of preventable harm in health care settings and the powerful stories of harm shared by patients and families have led to a revolution in health care quality improvement. Research in preventable harm began even before the larger safety movement received publicity from the Institute of Medicine’s *To Err is Human* (Brennan et al., 1991; Institute of Medicine, 1999), and harm in health care has continued to be a focus of The Joint Commission, the National Quality Forum (NQF), the federal government, and state boards for more than a decade (Wachter, 2010).

Despite all the attention, little impact has been made on the incidence of harm. One study showed that hospitals may be harming up to 18% of their patients (Landrigan, Bones, Hackbarth, Goldman, & Sharek, 2010), and reports indicate that only one in seven errors are reported to hospital administration (U.S. Department of Health and Human Services, 2012). If the definition of preventable errors is broadened to include errors of commission, errors of omission, errors of communication, errors of context, and diagnostic errors, the frequency of harm may be four times as high as stated by the Institute of Medicine in 1999 (James, 2013). Some organizations, however, are trying a new methodology to decrease preventable harm. Highly reliable organizations are complex, high-risk organizations that operate under trying conditions and have fewer accidents than expected, despite human error and unsafe systems (Weick & Sutcliffe, 2001).

Early Efforts to Improve Safety

Connecticut was an early adopter of required reporting of adverse events to the state Department of Public Health (DPH) with the intent of reducing patient harm. The DPH established a Quality in Health Care program for health care organizations (Connecticut General Statute [CGS] §19a 127l, 2002a) and required reporting as of October 1, 2002 (CGS, 2002b). As part of this program, Connecticut anticipated the use of federal patient safety organizations (PSOs), and regulations for Connecticut PSOs were published in 2005 (CGS, 2004). The role of a PSO is to improve patient safety and the quality of care delivered to patients through the collection, aggregation, analysis, or processing of medical or health-related information submitted by health care providers. Reports to a PSO, when provided as a patient safety work product, may be protected and privileged, but the reporting of adverse events is not superseded by PSO protections. Connecticut needed to define requirements for reporting, and the NQF list of serious reportable events was adopted as the framework. Several Connecticut-specific events were added to the list. The regulations to begin required reporting were adopted in 2007.

Despite a long-standing commitment by Connecticut hospitals and staff to quality and patient safety improvement and their participation in statewide and national collaboratives, patients in Connecticut hospitals continued to experience preventable harm. In 2012, 8% of Connecticut hospitals had a standardized infection ratio (SIR) worse than the national SIR of 0.56 for central line–associated bloodstream infections (CLABSIs). Connecticut’s 2012 SIRs for catheter-associated urinary tract infections (CAUTIs) and surgical site infection were also much worse than expected and ranked near the bottom of states’ performance (Centers for Disease Control and Prevention, 2014). The 30-day all-cause readmission rate for the state remained above the national average; as a result, a number of Connecticut hospitals were penalized in the Readmissions
Reduction Program (Centers for Medicare & Medicaid Services, 2014). Similarly, hospitals decreased the number of Stage 3 and Stage 4 pressure ulcers by approximately 60% in a statewide collaborative, but statewide pressure ulcer rates did not demonstrably decrease the number of hospital-acquired condition coded events in the state.

Many of the errors and preventable harm events were occurring at the bedside. A number of improvement projects were undertaken with the Connecticut Hospital Association (CHA), which utilized Institute for Healthcare Improvement tools to support the statewide collaboratives focused on preventing pressure ulcers (2007), methicillin-resistant *Staphylococcus aureus* infections (2008), and patient falls with injury (2009), and decreasing readmissions for patients with heart failure (2010). CHA participated in the STOP BSI project led by the Armstrong Institute for Patient Safety and Quality (2009) and the STOP CAUTI project led by the American Hospital Association’s Health Research and Educational Trust (2010). All the collaboratives relied on nursing standards and guidelines as well as best practices as identified in the research. Although pilot units or circumscribed projects experienced success, Connecticut hospitals found that one-unit initiatives did not have widespread adoption, making sustainability impossible; did not fundamentally contribute to changing leadership’s concept of transparency or understanding of event causation; did not utilize bedside nurses’ understanding of operations; and did not make an impact on hospital-wide performance.

**Impact on Nursing**

Mandatory reporting of events may result in disciplinary actions against nurses. There may be a disincentive for staff to self-report or report the actions of colleagues if the outcome could be disciplinary action for unintended errors that result in harm. Nursing practice acts specify the authority, power, and composition of boards of nursing (BONs) and in turn, BONs are charged with ensuring continuing competence of nurses and implementing disciplinary processes (Russell, 2012). One area BONs review is practice-related breakdowns or errors during aspects of the nursing process (Russell, 2012). However, many BONs have seen the toll that disciplinary action takes on staff nurses for mistakes and human errors; BONs now endorse the safety movement and some have even been trained in principles of Just Culture (Page, 2007). Just Culture, a term coined by David Marx, JD, is an accountability model that consoles those who make a mistake, educates those who are reckless in their decision making, and holds those accountable who intentionally subvert the processes set up to create certain outcomes (Marx, 2001).

**Adoption of High Reliability**

Connecticut was ready for a new model, one that could induce hospital leaders, staff members, physicians, and nurses to adopt a commitment to patient safety that was inspirational. In 2010, the CHA Board of Trustees, led by a nurse who was a hospital CEO, took the bold step of committing hospitals to eliminating preventable patient harm. CHA, also led by a nurse who was the CEO, officially adopted high reliability as the patient safety curriculum throughout Connecticut in 2011, and design of the initiative began. CHA partnered with Healthcare Performance Improvement (HPI), a consulting firm specializing in helping health care organizations adopt principles and practices found in other high-reliability organizations.

High reliability creates an organizational structure and teamwork-based safety culture so inevitable human mistakes do not lead to patient harm. This methodology differs from previous quality and safety efforts in that it simultaneously emphasizes interprofessional interventions, behavioral changes, structured leadership, and culture shifts toward a culture of safety as a core value (Weick, 1987).

The research on high-reliability organizations began in earnest less than 20 years ago when experts from various fields gathered at the University of Texas to determine how certain industries seemed to withstand the enormous complexity and rapid change that occurred on a daily basis without frequent adverse outcomes. Experts in high reliability determined that those industries were resilient and creative in their responses when things went wrong rather than responding based on policies and repeated educational efforts (Hines, Luna, Lofthus, et al., 2008). Researchers at the University of Michigan identified factors associated with high-reliability organizations. High-reliability science is facilitated by processes that focus on identifying sources of failures, encouraging leaders to be sensitive to frontline operations, developing resiliency to contain events, and deferring to expertise that includes reliance on all team members to achieve good outcomes (Weick & Sutcliffe, 2001).

High reliability has been used to manage high risk by the aviation industry, the nuclear power industry, and the U.S. Navy. In all three endeavors, a single human error can have catastrophic consequences. Health care has the same risk of human error, for example, wrong-site surgery, blood transfusion incompatibility, patient identification errors, and medication errors. High-reliability science for health care organizations has been endorsed by the Agency for Healthcare Research and Quality (Hines et al., 2008) and The Joint Commission (Chassin & Loeb, 2011).

**Changing the Culture**

Organizational readiness is a critical component to success, and it may take 1 to 2 years to prepare for high reliability (Smith, 2007). Before implementation, organizations need to consider several key factors of readiness, including identifying a champion, assessing competing factors, deferring to expertise, committing to transparency, and developing a simplified working framework. Implementing high reliability is a fundamental organizational culture change.

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A key element of success is having someone driving the process and promoting high reliability in an organization (Valente, 1995). This high-reliability champion ensures that the process becomes the organization’s highest priority in terms of patient safety and allows the organization to withstand fundamental management changes (Chassin & Loeb, 2013). Passionate about the topic, the champion must have a large enough organizational role to bring and keep all stakeholders on board with the process.

Assessing Competing Factors
Assessing preparedness is a critical step toward high reliability. Large-scale culture change requires the commitment of time and resources. (See Figure 1.) Therefore, organizations considering high reliability need to assess competing factors that will make them unable to reach the zero harm benchmark. If any compelling issues exist, a move to high reliability may be impractical. Organizations can conduct diagnostic readiness tests to consider topics, such as negative financial situations, impending hospital mergers, large building campaigns, federal or state inquiries, or the implementation of new electronic health record or information technology systems.

When CHA implemented high reliability in its hospitals, it created a multiyear statewide plan for two cohorts based on the hospitals’ readiness to make an institutional commitment. This cohort plan allowed flexibility and maximized participation by the hospitals. All 28 hospitals in the state have committed to implementing high reliability, and 26 have rolled out full high-reliability implementation with the participation of the CEO, frontline staff, and medical staff. In the first cohort, 13 hospitals participated; in the second cohort, 12 joined. (The hospital led by the CHA board chair had already implemented high reliability). The other two hospitals have enacted parts of high reliability but have not completed full implementation.

Deferring to Expertise
A distinctive feature of highly reliable organizations is their deference to expertise regardless of hierarchy. In these organizations, seeking help is encouraged and expected (Weick & Sutcliffe, 2001). When an airplane crashes, the aviation industry relies on the National Transportation Safety Board; when clinicians have difficulty diagnosing a patient, they call in specialists. The translation of the science of high reliability has not been developed fully in health care; therefore, organizations must seek out experts to assist with implementation.

The deference to expertise also occurs at the bedside. Leaders of high-reliability implementation at many hospitals were patient care executives or chief nursing officers. Close to operations and committed to safe patient care, they had too often seen patient harm result in disciplinary action against the nurse caring for the patient. Even when the error occurred upstream, if the nurse did not recognize it and administered the wrong dose or gave the wrong medication, the nurse was disciplined.

Committing to Transparency
High reliability requires robust institutional implementation, a change in the perspective of hospital safety to the benchmark of zero harm, and a commitment to implementing a fair and just culture for reporting events (Marx, 2001). Organizations must be commit-
ted to significant disruptive changes that acknowledge imperfections in the system, and workers must feel supported and safe when voicing concerns (Frankel, Leonard, & Denham, 2006; Reason & Hobbs, 2003).

Hospitals must shift toward a model that standardizes organizational response to error, endorses open communication and immediate feedback, and holds staff appropriately accountable (Marx, 2001). This approach is not blame free: In a just culture, unintended human errors are not punished, but there are fair consequences for those who engage in reckless behaviors that clearly violate policy, procedures, or protocols. This systematic approach to safety is particularly vital because early in the process, staff members will report serious safety events as they occur, leading to an apparent increase in the number of events before the expected significant decreases can occur.

High-reliability organizations have mechanisms for recognizing when intentional or willful misconduct may lead to harm. Two such mechanisms are “Mentoring Each Other for 200% Accountability” and “Practicing a Questioning Attitude.” These mechanisms are used when an action does not seem right to a person observing a staff member. The 200% accountability mechanism uses a technique called ARCCing it up, which means

- Asking a question for clarification
- Requesting a change
- Communicating a concern
- Using the Chain of command if the person does not alter his or her actions.

“Validating and Verifying” is another tool, one that ensures that an individual is practicing a questioning attitude. It means that the observer either reassesses the situation to make sure it complies with policy or practice or the observer checks another source for clarity. Suspicious behaviors may include diverting narcotics, bypassing two-person safety checks, and scanning barcodes on a paper rather than on a wristband. If a staff member intentionally bypasses policies and procedures, an accountability algorithm allows the organization to address the behavior and hold the staff member accountable.

**Developing a Simplified Framework**

The literature shows that addressing complicated issues means developing a highly understandable framework that can be replicated and implemented hospital wide (Berwick, 2003). Zero harm is readily understandable and is not influenced by rates or numbers. In fact, high reliability does not utilize risk-adjustment methodologies. Individuals affect the adoption of innovations, and congruence with current beliefs and behaviors greatly affects success (Davidoff & Batalden, 2005). Every individual must understand high reliability’s purpose and the importance of adopting evidence-based and prescribed behaviors.

A simplified framework includes the design of policies, procedures, and practices that turn structure into action, regardless of the individual’s position (Carroll & Rudolph, 2006). Everyone participates in the education and training on high reliability in the same manner with the same expectations, regardless of title or role. This construct supports the cascade of information and adoption of behaviors that have been effective in other industries. Regardless of the methodology of training, the framework needs to be easy to adopt and have a structured, organization-wide implementation and dissemination plan.

In Connecticut, frontline hospital staff members collaboratively designed a behavioral model called CHAMP, an acronym that spells out the core elements of the behaviors expected as a result of this project:

- Communicate clearly.
- Hand off effectively.
- Pay Attention to detail.

![SEC Safety Event Classification](https://www.journalofnursingregulation.com/SEC_Safety_Event_Classification)
FIGURE 3

CAUTI Success

This graph shows a narrower focus on a specific type of event and uses the National Healthcare Safety Network data from Connecticut. Illustrated is a view of catheter-associated urinary tract infections (CAUTIs) through the lens of high reliability with the interventions the Connecticut Hospital Association (CHA) applied. In partnership with regulatory departments, Connecticut hospitals adopted nurse-driven catheter-removal protocols to decrease the frequency of CAUTIs after the science showed that the protocols were effective.

<table>
<thead>
<tr>
<th>Year</th>
<th>National SIR</th>
<th>SIR</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>3.67</td>
<td>4.70</td>
<td>1.61</td>
</tr>
<tr>
<td>2013</td>
<td>4.23</td>
<td>4.95</td>
<td>2.07</td>
</tr>
<tr>
<td>2014</td>
<td>4.46</td>
<td>4.14</td>
<td>1.85</td>
</tr>
<tr>
<td>2015</td>
<td>3.36</td>
<td>3.91</td>
<td>1.58</td>
</tr>
</tbody>
</table>

Note. SIR = standardized infection ratio; HEN = Hospital Engagement Network; HRO = high-reliability organization; COPCQ = Committee on Patient Care Quality; HRET = Health Research & Educational Trust; ED = emergency department. CAUTI definition revised with exclusions by the Centers for Disease Control and Prevention on January 1, 2015.

- Mentor each other.
- Practice and accept a questioning attitude.

CHAMP emphasizes how low-risk behaviors reduce error rates and thus prevent serious harm. All hospital workers develop skills that create a culture of safety and fix systemic problems that would normally lead to patient harm.

Evaluating Reported Events

High reliability requires transparency and reporting of all events. Events are classified utilizing the Safety Event Classification (SEC®) system developed by HPI (Throop & Stockmeier, 2009). First, a determination is made as to whether there has been a deviation from generally accepted performance standards (GAPS). An organization can confirm deviations from GAPS by comparing expected performance with actual performance, taking into account known complications. When a deviation has been determined, the level of classification is assigned based on the level of harm. If the deviation reaches the patient and causes moderate to severe harm, including death, the event is classified as a Serious Safety Event (SSE). If the deviation results in minimal or no detectable harm, the event is classified as a Precursor Safety Event. If the deviation is blocked from reaching the patient, it is classified as a Near Miss Safety Event. (See Figure 2.)

When individuals follow a generally accepted standard of science and practice or they anticipate a known complication and take active steps to mitigate and manage it, even if there is an adverse outcome, it is not labeled as an SSE. This approach follows generally accepted performance standards considered at Peer Review and Morbidity and Mortality Reviews, but it contrasts with the prevailing safety theories that all patient harm should be preventable. Those prevailing safety theories are often the ones embraced by regulatory and accrediting agencies, and they form the basis of the classification of the NQF’s never events, upon which the Connecticut model for adverse event reporting is based.

The high-reliability model of safety recognizes that some harm may not be preventable for physiological or anatomical reasons or because the science has not advanced enough to prevent harm. For example, before 1999, catheter-related bloodstream infections were not generally considered preventable (Mermel, 2000). In 2015, many hospitals in Connecticut have gone for months without a CLABSI by implementing the CLABSI bundle to prevent line-
related infections (Pronovost et al., 2006). In medicine, the science is continually evolving.

All CHA hospitals completed a retrospective review of events: Each event was reviewed, analyzed, and classified according to the SEC system. This evaluation was completed during the common cause analysis (CCA), an intensive review of safety or sentinel events over the past 3 years. In addition to providing valuable information about past causes of safety events, the CCA enabled the calculation of each organization’s Serious Safety Event Rate® (SSER) (Throop & Stockmeyer, 2009). The CCA and SSER were used to begin the process of talking about events openly, to determine specific causes in hospitals, and to show each hospital there was opportunity to decrease the number of events. The SSER is now used in each participating Connecticut hospital to make harm visible; to keep staff members, physicians, and leaders more aware of the potential for harm; and to act as a primary measure of preventable harm to drive continuous improvement.

An increase in the SSER occurs as organizations become more adept at detecting, classifying, and reporting events. For HPI clients, an 80% decrease from the baseline SSER is typical within 2 years of widespread knowledge, understanding, and application of error-prevention tools and techniques. The paradigm shift of striving for zero harm leads to a short-term spike in reported incidents but long-term patient good.

Requirements for Implementation

To implement high reliability, organizations must commit to substantial changes. The most important change is putting safety first in every discussion, meeting, and decision. Leaders set expectations and model behavior. Connecticut hospitals have trained more than 40,000 staff members: nurses, physicians, environmental services personnel, pharmacists, respiratory therapists, facilities personnel, and C-suite members. Connecticut hospitals start every day with safety huddles, and safety stories are distributed every day to remind staff members that patients are still harmed. In response, staff members share their own patient harm stories because Connecticut hospitals acknowledge that everyone makes mistakes.

Implementation also requires promoting transparency. The event-reporting system must foster open and honest reporting, and responses must be fair and just. In Connecticut, to support the transparent sharing of patient safety improvement strategies and data, the high-reliability collaborative is hosted under the umbrella of a statewide PSO, the Connecticut Hospital Research and Education Foundation PSO. Adverse events reported to the state are collected by the PSO so trends can be identified. Stories are shared, with opportunities to learn from others’ errors. The relationship with the state DPH has changed because the DPH saw the commitment that hospitals were making to safety. DPH staff members have undergone training as well so everyone speaks the same language. Patient advocates were brought in to hear about the mistakes and the approach that the hospitals were endorsing. The patients now speak of high reliability.

High reliability also requires a sense of urgency, a devotion of resources, and the attention of leadership to find and fix problems. Connecticut hospitals start their day with morning safety huddles. Leaders report that these huddles eliminate meetings, decrease the time to resolve concerns, and promote a sense of teamwork. Nurses say they no longer have to report broken equipment or wait for shortages to be resolved. Standardization becomes easier across units and organizations. Continuum-of-care partners have also implemented high-reliability approaches as have ambulatory practices. Staff members in the nursing and medical schools are also being trained in high reliability.

Conclusion

Evidence indicates that large-scale, coordinated quality efforts can result in measurable reductions in harm to patients in specific interventions. Prior collaborative experience resulted in a level of trust among Connecticut hospitals that allowed them to quickly and decisively agree to adopt a new quality and patient safety model. This level of engagement and trust assisted greatly in the coordination and operationalization required for an initiative of this magnitude.

The results have been significant. The hospitals continue to track their SSERs, and CHA tracks an aggregate rate. Connecticut hospitals measured their SSE rate consistent with the copyrighted methodology provided by HPI. After establishing an initial baseline rate, the number of events and the rate increased as better transparency led to more reporting. As the high-reliability behaviors and comprehensive event reviews led to change, the frequency of events has decreased and the rate has declined by about 50% from the peak of occurrence. Most recently, the hospitals have used high reliability to look at intractable problems of patient safety, such as CAUTIs and surgical site infections. (See Figure 3).

Any organization can replicate the success of the Connecticut hospitals. By creating a flexible model that includes identifying a champion for culture change, performing an organizational readiness assessment, determining a framework and the behavioral model, and classifying event data utilizing the SSE system, organizations can implement high reliability to eliminate preventable patient harm.

References


