High Reliability Organizations: The Next Frontier in Healthcare Quality and Safety
EXECUTIVE SUMMARY

Over the past decade, influential health systems, regulatory bodies, and researchers have initiated a discussion about translating the tenants of high reliability organizations (HROs) to healthcare. Nuclear power plants and the aviation industry have received the most attention for using tragedies, like the Chernobyl disaster and avoidable crashes, to drive the adoption of a high reliability mindset. Despite robust documentation of serious adverse events and research on the key tenants of HROs, the healthcare industry has not fully committed to achieving zero harm. The goal of this essay is to summarize high reliability and how it differs from other improvement methodologies, explore the imperative to commit to high reliability, address barriers to adoption, provide practical recommendations for implementation, and predict what can be achieved as a result of this investment.
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OVERVIEW OF HIGH RELIABILITY ORGANIZATIONS IN HEALTHCARE

What is High Reliability?

High reliability is the ability for a complex organization delivering high risk services to achieve and sustain extremely low rates of harm over time. The five key characteristics used to test if an institution should be considered a high reliability organization have been widely accepted: preoccupation with failure, reluctance to simplify observations, sensitivity to operations, commitment to resilience, and deference to expertise. In healthcare, these criteria are often used to assist the organization in striving towards a singular strategic goal of patient safety, by committing to zero harm.

The Drive to High Reliability in Healthcare

The Institute of Medicine’s 1999 report, *To Err is Human*, is commonly regarded as the creator of the “modern patient safety field.” Despite pockets of successful improvements in patient safety since, such as efforts to improve infection control processes or reduce negative outcomes for patients on warfarin, the “overall impact is hard to see in national statistics.” In a study released more than 15 years after *To Err is Human*, attention was again brought to patient safety through shocking statistics. Researchers calculated the “mean rate of death from medical error” to be 251,454 people annually when utilizing 2013 US hospital admissions for extrapolation. When comparing this to Center for Disease Control (CDC) rankings, this makes medical errors the “third most common cause of death in the US.” Given this compelling data, the need to continue to accelerate improvement efforts in patient safety is still great, and adoption of a high reliability mindset throughout healthcare is the most promising way to do so.

A 2016 Harvard Business Review article identified three waves of surgical improvement that are relevant to the entire healthcare industry. The first wave, technical advancement, is
associated with improving technology and training to achieve better outcomes. 2 The mastery and dissemination of minimally invasive surgery techniques serves as a clear example of this wave.2 The second wave, standardizing procedures, focuses on the elimination of variation – often operationalized through checklists to ensure compliance with all steps of a high-risk process. 2 However, in large part due to coinciding increases in patient acuity and vulnerability,3 these methodologies of improvement are beginning to require more and more resources only to achieve a “flattening of the patient mortality curve.” 2 Technical advancement and standardization seem to have reached a tipping point and are now delivering diminishing returns. A third wave of improvement, “high reliability organizing,” 2 which embraces increasing variation and complexity in the pursuit of better patient outcomes, is the next step.

**Comparing High Reliability to Other Improvement Frameworks**

Models used for creating and sustaining improvements in structures and processes in healthcare are evidence of our conditioned bias towards incremental change. The Plan-Do-Study-Act (PDSA) cycle commonly associated with lean methodology is a framework for testing change that involves planning a test and collecting necessary data, implementing this test of change on a limited scale, studying the results, and then refining the change based on the initial test.4 Rooted in the scientific method, this framework is effective, but relies on incremental rather than drastic change. Creating behavior change in patients also uses an incremental approach. Imagine a hypothetical knee replacement surgery candidate who needs to lose 150 pounds within a year to qualify for surgery. The care team helping this patient prepare for their procedure would likely use the Stages of Change construct, or a similar model, to assist the patient in moving along a “continuum of motivational readiness” to optimize “individual change.”5 Contrastingly, a high reliability mindset focuses less on making incremental adjustments to processes, and more on a cultural transformation that leads to reliability by fostering the “capability to discover and
managed unexpected events.”1 Thus, one major difference between high reliability organizations and most healthcare organizations is the focus on drastic instead of incremental change.

The intention of high reliability is not to dismiss the power of incremental change, but to encourage a model where these tools support an overarching commitment to zero harm. The danger of incremental change informing strategic goals is illustrated by a simple hypothetical - imagine a hospital undergoing their annual planning process. Perhaps they achieved a margin of 2% and set the goal to increase their margin to 3% in the next fiscal year to begin to prepare for an upcoming capital investment. In this case, incremental improvement is appropriate and feasible. However, when applying this same approach to setting patient safety and quality goals, it quickly becomes unacceptable. Perhaps this same hospital performed 5 wrong-site surgeries in the last fiscal year, and is aiming to incrementally decrease to 3 wrong-site surgeries. The concept of aiming to create patient harm should be unacceptable, but has been lost in the best of intentions. A national goal set in response to growing concern about patient safety in the early 2000s read: “to reduce preventable patient injuries by 90%.”7 While a noble goal, if recent reports of deaths caused by medical errors are accepted, this goal translates to aiming to cause over 25,000 preventable deaths per year. A high reliability mindset would argue that such a target is unacceptable, and should instead be framed as aiming to perpetuate no preventable harm. Critics may point out that, at least in the short term, this goal is unachievable. While this is true, a distinctly different mindset and organizational culture emerges when the goal is some patient harm rather than zero patient harm.

A second major difference between high reliability and other improvement frameworks is the quantity of strategic goals that take top priority. When comparing high reliability organizations to the criteria of the Malcolm Baldridge National Quality Award, which recognizes non-profit organizations for performance excellence, “the major difference lies in strategic
emphasis.” 6 When given latitude, the targets that healthcare organizations have chosen to focus on have “fallen short of commitment to zero patient harm.” 6 While this is logical, given the vast complexity and limited resources that healthcare organizations must allocate responsibly, it also may be rooted in a misunderstanding of the goal of zero harm. Even after a significant culture change across the industry, “some ambiguity still exists about the relationship between safety as a desired characteristic of healthcare and the broader issues of health care quality in general.” 7 Berwick and Leape identify three areas that health care quality addresses, which are viewed as distinct from patient safety by many: overuse, misuse, and underuse. 7 In reality, patient safety is clearly centered in all of these areas. For instance, the misuse of an imaging machine could improperly expose a patient to unneeded radiation which may cause harm, overuse of medication could easily lead to an adverse event, and underuse of any number of diagnostic tools could leave an otherwise obvious medical condition untreated. Thus, in high reliability, compared to other improvement frameworks, two main differences exist: first, high reliability limits an organization’s strategic focus to a singular goal, zero harm, and second, this goal is achieved through drastic change supported by cultural transformation rather than technical improvement tools.

**BARRIERS TO ADOPTION: A SERIES OF PARADOXES**

A high reliability mindset shows promise to usher healthcare towards a new era of patient safety and quality, but adoption still lags. Characteristics inherent to healthcare, including its “complexity, professional fragmentation, and tradition of individualism” 7 are certainly barriers. Resistance can be further explained by the tensions at play in three common paradoxes: standardization vs variation, vulnerability vs leadership, and decentralized decision making vs a singular goal.
Standardization and Variation

Variation has received a bad reputation in healthcare. While variation in outcomes, such as higher rates of mortality among surgical patients, are concerning, lack of standardization should not be feared. As stated by Ghaferi et al: “pursuing a perfectly standardized system ignores the fact that each patient is different” and that “over-standardizing can also increase risks.” Research has shown that rates of mortality associated with inpatient surgery vary greatly, independent of rates of overall or major complications. That is, achieving even greater standardization does not necessarily lead to improved outcomes for patients.

The power of not confusing standardization with reliability does not stop with safety, but also has significant implications for patient satisfaction and affordability. A friend underwent multiple surgeries to address an esophageal defect, and while being wheeled into his fourth surgery, his surgeon noticed an atypical mole on his forearm. After updating the informed consent, the surgery team was able to remove and biopsy the mole while continuing with the planned procedure. This adjustment left my friend highly satisfied and, even more importantly, resulted in the early identification of a developing melanoma. By removing this melanoma proactively, my friend obtained better health outcomes than if the planned process had been followed. Furthermore, the cost of his care was reduced, as treatment of complex melanoma is more expensive than a slight addition to an existing operation. This simple example illustrates that flexibility does not need to imply a negative outcome, and even has the potential to improve outcomes. The moments where individuals are empowered to creatively address an unexpected problem are often where the most value is created. By adopting a high reliability mindset, healthcare organizations can make a clear distinction between standardization and variation, and create the reliability needed to achieve more of these moments. In time, this will minimize standardization as a barrier to the adoption of a high reliability mindset.
Vulnerability and Leadership

To embark on the journey towards high reliability requires an organization, beginning with its leaders, to reckon with its failures. To identify areas of improvement and create the agency needed for change, leaders must not only identify adverse events that systems often perpetuate, but also publicly share these failures. Vulnerability and acknowledgement of failure goes against many traditional archetypes of leadership, which typically bring to mind images of highly focused, stoic, emotionless leaders. Social science and leadership experts now agree that vulnerability “lies at the root of social connection,” and is linked to improved employee performance.\(^{16}\) Other bodies of work, including Lencioni’s *The Five Dysfunctions of a Team*, illustrate several dysfunctions that must be addressed to prepare a healthcare organization to embark on a high reliability transformation. While Lencioni notes that “vulnerability-based trust cannot be achieved overnight,” he advocates that the leader’s role is to “demonstrate vulnerability first” to ensure all team members understand that such behavior will not be punished.\(^{17}\) This will begin to address the dysfunction of an absence of trust. Second, Lencioni recommends addressing the dysfunction of avoidance of accountability by making goals, progress, and rewards for team achievement a transparent and regular practice.\(^{17}\) The absence of trust and accountability are relevant to high reliability as creating a culture that values bringing forward safety concerns and poor outcomes, and has the courage to fully address each of these, requires vulnerability and hypervigilance.

Decentralized Decision Making and a Singular Goal

A final paradox is the ability to foster flexibility and creativity in an organization while maintaining focus on a singular goal. At first thought, it seems impossible to define a goal with no ambiguity while still creating an environment where “semiautonomous activity,” or the use of professional judgement, can be effective.\(^{15}\) In high reliability organizations, a uniform
understanding of the central aim is not inconsistent with “variability of human action” and this variability is expected and encouraged. When there is flexibility in the map to arrive at a goal, but the aim is certain, the individuals responsible for implementing processes have the autonomy to react and achieve that target outcome more reliably. However, if there is a certain path, but uncertain end goal, the ability to improvise successfully in the face of unexpected impediments diminishes. In other words, high reliability encourages decentralized decision making while ensuring movement towards a central goal. Given that healthcare is highly decentralized, committing to a framework that allows for further decentralization may seem daunting to many leaders. But, if balanced appropriately with consistent communication of the singular goal of patient safety, reliability and therefore positive outcomes should increase rather than decrease.

**Steps Towards High Reliability**

Shifting a healthcare organization towards high reliability relies on being able to affirmatively answer four key questions: Does every staff member know what the goal is, and why it is the goal? Do those responsible for implementing processes that support this goal do so every time? When mistakes occur, do people speak up, and do leaders listen? Are errors effectively tracked, and shared, to inform the continual design of even safer processes? As illustrated by these questions, it is essential to recognize that zero harm will be grounded in supportive processes and data, but will be achieved through cultural transformation. Four practical steps to begin to implement components of the high reliability mindset within a healthcare organization are outlined below.

1. **Create Urgency**

Just as successful leaders create meaningful connections with their team, successful change often starts with an urgent need. The first 4 steps of Kotter’s 8 step change model all focus on preparation for action: establish a sense of urgency, form a powerful coalition, create a
vision, and communicate the vision.\textsuperscript{18} Without an urgency to create change, the avalanche of competing priorities ever present in most healthcare organizations wins out. The spark to initiate the movement to high reliability in some organizations may come from an internal adverse event, or a pattern in safety concerns, that makes evident the need to re-prioritize patient safety. Even if no recent tangible event exists, as made clear in the landmark report \textit{To Err Is Human} and numerous reports since, examples of unintentional harm abound in healthcare.

2. Address Incident Reporting

The Agency for Healthcare Research and Quality (AHRQ) states that there is no “single validated method for measuring the overall safety of care provided in a given health care setting.”\textsuperscript{9} While liberating in that this allows room for customization, a lack of best practices in measuring patient safety is a significant barrier. So much so, that the National Patient Safety Foundation’s 2015 report recommended a “common set of safety metrics that reflect meaningful outcomes” be established to accelerate progress in patient safety.\textsuperscript{10} AHRQ suggests several strategies for measuring patient safety, all which come with their own benefits and downsides. For example, using claims data to measure patient safety is relatively affordable and accessible, but lacks detailed clinical information.\textsuperscript{9} Reports directly from patients offer an important and alternative perspective, but can be difficult to collect and address consistently.\textsuperscript{9} Analytics tools that predict safety risks based on automated examination of a patient’s comorbidities and demographics could be effective, but would be high cost and reliable iterations are still in development.\textsuperscript{9} Another option, chart review, offers rich data but is resource intensive and only provides reactive information.\textsuperscript{9}

The most common tool utilized by hospitals, “voluntary error reporting systems,” provide employees which an electronic platform to draw attention to negative outcomes or concerning events.\textsuperscript{9} Even with such systems in place, gathering data about safety concerns consistently is a
major challenge for many health systems. From the initial step of asking an individual to report this information, barriers begin. For organizations that have a developing safety culture, some employees may not feel comfortable reporting concerns for fear of punishment. Other employees may not be aware of when and how to do so. Thus, a clear, easy, widely communicated method for reporting safety concerns is the first essential step to incident reporting. Ensuring that such reports are routed through a structure of accountability that allows individuals who can take action to address the issues, and loop back with those who reported and were involved in the concern, is a key second step. Additionally, it is important that the ability to circumvent the system exists when needed. For example, if an employee has a concern to report that directly involves their manager or the individual that the report is routed to, there should be alternative pathways in place so there is no incentive to leave such a concern unaddressed. Finally, the incident reporting structure should enable reports to be aggregated to include concerns from all sources, ranging from codes called as a result of a combative patient, to facilities maintenance creating risks for slips or falls, medication errors or near misses, communication breakdowns, and more. The ability to track trends and understand their root causes through the use of data is essential to another high reliability organization best practice, safety huddles.

3. Make Safety a Group Priority Everyday

Daily safety huddles have been widely adopted to implement the principles of preoccupation with failure and sensitivity to operations that are critical to high reliability organizations. While well intentioned, they often quickly lose their sense of urgency. Carefully considering the details of implementing these huddles will lead to sustainment of positive outcomes.

A key first principle is to ensure that the huddles are designed to address problems proactively rather than reactively. For example, instead of the leader of the huddle asking each
representative “Are there any safety concerns in your area?” instead ask “What are the safety concerns in your area?” This transforms the status quo from a negative connotation surrounding the raising of safety concerns to the assumption that there are always safety concerns to address. To this end, the leaders representing their areas at the safety huddle must also be proactive in their preparation for huddle. Whether implementing a series of cascading huddles, relying on an automated daily summary of relevant incident reports, or having targeted conversations prior to attending huddle, leaders must have their own “standard work” for such preparation. Such standard work should also be proactive in nature, and attuned to identifying circumstances that may create safety concerns in the future. Common examples may include patients with similar names, new medications, procedures, or equipment, and newly trained staff in a given area.

A second key principle is to ensure that safety huddles are not limited in time or place. It is unsurprising that most healthcare organizations have drastically different operating practices when comparing across days, nights, weekends, and holidays. Additionally, operations at the central or flagship location may be drastically different from outpatient or off-site locations. Thus, the huddle structure should be designed to incorporate all time frames and settings, rather than only reflecting the structure that is most convenient for leadership. To this end, the structure of huddles should be designed to be customizable and scalable, and not always facilitated by the same leadership.

Finally, it is important to track high level metrics over time to assess the impact of huddles. Key metrics to consider may include: days since a serious safety event and days since missed work due to employer injury. It is important to reflect both patient and staff safety in these metrics, so that the goal of zero harm is not limited to a subset of the healthcare community. Another key metric is the quantity of total incidents reported; as a culture of safety becomes robust, this would be expected to increase. Similarly, the number of incidents reported
anonymously should proportionally decrease, signaling a universal recognition that raising safety concerns is a practice to be praised not punished.

4. Ensure Staff Are Cared For

As more emphasis is placed on patient safety, significant adverse outcomes will inevitably still occur. The University of Iowa Hospitals and Clinics implemented a team, named the “COPE Team,” to help ensure staff are cared for in such events. The goal of the team is “to provide emotional support to staff that have had a work-related experience that might challenge their capacity to cope.” The team is an interdisciplinary team and includes chaplains, nurse ethicists, social workers, psychiatric nurses, and physicians. The team operates on a three-tiered approach that provides peer support, peer support mentors, and a referral network to further support. Making this type of resource available signals that an increased emphasis on safety will be matched with increased support for staff on the journey towards high reliability.

EXPECTED OUTCOMES

Beyond an improved organizational culture and reduction in adverse outcomes, healthcare organizations can expect additional benefits as a result of a commitment to the high reliability mindset. For example, performance on regulatory requirements, such as accreditation by The Joint Commission, will likely improve. The Joint Commission has publicly announced their emphasis on assessing the culture of safety present in organizations during on-site visits. They have recently released a tool that can assist healthcare organizations in evaluating their progression towards high reliability. As pay-for-performance continues to gain more momentum in the ongoing transition from fee-for-service to value based payment, an improvement in quality metrics may be associated with financial benefit. Quantifying such benefits is still challenging, as more research is needed on the outcomes of healthcare organizations that have committed to zero harm. However, a study analyzing the outcomes of
organizations who received the Baldrige quality award, similar in intention to high reliability, have generated “above-average performance…in safety, infections, immunizations, and patient satisfaction.” Unfortunately, the improvements that Baldrige organizations have achieved have not been matched with “reduced admissions, mortality, and costs.” According to the study’s author, the most obvious explanation is that these matters “were not perceived as high priorities for improvement.” Given that high reliability highly prioritizes reducing patient mortality, more significant reduction in this and associated metrics should be expected.

CONCLUSION

The commitment to become a high reliability healthcare organization is a complex task with many barriers. Compelling messages about the unintentional harm caused by unsafe systems and processes within healthcare contributed to a mindset where standardization and variation are binaries representing good and bad. The commitment to zero harm through a high reliability mindset reframes the process of creating safe outcomes through a balanced approach that incorporates process design, organizational cultural transformation, decentralized decision making, and robust data.

REFERENCES


