Chapter 2
Science of Improvement

Michael A. Rosen and Sallie J. Weaver

Introduction

Healthcare is in the midst of a large-scale transformation and modernization effort. A wide range of stakeholders including regulators, payers, and consumers all demand higher levels of value and transparency in care delivery performance. Quality improvement (QI) methods are one of the key approaches to achieving the new and elevated performance expectations for healthcare delivery systems. QI in healthcare is defined broadly as "the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development" [1, p. 2]. While the pressures exerted on healthcare systems for improved value are new, the application of QI methods are not. Researchers and practitioners have applied a broad range of QI methods for decades [2] and have achieved mixed results [3–5]. In this decades-long experience with QI, the field has learned much about the critical components of effectiveness.

This chapter provides an overview of state of the science and practice of quality improvement in healthcare. First, we describe the fundamental models and exemplar methods of QI in healthcare. There are many techniques, but they can all be organized using a common set of knowledge systems or domains. We describe these systems and discuss how common-structured approaches to QI in healthcare address these varied knowledge domains. Second, we draw insights and guiding principles from the area of high-reliability organizing. This area of scholarship seeks to understand

M.A. Rosen (✉) • S.J. Weaver
Department of Anesthesiology and Critical Care Medicine, Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine,
750 E. Pratt Street, 15th Floor, Baltimore, MD 21202, USA
e-mail: mrosen44@jhmi.edu; sjweaver@jhu.edu

C.E. Dandoy et al. (eds.), *Patient Safety and Quality in Pediatric Hematology/Oncology and Stem Cell Transplantation*, DOI 10.1007/978-3-319-53790-0_2

resilient performance in high-risk, yet highly safe, industries. Ultimately, QI is organizational change. Arguably, few organizations are as complex, interdependent, and difficult to change as healthcare organizations. QI models and methods offer tools that can facilitate change and continuous learning when used mindfully.

Quality Improvement Models and Methods

Quality improvement efforts draw on a broad range of methods to achieve better outcomes. However, the use of "systems thinking, data analysis, and [multidisciplinary] teams" [6, p. 203] underlies most QI approaches. The diversity of what is considered QI, and how it is conducted, creates challenges in large-scale assessments of its effectiveness [7, 8] as well as confusion among practitioners about where to begin. In this section, we review the variety of "knowledge systems" that underlie QI in healthcare, discuss common structured approaches that draw from these systems, and review a general set of values that characterize effective QI implementation.

The Knowledge Systems of Quality Improvement

The breadth and depth of theories, strategies, and tools employed in QI in healthcare can be overwhelming. Underlying this complexity, however, are several core domains of knowledge that must be integrated to achieve improved outcomes. Batalden and Davidoff [1] provide a useful framework for understanding the types of work involved in QI in healthcare. Specifically, they define five core "knowledge systems." Each of these knowledge systems described below focuses on different problems and employs different methods. Ultimately, successful QI requires integration across these knowledge systems. Figure 2.1 depicts the relationships between each knowledge systems of QI.

First, *generalizable scientific evidence* is derived from empirical studies of interventions and ultimately the distillation of this evidence into clinical guidelines. This knowledge system seeks to control for contextual factors in analysis in order to generate an understanding what therapies or other interventions are most effective overall. It is the evidence behind evidence-based medicine. However, generating evidence and creating guidelines are necessary but insufficient to produce change or improved care [3]. Second, *particular context awareness* involves generating knowledge about the elements of a specific implementation setting or work context. This includes systematically collecting and analyzing information about local care processes, structural constraints of an organization (e.g., staffing, information technology infrastructure, resource constraints), and local history (e.g., exposure to interventions in the past, personal relationships) that may impact QI efforts. This knowledge system provides insight into what changes may be required to enable a specific organization to achieve its desired outcomes. Third, *performance measurement* provides the

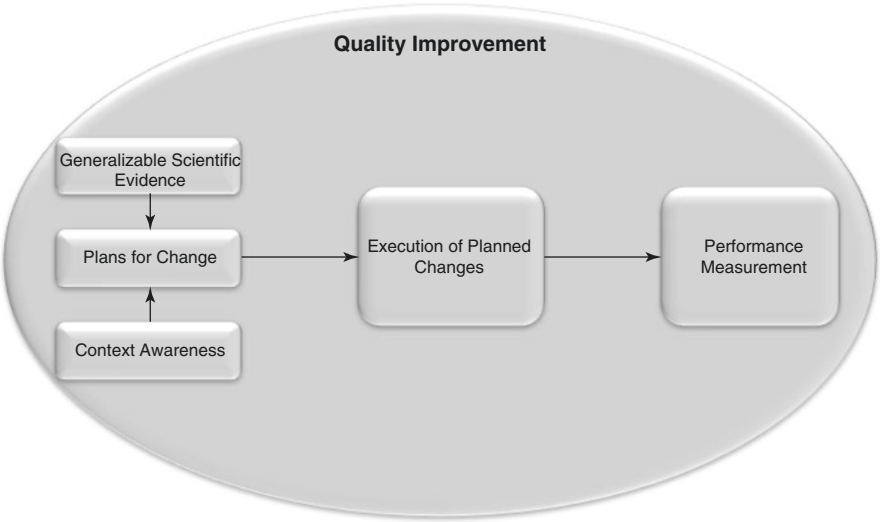

Fig. 2.1 Relationships between the five knowledge systems of QI (adapted from Batalden and Davidoff [1])

means of determining whether or not, or the degree to which, QI efforts are effective at improving targeted outcomes. Effectively measuring quality in healthcare is extraordinarily challenging [9], but progress is being made, and methods are maturing [10]. However, measuring performance alone does not improve performance [11]. Fourth, *plans for change* employs the breadth of systems-based improvement strategies for changing how care is delivered ranging from radical reengineering of systems and technology to training or passive information provision. This knowledge system provides a means to adapt clinical evidence to the local work system—to enable care providers to "do the right thing" (e.g., adhere to clinical guidelines) as reliably as possible. However, designing interventions and system fixes does not improve performance if these changes are not adopted by the organization. Fifth, *execution of planned changes* includes both understanding local barriers and facilitators of change as well as general frameworks for managing change in complex organizations. This knowledge system reviews improvement as organizational change, and as such seeks to connect to the people within a system, understand their perspective, and introduce QI changes consistent with their values and priorities. This is achieved through structured change management approaches.

Structured Approaches to QI in Healthcare

The five knowledge systems of QI in healthcare encompass an impressive breadth of activity. Working within any one of these domains requires deep expertise, and integrating across them truly requires an interdisciplinary team effort. Structured

approaches to conducting QI help these teams navigate this process. These approaches provide a set of conceptual and practical tools or steps that QI teams can follow and help to ensure that each knowledge system is incorporated into the QI effort. Below, we briefly review four structured approaches used in healthcare and discuss how they are related to the five knowledge systems.

Translating Evidence into Practice (TRIP)

Translating evidence into practice (TRIP) is a four-step method including (1) *summarizing the evidence* (i.e., identifying the most effective interventions and converting them in to behavioral specifications at the bedside), (2) *identifying local barriers to implementation* (i.e., employing multiple methods to determine "ground truth" of interventions in practice), (3) measuring performance, and (4) *ensuring all patients receive the interventions* [12]. The fourth step involves a series of activities to *engage* staff (i.e., establish the need and value of the program), *educate* staff on the interventions and evidence behind them, *execute* on the plan through design of an intervention toolkit adapted to local needs, and *evaluate* the impact of the intervention. The TRIP model addresses all five knowledge systems of QI. It provides a high-level framework for navigating the full spectrum of QI activities. Compared to other structured approaches, it places unique emphasis on moving from the available evidence to actionable and usable guidance at the bedside. However, large portions of the clinical care knowledge base are underspecified and will likely remain so for some time [13]. Therefore, not all QI efforts will focus on adopting evidence-based guidelines.

Plan-Do-Study-Act (PDSA) Cycle

PDSA is a widely used approach designed to create rapid cycles of improvement in healthcare through "small tests of change" [14]. Specifically, PDSA application begins with an investigation or framing of the problem followed by (1) *planning* an intervention, implementation, and evaluation; (2) implementing (*doing*) the intervention and evaluation plan; (3) *studying* the effects of the intervention by analyzing the evaluation data; and (4) *acting* based on what was learned (i.e., revisit early phases of PDSA, modify intervention, implement fully, or abandon project). This process allows for moving from general ideas to concrete solutions by rapidly and iteratively generating knowledge about what is working in a given situation as well as how it might be modified to be more effective. While conceptually simple, PDSA is sophisticated and can be challenging to implement [15]. It has become a framework that underlies many QI programs. Because of its emphasis on adapting general ideas or solutions to local contexts and use of measurement and evaluation, PDSA integrates across context awareness, plans for change, and measurement knowledge systems.

Lean Thinking

Lean thinking is a principled problem-solving approach that seeks to reduce waste, synchronize workflows, and optimize efficiency and resource management [16]. The application of lean thinking does not follow a prescriptive set of steps, but is guided by a set of principles outlining how work processes should be designed. Specifically, lean principles emphasize (1) articulating the things that create value from the customer's perspective, (2) identifying all of the steps that lead to this value (i.e., the "value stream"), (3) making those steps across the value stream flow efficiently, (4) producing what the customer "pulls" just in time, and (5) continuously removing waste in work processes [17]. As evidenced by the language of these principles, lean thinking is rooted in manufacturing, specifically the Toyota Motor company following World War II [18]. As such, it does not address the generalizable evidence knowledge system, nor does it address organizational change [19]. However, it is a powerful tool for context awareness (i.e., understanding how local processes work) and planning change (i.e., designing new, more efficient, work processes).

Six Sigma

Six sigma is a quality management approach originally formulated by Bill Smith of Motorola in the mid-1980s. The name six sigma refers to the statistical notion that a process should be designed to result in only 3.4 defects (anything that could result in customer dissatisfaction) per one million opportunities, that is, six sigmas (standard deviations) above the mean of a normally distributed process. The six sigma process is built upon total quality management's plan-do-check-act cycle and is implemented via two specific methodologies. The first, DMAIC, consists of five steps: (1) define the goals of the project and customer deliverables, (2) measure key aspects of the current process, (3) determine the root causes of defects in the current process, (4) improve the process by eliminating these defects, and (5) "control" the process so that any future deviations do not end up in full-fledged defects. The second methodology, define-measure-analyze-design-verify (DMADV), is recommended for use in situations where a new process or product is being developed. Like lean, six sigma does not address the evidence-based or change management-related knowledge systems of QI. However, quantitative data and metrics are at the heart of the approach which aligns six sigma nicely with the measurement knowledge system of QI.

Habits of Quality Improvement

The models and frameworks above are offered as reference points to help navigate the range of QI approaches and activities. There is no one correct way to conduct QI. Different methods can be combined in ways that suit the needs of a given

project. But, the likelihood of success for any QI effort increases with the degree to which the five knowledge systems are employed and integrated. In support of this "full-spectrum" use of QI, Plesk [6] articulates a set of four habits or routine patterns of thought and action in an organization that enable effective QI. First, organizations should cultivate the habit of viewing clinical practice as a complex process that cuts across traditional boundaries of disciplines or physical location. Second, organizations should build a habit of evidence-based practice, seeking to capitalize on the existing knowledge base of what works. Third, organizations should reinforce the habit of collaborative learning, openness, curiosity, and sharing. Fourth, organizations must develop a habit of change. These habits nicely summarize key behaviors for quality improvement. Table 2.1 summarizes these values and specific strategies used to enact them. In the following section, these ideas will be expanded upon and refined by learning from a special class of organizations.

Table 2.1 The habits enabling effective quality improvement in healthcare (Adapted from Plesk [6])

Habit	Definition and supporting practices
View clinical practice as a process	Healthcare outcomes are the product of complex and interdependent work processes. Organizations that are effective at QI can see past an individual- or discipline-focused approach and focus on how work is managed by all staff and how patients and families are involved. A wide range of process description tools can be employed to map and understand work. These include flow charts, hierarchical task analysis, fault trees, failure mode and effects analysis, and work diagrams
Use of evidence-based practice	Much of quality improvement efforts involve moving care delivery processes closer to standards and guidelines of what is known to work. There is a hierarchy of the quantity and quality of evidence available for different practices, and certainly some key decisions must be made in the absence of good evidence. Effective organizations are sensitive to the strength of evidence around their interventions. Guidelines for professional societies and government agencies can help to pull together evidence. Leading practices may be found in systematic reviews and single studies in the academic literature
Learn collaboratively	There will never be a randomized controlled trial for every component of a quality improvement program. Effective organizations are eager to learn from and with others to fill the inevitable gaps in the literature. Internal structures for sharing project status and lessons learned as well as participation in external collaboratives can help to gain practical wisdom to complement evidence-based guidelines
Change mindfully	Any improvement requires something to be done differently. Organizations continuously improving are continuously changing, and change is not easy. Effective organizations have a mindful approach to change that uses a structured approach, attends to pacing (avoiding change fatigue), and is inclusive throughout—conducting change *with* all stakeholders, not *to* them

High-Reliability Organizations

Research exploring organizations that operate in high-risk environments under extreme conditions yet are able to sustain low rates of errors or harm over time offers a great deal of insight for improvement efforts in healthcare. Originally defined by organizational scholars Karlene Roberts, Todd LaPorte, and Gene Rochlin as "high-reliability organizations" (HROs), these organizations, units, and teams master the ability to remain adaptive, anticipate the unexpected, and produce reliably safe outcomes despite significant risk inherent in the work they do and/or the context in which work is done [20]. Subsequently Kathleen Sutcliffe and Karl Weick revealed that these organizations sustained safe outcomes and high performance through processes of collective mindfulness, adaptation, and resilience, what they call mindful organizing [21, 22]. This collective body of evidence reflects much of what is known about HROs, how they organize, how they function, and how they learn. HROs are notable given their capacity to operate in complex, high-risk environments, where the impact of error can be catastrophic; yet they are able to learn from, adapt to, and utilize this complexity to their advantage. Furthermore, these organizations are better able to mitigate major errors through mindful management of near misses, unexpected outcomes, and minor errors. Nuclear submarines [23], the US naval aircraft carrier fleet [20], electrical grid operators [24], wildland firefighting incident command systems, and some healthcare teams [25, 26] are examples of HROs cited in existing literature. These "ultrasafe" groups, teams, and organizations achieve reliably safe outcomes by building the necessary social-relational foundations (e.g., a climate of mutual respect and trust, an understanding of key interdependencies and interconnections), and they actively organize their work with safety in mind [27].

The Pathway to Reliably Safe Outcomes Involves Three Key Components

The pathway to reliably safe outcomes involves (1) practicing the habits of mindful organizing, (2) reliability-enhancing work practices, and (3) actions that enable, enact, and elaborate a culture of safety. Weick and Sutcliffe's theory and research demonstrate that reliable outcomes (e.g., safety, quality) over time are the result of several social and cognitive habits that are focused on (1) uncovering and correcting unintended consequences and (2) adapting appropriately particularly at early stages when the signals foreshadowing an undesirable outcome or incident might be "weak" [21, 28]. These key processes and assumptions help high performers to (1) identify weak signals of the potential for undesirable outcomes early, (2) anticipate the need to adapt their efforts, and (3) recover quickly when the unexpected or unintended outcomes do occur. These processes are referred to as the habits of mindful organizing because they reflect the fact that high reliability is really an

ongoing process of actively organizing for safety, rather than a terminal destination or achievement [27]. Table 2.2 summarizes these key habits and defines them in detail.

These key habits reflect one of the central findings about HROs that initially may seem counterintuitive. While we tend to associate the idea of reliability with the image of highly standardized procedures, routines, or algorithms and think of "high reliability" as synonymous with high levels of compliance, this is not, in fact, the way HROs think about reliability. The underlying theory and the large number of studies examining HROs clearly demonstrate that *reliable outcomes* are actually the product of relatively flexible procedures [21, 28]. The findings underscore that the team members that work in and make up HROs are able to adapt and act in resilient ways that keep relatively minor glitches from turning into major catastrophes. They are able to create reliably safe outcomes because they share habits and mindsets that are vital for detecting and correcting minor unintended issues that can snowball into serious adverse events. In this sense, high reliability is really about creating a sense of collective mindfulness during daily care and mindful approaches to continuous improvement.

Organizations, units, and teams focused solely on efficiency tend to prioritize stability and inflexible routines in order to "get things done." However, the theory and studies of HROs argue that, in reality, there is inherent variation in any standardized routine due to environmental, situational, and social influences that inevitably impact how even the most highly structured routine unfolds at different times across different team members for different patients. Therefore, the idea that reliability is synonymous with inflexible routines and rote compliance with highly prescriptive procedures is erroneous. The lessons from studies of HROs underscore that approaches to improvement that rely highly on re-education on complex, prescriptive routines, standardization of procedures, and scripts are insufficient means of mitigating serious errors [20, 26]. Rather they point to developing and strengthening the habits of mindful organizing outlined in Table 2.3 as critical components of impactful, sustainable improvement in patient safety and care quality.

These habits alone, however, are not the only hallmarks of HROs. Team members must have the resources, as well as both peer and leadership support, to act on the concerns or weak signals in order for mindfulness to translate into reliable, safe outcomes. HROs combine the habits of mindful organizing with organizational practices and structures that support these habits. Selecting and mentoring for interpersonal skills and investing in skill building and training opportunities that foster an orientation toward continuous learning are examples of these "reliability-enhancing work practices" identified by Tim Vogus and Dawn Iacobucci. In their study of over 1600 registered nurses working in 95 nursing units, they found that these work practices were related to significantly fewer medication errors and patient falls [29]. Specifically, they found that these work practices impacted these outcomes by improving the use of some of the key habits listed in Table 2.2.

HROs also develop strong cultures of safety [23] and collective accountability for addressing system issues that contribute to undesirable outcomes [30]. Borrowing from Edgar Schein [31], a leading scholar on organizational culture, patient safety culture refers to one specific aspect of an organization's culture that can be defined as a:

Table 2.2 The habits of highly reliable organizing (adapted from Weick and Sutcliffe [21, 26, 28])

Habit	Definition
Be preoccupied with failure: Do not be tricked into complacency by your success	Errors, glitches, and unexpected circumstances are considered an inevitable component of operations, but they do not have to end with catastrophic outcomes. Pay close attention to weak signals; encourage yourself and others to identify potential symptoms of system malfunctioning early. Approach previous successes and situations or cases that "look just like that previous one" with a healthy dose of skepticism to avoid over confidence and complacency. Invest time and effort in imagining potential mistakes, glitches, or imperfect circumstances. Think about or simulate potential failure pathways to learn about the broad range of "weak signals" that might suggest the potential for an undesirable outcome
Be reluctant to simplify interpretations: Embrace complexity	Preserve details. Openly identify your assumptions, heuristics, categories, and cognitive biases in an effort to limit the tunnel vision unintentionally created by the assumptions and labels we apply in our minds. In negotiations and decisions, focus on points of divergence versus convergence in order to detect anomalies and to elicit unique information
Be sensitive to operations: Be real about what is actually happening, and resist the urge to focus only on information that confirms your hypotheses	Foster a deep situational awareness that reflects objective observations of actual work processes, rather than intentions or formal procedures. "See…what we are actually doing, regardless of what we are supposed to do based on intentions, designs, or plans" (2007, p. 59). Value and evaluate near misses. Do not interpret them as confirmation that that current approaches or operations are sufficient to mitigate error. Near misses are often the result of luck and pure statistical probability. Interpret them as cues indicating potential system failures that need to be addressed in order to prevent complacency
Commit to resilience: Anticipate, but know we cannot anticipate everything; improvisation and action under unexpected circumstances	Accept the inevitability of the unexpected and commit to absorb changes, persist, actively participate in improving the system, and continuously incorporate lessons learned from these inevitable glitches, workarounds, and unintended outcomes. Support creative thinking, improvisation within reason, use of ad hoc networks, and a healthy skepticism about the applicability of past practice to the current scenario
Deference to expertise: Defer to your experts doing the work on the front line	Open traditional hierarchical structures of command and decision-making to all organizational team members, especially during crisis situations. Push decision- making authority down and outward to frontline team members doing the work. Consider how structure and routines may be fluid. Decoupling vital decisions from higher-ranking positions far removed from frontline operations improves the efficiency of critical decisions and expands the variety of expertise available to make sense of cues that might suggest the potential for unintended consequences

(continued)

Table 2.2 (continued)

Habit	Definition
Interact heedfully: Pay attention to what is happening upstream and downstream	Pay attention to interdependencies and interconnections between people, departments, and other organizations where your patients may be receiving care. Help yourself and others to see your work as part of and a critical contribution to the larger shared, collective goals your team, group, or organization is working toward
Foster a climate of trust and respect: Improving the system means listening and learning with humility	Listen humbly and respectfully when others bring forward concerns or "gut feelings" that something may not be right, even if they have difficulty articulating the details. Do not discount disconfirming information or unique information or perspectives that differ from the majority opinion or the perceptions of the majority about a particular situation, patient, loved one, or team member. Share novel or disconfirming information when you have it respectfully.

Table 2.3 Components of the 3 E's model of enabling, enacting, and elaborating a culture of safety (adapted from Vogus, Sutcliffe, Weick [32])

Component	Description
Enabling	Leaders enable safer practices through • Directing attention to safety • Creating contexts where staff feel safe to speak up and act in ways that improve safety
Enacting	Frontline staff enact a safety culture through • Highlighting and accurately representing emerging threats to safety • Mobilize resources to resolve threats
Elaborating	Leaders and staff implement practices that • Rigorously reflect on safety outcomes • Use feedback to modify enabling practices and enacting processes

> …system of [shared knowledge, beliefs,] meaning, and symbols [related to patient safety] that shape how an organization's members interpret their experience and act on an ongoing basis. [32, p. 62]

The related, yet distinct, concept of patient safety climate refers to perceptions of the more observable aspects of culture like patient safety practices, procedures, policies, and the actions of leaders and peers related to patient safety that are shared by members of a given group (e.g., unit, department, profession, or organization) [33]. Culture and climate influence a broad range of issues, including (1) what cues or signals the members of an organization, profession, department, unit, or team view as indicators of potential harm, (2) their willingness to speak up about potential issues or opportunities for improvement (also known as a sense of psychological safety [34]), (3) and their orientation toward improvement of work and motivation to engage in it.

The broad range of evidence examining culture and climate demonstrate that formal and informal leaders play critical roles in shaping them over time [35, 36]. Formal leaders include group members with formal leadership titles, such as supervisors, unit

or department managers, department or committee chairs, medical directors, nursing directors, and administrative executive leaders. Informal leaders refer to group members that may not have formal leadership titles, but hold informal power through seniority, tenure, expertise, or relational trust. As shown in Table 2.3, Tim Vogus' "3 E's" to patient safety culture framework [32] emphasizes that formal and informal leaders can help to enable a strong culture of safety by drawing attention to safety-relevant aspects of their unit, department, or organization's culture. Leaders can direct attention to safety and quality by role modeling and acting in ways that demonstrate that safety comes first in situations where it may compete with other priorities like throughput. Additionally, leaders can direct attention toward safety by actively participating in and investing their time in safety-related activities and discussions with non-leadership team members. They can also enable a strong culture of safety by making it safe to speak up and act and creating or maintaining forums where threats to safety or quality are identified and discussed proactively. These formal and informal leader actions send strong signals about the extent to which safety, quality, and continuous improvement are valued, expected, and rewarded. This sets the tone and begins to establish the context necessary for translating the idea or belief that safety and improvement are important into daily practice.

The framework emphasizes that these enabling conditions are necessary in order for frontline care providers to effectively enact a culture of safety in their daily practice. Specifically, the framework suggests identifying and disclosing glitches, errors, near misses, or undesirable outcomes, as well as problem-solving and mobilizing resources to resolve such issues as key behaviors that reflect safety culture in practice. Finally, the framework underlines that organizations, units, and teams can continue to elaborate and evolve their culture through reflective learning practices, specifically by investing time in constructive reflection on outcomes and near misses and by using feedback or lessons learned from this reflection to modify the enabling practices and enacting processes previously described. Constructive reflection can take many forms, from formal presentations to informal discussions about defect, errors, or undesirable outcomes. Debriefings and after-action reviews [37–39], advanced versions of mortality and morbidity conferences structured as patient-centered learning discussions [40], and the learning from defects process that is part of the Comprehensive Unit-Based Safety Program (CUSP) [41] are all examples of processes and tools that can help facilitate this type of constructive, learning-oriented reflection and the integration of lessons learned.

High Reliability Is a Continual Process of "Actively Organizing for Safety" [27]

Overall, the theory and evidence about HROs teach us that reliably safe outcomes require attention and mindful work. It also underscores that the idea of high reliability is a continuous practice, not something to be achieved or checked off a checklist. There are tools available to help understand where your team or

organization may currently lie in terms of the habits, work practices, and cultural elements that are the hallmarks of HROs. For example, the Safety Organizing Scale [42] and several short self-assessments which appear in the first and second editions of the seminal book on HROs, *Managing the Unexpected* [26], can be useful.

Conclusions

Firm grounding in the theoretical foundations and science of improvement is critical for improvement practitioners. This chapter synthesized core definitions of continuous improvement and described key models of improvement from the patient safety, care quality, and organizational sciences. We also summarized insights from the science concerning high-reliability organizations (HROs) that excel at maintaining extremely low rates of error or harm despite operating in high-risk environments by building strong practices of mindful organizing. We summarized practical principles for high-reliability organizing and what we know from the science about how leaders, both formal and informal, contribute to the context and practice of improvement.

References

1. Batalden PB, Davidoff F. What is "quality improvement" and how can it transform healthcare? Qual Saf Health Care. 2007;16(1):2–3.
2. James BC, Savitz LA. How intermountain trimmed health care costs through robust quality improvement efforts. Health Aff. 2011;30(6):1185–91.
3. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Aff. 2005;24(1):138–50.
4. Schouten LMT, Hulscher MEJL, van Everdingen JJE, Huijsman R, Grol RPTM. Evidence for the impact of quality improvement collaboratives: systematic review. BMJ. 2008;336(7659): 1491–4.
5. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Q. 2010;88(4):500–59.
6. Plsek PE, Blumenthal D, Carlin E, Carlson R, Nordin J, Heckman M, et al. Quality improvement methods in clinical medicine. Pediatrics. 1999;103(1 Suppl E):203–14.
7. Balasubramanian BA, Cohen DJ, Davis MM, Gunn R, Dickinson LM, Miller WL, et al. Learning evaluation: blending quality improvement and implementation research methods to study healthcare innovations. Implement Sci. 2015;10:31.
8. Harvey G, Wensing M. Methods for evaluation of small scale quality improvement projects. Qual Saf Health Care. 2003;12(3):210–4.
9. Jha A, Pronovost P. Toward a safer health care system: the critical need to improve measurement. JAMA. 2016;315:1831.
10. Cohen ME, Liu Y, Ko CY, Hall BL. Improved surgical outcomes for ACS NSQIP hospitals over time: evaluation of hospital cohorts with up to 8 years of participation. Ann Surg. 2016;263(2):267–73.
11. Berwick DM. Measuring surgical outcomes for improvement: was Codman wrong? JAMA. 2015;313(5):469–70.

12. Pronovost PJ, Berenholtz SM, Needham DM. Translating evidence into practice: a model for large scale knowledge translation. BMJ. 2008;337:a1714.
13. Rosen MA, Pronovost PJ. Advancing the use of checklists for evaluating performance in health care. Acad Med. 2014;89(7):963–5.
14. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. BMJ Qual Saf. 2014;23(4):290–8.
15. Reed JE, Card AJ. The problem with plan-do-study-act cycles. BMJ Qual Saf. 2016;25(3):147–52.
16. Wickramasinghe N, Al-Hakim L, Gonzalez C, Tan J. Lean thinking for healthcare. New York, NY: Springer; 2014.
17. Womack JP, Jones DT. Lean thinking: banish waste and create wealth in your corporation. New York, NY: Simon and Schuster; 2010.
18. Ohno T. Toyota production system: beyond large-scale production. Portland, OR: Productivity, Inc.; 1988.
19. Andersen H, Røvik KA, Ingebrigtsen T. Lean thinking in hospitals: is there a cure for the absence of evidence? a systematic review of reviews. BMJ Open. 2014;4(1):e003873.
20. Rochlin GI, LaPorte TR, Roberts KH. The self-designing high-reliability organization: aircraft carrier flight operations at sea. Nav War Coll Rev. 1987;(Autum):76–90.
21. Weick KE, Sutcliffe KM, Obstfeld D. Organizing for high reliability: processes of collective mindfulness. In: Sutton RS, Staw BM, editors. Research in organizational behavior, vol. 1. Greenwich, CT: JAI Press; 1990. p. 81–123.
22. Sutcliffe KM. High reliability organizations (HROs). Best Pract Res Clin Anaesthesiol. 2011;25(2):133–44.
23. Bierly PE. Culture and high reliability organizations: the case of the nuclear submarine. J Manage. 1995;21(4):639–56.
24. Christianson MK, Sutcliffe KM, Miller MA, Iwashyna TJ. Becoming a high reliability organization. Crit Care. 2011 Jan;15(6):314.
25. Edmondson AC. Learning from failure in health care: frequent opportunities, pervasive barriers. Qual Saf Health Care. 2004;13(Suppl 2):ii3–9.
26. Weick KE, Sutcliffe KM. Managing the unexpected. 2nd ed. San Francisco, CA: Jossey-Bass; 2007.
27. Sutcliffe KM, Paine L, Pronovost PJ. Re-examining high reliability: actively organising for safety. BMJ Qual Saf. 2016;26(3):248–251.
28. Weick KE, Sutcliffe KM. Managing the unexpected. 3rd ed. Hoboken, NJ: Wiley; 2015.
29. Vogus TJ, Iacobucci D. Creating highly reliable health care: how reliability-enhancing work practices affect patient safety in hospitals. ILR Rev. 2016;7:0019793916642759.
30. Weaver SJ, Che X-X, Pronovost PJ, Goeschel CA, Kosel KC, Rosen MA. Improving patient safety and care quality: a multiteam system perspective. InPushing the boundaries: Multiteam systems in research and practice 2014 Sep; 24 (pp. 35–60). Emerald Group Publishing Limited.
31. Schein EH. Organizational culture and leadership. 4th ed. Hoboken, NJ: Jossey-Bass; 2010.
32. Vogus TJ, Sutcliffe KM, Weick KE. Doing no harm: enabling, enacting, and elaborating a culture of safety in health care. Acad Manag Perspect. 2010;24:60–77.
33. Zohar D, Luria G. A multilevel model of safety climate: cross-level relationships between organization and group-level climates. J Appl Psychol. 2005;90(4):616–28.
34. Nembhard IM, Edmondson ACMYC. Making it safe: the effects of leader inclusiveness and professional status on psychological safety and improvement efforts in health care teams. J Organ Behav. 2006;27(7):941–66.
35. Zohar D. Thirty years of safety climate research: reflections and future directions. Accid Anal Prev. 2010;42(5):1517–22.
36. Weaver SJ, Lubomksi LH, Wilson RRF, Pfoh ER, Martinez KA, Dy SM, et al. Promoting a culture of safety as a patient safety strategy: a systematic review. Ann Intern Med. 2013;158(5 Pt 2):369–74.

37. Paull DE, Mazzia LM, Wood SD, Theis MS, Robinson LD, Carney B, et al. Briefing guide study: preoperative briefing and postoperative debriefing checklists in the veterans health administration medical team training program. Am J Surg. 2010;200(5):620–3.
38. Vashdi DR, Bamberger PA, Erez M, Weiss-Meilik A. Briefing-debriefing: using a reflexive organizational learning model from the military to enhance the performance of surgical teams. Hum Resour Manag. 2007;46(1):115–42.
39. Makary MA, Mukherjee A, Sexton JB, Syin D, Goodrich E, Hartmann E, et al. Operating room briefings and wrong-site surgery. J Am Coll Surg. 2007;204(2):236–43.
40. Berenholtz SM, Hartsell TL, Pronovost PJ. Learning from defects to enhance morbidity and mortality conferences. Am J Med Qual. 2009;24(3):192–5.
41. Agency for Healthcare Research and Quality. AHRQ CUSP Toolkit: Learn from Defects Tool [Internet]. 2012 [cited 2016 Mar 1]. Available from: http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/toolkit/learndefects.html.
42. Vogus TJ, Sutcliffe KM. The safety organizing scale: development and validation of a behavioral measure of safety culture in hospital nursing units. Med Care. 2007;45(1):46–54.