3 Creation of Quality Management Systems: Frameworks for Performance Excellence

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Chapter Objectives

- Understand the process of evaluating and improving your organization's Quality Management System (QMS).
- Define the holistic structure needed for a highly reliable Quality Management System.
- Appreciate how a Quality Management System promotes quality improvement.
- Assess how accreditation requirements and oversight ensure a proper Quality Management System is functional within your organization.
- Learn how to use the Quality Management System to foster a culture of quality improvement and safety at all levels of the organization.

Introduction

In the current healthcare environment, creating value for the patient while providing safe, high-quality care is paramount. Listening to patients and families is essential to ensuring a positive experience. As innovative payment methodologies emerge, the quality of care is even more important at the system level. For hospitals, whether freestanding or system-based, to remain competitive and continue to provide excellent care, a mature structure for a Quality Management System (QMS) must be in place.

Vignette 3.1

Great Care Hospital (GCH) recently hired a new CEO, Dr. Maggie Improverson. Her

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experience at other hospitals included a distinct focus on quality and safety. The first order of business was to assess the state of the safety and quality of care within GCH. As leaders at Great Care Hospital (GCH) progressed through their quality journey, they often heard one common theme: "Our operations and work on quality improvement are functioning in siloes. No one works together, and our objectives are never defined." A large amount of staff time and effort was being put into quality improvement and safety projects, but the organization's results were not changing for the better, leading to staff and leadership frustration. Leadership was concerned that engagement would fall, and care would become less and less safe. Given this situation, the leaders at GCH decided to focus on how they currently managed overall quality and safety at their hospital and started the process of changing the structure and culture of improvement.

After assessing the situation at GCH, Dr. Improverson took a multi-faceted approach to build the structure and processes necessary to ensure safe, high-quality care. First, it was important that the organization understood the history of Quality Management Systems. W. Edwards Deming helped set many of the standards and approaches to quality management, called Total Quality Management (TQM), that continue to thread through our practices in healthcare quality improvement. Deming's landmark book, *Out of the Crisis* [1] published in 1982, quickly became a foundational guide to performance improvement. Principles such as those embodied in his 14 Points for Management were adapted for healthcare by Lighter in the text *Principles and Methods of Quality Management in Health Care* [2] and are summarized below in Key Point Box 3.1.

Key Point Box 3.1 Deming's 14 Points for Management Adapted for Healthcare

1. Stay in business.
2. Adapt to the new economic age.
3. Eliminate the need for inspection.
4. Reward quality.
5. Improve constantly.
6. Institute on-the-job training.
7. Help people and machines do a better job.
8. Drive out fear.
9. Break down barriers.
10. Eliminate slogans, quotas, and management by objective.
11. Restore pride in workmanship for hourly workers.
12. Restore pride in workmanship for managers.
13. Institute education and self-improvement.
14. Make quality everyone's job.

1. Stay in business – Healthcare leaders must understand customers' value proposition and respond accordingly if they want to remain in business. Interestingly, Deming included the provision "to provide jobs," which perhaps can be translated in the healthcare industry as an admonition to ensure products and services are tailored to the marketplace to make sure that workers are practicing "at the top of their licenses."
2. Adapt to the new economic age – In short, change is inevitable, and leaders will find it fruitless to resist the changes that are affecting healthcare today. Not only must leaders cope with the change, but they must, in turn, encourage staff and co-workers to find ways to innovate solutions, thus ensuring that an organization thrives in the new business environment.
3. Eliminate the need for inspection - Healthcare is probably one of the most heavily regulated and inspected industries except perhaps the nuclear power industry. Myriad organizations like The Joint Commission (TJC), DNV GL, Centers for Medicare and Medicaid Services (CMS), the National Committee on Quality Assurance (NCQA), the Utilization Review Accreditation Commission (URAC), and others oversee

hospital, medical practice, and payer operations to ensure compliance to standards and a baseline level of quality. In spite of all of this oversight, US healthcare continues to face challenges in performance compared with similar countries around the world [3]; similar to Great Care Hospital, performance improvement has not been integrated into operations to ensure that quality outcomes are the norm.

4. Reward quality – Hospitals, physicians, and payers must learn to be both trusted vendors as well as find suppliers with whom to build trusting relationships. The healthcare industry is moving in this direction, with value-based purchasing pushing providers to ensure quality performance. Great Care Hospital spends substantial resources on quality of services, however, has been unable to "move the needle" to achieve the next level of performance and create the trust relationship that ensures its customers are engaged with the institution.
5. Improve constantly – Deming was particularly prescient with this recommendation, and the principle behind the advice has been demonstrated in numerous industries besides healthcare. For example, automotive safety has benefited immensely from adopting technology to reduce the chance for errors, and these trends have been observed throughout the world as a significant differentiator among automobile brands [4]. Similarly, healthcare organizations like the Henry Ford Health System in Detroit have used patient safety as a key way to distinguish themselves in the marketplace, providing safety data on their website and making patient safety their priority [5]. The philosophy of continuous quality improvement constantly reinforced by leaders can lead to superior performance in providing safe care to customers.
6. Institute on-the-job training – Healthcare workers are accustomed to the need for continuing education requirements to maintain certifications and licensure, but on the job (OTJ) training goes beyond the occasional in-service or medical conference. Continuous improvement demands continuous learning, and that learning needs to be shared with everyone associated with processes that impact performance. Rather than waiting to convey new knowledge at the next departmental meeting, methods of distributing new ways of improving a process through regular daily communications, such as lean huddles or person-to-person communications, have to be created.
7. Help people and machines do a better job – Just as point 6 demands the institution of OTJ training, this point stresses that leaders must find ways of continually enhancing the interface between people and the machines used to deliver services. In today's healthcare environment, human factors design is becoming more germane to the elimination of errors and increasing safe behavior. The goal of human factors design is to "mistake proof" equipment and processes, creating a system that supports the safety of the patient and staff.
8. Drive out fear – The use of fear as a motivating factor in healthcare organizations has long been recognized as being ineffective. The days of the domineering surgeon who throws instruments and berates staff when problems arise are behind us, and the use of approaches such as Crew Resource Management and Just Culture have helped normalize behavior in healthcare institutions.
9. Break down barriers – This principle may be one of the major impediments to continuous improvement at Great Care Hospital. One of the crucial requirements of leadership is the ability to identify and then demolish barriers to effective communication and collaborative work. The senior staff at GCH likely will need to spend a great deal of time finding those processes that compete between departments and work to align the work of these departments to achieve synergy.
10. Eliminate slogans, quotas, and management by objective – The key message is that leaders should focus on the system as the arbiter of poor performance, rather than the workforce. In nearly every situation where performance lags, system and process design are

flawed, and the workforce is trying to make the poor process work. Staff members frequently find "workarounds" to compensate for the defective process until leaders listen to workers and find ways of redesigning the process. Slogans, exhortations, quotas, and numeric targets can never counteract an inadequate process.

11. Restore pride of workmanship for hourly workers – How often does one hear healthcare workers, including physicians and other caregivers, complain that "all we do is move numbers through the system"? Giving frontline caregivers that opportunity to enjoy their work, realize the good they're doing for the people for whom they provide care, and be appreciated for a successful care intervention, will reinforce the reasons that many of these professionals chose healthcare as a career and will lead to higher productivity and work satisfaction.
12. Restore pride of workmanship for managers – Managers, too, need reinforcement for a job well done. Relieving the concentration on goals and targets as the sole motivating factors and finding approaches and measures that enhance customer engagement and satisfaction, then linking those customer parameters to managers' recognition, can help managers regain a sense of purpose that often is the motivator to growth in leadership positions.
13. Institute education and self-improvement – "Everyone in the organization should enjoy a sense of wellness, and programs that encourage self-improvement through training and education programs have the potential of raising morale and worker engagement". For organizations like GCH, lack of worker engagement can lead to poor performance, and lack of engagement will impact commitment to change and improvement.
14. Make quality everyone's job – When the focus of a healthcare organization becomes excellent patient care, rather than just budgets and volume, customers will feel the difference and become engaged with the organization. Workers will similarly feel that coming to work is something that is fulfilling, leading to improved performance and collective success.

For organizations, like GCH that has stalled in its quality journey, Deming has some important ideas. First is the idea of a transformation. Dr. Improverson will be leading GCH on a journey to higher quality and greater safety through cultural and structural change. As the journey progresses, GCH will be able to set the foundation for future innovation and sustainable change. To promote this journey, it must be understood that incremental changes are unlikely to motivate staff to engage in moving the hospital to the next level of performance. The transformation is driven from the top, i.e., leaders must support the change with plans and resources that identify performance factors and delineate approaches to evaluating, measuring, analyzing, improving, and sustaining new processes to take the organization to a higher level of customer satisfaction and economic achievement. Leaders need to make the transformation part of everyone's job, not just use catch phrases and slogans. Leaders need to ensure that workers and managers "own" the change and take credit for the improvements. GCH's leaders will need to create a new work environment in which all these factors are addressed effectively. How can that happen? As we work through this chapter, we will see the path taken by Dr. Improverson.

High Reliability Organizations

Vignette 3.2

GCH has started examining the principles that will guide the hospital to higher performance. We have seen that Dr. Improverson has educated the staff on Deming's underlying principles of high performance. In addition, Dr. Improverson wants to instill the principles that will allow the organization to become aware of possible errors that could occur as well as ensure that the staff

and Quality Management System are resilient if an error should occur. To accomplish this, she has introduced the concept of high reliability. She has put in place principles that ensure GCH does the right thing every time and that safety and quality principles are applied by all frontline staff.

GCH wants to become a high reliability organization (HRO). This term has become a buzzword in the healthcare industry. It was first coined by Weick and Sutcliffe in 2007 in their book *Managing the Unexpected* [6]. The authors studied diverse businesses that must maintain structure and function in uncertain situations where there is a constant potential for error that can have disastrous consequences. They found that successful organizations used "mindful organizing," expressed in a set of five principles, three principles of anticipation, and two of containment (Table 3.1). Organizations that observe these principles experience fewer accidents despite their complexity of operations because that complexity becomes more understandable and thus manageable. People in these organizations focus both on performance-sustaining processes and increased efficiency, allowing them to not only catch errors early but also to use fewer resources to fix them [6]. Industries that are often mentioned as examples of HROs include aviation, nuclear power plants, and submarines but could certainly also include space travel or the Disney theme parks.

Table 3.1 High reliability principles

Anticipation	
Preoccupation with failure	Regarding small, inconsequential errors or deviations from the norm as a symptom that something is wrong Refusing to "normalize," i.e., getting used to small deviations Absence of errors does not mean lower vigilance or complacency
Sensitivity to operations	Paying attention to what's happening on the frontline Make sure that people understand the impact of their work on the larger group Situational awareness
Reluctance to simplify	Encouraging diversity in experience, perspective, and opinion Respect and value the skeptics
Containment	
Commitment to resilience	Developing capabilities to detect, contain, and bounce-back from events that do occur Learn from mistakes
Deference to expertise	Pushing decision making down and around to the person with the most related knowledge and expertise Encourage people to ask for help

There are many examples from other industries that detail failures in safety systems that led to catastrophic events. While it may seem that these events are unrelated to healthcare, by examining the underlying causes and failures, the similarities become clearer. A case in point was the January 28, 1986, explosion of the Space Shuttle Challenger. Given past launch pad explosions and other space-related events, the space program, in general, has been associated with high-risk/increased safety scenarios. Nevertheless, the Challenger broke apart 2 minutes into its tenth mission due to a failure of an O-ring in one of the rocket boosters. The failure was discovered after an extensive root cause analysis, and one of the major enabling factors was a culture of complacency and reluctance to speak up.

How does this apply to healthcare? Healthcare experts have tried to use parallels to these industries and apply them to the complex environment of caring for a vulnerable population, our patients. In healthcare, root cause analyses, hallmarks of high reliability organizations, are also performed to investigate potential serious safety events. One of the reasons people resist these comparisons is the oft-cited comment: "People are not widgets", patients and their diseases have much more variability than airplanes, rockets, or submarines. This has made the implementation of HRO principles in healthcare a challenge, but nonetheless very important within the quality journey.

When the principles of HRO are appropriately translated into the vocabulary of healthcare, it becomes clear that this framework, in fact, very much applies [7]. The goal, after all, is to identify

problems before they occur. Let us take the five tenets of the HRO approach and apply them to the healthcare sector (Table 3.1).

Preoccupation with Failure

We know that errors, mishaps, or even disasters can happen at any time. Ideally, we prevent issues from happening by thinking through the "what if" scenarios ahead of time. For example, when we were preparing for potential Ebola patients, we simulated and repeatedly trained, always thinking of the "what ifs." When a new unit or a new hospital is opened, hopefully, as Failure Mode, Effects, and Criticality Analysis (FMECA) has been conducted ahead of time (see Key Point Box 3.2) However, sometimes, we become aware of the risk through a report of a near-miss or "good catch" event that needs to be taken as seriously as an event that did reach the patient.

Key Point Box 3.2 Failure Mode, Effects, and Criticality Analysis (FMECA)

FMECA are methods designed to identify potential "failures" in a process before they occur. After mapping the process, a brainstorming team will assess the process and identify the steps in the process that may be high risk and be susceptible to failures. Each gap is rated using a scoring methodology that looks at occurrence rate and severity of risk. Example: a hospital performed an FMECA to identify areas of risk during an Emergency Department lockdown procedure.

Small signals may indicate future problems. When organizations analyze safety events, they classify them based on the severity of impact to the patient and the timeframe in which they were identified. For example, near-miss events are events that are identified and stopped before they reach the patient. In an HRO, near-miss events are of the utmost importance, as they identify ways in which errors were prevented from reaching and/or harming the patient. Please see Key Point Box 3.3 for more information on the event classification system many organizations use.

Key Point Box 3.3

Near-Miss Event: An event that does not reach the patient and causes no detectible harm

Precursor Safety Event: An event that reaches the patient but only causes mild or no detectable harm and that has the capacity to harm the next time it occurs

Serious Safety Event: An event that reaches the patient and causes moderate to severe harm

Vignette 3.4

To explain this important topic, Dr. Improverson used a recent, real event that happened at another hospital:

A patient received vecuronium, a paralytic agent, instead of versed, an anxiolytic and sedative agent without paralytic properties, and later died. The investigation found that the nurse overrode the Pyxis machine and pulled the wrong medication. But: (1) she was not the regular nurse for this patient; (2) to find versed in the Pyxis machine, she typed in "VE," and the first drug that appeared was vecuronium; (3) double-check of medication was not performed; (4) patient was not monitored in radiology unit; (5) why would vecuronium even be stored in a Pyxis machine on a step-down unit? This nurse is now accused of murder, but there are so many system issues involved that just blaming one person is over-simplifying the events.

Sensitivity to Operations

The earliest indicators of threats typically appear in small changes in organizational operations. These observations, most often by frontline workers, are important signals and, if acted upon, can help avoid the emergence of more widespread problems.

Reluctance to Simplify

Anyone who has ever participated in a root cause analysis (RCA) has realized that the first (and most obvious) answer is never the full explanation for what happened. It is recommended to ask at least five times "why" to get deeper and deeper into the multitude of events that contributed to the failure or error. Remember the Swiss cheese model, where several holes need to line up for an error to make it through the whole "cheese" [8]. It takes many holes that just by chance line up for an error to make it through all the safeguards.

Vignette 3.3

To help staff understand how important the recognition of safety events is and how even apparently unrelated or isolated incidences can lead to major problems, Dr. Improverson used a couple of recent issues that happened at GCH:

1. One patient with *C. difficile* infection? This can easily spread to a whole unit!
2. An infusion pump showed frequent occlusion alerts. Fortunately, several nurses reported this and a design flaw with these brands of pumps was found.

She was able to show with these examples that healthcare is not a static environment and those new threats can occur at any time. All staff must think about potential risks even in their daily routine work. She emphasized that complacency is a threat to safety and that highly reliable hospitals are always aware that they are operating in a high-risk environment and that there is no "routine day."

Commitment to Resilience

Despite our best efforts and past successes, errors will occur, and safety will be threatened; HROs learn from mistakes instead of being paralyzed by them. Events like the one described above will shake an organization to its foundations but will hopefully also lead to many new improvements at that organization and throughout the healthcare industry.

A promising movement is to learn not only from mistakes but also to adopt practices from areas where things go right. This is called the Safety II approach, compared to Safety I (learning from past mistakes) [9]. See Chap. 12 Safety II for more details.

Deference to Expertise

Highly reliable organizations identify the person with the greatest expertise, instead of expecting the most senior person to come up with answers, when addressing issues. To take full advantage of the existing expertise, a hospital or other healthcare environment needs to have a culture where everyone is able and willing to speak up, is feeling respected, and is commended for their input.

Now that Dr. Improverson has instilled the foundational principles of high reliability, she must assess the organization's current state as it relates to the implementation of a full Quality Management System. To accomplish this, senior leaders will have to provide structural support and resources to properly develop and maintain the QMS. A large part of the foundational support for the QMS is via accreditation processes. As Dr. Improverson evaluates her organization, she must assess if the current accreditation agency and related processes are meeting GCH's needs.

Regulatory and Accreditation Requirements

Hospital accreditation is a voluntary process. However, in order to be able to participate in federal programs and bill Medicare and Medicaid for

services provided, hospitals and other healthcare entities must ultimately be accredited by the Centers of for Medicare and Medicaid Services (CMS) or one of the organizations that were given the authority to do so on behalf of CMS (called deemed authority) [10]. Accreditation provides an acknowledgment that the organization is committed to patient safety and quality of care and strives for continuous quality improvement. There is evidence that the quality of care and patient satisfaction scores are higher in accredited hospitals [11]. Since federal payers cover so many patients, about 75% of all hospitals in the United States have decided to become accredited.

Only accrediting organizations that adhere to the Conditions of Participation (CoP) and the Interpretive Guidelines (IG), the CMS manual, will be approved as having deeming authority through CMS. Accreditation can be obtained directly through CMS or its state agency, but very few organizations choose this pathway. There is ongoing controversy whether organizations with deeming authority are thorough and rigorous enough to satisfy CMS standards, and CMS regularly conducts validation surveys to verify the accuracy of the other organizations' findings.

The Joint Commission (TJC) is the largest accrediting body, focusing mostly on hospitals, including children's and adult hospitals, acute and long-term care, as well as psychiatric hospitals, rehabilitation and specialty hospitals, surgery centers, and home health agencies. It received deeming authority in 1966 from CMS. It is constantly revising and updating its processes. In 2003 TJC started to include the National Patient Safety Goals, and in 2017 it introduced a new scoring grid that visually depicts the severity of the findings, the Survey Analysis for Evaluating Risk™ (SAFER™) matrix [12]. The SAFER™ matrix evaluates the likelihood for harm (low-moderate-high on the y-axis) against the prevalence of the finding (limited-pattern-widespread on the x-axis).

DNV GL received deeming authority for hospitals from CMS in 2008 and is accrediting a growing number of hospitals in the United States and internationally. Dr. Improverson, upon assessment of the current accrediting body for GCH, realized that merging the requirements of accreditation (through an organization such as DNV GL) with the structural benefits of QMS could greatly benefit GCH. From her experience, Dr. Improverson knows that structural criteria like those set forth in ISO 9001:2015 would additionally benefit their journey.

ISO 9001: 2015

Vignette 3.5

Upon her review of GCH's current QMS structure, Dr. Improverson noticed that she was not being made aware of concerns and risks within the hospitals in a timely manner. Also, she was not given regular updates on progress. Dr. Improverson saw the need to restructure the sharing of this information, as she would need to give regular updates to the Board on major objectives and initiatives across the hospital. She planned to look at ways to set forth the necessary institutional structures to accomplish better communication and strategic planning. She decided to start the integration of ISO 9001:2015 principles in the organization. She also knew that this could be linked to the accreditation process in the future and would lead to better integration of strategy and outcomes. One such accrediting body, DNV GL, links CMS requirements to ISO 9001: 2015 standards. This seemed like a great opportunity for GCH.

As GCH builds its QMS, there are certain structural criteria that are useful to follow. One such set of criteria are the ISO 9001: 2015 standard. Within an organization like GCH, that is restructuring and improving its Quality Management System, these structures are essential. Thus, the leaders of the hospital invested in training and resources to build this structure. Also, ISO 9001-2015 sets forth recommendations for how GCH hospital can set up committee

structures and senior leadership oversight to guide the strategic implementation of the QMS.

The International Organization for Standardization (ISO), an independent, non-governmental international organization, was created over 70 years ago to ensure that products and services are safe, reliable, and of good quality (https://www.iso.org/about-us.html) [13]. ISO standards provide a basic model for a Quality Management System for any industry and are updated regularly. The most current version is ISO 9001:2015. Although healthcare was late to adopt these standards, its use has become increasingly more common, and accreditation agencies such as DNV GL have made adherence to ISO 9001:2015 an integral part of their process.

ISO 9001:2015 is not prescriptive and can easily be combined with other quality management approaches, such as Lean and Six Sigma, the Toyota Production System, or the Malcolm Baldrige National Quality Award criteria. The Baldrige Award and ISO focus on leadership, strategy, customers and markets, as well as the workforce, process management, and results while assessing for continuous improvement, innovation, and agility. A commonly used tool in ISO is the Plan-Do-Study-Act (PDSA) approach.

Having a QMS focuses the organization on what is important and helps make regulatory compliance more achievable. Furthermore, regulatory standards often have not addressed basic management needs such as continual improvement, control of documented information, calibration of medical equipment, process-based internal audits/surveys, corrective action, and risk assessment. Coupling regulatory requirements with ISO 9001: 2015 addresses these needs.

ISO 9001:2015 has seven key tenets: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management [14]. As can be seen in Fig. 3.1, the ISO principles help guide the QMS. In addition, we can see that the ISO principles also embody several of Deming's principles.

ISO 9001: 2015 presents criteria, organized into "clauses," very similar to the criteria used in the Baldrige framework (see below). The most germane to QMS are:

Fig. 3.1 ISO 9001: 2015 principles

- Clause 5: Leadership (organizational commitment and oversight)
- Clause 6: Planning (addressing risk, risk-based thinking)
- Clause 7: Support (resources, competency training, document control)
- Clause 8: Operation (products and services, supply chain/management)
- Clause 9: Performance Evaluation (how are we doing, problem identification)
- Clause 10: Improvement (corrective action, continual improvement)

To be compliant with ISO 9001:2015, the hospital must demonstrate its ability to provide products and services that meet customer and regulatory requirements [15]. This starts with understanding what the strengths (and weaknesses) of the organization and the requirements of the stakeholders are. However, it also sets limits: QMS cannot over-reach and thus must have boundaries to ensure proper scope [14, 15].

ISO 9001:2015 (like other quality management systems) puts a heavy emphasis on leadership. Top management, including the Board, is not only ultimately responsible for the quality of care, but they are instrumental in assuring the success of the QMS. They must set directions and develop strategies to achieve the goals and objectives of the organization. Healthcare operations are complex, and many processes are dependent on each other. Standardization or at least harmonization among different areas is key to an efficient and smooth process. ISO ensures that the organization embodies a process orientation, focusing on inputs, process steps, and outputs of the process. Key elements include items such as resources, physical environment/facilities, and core competency (via job description and training processes) and policy requirements.

ISO 9001:2015 requires the organization to define and manage its risks associated with clinical service provision, including resources, equipment, and infrastructure. This includes both pro-active and retroactive evaluations, some of them very familiar in the healthcare environment including root cause analyses (RCA), Failure Mode, Effects and Criticality Analysis (FMECA), emergency preparedness, and others. Action plans and improvement process prioritization within the organization is based on the risk orientation of the process.

Baldrige Performance Excellence Award

Vignette 3.6

As GCH has matured in their QMS journey, they have set themselves up to begin the "Baldrige Journey." Baldrige is the preeminent award for quality and safety in the United States. The tenets of QMS and ISO 9001: 2015 lend themselves nicely to the criteria for the Baldrige Award (discussed below).

The Malcolm Baldrige National Quality Award program was founded in 1987 when Secretary of Commerce Malcolm Baldrige observed that US companies were failing in their efforts to compete internationally. Baldrige focused the Department of Commerce on stimulating US industry to apply "quality control" to their enterprises to lower costs and improve competitiveness. Section 2(a)8(A) of the law states, "[the act helps quality and productivity by] helping to stimulate American companies to improve quality and productivity for the pride of recognition while obtaining a competitive edge through increased profits," and subsection (B) goes on to say, "recognizing the achievements of those companies which improve the quality of their goods and services and providing an example to others" [16].

The Baldrige award was codified by law not just to enhance business productivity and profitability but also to recognize those companies through the award process that provide an example for others to follow their lead. This dual purpose has guided the program since 1987 with demonstrated success at changing several business sectors in the United States. Criteria were developed initially for manufacturing companies, but over the years, new sectors were added,

including healthcare in 2000, and the healthcare sector has become one of the most active in adopting the framework and competing for the award.

The framework consists of seven categories, each of which has several levels of criteria that do not serve as standards but rather ask "how" questions about an organization's structure, functions, and results. We will examine these areas in more detail, but first let us understand the foundation of the criteria, i.e., the Baldrige Core Values (Table 3.2). The Baldrige Framework is contained in a comprehensive booklet with updates every 2 years and is available for purchase at https://www.nist.gov/baldrige/products-services/baldrige-excellence-framework [17].

The Framework starts by requiring the creation of an organizational profile (OP) that delves deep into the enterprise structure and relationships (Table 3.2). In some cases, creating the OP provides leaders and managers with an understanding of their organization that has eluded them in the past. The Baldrige Core Value of "Systems Perspective" requires everyone in the organization, but particularly leaders and managers, to have an understanding of how work systems are created and interact so that they understand the overall system, rather than the little piece of the system with which they are engaged. The OP provides that overview that is hard to achieve in any other way. The OP serves as the organizing resource for all of the rest of the Baldrige Framework and Criteria. Each Category of the framework must relate to one of the components of the OP, or the systems concept cannot be achieved. Table 3.2 lists the elements of the OP, which provide that comprehensive view of the organization and help connect processes and work systems for improvement.

As the starting point of the Baldrige Journey, the OP forms the foundation of responses to the framework criteria. Criteria are written at three levels:

1. *Basic items* – the titles for each item.
2. *Overall items* – questions in boldface in the criteria booklet; these questions are the subject headings for the multiple items that summarize the multiple questions.

Table 3.2 Baldrige organizational profile

P.1: Organizational description	*Organizational environment* Healthcare service offerings Mission, vision, values, culture Workforce profile Assets (facilities, equipment, intellectual property) Regulatory environment
	Organizational relationships Organizational structure, including governance Patients, other customers, stakeholders Suppliers, partners, collaborators
P.2 Organizational situation	*Competitive environment* Competitive position Competitiveness changes Comparative data
	Strategic context Strategic challenges and advantages
	Performance improvement systems

3. *Multiple items* – the specific questions to address that get into the detail of the item.

Most organizations will focus on multiple items, but some will find it difficult to respond to these very detailed questions. Usually, less mature organizations find it difficult to respond to questions at multiple levels, which is one way to identify opportunities for improvement (OFIs). If a question in the multiple items appears to be relevant, but there is no apparent approach to address the question, then the organization has an OFI that requires an intervention.

Additionally, the Baldrige Framework uses a mnemonic to gauge the effectiveness of a work process or work system – ADLI:

- A*pproach* – methods the organization uses to address a process, e.g., a process outline or description
- D*eployment* – the extent and effectiveness that the approach is applied throughout the organization
- *Learning* – collection and analysis of data and experience from the day-to-day operation of the process to improve the process and other similar processes throughout the enterprise

- I*ntegration* – synchronization of all the elements and measures supporting process to achieve overall organizational goals

ADLI is a method of evaluating organizational effectiveness and maturity. Almost every organization has approaches for key processes, so the next level of maturity involves the extent of deployment of the approaches throughout the organization. Next, the question arises about whether the organization collects data about the operation of the process, i.e., how is the approach working? Finally, the highest level of maturity of application of the Baldrige Framework depends on how well the organization extends these approaches, deployment, and learning to all organizational processes. Integration indicates that the organization's processes are all working together to achieve strategic objectives.

Does that sound like GCH? Analysis of the work systems at GCH will likely reveal that there are several approaches, but deployment, learning, and integration are lacking – all leading to significant opportunities for improvements for leaders, managers, and the workforce. So, what can the hospital do?

Many healthcare enterprises have adopted the Baldrige Framework as the organizing approach for achieving the transformation that Deming recommends. The Framework promotes analysis of organizational processes using the Multiple Criteria and ADLI to assess the efficiency and effectiveness of the organization's work. The Framework is briefly outlined in Table 3.3, and we'll discuss some of the key elements that apply to healthcare entities like GCH.

Category 1, Leadership, is probably the crucial opportunity for improvement for Great Care

Table 3.3 Baldrige categories

Category 1	Leadership	Setting vision and values Promoting legal and ethical behavior Communication and engagement of the workforce, key partners and customers, patients Creating an environment for success Creating a focus on action
	Governance	Responsible governance system Performance evaluation of leaders and governance Legal/regulatory compliance Management of ethical behavior Societal contributions – societal well-being and community support
Category 2	Strategy development	Strategy development process Innovation Data analysis and decision support Work systems and core competencies Strategic objectives – balancing objectives among stakeholders
	Strategy implementation	Action plan creation, implementation, modification Resource allocation Workforce plans Performance measures Performance projections
Category 3	Customer expectations	Listening and learning from current and potential customers Market segmentation Healthcare service offerings
	Customer engagement	Relationship management Customer support and access Complaint management Satisfaction, dissatisfaction, engagement Use of voice of the customer data and market data

Table 3.3 (continued)

Category 4	Measurement, analysis, improvement	Performance measure data tracking Comparative data Measurement agility Organizational performance review Projection of future performance Continuous improvement and innovation using data
	Information and knowledge management	Evaluating data quality and availability Organizational knowledge management Sharing best practices Organizational learning management
Category 5	Workforce environment	Workforce capability and capacity Recruit, hire, onboard new workers Workforce change management Work accomplishment leveraging core competencies to reinforce customer service Workplace safety, health, accessibility Workforce benefits and policies
	Workforce engagement	Drivers of worker engagement Assessment of engagement Organizational culture – communication, performance management, safety, engagement Management of workforce performance Developing the workforce (personal improvement) Effectiveness and efficiency of learning and development systems Career development
Category 6	Work processes	Service and process design requirements and concepts Process implementation to address patient expectations and preferences Support processes Service and process improvement Supply network management Innovation management
	Operational effectiveness	Managing operation cost, efficiency, and effectiveness Security and cybersecurity Safety and emergency preparedness
Category 7	Healthcare and process results	Results for patient and customer service processes Work process effectiveness and efficiency results Safety and emergency preparedness results Supply network management results
	Customer results	Patient and customer satisfaction Patient and customer engagement
	Workforce results	Workforce capability and capacity Workforce climate Workforce engagement Workforce development
	Leadership and governance results	Leadership communication and engagement with workforce, partners, patients, customers Governance accountability results Law, regulation, and accreditation results Ethical behavior results Societal well-being and key community support results
	Financial, market, strategy results	Financial performance Market performance Strategy implementation results

Hospital. Leaders have agonized over the performance of the hospital for some time, but no clear direction has emerged from their angst, and there aren't any clear pathways to the performance excellence goals that they want to set. Baldrige organizations have developed Leadership Systems that employ behaviors that encourage employees to achieve stretch goals by clarifying vision and values through more advanced communication with all stakeholders, particularly the workforce. The work environment likely needs a redesign to create a focus on action, as well as inspiring and rewarding success. How might leaders achieve these goals? Using the experience from nearly two decades of Baldrige healthcare recipients is a good start [18]. Every Baldrige Award recipient provides a summary of its application to share with the public as a way of ensuring that the bright ideas and innovations that their teams have implemented are shared with others which can adapt these ideas to their organizations. For example, Memorial Hospital and Health Care Center (2018 recipient) has shared information on its leadership practices via the Baldrige website.

Additionally, each award recipient provides a contact person if someone wishes to get more detailed information about the organization's approaches. So, GCH's leaders need only click on the contact link on the website to send an email to the contact person and arrange a phone call to learn more. They may learn, perhaps, that Memorial's leaders make daily administrative rounds and participate in regular "town hall" meetings, send hand-written "thank you" cards for exemplary employee actions to improve patient care ("Really Impressive Moments"), or send the "Friday Facts" email every week. Most Baldrige recipients are eager to share these approaches with others and often present their best practices at conferences and online meetings.

Once a leadership system is in place, the team should turn to the other categories, and most organizations that commit to the Baldrige Journey appoint "Category Champions" for each of the first six categories. Often these champions are leaders from the C-suite; for example, the CEO might lead Category 1, Leadership, and if the organization has a planning department, the head of that group might lead Category 2, strategic planning. Each category is assigned to the expert in that area to ensure that the information needed to respond to the multiple criteria can be expertly addressed. Note also that each Approach-Deployment (AD) category has one or more associated results items to ensure that results are linked with approaches and deployment.

As the Category Champions organize teams to respond to each of the Baldrige categories and the detailed questions in the framework, they will select people from around the organization who have intimate knowledge of how each approach, or process, is deployed within their divisions or departments. As information is gathered, each of the items in ADLI needs to be addressed so team members will be tasked to answer questions like:

- *Approach*
  - What part of the overall organizational work system does our department perform?
  - What process or processes do we use in our department to implement our piece of the overall work system?
- *Deployment*
  - How is the process implemented within our department?
  - Who is involved in ensuring the process is done properly?
  - How well is the process running, e.g., does everyone follow the process in the same way?
- *Learning*
  - How do we measure process performance, i.e., what metrics do we use to determine efficiency and effectiveness?
  - How do we collect internal and external customer experience data with the process?
  - How do we integrate the information (quantitative and qualitative) to inform improvement plans?
  - How do we incorporate this integrated learning from the measures into improving the process?
  - How and when do we re-measure to ensure that improvement plans are effective?

- *Integration*
  - How is our performance improvement activity used by other departments to enhance this process or other similar or related processes?
  - How do we access and use performance improvement results from other departments to augment our efforts?

It is interesting to see the effect of this effort on organizational learning. Many times, as Category Champions are doing their analyses, they immediately find opportunities for improvement in their approach or deployment that can be the subject of improvement efforts, but even if A-D issues do not arise, there will inevitably be issues in measurement of performance or in the ability of each department to share and integrate their experience with others. In any event, just the process of conducting a Baldrige review virtually always spurs the Category Champions to identify issues that they can address to meet their own strategic objectives better.

GCH is poised to make significant gains using the Baldrige Framework. Not only will the framework provide the structure for organizing the hospital to make more cogent goals, but the use of ADLI will also help create a focus on the action ensuring that appropriate efforts will be made to achieve those goals. Moving from the broad agenda set by Deming's 14 Principles to action plans using the Baldrige Framework is achievable, regardless of organizational size. Managers now have tools to attain performance goals, and GCH will soon embark on the Baldrige Journey (Table 3.3).

Conclusions

Over months and years, Dr. Improverson transformed the structure, performance, and most importantly, the culture of GCH. From understanding the history of quality systems and high reliability principles to the importance of foundational elements like information technology and the workforce and customer focus, a system was put in place to ensure that problems were surfaced and addressed. Through this system, the quality and safety of care increased to the level of a top performing hospital. Dr. Improverson embodied the appropriate role of leadership to guide the hospital through the transformation and put in place a system that was built on valid data, a satisfied workforce, and most importantly, a satisfied patient and family.

Editors' Comments

This chapter is at the core of quality improvement and patient safety in healthcare – how does one (e.g., a hospital, a department, a quality leader) utilize a Quality Management System to drive toward higher levels of reliability? The authors answer this query by showing the readers in a simple manner the complexities of Quality Management Systems and the predominant systems that exist currently in American healthcare. The authors expound upon the 14 Points of Management, one of Deming's major early contributions. The editors would be remiss to not recommend Deming's book titled, *The New Economics for Industry, Government, Education* – 2nd Edition [19]. We have our own hospital-based quality improvement and safety teams reading this book which serves as a way to have the learner understand the beauty, simplicity, and provide confidence in quality improvement. The authors, as seen multiple times in this textbook, make the important connection between Quality Management Systems and the journey toward high reliability. It is important to show explicitly how these two major concepts intertwine; the authors do this nicely in the middle part of the chapter. The authors, throughout the chapter, demonstrate several types of Quality Management Systems and how they can drive improvements; the chapter ends with a thorough discussion of the Malcolm Baldrige National Quality Award program. One may argue that their organization "will never get there," "is not ready," "doesn't know where to start" on the Baldrige Journey; however,

the authors answer all these questions and discuss the value in being on the quality journey via the Baldrige Criteria, etc. The key take away from this chapter is that a Quality Management System is a keystone in a successful safety and quality improvement program. Without deliberately building a Quality Management System, a healthcare organization will become stagnant and ultimately suffer significantly. This chapter provides an excellent roadmap to embark upon the quality journey – with a roadmap.

Chapter Review Questions

1. Why do health systems need to become learning organizations?
   Answer: A learning organization exhibits the willingness to change and embraces continuous quality improvement. In the current healthcare environment, one based on value, quality, and safety, continuous improvement is essential. Also, learning organizations follow high reliability principles, making them agile in response and resilient to error.
2. What is the benefit of training an organization to be problem solvers?
   Answer: As issues, or errors, arise, organizations must be able to solve problems to ensure that mistakes to not repeat. A system must be able to identify high-risk problem areas and have standardized processes for solving them. Only then, can an organization improve its safety and quality performance and underlying culture.
3. Within the Baldrige Framework, what does ADLI stand for?
   A. Approach-Deployment-Learning-Integration.
   B. Alignment-Deployment-Learning-Integration.
   C. Approach-Deployment-Learning-Information.
   D. None of the Above.
   Answer: A
4. When you are paying attention to what is happening at the frontline, which high reliability principle is being followed?
   A. Reluctance to Simplify.
   B. Deference to Expertise.
   C. Preoccupation with Failure.
   D. Sensitivity to Operations.
   Answer: D
5. How can organization's benefit from going through the accreditation process (e.g., DNV GL accreditation)?
   Answer: Accreditation is an opportunity for systems to identify high-risk processes and develop sustainable solutions to issues. Also, using criteria like ISO 9001: 2015, organizations can design their quality management system to ensure appropriate structures are in place to support the QMS and that effective solutions to high-risk problems are overseen.
6. What does "having a culture of safety" mean?
   A. Making sure that patient feel safe.
   B. Making sure that employees feel safe.
   C. Having metal detectors at the hospital entry points.
   D. Always be prepared that something could go wrong.
   E. Having job security.
   Answer: D
7. What is the importance of "near-miss events" (select all that apply)?
   A. They provide a learning opportunity.
   B. They can be warning signals.
   C. They can indicate sloppy work.
   D. They can be used to determine who needs to be disciplined.
   E. Focusing on near-miss events will help prevent real events.
   Answers: A, B, E
8. What are important ISO 9001: 2015 principles (select all that apply)?
   A. Involve people at all levels.
   B. Work systematically, not in silos.
   C. Use a risk-based approach.
   D. Ongoing focus on improvement.
   Answers: all of the above
9. What is the role of senior management/leadership in a quality management system?

Answer: Senior management (both in ISO 9001:2015 criteria and Baldrige Performance Excellence criteria) oversee strategic inputs into the QMS and ensure that it is properly resourced. Senior management also tracks progress on key initiatives and maintains the oversight of high-risk areas throughout the system.

10. Dr. Improverson has begun an initiative to train the entire organization on QI methods and "Safety First" Culture. Which of the high reliability principles will Dr. Improverson be addressing in this initiative?

    Answer: Dr. Improverson will be addressing all HRO principles. (1) Preoccupation with Failure: with a "Safety First" mindset, staff will be able to proactively address safety concerns before they happen. This will manifest itself as "near-miss" events in the organization's safety event reporting system. (2) Sensitivity to Operations: training all staff will give QI and safety culture capability to the frontline. (3) Reluctance to Simplify: staff will be able to break down complex problems and develop appropriate solutions. (4) Commitment to Resilience: staff will be agile and empowered as problem solvers, and leaders will be able to support staff when an error does occur. (5) Deference to Expertise: staff will be able to reference experts within the system as well as grow as experts themselves.

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