

2024-08-06 Board Quality Committee Meeting

Tuesday, August 6, 2024 at 12:00 p.m.

Tahoe Forest Hospital - Donner Conference Room 10978 Donner Pass Road, Suite 3, Truckee, CA 96161

Meeting Book - 2024-08-06 Board Quality Committee Meeting

AGENDA	
2024-08-06 Board Quality Committee_Agenda.pdf	3
ITEMS 1 - 4: See Agenda	
5. APPROVAL OF MINUTES	
2024-05-07 Board Quality Committee_DRAFT Minutes.pdf	5
6. ITEMS FOR COMMITTEE DISCUSSION	
6.1. Patient Experience Presentation No related materials.	
7. CLOSED SESSION	
8. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION	
8.1. Informational Reports	
8.1.1. Patient & Family Centered Care	
8.1.1.1. PFAC Summary for Quality Board August 2024.pdf	8
8.1.2. Patient Safety	
8.1.2.1. BETA HEART Domain Update July 2024.pdf	10
8.2. Safety First No related materials.	
8.3. Process Improvement Projects No related materials.	
8.4. Board Quality Education	
8.4.1. IHI-Whole-System-Quality-White-Paper.pdf	11
ITEMS 9 - 11: See Agenda	

Page 2 of 64



QUALITY COMMITTEE AGENDA

Tuesday, August 6, 2024 at 12:00 p.m. Donner Conference Room – Tahoe Forest Hospital 10978 Donner Pass Road, Suite 3, Truckee, CA 96161

1. CALL TO ORDER

2. ROLL CALL Michael McGarry, Chair; Robert Barnett, Board Member

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA

4. INPUT – AUDIENCE

This is an opportunity for members of the public to address the Committee on items which are not on the agenda. Please state your name for the record. Comments are limited to three minutes. Written comments should be submitted to the Board Clerk 24 hours prior to the meeting to allow for distribution. Under Government Code Section 54954.2 – Brown Act, the Committee cannot take action on any item not on the agenda. The Committee may choose to acknowledge the comment or, where appropriate, briefly answer a question, refer the matter to staff, or set the item for discussion at a future meeting.

5.	APPROVAL OF MINUTES OF: 05/07/2024	ATTACHMENT
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6. ITEMS FOR COMMITTEE DISCUSSION

6.1. TIMED ITEM – 12:00PM - Patient Experience Presentation

Quality Committee will hear from a patient on their recent experience.

7. CLOSED SESSION

7.1. Hearing (Health & Safety Code § 32155)

Subject Matter: Case Review Number of items: One (1)

7.2. Approval of Closed Session Minutes

7.2.1. 05/07/2024 Closed Session Board Quality Committee

8. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

8.1. Informational Reports

8.1.1. Patient & Family Centered Care

8.1.2. Patient Safety

8.2. Safety First

8.3. Process Improvement Projects

Quality Committee will discuss the Vizient project plan, Management Systems, and future process improvement activities.

- - **8.4.1.** Sampath B, Rakover J, Baldoza K, Mate K, Lenoci-Edwards J, Barker P. *Whole System Quality: A Unified Approach to Building Responsive, Resilient Health Care Systems.* Boston: Institute for Healthcare Improvement (2021).

9. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS

10. NEXT MEETING DATE

The next committee date and time will be confirmed.

11. ADJOURN

*Denotes material (or a portion thereof) <u>may</u> be distributed later.

Note: It is the policy of Tahoe Forest Hospital District to not discriminate in admissions, provisions of services, hiring, training and employment practices on the basis of color, national origin, sex, religion, age or disability including AIDS and related conditions. Equal Opportunity Employer. The telephonic meeting location is accessible to people with disabilities. Every reasonable effort will be made to accommodate participation of the disabled in all of the District's public meetings. If particular accommodations for the disabled are needed or a reasonable modification of the teleconference procedures are necessary (i.e., disability-related aids or other services), please contact the Executive Assistant at 582-3481 at least 24 hours in advance of the meeting.



QUALITY COMMITTEE DRAFT MINUTES

Tuesday, May 07, 2024 at 12:00 p.m. Donner Conference Room – Tahoe Forest Hospital 10976 Donner Pass Road, Suite 3, Truckee, CA 96161

1. CALL TO ORDER

Meeting was called to order at 12:03 p.m.

2. ROLL CALL

Board: Michael McGarry, Chair; Robert Barnett, Board Member

Staff in attendance: Harry Weis, President & CEO; Dr. Brian Evans, Chief Medical Officer; Janet Van Gelder, Director of Quality & Regulations; Dr. Annamieka Conway, Medical Director of Quality (via phone); Barbara Widder, Administrative Assistant; Kevin Ward, PFAC Member

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA

No changes were made to the agenda.

4. INPUT – AUDIENCE

No public comment was received.

5. APPROVAL OF MINUTES OF: 02/28/2024

Director McGarry moved approval of the Board Quality Committee minutes of February 28, 2024, seconded by Director Barnett.

Open Session recessed at 12:06 p.m.

6. CLOSED SESSION

6.1. Hearing (Health & Safety Code § 32155)

Subject Matter: Case Review Number of items: One (1) Discussion was held on a privileged item.

6.2. Approval of Closed Session Minutes

6.2.1. 02/28/2024 Closed Session Board Quality Committee Discussion was held on a privileged item.

Open Session reconvened at 12:33 p.m.

Kevin Ward, PFAC Member, joined the meeting at 12:33 p.m.

7. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

7.1. Informational Reports

7.1.1. Patient & Family Centered Care 7.1.1.1. Patient & Family Advisory Council (PFAC) Update

Discussion was held and review of PFAC Summary and question if we should include additional community members.

Question was raised as to what would inhibit someone from coming to TFH for care? Outreach has been done to pull people in and there has been improvement based on patient satisfaction scores.

Suggestion to provide focused forums covering patient access, cost of care, community priorities, etc.

7.1.2. Patient Safety

7.1.2.1. BETA HEART Program Progress Report

Survey results were sent to Directors/Managers and discussion was held.

Care for the Professional Care Giver discussion held. We are making progress with burnout issues. Monthly debrief meeting has been established for providers by Samantha Smith, PA-C and Victoria Mercer, Ph.D.

Dr. Annamieka Conway, Medical Director of Quality departed the meeting during Open Session at 12:50pm

7.2. Safety First

Discussion was held on importance of critical lab values and reporting.

Cyber-attack awareness was discussed.

Greater recognition on morning huddle and being in tune to relevant topics until resolved.

Discussion was held regarding standard work bundles and that some have been developed by staff input.

7.3. Potential Quality Criteria for FY24 President & CEO Incentive Compensation

Quality Committee reviewed the Care Compare Star rating concurrent bundles for the Fiscal Year 2024 President and Chief Executive Officer Incentive Compensation Plan metric.

Board Executive Compensation Committee could agree to these bundles being the new roll up as a metric for the BOD Quality dashboard FY24-25.

7.4. Leading a Culture of Safety

Quality Committee discussed the key questions about our organization's capabilities and processes related to *Establishing organizational behavior expectations*, including foundational and sustaining strategies (page 25-29).

American College of Healthcare Executives and IHI/NPSF Lucian Leape Institute. *Leading a Culture of Safety: A Blueprint for Success*. Boston, MA (2017) Downloaded on 3/9/22 from https://www.ihi.org/resources/Pages/Publications/Leading-a-Culture-of-Safety-A-Blueprint-for-Success.aspx

Discussion was held.

7.5. Board Quality Education

Quality Committee reviewed the educational articles listed below and discuss topics for future board quality education:

- **7.5.1.** AHIMA. *Healthcare Data Governance*. Chicago, IL (2022). Downloaded on 10/20/23 from https://www.ahima.org/media/pmcb0fr5/healthcare-data-governance-practice-brief-final.pdf
- **7.5.2.** Drazen, J.M., Kohane, I.S., Leong, T.Y. (2023). *Artificial Intelligence in U.S. Health Care Delivery.* New England Journal of Medicine, 389: 348-358.
- **7.5.3.** Gallagher, T.H., & Kachalia, A. (2024) *Responding to Medical Errors Implementing the Modern Ethical Paradigm.* New England Journal of Medicine, 390: 193-197.

Discussion was held regarding additional article which was included in 7.5.3. "Looking AHEAD to State Global Budgets for Health Care".

8. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS

No discussion was held.

9. NEXT MEETING DATE

The next committee date and time will be determined at a later time.

10. ADJOURN

Meeting adjourned at 1:33 p.m.



Summary of Monthly Topics

January – Kat Sigafoose, Director of Patient Access, discussed our current customer service training/expectations of our registration staff and identified improvement opportunities through a "Secret Shopper" program. We elicited input from the PFAC with regard to evaluation criteria and process for implementation. Emphasized that positive experienced should be shared/reinforced with the involved staff to help incentivize. Discussed a proposed "Disruptive Patient" agreement and policy that has come about in response to increased incidents of disruptive and aggressive patients. Proposed new messaging/wording of signs displayed to notify patients of behavior expectations. Suggested de-escalation training for all staff to be considered as a requirement.

February – Jonathan Lowe, NP, a Behavioral Health provider, presented on Spravato (aka esketamine) treatment for chronic depression. This is the first FDA-approved psychedelic treatment, though the Covid pandemic halted/slowed its use. It is used primarily for treatment-resistant depression and so far over 750 treatments have been administered at TFH with a very high patient-reported success rate. Currently limited due to lack of a "buy and bill" system which would allow us to collect better reimbursement and cut out the need for using specialized pharmacies in other states outside of our health system. Jonathan discussed other current needs for our community to include more therapists, more space and expanded services, such as group therapy.

March – Heather Hiller, Clinical Quality Analyst, presented about the prevalence and warning signs of sepsis, and elicited input from PFAC with regard to spreading community education/awareness. Sepsis is the leading cause of death in US hospitals as well as the leading cause of hospital readmissions. TFH has implemented sepsis "bundles" that are utilized for initial intervention. TFH also initiated a Multidisciplinary Sepsis Committee 2 years ago, performs sepsis drills, and identifies awards for staff with great recognition/care for sepsis on a quarterly basis. We are well above the National and State compliance rate benchmarks for our CMS Core Measure that tracks Severe Sepsis/Septic Shock at 92.3% as of last year. Ideas on improving education/awareness through our local news outlets (Moonshine Ink), links to videos online, education through the Rec Center during "Golden Hour" sessions, and on our internet page or collaboration with our Marketing Department.

April – Alix Crone, Clinical Patient Experience Specialist, reviewed our current Patient Satisfaction scores from Press Ganey for our main service lines. We discussed the survey process and reviewed the questions asked on the surveys. We looked for potential factors and explanations into trends and changes occurring over the last couple of years to current. We discussed how scores and comments were shared with leadership, and improvement opportunities stemming from the feedback. One member recommended exploring use of ChatGPT to help organize feedback and identify immediate trends/themes within.

May – Ellie Cruz, Manager of Labor and Delivery, will be presenting on possible community labor doula services at Tahoe Forest. She educated on the positive clinical outcomes associated with the utilization of doulas, and seeking

PATIENT AND FAMILY ADVISORY COUNCIL (PFAC) SUMMARY REPORT

January 2024 – June 2024

buy-in for a doula program. The primary objective and goal is to obtain a registry of volunteers to serve as hospital doulas. TFH would cover the training classes for free in exchange for their volunteer hours. Ellie was seeking input from PFAC on how to spread the word within the community to gather interest.

June – Meg Rab, Director of Marketing and Advertising, along with Ted Owens, Executive Director of Governance and Business Development, came to gather input on general marketing and advertising ideas for the near and distant future. Presented new initiatives and re-allocation of funds currently in place. The overarching goal is to reengage our community. The PFAC members were able to provide feedback on the current branding/perception within the community, from which to help guide the messaging and mode of communication. We also presented suggestions for boosting our service lines where we do have more capacity (Urgent Care, Emergency Department), as there is concern that additional marketing/advertising to the outside would further inhibit access to care for the local population. Marketing will return this fall for additional updates on the current website.

Current Overview

- Ongoing goal is to have PFAC identify ways to help educate community on all services offered by TFHS, as well as provide input and feedback on current and future processes and systems.
- Plan for 2024 is to receive updates from the ongoing topic/concern of patient access, and to be at forefront of upcoming changes and plans to the health system's services offered.
- PFAC meets every month, 9 months in the year. We do not meet during the months of July, August, or December.
- Next PFAC meeting is September 17, 2024

Current Members and Start Date

Kevin Ward	9/20/2018	Carina Toledo	/ 7/2022
Sandy Horn	9/5/2019	Cris Valerio	2/ /2022
Violet Nakayama	10/31/2019	Jane Rudolph-Bloom	1/1/2024
Alan Kern	2/20/2020	Amber Mello	5/1/2024

BETA HEART Progress Report for Year 2024

(July 2024)

Beginning in 2020, Beta Healthcare Group changed their annual Incentive process to be "Annual", meaning that each year the five (5) domains have to be re-validated each year to be eligible for the incentive credit. General updates for 2024:

- Beta HEART Validation Survey completed May 9, 2023; validated in all 5 domains with a total cost savings of \$152,971
- Beta HEART Validation Survey completed May 22, 2024: validated in all 5 domains, cost savings of \$159,866.

Domain	History of Incentive Credits (2% annually)	Readiness for next Validation	Goal	Comments
Culture of Safety: A process for measuring safety culture and staff engagement (Lead: Ashley Davis, PSO & Beta HEART Lead)	Validated 2024: \$31,973.20	100%	-Greater than 60% completion rate for Culture of Safety Survey Pulse Check- In -Achieve Tier 2 in Zero Harm (OB & ED)	 Pulse check-in version of SCOR Culture of Safety survey was completed in March 2024 with 76% response rate (974 completions). Results to be shared and debriefings to start in May 2024. TFHD Women & Family Center was recognized for achieving Tier 1 in Zero Harm for Fetal Monitoring and Tier 2 for Maternal Sepsis and Perinatal Safety Collaborative; TFHD was the only BETA facility to achieve fetal monitoring assessment scores in the upper quartile of nursing and physician staff (cost savings of \$94,277). 5 leaders attended February 2024 workshop in Palm Desert, CA; topics include Culture of Safety and Rapid Event Response and Analysis.
Rapid Event Response and analysis: A formalized process for early identification and rapid response to adverse events that includes an investigatory process that integrates human factors and systems analysis while applying Just Culture principles (Lead: Christine O'Farrell, Risk Manager)	Validated 2024: \$31,973.20	100%	-75% or greater response time for event analyses within 45 days of event reported -75% or greater response time for closure of action items within 90 days of event reported	 TFHD incorporates the transparent and timely reporting of safety events to ensure rapid change in providing safer patient care. All investigations utilize "just culture" and high reliability principles and encourage accountability. The Reliability Management Team reviews all action plans to address strength of action items. 5 leaders attended February 2024 workshop in Palm Desert, CA; topics include Culture of Safety and Rapid Event Response and Analysis.
Communication and transparency: A commitment to honest and transparent communication with patients and family members after an adverse event (Lead: Christine O'Farrell, Risk Manager)	Validated 2024: \$31,973.20	100%	75% or greater response time for closure of event within 60 days	 Disclosure checklist updated and refined as we update process and leaders trained to respond to events. TFH and IVCH ED participating in Zero Harm program and focusing on standardizing handoff (cost savings of \$3,681) 7 leaders attended April 2024 workshop in La Jolla, CA; topics include Communication & Transparency and Care for the Caregiver.
Care for the Caregiver: An organizational program that ensures support for caregivers involved in an adverse event (Lead: Stephen Hicks, Peer Support Lead)	Validated 2024: \$31,973.20	100%	75% or greater response time for peer supporter deployment made in 0-12 hours	 Ongoing training and quarterly peer support and steering committee meetings. Currently have 40 peer supporters available to all staff. New peer supporters attended onsite training in April 2024. One peer supporter is now trained in Critical Incident first aid and plans for more peer supporters to go through this training. Plan for train-the trainer education in 2024 so we can train new peer supporters in-house. 7 leaders attended April 2024 workshop in La Jolla, CA; topics include Communication & Transparency and Care for the Caregiver.
Early Resolution: A process for early resolution when harm is deemed the result of inappropriate care or medical error (Lead: Christine O'Farrell, Risk Manager)	Validated 2024: \$31,973.20	100%	75% or greater response time for closure of event within 60 days	12 leaders to attend Early Resolution workshop in Huntington Beach, CA in September 2024.



Whole System Quality

A Unified Approach to Building Responsive, Resilient Health Care Systems

White Paper ihi.org

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Acknowledgments

IHI would like to thank the following individuals for their contributions to this white paper: Keith Murphy, Jeremiah Todd, Cordula Wagner, James Blazer, Bart Sellers, David Munch, Guido Bergomi, Carlos Frederico Pinto, Matt Pollard, Joanne Roberts, Hugh McCaughey, Julee Driscoll, Betsey Rhynhart, Christopher Fore, Grace Duffy, Henry Mintzberg, Andrea Kabcenell, Susan Hannah, Lisa McKenzie, Pedro Delgado, Christina Gunther-Murphy, John Whittington, Maureen Bisognano, Don Goldmann, Patricia McGaffigan, Rebecca Steinfield, Dave Williams, and Frank Federico.

The authors are grateful to Amar Shah, Nate Hurle, Kevin Little, Lloyd Provost, and Richard Scoville for reviewing the manuscript; and to Val Weber for her support in developing and editing this white paper. The authors assume full responsibility for any errors or misrepresentations.

How to Cite This Paper: Sampath B, Rakover J, Baldoza K, Mate K, Lenoci-Edwards J, Barker P. *Whole System Quality: A Unified Approach to Building Responsive, Resilient Health Care Systems*. IHI White Paper. Boston: Institute for Healthcare Improvement; 2021. (Available at <u>www.ihi.org</u>)

Institute for Healthcare Improvement

For 30 years, the Institute for Healthcare Improvement (IHI) has used improvement science to advance and sustain better outcomes in health and health systems across the world. We bring awareness of safety and quality to millions, accelerate learning and the systematic improvement of care, develop solutions to previously intractable challenges, and mobilize health systems, communities, regions, and nations to reduce harm and deaths. We work in collaboration with the growing IHI community to spark bold, inventive ways to improve the health of individuals and populations. We generate optimism, harvest fresh ideas, and support anyone, anywhere who wants to profoundly change health and health care for the better. Learn more at ihi.org.

The ideas and findings in IHI White Papers represent innovative work by IHI and organizations with whom we collaborate. White papers share the problems IHI is working to address, ideas we are developing and testing to help organizations make breakthrough improvements, and early results where they exist.

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Contents

Executive Summary	4
Introduction	5
Whole System Quality: Definition and Key Principles	7
Learning Organization Culture	11
Quality Planning: Defining Quality Goals to Meet Customer Needs	16
Quality Control: From Change to Sustainability	22
Quality Improvement: From Planning to Change	29
Whole System Quality: Shaping the Transition	37
Conclusion	43
Appendix A: Comparison of Quality Management Approaches	44
References	47



Executive Summary

While health care organizations have made significant strides in improving the quality of care, health system leaders note persistent challenges in building resilient and responsive organizations that continuously, reliably, and sustainably meet the evolving needs of their communities.

The Institute for Healthcare Improvement's research on strengthening organizational resilience and responsiveness to patients and populations has been underway for a number of years. In a dramatic demonstration of how health systems are actively *learning* how to manage quality in new ways at an accelerated pace, the COVID-19 pandemic surfaced a number of emerging and evolving patient, provider, and community needs and forced health systems to quickly redesign care delivery to meet those needs.

Decades of scholarship, coupled with insights from the pandemic, reveal a way forward for health systems that are pursuing quality in health care: through a process of rigorous learning, health care organizations can design resilient and responsive management systems to continuously deliver services that reliably and sustainably meet the evolving needs of patients, populations, and communities — in times of both stability and crisis.

This paper proposes a more holistic approach to quality management — whole system quality — that enables organizations to close the gap between the quality that customers are currently receiving and the quality that they could be receiving by integrating quality planning, quality control, and quality improvement activities across multiple levels of the system. Whole system quality requires leadership principles and practices that foster a culture of learning to reliably and sustainably meet the evolving needs of patients, populations, and communities. The paper details how these leadership principles and management practices can enable health systems to pursue quality — with ambition, alignment, and agility — through a commitment to learning.

The white paper includes the following:

- Definitions for whole system quality and the leadership principles required to support this approach;
- A description of how whole system quality links to customer needs, organizational vision, and quality strategy;
- Detailed descriptions of three interrelated components quality planning, quality improvement, and quality control that inform a more holistic whole system quality approach; and
- A proposed set of simultaneous activities that health care organizations can undertake to build a foundation for the transition to whole system quality.

Introduction

In the two decades since the Institute of Medicine published *To Err Is Human: Building a Safer Health System*,¹ the health care industry has made great strides in improving the quality of care, including decreases in surgical site infections and hospital-acquired conditions, among other fundamental quality improvements.² Despite these efforts, significant opportunities to improve health care quality remain, especially when considering the often unreported near misses.³ As Dr. Don Berwick noted, "[O]verall, so far as we can determine, the progress toward truly safer patient care remains frustratingly slow and spotty. Doing projects is not the same as transforming a system. Well-run airlines don't rely on 'safety projects'; the scientific pursuit of safety infuses absolutely everything they do, all the time."⁴ Pursuing quality holistically and embedding it into the health system requires positioning quality at the center of organizational strategy.

Today, quality in health care often means the attributes of products and services or conformance to requirements imposed by regulatory bodies. As *Forbes'* Steven Denning describes, "All too often quality management in its various forms and labels has come to mean improving quality in the sense of internal processes, and conformity to internal specifications. In a word, bureaucracy. All too often in quality management, the customer has seemed to be the last thing on anyone's mind."⁵

This reality would surprise the early quality theorists, whose work defined quality in terms of *meeting customer needs*. Deming introduced the concept of "customer-orientation," and Juran integrated this idea with the notion of meeting specified requirements to propose his view of quality as "fitness for use," comprising two elements: "features of products which meet customer needs" and "freedom from deficiencies" (see Figure 1).^{6,7,8}





Source: Juran JM, Godfrey AB. Juran's Quality Handbook (5th edition). McGraw-Hill; 1999.

Building on the ideas of quality movement pioneers, the Institute for Healthcare Improvement (IHI) proposes a strategic definition for health care quality: the endeavor of continuously, reliably, and sustainably meeting customer needs. This definition places quality at the center of the health care enterprise: quality *is* the organizational strategy, not merely a component of the strategy.

Like many complex organizations, health systems must consider the often-competing interests of myriad stakeholders to inform their strategy. To offer a clarity of purpose to organizational leaders, Peter Drucker proposed a useful distinction between primary and secondary customers:⁶

- **Primary customers:** Individuals whose lives are changed by pursuing quality. In the context of health care organizations, primary customers are defined as the health care workforce, patient population, and community members who are current or prospective consumers of health care services.
- Secondary customers: Individuals whose engagement is necessary to deliver quality to the primary customers. In health care organizations, secondary customers include payers, partners, regulatory bodies, and accreditation agencies, among others.

The Pursuit of Quality Through Continuous Learning

Leaders advocating for health system transformation cite the urgency and need for a qualityoriented enterprise which enables person-centered care delivery, evidence-based clinical practice, sustainable and high-value care models, alignment in incentive structures, and systemic redesign for health equity.^{9,10,11,12,13,14} Achieving this vision requires the proactive pursuit of quality by:

- Defining what quality means to patients, populations, communities, and the health care workforce, and crafting a strategy to achieve that quality vision in a sustainable way;
- Building structures and systems and embedding processes that make it easier for the health care workforce to work toward achieving the shared quality vision through continuous learning; and
- Fostering a culture of continuous learning by adopting leadership principles that enable problem identification, experimentation, and codification of solutions that work best.

While quality gives learning a purpose, learning steers organizations toward their quality vision. As leaders identify the needs of customers, gain insight into the interdependencies of their system, determine the drivers of persistent challenges for the workforce, and identify innovations and opportunities for improvement, the process of learning advances the organization toward its quality goals.

The idea of embedding learning into health systems has never been more relevant.¹⁵ In recent decades there has been an evolving understanding of learning, particularly in the context of health care. In 2007, the Institute of Medicine presented a vision for a learning health system to link the disconnected insights and knowledge from policymakers, clinical practitioners, and scientists.¹⁶ Since the term was first introduced, scholars of management theory, systems thinking, and organizational development have expanded the view of learning to encompass tacit knowledge of the contextual insights, information, and experiences of all who engage with the organization – from customers to the workforce to external partners.^{17,18,19,20,21}

With this perspective in mind, Peter Senge introduced the term "learning organization" to identify an institution "where people continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning how to learn together."²² IHI's understanding of learning in pursuit of quality is drawn from this definition.

The COVID-19 pandemic spotlighted the key role of learning to solve urgent health system problems and spurred one of the most productive periods for rapid learning. The task of putting practical knowledge about both *what* and *how* to implement the COVID-19 response into the hands of leaders, managers, and practitioners has never been more urgent.

For example, in their quest to quickly adapt existing services to meet the needs of patients and populations, as well as their workforce, health systems introduced tiered escalation huddles to rapidly learn about and quickly respond to problems as they emerge;²³ rapidly developed standard processes to manage use of high-demand resources such as personal protective equipment and ventilators;^{24,25} and adopted targeted measurement systems to track caseloads, provider capacity, and supplies to inform key strategic and operational decisions.²⁶

Perhaps even more importantly, health system leaders have embraced behaviors during the COVID-19 pandemic that further enable a culture of quality: communication of a clear sense of purpose has unified the workforce in managing the crisis;²⁷ frontline staff have some freedom to rapidly experiment and innovate to meet patient needs;²⁸ and leaders recognize the importance of tacit knowledge and create opportunities for robust dialogue to exchange insights and information.²⁹ In the midst of the pandemic, quality improvement has proved helpful in facilitating rapid learning.³⁰ A distinctive characteristic underpinning the health care system's response to the global coronavirus pandemic is shared organizational commitment to learning. In the face of extreme complexity and uncertainty, health systems are compelled to adopt a dynamic approach to leadership and seek to continuously learn as circumstances evolve.

Whole System Quality: Definition and Key Principles

Building on the definition of learning organizations from Senge, the view of a leader's role in promoting quality from Deming, and the notion of a quality-centric organization from Juran, IHI proposes a holistic approach to integrate learning into health systems: whole system quality.

- Whole system quality (WSQ) is the organization-wide pursuit of quality through management practices that facilitate knowledge exchange and leadership principles that foster a culture of learning (see Figure 2).
- Organizations that practice whole system quality look deeply within and beyond themselves to learn how to continually, reliably, and sustainably meet the evolving needs of patients, populations, and communities.

 Whole system quality comprises integrated quality planning, quality control, and quality improvement activities that inform an organization-wide, interlinked, and customercentric strategic approach to quality.

Figure 2. Whole System Quality Practices and Principles



Whole System Quality Management Practices

WSQ management practices include the roles, responsibilities, and activities across the health care organization, from patients and families to the board of directors. These practices are divided into the three domains of the Juran Trilogy: quality planning, quality control, and quality improvement.³¹

- Quality planning (QP) is a process an organization undertakes to identify customer needs, define quality goals, and design and deploy a strategy to reliably meet prioritized needs.
- Quality control (QC) entails establishing performance standards, developing continuous information relay systems to track performance, identifying gaps between actual and desired performance, and applying standard work to close the gap.
- **Quality improvement** (QI) involves a structured approach to system redesign to achieve new levels of performance through the science of improvement.

Many practitioners will recognize the combination of QP, QC, and QI components in the whole system quality approach as a "quality management system." The concepts of QP, QC, and QI are described in more detail later in the paper. For more discussion on the theoretical context for whole system quality, see Appendix A.

While the Juran Trilogy doesn't include quality assurance, this domain serves as a crucial externally-driven mechanism to evaluate the performance of the system and identify persistent gaps. While recognizing that quality assurance remains an important part of quality activities in any organization, IHI's whole system quality approach excludes quality assurance to highlight the internally-driven management practices in pursuit of quality. Amar Shah provides a framework for quality management that integrates quality assurance.³²

Whole System Quality Leadership Principles

Table 1 presents the whole system quality leadership principles: the social norms and patterns of behavior that form the foundation for implementing the various quality management activities. These principles (described in more detail later in the paper) apply to leadership at all levels of the organization (e.g., unit, department, executive, board).

Principle	Definition	Example
1. Build a shared sense of purpose	The co-production of a cohesive and unified vision for a future state of the organization to cultivate a shared sense of purpose	During the quality planning process, capture what matters to staff, patients, partners, and payers, and identify themes to develop a five-year quality strategy and annual quality goals.
2. Practice systems thinking	The ability to see the interconnected elements of the system, and to distinguish patterns instead of conceptualizing change as isolated events	Build models (e.g., process maps or flowcharts, enterprise value stream maps, performance measurement system) to understand the current system and the interdependence between its components to produce the intended results.
3. Engage in collective learning and dialogue	The process of collective inquiry, dialogue, and co- production to advance the organization toward the shared vision and goals	At every opportunity, practice dialogue by suspending assumptions, acknowledging internal dynamics, leading with curiosity and humility, asking questions (what and how, not who and why), discovering new ways of seeing and understanding the system, and generating ideas together.
4. Practice personal inquiry and reflection	The discipline of self- reflection, unearthing deeply- held belief structures and understanding how they dramatically influence behaviors	Dedicate time to introspect on personal biases and how they manifest in perspective, experience, and decision making. Learn and appreciate the context expertise of marginalized populations and recognize individual power that leaders, at senior and local levels, can exercise to design intentionally equitable systems.

Table 1. Whole System Quality Leadership Principles

Figure 3 depicts the whole system quality approach that integrates quality planning, quality control, and quality improvement activities for key health care system stakeholder groups. These activities inform an organization-wide, interlinked, and customer-centric strategic approach to quality and promote learning across the organization toward the pursuit of whole system quality.

Figure 3.	Whole System	Quality Appro	oach: Quality	Planning,	Quality	Control,	and Qua	lity
Improven	ment Activities	by Stakeholde	er Group					

Quality Planning	Quality Control	Quality Improvement	
Offer input to inform organizational strategy as primary customer group	Offer feedback on quality experience to inform understanding of performance	Engage as co-producer in relevant QI activities	Patients, Families, and Communities
	POINT OF	CARE	
Inform plans and requirements to execute on the strategy locally	ldentify and solve problems as they arise (gaps with standard), escalate as necessary	Lead and engage in local QI activities and identify potential QI projects	Clinicians
Translate strategy into a plan for unit setting and outline requirements for execution	Monitor performance and direct solutions, escalate problems as necessary	Lead QI projects and capture ideas for potential QI work	Unit-Level Leaders
Facilitate strategic planning process, support research and analysis activities	Support development of QC standard work and infrastructure	Support local QI activities and inform project prioritization efforts	Quality Department Staff
Work with executives and unit leaders to articulate how to execute on strategy	Identify cross-cutting problems and trends close feedback loops	Sponsor QI projects, lead cross-cutting QI efforts	Departmental Leaders
Identify customers, prioritize needs, and develop strategy	Mobilize resources to address emergent and cross-cutting problems	Sponsor and commission prioritized QI projects	Executive Leaders
Ensure organizational strategy is quality-centric	Review quality performance on a regular basis	Review performance of major QI projects on a regular basis	Board of Directors

Ultimately, whole system quality serves as a framework to inform the necessary management practices and leadership principles to embed quality at the center of the organizational enterprise. Figure 4 illustrates the continuous model of learning from customers, strategic visioning and planning, and refining the integrated delivery system that is the journey to WSQ. In many ways, this model is higher-order quality planning to inform and guide a health system's evolution toward a quality enterprise.





As a health system pursues the goal of closing the gap between the current state and future state of quality, it must engage in a series of customer orientation, visioning, strategic planning, and organizational development activities. As depicted in Figure 4:

- The journey begins with understanding the needs of patients, local populations, and the workforce as well as regulators, funders, and other partners.
- With stakeholder needs identified and prioritized, organizations can evaluate their current state of quality, define their quality aspiration, and craft a strategy to close the gap between the two.
- The organizational quality strategy that guides, and the quality policies that support, the delivery of quality are part of the quality planning aspect of WSQ.
- Guided by organizational values and a culture of learning, an organization pursues its
 priorities for improvement through a WSQ approach that deploys elements of quality
 planning, control, and improvement across the different levels of the health system.
 Fostering the leadership principles and building capability to practice continuous learning
 across the organization is required for quality management practices to take root.

Learning Organization Culture

Fostering a culture of improvement and continuous learning requires whole system quality leadership principles (see Table 1 above) — the social norms and patterns of behavior that form the foundation for implementing the QP, QI, and QC activities depicted above in Figure 3 — that enable problem identification, experimentation, and codification of solutions that work best.

These principles apply to leadership at all levels of the organization (e.g., unit, department, executive, board).

Engaging in these leadership principles over time will ultimately advance organizations toward the aspiration of psychological safety, a culture of trust, constancy of purpose, equity, and innovation – all hallmarks of success.^{33,34,35}

- **Psychological safety:** Anyone in the organization, including patients and families, can comfortably voice concerns, challenges, and ideas for change
- **Culture of trust:** An environment of non-negotiable respect, ensuring that people feel their opinions are valued, and any negative or abusive behavior is swiftly addressed
- **Constancy of purpose:** Apply organizational mission, vision, and values to every decision and always in service of quality (to continuously, reliably, and sustainably meet the evolving needs of patients, populations, and communities)
- **Commitment to equity:** Continually foster critical dialogue on identity and experience, take corrective action to address institutional and structural inequities, and create conditions in which all people, staff members and customers alike, have every opportunity to attain their highest potential
- **Discipline of innovation:** "The effort to create purposeful, focused change in an organization's social or economic potential."³⁶ This is achieved through a systematic examination, within and beyond the organization, to identify the areas of change that offer opportunities for creating new sources of value. Areas of change include adopting new ideas for application as well as abandoning practices that no longer serve the organizational vision.³⁷

Four Elements of a Learning Organization

Creating the necessary infrastructure for whole system quality requires a shared commitment to continuous learning. To that end, an organization must cultivate a community of learners, each curious to explore new ideas and practices. Such a mindset, established through shared behaviors and social norms, would relieve the workforce of "unproductive performance pressure, freeing [them] to offer ideas and to experiment in order to develop effective solutions."³⁸

Peter Senge, a systems scientist and leading scholar in organizational development, coined the term "learning organization" to describe a group of people working collectively to create a future they desire through continuously seeking to learn and understand their current circumstances and their full potential.³⁹ An organization committed to profound learning is one in which each individual contributes to the shared vision, appreciates the interdependencies of the system, participates in dialogue with candor and curiosity, and practices self-reflection and meta-cognition.⁴⁰ These behaviors serve as a foundation for building a community where knowledge and understanding is highly prized, openly shared, and consistently applied to create the envisioned future.

The culture of a learning organization coupled with a management structure that enables exchange of insights, priorities, and plans unlock the capacity for any organization to realize their vision for quality. As first introduced in Table 1 above, the four whole system quality leadership principles that enable learning and knowledge sharing, and that build on the organizational learning model Senge proposed, are outlined again below.⁴¹

- 1. **Build a shared sense of purpose:** A participative process of establishing a shared vision focuses the learning objectives and ensures that all activities and efforts are aligned toward a singular purpose.
- 2. **Practice systems thinking:** Systems thinking serves as a critical tool to appreciate the complexity of the dynamic, interconnected health care system and identify the challenges and opportunities in pursuing quality goals.
- 3. **Engage in collective learning and dialogue:** Team learning, or the process of collective inquiry, dialogue, and co-production, expands the problem-solving capacity of the organization by providing access to insights, information, and expertise across different levels and groups.
- 4. **Practice personal inquiry and reflection**: The discipline of self-reflection, unearthing deeply-held belief structures, and understanding how these structures dramatically influence behaviors enables each member of the organization to contribute to dialogue in a meaningful way.

Leadership Behaviors That Foster a Learning Organization to Support Quality

As health systems pursue organizational learning, they collectively learn how to learn — and how to build the capabilities to tackle any challenge they might encounter in the pursuit of quality. Senior leaders set the tone for organizational learning through their positional and symbolic power. By modeling the behaviors they seek to cultivate, executives and departmental leaders encourage, support, and normalize learning practices, ensuring psychological safety to acknowledge and help resolve individual and system issues.

Informal leaders at the point of care, who build meaningful relationships across the organization, appreciate the interdependencies of the system and consistently demonstrate a personal conviction to a shared vision and values and improving organizational quality. These informal, local leaders (e.g., physicians, nurses, social workers, senior residents, technicians) have the unique power to foster organizational learning behaviors and patterns among their peers.

Table 2 helps define the leadership roles and activities, at both the senior and local levels, necessary to develop a learning organization aligned with the four WSQ leadership principles described above.

WSQ Leadership Principle	Senior Leadership Role and Activities (Executives and Departmental Heads)	Local Leadership Role and Activities (Individuals and Team Leads)
 Build a shared sense of purpose The co-production of a cohesive and unified vision for a future state of the organization to cultivate a shared sense of purpose 	 Role: Act as the steward of the organizational vision, seeking to understand, record, and iterate on the purpose as it evolves Activities: Share your own personal connection and contribution to the vision Design and iterate on a process for all staff to express what really matters to them and be heard Continually reflect on whether the current organizational system, processes, and structure are designed to achieve the vision and purpose 	 Role: Reflect on a personal vision and connect it with that of others on the team and in the organization Activities: Dedicate team meetings to sharing personal aspirations, goals, and visions and connect them to the organization's vision Organize joint sessions across departments to share personal aspirations and team visions and how they align with the organization's vision Develop action plans to pursue the vision together, both within and across teams
2. Practice systems thinking The ability to see the interconnected elements of the system, and to distinguish patterns instead of conceptualizing change as isolated events	 Role: Build and promote a holistic view of the system Activities: Build and refine models for understanding the current state (e.g., linkage of processes, enterprise value stream maps) Understand variation and process capability to know if the system is capable of achieving the vision and, if not, commission efforts to improve the system Regularly review data from a concise, balanced set of measures that represent the work of the organization Examine the external and environmental forces – from evolving community needs to the regulatory landscape – to 	 Role: Gain an awareness of and appreciation for institutional interdependency Activities: Develop stories of the role, work, challenges, and opportunities for each team, and share them across the organization Identify goals that are at cross-purposes; name them and openly discuss how to align incentives and activities Use balancing measures to ensure improvements don't create unintended effects

Table 2. Leadership Roles and Activities That For	ster a Learning Organization to Support Quality
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WSQ Leadership Principle	Senior Leadership Role and Activities (Executives and Departmental Heads)	Local Leadership Role and Activities (Individuals and Team Leads)
	 identify emerging challenges and opportunities Eliminate management systems that encourage individual profit centers and encourage suboptimization of departments and units 	
3. Engage in collective learning and dialogue	Role: Foster a culture of learning, demonstrating inquiry, reflection, and dialogue	Role: Seek to learn from and understand one another through inquiry and dialogue
The process of collective inquiry, dialogue, and co- production to advance the organization toward the shared vision	 Activities: Acknowledge the dynamics within the executive team, including the functional and dysfunctional aspects, and points of consensus and controversy Develop an executive team learning agenda (note, inquire, learn, and refine a list of organizational known knowns, known unknowns, unknown unknowns) In every opportunity, articulate tacit beliefs, invite opportunities to challenge assumptions, and look for new ways of seeing the whole system Seek to learn from other leaders and organizations, exploring alternative ways of thinking and working, and identifying best practices to adopt Harness data to understand challenges and explore opportunities for improvement 	 Activities: Use problem escalation as an opportunity for dialogue, within and across teams Practice dialogue in meetings, making time to inquire about the current circumstances and understand the challenges as they are expressed Celebrate problem identification and articulation Use process maps, root cause analysis, and cycles of influence to identify underlying drivers of challenges
4. Practice personal inquiry and reflection	Role: Continually reflect on the gap between the current state and the organizational potential future state, and publicly demonstrate commitment to learning	Role: Embrace challenges as an opportunity for improvement, exchanging experiences and ideas with peers and senior leaders to foster learning

WSQ Leadership Principle	Senior Leadership Role and Activities (Executives and Departmental Heads)	Local Leadership Role and Activities (Individuals and Team Leads)
The discipline of self-reflection, unearthing deeply- held belief structures and understanding how they dramatically influence behaviors	 Activities: Be humble, candid, and transparent Listen deeply by asking questions and respecting individual expertise Understand problems before pursuing solutions Be introspective to identify personal biases and limited perspectives Reflect on how current processes, incentives, and culture contribute to organizational challenges 	 Activities: Use the language of challenges and needs rather than blame Openly share and exchange perspectives on challenges, opportunities, suggestions, and ideas for improvement Practice deep listening and speaking with candor Focus on the process rather than the people

Quality Planning: Defining Quality Goals to Meet Customer Needs

In a context where quality is divorced from organizational strategy, quality assurance often propels quality-related activities as organizations try to comply with evolving regulatory mandates or accreditation requirements. With external forces driving priorities for organizational quality, many health systems fall into a cycle of reactive quality management. As quality becomes increasingly central to organizational strategy and management, leaders need a mechanism to discern the relative importance of quality efforts and proactively pursue activities that will more effectively advance organizational strategic goals.

The quality planning (QP) process, defined by Juran as a means of "developing the products and processes required to meet customers' needs,"⁴² enables an organization to prioritize customer needs, design a strategy and quality goals to meet those needs, and deploy the strategy across the system. As the first and critical step in shifting an organization from a reactive to a proactive quality orientation, quality planning offers much value in reducing the waste of misaligned and poorly coordinated quality efforts across an organization.

Quality Planning Process

Table 3 provides an overview of the three phases of the quality planning process, with each phase addressing a strategic organizational gap.

Table 3. Organizational	Gaps Addressed b	y Three Phases	of the Qualit	y Planning Process
5			•	

Organizational Gap	Quality Planning Phase
Understanding customer needs : There is an incomplete understanding of the needs of patients and populations, often due to limited or discontinuous channels to capture needs	Define the Organization's Quality Aspiration: Quality dimensions are identified by prioritizing customer needs and aligning them with the organizational mission
Designing a strategy and quality goals that meet customer needs: Strategy is misaligned with identified customer needs as a result of poor integration of emerging ideas and customer insights with strategic planning	Design the Quality Strategy: Quality is central to strategic development and planning activities
Building a delivery system that responds to the organizational strategy: Strategy remains unrealized due to inadequate investment in strategy deployment and systemwide alignment	Deploy the Quality Strategy Systemwide: Strategy implementation is well-planned, well-timed, and well-executed across the entire system

The quality planning process shown in Figure 5 seeks to respond to each gap using a systematic and sequenced approach, with specific processes outlined for each phase of the QP process. The steps are intentionally numbered to follow the defined sequence.

Figure 5. A Sequenced Approach to Quality Planning



Define the Organization's Quality Aspiration

Quality is defined as a prioritized list of customer needs.

1. Engage customers to identify and prioritize needs

The process of determining the needs of these diverse stakeholders involves an "organizationwide generation of market intelligence, dissemination of the intelligence across departments, and organization-wide responsiveness to it."⁴³ Health systems can pursue a customer-centric

quality strategy through a rigorous process of environmental scanning and customer-orientation activities (e.g., patient, staff, and community interviews, focus groups, surveys, market trend reports, community needs assessments) that inform market segmentation, strategic differentiation, and service innovation efforts.⁴⁴

2. Develop a shared vision, mission, and values

The idea that vision, mission, and values can guide a business and provide meaning for employees has been widely documented, underscoring how a forward-looking perspective and enduring values contribute to an organization's longevity and sustainability.⁴⁵ A common pitfall that compromises the process is senior leadership developing a vision, mission, and values without engaging or getting input from employees and other key stakeholders.⁴⁶ To mitigate this risk, organizational leaders must develop a *shared* vision. Once a shared purpose has been articulated, the annual planning process can begin by reaffirming the established mission, vision, and values.

3. Establish an organizational definition of quality

Defining quality is an important early step in quality planning because it helps to orient all later stages of the QP process. The organizational definition of quality:

- Serves as the foundation for planning, achieving, and monitoring quality;
- Guides the areas of focus, priorities, measures of progress and reporting; and
- Facilitates communication both internally and externally.

Most definitions of quality are: 1) guided by alignment with organizational strategy, 2) evidencebased, 3) strongly supported by leadership, and 4) aimed at promoting excellence at all levels of an organization.⁴⁷

In practice, health systems can only begin to weigh and balance diverse needs once they have captured the perspectives of all stakeholders. In 2017, the East London NHS Foundation Trust in the UK hosted the Big Conversation, with 35 workshops involving more than 1,000 people, to define the purpose and quality aspiration for the organization through appreciative inquiry.⁴⁸ A qualitative analysis of the data captured in the process led to the development of the organizational strategy.

Similarly, the Sheffield Teaching Hospitals NHS Foundation Trust (a five-hospital system in Sheffield, UK) developed a patient-centric quality strategy informed by staff, patients, the governance board, regulators, and other partners.⁴⁹ Through a series of individual conversations, group discussions, presentations, and surveys, the Sheffield Trust gained insight into key factors that were vital to understanding priorities, building a shared vision, and defining quality for customers.

Design the Quality Strategy to Achieve Quality Goals

Quality is central to strategic development and planning activities.

4. Analyze the existing system and identify opportunities for improvement and innovation

Designing a system that fulfills the organization's definition of quality begins with an understanding of the current state of quality and the organizational system that delivers

the current results. By examining the current organizational system and performance, leaders can evaluate areas of strength and opportunities to improve the system as the organization strives to achieve its defined quality goals. Diagnostic tools that organizations might use to understand their current state of quality include, for example, a strategic review, SOAR (Strengths, Opportunities, Aspirations, Results) analysis, value stream mapping, quality initiative evaluation, and gap analysis.

5. Develop breakthrough objectives and annual goals as an articulation of the quality strategy

Leaders use the organization's articulated vision, mission, and values, and the identified gap between current system performance and the articulated quality definition, to prioritize breakthrough objectives, which are three- to five-year goals that outline the path to advancing an organization's purpose. By evaluating a set of dynamic internal and external factors, health systems can arrive at an appropriate set of objectives. Internal factors include elements that are within the organization's control such as available resources, capacity, and capability. External factors comprise externally-driven environmental elements that are not within the organization's control, for example, government, policy and regulatory changes, the global economy, and international politics. Organizations often use the symbolic term "True North," derived from Lean management, and visual representations to communicate and reinforce these breakthrough objectives.

Western Sussex Hospitals NHS Foundation Trust in the UK, for instance, developed a Patient First True North framework that is centered on the patient and serves as "the one constant all efforts should strive to achieve, directly or indirectly."⁵⁰ The framework, borne out of a Trust-wide transformation initiative, communicates their strategic focus and ensures systemwide alignment.⁵¹

Deploy the Quality Strategy Systemwide

Strategy implementation is well-planned, well-timed, and well-executed across the entire system.

6. Translate quality goals and objectives into actionable plans and requirements

Strategic alignment, which involves translating the organization's priorities and goals for quality into actionable plans, begins at the highest level of the organization and is propagated throughout the organization, at all levels, using participative dialogue. This dialogue, widely known as "catchball,"⁵² serves as a structured cascade mechanism for disseminating and contextualizing the breakthrough objectives and annual goals throughout the organization.

By enabling both top-down and bottom-up communication, the cascading process facilitates development of a shared understanding of organizational goals as well as consensus on how to achieve the goals.⁵³ As the plan is disseminated across the organization, departments and teams develop their "local" plans, identifying how their activities contribute to achieving the breakthrough objectives and annual goals. Thus the articulated systemwide quality strategy – which encompasses the quality definition, annual goals, and related key measures (discussed below) – serves as the foundation that guides all activities implemented by each department, unit, team, and staff member in service of achieving that strategy.

7. Align quality goals with systemwide measures

Aligning performance measurement for each quality goal is critical to understanding whole system quality and enabling a coordinated approach to achieve quality goals.¹¹ Systemwide measures cascade top-down throughout the organization, from senior leaders to point-of-care staff and from strategic organization-level dashboards to department- or unit-level tactical and operational dashboards. Performance measures also cascade bottom-up, enabling departments and units to align their work with high-level strategic objectives, and for unit-level performance metrics to roll up to the systemwide dashboard. Through this cascading process, key performance indicators (KPIs), aggregate measures that succinctly reflect organizational progress toward long-term strategic goals, are represented within a single measurement dashboard, providing visibility from summary-level to detail-level performance across quality dimensions.⁵⁴

8. Establish a quality management infrastructure

Quality planning efforts culminate in a set of aligned top-to-bottom plans to achieve annual goals that roll up to breakthrough objectives to create quality services that meet customer needs. These plans are then implemented by units and departments. Measures of local performance, aligned to the system-level breakthrough objectives, become the so-called "control" parameters that enable leaders and managers to oversee the system, and to understand whether the system is performing in accordance with the goals established for the unit/department by the system. The quality management infrastructure brings together quality planning and quality control activities.

To build a governance structure that establishes a line of sight for quality, from the boardroom to the bedside, Johns Hopkins Health System (JHHS) adopted a cascading process for strategy development and deployment across the organization. JHHS applied the A3 problem-solving approach, originally employed by Toyota to facilitate continuous improvement, as an instrument to facilitate their catchball process.⁵⁵ In another example, the East London NHS Foundation Trust developed a one-page driver diagram capturing the strategic activities taking place across the Trust.⁵⁶ This plan is cascaded from the Trust level to the facility/site level, and ultimately to the directorate level, to contextualize quality activities and goals across the system.

Quality Planning: Engaging Key Stakeholders

As one of the three vital components of whole system quality, a robust quality planning process engages individuals throughout the organization to establish a shared vision, mission, and values; define quality; identify and prioritize customer needs; and design a strategy and quality goals to meet customer needs (see Figure 6).

Quality Planning	Quality Control	Quality Improvement	
Offer input to inform organizational strategy as primary customer group	Offer feedback on quality experience to inform understanding of performance	Engage as co-producer in relevant QI activities	Patients, Families, and Communities
	POINT OF	CARE	
Inform plans and requirements to execute on the strategy locally	Identify and solve problems as they arise (gaps with standard), escalate as necessary	Lead and engage in local QI activities and identify potential QI projects	Clinicians
Translate strategy into a plan for unit setting and outline requirements for execution	Monitor performance and direct solutions, escalate problems as necessary	Lead QI projects and capture ideas for potential QI work	Unit-Level Leaders
Facilitate strategic planning process, support research and analysis activities	Support development of QC standard work and infrastructure	Support local QI activities and inform project prioritization efforts	Quality Department Staff
Work with executives and unit leaders to articulate how to execute on strategy	Identify cross-cutting problems and trends close feedback loops	Sponsor QI projects, lead cross-cutting QI efforts	Departmental Leaders
Identify customers, prioritize needs, and develop strategy	Mobilize resources to address emergent and cross-cutting problems	Sponsor and commission prioritized QI projects	Executive Leaders
Ensure organizational strategy is quality-centric	Review quality performance on a regular basis	Review performance of major QI projects on a regular basis	Board of Directors

Figure 6. Quality Planning Activities by Stakeholder Group

- Patients and families play a central role in defining quality and developing a strategy to meet their needs. Engaging patients and families, primary customers of the health system who are most affected by the care delivery process, is crucial to defining the quality aspiration. Mechanisms to involve and engage patients, families, and the community at large include surveys, focus groups, concept testing, as well as more generative approaches such as customer observation, journey mapping, and co-design processes. Organizations that engage in generative methods to discover and prioritize latent needs have been shown to build stronger relationships with their customers, deliver superior value, and pursue innovative solutions.⁵⁷
- Clinician engagement is critical to building a shared vision of quality across the
 organization, identifying strategic priorities based on the realities at the point of care,
 and developing an actionable strategic plan. As internal secondary customers, clinicians
 and the entire health care workforce are key stakeholders; as such, their needs are also
 essential to defining the organization's quality vision. Joy in work and workforce
 enablement must be as integral to an organization's quality aspiration and strategic
 priorities as patient safety, equity, and efficiency.
- Unit-level leaders are tasked with adapting the systemwide strategy to the local context. A health system's breakthrough objectives and annual goals must be translated into actionable and measurable plans at the unit level. Unit-level leaders play a key role in identifying the specific point-of-care activities necessary to implement the plan and the resources required to do so effectively. The catchball process facilitates conversations between these local leaders, departmental leadership, and the executive team to

establish a reasonable set of goals and allocate appropriate resources to execute on them.

- Quality department staff provide a key support function in quality planning, facilitating
 the QP process, analyzing data to inform key strategic decisions, and creating materials
 to support clinical teams with prioritized quality interventions. In the first phase of QP,
 Define the Organization's Quality Aspiration, quality department leaders create and
 manage the process of gathering and synthesizing customer intelligence and market
 insights. This information is shared with the executive team to inform the organizational
 definition of quality. In the second phase, Design the Quality Strategy to Achieve Quality
 Goals, the quality department supports the analysis of the existing system to identify
 what is working well and opportunities for improvement. In the third phase of planning,
 Deploy the Quality Strategy Systemwide, quality department staff facilitate the catchball
 process to translate goals into plans and requirements.
- **Departmental leaders** ensure systemwide alignment throughout the quality planning process. As the breakthrough objectives and annual goals are propagated throughout the organization and translated into plans and requirements, departmental leaders play a crucial role in identifying the interdependencies of the whole system and collaborating with peers to support, align, and resource cross-functional projects and priorities.
- Executive leaders establish priorities, drive overall quality planning activities, and ensure organization-wide communication. From establishing strategic priorities to iterating on the annual plan in partnership with departmental leaders and the quality department, senior executives are the stewards of the quality planning process. Their role is to articulate the quality definition, based on the needs of their internal and external customers. In addition to driving the overall quality planning activities, the executive team must also practice transparency and continuously communicate with the workforce and customers about updates on and milestones in the process, as well as the rationale behind strategic choices.
- **Board of directors** play an oversight role in the quality planning process. Their primary responsibility is to ensure that the quality priorities align with a long-term vision not only for the organization, but also for the community as a whole. With a customer-centric orientation of quality, the trustees provide ongoing feedback on the health system's strategic priorities and the annual plan.

Quality Control: From Change to Sustainability

The Sustaining Improvement IHI White Paper defines quality control as "ensuring that a process remains stable ('in control') over time – that is, its performance remains within the upper and lower control limits. QC is usually performed by those closest to the process."⁵⁸ (In a statistical process control chart, the control limits denote the boundaries between which data can fluctuate based on random variation.)

Quality Control and Quality Assurance

In *Juran's Quality Handbook*, Joseph Juran notes that while both quality assurance (QA) and quality control (QC) serve a similar purpose — each compares actual quality with the quality goal — the difference between the two lies in their focus. Quality control is an activity performed by those doing the work to inform ongoing activity. By contrast, quality assurance informs those actors — often situated outside the daily quality production system — who need to know that the work is meeting the quality goals. QA often occurs with a considerable time lag — weeks or months after the actual delivery of the service. In health care, external stakeholders (e.g., patients and families) often also drive quality assurance. QC by contrast, according to Juran, focuses on daily operations, ensuring that processes are stable and correcting abnormalities.

Traditional quality assurance systems (e.g., accreditation, licensing, credentialing, quality inspections and audits) are mostly concerned with external assessment of the quality of institutional functions and the workforce capabilities to deliver quality work, and are often given statutory responsibilities. While QA was once the principle method for driving better health care quality, more recently health systems have adopted proactive QC approaches to continuously assure quality. QA has increasingly been accommodated in WSQ design⁵⁹ and QA itself has adopted QI learning methods to address defects that are uncovered in the audits.⁶⁰ In this sense, quality control activities can be thought of as a subset of the broader group of quality assurance activities. Today, health system senior leaders continue to participate in QA, often via the review of a dashboard containing the KPIs described above that result from the quality planning process, and by responding to the "grades" they receive from external auditing agencies.

Quality Control and High Reliability

Quality control is related to another concept that has gained currency in recent years in health care quality: high reliability. The Joint Commission describes high reliability as "consistent excellence in quality and safety across all services maintained over long periods of time."⁶¹ In practice, the behaviors and tools used to ensure quality control and high reliability are similar.

As with quality improvement and planning, the quality control concepts described in this paper draw on different methodological schools of thought (e.g., high reliability, Lean, Quality as a Business Strategy) as well as the experiences of health care systems that have developed their own robust approaches to quality management (e.g., Kaiser Permanente's performance improvement system, Intermountain Healthcare's operating model, the Virginia Mason Production System, the Cleveland Clinic Improvement Model).

Effective Quality Control Systems

Today's health care system still has major quality defects, requiring attention not only in terms of quality planning (to identify the quality strategy, priorities, goals, and measures) and quality improvement (to operationalize the quality strategy to achieve goals), but also via systems that ensure quality control (to monitor performance against goals and adjust as needed).⁶²

The *Sustaining Improvement* IHI White Paper identifies six main drivers of quality control that represent the key elements of an effective quality control system within a health care organization.⁶³

- **Standardization:** Processes to define and disseminate standard work (what to do, how to do it, and why) span the organization.
- Accountability: Processes to review execution of standard work and fidelity are in place across the organization.
- **Visual management:** Process performance information is continuously available to synchronize staff attention and guide current activities.
- **Problem-solving:** Methods for surfacing and addressing problems that are solvable at the point of care, and for developing improvement capability, are broadly understood.
- **Escalation:** Point-of-care staff scope issues and escalate those that require management action to resolve (e.g., requiring cross-departmental coordination).
- Integration: Goals, standard work, and quality improvement project aims are integrated across organizational levels and coordinated among units and departments.

The whole system quality approach described in this white paper also defines a set of activities at each layer of the organizational structure based on these six drivers of QC, and including patients and the board of directors, to outline relevant activities for quality control (see Figure 7) as described below.

Quality Planning	Quality Control	Quality Improvement	
Offer input to inform organizational strategy as primary customer group	Offer feedback on quality experience to inform understanding of performance	Engage as co-producer in relevant QI activities	Patients, Families, and Communities
	POINT OF	CARE	
Inform plans and requirements to execute on the strategy locally	Identify and solve problems as they arise (gaps with standard), escalate as necessary	Lead and engage in local QI activities and identify potential QI projects	Clinicians
Translate strategy into a plan for unit setting and outline requirements for execution	Monitor performance and direct solutions, escalate problems as necessary	Lead QI projects and capture ideas for potential QI work	Unit-Level Leaders
Facilitate strategic planning process, support research and analysis activities	Support development of QC standard work and infrastructure	Support local QI activities and inform project prioritization efforts	Quality Department Staff
Work with executives and unit leaders to articulate how to execute on strategy	Identify cross-cutting problems and trends close feedback loops	Sponsor QI projects, lead cross-cutting QI efforts	Departmental Leaders
Identify customers, prioritize needs, and develop strategy	Mobilize resources to address emergent and cross-cutting problems	Sponsor and commission prioritized QI projects	Executive Leaders
Ensure organizational strategy is quality-centric	Review quality performance on a regular basis	Review performance of major QI projects on a regular basis	Board of Directors

Figure 7. Quality Control Activities by Stakeholder Group

- Patients and families offer feedback regarding quality performance (i.e., how well does the system meet their needs). Mechanisms for enabling patients to provide feedback on quality include whiteboards in hospital rooms and easy-to-access digital feedback forms in hospitals and other settings. Near real-time feedback offers a channel for quality control and other feedback (e.g., submitted after the patient leaves the facility, or delivered to the care team days or weeks after an incident occurs) is an important source of quality assurance information. The leadership principles described above (see Table 1) highlight the norms and practices that promote the submission and discussion of this kind of feedback.
- Clinicians play a key role in quality control, especially via execution of standards articulated in evidence-based protocols. Many health systems have invested in broad systems of clinical governance to "standardize what makes sense" for key clinical services (e.g., care pathways for procedures and for specific chronic diseases like heart failure and chronic obstructive pulmonary disease, along with role-specific standard work). Strong quality control systems make these care pathways the easy default by building recommendations directly into the clinical workflow, often using the electronic health record, and allowing physicians to articulate exceptions that can receive an immediate or near-immediate response.
- Unit-level leaders, such as a senior charge nurse or assistant nurse manager, play an essential role in quality control. They are responsible for daily monitoring of a team's performance, identifying gaps between desired and actual performance, and working with the team and others (e.g., quality staff) to identify, test, implement, and sustain solutions. Unit-level leaders are often key to determining whether a quality control system succeeds or fails. Coached by senior leaders and middle managers, unit-level leaders also model the behaviors that promote dialogue and trust, as discussed below. They promote learning from failure as well as from success, and they turn problems into opportunities for learning.
- Quality department staff play a vital supporting role by assisting staff and leaders throughout the organization with problem-solving, testing and implementing improvements, facilitating data collection and analysis where necessary, and helping teams understand where they need to change current policies and procedures to align with current work and how best to do so.
- Departmental leaders (e.g., a cardiac or respiratory operations director) offer support to both teams and leaders at the point of care. They identify emerging trends across multiple units (e.g., shortages of drugs and equipment), use their influence to quicken solutions (e.g., facilitate deployment of specialty staff like social workers, pharmacists, or specialists where necessary), and also manage emerging problems that exist at the intersection of teams (e.g., immediate problems with patient flow that are often not managed by any specific team, but are the result of challenges in multiple parts of the organization).
- Executive leaders identify whether the organization is meeting the needs of customers on a daily basis. They review safety, flow, staffing, and other quality data and focus on abnormalities, which they often delegate or escalate into specific improvement projects;

provide coaching for other leaders and model effective problem-solving behaviors (e.g., appreciative inquiry); and ensure that the current system as a whole is functioning effectively (e.g., appropriate structures are in place across teams to ensure that quality goals are being met, appropriate standard work is in place, teams are using tools like visual management in effective ways).

Executive leaders engaging with quality control demonstrate two fundamental activities: facilitating solutions to emergent problems, and going to the point of care to offer coaching, guidance, and encouragement and to champion continuous learning. An effective quality control system includes standard work not only for clinical staff, but also for managers and administrative leaders (e.g., tracking and resolving problems on a daily basis).

• **Board of directors** review operational performance on a regular basis (e.g., financial performance) to ensure progress according to expectations, and to support further analysis and focus leaders' energies on areas for further work.

Quality Control Practices and How to Operationalize Them

Effective quality control systems use practices like huddles, visual management, and leadership presence at the point of care to support problem-solving and barrier removal.

- Standard work: A fundamental quality control practice, defined standard work for key clinical and administrative processes outlines key steps, the roles of relevant staff, and a rationale for why each step is important. These activities might range from patient call light response to management review of a team's progress in meeting strategic objectives. Leading organizations like Intermountain Healthcare have developed clear standard work at multiple organizational levels, co-produced with staff. Some organizations use the Training Within Industry approach, championed in manufacturing during the 20th century, to build and teach standard work.⁶⁴
- Huddles: Daily and/or weekly huddles⁶⁵ offer the foundation for quality control by
 providing an opportunity for team members to identify problems, review simple
 measures of fidelity to standard work and operational control, and update leaders, while
 also providing a forum for escalating problems as necessary. The huddle enables a
 team to review problems that occurred in the recent past and identify opportunities to fix
 them, and also to look forward to anticipate problems and needs and deploy resources
 to prevent problems from occurring or recurring.
- Visual management boards: Visual management boards offer a simple means to ensure good team communication, establish and maintain discipline around measurement, and ensure tracking of problems that require resolution.^{66,67}
- Leadership presence at the point of care: Research suggests that leadership presence at the point of care can support execution of standard work, create opportunities for coaching and learning, and reinforce continuous problem-solving and improvement. For example, at Kaiser Permanente, leadership rounding — in the form of executive rounds or daily operational rounding in departments and on clinical units — incorporates questions

about quality, safety, service, and efficiency and helps identify opportunities for rapid improvement.⁶⁸ Understanding the nature of local work helps senior leaders move beyond traditional roles as financial and policy experts.

Organizations should use Plan-Do-Study-Act (PDSA) cycles to test these practices on a small scale, starting with a limited number of high-performing teams, refine the practices based on learning, and then scale up the practices to implement them more broadly across the organization.

Tiered, escalating daily huddles: Organizations with advanced quality control systems embrace tiered, escalating daily huddles to ensure timely communication at all levels throughout the organization. Daily huddles give participants a rapid, updated "line of sight" to the key processes of their work, allowing them to escalate problems, resolutions, and learning from the unit level to the department level to the executive level – that is, unit-level leaders meet with department-level leaders (or one designated leader), and departmental leaders then meet with executive leaders (or one designated executive). This process proceeds, usually in a sequential manner each morning, with attention to a common set of agenda items, and often requires a 90-minute to two-hour "no meeting zone" to create dedicated time for executives and other managers to attend daily huddles and have their own linked huddles.

Health systems such as Cleveland Clinic, Intermountain Healthcare, Virginia Mason Medical Center, and Baptist Health Services in the US and East London NHS Foundation Trust in the UK have implemented escalating daily huddles, which also supports continuous teamwork and the development of a strong safety culture. While health systems have used escalating huddles for some time, evidence from scientific evaluation is still in its early stages. Early evidence supports benefits for safety and efficiency (e.g., length of stay) for such strategies.⁶⁹ Some evidence suggests that this type of huddles can also increase staff situational awareness of safety.

Visual Management Boards with Linked Measures

The use of visual management boards by point-of-care teams and at each layer of management supports quality control throughout the organization. This approach has been tested to good effect in sustaining improvement.⁷⁰

Point-of-care visual management boards typically merge both quality control and improvement. For example, teams at Fairview Health Services select two measures linked to the organization's strategic domains (e.g., quality, safety, engagement, efficiency) and review two or three quality control standards each day (e.g., compliance with a falls prevention bundle). Teams charter improvement work focused on any gaps revealed in their daily review of data for key measures displayed on the visual management board.

At higher levels of management, daily review of a visual management board typically includes a set of 10 to 20 key measures of operational stability in areas such as safety (e.g., number of adverse events or number of high-risk patients), efficiency (e.g., on-time discharge across units), and workforce (e.g., staff illness and absence). This board or an adjacent board may also reflect any locally escalated problems with planned resolutions, with an assigned individual and follow-up tasks. With less regular review (e.g., weekly or monthly), higher-level leaders separately track a set of measures linked to the organization's current strategic priorities and improvement work

planned to execute on that strategy. At Baptist Health, for example, middle management's visual management board includes a small set of operational measures for each domain in the organization's strategy (e.g., safety, efficiency) and aggregates this data across multiple areas such as the cath lab, facilities, and the OR.⁷¹

In general, when using visual management as a tool for quality control, the focus is on the relevant system or subsystem that a leader manages and is uniquely positioned to see and influence. For example, a director overseeing multiple teams tracks measures that reflect the interactions of those teams (e.g., flow measures) on the visual management board. An executive-level visual management board includes both aggregate measures (e.g., total adverse events) and operational measures for the system as a whole (e.g., may focus on subsystem gaps in particular departments or between departments such as hospital-wide patient flow, total length of stay, and other similar measures).

Little research examines the effect of visual management boards in isolation, as they typically complement huddle structures. Visual management boards are a fundamental tool of Lean approaches to management, and recent reviews find overall positive effects from Lean approaches on quality, efficiency, and staff engagement.⁷² Reviews of visual management from the manufacturing industry cite critical success factors such as modeling leadership behavior (e.g., leaders create their own boards to model desired behavior), providing implementation support for teams, and ensuring relatively simple visual management processes and displays tied to daily work.⁷³

Leadership Presence at the Point of Care

Both middle and senior managers should routinely (i.e., at least daily for middle managers and at least weekly for senior leaders) attend point-of-care team huddles and speak with staff about their understanding and execution of standard work.

Although different approaches are used for leadership presence at the point of care (e.g., Gemba walks, leadership rounds, leader walkarounds), the concept typically includes a few simple questions posed to point-of-care teams:⁷⁴

- What are the team's targets or goals for today?
- How are you doing now?
- What is your plan?
- How can I help you?

Leaders are trying to assess how well staff understand the standard work and their ability to problem-solve, including determining causes for problems they encounter in care processes, articulating the desired state of quality on the unit, and identifying any gaps between the current state and desired state. Through their presence at the point of care, leaders serve as coaches and teachers, help remove barriers, and connect unit-level work to organization-wide strategy and goals.

At East London NHS Foundation Trust, for instance, the executive team holds "walkarounds" with 200 to 250 teams every year, working with the teams to understand challenges, improvement work, and bright spots. Leaders share notes with service leaders, and quality staff

analyze any resulting themes for broader sharing (e.g., with the board of directors). The literature supports the impact of this type of leadership presence, while also noting that a lack of follow up by leaders can be destructive to staff morale and reduce engagement.⁷⁵ Health systems should thus have a robust system to track problems and follow up. Baptist Healthcare in Oklahoma offers an example of such a system, integrated with tiered, escalating daily huddles and a visual management system.⁷⁶

Quality Control as a Source of Staff Empowerment

Quality control comprises point-of-care activities performed by staff who do the work (or their immediate supervisors) to ensure that the work meets quality specifications (ideally identified via staff involvement in quality planning). As Don Berwick noted in 1991, quality control should not be a "dirty word" in health care.⁷⁷ Quality control offers teams a foundation to understand their work and make improvements. If a team does not understand the performance of the current system, how can they understand the impact of the changes they make to improve that system?

Tools used to ensure quality control (e.g., daily huddles, visual management, leadership presence at the point of care) are most effective when implemented in conjunction with good processes for escalating problems. This ensures that problems are escalated to the most appropriate level of the organization for attention and effective resolution, helping to "close the loop" rather than potentially getting lost amid routine business operations. Leaders model the desired behaviors that create a culture of quality (as discussed in more detail below), encouraging staff throughout the organization to surface and track problems and embrace a learning mindset that supports experimentation, even if the initial solution does not prove successful.

Quality Improvement: From Planning to Change

The quality improvement system reflects an intermediate phase between quality planning and quality control (see Figure 8). Organizations identify the quality strategy, priorities, goals, and related measures through the quality planning process. The quality improvement system enables the organization to operationalize the quality strategy and constitutes the necessary structures and resources to bring performance to a new level to achieve the quality goals. Successful improvement initiatives eventually transition to a quality control phase, in which organizational units (e.g., teams, departments) monitor performance using measures related to quality goals, make adjustments as needed, and continuously execute on standard work.

Figure 8. Relationship Between Quality Planning, Quality Improvement, and Quality Control

Quality Planning	Quality Improvement	Quality Control
 Identify the quality strategy, priorities, goals, and measures 	Operationalize the quality strategy at the unit and departmental levels by chartering improvement projects to achieve quality goals	 Monitor performance using measures related to quality goals, make adjustments as needed, and continuously execute
	 Ensure the necessary structures and resources are in place to bring performance to a new level and to achieve 	on standard work

quality goals

The specific structure of the quality improvement system in each organization may differ, but successful QI systems share similar elements as described below.

- Common approach to problem-solving: One agreed upon approach to problem-solving provides a common language, methods, and tools that are used throughout the organization. There are numerous relevant approaches such as the Lean methodology, the Model for Improvement and Plan-Do-Study-Act (PDSA) cycles, Six Sigma tools, DMAIC (Define, Measure, Analyze, Improve, Control) improvement cycle, 7 Quality Tools, A3 problem-solving, or a blend of methods and tools from different approaches.^{78,79}
- Improvement capability and capacity among designated staff: Organizations need to support improvement work via dedicated time and training for staff. Although many larger health systems have full-time quality staff, it's also important to train staff throughout the organization in the fundamentals of improvement methods and tools, including physicians.
- Process to track and scale up improvement: Organizations need a structured internal scale-up process to track the status of improvement work over time, identify and solve common barriers to progress, and share lessons learned among teams while driving the spread of successful changes throughout the organization.

Common Approach to Problem-Solving

Health care organizations have adopted various improvement approaches — including a focus on high reliability, Lean methodologies, and the Model for Improvement, among others — and many organizations use a combination of several approaches and methods. A health system needs a consistent approach to improvement across the organization and the partnership between the quality department and senior leadership can help ensure this is the case. For example, leaders serve as sponsors for improvement initiatives and, in doing so, can coach teams to use a common set of improvement tools (e.g., 5 Whys, root cause analysis, A3, PDSA)

as methods for frontline improvement. Quality staff, in turn, provide consistent improvement training based on the common approach to support teams' work throughout the organization.

Several years ago, Kaiser Permanente developed its own unique approach to improvement by borrowing from different established methods, including systems thinking, statistical process control, Lean and Six Sigma, and user-centered design.⁸⁰ At the Providence health system, the improvement curriculum includes the foundations of quality improvement, the business of health care, change management, and the science of spread and scale, blending concepts from the science of improvement, Lean management, and leading management theories on change and leadership. For years, Providence has also trained leaders in the principles of high-reliability organizations.

As with quality control and planning, key stakeholders play important roles in supporting a common approach to improvement and ensuring effective system-wide quality improvement (see Figure 9).

Quality Planning	Quality Control	Quality Improvement	
Offer input to inform organizational strategy as primary customer group	Offer feedback on quality experience to inform understanding of performance	Engage as co-producer in relevant QI activities	Patients, Families, and Communities
	POINT OF	CARE	
Inform plans and requirements to execute on the strategy locally	Identify and solve problems as they arise (gaps with standard), escalate as necessary	Lead and engage in local QI activities and identify potential QI projects	Clinicians
Translate strategy into a plan for unit setting and outline requirements for execution	Monitor performance and direct solutions, escalate problems as necessary	Lead QI projects and capture ideas for potential QI work	Unit-Level Leaders
Facilitate strategic planning process, support research and analysis activities	Support development of QC standard work and infrastructure	Support local QI activities and inform project prioritization efforts	Quality Department Staff
Work with executives and unit leaders to articulate how to execute on strategy	Identify cross-cutting problems and trends close feedback loops	Sponsor QI projects, lead cross-cutting QI efforts	Departmental Leaders
Identify customers, prioritize needs, and develop strategy	Mobilize resources to address emergent and cross-cutting problems	Sponsor and commission prioritized QI projects	Executive Leaders
Ensure organizational strategy is quality-centric	Review quality performance on a regular basis	Review performance of major QI projects on a regular basis	Board of Directors

Figure 9. Quality Improvement Activities by Stakeholder Group

- Patients and family members engage as co-designers and co-producers in QI activities. For example, some health systems engage Patient and Family Advisory Council members on quality improvement teams. At IOV, a provider of cancer treatment services in Brazil, a small number of patient volunteers, many of whom work in quality in other industries, engage as team members in QI projects.
- **Clinicians** lead and engage in local QI activities and identify potential QI projects. Many QI projects, especially those relating to the safety or effectiveness of care, benefit from having a physician lead. At Northwell Health, a physician serves as the QI coach for a

pilot team-based quality management system, and physicians have led QI work in areas such as reducing the use of unnecessary prescribing.

- Unit-level leaders lead QI projects and capture ideas for potential QI work. For example, they may lead weekly huddles to review improvement work, ensure consistent execution on standard work, and ensure QI project plans are in place.
- Quality department staff support local QI activities and inform project prioritization efforts. The most important job of quality staff is to build QI capability in others rather than do the QI work themselves. Quality staff support improvement teams in a number of ways, including providing data analysis support, ensuring the accuracy and flow of data, teaching staff how to use QI tools for analysis and improvement, and helping teams keep improvement projects on track.
- Departmental leaders sponsor QI projects, oversee the improvement work of unit-level teams, and may lead select improvement work that impacts multiple departments in the organization. Departmental leaders focus on areas that are not under the control of a given team such as flow of people, information, and patients between teams. Middle managers (above the unit level) also play an essential role in managing the productive tension between problems that surface in routine work and problems or opportunities identified through the quality planning process, and ensuring appropriate prioritization of improvement work.

For example, at Cincinnati Children's Hospital Medical Center, division directors work to advance institutional objectives by managing a portfolio of improvement projects to achieve strategic goals while also ensuring alignment of individual teams' work with those goals.⁸¹ The health system developed an educational program called Advanced Improvement Leadership Systems to increase these leaders' capability to do so. Sessions include assessing the current state, safety and productivity, care coordination and outcomes, patient and family experience, and execution of system goals.

- Executive leaders sponsor larger-scale improvement projects, which may include new processes or new products, and launch new organization-wide initiatives such as the development of the quality management structure itself, which comprises a set of smaller-scale improvement projects with leaders for each project. To engage executives in improvement, Providence health system started by structuring an improvement project at each hospital, led by the chief financial officer (CFO), chief nursing officer (CNO), and chief medical officer (CMO) at the facility. The CEO selects projects based on a review of quality and cost data and on system priorities. The CFO-CNO-CMO partners work together over five months to advance the projects, supported by five training sessions in which they learn about the science of improvement and change management. For example, one hospital leadership team focused on reducing unnecessary cardiac interventions. The CFO, CNO, and CMO at that hospital partnered with service leads to support advancement of the project and keep the work on track.
- **Board of directors** review progress of select improvement work on a regular basis, often based on a performance dashboard for the health care system.

Improvement Capability and Capacity for Designated Staff

Many organizations now have dedicated quality staff (and often a quality department) who support improvement at the system level. These staff may be referred to as performance improvement experts, improvement advisors or specialists, coaches, consultants, Six Sigma Black Belts, or other titles. Too often, however, these staff have taken on a role that is heavily rooted in quality assurance – data collection and analysis for those who "need to know" such as payers and regulators – rather than supporting true quality improvement work.

For example, Kabcenell and colleagues found that quality department staff spend less than 30 percent of their time on reducing defects and variation in key processes, and on direct performance improvement work; instead, most of their time is dedicated to data collection and compliance activities.⁸² Ideally, quality staff spend significant time both supporting local improvement work and the organization's progress in achieving breakthrough objectives and major clinical redesign.

The quality infrastructure in many health systems is often inadequate, as is training for quality or performance improvement staff to effectively support continuous improvement and other quality activities.⁸³ Investment in dedicated staff roles to support quality, scoped appropriately, helps establish a strong foundation for a hospital's quality efforts.⁸⁴ Plain language training in a small number of concepts, using adult learning principles, works best.⁸⁵

Optimizing the Role of Quality Staff

Quality staff are most effective when they spend a majority of their time at the point of care, working together with teams to advance the organization's priorities while also helping teams solve emerging problems as they arise. For example, at IOV in Brazil, two full-time performance improvement experts trained in Lean methods support six cancer clinics. As part of their roles, these experts hold open office hours for two hours each week when managers and staff receive coaching on improvement work. These experts also provide support for the organization's quality planning, improvement, and control infrastructure, helping teams build measurement systems (e.g., visual management boards) and guiding their improvement work.

Cleveland Clinic dedicates one continuous improvement expert to each of its hospitals in addition to maintaining other quality staff. East London NHS Foundation Trust employs 15 improvement advisors — experts in improvement science — in addition to more than 100 trained improvement coaches who are dispersed throughout the organization.

Kaiser Permanente (KP) found success with a model that embeds one improvement advisor at each medical center, who reports directly to an executive responsible for leading KP's quality planning, improvement, and control activities.⁸⁶ In addition, given the size of the KP health system, these embedded advisors receive support from regional and national master Six Sigma Black Belts, who also serve as internal consultants to support medical center executives in making the transition to their performance improvement system.⁸⁷ The Black Belts have at least 15 years of experience in improvement (either in health care or in other industries), change management, and managing complex portfolios of projects, in addition to deep expertise in the science of improvement. The total number of improvement advisors increased from 3 to 500 in three years as part of KP's strategy to develop a systemwide approach to quality.

Further, quality staff play both a "horizontal" and "vertical" role, supporting linkages between improvement activities across departments and between departmental activities and organization-wide strategic priorities, as well as facilitating shared learning across teams.⁸⁸

While quality staff require more in-depth training to support them in their roles, it's also important to provide some level of foundational training for all staff to enable them to effectively engage in improvement efforts. Many health systems have introduced broad quality improvement training for staff throughout the organization (point-of-care staff, clinicians, unit leaders, division managers, executive leaders), at different levels of expertise, depending on need, priorities, and local context. In general, only a small number of staff require the highest level of expertise (e.g., to lead systemwide improvement, apply advanced statistical process control tools), but it's helpful when staff throughout the organization have the necessary knowledge and skills to apply basic QI concepts, methods, and tools. IHI experts have previously written about a "dosing" approach that establishes and deploys targeted levels of improvement knowledge and skills throughout an organization to build improvement capacity and capability.⁸⁹

Process to Track and Scale Up Improvement

Health care organizations need mechanisms to understand progress on improvement and share learning across teams in order to scale up improvements throughout the organization. Health systems can use a variety of approaches to structure scale-up processes and develop an internal learning system for improvement.⁹⁰ Internal learning systems can be permanent (i.e., the management structure supports continuously shared learning from ongoing improvement work) or temporary (i.e., the structure supports specific, time-bound improvement workstreams focused on particular topics such as an internal sepsis reduction "campaign").

Examples of Permanent Improvement Learning Systems

Lean organizations often use "policy review" to understand progress on achieving the organization's current priorities, typically executed on using improvement work, and may have regular updates (e.g., weekly, biweekly) at multiple levels of the organization to monitor progress on achieving strategic priorities. For example, a team may report its progress in improving aspects of patient experience scores (e.g., HCAHPS) as part of an organizational priority for improving patient experience established during quality planning.

At Fairview Health, for instance, unit- and department-level leaders have weekly meetings to review measures and progress in executive strategic improvement work to advance organizational priorities. Intermountain Healthcare uses as similar process of monthly "stepbacks" where managers meet with the next-level leader to review progress in meeting goals for strategic priorities, with a designated visual management board structure used for this purpose.

Clinical governance models offer yet another version of a permanent quality improvement learning system. Traditionally led by physicians, these models offer teams a mechanism to deploy improvement work in specific areas, such as patient falls or infections, across sites. For example, at Hackensack Meridian, the clinical governance model facilitated improvement work focused on hypertension management. Johns Hopkins Hospital funds quality "vice chair" roles

at 50 percent salary to support clinical improvement activities, and these leaders meet regularly to share learning to advance their priorities.⁹¹

Examples of Temporary Improvement Learning Systems

IHI's Breakthrough Series Collaborative model offers a classic approach for structuring improvement work when multiple teams are engaged in implementing a common set of changes; many health care organizations have implemented the Breakthrough Series model at the system level to address diverse topics like readmissions, patient falls, or other quality improvement priorities.⁹² In this model, multiple teams convene at regular intervals for Learning Sessions, providing teams with the opportunity to learn from each other about changes being tested, exchange tips for testing and implementing changes, and share data on teams' progress. Action Periods occur between Learning Sessions to enable teams to test evidence-based changes locally. A strong data management system, with regular submission of data for three types of measures (process, outcome, and balancing), provides the foundation for an effective Breakthrough Series Collaborative.

East London NHS Foundation Trust's collaborative on reducing waiting times is an example of a successful temporary learning system – engaging multiple teams, senior leaders, local leaders, and QI experts, with the overall learning system sponsored by the system's chief operating officer. In addition to offering traditional Collaborative Learning Sessions, East London also held sessions every two months where sponsors, project teams, and QI staff convened to gauge the effort's progress.⁹³

Other structures such as communities of practice can also help facilitate shared learning about improvement, especially in larger health systems.⁹⁴ For instance, Kaiser Permanente introduced communities of practice in specific content areas (e.g., falls management) to facilitate shared learning across sites. These communities include physicians, staff, and managers and are led by a content expert. Designated websites facilitate sharing ideas, stories, and practices and might also include storyboards or articles related to topics relevant to the community.

Given the variety of options for developing an improvement learning system, organizations should align their structure to the nature of the goal. The development of targeted clinical pathways among many hospitals in a large system often aligns well with a clinical governance model. Targeted work to spread known changes across similar services (e.g., falls reduction in medical units) often fits well with a Breakthrough Series Collaborative approach. Organizing a complex set of improvement priorities across multiple levels of the organization, with tiered goals linked up and down the hierarchy, often fits well with a policy review approach.

Quality staff support the organization and functions of the improvement learning system, standardizing learning so that it can be easily disseminated, understood, and adapted by local teams throughout the system. For larger health care systems, multiple learning subsystems might exist based on regional preferences and the best-fit solution. In Kaiser Permanente's quality management model, for instance, some sites participate in external Collaboratives and some regions have established internal Collaboratives with partner hospitals to advance specific quality goals.⁹⁵ Quality leaders also support the transition from quality improvement to quality control by teaching teams how to build standard work, reviewing standard work across

teams to ensure alignment and consistency. Quality leaders can also lead efforts to measure the uptake of interventions at a system level.

Strategies for Successful Organization of Improvement Activities

- Create a prioritized list of a small number (three to five) of system-level improvement initiatives on which to focus at one time: In a 2007 IHI White Paper, Tom Nolan outlines the elements of successful system approaches to improvement; most importantly, less is more.⁹⁶ Jim Lancaster writes that an organization should not have more than four or five major improvement initiatives happening at one time; this also holds true at the department, unit, and team levels.⁹⁷ Further, these initiatives should result from the quality planning process described above.
- Senior leaders need to create a shared understanding of the science of improvement throughout the organization: The Model for Improvement and PDSA cycles are perhaps the most fundamental elements of improvement science since they apply to quality control (What is standard work? What actually happened? Why? What next?), quality improvement (What was the planned change and our prediction? What happened when we tried it? How does that compare to our prediction? What do we do next?), and quality planning (What do we need to accomplish this year? How will we know that we succeeded?).

Simple reinforcement by senior leaders of PDSA as a metaphor for the organization's work — or similar framings like DMAIC (Define, Measure, Analyze, Improve, Control) or the Toyota Kata five questions (What is the target condition? Actual condition? Obstacles? Next step? When can we go and see what we learned from taking that step?) — provides a good foundation for creating a culture of improvement and learning by making improvement part of everyday work.

- Ideas for improvement activities flow both up and down the organization: Staff continuously surface and solve problems in the work through QC. At the same time, teams conduct QI projects and implement changes rooted in the system's strategic priorities identified through the QP process. Thus organizations must create space (and most fundamentally, time) for both point-of-care and staff-driven improvement efforts and activities, and for projects driven by the QP cycle. Both are important. Urgent issues surfaced at the point of care may, at some times, displace prioritized QI projects commissioned during the QP process. Unit-level leaders, working in tandem with department directors, determine the appropriate prioritization. The policy review system (to review priorities, goals, and data on measures surfaced during QP), as well as the problem escalation system, can inform this decision-making process.
- Patients co-produce improvement activities: Research suggests that full patient
 participation in improvement activities can result in a threefold increase in a project's
 likelihood of success in achieving aims.⁹⁸

Whole System Quality: Shaping the Transition

Introducing the practices described in this paper to develop a whole system quality approach might seem like an overwhelming undertaking. Organizations that are the most advanced in establishing whole system quality infrastructures and processes have spent more than 10 years making quality the center of their missions and visions, and building the necessary systems and capabilities to do so.

Health care organizations need to consider two dimensions when assessing their approach to whole system quality:

- Penetration: QI, QC, and QP skills and activities exist throughout the organization.
- **Cohesion:** QI, QC, and QP work together as a cohesive system rather than independent, siloed activities.

Many organizations develop pockets of excellence in quality control, quality planning, and quality improvement, but fail to effectively link the disparate efforts and thus the quality activities do not penetrate the organization.

Examples from the Field

Below we share the experiences of Intermountain Healthcare, Cleveland Clinic, IOV, East London NHS Foundation Trust, Kaiser Permanente, and Fairview Health as just some examples from which other health care organizations may learn as they seek to establish whole system quality.

Organizations like Intermountain Healthcare and Cleveland Clinic have followed a particular trajectory in building their quality management systems. They often start with a focus on finite improvement work (e.g., a focus on improvement tools and methods, or improvement projects in a particular clinical or administrative area), then transition to a focus on management and quality control (e.g., the introduction of Lean management systems) to sustain improvement, and finally integrate a focus on quality planning and increased customer focus once this infrastructure is in place (at this point, the quality plan is really actionable at scale). Other organizations, like East London NHS Foundation Trust, start their journey by reducing quality assurance activities to create space for targeted quality planning, improvement, and control activities.

In many ways, this trajectory makes sense. Given years of investment, teaching quality improvement methods and tools relies on many widely available resources and approaches. Establishing management interventions to sustain improvement proves challenging, but is still feasible and often builds on existing management systems such as huddle practices or similar communication methods. Further, tools like Lean management huddle boards can be introduced using improvement methods (e.g., PDSA cycles), so use of these tools logically follows the introduction of quality improvement, and the capacity to apply improvement methods enables staff to act on problems surfaced in daily work.

Engaging senior leaders is often the *most difficult* element, and thus it's logical that quality planning is often the last area of focus. Yet, organizations that fail to prioritize senior leader engagement early in their transition to whole system quality often find it difficult to sustain early gains in building the system itself. Just as Lean management practices provide the "glue" that sustains improvement at the microsystem level, senior executive engagement proves the effective ingredient for sustaining the system as a whole. While we acknowledge the paucity of high-quality literature studying Lean management and total quality management, most existing reviews cite leadership engagement as one of the most critical success factors informing the viability of such efforts.⁹⁹

In developing and rolling out its quality management model, Kaiser Permanente adopted Kotter's 8-Step Process for Leading Change.^{100,101,102} According to this model, Kaiser's approach included, among other steps, building an internal national quality committee, selecting a set of system-level quality measures, benchmarking performance against exemplars such Baldrige award winners (quality planning), building data transparency for selected measures (quality planning and control), and creating an organization-wide infrastructure to drive quality (quality control and improvement). They used, in part, the continued "quality chasm" highlighted at the beginning of this white paper as part of their platform for change to create a sense of urgency, in addition to their own results compared to top-performing health systems.

At Fairview Health and IOV, organizational mergers created an opportunity and a sense of urgency to realign each organization around a new set of values, ways of working, and organizational structure to drive sustained quality. Fairview Health used 10 organizational commitments (e.g., "set and hold standards") to organize and inform their quality transformation work, connecting all management interventions (e.g., introduction of tiered, escalating huddles) to these 10 commitments, which enabled the health system to more broadly communicate their vision and build the foundation for a new way of working. IOV in Brazil used its merger as an opportunity to spread practices that had been introduced incrementally and build a robust Lean management system.

Essential Elements for Building the Foundation for Whole System Quality

Fully implementing a whole system quality approach requires multiple years of work. Notably, the three components of whole system quality – quality planning, improvement, and control – do not exist in isolation; all three link together as a system. Since all three components are essential, we recommend that organizations simultaneously introduce scaled-down activities for each component rather than focusing solely on one component for one year or more at the exclusion of the other two.

To begin building the foundation for whole system quality, we propose a smaller set of simultaneous activities — that focus on the six essential elements described below — on which organizations can focus over one to three years as they work toward their longer-term transition to whole system quality. This foundation can be used for initial testing of the WSQ approach, to learn what does (or does not) work and to inform later organization-wide scale up of the approach.

Element 1: Establish "model teams" to demonstrate quick wins.

Early in their journey, health systems need to establish "model teams" to work on addressing quality control, planning, and improvement together at a microsystem level, with a focus on demonstrating quick-win results (e.g., improvement in a specific area, cost reduction). The continuous value management approach developed by IHI and NHS Scotland can serve as a pathway for building these model teams.¹⁰³ This method includes a weekly huddle to review quality, productivity, and cost data, as well as continuous improvement work (quality control and improvement) linked to a small set of measures that tie directly to organizational strategy (a link to quality planning). The approach has demonstrated potential cost savings of 10 to 15 percent per patient in a cardiac ICU or a respiratory unit through increased patient volume and reduced spending on drugs, supplies, and supplementary staffing.

Element 2: Refine the role of quality department staff and rightsize the QI function to optimally support the QP and QC workstreams.

As noted above, quality departments serve many functions (e.g., training, coaching, facilitation, dissemination, learning), supporting the organization's overall quality work and helping build capability within the organization to achieve strategic quality goals. Quality department staff can effectively serve as technical experts to support work by senior leaders and others, while strengthening the capability of point-of-care staff and managers to execute the quality management system and associated improvement work.

Operational leaders need to review the roles and responsibilities of quality staff to identify the right balance between quality assurance activities and support for the quality management system itself (e.g., supporting executives in quality planning, supporting teams in QC and QI), and to ensure a consistent improvement approach is used throughout the organization. The suggested allocation of quality staff to support whole system quality versus support for regulator and payer needs is 70 percent (at a minimum) and 30 percent, respectively.

Element 3: Introduce rudimentary quality planning to put customer needs immediately at the forefront.

From the beginning of their efforts to implement a WSQ approach, executive leaders need to work with quality staff and service-line leaders on quality planning, including defining customer needs (using methods like focus groups, surveys, and segmentation), developing a strategy to meet these needs, and identifying associated measures to gauge progress. Begin by reviewing the organizational strategy, revise it to ensure strategic domains are mutually exclusive and comprehensive, and develop a relatively small set of measures for each domain, using data from these measures to identify areas for improvement and prioritize improvement projects. Over time, increasing detail on the needs of various customer groups informs quality planning.

Element 4: Build a skeleton problem-escalation system to support whole system quality control.

A system-level approach to problem escalation requires daily huddles are implemented at multiple layers of management (e.g., unit, department, division, facility, system) to support two primary functions: 1) risks and adverse events are identified on a daily basis and elevated to the attention of managers and leaders for action and resolution, and 2) managers at all levels are able to regularly monitor operations and ensure effective deployment of resources where necessary (e.g., additional nursing or social work support). Health systems like Intermountain Healthcare and Cleveland Clinic have adopted such tiered problem-escalation huddles, with associated measures and problem tracking, as a foundation for their WSQ approaches.

Quality control requires problem escalation since issues that arise may not always be within the unit-level team's control to address; thus there needs to be a timely system in place to escalate issues to leaders when necessary and to remove barriers. A tiered escalation process also creates the expectation of a regular review of daily performance across teams – the foundation for effective quality control.

Element 5: Develop a learning system to ensure strong linkages between all QP, QI, and QC activities.

The quality planning, improvement, and control activities all need a senior-level sponsor (e.g., an executive or vice president). The chief quality officer, for example, might sponsor the workstream to optimize quality department staff; the chief operating officer or chief nursing officer might sponsor the problem-escalation workstream; the chief financial officer or chief medical officer might sponsor the "model teams." These senior leaders meet regularly with quality department staff, who continuously harvest learning from individual teams to ensure best practices are shared and to support continuous evolution of the organization-wide learning system.

The introduction of the learning system itself will form part of the organization's quality plan in early years, and thus review of the learning system operations becomes part of regular monthly strategy review meetings at each level of management to gauge progress. At Kaiser Permanente, for instance, regional and facility-level quality improvement consultants serve a key "linkage role" to ensure learning is shared across the health system. At East London NHS Foundation Trust, QI professionals also serve to create linkages among teams that support a learning system and use a single digital platform to track improvement activity.

Element 6: Introduce leadership coaching to clarify and reinforce execution of the norms, values, and behaviors that support whole system quality.

As described in the paper, the WSQ transformation requires certain behaviors to achieve a culture that consistently meets customer needs (i.e., the definition of "quality"). Investment in leadership coaching, including existing organizational values, desired future state, and behaviors that support desired values (e.g., coaching staff where necessary, developing measures that link to values such as staff engagement measures), can help in this regard. Coaching often initially requires support from external experts, shifting to internal quality

improvement experts as the organization advances, with executives and managers themselves ultimately becoming coaches for staff on behaviors that support whole system quality.

Whole System Quality Organizational Assessment

So, how do you determine at what stage your organization is for implementing a WSQ approach? Organizations should begin with an assessment to understand their overall areas of strength and opportunity. Table 5 outlines a basic organizational assessment with examples. Organizations may also pursue various quality awards, as discussed in Appendix A.

Depending on current assets and current stage of WSQ implementation, organizations may choose to focus on specific essential elements rather than all six at once. For example, an organization with strong improvement capability and strong linkages between the work of point-of-care teams and executive-level strategy (as well as executive-level strategy that is informed by the work and needs of point-of-care teams) may elect to focus on element 5 (the learning system) and element 1 (building "model teams") in order to establish a stronger foundation for quality control and continuous learning. An organization with a strong quality control system may seek to focus on element 3 (rudimentary quality planning) and element 6 (leadership coaching) to tighten the connection and strengthen alignment between point-of-care work and executive-level strategy.

Stage of WSQ Implementation	Description	Supporting Clarification
Stage 0	 The organization has a clear strategy. Quality priorities are not integrated or aligned with organizational strategy. QC and QI activities are driven by individual leaders (e.g., at the unit level) and/or by inspection and meeting quality assurance requirements. 	 At this stage, an organization has multiple QI projects occurring, but these projects have many different focuses without (or limited) clear connection to, or review by, senior leaders. The organization may have dedicated quality department staff, but they focus most of their time on meeting the needs of payers, regulators, and accreditors rather than on supporting point-of-care teams and middle managers in executing change.
Stage 1	Quality is articulated in the organization-wide strategy and goals, but systems and processes do not exist to operationalize quality.	 Leaders monitor quality as part of an executive-level dashboard, with select improvement work informing the dashboard, but the organization lacks consistent systems (e.g., tiered escalation huddles) to drive organization-wide QC. Quality activities are time-bound, not perceived to be part of everyday work. QI projects often fail to sustain results because standard work is not followed over time and specific QC activities are not in place to monitor ongoing performance.

Table 5. (Organizational	Assessment:	Stages of	of Whole S	ystem Quali	ty Im	plementation

Stage of WSQ Implementation	Description	Supporting Clarification
Stage 2	 Quality is integrated into the organizational strategy, but largely pursued in silos across the organization. Quality plans reflect clinical quality goals. 	 The organization includes pockets of excellence, within certain divisions, departments, or units making quality part of their routine work, but quality does not happen at scale at the system level. Quality is reflected in strategic plans across the organization, but it is focused on traditional clinical quality (e.g., patient falls, infections) without attention to many other aspects of quality (e.g., equity, a deeper focus on person-centered care, meeting patient needs and expectations).
Stage 3	 The organization's mission, vision, and values reflect its definition of quality. The organizational strategy is a quality-driven strategy. Quality goals and priorities are clearly articulated, communicated, resourced, monitored, and supported organization-wide. The organization is able to demonstrate results in terms of quality, efficiency, and cost, linked to its whole system quality. 	 The organization has a clear strategy oriented toward quality that is well understood by all staff via dedicated strategic planning work that engages staff at all levels and makes their feedback a key input into devising the strategy. Quality is fully integrated into the strategy. Quality is fully integrated into the strategy. Staff understand quality is defined as "consistently and reliably meeting the needs of the customer" rather than a narrower definition that focuses only on clinical quality, quality that only comes through improvement projects, or quality that is separate from daily work. Staff at all levels understand how their daily work impacts the strategic goals of the organization, and in turn has quality implications, since the strategy is focused on quality. Staff have clear measures to monitor performance and improvement work where necessary, to continuously move this strategy forward. Leaders see their job as translating strategy at the division, department, and unit level, while continuously building the capability of all staff to do their jobs well while making changes where necessary, using improvement methods.

Conclusion

In recent decades, the patient safety movement, the rise and influence of regulatory and accreditation systems, value-focused management, and consumerism are largely credited for spurring the growing importance for health care organizations to implement a system for quality management. While some health systems have made great progress in improving quality, many continue to operate in a pattern of reactive quality management, working to continuously address issues caused by poor quality instead of designing systems to prevent them altogether.

The whole system quality approach offers health care organizations a mechanism to embed quality into their enterprise. As health systems pursue a whole system quality approach, they will institute the management infrastructure and cultivate the learning disciplines needed for a more holistic, integrated, and strategic approach to quality — and thus consistently and reliably meet the needs of patients, populations, and communities.

Appendix A: Comparison of Quality Management Approaches

While several quality management models (e.g., total quality management, Lean management, Training Within Industry, high-reliability organizations) resemble the whole system quality approach, WSQ aims to integrate the best aspects of each to build a common approach. Many practitioners will recognize the combination of QP, QC, and QI components in the whole system quality approach as a "quality management system."

Total quality management (TQM), the dominant approach historically used in health care, is less commonly used today in the US but still has proponents in Europe.¹⁰⁴ TQM is more heavily rooted in Deming's thinking and emphasizes his 14 Points for Management as a roadmap for leaders.¹⁰⁵ Organizations using the TQM approach may devote more attention to developing managers and leaders who can coach their staff according to these principles — by, for example, focusing on ensuring all staff have at least some improvement training and can thus contribute to continuous improvement in the organization to achieve the highest possible quality.

Many elements of TQM continue to inform Lean management, which is commonly used in health care today to manage quality.¹⁰⁶ In reality, Lean management and TQM are similar and share common intellectual influences (e.g., Deming, Juran, Toyoda, Ohno, Ishikawa, Shewhart). Lean management is rooted in the Toyota Production System, with a focus on standardized work at all levels, organization by "value streams" to improve flow and make timely work delivered to the customer a central motivator, and continuous attention to building improvement capability in staff at all levels. Organizations implementing Lean and TQM use many of the same diagnostic tools to understand the nature of process problems (e.g., forms of Pareto analysis) and many of the same measurement tools to understand variation over time (e.g., run charts, control charts).

Training Within Industry (TWI) – a set of approaches to build and teach standard work, first used in the US for workforce remobilization during World War II^{107} – also had significant influence on quality, though with less application in health care. This approach focuses on building standard work to simplify jobs, building a foundation for constant scientific learning, and ensuring rapid training. Today, the TWI approach informs many Lean management applications, especially TWI's focus on building standard work.

A high-reliability organization in health care puts safety at the center, with a focus on building a culture where everyone in the organization understands how their job contributes to safer patient care. In practice, the management approaches adopted in high-reliability organizations (e.g., huddles, standard work, rigorous measurement) are similar to those adopted by Lean organizations, and many organizations today implement tools and practices from both approaches.

The various quality management (QM) methods may each have a different focus and use distinct, but overlapping, sets of tools, but they still share many similar features:

- A focus on the customer as the definer of quality;
- A set of tools to effect continuous quality improvement at a system level, rooted in scientific thinking, comparing actual performance to predicted performance, and then analyzing gaps to inform action; and
- Some reference to the need to link quality to customer demand and, in this sense, linking customer needs directly to strategy.

Which Approaches Are Most Effective?

The published literature shows mixed results for most of these quality management approaches. For example, reviews of Lean interventions in health care find overall positive effects on quality, efficiency, and staff engagement.^{108,109} Studies over longer periods of time show positive impacts on quality and cost, but analysts note the poor quality of many studies.¹¹⁰ Overall, more studies analyze the impact of Lean tools rather than Lean transformation as a unifying management approach. Individual organizations adopting Lean as a wholesale approach to management and leadership transformation have noted significant improvements. For example, after a period of losses, Virginia Mason Health System reported positive margins every year since implementing the Virginia Mason Production System and received recognition as a Leapfrog Top Hospital in numerous years.¹¹¹

The literature on total quality management shows similarly mixed impacts. Some research suggests that essential practices for TQM success (e.g., staff empowerment, systemwide focus on quality improvement, customer focus) have a mixed effect on total performance, with stronger evidence for impact on clinical outcomes than on the system as a whole for other elements of performance (e.g., efficiency, overall competitiveness).¹¹² Researchers note obstacles to success using the TQM approach include poor employee engagement, lack of leadership support, and inadequate training. They cite leadership engagement (not just passive support) and the transition from a top-down management style to a more collaborative approach with managers and staff as crucial to longer-term success.^{113,114}

Similarly, reviews of the high-reliability organization (HRO) model find that the overall quality of evidence is low, but also find positive impact on process measures (e.g., reporting of safety measures) and outcome measures (e.g., total serious adverse events) with this approach.¹¹⁵

In general, the effectiveness of the various QM approaches in health care has not been studied with a high level of rigor, perhaps because health systems adopt these approaches to address practical problems, often without relationships to formal evaluators. Each method has predictable benefits based on its relative focus (e.g., safety, waste reduction, employee-driven quality).

It is not least for this reason that IHI does not advocate for using a single approach, but rather for incorporating the best and most common aspects from each quality management method to offer the whole system quality approach as a unifying framework. Whole system quality

embraces many of the cultural principles adopted by TQM organizations, the management practices adopted by Lean organizations, and the focus on defect reduction and the linkage between culture and safety advanced in HROs.

Quality Awards and Accreditation

Several awards and accreditation programs recognize organizations for their quality efforts, including the Malcolm Baldrige National Quality Award, the Deming Prize, the Shingo Prize, ISO 9001 certification, and The Joint Commission's High-Reliability Organization certification. These awards and certifications all have in common the articulation of a set of standards across numerous quality domains, and can serve as useful roadmaps for organizations as they strive to understand their level of success in various elements of quality.

However, we caution that these forms of recognition should not be confused with the management approach itself. Pursuing such recognition can be extremely time-intensive for health care organizations, diverting time away from vital activities such as building staff capability, instituting relevant measurement and management systems, and improving processes and work.¹¹⁶ That said, the organizations sponsoring these recognition systems harvest rich learning about the quality journey and most offer examples of best practices from which other organizations can learn.

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