Patient Safety and Quality Improvement in Healthcare

A Case-Based Approach

Rahul K. Shah
Sandip A. Godambe
Editors

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Foreword

Emily died in our hospital. She was 3 years old. She passed away following a preventable medical error. As recently as 20 years ago, an event such as this might only show up when a grieved family brings suit against the hospital and providers. Yet today, the national dialogue and focus on patient safety and transparent outcomes has dramatically changed. In most hospitals, not only would Emily's passing be analyzed in meticulous detail, but the results would be promulgated within and across the hospital to ensure that providers and the hospital system minimize any chance of recurrence. Further, with resilience engineering and the growing concept of Safety II, hospital systems and individuals may even learn to anticipate the circumstances that predispose to preventable errors [1–3] and prevent them before they occur.

A plethora of texts exist that are filled with theory and concepts intending to teach about making sure "Emily" never happens again—in any of our hospitals. In their text, Shah and Godambe have taken the conversation and teaching about quality and safety to a more practical level. They have not only challenged the talented group of chapter authors to discuss esoteric safety and quality theory, but also to bring these concepts to life through case-based scenarios. This approach brings important safety principles into stark reality as real clinical world events showcase practical approaches to implement change and achieve results. Chapters such as Behavioral Economics by Jack Stevens, Workplace Safety by Joel Bundy, and Human Factors Engineering by Jon Gleason exemplify the innovation and creativity their text displays. Those chapters represent some of the most cutting edge and challenging aspects of quality and safety.

I applaud Drs. Shah and Godambe for compiling a different kind of quality and safety text. One well worth the read for both students and experts. There is something for everyone in this well-done epistle.

Columbus, OH, USA — Richard J. Brilli, MD, FAAP, MCCM

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Preface

Do we really need another book about hospital safety and quality? There are journals, webinars, and myriad national conferences that help drive the field forward. The socio-political-legal environment in the United States has never been more focused on ensuring that American healthcare protects patients and drives quality. There are numerous safety and quality assessments, task-forces, and committees coupled with insurers, industry, and innovators working towards the goal to create the best healthcare delivery system. So, do we really need another book about hospital safety and quality?

The passionate authors of this text provide their insights as to where the field of improvement and safety science is with regard to the views and aspirations of the aforementioned healthcare advocates and customers. The authors are the top safety and quality leaders. We all have and continue to lead and participate in all of the aforementioned programmatic approaches towards hospital safety and quality. However, we still feel the void. We are inundated by theoretical frameworks, "what-ifs," and extrapolations from one industry to another, all trying to help us drive safety and quality to new plateaus in our organizations. However, we still feel a void. The feeling can be summed up as such: "what about us?" A gap in the programmatic approach is that the materials, conferences, and teachings oftentimes fall short of providing the audience with tangible, concrete examples, with direct linkages from a structure to measured processes to discrete outcomes.

Additionally, our responsibility to train our teams and future leaders in improvement and safety science cannot be forgotten – "if the student has not learned, the teacher has not taught," a phrase used often by our Toyota sensei (John Heer, Manager, Toyota Production System Support Center (TSSC) – Australia, personal communication). W. Edwards Deming eloquently said, "there is no substitute for knowledge" [1]. The lessons from healthcare are applicable to other work sectors and vice versa – some of our expert authors, not surprisingly, come from other industries.

This textbook uses a case-based approach to share knowledge and techniques on how to operationalize much of the theoretical underpinnings of hospital quality and safety. We were fortunate to have the leaders in quality and safety embrace this concept as it resonated with their sentiments as well. Furthermore, they all stepped up to contribute to the 22 chapters in this edition. We are confident that a case-based approach with vignettes through the chapters will help solidify the theoretical underpinnings and drive home the learnings. At the end of each chapter, there are comments by the editors which

highlight what we believe are important concepts or connections between the various chapters in the book.

As we strive to reach zero harm to our patients and staff, we must embrace different ways of thinking. This textbook presents a novel approach towards hospital safety and quality with the goal to help us reach zero harm in our organizations.

Washington, DC, USA — Rahul K. Shah
Norfolk, VA, USA — Sandip A. Godambe

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Acknowledgement

This book is the result of the hard work of many dedicated authors with the support of their respective families. It has been a pleasure to work with them and make this dream concept of a case-based learning textbook a reality. We would especially like to thank the countless patients and families, trainees, and colleagues, past and present, whose thoughtful questions and expectations of excellence have made us better improvement and safety scientists and clinicians. Finally, many thanks to our loving families, especially our wives, Banu and Libby, and children, Nisreen, Amir, Maya, Samir, and Riya, who have made sacrifices, yet have been there to support, entertain, and inspire us!

We would like to remind everyone of our goal – to strive for and attain the goal of zero harm!

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About the Editors

Rahul K. Shah, MD, MBA obtained a combined BA/MD degree from Boston University School of Medicine (2000), thereafter completing an otolaryngology residency (Tufts University) and a pediatric otolaryngology fellowship (Children's Hospital Boston, Harvard University). He joined the faculty of Children's National Medical Center (2006), rising to the rank of Professor (2017) at George Washington University School of Medicine and Health Sciences. Dr. Shah's research interests include resource utilization and outcomes, patient safety, and medical errors; he has received numerous awards for his research. He is recognized as a leader in patient safety and quality improvement, and has chaired and serves on myriad national committees related to patient safety and quality improvement. Dr. Shah was Executive Director of the Global Tracheostomy Collaborative, an international not-for-profit quality improvement initiative. He was the inaugural Associate Surgeon-in-Chief at Children's National Medical Center and the Medical Director of Peri-operative Services from 2011 to 2014. Dr. Shah served as President of the Medical Staff at Children's National Medical Center from 2012 to 2014. In 2014, he was appointed the inaugural Vice President, Chief Quality and Safety Officer for Children's National Health System and in 2018 was appointed the inaugural Vice President, Medical Affairs as an additional executive responsibility; he has served as the acting Chief Medical Information Officer (July–December 2019). Dr. Shah has authored over 130 peer-reviewed articles and has given hundreds of national and international presentations. Under his leadership, Children's National has received numerous safety and quality distinctions and is a recognized leader in pediatric safety and quality.

Sandip A. Godambe, MD, PhD, MBA is a physician leader who obtained a combined MD-PhD degree from Washington University School of Medicine's Medical Scientist Training Program. He then completed a pediatrics residency (Boston Children's Hospital, Harvard University) and pediatric emergency medicine (PEM) fellowship (University of Tennessee, Le Bonheur Children's Hospital). He worked briefly at Norton Children's Hospital and then joined the faculty at the University of Tennessee as the Co-Medical Director of Emergency Services. Dr. Godambe obtained his MBA degree with a focus on quality (University of Tennessee) and then became the inaugural Medical Director of Medical Staff Quality. He moved to Children's Hospital of The King's Daughters (Norfolk, VA) where he became the inaugural Vice President of Clinical Integration and Quality and the Chief Quality and Safety Officer. Dr. Godambe has led CHKD to numerous quality and safety awards on their journey to becoming a high-reliability organization. As a Professor of Pediatrics, Vice Chair of Pediatrics – Quality and Safety, and Co-Program Director of the Improvement Science Fellowship with Eastern Virginia Medical School, he leads many educational venues for students and trainees with regard to quality and safety. He is recognized as a leader in patient safety and quality improvement and has led or served on a myriad of state and national committees related to healthcare quality, safety, and emergency medicine. He is the regional co-leader for the Atlantic subsection of Children's Hospital Solutions for Patient Safety (CH-SPS) and a clinical steering committee member for the National CH-SPS and Child Health PSO. He has served as a Senior Examiner for the Baldrige Performance Excellence Program. He is well versed in Improvement Science through his work experience and training in Lean, Six Sigma, Institute of Healthcare Improvement (IHI) Model for Improvement, and the Toyota Production System. He is currently an IHI Improvement Advisor. He has authored over 100 publications, chapters, and abstracts in emergency medicine, quality, and immunology. He is the co-editor of

five books: multiple editions of the *5-Minute Fleisher and Ludwig's Pediatric Emergency Medicine Consult*, *PEM Question Book*, and this textbook. He currently serves on the editorial boards of two journals and is a reviewer for multiple clinical, safety, and quality journals. He has given over 200 national and international presentations.

1 Introduction: A Case-Based Approach to Quality Improvement

Sandip A. Godambe and Rahul K. Shah

Chapter Objectives

- To demonstrate the burning platform of patient safety and quality improvement in the current healthcare era as it relates to the achievement of zero harm
- To explain how varying improvement methodologies can co-exist to drive improvement in an organization with the use of an adapted simple, common language that fosters improvement across all layers of the enterprise
- To connect the work of patient safety and quality improvement to the mission, vision, and values of an organization
- To understand the value of learning best practices and methods from non-healthcare industries

Vignette 1.1

A tertiary care free-standing hospital has a problem with catheter-associated urinary tract infections (CAUTIs). This problem is not new. The organization tackled CAUTIs 4 years prior with the creation of an overarching structure which resulted in new processes and better outcomes. As the compliance with these refined processes improved, the absolute number of CAUTIs went down. However, in the past 18 months, the number of CAUTIs has slowly crept back up. This issue is further compounded by the fact that the rate has significantly worsened even as the organization has reduced their Foley catheter days dramatically. The clinicians only place catheters when they are most needed; hence the numerator has increased, while the denominator has decreased in the CAUTI rate equation. The executive leadership and Hospital Board demand an improvement from the quality and safety team. This can be the self-defeating prophecy for many teams trying to reduce the CAUTI rate – the absolute number of events is decreasing but the rate (which is used for benchmarking) continues to increase.

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Opening Question/Problem

This chapter is not about CAUTIs or specific tactics to reduce these infections – that will be discussed elsewhere in this text. Rather, this chapter discusses the improvement framework and approach toward patient safety and quality improvement that transcends individual hospital acquired conditions and can be broadly applied to quality improvement initiatives in the organization.

Introduction/Overview

There have been significant strides made to advance patient safety and quality improvement in the past two decades. Hospitals, and other organizations, reacted to the clarion call from the Institute of Medicine's seminal work, *To Err is Human* [1]. Since this publication, hospitals and healthcare systems have made tremendous investments in people, processes, and technology – all with an aim to improve the quality and safety of care delivery. We have seen improvement; however, there are issues that still persist and have not improved at the same rate as other measures. Many organizations are struggling with their progress toward zero harm; they have seen a plateau in their improvement and are looking for novel approaches and strategies.

Early in the journey, there was an educational component which was missing in this work. As such, initial efforts were appropriately targeted toward increasing capability (the ability, from a skills perspective, of healthcare workers to embark upon quality improvement initiatives) (Key Point Box 1.1).

Key Point Box 1.1 Capability Vs. Capacity

Capability – the intellectual understanding, knowledge and practical application of improvement science

Capacity – the ability to take on quality improvement projects

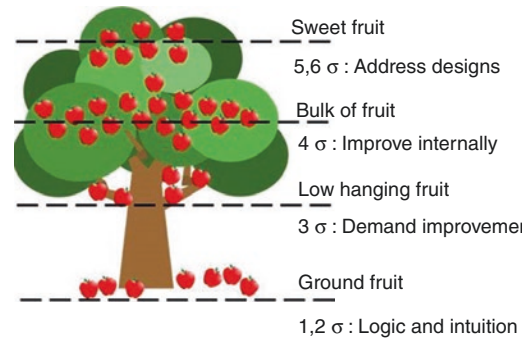

Fig. 1.1 Climbing the quality tree. (Image courtesy of Rahul K. Shah)

Much of the efforts immediately after *To Err is Human* focused on extrapolating the theoretical underpinnings from systems science, reliability, and quality improvement from other industries to educate those of us in healthcare. This was initially quite successful, as there was a whole new lexicon introduced into healthcare. Previously fertile ground was now inundated with theoretical quality improvement applications. As expected, improvement followed as the proverbial low-hanging fruit (Fig. 1.1) was harvested. Some of the success in the early 2000s was a result of the Hawthorne effect (which states that improvement will occur when those performing the work know they are being observed); however, not surprisingly, in many instances, these results were not sustained (Key Point Box 1.2).

Key Point Box 1.2 Sustain

A common problem in quality improvement is the ability to sustain projects for prolonged periods of time. Smart aim statements usually include verbiage to indicate the degree of improvement over a prescribed period of time (6, 9 months, etc.). It is the leader's role to ensure that the project "sticks" and that true improvement is achieved.

Nevertheless, healthcare was quick to embrace this renewed interest in the safety of their patients

and the quality of care delivery; furthermore, the public, government, and payers were expecting such improved care to be delivered quickly.

During the past decade, it has become clearer that the low-hanging opportunities have been addressed. A clear understanding of the journey of healthcare improvement, via the continuous quality improvement framework, resulted in organizations realizing several disadvantages. They were in for the long-haul and real improvement would take years, not months. Improvement would be elusive, rather than straightforward. It would yield further disappointments, not all success.

To increase, or at least continue, their trajectory of improvement, health systems need to change their level of sophistication. Figure 1.1 demonstrates a rubric, and guiding principle, used and presented by one of the editors (RKS) in explaining the complexity necessary to continually improve outcomes for our patients. To understand where healthcare is at present in the quality improvement journey, one can overlay the improvements in healthcare, since 2000 to present, with the level of sophistication necessary to achieve sustained outcomes (Fig. 1.1).

Vignette 1.2

Four years prior, the organization made the reduction of hospital acquired conditions, especially infections, a priority. A new structure was put in place. A physician and nurse co-led the CAUTI team which also included stakeholders from the inpatient floors, the operating room, and the emergency department. The team chartered this work and put in place processes to address the key drivers from their CAUTI road map, using the IHI Model for Improvement. The initial results were impressive – an 80% reduction in CAUTIs in just a few years. However, over the past 18 months, outcomes have slipped, and there has been an increase in CAUTIs. Much has changed in the past 5 years in hospitals with regard to quality improvement. The CAUTI team believes that they need to refresh their quality improvement approach. They are struggling with how to do this with competing organizational priorities. This is further complicated by the ever-changing national perspective, and potentially competing improvement methodologies, which may be frustrating staff.

In the early 2000s, much of the improvements were a result of targeting low-hanging fruit and using basic resources to drive improvements. We would train teams on whatever improvement methodology aligned with our organizational quality improvement teams (Institute for Healthcare Improvement (IHI) Model for Improvement [2], Lean, Six Sigma, etc.). Usually, that basic theoretical education sufficed to collect the "easy to reach" improvement opportunities. This was essentially the era of demanding improvement.

As we evolved our understanding and techniques, the issues became more complex and mandated differing strategies. Organizations started collectively focusing on improvement. Improvement science transcended the quality improvement department, such that it was considered to be the job of hundreds of individuals in an organization. When leadership held teams (and themselves) accountable for outcomes and demanding improvement, said improvements were made to a higher degree of reliability. The next evolution in outcomes will require structures and processes that have specific and unique internal improvements and address systems design.

Healthcare is emerging from its, at times, insular history and is now turning to other industries such as our airline counterparts, Toyota, the US Navy, Alcoa, and others, for models of operational excellence that support a culture of safety and continuous process improvement. Dr. W. Edwards Deming [3] spoke of the importance of systems thinking as a key ingredient for improvement. His System of Profound Knowledge consists of four key points:

appreciation of system, theory of knowledge, psychology of change, and understanding variation. It has had significant impact on some of the aforementioned models of excellence [4]. The Theory of Knowledge incorporated the Plan-Do-Study-Act (PDSA) cycle which is the most commonly discussed unit of improvement science-directed change.

Dr. Donabedian emphasized the importance of systems awareness and design [5]. His widely used theoretical framework (commonly referred to as the Donabedian triad) is composed of three crucial points: structure, process, and outcome. In our organizations, we employ the Donabedian quality triad when embarking on projects or when delving deeper to understand why a system is not performing as expected (Key Point Box 1.3). By having the improvement team take a step backward and move "upstream" from the outcome, the role of structure and process becomes clear. The improvement team needs to look beyond outcomes and ask the provocative questions of what structures are in place and if we are holding teams accountable for the processes that we deem necessary to drive improvement.

Key Point Box 1.3 Donabedian Quality Triad
Structure, Process, Outcome

Vignette 1.3
The initial work in CAUTIs for the organization started approximately 4 years prior. The organization was admittedly and knowingly behind other organizations as they had lost focus and sustainment. To address this, a structure was put in place. Not only was thought given to the constituency of the team (size, representation, need for contrarians, etc.) but also to its reporting structure. The improvement team was explicit in its desire to recruit an executive sponsor to champion the work and provide organizational alignment – ultimately between executive management and the Board. The committee was chartered and reported to progressively more influential hospital level quality committees. The absolute number of CAUTIs were tabulated monthly and presented in a collated format, along with the other hospital acquired conditions, to management, leadership, and the Board in a consistent fashion. Once the improvement team's membership and reporting structure had been clearly delineated, attention was turned to processes. For the CAUTI work, best practices were gleaned from literature, national collaboratives [6], hospital associations, and infectious disease experts. In turn, a decision was made to adopt a bundle from a national collaborative. The bundle, consisting of five items, was adopted and adherence to it was measured.

With a trend in CAUTIs that was contrary to our global aim, and continuing to affect patients, this organization took a pause. They evaluated not only the structure and processes but took a higher level approach to ask if they were using the correct methodologies. The initial key driver diagram from 4 years ago was reviewed and refreshed. Many members of the prior team had moved on from the organization or were not actively involved in the present work. A revised key driver diagram was created and shared throughout the organization.

There exist several quality improvement methodologies and myriad permutations of the foundational methods. Many healthcare organizations are steeped in the understanding of the IHI Model for Improvement and Lean [2, 4]. The IHI Model for Improvement uses a conceptual framework to understand variation, clarify processes, plan tests of change, and measure and accelerate improvement and includes aims, key drivers, and measurement. Lean is an improvement methodology based on the tenets of reducing waste and driving efficiency. It was derived

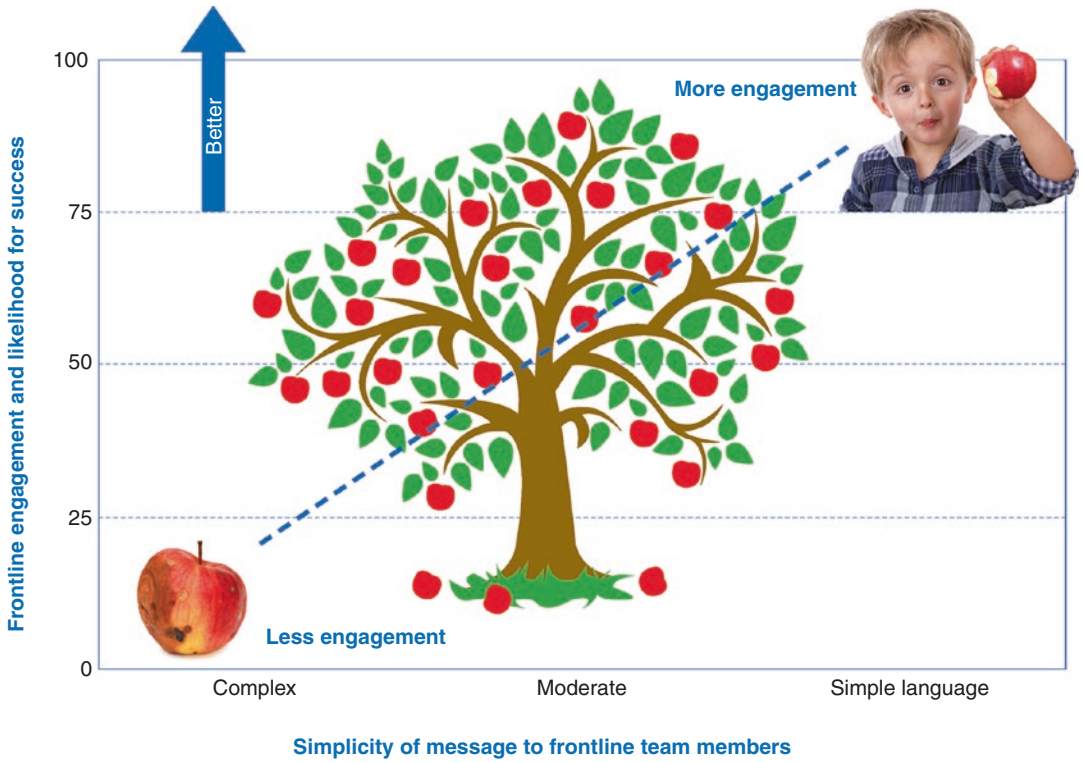

Fig. 1.2 Simplicity of the message and delivery of the fruit of the quality tree. (Image created by Eric Cardenas)

from the Toyota Production System (TPS) [7, 8] and focuses primarily on its technical tools.

A case-based approach to quality improvement cannot be wedded to a particular quality improvement methodology. Organizations should have some latitude and resist being vehemently dogmatic, on which improvement methodology is employed. Of course, it is strongly suggested that an organization have a predominant methodology for quality improvement that is understood by the entire organization. However, to climb the quality tree, it must be conceded that, at times, additional methodologies may need to be incorporated into the strategy. Furthermore, we would caution that being resistant to ideas from other staff about their preferred improvement methodology may harm improvement culture in the long run.

Simplicity is crucial to the message for our frontline team members, who may not understand the complexities of improvement and safety science, as they are the agents driving change. Recall the aforementioned discussion about the apple tree (Fig. 1.1). Now realize that these apples need to reach their customers or our frontline team members. The more complex the bureaucracy or the language, the more likely that the apples will spoil and not reach the mouths of our frontline team members. This would be crippling, as they are hungry for the skills that will make them better problem-solvers (Fig. 1.2). We need to realize that improvement science, while having multiple theoretical models, can be simplified to a common local language that is inclusive and respectful of all methods while still facilitating change across the health system continuum.

Vignette 1.4

After the appropriate structure had been put in place with the necessary multidisciplinary stakeholders, a clear reporting structure to executive leadership and the

Board, and an involved executive sponsor, attention was turned toward traditional quality improvement methodologies. A key driver diagram with a global aim, SMART (specific, measurable, applicable, realistic, timely) aim, appropriate drivers, and interventions was created and then shared broadly throughout the organization. The key driver diagram and review of the CAUTI processes and outcomes were evaluated by the Chief Quality Officer on a monthly basis. Resources (educational, personnel, financial, etc.) were deployed to the micro-units in need to properly reinvigorate their teams. Small groups of frontline individuals were pushing back that they had competing priorities and were unable to do their core work. The CAUTI steering committee was appropriately worried that this would, once again, set back the improvement project.

It is clear that operational success requires systems thinking and realignment which, in turn, requires a structured framework. Some frameworks are inherently complex, such as the Baldrige Framework for Performance Excellence [9], and require considerable organizational and individual commitment and planning. Others appear to be simple like the TPS (Fig. 1.3) which emphasizes the development of individuals, with a focus on the frontline and customers, and the creation of teams of problem-solvers that readily bring problems to the surface. The authors are not advocating for one over another – they each have a role. It is important for the reader to understand the basic tenets of these frameworks. The reality is that the ability to do the latter (TPS) well takes considerable organizational commitment and alignment and probably has not been mastered perfectly by any health system at the time of writing of this text. Jamie Bonini, Vice President of Toyota Production System Support Center (TSSC), best described TPS as "an organizational culture of highly engaged people solving problems (or innovating) to drive performance" (personal communication). Implied in this statement is the importance of transparency, accountability, a focus on developing our frontline team members, and supporting a problem-solving culture.

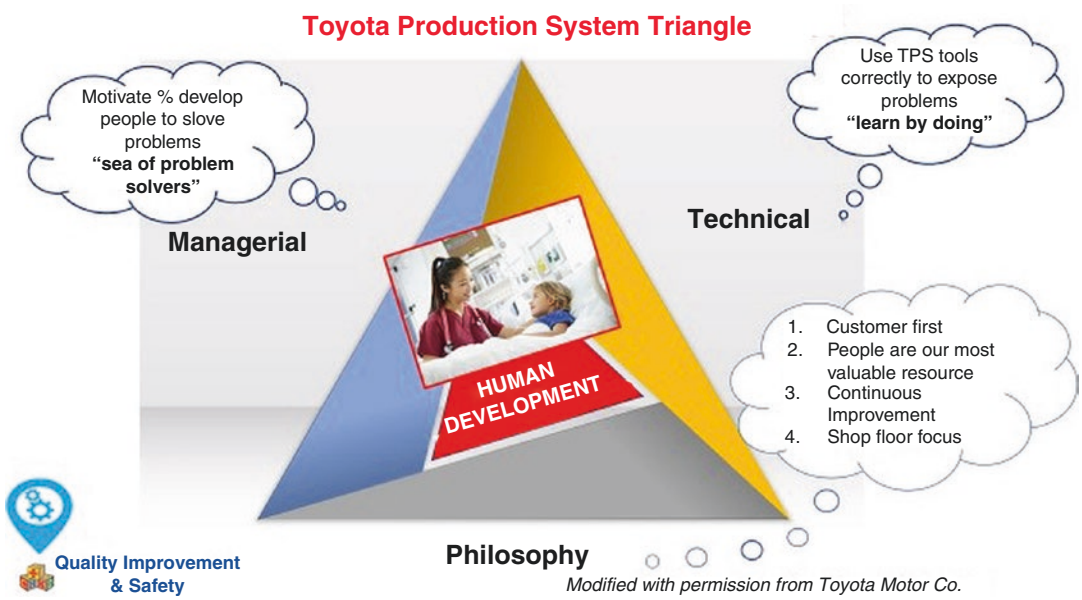

Fig. 1.3 Toyota production system triangle. (Modified from an original figure from Toyota. Used with the permission of Toyota)

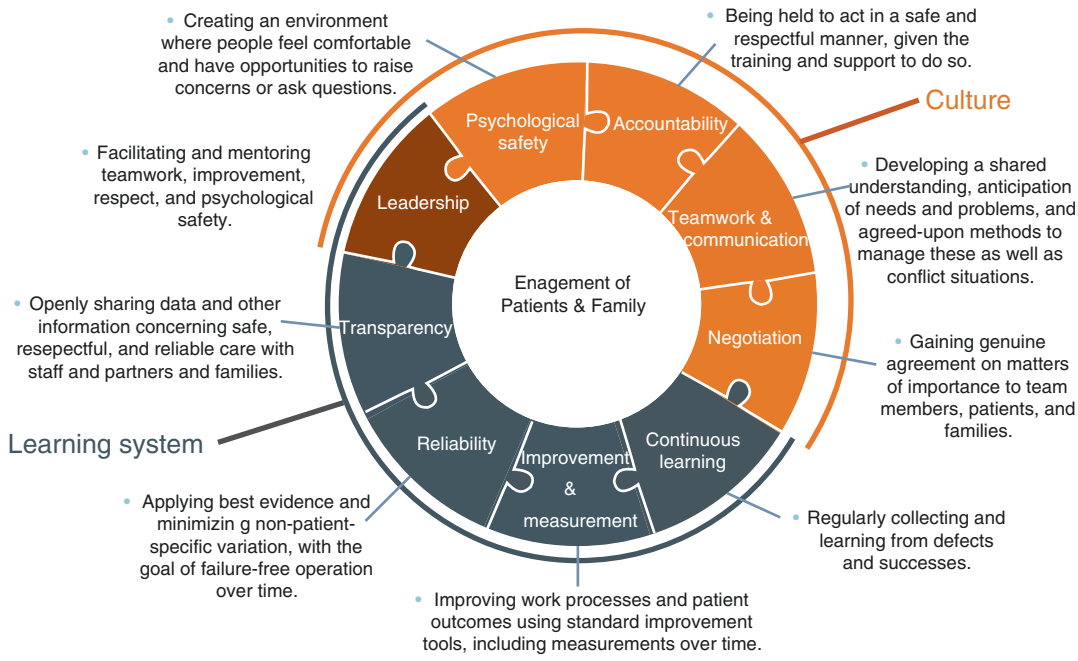

Fig. 1.4 IHI framework for safe, reliable, and effective care [10]. (Reprinted from www.IHI.org with permission of the Institute for Healthcare Improvement, ©2019)

This cannot be achieved overnight. Frankel et al. [10] proposed a Framework for Safe, Reliable, and Effective Care (Fig. 1.4) which describes the culture and learning system domains as being foundational and crucial to the success of safety and quality systems.

Quality improvement efforts in a healthcare organization need to be cognizant of the organizational Culture (intentionally with a capital "C"). Culture is the shared norms of a system. There are hundreds of definitions of Culture. Indeed, each organization most likely uses some permutation of the aforementioned definition. The CAUTI vignette, which has been carried through this introductory chapter, has Culture as a key component. The authors and editors of this text have shared many examples of how quality improvement initiatives fail, or are not sustained, primarily due to the lack of appreciation of the importance of Culture. There is no quick fix or methodology to improve Culture. It is beyond the scope of our introductory chapter, in this case-based approach to quality improvement textbook, to expound upon Culture. However, it must be appreciated in these case vignettes that efforts to drive quality improvement, without an understanding and appreciation of Culture, will not be successful.

Vignette 1.5

It was found, when digging deeper into the CAUTI outcomes, that the operating rooms and emergency department did not espouse the same values and Culture with regard to CAUTI as that held by the inpatient units. One can immediately see the problem and how it can spiral into a bigger issue. If two of the three stakeholders had a different cultural approach to CAUTIs, then there would be no shared mental model. The emergency department and operating rooms did not feel ownership of the issue, as they believed that their care was transient and the patient was ultimately admitted to the inpatient unit. To break this cultural logjam, the Chief

Medical Officer brought the leadership of these three areas together in a small group meeting. The objective of the meeting was to discuss, in an open forum, why two of the stakeholders were not appreciating their team's role in CAUTIs. Contrary to one's impression, the 1-hour meeting did not perseverate on the pathophysiology of CAUTIs nor on specific tactics and strategies to reduce CAUTIs. Rather, a significant portion of the meeting addressed the mission, vision, and values of the organization. By elevating the meeting to a shared understanding of the organization's commitment to their patients, families, and community, the Chief Medical Officer was able to imbue the organization's desired Culture to these teams. Of course, this broader realization did not happen overnight. The initial meeting with the Chief Medical Officer put in motion the goals of the three teams and laid out how their work on CAUTIs would be a microcosm of the bigger work and global aim.

A successful approach to those stakeholders that are recalcitrant, or do not see an issue as a "problem" to be owned, is to move the issue to a higher level and focus on the mission, vision, and values of the organization. This is not a quick solution, and the recalcitrant leader may need to be reminded frequently, perhaps at the start of each meeting on the topic, of their role in the organization and how that ties into the mission, vision, and values (Key Point Box 1.4).

Key Point Box 1.4 Mission, Vision, Values
Mission – the role of the organization
Vision – forward-looking statement of what the organization wants to achieve in the future
Values – principles and ideals that bring the organization together

It would be disingenuous to state that, immediately after this meeting, these groups were engaged. Culture change takes time – often years. Once the Chief Medical Officer had the small group meet, she further charged them to report back to her monthly with their CAUTI data. At subsequent meetings, the Chief Medical Officer made it clear that the three leaders were accountable for the CAUTI outcomes in the organization.

Vignette 1.6
The hospital's Board had heard about the increase in CAUTIs and wanted this to be presented by the Chief Quality Officer at the next Board meeting. The Chief Quality Officer struggled with presenting the data as an absolute number of cases versus a rate (numerator/denominator). The Chief Quality Officer had also contemplated the best manner in which to show the executive leadership and Board other hospital acquired conditions. She believed that if the Board was engaged at present, and asking for data regarding CAUTIs, she should seize this moment and put CAUTIs in context with other hospital acquired conditions. She struggled with how to best show the Board the entirety of the information in an understandable and meaningful way.

Rates are often used in quality improvement and take various forms in their presentations. The most common is the number of events divided by a frequency. For CAUTI, the rate is usually expressed as the number of catheter-associated urinary tract infections divided by the number of catheter days. Some individuals (board members, executive leadership, or non-clinical leaders) may not be able to immediately grasp the significance of small changes in rates as having an impact on patients, especially as we near zero. Dr. Richard Brilli, Chief Medical Officer at Nationwide Children's Hospital, has been a proponent on using actual

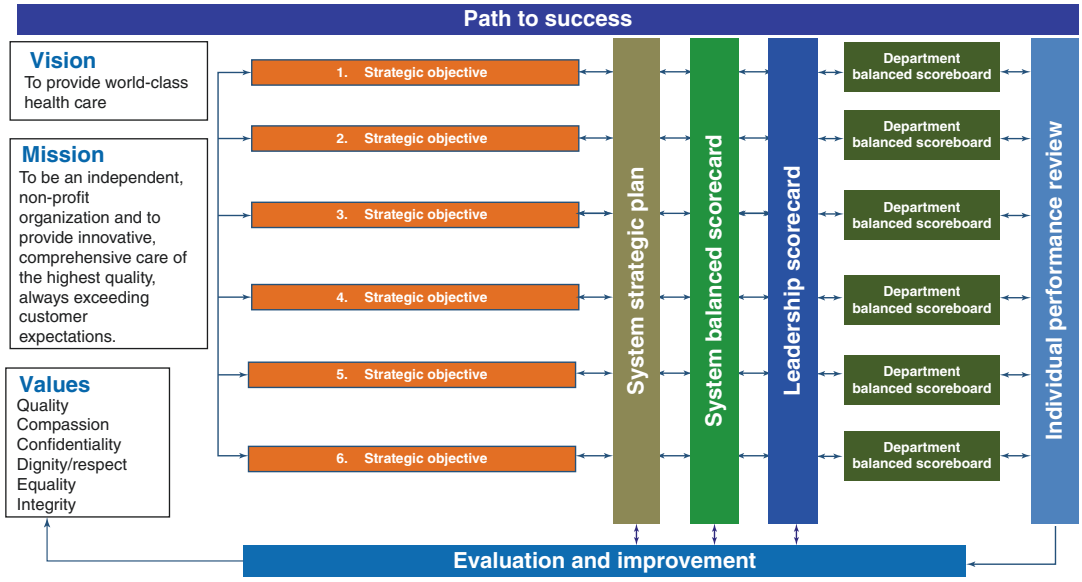

Fig. 1.5 Organizational structure needed for success

event frequency data, as well as rates, to help organizations understand the scope of a problem [11]. It is much more tangible for leadership, Boards, and frontline team members to know that there were, for example, 17 CAUTIs in the past year and 3 in the past quarter. To tersely state a rate for this audience would not be providing them the full context. As we continue to climb the quality tree, outcomes are going to significantly improve, and the numerators (number of actual events) will continue to fall. Rates should also continue to drive down to zero. Dr. Brilli was among the first to stress the importance of zero as our goal for harm reduction. Tacit in this goal is that we may need to be agile in how we present our data – sometimes as an absolute number of events and other times as a rate.

When faced with an improvement project, it is crucial that the initiative is aligned with the organizational mission, vision, and values (Fig. 1.5). We have seen that, in our institutions and when working with other organizations, both the frontline and executive leadership need to be able to see how their work connects to the trajectory of the organization.

At Children's National, under the leadership of our Executive Management and Board, we embarked upon a journey in which the accountable executives over Patient Care Services (Chief Operating Officer and Chief People Officer) crafted contemporary organizational values. These values are Compassion, Commitment, and Connection (Fig. 1.6).

The importance of explicitly stating the organizational core values, and using them as levers to drive engagement and improvement projects forward, cannot be understated (Fig. 1.5).

Vignette 1.7

Despite aligning organizational awareness around CAUTIs by using the Harm Index to demonstrate to the employees and Board that this issue was still pervasive, some employees were not making the connection to bundle compliance and the goals of the organization. Frontline employees were completing the CAUTI bundles approximately 50% of the time on average, and, when looking at various microsystems, the bundle compliance ranged from 30% to 70%. Therefore, the quality improvement team was not surprised that the organization was still having a CAUTI every

Fig. 1.6 Children's National core values and behaviors with alignment to the organizational mission. (Courtesy of Children's National Hospital, Washington, DC)

45 days. The CAUTI steering committee heard from frontline staff that they believed there was no connection of their work to the goals of the organization. The CAUTI steering committee began to change their messaging. The team began to include the "why." The leaders of this work started each of their CAUTI meetings with a patient story that related back to the organizational mission, vision, and values. Often times, a non-CAUTI story was utilized. This tactic spread organically through the organization and, before long, patient safety stories were shared at the top of each pertinent meeting. The patient stories generally lasted about 2–3 minutes and were strategically used to connect the meeting, and work of the team, to the mission of the organization.

Starting each pertinent meeting with a safety story is hugely impactful. A safety story is a brief vignette of an event that occurred in the organization, region, or otherwise, told by a member of the committee. The story should be brief (90 seconds or less), and the chair of the committee should provide just a couple of minutes of discussion to connect the story, address open items, and move the meeting to the agenda items. An example of a patient safety story presentation would be: "I would like to start this meeting off with a patient story. The patient was on the hospitalist service on hospital day #3 when she spiked a fever. The child had multiple lines and was admitted for an aggressive respiratory infection. The child was pan-cultured and found to have a urinary tract infection with a Foley catheter, so this was deemed to be a CAUTI. The child was transferred to the ICU for urosepsis, and required aggressive antibiotic therapy for 3 days. She was then discharged home after a total hospital stay of

9 days. When reviewing the risk factors for the CAUTI, it was noted that the unit's bundle compliance for CAUTI is only 60%. For this child, the CAUTI bundle was not performed each time for all elements. As a side note, the hospital census is high and the ICU is at full capacity" (Key Point Box 1.5).

Key Point Box 1.5 What Is a Bundle?
A bundle is a group of process interventions (almost always evidence-based) put into place for a specific metric, which has been demonstrated to improve outcomes.

The specifics of how to tell a patient story are important to share as the authors have often seen patient stories taking 10–15% of an allotted meeting or note stories that are not connected back to the meeting agenda. Other times, the stories are so profoundly impactful (e.g., patient death or egregious deviation from care) that a portion of the meeting must be used to immediately address some area(s) of concern identified in the patient story. Such a story is not effective if it did not achieve its goal of connecting the dots for the committee members and grounding the team in their work, but instead "hijacked" the agenda from the meeting's intended purpose. A safety story should be a succinct vignette, preferably related to the organization in some manner and presented in 90 seconds or less, that is used to demonstrate organizational alignment and the work of those in the meeting. Additionally, the importance of patient and family participation on improvement committees cannot be overstated. We need to remember that, at some point, all healthcare providers will also be consumers of healthcare. We would want to be given the same respect and ability to be involved in our care or the care of our loved ones.

We are confident that this introduction has provided the reader an idea as to what to expect in the ensuing chapters. Quality and safety is the paramount priority of most organizations globally and unequivocally for healthcare organizations. Naturally, there is much information as to how to proceed, but the journey to zero harm requires careful planning and time. Success takes a shared vision, simple and measurable strategic objectives, leadership and frontline engagement, common operational language, perseverance, and the desire to succeed.

Thomas Nolan's Framework for Execution [12] (Fig. 1.7) and the Toyota Production System

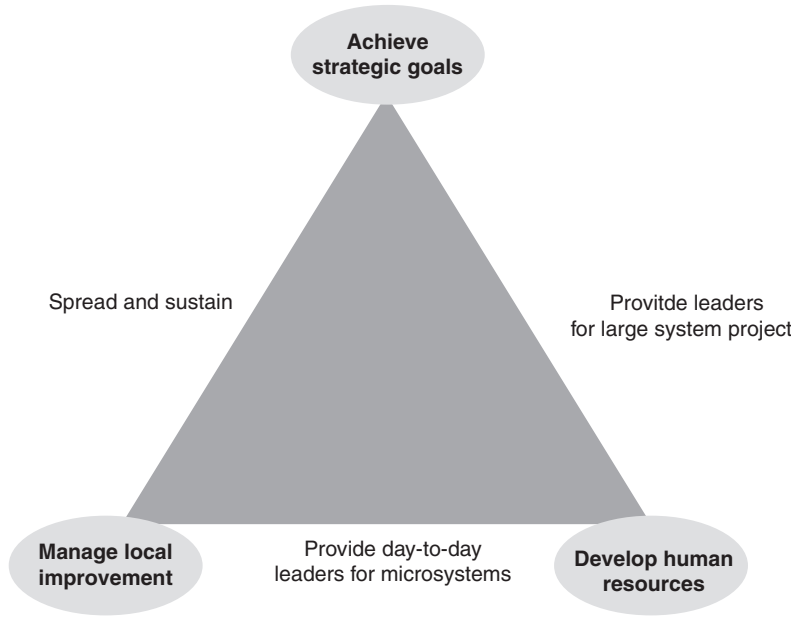

Fig. 1.7 Framework for execution. (Reprinted from www.IHI.org [12], with permission of the Institute for Healthcare Improvement, ©2019)

Triangle (Fig. 1.3) are some of the simplest representations by which to drive improvement. Both will be discussed in the ensuing chapters. Nolan discussed the criteria necessary for breakthrough performance: (1) to define breakthrough performance goals; (2) to create a portfolio of projects that support these goals; (3) to deploy appropriate resources to ensure the success of these goals; and (4) to create the oversight and learning system to monitor and ensure success. High reliability, as discussed by Weick and Sutcliffe [13], is the goal for healthcare enterprises and their combined membership. It is not for the faint of heart, but it remains elusive until the many aforementioned criteria are attained. We will be discussing their various components in depth in this text.

Editors' Comments

Each chapter will be followed by a synoptic chapter summary by the editors to put the article into the broader context of the textbook and healthcare quality improvement overall. To simply reiterate the abstract would not be of value. Rather, this concluding section for each chapter will attempt to pull the chapter and textbook together and be forward-looking in nature for the reader.

This introductory chapter attempts to rekindle the burning platform in healthcare by pushing us to strive for zero harm. To do this, we implore readers to strive for zero harm. To increase the level of sophistication in quality improvement, the authors stress the importance of the Donabedian quality triad of structure, process, and outcomes. In beginning quality improvement projects and when evaluating those that are in sustain mode, it is crucial to ensure the project has the right structure and that process measures are being completed and sustained as expected with controls in place for accountability.

A key goal of this chapter is to also drive home the concept of absolute numbers of harm compared to a rate and how to engage an organization's Board to understand and be able to participate in discussions regarding hospital-acquired conditions. Additionally, engagement of our frontline team members, our patients, and their families is needed for success. We need a common and simple operational language which everyone can understand and rally around.

Finally, Culture is important when evaluating why a quality improvement project has stalled or is not achieving the desired outcomes. Understanding your organizational Culture and ensuring its alignment with quality improvement efforts is compulsory, especially with stalled initiatives. Many times, Culture is not explicitly addressed and is evaded to avoid potentially difficult conversations. One must use the levers necessary to prioritize and highlight the role of Culture in quality improvement initiatives.

Chapter Review Questions

1. Describe how quality improvement strategies have evolved over past decades.

   Answer: Initial quality improvement strategies focused on the low-hanging fruit, and, as improvements occurred, it became necessary to move to higher levels of sophistication and reliability. At present, organizations are on different parts of the quality journey, and, as such, their improvement strategies have differing levels of sophistication (Fig. 1.1 *and* 1.2).
2. What is the difference between capacity building and capability building?

   Answer: Capability building is the "ability," or skill set, for improvement science. Capacity is the "time," resources, or organizational ability, to improve. An individual may have capacity to lead improvement, but an improvement initiative will be stymied without capability.

3. How does Culture influence quality improvement initiatives?

   Answer: Culture drives improvement. Without attention to Culture, much improvement will be the result of the Hawthorne effect and will not be able to be sustained. The value of Culture development cannot be underestimated.
4. What are the elements of the Donabedian quality triad?

   Answer: Structure, Process, Outcome.
5. How can an organization's mission, vision, and values be used as levers for quality improvement?

   Answer: It is crucial that staff appreciate and understand their role in quality and safety and how it aligns with the organization's role. The mission, vision, and values help the frontline staff, manager, leader, and Board member connect their safety and quality work with organizational improvement efforts.
6. How can patients and their families be incorporated into organizational quality improvement initiatives?

   Answer: It is imperative to include the voice of the family and patient in organizational quality improvement. If we fail to include these stakeholders, then our work is not complete. It is quite easy to include patients and families by working with your Patient/Family Advisory Council, Volunteer Services, or other such liaisons in your organization.
7. Describe the characteristics of the ideal system for continuous process improvement.

   Answer: The purpose of this question is to get our readers to start thinking about the ideal system for continuous process improvement. The remaining chapters of this text provide further insights, and we will return to this very question throughout the text in the editor's comments. For now, we will state that the ideal system for continuous process improvement understands this is difficult work that takes considerable organizational planning and foresight. Capability and capacity need to be built at the frontline level with significant senior leadership, and Board, commitment and visibility. The goal of this system is to develop processes and procedures that are clear, simple, and understandable and that occur reliably. The organizational culture needs to encourage bringing problems to the surface and, for the most part, local ownership of problem-solving.
8. True or False: Healthcare systems are unique and complex, so few concepts from other industries are applicable to healthcare.

   Answer: False. Healthcare has learned, and continues to learn, much from other industries. Specific examples are included throughout the chapter.
9. Based on the discussions in this chapter, which of the following is important to carrying out a successful quality improvement project?

   A. Alignment with organizational goals and priorities.
   B. Inclusion of patients and/or their families.
   C. Assigned accountability and visible support of senior leadership.
   D. Supportive culture that permits transparency.
   E. All of the above.

   Answer: E.

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2 Organizational Safety Culture: The Foundation for Safety and Quality Improvement

Michael F. Gutzeit, Holly O'Brien, and Jackie E. Valentine

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
COSS	Culture of Safety Survey
DSB	Daily Safety Briefing
EPT	Error Prevention Tools
HRO	High Reliability Organization
RTI	Rounding to Influence
SSE	Serious Safety Event
SSER	Serious Safety Event Rate

Chapter Objectives

- To explain and define the role of patient safety culture in healthcare organizational culture
- To understand the essential role of leadership in shaping the culture of an organization
- To share specific examples of safety tools, behaviors, and language used in creating a patient safety culture that connects across an entire organization
- To appreciate the role safety plays as an important component of a quality improvement program
- To offer methods of sustaining advances in a patient safety culture

Vignette 2.1

A pediatric healthcare organization had a recent change in several key executive roles.

Financial performance was meeting target, and much of the Board of Directors agenda was devoted to the topic of strategic efforts to maintain healthy financial performance. While there are many quality and performance improvement efforts underway in the organization, these lack coordination and have multiple consultants and teams working in silos. Despite best

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intentions for collaboration, there is intense competition among internal groups for limited resources. There have been several attempts to initiate a defining set of universal values for the organization which would help to align current and future projects and workflow changes. In the past, there had been adoption of some values defined at the leadership level, but middle-management and frontline staff were confused about universal implementation of these values due to a lack of a consistent educational platform and expectations about their relevance to everyday work at the frontline. Following a gap analysis of the organization's current state of safety, experience, and clinical outcomes, the Board of Directors and Executive leadership agreed that building an organizational safety culture is crucial to meet the desired quality improvement vision for the enterprise to achieve staff and patient experience performance goals, as well as maintaining a healthy financial profile. The key decisions at the executive level involve how to begin the culture work, what type of existing framework to use, and how the potential impact on culture will be measured. The executive team determined that starting with safety as a core value meant starting with clear and apparent leadership commitment and direction to this undertaking which would be evident to all in the organization.

Opening Question/Problem

This chapter is about the foundational elements of building an organizational safety culture starting with leadership and its commitment to safety. It is intended to provide a variety of options as well as a case example that is meant to be illustrative. Recognizing that each organization has a unique set of circumstances and issues, the information should be helpful regardless of where an organization is on its own patient safety journey. Additionally, the key principles and examples could be applicable to industry outside of healthcare.

Introduction

An organization is defined by its culture. Culture influences and is influenced by the mission, vision, and values of organizations. It is the common denominator that drives performance, engagement, and sustainability. It is hard to directly measure culture but it can often be perceived and is judged by others through the first experience with that organization as a customer or team member. Culture also reflects the value placed on the flow of information and engagement both up and down the organizational chain of command and input from patients/families/clients and others with perspective ("Voice of Customer") as well as an approach to inevitable and necessary growth through change management. A specific component of organizational culture in healthcare is the safety culture, which is one component of the organizational culture. The safety culture is the sum of factors which demonstrate a resolve to health and safety management by leadership to the organization [1]. Figure 2.1 depicts conceptualizing the components of a patient safety culture.

Most importantly, organizational culture includes behavioral expectations that are applied consistently. New hires are made aware of this

Fig. 2.1 The components of a patient safety culture

culture through the onboarding process and prior to that with a hiring process that takes into account candidate attributes consistent with the organizational culture.

To illustrate this by example, at one large children's healthcare organization (Seattle Children's), every new hire is required to take a four hour interactive Error Prevention class on the second day of employment; those in clinical care settings take an additional four hours of Patient Safety Orientation that shares more specifics on keeping patients and staff safe. The purpose is to share the priorities of safety that are universally expected throughout the organization. The orientation includes methods and resources to support a patient safety goal of eliminating preventable harm to patients and staff. Topics such as Infection Prevention priorities, integration of simulation into learning, delivering effective and equitable patient-centered care for a diverse population, and comprehensive language and interpreter services for families are shared. Using real examples from past safety-related events helps raise situational awareness and emphasize the vulnerabilities that exist in caring for children in complex social environments.

Within 90 days of hire, all leaders at supervisor level and above are required to attend a four hour integrated Leadership Methods course (see Appendix 2.1). This course defines the organizational expectation of the leaders' role in safety. The course uses the Institute of Medicine (now known as the National Academy of Medicine) six domains of quality as a foundation.

Organizational culture supports and enables a safety culture. It is imperative to appreciate that over time, a culture of patient safety reflects the existing normative culture in any organization. If the foundation of culture is not well established, a culture of safety will be difficult to sustain. Ideally, every individual in a healthcare organization is part of the safety culture regardless of their role or proximity to patient care, because every role contributes to the health of the organization and, ultimately, the safety of all.

Building a Safety Culture Begins at the Top

Leadership commitment to a safety and patient safety culture is absolutely necessary because leaders shape and model culture in ways that are tangible and intangible, explicit and implicit. To change and build culture, top executives must demonstrate the behaviors they want to see. In fact, Sammer et al.'s findings from a meta-analysis [1] showed senior leadership accountability is key to an organization-wide culture of safety and that it is the leaders that design and implement the strategy and structure that guide safety processes and outcomes and ultimately the safety culture. This point is also made in a publication by Yates et al. [2]. In an editorial on "Creating a Culture of Safety," by Dickey from 2005 [3], it was noted that improving a culture of safety must begin with the chief executive officer. The executive leadership team must enable and build safety culture knowledge. Sammer et al.'s findings also [1] revealed that safety culture is a complex phenomenon that is sometimes not clearly understood by hospital leaders, thus making it difficult to operationalize. To understand culture it needs to be defined. The Agency for Healthcare Research and Quality's (AHRQ) definition is: "The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviors that determine the commitment to, and the style and proficiency of, an organization's health and safety management" [4].

Moving from Leadership to the Frontline

In building a sustainable safety culture, it is important for the frontline staff to understand the mission, vision, and values of the organization. This helps generate a common purpose, language, and focus. There are many contributing factors that must come together over time to continue advancing the priority of a safety culture as shown in Fig. 2.2.

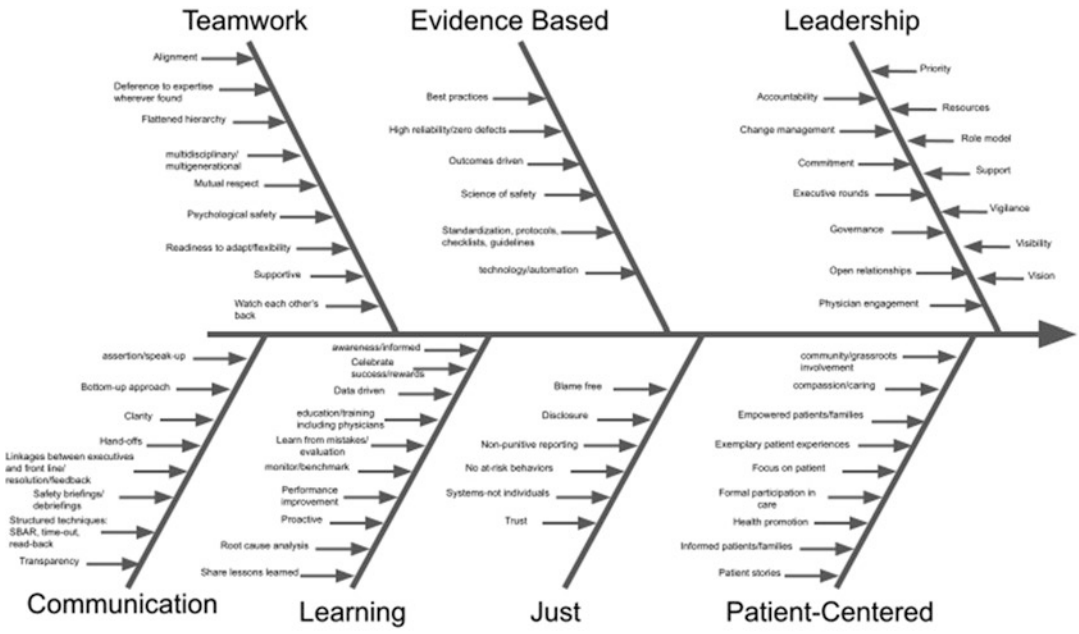


Fig. 2.2 Hospital culture of patient safety contributing factors. (Reprinted from Sammer et al. [1], with permission from John Wiley and Sons)

Choices made and behaviors demonstrated at the executive and other leadership levels will subsequently influence those same types of choices and behaviors at all levels of the organization. One important and practical demonstration of a culture focused on safety (and especially patient safety) is to observe whether staff hold themselves and each other accountable by cross-checking one another and provide real-time feedback when deviation from generally accepted performance standards is identified such as following hand hygiene policy and best practice (i.e., 200% accountability; see Key Point Box 2.1). Very simply put, each person holds coworkers and themselves equally accountable for patient safety. A 200% accountability concept must be supported by the ability to provide open, honest, and transparent feedback without fear of retribution or retaliation following unexpected outcomes that cause harm. This includes full support for families and staff involved in these inevitable events.

Key Point Box 2.1: 200% Accountability
An organizational expectation that each person is 100% responsible for following behavioral and best practice norms as well as holding others 100% accountable for the same

Moving to Improving Culture

Understanding the current state of organizational culture is usually the most important first step in building a patient safety-focused culture. Most validated psychometric surveys are indicators of the workforce's perceptions of safety culture and engagement for those integrated survey tools. The administration of an annual or biannual culture of safety survey is most often cited as a lagging (trailing) indicator of cultural safety, but it could also be considered a leading metric. To elaborate on this concept, consider that if the cur-

rent culture norms continue as is in an organization, it will be predictive of the future organization cultural direction unless there is a change. If there is desire or a restlessness that improvement is needed in the current organizational culture, the results of such safety surveys should give an idea of how high the bar needs to be set to affect culture change when planning for improvements.

Some of the validated psychometric culture of safety surveys (COSS) (see Key Point Box 2.2) organizations use today to monitor workforce perceptions of culture are the Agency for Healthcare research and Quality (AHRQ), the Safety Assessment Questionnaire (SAQ), the Safety, Communication, Organizational Reliability and Engagement (SCORE), the Advisory Board and the Press Ganey Integrated Engagement, Resilience and Safety Culture Survey. These surveys will identify workforce perception of the safety culture at a point in time. Achieving at least a 60% survey response rate from staff gives the most meaningful results which can be analyzed and potentially acted upon. Ensuring anonymity is also crucial for participation and candid responses.

The Joint Commission (TJC) requires, and other regulators recommend an assessment of the safety culture at a minimum of every 2 years with a validated survey. This is also required to receive top recognition on the Leapfrog Hospital Survey [5]. With a focus on leadership and culture, regulatory agencies are looking for survey results shared from the board to the frontline teams with clear action plans and a continuous history of improvement. A Joint Commission Sentinel Event Alert, published in December 2018, noted the importance of leadership accountability to advance a strong safety culture and frontline team member's willingness to report both near misses and patient safety events that reach the patient [6].

Key Point Box 2.2: Culture of Safety Survey (COSS)
A survey to gain insight about how staff and others involved in the delivery of care organizational operations view the current patient safety practices

To emphasize the importance of these safety survey tools and their potential use, consider an organization that received a sub-optimal Leapfrog Hospital Survey score. Further analysis revealed one of the most heavily weighted questions impacting the score was related to the administration and organizational action planning from the culture of safety survey (COSS) results. The COSS had not been administered for over two years, and previous surveys lacked a clearly demonstrated organizational dissemination of results, communication to staff, and leadership oversight and follow-up on actions with the teams involved in the actions. The important lesson is that any survey must be linked to follow up communication and sharing of results along with a clear plan and timeline with support for action. This is important in building the desired culture in an organization and was demonstrated in six large hospitals researched by Campione and Famolaro [7].

An effective strategy to achieving desired input leading to action could be to debrief the survey results with a team through an independent facilitator which might occur without the leader of the unit present. This encourages candid and comprehensive feedback and engagement of staff. Closing the loop on such discussions with staff and leaders is important as is celebrating successes and measurable improvements. As much as possible, a supportive, non-punitive, and actionable organizational response to low performance score is imperative. Open-ended comments from surveys can also provide additional insight if they reflect a systemic issue. Actions must be prioritized and using data whenever possible helps sustain the effort.

Vignette 2.2
Leaders had reviewed the annual culture of safety survey results, but did not have a real understanding of meaningful actions to take on for improvement nor any ownership or accountability from the leadership team on expectations. Safety appeared to be a lower priority overall in the organization without clear expectations

and guidance on relevant and sustained action plans for performance improvements. With a baseline cultural assessment complete, a strategy was set and operationalized that created clear standards and expectations. A curriculum was initiated for every leader and frontline workforce member in the organization to build capability and capacity in safety culture behaviors, terminology, and habits to reduce the probability of error. An aspirational goal of zero harm, like many other healthcare institutions, was set. The board and senior executives recognized it would require a large upfront commitment of time and resource allocation. Borrowing from examples in non-healthcare industries provided awareness that crucial elements of developing consistent system reliability and culture would be essential to achieve similar results. The executive team agreed to keep a visible commitment to safety as a top ongoing priority.

Leaders Being Present and Leading by Example

The following are ways that leaders can operationalize and visibly demonstrate a commitment to building and maintaining a commitment to safety and reliability [8].

1. Daily Safety Briefings (DSB) are recognized as best practice to achieve an enterprise-wide daily operational surveillance and management system to enhance the awareness and priority of safety. The Daily Safety Briefing starts at the local level with team or unit huddles throughout the organization. This structure allows reports of safety and operational concerns to be communicated and resolved as quickly as possible. A system-wide, daily 15-minute huddle facilitated by an executive with reports from key operational leaders for escalation of high-risk issues, deficiencies, distractions, cross-departmental issues, and abnormal conditions, allow the leadership teams to become more sensitive to operations, and the immediate needs of patients, staff, and facilities are addressed. The timing for the DSB should be consistent from day to day with minimization of scheduled meetings during this interval to allow maximal participation. Utilizing a modified weekend and holiday structure shows continuity of leadership support. Key factors for a successful and sustainable Daily Safety Briefing include leadership presence at the huddle and on the call, preparation by reporting teams, defined follow-up on concerns raised to build trust in the process as well as clear expectation and accountability to participate in the Daily Safety Briefings.
2. Rounding with purpose on individual units. In addition to being visible for operational leaders at the Daily Safety Briefings, executives should set the expectation for leaders at all levels to participate in mandatory rounding on a regular basis. The purpose is to connect with the frontline leaders, teams, and patients/families to observe firsthand the work being done. This will allow a determination of work as it is actually being done compared to how it is imagined being done: reality vs. perception. Rounding promotes an opportunity for leaders to provide a few key strategic and tactical system items to staff and solicit their feedback on goals, priorities, concerns, and barriers. This effort supports building relationships and to close the loop on issues raised from previous rounding interactions or the Daily Safety Briefings. It gives leaders the opportunity to provide positive feedback and to recognize and reward those individuals who demonstrate the safety culture behaviors and language. Many different types of rounding methods are evolving across healthcare systems and are beneficial for building staff engagement, patient/family, experience, and culture of safety scores across all domains. Examples of

rounding practices for leaders include the following:

(a) Round with every patient every day: Operational leaders round on every patient every day with a focus on one or two important questions that could be related to improvement ideas from the patient experience or culture of safety surveys such as teamwork within and across teams and feeling safe to speak up and escalate an issue [9].

(b) Round once a month with every staff member – Rather than waiting for the annual engagement or safety surveys, organizations can implement a continuous feedback model in which each staff member has an opportunity to speak with their leader to share ideas and concerns or show appreciation and receive interval updates on goals and developments.

(c) Executive Walk-Rounds – A method to coach and focus on key organizational goals. This is a way to validate that frontline teams understand the importance of specific priorities such as hospital acquired conditions (HACs), hand hygiene and other work important to improving patient outcomes, such as care bundle reliability. [10, 11] (Key Point Box 2.3).

Key Point Box 2.3: Care Bundles
Evidence-based practices that when performed collectively with high reliability have been demonstrated to improve patient care

Whichever rounding method(s) is implemented, it is important to start with intention and purpose and build confidence, capability, and capacity in all leaders to round and close the loop on issues raised whenever, and as soon as possible. Rounding times could be used to emphasize a specific organizational value or for recognition where individuals and systems have performed well. (Key Point Box 2.4).

Key Point Box 2.4: Communication of Shared Learnings
- Thematic leadership rounding such as a specific organizational value, error prevention tool, or regulatory concept
- "Close the loop" follow-up on issues
- Intranet posting of recognition for specific examples of excellence in safety
- Periodically starting the Daily Safety Brief with an example of a "good catch"

Consistent messaging across leadership levels will demonstrate the cultural priorities of the organization at the system level down to the unit or department level.

Organizational Case Example: Embedding Safety Culture Tools, Behaviors, and Language

The following is an actual case of how Seattle Children's (formerly Seattle Children's Hospital) used a structured process to embed safety tools and behaviors to drive their safety culture at the frontline with leadership support. A consultant in high reliability organization was utilized to collaborate on this journey. At the outset a standardized Safety Event Classification (SEC) taxonomy and algorithm system was used to classify reported safety events from a previous 12-month period. This is a method of defining and investigating thoroughly near miss events (NME), precursor safety events (PSE), and serious safety events (SSE) to determine a baseline Serious Safety Event Rate (SSER). A serious safety event is defined as an unintended incident that reaches the patient causing moderate to severe harm, including death. In a serious safety event, clear deviations from generally accepted practices or standards have occurred, such as unknowingly going against policy due to lack of training or distractions. An event classified as an SSE is generally considered preventable. The Serious Safety Event Rate is calculated monthly as the number of serious safety events for the previous

12 months per 10,000 adjusted patient days [12]. The ultimate goal is zero serious safety events which is commonly used within an organization as one metric to determine the improvement in patient safety culture, systems reliability, and overall performance improvement. The transparency of sharing safety event stories and meaningful safety data as learning opportunities had a significant and positive influence in improving Seattle Children's organizational culture and reliability. It helped reinforce that everyone in the organization, no matter the role, contributed to improving the SSER.

Vignette 2.3

Seattle Children's chose to invest a significant amount of resources to train all leaders using a leadership curriculum with dedicated weekly effort called Rounding to Influence (RTI) which set expectations on reinforcing and coaching to the safety culture journey (see Appendix 2.1). All frontline clinical and non-clinical leaders and workforce members were trained in error prevention tools (EPT), behaviors, and a cultural language (see Appendix 2.2), which in theory should reduce safety events [13]. The tools focus on reducing the probability of errors by enhancing communication, such as using standard structured formats for handoffs, repeating, and reading back information to ensure the receiver has the correct information or task. Specific tools and a brief explanation are described in Appendix 2.2. Frontline teams and leaders learned and applied these error prevention tools in both clinical and non-clinical settings. The purpose is to create a unified set of safety behaviors and common organizational language that can help eliminate defects and errors as seen in other high reliability organizations and peer institutions by building habitual excellence in the use of this language and behaviors. Progress toward a safety culture was accomplished at Seattle Children's for the training sessions with built-in sustainability structures to ensure all new hires and leaders are on-boarded to the culture training. The Daily Safety Briefing was operational 7 days per week and recognized as a best practice during the consultant quarterly assessment. The reporting of patient safety events, both near misses and events that reached the patients, had almost doubled. Most importantly, the overall outcome metric, the Serious Safety Event Rate, was steadily decreasing. However, when the consultant came to do a quarterly assessment on the safety culture strategic initiatives, the patient safety and executive teams were disappointed to hear the results of rounding observations on the units. The consultant used a technique called 5 × 5 Rounding (Key Point Box 2.5) where five individuals from different disciplines and different areas were asked about their current understanding and application of the error prevention tools and safety behaviors.

The results demonstrated most staff members recall an error prevention tool only 20% of the time (i.e., could share one or two safety tools out of 7 (Appendix 2.2)). The consultant felt the behaviors and language, although taught in the classroom had not penetrated to the frontline culture, as would have been expected at this point in the journey.

Key Point Box 2.5 5 × 5 Rounding

A monthly observational and coaching rounding tool where a leader asks five staff member from five different disciplines about the penetration of culture tactics to influence behaviors with the knowledge and application of error prevention tools and behaviors at the frontline

5 × 5 Rounding for Observational Assessment, Coaching, and Improvement

Following this assessment, the patient safety team, with support from leadership, instituted an observational 5 × 5 rounding/coaching assessment methodology on a monthly basis to observe and coach both the leaders on their Rounding to Influence and the workforce on the importance and use of the error prevention tools and safety behaviors. A specific and time-bound goal was set and measured. The patient safety team developed a 5 × 5 Rounding script (Table 2.1) and used it to ask workforce members which error prevention tools they were familiar with or which ones resonated most with them. They asked for an example of an error prevention tool along with a situation demonstrating its proper application. Coaching occurred in the moment to reinforce learning.

Table 2.1 5 × 5 Observational coaching form used by patient safety and directors to assess penetration of error prevention tools and behaviors across roles at the frontline

5 × 5 Rounding response capture tool	
Unit/department	
Shift	☐ Day (7 am–7 pm) ☐ Night (7 pm–7 am)
Role (leader, provider, clinical/support, non-clinical)	
Title (attending, RN, respiratory therapist, unit coordinator)	
Completed EPT class	☐ >6 months ago ☐ 3–6 months ago ☐ < 3 months ago ☐ Not yet completed
EPT tools recalled	☐ ARCC ☐ QVV ☐ Read/repeat back ☐ SBAR ☐ Standardize H/O's ☐ STAR ☐ Stop and resolve
Can you give an example of using tool?	☐ Yes, correct use ☐ No, incorrect use ☐ No, no example
Can you give an example of someone else using tool?	☐ Yes, correct use ☐ No, incorrect use ☐ No, no example
Safety stories shared at meetings and huddles?	☐ Yes ☐ No
Do you know who your safety coaches are in your area?	☐ Yes ☐ No
Unit/department	
Receptivity	☐ Very receptive ☐ Somewhat receptive ☐ Neither ☐ Slightly non-receptive ☐ Very non-receptive
Comments	

Adapted with permission from Healthcare Performance Improvement (HPI). Copyright Seattle Children's 2014

While rounding, it was clear that the highest performing areas were those where the local leader influenced the outcomes due to their personal investment with understanding and utilization of culture principles.

These observations and results helped guide the Rounding to Influence monthly focus in order for leaders to coach their frontline teams on the application of the error prevention tool. This, in turn, demonstrated the organizational importance and priority of a strategic initiative to eliminate preventable harm with these tools and behaviors. There was a direct correlation to the improvements seen in the overall results each month with the current Rounding to Influence message (Fig. 2.3).

Eventually all directors were trained in 5 × 5 rounding so they could do their own assessment and coach the leaders in their reporting structure to further enhance knowledge and application of the tools and language at the frontline. For inter-rater reliability, the patient safety department continued to round on a monthly basis to track process and outcome metrics at a global level. Every month, leaders reported out their teams error prevention tool recall rate to senior executives which demonstrated accountability to the safety culture work and determination to eliminate preventable harm. The hypothesis is that by developing habitual use of safety tools and associated behaviors, a reduction in the serious safety event rate would result (Fig. 2.4).

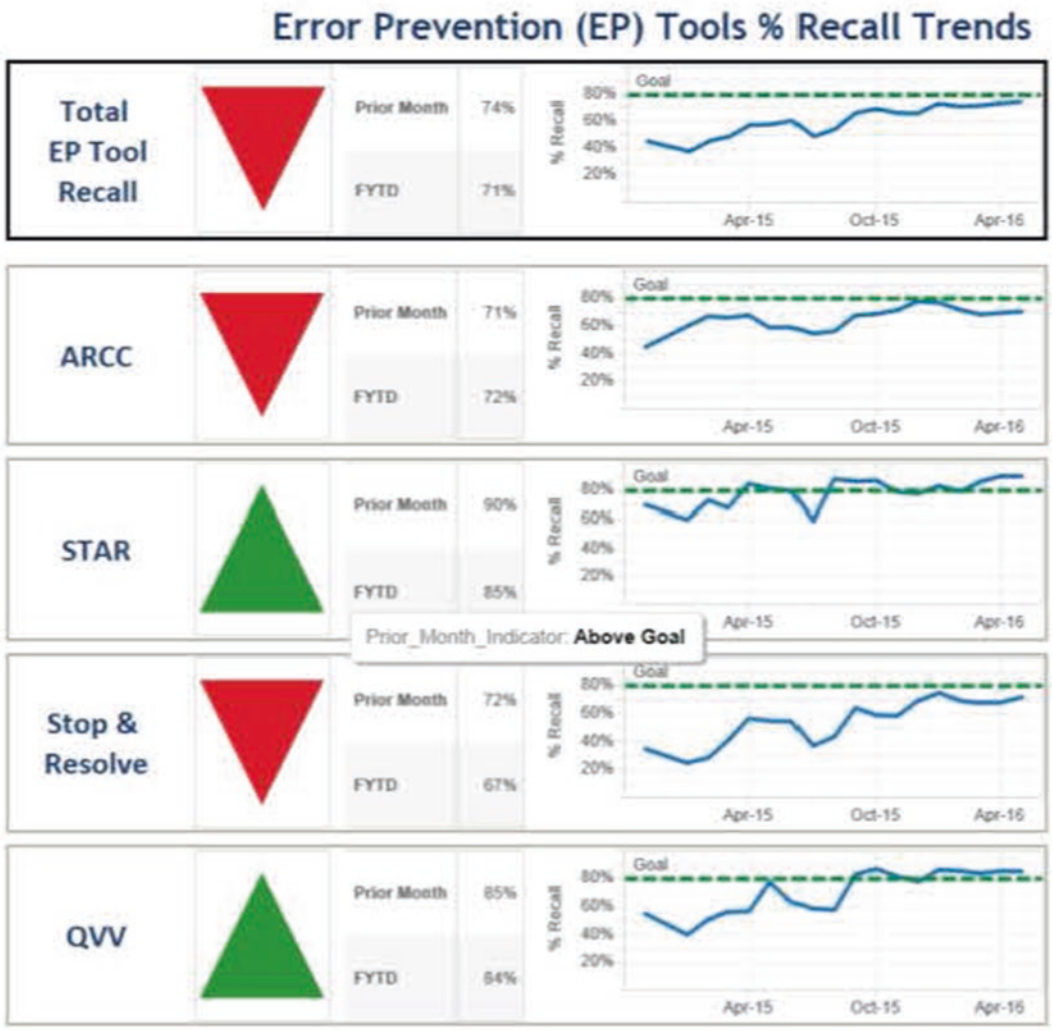


Fig. 2.3 5 × 5 observational coaching tool results built in a tableau report. Ability to drill down by area and role. (Adapted with permission from Healthcare Performance Improvement (HPI). Copyright Seattle Children's 2014)

With the assurance that the proper foundation had been set up with leaders now having safety culture knowledge, a strategy had been identified and communicated, and key tactics to improve culture and reliability had been operationalized, the organization decided to pilot the integrated Safety Communication Organizational Reliability and Engagement (SCORE) safety culture survey. One valuable result of conducting this pilot was demonstrating the impact of leader rounding with frontline teams and closing the loop on issues raised (see Fig. 2.5). The survey was administered in four key areas of the organization, with a 85% response rate (n = 849). For the teams that could answer "yes" to the question "my leader rounds regularly" and also "yes" to the question "they closed the loop on concerns raised," there was a positive correlations to all culture domains.

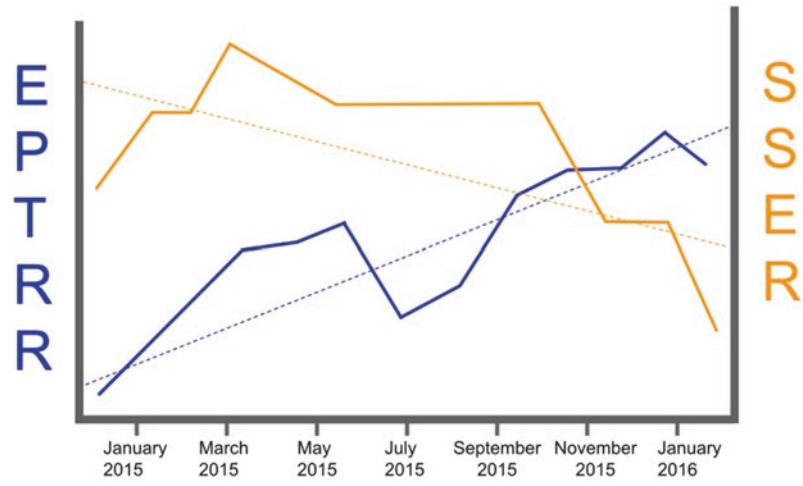


Fig. 2.4 This juxtapose graph demonstrates as the percentage of Error Prevention Tool Recall Rate (EPTRR) increases (blue line), the Serious Safety Event Rate (SSER) decreases (orange line) over time, Jan 2015 to Oct 2015. (Adapted with permission from Healthcare Performance Improvement (HPI). Copyright Seattle Children's 2015)

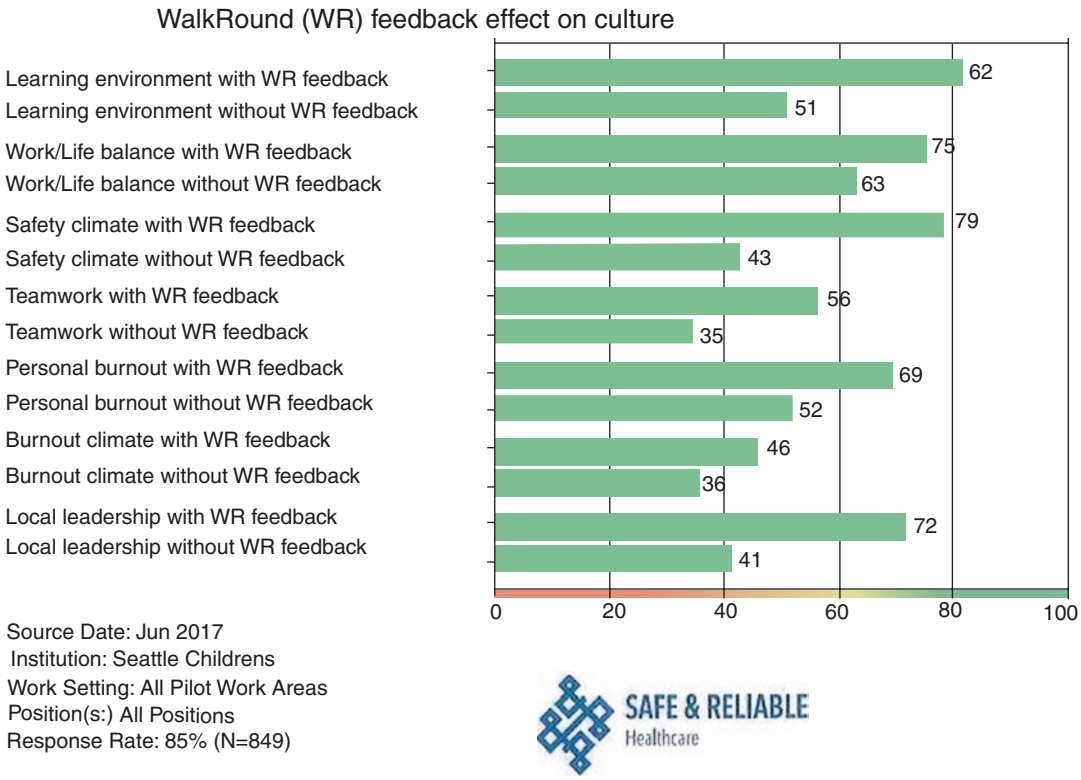


Fig. 2.5 SCORE pilot leadership rounding effects on culture domains. (Image courtesy of Safe & Reliable Healthcare, LLC Copyright 2017. Data shared with permissions of Seattle Children's)

In particular, the culture domains of Learning Environment, Safety Climate, Teamwork, and Local Leadership showed a >30% improvement in results. Each of these domains represents crucial elements of a positive organizational safety culture. These results mimic previous studies demonstrating the influence of leadership rounding on quality outcomes, workforce well-being/

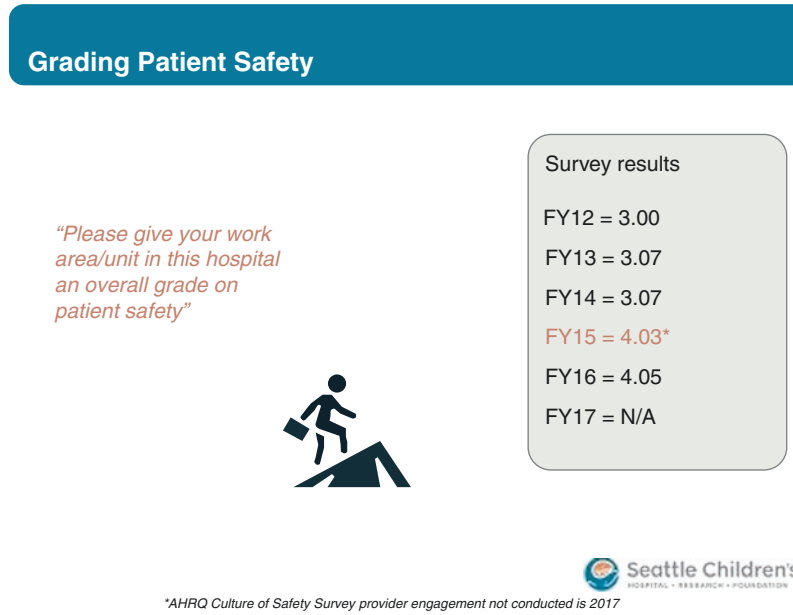


Fig. 2.6 Three years into Seattle Children Hospital's safety culture journey a full point increase was seen and sustained in this AHRQ Culture of Safety Survey Question. Likert Scale 1–5 (5 is best). (Data used with permission Seattle Children's. Copyright 2017)

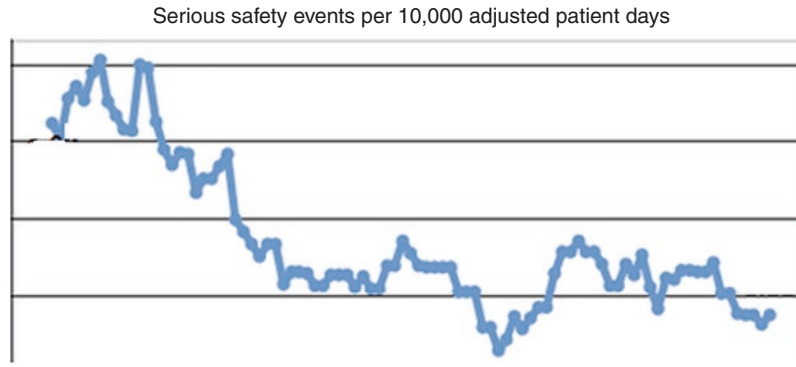


Fig. 2.7 Serious Safety Event Rate over time (lower is better), August 2011 to January 2019. (Used with permission from Healthcare Performance Improvement (HPI). Copyright 2019. Data used with permission of Seattle Children's)

resilience and ultimately the improvement in an overall organizational patient safety culture to eliminate preventable harm to patients [14, 15].

Vignette 2.4

The executive team was pleased to see the results of the efforts paying off in the multiple initial tactics to improve safety and drive the serious safety event rate down. They could also see the positive effects the leadership influence had on culture. An increase in safety behaviors and use of safety tools being supported by leaders resulted in a significant reduction of the serious safety event rate.

The greatest result change was demonstrated with the Agency for Healthcare Research and Quality culture of safety question: "the grade I give my unit for safety." This improved over a full point on the Likert Scale (1–5) going from a 3.01 to a 4.02 and was sustained for two consecutive years; a change of this order of magnitude is considered significant (Fig. 2.6).

The organization also celebrated a full year without a serious safety event and the serious safety event rate dropped by 80% (Fig. 2.7). The reduction in the serious safety event rate has overall continued to decline since the strategies with standards and expectations were operationalized.

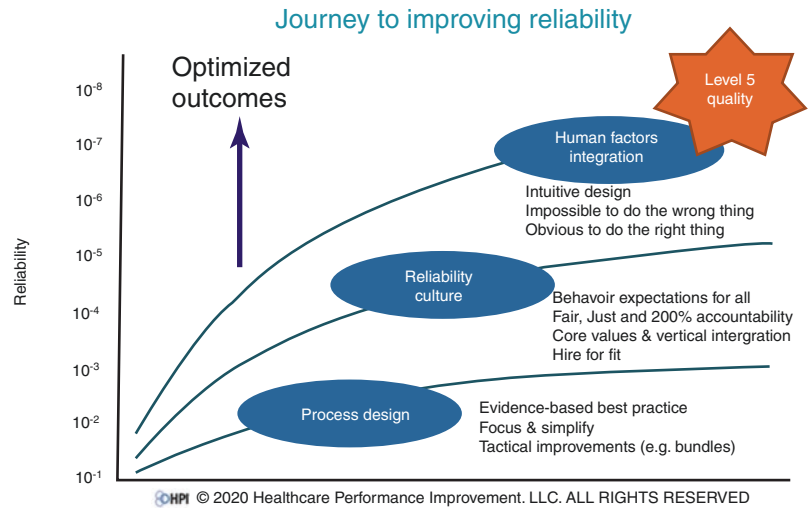


Fig. 2.8 The exponential effects of culture on reducing the probability of harm over time. (Used with permission from Healthcare Performance Improvement (HPI). Copyright 2010 Healthcare Performance Improvement)

These vignettes and case study have shown the power of leadership and culture on safety and an unmeasurable return on investment in relation to the ultimate goal of eliminating preventable harm. Figure 2.8 shows the exponential reduction in risk of harm when there is a focus on culture and safety as a core value.

In Fig. 2.8 the vertical (Y) axis shows the risk of harm with *HIGHER* meaning less chance of harm. The lowest line in the graph shows improving systems and processes, reduces the probability of error from 1 in 10 to 1 in 100, and is an important first step. The middle line denotes the exponential improvement in reducing the probability of error with introducing the culture work. The highest line is achieved through efforts incorporating human factors consideration. For example, anesthetic gasses each have universal and unique connection shapes and colors. This makes it physically impossible to inadvertently connect an incorrect gas on the anesthesia machine. The healthcare environment is complex and always evolving. When possible, reducing variation and minimizing human error improve safety as demonstrated by the airline and nuclear regulatory industries.

Vignette 2.5

The healthcare system's senior executives have been observing the evolving culture of the organization. They are realizing that while there is enthusiasm to work on quality improvement, there is a need to clarify what that actually means. Therefore, the CEO has identified a small group to identify one model of quality improvement that can then be shared throughout the system.

The leadership is in full agreement. A broader team of leaders throughout the system has been assigned the task of conducting an in-depth analysis of safety risks with the goal of reducing harm through targeted efforts and projects. This team is reviewing several models to determine the best option for a quality system and is tasked with taking on the bigger responsibility of overall quality and performance improvement.

All safety is quality but not all quality is safety. Utilizing a performance improvement framework that focuses on improvement science will strengthen safety efforts and safety culture by anchoring these efforts into a comprehensive plan. Any one of many models (Six Sigma, Lean, Model for Improvement, etc.) may be helpful in changing organizational culture. Many healthcare systems use the six domains of quality as a foundation to frame their safety and quality programs. The six domains were developed by the Institute of Medicine in 2001 [16]. It is important

to diversify the organizations quality improvement work across all the domains. Balance of the domains is essential for inclusiveness in decision-making and to appropriately distribute the effort. For example, if safety is the only focus, then other domains (efficiency, timeliness) might be out of balance and productivity, or workflow might be significantly negatively affected. A clear and practical example of this involves the implementation of an enterprise electronic health record (EHR) at one of the organizations affiliated with authors of this chapter (MG, HO). Knowing that medication errors are a common source of patient harm, the organization invested significant effort into prevention by including a variety of best practice alerts and similar "pop-ups" for medication ordering and dispensing prior to implementation. This led to the unintended consequence after "go-live" of burdening the end user with significant workflow challenges and delays due to the volume and frequency of these alerts. The domain of safety was overemphasized at the expense of the domains of timeliness and efficiency.

Spreading initiatives and resources across the domains insures having a broad portfolio of quality improvement projects. The organization should have a continuous improvement approach to quality. Improvement never ends. Change is inevitable. The balancing process is in prioritization and calibration of projects to system and workforce capacity. Feedback such as "There are too many projects," "People can't absorb all the changes," and "Things are moving too fast" is legitimate. The leaders of the organization must be aware, support the changes, and help the frontline understand the desired key outcomes in an ever-changing environment. To do so, it requires a consistently applicable and understandable change management process (described below).

A typical organizational portfolio will necessarily include initiatives such as reduction of hospital acquired conditions, improving patient/family experience work, staffing model projects, and financial initiatives. When the quality improvement model is defined, the work of managing change needs to be addressed as well. A surveillance system should be in place to determine when too much change may be overwhelming people and the system. This could include feedback from rounds, employee engagement surveys, focus groups, or unexplained delays in project timelines.

Vignette 2.6
The leaders of the healthcare system are starting to feel more comfortable discussing quality improvement methodology, have a clear plan to prioritize projects, and have developed a consistent process for rounding with staff. While rounding, they receive frequent feedback that there are a lot of changes and that the leaders seem to be missing an opportunity to communicate and discuss the most important changes affecting staff. Staff are reporting they don't always have time to check emails and are requesting other forms of communication to help them keep up on relevant changes.

Change is inevitable. Growth is necessary. Project teams must have change management as part of the plan while implementing projects. The leaders of the organization must be aware, support the changes, be visible during the change, and help the frontline understand the desired key outcomes in an ever-changing environment.

Change disturbs the current state. Anyone involved in an organizational change seeks to understand how the change will affect them, their role, their workflow, and their team.

There are several change management models that can assist organizations. All have processes to guide teams through change. By using a consistent framework for change, leadership can demonstrate a commitment to providing the appropriate resources and processes for it.

Another approach to achieve safety improvement used by many healthcare systems in the past few years is the high reliability organization (HRO) model. Though not specific to healthcare, many health systems find it useful in improving their cul-

ture. Dr. Karl E. Weick and Dr. Kathleen M. Sutcliffe have published texts about this model which are often cited as excellent reference points [17]. They studied industries such as nuclear power and flight operatins on aircraft carriers which were able to significantly decrease serious safety events. By focusing on the principles of anticipation and containment of accidents, an HRO can ultimately reduce serious safety and harm events. Building an HRO is predicated on improvement through learning. In other words, an organization must be willing to explore risks, learn from mistakes, and have the underpinning of a culture that supports identifying, analyzing, and mitigating errors and potential errors. The foundational elements of leadership methods, detecting and bringing problems to awareness, error prevention tools, and focus on a culture of patient safety across the organization lead to high reliability (Fig. 2.9).

The language used in the five principles noted in Fig. 2.9 can sometimes be confusing. The following explanations are to help clarify.

The first three are principles of anticipation for unexpected events; the final two are principles of containment when the system is impacted by an inevitable, disruptive significant event.

1. *Reluctance to simplify*: This is an appreciation that work in healthcare is complex and dynamic; thus people in this environment seek underlying, deeper causes when thing succeed or fail rather than superficial explanations. Consider an administered drug error in a patient. While it might be straightforward to identify the individual at the terminal point in the process, it is highly likely there are underlying systems issues that led to the failure mode (Key Point Box 2.6).

Fig. 2.9 The principles of high reliability in organizations. (Adapted with permission from Weick and Sutcliffe [17])

Key Point Box 2.6: Failure Mode
A cause of failure or one possible way a system may fail

2. *Preoccupation with failure:* Healthcare relies on human delivery of processes. Human systems are inherently imperfect. Therefore, everyone is aware of and thinking about the potential for failure. Near miss events are seen as opportunities to learn about systems issues and improvement. Lack of significant events should lead to heightened vigilance rather than complacency. Preoccupation with failure is practiced when the organization focuses on the small close calls and near misses as failures, studies how those failures occurred, and implements change to prevent the errors from reoccurring. Ideally, the organizational culture and leadership should be encouraging staff to report error, seek out the failures, and affirmatively recognize staff for identifying the errors.
3. *Sensitivity to operations:* This is vital to a strong culture. This sensitivity is sometimes referred to as situational awareness. It is a constant awareness of how the current state supports or might jeopardize safety. Leaders should be rounding with the frontline staff in a standardized fashion and, most importantly, with a process to close the loop on issues. The frontline staff very often know what the safety concerns are and can provide input about potential resolutions. Leaders must be aware of the differences between the work as they imagine it is being done in distinction and how the work as it is actually done at the frontline. Workarounds or alterations to the

designed process might represent a sign of potential failure points.

4. *Deference to expertise:* People in HROs appreciate that those closest to the work are the most knowledgeable about the work. In a critical situation or emergency, the person with greatest knowledge of the issue might not be the person with the most seniority. In an HRO, everyone is expected to share concerns with others, and the organizational climate is such that all staff members are comfortable speaking out about potential safety problems. The people that do the work must also be included in improvement projects because they are the true subject matter experts to identify what can be successful in the system that supports their work. This principle leads to optimal organizational learning.
5. *Commitment to resilience:* High reliability organizations assume there is an ever present risk for failure, and they simulate rapid assessments of, and responses to challenging situations. This also supports trusting, supportive relationships. Teams will be comfortable speaking up in unsafe situations because it is recognized that return to normal operations in times of duress relies on collaboration. Through leadership's continuous commitment for appropriate resources, the staff will feel supported, competent, and empowered to lead and create change.

By using all five of these principles of high reliability, the organization's culture of safety will improve. But becoming a high reliability organization is a never ending process with a tireless commitment to understanding where the next improvement can reduce risk.

Vignette 2.7

While there have been many gains, the leaders still have strong concerns about some of the behaviors they are seeing. They are hearing reports of bullying, incivility, and disruptive behaviors. They are finding out that teams may be working well in their individual microsystem but they are not working well with each other across the system.

The organizational values have been established, but clear rules around behavior expectations may not have been explicit. Rules regarding the behaviors within a culture are just as important as the values themselves.

How do behaviors affect culture? Demonstrating and following expected behaviors by all staff and leaders is the real test of how effective the culture has been. At some point there will be an organizational challenge which will test the resolve of leadership to follow the culture path. One important consideration when building a successful and sustainable safety culture is through developing appropriate accountability known as a just culture [18, 19] (Key Point Box 2.7). If staff have a sense the culture allows retribution, retaliation, and other punitive measures, it will stifle event reporting.

Key Point Box 2.7 Just Culture

Balanced accountability for organizational systems and the behaviors of individuals within those systems

Vignette 2.8

As the organization became more competent and knowledgeable about the principles and science of safety performance improvement and culture building, inevitable requests for additional resources, staff, and learning opportunities grew significantly. Leaders as well as board members were encouraged by the direction of change but were also wary of commitments to such resources without some validation of an acceptable return on investment.

There is evidence that reasonable safety investments are consistent with financial health for organizations. There are data emerging which quantifies the financial outcomes of investment in safety culture [20]. One network that has been tracking this concept is the Children's Hospitals Solutions for Patient Safety network. The network consists of >140 children's hospitals working together to reduce harm to patients. Their website references the aggregate cost savings from 2012 to 2018 (>$182 M) to these member organizations gained by harm avoidance resulting from this effort over the past 6 years as well as the number of patients spared harm (>11,000) [21].

It should be recognized that while a culture of safety is a top priority for organizations, it cannot be the *ONLY* priority. The financial commitment to safety must be included in the overall process of budgeting, sequencing, and change management capacity which is unique to every organization.

Sustainability of a Safety Culture

Recognizing the dynamic elements in play in all organizations, perhaps the most important question is how healthcare organizations maintain and sustain a culture of safety.

As has been mentioned throughout this chapter, healthcare is changing at an unprecedented rate with many real and potential disruptors such as non-traditional organizations engaging in the field consolidation and expansion of organizations and technology [22, 23]. These changes coupled with a consumer-driven focus that threatens to make healthcare more transactional can all lead to distractions and drift in organizational focus.

Despite this, healthcare organizations must remain committed to their first mission and core principle: safe and effective care delivery. It is the expectation of staff, providers, patients, and families.

There are a number of properties which have been identified to build and sustain a culture of safety. Any such list is open to healthy debate. We would like to share three that we feel should top any list of an organization hoping to sustain the hard won efforts to build a safety culture.

First is the commitment of leadership (and the governing board) to prioritizing the vision of safety and elevating it to the highest level of organizational attention which is often occupied by finance and strategy. Safety does not replace either one of these but is complementary to the long-term health of the organization. Leadership through actions, visibility, and modeling the behavior expectations is constantly reinforcing the safety culture.

Next is developing the necessary components to build a high reliability focus that is based on having a process to anticipate, detect, analyze, and act upon inputs and events. This requires building the infrastructure components to adequately support these processes.

Finally there must be a culture with accountability, behavior expectations, and a way to develop leadership in these areas to weather the inevitable reality of organization change and turnover. These characteristics connect the board, leadership, staff, providers, learners, and patients/families.

Leadership and the culture of an organization must be focused always on learning and improving. The culture drumbeat must be relentless – culture never "coasts" or takes a break.

Editors' Comments

It is well-known saying from business guru, Peter Drucker, that "Culture eats strategy for breakfast." There should be no question as to why this textbook using practical, case-based approaches to safety and quality improvement in healthcare should use begin with the foundation of all improvement work: culture. The authors use a vignette to trace the accountability of culture. It should go without saying that culture starts at the top with an explicit organizational commitment to the culture of the organization. The core values described at one our institutions in Chap. 1

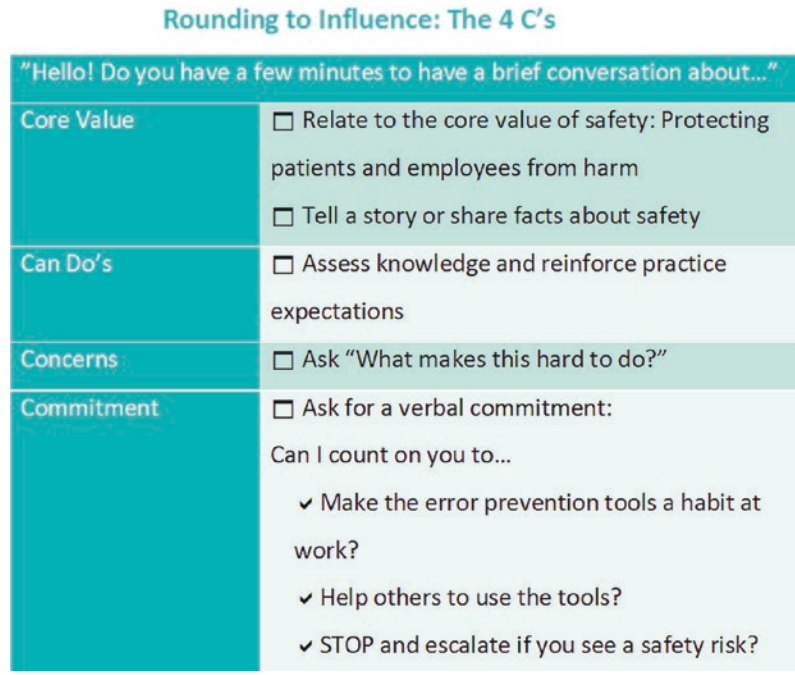
is an example of how culture starts from the top. Culture then needs to be implemented and operationalized at the interface between management and the frontline. The authors develop the vignette to show strategies on how to ensure culture permeates these levels.

A key image in this chapter demonstrates the exponential reduction in risk of harm when employing high-reliability culture techniques. As we all anxiously wait for human factors integration, we must rely on culture to take us to the next levels of reliability. A theme throughout this textbook will be high-reliability principles as described by Weick and Sutcliffe in managing the unexpected. Throughout the text, we will see how these principles relate to the specific topic of the chapter. This may appear redundant, but it is intentional. As editors we want the reader to be left with a thorough understanding of how high-reliability principles must be weaved into operations, management, and leadership to drive culture and thus outcomes. The authors end the chapter discussing one of the most pressing issues in safety and quality improvement in healthcare – sustaining the gains. Safety of culture surveys are discussed as an objective way to measure and track culture; however the urgent need to ensure our safety and quality gains is solidified, and hardwire cannot be underestimated. Culture is core to safety and improvement as thoroughly described in this chapter.

Appendices

Appendix 2.1: Examples of Leadership Methods Curriculum for High Reliability

- Safety as a core value – Link all decisions explicitly to safety and begin every meeting with safety story.
- Leaders Round to Influence – Helps sets the tone and reinforces the behavioral expectations for safety and reliability (Fig. 2.10).
- 5:1 Feedback – Intentional focus on observing



Rounding to Influence: The 4 C's

"Hello! Do you have a few minutes to have a brief conversation about..."	
Core Value	☐ Relate to the core value of safety: Protecting patients and employees from harm ☐ Tell a story or share facts about safety
Can Do's	☐ Assess knowledge and reinforce practice expectations
Concerns	☐ Ask "What makes this hard to do?"
Commitment	☐ Ask for a verbal commitment: Can I count on you to... ✔ Make the error prevention tools a habit at work? ✔ Help others to use the tools? ✔ STOP and escalate if you see a safety risk?

Fig. 2.10 4 C's Rounding to Influence rounding template to highlight the importance of a safety culture focus. (Used with permission from Healthcare Performance Improvement (HPI). Copyright 2008 Healthcare Performance Improvement)

and calling out five positive workforce behaviors for one corrective feedback.
- Performance Accountability – A fair and just culture promotes an environment of trust, fosters self-reporting of error, and increases staff engagement. Recognizing honest mistakes from knowing violations.
- Daily Safety Brief.
- Unit Safety Huddles.

Appendix 2.2: Examples of Error Prevention Tools

I. STAR- *S*top *T*hink *A*ct *R*eview, a self-check on every task, "Am I getting the result I expected with my action?" (labeling a specimen, paying a vendor, sending an email).
II. Read back/repeat back and asking clarifying questions.
III. Stop and resolve – not proceeding in the face of uncertainty and taking the time to go and ask for help.
IV. QVV – Qualify, Validate, and Verify with a trusted source when something does not feel right or information received is not what is expected (HPI © 2006).
V. SBAR – Situation, Background, Assessment and Request/Recommendation. Used in both written and verbal communication to relay key information that requires an action from another individual.
VI. ARCC – Used to escalate concerns in a non-judgmental way by *Asking* a question. If that does not change course, the next step is to *R*equest a change. If the issue is still not addressed or changed, then then the next step is to raise a *C*oncern and ultimately the last step is to go up the *C*hain of Command (HPI © 2006).
VII. This is similar to AHRQ TeamSTEPPS and CUS (I have a *C*oncern, I am *U*ncomfortable and this is a *S*afety issue).
VIII. Error prevention tool(s) and behaviors – Come in a variety of frameworks to enhance communication, safety and process reliability (Figs. 2.11 and 2.12).

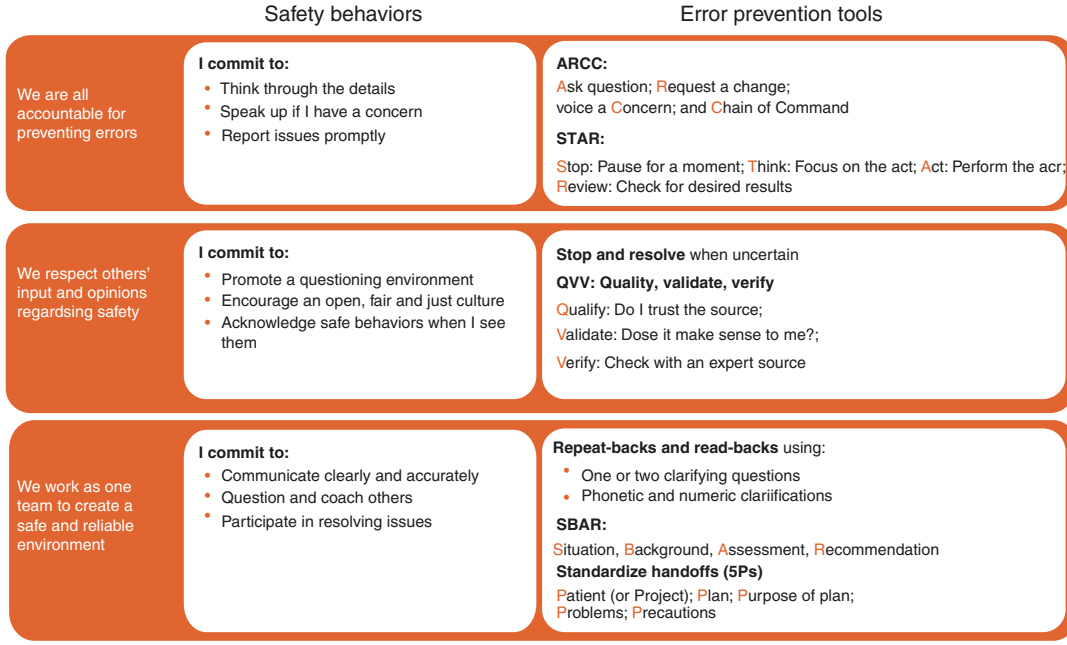


Fig. 2.11 Safety behaviors and error prevention tool integrated to customer service standards for safety and reliability. (Adapted with permission from Healthcare Performance Improvement (HPI). Copyright Seattle Children's 2012)

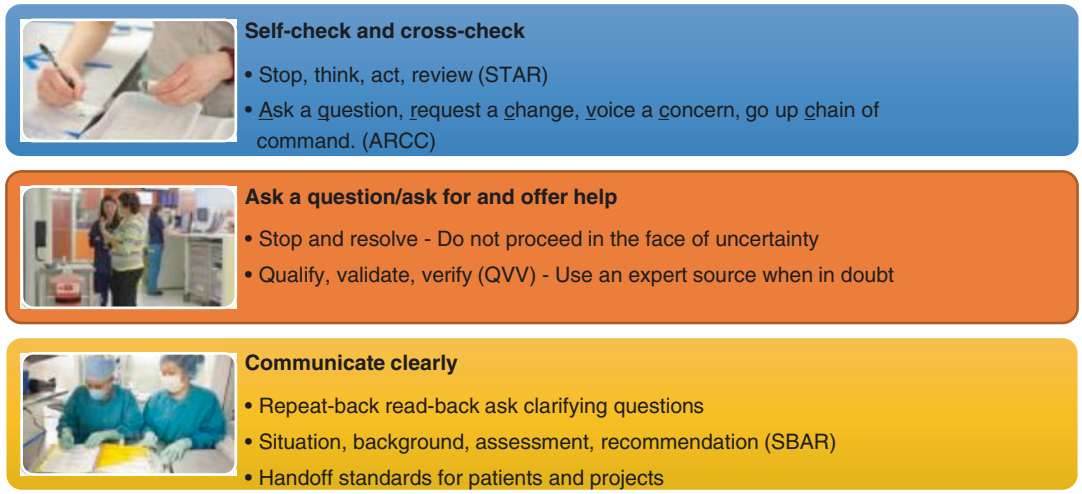


Fig. 2.12 High level overview of error prevention tools and behaviors summarizing objectives of use and purpose. (Adapted with permission from Healthcare Performance Improvement (HPI). Copyright Seattle Children's 2012)

Chapter Review Questions

1. Organizational culture is the same as a culture of patient safety. True or False?
   Answer: False.
2. Describe the building blocks of a patient safety culture.
   Answer: Leadership, Behavior and Accountability, Organizational Culture, Safety – all are foundational to a culture of patient safety.
3. Organizational culture is independent of leadership changes.
   Answer: False. Leadership sets the course for culture and significant changes in leadership have an effect in some way on organizational culture.
4. Error prevention tools should be learned by a few key individuals in an organization to avoid confusion.
   Answer: False. It is essential that everyone in the organization is responsible for safety and all contribute in some way to patient safety.
5. Identify the six domains of quality
   Answer: The acronym STEEEP: Safe, Timely, Effective, Efficient, Equitable and Patient (Family) Centered.
6. High reliability organizations exist in many industries, including healthcare.
   Answer: True. Healthcare has learned much from other industries such as airlines about HROs.
7. What is a just culture?
   Answer: Balanced (appropriate) accountability for organizational systems and the behaviors of individuals within those systems. It is a way to develop a non-punitive culture.
8. Can investing in patient safety lead to financial benefits to an organization? Why or why not?
   Answer: Yes. There is growing evidence that focusing on patient safety can improve patient safety and have a beneficial effect on organizational finances.

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3 Creation of Quality Management Systems: Frameworks for Performance Excellence

Adam M. Campbell, Donald E. Lighter, and Brigitta U. Mueller

Chapter Objectives

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

Introduction

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

Vignette 3.1

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

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

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

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

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

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

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

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

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

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

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

High Reliability Organizations

Vignette 3.2

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

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

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

Table 3.1 High reliability principles

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

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

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

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

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

Preoccupation with Failure

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

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

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

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

Key Point Box 3.3

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

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

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

Vignette 3.4

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

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

Sensitivity to Operations

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

Reluctance to Simplify

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

Vignette 3.3

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

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

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

Commitment to Resilience

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

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

Deference to Expertise

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

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

Regulatory and Accreditation Requirements

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

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

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

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

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

ISO 9001: 2015

Vignette 3.5

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

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

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

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

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

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

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

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

Fig. 3.1 ISO 9001: 2015 principles

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

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

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

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

Baldrige Performance Excellence Award

Vignette 3.6

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

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

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

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

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

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

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

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

Table 3.2 Baldrige organizational profile

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

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

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

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

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

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

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

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

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

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

Table 3.3 Baldrige categories

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

Table 3.3 (continued)

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

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

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

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

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

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

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

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

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

Conclusions

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

Editors' Comments

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

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

Chapter Review Questions

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

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

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

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

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4 Reliability, Resilience, and Developing a Problem-Solving Culture

David P. Johnson and Heather S. McLean

Abbreviations

HRO	High reliability organization
LOR	Level of reliability
MFI	Model for Improvement
mFMEA	Modified failure mode and effects analysis
PDSA	Plan-Do-Study-Act
SMART Aim	Specific, measurable, achievable, relevant, timely aim

Chapter Objectives

- Understand how to use the Model for Improvement to drive change in an organization.
- Understand how to incorporate principles of reliability science within the Model for Improvement framework to achieve an outcome by coupling safety culture and process design.
- Learn how to incorporate the power of problem-solving and the expertise of frontline staff to achieve an outcome.
- Recognize the interplay of problem-solving techniques like the Model for Improvement with reliable process design and resilient safety culture.

Vignette 4.1

A tertiary care, academic hospital has a problem with hand hygiene compliance rates. This is not a new problem, but with the added focus of a new "Zero Harm" campaign, the executive team demands that all hospital units achieve hand hygiene performance rates of 100%. Despite efforts to educate and remind employees to clean their hands, hand hygiene performance rates remain at 85–92% with wide variation across areas. The Chief Medical Officer seems visibly frustrated that these efforts have failed, and she charges the quality improvement team with fixing the problem.

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Opening Question/Problem

The intent of this chapter is not about how to perform effective hand hygiene but rather how to design a quality improvement project using high-reliability concepts operating within the Model for Improvement framework [1]. This case-based example of a quality improvement project about hand hygiene will illustrate these concepts throughout the chapter [2]. Understanding the principles of high-reliability science that couples reliable process design with the values of resiliency in the safety culture are key to achieving and sustaining higher levels of performance. While the results achieved in this case are not at the level of a highly reliable process (>1 error in 10,000–100,000 events), it illustrates how a project team can incorporate specific change concepts with known levels of reliability to achieve their desired level of reliability.

Vignette 4.2

A multidisciplinary improvement team, representing the medical-surgical care units, has been assembled including two nurse managers, an infection prevention nurse, medical director, nursing care assistant, and hand hygiene auditor. The team evaluates the system that has been in place for years and notes the presence of a hospital-wide hand hygiene auditor program that directly observes and records encounters, monthly dashboards displaying unit performance, posted signs, and intermittent educational programs targeting units with poor compliance. Hand hygiene performance data with targets are included on the unit, and aggregated balanced scorecards are updated monthly. Managers are held accountable for meeting these targets annually and share data with nursing staff during monthly meetings. Hand hygiene results have been plotted on a statistical process control chart that displays the combined units' monthly average hand hygiene compliance percentage. The results show a baseline median of 87% and wide variation with a range of 64–94%. The team decides to use the Model for Improvement to design the project. They map the process, conduct a modified failure mode and effects analysis (systematic method of identifying and addressing potential failures) (Key Point Box 4.1), develop a SMART aim statement, examine key drivers, and prioritize interventions in a key driver diagram (Fig. 4.1) [1].

Key Point Box 4.1 Modified Failure Mode and Effects Analysis (mFMEA)

A simplified version of the method used by process and product designers to identify and address potential failures before implementation of change. This method is used in a proactive manner rather than tools that evaluate a problem that has already occurred such as root cause analysis or cause and effect (fishbone) diagram. The mFMEA is used with the project team as a group exercise with the goal of defining a high-level process map, then identifying failures in each step of the process, and finally proposing solutions to address the failures. The solutions proposed in this exercise can be used to populate the "interventions" section of the project key driver diagram.

Model for Improvement

When facing a difficult problem or task, one needs a structured problem-solving technique to provide a framework for an effective, focused, and disciplined approach. The Model for Improvement (MFI), the subject of *The Improvement Guide*, provides such a framework for any type of improvement task – from personal life, to industry, and, of course, to healthcare [1].

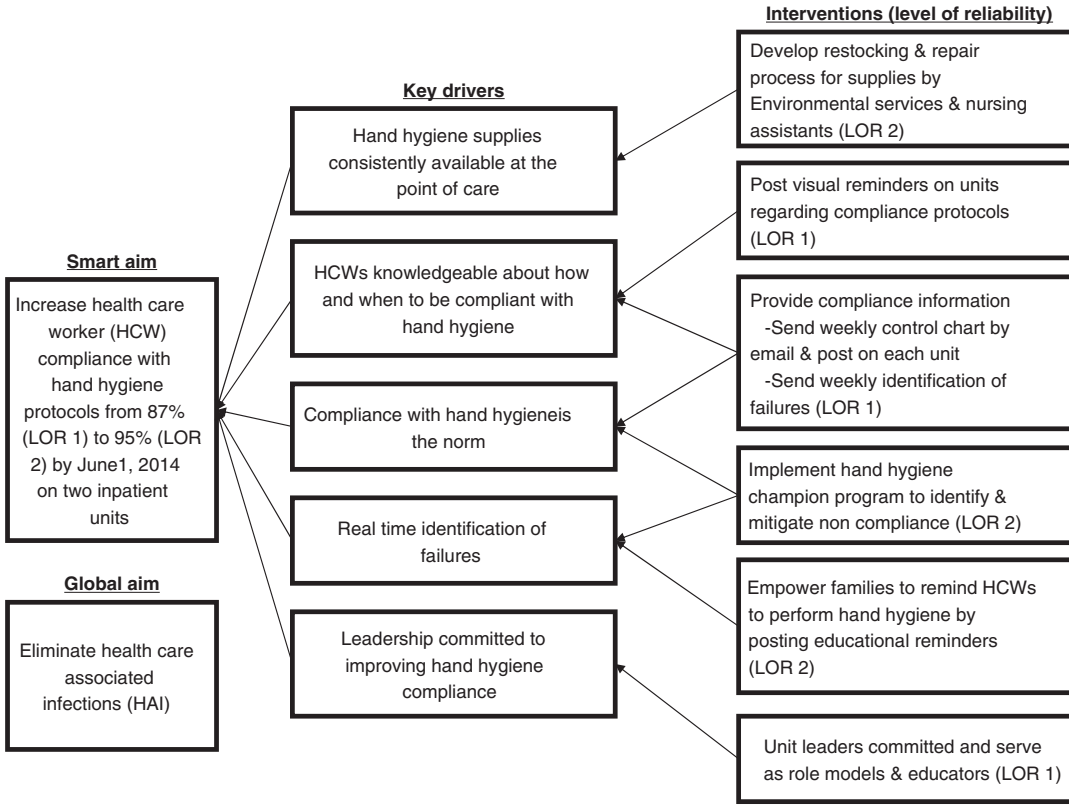

Fig. 4.1 Hand hygiene project key driver diagram. (Reproduced with permission from Hospital Pediatrics, McLean et al. [2] © 2017 by the AAP)

This model, comprised of three questions followed by the Plan-Do-Study-Act (PDSA) cycle (Fig. 4.2), has proven to be a powerful tool for driving improvement. The three questions include (1) What are we trying to accomplish? (2) How will we know that a change is an improvement? (3) What change can we make that will result in improvement?

Many healthcare professionals believe improvement occurs by holding meetings which often don't result in actionable plans. The topics in these meetings may drift, and often a consensus plan is never reached. The attraction of the MFI is twofold. First, a small amount of initial planning to sequentially answer the three questions, followed by focused testing (PDSA cycles) based on those theories, can result in more efficient improvement. Second, as the MFI becomes more widely used in healthcare, it can serve as a universal language between hospital units, hospitals, and health systems to help spread quality improvement successes.

Question 4.1: What Are We Trying to Accomplish?

While this question seems easy enough to answer, many teams experience difficulty articulating exactly what they are trying to accomplish unless they specifically set out to answer this question. In healthcare, team members often come to the table to discuss a problem, and lengthy conversations can ensue with multiple ideas put forth. If each member were asked exactly what they are trying to accomplish, few would be able to articulate a goal, and many might articulate *contrasting or conflicting* goals. This poses numerous prob-

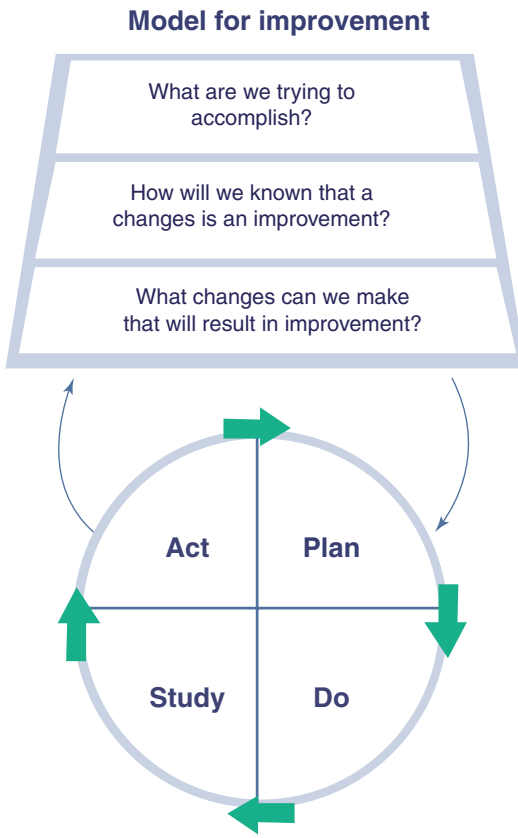

Fig. 4.2 Model for improvement. (Reproduced with permission from Associates in Process Improvement [9])

lems, not the least of which is that team members might be working to accomplish different tasks, and sometimes these can be at odds with each other.

Teams benefit when they spend time documenting exactly what they want to accomplish. Though creating this aim itself can take considerable time for some groups to achieve, this diligence will help prevent scope creep, and the long-term benefit toward the team's goals will be considerable. Goals that use the SMART aim mnemonic [3] provide a concise, easily understandable goal for team members and non-team members alike. These goals are Specific, Measurable, Achievable, Relevant, and Timely. The handwashing SMART aim for the hospital in this chapter is to increase healthcare worker compliance with hand hygiene protocols from 87% to ≥95% within 9 months in two pediatric inpatient units, leaving very little doubt to anybody who knew their work exactly what they were striving to do.

Question 4.2: How Will We Know That a Change Is an Improvement?

In quality improvement, measurement and data analysis are paramount. To determine if a change results in improvement, a team needs to know exactly what it is they are trying to improve and what is the unit of measurement for success. Often, the main measure of interest is articulated in their SMART aim statement which provides the team with some guidance. However, sometimes the measurement requires some clarification, and an operational definition is needed [1, 4]. For example, in our hand washing example, what does it mean for somebody to properly wash their hands? Does it have to be with foam? Can it be soap and water? When does hand washing have to occur in relation to donning a gown and gloves for patients on isolation? Such definitions provide clarity to the team to ensure they are comparing "apples to apples" during their improvement cycles with data collection and provide a concrete definition of what is to be improved. The operational definition for measurement also provides the staff with a standard work process expectation as they enter and exit patient rooms.

Once a team knows what to measure and how to measure it, the methods of analyzing the data become important. Since improvement, by definition, occurs over time, it is necessary that the data be tracked as such, with more frequent data collection (daily or weekly) being preferred over longer periods of time. Multiple, successive data points provide near real-time information to teams as they test changes, implement proven changes, or work toward sustainment. When analyzed with run or statistical process control charts, teams use specific statistical rules to understand variation in their data, separate data signals from noise, and quickly learn the impact of their tests of change on their systems. Identifying common cause variation (variation inherent to a system) and special cause variation (variation that is not expected within the system)

provides teams valuable insight into each intervention's impacts and the actions they should take [1, 5, 6].

Question 4.3: What Changes Can We Make That Will Result in Improvement?

For many novice teams, this is where quality improvement work both begins and ends. Everybody wants to provide a solution, and team members jump to answer this question before answering questions 1 and 2. A group describes the problem, people say with some certainty what should happen to fix the problem, discussion ensues, action items are identified, and the meeting adjourns. No real goals. No measurement plans. And there will likely be frustration at the follow-up meeting because the only "proof" of whether or not something helped is personal anecdotes. When using the Model for Improvement, this question should only be addressed after questions 1 and 2 are answered. With a unified goal, the team knows exactly what measure they are following to determine whether or not their interventions are altering their system.

The key driver diagram (Fig. 4.1) for the case vignette visually depicts all three questions of the Model for Improvement. A key driver diagram can quickly anchor a team, answering the first two questions very clearly in the *aim* statement and with the key drivers. The team is then ready to brainstorm some ideas for question 3 and can easily see how any potential ideas relate to the key drivers and the SMART aim, resulting in more focused discussions and preventing scope creep. The diagram is also a living document, changing as the project progresses with new knowledge and potential interventions.

Testing Changes: The Plan-Do-Study-Act (PDSA) Cycle

The Plan-Do-Study-Act (PDSA) cycle might be the most well-known quality improvement acronym but might also be the most poorly understood conceptually. There are multiple misperceptions of the cycle itself [7], and, perhaps as a result, the medical literature is full of instances where the term PDSA was invoked, but there is no evidence that PDSA cycles actually took place [8]. The PDSA cycle, which is informed by and used in conjunction with the first three questions for the Model for Improvement, enables teams to learn quickly about the feasibility and effectiveness of the proposed interventions. The PDSA cycle is based historically in the scientific method with the intention of producing new knowledge based on hypothesis testing [4]. Therefore, a true PDSA cycle requires not just putting a change in place but also deliberately studying the results in relation to the team's hypothesis. The bidirectional arrows between the first three questions and the PDSA cycle in the Model for Improvement are deliberate and vital to its purpose (Fig. 4.2) [9]. In essence, each PDSA cycle builds the team's knowledge of their process over time by gaining insight from data through these sequential tests of change (Fig. 4.3) [1].

Having answered the first three questions of the Model for Improvement, a team now has a specific SMART aim statement and understands how they will know if the changes result in an

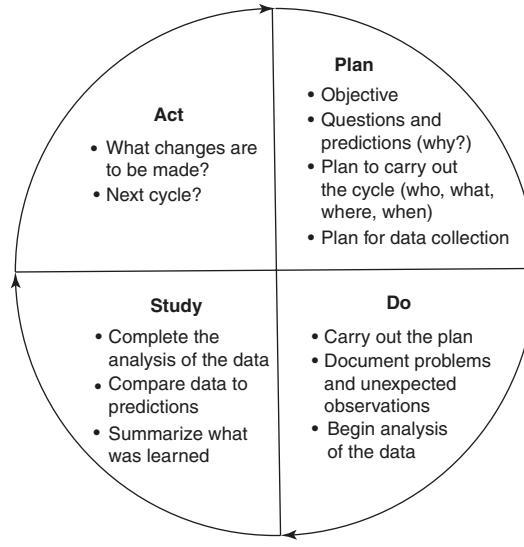

Fig. 4.3 The Plan-Do-Study-Act cycle. (Reproduced from the Improvement Guide Fig. 5.2 with permission from Wiley Books; Clifford et al. [1])

improvement (their chosen measure), and they will have brainstormed ideas that might improve their system. Teams are now ready to conduct their PDSA cycles.

Plan

Teams first *plan* a small test of change based on their team's predictions. Taking one of the proposed interventions, the team can try to incorporate that on a limited scale to begin to understand the effectiveness. For example, in our case vignette, the team would learn much faster by testing interventions on a single room than "rolling out" a new policy to an entire hospital. The team should be explicit about the details of their test – where it will happen, what they will do, what data they will collect and how, and even predict what might happen. The team needs not to have consensus before testing an intervention as there might be significant resistance to change. In fact, allowing team members to predict failure can assist teams' cohesiveness and encourage everyone to share their thoughts and concerns.

Do

They then *do* the test exactly as it is laid out. The intervention might be done by a single provider or in a single room. As the intervention is tested, data are collected to inform the next steps.

Study

Using feedback from the person or people doing the test or those impacted by the test, they then *study* the results. The study of the results can be either in the form of qualitative data or a quantitative measure related to the SMART aim. Did it go as planned? How were the staff impacted by the change? Did it have the intended effect? Do the results move the team closer to their intended goal? How do the data change the perceptions (if at all) to those that were resistant to the change? If their concerns were borne out by the data, what other changes would they suggest? If the test resulted in signs of improvement, how can these data be used to begin to assuage their hesitancy for change?

Act

Through the new knowledge gained in this testing, the team then *acts*. They choose to either adopt, adapt, or abandon this test. In rare cases when the first test achieved its desired effect perfectly, the team may adopt the test and attempt it on a larger scale, ramping up to conduct another PDSA cycle with multiple providers or multiple rooms. More commonly, there are mixed results from which important lessons are gleaned about the intervention's potential effectiveness. Modifications to the test of change are done, and a new PDSA cycle is conducted again on a small scale. Finally, in some scenarios, the tested intervention does not have the desired effect or is not well-received by those whom it will affect, and the team chooses to abandon the intervention altogether. Regardless of whether the team chooses to adopt, adapt, or abandon, the PDSA cycle is a success because they gained important insight into their system without disruption.

The Strength of the Model for Improvement

The Model for Improvement brings structure and discipline to any quality improvement project and applies to all organizational levels [5]. This focused stepwise learning process based on testing theories through the iterative PDSA cycles allows teams to learn from their tests, use accepted statistical methods, and improve their process faster than other approaches [5]. This model is also easy to teach and can be adopted by frontline staff who can begin to work as teams and solve everyday issues that might not rise to the level of management or leadership. Allowing staff to solve their own problems and have early wins can improve morale and resilience. Finally, the structure of the Model for Improvement can be utilized as the framework alongside many other quality improvement methods such as Lean and Six Sigma.

In our vignette, the previous system was not achieving the desired results despite hard work

and the best intentions. We needed to use a structured problem-solving approach. The creation of a SMART aim statement provided a unified vision for the team, and each person knew what they were striving for and how to play their part (Question 1 in The Model for Improvement). Data analysis using the control chart (Fig. 4.4) allowed them to analyze their data in real time, providing important insight as to whether or not the tested changes were making a difference (Question 2 in The Model for Improvement). The key driver diagram allows them to propose interventions that would result in improvement (Question 3 in The Model for Improvement) and then proceed with PDSA cycles to inform their decisions. With this new problem-solving structure in place, the frontline staff could now address concerns using the Model for Improvement and be empowered to voice larger concerns to their leadership.

Vignette 4.3

Now that the initial phases of the project were complete, the team is excited to start testing the interventions they had planned. First, the team decides to develop new posted paper signs and computer screensavers to remind staff to clean their hands to see if fresh new ones placed in different areas would help nurses who no longer noticed the old ones. In addition, unit leaders (nurse managers and medical directors) decide to leverage their roles by discussing hand hygiene performance during meetings and to provide regular, frequent feedback to nurses, nursing care assistants, and physicians. The team uses a control chart (Fig. 4.4) to display weekly hand hygiene compliance data and posts them in

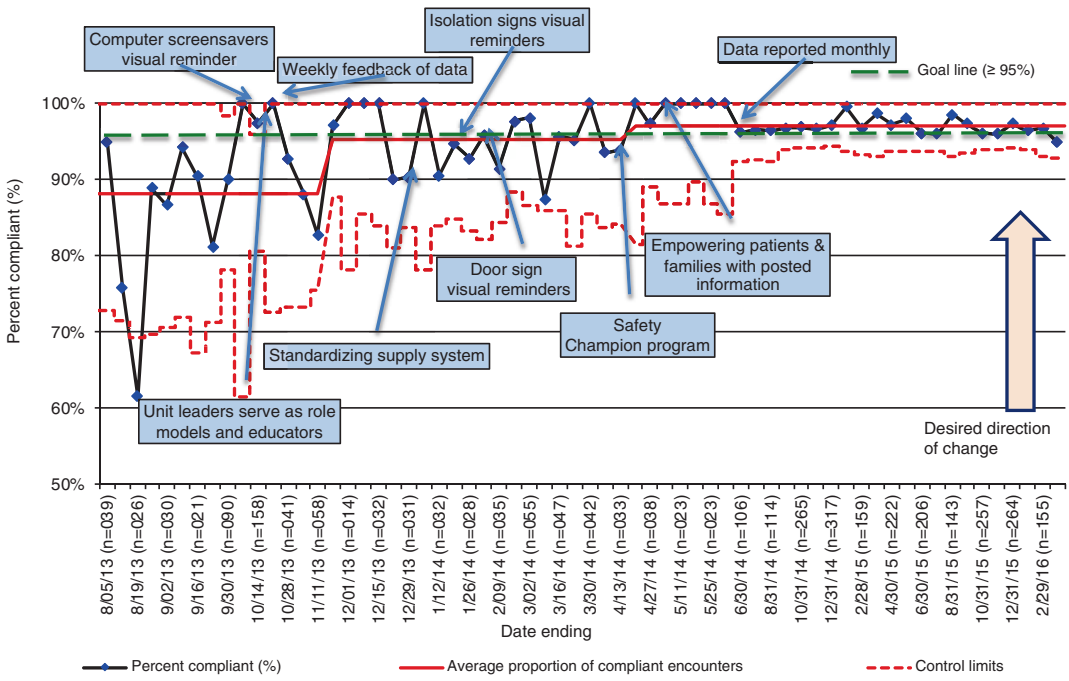

Fig. 4.4 Statistical process control chart (percent or p-chart) showing percent compliant hand hygiene encounters on two inpatient units with annotations of test of change. The x-axis is labeled with every other week or month, and data points are weekly until June 2014 when they are measured monthly. (Reproduced with permission from Hospital Pediatrics, McLean et al. [2] © 2017 by the AAP)

workrooms and distributes them in emails so the performance is viewed by all nurses, physicians, and other staff working on the units. Performance improves >95% at first but, unfortunately, drifts back down to the mid-80s in a few weeks. The team feels frustrated with these results and decides to take a step back. A quality improvement coach suggests the team needs to understand the principles of reliability science before proceeding with the project. The team agrees that the interventions used so far will not sustain a high level of performance and want to learn more about how they can design the process in a different way.

In this case vignette, the team has so far focused on using the Model for Improvement framework to improve a process. The team is missing two key elements and needs to incorporate them into their work if they are going to achieve and sustain the results they are seeking – developing a more *reliable* process and *resilient* safety culture. Both are needed for the team to achieve the goals of this project. So what does this mean? How can the team apply these principles to improve hand hygiene? (Key Point Box 4.2).

Key Point Box 4.2 Reliability and Resiliency
Reliability – the measurable capability of a process, procedure, or health service to perform its intended function in the required time under commonly occurring conditions [10]

Resiliency – the safety culture of an organization is able to systematically understand failures that occur and make adaptations to improve over time [11]

First, let's understand how to develop a more reliable process. The term reliability, as it applies to healthcare, as described by Berwick and Nolan in 2003, is defined as "the measurable capability of a process, procedure, or health service to perform its intended function in the required time under commonly occurring conditions." [10]. Reliability can be quantified as a ratio of failures or errors per number of opportunities (Fig. 4.5). Most healthcare processes operate at levels of reliability with error rates of 10 or more per 100 opportunities (10–30% or 10^{-1} failure rate or level of reliability of 1 [LOR 1]) as compared to high reliability organizations (HROs), such as the nuclear power industry or commercial aviation, which have failure rates of 0.0001% or 10^{-6} (LOR 6) [12]. The hand hygiene failure rate the

Ratio of errors/opportunities	Reliability	Failure percent rate	Failure rate	Examples
1/10	0.9	10	10^{-1}	Hand hygiene compliance
1/100	0.99	1	10^{-2}	Pediatric adverse drug events
1/1000	0.999	0.1	10^{-3}	General surgery deaths
1/10,000	0.9999	0.01	10^{-4}	Road safety
1/100,000	0.99999	0.001	10^{-5}	Giving wrong blood to patient
1/1,000,000	0.999999	0.0001	10^{-6}	Nuclear industry

More reliable

Fig. 4.5 Measures of reliability displayed as ratios of failures per number of opportunities, reliability, failure percent rate, and failure rate with examples from healthcare and industry for each level to illustrate these differences mathematically. (Adapted from Pediatric Clinics of North America, Luria et al. [12], © 2006, with permission from Elsevier)

team observes is 10–15% or level of reliability of 1 (LOR 1). We know from our vignette that this is expected since the process in place includes only training, feedback, and reminders. The Chief Medical Officer in our case is asking the team to design a process with a higher level of reliability equal to or better than 1 or fewer failures per 100 opportunities (1% failure rate or 10^{-2}). In order to achieve this failure rate, the team in the vignette will need to incorporate additional interventions into the project design if they are going to achieve this level of reliability. Studies of human factors engineering and design show us that the team needs to consider interventions such as incorporating decision aids, redundancy, and taking advantage of habits and patterns in order to achieve this level of reliability [12]. Put another way, the team will need to "hard wire" the process by using these types of tactics to create a more reliable design. Use of a visual trigger placed at the entrance of the patient room that notifies the healthcare worker of noncompliance in real time is an example of a human factors engineering intervention that could be used to improve hand hygiene compliance results. Smart process design is critical, but without changing the culture or behaviors of the people working in the area, the team will not be able to achieve and sustain the results they are seeking. To understand more about coupling reliable process design and resilient culture into a healthcare improvement project, we can learn from industries that are high reliability organizations (HROs).

High reliability organizations, such as nuclear power and commercial aviation, achieve both a reliable process and resilient culture with error rates in the order of 1 in 10,000–100,000 opportunities. Weick and Sutcliffe examined HROs and described key features that can be applied to complex healthcare processes, measure performance, and design interventions to achieve desired results. These authors identified five principles of high reliability that are common to HROs shown in the box below (Key Point Box 4.3) [11]:

Key Point Box 4.3 Five Principles Common to High Reliability Organizations (HROs) [11]

1. Preoccupation with Failure – small failures are noticed, reported, and learned from continuously by the organization
2. Reluctance to Simplify – embrace complexity and welcome diverse experience
3. Sensitivity to Operations – attentive to frontline workers' expertise
4. Commitment to Resilience – ability to learn and bounce back after failure
5. Deference to Expertise – authority migrates to the person with most expertise regardless of rank

In summary, the team can use the Model for Improvement framework for the overall project design and implement both reliable process and resilient safety culture change concepts as interventions that are indicated on the key driver diagram (Fig. 4.1). Using PDSA cycles and tracking the impact of these multimodal changes over time on the control chart (Fig. 4.4) will help the team understand when they have achieved special cause variation and reached their goal of ≥95% compliance (less than 5 failures per 100 opportunities) with hand hygiene protocols.

Vignette 4.4

Empowered with a new understanding of concepts of reliability and resiliency, the team reviews the key driver diagram (Fig. 4.1) and decides to test interventions with a level of reliability (LOR) greater than 1. Now it is clear that the reminders, education, feedback of data, and engagement of leaders were examples of level of reliability 1 (LOR 1) interventions and these alone will not give the team the results they desire of less than 5 failures per 100 hand hygiene opportunities. The team

also realizes they need regular interaction with frontline staff and real-time observation of the unit practice to get to the root of the problem. It is clear to the team that engaging the true experts (deference to expertise and sensitivity to operations) in the testing and implementation is the key to achieving and sustaining the goal.

During observation of hand hygiene practice on the units, the project team learns from frontline staff that hand sanitizer canisters in and outside of each patient room are not replaced consistently. As a result of this problem-solving, the team decides that it is important to standardize the hand sanitizer resupply process for both the environmental services worker and the nursing care assistant roles. The idea is to not only create standard work but also to have each worker role responsible for the hand sanitizer and soap resupply process. Therefore, if one individual fails to replace a hand sanitizer canister, then the other one will catch it so that it would be a rare occurrence for there to be no sanitizers available at the point of care, thereby incorporating the design concept of redundancy into the system. During additional observations and discussion with frontline staff, the team recognizes the value of when a healthcare worker gently reminds another person to clean his/her hands before entering or leaving the patient room. In order to foster a culture in which compliant hand hygiene practice is the norm, the project team decides to implement a multidisciplinary hand hygiene champion program to provide real-time mitigation across the units. The idea is to have a knowledgeable peer recognize noncompliance (separate from the hospital-wide auditing process) and provide gentle and respectful feedback, therefore turning a noncompliant encounter into a compliant one. Not only will this practice improve hand hygiene compliance results, but it will also create an environment where people feel comfortable raising concerns that foster a resilient safety culture. Finally, during observations and discussion with patients and families on the units, the decision is made to involve the patients and families as partners in this process. Since care is centered around the patient and family, empowering them to speak up provides an additional layer of accountability and further strengthens the culture of safety. Implementation of all three of these change concepts positively impacts safety culture and process design by incorporating the high reliability principles described by Weick and Sutcliff (See Key Point Box 4.3).

Value of Problem-Solving

Problem-solving involves an intentional process to break down complex issues into actionable components in an effort to create solutions. The Model for Improvement represents only one problem-solving technique, but many more methods exist that can help inform or augment a team's problem-solving strategy. For example, the "5 Whys" can help determine the root cause of a problem [13] and inform a team's plan to test changes through the Model for Improvement. Toyota Production System's 8 Steps of Problem Solving, discussed elsewhere in this text, provides another established framework to solve problems and ultimately improve outcomes.

In healthcare, problem-solving often requires altering the fundamental way a system operates, impacting the frontline staff much more directly than management and leadership who classically are the ones determining how to solve the problem. Quality improvement and patient safety in healthcare require a different approach – an approach in which the experience, expertise, and knowledge of the frontline staff are valued and in which they are given the freedom to improve

their environment for the better of their patients. This embodies the essence of Weick and Sutcliffe's five principles of HROs [11]. When done well, most problems can be solved quickly by those doing the work to reduce "workarounds." Management and leadership personnel are then freed to spend more time with forward-thinking exercises and less time "putting out fires."

W. Edwards Deming's theory of profound knowledge focused intently on people's abilities and their innate desire to feel like an important contributor to their workplace [14]. A key component of this desire is its ability to solve daily problems and see immediate results. Fostering a sense of cooperation instead of competition will raise the level of performance of an entire team, resulting in better results than the sum of each team member's abilities [14]. When teams can harness these abilities and use a disciplined framework such as the Model for Improvement, the frontline team members' understanding of their process, observation of the issues at hand, and ideas for improvement can be harnessed to problem-solve efficiently and effectively.

Importantly, as teams work together, they must not only think of their own results but the goals of the entire organization. Russell Ackoff, a revolutionary systems thinker, wrote: "If each part of a system, considered separately, is made to operate as efficiently as possible, the system as a whole will not operate as effectively as possible." [15] In essence, working in "silos" might help one team meet a metric, but that team's "win" may hinder the system as a whole. This issue is not unique to healthcare. As an example, General Stanley McChrystal led the Joint Special Operations Task Force in Afghanistan and had to rethink how his teams worked together. He discovered that traditional military hierarchy was not nimble enough to effectively accomplish his Task Force's goals. By creating a "team of teams" (also the title of the book), he was able to empower the frontline members on his units to solve problems efficiently and effectively. This approach also created relationships between the teams such that the broader mission's goals were taken into account as decisions were made in the field [16]. In effect, he harnessed and magnified each team members' ability as they worked within and between teams. This approach empowered team members to speak up and to problem-solve within the boundaries to their stated mission, fostered a sense of self-worth and cooperation, shattered silos, flattened hierarchy, and led to efficiencies and successes that the Task Force had not previously seen.

The ability and desire of people to problem-solve based on their knowledge of their system propelled McChrystal's model to success. This approach essentially established a high reliability organization by building reliability and resilience where it was needed most – in the people who were carrying out the important work. Healthcare can harness problem-solving in a similar manner. Frontline workers, based on their knowledge of the system, can provide ideas to lead to improvement through structured approaches such as the Model for Improvement. When teams discover changes to the system that are successful, "cross-talk" between silos can lead to larger improvements through more reliable process design. And, perhaps most importantly, this cross-talk between silos can lead to profound resilience as teams around an organization are able to speak freely to each other and to leadership, identify and verbalize a problem, and propose action knowing that their voice will be heard.

Vignette 4.5

Brainstorming and feedback from staff now regularly occur during safety and operational meetings as well as during intermittent, unannounced visits to the units. Use of the multidisciplinary champions helps to sustain the results and continue to incorporate the principles of high reliability. Following standard statistical process control chart rules, the centerline shifted twice during the project when special-cause variation occurred (Fig. 4.4). The project control chart now shows the

results they desire with hand hygiene compliance sustained ≥95%. Project results are reported to executive leadership of the hospital with an emphasis on pairing reliable process design with a resilient safety culture that is needed to give these two units the results they need. The hospital Chief Medical Officer celebrates the results of the project and helps the team plan for spread to other units in the hospital.

Conclusion

In this chapter, the example of the challenges faced, and successes achieved, by an actual improvement team highlights the importance of using a structured improvement approach (the Model for Improvement) and in harnessing the knowledge and ability of frontline staff to problem-solve. This, in turn, creates a resilient safety culture that is coupled with reliable process design. The Model for Improvement propelled the team to the next level, assisting them in identifying a SMART aim and producing theories that would help them test and measure interventions to determine if intended changes were occurring. These small wins achieved through using the Model for Improvement improved morale, provided frontline staff a voice, and engaged staff in identifying solutions that could be tested. Each organization must make incremental changes, using examples of small wins gained through quality improvement methods to reinforce frontline problem-solving. With this, reliability and resilience become symbiotic with the quality improvement methods, each building on the other, creating an upward spiral toward any healthcare organization's goal of becoming an HRO and bringing them closer to a goal of "Zero Harm."

Editors' Comments

Reliability, resilience, and problem-solving are the core of improvement science. This chapter highlights the difficulties we face in healthcare using a vignette of hand hygiene. The vignette demonstrates that something as simple as washing one's hands prior to caring for a patient is complex to perform reliability and consistently. There is no better exemplar than hand hygiene; if we cannot deconstruct this issue into its constituent parts and perform it with reliability and with resilience, then we will fall short of major improvement initiatives, which are sorely needed in healthcare, such as reducing readmissions, decreasing length of stay, and optimizing patient throughput.

We would like the reader to appreciate the significance of the Model for Improvement and strategies to approach change (PDSA cycles); the authors go in depth on these concepts to ensure that the reader will have the requisite knowledge to try and use these approaches for their improvement. This chapter espouses the traditional surgical mantra of see one, do one, teach one; the chapter is fundamental and written at an appropriate level to serve as a primer or toolkit for a novice to understand the techniques and try these on a small scale in their span of control.

The important concept of reliability is further developed in this chapter with the authors once again pulling from Weick and Sutcliffe's five principles of high reliability organizations. We feel it crucial for the reader to continually hear about these five principles and see how they are applied to various situations; it is in this way that the reader will develop a profound respect and understanding of the power of these principles as an overarching framework for improvement science.

Conceptually, the hardest part of the chapter is to describe and attempt to reach problem-solving. We believe the authors convey this very well toward the end of the chapter. Once we understand reliability and resilience, the difficulty is how to develop

and sustain a problem solving culture. The authors draw from their experience and the literature to provide approaches for this difficult part of quality improvement.

Chapter Review Questions

1. What are the three questions the Model for Improvement asks teams to address in the design of a project?

   Answer: (1) What are we trying to accomplish? (2) How will we know change is an improvement? And (3) what change can we make that will result in improvement?
2. What is the difference between the concepts of reliability and resiliency?

   Answer: *Reliability* is the measurable capability of a process, procedure, or health service to perform its intended function in the required time under commonly occurring conditions [10]; *resiliency* is the safety culture of an organization and its ability to systematically understand failures that occur and make adaptations to improve over time.
3. What are the five high-reliability principles that are described by Weick and Sutcliffe?

   Answer:
   (1) Preoccupation with Failure – small failures are noticed, reported, and learned from continuously by the organization
   (2) Reluctance to Simplify – embrace complexity and welcome diverse experience
   (3) Sensitivity to Operations – attentive to frontline workers' expertise
   (4) Commitment to Resilience – the ability to learn and bounce back after failure
   (5) Deference to Expertise – authority migrates to the person with most expertise regardless of rank
4. True or false: "Zero harm" results in patient safety can be achieved by incorporating reliable process design into a healthcare system alone.

   Answer: False (need to use both reliable process design and resilient safety culture concepts in order to achieve "zero harm" results).
5. True or false: Engagement of frontline staff in the PDSA cycles for improvement can be essential for successful problem-solving and positively impacts the safety culture of the organization.

   Answer: True.

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5 Building an Engaging Toyota Production System Culture to Drive Winning Performance for Our Patients, Caregivers, Hospitals, and Communities

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Abbreviations

CMS	Centers for Medicare and Medicaid Services
DART	Days Away, Restricted, or Transferred
ED	Emergency Department
EHR	Electronic Health Record
FTA	Fast-Track Area
HRO	High-Reliability Organization
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
LVN	Licensed Vocational Nurse
MIT	Massachusetts Institute of Technology
MVV	Mission, Vision, and Values
NASEM	National Academies of Sciences, Engineering, and Medicine
NICU	Neonatal Intensive Care Unit
PDCA	Plan-Do-Check-Adjust
PDSA	Plan-Do-Study-Act
PIs	Pressure Injuries
PO	Per Oral or By Mouth
RN	Registered Nurse
TPN	Total Parenteral Nutrition
TPS	Toyota Production System
TSSC	Toyota Production System Support Center
WOT	Wound Ostomy Team

All vignettes in this chapter are fictional. A glossary can be found at the end of this chapter.

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Chapter Objectives

- To share perspectives and learnings from the early years of applying Toyota Production System (TPS) principles to healthcare
- To show how TPS principles align with high-reliability organization (HRO) principles
- To make TPS principles relatable and understandable to people with varying backgrounds, especially in healthcare
- To show the value of creating frontline problem-solvers to improve performance
- To share perspectives and learnings on building a successful, high-performing TPS culture in healthcare

Opening Vignette

It is early morning at a Toyota plant. The morning huddle with the various line teams has disbanded, and the production output has been increased to meet greater demand, so a new Toyota vehicle will come off the line every 55 seconds. At the morning huddle, everyone was notified that new loading fixtures will be installed to better assist with positioning large dashboards during installation into the new production vehicles. As production occurs, the team tasked with attaching the dashboards notices that several loading fixtures seem to cause slight blemishes on the dashboards, which are visible only under certain lighting conditions.

A team member immediately pulls a cord (called an andon cord) which activates a flashing light and musical tone to signal that a problem has occurred. A problem-solver, who is also the team leader, hears the musical tone and arrives within 20 seconds to assist with the situation and immediately begins investigating the problem.

Not too far behind are other plant leaders who coach a problem-solving exercise with the local team. The team follows the process upstream from the point at which the problem occurred and finds that the new loading fixture lightly rubs some dashboards during the loading process. The clearance between the fixture and the dashboard was insufficient. The countermeasures are immediately deployed, including increasing the clearance from 1/8 inch to 3/4 inch and placing tape around the fixture – which prevented scuffing if the fixture accidentally contacted the dashboard during placement. After the countermeasures were operationalized, no further defects were noted.

This fictitious example demonstrates timely problem-solving that those in healthcare are trying to emulate, where a defect or problem is quickly identified and analyzed, while the evidence is fresh. The frontline team temporarily stops the production line so that the cause of the defect can be uncovered and immediate group problem-solving can occur. The countermeasures were rapidly implemented which prevented any future recurrences. The alignment of the assembly plant with its suppliers can, at times, facilitate this rapid and joint problem-solving. The organizational culture that supports this took years to develop through shared experimentation and learning. It is not unique to this particular Toyota plant. Rather, this culture can be found at any of their plants around the globe. The frontline workers and Toyota leadership know that no defect is to be passed forward. Pushing defects through the system results in increased costs from *muda* (waste) such as rework, recurrence of defects, customer and employee dissatisfaction, and possible safety concerns.

Systems, both human and computerized, need to be in place to rapidly identify defects, deviations from the standard, or abnormal conditions. Healthcare providers, patients, and leaders of other industries often wonder if similar systemic

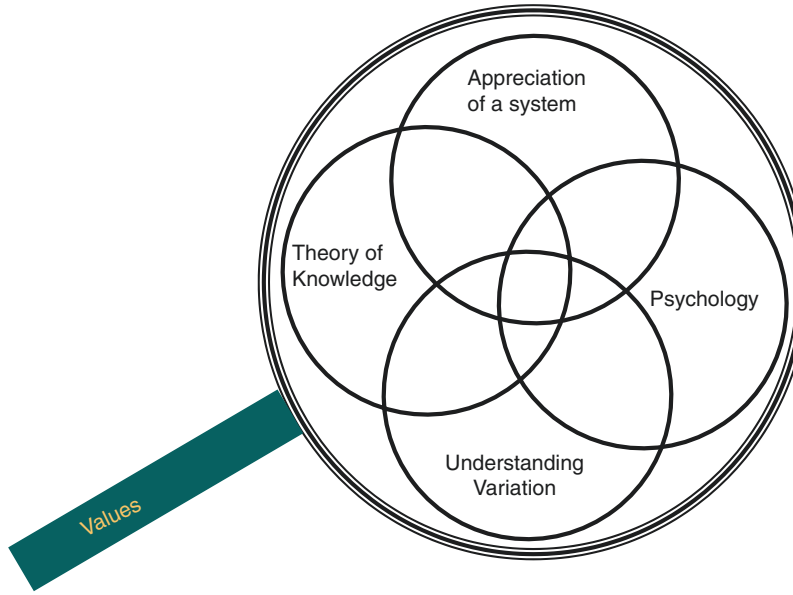


Fig. 5.1 Deming's system of profound knowledge. (Reprinted from by Langley et al. [1] with permission from John Wiley & Sons)

cultural changes can be instilled in their organizations. Such an ideal state employs all four parts of Deming's System of Profound Knowledge [1] – Appreciation of System, Theory of Knowledge, Understanding Variation, and Psychology of Change. All of these parts are interrelated (Fig. 5.1). An examination of the figure shows that the ability of the parts to interrelate and work well together is dependent upon the values of the organization (represented by the handle of the magnifying glass).

Paul O'Neill has discussed the value of habit in changing culture. As the CEO of Alcoa, his focus on employee safety aligned his frontline workforce around a universally acceptable and popular agenda along with delivering improved organizational profitability. The encouragement of habit formation was key in his empowerment of the frontline [2]. Such principles have been applied by Toyota in the Toyota Production System (TPS) since the 1950s. Similarly, through their focus on organizational safety and development of frontline team members, Toyota's financial outlook has improved. More importantly, they have developed a sustainable organizational culture focused on frontline development. It will become apparent that TPS is much more than habit creation, but rather an organizational culture and quality management framework that can help an organization become a learning system, a high-reliability organization, and a desired place to work that achieves and sustains rigorous safety, quality, value, and financial goals.

Weick and Sutcliffe [3] described the need for increased organizational "mindfulness" in the quest for high reliability. A high-reliability organization (HRO) operates under trying conditions but nonetheless manages to have fewer than their share of adverse events. We will return to this discussion of high reliability at the end of this chapter as TPS is a problem-solving, culture-centered improvement system that embodies and facilitates the successful implementation of the five HRO principles:

1. Preoccupation with failure
2. Sensitivity to operations
3. Reluctance to simplify
4. Commitment to resilience
5. Deference to expertise

As mentioned in other chapters, preoccupation with failure refers to the constant vigilance about seemingly small or inconsequential issues being signs of bigger problems. Sensitivity to operations refers to the focus on what is happening on the "shop floor" or where production of goods or delivery of services is occurring. A

reluctance to simplify interpretations encourages diversity in opinions, experiences, inputs, and perspectives. Finally, the latter two principles are most applicable when an error or defect occurs, as no system is perfect. There will need to be anticipatory processes in place that facilitate learning when failures do occur. Commitment to resilience refers to an organization's ability to contain problems and create rapid solutions after errors are investigated. Deference to expertise involves people with the most relevant expertise, regardless of their position in the organizational hierarchy, in any post-event assessments or problem-solving. The introductory vignette demonstrated these principles. Problems are to be expected, so we need to design systems to rapidly detect and react to these problems and prevent recurrence.

From our travels to various hospitals that are supposedly implementing "Lean" as their improvement methodology, the core values that the Toyota Production System represents are often misrepresented and/or misinterpreted.

Here are a few common misconceptions:

- Misconception 1: "LEAN is an acronym that stands for *L*ess *E*mployees *A*re *N*eeded." Leaders and consultants can be quick to assume that a reduction in workers is the answer to cost reduction – which is entirely contradictory to Toyota's philosophy of respect (*will be discussed further in the sections, "TPS Triangle: Philosophy Arm" and "TPS Approach to Delivering Value"*).
- Misconception 2: "You need to spend large amounts of money for consultants to successfully implement TPS in your organization." Toyota considers its people as its most valuable asset. Building an organizational culture of highly engaged and empowered individuals starts from within (*will be discussed in the proceeding sections*).
- Misconception 3: "Implementing TPS in healthcare means we're all going to work like robots." When created and implemented correctly (i.e., developed by the people who do the work and validated continuously at the *genba* or workplace), standardized work is one of the most powerful tools in TPS that keeps processes and practices safe, reliable, and evidence-based. In healthcare, the goal is to standardize around the patient, so that team members can do what they are trained to do – which is to care for people and patients (*will be discussed further in "TPS House" section*).

TPS Approach to Delivering Value

> I will say again: the only way to generate a profit is to improve business performance and profit through efforts to reduce cost. This is not done by making workers slave away, to use a bad expression from the olden days, or to generate profit by pursuing low labor costs, but by using truly rational and scientific methods to eliminate waste and reduce costs. – Taiichi Ohno [4]

Over the past two decades, the healthcare industry (especially in the United States where costs are among the highest globally and outcomes are not necessarily the best overall) has been challenged to improve value in its care delivery systems. Some US healthcare professionals and administrators have suggested that the increased costs are related to the increasing complexity of the procedures or the use of more advanced and, at times, more expensive technology. However, compared to other countries performing comparable procedures, the US health systems remain costlier with poorer outcomes [5].

Value is defined simply as quality divided by cost [6]. Healthcare leaders are often asked by their senior leaders and board members for the return on investment (ROI) for quality and safety. This discussion is difficult, at best, as some benefits cannot be readily measured [7]. Many industries, including healthcare, determine the price of their services using the following equation:

$$\left[\text{Selling Price, as set by the company}\right] = \left[\text{Cost of Goods or Services}\right] + \text{"Profit"}$$

In this equation, as the costs of goods and services will increase over time due to increases in raw materials or staff costs, the selling price is usually increased to achieve the needed profit. We know that the healthcare market will only bear small increases in costs, if any, given the amount of gross domestic product already allocated to overall population medical needs, including direct care, preventative care, technology, research and development, and pharmaceuticals [8]. Similarly, Toyota has long believed that its customers and market conditions limit the price that can be charged. The automotive market is very competitive and will not bear high prices. To survive and reinvest in the future, a company must be profitable by reducing its costs. Toyota rewrites this equation as

$$\left[\text{Selling Price, as set by the market}\right] - \left[\text{Cost of Goods or Services}\right] = \text{"Profit"}$$

Therefore, organizations need to control costs to assure a reasonable profit to reinvest and survive. In healthcare, fruitful partnerships must occur with our patients, their families, insurers, communities, school systems, other health systems, and pharmacies to ultimately reduce costs and deliver value. Toyota proposes reducing costs using TPS as described by the TPS Triangle (Fig. 5.2) and the TPS House (Fig. 5.3). Reduction of costs through the reduction of workforce is not congruent with TPS principles and is detrimental to workforce morale and advancement of corporate production and quality goals:

Fig. 5.2 Toyota Production System (TPS) Triangle. (Used with the permission of Toyota)

> Cost reduction must be the goal of consumer product manufacturers trying to survive in today's marketplace…there is no magic method. Rather a total management system is needed that develops human ability to its fullest capability to best enhance creativity and fruitfulness to utilize facilities and machines well, and to eliminate all waste – Taiichi Ohno [4]

In healthcare, the focus is on preventive and proactive care (e.g., routine physical exams, immunizations, proper diet and exercise) to prevent the more expensive care like emergency department visits. Improving operational efficiencies is the desired result. This includes waste reduction, outcomes, and costs all while increasing workforce and customer satisfaction.

Scientific Method and Becoming a Learning Organization

Taiichi Ohno, the former Vice-President of Toyota Motor Company and TPS leader who helped develop TPS in the 1950s–1970s, often spoke of the intelligent frontline team members who surface problems, work to quickly create countermeasures, and solve these identified problems through testing and application of scientific methodology. In this intentional process of creating and testing hypotheses, a robust learning sys-

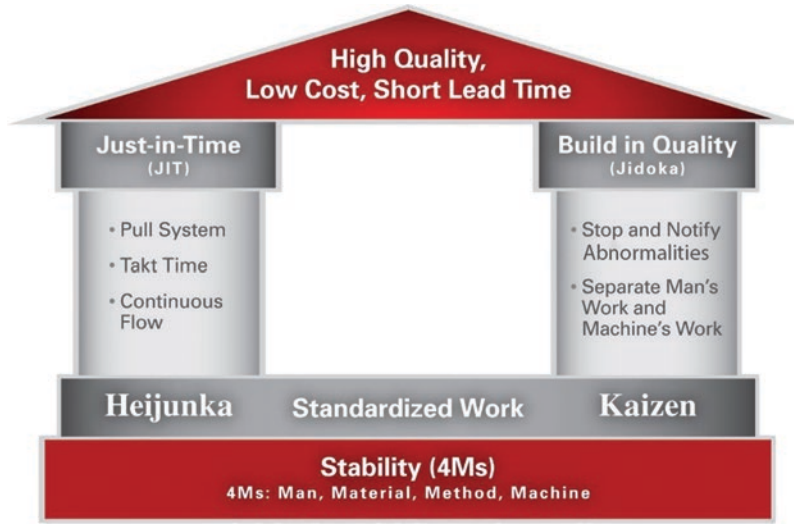


Fig. 5.3. Toyota Production System House. (Used with the permission of Toyota)

tem results. The National Academies of Sciences, Engineering, and Medicine (NASEM), formerly the Institute of Medicine (IOM), has recommended in its numerous publications [9–11] that health systems emulate this very environment, as it greatly enhances organizational agility while creating a system that is most desired by patients, their families, and society as a whole. The role of senior leaders or administrators is to lead, coach, and facilitate the work of frontline members and their development of problem-solving expertise. Simultaneously, these leaders should increase their visibility to the frontline team members and regularly visit the shop floor or areas (e.g., clinical and nonclinical) where the improvement is desired, during which time they can observe, receive input, and provide guidance. The value of local or unit-based huddles, especially with senior leaders present, cannot be overemphasized to drive frontline engagement with TPS and improvement efforts. Decades after the creation of TPS, the Institute for Healthcare Improvement (IHI) High-Impact Leadership framework espouses these very concepts [12].

TPS places tremendous value on the development of the frontline worker and the creation of a corporate culture where people are trained to become problem-solvers or scientists. The application of the scientific method in real time on the automotive shop floor allows learning to occur rapidly, which in turn leads to innovation. This corporate approach supports the development of teams of problem-solvers who are empowered to drive change and innovate. The frontline Toyota workers are vital corporate assets and, by investing in their growth (a concept known as people development), they help create a learning factory where knowledge is gleaned from planned experimentation. This new knowledge is applied and shared throughout the organization – corporate agility results, employees feel valued, everyone wins, and a competitive corporate edge arises. Taiichi Ohno once said that "knowledge is something you buy with money. Wisdom is something you acquire by doing it [13]." You learn by doing!

History's Effect on the TPS

Historically, Toyota started out by making automatic looms. Some principles of TPS were introduced during this time of Toyota's development. The founders of Toyota wanted to provide a greater service to society through automotive manufacturing [4]. The automotive arm of Toyota started in the 1930s, well after other global automakers. Not surprisingly, they had to overcome specific challenges when competing with these larger volume, more technologically advanced, global competitors like General Motors and Ford Motor Company.

Additionally, post-World War II Japan had some challenges not seen in the United States:

1. Geography, especially given its island location off the coast of Asia, with space challenges and limited natural resources.
2. Impaired industrial infrastructure.
3. Limited market for automobiles.
4. Only 2% of automobiles sold were Japanese in origin, and, therefore, the market was dominated by foreign manufacturers.
5. Vehicles were much more technologically complex when compared with Toyota's former business line, automatic looms [4].

Due to these challenges, Toyota further refined TPS through practical trial and experimentation in the 1950s and 1960s. Its founders realized early on that their people, especially their front-line workers, were most capable of learning, creating, and problem-solving. For this reason, they were the most valuable resource and needed to be treated with respect. The value of Toyota's front-line workers is emphasized by the fact that they are always referred to as team members. In a 1988 *New England Journal of Medicine* article [14], Donald Berwick, President Emeritus and Senior Fellow at the IHI and former Administrator of the Centers for Medicare and Medicaid Services (CMS), advocated that healthcare adopt the continuous improvement (*kaizen*) approach to healthcare, which engages people's minds by applying the scientific method to problems. Suddenly, defects are positively looked at as opportunities to learn and improve rather than punitively as a way to identify potential "bad apples."

Steven Spears in *The High-Velocity Edge* [15] fondly described that "Toyota's success is attributable to its 'velocity of discovery' – the speed with which the company improves, innovates and invents." Toyota's founding fathers achieved this by "ensuring that pieces of a larger whole are harmoniously synchronized rather than discordant." The downstream needs and processes paced work further upstream, creating the feeling of a synchronized orchestral piece with all units linked together to deliver the product or service to the end customer. The concept reduced wasted inventory and improved efficiency and quality. Toyota discovered how to do more work, rapidly and more reliably, without using more labor.

The 1973 global gas crisis brought attention to Toyota Motor Company. They were producing high-quality, safe, small cars efficiently in the quantities needed by their customers with very little waste (*muda*), and remained financially stable during this economic downturn. James Womack and his colleagues at the Massachusetts Institute of Technology (MIT) had been studying Toyota and published *The Machine That Changed the World* in 1990, which highlighted the successful principles of TPS and used the words "Lean production" to refer to TPS [16].

Lean has taken on a wide range of meanings to different organizations due to the misunderstanding of TPS principles. Additionally, Lean can be unfortunately mistaken by the workforce to be a job elimination tool – a way to match staffing to hourly demand, sending people home early when deemed necessary, or to staff light daily [17]. This is contrary to the value that Toyota places on the development of its team members.

Steven Spears and H. Kent Bowen [17, 18] describe four rules that need to be followed in the application of Lean principles which are congruent with TPS principles:

- *Rule 1*: "All work is highly specified regarding content, sequence, timing, and outcome."
- *Rule 2*: "Every customer-supplier connection must be direct, and there must be an unambiguous yes-or-no way to send requests and receive responses."
- *Rule 3*: "The pathway for every product and service must be simple and direct."
- *Rule 4*: "Any improvement must be made in accordance with the scientific method, under the guidance of a teacher, at the lowest possible level of the organization" [18].

The aforementioned rules have built-in signals to highlight problems automatically and rapidly and to make organizations adaptable to changing situations. These principles require organizational commitment, but, when adhered to closely,

will best align with TPS philosophy. This will become evident in the proceeding sections.

The TPS Triangle

The TPS Triangle (Fig. 5.2) has been used to describe TPS outside of Toyota for greater than 25 years, which coincides with the founding of the Toyota Production System Support Center (TSSC). TSSC is a nonprofit subsidiary that shares TPS with people, companies, and nonprofits outside of Toyota to contribute to society. At first glance, the simplicity of the TPS Triangle is evident. The people of any organization drive its excellence, so at its center is the emphasis on people development. TPS is an organizational culture of highly engaged people solving problems or innovating to drive performance. This culture is created and sustained by a three-part system of (1) philosophy, (2) technical tools, and (3) managerial roles.

The *philosophy side* has four key points:

1. *Customer first* – Understand the customers deeply and provide exactly what they want, only when they want it, and in the amount wanted.
2. *People are the most valuable resource* – Our employees, staff, and volunteers are our most valuable resource and should be engaged and treated as such.
3. *Continuous improvement* – The sum of many, many small improvements by many people accumulates to significant overall performance improvement and innovation.
4. *Shop floor (gemba or genba) focus* – Focus attention on where the customer value-added work is done. In healthcare, this is typically in clinical areas, such as the emergency department, operating room/theater, inpatient unit, or outpatient unit, but it does not need to be, as a project can extend into finance or other nonclinical areas.

These philosophies also fit well for healthcare. First, customers are the priority. In healthcare, the most obvious customers are our patients and their families. We have other customers as well. A hospital unit or team member who receives a patient from another unit or team member is the customer of the upstream unit or colleague. No defect shall be passed on to the next customer. Customers can be internal or external to an organization, including insurers. We should strive to meet or exceed our customers' expectations. Customer and workforce safety are most important. For instance, an emergency department team needs to stabilize an ill patient to the best of their ability before admitting them to the inpatient medical-surgical or intensive care unit. They need to answer the questions of the patient and their family. Similarly, the accepting unit and medical team should expect a patient to be stabilized as much as possible, to receive a proper sign-out from the upstream team, and to have all of the needed chart documentation completed in a timely fashion. This allows for the excellent, team-based clinical care to continue and decreases the possibility of the patient becoming susceptible to a medical error. For this reason, we need to be cognizant of who our many customers are. To reiterate, we do not pass on defects to our customers as this creates customer and workforce dissatisfaction, increased costs from rework of defects, and potential safety problems.

Second, people are the most valuable resource. Only people, after all, are capable of continual learning, especially problem-solving and innovating. For this reason, they must be treated as an organization's most valuable resource and be provided a safe working environment, job security, intellectual challenges, and jobs that add value. The effectiveness and commitment of an organization depend on the motivation and capability of its people. The role of management, or senior leaders, is to motivate and develop these frontline people. In healthcare, we generally think of our caregivers – physicians, nurses, and other allied health professionals who care for patients – as the core frontline people.

Third, these motivated team members move forward to drive continuous improvement and associated problem-solving, also known as *kaizen*, which occurs in small manageable steps. All team members come to work to both do and improve their work. Finally, key improvement

activities occur on the shop floor with the following assumptions: (a) the shop floor (*gemba* or *genba*) is constantly changing; (b) one must be on the shop floor to understand the current state; and (c) the input from the members on the shop floor is invaluable to understanding the current conditions, feasibility of change, and goal of any change, and to set SMART (*S*pecific, *M*easurable, *A*ggressive yet attainable, *R*elevant, and *T*ime-sensitive) targets.

By accepting that all humans learn the most by doing, organizational leaders need to provide frontline team members and managers opportunities to learn, practice, and also fail. The role of a manager, as defined by the *managerial side* of the Triangle, is to engage and develop all team members into problem-solvers. On the *technical side* of the Triangle, team members use many TPS tools and methods (reviewed shortly in the TPS House discussion), to expose problems correctly. In the TPS culture, problems are also brought to the surface quickly as discussed in the initial vignette. We cannot solve problems we cannot see. In healthcare, organizations are investing in better training of their team members in improvement science methodologies to promote problem-solving as soon as a problem is identified. By teaching team members a common institutional standard way to approach problems, they have a common language through which they can immediately describe their initial problems, their ongoing progress, and resolution. This reason for the common language is no different than the reasons that have supported the need for common resuscitation methods, such as basic life support or advanced cardiac life support (BLS/ACLS), in the clinical setting or the use of the scientific method in the laboratory setting.

Toyota places considerable value on customer input and satisfaction. They strive to provide customers with exactly what they want, when they want it. By encouraging patients or their families to provide feedback or speak up, health systems can design desirable services for their patients. By incorporating these family members into the discussion or improvement project involving the care of their loved one, more informed decisions can be made, increasing the likelihood that the project will be successful, lead to meaningful change, and ultimately increase patient and family engagement and satisfaction. Similarly, by encouraging families to initiate rapid response teams, problems can be brought to the surface sooner [19]. Rapid response teams are comprised of hospital team members that respond to the bedside of a patient with early signs of deterioration in response to staff or, in some situations, family member concerns. This is also a perfect example of the application of the aforementioned HRO principles – preoccupation with failure, sensitivity to operations, and deference to expertise. Our frontline workers and families are very aware of the minute-to-minute changes in the clinical status of their loved ones.

By now, Toyota's obvious focus on connecting production to customer preferences and demand, and the focus on the development of frontline team members, is apparent. This reduces waste, promotes the rapid identification and resolution of problems, and ultimately creates a learning system.

Key Learning Points

1. TPS is an organizational culture of highly engaged people solving problems or innovating to drive performance. This culture is created and sustained by a three-part system, as described by the TPS Triangle, of (1) philosophy, (2) technical tools, and (3) managerial roles.
2. In healthcare, this culture must be a win for patients and their families, a win for caregivers, a win for hospitals, and a win for the community.
3. An organization's people are the best learners and advocates that can help drive excellence.
4. Problems need to be brought to the surface quickly as we cannot fix things that we cannot see. Problems detected early are often smaller and more manageable. Missed problems, or delayed detection of problems, can permit problems to

evolve to those that are larger, less manageable, and detrimental.
5. Defects are not to be passed on to our customers, as this creates customer and workforce dissatisfaction, increased costs from the rework of defects, and potential safety problems.
6. Problem-solving is a crucial skill set.
7. The voice of the customer is important and needs to be incorporated into any improvement project.

Toyota Production System House

The Toyota Production System House (Fig. 5.3) depicts the key technical elements of TPS. These concepts will be discussed in detail followed by vignettes from various healthcare organizations that have applied TPS-based improvement science to local problems with direct guidance from TSSC.

The TPS House is covered by a roof which represents the performance that TPS is designed to deliver – very high quality, low cost, and short lead (or wait) time. Safety comes above all else. To achieve high performance, there are two main pillars: just-in-time (JIT) and *jidoka* (building in quality at the source). JIT and *jidoka* require some foundational elements starting with the 4Ms. This stable foundation enables stable operations. Specifically, the foundation requires *M*anpower (People),[1] *M*achine, *M*aterial, and *M*ethod – which need to be of high quality and reliability, and properly chosen. Manpower (People) need to perform reliably with good work habits, proper skill level, good attendance, and low turnover. For instance, a common challenge in nursing and other healthcare roles is managing the rotating shifts over the 24 hours of a day, 7 days per week, and the associated turnover. Finding the correct people for these roles is crucial, as is assuring everyone is working to the top of their licensure and expected competency. Machines need to be available in the right number and location, and be reliable (not break down or create defects). This is especially true in critical areas such as the operating room/theater or intensive care units where key machines such as ventilators must be dependable. Materials (such as references, standardized work documents, and manufacturer guidelines) need to be easily accessible to the people who do the work. Materials in healthcare also refer to the patient, their EHR, and their specimens. We want material to flow. The methods are the best, optimal practices for delivering care and services and are often the result of local continuous improvement efforts. At times, they can be best practices developed at other organizations but adapted and perfected locally through small tests of change. Often included in the foundation is the environment, which can also be referred to as *M*other Nature (or the fifth *M*). The environment needs to be clean, clutter-free, and organized so that it can facilitate high quality, lower costs, and shorter lead times without the introduction of defects.

The 4Ms foundation is required to support and enable the layer immediately above it, which is comprised of *kaizen*, *heijunka*, and standardized work.

Kaizen refers to continuous improvement and problem-solving. TPS encourages continuous improvement since it is small steps of change that, when added together, can result in great innovation. *Kaizen* is the bridge that brings customers and improvement team members together. This has been especially impactful in healthcare when caregivers can experience their processes through the eyes of patients and their family members. Engaging customers/patients as we address imperfect processes helps to create an environment where respect for people, a key TPS concept, is realized. This concept is referred to as "humanize." It helps reinforce why we need to improve and can help provide the motivation to support change remembering that 100% of what we do ultimately impacts our customers/patients 100% of the time.

Heijunka refers to the leveling of work or production. By leveling work, you prevent process bottlenecks or the buildup of inventory in the

[1] Manpower is mentioned here but this refers to humans of all genders.

industrial setting. In the healthcare setting, you can distribute the work evenly so as not to overburden any single person, preventing safety and quality issues. For instance, hospitals have applied this to their operating room scheduling process by distributing the types of cases evenly to the various operating rooms, optimizing work, and balancing the overall flow throughout the week.

Standardized work (a step-by-step document written by the people who do the work outlining the current best thinking on how to perform the process, including step sequence and timing) needs to be defined to maintain changes. Standardized work at Toyota is a framework for maintaining *kaizen* improvements. Once the current practice is known, efforts are made to document and train to this standard until a better way is developed. When a better way is discovered, new work method standards are created. One key point is that standards are a starting point with the expectation that they will be improved. At times, healthcare providers are resistant to standardization without fully understanding that it is a starting point for the improvement process. ThedaCare in Wisconsin has therefore coined the term "flexible regimentation" where regimentation refers to the creation of a common standard process for "performing a specific service based on the best available evidence," and flexible refers to the ongoing work to improve this standard [20]. Standardized work also reduces variation in supplies and instruments used in the operating theater since uniform predetermined supplies and instruments are used for each type of surgery among the various medical providers. As a result, it also plays a critical role in surfacing problems. When abnormal conditions occur, the behavior of following standardized work allows members performing tasks to identify problems rapidly.

The two pillars of the TPS House are just-in-time (JIT) and *jidoka*. The JIT pillar advocates continuous flow, *takt* time, and the use of pull systems. Production is tightly run, where the key components reach an assembly line at the time needed and only in the quantity desired. Everyone in the production process works in sync and is aware of *takt* time. *Takt* time is calculated by dividing the operable time per day by the required number of units of a particular product per day (output). With a high level of JIT, any disruption to flow is immediately visible, so immediate problem-solving can be initiated.

Pull production is important to the concept of continuous flow. Toyota, from its earliest years, realized that extra inventory was disadvantageous. Toyota had very limited financial resources and space in its early years to afford the storage of inventory, so they had to be innovative and find alternative manufacturing solutions. Taiichi Ohno once said, *"manufacturers and workplaces can no longer base production (from) desktop planning alone and then distribute, or push, their products onto the market. It has become a matter of course for customers, or users, each with a different value system, to stand in the front line of the marketplace, and, so to speak, pull the goods they need, in the amount and at the time they need them."* This reduced inventory has given Toyota the ability to tightly regulate their processes to uncover defects when problems arise. The problems become easier to find, and this, in turn, reduces problem-solving time. Ohno further eloquently stated that the goal of *"Toyota Production System is to produce what you need, only as much as you need when you need"* [4, 13]. He realized that mass production without a linkage to the true customer needs would not work long term.

Jidoka (automation with a human touch) refers to processes with built-in quality that immediately signal when a problem occurs, so that a person does not have to monitor a process just looking for defects. An everyday example of *jidoka* is the seat belt alarm that beeps whenever a seat belt is not properly fastened. Back when Toyota was originally an automated loom manufacturer, *jidoka* referred to a loom's stoppage if a string broke, alerting the worker, which, in turn, prevented the manufacture of cloth with defects. At a Toyota plant, *jidoka* may refer to a sensor that stops the line and brings attention to a defect or process abnormality that is then immediately rectified so that the defect or abnormality is not passed on further, leading to a larger problem. Any of the Toyota visual defect detection systems

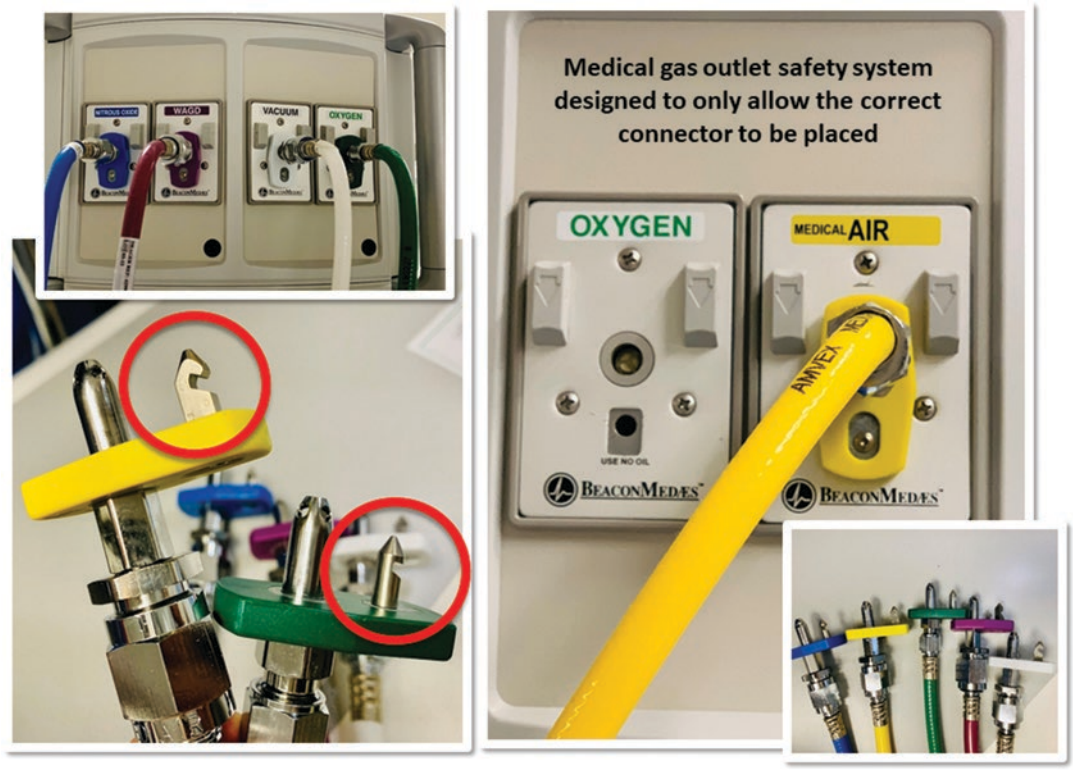


Fig. 5.4 Use of *poka-yoke* to prevent the accidental mixing of anesthesia gases. Note each gas hosing and connector is different to prevent incorrect connections, which, in turn, can lead to an error and potential patient harm

(andons), which can stop an assembly line at their plants, can facilitate the problem-solving process, since problems are immediately pinpointed to their respective microsystem. These can also be manually pulled by a team member. The only reason to stop the line is to ensure that it will never have to be stopped again for the same circumstances. Quick fixes or stopgaps are never a solution. However, they may be temporarily utilized when recurrence prevention takes time to complete.

Andons and *poka-yoke* are important parts of *jidoka*. As mentioned in the introductory vignette, andons are tools for visual control. *Poka-yoke* refers to a built-in quality that prevents defects from occurring. In car manufacturing, parts may be created that only fit one way to prevent incorrect assembly. At home, our riding lawn mowers automatically turn off if the rider gets off the seat while the mower is still running. Similarly in healthcare, the various anesthesia gas connectors only fit specific gas lines, thus preventing the accidental mixing of medical gases (Fig. 5.4). This type of human factors integration has eliminated the accidental fatal administration of gases other than oxygen during operative cases.

In short, *jidoka* prevents the continued propagation of defects and reduces the chance that they will reach the customer, as well as signals problems so that people can immediately investigate their causes to then devise improvements to prevent recurrence. For *jidoka* to succeed, much effort must be placed on work standards, as only once "normal" is defined and made visual can "abnormal" exist. This high level of standardized work has proven to be a challenge for many healthcare organizations. Additionally, the structure of an organization must include people who respond quickly to an andon and have the time and mindset to solve problems, so they never recur. Without such a structure, andons will not be effective.

Looking back at the TPS House (Fig. 5.3), when both the JIT and *jidoka* pillars are balanced above the two lower levels of the TPS House, the roof of the house is level so that the House's goal of producing high-quality and low-cost products with a short lead time can be met. JIT and *jidoka* both deliberately signal and highlight problems during operations. As these problems are solved to prevent recurrence, performance for safety, quality, cost, and lead time improves.

Problem-Solving

As previously mentioned, problem-solving through the use of the scientific method as part of *kaizen* is the essence of TPS. Clarifying and narrowing a problem is crucial, as represented by the funnel (Fig. 5.5). Problems are barriers to progress for an organization but need to be anticipated. There are some problems that require a deeper and more focused approach, such as the eight steps of problem-solving (Fig. 5.5) as described in *Lean Hospitals: Improving Quality, Patient Safety, and Employee Engagement* [17]. Yet others can be quickly resolved using a "just do it" approach.

Generally speaking, the determination of what is a problem requires the definition of a standard of practice or care. Often when problems are uncovered, they are due to the following issues: there is no standard; the standard is not known; the standard is ignored; or normalized deviance results from standards not being completely followed. By creating standards and tracking the variations from the standard, the deviations are readily visible and can be targeted by Toyota's "disciplined, yet flexible and creative community of scientists" [18] who help Toyota move toward a zero defect rate, similar to a health system's analogous journey to zero harm. By having standards in place, experiments, or rapid cycle tests of change, can occur to see if the standard can be improved further. However, without standardization, experimentation cannot occur in a way where its effects can be measured or appreciated.

The eight-step problem-solving method (Fig. 5.5) breaks down problems through the use of a didactic approach in a manner analogous to the scientific method, which is only mastered through practice [17]. The eight steps are often captured on A3-sized (11-inch × 17-inch) paper, which forces teams to stay focused, concise, and

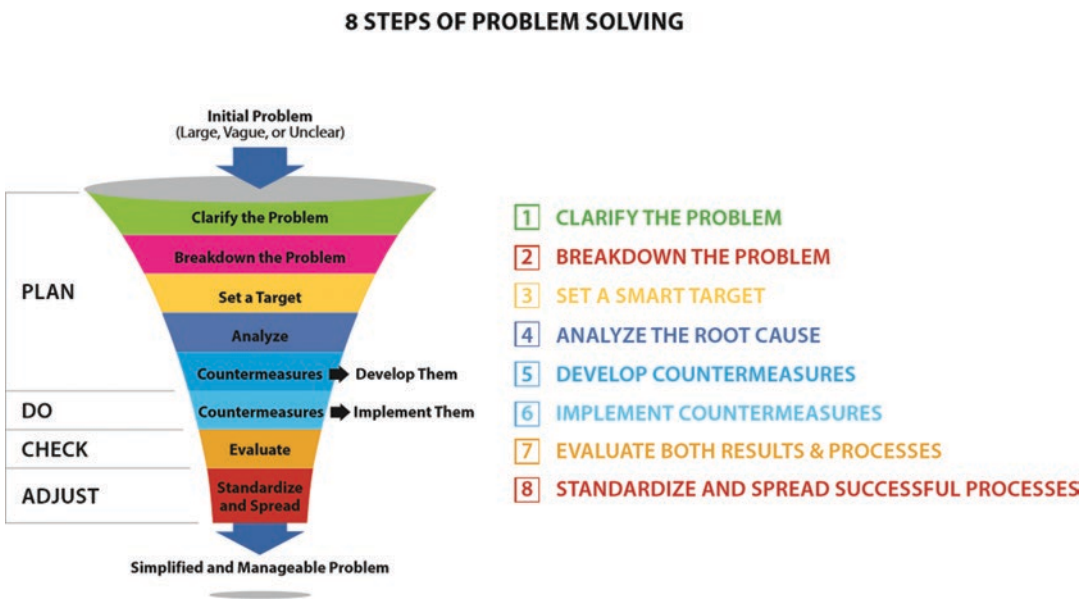


Fig. 5.5 Eight steps of problem-solving. (Figure Courtesy of Eric Cardenas and adapted from Graban [17])

simplify the problem. This A3 problem-solving document is portable, can be used to articulate the goals of the project and how they were developed, and can become the expectation for all improvement projects. The most important part of the A3 is the problem-solving and continuous improvement thinking behind the template. While the A3 is a useful summary document, using the template enables and supports teams' thought processes as they work through a systematic approach to problem-solving rather than simply filling in the boxes on a form.

In his 2011 book, *Thinking, Fast and Slow*, Daniel Kahneman [21] describes how we as humans are wired for automatic, rapid interpretation of input with little or no effort or voluntary control. Dr. Kahneman refers to this as System 1 thinking. In other words, we are quickly able to move from a problem to a solution. In healthcare, this thinking serves us particularly well in life-saving situations. However, not every problem we face in healthcare is a dire emergency. Many of the long-standing problems that we have been unable to solve in healthcare today require us to deliberately seek objective alternative interpretations of data/events or what Dr. Kahneman refers to as System 2 thinking. Anyone who has been on the sharp end of "standard" solutions based on assumptions to problems (including endless e-mail reminders to "just be more careful," countless "read and sign" policy attestations, and redundant in-service education), as a means to "solve" the same issues over and over, can attest that there must be a better way. The eight-step problem-solving provides a structure supporting the System 2 thinking necessary to make sustainable improvements that can transform healthcare. The eight steps using Plan-Do-Check-Adjust as a familiar framework are reviewed in Fig. 5.5; of note, Plan is inclusive of the first five steps of the eight steps.

In step 1, the problem is clarified through fact-based quantifiable data. The current situation is compared to the ideal situation, and the gap is identified. In step 2, the problem is broken down into smaller concrete problems by asking the following questions of the data: what, where, when, and who? When breaking down a problem, it is important to avoid "why" questions that prematurely lead to root causes, as this can misleadingly stop the strategic breakdown of data. Usually, based on the frequency or relevancy of an occurrence, the prioritized problem is chosen. This point of occurrence is identified on the process map. This is confirmed by walking, or observing, the shop floor (also called *gemba* or *genba*) in a process called *genchi genbutsu* (to go look, to see, to understand, to take action). In step 3, we set a target for the prioritized problem which is measurable and concrete, yet challenging. The SMART acronym is often used to lead teams through target setting. SMART stands for *S*pecific, *M*easurable, *A*ggressive yet Attainable, *R*elevant (to the problem), and *T*ime-sensitive. In step 4, the root cause is sought after by looking at all of the possible causes. Facts are gathered through *genchi genbutsu* and the "5-Why" approach is used to uncover the root cause. The 4Ms (Manpower, Machine, Material, and Method) can provide a structure when seeking root causes, and it can also ensure that the problem is looked at systematically without prejudice. By purposefully asking "why" several times, and validating information through *genchi genbutsu*, facts are separated from opinions and assumptions, thus resulting in true root cause(s). Most experts consider step 2 (breaking down the problem) and step 4 (analyzing the root cause) crucial for problem-solving to occur.

In step 5, many potential countermeasures need to be considered. A countermeasure is a set of actions that seeks to prevent the problem from arising again. Countermeasures are different from "solutions" that may just seek to deal with the symptom of the problem vs. the root cause(s). For every root cause, at least one countermeasure should be identified, understanding that one countermeasure may address more than one root cause.

Countermeasures will need to be prioritized based upon costs, ease, feasibility, and other factors. Countermeasures need to be in line with the ultimate goal and organizational priorities. These, in turn, are used to create a clear and concrete plan of action. Consensus needs to be reached around these countermeasures through discussions among

stakeholders, especially those with upstream and downstream process owners, to ensure the implementation of selected countermeasures will not negatively impact other processes.

In step 6, efforts are aligned to implement countermeasures with speed and persistence. When creating the action plan, consider the following:

- Who will be involved and affected (e.g., stakeholders)?
- What is to be achieved and how will it be achieved?
- When are potential completion times?
- Where will the work occur?
- Why is it important work?
- How is it going to be messaged throughout the organization?

Also consider all costs involved (e.g., potential downtime, manpower hours). The improvement team's efforts are messaged to the entire organization to inform and garner support. Monitor progress through the tracking of predetermined metrics. Be persistent and in line with the aforementioned HRO principles. Multiple tests of change may need to occur before success is achieved. The value of the Plan-Do-Study-Act (PDSA), also known as Plan-Do-Check-Act (PDCA), cycle, which has been extensively discussed in other chapters, cannot be understated to test countermeasures. Through the data-driven eight-step process, proper predictions for ideal solutions or countermeasures to problems are made, which consequently increases the likelihood that the ensuing planned tests of change (PDSA/PDCA cycles) will be successful.

Step 7 emphasizes the importance of evaluating results based on the SMART target set in step 3. Evaluate all results from the perspective of the customer, the team members, the organization, and society, seeking to understand the reasons behind the successes and failures. In addition, identify and celebrate potential return of investment(s), or ROIs. This can include cost savings and immeasurable benefits such as people development, team engagement, and a renewed commitment to *kaizen*.

Step 8 stresses the importance of standardizing successful interventions and creating new standards. Share and spread the improved standards with other parts of the organization or other organizations. Plan the next round of continuous improvement.

By developing a standard method for problem-solving, through the eight-step process and A3 document, Toyota has created a procedure for communicating within a team and across its organization. This method allows innovative solutions to spread across teams in a more understandable way. It incorporates PDCA/PDSA cycles for running small tests of change. This data-driven approach requires discipline and fact-based root cause analyses. The direction of an organization is not left to conjecture or the whims of a few strong personalities. In short, at its core, the Toyota Production System is:

- An integrated approach to problem-solving that creates an organizational culture of highly engaged people, solving problems to drive performance. High levels of JIT and *jidoka* expose and signal problems to solve.
- A way to achieve sustainable improvements that help foster a culture of continuous improvement and support the transformative change needed in healthcare.
- An organizational culture created and sustained by a three-part system, as described in the TPS Triangle of (1) philosophy, (2) technical tools, and (3) managerial roles.

Key Learning Points

1. The implementation of TPS requires the creation of a stable foundation which incorporates the four (or five) Ms – Manpower (People), Machine, Material, Method (and Mother Nature).
2. The two pillars (just-in-time and *jidoka*) and all of the foundation levels of the TPS House need to be equal so that its roof can remain level and deliver high-quality goods at a low cost with short lead time. This emphasizes the impor-

tance of all the components of the TPS House to achieve sustainable improvement.
3. The creation of standardized work is an important basis for measuring and driving improvement.
4. Just-in-time (JIT) focuses on customer demand and refers to the production and conveyance/transportation of only what is needed, when needed, and in the quantity needed. It meets the exact demand of the customer in terms of product, timing, and volume.
5. Building quality into a process (*jidoka*), so that defects become readily visible, is crucial to uncovering defects (andon). This has proven to be difficult for healthcare delivery systems to install for a multitude of reasons. Facilitating problem detection is the best way to ensure its rapid resolution.
6. The most important part of the eight-step process is the problem-solving and continuous improvement thinking behind the template. While the A3 is a useful summary document, using the template enables and supports teams' thought processes as they work through a systematic approach to problem-solving rather than simply filling in the boxes on a form.
7. Team member problem-solving skill development is critical and should be facilitated by all leaders and managers. These same leaders and managers need to be problem-solving experts themselves.
8. The shop floor (*gemba* or *genba*) is where all improvement occurs and, for this reason, local team members need to be incorporated into, and at times lead, improvement teams. Leaders need to visit the shop floor often to be visible to team members and better understand any problems they may face (*genchi genbutsu*).
9. The aforementioned summary points complement the definition of TPS. As a reminder, the Toyota Production System is an organizational culture of highly engaged people solving problems or innovating to drive performance. This culture is sustained by a three-part system, as described in the TPS Triangle, of (1) philosophy, (2) technical tools, and (3) managerial roles.

Vignettes with Relevant Discussion

The next sections describe vignettes from actual TPS-driven improvement projects from several health systems, followed by a discussion of the TPS concepts relevant to each vignette. The fictional patient cases are based on actual cases that have occurred at many hospitals but have been modified to protect the anonymity of each case.

Vignette 5.1 Improving the Delivery of Critical Nutrition to Our Most Vulnerable Patients

A 500-gram baby boy is born prematurely at 25 weeks and is cared for by the neonatal intensive care unit (NICU) team. He cannot breathe on his own since his lungs are not fully developed, so he is intubated and placed on a ventilator. At this point, his odds for survival may not be good as a majority of his organ systems are not mature, especially his respiratory, immune, renal, and neurologic systems. His caloric expenditures are high and they will need to be continually replenished, as his energy reserves have not been built up. The baby is immediately started on intravenous fluids, and the decision is made to start him on total parenteral nutrition (TPN). The TPN is ordered at 11 AM and will be delivered in the evening. It will likely be hung at the patient's bedside and the infusion started

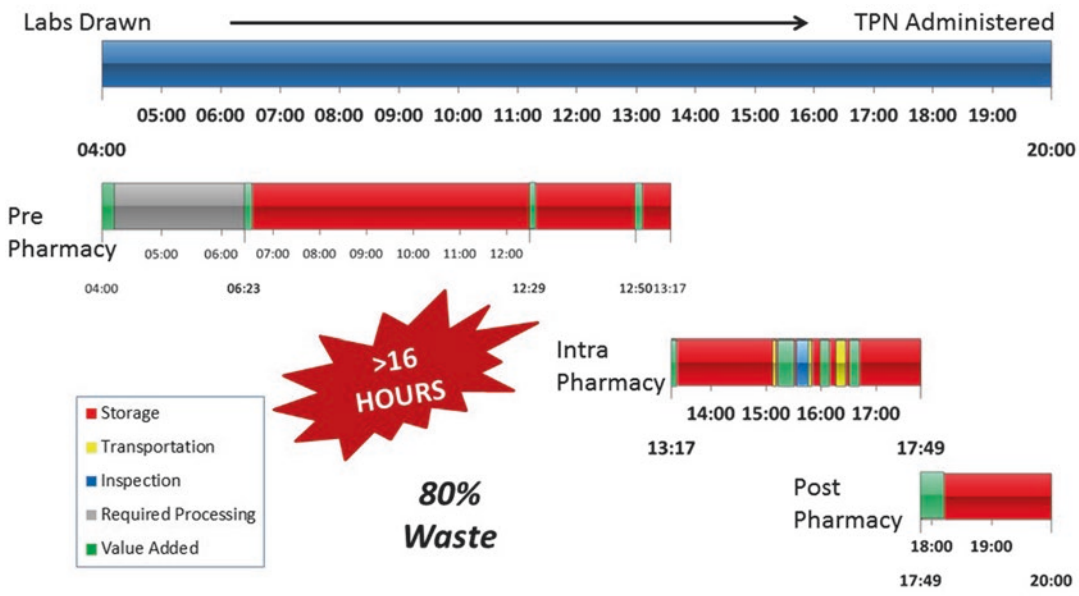


Fig. 5.6 Process map for TPN flow – initial state for a single patient

by 9 PM, 10 hours after the order was placed and 17 hours after his blood was first drawn to assess the various serum electrolyte levels. The parents inquire whether this TPN delivery time is the norm, and they are told that this is, in fact, the case at most organizations.

A process that has taken hours, rather than minutes, can hinder a clinical team's ability to render excellent care and meet the changing needs of a critically ill premature infant. TPN is produced with the hopes of mimicking the nutritional supplementation pathway available in utero from an infant's mother. The members of the TPN process improvement team sought to improve the TPN ordering, production, and delivery processes and reduce the time from TPN order to TPN infusion for an infant [22]. Figure 5.6 shows the process map from the ordering to delivery of TPN for a single patient on a single day.

There was considerable non-value-added time (or 80% waste) built into the original process, as shown by the areas in blue, red, and yellow. Figure 5.7 illustrates the different types of waste (*muda*). Figure 5.8 shows the same process after the various changes were implemented.

Multiple changes were implemented. The TPN production areas were reorganized to maximize efficiency using 5-S concepts (5-S = *S*ort, *S*et in order, *S*hine, *S*tandardize, and *S*ustain; Fig. 5.9). Within the pharmacy, the technicians' workflows were streamlined by placing supplies at the point of use, decreasing par levels (and therefore, on-hand inventory), and decreasing the automated TPN compounder's changeover time by standardizing its setup and breakdown (Figs. 5.9 and 5.10). The latter was created by using a video to demonstrate the standard setup and breakdown procedures, and technicians were then trained to this standard. This training was routinely repeated to ensure that there was no normalized deviation from this standard.

Within the NICU, medical team rounding, which involved the physicians, nurses, and phar-

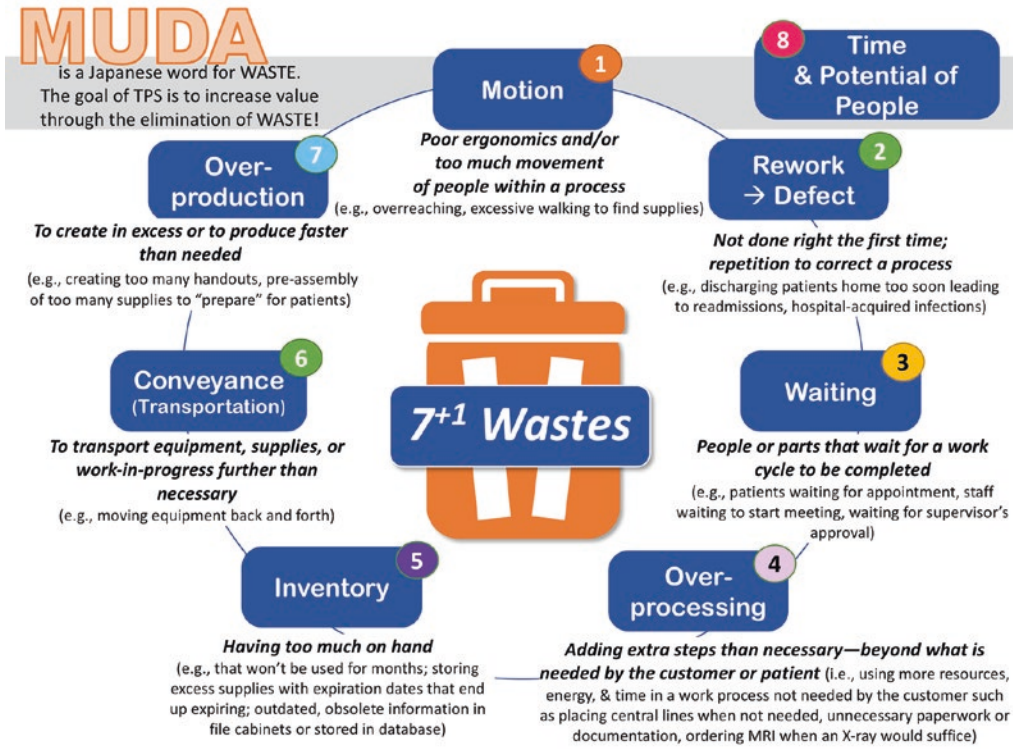


Fig. 5.7 The 7 + 1 types of waste. The seven (7) types of muda (waste) are motion, rework (that lead to defect), waiting, overprocessing, inventory, conveyance (transportation), and overproduction. In healthcare, wasted time and potential of people is commonly referred to as the eighth waste, which includes the inability to support people to function to the highest of their licensure

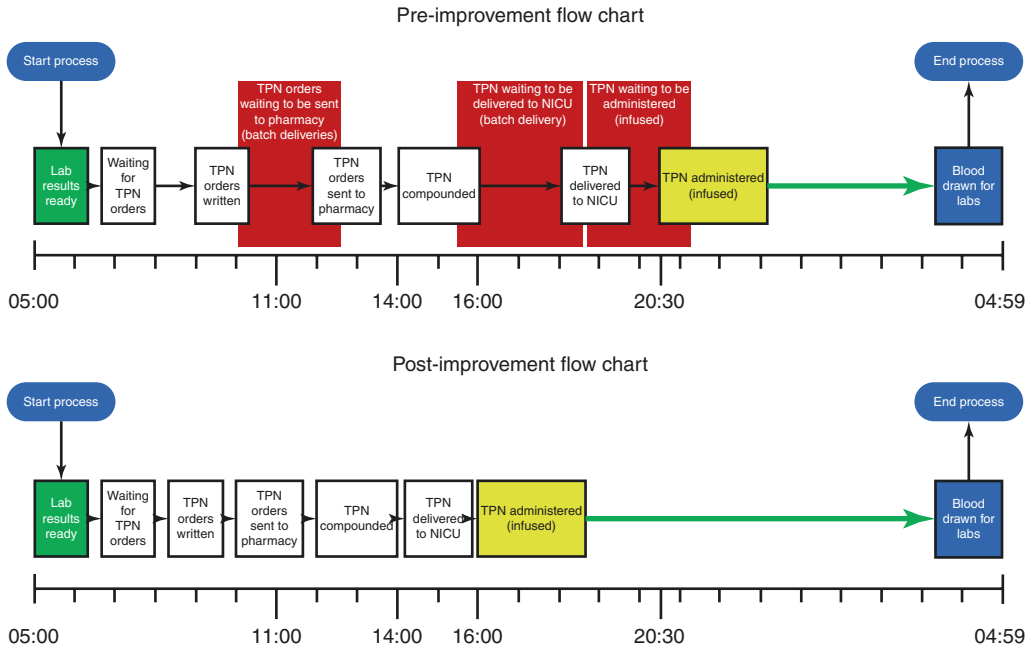


Fig. 5.8 Process map for TPN flow – pre-improvement (top) vs. post-improvement (bottom). The top figure shows the waste in the system pre-improvement. The red boxes in the first map indicate waiting time (representing waste or muda). The bottom figure represents TPN flow post-improvement

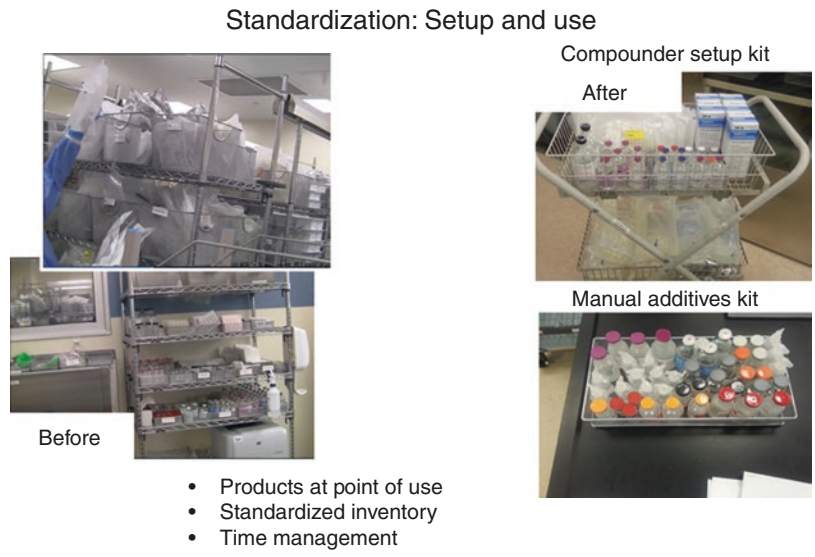


Fig. 5.9 Standardization of the TPN materials and additives

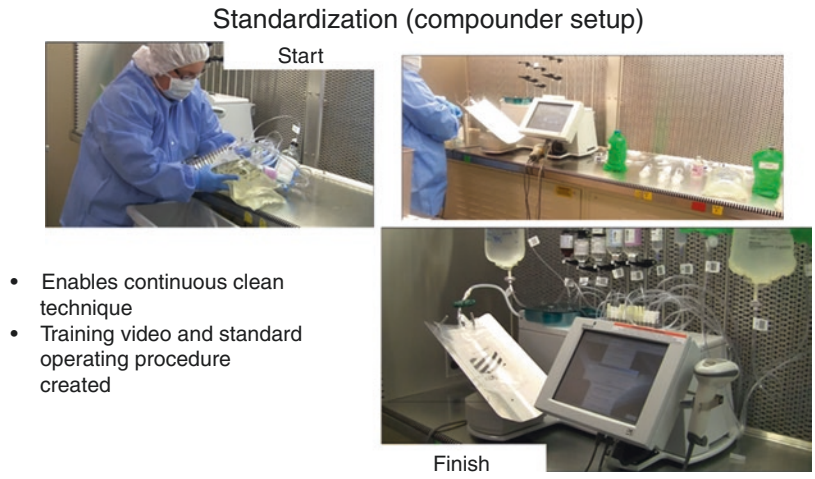
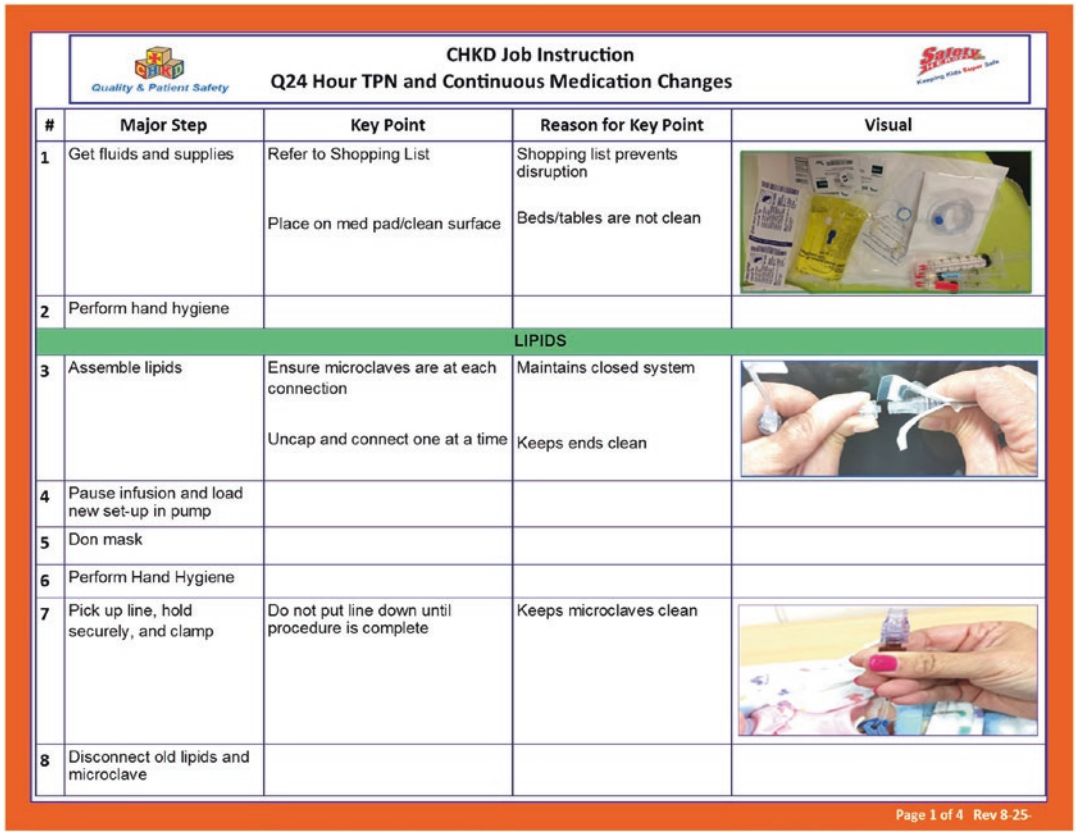


Fig. 5.10 Standardization of the TPN compounder setup

macists, was standardized over all 7 days of the week. The goal was to have most TPN orders sent to the pharmacy for compounding before the end of the morning.

Additionally, the daily TPN initiation times were changed, so this task fell to the day shift (7 AM–7 PM) team which, in turn, releveled the work (*heijunka*), since many more tasks traditionally fell onto the evening shift (7 PM–7 AM) team. Job instruction sheets (JIS) were created to teach the day shift nursing team how to start the TPN infusion and related standardized work. Since all patients who were receiving TPN also had central venous catheters, the efforts to standardize TPN delivery also required the creation of standards as to how TPN was infused using these central lines (Fig. 5.8). The JIS showed the "what" of each step in the "Key Point" column and the "why" behind each step in the "Reason for Key Point" column (Fig. 5.11). Additionally, to improve TPN delivery times, a TPN ordering software program was created within the electronic health record (EHR) with built-in algorithms that prevented ordering errors. Since this program communicated directly with the TPN compounder, errors from the re-transcription of



CHKD Job Instruction
Q24 Hour TPN and Continuous Medication Changes

Quality & Patient Safety

#	Major Step	Key Point	Reason for Key Point	Visual
1	Get fluids and supplies	Refer to Shopping List Place on med pad/clean surface	Shopping list prevents disruption Beds/tables are not clean	
2	Perform hand hygiene			
		LIPIDS		
3	Assemble lipids	Ensure microclaves are at each connection Uncap and connect one at a time	Maintains closed system Keeps ends clean	
4	Pause infusion and load new set-up in pump			
5	Don mask			
6	Perform Hand Hygiene			
7	Pick up line, hold securely, and clamp	Do not put line down until procedure is complete	Keeps microclaves clean	
8	Disconnect old lipids and microclave			

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Fig. 5.11 Job instruction sheet (page 1 of 4) for TPN administration

paper orders into electronic orders were eliminated. This is a great example of *jidoka*!

The TPN delivery improvement project resulted in a 45% reduction in the average time of TPN delivery to the patient after the initial order. All previous transcription errors which resulted from the rework that had been part of the initial process were eliminated as well. By addressing the TPS House's roof, its JIT (especially with the creation of a pull system) and *jidoka* pillars, lead time reduction and the maintenance of high quality were achieved (Fig. 5.12).

Key Learning Points

1. Understand the current state of a process before implementing change, identifying value-added and non-value-added times. Value-added time refers to time that improves a process and is important to your customers (patients, in this situation).
2. Organize the work areas to maximize efficiency while minimizing inventory. These concepts of organization are referred to as the five *S*s – *S*ort, *S*et in order, *S*hine, *S*tandardize, and *S*ustain.
3. Processes need to be designed to focus on the customer first, not what is easiest based on layout, machines, or old habits.
4. Standardization is a critical first step for quality improvement. Without a standard, *kaizen* cannot take place.
5. *Heijunka*, or leveling of work, is critical to prevent team member burnout, improve patient safety, and improve efficiency.
6. Building in quality, or *jidoka*, as with the TPN compounding software pro-

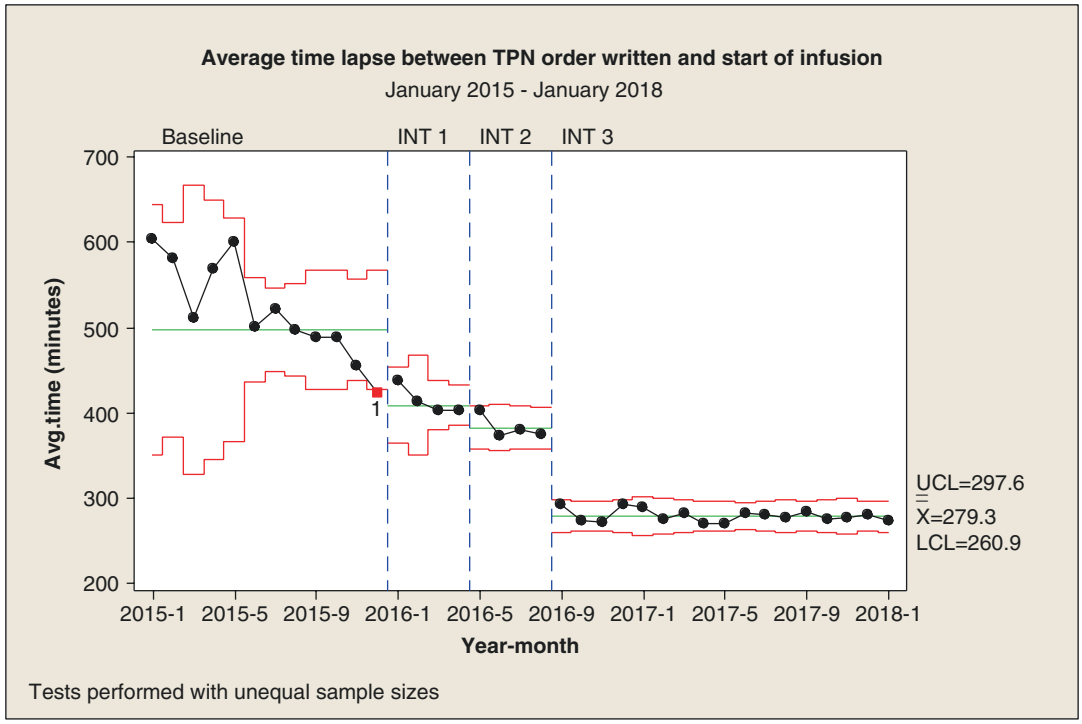


Fig. 5.12 Average time between the TPN order written and start of the TPN infusion. The X-bar chart shown below displays the reduction in average TPN delivery times from approximately 500 to 280 minutes through the changes described in this vignette. Mean values for each phase are denoted by the green lines

gram, can improve the ability to detect defects.

7. Use job instruction sheets (JIS) to share and teach standard work to frontline team members. The JIS show the "what" of each step in the "Key Point" column and the "why" behind each step in the "Reason for Key Point" column. The pictures provided in the "visual" column provide further clarification and guidance for each major step.

Vignette 5.2 Improving the Pain Medication Reassessment Process in the Emergency Department

It is the first Wednesday of the month, and Margo, the nurse manager for the emergency department (ED), is in her office preparing to meet with her supervisors. As she looks over the ED Quality Data Metric Report she just received, she shakes her head in disbelief. Once again, the ED is below the target for pain reassessment – a key measure of pain management for her department. Not just a little under the target, data showed that only 55% of ED patients were being reassessed by their nurse timely (per hospital and regulatory requirements) after receiving pain medications. "Barely half!" she exclaimed to herself as she glanced back at the file cabinet that held all the pain management in-service education provided to each shift for the past six (6) months. She remembered that she even had kept a copy of the colorful poster created by the unit secretary to remind staff of the importance of reassessing patients for pain – a staff member's

idea to help improve their compliance. "After everything we have done, how can our compliance be so low?" she thought to herself as her management team begins to fill the room for their weekly meeting.

Per usual, each supervisor provided a brief update on their areas of responsibility. Walter, Margo's newest supervisor, was just finishing his update when he shared a flyer from the Lean Department offering an A3 class. "I really am interested in taking this class. I just have to get your approval and bring a real problem for which we have data. I will need your help to identify a small team, including line staff that we can pull offline for 1 hour a week, dedicated to solving the selected problem for the next few months. What do you think?" Margo sighed, "Here's the most recent pain reassessment compliance data. Let's do this – I'm all in!"

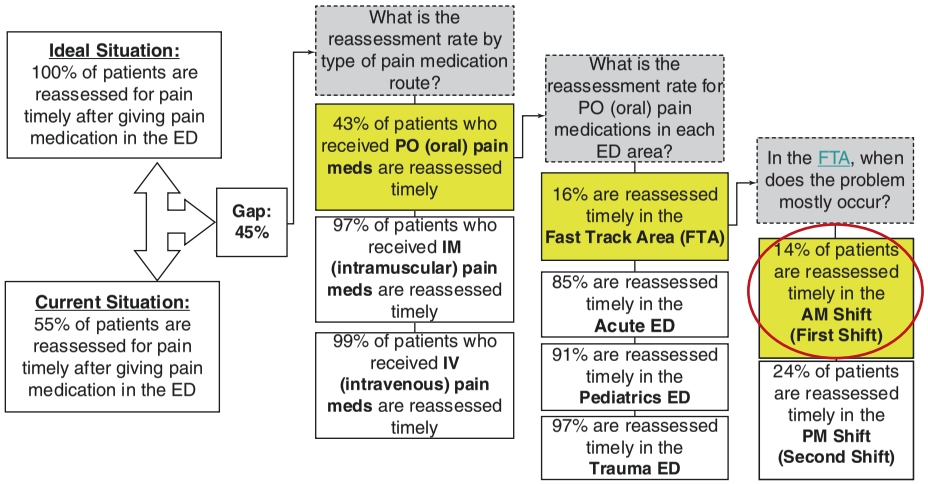
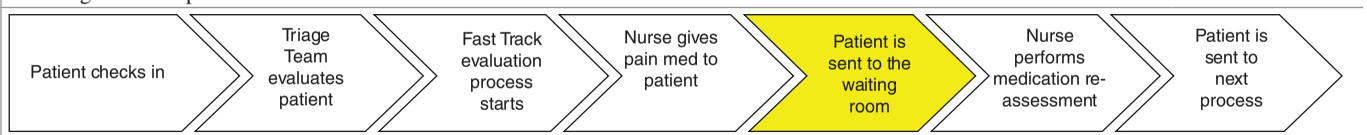
A pain reassessment team was formed and included Margo, the nurse manager; Dr. Beverly Chase, an emergency medicine physician; Randy, an RN (registered nurse); Lisa, an LVN (licensed vocational nurse); and Walter, the newly appointed team leader for this initiative. They called themselves, "The A-Team" and agreed to meet every Wednesday for 1 hour just before the weekly staff meeting. The following is a summary of the team's improvement efforts (Table 5.1) which walks through the eight steps of problem-solving (Fig. 5.5).

This vignette illustrates the robust methodology outlined in the eight steps of problem-solving. Normally all eight steps are captured on a single A3-sized document, but were formatted here to meet the publication needs of this textbook. As mentioned earlier, the use of the A3 document as a standard permits easier communication, idea sharing, and standardization and spread of successful change ideas across an organization.

Key Learning Points

1. The eight-step (A3) problem-solving process can be successfully applied to solve long-standing problems in healthcare.
2. Breaking down the problem using data (step 2) is key to helping the team prioritize and focus their improvement efforts on the most problematic area first.
3. In step 4, the 5-Whys analysis is used to arrive at the root cause. For instance, a team member asks "why" moving down the causal analysis tree to arrive at the root cause. To double-check the rationale, one can state "therefore" to move upwards from the root cause.
4. Generally in step 4, we look for one root cause to a problem. In some cases, there will be a root cause with additional contributing causes. In these vignettes, the main and contributing causes are being classified as root causes for the sake of simplicity.
5. Developing standardized work is a critical first step for quality improvement. Without a standard, kaizen (continuous improvement) cannot take place.
6. Building in one-piece flow into the process where patients are brought back into the FTA, stay until pain is reassessed, and re-medicated for pain if indicated, decreases the waste of motion and waiting for the patient and improves care and experience.
7. Commitment, support, and humility are modeled by the nurse manager as she encouraged the new supervisor to lead the improvement team, allocated dedicated time for team members to do improvement work, and supported the team by joining as a member and not the

Table 5.1 Eight steps of problem-solving for Vignette 5.2

Step 1: Clarify the problem – background data/ information	Pain is the most common reason patients come to the emergency department [23, 24]. Inadequate and untimely pain management in the ED is a global problem – despite the availability of resources, protocols, and effective interventions [25] Internal audits revealed that only 55% of ED patients were being reassessed within the appropriate timeframe (per hospital and regulatory requirements) after pain medication was administered *Ideal situation*: 100% of patients who receive pain medications (meds) are reassessed for pain timely in the ED *Current situation*: Only 55% of patients who receive pain medications (meds) are timely reassessed for pain in the ED There is a need to improve pain reassessment in the ED which is a high patient volume unit with considerable acuity and, as a result, prone to problems
Step 2: Breaking down the problem	 Breaking down the problem:
Identify the point of occurrence	
Prioritized problem	Only 14% of patients who received PO (oral) pain medication in fast-track area (FTA) and who are sent back to the waiting room during the first shift are reassessed for pain timely (the ED staffing is traditionally based on two 12-hour shifts. The first shift refers to the 7 AM to 7 PM shift. The second shift refers to the 7 PM to 7 AM shift)

(continued)

Table 5.1 (continued)

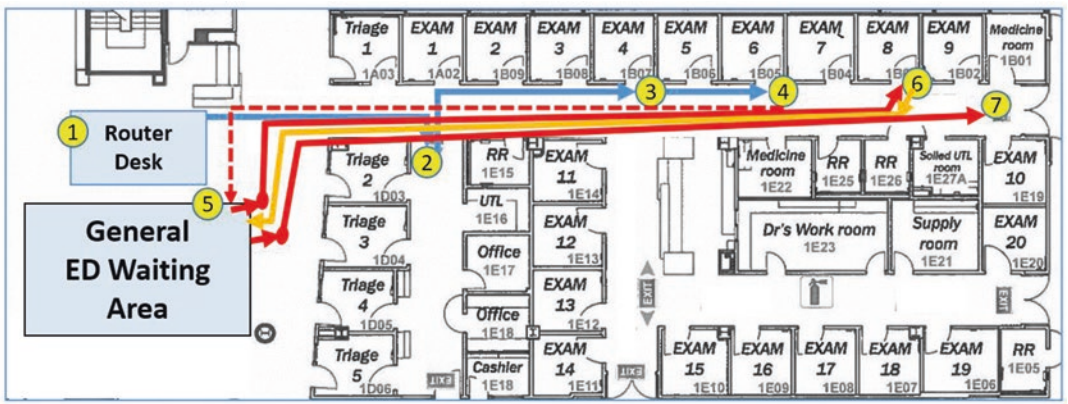
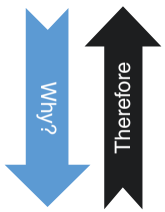
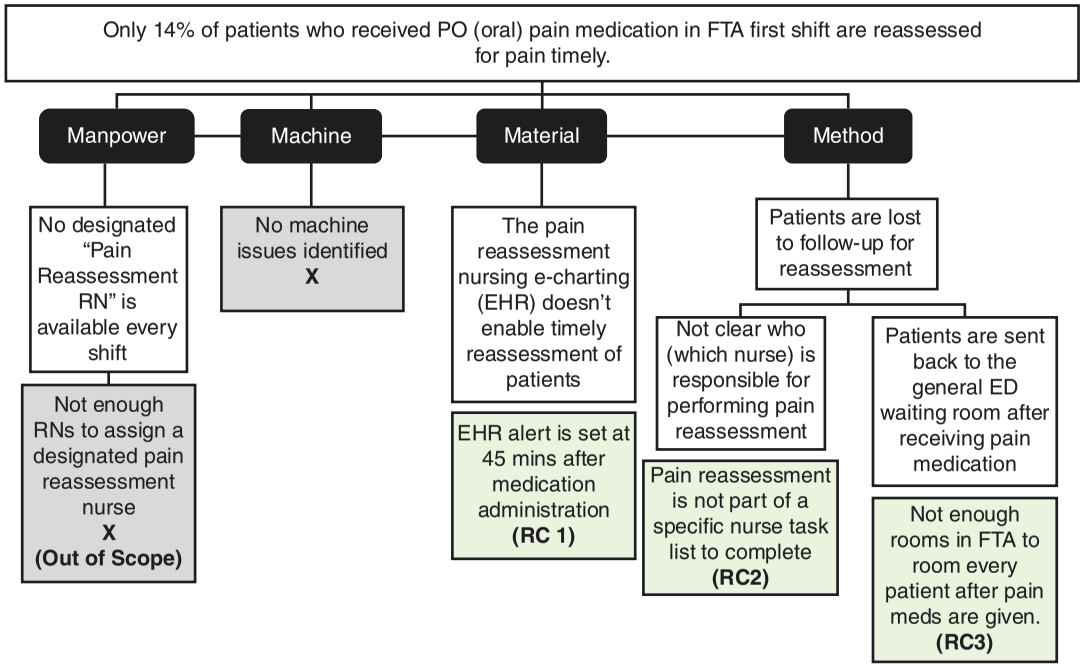
Current conditions/*genba* observations	To validate the internal audit, the team conducted *genchi genbutsu* and observed FTA first shift's processes The FTA team observed: *Manpower*: Nursing staffing – i.e., registered nurses (RNs) and licensed vocational nurses (LVNs) – is frequently at a bare minimum *Machine*: No issues identified *Material*: The EHR alert for pain reassessment is set at 45 minutes, leaving the nurses only 15 minutes to complete the task *Method*: There is a misunderstanding on who should reassess a patient's pain level. When RNs were asked, most responded that it is the responsibility of the nurse (RN or LVN) who gave the medications to reassess the patient, while most LVNs stated that it is the responsibility of RNs to reassess a patient's pain level after pain medications are given Workflow – Below is the current process and diagram of the flow of the patient visiting FTA needing pain management: Task 1: Patient checks in at the router desk Task 2: Patient is called into FTA to be evaluated by the triage team Task 3: Patients are sent to either room 4 or room 5 to have their medical evaluation process initiated Task 4: During the evaluation of the patient, if pain medications are needed, they are sent to room 6 or room 7 to receive pain medications Task 5: After a patient receives pain medications, they are sent to the waiting room Task 6: If applicable, a patient is called from the waiting and directed to room 8 for further workup Task 7: Patients are called back to room 7 to obtain discharge information Diagram of workflow: 
Step 3: Target setting	Improve timely reassessments of patients who receive oral medications in the FTA during the first shift from 14% to 100% by December (3 months)

Table 5.1 (continued)

Step 4: Analyze the root or main cause(s)/ identify root or main causes (RC)





The team identified three root causes (green boxes below, RC 1–3) by asking "why" the prioritized problem happens, followed by checking the logic of the root causes by stating "therefore" for each root cause up to the prioritized problem (Generally in step 4, we look for one root cause to a problem. In some cases, there will be root cause with additional contributing causes. In these vignettes, the mean and contributing causes are being classified as root causes for the sakes of simplicity)

For this step, ask "why" as you move down the casual analysis tree and arrive at the root cause. One can double-check the reasoning by moving up, or backwards, on the tree and state "therefore".

(continued)

Table 5.1 (continued)

Step 5: Develop countermeasures

For each root cause, the team develops at least one countermeasure, understanding that one countermeasure may address more than one root cause

Root Causes (RC)	Countermeasures (CM)
RC 1: EHR alert is set at 45 mins after medication administration	Change electronic health record to support reassessment policy requirements (CM1)
RC 2: Pain reassessment is not part of a specific nurse task list to complete	Modify FTA reassessment workflow by developing standardized work (CM2)
RC 3: Not enough rooms in FTA to room every patient	Reconfigure ED set up to allow patients to remain in the FTA after pain medication administration (CM3)

Step 6: See countermeasures through

The team needs to develop a plan for how the countermeasures will be implemented. The plan includes who will be accountable and when actions are to be completed:

Countermeasures (CM)	Plan	Who?	When?
Change EHR to support reassessment policy requirements (CM1)	1. Change the EHR alert from 45 minutes to 30 minutes to allow more time for the nurse to complete pain reassessment. 2. Meet with the EHR workgroup to gain consensus 3. Implement changes to EHR 4. Train staff and establish go-live date	WW WW WW MK/WW	10/1 10/15 10/25 10/30
Modify FTA reassessment workflow by developing standardized work (CM2) and reconfigure ED set up to allow patients to remain in the FTA after pain medication administration (CM3)	1. Dedicate a room for patients to remain in FTA post pain med administration for reassessment 2. Validate process, update standardized work. 3. Obtain equipment (e.g., 6 chairs) 4. Infrom team–in all shifts–of new process 5. Update standardized work and audit standardized work; provide updates at weekly visual management board meeting	BC BC/WW DR MK/WW WW	10/15 10/20 10/30 10/25–10/30 10/15

Table 5.1 (continued)

Step 7: Evaluate both results and processes	Compliance to pain reassessment during the FTA first shift improved from 14% to 94%, and overall ED compliance improved from 55% to 90%. While significant improvement was achieved, the 100% target was not met. Barriers: Despite the new processes in place, dedicated time for improvement work (e.g., auditing of standardized work) became limited due to high staff turnover and slowed progress for a period of time. Some of the additional benefits and return on investment (ROI) ignited enthusiasm for a team-based approach to develop standardized work for other processes in the ED. The team was propelled to create workflows for other areas within the ED, including the transition of care to the urgent care center. Improved psychological safety (achieved 100% positive response in a staff engagement survey) and human development (staff acknowledging how their work, ideas, and involvement support the organizational goals) created a structure platform for weekly multidisciplinary problem-solving discussion	Date:12/15
Step 8: Standardize and spread successful processes	Pain reassessment data for FTA is displayed on a visual management board – now monitored and analyzed weekly for all shifts to ensure improvement is sustained and ideas to further improve are captured. Part of the huddle in front of the visual management board is the discussion of the instituted continuous observations of standardized work and how the process can be further improved. The new electronic health record alert change (from 45 to 30 minutes) was adopted throughout the healthcare network. Further, causal analysis is now performed on individual cases not in compliance, and results are communicated back to individuals and the team for further ideas to improve and for immediate recurrence prevention discussion. Improvements are shared within the ED and across the organization. Reflections: While the target of 94% timely pain reassessment was not achieved, the team became empowered and encouraged to exceed this target in the coming months – not only on the first shift but also on the second shift. Having current data displayed and readily available to all has ignited shared accountability and healthy competition to improve care and meet compliance across the unit.	Date: Ongoing

leader (HRO principle of deference to expertise).
8. The 4Ms provide an excellent framework for systematic root cause analysis.
9. Visual management boards help to provide a forum for communication of key performance metrics, building staff engagement and knowledge of departmental goals, and their individual role in helping to meet them.
10. The implementation, standardization, and resulting spread of the new electronic health record alert for pain reassessment were successful since it had first been tested on a small scale.

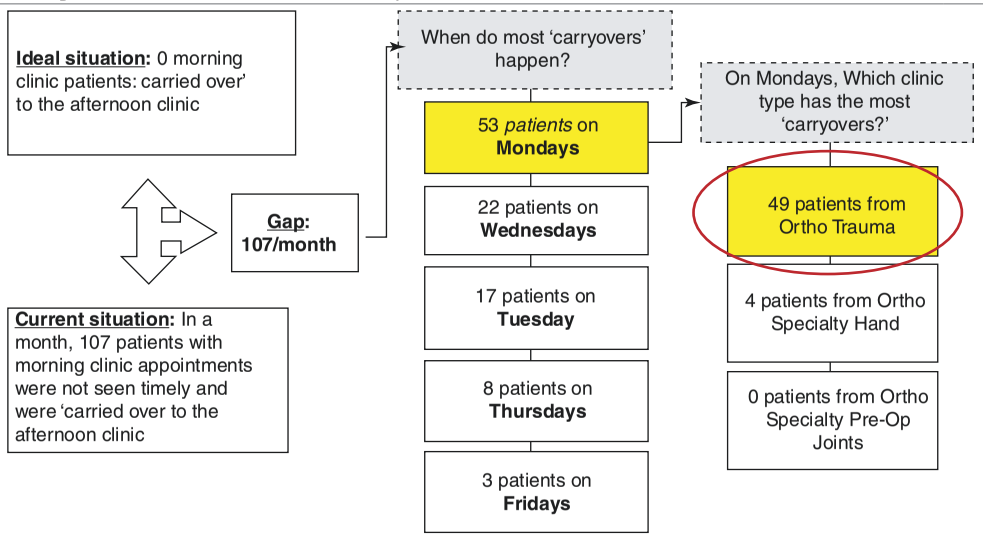
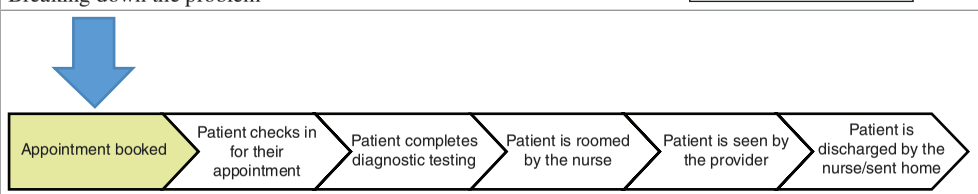
Vignette 5.3 Improving the Clinic Cycle Time for Orthopedic Patients

A 38-year-old male motorcyclist (Mr. M) was brought to the ED after he was accidentally hit by a car. His chief complaint was that his right wrist was painful. The patient stated that, when he fell off his bike, he landed on his right wrist. Diagnostic tests were performed, and the orthopedics trauma team (abbreviated ortho trauma) was consulted. Based on the X-ray, the patient was diagnosed with a new acute distal radial bone (wrist) fracture. Ortho trauma stabilized, reduced, and splinted the injured wrist. The patient was sent home and was instructed to go to the ortho trauma clinic the next day (Monday) when it opened at 7:30 AM to be seen by a hand specialist.

Scrambling for transportation, Mr. M had to take two separate buses to make it to the clinic by 7:30 AM. On the way, Mr. M called his boss to let him know what happened to him and that he would be into work immediately after his appointment was finished. The clinic was packed with patients – all with some sort of cast or bandage on one limb or the other. At 7:45 AM, Mr. M was relieved when his name was called, and he was escorted back into an exam room by a nurse. After asking him a few questions, and performing a brief assessment, the nurse informed Mr. M that the hand specialist team would soon be reviewing his case and would be in as soon as possible. After about 30 minutes of waiting, Mr. M fell asleep in the chair, exhausted for having spent the entire evening in the emergency department the night before. He was awakened a few times as the nurse reentered the exam room to check on him and, each time, she reassured him he would be seen as soon as possible. Around noon, Mr. M peaked his head out the door asking the nurse for directions to the nearest restroom. When he returned, the nurse informed Mr. M that he may want to get something to eat in the cafeteria as he most likely would not be seen until after 1:00 PM. Hungry, tired, and frustrated, Mr. M left the clinic, quickly ate, and called his boss to let him know he still hadn't seen the doctor yet and would most likely not make it into work at all. Mr. M returned to his exam room at 1:00 p.m. as instructed by the nurse. Mr. M was seen by the hand specialist at 1:30 PM – 6 hours from the time he arrived at the clinic that morning! While relieved when he was informed by the specialist that he did not need to have surgery on his wrist, Mr. M couldn't believe he had lost a whole day of work – a day he wasn't going to get paid for. Mr. M was given clinic discharge instructions by the nurse that included a follow-up appointment the following Monday. As he left the clinic at 2:15 p.m. he wondered, "How am I ever going to pay for all this and get my bike fixed? I have to work – I just can't take another day off from work to sit here all day."

Table 5.2 walks through the 8 Steps of Problem-Solving for this vignette.

Table 5.2 Eight steps of problem-solving for Vignette 5.3

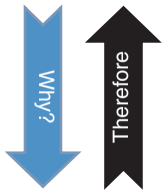
Step 1: Clarify the problem-background data/information	The organization's guiding principles include putting patients first, improving their experience, and respecting people. In the ortho trauma clinic, patients report staying for their visit longer than anticipated. Along with overall patient experience, "perceptions of information, instructions, and the overall treatment provided by physicians and other caregivers" are also negatively influenced by prolonged clinic times [26]. An internal review of data revealed that some patients who were scheduled for morning appointments were staying until later in the afternoon. The clinic termed these patients "carryovers" – patients scheduled in the morning clinic with cycle times so long they were "carried over" to the afternoon clinic, negatively impacting the clinic cycle time throughout the entire day. As part of an overall improvement initiative to reduce the ortho trauma clinic cycle time (time from when patients are checked into the clinic until the time they are discharged), the team prioritized understanding and reducing the number of "carryovers" (high volume, high risk, and problem-prone). *Ideal situation*: 0 patient "carryovers" from morning appointments to the afternoon clinic *Current situation*: In a month, 107 patients were unable to be seen timely and were "carried over" to the afternoon clinic.
Step 2: Breaking down the problem and method of measurements	 Breaking down the problem
Identify the point of occurrence	

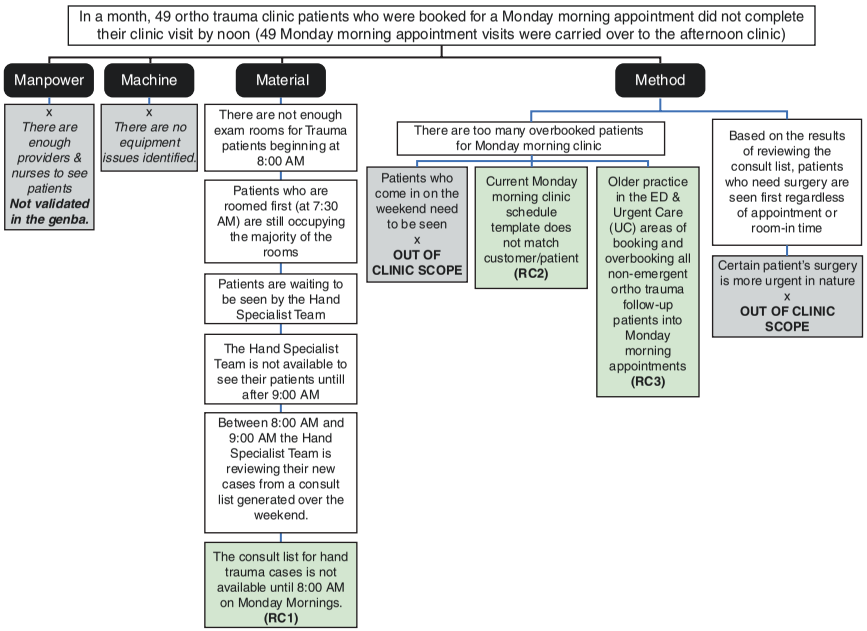
(continued)

Table 5.2 (continued)

Prioritized problem at the point of occurrence	In a month, 49 ortho trauma clinic patients who were booked for a Monday morning appointment did not complete their clinic visit by noon (49 Monday morning appointment visits were carried over to the afternoon clinic).
Current conditions/*genba* observations	Based on the prioritized problem, *genba* observations were conducted by ortho trauma clinic staff for the next two Monday mornings and found the following to be consistent: *Manpower*: There are enough providers and nursing staff to see patients *Machine*: No issues identified *Materials*: Trauma patients, who come in through the emergency department (ED) and urgent care clinic (UCC) over the weekend, are told to report to ortho trauma clinic at 7:30 AM Monday for follow-up (patients are booked and overbooked into the morning appointment slots). This was identified when the team visited the ED *genba* Hand patients are prioritized and are traditionally given the earliest morning appointments. This was also learned from the visit to ED *genba* A list of patients with non-emergent hand injuries is created by the trauma consultant. The list prints out at 8:00 AM in the ortho trauma clinic on Mondays Each case is reviewed by the hand specialist team to determine the treatment plan and whether surgery will be required when they meet from 8:00 to 9:00 AM on Mondays If the hand specialist team determines a patient will need to be scheduled for urgent surgery, the patient is prioritized to be seen regardless of their clinic appointment time *Method*: ED and UCC traditionally book and overbook all non-emergent trauma cases from the weekend to early Monday morning appointments. This was garnered from ED *genba* and validated in the ortho trauma clinic
Step 3: Target setting: set *SMART goal	Decrease the monthly number of ortho trauma clinic patients with Monday morning appointments who are carried over to the afternoon clinic by 50% (from 49 to ≤25 patients) in 1 month

Step 4: Analyze the root or main cause(s)/ identify root or main causes (RC)





The team identified three (3) root causes (green boxes below) by asking "why" the prioritized problem statement is happening, followed by checking the logic of the root causes by stating "therefore" for each root cause up to the prioritized problem.

(continued)

Table 5.2 (continued)

Step 5: Develop countermeasures	

Root causes (RC)	Countermeasures (CM)
RC 1: The consult list is only available to the hand trauma specialists on Monday morning at 8:00AM	• Increase the number of times the hand trauma specialist team is given the consult list in a week (CM1) and standardize expected time (i.e., before 7:30AM) (CM2) • Revise hand trauma specialist appointment time slots to 8:20 • AM(CM3) Standardize completion time of trauma specialists' review of the consult list (i.e., by 8:20AM) (CM4)
RC 2: Current Monday morning clinic schedule template does not match customer/patient demand	• Identify types of appointments that are getting overbooked (CM 5) and create a new appointment types (e.g. Trauma Hand) to match patient/customer demand (CM6)
RC 3: Older practice in the ED & Urgent Care (UC) areas of overbooking patients into Monday morning slots	• Provide copies of new schedule to areas who schedule patients (CM7)

<table>
<tr><td>Step 6: See countermeasures through</td><td>The team needs to develop a plan for how the countermeasures will be implemented. The plan includes who will be accountable and when actions are to be completed:
<table>
<tr><th>Countermeasures (CM)</th><th>Plan</th><th>Who?</th><th>When?</th></tr>
<tr><td>Increase the number of times the hand trauma specialist team is given the consult list in a week (RCI/CMI) and standardize expected time (i.e., before 7:30AM) (RC1/CM2)</td><td>1. While EHR restructures electronic consult process, consult list will be sent by the Ortho Trauma team by 07:30AM
2. Notify hand team of new changese</td><td>Dr. H</td><td>8/22</td></tr>
<tr><td>Revise hand trauma specialist appointment time slots to 8:20AM (RC1/CM3)</td><td>1. Communicate go-live date (8/23) of updated template to team
2. Reschedule current patients who still have 7:40AM appointments and inform patient of rationale of changes (i.e., to decrease waiting times)</td><td>NP</td><td>8/20</td></tr>
<tr><td>Standardize completion time of trauma specialists' review of the consult list (i.e., by 8:20AM) (RC1/CM4)</td><td>1. Communicate updated template to Hand team
2. Revise schedule of Hand team to be at the clinic in time to review consult list starting at 7:30AM.</td><td>Dr. H</td><td>8/20</td></tr>
<tr><td>Identify types of appointments that are gettiing overbooked (RC2/CM 5) and create a new appointment types to match demand (RC2/CM6)</td><td>1. Follow up with scheduling department on request for updated EHR appointment type (to add "Ortho Trauma Resource: Hand Trauma) based on data
2. Reallocate Trauma Clinic resources (i.e., 12 appointment 20-min slots, 2 rooms, manpower) to Hand Trauma based on data
3. Schedule and commnunicate go-live date (8/23) of updated template to team</td><td>Dr. M</td><td>8/23</td></tr>
<tr><td>Provide copies of new schedule to areas who schedule patients (RC3/CM7)</td><td>1. Reach out to services and areas who schedule non-emergent hand trauma appointments (i.e., the emergency department, urgent care, other clinics)
2. Provide copies of new schedule (both printed and electronic copy)
3. Develop electronic calendar system to improve sharing of future updates</td><td>Dr. M</td><td>8/20</td></tr>
</table></td></tr>
<tr><td>Step 7: Evaluate both results and processes</td><td>The monthly number of morning ortho trauma clinic patients carried over to the afternoon decreased from 49 to 21 patients – a 57% improvement
Some of the additional benefits and return on investment (ROI):
Mondays' clinic cycle time decreased from an average of 3 hours and 36 minutes to 2 hours and 15 minutes, which is a 37.5% improvement
Several staff ideas for improvement continue to be discussed and small tests of change are initiated during weekly team meetings</td><td>Date: 9/30</td></tr>
<tr><td>Step 8: Standardized successful processes</td><td>Carryovers are tracked and analyzed daily (through ortho's visual management board). The team developed routine data-based discussion (at least weekly) with the ortho clinic team members to analyze and address clinic issues to make small incremental improvements each day to optimize capacity
Reflections: While the 57% improvement is a positive change, the team is looking forward to their next PDCA to continue to level out the clinic schedule and daily operations to achieve their ideal state to see all their patients in a timely manner</td><td>Date:
On-going</td></tr>
</table>

Key Learning Points

1. The TPS eight-step process and the problem-solving thinking of the A3 process can be successfully applied to outpatient clinic problems by an interdisciplinary team of clinicians and surgeons, nurses, and ancillary staff with administrative support.
2. The balancing of the clinic schedule by designating specific hand clinic slots to match customer demand, and revising/streamlining the hand specialist workflow, eliminating unnecessary batching of case reviews, is an excellent demonstration of *heijunka* (level loading or balancing of the workload).
3. The importance of *genba* (shop floor) and *genchi genbutsu* (go look, go see, to understand and take action) was demonstrated especially in steps 2 and 4 (breaking down the problem and root cause analysis) of the eight-step process. Data told the team that "trauma" patients were the most problematic. However, through *genchi genbutsu* the team was able to go beyond the available data. Through direct observations in the *genba*, the team identified that patients required to be seen by hand trauma specialists within "trauma" were the early morning bottleneck which led to long waits for all trauma patients and a significant factor in causing carryovers.
4. The importance of involving a team of experts, including members from other areas of the hospital (ED) and reinforcing the HRO concept of deference to expertise, is highlighted in the vignette.
5. The changes implemented by the ortho team led to a significant reduction of *muda* (waste) for patients (waiting) and clinic staff (rework of having to recheck on patients multiple times).

Vignette 5.4 Reduction of Pressure Injuries in Patients and Days Away, Restricted, or Transferred (DART) Days in Their Providers

An 8-year-old complex medical needs patient born with a large omphalocele (open abdomen associated with a chromosomal defect during prenatal development where parts of the intestine and liver grow outside the abdominal cavity) was placed on mechanical ventilation in a pediatric intensive care unit as part of the postoperative clinical pathway associated with her plan of care following the surgical reduction of an intestinal obstruction secondary to adhesions. The clinical team managing the care of this patient was afraid to turn her to the lateral or prone position for fear of disrupting the recent repair. Given the patient weighed 30 kg and had multiple attached devices, including monitoring equipment, this patient could not be turned by a single staff member without risking employee back injury. The nurse completed her Braden Q assessment just after the beginning of her shift (8:00 AM) but scored the patient a 22 (low risk of developing a pressure injury on a scale of 0–26), not recognizing the high risk due to the patient's immobility. The nurse is called to the care of another patient in respiratory distress and does not complete her head-to-toe skin assessment on this patient. The other patient is finally stabilized, and the nurse begins to document her care of both patients in the EHR, noting that it was now 4:39 PM and that she was administering scheduled medications for her patients. The nurse ends her shift at 7:00 PM, and the oncoming nurse completes a head-to-toe skin assessment along with the Braden Q assessment. She finds an advanced (stage 3) pressure injury (PI) on the patient's occiput and proceeds to treat the patient based on recommendations from the wound

ostomy nurse. After applying the prescribed treatment for the PI, she remembers that her coworker injured his back turning a similar patient 2 weeks prior and has yet to return to work. She asked the charge nurse for assistance to turn the patient.

Members of the pressure injury reduction team sought to address the number of PIs that were developing across the organization. They used the eight-step problem-solving methodology (Fig. 5.5) and quickly walked through the various steps of identifying the gap in performance, breaking the problem down to a manageable scope. Figure 5.13 shows, by breaking down the problem (step 2 of the eight steps of problem-solving; Fig. 5.5), that Unit I had the highest occurrence of PI. By carefully examining the PI cases in Unit I, they found that PIs developed in patients that were not turned regularly and in patients with multiple devices used for complex medical treatment. In accordance with step 3 (target setting), they chose to address the patients who were inconsistently turned. While focusing on that cohort of patients, they uncovered several staff injuries related to lumbar strain and were able to use data gathered from direct observation, the EHR, and occupational health to identify that the problem was bigger than initially anticipated. This team set a target (step 3 of the eight steps of problem-solving; Fig. 5.5) of reducing the occurrence of PIs located on the occiput of patients. While working through the 5 whys (step 4 of problem-solving; Figs. 5.5 and 5.14), the team found that patients were not turned when two things were present: (1) the lack of perception of the risk of the patient's ability to develop a pressure injury (identifiable when the Braden Q Scale is used appropriately) and (2) the patient was perceived to be too heavy to turn alone. As the first countermeasure, the team worked with frontline staff to create a simplified standard for assessing patient risk of developing pressure-related injuries by simplifying the verbiage of the Braden Q Scale (a risk assessment tool used to identify patients at risk for developing pressure injuries, where the lower the score, the higher the patient's risk of developing a PI). Using the wound ostomy team (WOT), they tested inter-rater reliability between frontline staff and the WOT using the newly developed modified standard tool for assessing risk, the modified Braden Q [27] (Fig. 5.15).

Once the gap between the WOT and the frontline staff's Braden Q Scale results was narrowed, the team turned their focus to creating a standard used to train staff on turning patients alone, using a safe and simplified method (countermeasure 2). All Unit I staff were trained using JIS, and the standard was maintained using random audits by peers, WOT, and local leadership. As a result of staff using the new standard for turning patients alone, employee

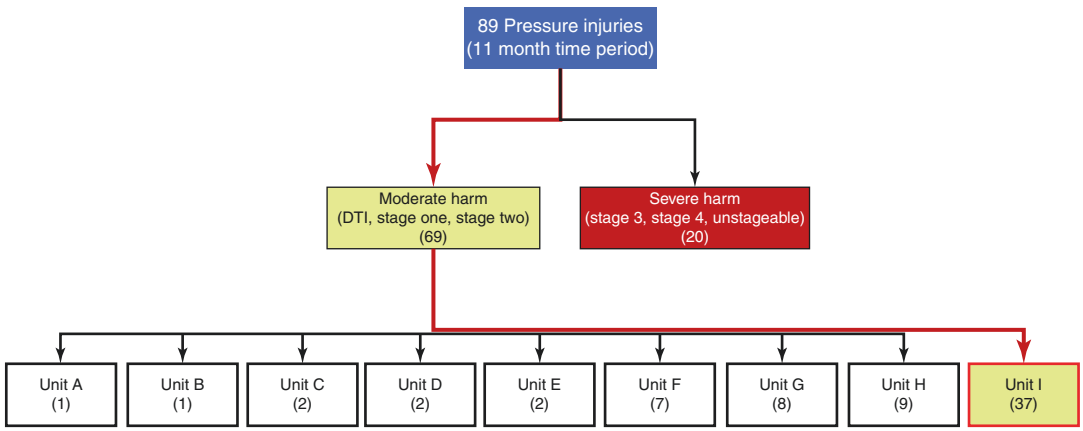


Fig. 5.13 Step 2 of problem-solving – breaking down the problem

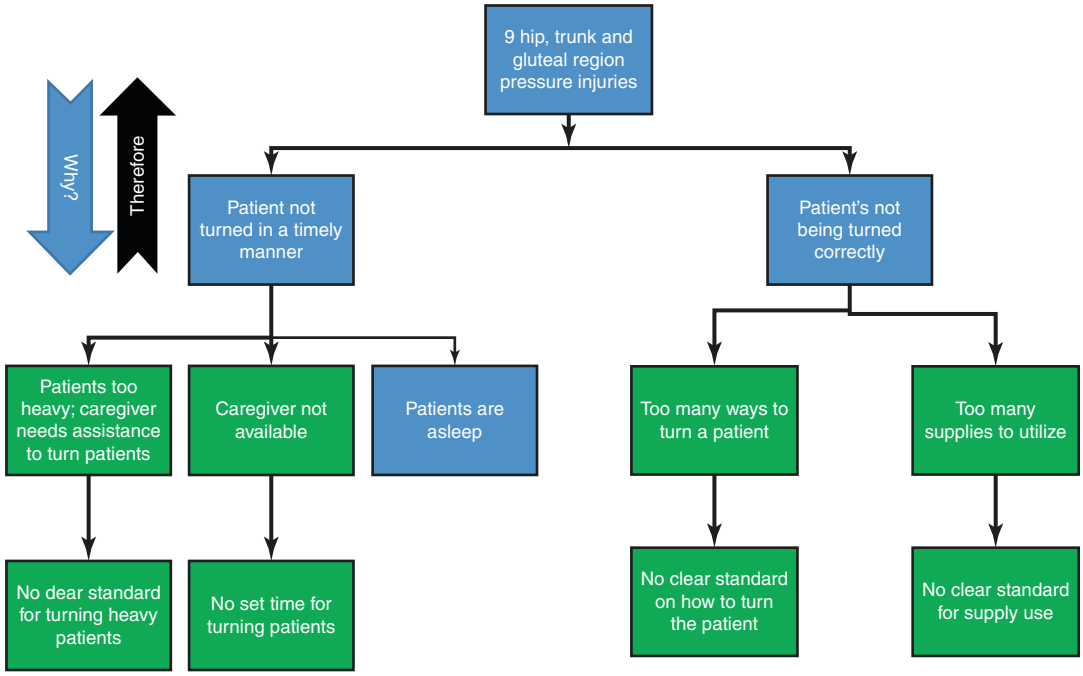
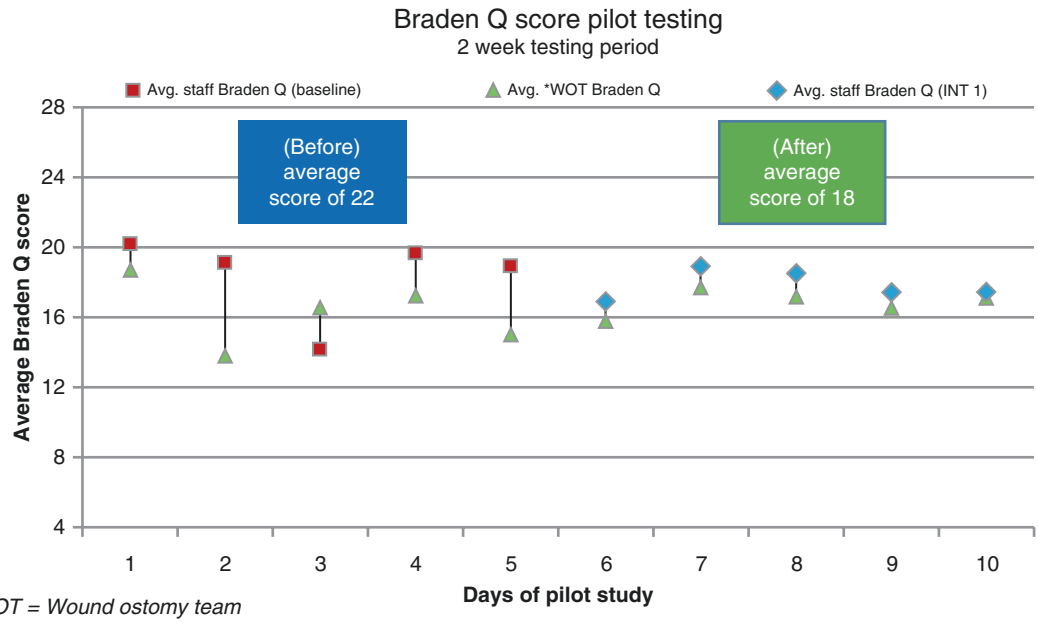


Fig. 5.14 Step 4 of problem-solving – root cause analysis using the 5 whys. The question "why" is asked repeatedly to arrive at the root cause(s). The lowest green boxes represent the root causes. To double-check the analysis, "therefore" can be applied as shown in step 4 of Vignettes 5.2 and 5.3



**WOT = Wound ostomy team*
Baseline Data Source: Electronic Health Record
Intervention 1: Use of a modified Braden Q scale

Fig. 5.15 Narrowing the gap between staff and WOT Braden Q scoring after training

injuries measured by the number of days away, restricted, or transferred (DART) has been reduced.

This vignette demonstrates the challenges of patient care. Ill and immobile patients are prone to PI, which often are subtle before they become larger and more obvious. The TPS encourages the creation of processes that bring these problems readily to the surface. Unlike the automotive assembly line, it is difficult to create processes that automatically uncover a PI and stop hospital processes, as described earlier for the *jidoka* pillar. In healthcare, there is value in setting up auditing processes and assigning accountability to identify PI in a more timely fashion, such as regular clinical skin assessments and creation of wound care teams that routinely audit at-risk patients.

Similarly, prevention strategies are helpful. The team's problem-solving exercise revealed that PIs were related to the absence of standards on how to take care of at-risk patients, especially the use of standard preventive methods (e.g., regular patient turning) and bedding materials (those that would facilitate turning or reduce pressure on at-risk body surfaces). Frontline team members had not been trained to adequately assess a patient's skin to detect and classify these pressure injuries as they occurred, so they were trained by the WOT. As shown in Fig. 5.15, the frontline staff responded well to their training on the use of the Braden Q assessment tool, so much so that their assessment scores nearly mirrored those of the expert WOT (compare days 1–5 vs. days 6–10).

The problem-solving exercise (Fig. 5.14) also revealed that heavy patients posed a challenge to the staff with regard to turning. The use of the Turn and Positioning System (TAPS) (Fig. 5.16) enabled patients to be turned with minimal risks to the frontline staff. This equipment was stocked on all units that cared for heavier patients, and frontline staff members were trained to the newly created standard using a JIS (Fig. 5.17) and simulation (Fig. 5.18), which improved their ability to care for patients at risk for PI through the implementation of prevention and early detection strategies.

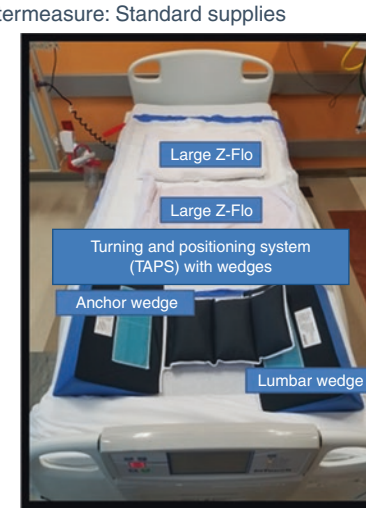


Fig. 5.16 Standardized supplies to enable easy turning (Z-Flo pillow, wedges, and TAPS) of patients

Key Learning Points

1. The phrase "if the student has not learned, then the teacher has not taught" emphasizes the value of teaching a standard process or method. If frontline team members are not taught a standard and the learning is not reinforced, variations in practice as well as normalized deviation will occur. This can have devastating consequences.
2. The creation of standardized work, which emphasizes best practices and the use of JIS to teach to the standard, can help improve outcomes.
3. The eight steps of problem-solving, when done properly, can discover hidden root causes.
4. In healthcare, the use of timely, unbiased, and robust auditing processes can be an alternative to *jidoka*, which is used extensively at the Toyota manufacturing plants.

CHKDHS Job Instruction: Positioning Patient with TAPS
(Placed in Bed Supine)

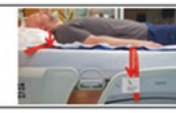
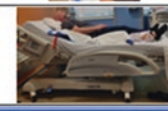
#	Major Step	Key Point		Reason for Key Point	Visual
1).	Gather supplies based on shopping list criteria	**Shopping List Criteria:** Tissue/Perfusion ≤ 2 ***OR*** Braden Q Score ≤ 18 ***AND*** Weight >35kg	**Supplies:** 1 Turning Assisted Positioning System (TAPS) with TAPS Sheet ***AND*** 1 Gizmo ***AND*** 2 Large Z-Flo	Use of shopping list criteria reduces chance of disruption of workflow	
2).	Setup bed	*With bed at waist level of the clinician and side rail down:* 1). Place 1 Large Z-Flo at the head of the bed aligned with the width of the bed 2). Position TAPS lenghwise with the mattress; black straps down, just below the Z-Flo 3). Place TAPS sheet on the top of TAPS 4). Place 1 Large Z-Flo near foot of the bed, aligned with the width of the bed		Ensures appropropriate product is used to reduce the patient's chances of developing a pressure related pressure injury	
3).	Place patient in bed per protocol, raising side rails closest to patient's left arm.				
4).	Position patient supine (from patient's right side)	Align top of shoulder with top of TAPS.		Assures appropriate position on TAPS Reduces additional sliding of patient	
5).	Position TAPS Anchor Wedge	1). Place anchor wedge black side up, under the TAPS, under the patient's right thigh 2). Push anchor under legs through to the patient's left side 3). Place lumbar wedge, under the TAPS, behind the patient's right lumbar without wedging under the patient		Reduces additional sliding of patient Reduces pressure to sacrum	
6).	Position all lines and wires	1). Use the Gizmo to untangle and gather all lines and wires 2). Drape them across the patient 3). Lead lines and wires to their respective devices 4). Raise side rails		Reduces chance of device related pressure injury	
7).	Reposition Bed	1). Raise foot of bed to desired height 2). Raise head of bed to desired height		Reduces patient sliding	

Fig. 5.17 Job instruction sheet shows the use of TAPS to position the patient

Used medical simulation

Fig. 5.18 Using simulation to teach the new standard described in the job instruction sheet

Building a Successful TPS Culture

Building a TPS culture takes planning, considerable culture building, and training, similar to our medical education processes. For instance, when physicians, nurses, and other allied health professionals are trained, they go to a school where they are taught key concepts and fundamental principles. While in school and during their internships and residencies, they are exposed to practical concepts and procedures and learn through observation while under the guidance of their teachers or coaches. During these training years and early part of their careers, they are paired up with good coaches who provide continued guidance. Learning TPS is no different (Fig. 5.19) in that most learning is by doing, or practice, under the auspices of a good coach. There are three phases – education by concept, exposure/observation, and practice with a good coach. Key to this success are good coaches who can provide guidance to TPS teachings. These phases can occur in one of the two likely ratios (10:10:80 or 20:20:60). In other words, 10–20% of TPS can be learned with formal training/classroom exposure and 10–20% from exposure or seeing TPS in action. However, the greatest learning is from hands-on experience or direct involvement with team problem-solving, a key aforementioned point from the teachings of Taiichi Ohno – learning by doing. Compared to medicine, TPS concepts are relatively simple. In fact, they are so deceptively simple that people sometimes skip the learning by doing.

As with any project dealing with change, the goal is to start with small tests of change. TSSC also embraces the model line concept, where building the TPS culture should first occur within a single service line or program. That single area is developed fully to the point where it can serve as a model of successful TPS implementation for others within a system to look to for advice, support, and leadership. The newly trained unit members and leaders can also be redeployed to coach similar improvement projects elsewhere in the organization.

Chandrasekaran and Toussaint [28] recently described a set of best practices that can help sustain a TPS culture within a health system. First, instill TPS behaviors in managers at all levels of the organization. Senior leaders need to be present and visible at regular intervals in the various organizational huddles. There will

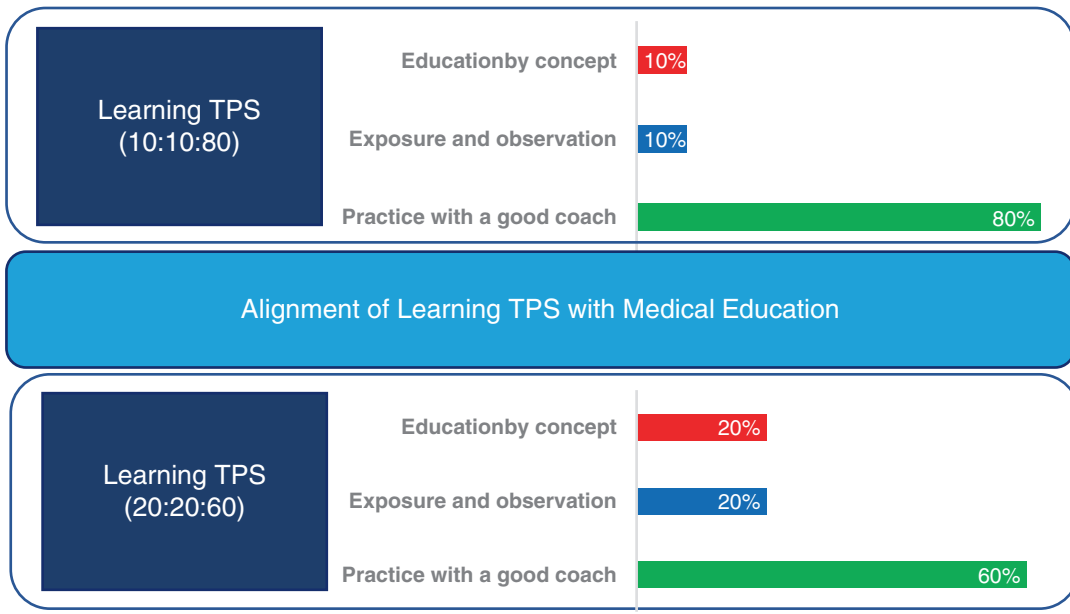


Fig. 5.19 Three phases of TPS training and implementation and their alignment with medical education

need to be succession planning for the senior leaders, especially the CEO and various board members, with specific preference to those who understand and embrace TPS. Stories of success need to be created and shared. Finally, the quality and cultural management system needs to be a TPS-based operating system. All of these aforementioned concepts will permit problems to come readily to the surface to be resolved in a timely fashion, since problem-solving is part of the daily culture and expectation.

The application of TPS principles to a healthcare organization requires a new mindset that might at first appear foreign, especially with regard to the role of leaders. Kim Barnas, while a senior leader at ThedaCare in Appleton, Wisconsin, best described this mindset or business improvement system as comprising of eight key elements which are similar to TPS or their lean principles [29]:

1. *Status reports* – local daily dialogues that occur throughout the organization which enable situational awareness.
2. *Daily team huddles* – enable teams to discuss opportunities for improvement, challenges, and ongoing improvement projects.
3. *Managing or auditing to the established standard.*
4. *Problem-solving.*
5. *Transparency* – defects and problems are brought forward along with accomplishments.
6. *Advisory teams* – advisors comprised of team members or leaders from across the organization are available to individual units to provide knowledge and expertise where needed.
7. *Scorecard* – tracks actual monthly performance metrics against goals.
8. *Leadership standard work* – leaders round regularly and set standard work expectations for all team members, including themselves (see reverse fishbone diagram; Fig. 5.20).

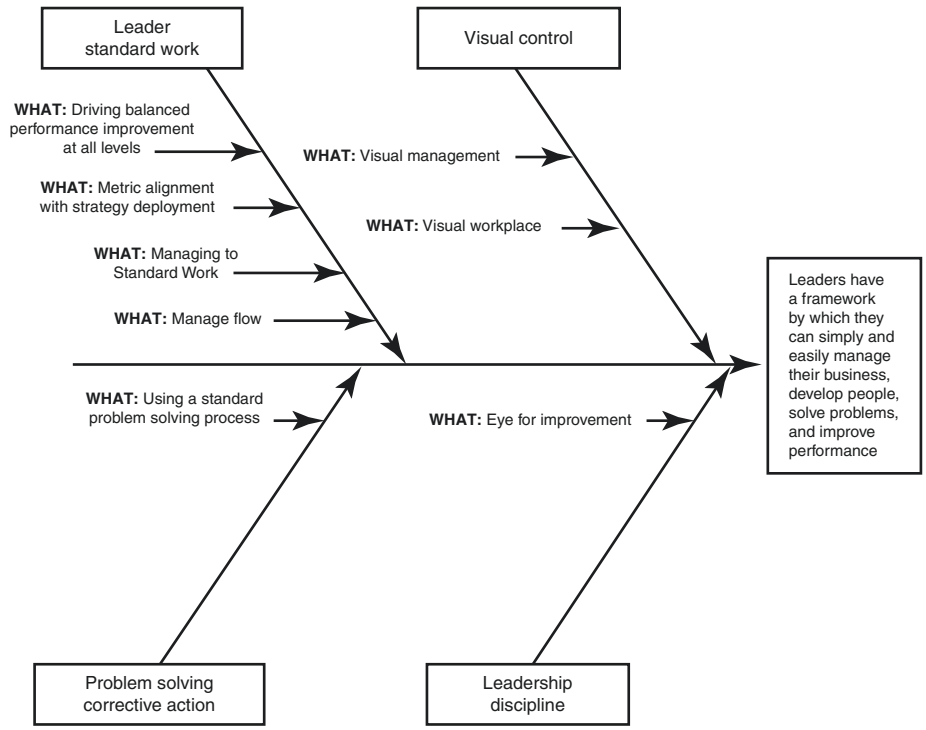


Fig. 5.20 Reverse fishbone diagram that depicts the role of any leader. This is a cause-and-effect diagram [30] in which the desired leadership outcomes were first defined and then the actions needed to create the effect were tested and implemented if successful. (Reprinted with permission from Kim Barnas [29])

The latter point emphasizes the role of any leader in an organization committed to adopting TPS. Every organizational leader has a structured day which begins by assessing and understanding the current state and anticipating problems (Fig. 5.20). The goal is to move from a "firefighting" mentality to an anticipatory focus where problems can be solved before they become critical. Leaders need to become more visible, more respectful, actively supportive of the organization's improvement initiatives and daily work, and process improvement focused. As discussed in the Bundles and Checklists chapter (Chap. 13), some hospital leaders use *kamishibai* cards (K-cards) as rounding tools to improve compliance with best practice bundles. Problem-solving is everyone's responsibility. Teams work together to solve problems using the scientific method and leaders encourage and facilitate this. All improvement projects must be aligned with corporate goals which are rigorously reviewed annually.

Summary and Closing Discussion

The application of the Toyota Production System to healthcare is a recent development. While there are many differences between manufacturing and healthcare, we believe that the principles are applicable. The TPS culture can be invaluable when properly inculcated into the daily mainstream operations of an organization and can especially assist with its cultural and quality transformation. TPS is, after all, an organizational culture of highly engaged people solving problems to drive performance that is created and sustained by the three-part system described by the TPS Triangle (Fig. 5.2).

Many healthcare organizations have started the "mindfulness" journey to becoming a high-reliability organization – and as a result, improve their quality and safety outcomes. Weick and Sutcliffe [3] referred to mindfulness as the quality of attention. The agility needed to address the ever so changing opportunities, and threats facing mindful organizations and their team members, is due to the constant refinement of existing expectations, continual improvement of cognitive foresight, and rapid learning from events as they occur. Toyota is one such mindful organization where their journey to sustained excellence has occurred through careful planning and the focus on the development of its team members – one member at a time. They have realized that the HRO journey takes time, may have occasional setbacks, yet have processes in place that promote resilience. They have created a successful organizational culture that they have to reinvigorate every time a new plant opens or its team members retire or transfer. Toyota has accentuated the value of continuous process improvement and the related problem-solving. It has integrated the principles of the TPS Triangle (Fig. 5.2), as well as the technical tools described in the TPS House (Fig. 5.3), throughout its global operations.

TPS requires senior leadership team and management commitment and visible participation, especially with the modeling of desired behaviors, new habit formation, problem-solving skills for all, and all of the HRO principles mentioned earlier in this chapter and throughout this textbook. The power of TPS is in the method which mandates constant demonstration of competence through the application of learned principles, participation in improvement projects, and accountability for personal growth and that of your respective teams. In short, TPS leaders are visible, known to all, and enable the success of their teams. They are lifelong learners, teachers, and coaches.

Process visibility is also crucial. Only if the current state of pre-existing processes can be defined can problems be brought to the surface and processes improved, ultimately leading to better outcomes. Problem-solving is everyone's responsibility, as is the resulting shared learning. Taiichi Ohno coached his disciples by drawing a chalk circle onto the floor (often referred to as Ohno's Circle [31]) and then asking them to stand in it and thoughtfully observe the actual processes on the shop floor. His disciples then reported on the various problems observed and were asked to use data-driven and observation-confirmed problem-solving to arrive at solutions. Data was collected through simple observations

initially. Later, more complex data collection was made possible from the various automated *jidoka* tools that had been implemented on the shop floor. The resulting problem-solving occurred quicker. The value of each team member's learning by doing cannot be overstated.

As a corollary, healthcare teams are inappropriately focused on the unavailability of automated data rather than embracing the value of collecting data through simple, yet purposeful, observations from which to drive cycles of change. The "just do it" mentality is sometimes lost in the pursuit of perfection, but all improvement methods mentioned throughout this text will not be successful if they succumb to analysis paralysis. Toyota encourages small PDCA/PDSA cycles using simple data collection methods and austere, inexpensive countermeasures. The proper use of problem-solving permits better prediction to increase the likelihood of successful PDCA/PDSA cycles.

Toyota prides itself on its safety record for its team members and customers, but this can only happen if issues are rapidly addressed through multiple test cycles of change. After all, it is the cumulation of small cycles of change that eventually lead to bigger changes and breakthrough innovation. Even if automated data were available, verification of the current state through observation of the shop floor through *genchi genbutsu* is of utmost importance to breaking down any problem and analyzing for the root cause (steps 2 and 4 of the eight steps of problem-solving; Fig. 5.5). Also as described in the HRO principles – sensitivity to operations and deference to expertise – Toyota's frontline teams are the experts and always assist with any unit and even an interfacility-based problem-solving exercise. Toyota's leaders are present, directly interacting with team members and coaches to facilitate the problem-solving process. This is quite the contrast from some healthcare organizations where problem-solving may occur without the direct involvement of and guidance from their senior leaders. Ideally, there should not be any perceived or actual barrier to the bidirectional communication or flow of ideas and feedback between the organization's leaders and its team members. Not surprisingly, Taiichi Ohno valued leaders who excelled at mentoring and teaching.

TPS also provides organizations with a framework for sustaining results through the creation of a culture where organizational goals and expectations are evident to all team members and linked to the yearly organizational strategic priorities. Often the best judge of organizational culture is as an outsider looking in. Multiple clients of TSSC, Toyota's not-for-profit entity charged with sharing TPS outside of Toyota, have commented that Toyota's team members "point in the direction that they will be walking before crossing a street" and "do not walk while talking or texting on their mobile devices" – both key safety behaviors they practice when in one of Toyota's busy manufacturing plants. Clearly the value of modeling behaviors is not lost upon Toyota team members. Similarly, Toyota leaders and managers are required to demonstrate ongoing mastery of problem-solving methods. This continuous cultural reinforcement, facilitated by TPS, is paramount for sustaining and continually building upon past results that leads to new, improved, and innovative products and methods.

Clearly, Toyota and its production system and its history deserve our attention. Toyota's corporate DNA [18, 32] appears to have encoded the principles of the TPS Triangle which, in turn, has been engineered into the DNA of its leaders and team members. Healthcare and other industries are trying to understand how a similar transformation can be facilitated within their respective realms. Toyota's journey has been deliberate. It has been subject to its constraints in its initial development from the global economic climate facing post-World War II Japan, ongoing challenges from the changing global landscape, and a result of the successful application and practice of the scientific method by all of its leaders and team members.

As a final thought, healthcare systems are complex and problems are inevitable, especially with regard to human error. We need to simplify these complex processes, and eliminate faulty processes that make errors more likely to happen, by employing the TPS. TPS is a different way of thinking and can be the methodology to move

any organization along its HRO journey. Its success requires commitment and internal reflection from an organization's leadership and team members. A review of Toyota's history reveals a well-orchestrated journey with the development of processes to address and learn from the unexpected! A few healthcare organizations have succeeded in the application of TPS, but they have been on a multiyear journey with ongoing commitment to becoming even better. It remains to be seen whether the application of TPS will start increasing the velocity of change and innovation in healthcare, as we try to attain the goals of delivering value to our customers, both patient and team member, with zero harm.

Key Closing Points

1. The Toyota Production System is an organizational culture of highly engaged people solving problems or innovating to drive performance. This culture is sustained by a three-part system, as described in the TPS Triangle, of (1) philosophy, (2) technical tools, and (3) managerial roles.
2. The TPS philosophy consists of four key points: (1) customers first, (2) people as the most valuable resource, (3) continuous improvement, and (4) shop floor focus.
3. Bringing problems to the surface is important. Problem-solving skills, as part of *kaizen*, are important to teach team members.
4. Team members learn best by doing.
5. When done properly, culture driven by TPS is a win for patients and their families, a win for caregivers, a win for hospitals, and a win for communities! If it is not win, win, win, win…, then it is not TPS.
6. TPS adoption can assist with the high-reliability journey of any healthcare organization.

Editors' Comments

This chapter represents a comprehensive overview of one of the most productive, efficient, and well-known improvement process frameworks historically: the Toyota Production System. The editors sincerely appreciate the efforts of Toyota in creating this thorough chapter aimed at describing their company's journey to develop the Toyota Production System. We find the granularity of the chapter of significant value for the reader so that one can understand the nuances and broad applications of the Toyota Production System.

The most exciting part of the chapter is the direct application to healthcare. The second half of the chapter focuses on the use of the Toyota Production System methods and processes in healthcare; the authors accomplish this by using actual cases with the methods detailing the specific interventions with the resultant data. Without the specific information, the reader would have been left with a theoretical understanding of their system; however, the second half of the chapter brings the teaching full circle by showing the reader how the Toyota Production System has been applied and continues to be applied in healthcare – driving outcomes that heretofore were not able to be achieved. The value of its eight steps of problem-solving methodology cannot be understated. The TPS, its Triangle and House, and its problem-solving methodology can stand alone or be used in part with other methods including the IHI Model for Improvement (as discussed in Chaps. 4 and 9).

This chapter epitomizes the concept of this textbook: to take theory and demonstrate how to put it in action and the benefits that can be derived from such an application. The quest for zero harm was the impetus for the editors – we keenly

realize that to get to zero harm, we will need to think differently and broaden our toolkits. This chapter achieves the trifecta of teaching a theoretical framework, applying this to healthcare, and inspiring us with the case studies.

Acknowledgments The authors would like to thank Adam Campbell, Maya Godambe, Michael Goss, Nathan Hurle, Elizabeth Martinez, Lisa Parker, Elizabeth Pittman, and Teresa Saulnier for the critical review of this chapter.

Glossary of Relevant Terms

5-S refers to a visually based process for organizing the workplace to reduce waste, especially time spent looking for supplies, and consists of the following components: *S*ort, *S*et in order, *S*hine, *S*tandardize, and *S*ustain. 5-S becomes 6-S if you include Safety.

Andon a signal which is automatic or manual that indicates to everyone in its proximity that a problem has been detected. It often also tells the nature and location of the problem and, therefore, is critical to effective problem-solving.

Fishbone, *Ishikawa*, or Cause-and-Effect Diagram a tool used to identify potential causes for an effect or problem. This is very effective when used in conjunction with problem-solving.

Gemba/Genba refers to the shop floor or place of work being examined.

Genchi Genbutsu refers to the purposeful process of walking and making humble observations on the shop floor or where the work takes place. "To go look, to go see, to *understand*, to take action."

Heijunka refers to leveled work or production.

Humanize to create an environment where respect for people, a key TPS concept, is realized remembering that 100% of what we do ultimately impacts our customers 100% of the time.

Jidoka refers to "automation with a human touch" or the process of building in quality or quality at the source. *Poka-yoke* and andons are part of *jidoka*.

Just-In-Time refers to the production and conveyance/transportation of only what is needed, when needed, and in the quantity needed. It meets the exact demand of the customer in terms of product, timing, and volume.

Kaizen refers to continuous improvement and problem-solving.

***Kamishibai* card (K-card)** a tool used to ascertain team member knowledge of a given best practice (often used to perform audits of standardized work or as rounding tools to improve compliance with best practice bundles).

Kanban refers to a signal, which usually is an information-laden card, attached to equipment or supplies that enhances a pull system by signaling upstream of the need for new production and delivery of a product to the point of need, i.e., usually the location of the card.

Lead Time the time from initiation to completion of a process.

Muda refers to the waste in a process within an organization. There are seven categories of *muda*: *m*otion, *r*ework/defects, *w*aiting, *o*verprocessing, *i*nventory, *c*onveyance/transport, and *o*verproduction. The acronym MR. WOICO is often used to help teams remember the different types of wastes. In healthcare, wasted time and potential of people is commonly referred to as the eighth waste.

One-Piece Flow refers to the continuous flow of goods or parts from step to step without any batching, no work-in-process intermediate product or any intermediate accumulation of inventory. Often, to facilitate, one-piece flow steps in a process are laid out in a cellular or U-shaped layout.

Poka-yoke is a part of *jidoka* and refers to the hardwiring of a process so that errors cannot occur. This is also referred to as mistake proofing.

Pull System refers to the integrated system of production and delivery from downstream to upstream processes where upstream suppliers deliver product to downstream processes

only upon signaled need. This reduces excess inventory.

Push System refers to operations where products are made and inventory created based upon expert corporate forecasts.

Shop Floor see *gemba* or *genba*.

Standardized Work is a key framework for *kaizen* improvements. It is a step-by-step document written by the people who do the work outlining the current best thinking on how to perform the process. Once standardized work is established, planned tests of change can occur to eventually get to a better standard.

***Takt* Time** is the rate at which products or services should be produced to meet customer demand. *Takt* time is the total available production time divided by customer demand. For instance, if any emergency department is open 24 hours per day and sees approximately 240 patients per day on average. Its *takt* time is then 6 minutes.

Value Stream (or Process) Map is a visual flow map that shows how activities or processes are interconnected to design, order, and provide a given product or service.

Chapter Review Questions

1. Which is a key characteristic of the Toyota Production System (TPS)?
   A. All important decisions must be made only by the senior leadership team from the confines of their boardrooms or offices.
   B. TPS dedicates many resources toward developing and encouraging team member problem-solving skills.
   C. TPS was created in the 1980s.
   D. TPS was widely adopted by many US car makers in the 1950s and 1960s.

   Answer: B. If you examine the TPS Triangle, the core value of the TPS is to focus on the development of the frontline team member. TPS philosophy encourages a shop floor focus which is visited regularly by senior leaders.
2. *True or false*: Transparency is an important cultural trait that needs to be adopted by healthcare organizations to bring problems to the surface quickly.

   Answer: True. Healthcare systems cannot fix problems that are not known. Team members need to be given the authority and asked to be accountable to bring problems to the surface while they are small and manageable. Safety events at healthcare systems may be related to recurrent problems that were either hidden from the surface or not addressed completely when they were noted the first time. Transparency builds trust with team members, customers, and other stakeholders.
3. What are the key TPS traits that are most beneficial for healthcare?
   A. Senior leaders are visible in *kaizen* activities and model desired behaviors.
   B. Problems can be best visualized through *genchi genbutsu*.
   C. Andons are part of *jidoka* and can be used to identify abnormalities.
   D. Leveling the work (*heijunka*) can improve patient safety.
   E. All of the above.

   Answer: E. All of the answers listed are correct. Briefly, the TPS Triangle (Fig. 5.2) discusses the importance of senior leader modeling of desired behaviors and the value of the shop floor for visualizing and bringing problems to the surface. The TPS House (Fig. 5.3) discusses the key tools or technical aspects of TPS, including h*eijunka* and andons.
4. Who are your customers when you, as the emergency department physician, are admitting a 7-year-old male patient in the emergency department to the inpatient unit?

   Answer: The most obvious customers are the patient and his family who are with him during his emergency department and inpatient stay. Additional customers include the inpatient unit staff and physicians. As the ED clinician, you must stabilize the patient to the best of your ability. You must then prepare and give the best handoff to the inpatient unit. You must also call the primary care physician to let them know about their patient that you just admitted to the hospital.

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Additional Resources

Catalysis is the first organization of its kind to exclusively focus on educational programs and resources designed to transform healthcare value. Their website is: www.createvalue.org

Toyota Production System Support Center (TSSC) website has multiple examples of the application of TPS: www.tssc.com

Video highlighting the TPN project discussed in Vignette #1: https://www.youtube.com/watch?v=cekpkEYc2cY

6 What to Do When an Event Happens: Building Trust in Every Step

Michaeleen Green and Lee E. Budin

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ETTO	Efficiency-thoroughness trade-off
FMEA	Failure mode and effects analysis
PSO	Patient safety organization
RCA	Root cause analysis
VA	Veteran's Administration
WAD	Work as done
WAI	Work as imagined

Chapter Objectives

- Clarify structures and methods to use when an event occurs.
- Highlight decision points and application of methods in varied situations.
- Demonstrate links between experience, learning, and improvement.
- Consider how decisions can affect trust and how application of methods used in event management, analysis, and follow-up can influence safety and improvement culture.

Opening Question/Problem

When a potentially serious harm event occurs, there is a duty to complete a thorough analysis to understand the cause of harm and the opportunity to prevent a similar, repeat occurrence. Historically, accidents are routinely followed by a public statement from a visible leader making the promise to find and fix the problem and assure accountability. The promise to find out what happened and fix the problem is a genuine commitment; however, the practical steps to fulfill this promise are intertwined with cultural nuances that shape the journey to prevent harm.

If errors were only a result of predictable patterns of broken parts, the promise of a certain fix could be made with confidence. The limits to confidence in the planned solution come from the realization that event occurrences are varied and often involve human performance in the context of complex and dynamic socio-technical systems. In this chapter we present a series of case vignettes that illustrate how the response to an

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event, including but not limited to an event investigation, is profoundly linked to culture. To examine the effectiveness of response in each situation, we have considered the Kirkpatrick framework which is a model suggested by Perry et al. to evaluate program effectiveness by assessing the impact on experience, learning, improvement, and outcomes [1]. The prevention of harm depends on reliable and resilient human performance in emergent situations that are not always predictable. Supporting resilient human performance is often not a quick find and fix but rather a journey through layers of culture that include accountability, leadership, learning, and improvement cultures. These are all critical components of the culture of safety needed for the prevention of harm and appropriate response to the occurrence of harm events. Said another way, the promise to investigate and ameliorate what went wrong is not a sufficient response to an event but rather, it is essential to consider event response in the broader context of building the culture of trust and continuous improvement.

The key takeaway from this chapter is to understand not only what to do but to also consider how each action, the conduct of those involved, and the communication in response to a serious event will have an impact on safety culture and outcomes with a particular focus on the impact on trust. As Berwick suggests:

> Because the improvement of health care is a team effort, the issue of trust comes to the foreground. Many forms of trust are relevant to improvement: trust that the future can be better than the present; trust in patients and families, allowing us to hear their needs as legitimate and reasonable; and trust in our own capacities to learn and change, even in a hostile environment. [2]

While the relationship between actions, decisions, and trust may vary based upon the culture of an organization, fostering trust should remain top of mind while carrying out responsibilities to respond when a harm event occurs.

In this chapter we highlight case vignettes that are noteworthy enough to warrant consideration for an investigation and response either through a root cause analysis (RCA), the most commonly used investigation approach, or an alternative response. Conducting an RCA has become a familiar standard in healthcare. The Joint Commission's Sentinel Event policy indicates:

> …appropriate response to a sentinel event includes the completion of an analysis of the causal and contributory factors. Root cause analysis, which focuses on systems and processes, is the most common form of comprehensive systematic analysis used for identifying the factors that underlie a sentinel event. A hospital may use other tools and methodologies to conduct its comprehensive systematic analysis. [3]

Expectations for conducting comprehensive systematic analysis and reporting findings are defined not only in accreditation standards but may also be defined by state law [4]. While specific rules defined in these laws may vary by state, the intent to utilize learning from harm occurrences for improvement is consistent. Approaches used for comprehensive analysis are based upon accident models that have evolved over time including those described in Fig. 6.1 that are considered throughout this chapter [5–8]. Each of these models represents an effort to understand causal relationships resulting in harm. The healthcare industry has adopted RCA methodology that was well established in other industries for accident investigation, and standard step-by-step approaches to conducting RCAs are well documented and easily accessible. It is important to note that available references on how to conduct an RCA have evolved and improved over the last two decades. Through experience and maturity in well-developed patient safety programs, we have learned to not only consider cause and effect but to also focus on the engagement of and impact on the people involved in the event occurrence. For example, both the step-by-step guide published by the Veteran's Administration [9] and the National Patient Safety Forum's root cause analysis and action approach (also referred to as RCA^2) [10] not only provide guidance on the steps needed for identifying a root cause but also provide consideration for those who need to be involved and how participants should be engaged to establish the basis for successful implementation of identified actions for

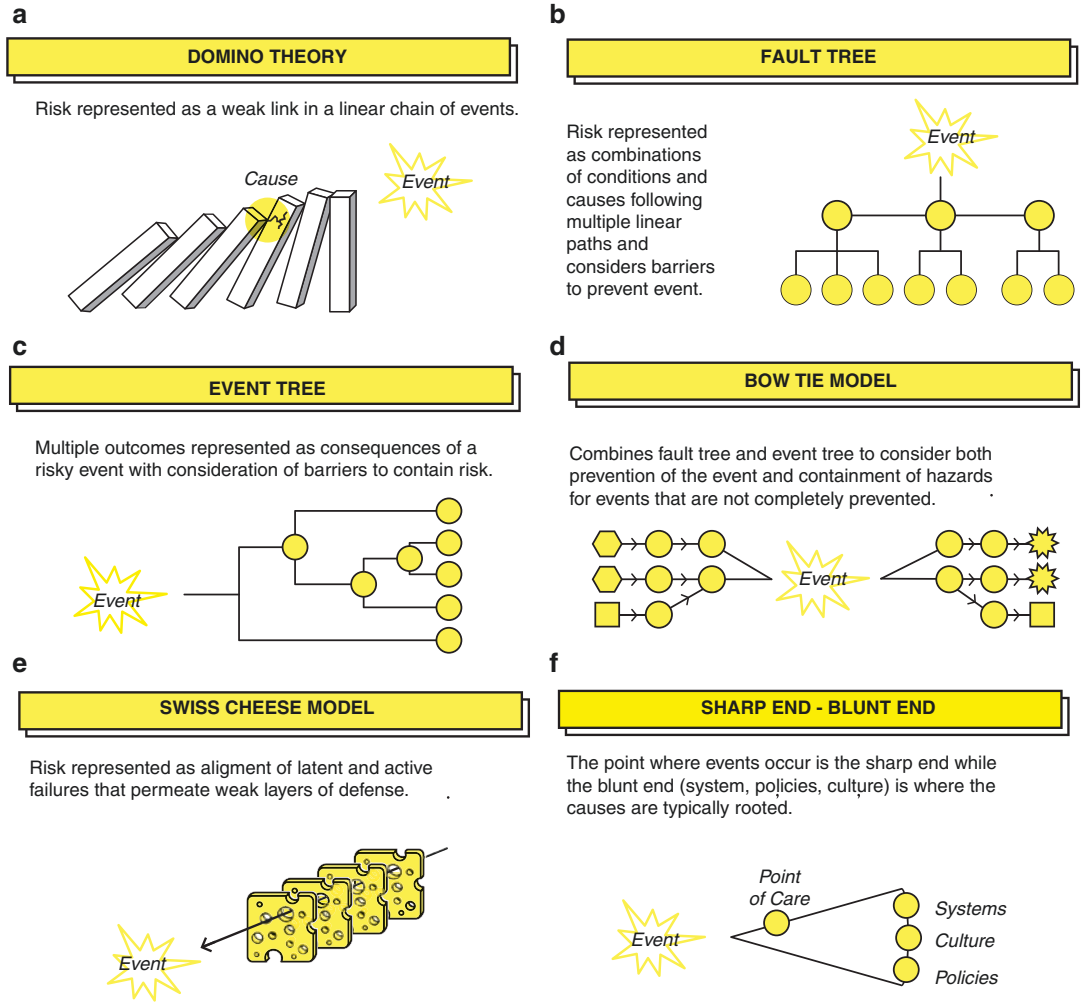

Fig. 6.1 Understanding events: accident models used to understand cause and effect relationships. **(a)** Domino theory; **(b)** fault tree; **(c)** event tree; **(d)** bow tie model; **(e)** Swiss cheese model; **(f)** sharp end-blunt end. Figures based upon descriptions of traditional accident models from several references including [5–8]

improvement (see Box 6.1 for websites). That is, the success of the analysis is not in just finding a root cause but rather in the engagement in learning from error, appreciating risk, and sustaining improvement. Both of these resources reflect the evolution of the RCA practices recognizing the value of methods that go beyond just asking "why." This is particularly important in healthcare where errors are very likely to involve human performance within complex systems. Additionally, the evolution of our understanding of how errors emerge from complexity warrants a new and broader lens described by Hollnagel and others as a new view of safety including a stronger emphasis on resilience:

> Simple linear models, such as Heinrich's (1931) Domino Model that is at the heart of Root Cause Analysis, later supplemented by composite linear models such as Reason's Swiss Cheese Model, were soon adopted as the basic safety tools in health care. Few people noticed that the very same models were being progressively challenged by industrial safety outside healthcare as inadequate to the newer, more complex working environments.
>
> During the second half of the 20th century the focus of industrial safety efforts shifted from technological problems to human factors problems

> and finally to problems with organisations and safety culture. Unfortunately, few of the models used to analyze and explain accidents and failures developed in a similar way. The result is that safety thinking and safety practices in many ways have reached an impasse. This was the primary driver for the development of resilience engineering in the first decade of this century (e.g., Hollnagel, Woods & Leveson, 2006). Resilience engineering acknowledges that the world has become more complex, and that explanations of unwanted outcomes of system performance therefore can no longer be limited to an understanding of cause-effect relations described by linear models. [11]

Since the absence of harm is likely dependent upon continued resilient human performance in complex environments and trying conditions, our mindset of how to respond when an event occurs must evolve beyond find and fix. The cases described in this chapter will consider how to respond when an event occurs but will also consider how we must take a broader lens and consider implications of the human experience before, during and after the event. The effort to understand what went wrong and how to fix it is not diminished in importance; however, the effect of event response decisions, behaviors, and communications on culture, trust, learning, and improvement must be elevated to the same level of importance to move the needle on prevention of harm (Key Points Box 6.1).

Key Points Box 6.1 Root Cause Analysis in Healthcare

Tools	Description	Website
Root cause analysis tools: VA National Center for patient safety's root cause analysis (RCA) step-by-step guide	Describes the step-by-step approach utilized by the Veteran's Administration	https://www.patientsafety.va.gov/docs/RCA_Step_By_Step_Guide_REV7_1_16_FINAL.pdf [9]
RCA^2: Improving root cause analyses and actions to prevent harm. National Patient Safety Foundation	Guidelines based upon examination of best practices designed to standardize and improve investigation of errors, adverse events, and near misses	http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx [10]

As we contemplate the impact of decisions in the response to each case vignette below, we are anchoring to the following preconditions that are presumed likely given the regulatory requirements for event investigation:

1. There are existing norms within the organization for a response to an event.
2. There are structures, policies, and defined resources that define some responsibility within the organization for event investigation and response.
3. The current practice is generally aligned with recommended RCA approaches (see references and Internet resources in Key Points Box 6.1 and at the end of this chapter).

This chapter does not intend to declare a definitive best practice approach but rather recognizes that practices continue to evolve and are married to the culture within the organizations and sociopolitical environment where they emerge and are put into action. This chapter highlights the interconnectedness between culture and event response that calls into question looking for a best practice and instead calls for assessment of how to better understand the impact on culture along the way. To establish a baseline for consideration of the impact of key decisions and their impact on culture, we offer an event response roadmap in Fig. 6.2 as a framework for considering event investigation and response. It is presumed that the basic components of each of these responsibilities exist in some form in most healthcare organizations with varying degrees of maturity and reliability. As evidenced by the evolving body of literature on harm prevention, the event response approach

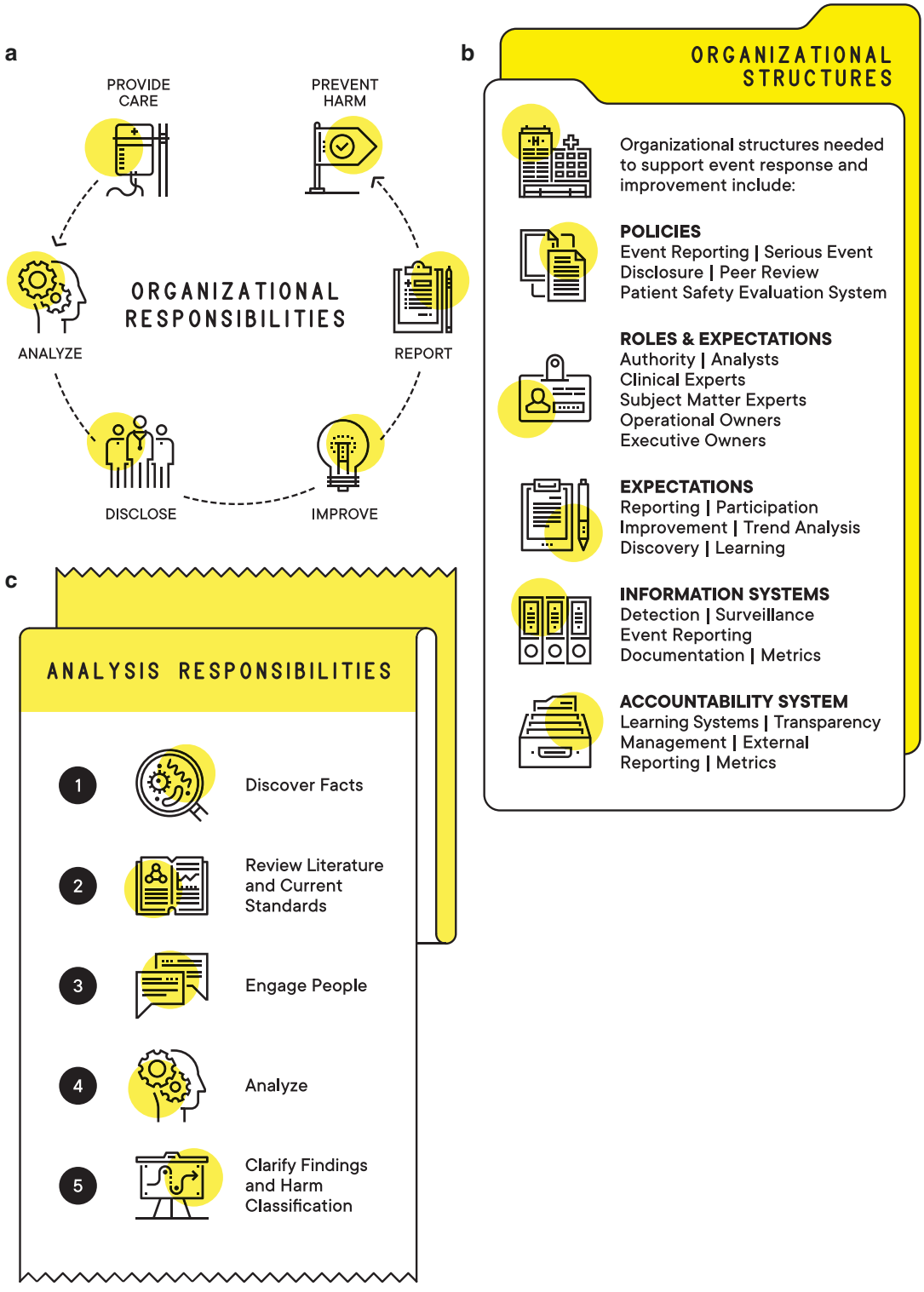

Fig. 6.2 Event response roadmap. **(a)** Organizational responsibilities; **(b)** organizational structures; **(c)** analysis responsibilities

will continue to evolve as long as harm events occur and as we broaden our lens in considering human performance within complex systems.

Understanding the Story

Vignette 6.1
Josea was admitted to the hospital for treatment of diabetic ketoacidosis (DKA). On the second day of admission, the plan was for the nurse to follow the titration protocol for fluids and insulin based upon glucose and bicarbonate levels that had been ordered. Josea's status began to deteriorate, so his nurse paged the physician who began to question the treatment plan and whether there was an additional cause of his DKA beyond the presumed viral infection. Rather than staying on the titration protocol, the physician changed the plan and ordered a consultation from infectious diseases colleagues. When Josea's bicarbonate levels continued to stay surprisingly low, a rapid response team was called. While the team was working through the diagnostic dilemma, uncertain of the cause of the surprisingly low bicarbonate levels despite the glucose levels normalizing, an intern noted that several of her patients had inexplicable changes in their electrolyte results. After calling the lab for clarification, it was discovered that a problem with an interface had resulted in errors in the lab result reporting for over 24 hours (correct lab results were reported with incorrect values). Once this was detected and the care plan was established based upon the correct results, Josea's fluids were slowed down to an appropriate level. The harm incurred included increased monitoring and lab work and he had to stay an additional day for extended monitoring.

We start by considering a case with detection of harm that is likely *preventable* but not *prevented* in this case. In fact, the situation described in this case could occur intermittently without detection, prevalent error, or harm. Historically, a response to this type of event would be to discipline the person with the closest proximity to the error as it was initially recognized. The application of accident models (described in Fig. 6.1) to understand cause and effect relationships has advanced our understanding of underlying systems, latent errors, and root causes. A first reaction, and perhaps the detail provided in an event report, may focus on why the clinical team did not question the inconsistent results sooner, complete a more thorough assessment, or recognize the pattern of abnormally low lab results. In this situation, a root cause analysis can be used for a more comprehensive analysis of the causal chain of events and an action plan that focuses on system-level improvements to address the cause and reduce the likelihood of recurrence.

This is a straightforward case that may be sufficiently understood using simple deductive reasoning to explore the causal chain of events to discover a root cause [12]. This approach is illustrated in Fig. 6.3 by asking why each step in the causal chain occurred and by considering weaknesses in layers of defense at both the sharp and blunt ends that, if strengthened, could have prevented the harm. This approach can be used to highlight a component failure in a causal chain of events, but the analysis is likely to only be effective with the engagement and candor of both the people involved in patient care and those that understand the underlying systems. Trust is essential to accurately clarify the chain of events through a review of data sources and interviews with staff involved. The patient experience should also be fully represented in the construction of the story. The value from an RCA often results from combined insights from a group that would otherwise never convene to collectively understand how parts of a complex system are causally related. Further value results from clarifying preventable actions in concert with system-level improvements. Sustained value comes when trust and collaborative approaches to understanding risks, detection opportunities, and harm prevention methods become pervasive through collaborative learning and improvement.

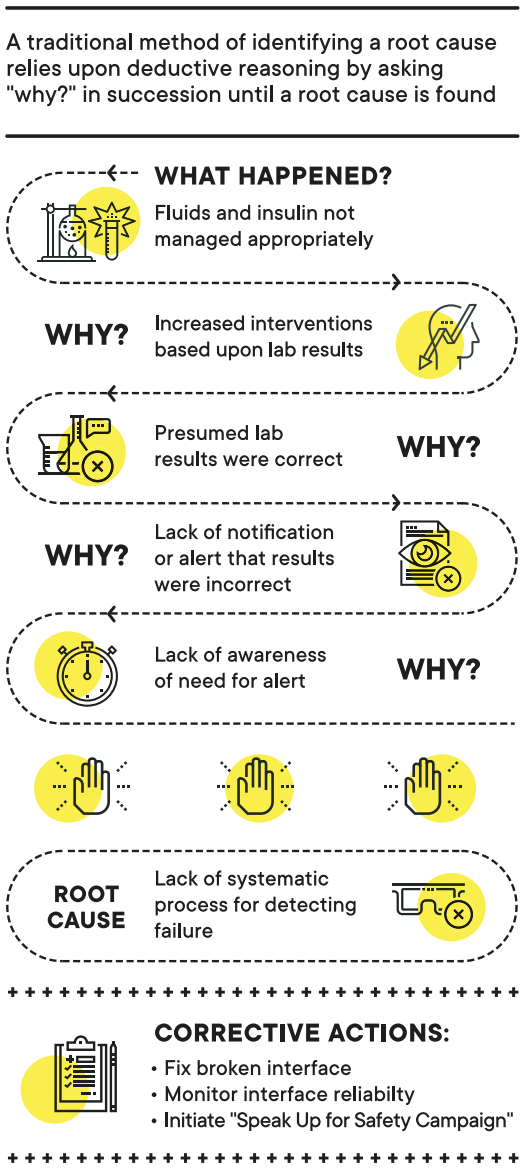

Fig. 6.3 Finding root cause by asking why

While this approach is likely to yield success in finding a system-level problem, sustaining success in fixing the problem is often not as simple as perceived when analyzing retrospectively. Further, generalized assessment of needed changes in behavior, such as encouraging staff to speak up, can be difficult to implement and may not address the underlying risks that contributed to the event occurrence. Fixing broken parts still makes sense, but preventing harm in complex and dynamic socio-technical systems is not limited to fixing broken parts but also requires attention to the longer efforts to change culture and build resilience. Braithwaite, Wears, and Hollnagel call attention to the need for a shift in approach:

> Even staunch health care supporters have gradually realized that real progress will require abandoning the Taylorist approach. Indeed, Berwick (2003) has indicated that: '… prevailing strategies rely largely on outmoded theories of control and standardization of work.' It seems to be a cornerstone of the human condition that people believe – or want to believe – that they will be able to solve today's problems, improve things, reduce errors, and ameliorate harm – all with just a few more resources, a bit more effort, another set of recommendations from a wise enquiry, a little more knowledge of the amount and rate of harm being delivered, increasingly precise measurements of system features, tightening up practices or a new whizz-bang IT system that is just around the corner. [13]

Traditional approaches of retrospective review often result in new policies and reeducation of staff. This type of response may result in some immediate risk mitigation, but the benefits are typically short-lived. The effort to engage front-line staff early in the investigation fosters trust and promotes open discussion and discovery of strategies to prevent harm, considering Dekker's insight that "the challenge is to create a culture of accountability that encourages learning. Every step toward accountability that your organization takes should serve that goal. Every step that doesn't serve that goal should be avoided" [14]. The trust is further developed and utilized when creating solutions that do not add additional complexity but rather improve usability and strengthen relationships to reduce risk in all situations and not only in situations involving the parties who otherwise would have been retrained or reprimanded. In this case, the reduction in risk relies not only on fixing the broken component but also on improving detection and awareness of this risk. With the complexity of caring for hospitalized patients, nearly all providers fail to challenge mundane things such as electrolyte reporting. In retrospect it might have been a clear cause, but the intensity of routine care does not make it plausible to challenge every result that

was not as the provider might have suspected. In fact, assuming all unexpected results are wrong can prompt trade-offs that could then further delay appropriate treatment or create distraction from important information needed for clinical decision-making.

A corrective action plan to address a root cause can be satisfying but carries a separate risk of hindsight bias, tunnel vision, and a tendency toward blame. These analysis pitfalls are illustrated in Fig. 6.4. In this case, the hindsight view may result in questioning why the lab was not called earlier because, with the benefit of hindsight, that action may have helped solve the problem more quickly. Efforts to mandate presumed solutions may result in adding complexity and burden that is ultimately not helpful in preventing the next event. Tunnel vision in the analysis of this case could be a result of focusing on the communications that did or did not happen and not recognizing some of the other factors in the socio-technical environment. The risk of blame is inherent in any event response that includes attributing an error to a specific cause. Even when there is no intention to blame, asking why they didn't know, didn't recognize, or didn't act is likely to result in at least a perception of blame.

In this case with a straightforward causal chain of events, the avoidance of blame can be a bit easier. That said, it is not uncommon for clinicians involved in the event to have already considered what they could or should have done to prevent harm from reaching the patient. This reflection is inherent in the culture of healthcare providers who have taken an oath to first do no harm. The effort to strengthen trust and limit the biases inherent in retrospective review calls for attention to the impact on second victims and the effort to ensure a just culture as emphasized by Dekker:

> Organizational justice does involve paying attention to second victims – practitioners involved in an incident that (potentially) harms or kills other people, and for which they feel personally responsible. There is a relationship between resilient individuals (who are supported in recovering from or even growing in the face of such inci-

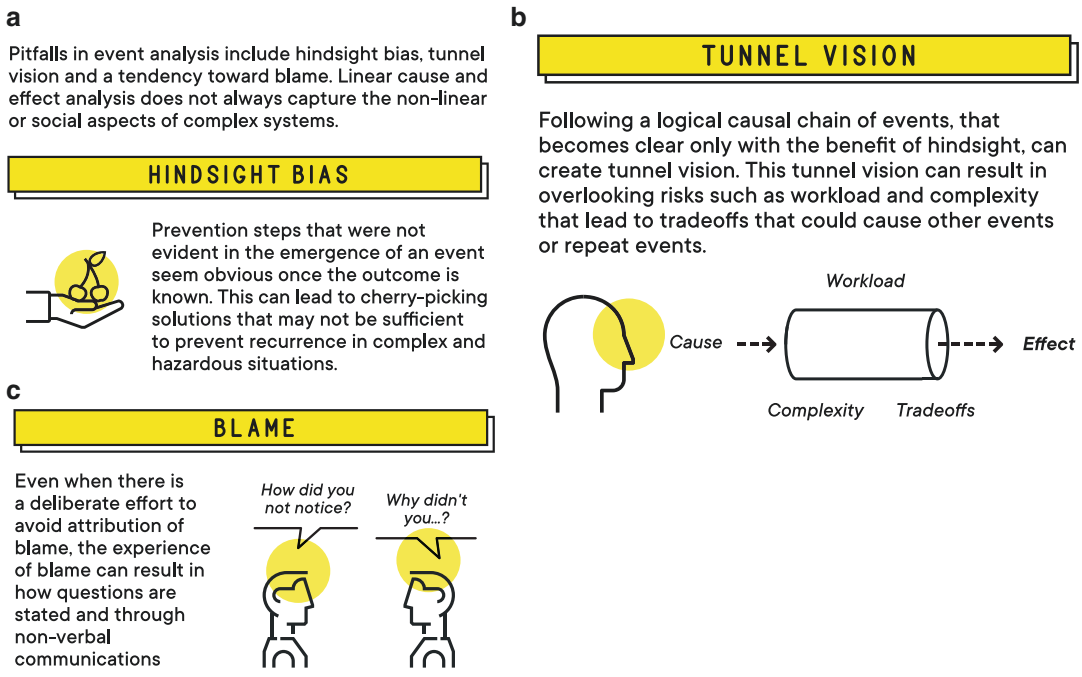

Fig. 6.4 Examples of analysis pitfalls: **(a)** hindsight bias, **(b)** tunnel vision, and **(c)** blame

> dents) and resilient organizations (which are able to face up to their vulnerabilities and learn from them). [15]

Awareness of the risks associated with second victims and just culture help shape inquiry that avoids asking staff why they did or didn't do something that is clear in hindsight but was not evident in the emergent situation. Questions that satisfy curiosity but do little to represent the realistic experience of those involved can further create defensiveness and limit candor. As Berwick describes, "Trust is central to this entire endeavour. Questions that are asked with distrust, jealousy, or defensiveness will not be authentic. Also, the answers will not be listened to" [2]. An understanding of how errors occur in complex systems and, in particular, how humans must adapt within complex and dynamic socio-technical systems helps to guide an effective inquiry process. In addition to authentically retelling the story of the event as it occurred, the safety analyst must be cognizant of the challenge of clarifying the causal relationship to harm while also showing the perspective that was experienced by those directly involved at the time of the event when the emergent problem was not evident.

Understanding the impact of the experience on patients and their families is paramount. The clinical team is often in immediate communications with patients and families that are trying to understand changes in the plan of care. While disclosure of errors is important, it can be challenging when the causes are not yet understood. In all cases, embracing reflective practice is important to clinician's evolution of practice; however, the participation in event investigation must foster reflective practice and trust rather than exacerbate a tendency toward blame including self-blame. It is also important that the avoidance of blame most proximate to the event does not just shift the blame elsewhere. For example, a finding that the clinical team is not at fault but shifting blame to staff in other roles stops short of finding a path to sustainable prevention of future harm. The evolution of thinking about accident models (Fig. 6.1) has helped illustrate the importance of not attributing blame at the point of care (the sharp end), but shifting blame elsewhere (the blunt end) is equally unproductive. Dekker goes even further to describe the risk of shifting blame to the system rather than the individual indicating that "at the sharp end, there is almost always a discretionary space into which no system improvement can completely reach. Rather than individuals versus systems, we should begin to understand the relationship and roles of individuals in the system" [16].

Increased attention to the experience of humans in the system has helped to improve the RCA approach keeping these analysis pitfalls in mind. As Dekker states, "of course we should look at the system in which people work, and improve it to the best of our ability. But safety-critical work is ultimately channeled through relationships between human beings (such as in healthcare), or direct contact of some people with the risky technology" [16]. Insufficient attention to perceptions of staff regarding both the authenticity and fairness of the analysis may limit improvement and learning opportunities and may also damage the trust relationship necessary for the prevention of future harm. Similarly, hindsight bias can further disrupt the learning and improvement journey and the effectiveness of the response. Hindsight bias can be so natural to the way humans respond once an outcome is known, that those involved with figuring out the find and fix may unwittingly predetermine the outcome of the analysis and event response. Dekker offers the reminder that "hindsight gets you to oversimplify history. You will see events as simpler, more linear and more predictable than they once were" [17]. That said, the goal is not to make the analysis more complicated or burdensome. The goal of the investigation process is to recreate the story of the event representing the authentic emergence of the event rather anchoring to a limited hindsight view.

The limitations of the effectiveness of RCA corrective action plans were highlighted by Wu et al. as they challenged the reliance on root cause analysis as the central method to learn from mistakes and mitigate hazards [18]. The commitment to learning and improvement must consider that a mindful approach to inquiry that extends beyond asking "why?" again and again can elucidate a far richer understanding of what happened and

why, while further promoting the trust relationship. For this, the involvement of people that can distinguish between work as imagined (WAI) and work as done (WAD) is essential. Hollnagel clarifies the risk overlooking the distinction between WAI and WAD:

> The difference between WAI and WAD may well be unavoidable, but it is not unmanageable. It can, however, only be managed if we recognize its existence and understand the reasons for it. The single most important reason is the human tendency to trade off thoroughness for efficiency. This is the reason why solutions often are incompletely thought through, and why we accept oversimplified descriptions as the basis for our plans and analyses. But we do so at our peril. [19]

This highlights the importance of involving frontline staff and diverse viewpoints. Also essential is a team with and knowledge in inquiry, investigation, and safety science and leaders willing to address conditions that limit human performance. Effective inquiry will yield more clarity than simply asking questions that begin with "why." Even with a goal to understand what has happened and why, in inquiry process must consider Hollnagel's clarification that "incidents and accidents do not only happen in a linear manner, but include emergent phenomena stemming from the complexity of the overall health system. Asking for 'why and because' does not suffice to explain the system in use and does not lead to an improvement in safety" [11].

The skills of effective inquiry are not easily explained and may need to be honed over a lifetime. At a minimum, effective inquiry involves listening and eliciting the story of an event from those that experienced it directly. That is, effective inquiry and analysis are not limited to illustrating a linear causal chain of events, but rather are an opportunity to recreate the story of an event as it emerged from the perspective of those involved and without the advantage of hindsight. The effort to elicit the story of the event, shown in Fig. 6.5, shows a nonlinear view that is not as tidy but may be a more realistic representation risk factors related to the emergent event. This approach also highlights the need for trade-offs at the time of care provision that may not be evident when focused only on the linear chain of events used to attribute cause and effect. Both the linear cause and effect relationships shown in Fig. 6.3 and the nonlinear relationships shown in Fig. 6.5 represent the story of this event, but the framing of the story can lead to different actions for improvement. The deductive reasoning used in Fig. 6.3 is used to identify a root cause to be addressed at the system level but overlooks some of the system complexities shown in Fig. 6.5.

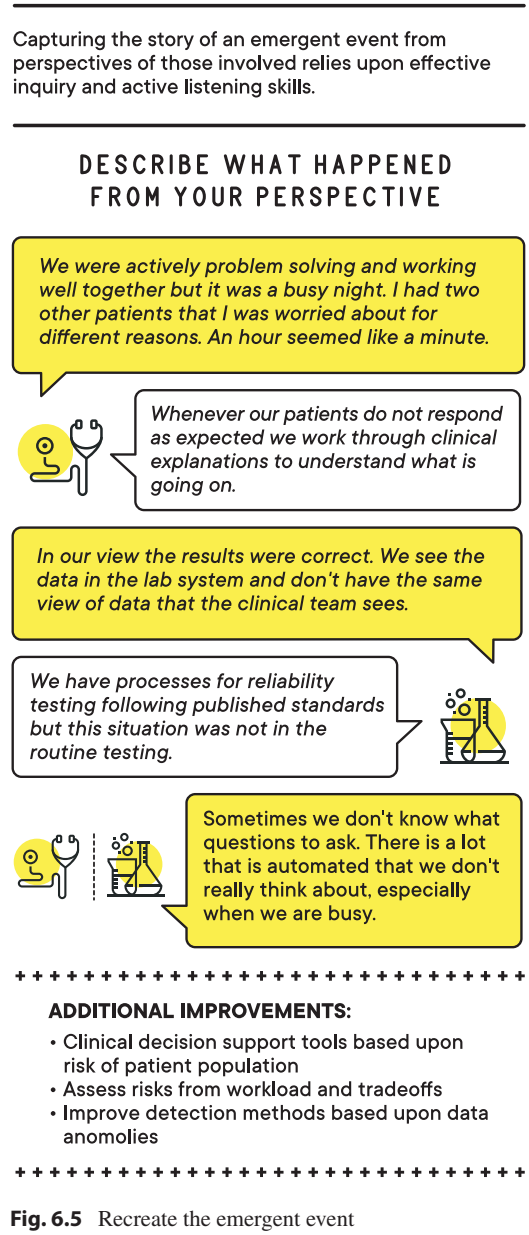

Fig. 6.5 Recreate the emergent event

To be sure, deductive reasoning is an intuitive way to think about error and has helped reduce harm events. In fact, deductive reasoning is a well-practiced skill used by humans to solve straightforward problems in everyday situations. According to Dekker, "Newton's and Descartes' ideas have pretty much set the agenda for how we, in the West, think about science, about truth, about cause and effect. And how we think about accidents, about their causes, and what we should do to prevent them" [20]. This explains our reliance upon reductionism to understand how systems work. That is, we can understand a complicated problem by taking apart the components and reduce to smaller components until the problem becomes understandable. In the case above, finding and fixing detected problems with the interface between information systems is important especially when this component failure could recur. This fix to this detected problem would prevent the same type of error that emerges in the same way. But is it also evident that issues excluded from this causal chain of events, including workload, user interface, and siloed workflows are factors that could cause additional errors that would not be addressed if we look only at the linear chain of events. The reductionist approach helps break down the system components along a specific causal path and is often easier to complete; however, it runs the risk of overlooking other critical aspects of system complexity that are necessary to fully appreciate the risk of other emergent errors and opportunities to ensure the safest care possible moving forward. While using reductionist thinking is a familiar approach for understanding complicated problems, it is not sufficient to understand complexity in adaptive systems [21] as clarified by Dekker in his examination of complexity and systems thinking. This suggests that we should go beyond the simple linear chain of events to consider how errors emerge and how they can be detected in the complex environments where healthcare is delivered. Attributing a cause to a system-level error is not a sufficient application of systems thinking. To understand how errors emerge from complexity, it is important to not just attribute a cause to a system component but instead to understand the risk represented in the emergent event experience as these risks are likely indicators of future errors if not fully addressed.

As we explore each additional case through this chapter, we will highlight both decisions and nuances that warrant some additional consideration while navigating how to respond to an event in varied situations. The emphasis on recreating the story from the emergent perspective is rooted in a recognition that trust will be lost if the story becomes infused with hindsight bias, tunnel vision, or blame. The emphasis on trust in this chapter also recognizes that that path of the next harm event may not follow the same causal chain of events. The event response and analysis experience of those involved will also have an impact on engagement in the detection of other risks that emerge from similar situations. By focusing not just on the component failure but also focusing also on the human experience, we can build a mindset of resilience regarding additional risks. Moreover, it is possible that the experience of those involved in the event analysis and response, either positive or negative, will have longer-lasting impact on the culture of safety and safe practices than the specific corrective actions identified (Key Points Box 6.2).

Key Points Box 6.2

- Recreate the story from the emergent perspective.
- Assess the entire situation including the effect on people rather than just cause and effect.
- Make trust and authenticity top priorities in event response.

Staying Ahead of Hubris

Vignette 6.2

In a busy primary care practice, the nurse called back a patient who coincidentally had a name very similar to another patient

in the waiting room. They shared last names and their first names differed by only one letter. Further complicating matters, these two young ladies were both 12 years old and were both there for well visits. Vanisha (the patient who was called back) had not completed her human papillomavirus (HPV) vaccination series, while Manisha had. Unfortunately, Manisha and her mother thought that it was Manisha who was called back, and the care team progressed with the visit of Manisha while charting in Vanisha's record. The physician discussed the need for HPV and influenza vaccination, the nurse drew up the vaccines, and just prior to inoculation, Manisha's mother pointed out that she had already received both doses of HPV vaccine. Initially, the nurse and physician challenged the mother's assertion, but eventually it became clear that there was confusion around the patient's identity. In discussing what happened in the office lounge over lunch, the physician was boasting that they got lucky that they didn't deliver an unwarranted vaccine. While the risk of side effects is low, there was no reason to accept any such risk. He was overheard by the practice's charge nurse stating, "I guess it's better to be lucky than good." While she agreed it was great that Manisha didn't have an unwarranted vaccine delivered, the wise words of Don Berwick, "Hope is not a Strategy," echoed in her head. She saw this as an opportunity to prevent a similar mishap in the future and recommended contacting the system's patient safety team who sanctioned further analysis.

It is often reported that the occurrence of harm events in healthcare is likely underestimated. One cause of this diminution of reported events occurs when the harm is prevented by mere chance or things that are out of the system's control. In this case vignette, there was no harm because a parent asked the right question at the right time to prompt the detection of this potential error. In the case of a no-harm or minimal harm event, there is no regulatory obligation to conduct an investigation or launch an improvement effort. Depending on the safety culture of the organization, this event may not be reported in a voluntary reporting system, or it may be reported, and the success of the avoidance of harm may be celebrated. While affirmation of positive safety behaviors contributes to building trust and resilience, the role of luck in this case should also be appreciated. When Weick and Sutcliffe describe characteristics of high-reliability organizations, they distinguish those that remain skeptical despite success indicating that "success narrows perceptions, changes attitudes, reinforces a single way of doing business, breeds overconfidence in the adequacy of current practices, and reduces acceptance of opposing points of view" [22]. Remaining wary despite a favorable outcome can mitigate the risk of overestimating reliability while underestimating the role of luck in preventing harm.

In this case the initial response to the event may be limited if the continued risk is not fully appreciated. The first reaction may focus on the atypical circumstances of the case and reassurance that the process works all the time, except of course, for this one unusual situation. Some may say that the error was caught because the system is working and speaking up just in time is an indicator of a strong safety culture. There may not be enough will to dedicate the time and resources to perform a timely and in-depth analysis in pursuit of reliability. Hollnagel considers the trade-offs in the resources spent digging deeper into causal chains:

> Since the purpose of an accident investigation is to find an adequate explanation for what happened, the analysis should clearly be as detailed as possible. This means it should not stop at the first cause it finds but continue to look for alternative explanations and contributing conditions, until no reasonable doubt about the outcome remains. The corresponding stop rule could be that the analysis should be continued until it is clear that a continuation will only marginally improve the outcome. [23]

When determining if a no-harm or minimal harm event warrants further investigation, it is

incumbent upon the organization to balance the potential lessons learned that prevent future harm against the effort and potential erosion of trust if the dedication of resources for an in-depth investigation does not make sense to those closest to the situation. In this case, the decisions regarding how to respond to the event are less about the determination of actual harm and more about understanding the complexity of the situation and likelihood of recurrence of the risk. The resistance to conducting an in-depth analysis could be overcome with persistence but the intended result of sustaining reliable changes in process and behavior may become even more elusive without the burning platform that is usually associated with harm events. The goal is not to analyze more but rather to engage staff in learning and improvement that includes remaining sensitive to the inherent risks. The decision on how to respond in this case is best informed by considering the approach that is most likely to garner the resources and commitment to improve.

Even with recognition of risk in this situation, the best path to learning and improvement may be found through less analysis and more attention to how clinical teams can partner with patients and families for better outcomes and experience for both staff and patients. A mature patient safety program has likely developed a portfolio of methods of event response that are not limited to root cause analysis. An alternative approach in this case is to consider is an apparent cause analysis to understand what happened. In cases where the causes or contributing factors are apparent, a decision to spend less effort digging into the causal chain of events and more effort on the improvement approach may be warranted. The North American Electric Reliability Corporation (NERC) suggests that the why staircase approach is typically a good fit for apparent cause analysis and further suggests different analysis approaches for different situations. Alignment of the right approach for the right situation considers both efficiency and effectiveness and recognizes that not all cases warrant the same approach used for more complex cases [24]. The use of apparent cause analysis is an option for judicious use of resources and can still lead to rigorous improvement by applying improvement science to the implementation as described by Crandall et al. [25].

The resistance to a full investigation for a near miss event does not have to be a barrier and can instead be used as leverage to focus on learning and improvement. If staff insist that the event is unlikely to recur because the process is usually reliable, there is also an opportunity to focus less on what went wrong and instead focus on understanding what happens when the process goes well and the importance of relationships and communication in assuring the best outcome. Dekker clarifies that the search for the root cause, or broken part, can be limiting. “If we want to understand why it ended up broken, analytic reduction doesn’t get us very far. Instead we need to go up and out, rather than down and in. We have to begin to probe the hugely intertwined web of relationships that spring out and away from the broken part, into the organizational, the institutional, the social” [26]. This suggests focusing on creating the culture and environment that supports human performance in risky situations. By shifting focus from the inquiry into what went wrong and instead considering the use of appreciative inquiry [27] as suggested by Trajkovski et al. as a way to understand what often goes right, there is a path to overcoming the resistance to both staff and patient and family involvement in the event response efforts. In some organizational cultures, this may yield better engagement in learning and improvement. Moreover, this process is likely to extend beyond fixing a process or technical component and, instead, extend further to consider relationships and how people adapt and collaborate for the prevention of harm.

A focus on the positive is often well received but must not overlook a realistic perception of risk. The effort to accurately assess risk can benefit from considering not only an internal assessment but participation in learning communities that foster greater transparency to better appreciate the risk. Events that are relatively rare occurrences are often perceived as unlikely to recur only because we lack perspective on occurrences elsewhere or lack appreciation for the severity of

potential consequences. This case vignette describes similarities to the confusion that led to the wrong procedure performed on a young child reported by the Associated Press in 2000. The report also described an overwhelming sense of devastation that the error had not been prevented [28]. Appreciation for risk and motivation to improve should not be limited because we lack frequent devastating events or publicity for close calls. This blind spot can be ameliorated by participation in a patient safety organization (PSO) or other learning communities that foster transparency of information about the pervasiveness of risk in healthcare environments. Greater transparent learning about harm and risk of harm can inform the assessment of rare events as they are detected more frequently when information is shared within a larger community with similar risky environments. To better understand the complexity, risk, and likelihood of recurrence, hazard assessment may be a more effective approach than cause analysis in this case. Again, the decision on how to respond considers the trade-off between a more detailed approach such as conducting a failure mode and effects analysis (FMEA) [29] or a simple hazard assessment matrix that highlights relationships between the probability of occurrence and severity of impact [5]. Both methods shown in Fig. 6.6 are similar in the factors considered in the assessment. The event response should consider the likely effect on the engagement of staff in sustainable improvement when choosing between the more thorough and detailed approach or the simple and efficient alternative. In this case the approach of using the simple matrix may be a sufficient first step to inspire the engagement in learning and improvement with continued sensitivity to the risk of harm.

As part of the event response process, it is common for events to be classified in terms of level of harm including near miss and minimal

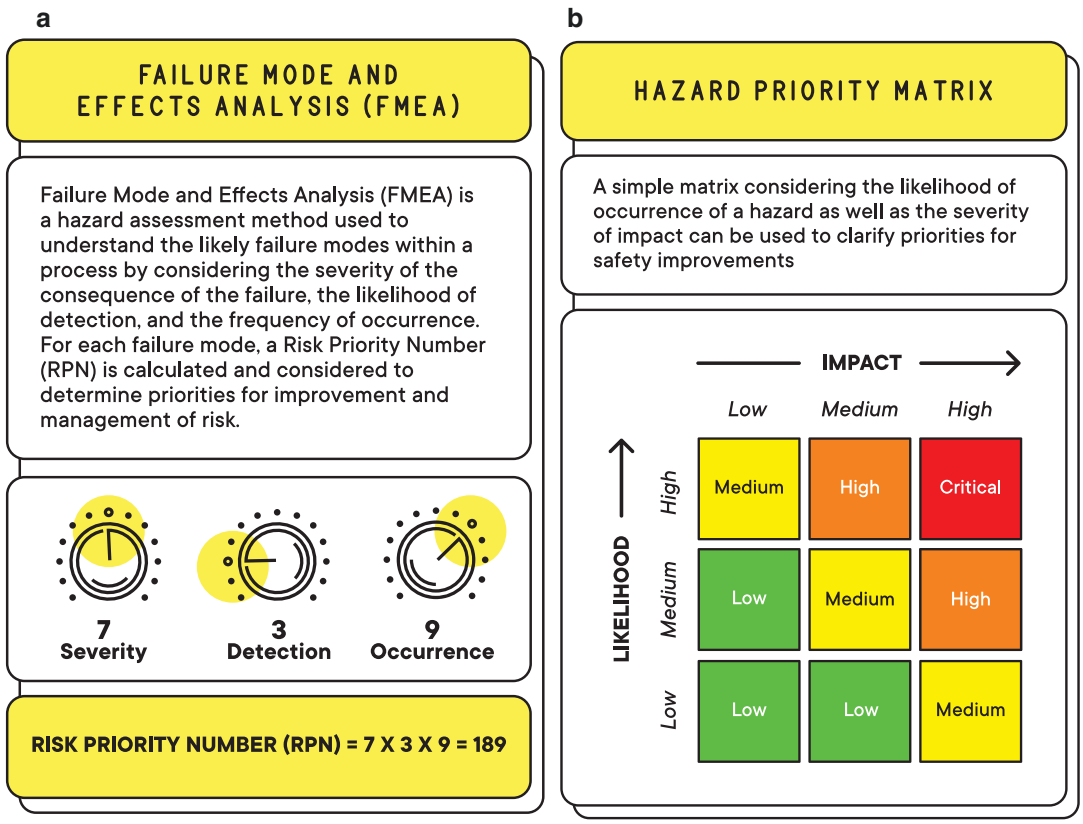

Fig. 6.6 Hazard assessment: **(a)** failure mode and effects analysis (FMEA); **(b)** hazard priority matrix

harm events. This event is not likely to be classified as a harm event because the patient did not experience actual harm. There could also be a debate on whether or not this event constitutes an error or if would be considered a near miss event. Hoppes and Mitchell summarize several harm classification systems in their white paper [30]. Regardless of what classification system or harm scale is applied, there could be some disagreement in how this event should be considered. While an effort is often made to assure consistency in classifying harm, consistency is elusive due to subjectivity in the classification process. Walsh et al. studied the reliability of harm classification and found that "Unfortunately, evidence to date suggests that clinician ratings of severity for adverse events are highly variable, with Cohen's Kappa coefficients ranging from 0.4 to 0.76. In spite of the importance of adverse event ratings, there has been little information on how to optimize the reliability of ratings" [31]. Williams et al. discovered similar challenges in reliability in assigning levels of harm [32]. Despite strategies to ensure inter-rater reliability, harm classification is often inconsistent. Pitfalls include distinguishing between potential harm and actual harm. There can also be subtle and subjective distinctions between levels of harm severity.

Does this matter? Application of harm scales is often used to clarify safety outcome data and to capture error rates to measure safety over time. Dekker challenges the usefulness of error rates as safety outcome measures indicating that "most organizations which have suffered big calamities over the past decades had exemplary performance on incidents and injuries" [33]. He further clarifies that an "organization does not have a great safety culture because it has a low number of incidents. In fact, the opposite is true" [33]. That is, robust detection and reporting may be a stronger indicator of safety than error rates that rely upon a subjective classification of harm. The Agency for Healthcare Research and Quality (AHRQ) also highlights the limitations to current data systems recognizing that event data cannot be translated to error rates without population data [34]. This specific case of a no-harm event illustrates that, regardless of harm classification method or outcome metric utilized, the risk in the environment identified will most likely not be reflected in the harm classification and therefore will not be reflected in an error rate. If harm classification data and error rates do not capture risks that show subtle changes in culture or gradual drift from safety-critical boundaries, they are unlikely to help with prediction or prevention of risks that are emergent from culture and complexity rather than a result of component failures.

What becomes more important is the engagement of staff in cultural aspects of learning and improvement. If the attention to error rates is the key to engagement in learning and improvement, then establishing trust in the reliability of those data becomes particularly important. Since harm classification has poor inter-rater reliability, understanding the impact of over-calling or under-calling the resultant harm is also important. Some organization cultures may find a better path to engagement by focusing on the positive outcomes and collaborative relationships. In some cases, it is perhaps better to give less attention to the harm classification and error rates and focus more on the collaborative culture needed to prevent a drift away from safety-critical behaviors and safety boundaries. The key point is again, focus on understanding how the decisions made throughout the event response will impact the experience of people involved. Each decision that enhances trust and improves culture is likely to benefit the longer-term goal of sustained improvement. A broader lens considering how to respond to an event can be realized by recognizing that focusing solely on finding and fixing a problem often does not result in reliable adoption of a change in practice. This is especially true when culture and behavior are part of the solution. The focus on trust, culture, and engagement of frontline staff in designing new ways to work is better aligned with improvement science methods that do not start with solutions, or corrective actions, but rather rely upon disciplined methods to engage frontline staff in designing improvements that are realistic and sustainable (Key Points Box 6.3).

Key Points Box 6.3

- Remain wary despite successful outcomes.
- Do not equate harm and hazard.
- Focus response to engagement in improvement.

Managing the Consequences

Vignette 6.3

Jason underwent the removal of a large lipoma that had appeared on his face. Prior to his to procedure, Jason's care team reviewed the procedure consent form with his parents. The procedure went as planned except the depth of the lipoma was greater than anticipated and closure was performed with unexpected difficulty. Jason was discharged after his outpatient procedure after the plastic surgeon chose to not disclose the unanticipated challenges as she thought there was an acceptable outcome despite the unexpected challenges. Notes in the outpatient chart indicated that Jason had a significant keloid development at the site. His parents expressed dissatisfaction with the results but stopped this part of the conversation when the surgeon stated that scarring was addressed in the consent form. Despite sensing the family was not pleased, the plastic surgeon discussed the plan for additional scar revision procedures. Jason's family agreed to the plan of care and left with the plan to return for a scheduled procedure. Prior to the procedure, an attorney contacted the hospital to request a copy of his records.

This case describes a situation that may not be identified for analysis or follow-up until medical malpractice activity raises concern about possible liability. Depending on reporting culture and surveillance systems, an unexpected outcome may be detected immediately; however, some complications may not be easily detected for further review or analysis. Once identified, if the outcome is not the expected or intended outcome, further consideration regarding preventability is warranted, but a presumption of error is not warranted. In this case, understanding cause and effect may not be as challenging as clarifying preventability and potential liability.

There is substantial improvement momentum in eliminating hospital-acquired conditions as shown in the results of the collaborative effort described by Lyren et al. [35]. This represents an important shift that many conditions that used to be accepted as known complications are now considered preventable. The shift in considering hospital-acquired conditions as preventable was made possible by collaborative work to develop the evidence base that clarifies how these conditions can be prevented with changes in practice. Yet there are still many complications where preventability is unclear. In their white paper, Hoppes and Mitchell offer a timeline that illustrates the shift in thinking about harm over several recent decades and further state that "Learning and improvement should also occur from events that are classified as known complications or no harm, as there is often opportunity for risk reduction in complications and no harm events and/or trends of events that may not be considered preventable at the time of occurrence. Learning from near misses is one of the tenets of patient safety" [30]. For many complications that occur in the course of care, clarifying preventability is not limited to understanding cause and effect but also understanding the current standard of care.

Determining deviation from the standard of care may not always require a comprehensive root cause analysis but does warrant some retrospective review. Hoppes and Mitchell emphasize the importance of understanding whether there was a deviation in practice standards and offer a decision tool that highlights both the reliance on evidence-based practice as well as assessing care decisions in the context of the situation when the outcome occurred [30]. Like the first case, the goal is to understand the story of the emergence of the outcome in the context in which it occurred. Response to this event should include a review of

the literature and current standards defined by policies or protocols. Many cases like this include decisions that include a trade-off of risk and benefit. Ideally, the risk and benefit relationship and consideration of a known complication would be clarified through communication and consent prior to the care episode; however, there may not be adequate anticipation or documentation to clarify risk-benefit trade-offs as they occur. There also should be an assessment of decisions made in managing uncertainty and reasonably unforeseen circumstances.

This is another situation that calls for caution regarding hindsight bias. Once an outcome is known it can be easy to cherry-pick a possible cause without looking at the complexity of managing the trade-off between multiple concurrent risks. Dekker suggests that it is important to "recognize that it is often compliance that explains people's behavior with norms that evolved over time – not deviance. What people were doing was reasonable in the eyes of those on the inside of the situation, given the pressures and priorities operating on them and others doing the same work every day" [36]. This highlights the importance of involving peers in the assessment of whether a deviation has occurred. The application of an algorithm such as the decision tree for unsafe acts [37] and applying the substitution test or a review of literature regarding management of known complications can be very helpful to assess if a decision was an error or a reasonable clinical judgment. The involvement of peers in the application of these tests is essential.

The response to this event should also include learning that is not limited to understanding the clinical decisions and processes. In some cases, the liability is created through breakdowns in trust rather than errors in care. Again, the analysis in this case may benefit from less emphasis on digging into the causal chain of events and more about understanding the communication and management of the trust relationship. Additional perspectives regarding patient-family experience and patient relationships can be valuable in this assessment. Focusing learning and improvement in detecting and containing the trust problem may offer a greater benefit than a determined effort to attribute the clinical outcome to a specific cause. In this case, the problem to be contained is the breakdown in communication resulting in the breakdown in trust.

This case also highlights the importance of disclosure as part of the event response. It is common for healthcare organizations to have policies that guide the communication of adverse outcomes. Policies may clarify the mechanics of the process but are likely insufficient support to those that must navigate these crucial conversations. The art of effective communication in disclosing adverse outcomes will be shaped by the organizational culture and will reflect both risk tolerance and approach to just culture within the organization. The skill and discipline in effective disclosure continue to evolve in healthcare organizations along with the understanding of the benefits and ethics associated with disclosure. Resources such as the Communication and Optimal Resolution (CANDOR) toolkit [38] can be a place to start. The effort to bolster or restore trust through disclosure of details of a complication, absent identification of an error, relies upon effective communication and a specific understanding of the trust relationship in question.

In this case, where the patient continues to seek care despite ongoing litigation, there is an urgency to restore the trust relationship. Regardless of the assessment of deviation or preventability, the priority is to manage the immediate needs of those involved. Dekker's explanation of just culture highlights the importance of restorative justice and suggests that "Restorative justice asks very different questions in the wake of an incident: who is hurt? What are their needs? Whose obligation is it to meet those needs?" [39] The consideration of these questions is not only applicable in considering communication and support for the patient but also for the others involved in the experience of the adverse outcome. Dekker succinctly describes reporting obligations and ethics for adverse outcome and disclosure:

> The ethical obligation to disclose your role in an adverse events comes from a unique, trust-based relationship with the ones who rely on you for a product or service. Disclosure can be seen as a marker of professionalism. Disclosure means making information known, especially information that was secret or that could be kept secret. Information

about incidents that only one or a few people were involved in, or that only professionals with inside knowledge can really understand, could qualify as such. [40]

In this case there is not an error to disclose but rather an opportunity to strengthen communication and understanding about the outcome and ongoing care. This case also reinforces the message that the event response is all about trust whether the focus is preservation of trust or restoration of trust. Both are important and the entire array of trust relationships, clinician to patient, patient to organization, and organization to clinician, should be considered when managing the response to this event.

Lastly, this case highlights the need to coordinate an array of resources to manage the event response. It is necessary to consider not only event investigation and improvement resources but also to assure a collaborative and aligned approach involving communication, patient relations, and disclosure processes. The alignment of these concurrent processes will help assure a cohesive experience for the people involved in all aspects of this event response (Key Points Box 6.4).

Key Points Box 6.4

- Event management is distinct from event analysis.
- Engage and leverage resources to manage and coordinate parallel processes (i.e., analysis, communication, patient relations).
- Attempt to restore trust through effective communication and disclosure.

Responding with Unanticipated Urgency

Vignette 6.4

Jackson was thrilled to hear that he was going to be discharged after being treated for congestive heart failure. He expressed his delight while reviewing his prescriptions and plan for follow-up visits at the time of his discharge. The timing was great as he was going to join his family on a trip the following week. Just before leaving for the airport, Jackson realized he did not feel well and went to the emergency department instead. During triage he asked if he could also visit the pharmacy to fill his prescriptions as he had not filled them after his discharge. Jackson was admitted, returned to baseline, and was then discharged late the next day. Two weeks later the hospital received a notification from the Department of Public Health that indicated that concerns were raised that Jackson did not receive adequate care prior to his first discharge which resulted in his readmission. Since the readmission occurred within 7 days, this case met the criteria for further review, and the hospital leadership expressed concern about financial penalties associated with readmissions. The care team indicated that they believed the readmission was related to nonadherence with his medication regimen.

This case is similar to the Vignette 6.3 in that it may not be detected until notification is received from an outside agency. Also like the case above, this could result from a patient complaint to a regulatory body, or it could result from external quality surveillance systems with different sensitivities than those used internally. For example, some external quality groups may prompt review based upon a readmission or the use of a billing code that may or may not be related to an error. In all events, the timeliness of the response is important, but in this case, the obligation to report findings externally may exert additional pressure on both the efficiency and thoroughness of the response.

To respond to this pressure, the initial investigation should consider the right type of analysis for the situation. It is important to recognize the

accreditation bodies share the goal of ensuring the response to the event advances understanding of how to identify hazards to be addressed to ensure safety and reliability in the system. For the case described here, there is less complexity in understanding the cause of the readmission and a need for greater attention on how to strengthen detection and containment. As Weick and Sutcliff indicated, while the unexpected is pervasive, "what is not pervasive are the well-developed skills to detect and contain errors at their early stages" [41]. While it is reasonable to assume that Jackson has culpability for having not obtained his prescriptions, stopping the review at this point will lead to missed opportunities to help future patients. Patients and families are often overwhelmed by the information at discharge and might not fully appreciate the importance of the timing of acquiring medications.

In this case an apparent cause analysis is likely sufficient to understand the factors that led to the readmission as long as it clarifies opportunities for better detection and containment of risk. McLeod and Bowie also highlight the usefulness of a bow tie analysis to understand both causal and contributing factors and safeguards necessary for detection, containment, and management of hazards [42]. As shown in Fig. 6.1, the bow tie analysis combines the concept of a fault tree and an event tree with the top hazard placed in the middle of the two sets of branching logic. While the branches of the fault tree consider potential causes similar to a root cause or apparent cause analysis, the addition of the event tree is utilized to understand consequences after the event occurs. This approach helps to expand the analysis to include not only consideration of how to prevent the hazard but also consideration of mechanisms needed to contain problems while they are small and steps that can still be taken to prevent harm. In this case, an improvement focused on containment may emphasize follow-up communication after discharge rather than focus only on what happens prior to discharge. Using the bow tie analysis method in this case may offer an efficient alternative to a root cause analysis and may also offer a broader lens to focus on the learning and improvement needed.

In this case, managing the event response requires a close partnership between resources that investigate events and resources that manage relationship and communication with the involved regulatory agency. This may be one in the same team or may include two groups working in alignment. The response to the event is not necessarily different than what would occur if the event had been detected internally; however, the learning and improvement opportunity may include attention to improving detection and surveillance systems and may also include opportunities to focus on proactive hazard assessment to better appreciate risks that are currently not sufficiently detected or contained.

This case also has similar challenges to the prior case in that the response to the event may highlight opportunities related to communication with patients and families. Subsequent care and communication rely upon restoring the trust relationship even though the regulatory agency may now be a participant in communications between the organization and the patient and family. While all parties have the shared goal of the best possible outcomes and experience going forward, the restoration of trust through all lenses will rely upon the effective coordination of communication and due diligence in responding to this event (Key Points Box 6.5).

Key Points Box 6.5

- Find balance between efficiency and thoroughness in response.
- Engage resources to manage and coordinate parallel processes (e.g., event response and communication with accreditation body).

Clarifying More than Causality

Vignette 6.5

Evelyn arrived at the emergency department via ambulance. She was stabilized at

an outside hospital, but given the complexity in Evelyn's condition, admission at the hospital with the team of specialists involved in her care was justified and a plan that comforted her parents. Although Evelyn was stable, there were many handoffs between hospitals, transport, and from the emergency department to the inpatient unit. During handoffs, it was unclear whether her antiepileptic medications had been administered, and at some point, it was assumed and reported that they had not. Subsequently, when she arrived at the unit where she was well-known, her nurse who endured several episodes of status epilepticus with her in the past and made sure she gave her medications as soon as she could get them on the floor. Unbeknownst to her, they had been given in the referring hospital, and this was a repeat and unnecessary dosing. She was noted to have increased somnolence, and the repeat dosing was identified. The levels drawn when the error was noted were found to be at the lower end of the range known to be at risk for toxicity. She remained somnolent well beyond the expected timeframe, and this led to a prolonged admission and further testing. While it was presumed that her change in level of alertness was due to the dosing error, her lack of improvement was not explained by this error, and this led to a delayed diagnosis of viral encephalitis. While this delay did not cause interventions to be withheld, it was realized that this could be a real risk in other situations when attributing symptoms to the wrong cause.

This is a case that presents unique challenges in understanding the best response. Traditionally, a potential error in diagnosis would only have been evaluated through a morbidity and mortality conference. This evaluation is still appropriate; however, with the increasing understanding of the complexity in healthcare, there is recognition of the benefit of understanding diagnostic errors through a systems view. The Society to Improve Diagnostics in Medicine highlights the National Academy of Medicine (formerly the Institute of Medicine) definition of diagnostic error "as the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" and additionally emphasizes "diagnostic error stems from the complexity of the diagnostic process, complexities in how health care is delivered, and the same kinds of cognitive errors that we all make in our everyday lives" [43].

An event report resulting in an analysis of a diagnostic event is likely to be prompted by an unexpected outcome that may or may not be caused by an error. This case is similar to the known complication case above in that the initial challenge is to clarify whether there was a deviation in the standard of care. Again, this determination will likely rely upon the expertise of peers, a literature search, and application of tools such as the substitution test. In this case a comprehensive retrospective review through a root cause analysis can help assess not only potential errors in the diagnostic process but also contributing factors from the complexity of the system and environment. What can be particularly challenging is understanding the factors that may be causally related to the outcome when it is difficult to clearly distinguish whether the outcome resulted from these factors or progression of the disease.

While conducting a root cause analysis meets the expectation to conduct a comprehensive analysis of causal factors, the pitfalls of a root cause analysis, including the risk of hindsight bias and misattribution to a component failure, are particularly evident in this case. Our understanding of why diagnostic errors occur and how to prevent them is developing but is not as well established as our understanding of process errors and component failures and how they can be fixed [44]. There is notable attention to learning in the medical community about the risks of cognitive biases and some promising attention to the development of clinical decision support resources, but there is still only limited evidence on how to detect and prevent the array of diagnostic errors that occur but are largely unreported.

A starting point may be a recognition that the nature of a diagnostic error is fundamentally different than a process error or a component failure. That would suggest that our response to this type of event includes understanding the performance shaping factors present in the situation and environment and that may mean going *up and out*, as Dekker suggests, rather than going *down and in* to attribute the error to a single root cause [26]. Contributing factors may not be limited to linear cause-effect relationships but may also include dynamic coincidences of performance variability with humans performing within complex adaptive systems. The analysis should appreciate the complexity in the system and consider the suggestion from Braithwaite, Wears, and Hollnagel's that "adverse events increasingly needed to be explained as unfortunate combinations of a number of conditions, rather than as failures of single functions or components – including 'human error'" [13]. Once again, the goal of the retrospective review is to recreate the story as it emerged from the perspective of those involved rather than through a limited hindsight view.

Since humans are integral to the diagnostic process, an analysis to understand diagnostic error must be informed by knowledge of human performance, complexity, performance shaping factors that influence decision-making, medical knowledge, and understanding of the diagnostic process. This means that the mental model of understanding causal relationship to error must shift from linear thinking about resultant events caused by linear component failure to considering emergent events that occur in dynamic and evolving situations where humans are adapting to unknowns and problem solving in the moment. Hollnagel's description of the efficiency-thoroughness trade-off, or ETTO principle, is particularly helpful in understanding this case. The ETTO principle describes the balance between time to think and time to do in the context of time pressure and, at times, competing priorities. Hollnagel further clarifies:

> The ETTO principle refers to the fact that people (and organisations) as part of their activities frequently – or always – have to make a trade-off between the resources (time and effort) they spend on preparing an activity and the resources (time and effort) they spend on doing it. The trade-off may favor thoroughness over efficiency if safety and quality are the dominant concerns, and efficiency over thoroughness if throughput and output are the dominant concerns. It follows from the ETTO principle that it is never possible to maximize efficiency and thoroughness at the same time. Nor can an activity expect to succeed, if there is not a minimum of either. [45]

A tendency toward greater efficiency could result in the wrong action, and a tendency toward thoroughness could result in an action that occurs too late. In this case the correct diagnosis was in the differential but was not quickly identified as the correct cause of the symptoms seen. Thankfully, because her viral encephalitis only required supportive care, there was no intervention withheld; however, it is easy to think of situations where this delay could result in an adverse outcome. The concept of managing the risk associated with trade-offs is particularly relevant for diagnostic challenges. While generally, thoroughness is aligned with the caution that could benefit safety, there are some situations that the risk of delay of intervention outweighs the importance of using thoroughness to assure certainty of the diagnosis and plan of care. While the trade-offs in diagnostic decision-making may be evident in hindsight, increased reliability relies upon conditions that support the ability of clinical teams to assure timely interventions while making sense of uncertainty often in rapidly evolving situations. Weick and Sutcliff offer that "sensemaking is about updating plausible stories, often by means of action, while looking for data that question initial hunches" [46]. Safety in light of diagnostic dilemmas relies upon constantly finding the right balance between efficiency and thoroughness trade-off decisions that are needed for both the diagnosis and the delivery of timely interventions.

A corrective action plan resulting from the analysis of a diagnostic error is likely to consider how to predict and prevent similar errors in the future. The limitation in predicting diagnostic error is, in part, due to the likelihood that

diagnostic errors are more likely to be emergent from complexity rather than something that could be predicted by interpreting data on previous no-harm or low-harm events. The mental model that near miss event reporting data is predictive for this type of emergent error may not be realistic. The experience of a retrospective review of this event is likely to become integral to the reflective practice of the providers involved but difficult to spread. Transparent and broader learning from retrospective case review is valuable and important to increase awareness of risk. The challenge in error prevention is this case is the pervasiveness of the ETTO principle in action in the complex high-risk environments where care is delivered. A corrective action plan in this case is not likely to be limited to quick wins or easily assignable tasks but instead is likely to include strategies to change collaborative culture and practices, to enhance team behaviors, and to support human adaptation in complex changing environments filled with uncertainty and competing pressures.

This case also highlights challenges related to just culture and adverse impacts on second victims that were described in previous cases. However, in cases with resultant harm, the effects on people involved are likely to be felt more acutely and profoundly. This event presents similar disclosure challenges as discussed in the previous cases, but based upon the outcomes, restoring trust in this situation can be difficult. The questions associated with restorative justice mentioned above are relevant in both cases: *Who is hurt? What are their needs? Whose obligation is it to meet those needs?* The event response in any case should also consider how to provide appropriate support to the patient, the patient's family, and the care team (providers) in the aftermath of the event experience.

The attribution of a harm classification to this event can also be challenging especially if the causal relationships cannot be determined with certainty. This effort should rely upon peers with the medical knowledge to assess the plausibility and probability of the presumed causal relationships. The uncertainty regarding causality and preventability could result in a subjective classification decision ranging between considering the event a significant safety event or not a safety event at all. Considering the challenges with inter-rater reliability in the attribution of harm, it may be difficult to find a standard to establish which harm classification outcome is correct. As described throughout this chapter, each decision has an impact on trust relationships. Looking outside of the organization either for external event review or event reporting to a patient safety organization or similar learning organization can help to guide these decisions. Similarly, a better understanding of just culture and restorative justice can also help shape these difficult decisions. Like all the cases considered in this chapter, what may be most important is how these decisions help guide improvement in the learning, improvement, and safety culture (Key Points Box 6.6).

Key Points Box 6.6

- Consider plausibility and probability when the causal relationship to outcome is uncertain.
- Understand efficiency-thoroughness trade-off in a realistic context.
- Attend to the second victim and just culture risks.

Summary

In this chapter we have considered an array of situations that highlight the decisions encountered while navigating the response to events that occur in healthcare organizations. Through each situation we have emphasized the importance of trust and authenticity; tritely stated – no two situations will have the same response. Determining how to navigate event response requires understanding the culture that exists within an organization and the culture that is needed, and that the path to a better future is created through trust. This emphasis is rooted in the belief that experience with harm events has a notable impact on the people involved, and that the people are the key to safety in complex and dynamic sociotechnical systems.

Safer care is reliant upon human ability to work collaboratively and adapt to complexity, problem solve, manage the unforeseen, and appreciate safety boundaries while balancing trade-offs. Because of this, the response to events must emphasize social relationships as much as causal relationships. Perhaps the greatest learning from harm events comes from the appreciation that humans are uniquely able to adapt to complexity and do so more quickly and naturally than processes, protocols, or technology. The key takeaway from this chapter is to assess each decision made while responding to harm events when they occur. Start by listening and understanding the experience of all the people involved in the event and continue to understand how each person experiences the key steps in the event response. Lastly, to increase the likelihood of sustained improvement, understand how each experience will influence the relationships, trust, and culture that are needed to support human performance needed to adapt and manage the risk of harm in complex environments.

Internet Resources

- Agency for Healthcare Research and Quality: AHRQ.gov [47].
- Erik Hollnagel website: www.erikhollnagel.com [48].
- Institute for Healthcare Improvement: IHI.org [49].
- Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org [50].
- Safety Differently: The Movie: https://youtu.be/moh4QN4IAPg [51].
- Teaching and Assessing Critical Thinking: https://medicine.dal.ca/departments/core-units/cpd/faculty-development/programs/TACT.html [52].

Editors' Comments

Embracing high-reliability principles can drive hospitals toward unprecedented outcomes in quality and safety. Many chapters in this textbook speak of the five principles of high reliability from Weick and Sutcliffe. Broadly the principles are grouped into anticipatory and containment; highly reliable organizations focus on anticipating where, how, when, etc. problems can occur, and they also have systems in place to contain them once they inevitably occur. This chapter deals with the second grouping from Weick and Sutcliffe, containment. The title of this chapter summarizes the point of Green and Budin: "What to do When an Event Happens: Building Trust in Every Step." The chapter, through the series of vignettes, demonstrates how trust in one another, our colleagues, and the system is the keystone of being ready for how to respond when an event occurs.

The chapter thoroughly explains the role of root cause analyses (RCA) and how they can drive an understanding of an event as well as the response and action planning; our organizations complete approximately 12 RCAs a year between our 2 organizations (editors, RS-SG). We believe that for our organizations with 500+ beds and 30,000+ pediatric admissions with large emergency departments and many ambulatory settings between our facilities, this number of RCAs is "healthy" for our organizations; too many would be onerous and not value add, and doing less than this amount would not provide a robust safety and quality program. Each organization will ultimately decide on what healthy rhythm and amount of RCAs are best for their culture. Not all RCAs represent events that go poorly, but we also try to learn from events that go well and celebrate these moments.

As the authors indicate in the fourth vignette, it is important for an organization to align their resources and responses to an event in parallel. This includes the event response (e.g., root cause analysis), inter-

acting with the family (i.e., disclosure, involvement of the ombudsman, etc.), the risk management component (reporting to the institution's insurer), supporting the second victim if one exists, etc. There are myriad tasks that should occur in parallel once an event occurs; to wait and line them up to accomplish them one-by-one can perhaps be deleterious and result in worsening a culture and not properly addressing latent system defects.

Ultimately this chapter moves us past simply performing rote steps in response to an untoward or unexpected outcome; the chapter implores us to use the culture of the organization and the trust that has developed to deftly navigate an appropriate response.

Chapter Review Questions

1. Describe how hindsight bias can affect the attribution of root causes in a retrospective review of a harm event.

   Answer: When considering an event through retrospective review, those involved in the analysis have the benefit of already knowing the outcome. This can lead to a belief that the same error will occur in the same way and that prevention is simple. While this may be true for some errors that result from simple process breakdowns, this is often not true for errors that emerge in complex adaptive systems. This can lead to selecting seemingly straightforward solutions that are not sufficient because they do not consider the challenges of making inevitable trade-off decisions in complex environments where conditions include managing unknowns or emergent challenges.
2. Describe the differences in methods used for retrospective review.

   Answer: Most accident models used for cause analysis focus on understanding failures considering linear chains of events. The bow tie analysis method considers opportunities for containment as well as opportunities for prevention. Effective use of inquiry can broaden the perspective to consider the story of emergent events without reliance on hindsight.
3. What are alternative approaches to event response when a retrospective review is not required?

   Answer: Alternatives include the use of hazard assessment tools such as failure mode and effects analysis (FMEA) or a hazard assessment matrix (see Fig. 6.6). Appreciative inquiry is another alternative approach for engagement in the discovery of improvement ideas when a retrospective review is not required.
4. True/False – Effective inquiry means always asking why five times.

   Answer: False. While the approach of asking "why?" five times is a structured approach to deductive reasoning, the limitations of this approach should also be recognized. Hindsight bias, tunnel vision, and attribution of blame are risks associated with this approach. The risks of these analysis pitfalls should inform an inquiry process that also considers complexity, competing priorities, and other factors that influence trade-off decisions. The best use of inquiry is to authentically re-tell the story as it emerged. Is it important not only to go "down and in" to understand linear causal chains but just as important to go "up and out" to understand trade-offs that occur in the complex adaptive system.
5. Identify the impact of key decisions in other situations such including: error affecting many patients, exposure to staff and patients, or staff injury.

   Answer: Each of these scenarios should include consideration of what resources are needed for event management. Similar to some of the cases described in this chapter, it is often not sufficient to focus on analysis and corrective actions but important to also consider management of the entire situation. An error affecting multiple patients will require consideration of how to manage the opera-

tions tasks of communicating, evaluating, and providing subsequent care to multiple patients. A situation involving exposure to both staff and patients may require separate but coordinated resources to urgently evaluate and care for both staff and patients. Lastly, response to cases involving staff injury may require the involvement of additional expertise and may involve different policies and information systems that are not always aligned with resources used in response to patient events.

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Communication with Disclosure and Its Importance in Safety

7

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Chapter Objectives

- To demonstrate the critical role of communication in contributing to and preventing medical errors
- To demonstrate the structure and processes needed to support effective communication
- To demonstrate how effective bidirectional communication drives a culture of safety

Vignette 7.1

An 8-month-old child required extracorporeal membrane oxygenation (ECMO) due to progressively worsening respiratory status. The child was admitted with a diagnosis of respiratory failure, and the team had increasing difficulty oxygenating the patient. Given the patient's illness severity and potential for a good resolution of symptoms with proper support, the decision was made to place the patient on ECMO.

This patient was located in the pediatric intensive care unit (PICU), and given the instability of the patient, the decision was made to perform cannulation of the blood vessels and initiation of ECMO at the patient's bedside. Per the surgical team's routine practice, the ECMO cart was readied outside the patient's room with the materials that are required for placement of the ECMO cannulas into the blood vessels of the patient. It is routine practice in this institution to place both the size of cannula the surgeon estimates will be required for successful oxygenation and filtration of the patient's blood and the next size down on the cart holding the materials. This estimation is made based on the child's weight,

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but anatomical differences can cause this estimation to fail, and at times, a catheter size smaller than originally estimated is required. Both of these cannulas are placed on the cart, so they will be immediately available to the surgeon performing the procedure.

The surgeon verified the cannula size needed outside the room and then returned to the patient's bedside to perform the procedure. It is the team's routine to place the desired size of catheter as well as the next size down on the sterile field so the equipment is at hand should vein size dictate a smaller catheter be placed. The scrub nurse placed the 27 French catheter on the portable table next to her while awaiting the procedure, but this table was moved out of the room unbeknownst to her to make room for the portable fluoroscopy machine. The surgeon took the catheter that remained on the surgical table and proceeded to cannulate the patient. The catheter size was not verified prior to placement into the child's blood vessel. In the operating room, a time-out is completed prior to surgery verifying the necessary materials and procedure to be completed. Outside the operating room, this is not a routine practice. In this case, no time-out was completed, and the patient was cannulated successfully with what the surgeon thought was a 27 French catheter and placed on the ECMO circuit. The actual catheter size was a 23 French catheter. The surgical team then left the PICU to perform another case in the operating room.

It was immediately noticed by the ECMO technician that the catheter placed into the blood vessel was not a 27 French catheter but was the next size down. The decision was made by the cardiac intensivist to attempt to use this catheter to provide adequate therapy. Throughout the night the ECMO technicians had difficulty maintaining appropriate blood flow volume through the ECMO circuit and thus struggled to provide the highest level of care to the patient.

The next morning, the ECMO team relayed the difficulties in achieving proper blood flow to the cardiac intensivist. The surgeon was also notified, and the decision was made to replace the 23 French cannula with a 27 French cannula. The family was notified of the error in placing the incorrect size catheter and the resultant difficulty with blood flow it caused. They agreed to have the second procedure to place the correct size catheter. The team completed this procedure which required the patient to be taken off the ECMO circuit for approximately 5 minutes, and during this time the patient had a medical arrest which required a short period of cardiopulmonary resuscitation with return of spontaneous circulation within 5 minutes. The child did well once the new catheter was inserted and was able to be weaned off ECMO at a later date with no apparent lasting harm.

Many adverse events involve communication difficulties. Approximately 30% of adverse events in the operating room and 70% of sentinel events, in general, involve a breakdown in effective communication [1]. Studies completed in the relatively controlled setting of the operating room still indicate that interruptions, distractions, and provider stress contribute to communication errors [2]. The case in the vignette was performed at the bedside in an inherently stressful environment where the patient required bedside ECMO cannulation. The chaos surrounding emergent cannulation stands in direct contrast to the controlled and planned environment of most procedures completed in the operating room.

This case highlights several communication-related opportunities for improvement among the team during the event itself. The first opportunity is in pre-procedure/event preparation. A team should always prepare prior to an event. Even in an emergent situation, a team has the luxury of

taking a few seconds to brief on the procedure, necessary equipment, possible complications/contingencies, and expected sequence of events. In this case, the team did not have this opportunity to "pre-brief" given the unstable nature of the child and the perceived necessity of a quick decision to place the child on extracorporeal membrane oxygenation. Regardless of the situation, there is always time to ask for quiet in a procedural space and for extraneous conversation to be held outside the immediate procedure area. This strategy of asking for "quiet space" can effectively reduce some of the chaos and distraction common in high-risk situations with clinically deteriorating patients [3]. Some organizations have employed similar strategies regarding medication practices. For instance, it is common to have a "protected zone" around the automated medication-dispensing machine where nurses can focus solely on selecting the proper medication prescribed and drawing up the correct ordered dosage. Often these areas are marked off by signage or tape on the floor, and other staff members are educated to not interrupt or distract the staff member involved in work requiring critical focus in that space (Key Points Box 7.1).

Key Points Box 7.1
A pre-procedural time-out or a pre-event brief can help to orient the team to the expected facets of a procedure, the necessary equipment, and potential areas of risk to the patient. Many studies link pre-procedural time-outs or pre-event briefs to improved outcomes for patients [3].

One communication strategy that the team did not use in this case was a pre-procedural time-out. The pre-procedural time-out reduces intraoperative errors [3]. One component of most time-outs is the inclusion of the specific equipment a practitioner requires to perform the procedure. In this case, had the team used a time-out and specified that the size of ECMO catheter was to be a 27 French, the scrub nurse would have realized that only the 23 French catheter was on the procedure cart and could have ensured the proper size were present (Key Points Box 7.2).

Key Points Box 7.2 Components of the Time-out
1. Verify the correct patient.
2. Verify the correct procedure.
3. Verify the correct site.

A vital aspect of time-outs is the closed-loop communication that they facilitate and require. Had the surgeon asked for a 27 French catheter explicitly and the scrub nurse confirmed they provided a 27 French catheter back to the surgeon, the inadvertent placement of the incorrect size catheter would have been avoided. One must use techniques to decrease error such as reading back an order that is given to the provider or asking clarifying questions to clearly delineate what is being asked of an individual. In this case, if the surgeon had paused to ask their colleague handing them the catheter to confirm that it was, in fact, the 27 French size they desired, the erroneous placement would have been avoided.

When physicians foster an environment in which they are open to others questioning them, this helps breakdown perceived power hierarchies between team members. The hierarchy in medicine can contribute to error because team members may not be comfortable speaking up and reporting problems in a timely fashion [4]. In the apparent cause analysis regarding this case, the team members related that there was no interplay of questions between the involved individuals, some of which may have been due to the hierarchical nature of the service that performed the procedure.

It is well known that hierarchy can be a detriment to safety culture [5]. In the past, the power gradient present between more senior leaders and direct reports have led to deadly consequences in industries outside of healthcare with one of the best-known failures was the KLM 4805 flight col-

lision in the Canary Islands in 1977 that killed 583 people in healthcare [6]. In this example, the junior pilot knew that the pilot's attempt to take off was an error but did not challenge the senior pilot due to cultural norms and deference to seniority. This silence was a contributing factor in this tragedy. Organizations that seek to employ high reliability principles in their safety work must seek to break down hierarchical power structures so that all members of an organization feel empowered to speak up and make patient safety threats known. An organization that encourages all members of the team to make safety threats known immediately can lessen the risk of events occurring and therefore lessen the chance of harm to patients.

Once an error occurs such as using the wrong size cannula in our case, it is our professional duty to disclose this to the patient and family. Many professional organizations such as the Joint Commission and the American College of Physicians endorse the practice of disclosure as a professional and ethical duty after an error occurs [7–9]. Patients and families also expect that we will be transparent and honest with them if an error occurs. It is also important to note that disclosure is a process and usually occurs over time as more information is available to help understand why an error occurred.

Before we go further in the discussion of disclosure, it is necessary to define what disclosure is. Full disclosure includes an acknowledgment that an error occurred as well as an explanation of the error and connection between the error and harm to the patient and further treatment to mitigate the error [10, 11]. Patients and families also want to know how the organization will prevent this from happening again. Of course, disclosure should be done in a way that the patient and family understand the event and its effects.

Studies have shown that barriers are still present to providing full disclosure to patients and families usually because of fear of malpractice [12]. Hospitals and health systems can offer support to physicians through their patient safety, patient advocate, and/or risk management departments to help guide physicians on how to do disclosure. Petronio et al. describe a two-step process called the Mistake Disclosure Management Plan (MDMP) for disclosure. The first step is to prepare the physician and the second step is mistake disclosure strategies. The preparation step considers the emotional impact of the error on the physician and also involves investigating the error to understand how it occurred. The mistake disclosure strategies step considers the timing of the disclosure, the people included in the disclosure, as well as the steps of disclosure including the event and an apology [12]. When an error occurs in a pediatric patient, parents determine whether or not their child should be present for the disclosure [13] (Key Points Box 7.3).

Key Points Box 7.3
Mistake Disclosure Management Plan is a two-step process for disclosure including a preparation step and a strategy step. The preparation step considers the emotional impact on the physician as well as the error investigation. The strategy step includes the timing of disclosure, people included in the disclosure, and the steps of disclosure.

Disclosing an error especially if there was harm to the patient is essentially delivering bad news such as a diagnosis of a new illness. As with delivering bad news, physicians need to prepare that patients and families may react emotionally and need time to process the information. Patients and families should be given time to process the information and the opportunity to seek clarification. This may even happen after the initial disclosure conversation has occurred. The physician should avoid blaming others or making excuses for the error as this may further erode trust in the hospital. The physician should also avoid speculating or jumping to conclusions as to why it happened especially if an investigation is still underway at the time of the initial disclosure conversation. Patients and families feel strongly that the attending physician involved in the error do the disclosure with the patient and family. This helps maintain trust in the physician and team.

Patients and families also want to know that the institution and physician take this event seriously and are committed to improving safety and preventing the error from occurring again. This may mean they want to know about specific improvements put in place to prevent a recurrence of an event for themselves and other patients [14].

Lastly, a key piece of disclosure is an apology. Patients and families appreciate an authentic apology because it is an act of empathy. As of December 2018, 39 states as well as the District of Columbia have apology laws to support medical professionals in apologizing to patients and families when something unexpected happens such as a medical error with harm. These laws help prevent saying "I'm sorry" to be used against a physician in a medical malpractice case [15, 16].

Some health systems including the University of Michigan Health System have adopted a communication-and-resolution program (CRP) to disclose unexpected patient outcomes either from complications or medical error. CRP includes disclosure and apology to the patient and family quickly while also investigating the outcome. If the investigation reveals a deviation in the standard of care, then the institution offers a financial settlement to the patient and family and makes system improvements to prevent the outcome from transpiring in the future. If the care provided was appropriate, then the institution shares the findings with the patient and family and defends the physician if litigation ensues [16].

Vignette 7.2

The members of the team realized several opportunities for improvement in the practice of ECMO cannulation and desired to perform a cause analysis. The team members performed this analysis with all team participants including the surgeon who placed the catheter and the cardiac intensivist. They determined the gaps in practice that allowed the mistake to occur. One key gap identified was the omission of the time-out process. The time-out was not completed because it is not routine to complete a time-out when not in the operating room despite the staff members all being surgical staff. This realization led to an organization-wide decision to require a time-out whenever a procedure is done, regardless of physical location. This decision was disseminated through presentations at the surgical morbidity and mortality conference, the ECMO morbidity and mortality conference, and the hospital-wide surgical quality assurance conference.

Key Points Box 7.4.

Key Points Box 7.4

Response to a patient harm or near miss event should first be to establish patient safety; second to sequester any equipment, devices, or products involved; and to begin an investigation or review of the event [17]. The purpose of an investigation is to gain an understanding of what led to the event's occurrence and to assist in determining an apparent or root cause(s). By identifying the cause, corrective and preventative actions should be set to proactively prevent the recurrence of the same or similar event.

Effective communication plays a crucial role during the investigation and interview process, and also after the root cause(s) has been identified to close the feedback loop. Lack of or insufficient communication can also be a cause of an error. In the apparent cause analysis regarding the case of the wrong size cannula placement, the interviewed team members relayed the lack of communication was part of the root cause of the event that led to a secondary procedure to replace the cannula.

Just as closed-loop communication may have prevented the error from occurring in our case, closing the communication loop, known as a feedback loop of a root cause analysis or apparent cause analysis is just as important. Communicating outcomes of an incident analysis should occur with those involved, those who reported, those that may be affected in the current state and future, and especially team members and leaders held accountable for implementing recommendations as determined in the analysis [18] (Key Points Box 7.5).

Key Points Box 7.5 When Communicating Outcomes of an Incident Analysis, Make Sure to Communicate to

1. Individuals who were involved in the event
2. Individuals who reported the event (if they were not involved in the event)
3. Individuals who may be affected by the current and future state
4. Individuals held accountable for implementing the recommendations from the analysis

Participating in an investigation after being involved in an event can be intimidating, and even frightening. Verbal communication, from the interviewer to interviewee, should explain the purpose of the investigation, not assign blame and clearly communicate that the interview is being conducted to identify system issues or vulnerabilities [17]. Effective communication techniques of the interviewer include active listening, open questioning, and paraphrasing to verify what was heard (Key Points Box 7.6).

Key Points Box 7.6 Interviewer Techniques for Effective Communication Include the Following

1. Active listening.
2. Open questioning
3. Paraphrasing to verify what was heard

Information collected during the interview process is assembled as a visual tool – examples include process mapping and cause and effect or fishbone diagram – used to communicate the event flow and contributing factors, and used to highlight gaps or opportunities for improvement. Clear and concise delegation of action items to responsible parties can be considered part of the feedback loop after an event.

All patient safety issues may not lead to a full investigation and analysis process. Incidents submitted through electronic reporting or paper methods also require feedback loop communication. For example, if actions resulting from submitted incident reports were shared with the original submitters, they would gain a better understanding of the potential benefits to future patients and the health system of increased and timely event reporting. They would also see that these benefits outweigh the challenges of report entry and the associated risks. The timely reporting and resolution of problems is integral to journey to high reliability which is discussed in other chapters of this text [19].

Vignette 7.3

The safety event classification team reviewed this case at a regularly scheduled meeting. The ECMO and perioperative team involved presented their report on the event and made recommendations for practice improvements to ensure this type of error would not happen in the future. These recommendations were publicized throughout the organization. Appropriate reports were made to the state as this case involved an improper implant which requires reporting in this hospital's state.

The importance of communicating medical errors throughout the organization cannot be underestimated. According to the Lucian Leape Institute, established by the National Patient Safety Foundation, transparency is the "most important single attribute of a culture of safety"

[20]. Healthcare organizations with strong safety cultures are transparent in the sharing of medical errors because they aim to prevent future events. In the absence of transparency, distrust and hostility permeate the organization [20]. The landmark publication *To Err Is Human* shed light on medical errors by highlighting that the majority of errors do not result from individual negligence but rather are caused by broken systems that inadvertently set caregivers up to make mistakes [21]. Healthcare leaders must encourage and reward frontline team members for reporting near misses to identify possible broken systems. Early reporting helps prevent future errors which may have devastating effects on patients especially if the error reaches the patient and causes irreversible harm [22]. As healthcare leaders have increased their knowledge around medical error causation, organizations have begun encouraging caregivers to share events to identify necessary system and process improvements [21].

Healthcare leaders must appreciate that organizations often sustain collective harm in self-esteem and confidence following significant medical errors [23]. Witnessing or hearing about medical errors reminds us of our own fallibility and the delicate nature of the procedures and treatments we routinely perform on patients every day. Caregivers must feel safe in their environment to openly discuss medical errors, and they must believe they will be treated fairly for disclosing mistakes [24]. Healthcare leaders contribute to building this environment and earning caregiver trust by compassionately communicating medical errors and supporting those involved. The transparent communication of medical errors is essential to promote healing and performance improvement throughout the organization [23].

When preparing to communicate a medical error throughout the organization, it is vital to consider who will be communicating the message, what will be communicated, and how it will be communicated. Individuals involved in the medical error communication should know the event well and understand the key learnings. The individuals should communicate the medical error in a sincere, compassionate, factual manner. Individuals must reliably communicate the event to build trust and collegiality among team members. Individuals should not invoke their personal opinions or judgments into the report. Ideally, the individual or team communicating the medical error should also understand systems failures to prevent delivering a message of blame and shame. The team communicating the medical error should partner with the hospital or department leadership, quality and safety leadership, as well as risk management and/or the legal team, to provide input into the message. Often, quality and safety leaders communicate medical errors at various councils throughout the organization and are very effective at doing so. However, leaders should not miss the opportunity to allow those involved in the medical error to participate in communicating the event if they wish because doing so keeps them a part of the learning and reduces their feelings of isolation [24]. Team members involved in events often grieve and need to be included in the solution. By involving the affected team members when sharing an event, those involved understand the process better and often find support from their colleagues. This may be critical to keep them engaged in their profession and prevent them from leaving healthcare (Key Points Box 7.7).

Key Points Box 7.7 Event Communication
When communicating an event, ensure that those involved with the event – hospital and department leadership, quality and safety leadership, as well as risk management and/or the legal team – provide input into how to communicate the event and follow up.

The National Patient Safety Foundation advises medical errors should be communicated with the goal of improving care [24]. Therefore, individuals must consider the appropriate places to share the medical error, the purpose of sharing the medical error, and how much detail is needed to effectively communicate. For example, significant medical errors should be communicated to the healthcare organization's executive leadership team and quality board because they are

responsible for prioritizing transparency, safety, and continuous improvement [24]; in the quality improvement parlance, this is referred to as "spread." This can be accomplished by showing pictures or taking them to the clinical space where the event occurred to show them how it could happen. This can be a very powerful experience for leaders and board members. In general, communication at this level involves a general overview of the error, contributing factors, and strategies to prevent the medical error in the future. It is also important to assess the clinical knowledge base of those on the executive team or board when you are communicating. When the ECMO case was presented to the quality board, board members immediately questioned why two different sizes of ECMO cannulas were even available in this situation. From their viewpoint, having only one size catheter available would be an easy fix. However, the clinical leader presenting the case was able to paint a picture to the board of what it looked like to connect a patient to ECMO and how complicated the procedure was. The clinical leader was able to explain how not having both sizes available would be detrimental to the patient if the team had to run throughout the hospital to find another size and how it is not a rare occurrence to need a different size. The board understood the complexity of the situation following the explanation and gained a better understanding of why time-out procedures are critical and need to be hardwired outside of the operating room (Key Points Box 7.8).

Key Points Box 7.8 Spread the Message
Individuals must consider the appropriate places to share the medical error, the purpose of sharing the medical error, and how much detail is needed to effectively communicate.

Medical errors should also be shared with frontline caregivers to promote vigilance and identify system and process improvements [23]. Hospital quality councils or morbidity and mortality conferences often serve as the venues for medical error communication. Some organizations have scheduled quarterly or monthly sharing of events to ensure the learnings are spread. Individuals sharing the case in these venues often provide more detail around the event including a synopsis of the patient's clinical presentation, happenings leading up to the event, the event itself, the patient outcome, causative factors, suggested mitigation strategies, and how the event impacted the clinical team. Caregivers directly involved in the event should be made aware that the case will be discussed in the venue. When medical errors occur, caregivers often lose confidence in themselves and still feel accountable even if the case is treated and discussed from a systems perspective [25]. These caregivers have been referred to as second victims and often experience significant emotional turmoil after the event and need support from their colleagues [26, 27]. Therefore, involved caregivers should be included in the communication process, and their concerns should be addressed before releasing the event information. Not doing so will compromise transparency efforts [21]. Moreover, most caregivers involved in medical errors want to contribute to future prevention efforts, so it is worth the extra effort to ensure they are treated with compassion and respect throughout the communication process [23, 25] (Key Points Box 7.9).

Key Points Box 7.9 Second Victims
Caregivers who were directly involved in the event often lose confidence in themselves and still feel accountable even if the case is treated and discussed from a systems perspective [25]. They often experience significant emotional turmoil after the event and need support from their colleagues.

Event sharing in these venues often leads to a robust discussion about the event and potential system fixes, so these conversations need to be facilitated by informed, well-prepared individuals identified in advance. In today's environment, these discussions are often very supportive and

even therapeutic, but the facilitator must be prepared to address and discourage any comments that are hurtful or discouraging to the caregivers involved. The facilitator's primary focus during these discussions should be to maintain a safe environment for everyone to discuss the medical error; not doing so will quickly erode the trust of the caregivers [23]. Healthcare leaders should keep in mind these discussions are critical to identify future medical error mitigation strategies and to promote a safe culture, but the discussions will only be effective if caregivers feel comfortable discussing cases. When the ECMO event was discussed in the hospital quality council, the clinical team involved in the event presented the case and were relieved to find themselves surrounded with support from their colleagues. The council also agreed to support hardwiring the time-out process throughout the hospital following the discussion of the event.

Quality and safety leaders should also report medical errors to their patient safety organizations (PSOs) if they are involved in one. There is power in reporting significant medical errors to the PSO because the data is compiled and analyzed with other like organizations and trends are often identified that would not have been identified at the individual facility level. The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) has enabled the creation of PSOs and provides federal legal protection to information reported to a PSO for the purpose of improving patient safety [28]. The event investigation information gathered and reported to the PSO is called "patient safety work product (PSWP)" [28]. It is important for quality and safety leaders to understand this protection to address any concerns their organization has with sharing this important information with the PSO; of course, we suggest this be done in collaboration and with engagement from your organization's risk management team (Key Points Box 7.10).

Key Points Box 7.10
Caregivers often appreciate knowing their organization shares safety events with other organizations to prevent harm beyond their walls.

Communication is woven throughout healthcare delivery and is critical to ensuring the highest quality and safest care. As illustrated by the case vignette, breakdowns in communication can lead to unintended outcomes and preventable harm. However, communication must be leveraged to help patients, families, and team members recover after the event and be used to help prevent future events. Strong communication only enhances quality improvement and patient safety efforts to make systems safer and more reliable. The communication of medical errors is critically important in promoting a culture of safety. Healthcare leaders should not underestimate the power of transparency in preventing future harm.

Editors' Comments
The prior chapter helped the reader understand how to respond when an event occurs; this chapter builds on the prior chapter by going deep on the topic of communication and disclosure after an event. A key phrase by the authors in Chap. 7 is "bidirectional communication" – by understanding and communicating with front line and families and subsequently listening to them, trust can be built and lead to a successful resolution.

The authors cite the commonly known literature that attributes communication breakdowns to harm. This is perhaps one of the key learnings of the chapter and one that the editors of the textbook have seen time and time again in their institutions and when reviewing events that have transpired in other organizations. As the authors astutely point out, there are myriad forms of communication and breakdowns that can occur. The corollary is that there are many opportunities for communication to help and ameliorate an issue – the chapter highlights several of these (e.g., time-out).

A significant portion of this chapter explains the importance of disclosure and how to properly communicate such. It is not as simple as saying "sorry." The authors explain the role of a Mistake Disclosure

Management Plan which is an excellent resource that organizations should consider having ready to use when necessary.

The chapter also provides a primer on how to communicate through an organization regarding an event that has occurred. In our institutions, we inform the entire hospital as well as the board when a significant error or similar instance occurs. The authors nicely take the reader through steps that need to be considered when reporting through an organization and beyond as well as to when report.

As we have seen in other chapters, the authors do again discuss the importance of communication with regard to those affected or involved with the error, issue, etc. As organizations continue to advance their culture toward high reliability, we must always be aware of those involved with the issue.

Chapter Review Questions

1. Effective communication/interview techniques during an event review include:
   A. Active listening
   B. Using open-ended questions
   C. Paraphrasing what was heard
   D. All of the above

   Answer: D. Explanation: Verbal communication, from the interviewer to interviewee, should explain the purpose of the investigation, not assign blame and clearly communicate that the interview is being conducted to identify system issues or vulnerabilities [17]. Effective communication techniques of the interviewer include active listening, open questioning, and paraphrasing to verify what was heard.
2. Closed-loop communication should be used to:
   A. Reduce misunderstandings.
   B. Keep the conversation between two individuals.
   C. Reduce unnecessary dialogue.
   D. Convey "you" statements.

   Answer: A. Explanation: Closed-loop communication is used to clearly communicate information and should explain the purpose of an event, reduce misunderstandings, and can occur in a team setting. It should be non-judgmental as well.
3. Full disclosure of an error includes the following except:
   A. Acknowledgment that an error occurred
   B. Explanation of the error and harm it caused
   C. Blaming the person who committed the error
   D. Treatment plan if harm occurred

   Answer: C. Explanation: Full disclosure includes an acknowledgment that an error occurred as well as an explanation of the error and connection between the error and harm to the patient and further treatment to mitigate the error. Blaming the individual who committed the error is not productive and not part of the full disclosure process.
4. Response to patient harm involves which of the following:
   A. Establish patient safety.
   B. Sequester any equipment, devices, or products involved.
   C. Begin an investigation or review of the event.
   D. All of the above.

   Answer: D. Explanation: Response to a patient harm or near miss event should first be to establish patient safety; second to sequester any equipment, devices, or products involved; and to begin an investigation or review of the event. The purpose of an investigation is to gain an understanding of what led to the event's occurrence and to assist in determining an apparent or root cause(s).
5. Significant medical errors leading to harm should be shared with all of the following:
   A. Patient involved.
   B. Frontline staff
   C. Executive leadership
   D. Board of directors
   E. Patient safety organization
   F. All of the above

Answer: F. Explanation: Significant medical errors leading to harm should be communicated with all of the above parties to ensure that the patient receives the appropriate treatment in response to the error and to prevent the error from happening again in the institution as well as other institutions.

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Using Data to Drive Change

8

Lisa L. Schroeder

Chapter Objectives

- To describe the importance of data in the design, implementation, and assessment of improvement work
- To describe key differences in qualitative versus quantitative data and the advantages of each in driving improvement
- To explain the differences in information gained from run charts versus control charts
- To understand the value of Pareto charts and scatter plots in the improvement process

Vignette 8.1

A Pediatric Emergency Department (ED) and Level 1 Trauma Center with over 67,000 visits annually admits approximately 9% of presenting patients. As one of the hospital's board metrics, the ED tracks the proportion of patients leaving without being seen (LWBS) by a provider. While the daily LWBS rates are often low (<1%), some days the rate reaches over 10% of patients presenting for care, and averages have been running at approximately 3.3% (over 2000 patients/year). Benchmark hospitals consistently record rates of less than 2.5% with low variability. ED leadership has followed this number for years but has had difficulty driving change, partially due to the multiplicity of factors that they believe drive the LWBS rates, including seasonality, acuity, overall numbers of patients daily, hospital inpatient census, staffing, efficiency of providers, etc. Hospital administrators have challenged the ED to reduce these rates, emphasizing that the emergency department is the primary portal of entrance for the majority of admissions and should be the first choice for parents with sick or injured children.

Opening Question/Problem

This chapter is not about specific tactics to reduce the number of patients leaving prior to being seen in the ED, nor is it about teaching statistics; it is

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about learning to utilize data in several different formats to help assess situations, develop action items, and track progress toward incremental improvement goals. Providing frontline caregivers actionable, visible, meaningful data around team-level goals supports improvement initiatives that drive change.

> It is a capital mistake to theorize before one has data. Insensibly one begins to twist facts to suit theories, instead of theories to suit facts. (Sherlock Holmes [1])

Data as Foundational to Improvement

Healthcare represents a complex, ever-evolving, and sometimes unpredictable system. Driving change in such a system can feel daunting and perhaps even unachievable at times. In an attempt to provide some direction for the assessment of quality of care, Avedis Donabedian proposed a shift from focusing primarily on the outcome of medical care in defining quality to focusing on a triad of measures, comprised of structure, process, and outcome measures in his 1966 landmark article "Evaluating the Quality of Medical Care" [2]. In this foundational model, "structure" refers to the resources available, qualifications of providers, governance, etc., "process" relates to the way the work is done or the components of care, and "outcome" indicates the result achieved. He further points out that focusing on outcomes as measures of quality, while important, must be done with discrimination. The use of outcomes alone to validate the quality of care contains inherent risks. First, not all outcomes are easily measured. While results such as mortality are straightforward, parameters such as satisfaction or quality of life may not be clearly defined. Additionally, the question of relevance comes into play when considering outcomes as measures of quality. For example, survival as a sole criterion of success may not be appropriate in situations that produce severe crippling conditions or poor quality of life. Finally, measuring outcomes alone does not provide insight into the factors that may have attributed to the overall outcome. In response to this message, Dr. Donald Berwick suggested that the priority of measuring quality should not hinge solely on end results, but rather "a more subtle interplay among structure, process and outcome" [3].

Donabedian goes on to conclude that in order to drive change "more often one needs to ask, 'What goes on here?' rather than 'What is wrong; and how can it be made better?' This does not mean that the researcher disowns his own values or social objectives. It does mean, however, that the distinction between values and elements of structure, process or outcome is recognized and maintained; and that both are subjected to equally critical study. Partly to achieve this kind of orientation, emphasis must be shifted from preoccupation with evaluating quality to concentration on understanding the medical care process itself" [2]. As more emphasis is placed on quality improvement in healthcare and more resources are focused on eliminating harm, it is important to understand the impact of initiatives that are proposed or put into place. This understanding is best achieved through the gathering and interpretation of data, in both qualitative and quantitative forms. Merriam Webster defines data as "factual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation" [4]. Although various models to guide improvement have been described over the years, each includes the critical need for data to understand the current state or performance and to learn if interventions result in meaningful improvement.

In this era of advancing informatics, data has become much more available in many forms as well as varying levels of reliability. This availability can help in all stages of an improvement project yet must be used responsibly with an understanding of limitations, especially when comparing different systems or institutions [5].

Carefully planned data collection is critical to each stage of improvement, and analysis can help assess the scope of a problem, learn where the greatest opportunities for improvement lie, plan interventions based on potential impact, and track ongoing successes or failures. This assessment is critical in helping to set priorities for new or ongoing improvement initiatives. Data can also help in determining the need for further sup-

port and resources such as people, tools, and technology to help drive improvement.

Finally, in order to be used to influence practice, data must be perceived as valid. Healthcare workers, as improvement scientists, expect timely, credible data to drive improvement and avoid potential harmful changes stemmed by inaccurate data [6].

Vignette 8.2

Although the numbers of patients eloping prior to evaluation by a provider have been tracked for years, little had been done with the data other than the acknowledgment that the rate of LWBS patients increased dramatically when the daily ED census increased, especially when it reached about 190 in a 24 hour period. In addition, peaks in LWBS rates were sometimes noted during times of high inpatient census and when the ED was boarding admitted patients, when the mental health patient volumes increased, or when many time-consuming ED procedures needed completion, such as suturing or procedural sedation. The ED had increased staffing during traditionally "busy" hours but had not noted a significant or sustained decrease in the number of patients leaving without being evaluated by a provider.

While data was available to suggest certain contributing factors, much of the information regarding the reasons for the high rates of patients leaving prior to treatment were based on superficial evaluation of data and assumptions. It was largely assumed that many of the factors which appeared to be associated with high LWBS rates were outside of the control of the ED or the hospital, and this was simply a byproduct of working in a busy ED. The culture was simply to accept it and try to work harder and faster during busier times.

Improvement teams need data, both qualitative and quantitative, to assess and judge their work. Gerald Langley describes five types of data useful in supporting improvement efforts. These include continuous measurements, counts of observations, documentation of individuals' thoughts or feelings about an issue, ratings, and rankings [7]. Data collection must start with a plan, including what data will be collected, how the data will be collected and by whom, and when and where the data will be collected.

The role of data in helping to tackle complex issues can be more clearly understood if one considers the five stages of quality improvement cycles, as delineated in Key Point Box 8.1. The first two phases focus on ensuring the right issue is identified and studied. The third phase centers around the implementation of strategies. Phases 4 and 5 focus on outcomes and sustainment of improvements [8]. Each of these phases relies on the evaluation of gathered information to help inform decisions.

Key Point Box 8.1

Phases of quality improvement projects	
Phase 1 – Defining the problem	What is the problem?
	Is there a problem?
Phase 2 – Diagnosing the problem	What are the defects?
	What can we improve?
Phase 3 – Implementing change	How can we improve?
	What experiments should we try?
Phase 4 – Measuring improvement	Have we improved?
Phase 5 – Sustaining improvement	Is improvement sustained?

Defining the Problem

Phase 1 asks "What is the problem?" or "Is there a problem?". This phase, while seemingly the most basic, asks for problem identification and clarification, along with its impact, and may rely on both qualitative and quantitative data.

Vignette 8.3
ED leadership understood that patients and families often have a choice in healthcare, yet believed that acutely ill or injured children are best cared for in a specialty pediatric hospital. Further, the hospital administration understood that each family eloping prior to evaluation could have negative health impacts on children who were not seen and a negative financial impact on the hospital overall. They needed to understand when and why families were choosing to leave their hospital without being seen. It had long been believed that overall volume and wait times to see a provider were the driving factors in families choosing to leave, though percentages of LWBS patients were now increasing despite stable to slightly decreased overall ED census.

In order to clearly define the problem, multiple types of data are often necessary. Historical data can help assess current performance and establish a case for the need for improvement, as well as helping to establish overall targets or aims for the project. It can also aid in prioritization of problems and projects, especially with complex, multifactorial problems. Carefully planned data collection may also add insight and understanding to the needs and opinions of key stakeholders. Several different tools can be used to help establish baseline data.

Run Chart

The run chart is a simple graph of data over time, typically looking at only one variable, that can help determine how a process is performing and the impact of changes. When variation is observed, run charts can help begin to identify whether it is random or nonrandom.

In creating such charts, understanding the types of data being collected is key, specifically whether it is attribute or continuous data. Attribute data is counted (discrete) and easier to obtain. It can be broken down into *count* (incidences, nonconformities, or defects) or *classification* data (defectives or nonconforming units). Continuous data, on the other hand, is measured, such as the length of time from initial presentation to being seen by a provider. This type of data often provides more information for planning or evaluating a system. See Key Point Box 8.2 for more information regarding types of data. Chapter 9 discusses the differences between these variables further as well as the use of run and control charts.

Key Point Box 8.2

	Attribute	Continuous
Characteristics	Countable	Measurable/ continuous
Types	Count data	
	Classification data	
Examples	Number of patients affected	Percentage of patients affected
	Number of days between events	Rates of occurrences
	Number of patients with total length of stay over 3 hours	Average length of stay

Common specific types of data used for improvement include count, classification, percentage, and rate data. Counts (frequencies) are fairly straightforward – the total number of events occurring during a defined time frame, such as the number of patients presenting to the ED per day. Classification data are documented into one of two categories (e.g., defective or not defective). Percentages give information about the rate of occurrence, which may be necessary to understand if change is really happening, especially in situations in which the denominator may not be consistent. For instance, when measuring LWBS numbers, raw numbers may not tell the true story regarding the progress of an initiative. A total of five patients leaving without evaluation on a day

when only 150 present for care (3.3% of total patients) may be evaluated differently than a day in which 5 patients out of a total 260 leave (1.9%). However, careful analysis of either set of data using various stratification strategies may reveal other trends and conclusions not evident from the initial perusal of the gross data.

A rate is similar to a percentage in that it includes a numerator and denominator; however, with rates the two numbers are not alike. For instance, when studying patient falls for hospitalized patients, one may want to look at the number of falls per 100 patient days as opposed simply to what percentage of patients fall while hospitalized. In this scenario, the numerator is the number of falls, but the denominator is the number of inpatient days for the month, creating a rate. Measures which include rates should include the word "per" in the title (e.g., falls per 1000 patient days) [9].

Run charts are fairly quick and easy to put together and are somewhat intuitive to understand. A run chart is developed by first creating an x-axis (horizontal line) which represents a unit of time or a sequence then the y-axis (vertical line) to represent the range of data which are collected. A minimum of 10 data points is suggested for meaningful interpretation. Each point is then connected by a single line, and the median value for the data is determined, adding that line to the chart. The use of the median is preferred over the mean in run charts as it gives a good estimate of central tendency, without putting undue importance on extreme values that will affect the mean. The median remains constant regardless of whether the data display a normal or skewed distribution [10].

Figure 8.1 depicts a run chart demonstrating the percentage of patients leaving the ED prior to being seen by a provider daily through the month of April, with a median of 2.6%.

Now that the run chart is created, it can be used to begin to analyze process variation. Random variation is natural variation inherent to any process and is due to regular or ordinary causes. The presence of only random variation indicates stability in the process. Nonrandom variation, however, suggests irregular or unnatural causes and

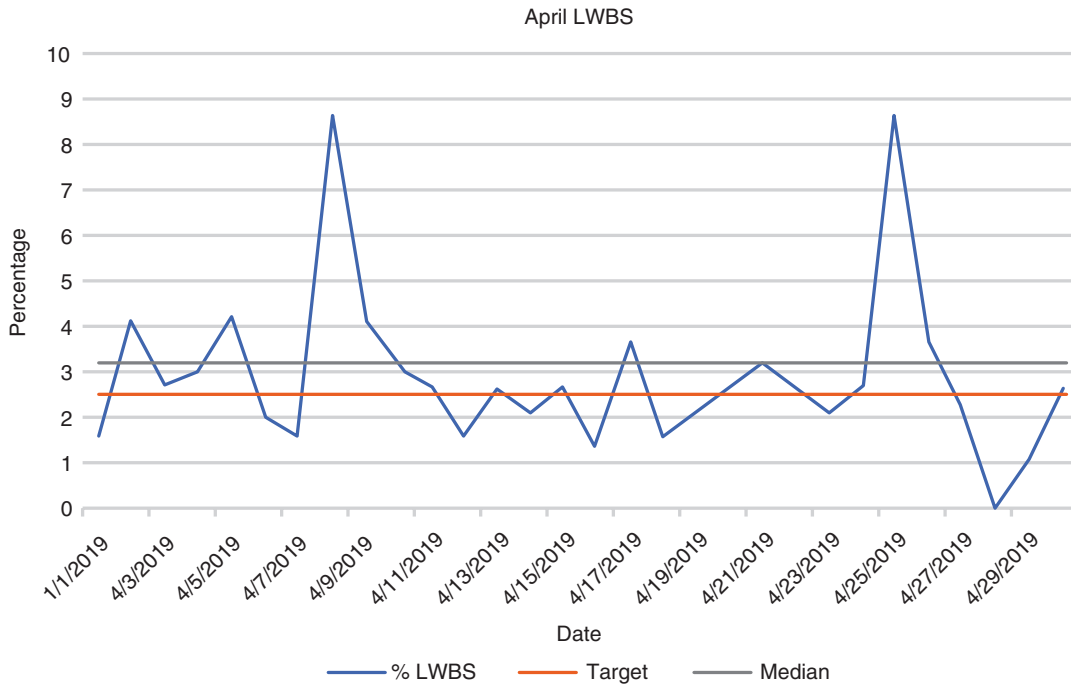


Fig. 8.1 Run chart demonstrating left without being seen rates

creates unpredictability in a process. While all processes will display some degree of random variation, nonrandom sources of variation should be identified and eliminated specifically prior to attempts to shift the median by changing an entire process. Nonrandom variation can also be desirable, especially when it displays improvement in your processes or outcomes due to a planned intervention. Chaper 9 (Quality Methodology) discusses rules for determining random vs. nonrandom variation, focusing on shifts, trends, number of runs, and any astronomical points. Assessing variation from a run chart begins with the identification of runs. A run is defined as one or more consecutive data points above or below the median. Points falling on the median are not counted. Once runs are identified, analysis can begin. Although a variety of rules and options have been created for the analysis of run charts, the Institute for Healthcare Improvement (IHI) has agreed on four simple rules which they feel are the most relevant to healthcare [9, 10].

Rule 1: Shifts

The first rule in assessing a run chart is to identify a shift in the data. This rule helps deter one from becoming too excited or disheartened by a small number of data points moving the same direction. A shift occurs when six or more consecutive points fall on the same side of the median. In our example in Fig. 8.1, the run beginning April 10 contains seven consecutive points below the median, indicating a shift. This shift should lead one to investigate further to learn potential reasons for this nonrandom pattern.

Further evaluation revealed that during those days, the hospital inpatient census was lower than usual with fewer scheduled surgeries than usual, in addiiton to ED volumes being lower. As a result, admitted patients were transferred to the floor more quickly and there were no ED rooms occupied by "boarded" inpatients. Additionally, staffing was very good that week due to very few "call-ins". This combination of more available exam rooms and excellent staffing led to a decreased wait time, and fewer patients leaving prior to evaluation.

Rule 2: Trends

The second rule is applied to define trends in data. The IHI defines a trend as five or more data points constantly going the same direction, without regard to whether they cross the median [10]. Points that repeat a previous value are not included when determining trends. In our example, no trends are identified.

Rule 3: Too Many or Too Few Runs

The third rule simply identifies the number of runs present in the chart vs. the number expected based on the number of useful observations. The number of useful observations is first calculated by subtracting the number of data points that fall on the median line from the total number of data points. This number is then identified on a standard table that identifies the number of runs that should be observed based on the number of useful observations. The table most commonly used was developed by Swed and Eisenhart in 1943, an excerpt of which is included in Table 8.1 [11]. If too few or too many runs exist, compared to the expected number range, this signals nonrandom variation. In our example above, there are 30 useful data points (none fall directly on the median line) and 11 runs. According to the table, the lower number of expected runs is 11, and the upper number is 21, indicating that variation is random.

Rule 4: Astronomical Data Points

Rule 4 is an observational rule to quickly identify a data point that may warrant further investigation. While every chart has high and low points, here we are looking for points that drastically vary from the rest of the data. On our run chart, discreet spikes are noted on April 8 and 25, significantly higher than other dates during the month, suggesting astronomical points. These data points should lead to further investigation, including double-checking the data to make sure the same rules were applied in collecting it for

Table 8.1 Table to determine whether too few or too many runs exist on a run chart

Number of useful observations	Lower number of expected runs	Upper number of expected runs
10	3	9
11	2	10
12	2	11
13	4	11
14	4	12
15	5	12
16	5	13
17	3	13
18	6	14
19	6	15
20	6	16
21	7	16
22	7	17
23	7	17
24	8	18
25	8	18
26	9	19
27	10	19
28	10	20
29	10	20
30	11	21
31	11	22
32	11	23
33	12	23
34	12	24
35	12	24
36	13	25
37	13	25
38	14	26
39	14	26
40	15	27
41	15	27
42	16	28
43	16	28
44	17	29
45	17	30

Used with permission of *The Annals of Mathematical Statistics*, from Tables for Testing Randomness of Grouping in a Sequence of Alternatives, Swed and Eisenhart [11], permission conveyed through Copyright Clearance Center, Inc.

that occurrence, then taking a deeper look into potential causes of this variation.

Run charts overall are great for understanding current performance of a process. They are useful in establishing baseline data and following as interventions are implemented. Annotating run charts to indicate points of intervention or PDSA cycles can help demonstrate the effects of the interventions. (See Chap. 9, Quality Methodology).

Statistical Process Control Chart (Shewhart Chart)

The statistical process control chart (a.k.a., Shewhart chart or control chart) also displays data in time order but includes the mean with upper and lower control limits, statistically defining the predicted boundaries within which data are expected to fall. Thus, it highlights situations where data fall out of normal variation, or "out of control." The control limits are set at three standard deviations above and below the mean, indicating a 99.73% probability that a data point will fall within the control limits. While run charts can only indicate whether variation is random or nonrandom, control charts can be used to help distinguish between common cause and special cause variation. Common cause variation refers to expected or natural variation inherent to the process, whereas special cause refers to variation related to specific circumstances. Data points falling outside of the upper or lower control limits indicate special cause variation. There are four other special cause rules which can be applied and are discussed in Chap. 9 (Quality Methodology). In addition, control charts allow you to determine the capability of the process and help predict the future behavior of the process. The three types of *control* charts most commonly used include C-charts, which count the number of occurrences, P-charts which depict percentages of occurrences, and U-charts depicting rates of occurrences.

Figure 8.2 represents a P-chart, illustrating the daily percentage of patients leaving prior to evaluation by a provider in the month of April. Although variation exists, most data points remain within the control limits, indicating common cause variation. On two dates however, (April 8 and 23), the LWBS rate exceeded the upper control limit, indicating special cause variation. This should serve as a signal for further evaluation. When the team investigated these

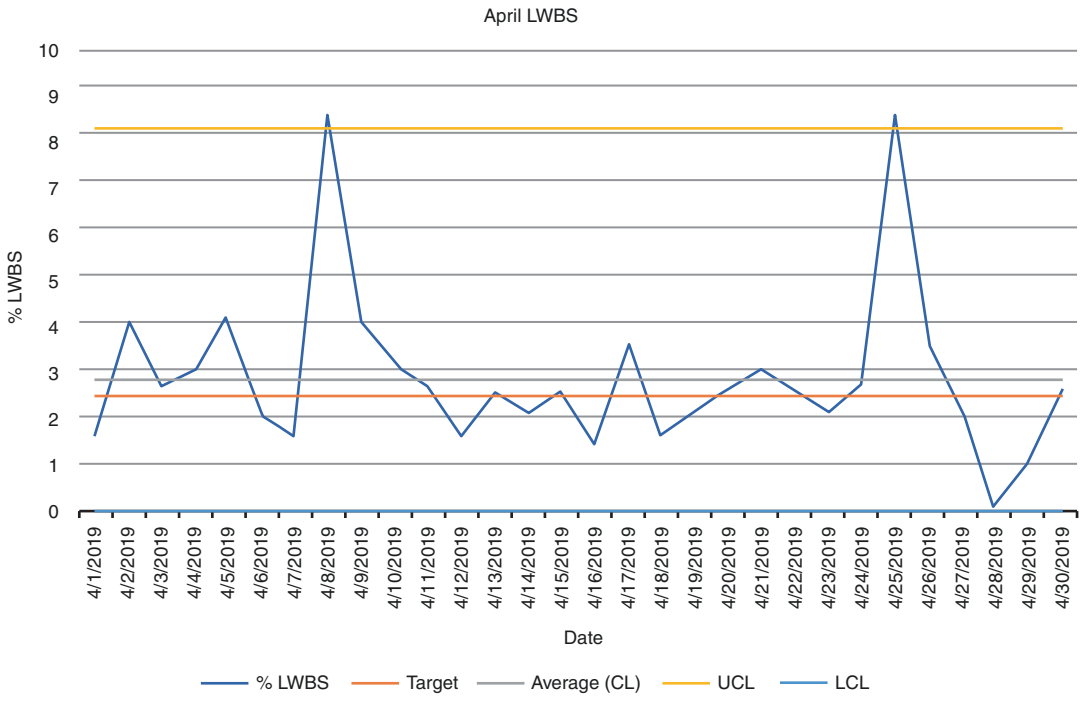


Fig. 8.2 P-chart (control chart) representing left without being seen rates for April

dates, they learned that the ED had significant issues with inpatient boarding both days, with inpatients occupying 40% of their rooms for over 12 hours on the 8th and 25% of the rooms on the 25th, a day which also included a high volume of patients requiring 1:1 observation in the ED. This demonstration of the effect of boarded patients on LWBS rates was shared with administration and inpatient units to help create a better understanding of how issues in other areas of the hospital, such as lack of an overflow unit, can affect the LWBS rate.

Qualitative Measures

Qualitative data collection at the beginning of a project can help gain deeper insight into issues, capturing feelings, opinions, and ideas from both staff and the customers (patients and families). Surveys, especially those with free text questions may lend insight into the process from varying points of view. Surveys carry the advantage of being quick, relatively easy to create and distribute to large numbers of respondents. However, response rates can be extremely variable, and since the questions are set, there is limited to no ability for follow-up or clarifying questions.

Interviews can be performed individually or in groups and can be particularly helpful to appreciate deeper meaning underlying individual or group perspectives or feelings. Interviews by nature are time-intensive, requiring skilled facilitators and notetakers, as well as the skills necessary to reliably analyze large amounts of narrative. Qualitative data are particularly helpful in understanding the story or deeper context associated with a process. Qualitative data are generally depicted by sharing of a story, for example, describing a scenario associated with a patient that left before being seen. Additionally, common themes elicited from qualitative data from interviews or surveys can be used to help identify perceived barriers to implementing changes, to identify competing priorities among stakeholders, to uncover biases that may interfere with progress, etc. This may provide information crucial to the improvement planning process.

Diagnosing the Problem

Phase 2 of a quality project is considered the diagnostic phase, asking the questions "Where are the defects in the process?" and "What can we improve?". In this phase, the team takes a deeper dive into the problem, focusing on structures and processes involved. The goal of this phase is to identify areas of greatest impact, prioritize opportunities for improvement, and identify barriers that may impede the project's success.

The data tools already mentioned may again help support this phase, though a deeper understanding is crucial here. The initial phase highlighted that a problem exists or that the current state is not the desired state and may have led to some hypotheses as to causes, but in this phase the focus is on identifying the roots of the problem.

Scatter Plot

A scatter plot creates a geographic representation of the relationship between two variables. One variable is placed on the *x*-axis and the other on the *y-axis*. For a scatter plot to be useful, it should include at least 20–30 data points. If the two variables are related, the points will follow a diagonal line or a curve. Scatter plots are very useful in demonstrating *correlation*, but one must keep in mind that correlation does not necessarily indicate causation. More closely clustered dots on the graph indicates a stronger relationship between the two variables than dots which are spread further apart. When the pattern of dots rises from the lower left to the upper right of the chart, a positive correlation is suggested, that is, when one variable increases, the second increases as well. On the other hand, an inverse relationship is suggested when the pattern of dots declines from the top left to the bottom right of the graph.

Figure 8.3 demonstrates a positive relationship between the number of patients presenting to the emergency department per day and the LWBS rate. This graph shows that when the census remains under about 180 patients/day, LWBS rates remain consistently under 3%. However, when daily census surpasses 190, there is a sharp increase in the rate of patient eloping prior to evaluation, with rates rarely falling under 4%.

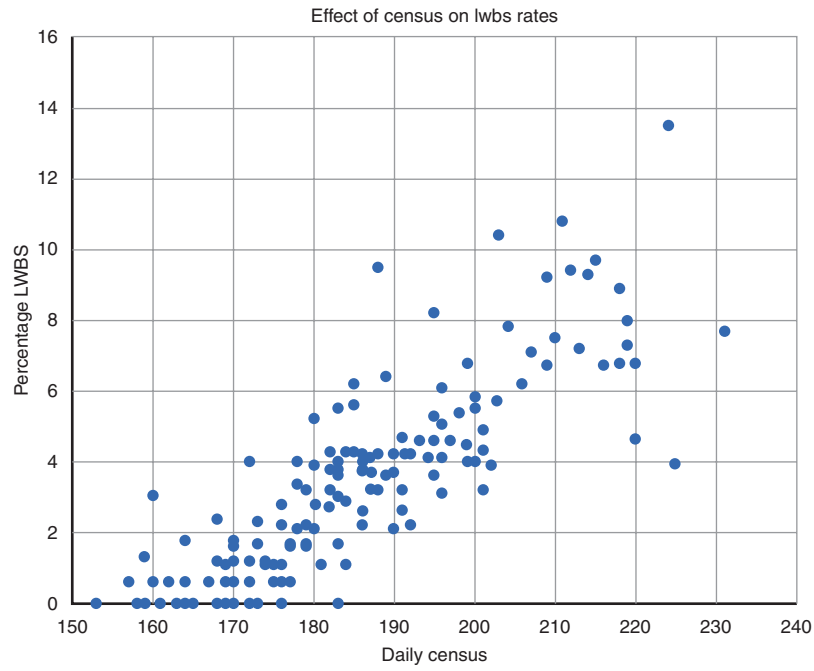


Fig. 8.3 Scatter plot demonstrating the relationship between total census and LWBS rates

Scatterplots also allow us to see unusual patterns, such as data affected by special cause variation or clustering of data points that may suggest the need for further investigation. In the example above, the plot demonstrates correlation, but does not account for all causes, as there are several outliers on the plot. While the trend indicates a strong relationship, clearly there were certain days in which the census was quite high, but LWBS did not spike, as well as a few outliers in days with lower census. These easily visualized outliers may suggest special cause variation for particular points. Additionally, trends may be suggested by scatter plots as well, which may lead to the need for further investigation of causes for the patterns. Importantly, one must remember that regardless of the strength of the correlation, a scatter plot does not identify the reason for the correlation, only the relationship. Key Point Box 8.3 highlights key concepts for scatterplots.

Key Point Box 8.3

Scatter plots
Need at least 20–30 points to be useful
Show correlation, not causation
Great for pattern recognition
Outlying points indicate variation

During this diagnostic phase, more emphasis should be placed on *control charts* as well. In the first phase, a baseline is established, and variation may have been identified, but in this phase, identified variation should be studied. Identification of the type of variation the process is experiencing will help to determine the next steps in improving the methods. When a process only displays common cause variation, one can reliably predict how a process will perform, within statistical limits.

Common cause variation, though expected, should not necessarily be accepted as unimportant to address. It does not tell you that a process is good, only that it is stable and therefore predictable. For example, in our case, the LWBS rates are mostly in control, but still undesirable compared to the goal of 2.5%. Changes to processes should be considered when the process demonstrates control but unacceptable results. The use of subject matter experts can be helpful to determine when stable systems (i.e., showing common cause variation) need improvement.

Special cause variation should be studied carefully in this phase as well. This type of variation results from unnatural or irregular causes that are not inherent to the process as a whole. They indicate instability in a process or chaos. When a process demonstrates instability and unpredictability, changes to the process as a whole may lead to wasted efforts or further instability. Because they indicate a lack of control in a process, special causes should be investigated to determine the underlying reason for the variation, so steps can be taken to eliminate or minimize the cause of the variation when that variation has a negative effect. It is important to remember that positive variation can create special cause as well, and these instances should also be investigated to learn what went well for a particular event and if those factors could be replicated for future improvements. While some instances of special cause variation are truly unique, sometimes patterns can be identified when a deeper look is taken. One helpful tool in assessing variation is the abnormality tracker.

Abnormality Tracker

The abnormality tracker (a.k.a., histogram) can be used to assess factors associated with variations or outliers. By tracking individual factors that may contribute to certain outcomes, it may be possible to identify areas for improvement. This tool can be created very simply by creating a visual system in which a simple tally mark is placed each time there is variation, with an assessment of the perceived causes at the time. This will basically create a visual histogram showing frequencies of events – how many times a particular event occurs related to the identified problem. An abnormality tracker is simple to use and requires no specialized statistical program but provides a good visual depiction of the reasons for process failures. It can also help provide

a subgrouping strategy for your ensuing data analysis.

For instance, in the case of ED LWBS, the overall problem was thought to be related to the volume of patients. While this was partially true, a deeper look revealed that certain additional factors contributed significantly to the rate. The team tracked the number of patients boarding in the ED awaiting inpatient beds, the number of patients requiring mental health evaluations, the number of patients with extended time from admission order to inpatient bed placement, and the overall wait time to see a provider.

Figure 8.4 demonstrates the abnormality tracker used. The staff added to the tracker any day in which the LWBS rate was over 2.5% (the stated goal), with a tally for each of the identified contributing factors. From this, they were able to determine that the likelihood of patients leaving prior to evaluation increased when wait times surpassed 2 hours from the time of arrival, which led the team to brainstorm ways to decrease the time to initial contact with a provider. In addition, the impact of patients requiring 1:1 monitoring is demonstrated as an important contributing factor. Interestingly, some potential causes of staff though would be major contributors to the problem, such as multiple sedations in a day did not appear to affect the LWBS rate significantly.

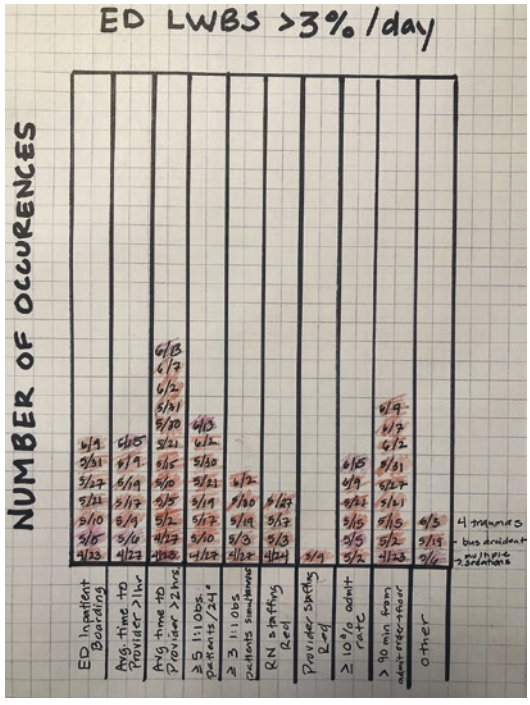


Fig. 8.4 Abnormality tracker depicting factors contributing to LWBS rates

Pareto Chart

The Pareto chart has been widely used in quality improvement work. It was developed by Vilfredo Pareto, an Italian economist and philosopher, who noted that 80% of the land in Italy in the 1800s was owned by 20% of the population. This concept, referred to as the Pareto principle, states that for many events or problems, a small number of factors will account for the majority of the reasons that the problem occurred [9]. Key Point Box 8.4 highlights key features of Pareto charts.

Key Point Box 8.4

Pareto charts
Bar and line graph
Bars arranged in descending order
Useful to analyze frequencies of events
Helpful to determine predominant factors

The Pareto chart is a type of histogram that includes both bars and a cumulative line. The bars, which represent frequencies, are arranged in descending order, and the cumulative total is represented by the line. The right-sided vertical axis measures the percentage of the total contributions of each factor. This is particularly useful when analyzing complex problems that may have many underlying causes to help identify the most common sources of defects, which can help with prioritization of tests of change. Figure 8.5 illustrates the ice cream flavor preference for ED staff members, which was used to help determine which flavors to buy for the celebration when the team reached the goal of a 0.5% reduction in overall LWBS rates. Since the budget only allowed the purchase of three flavors, a quick survey was taken to ensure that the majority of pref-

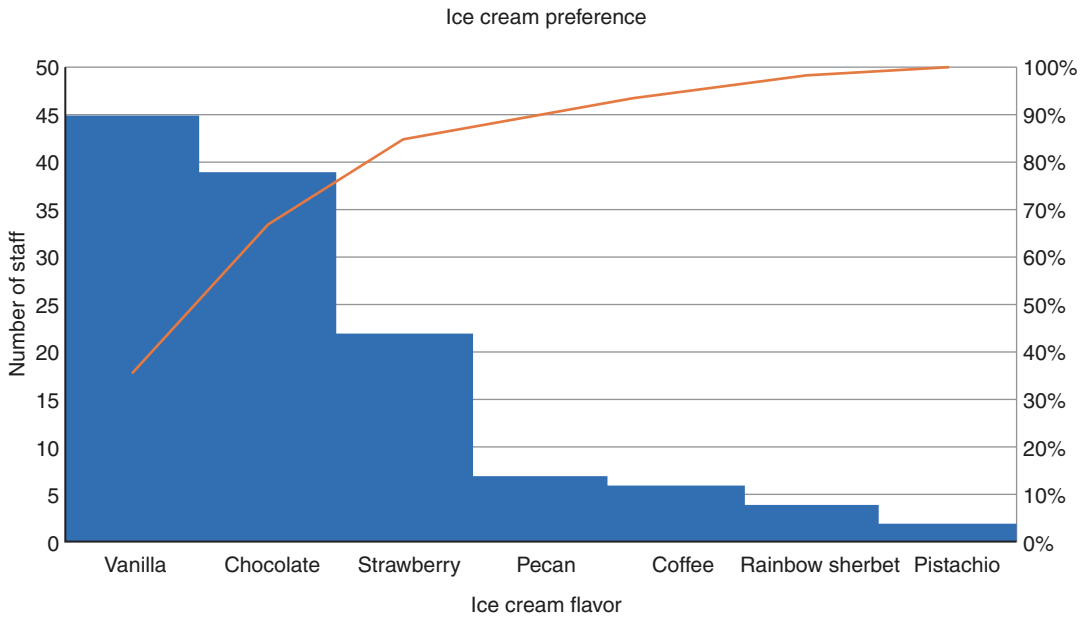


Fig. 8.5 Pareto chart

erences would be covered. From this, we learned that almost 90% of the staff preferred either vanilla, chocolate, or strawberry ice cream.

Qualitative Data

In the diagnostic phase of the project, qualitative data may be equally important as quantitative in helping to identify potential interventions and possible barriers. As in the first phase, interviews can help gain valuable insight and help discover potential barriers to improvement strategies. Simple discussions with staff may uncover cultural barriers to change and may surface innovative ideas. Interviews with families (customers) may lead to a deeper understanding of the problem and factors which may make them more likely to behave in one way or the other.

Another qualitative method to evaluate a process is through observation. Observations represent a powerful method of gathering information to truly understand how a system is functioning from another perspective. As discussed in other chapters, direct observations done on the "shop floor" may be critical to understanding the problem better. Gemba walks, as discussed in Chap. 5, present a great opportunity for observation. By using direct observation, one can see behaviors and the impact of human factors in a real-world setting. They may also include observing each step in a process, including time stamping of each individual step. Observations can be time-intensive and can be subject to the "Hawthorne" effect, in which individuals alter behaviors due to their awareness of being observed. Therefore, there is value in performing multiple observations using several trained observers.

Vignette 8.4

The improvement team had noted that the rates of patients choosing to leave prior to evaluation tended to increase when wait times were long. However, they noted on some days with extended wait times very few families left. The team spent several hours in the waiting room observing behaviors, noting that certain behaviors of the nurses at the front desk impacted the likelihood of a family choosing to stay or go. For

instance, one nurse greeted every family on arrival and made a point to let them know that the wait was longer than usual that day but assured the families that their child was important and would be seen as soon as possible. She further asked them to let her know if anything changed or they would like for her to reassess their child. She also frequently scanned the waiting room for patients who had been there longer than an hour and touched base with the families. In contrast, the team observed another nurse who seemed overwhelmed with each patient signing in. She also let them know that there was a long wait, so they should take a seat and the team would get to them when they could. After the initial assessment, she did not offer comfort measures or reassessment while waiting. The team quickly learned that families were much less likely to leave if they felt that they were attended to.

Although the collection of this type of qualitative data may be time-consuming, it provides insight that numbers alone simply cannot, especially when formulating plans for interventions.

Implementing Change

The third phase of improvement projects is often referred to as the intervention phase. In this phase, potential interventions are identified, performance measures are defined, improvement experiments are implemented, and progress is continually monitored. Reliable data collected in the diagnostic phase will help guide the team in creating interventions and implementation strategies. This phase is often referred to as the PDSA or plan-do-study-act cycle and is discussed in detail in Chap. 9 (Quality Methodology). This phase, often referred to as the experimentation phase, includes small-scale trials with continuous assessment of the impact to guide further refinements prior to disseminating the strategies more widely. Tests of change are initiated, studied, adapted, and studied again. Data management and monitoring in this phase must be robust, timely, and transparent in order to plan next steps and to maintain engagement. Staff may have a difficult time adapting to multiple changes if they cannot appreciate the effects of the changes. Further, the knowledge that each change will be studied for positive effects as well as unintended consequences, and a more permanent change will not be initiated until the process is fully vetted helps improve staff acceptance of the process.

The importance of knowledge gained from each experiment, regardless of success is evident throughout history, perhaps most famously by Thomas Edison. In his biography, "Edison: His Life and Inventions" an anecdote is shared by his longtime associate Walter Mallory, highlighting one of Edison's most famous quotes. When asked "Isn't it a shame that with the tremendous amount of work you have done you haven't been able to get any results?", Edison reportedly smiled replying "Results! Why, man, I have gotten a lot of results! I know several thousand things that won't work" [12].

Several of the tools already described can be helpful in this phase, particularly control charts and abnormality trackers. As each new experiment is initiated, it is critical to study the effects, both positive and negative, of that implementation. It is important to consider any "balancing measures" or other areas that may be affected by the implementation of the intervention. Balancing measures help the team ensure that possible unintended consequences of a new process are recognized and addressed. For example, a plan to decrease ED inpatient boarding of patients by emphasizing rewarding physicians for early discharge of inpatients could lead to some patients being discharged before they were truly ready, leading to return visits. This information is then used to adapt the experiment and plan the next steps.

Additional details about the PDSA cycle, especially its merits and potential pitfalls when misused, can be found in multiple other texts, including *The Improvement Guide* [7] and *Quality Health Care* [9].

Vignette 8.5
Since the team did not feel that they could significantly affect the variable rates of patient arrival or overall daily census, and reducing overall time in department was important but would take longer to achieve, relying on many areas of the hospital, they decided to start with interventions that would not require a significant increase in resources. The first intervention included a script for the greeting nurse and regular rounding on waiting patients to reassess and remind them that we know they are waiting and want to address their urgent and emergent healthcare needs. Many of the staff began offering simple comfort measures to families when they checked on them, such as water or blankets. Within the first week, there was a small decrease in the LWBS rate, despite no decrease in overall census or door to doctor time. With this, the staff also noticed that not only were families less likely to leave, they were less upset with the wait times. Soon, the staff began to provide suggestions on other things that could be done for patients while they were waiting, such as educational videos about seasonal conditions, initiation of oral challenges for children with suspected gastroenteritis, standing orders for certain situations, etc. Within a month, LWBS rates decreased by 0.7%, and a culture shift was palpable.

Visual Management Boards

Visual management boards may be particularly helpful in this stage of rapid process change. A well-designed visual management board provides information about performance at a glance, typically including unit specific measures chosen to align with the overall strategy of the system. This is the ideal platform to display metrics reflecting current improvement efforts and projects and engage an entire team in the improvement initiative. A dynamic visual tracking board can also help to identify problems or defects earlier than traditional methods. The idea of creating such a board may seem daunting to some, but it does not have to be complicated. By nature, the board needs to be easily changed and updated to reflect the current state.

A few tips can help to ensure the success of a management board:

1. Keep it simple. It should be easily understood by all the staff in the department and ideally by visitors from other areas of the organization. When the Chief Nursing Officer or CEO stops by, he or she should be able to understand what is being measured and progress being made. Similarly, if displayed in a public access area, visitors or families should be able to recognize progress on the board as well.
2. Choose process measures that are achievable and frequent enough occurrences to provide meaning with regularity. Displaying variations that occur only once or twice a year may not provide meaning on a day-to-day basis for many staff members. For instance, an ED may want to track the frequency of mislabeled specimens occurring weekly as each mislabel may lead to recollection of specimens, creating discomfort for patients, prolonging the overall length of stay for the patient, and decreasing capacity to see the next waiting patient. However, regular tracking of patients who have a splint applied to the wrong extremity, an occurrence which certainly prolongs the length of stay due to the need for a repeat procedure, but occurs less than once a year is unlikely to provide meaning toward the overall goals of the department.
3. It is called a visual management board – make sure it lives up to its title! The board should be populated with tools such as graphs, charts, and other visual tools such as red/green indicators so staff can understand the current state at a glance. Consider presenting data over time.
4. Choose its location wisely. As in real estate, location matters. The visual board should live in an area accessible to all staff who may be affected or influenced by it. Some even

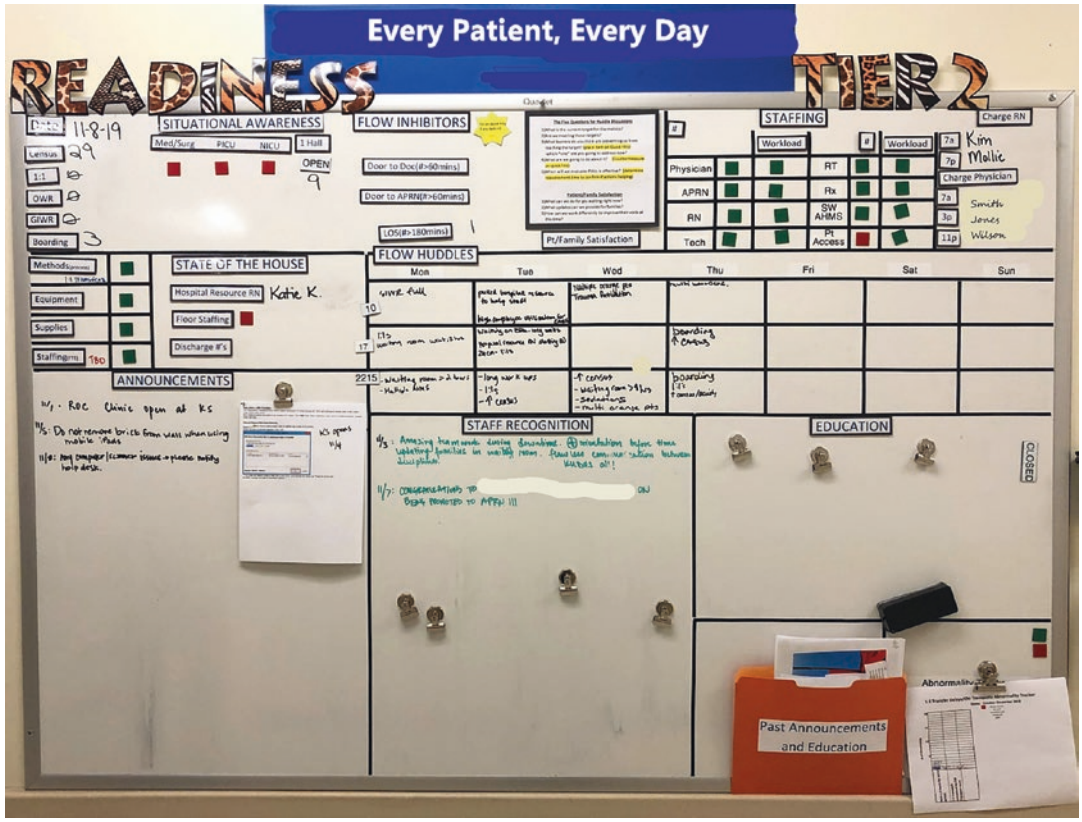


Fig. 8.6 Visual management board – whiteboard version

advocate for more public placement, visible to visitors and patients as well, though not all institutions are comfortable with this level of transparency.

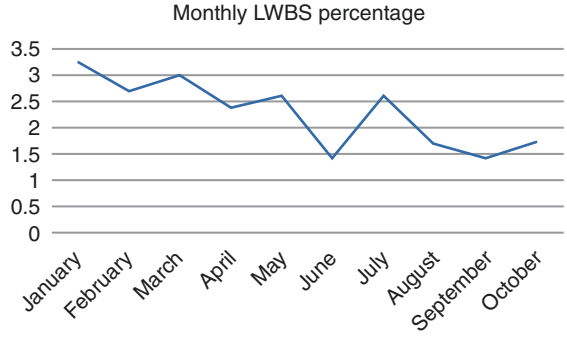
Choose the type of display. Visual management boards can be as basic or as technical as you like. They may be as simple as paper or poster board, as adaptable as whiteboard, or as technical as electronic displays. Each has its merits. Paper versions are simple to create and require less technical expertise and very little money. However, changes can get very messy or require reworking of the board frequently. Size constraints may come into play as well. Whiteboards are popular in healthcare for a variety of reasons. They are relatively inexpensive, they appear a little more "permanent" than paperboards, and they are easily changed and available in a large variety of sizes. Electronic boards carry the advantage of the ability to capture and record changes automatically, as well as being able to update certain data points close to real time. The ease of use and adaptability depends largely on the skills of those responsible for the creation and changes. Electronic boards also come with a heftier price tag and the risk of inaccessibility when technology fails. Thus, the most important factors in choosing which type of board to use are the needs, preferences, and budgets of those who will be using them daily (Figs. 8.6 and 8.7).

Vignette 8.6
The ED visual management board had traditionally included historical data (the prior day's numbers) and longitudinal metrics. With the LWBS initiative, a switch was made to more real-time results to inform

October 27, 2019- 1600	Current state	4 Hour avg.
Census	41	22
Length of stay (minutes)	142	107
Door to provider (minutes)	32	20
Patients in waiting room	7	1
1:1 Observations	1	1
Pts. Waiting for inpatient Bed > 1 hour	1	0

Staffing	
RN	
MD/DO	
ANP	
RT	
Tech	
Registration	
Child life	
Pharmacy	
Social work	

Process metrics



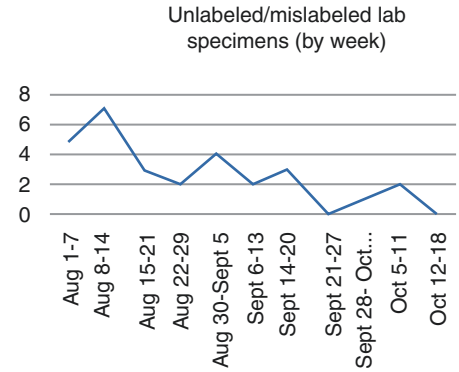


Fig. 8.7 Visual management board – electronic version

staff. Current census numbers were displayed on the board, in addition to numbers of patients waiting over 1 hour to be seen and those with a total length of stay over 3 hours. In addition, the board contained quick visual clues representing potential barriers that may affect flow for the day, such as faulty equipment, short staffing, high inpatient census, etc. With this, staff could see the current state of the department at a glance, and certain triggers were put into place that required action by the team working at the time. For instance, in any shift during which there were more than four patients who had been in an exam room for over 60 minutes without being seen, the team was expected to huddle and create a plan to brainstorm ways to help the families get what they needed. This may include shifting of resources "quick rounding" by providers to get evaluations initiated, "check-ins" from nursing staff, calls to the inpatient units asking for help moving admissions out of the ED to the floors, etc. The point is that each day may present different obstacles leading to the extended wait, but with the availability of carefully chosen real-time data, the teams had the information they needed to assess the current obstacles and create plans for improvement. Staff felt more empowered to help make changes.

Measuring Improvement

The fourth phase of the quality improvement cycle focuses on assessing the impact of interventions, asking the question, "Are we improving?". In this phase, the impact of experiments is

measured for both positive and negative effects. Processes are closely monitored for stability, with attention to data that may suggest a trend, either favorable or unfavorable, that may indicate the need for further assessment or adaptation of the process. Special causes should, of course, be evaluated as they present as well.

Sustaining Improvement

Finally, once improvement has been achieved and the process has stabilized, it is essential to monitor sustainment. Without ongoing monitoring, even projects that have demonstrated dramatic process and outcome improvements may experience slippage. As improvement projects wrap up, resources may be diverted to other priorities, creating the possibility of losing some of the benefits of the new process. Thus, when a project enters this phase, it is critical to consider the overall sustainability of the process and to choose metrics to continue to monitor the system's performance. The amount of rigor and detail necessary for this monitoring phase will vary depending on the level of complexity and the anticipated risk of the process reverting to its original state. Often, after a period of demonstrated sustainment, control charts can be used to follow progress, with particular attention given to variations that appear.

Summary

Understanding the need for reliable data to drive change is an integral part of improvement. The challenge lies in determining which data to collect and which of the many tools may work best for the particular project at hand. The tools chosen will depend on the complexity of the problem, the phase of the project, and the resources available, but do not have to be elaborate or require a statistician's expertise. When considering your data, plan carefully, experiment willingly, learn from successes as well as missteps, and consider the impact on the team and workflow. Improvement will follow.

Chapter Review Questions

1. True or False – Scatter plots are useful in determining the cause of variation.

   Answer: False. Scatter plots are useful for identifying patterns and correlation, but do not provide information regarding causation.
2. Which phases of improvement benefit from data analysis?
   A. Planning phase
   B. Implementation phase
   C. Sustainment Phase
   D. All of the above

   Answer: D. All phases of improvement, from defining the problem through sustaining the improvement, can benefit from carefully planned and evaluated data collection.
3. True or False – Run charts can be used to follow basic trends but cannot distinguish common cause variation from special cause variation.

   Answer: True. Run charts may provide an indication of nonrandom variation, but cannot distinguish a special cause. Control charts are useful for determining special cause variation.
4. True or False – The Pareto principle indicates that the majority of problems or defects in a process are caused by a relatively small number of factors.

   Answer: True. The Pareto principle suggests that 80% of the problem can be attributed to 20% of the causes.
5. True or False – Qualitative data is too subjective to be useful in most quality improvement initiatives.

   Answer: False. Qualitative data plays an important role in improvement projects, particularly in understanding what people believe and how they feel about a problem.

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Quality Methodology

9

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Abbreviations

KDD Key driver diagram
PDSA Plan-Do-Study-Act

Chapter Objectives

- Utilize the Roadmap for Quality allowing for enhanced communication, collaboration, and coordination among team members and among separate teams that may be working toward an overall goal
- Leverage quality tools to identify a goal and create a high-level plan and individual team plans which will support the overall goal of the improvement project
- Execute effective PDSA cycles with predictions, measurement, and decisions to determine the next steps
- Understand nonrandom variation, common cause variation, and special cause variation
- Understand the steps for successfully implementing change
- Learn strategies to spread and sustain improvements

Vignette 9.1

According to the 2017 CDC National Center for Health Statistics, nearly 6.2 million children under the age of 18 have asthma [1]. Childhood asthma leads to increased emergency department visits, hospitalizations to acute care and intensive care settings, missed days of school for children, and missed days of work for parents resulting in a significant financial and social burden for patients and families. Evidence demonstrates that early identification and management of asthma, avoidance of asthma triggers, and strict compliance with daily medication regimes create the best possible outcomes for children with this chronic condition. A tertiary, free-standing children's hospital has seen a fairly flat 12-month rolling average in emergency department visits as well as hospital admissions despite a multitude of disconnected teams working to solve the problem within

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their given areas with their current resources. To date, no significant improvements have been demonstrated. What needs to change to create better outcomes for patients with asthma seeking care in this hospital?

Due to the disconnection of asthma teams, quality leaders observed unsuccessful tests of change being inappropriately duplicated, disparate improvement goals, inconsistent application of evidence, and limited quality improvement methodology being used. A newly developed asthma improvement team structure will seek to coordinate, allow for collaboration, and enhance communication of these nine teams. Quality team members are newly assigned to the project to redefine the structure and methodology necessary to drive the success of the teams.

Identifying Improvement Opportunities

Identifying improvement needs in any healthcare organization can happen through a variety of means; examples include Community Health Needs Assessment (Affordable Care Act requirement), failures or risks (regulatory reviews or audits, serious and near miss events of harm, safety event reports, or external performance benchmarks), patient feedback, high-volume care, and organizational priorities (i.e., strategic plan) [2].

Understanding the Process for Improvement

Once improvement opportunities are identified, quality improvement methodology is imperative to achieving successful improvement. People with formal and informal roles in quality improvement will be more effective in leading change through the use of quality tools. The Model for Improvement from the Institute for Healthcare Improvement (IHI) allows teams to identify the scope of work and metrics and continually address the work within the framework of Plan-Do-Study-Act (PDSA) cycles [3]. Below are the key Model for Improvement concepts (see Fig. 4.2, Chap. 4):

1. What are we trying to accomplish? (Aim)
2. How will we know that a change is an improvement? (Measures)
3. What changes can we make that will result in improvement? (Interventions)

Leadership

System-level quality improvement requires teams to interface to solve strategic problems but requires strong leadership. Leaders must identify a strategy to improve that is likely different than small-scale and local quality improvement efforts. In the case vignette described, asthma was deemed a "Transformation Project" (descriptors for high-visibility, crosscutting, major initiatives) and endorsed by the executive team. A transformation project carries several benefits: (1) focus on the "system approach", (2) commensurate resource allocation, (3) executive sponsorship, (4) engaged stakeholder and steering groups, (5) environment for local team leaders to collaborate, and (6) regular executive and governance review of metrics.

To embark on the asthma transformation journey, a multidisciplinary team assembled to analyze baseline data and created a plan to improve the outcome. Executive leaders deployed quality, analytics, project management, informatics, and operational resources for the team in order to drive system-level improvement through enhanced coordination, collaboration, and communication, all missing elements in the prior overall state. Local teams were identified as inpatient, emergency department, primary care, home healthcare, school health, pulmonary, allergy, a newly formed asthma care management team, and a pediatric intensive care team-a collection of nine teams all working toward the same goal. The newly coordinated asthma structure was designed to extend horizontally across

teams and vertically, between frontline and leadership. A new culture was created where individuals recognized their role in reducing the burden of asthma.

With local teams aligned around asthma outcome goals, a clear aim statement was developed. The local teams were asked to standardize the data definitions on the measures for "asthma admission" and "emergency department visit." This early precision around inclusion and exclusion criteria allowed for consistent tracking of data. This organization had an existing asthma registry containing years' worth of patient-level data, allowing for prospective and retrospective data analysis.

The teams started with the Roadmap for Quality (Fig. 9.1) which outlines each step to guide the teams' progression through the improvement journey. Each stage has associated tools to complete tasks and provide learning as the improvement process continues.

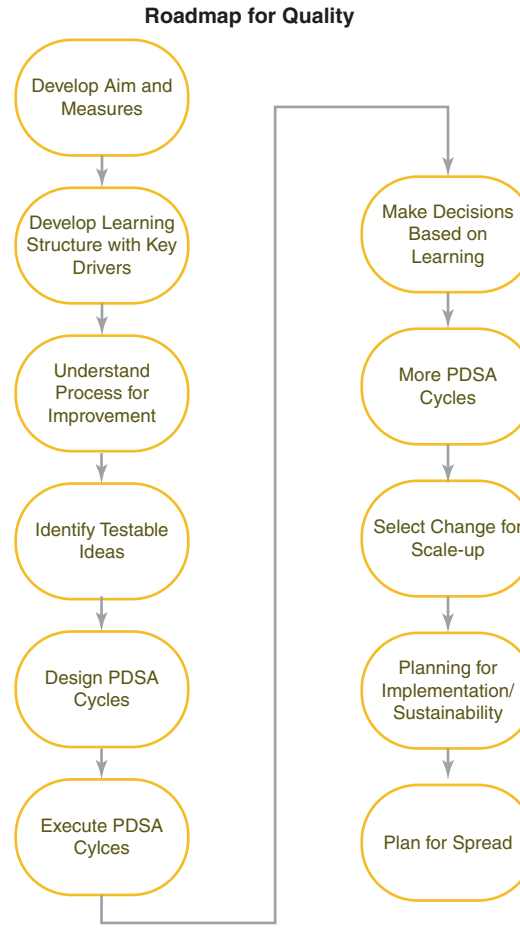


Fig. 9.1 Roadmap for quality

Aim and Measures

Step one in the Model for Improvement requires clarity on "What are we trying to accomplish?" The Roadmap for Quality thus begins with the identification of an aim statement and associated measures. When teams came together and successfully identified an aim inclusive of detailed measurement, the improvement journey commenced.

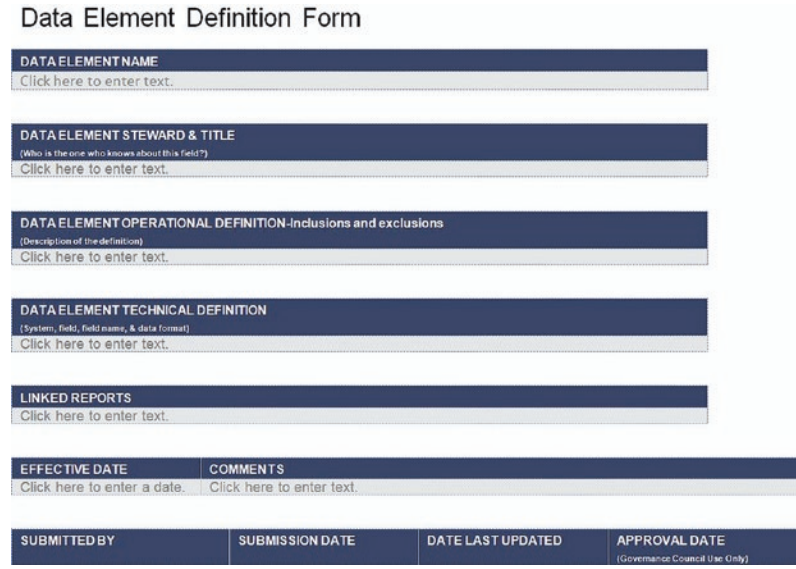
Global aims development precedes specific aims and identifies the direction and intent of the work. A global aim is broad with no measures or timelines included. In this vignette, the Global Aim was:

> We aim to substantially reduce the burden of asthma for our patients, their families, and our community.

Global aims are not specific enough to provide focused improvement targets, so a SMART (*S*pecific, *M*easurable, *A*ttainable, *R*elevant, and *T*ime-bound) aim is established to provide focus. The asthma team arrived at the following SMART aim for inpatient admissions and emergency department visits:

> We will reduce Inpatient Hospitalization rate from 2.7% to < 2.0% (approx. 26% reduction), and ED visit rate from 5.8% to <5.0% (approx. 14% reduction), for all Asthma registry patients by December 31, 2017.

In this vignette and in many successful improvement projects, the use of data analysts to enhance the development of data definitions is beneficial. Clearly defined metrics ensure teams are able to maintain data to follow over time, lessening the risk of mid-project modifications. If done well, data element definitions help the team members understand the common goal and answer the question of "What Are We Trying to Accomplish?" A tool to ensure consistent and repeatable data definitions is helpful (Fig. 9.2).


Data Element Definition Form

DATA ELEMENT NAME
Click here to enter text.

DATA ELEMENT STEWARD & TITLE
(Who is the one who knows about this field?)
Click here to enter text.

DATA ELEMENT OPERATIONAL DEFINITION-Inclusions and exclusions
(Description of the definition)
Click here to enter text.

DATA ELEMENT TECHNICAL DEFINITION
(System, field, field name, & data format)
Click here to enter text.

LINKED REPORTS
Click here to enter text.

EFFECTIVE DATE	COMMENTS
Click here to enter a date.	Click here to enter text.

SUBMITTED BY	SUBMISSION DATE	DATE LAST UPDATED	APPROVAL DATE (Governance Council Use Only)

Fig. 9.2 Data element definition

Vignette 9.2
Nine separate asthma teams worked together developed a system-level key driver diagram (aka Learning Theory). Though committed individuals were doing good work in isolation, the need was clear to develop a unified plan with ideas for common drivers and interventions (testable ideas) that could serve in a crosscutting manner allowing more than one team to benefit from PDSA cycles for overlapping interventions. Some teams had garnered past success with identified interventions which were included in the system-level key driver diagram (Fig. 9.3).

Develop Learning Structure with Key Driver Diagrams

Key driver diagrams (KDDs) connect the aim/outcome, with key drivers and interventions (testable ideas) to create a "Learning Structure," and address the three questions that are part of the Model for Improvement (the Aim, Measures, and Interventions) (Fig. 9.3). Key drivers are big picture items ("what needs to happen") that allow the teams to reach their aim. To identify drivers, the teams use evidence, data, interviews, observations, and discussions. Drivers such as technology, engagement, and education are commonly identified on a variety of clinical improvement projects. Other drivers in this case vignette included asthma care coordination, community engagement, and medication management.

A key driver diagram is a fluid document and should be reviewed continuously and updated as needed. As teams progress through the improvement work, they may discover additional drivers that were not identified initially. Good version control is critical to ensure all improvement teams have the most recent version. The KDD may include color coding to identify work completed, work in progress, or work on hold. Drivers can also be labeled with team identifiers to highlight the areas where teams have the opportunity to collaborate.

In the nine-team example from the vignette, it was crucial to have each team develop local team-level KDD to identify contributions toward the system-level aim. As a result, each of the nine teams completed their own team-level KDD (inpatient team-level KDD, Fig. 9.4). A team-

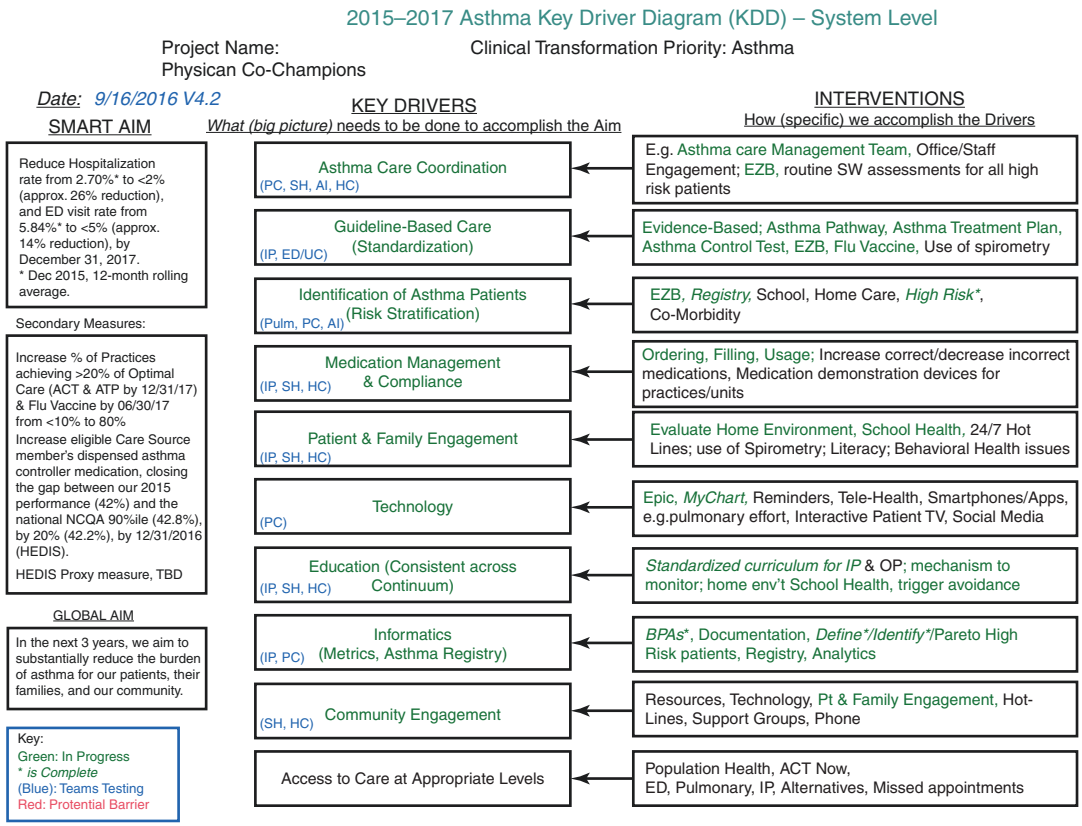


Fig. 9.3 Key driver program

level KDD helps each team focus on work within their control.

Identify Testable Ideas

With a maturing KDD, the intervention column is truly the opportunity to identify "testable" ideas. Said differently, interventions are the "how to" for each key driver. Sources of intervention might be better practice learned from within or outside of an organization, an evidence-based intervention, learnings from PDSA cycles, or even a best guess theory. A tenet of quality improvement is recognizing that many valuable "testable" ideas are generated by frontline providers and caregivers. Frontline staff live in the current process, thus are often the people who encounter and experience the problems and have spent time thinking of possible solutions. Their input must be solicited. In the case vignette regarding inpatient asthma care, frontline staff revealed that they didn't have a good way of remembering and tracking everything they were supposed to accomplish for an asthma patient prior to his/her discharge. Data analysis informed by the frontline observation of the process demonstrated that one important discharge element, the Asthma Treatment Plan, was only updated <10% of the time upon discharge.

Typically, multiple interventions are considered and depicted on a KDD. The interventions are commonly prioritized by the ease of testing, the expected impact on change, strategic alignment with other improvement efforts, or any combination of these reasons. Once interventions are considered, they are tested through Plan-Do-Study-Act (PDSA) cycles. Interventions may be connected to one or several drivers. The arrows in Fig. 9.4 indicate where interventions connect to

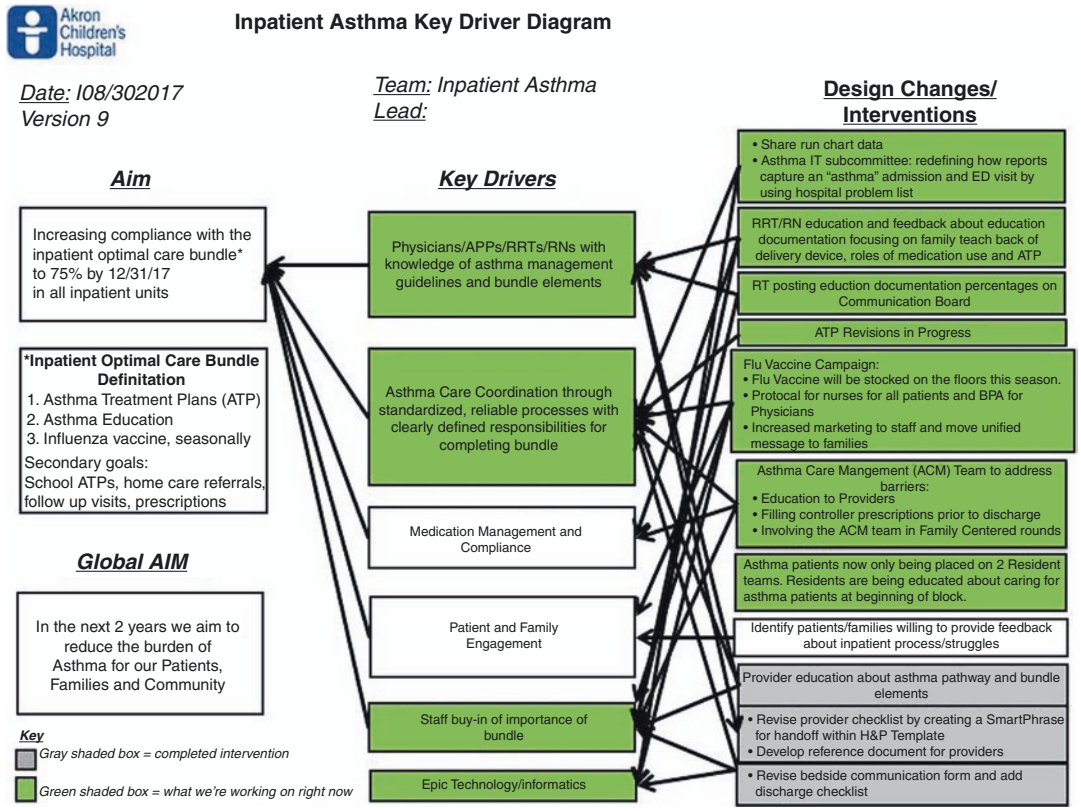


Fig. 9.4 Inpatient key driver program

drivers. Teams should test interventions regularly using PDSA cycles.

Design PDSA Cycles

The use of a standard PDSA cycle template (Fig. 9.5) is highly beneficial as it serves as the historical documentation of the many PDSA cycles the teams will complete over the course of an improvement project [3]. Projects may take years to accomplish during which time the composition of the improvement team may change. The PDSA documents memorialize all tests of change. Often, the PDSA templates inform the sequence of PDSAs, allowing one PDSA to inform the next PDSA.

Those involved in the tests of change should participate in the completion of the PDSA form. The team should agree on a date and a location and identify the people involved in the test. A poorly designed PDSA cycle increases the risk of drawing incorrect conclusions from the results leading to misinformed decisions regarding adoption, adaption, or abandonment of a particular intervention. Measurement of a PDSA impact can be enhanced by an assigned observer who is not directly involved in the test. The team should determine what information would be needed to answer the question the PDSA is designed to answer. Teams should also predict the impact of an intervention, particularly because those interventions with the highest likelihood of achieving improvement may be prioritized for early testing. Much can be learned from a simple test which does not require large numbers of patients, many days of testing, or multiple team members. The majority of the PDSA cycle should be spent in planning.

A well-planned PDSA cycle yields information that informs the team about the subsequent PDSA cycles [4]. PDSAs should start small.

Fig. 9.5 PDSA template form

PDSA WORKSHEET

Team name	Date of test:	Test completion date:
Overall team/project aim:		
What is the objective of the test?		
What 90 day goal does the change impact?		

PLAN

Briefly describe the test:

How will you know that the change is an improvement?

What driver does the change impact?

What do you predict will happen?

Task Plan:

List the tasks necessary to complete this test (what)?	Person responsible (who)?	When?	Where?
1.			
2.			
3.			
4.			
5.			
6.			

Plan for collection of data:

DO

Test the changes:

Was the cycle carried out as planned: Y / N

Record data and observations:

What did you observe that was not part of your plan?

STUDY

Did the results match your predications? Y / N

Compare the result of your test to your previous performance:

What did you learn?

ACT

Decide to Adopt, Adapt, or Abandon

- ☐ Adapt: Improve the change and continue testing the plan. Plan/changes for next test.
- ☐ Adopt: Select changes to implement on a larger scale. Develop an implementation plan and plan for sustainability.
- ☐ Abandon: Discard this change and try a different one.

For example, one PDSA cycle for the inpatient asthma team involved adding a bedside paper checklist reminder to review the patient's Asthma Treatment Plan, confirm asthma education completion, and confirm influenza vaccination status. This checklist was the first test of a reminder system that may ultimately become part of the electronic medical record decision support functionality. The data assessing the PDSA "value" would include how often the checklist was completed and how many patients had all three of these bundle elements completed.

Execute PDSA Cycle

This is the "Do" part of the PDSA. Any person involved in the testing, especially frontline staff, should be made aware of the test and clearly understand that the intervention is not a permanent change. The asthma checklist was placed at the bedside of five asthma patients for a 24-hour period. The team was delighted to find that all five patients with asthma had the bundle completed. The team was surprised that parents asked about the checklist and why the bundle items were important for their child. They had not

anticipated this reaction from parents, but inspired a parental checklist to inform parents about what should be completed before their child is discharged. This is an example of how a well-planned PDSA could yield data on the desired impact but also facilitate additional learning. The parent and staff partnership creates a shared accountability for bundle completion. This unexpected event during the PDSA cycle would prove to become a future intervention to be added to the KDD.

Make Decisions Based on Learning

Studying the data ("S" of PDSA) qualitatively and quantitatively will assist the team in deciding if (1) the intervention worked as predicted, (2) the intervention enhanced performance, and (3) there were additional learnings. During early PDSA cycles, teams may find the data recorded does not definitively determine the success or failure of the intervention. This revelation affords the team the opportunity to identify additional data needs. Again, small tests of change provide valuable information even if the test resulted in a failure. Teams can gain valuable insight when failures occur and with little financial or human capital expended due to the small-scale testing. Teams can execute many PDSA cycles and learn about the system rather quickly.

The final PDSA step is to "Act." As PDSA cycles are completed, teams determine if the intervention should be adopted, adapted, or abandoned. Adoption simply means the PDSA was successful and the team views the intervention as useful in support of the corresponding key driver. This intervention could be eventually implemented as a permanent change and/or tested more broadly, with more patients, or in different settings. Adapting an intervention indicates the team needs to improve the intervention and retest. Abandon is the decision to drop the intervention because the data reflected no appreciable change, the intervention was too burdensome, or the intervention proved unreliable. This adopt, adapt, abandon conclusion should be noted on PDSA tracking forms and if adopted or abandoned, then noted on the key driver diagram.

More PDSA Cycles

When interventions require adaptions, additional PDSA cycles should be planned and completed as methodically as prior PDSA cycles. Concurrent PDSA cycles can be completed by leveraging multiple teams in different areas, though careful planning must be made not to deploy too many PDSAs simultaneously to affect the same key driver. If there is improvement noted while there are multiple simultaneous PDSAs, it may be unclear which intervention yielded the improvement. The inpatient asthma team conducted the "Checklist" PDSA cycle in one acute care unit and tested "filling controller medications before discharge" in another acute care unit.

Select Change for Scale-Up

When interventions are successful in the small-scale test of change, the team should plan to expand the intervention testing. These tests can be documented and memorialized using a PDSA ramp summary (Fig. 9.6). If the intervention is not successful under altered conditions, be sure to evaluate an adaption to the intervention and conduct another PDSA. Consider if the adaption may negatively affect the areas where the testing was initially completed. If the intervention proves to be successful when scaled up, the intervention is ready for broad adoption.

Plan for Implementation and Sustainability

If interventions are to be implemented, corresponding changes need to happen to successfully implement the intervention. Policies, guidelines, education, and Standard Work Instructions may need to be updated to ensure the intervention is made permanent. Testing for a day or a week could be well tolerated, even a temporary ramp-

		Cycle 1	Cycle 2	Cycle 3	Cycle 4
Document BEFORE test	Test Description:				
	Test Population:				
	Location of test:				
	Date/Time (From – To):				
	Prediction:				
	Action taken:				
Document AFTER test	Test Results:				
	Action – Adapt, Adopt, Abandon				

Fig. 9.6 PDSA ramp summary

up of tests could be absorbed and fulfilled reliably. However, large-scale and more permanent implementation and sustainably can only exist when the intervention becomes the new normal. The asthma bundle checklist education was delivered to the inpatient staff on all acute care units, and an electronic health record bundle checklist was built. Policies were updated to include information defining the standard work for the bundle checklist completion.

Sustaining the observed gains is an essential component of improvement work. Using tactics like hardwiring interventions helps guarantee the successful implementation of the interventions even when the focus is turned to other improvement projects [5]. Collecting and reviewing data regularly helps to detect when an intervention begins to fail. If the data identify the intervention as being used regularly, the data collection frequency and sample size may be reduced [5]. Assigning a group or person to monitor the data over time will ensure early recognition of a change in the data.

Spread

Spreading the work to other relevant areas will include the same considerations as when implementing the work in a single area. Policies, guideline, tools, and Standard Work Instructions may need to be altered to support the new interventions. Determine what other areas would benefit from the intervention(s), engage the leaders from those areas to share the success of the interventions, and make the case for the change [6]. There is value in sharing the data and a story of how the intervention has led to improvement, as this may accelerate change adoption in new areas. It is important to identify other organizational activity that may conflict with the spread of the team's work and plan the pace and direction of the spread accordingly.

Data

Learning from data during the course of an improvement project is essential. Data are collected, analyzed, and acted upon prior to the kickoff of the project, for the duration of active improvement (PDSA) and during the sustain phase where intermittent monitoring ensures continued success of the improvement.

Data collected prior to the commencement of improvement work identifies the prevalence and significance of the problem and can be used to breakdown a problem categorically (Pareto chart) [7]. A Pareto chart focuses the direction and priorities of the improvement work. Pre-improvement data will create the baseline measure of the outcome or process being targeted

for improvement. By presenting pre-improvement data in the context of organizational strategy, the need for specific improvement work can be made more compelling.

Data collected during the improvement work should clearly align with the desired outcome of the work. Occasionally, direct measurement may not be possible, requiring a proxy measure to be carefully selected. A proxy measure will allow for change to be detected rapidly, but with a strong correlation between the interventions and the outcome. Data collected during active improvement will assist teams with decision-making relevant to success or failure of interventions, determine next steps, and may identify problems that were not initially apparent. Data should first be collected and displayed using a simple run chart and progress to more sophisticated means using appropriate control charts (often referred to as a Statistical Process Control Chart or Shewhart chart).

Post-implementation data should be monitored to track the effectiveness of the interventions on the desired outcome/process metric. These data can be measured with a sustain phase plan. The burden of data monitoring should be reduced during the sustainability phase of any project and should be measured using a control chart (Shewhart chart) so that processes moving out of "control" can be easily identified.

Types of Quality Improvement Measures

There are a number of strategies to categorize quality improvement measures. Avedis Donabedian succinctly categorized measures in three ways: structure, process, and outcome [8]. Others have considered a fourth category for quality improvement measures, a balancing measure.

Structural measures include those measures that represent the physical space and equipment used to deliver care or manage a process. Some think of these as measures of the environment – and are clearly distinct from process, outcome, and balancing measures. This is occasionally binary, meaning it either exists or it does not, and for that reason is often easier to measure. It is believed that structural measures are often foundational to the ability for subsequent process or outcome measures to be achieved. For example, a structural measure in our asthma vignette may be the availability of a care manager position for asthma patients. This role either exists or doesn't and doesn't address how care management occurs, how the care manager is contacted, or even how frequently/infrequently patients use the emergency department or are compliant with home medications when contacted by the care manager.

Process measures generally represent one or more specific steps of a process that are thought to possibly lead to a particular desired outcome. Most outcomes are derived from a structure that supports success and the multiple processes that each contribute collectively to an outcome. Some have used the analogy of a ladder to Donabedian's structure, process, and outcome measures. The ground that the ladder is seated on is the structural measure, and the rungs of the ladder serve as individual process measures, each contributing to the journey to the top of the ladder, which is the desired outcome. The inpatient asthma team studied and tested the administration of the influenza vaccine to patients admitted to the hospital as a process measure – asking if they were able to reliably administer the vaccine.

Thirdly, outcome measures represent the state of the patient or population of patients and what is important. It may demonstrate overall system-level performance for patients or the financial picture associated with the improvement. Said differently, an outcome measure is the actual thing that we want to change or improve in the end. In our asthma examples, the outcome measures are emergency department (ED) visits and inpatient hospital admissions. The idea of avoiding either situation is important to the patient (and his/her family).

Lastly, balancing measures are considered to ensure an improvement in one area is not negatively impacting another area. It may be difficult to identify balancing measures, and the impact

may be realized in a clinical metric or an administrative/financial metric. While trying to reduce inpatient admissions, the emergency department may keep asthma patients in the emergency department longer or send more of them home when an admission would possibly have been wiser. Therefore, admissions decrease, but ED length-of-stay (LOS), ED revisits, and patient satisfaction could each be negatively impacted. It is difficult, often times, to capture all potential balancing measures, but great thought should be given to try and ensure the breadth of balancing measures are captured.

Features of a Good Measure

Data considerations and metric determinations start with the aim statement. Useful metrics ensure buy-in for the improvement project [9]. When selecting the aim or goal, consider the following features of a useful metric:

1. *Understandable* – The metric is defined in such a way that it conveys, at a glance, what it is measuring and how it is derived. When creating a data definition for the metric, keep the metric clean and simple to understand without multiple exceptions that potentially add unnecessary complexity to the metric and the data collection process. Test out a metric by trying to explain it to someone outside the improvement team.
2. *Credible* – Credible is offering reasonable grounds for being believed. The credibility of a metric can be increased by staying consistent, using the best evidence, citing definitions from outside organizations, or simply having an understandable metric.
3. *Comparable* – Being able to compare a metric across time periods, groups of users, national benchmarks, or competitors allows the improvement team or sponsor to understand the metric performance.
4. *Actionable* – This is by far the most important criterion for a metric requiring consideration of what will be done differently based on changes in the number. If the improvement leader or team has little potential to influence change, then the improvement project should be either abandoned, turned over to a team that has the ability to influence, or enlist a sponsor with span of control to champion the change.
5. *Aligned* – To assess if a metric is aligned, it would be useful to ask, "How does the metric relate to other metrics in the hospital and the hospital's overall objectives?" Improvement should be tied to strategy, whether organizational, departmental, or local.
6. *Accessible* – To assess if a metric is accessible, consider the following:
   - Where are the data available?
   - Are the data collected manually?
   - How much manipulation do the data need in order to be in the desired format?
   - How many calculations does the metric involve?
   - How many people have to touch the metric?

Variation

To understand changes in the data and what those changes mean, improvement teams need to understand what random and nonrandom variation, as well as common cause and special cause variation [7]. When run charts are used to display data, random and nonrandom variation differentiates change that occurs randomly or change that is distinct. For control charts, variation is considered common cause if it represents the ebb and flow of a process that is unchanged, whereas special cause variation indicates the improvement work has either positively or even negatively impacted the measure. Recognizing variation characteristics that signify change in the data alerts the team to explore the reason for the change.

There are two main types of variation in any systems: intended and unintended variation. Intended variation is an important part of effective, patient-centered healthcare. It is similar to the concept of variety – one size does not fit all. It is often called purposeful, planned, guided, or

considered. It is acceptable to both the healthcare consumer and those who work within the delivery system. Unintended variation is due to changes introduced into healthcare structure or process that are not purposeful, planned, or guided. This type of variation creates inefficiencies, waste, rework, ineffective care, errors, and injuries. Most healthcare improvement projects focus on reduction of these unwanted variations as they are unwelcomed by the consumer and those within the delivery system.

A basic premise of improvement work is the idea that variation is a measure of quality and variation has one of two causes: common cause or special cause. Knowing the source of variation and identifying the nature of variation is a critical quality improvement skill. Common cause variations are those causes inherent in the process over time that affect everyone working in the process and affect all outcomes of the process. Conversely, special causes are not part of the process all the time or do not affect everyone but arise because of specific circumstances or interventions.

This premise and understanding of the causes of variation become important as data are collected, and the team determines the next steps in the work. Leaders and teams must be vigilant in not unduly reacting to common cause variations but certainly need to be poised to react to special cause variation. Teams should be able to clearly understand what their data are telling them, so they are able to convey the improvement story and make decisions about the next steps in the work. Some basic descriptive statistical analysis review may be necessary. Understanding the type and distribution of the data will allow the team to determine how to best summarize, present, and analyze data during all phases of the improvement project.

More Considerations for Data and Measurement

Identifying the process or outcome to be measured will help frame the baseline data so that it is in alignment with the aim statement. This numerical baseline data can be easily represented in a histogram (a chart that relates the frequency of one variable on the Y-axis, over time, on the X-axis). (See Key Point Box 9.1) The chart below (Fig. 9.7) reflects the rising frequency of ED asthma visits as a count per year and is not adjusted as a comparison to all patients with asthma or all emergency department visit reasons.

Key Point Box 9.1
A histogram is a graphical representation using bars to depict the frequency of continuous variables as they fall into a given range. The height of each bar indicates how many fall into each category range.

Numerical data can also be divided into categories related to the frequency of problem types for process failure and is best visualized in a Pareto chart. A Pareto chart contains discrete X-axis bars representing the frequency of each problem and the Y-axis depicts the % of the failures attributed to each problem. Generally, a line

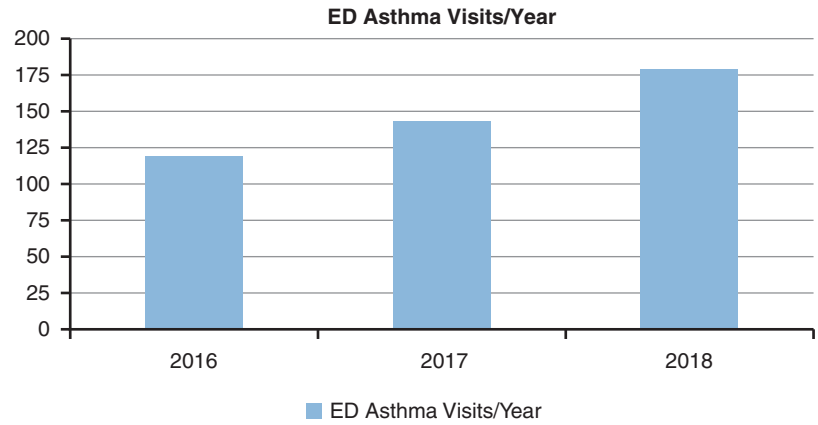


Fig. 9.7 Asthma ED visits/year

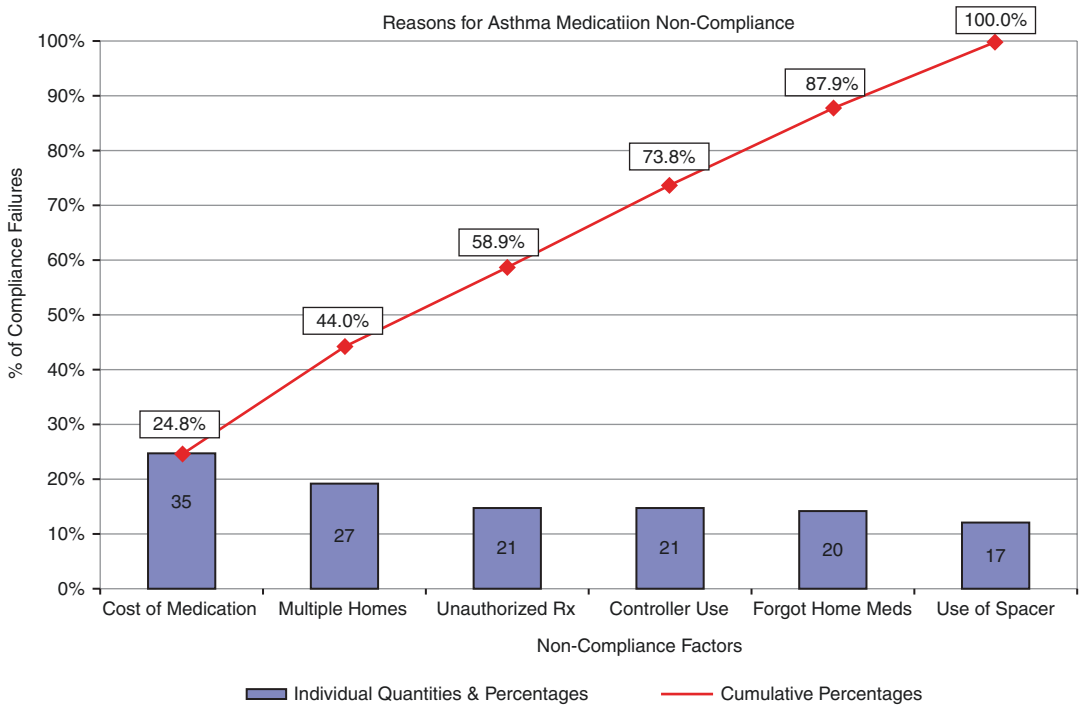


Fig. 9.8 Reasons for asthma medication noncompliance

is generated depicting a cumulative frequency from left to right on the chart. A Pareto chart helps identify problems may be causing more failures and may guide intervention testing (PDSAs). In Fig. 9.8, the reasons patients with asthma are not compliant with their prescribed medications are identified by category and frequency. This information was collected through a patient questionnaire, and the data were entered to generate the Pareto chart. The information was shared among the teams with each team being charged to identify potential interventions they wanted to test using the Plan-Do-Study-Act cycle. These interventions were included in the key driver diagram.

Data Display

Quality improvement data (both pre-improvement data and PDSA data) can be plotted using a run chart [7]. A run chart can plot a count or rate (Numerator over Denominator) across time using points connected by lines. This type of visual chart reflects a basic understanding of the data in comparison to a standard grouping (histogram), is a quick and easy way to begin the tracking of data, and allows for a clear picture of the performance of the process or outcome. Interventions tested through the PDSA cycle may impact the process/outcome and change to the performance of the system, which can be seen in the asthma ED visit rate run chart. In the case of the asthma patients, data are plotted as the number of ED asthma visits as a numerator over the number of patients in the hospital's asthma registry (denominator) per month. The "n" represents the number of patients in the asthma registry for that month. The time series of the run chart should be displayed on the X-axis and the rate on the Y-axis.

A run chart should optimally have the following elements:

- Labels along both axes with a clear description of the measurement (%, days, weeks, minutes)
- Equal X- and Y-axis tick marks
- Title which clearly and simplistically describes what is being plotted

- Arrow showing the desired direction of change that is an improvement
- Appropriate scale
- Identified and labeled goal
- Annotations
- Line drawn to show the median of the data

The scale should be appropriate for both the current range of data being displayed and what future data may need to be plotted. When the scale is small compared to the range of the data set, improvement can be difficult to detect; conversely, when the scale is too large, the data may appear to have significant gains or losses, when in fact, this is simply a product of an inappropriate scale. Most of the current data should fall in the middle of the chart, so variation in either direction becomes apparent.

Any observer of the chart should be able to quickly understand what is being measured and if the performance is improving or declining. The chart should also display the goal of the project so teams can demonstrate what the final target is and how close the team is to accomplishing the goal set out in the Aim statement (Fig. 9.9). Teams should become accustomed to regularly annotating the chart to reflect PDSA cycles, unusual situations (i.e., abnormally low or high denominators), or any other notes that may not be remembered as the work progresses. Use the first 10–12 data points to calculate the median (the number in the middle of the data set) and plot the median on the run chart parallel to the X-axis. The median can be extended across the chart to reflect the original baseline or may shift when a system change is identified according to run chart rules, as improvement happens. The centerline in a run chart is the median value. If baseline data are not available, use the first 10–12 data points available once the data collection is possible as early improvement planning will not likely affect the early data measurement points. Run chart rules related to the median allow for the detection of changes resulting from the testing of interventions [10].

There are several run chart rules for nonrandom variation; the descriptions below are intended to give the reader a primer on nonrandom variation and are not exhaustive or all-inclusive of the rules [7]. These probability rules indicate a nonrandom change in the system and alert the team that the process or outcome has changed – sometimes for the better or potentially for the worse. These rules are based on successive data points and their relationship to the median. These rules do not indicate if the process is stable or "in control," only that some intervention(s) has probably caused the observable change and the change is not random. Instances of nonrandom variation in data should

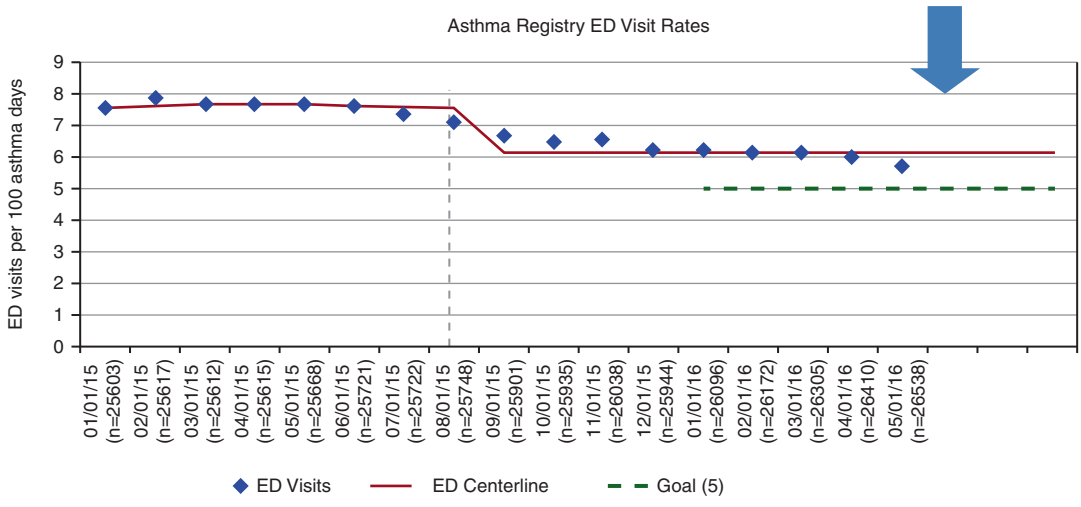


Fig. 9.9 Asthma registry ED visit rates

be investigated, prompting the formulation of a theory as to why the change occurred and annotated on the run chart. Run chart medians can be shifted or recalculated based on data changes identified within the grouping of nonrandom variation in data as long as none of the data points were also used to establish the baseline median.

Run chart rules depicting nonrandom variation [10]:

1. Shift – Six or more consecutive points all above or all below the median (Fig. 9.10)
2. Trend – Five or more consecutive points all going up or all going down (Fig. 9.11)
3. Runs – Alternating points in a "zigzag" pattern (Fig. 9.12)
4. Astronomical point – A point that is obviously and blatantly significantly different from all of the other data points

When run chart data do not meet these nonrandom variation rules, any data changes can be considered normal or random variation. When data has been collected past the baseline stage and results in 10–12 additional data points, teams may consider abandoning a run chart in favor of one of the many types of control charts (Shewhart charts) in order to create a clearer picture of the nature of the data.

Control Charts (Shewhart Charts)

Control charts are similar to run charts in that they too plot data over time. Control charts differ from run charts in that they can identify the process as being "in or out of control" or the stability of the process and the ability of the process to function predictably. Control charts accomplish this predictability through the use of statistical process control to determine the stability of the system. Predictable processes follow a known pattern, and predictions are made based on that pattern, depicting clearly common cause or special cause variation. In statistics, that pattern is known as distribution. Knowing the distribution of the data allows for an expected outcome. For a stable, predictable process, 99.7% of the data points will fall within three standard deviations (+ or −) from the mean of the data. Each standard deviation away from the mean is used to identify variation from the average performance (mean). Once a data point falls outside of the third deviation, the process is no longer predictable and that point is identified as an outlier (a type of special cause variation). Because data falls outside the limits 0.3% of the time, it would be highly unlikely that a data point outside the control limits would be attributed to common cause variation.

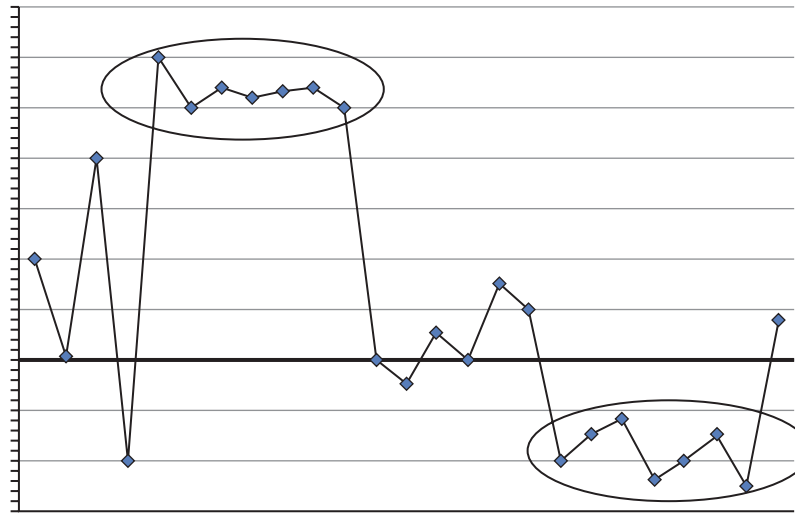


Fig. 9.10 Six points above/below the mean

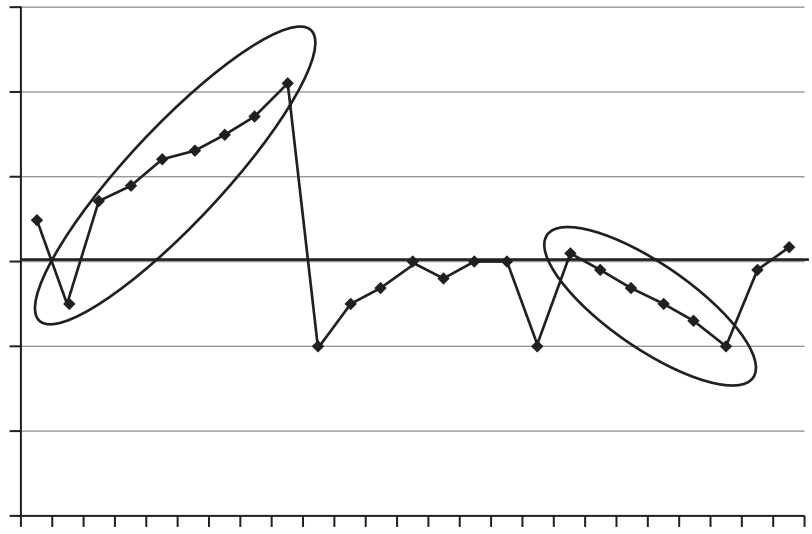


Fig. 9.11 Trend five or more points

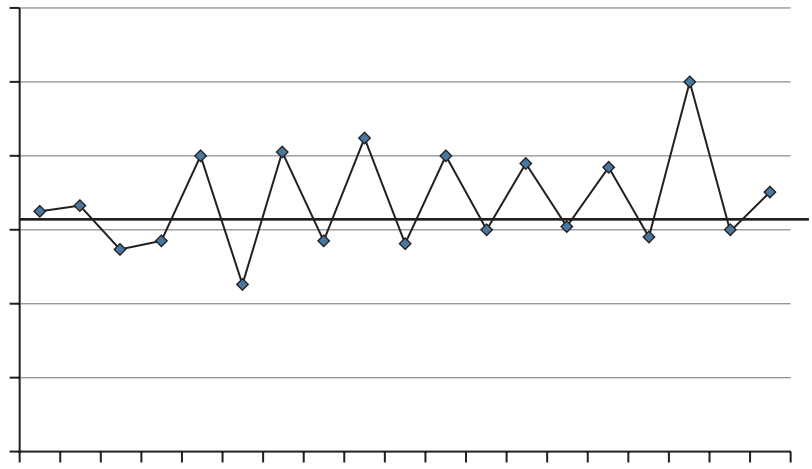


Fig. 9.12 Alternating points zigzag pattern

Data within the control limits could still be identified as special cause if they meet the definition for data that differs from the normal distribution. If the goal of the improvement work is to raise or lower an average, data patterns will exist inside the expected distribution that signals a change which indicates the interventions are moving the data toward the goal (new average). These rules are discussed after some basic understanding of control charts is established.

The anatomy of a control chart is as follows (Fig. 9.13):

- There are an upper control limit (UCL) and a lower control limit (LCL).
- Typically, the upper (UCL) and lower (LCL) control limits are ±3 standard deviations from the mean.
- The centerline is the actual process mean (average).

Figure 9.14 represents a normal distribution of data. If this familiar distribution is rotated to the side, a control chart becomes more understandable. There are many available templates that allow a user to enter a time series, title, and

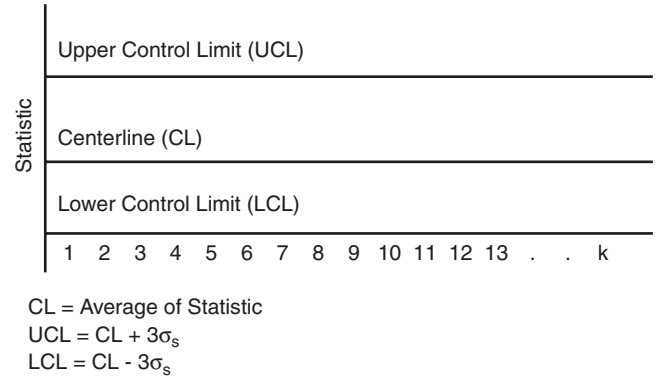


Fig. 9.13 Anatomy of control chart

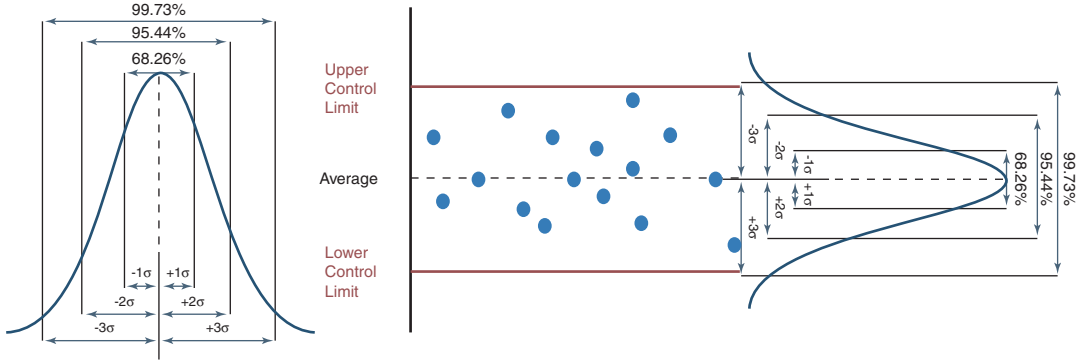


Fig. 9.14 Control chart bell curve

accompanying data to ultimately generate a control chart. Creating control charts through manual computation is not overly challenging but will require the use of some additional resources.

The type of control chart used to display data depends on the type of data being used. The decision tree in Fig. 9.15 is helpful when choosing a control chart. Continuous vs. attribute data is the initial bifurcation in the decision tree. Continuous data are data that have a broad range of values that could be anywhere within a range of data. Common examples of continuous data are body weight or time in seconds. Attribute data, on the other hand, is more discrete and usually can only take a limited set of values. For example, attribute data may be either in range or out of range.

Identifying Special Cause Variation

Points that fall outside the control limits are indicative of special cause variation and require investigation. Other special cause rules also indicate a change to the process with the data points remaining within the control limits. The system may be performing within control, but not where the team has set the goal. The following special cause rules help to identify such changes as the interventions are tested through the PDSA cycle and are used to answer the improvement question related to "Is the change an improvement?" Most importantly, these rules allow teams to determine the need to react to the data and make changes or if the data is demonstrating normal variation and do not require mediation.

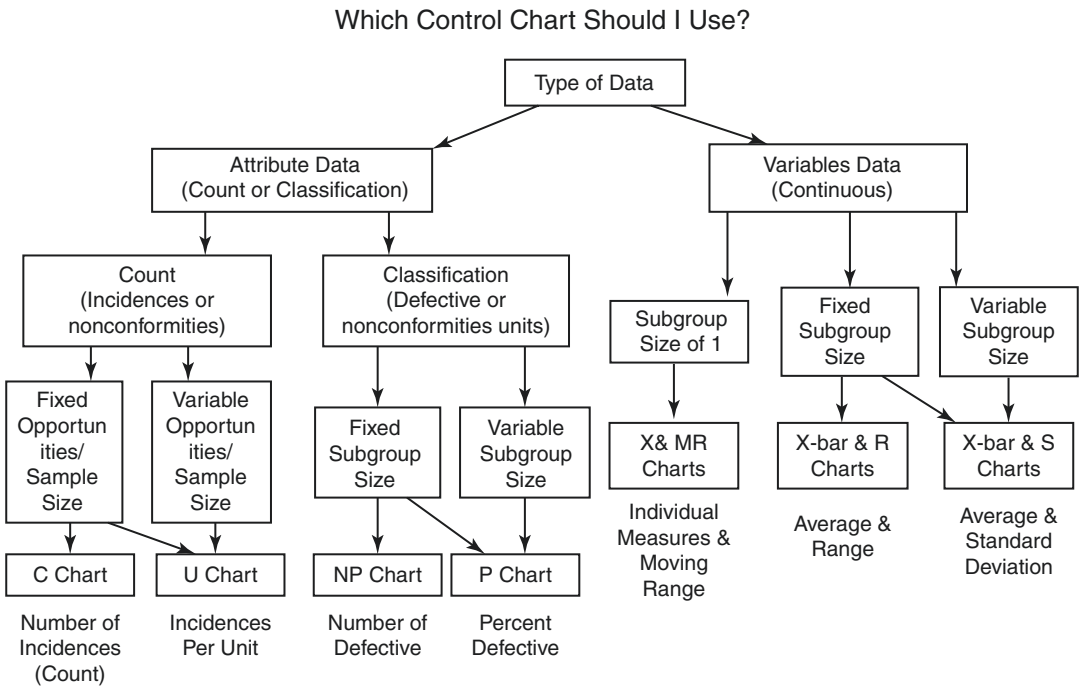


Fig. 9.15 Control chart decision tree

The rules governing special cause variation for control charts are as follows [7]:

1. Eight or more consecutive points above or below the centerline (Fig. 9.16)
2. Six or more points increasing or decreasing (Fig. 9.17)
3. Two out of three consecutive points near an upper or lower control limit (Fig. 9.18)
4. Fifteen consecutive points near the centerline (Fig. 9.19)
5. A single data point outside of the control limits (Fig. 9.20)

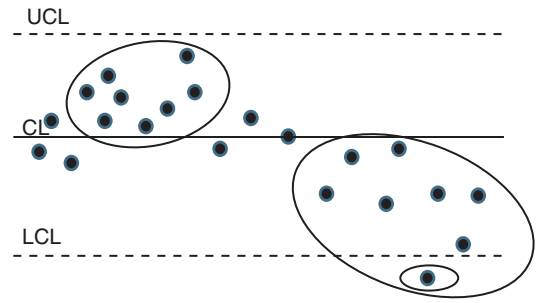


Fig. 9.16 Eight or more consecutive points above or below the centerline

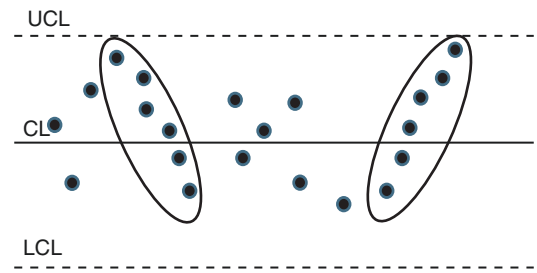


Fig. 9.17 Six or more points increasing or decreasing

Don't Get Lost in Data

Quality improvement in healthcare is a moral imperative. Each and every patient deserves high-quality care. As such, improvement teams must never allow the measurement and nuances of healthcare data to negate the fact that the data often represent real people or processes that

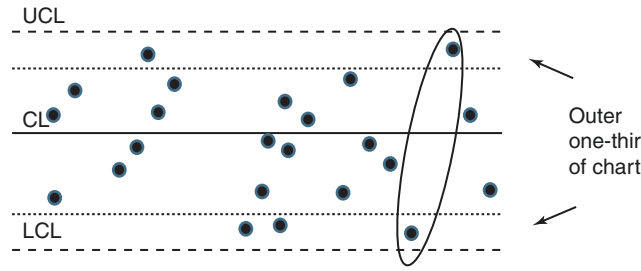


Fig. 9.18 Two out of three consecutive points near outer third of control limit

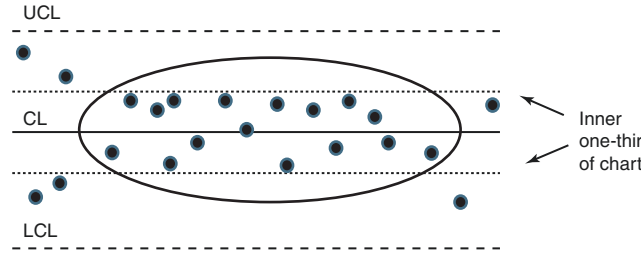


Fig. 9.19 15 consecutive points close to centerline

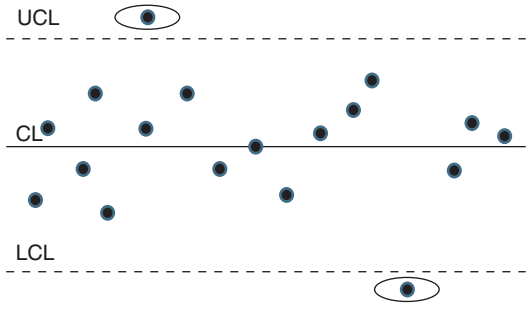


Fig. 9.20 Single data point outside of the control limits

affect people. Goals and ongoing measurements often contain language about percent reductions or increases, dollar costs, failures, and special causes. Inspiring improvement requires leaders to be sure to equate numerical measures back to the people impacted by the care delivered every day. A better practice is to consider phrasing goals in terms of the number of patients, so this notion is not forgotten as teams move forward in their work. This understanding will serve as a motivator for continuous improvement.

Editors' Comments

Each and every chapter in this textbook is important; each and every chapter is value-add for the novice as well as experienced improvement scientists. This chapter serves as a primer for the novice or casual quality improvement scientists and forward thinking and directional for those that are more advanced in their improvement journey. Using the case vignettes, the authors masterfully navigate the quality improvement process using methodologies as their framework. We sincerely appreciate the authors demonstrating specific strategies that they have employed in their organization (e.g., "data element definition form"). These concrete examples are invaluable for organizations that want to use this chapter as a foundation to build upon or advance their quality improvement journey.

The core of improvement science is using a roadmap in an iterative manner. The authors thoroughly explain key driver diagrams and eloquently link these to the iterative tests of change. Again, we are most appreciative of the demonstrations of how they actually implement and operationalize these tools in their respective organizations.

We are inundated by payers, the government regulations, and the public with requests for more and measures. The end of

the chapter nicely builds on the need to have pertinent and solid measures with how to best use data. It is not expected that this chapter is completely thorough; indeed, the Editors refer the reader to Lloyd Provost and Sandra Murray's definitive and expansive textbook on data for quality improvement [7]. However, the authors of this chapter demonstrate the value of data, how to be wary of data, and how to best use data to create measures that matter.

Each and every chapter in this textbook is a value-add. This chapter is crucial. We strategically placed this as the ninth chapter so that the improvement scientist is primed at this point of their reading journey to become committed to the quality improvement methodologies as outlined in this chapter.

Chapter Review Questions

1. True or False – The three basic elements that constitute the framework of a key driver diagram are: Aim Statement, Drivers, and Interventions?
   Answer: True
2. Multiple Choice – What does "SMART" stand for when discussing a "SMART" Aim (goal)?
   A. Specific, Measurable, Attainable, Relevant, and Time-bound
   B. Standard, Measurable, Articulate, Range, Testable
   C. Standard, Mindful, Attributable, Relevant, and Testable
   D. Statistical, Meaningful, Attainable, Real, Tangible
   Answer: A
3. Why is it important to make a prediction about a PDSA cycle?
   Answer: Making a prediction about the success of an intervention, before the testing, establishes a level of confidence in the intervention affecting the process or outcome and assists the team in determining the testing priority of the interventions. By comparing the actual results to the predictions, shared learning can occur.
4. True or False – Special cause variation should be investigated because this type of variation is unexpected and don't exist in the system all the time.
   Answer: True
5. Which of the following should be included on any type of run chart or control chart?
   A. Labels on the axes and the chart
   B. An arrow describing the desired change of direction
   C. A clear and equivalent time series and tick marks appropriate for the data set
   D. All of the above
   Answer: D

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Designing Improvement Teams for Success

10

Nicole M. Leone and Anupama Subramony

Chapter Objectives

- Describe the importance of high-functioning teams in driving quality improvement in healthcare settings.
- Generate strategies to build and lead effective teams using improvement science tools and organizational tactics.
- Use principles from psychology of change to create a burning platform to drive change.

Vignette 10.1

Over the last few years, the infection control team of a children's hospital within a larger hospital system was focused on helping teams decrease central line-associated bloodstream infections and catheter-associated urinary tract infections. In this time period, the number of nosocomial *C. difficile* infections has risen. At a system-level quality meeting, *C. difficile* rates for the children's hospital system are presented, showing a rate significantly higher than the benchmark. The pediatric Chief Medical Officer returns from the meeting and charges the quality team to create an action plan and reduce rates as soon as possible.

Opening Question/Problem

Quality improvement opportunities in complex healthcare settings are omnipresent; this chapter describes the importance of creating multidisciplinary teams and leading these teams effectively and efficiently. Intentional thought on creating an effective team with a burning platform will greatly aid in achieving the aim of the initiative.

Introduction

The creation of effective teams is a key element of all organizations, though may be especially important in healthcare settings, given the complexity of healthcare systems. In general, a team

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is defined as a group working collaboratively and interdependently to achieve a common goal, to which they are all held accountable [1]. In many healthcare organizations, teams are developed using staff with varying knowledge, skills, and experience to help solve complex problems and create pragmatic, innovative solutions. Keeping these teams on track to achieve their aims requires care and purpose. This chapter will review the development of improvement teams, how to make these teams productive, and how to keep the teams strategically aligned with a burning platform.

Vignette 10.2
The Chief Medical Officer of the pediatric hospital has apprised the Chief Quality Officer of the respective hospital about the increased *C. difficile* rate and the discussion of this at a system-level meeting. Understanding the urgency to fix the issue, she quickly alerts the medical directors of the inpatient units to stop sending tests for C. difficile unnecessarily. The leadership of the Oncology unit expresses some reluctance at the shotgun approach to a problem without systematically assessing the potential myriad contributing factors.

Evolution of Teams for Quality Improvement

Quality improvement initiatives have their roots in teams. The methodologies that constitute improvement science were originally used in the scientific approach to improving the efficiency of manufacturing processes [2]. Key leaders include pioneers such as Frederick Winslow Taylor, W. Edwards Deming, Walter Shewhart, Joseph M. Juran, and Taiichi Ohno who in aggregate developed and perfected ways for organizations, specifically manufacturing, to be more effective and efficient in producing error-free products [2–7]. Central to these methodologies was the use of teams to analyze a problem, design tests of change, test solutions, and determine and measure metrics of success.

What Is a Team?

Underlying improvement projects is a well-crafted team who work together to carry out a change process. Members of the team work collaboratively for a shared purpose, with shared responsibility for achieving results. Teams can be used when the problem to be addressed is complex, when learning of the system is a necessary prerequisite, when there is no clear answer to a problem, when innovative ideas are needed, and when cross-collaboration among differing disciplines are necessary. For teams to be successful, they need clear and attainable goals, an appropriately scoped initiative, expertise, and resources from across the organization [1]. An important distinction is between a team and a working group. A working group's output is a sum of what the individuals in the group attain; in contrast, a team's performance represents both individual work and collective work that represents the joint contribution of multiple team members [8]. Working groups are used for information sharing, to provide counsel, and to help individuals improve their performance on discrete initiatives. They usually include a clearly defined leader, involve individual work products, and are measured by their influence on others; in contrast, teams focus include multiple leaders in shared leadership roles, have both individual and mutual accountability, develop collective work products, include open-ended discussions and active problem-solving group discussions, and are measured by assessing their collective work products [8] (Key Points Box 10.1).

Key Points Box 10.1
Teams are a group of people who work collaboratively and interdependently towards an aim; the output of a team represents collective work jointly produced by multiple team members.

Identifying Team Members in an Organization

Teams play such a significant role in driving improvement in organizations that the strategic design and crafting of a team are vital. The team's inclusion of experts in the process that needs to be changed is a necessary first step (commonly referred to as subject matter experts which can be any level of employee). In fact, studies done at the Hawthorne factory in the mid-twentieth century showed that engaging frontline staff in redesigning a process improved both the efficiency of the process and improved and sustained reliability to the process [4]. Deferring to the expertise of the frontline staff to be able to improve a process with practical context, as opposed to having leaders' remote to the frontline, was thought to be a contributor to the success. Walter Shewhart, who developed the statistical process control chart, a key tool in improvement science, made a strong case for engagement of frontline staff in improvement activities. He championed the development and deployment of statistical process control charts to be displayed on manufacturing floors to allow frontline staff to identify special cause variation, stop the line, conduct just-in-time analyses, and find and fix issues as they arose [4]. This frontline engagement approach to improving the efficiency of a process was transformative, and its effect persists in improvement science methodologies [9]. A team cannot be assembled without pertinent subject matter experts.

When building a team, understanding how stakeholders view potential improvements is imperative to developing the appropriate team composition. While it may be easier to identify stakeholders who are enthusiastic and will drive change, it may be more challenging to find those who are indifferent or opposed (commonly referred to as contrarians) and engage them in an improvement team. Effective teams are not created with all those individuals that may be the easiest to work with and the most convenient. Indeed, highly effective teams include staunch supporters and similarly strong contrarians.

A stakeholder analysis illustrates the position of each stakeholder with regard to the project, can be used as a tool to understand why they may not be at the level of engagement necessary, and then helps the team determine how much effort should be spent moving that commitment from its current status to that which is necessary to achieve their goals [1]. A representative team composition can be built using the rubric shown in Fig. 10.1. This rubric categorizes stakeholders into four main categories: those with high influence and high interest, high influence and low interest, low influence and high interest, and low influence and low interest. Those with high influence and high interest should be fully incorporated into the team, as they have the resources and passion to drive the project forward. There should be a respectful collaboration with stakeholders of more mixed influence and interest, particularly those who are not initially supportive but offer high potential for cooperation (the team may direct specific efforts to engage these

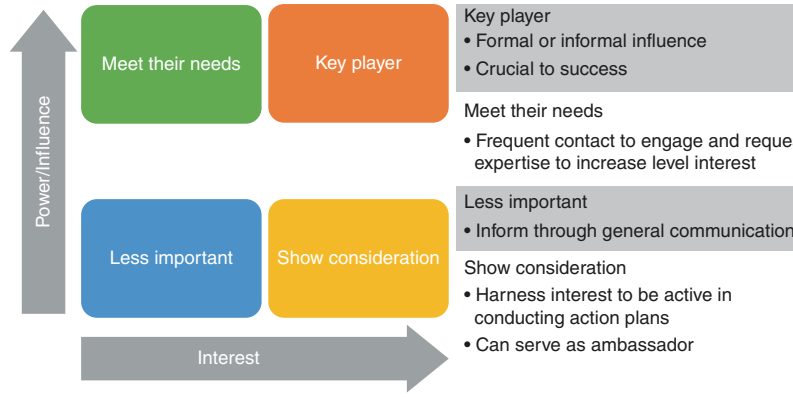

Fig. 10.1 Stakeholder analysis

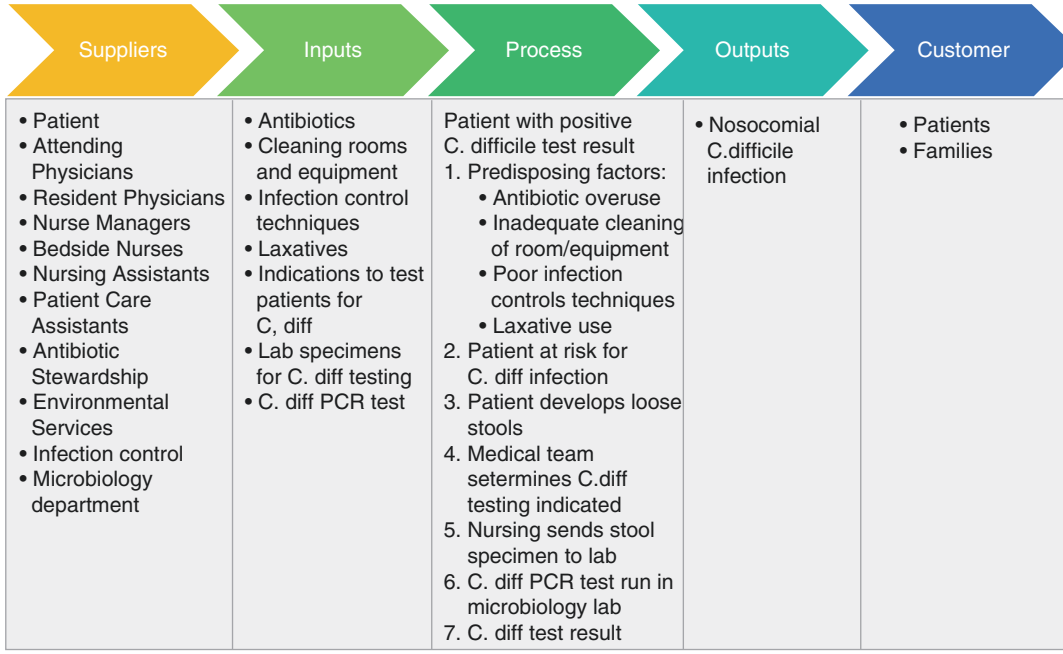

Fig. 10.2 SIPOC tool

individuals). Those with high influence and more neutral positions may have resources that could be offered to the team and should be informed and engaged. The team that identifies stakeholders who are non-supportive with low potential for cooperation can be prepared to deal with these individuals [1, 10].

An alternate tool that can be used to identify key team members is the SIPOC tool, which maps a process and includes all *S*uppliers, *I*nputs, *P*rocesses, *O*utputs, and *C*ustomers [Fig. 10.2] [1]. Defining the suppliers and inputs of a process, as well as the customers who will use the outputs of the process, can be helpful in more complex projects to assure all key stakeholders, especially those who are not immediately apparent, are considered [1]. Using this tool to identify hidden team members can prevent the inadvertent exclusion of a member that would potentially be impactful. Identifying key stakeholders late in the game and necessitating a latecomer to "catch up" could possibly derail work already in progress [1, 11]. The SIPOC tool may have the added benefit of starting out the improvement team with a narrow focus on a single process, avoiding the common pitfall of working on a problem that is too broad. In addition to identifying team members, these tools can also aid in identifying other valuable stakeholders who may not be part of day-to-day operations, but may prove to be valuable allies as the team progresses; these other stakeholders should of course be kept abreast of progress on the team and can be used as consultants to the project in an as needed capacity [1] (Key Points Box 10.2).

Key Points Box 10.2
Developing cross-functional teams for improvement projects requires thoughtful consideration; specific tools such as a SIPOC can help provide structure to designing a team for success.

Considerations Around Designing a Team

While these tools may assure that a team accurately reflects the need of the project, it is also equally important to be mindful of the size of the

team. Smaller teams may be more agile, more innovative, and ultimately, more effective. Examples of these teams include many internet start-ups including WhatsApp and Amazon, whose CEO Jeff Bezos coined the "two-pizza rule," suggesting that any team that could not be fed by two pizzas was too big [12]. Strategies to assure the optimal size of teams include breaking down improvement teams into smaller projects, empowering team members to be the decision-makers, building a trust culture to allow team members to be agile in decision-making, focusing on informal ways of sharing information as opposed to taking formal minutes or creating presentations which can be less efficient, building platforms where team members are actively communicating (collaboration platforms), and effectively using technology to program manage [13].

Over and beyond choosing the right constituents for and the size of the team, other considerations in creating effective teams include understanding how members of these teams will work together. There is science behind the concept of which elements make teams more effective at their work, including problem-solving. While the functional role of team members is important, the psychological role that a team member plays may be equally important [14]. Teamwork is dependent on elements such as affective states, behavioral processes, and cognitive states of teams, much of which is influenced by the personality types of individual team members [14]. When teams are being created, it is imperative to craft a well-balanced mix of team member personalities including those team members who are results-oriented, relationship-focused, process and rule followers, innovative and disruptive thinkers, and pragmatic [15]. A mix of personality types allows for effective teamwork that translates inputs (expertise, capabilities, knowledge) into outputs (process changes, products). The diversity of a team cannot be understated; it is well demonstrated that diverse groups in terms of race, ethnicity, and gender are more rigorous in problem-solving [16] (Key Points Box 10.3).

How teams work together is integral to how they will function. Increasingly, it is becoming apparent that effective teams have several key components: mutual trust among team members rooted in emotionally intelligent behaviors, a clear group identity, and a belief that the team is more effective working together compared to working alone. Central to this is the idea is the concept that self-awareness and regulation of emotions translate into the group setting; teams should work on setting standards for behaviors that help foster trust, group identity, and a feeling of group efficacy [17].

Key Points Box 10.3
Designing a team should take into account key stakeholders, level of engagement, skillset, and personality types of individual team members; teams should be the right size to be able to work together and have mutual trust that the team will be more effective working together compared to team members alone.

Roles and Responsibilities for Team Members

Once stakeholders are identified, role delineation is imperative. The core team is comprised of several important team roles (which should be delineated on the project charter): team member, team leader, coach, and senior sponsor.

Team members contribute to the overall success of the team by sharing their knowledge and experience during team meetings and participating in implementing changes. As previously discussed, it is imperative to include members of the clinical team, particularly the frontline staff or those in the know of current work processes, who will be able to give context to key drivers to achieve an aim within a clinical setting. These members include physicians, nurses, and other clinical staff. Sometimes, these individuals may be seen as informal leaders in their work environments and may have key relationships that allow

them to operate as key influencers to promote change. Teams should include subject matter experts to give content expertise and provide deep knowledge in the area for improvement. Many teams can and should include patients and/or family members on their improvement teams. Inclusion of the patient voice lends credence to the improvement project and assures that the changes are patient-centered (Fig. 10.3).

Even with team members whose members have formal authority within an organization, effective teams need a clearly defined leader who runs the day-to-day operations, leads meetings, and may become a liaison to clinical and executive leadership. Often times, the team leader is not the team member with the highest title or most power in the organization. The team leader serves as the communication link between the team and the rest of the organization. It is the leader's responsibility to maintain the data related to the project, as well as supervise preparation of reports and presentations; the team leader is the public and organizational face of the team and is accountable [1]. Returning to the *C. difficile* reduction vignette, a physician in the hematology-oncology unit who is enthusiastic and results-oriented may be a clear leader for the project.

If the team is an improvement team, there may be an improvement coach (referred by many dif-

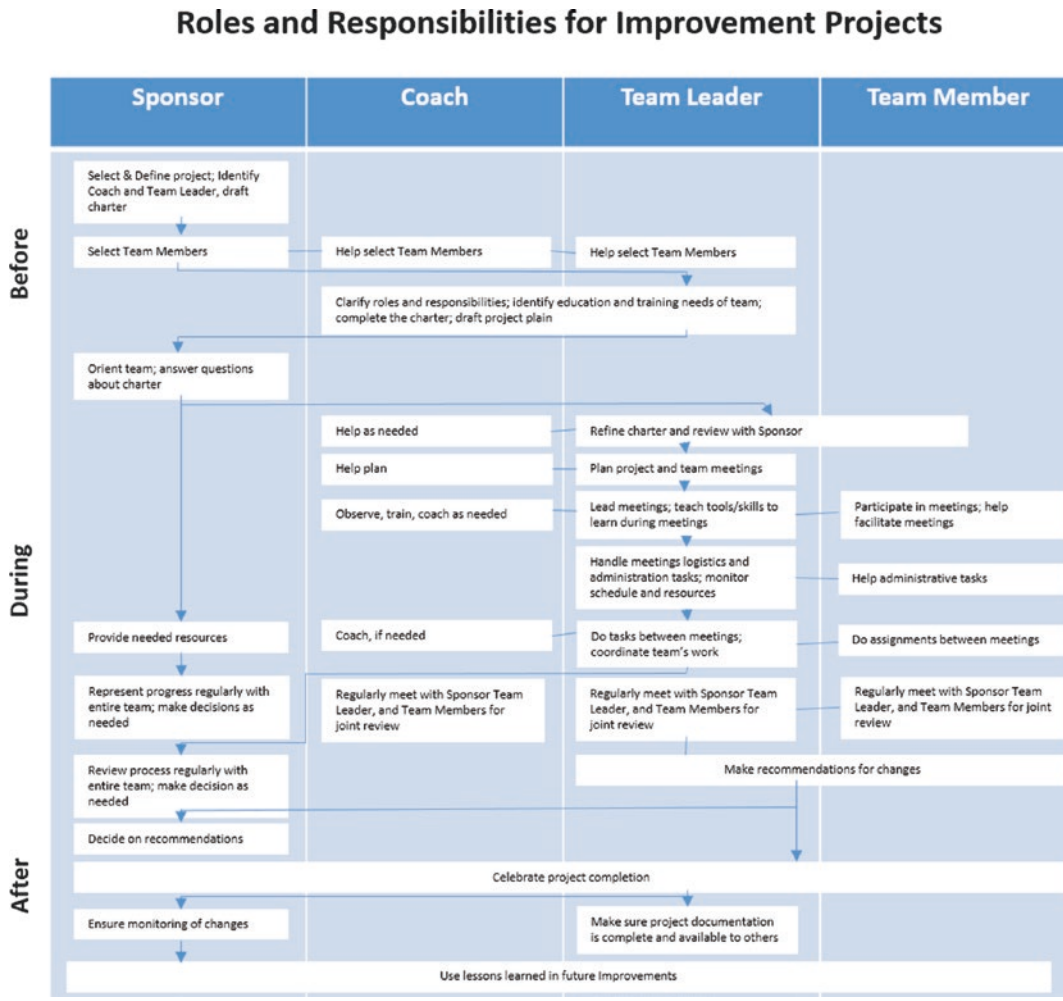

Fig. 10.3 Roles and responsibilities for improvement projects [1]. Reprinted with permission from Scholtes et al. [1]

ferent titles in different organizations). The coach is someone experienced in quality improvement who can bring in improvement science as needed; of course, it is unreasonable for them to teach quality improvement principles to a team. Oftentimes, in improvement work, the team leader may also fill the role of coach, depending on their background and skillset. An effective coach should advise how to best apply improvement science methodology to the problem, demonstrate appropriate data collection and analysis techniques to ensure accurate interpretation of results, and then encourage decisions be made based on the evidence gathered [1]. In the previous *C. difficile* example, the Chief Quality Officer, or perhaps a project manager or data analyst within the hospital's quality division, would fill this role.

Lastly, an executive sponsor is oftentimes necessary, especially when there may be challenges in carrying out specific interventions, a significant change needs to occur outside the limits of the team's authority, or considerable resources may be needed. The executive sponsor is a leader in the organization who serves to lift barriers by providing resources or influencing change and will ensure alignment of the project's aim with the organizational goals, thereby increasing the likelihood of success [1]. In the case vignette for this chapter, the *C. difficile* reduction initiative, the Chief Medical Officer is the logical executive sponsor. Memorializing both the aim of a project and key team members in a project charter or other formal document solidifies team roles and responsibilities as well as communicates to senior leadership the scope of an improvement project; some organizations take the additional step of having the executive sponsor sign this formal document as a team charter [18] (Key Points Box 10.4).

Key Points Box 10.4
Teams are made up of several important key roles including, for example: team members, team leader, team coach, and senior or executive sponsor.

Vignette 10.3
Rethinking her initial shotgun approach, the Chief Quality Officer assembles a team to develop an improvement project to decrease nosocomial *C. difficile* rates. She invites the head of the antimicrobial stewardship team, the director of infection control, a quality improvement consultant, and the data analyst for quality to a meeting. They ask the Chief Medical Officer to be the executive sponsor. They review the current state and develop an aim and key drivers. In a kickoff planning meeting, the quality improvement consultant suggests the team produce a SIPOC tool to help identify additional team members. They identify a lab technician and an antimicrobial stewardship champion as additional members and, after stakeholder analysis, recognize they currently have minimal interest or engagement with this issue. They plan to have the Chief Medical Officer socialize the project to each of them and develop a communication plan to increase their interest in the project. Later, during walk-rounds, the Chief Quality Officer meets a passionate nurse who she witnesses peer coaching a surgical fellow on proper infection control practices. The Chief Quality Officer approaches the nurse to ask her perspective on the biggest safety issues involving nosocomial *C. difficile*, and she eagerly voices her suggestions and concerns.

Running Effective Meetings

Running effective meetings is a crucial skill in improvement activities and one of the many important responsibilities of the team leader; indeed an entire chapter can be written on just this topic of teamwork. Time spent in meetings has to be of value; if meetings are ineffective, in addition to the time wasted in a meeting, engagement and goodwill in working on the team can dissipate quickly. A careful assessment and

purposeful leadership in meetings are integral, therefore, in both running effective meetings and assuring the team achieves its aims.

Preparation for a meeting is vital in assuring that the meeting is a success. A first and important step is to establish clear goals for a meeting. Given the time that a meeting takes and the intrusion into day-to-day work, a deliberate approach to agenda creation can dramatically improve both the efficiency of a meeting and the engagement of team members [19]. A key element in laying the groundwork for a meeting is to elicit input from team members on what topics need discussion in a larger forum; involving team members in agenda creation has the added benefit of improving engagement and attention during the meeting. Agenda items should be pertinent to the entire team; they should represent issues that involve a coordinated, interdependent response. One recommendation is to list agenda items as questions to focus participants' discussion to answer specific questions. In addition, each agenda item should have a purpose – to share information, solicit input for a decision, or to collaborate to make a decision; clarity around this can aid team members in effectively participating. Team leaders should consider that it may be more efficient to share information through alternate routes rather than use meeting time. Distributing the agenda ahead of the meeting and being prescriptive regarding what people should prepare will ensure that the time spent together is most efficient. Assuring that each agenda item has a specific time allotted to it as well as a facilitator identified ensures that team members understand their specific role in a meeting [19]. In addition to timing specific agenda items, considerations should be made around duration of the meeting; meetings that are 30 or 45 minutes and not stacked back-to-back (in succession) may give team members the ability to tackle other business in between meetings and allow meetings to start on time which in and of itself will increase efficiency of the team [20, 21].

The team leader must lay the groundwork for collaboration for the team, especially in interdisciplinary teams. It is imperative for improvement teams to understand the global aim for improvement efforts, at each step of the way. Using the initial minutes of a meeting to re-establish the aims of a specific project and the rationale for the meeting may be a strategy to prime team members for the meeting. While it may be repetitive, understanding and confirming the "why" of the project develops team bonds and underscores the rationale to spend time on the initiative. For example, in healthcare environments, teams that include patient/family stories or safety stories help set the tone for the meeting and tie team members to the mission of both the improvement effort and the organization.

Facilitation of meetings is an important role of the team leader. Starting with introductions may help promote collaboration and respectful communication, especially in teams where traditional hierarchies may impact the way team members interact with each other. To assure that all members are treated respectfully and those who are not considered formal leaders feel empowered to speak, simple icebreakers or other tools to promote collaboration may be important. Informal chitchat may help to break the ice and pull a team together – leaving time at the beginning of a meeting to promote socialization has been shown to promote team work [22]. Team leaders are responsible for facilitating the discussion during a meeting. Generally speaking, leaders of meetings should take an inquisitive approach – asking questions, probing for answers, modeling active listening, and drawing out reluctant participants. To assure all ideas are brought forth, one consideration is to allow for individuals to respond to specific questions via web-polling or by writing down ideas before sharing as a group [20]. An example of this is "brain writing" which instructs team members to individually reflect and write down ideas before sharing [1]. Other strategies to keep meetings efficient include controlling the size of the meeting so that there is robust discussion and yet everyone feels engaged, corralling the conversation so that it is pertinent and does not go off-tangent as well as preventing a few from monopolizing the conversation [23].

In this era, use of devices such as cell phones and laptops may interrupt and impede free flow of conversation and decrease members' atten-

tiveness to the project. The team leader should be encouraged to set ground rules regarding using devices. Perhaps the onus on controlling wandering attention falls to the team leader to run a tight, focused, meeting; indeed, the value of the meeting should compel attention and hopefully prevent drifting attention. Furthermore, limiting membership in team meetings to core people can decrease device use and inattention [24].

However well planned a meeting is, if the meeting does not conclude with a clear action plan, many of the gains from the meeting may be lost. One helpful strategy is concluding a meeting 5–10 minutes before the end of the allotted time to do a recap and confirm an action plan and assigned responsibilities. Assigning roles as explicitly as possible with specific tasks and due dates and then sending out a structured meeting summary to memorialize the discussions into a document serves to commit the team to the action promised [22] (Key Points Box 10.5).

Key Points Box 10.5
To run an effective meeting, team leaders should prepare purposefully, set team norms for behavior, and facilitate to promote collaboration, especially in diverse teams.

Vignette 10.4
The Chief Quality Officer calls a kickoff meeting for a new C. difficile reduction team. In addition to the members from the previous meeting, she invites the nurse who she met on the hematology-oncology unit to provide clinical expertise, a fellow and physician who practice on the unit, a representative from housekeeping, the medical director of the unit, and a pediatric resident. She designated a quality consultant and data specialist for her team. She asks the physician and nurse to co-lead the team with the support from the quality consultant and coaching from the Chief Quality Officer. They develop the scope of the project and sign a charter, cosigned by the Chief Medical Officer who serves as the executive sponsor.

The team started with introductions, and the clinical leaders shared the problem and shared a patient story about an adolescent boy with cancer who was close to discharge when he developed nosocomial *C. difficile*, which prolonged his hospitalization, and he had to miss his senior prom. The team leaders use an inquisitive approach to stimulate discussion around ideas for key drivers and ultimately focus on working on lab stewardship as well as improving housekeeping effectiveness as early PDSA cycles. Despite hesitation of some staff to initially speak up due to one of the physicians monopolizing the conversation, the team leaders have enthusiastically requested input from all team members. Over time, nosocomial *C. difficile* rates dropped by half by changing multiple processes: cleaning of rooms, nursing documentation of stools, algorithms for testing, infection control practices, and overall antibiotic utilization. After going 30 days without an infection, the team walks the units to congratulate the frontline on this milestone.

Creating a Burning Platform

Multidisciplinary teams may need assistance from leaders to develop true cohesion. Creating a sense of urgency behind the desired changes serves to unify team members and make it easier to attain buy-in from stakeholders. The burning platform metaphor is based on a true event and has been used for many years to illustrate a high level of urgency leading to change [25]. In July of 1988, a catastrophic explosion occurred on the Piper Alpha oil-drilling platform in the North Sea off the coast of Scotland, where over 200 crew members were employed. A superintendent, 1 of

only 63 men to survive, recounted the decision he faced shortly after the explosion: jump approximately 15 stories off the platform into extremely frigid ocean waters or remain on the burning platform. Though he knew jumping into the cold water was extremely risky and would likely lead to his death were he not to be rescued quickly, he believed staying on the platform would lead to certain death. He chose to make a frightening and potentially fatal decision because he believed the status quo, or resisting the change, was too costly. We can see similar sentiments during our implementation of process improvements: major changes can be frightening and risky to some; executing these changes often requires true determination to act [25]. While a structured approach to creating a team is important, it may only go so far; leading change is as much about understanding the culture of an organization as it is about the psychology of the people that make it up. In healthcare organizations, similar to other larger organizations that use cross-functional teams, it is imperative to understand strategies to manage diverse teams from different backgrounds [26].

All too often, improvement leaders will encounter resistance during the course of their project, stemming from concerns with loss of control, fear of the unknown, increased workload, and a lack of confidence that their current skills will translate to success with a new process [27]. Effective quality improvement efforts must have strategies to negotiate this resistance, built on psychology of change principles. The Institute for Healthcare Improvement developed a Psychology of Change Framework which describes activating people's agency through unleashing intrinsic motivation, co-designing people-driven change, co-producing via an authentic relationship, distributing power, and adapting in action [28] (Fig. 10.4).

Unleashing intrinsic motivation involves enabling team members to use reasons that are personally motivating by themselves in order to drive change, not being forced to carry out an improvement in which they have no interest [28]. Crafting a powerful narrative behind the team's purpose and goals, or offering time for members to share personal stories, can unite team members and launch improvement efforts [29]. Incorporating concepts from motivational task design can help access people's intrinsic motivations, which is generally more sustainable than

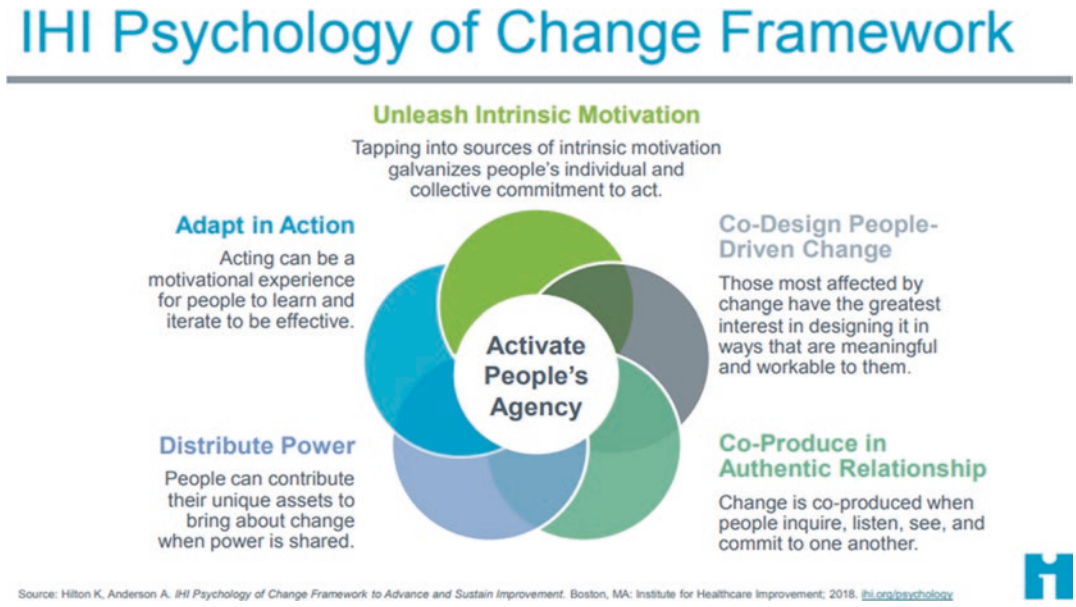

Fig. 10.4 The IHI Psychology of Change Framework [28]. Reprinted from www.IHI.org with permission of the Institute for Healthcare Improvement (IHI), ©2019

extrinsic motivation, such as earning monetary rewards or avoiding punishment [30]. Psychologists have shown that intrinsic motivators include the experience of meaningfulness (the task is important), the feeling of ultimate responsibility (the outcome is dependent on the team member's performance), and visible results (allowing the team member to get real-time feedback on their performance) [30].

Co-designing people-driven change speaks to the idea that the team consists of the people that it is most likely to affect – building a team with the right key stakeholders including frontline participants avoids the consultant model, whereby improvement teams swoop in and swoop out after the project is completed [30]. Using the SIPOC tool can be key to ensuring change is truly people-driven by identifying and including all stakeholders to develop initial improvement ideas together.

Co-production in authentic relationships is about fostering respectful and responsible team dynamics, avoiding hierarchies and promoting dialogue even regarding contentious issues [28]. This concept values different perspectives and promotes an environment where everyone feels safe sharing their opinion. One of the key tools in building these relationships is the one-to-one meeting, in which leaders focus on asking open-ended questions, intently listening to the responses, and ending with a strategic exchange of resources and a clear commitment to the next steps [31].

Distribution of power allows for a team to work collaboratively on a level playing field, avoiding any natural work-related hierarchies from drifting into the improvement work. Leaders should be aware of their own implicit and explicit biases and how these may lead to power imbalances within the team [28]. Ideally, improvement teams should adopt a distributed leadership structure, where responsibilities are shared among several smaller groups which may be divided based on task or location [31]. Sharing power and holding team members accountable for tasks in a positive way is motivational, relaying an urgency to act which is crucial to improvement work [32].

And finally, adaption in action – actions that motivate teams to move forward, even when actions may lead to failure. Inherent in the PDSA cycle is the ability to learn from prior actions, particularly failures, and adapt the test of change for further improvement. Making this continuous learning visible to team members can be reassuring that their efforts are integral to the advancement of the improvement process, strengthening their continued participation [33] (Key Points Box 10.6).

Key Points Box 10.6
Strategies to create a burning platform include understanding people's psychological nature and interests in working with a team to drive improvement.

Resources

- *The Team Handbook* online resources www.teamhandbook.com [1].
- The IHI has numerous templates and tools for project management for quality improvement www.ihi.org [34].
- The Healthcare Improvement Skills Center 3.0 has multiple downloads and links for quality improvement http://www.improvementskills.org/courseinfo/resources.cfm [35].
- *Harvard Business Review* has numerous articles strategies for team building and running effective meetings https://hbr.org/ [36].

Editors' Comments
We challenge readers to show us any quality improvement project done by a single individual. Quality improvement is done with teams, by teams, and for teams. This chapter is at the core of quality improvement. The improvement team may not be apparent (usually working behind the scenes), but without it – nothing substantive will occur. However, suc-

cess is not an accident. Building and leading teams can be taught and needs to be learned and appreciated. This chapter serves as a primer for the reader to understand the value of teams, how to construct teams, and how to work within teams.

A significant learning from this chapter is the need to have role delineations for teams; without team members understanding the role they are going to play, a team will not function at the optimum level. The authors expound upon this point and help the reader understand the different roles and the intrinsic value in each and how they contribute to the overall success of the initiative.

Teams need meetings to be productive. The bane of many administrators' time is meetings. The authors give wonderful examples and strategies on how to make meetings effective (e.g., a distinct period at the end of each meeting to summarize the meeting, discuss action items, and assign responsibilities).

The authors end where any quality improvement initiative should begin, the burning platform. If the leader, or even the team, cannot articulate the burning platform and the imperative for action, then others will not follow, and the quality improvement initiative will not have a foundation to start its work.

Often times, improvement scientists perseverate on the data and necessary improvement charts yet forget about the teams, how to run meetings, how to create a burning platform, etc. – it is these factors that probably lend the biggest part to the success of a quality improvement initiative. One can find many platitudes regarding teams, the Editors strongly believe that the success of a quality improvement initiative is directly correlated to its focus on creating the right team and platform.

Chapter Review Questions

1. What is a team?

   Answer: A team is a group of people that work collaboratively on a complex problem; they work interdependently for a shared purpose. For teams to be successful, there needs to be established goals, right-sized scope, expertise, and resources from the larger organization.
2. How can the design of a team impact its effectiveness in achieving an aim?

   Answer: Identifying key stakeholders across the organization using tools such as a stakeholder analysis or SIPOC can assure that the right people are on the team. Considering team member attributes such as personality types and diversity can aid in making sure a health mix of people contribute to a team.
3. What are the different roles in a team?

   Answer: Key team members include the team leader, team coach, team members, and sometimes an executive sponsor; each of these roles has clear responsibilities tied to the overall aim of the team.
4. What are some strategies that can be used to lead effective meetings?

   Answer: Running effective meetings involves appropriate preparation in terms of agenda creation, communication both prior to and after meetings, and successful facilitation of discussion.
5. What are some examples of how a leader might use intrinsic motivation to activate people's agency?

   Answer: Sharing a personal narrative that relates to the leader's dedication to the improvement work at hand can demonstrate the motivation for the initiative. Stories that have specific details and use vivid imagery are often more effective. Also, providing opportunity for team members to share their own experiences and values can unify the team and elicit emotions that can help motivate efforts [37]. Another way to intrinsically motivate team members is by using the design concepts of meaningfulness, responsibility, and results. A leader can replicate these conditions by ensuring team

members understand how the task fits in with the overall goal, are given autonomy in its execution with the knowledge that the outcome is their direct responsibility, and are able to access real-time results to receive the feedback necessary to make changes [30].

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Handoffs: Reducing Harm Through High Reliability and Inter-Professional Communication

11

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Chapter Objectives

- Define handoffs, and review common areas where lapses in communication can lead to patient harm.
- Summarize the history of handoffs in graduate medical education.
- Explore standardized handoff models for written and verbal communication.
- Identify strategies for implementation of effective handoffs for inter-professional teams.

Introduction

Optimal continuity of care between patients and providers requires a strong foundation in communication. With increases in transitions of care, structured communication has become integral in the education of all healthcare providers to improve patient safety. This education has been primarily focused on provider types as distinct disciplines and specialties; however, patients intersect multiple provider types when accessing medical care, thus emphasizing the need for a collaborative inter-professional approach.

Miscommunication Can Lead to Adverse Events

No matter one's discipline, providers must make effective communication a dedicated practice. Lapses in communication due to incomplete, inaccurate, or omitted information are leading causes of adverse events, including sentinel events [1]. Up to two-thirds of sentinel events have been linked to inadequate communication, of which half were attributed to poor transitions of care between providers [2] (Key Points Box 11.1).

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Key Points Box 11.1
Miscommunications can occur when the information delivered is as follows [1]:

1. Inaccurate
2. Incomplete
3. Not timely
4. Misinterpreted
5. Not required

Defining Handoffs

The vulnerable state that transitions of patient care pose can be mitigated by conducting handoffs. Handoffs, also referred to as handovers or sign-out, involve the process of transfer and acceptance of patient care information and responsibility from one provider to another [3–5]. Providers may include a range of healthcare workers, such as physicians, nurses, and advanced practice providers (Key Points Box 11.2).

Key Points Box 11.2
Handoffs involve the process of transfer and acceptance of patient care information and responsibility from one provider to another [3–5].

Handoffs characteristically involve two roles: the sender and receiver. The sender transmits patient information and releases patient care to the receiver who receives the patient information and assumes responsibility of the patient. Ideally, this exchange of information occurs face to face. Both roles should demonstrate active listening and participation; handoffs should allow opportunity for discussion and clarification of information [6]. Active listening, paired with the fresh perspective of the receiver, has been shown to reduce fixation errors [5]. The overarching goal is for both the sender and receiver to develop a shared mental model, "the perception of, understanding of, or knowledge about a situation or process that is shared among team members through communication" [7] (Fig. 11.1).

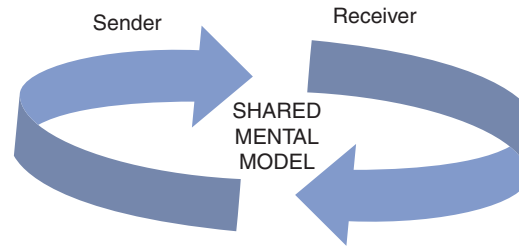

Fig. 11.1 Creation of a shared mental model between sender and receiver

Table 11.1 Examples of handoffs by location and provider type

Type	Provider
Shift change	Physician to physician or nurse to nurse
Temporary coverage	Nursing coverage for a break or a surgical technician scrubbing out during a surgical case
Across staffing	Primary care provider to an on-call provider
Across specialties	Anesthesiologist to surgeon
Across settings/ organizations	Emergency department to intensive care unit
Provider types	Healthcare provider to caregiver at a nursing home facility

Handoffs Throughout the Hospital

There are a wide variety of handoffs that occur during a hospitalization, and each one has the potential for errors and communication deficits. Handoffs occur between a variety of professionals – between those in the same profession, such as nurse to nurse during shift change, as well as inter-professional handoffs between different professional types, such as nurse to radiology technician, and inter-unit handoffs (i.e., operating room (OR) staff to intensive care unit (ICU) staff) (see Table 11.1).

The wide variety of handoffs are important to recognize as the language of medicine is the same across healthcare professionals, but the communication priorities may vary between provider types. For instance, what is prioritized in a nurse-to-nurse handoff (e.g., reviewing orders, wound care specifics, intravenous line flushes) varies from what is prioritized in physician-to-

physician handoffs (e.g., information about diagnoses and specific treatment goals/plans). As expected, there is variation in the information provided based on provider workflow and responsibilities.

Walking through a hospitalization for a patient may help demonstrate possible points of communication vulnerability.

Vignette 11.1
Jessica is a 15-year-old female, with a history of asthma, who was in her usual state of health until she developed fever, worsening cough, and increased work of breathing in the setting of a 1-week history of cough and runny nose. She has had poor oral intake and a physical exam that is notable for crackles over the left lower lung field. She has a fever and an oxygen saturation of 100%. Jessica is admitted for community-acquired pneumonia with concern for dehydration. She is started on empiric intravenous (IV) antibiotics.

For Jessica, the patient in the case, the first handoff occurs between the physicians and nurses in the emergency department and the inpatient physician and nursing staff. At this juncture, it is critical to communicate where the patient is in the course of their management, e.g., when/which medication doses were last given, what testing has been completed, and what treatments are outstanding or need to be followed up. Ideally, all data (e.g., lab results) are available to all providers via the electronic health record (EHR). However, delays in charting due to competing priorities may result in the lack of a shared mental model, thereby leading to duplication of therapies or delays in care.

Vignette 11.2
Jessica is admitted to the inpatient unit, where she is examined by the nursing and physician teams. She is given IV fluids with continuation of the antibiotics that were started in the emergency department. Over the course of her first day of hospitalization, she develops increased work of breathing, pain in her chest, and a slow drop in oxygen saturation to 90%. She is started on supplemental oxygen by nasal cannula.

Once a patient is admitted, and the results of the testing, therapeutic interventions, and the physician and nurse assessments are complete, a plan of care is created by the inpatient unit team. In many hospitals, nurses and physicians who care for hospitalized patients provide care during scheduled shifts. Thus, nurses and physicians handoff patient care to the providers on the next shift (e.g., the day shift hands off to the night shift). Notably, nursing handoffs have evolved over time to include bedside handoffs which incorporate the patient and or family [8]. This practice provides a patient-centered approach to care by incorporating the input of the patients and their families and ensuring they are aware of and in agreement with treatment plans and procedures. As mentioned previously, nursing handoffs have a different focus than physician handoffs, and both are equally important to patient care. Ideally, a shared mental model is achieved with agreement between provider types for the severity of illness, plan of care, action items, and contingency plans for the next shift.

Vignette 11.3
Due to Jessica's worsening condition, the decision is made to obtain a chest X-ray in the radiology suite.

The next handoffs for Jessica are between the inpatient medical team and the radiology team. Nursing must provide adequate information regarding the patient's condition to alert the radiology staff to possible issues with procedures: primary medical problem (e.g., pneumonia), per-

tinent medical history (e.g., asthma), allergies, oxygen requirements, and sedation needs. It is critical that the team that is accepting the patient, no matter how briefly, be aware of the critical needs of the patient: Do they require oxygen? Do they have allergies to contrast?

Vignette 11.4
The chest X-ray reveals the previously noted pneumonia but now with a new parapneumonic effusion (infected fluid in the lung). Jessica continues to have increased work of breathing, fevers, and oxygen desaturation, requiring increased respiratory support. The decision is made to surgically drain the fluid collection in her lung.

If a surgical procedure is required during the hospitalization, several other handoffs must occur: First is a communication of the patient's history and diagnoses to the consultants – the surgeon as well as the anesthesiologists. Both consultants must be aware of issues that are specific to the patient (e.g., history of asthma), including information that will likely be present in the medical record such as diagnostic results, but again could be overlooked or not yet present in the medical record in urgent situations. For transitions of care such as these, it is most helpful to communicate a cogent patient summary, highlight the current diagnoses and pertinent past medical history, and discuss any intra-procedure needs (e.g., obtaining a specimen culture of the pleural fluid).

Vignette 11.5
Jessica has a left-sided chest tube placed without complication. Postoperatively, she is transferred to the intensive care unit for further management.

Following the procedure, the events, findings, information regarding intraoperative medications, IV fluids, chest tube drains, and plans must be communicated from the surgeons to the physicians who are caring for the patient after surgery. Similarly, the postanesthesia unit nurses must transfer information to the receiving intensive care unit nurses. Ideally, for areas such as the intensive care unit, this communication is face to face and with all members of the interprofessional team [9] (Key Points Box 11.3).

Key Points Box 11.3
The surgical team must communicate with the medical team how they would like the chest tube managed including parameters for removal. Delays in communication can result in adverse events and unnecessary utilization of resources, resulting in increased costs.

Vignette 11.6
Jessica makes a rapid recovery. On hospital day 4, the chest tube is discontinued, and she is transferred from the intensive care unit back to the general inpatient unit.

The transition between units is often typically between clinicians of the same type, e.g., physician to physician and nurse to nurse. The same procedures and protocols that apply to change of shift handoffs should be utilized with this transition as well, such as time of next scheduled medication dosing and wound care instructions for the chest tube site (Key Points Box 11.4).

Key Points Box 11.4
Handoffs from physician to physician should be timely and utilize the same framework and information that is required for inter-shift handoffs. If a patient who is transferred from the intensive care unit to the inpatient unit clinically deteriorates, the general inpatient team needs to be aware of the intensive care unit course and current clinical needs.

Vignette 11.7
Jessica no longer requires supplemental oxygen and is able to take all medications by mouth. She is instructed to complete the course of antibiotics and to follow up with her primary care physician in 2 days.

Following the resolution of the illness that caused the admission, the patient must be readied for discharge. The final handoffs to occur in a hospitalization are from the hospital to the discharge location – whether that be home (where the receiver of the handoff is the primary care provider), a rehabilitation center, nursing home, or another hospital. Each of these locations requires a different type of communication, which must be timely, concise, and accurate. Delays in communication with primary care providers can result in the lack of appropriate follow-up or medical management, resulting in readmission. When handoffs are suboptimal, delays in treatment and adverse events can occur. Additionally, poor handoffs can impact patient and provider satisfaction, cause prolonged hospital stays, and contribute to increased cost of care [9].

Evolution of Handoffs

Despite the seemingly straightforward approach, high-quality handoffs are a complex process, and prior to the 2006 Joint Commission National Patient Safety Goal, handoffs were not formally taught nor required [1]. The complexity of handoffs is further elevated by the frequency of provider transitions, particularly in institutions that have medical trainees. Beginning in 2003, the Accreditation Council for Graduate Medical Education (ACGME) mandated a reduction in the length of time trainees could provide continuous care in the hospital, resulting in a substantial increase in change-of-shift transitions and ultimately the number of handoffs [10, 11]. Additionally, nurses are also vulnerable to prolonged shift durations. A study by Scott and colleagues showed that on average nurses work between 8 and 12 hours, and the risk of error nearly doubled when they worked 12.5 hours or more [12].

Transitions of Care and Graduate Medical Education

A large proportion of the most complex and ill patients in our healthcare system are cared for in institutions where physicians and other members of the healthcare workforce receive clinical training. This has a significant effect on the quality of handoffs in three ways.

Increased Frequency of Handoffs

Since the advent of the ACGME's work hour restrictions in 2003, hospital systems that utilize Graduate Medical Education (GME) trainees as their frontline workforce have been required to adapt their schedules. Restrictions in the number of hours worked per week and a decrease in the duration of shifts created condensed schedules with increased numbers of providers caring for each patient. Shifts that were previously 24 hours in length changed to 12-hour shifts, resulting in a dramatic surge in the number of handoffs between physicians. A typical teaching hospital might have up to 4000 individual patient handoffs occurring in the course of a day [1].

Lack of Standardized Training in Handoffs

Many physicians functioning as the faculty for graduate medical education trainees were not formally trained in the process of giving handoffs. Therefore, they lack knowledge of the standardized training curriculum for handoffs used in GME. Furthermore, faculty may lack competency in assessment and coaching of residents and fellows during observations of handoffs. While changing, many medical and nursing schools have not yet adopted a standardized curriculum and training of their students in provid-

ing effective handoffs, resulting in the burden of training falling on hospital systems that sponsor residency training [13].

Variable Clinical Experience of Providers

Without proper supervision, inexperienced physicians may not be capable of recognizing important clinical findings that could result in a delay in care or improper care of their patients. The hospital system is especially vulnerable at the time surrounding change of shift, which is now happening more frequently due to duty hour restrictions/shortened shift lengths. Written and verbal handoffs may be disorganized, unprioritized, or fail to paint an accurate picture of the patient's condition and needs. This potentially results in delays in care due to prolonged handoffs or "receiver fatigue" where critical clinical information is lost in a presentation filled with extraneous information.

In an effort to continuously improve the process of training future physicians and address the persistent lack of improvement in the quality and safety gaps surrounding patient care, the ACGME devised the Next Accreditation System (NAS) to include evaluation of the Clinical Learning Environment (CLER) of the hospital systems that are training residents and fellows. They identified six areas of focus during annual CLER visits, which include (1) identification and intervention in patient safety issues, (2) quality and performance improvement efforts, (3) supervision of trainees, (4) professionalism, (5) management of burnout and fatigue (resident wellness), and (6) transitions in care [14]. Many of the tenets of providing quality handoffs have been incorporated into the CLER evaluation process. Areas that are evaluated include the training of residents, fellows and faculty in a common clinical site-based process for handoffs, knowledge of transition of care policies among all physicians, presence of efforts to assess and continually improve handoffs, and the participation of faculty, residents, fellows, inter-professional teams, and families in the handoffs process.

Strategies for Effective Handoffs

Avoiding communication failures during handoffs can be lessened by standardizing the content communicated between the sender and receiver in both verbal and written formats [1]. Handoffs can improve communication if the information is consistent and delivered in a predictable format. Critical information, such as illness severity, code status, vital signs, allergies, medications, pertinent events leading up to illness or hospitalization, ongoing assessment, pertinent diagnostic test results, plan of care with action items, and contingency plans, should be included in handoffs [1] (Key Points Box 11.5).

Key Points Box 11.5
Handoffs should include (1) illness severity, (2) code status, (3) vital signs, (4) allergies, (5) medications, (6) pertinent events leading up to illness/hospitalization, (7) ongoing assessment, (8) pertinent diagnostic test results, (9) action items, and (10) contingency plans [1].

Verbal handoffs should be timely, conducted face to face, and occur in a location that is free of excess noise and distraction. Written handoff tools complement the verbal handoff communication and facilitate opportunities for detail and for clarification when information is disparate. When possible, handoffs should include all members of the inter-professional team, which can promote ongoing discussion and ensure the maintenance of a shared mental model [15] (Fig. 11.2).

The **right incation** is:

- Quiet, free of distractions and nonemergent interruptions
- Consistent, same time, same place
- Protective of sensitive patient related informations as per the Health Insurance Portability and Accountability Act (HIPAA)

The **right people** include:

- All members of the inter-professional team involved in the patient's care; including patient and family
- Faculty educators at training programs who can perform workplace assessments and provide feedback on handoff quality

The **right information** is:

- Up to date and includes: current patient condition, treatments, concerns, and anticipated changes for the next shift
- Organized in a standardized format
- Transcribed using EHR tools to avoid errors

The **right style of communications** is:

- Face to face
- Provided in both verbal and written form
- Conducive to questions and opportunities for clarification
- Focused on the creation of a shared mental model

Fig. 11.2 The "rights" of effective handoffs [1]

Handoff Models

There are several handoff mnemonic models used to structure both written and verbal handoffs (see Table 11.2 for examples). One commonly used mnemonic is SBAR, which stands for Situation, Background, Assessment, and Recommendation. SBAR is a handoff communication tool developed by the US Navy and has since been adopted in many healthcare settings and is most frequently used by nurses. SBAR was designed to communicate urgent patient information in a relatively quick manner [2].

An extensively studied model, the I-PASS Handoff program, uses the organizational framework of a mnemonic as an anchor for an interventional bundle that includes strategies for team communication. The I-PASS Handoff program includes seven core elements: (1) the I-PASS mnemonic (I = illness severity, P = patient summary, A = action list, S = situation awareness and contingency planning, and S = synthesis by receiver), (2) a workshop for teaching team communication through the use of TeamSTEPPs and handoff techniques, (3) skills training through simulation and role-playing exercises, (4) independent study module, (5) faculty development, (6) a direct observation tool for feedback, and (7) campaign for adoption and sustaining practice. This study demonstrated a reduction in preventable adverse events by 30% and medical errors by 23% when implemented by nine children's hospital [17]. The I-PASS Handoff program has since been adopted by more than 50 hospitals, studied in many iterations and is frequently referred to as the gold standard for effective handoff communication between physicians [1, 12]. It has also been adapted effectively for nursing shift report across varied clinical settings [18] (see Table 11.3) (see Fig. 11.3).

Table 11.2 Handoff mnemonics examples [1, 16]

ISBAR	*I*dentify *S*ituation *B*ackground *A*ssessment *R*ecommendations
SIGNOUT	*S*ick/do not resuscitate *I*dentifying data *G*eneral hospital course *N*ew events of the day *O*verall health status *U*pcoming possibilities/plan *T*asks to complete
HANDOFFS	*H*ospital location *A*llergies/adverse reactions *N*ame *D*o not attempt to resuscitate *O*ngoing medical problems *F*acts about hospitalization *F*ollow-up *S*cenarios
PSYCH	*P*atient information/background *S*ituation leading to hospital course *Y*our assessment *C*linical information *H*indrance to discharge

Table 11.3 The I-PASS handoff model with overview of elements [17]

I	*I*llness severity	Alerts the receiver to the patient clinical status: *stable, watcher, or unstable*
P	*P*atient summary	Provides an overview of the patient's pertinent past medical history, events leading up to hospitalization, and interim hospital course
A	*A*ction list	Tasks that require completion for the next shift
S	*S*ituation awareness and contingency planning	Preparatory considerations for a change in clinical status. Should be relayed in "if, then" statements
S	*S*ynthesis by receiver	Opportunity for clarification and inquiry to ensure shared mental model between sender and receiver

Example Patient Handoff Document

		I	P	A	S	S
		S W U	Patient Summary Statement & Problem Based Hospital Course	Action List	Situation Awareness/Contingency Planning	Synthesis by Receiver
Bed 124	15-year-old F Allergies: none Weight: 56kg Access: Peripheral IV	W	Summary: 15-year-old female with past medical history of asthma, now with left lower lobe pneumonia complicated by dehydration and increased respiratory distress with supplemental oxygen requirement. 1. Pneumonia: - Ampicillin IV every 6 hours - Oxygen via nasal cannula; 3 liters/min 2. Dehydration - IV fluids; 100mL/hr	[] Obtain Chest x-ray [] Monitor urinary output	If evidence of pleural effusion (fluid collection) on chest x-ray, then obtain surgical consultation for chest tube placement	

**SWU= Stable, Watcher, Unstable; designations for illness severity*

Fig. 11.3 Example of written/printed handoff tool using the I-PASS model

Implementing and Sustaining Effective Handoff Programs

Implementation of a standardized handoff system requires support from hospital administrative leadership for the rollout of the program, educational efforts, time needed to train staff, and, most importantly, resources needed to provide workplace-based assessments with feedback to achieve the desired behavior change. Dedicated time and physical space for handoffs are also important. New space may be needed to have a quiet, uninterrupted discussion, and it may be necessary to have extra staff to cover patient needs while handoffs are occurring.

Information such as accurate weights, allergies, code status, and location are critical to all handoffs. Integration of the EHR for a printed/written handoff tool that supplements/supports verbal communication allows for seamless information transfer and avoidance of transcription errors. Nursing and physician handoff written documentation differ in various aspects of focus, with physician handoffs being more related to contingency plans and action items, while nursing handoffs focus on different action items that include when medications are to be given, fluid intake and output, activities of daily living, and pain management (pain scales and PCA (patient-controlled analgesia) orders). There is common ground between nursing and physician written handoff elements. A Continuity of Care Document is a potential EHR-based framework to support the supplemental written document for use in handoffs by multiple provider types [19].

Once a handoff system is established in a hospital, it will need ongoing evaluation and support using a continuous improvement approach to keep the process at the front of the clinicians' minds and prevent attrition of adherence to standard handoff protocol. Sustaining quality improvement efforts is difficult in any setting and often more challenging in the healthcare setting. Fryman and colleagues outlined the use of quality improvement cycles involving direct observation of handoffs, and audits of the use of the

written handoff tools from the EHR demonstrated success in sustaining change in their system [20].

Future Direction of Inter-Professional Handoffs

The Joint Commission and the CLER standards specifically mention inter-professional handoffs as a future standard. Calling for the development of interdisciplinary handoffs between obstetrics and neonatology physicians, Vanderbilt and colleagues described how a common handoff would greatly benefit the neonate and mother's health and outcomes [3]. There has not been a significant amount of research on this topic in the literature, but Kostoff and colleagues showed improvement in pharmacy students' self-perception of inter-professional competence by using the SBAR format for communication between pharmacists and other disciplines [2]. Similarly, Solan and colleagues demonstrated that multidisciplinary handoffs involving residents and charge nurses improved perceptions of communication [21]. The gold standard for communication at transitions of care would include training entire hospital systems to perform handoffs in a standardized, highly reliable fashion, with sharing of information via an EHR-generated handoff document to support the verbal communication.

Summary

Handoffs provide a unique opportunity to enhance inter-professional communication. Given the increased frequency in which patients intersect different healthcare providers across disciplines, settings, and organizations, deliberate education in structured communication is essential to patient safety. There are several standardized frameworks, such as I-PASS, that can be used to structure both written and verbal handoffs. No matter what framework is used, it is important to maintain anchoring elements such as illness severity and contingency plans and ensure time for clarification and synthesis between sender and receiver. When handoffs include all members of the inter-professional, clinical teams are more effective in developing shared mental models regarding their patients, and improvement in patient safety follows.

Editors' Comments

It is well accepted in the healthcare safety and quality realms that communication breakdowns are a key contributor to adverse outcomes and harm. A component of robust communication is handoffs. Care transitions are a vulnerable period for patients as they move within systems and through different types of care delivery models. During these transitions in care, the reliance on accurate, timely, relevant handoffs cannot be overstated.

In this chapter, the authors approach the topic by demonstrating the burning platform: communication is crucial, and handoffs can save lives. They present a nice history of handoffs in medicine from the perspective of graduate medical education; this historical perspective has relevance as the lessons and strategies can be extrapolated to other care settings as well.

The authors move the concept of handoffs further by demonstrating key components of handoffs and what is considered to be crucial information. The mnemonics as well as the evidence-based materials help frame the value-add of handoffs within the context of care delivery. Once the improvement scientist knows the parts of the handoff which are important, then they can decide on the best tool to implement for handoffs.

There are handoffs that can be as simple as a department specific tool that is maintained by house staff to proprietary tools described by the authors that can be implemented and scaled within an organization.

The end of the chapter considers the next iteration of handoffs and weaves in the importance of inter-professional teams.

The editor's organizations have embraced the concept of inter-disciplinary teams, and the initial results demonstrate transformational capacity. The role of handoffs will be ever more important when inter-professional teams become the norm. This chapter presents a stepwise approach to understanding the intrinsic value of handoffs all the way to describing techniques to implement handoff programs within your healthcare system.

Chapter Review Questions

1. What are handoffs and what is the intended goal?

   Answer: Handoffs involve the process of transfer and acceptance of patient care information and responsibility from one provider (sender) to another (receiver) with the goal of creating a shared mental model.
2. 2: True or false – communication failures can be decreased by standardization of handoffs.

   Answer: True. Both written and verbal handoffs can improve communication if information is presented in a consistent and predictable format.
3. What type of information should be included in handoffs?

   Answer: Critical information, such as illness severity, code status, vital signs, allergies, medications, events leading up to illness or hospitalization, ongoing assessment, pertinent diagnostic test results, plan of care with action items, and contingency plans, should be included in handoffs [1].
4. List the four "Rights of Effective Handoffs".

   Answer: (1) The right location (quiet, consistent time/place). (2) The right people (members of inter-professional team and faculty educators that can assess handoff). (3) The right information (organized in standard format, up-to-date using EHR tools for transcription). (4) The right style of communication (face to face, includes both verbal and written handoffs, allows for questions/clarifications, and creates a shared mental model).
5. Define the I-PASS mnemonic elements. What advantages have been demonstrated from the I-PASS Handoff program?

   Answer: I-PASS stands for illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by receiver. The program is a standardized bundle that provides strategies to enhance team communication. Implementation of the program at nine children's hospital was shown to decrease preventable errors by 30% and medical errors by 23%.

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Safety II: A Novel Approach to Reducing Harm

12

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Chapter Objectives

- Highlight the differences between Safety I and Safety II approaches
- Understand how Recognize, Respond, and Learn function as Safety II pillars
- Understand how individual factors, relationship and interactions, structural and environmental factors, and innovative approaches impact Safety II practice in a healthcare microenvironment

Opening Question/Problem

The most common approach to improving safety in all industries, and especially in healthcare, is learning from errors and harm. This "find and fix" approach is termed "Safety I." After an untoward event (or sometimes a near miss) occurs, a subsequent analysis is performed to identify where individuals and/or systems failed, with steps outlined to prevent event recurrence [1–3]. While the Safety I approach has led to dramatic safety improvements, Safety I has multiple shortcomings [4]. First, neither learning nor improvement happens until *after* an undesired event. Second, as individuals and systems improve to prevent recurrent errors, remaining errors/failures become "one-offs," each unusual and unique such that learning from prior events is uninformative. Third, focusing on what went wrong leads to more rules and regulations, trending toward rigid systems which cannot respond to the unexpected (assuming people follow the "rules"). Finally, since in every industry humans complete or supervise most activities, focusing on human error with the necessary enforcement of performance expectations can demoralize staff, thus potentially limiting a valuable resource – the human mind – from contributing to error reduction.

Another common approach to improving safety is the failure modes and effects analysis

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(FMEA). FMEA involves proactively identifying potential problems and then quantifying their likelihood of occurrence, the odds the problem will escape detection, and the severity of harm the event might cause [5]. A scoring system prompts system/protocol redesign to minimize the threat from potential events which are highest risk, highest likelihood, and most likely to escape detection [6]. However, FMEA has limited value in error prevention because it is usually narrow in scope, does not address all potential errors, and usually primarily focuses on problems predictable well in advance.

We believe the way forward is a new approach – Safety II [7]. Hollnagel, who initially developed the Safety II concept, describes a model for Safety II with four components: actions which he refers to as "potentials" [8]. These actions are Monitor, Anticipate, Respond, and Learn. (Key Points Box 12.1)

Key Points Box 12.1

Monitor: Being able to see what is happening in a situation. Requires valid information about the conditions and presentation of that information to those who can execute further Safety II steps. The level of detail and timescale of monitoring may depend on the situation and the role of the individual monitoring.

Anticipate: Being able to use information about the situation to develop expectations about what might happen next. May include assigning probabilities to different events.

Respond: Being able to take action to prepare for anticipated future events or change the course of events. Because protocol/policy determines actions under normal circumstances, responding in Safety II fashion typically involves deliberate "deviation" from protocol or real-time innovation.

Learn: Being able to learn from monitoring/anticipating/responding events. May involve both learning about how to handle the identical situation in the future, but more importantly learning about how to improve monitoring, anticipating, and responding.

These four components/actions are interdependent: they often occur in parallel, and improving capabilities in one step can improve the ability to successfully perform the others. We believe that, especially in bedside clinical care, monitoring and anticipating are so tightly linked, they constitute one action we term "recognizing," followed by responding (e.g., taking action, or deliberately deciding no action is necessary), and learning how to improve our ability to recognize and respond.

We believe adding Safety II to current harm prevention strategies will lead to improved outcomes for the following reasons: (1) responses to all possible scenarios cannot be put into protocol because of the complexity of healthcare systems; therefore, flexibility and resilience will always be needed to cope with unanticipated conditions; (2) mindfulness, situational awareness, and clinical judgment add the power of human intelligence to rote following of expected procedures; and (3) allowing people to find "work-arounds" or alternative ways to perform their normal tasks can sometimes improve efficiency and safety simultaneously.

The following scenario illustrates Safety II in a nonclinical situation:

Vignette 12.1

While driving through a neighborhood, you see a soccer ball roll into the street just ahead. Within a split second, you anticipate a child might soon dash into the street, so you take an unusual action by putting your foot on the brake and slowing down or maybe even stopping. Soon after you stop, a child dashes out into the street to retrieve the ball. You wipe your forehead in relief at

the near catastrophe avoided. Further, you make note children are playing in a particular driveway on this street and decide to drive more slowly when coming down this street in the future. You also note that sometimes you text and drive and are grateful you were not texting in this situation.

In this case, you were able to monitor because you were looking out the windshield and not texting (good situational awareness). Seeing the soccer ball led to anticipating – having a strong suspicion a child was about to run in front of you (probably informed by past learned experience). Responding entailed slowing down and/or stopping the car suddenly – perhaps in a manner typically considered dangerous and against "preferred" behavior. Finally, you learned how to better monitor (eliminate a texting habit) and anticipate (expect children playing on this street or even while driving in general). Illustrated here, no accident or error occurred, and in fact, an accident was likely avoided. Additionally, important learning occurred, reducing the accident risk in the future.

One other core feature in Safety II is resilience. Elements of resilience are foresight (predicting something untoward will happen), coping (preventing something untoward from becoming worse), and recovery (ability to return to normal functioning once something untoward occurs) [9]. While related to individual psychological resilience, system resilience involves the ability of the system or individual to perform under varying conditions, e.g., responding appropriately to both negative and positive conditions [10]. Resilience is central to how error is avoided and success obtained. Safety II considers the human component of systems as necessary to maximize flexibility and resilience [7, 11], whereas Safety I sees human variation as a liability requiring design out of the system.

Vignette 12.2

CJ arrived in the Emergency Department (ED) with persistent fevers, headaches, sore throat, and emesis. After sending appropriate studies, empiric antibiotics were started for presumptive meningitis. CJ was admitted to the pediatric intensive care unit (PICU) for further management due to altered mental status.

In the PICU, she developed septic shock. A new murmur led to diagnosis of native valve Methicillin-Susceptible S. aureus (MSSA) endocarditis. Following a complicated hospital course, she was eventually ready for discharge with plans for a continuous nafcillin home infusion. When the physician began to place the order in the electronic medical record (EMR) for nafcillin administered as a continuous infusion, the option was not available.

Due to her system knowledge, the clinical pharmacist recognized multiple risks in this unusual situation. She worked with informatics to immediately build an order in the EMR. Because this is an unusual dosing method for inpatients, she notified the verifying pharmacist that he would receive an order to verify an outpatient continuous nafcillin infusion. "Anticipating" that inpatient pharmacists might not have the knowledge or experience in preparing the infusion, she contacted the IV room pharmacist to discuss medication preparation details; for example, the medication must be drawn up using an exact normal saline volume and placed in a specific bag, and because nafcillin is stable at room temperature for only 24 hours, the bag needed refrigeration prior to administration. Finally, she sent a communication to all pharmacy staff to ensure their awareness of this variation in standard practice and that future orders might include continuous nafcillin infusions.

The clinical situation described – "needing to order, dispense, and deliver a medication in a novel way" – required recognizing the situation and anticipating its risks and responding. The outcome was good and no adverse medication-related event occurred. The final step was ensuring individuals and the institution learned from this unique situation and thus increased the odds of success in both similar and dissimilar future situations. After this case was over, debriefings were performed to identify how to avoid this problem or closely related problems in the future and to identify what allowed this pharmacist to recognize a developing problem and respond in the way she did.

Recognize (Monitor and Anticipate)

Improvement Strategy

The first step in using the Safety II approach in a healthcare setting is recognizing what might happen next. Recognition combines observing (monitoring) for signals and using that data to anticipate.

If individuals cannot monitor and interpret their surroundings, everything becomes a surprise. An individual's role determines the monitoring breadth, depth, and timescale. Microsystem managers may monitor their particular unit over hours, days, or weeks, while bedside providers monitor a patient moment-by-moment.

Successful monitoring depends on multiple factors. Is data available describing the situation or environment? Is that data available to the individual(s) responsible for the monitoring and in a timely manner? Does the individual responsible for monitoring have sufficient skill/experience to interpret the data presented? Finally, is the monitoring individual alert, non-distracted, and able to focus on the situation (mindful and situationally aware)?

We performed qualitative research to identify individual or system characteristics that may contribute to Safety II application in our PICU [12]. The study identified 19 themes, grouped into 4 domains, which appear to improve recognizing (monitoring and anticipating), responding, and learning (Fig. 12.1). Characteristics (themes) that improve an individual's ability to monitor more effectively include an aptitude to pay attention to detail (focus) and to assume a more global perspective (thinking beyond one's role and to be more sensitive to signals). The ability to monitor individual patients, as well as the overall state of the unit, is also affected by structural and environmental factors, including familiarity with and proximity to coworkers; patient number, acuity, and intensity; and shift resource availability. Thus, monitoring may improve by eliminating non-value-added tasks to decrease distraction, streamlining mundane tasks, and introducing moments during the day dedicated to performing monitoring and anticipating. Finally, providers must be alert to their mental state and the thoughts in their head (mindfulness) and the environment/situation around them (situational awareness) [13]. In healthcare, mindfulness and situational awareness are characterized by actively observing oneself, the patient, and the problem [14] and then being able to convert the flood of data around us into useful and actionable information.

Tightly interwoven with monitoring are foresight and anticipating dangers. How do individuals anticipate the future, and how do they attach various probability levels to possible future outcomes? One possibility is that individuals with experience recall previous situations and apply heuristics such as recognizing "I've seen this before, and I remember what happened next." Another possibility is that individuals know what aspects of their current observations do not reflect a prior experience (because no two situations are identical), leading them to a "sixth sense" which causes them to go into higher alert or prompt further investigation and inquiry. Supporting these hypotheses, the PICU providers in our qualitative research [12] observed that colleagues proficient at anticipating have more experience and expertise. The providers

Driver	Individual Characteristics	Relationships and Interactions	Structural and Environmental Factors	Innovation Approaches
Monitoring	• Attention to Detail • Taking a Global Perspective		• Familiarity and Proximity • Number, Acuity, and Intensity of Patients • Shift Resource Availability	
Anticipating	• Taking a Global Perspective • Experience and Expertise	• Personal Relationships • Teamwork • Culture of Questioning • Communication • Training to Introduce Cultural Values		
Responding	• Taking Control • Staying Calm and Maintaining Focus • Experience and Expertise			• Relying on Teamwork if Something Novel is Considered • Teams Responding to Challenging Circumstances • Skepticism • Bringing Atypical Approaches from other Microenvironments
Learning	• Appreciating the Consequences of Mistakes	• Careful Examination and Feedback after Errors are Made		

Fig. 12.1 Interrelationship between the 4 Safety II components and 19 themes from qualitative research [12]

with substantial experience drew on their memories to remember similar situations and were more reliably able to predict the future.

For people with less experience, we can accelerate experience acquisition through simulation, especially if used to practice uncommon or unfamiliar situations. Using simulation may also effectively teach responding skills (discussed later). Strategies for improving a system's anticipatory ability may include ensuring availability of individuals with anticipation skills and having the microsystem deliberately take moments to pause and anticipate/predict the future (e.g., during handovers).

Anticipated Results of the Improvement

Taking steps to reduce distractions and improve mindfulness/situational awareness enables individuals and organizations to more effectively monitor patients, units, and the organization as a whole [15, 16]. Focusing on mindfulness, being present, and taking time to anticipate that things may not go as expected will impact an individual's ability to see the "accident waiting to happen." This is in contrast to working in autopilot mode and being forced to respond/recover more often than desired, i.e., being reactive instead of proactive. Ideally, improvements in monitoring will allow information to flow to individuals, keeping in mind that too little information will miss important signals while information overload will increase noise. The shortest possible time lag between data acquisition and its presentation to decision-makers gives those individuals more time to anticipate an event before it occurs and to initiate a response. Later, when learning occurs, the ability to identify leading indicators (data which accurately predicts the future) will improve.

How the Improvement Worked in Context of the Case

In our case, the pharmacist recognized potential problems which could put the patient at risk. More specifically, her recognition (combining monitoring and anticipating) occurred when she saw that the desired antibiotic therapy could not be ordered in the current EMR. This led to her anticipating multiple steps where future errors could occur, and getting the patient the proper therapy would require adaptive/novel responses by multiple microsystems within the hospital.

Struggles/Limitations/Opportunities

A key limitation to recognizing (monitoring and anticipating) is knowing both what to monitor and correctly interpreting the date being monitored (i.e., turning raw data into actionable information). Asking healthcare providers simply to "monitor more inputs" is unrealistic, and thus the Safety II learning step is to become better at monitoring the right things. Using the philosophy "a picture is worth a thousand words," a graphical information display (such as vital signs or PEWS scores) can potentially allow providers to more efficiently monitor patient status without adding significant workload burden. Visual monitoring systems require leveraging data from the electronic medical record and likely expertise from information technology (IT) and clinical informatics specialists.

Limitations which could preclude frontline healthcare providers from anticipating potential harm include but are not limited to workload, distractions (from patients, families, coworkers), and fatigue. Anticipating the future is a deliberate act requiring both time and mental energy. To foresee harm, individuals must be mindful and have situational awareness of their current surroundings. In our clinical example, the team utilized a "stop and resolve" mind-set to determine actions needed prior to using a continuous nafcillin infusion, thus increasing odds of things going right. If the clinical pharmacist in our case had not had the time to "stop and resolve" what was needed prior to moving forward with an unfamiliar therapy, the potential for error and harm would have been substantial. Safety II requires a conscious effort and deliberate actions to ensure a successful outcome.

Finally, a major limitation of recognition is that predicting the future will always be imperfect. Consequently, individuals and systems may be reluctant to perform in a proactive manner (anticipation) if they do not feel the anticipation prediction is accurate or likely. Consequently, if an action is taken to head off an anticipated untoward outcome, and the untoward event never occurs, one cannot be certain the proactive action avoided an untoward event. One opportunity to improve the efficacy of anticipatory behavior may be through predictive analytics, which utilizes "big data" and statistical analyses to develop predictive models about future outcomes and thus can assist human decision-making [17].

Respond

Improvement Strategy

The third Safety II component involves responding to a situation once monitoring and anticipation suggest an action is required. At this point, an individual, team, or system has made a deliberate decision that the current protocol or policy is not appropriate and following the usual or expected practice may lead to error or harm. Multiple questions then arise: How confident are the individual or team that following the expected plan will lead to error/harm? How do they know that any alternative path is safe (or at least safer than the expected path)? Among multiple possible actions, how does the individual or team choose the optimal path? Do nonidentical but similar past situations provide guidance? Will punitive action follow an innovative response? If the alternative actions still lead to error/harm, will a retrospective review conclude that the individual or team had intentions to take the safest action(s)?

Central to responding is creativity. Often called "thinking outside the box," in reference to

a psychological experiment from the 1960s, merely telling people they need to think outside the box does not improve their creative ability [18]. Recent research suggests that the presence or absence of particular neural networks predicts an individuals' ability to think creatively [19]. In our qualitative research, when asked how safety successfully occurs in the PICU, interviewed staff mentioned the ability to respond with innovation and creativity more often than other Safety II actions (Monitor, Anticipate, Learn) (Fig. 12.1). Personal characteristics or demeanors most often related to enhancing "responding" included staying calm, working in multidisciplinary teams, expecting rapid-fire questioning, and seeking ideas from outside the microsystem.

Anticipated Results of the Improvement

Creating an environment where intended variation in practice is acceptable within limits, with the intention to avoid devolving into randomness or chaos, allows individuals and teams to perform at their highest level and feel empowered to respond to changing circumstances. Ideally, if monitoring and anticipating are working well, instances where responding is needed will be infrequent, and the magnitude of responses will likely be less.

How the Improvement Worked in Context of the Case

In our case, because the clinical pharmacist anticipated multiple problems that could result from needing an unusual drug delivery method for continuous nafcillin, she was able to initiate a preemptive response. Aiding the effectiveness of her response was her understanding of the complete process, from ordering to drug delivery. She was able to "anticipate and implement" strategies to minimize the potential for error – thus enhancing the probability that things would go right. Specifically, her response included clarifying with infectious disease experts that a continuous nafcillin infusion was the intended treatment plan. She worked with various disciplines to build an order in the EMR. She educated individuals who would be involved in verifying and preparing the medication order. Lastly, she implemented error-proofing strategies, communicating specific instructions for medication storage and administration with the nursing staff.

Struggles/Limitations/Opportunities

A limitation to an individual's or team's ability to respond creatively is microsystem and organizational culture. Almost by definition, responses involve "going off script" or protocol. In an organization where prior variations in practice resulted in punitive action, individuals may be unwilling to alter their behavior. They may even take the attitude that "I'm just going to do what I've been told to do, and if something bad happens it is management's fault." Developing a culture wherein employees can thoughtfully vary practice in response to conditions may require leaders to spend time on the front lines demonstrating appreciative inquiry (i.e., focusing on what works and what people care about, through discovery, dreaming, designing, and deploying) [20, 21].

Other potential limitations stem from some still unanswered questions. For example, is the ability to innovate an inherent psychological skill or something that can be learned? If only certain individuals have the ability to respond creatively, should a team have a critical mass of these individuals at any given moment? Can creative individuals be identified prospectively? Finally, are there ways to assess the effectiveness of creative thinking among individuals (i.e., the person who consistently identifies the "right" path, compared to the person who just creates more problems)?

Learn

Improvement Strategy

The ability to recognize and respond are related. By learning from experiences, individuals may

be better informed about which cues to monitor, thus improving their potential to anticipate and respond. Healthcare is a complex sociotechnical system that is continuously changing, creating new situations that are often not predictable and which lead to planned and unplanned adaptations [22]. The ability to learn from responses that went well and improve performance is a key difference between Safety I and II. This shift in approach from responding to past untoward events to being proactive and learning from what and why things go right can support an organization's potential to handle a wider variety of conditions.

Anticipated Results of the Improvement

Individuals and organizations learn from not only what goes wrong but also what goes right. At a basic level, when things go right, one can step back to praise those who did well and learn how to respond to the same conditions in the future ("learning from excellence") [23, 24]. At a higher order of thinking (requiring *cognitive* processing), learning in Safety II will provide generalizable knowledge about how to better recognize (monitor and anticipate) and respond to all possible conditions encountered.

How the Improvement Worked in Context of the Case

In our case example, we had a clinical pharmacist who was able to recognize and respond, and no errors occurred. If she and the system took no further action beyond heading off harm in this dangerous situation, the learning opportunity to improve future system responses is lost. In our vignette, "doing things right" was followed by intentional steps to learn. Questions asked and answered included how do we ensure that in the future, continuous intravenous nafcillin is an expected ordering option, and what other medications cannot be ordered in our EMR? This proactive performance by the pharmacist led to organizational learning, resulting in a novel EMR protocol for ordering continuous antibiotic infusions, including but not limited to nafcillin. A more generalizable level of learning can happen when we identify how the pharmacist was able to function in this way and create improvements that make the ability to recognize and respond more likely in the future.

Struggles/Limitations/Opportunities

Resources allocated for the sole purpose of learning are often viewed as an expense rather than an investment. Because drawing a direct connection to patient-level outcomes is difficult, the educational budget is frequently the first cut. Fairbanks warns, "Management initiatives must be undertaken sensitively and carefully to avoid underappreciating the value of apparently nonproductive resources that are contributing to resilience potential and which might be otherwise misjudged as waste" [25].

In addition to learning from what goes right in actual clinical situations, the increased use of simulation can increase learning opportunities. Simulation-based education allows for reproduction of high-risk low-frequency events. Experiential learning occurs by immersing teams in high-fidelity scenario-based simulation with deliberate exposure to disturbances, prompting inexperienced practitioners to learn trade-offs and consequences while managing these disturbances. Allowing the team to replay the same scenario and apply newly learned behaviors or explore different solutions creates learning reinforcement. Most learning occurs during focused debriefing immediately following a simulation event. Appreciative inquiry during debriefing can explore methods and frames of mind that prompted innovative or positive productive behaviors. Directed immediate feedback and the opportunity to practice teamwork and communication can contribute to decreased cognitive load, improved adaptive capacity, and a wider range of conditions with sustained high performance. In these ways, simulation allows the opportunity for providers to learn the skills of monitoring, antici-

pating, and responding without putting patients at risk. (See Key Points Box 12.2).

Key Points Box 12.2 Summary

- Safety I is the process of learning and responding after an error has occurred. While important, it is ultimately limited in eliminating all patient harm.
- Safety II does not replace Safety I. Safety II is the process of learning from what goes right, which offers far more opportunities for spreading improvement.
- Applying Safety II utilizes four components (steps/potentials): Recognize (including Monitor and Anticipate), Respond, and Learn. Each of these is dependent on the others.
- Research has identified both individual and system traits which affect the ability to implement the four Safety II components [12].

Editors' Comments

We have seen dramatic improvement in patient safety and care quality over the past decade. However, too often safety improvements reach a plateau before we have reached the goal (presumably zero patient harm). For example, hand hygiene compliance might stall at 98%; serious safety events continue at a low but non-zero rate; a small number of blood stream infections continue to occur. Often our initial belief is that if we keep doing the same things we have been doing to improve, but just do more of it, we will finally get to where we want to be. However, a well-known saying (controversially) attributed to Albert Einstein is that "the definition of insanity is doing the same thing over and over again and expecting a different result." Are we insane in healthcare? Will continuing to employ the same strategies that enabled us to have drastic reductions in key safety and quality measures finally get us to perfection? Does our current approach – forcing more standardization – have a theoretical limit in complex systems that are continuously evolving?

Safety II may be part of the solution. The application of Safety II is in the early stages and the authors of this chapter, from Nationwide Children's Hospital (NCH) in Columbus, Ohio, lead this work in pediatric healthcare. The chapter presents a thorough and foundational understanding of why Safety II has emerged and how it creates a different approach to improving safety. Readers of this chapter should appreciate the differences between the current safety improvement strategies in many of our organizations and how Safety II implores us to think differently. The pillars of Safety II presented in the chapter and their descriptions are important for the reader to understand and be able to discuss. The authors eloquently demonstrate how the four components of Safety II (Monitor, Anticipate, Respond, Learn) can coexist with our Safety I strategies (retrospectively analyze and fix) as the two strategies are not mutually exclusive.

The best methods for actually implementing Safety II thinking and approaches in an organization remain underexplored. The intent of this chapter is to introduce this way of thinking and use NCH as an exemplar of how to ingrain a different mind-set than what we have currently (Safety I). As we strive to reach zero harm, we must embrace different techniques, with Safety II as a prime candidate for the way forward.

Chapter Review Questions

1. Which of the following are key differences between Safety I and Safety II?
   A. Safety I focuses on what went wrong. Safety II focuses on what went right.
   B. Both Safety I and Safety II see humans as a liability, to be "designed" out of systems.
   C. Safety I tends to focus on making systems more rigid, while Safety II focuses on making systems more flexible.
   D. All of the above.
   E. A and C.

   Answer: E is correct – Safety II sees human foresight and ingenuity as an asset toward improving safety. The key features of Safety II are that by allowing flexibility/adaptation/resilience to complex or unexpected circumstances, we can proactively prevent errors from ever occurring.
2. What are the four main potentials/components of Safety II?
   A. Monitor, Anticipate, Respond, Learn
   B. Monitor, Avert, React, Leave
   C. Investigate, Restrict, Enforce, Discipline
   D. Monitor, Reason, Action, Lesson

   Answer: A. Hollnagel proposes that Safety II involves four integrated actions as listed in (A). We suggest that two of these – Monitor and Anticipate – might be seen as "Recognize."
3. Which of the following statements is *false* regarding the shortcomings of Safety I?
   A. Learning does not occur until after a critical event has occurred.
   B. Over time, errors become unusual and unique making learning from events challenging.
   C. The result is often increased rules and regulations.
   D. Human error is not considered in the analysis of events.

   Answer: D. The first three answers are all problems with the Safety I approach. This does not mean that Safety I is useless, but that addition of Safety II to our toolkit will improve safety further. Safety I often assesses for human errors leading to harm.
4. What are the three main components of resilience?
   A. Toughness, Plasticity, Recoil
   B. Foresight, Coping, Recovery
   C. Anticipation, Flexibility, Recoil
   D. Mindfulness, Anticipation, Recovery

   Answer: B. "Resilience" is the ability of an individual or system to function under circumstances beyond the usual or outside conditions for which the system was designed. Therefore, coping and then recovering to normal function are required.
5. Which of the following statements is *true* regarding the weaknesses of a FMEA (failure modes and effects analysis)?
   A. Has limited value in error prevention as the scope is often too broad
   B. Primarily focuses on preventing predictable problems
   C. Is a core tool in Safety II methodology
   D. Often addresses all potential errors preemptively

   Answer: B. While FMEA is useful, the process is still limited because of the requirement to imagine well in advance things that might go wrong and then make strategic decisions about which possible failure modes to design out of a system. Safety II allows for coping with previously unimaginable circumstances effectively.
6. Which of the following safety approaches praises individuals who perform well with the attempt to learn how to respond to the same conditions in the future?
   A. Learning from experience
   B. Learning from praise
   C. Learning from positivity
   D. Learning from excellence

   Answer: D. Learning from Excellence describes reporting and analysis of actions individuals took to succeed in a situation. Then the analysis is used to improve safety in similar situations in the future.

7. Which of the following is true regarding the difference between Safety I and Safety II methodologies?
   A. The intention is for Safety II to replace Safety I as it is more effective at preventing safety events in the healthcare setting.
   B. Safety I efforts are focused on the primary prevention of events, while Safety II evaluates events after they have occurred.
   C. Safety I considers deviation in actions to be a liability, while Safety II considers intentional variation by humans as positive and necessary.
   D. Safety I involves deviation from the protocol, while Safety II stresses the importance of following institution policies and procedures.

   Answer: C. Safety II does not replace Safety I. However, Safety II recognizes that flexibility in actions can help a system to "bend and not break."
8. Predictive analytics, which leverages previously acquired data to develop predictions about the future, is an example of which of the four main Safety II components?
   A. Anticipate
   B. Learn
   C. Resilience
   D. Respond

   Answer: A. The anticipating step of Safety II requires the ability to predict the future. While humans may do this based on experience, heuristics, or "gut instinct," technological advances in predictive analytics may augment our ability to know when an event is about to occur.

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Bundles and Checklists

13

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Chapter Objectives

- Describe the similarities, differences, and appropriate applications of checklists and bundles.
- Describe a variety of improvement opportunities amenable to checklists and bundles.
- Review key literature findings supporting the use of checklists and bundles.

Vignette 13.1

Over the course of just a few years, a fictitious large free-standing children's hospital began to notice an increase in patient-related safety events with dire consequences, including two wrong-site surgeries and a retained foreign body after surgery. At the same time, the hospital was experiencing a large volume of hospital-acquired infections and significant clinician-driven variation in perioperative care. While this hospital's staff believed in

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providing safe, high-quality care, they also valued individual autonomy and decision-making and resisted many forms of standardization. While outcomes were generally quite good, persistent periodic safety events coupled with evolving literature formed a burning platform for change.

Opening Question/Problem

In 1990, James Reason described the Generic Error Modeling System (GEMS) taxonomy for error classification which focused on cognitive factors in human errors [1]. The GEMS model was based on Jens Rasmussen's three major categories of error: skill-based slips and lapses, rule-based mistakes, and knowledge-based mistakes [2]. Despite an increasing understanding of human error, healthcare was slow to adopt methodologies to reduce the likelihood of error. In the year 2000, the Institute of Medicine report "To Err is Human," highlighting the human and economic toll of medical error [3].

Bundles and checklists are two simple tools, which when judiciously and appropriately applied, can be used to reduce the likelihood of slips and lapses as well as rule-based mistakes. Through a series of case vignettes and a review of the literature, this chapter describes the use of checklists and bundles in healthcare to improve patient safety.

Vignette 13.2
The opening slide read "Keep Me Safe, Heal Me, Be Nice to Me." The audience uncomfortably shifted in their seats as the Quality Department proceeded to share the stories of two patients that required second operations due to wrong-site surgeries. The presentation then shifted to other preventable hospital-acquired conditions, such as catheter-associated blood stream and urinary tract infections, ventilator-associated pneumonias, and pressure injuries. The rate of hospital-acquired conditions was on the rise throughout the organization, most notably in intensive care units. These preventable events resulted in higher morbidity, longer hospital stays, and increased healthcare utilization and costs. The last slide read "First Do NO Harm."

Hales et al. define a checklist as a "list of action items, tasks or behaviors arranged in a consistent manner, which allows the evaluator to record the presence or absence of the individual items" [4]. Perhaps the most well-described use of checklists pertains to aviation, where their use can be traced back to 1935 when a Boeing B-17 Flying Fortress crashed shortly after takeoff at a US Army Corps demonstration flight, killing the pilot and co-pilot. At the time, the B-17 was the most complex airplane in aviation history, yet analysis of the wreckage did not demonstrate any mechanical issues. Rather, human error was to blame. The pilot simply forgot to release the flight control gust locks, causing the airplane to nose dive into the ground. After the crash, the checklist was introduced and soon became a mandatory tool for all pilots in the Boeing fleet. The use of checklists in aviation extended from military aircraft to commercial aircraft, and the current enviable accident rate within aviation includes checklists as a key factor.

From a human factors' perspective, cockpit checklists are intended to achieve six objectives [5]:

1. Provide a standard foundation.
2. Provide a sequential framework.
3. Allow mutual supervision (cross checking).
4. Dictate the duties of each crew member.
5. Enhance a team concept.
6. Serve as a quality control tool.

Each of these attributes of cockpit checklists is equally relevant to healthcare. For example, providing a standard foundation for care delivery allows clinicians to focus on the unique attributes of individual patients or situations rather than spending mental energy on basic standards. Another key concept is "mutual supervision" or "200% accountability" which allows all caregiv-

ers, regardless of degrees or seniority, to provide team-member checking. If performed consistently, teams become stronger and quality improves.

One of the first people to recognize the potential for checklists to transform the quality and safety of healthcare was Dr. Peter Pronovost, a critical care physician at Johns Hopkins Hospital. In 2001, Dr. Pronovost introduced the concept of a checklist to reduce catheter-related blood stream infections at Johns Hopkins. At the time, these infections were often considered to be a known complication of care and were not necessarily thought to be preventable. Dr. Pronovost's work helped change this mindset. After initial local success, Dr. Pronovost was approached by the Michigan Health and Hospital Association to implement checklists in intensive care units across the state through a project commonly known as the Keystone Initiative. In groundbreaking work published in the New England Journal of Medicine and lauded in many layperson presses, 103 ICUs demonstrated a decrease in the median rate of catheter-related bloodstream infections from 2.7 (mean 7.7) infections per 1000 catheter days at baseline to 0 (mean 2.3). These improvements were sustained during 18 months of follow-up [6] and led to a paradigm shift in the approach to infections and other hospital-acquired conditions.

In 2006, Dr. Atul Gawande, a general and endocrine surgeon at Brigham and Women's Hospital in Boston, was approached by the World Health Organization (WHO) to join a group of people tasked with reducing avoidable death and harm from surgery [7]. At the time, more than 200 million operations were performed annually around the world with complication rates estimated to be 3–17%. Furthermore, more than a million people died each year due to complications of surgery. The WHO group considered numerous approaches to improving surgical safety. Training programs, pay-for-performance models, and the development of benchmarks and guidelines were all considered potential opportunities to improve safety. At the time, the routine use of a surgical checklist and surgical "timeout" had not yet been considered.

Inspired by the pioneering work of Dr. Peter Pronovost, Dr. Gawande suggested that an effective intervention needed to be simple, measurable, and transmissible. The eventual result was the WHO Safe Surgery Checklist which outlined 19 checks including 7 before anesthesia (e.g., patient allergies), 7 after anesthesia but before incision (e.g., correct procedure and site), and 5 at the end of the operation (e.g., equipment counts). In a pilot study involving eight hospitals with varying levels of sophistication, the rate of major complications dropped from 11% to 7%, and the inpatient death rate following major operations fell from 1.5% to 0.8% [8]. In the ensuing decade, the Safe Surgery Checklist was implemented in thousands of hospitals around the world. Indeed, at present, it is hard to find a patient having surgery without the use of checklist.

Vignette 13.3

The ICU leadership team met to address the problem of the increasing rate of hospital-acquired conditions. The scope and severity of the problem were recognized. Brainstorming sessions ensued with a focus on receiving input from key stakeholders. These stakeholders included frontline ICU clinicians (residents and nurse practitioners), bedside nurses, respiratory therapists, nursing leadership, and attending physicians. The staff highlighted the significant variability among providers regarding management of patients, particularly in addressing the prevention of hospital-acquired conditions on daily rounds. Audit data from daily rounds revealed that these subjects were not being consistently discussed. For example, not all providers rationalized the use of lab work or established the necessity of indwelling devices. After a series of brainstorming sessions with stakeholders, a list of rounding topics was developed. Stakeholder meetings continued until consensus was achieved on each of the rounding topics,

establishing that these core topics were vital to patient management and safety, and merited daily discussion on rounds. These core topics were incorporated into a daily rounding checklist. This checklist was then implemented in the ICU. Patient care goals were also incorporated to improve communication between the medical team, bedside staff, and families. All front-line clinicians, attending physicians, and bedside staff received education and training on the checklist. The front-line clinicians were tasked with completing the checklist on every patient during rounds, although the attending physicians were ultimately responsible for its completion. A checkbox within the electronic medical record to document that the daily rounding checklist had been performed was implemented to serve as a way to track compliance.

In the past decade, the use of checklists has become increasingly common in healthcare. For example, Weiss et al. examined the use of "prompted" checklists in the medical intensive care unit of a tertiary care university hospital. Physicians were prompted to address six parameters from a daily rounding checklist if those parameters were missed during rounds. A control group used the same checklist without prompting, and both groups were compared to a pre-intervention group. Patients in the prompted checklist group were found to have increased median ventilator-free duration, decreased empirical antibiotic and central venous catheter duration, and increased rates of deep vein thrombosis and stress ulcer prophylaxis. Remarkably, prompted group patients had lower risk-adjusted mortality, whereas control group patients had the same outcomes as the pre-intervention group. As an expected caveat, the authors noted that the availability of a checklist alone is not sufficient and that the manner of checklist implementation is critical [9].

Several studies have demonstrated the potential for checklists to improve quality of care and rounding efficiency in pediatric intensive care units (PICUs). A PICU Safety Checklist incorporated into the electronic medical record at Children's Hospitals and Clinics of Minnesota resulted in improvements in quality and safety metrics such as invasive device use, medication costs, antibiotic and laboratory use, and compliance with standards of care [10]. Efune et al. described how the use of a rounding template at Children's Health Medical Center Dallas (see Table 13.1, sample rounding checklist), which included evidence-based ICU standards of care, improved the reliability of discussing patient care goal elements during rounds [11]. Authors at Stanford University demonstrated that a "daily patient goal sheet" in the PICU improved communication between healthcare providers, helped nurses identify the in-charge physicians, and was helpful for patient care [12].

In an analysis of 29 articles regarding safety checklists in medicine, Thomassen et al. found that checklists improved guideline compliance, improved human factors (i.e., the interaction between humans and other elements of a system), and reduced the incidence of adverse events. Four of the included studies demonstrated a decrease in mortality, and none reported an increase in adverse events. The authors concluded that safety checklists are effective tools in various clinical settings [13].

These studies clearly demonstrate that the use of checklists can be effective in a variety of different clinical venues and healthcare systems. However, for maximal clinical impact, checklists must be kept simple and focused. A bloated checklist is likely to be ignored or only partially completed.

Vignette 13.4

Six months later, the hospital-acquired condition rate in the ICU was re-examined. Despite initial optimism from ICU leadership regarding the implementation of the checklist, the rate of hospital-acquired conditions failed to improve. Input from key stakeholders revealed that the project had potentially experienced "scope creep" from the addition of patient goals into the rounding checklist. To address this, the team decided to narrow the focus to a set of evidence-based, condition-specific, "bundle elements."

Table 13.1 Sample rounding checklist

						MRN		
Day		1	2	3	4	5	6	7
Date		__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Sedation	Goal							
	Sedation holiday	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	Paralytic holiday	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	Signs of withdrawal	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
Lines		Site/ day/*remove*?	Site/ day/*remove*?	Site/ day/*remove*?	Site/ day/*remove*?	Site/ day/*remove*?	Site/ day/*remove*?	Site/ day/*remove*?
	CVL							
	Art line							
	Foley care qshift?	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
Meds	Discont/chg to enteral?	☐Discussed	☐Discussed	☐Discussed	☐Discussed	☐Discussed	☐Discussed	☐Discussed
	Drug levels	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	Adjustment for organ system dysfunction	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	GI prophylaxis	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
	DVT prophylaxis	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
Resp/Vent	Goal blood gas	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A
	Goal sat							
	ERT performed	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A

(continued)

Table 13.1 (continued)

						MRN		
	ERT result	☐P ☐F ☐N/A	☐P ☐F ☐N/A	☐P ☐F ☐N/A	☐P ☐F ☐N/A	☐P ☐F ☐N/A	☐P ☐F ☐N/A	☐P ☐F ☐N/A
	ETT leak	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	Hold feeds for ext	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
Patient care	HOB elevated/oral care	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
	Skin regimen	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
	Turning q2h?/bath q24h?	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
	Bowel regimen	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A	☐Y ☐N ☐N/A
	Initiate or advance feeds	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
	Nasal ETT or nasal NIPPV? Nares ok?	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N	☐Y ☐N
Labs	Lab schedule	☐Reviewed	☐Reviewed	☐Reviewed	☐Reviewed	☐Reviewed	☐Reviewed	☐Reviewed
Goals	Goal BP	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A	☐N/A
	Goal fluid balance – net even/pos/neg?							
Care coord	Anticipated PICU d/c day							
	Milestones necessary for d/c							

The concept of a healthcare "bundle" was developed in 2001 by the Institute for Healthcare Improvement (IHI). In a joint initiative with the Voluntary Hospital Association, the Idealized Design of the Intensive Care Unit (IDICU) initiative aimed at improving the reliability of critical care processes to improve outcomes at 13 participating hospitals. Collaborators initially found wide variation in care processes and were not able to improve outcomes despite strong participation in the collaborative. An alternative approach was sought, and "bundles" were developed for patients on ventilators and those with central lines.

Bundles are defined by the IHI as, "A small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually." According to the IHI, bundles have the following properties [14]:

1. The bundle has three to five interventions (elements), with strong clinician agreement.
2. Each bundle element is relatively independent.
3. The bundle is used with a defined patient population in one location.
4. The multidisciplinary care team develops the bundle.
5. Bundle elements should be descriptive rather than prescriptive, to allow for local customization and appropriate clinical judgment.
6. Compliance with bundles is measured using all-or-none measurement, with a goal of 95% or greater.

A 2009 article by Lachman and Yuen described some additional characteristics of healthcare bundles [15]. For example, they note that each bundle intervention should be scientifically grounded (i.e., evidence-based) and that experts believe that the bundle elements are essential to improving outcomes. They also note that not all possible therapies are included in a particular bundle and that bundle elements should not be "forced" if clinically inappropriate or contraindicated. However, consensus can also drive common-sense inclusion of bundle elements in the absence of evidence. For example, the use of a parachute when jumping from a plane is often cited as a necessary element without a clinical trial [16].

In one of the first large studies demonstrating the value of bundles in healthcare, Resar et al. demonstrated a 44.5% reduction in ventilator-associated pneumonia rates among 35 hospitals that consistently adhered to ventilator bundle elements [17]. Since then, several studies have demonstrated the value of bundles in improving patient safety and reducing hospital-acquired conditions. In a study of 29 pediatric intensive care units across the United States, catheter-associated bloodstream infection rates were reduced by 43% through the implementation of two central line care bundles; one focused on central venous line insertion, and one focused on maintenance [18]. Another quality improvement collaborative involving nine Department of Veterans Affairs hospitals yielded a 48% decrease in catheter-related bloodstream infections and a 41% decrease in ventilator-associated pneumonia by engaging multidisciplinary teams to implement evidence-based ventilator and central line insertion bundles, team rounds, and a daily patient ICU bedside checklist [19].

In a partnership with the Institute for Healthcare Improvement, the Surviving Sepsis Campaign incorporated bundles into the diagnosis and treatment of patients with severe sepsis and septic shock. The results have been dramatic. For example, a study of two adult hospitals demonstrated that lack of adherence to the 6-hour sepsis bundle yielded a relative risk of in-hospital mortality of 2.12 [20]. More recently, a meta-analysis of 50 observational studies demonstrated that hospitals that implemented performance improvement programs were able to increase adherence to the 6- and 24-hour sepsis bundles with a resultant decrease in mortality (OR = 0.66) [21].

Similar results have been demonstrated in pediatrics. After the death of a pediatric patient with sepsis, New York State mandated an evidence-based approach to sepsis treatment in 2013 [22]. An amendment of Title 10 of the New York State Codes, Rules, and Regulations required hospitals to develop and implement sepsis protocols for the early recognition and treatment of sepsis and to report data regarding

performance on key measures to the New York State Department of Health. While protocols varied by hospital, all protocols were required to include a pediatric bundle consisting of three interventions to occur within 1 hour: blood cultures, broad-spectrum antibiotics, and a 20 ml/kg bolus of intravenous fluids.

In 2018, a cohort study was published in the Journal of the American Medical Association describing the impact of the New York State mandated bundle for 1179 patients aged 18 years and younger with sepsis and septic shock treated at 59 hospitals. In this cohort, completion of all bundle elements within 1 hour was associated with a lower risk-adjusted odds of in-hospital mortality (odds ratio, 0.59, $P = 0.02$). Of interest, completion of individual bundle elements within 1 hour did not lead to lower risk-adjusted mortality [23]. This important result points to the "all-or-none" nature of bundles. In other words, bundle elements work synergistically and must all be completed in order to obtain the desired outcome. Clinicians should not choose which bundle elements to complete at any particular encounter. Furthermore, it also demonstrated the importance of consistently implementing the entire bundle without omitting patients.

Another innovative use of bundles was demonstrated by the Solutions for Patient Safety (SPS) network (https://www.solutionsforpatientsafety.org/), a cohort of pediatric hospitals dedicated to eliminating patient and employee harm. The SPS approach to reducing hospital-acquired conditions (HACs) involves the identification and dissemination of evidence-based bundles that are developed by expert panels. Each hospital in the collaborative targets 90% reliability for each bundle and reports both outcome and process (i.e., bundle reliability) data for each HAC.

The SPS approach to reducing harm in hospitalized children has proven to be effective. For example, in a cohort of 33 SPS hospitals participating in a collaborative to reduce pressure injuries (PIs), stage 3 PIs declined from 0.06 to 0.03 per 1000 patient days, and stage 4 PIs declined from 0.01 to 0.004 per 1000 patient days after implementation of a 5 element bundle [24]. In the first 3 years of the SPS network, significant harm reduction occurred in 8 of 9 hospital-acquired conditions (HACs) [25], and the network has now grown to more than 130 hospitals. The SPS operational definitions and bundles are available online [26].

Vignette 13.5

Despite initial enthusiasm for the bundles, the hospital-acquired condition rate in the ICU continued to be unacceptably high. Review of the literature demonstrated strong evidence supporting bundle implementation, yet ICU leaders were frustrated with the lack of improvement. To better understand how the bundles were being used, a measurement plan was developed. Audits were performed to examine compliance with bundle elements. While a few of the individual elements had compliance rates above 90%, most elements demonstrated lower rates of compliance. Moreover, when bundle compliance was measured using an "all-or-none" approach, bundle reliability was found to be well below 50%.

Bundle implementation by itself is not adequate to improve outcomes. Rather, bundle elements must be performed reliably. The importance of consistent bundle adherence was demonstrated in a study of 984 adult ICUs in 632 hospitals. Most of these ICUs had central line bundle policies, but only 69% reported excellent adherence to at least one bundle element (excellent adherence was defined as implementing the bundle in ≥95% of patients). ICUs that demonstrated excellent adherence to at least one element had an incidence rate ratio (IRR) of 0.77, and ICUs that had excellent adherence to all five elements had an IRR of 0.67. No association between bundle compliance and outcomes for CLABSI rates was found for hospitals that had a written bundle policy but did not measure bundle compliance or had measured compliance of less than 75% [27].

Bundle compliance is measured using an "all-or-none" methodology. In a commentary in the Journal of the American Medical Association, Thomas Nolan and Donald Berwick described three advantages of an "all-or-none" approach to

performance measurement [28]. First, this approach more likely reflects the interests and desires of the patients. In other words, patients and their families likely expect that all evidence-based measures are reliably performed. Second, all-or-none measurement fosters a systems approach to improvement rather than relying on individual performance. Finally, all-or-none measurement offers a more sensitive scale for assessing improvements. Whereas it may be relatively easy to achieve 95% compliance with individual elements, an all-or-none approach often highlights the frequency with which certain bundle elements or steps in a process are skipped.

As outlined by Gurses et al., several contributory factors impact bundle adherence [29]. These factors include a lack of clarity around the specific goals (tasks) for the patient; confusion about how to complete a step of a guideline (methods); who should do what (individual responsibilities); a lack of understanding of the exceptions to the guideline; and the sanctions (if any) if the protocol is not followed. Every healthcare system needs to consider each of these factors when building a bundle.

To achieve excellent bundle compliance, each element of the bundle must be assessed for accessibility. Limiting the bundle to the most salient elements highlights the value of each one. Following a rigorous selection process, including multidisciplinary consensus, can help to promote the high reliability needed for bundle adherence.

Measurement of bundle adherence, often referred to as bundle reliability, is a key component of any improvement efforts involving bundles. The creation and distribution of a bundle are not in and of itself sufficient. Rather, bundle adherence should be measured in a continuous feedback cycle. One approach to measurement is through automated monitoring of documentation in the electronic medical record. While this approach is often used, it does not provide an opportunity for real-time feedback.

Kamishibai, or K-cards, is an approach to improving bundle reliability that has been encouraged by the Solutions for Patient Safety network. This quality tool is named after a form of storytelling that was used by Buddhist monks in the twelfth century to express stories of moral significance. The monks would show drawings on pieces of paper and tell a story related to the drawings [30]. Reflecting the moral gravity of high-quality manufacturing, the Toyota Production System adopted the moniker Kamishibai and built boards as visual controls for important processes and tasks. Each task or step in a process is displayed on a double-sided card (red and green). If the step is completed appropriately, the card is placed on the board with the green side showing. If a problem is encountered or a step is skipped, the card is placed with the red side showing. This allows leaders to easily recognize if critical tasks are being executed consistently. As part of their standard work, leaders routinely view the board to assess the status of the process in question.

In healthcare, K-cards can be used for auditing and visual control of bundle reliability. The individual bundle elements are listed on the front (green) side of the card, and a description of each element is provided on the back (red) side (see Fig. 13.1, Sample CLABSI K-card). The auditor observes the process in question using the K-card as a reference. If all elements of the bundle are completed correctly, the clinician is praised, and the card is placed back on the board with the green side up. If any element is not completed as intended, the auditor provides real-time feedback. For each K-card audit that is completed, a record is kept of which individual items were missed. The card is then placed back on the board with the red side up (see Fig. 13.2, K-card audit board). The board is often hung in a common area allowing all clinical staff to easily understand the performance of their unit relative to the bundle. When all K-cards for a given audit cycle are completed, the results are tabulated and recorded.

While the implementation of K-cards to increase bundle reliability in healthcare is a relatively new concept, a growing body of anecdotal and peer-reviewed evidence supports this approach. Most notably, K-cards are a key component of the Solutions for Patient Safety approach to eliminating patient harm in children's hospitals, as previously described. A recent peer-reviewed article describes how one pediatric unit within the American Family Children's Hospital in Wisconsin was able to

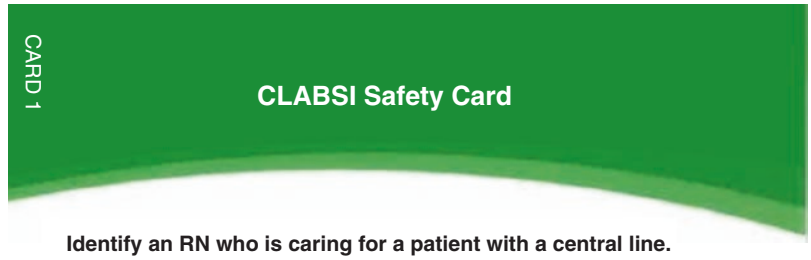

Fig. 13.1 Sample CLABSI K-card. Used with permission from Children's Health © 2019

Identify an RN who is caring for a patient with a central line.

ASK NURSE TO SHOW YOU IN CHART, DOCUMENTATION OF:

1. Was necessity of the line discussed at least once within the past 2 completed shifts?
- Does the patient have a temporary or long term line?

Temporary: Intended for short term use (</= 30 days); Sutured in or stat lock applied; Common locations - umbilical, neck, femoral

Long Term: Intended for long term use such as chemotherapy or TPN (> 30 days); Common types: IVAD, Broviac, and Tunneled
- If Temporary. Ask nurse to show you documentation of discussion: (N/A if admitted to hospital or line placed within last 24 hours)
- If Long Term, Question is N/A : go to the next question

2. Are daily care elements documented at least once within the past 2 completed shifts?
- If CHG ordered, did the patient receive a CHG bath at least once within the past 2 completed shifts? (N/A if not ordered, medically contraindicated, admitted to hospital or line placed within last 24 hours, or family refusal despite documented provider discussion)
- Is there documentation of a linen change at least once within the past 2 completed shifts? (N/A if admitted to hospital or line placed within last 24 hours or if medically unstable for linen change)

GO TO BEDSIDE WITH NURSE AND OBSERVE:

1. Was the line maintained according to bundle?
- Dressing is clean, dry and occlusive
- Dressing and tubing dates of change are labeled appropriately
- Tubing is away from potential contamination (ostomy bag, diaper)
- Curos caps are covering all access points on all lines (N/A if assessed as choking hazard)

2. Assess for risk factors necessitating the need for a protective overlay/drape.
- Risk factors may include: femoral line placement, line near excessive secretions or emesis, line placed near ostomy, or patient with excessive stooling.
- If any risk factors are identified, is there a protective overlay/drape placed correctly? (N/A if no risk factors)

NEXT STEPS:

Place GREEN side of card showing If ALL elements are compliant at time of observation.
- Give in the moment praise for keeping patients safe.
- Complete Safety Board documentation and Rounding for Children's Health survey.

Place RED side of card showing if ANY elements are non-compliant at time of observation.
- Discuss with nurse plan to correct any non-compliant elements in a timely manner.
- Complete Safety Board documentation and Rounding for Children's Health survey.

children'shealth®

Fig. 13.2 K-card audit board. Incomplete cards are placed on the left. Completed cards are placed on the right with the green side showing only if all bundle elements were completed correctly. Used with permission from Children's Health © 2019

reduce their CLABSI rate from 1.83 to 0 per 1000 line days after the implementation of K-cards [31]. (Key Points Box 13.1)

Vignette 13.6

End users (bedside nurses, clinicians) in the ICU commented to the project team that the bundle elements were currently not a normal part of their workflow and so were often forgotten. To improve bundle compliance, the team turned their attention back to the rounding process. The bundle elements were incorporated into the daily progress note using both free text and data from the electronic medical record. The daily progress note was chosen as the format in which to implement the bundle elements because it served as a script for patient presentations by the majority of ICU front-line providers. Audits revealed an increase in bundle compliance; however, the "all-or-none" bundle compliance rate remained below 50%. A second "plan-do-study-act" (PDSA) cycle was implemented, and the bundles with their individual elements were displayed on laminated "badge buddies" which were subsequently distributed to the critical care medicine physicians in training. These senior trainees facilitated bedside rounds and were tasked with ensuring the bundles were appropriately discussed for each patient on morning rounds. Audits were repeated, and this time the "all-or-none" compliance rate increased above the team's goal of 95%. Through the incorporation of bundle elements into the current ICU workflow, the project team was able to improve bundle compliance and reduce the incidence of hospital-acquired conditions [11].

Key Points Box 13.1

- A checklist is a "list of action items, tasks or behaviors arranged in a consistent manner."
- A bundle is "a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually."
- Bundle compliance is measured using an "all-or-none" methodology.
- Kamishibai refers to a form of storytelling that was used by Buddhist monks in the twelfth century. Kamishibai, or K-cards, is an approach to improving bundle reliability that has been encouraged by the Solutions for Patient Safety network.

Editors' Comments

Bundles and checklists save lives; the editors have seen it with their own patients, their practices, their hospitals, and their own family members.

We reiterate, unequivocally, bundles and checklists save lives.

These repetitive declarations cannot be truer now and in the future with the burgeoning data and the speed at which information comes to healthcare providers. There needs to be a way to organize information and prioritize data. If we can agree that bundles and checklists were trendy, en vogue, helpful, etc. in this decade, then in the next 5–10 years, bundles and checklists will be imperative, ubiquitous, and compulsory.

This chapter is a keystone for this textbook; the reader will be able to understand the role of bundles and checklists in healthcare and their practices and how to operationalize these tools. The author's objectives are to ensure the reader understands on a cursory level the difference between bundles and checklists. The editors have often time utilized the quality improvement vernacular of "bundles" when discussing outcomes, harm, and hospital-acquired conditions with our executive leadership and hospital boards.

Many people intuitively understand checklists, but the concept of bundles is worth explaining; importantly, the potential to partially utilize bundles cannot be underscored. The editors often hear from improvement teams that despite their efforts, they cannot move the needle on a particular outcome. When we dig deeper, we have learned that although the quality improvement leader states that the team is utilizing a bundle, they are not following and tracking all components of the bundle – they are only following, for example, 75% of the bundle elements (in other words, following 3 of the 4 bundle components). This is a very important point for the reader to understand – when teams are using bundles, make sure you know how much of the bundle is being implemented as then the outcomes can be put in the proper context.

The authors end the chapter with tangible examples of checklists. Once completing this chapter, the reader should assess their microenvironment and ensure they are utilizing bundles and checklists where appropriate; the guidance and pearls from this chapter should serve as a scaffold for the improvement scientists.

Chapter Review Questions

1. True or false: Bundles and checklists are the same.

   Answer: False
2. Describe some similarities and differences between bundles and checklists.

   Answer: A checklist is a list of action items, tasks, or behaviors arranged in a consistent manner. A bundle is generally limited to 3–5 elements and is measured in an all-or-none manner. In healthcare, checklists and bundles are both tools that can be used to standardize care, avoid unnecessary variation, and reduce the potential for human error.
3. Describe some practical applications of checklists in healthcare.

   Answer: While there are numerous potential applications for checklists, the most widely reported are the surgical checklist and the ICU rounding checklist.
4. Describe some practical applications of bundles in healthcare.

   Answer: Bundles have most frequently applied to common hospital-acquired conditions such as pressure injuries, medication errors, central line associated bloodstream infections, and surgical site infections.
5. Which of the following does not describe a bundle?

A. Typically has three to five elements.
B. Each element is relatively independent.
C. Should be developed by a multidisciplinary team
D. Bundle elements should be prescriptive without room for local interpretation.
E. Compliance should be measured "all-or-none."

Answer: D

6. What is the "all-or-none" concept that is used to describe bundles?

   Answer: A bundle is only considered to be correctly performed if all bundle elements are completed. Bundle reliability is reported as the percentage of bundles audits in which all elements were performed.

7. How are K-cards used to measure bundle reliability?

   Answer: K-cards are a visual tool for auditing and displaying bundle reliability. Typically, the front of the card is green and the back of the card is red. If all elements of the bundle are performed correctly, the card is placed on the board with the green side showing. If any element is not correctly performed, the card is placed with the red side showing. On a regular basis, the results of the bundle audits are tabulated. Bundle reliability is reported as the percent of bundles that are correctly performed.

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14

Pathways and Guidelines: An Approach to Operationalizing Patient Safety and Quality Improvement

Andrew R. Buchert and Gabriella A. Butler

Chapter Objectives

- To demonstrate how clinical pathways and guidelines can be used as a tool to reduce patient harm, improve clinical and quality outcomes, and advance organizational strategy.
- To understand the essential elements of successful clinical pathways and guidelines to drive improvement.
- To explain the process of clinical pathway and guideline development, measurement, and sustainability.
- To highlight examples of positive organizational impact from clinical pathways and guidelines.

Vignette 14.1

A tertiary-care children's hospital is seeking a solution to rising demand for services, increasing hospital census, escalating costs, and fragmented care. Concurrently, however, the hospital is growing clinical service lines and increasing its focus on patient, family, and staff/provider satisfaction. An assessment of the current state reveals high variability in resource utilization and length of stay, opportunities to improve key quality and patient safety metrics including unplanned readmissions and healthcare-acquired infections such as CLABSIs and CAUTIs, and a need for a better connectedness along the entire continuum of care including both pre- and post-hospitalization. The executive team turns to the safety and quality leaders of the organization to design an approach that will bridge silos and lead to wide-ranging improvements to ensure the safest, highest quality, most evidence-based, and efficient clinical care.

Opening Question/Problem

Despite evidence that the healthcare industry can adapt process improvement methodologies and high reliability techniques from other leading

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organizations in safety and quality to drive improvement and decrease patient harm, the healthcare delivery system remains dependent on the human-to-human interactions between providers and patients [1]. There is a need for an approach to reduce variability in care that crosses and breaks down silos and allows for clinical algorithms that incorporate both evidence- and consensus-based decision-making and that is data-driven. This chapter will focus on the utilization of clinical pathways and guidelines as a vehicle to drive organization-wide improvement and will explore the methods for development, measurement, and sustainability of this tool through a series of case vignettes.

Vignette 14.2
The organization has a long-standing culture of utilizing clinical effectiveness guidelines to help guide care. Over the course of the preceding 10 years, the organization has developed at least 200 guidelines for both common and rare diagnoses that have been developed and regularly updated by frontline clinical champions. The quality and safety leaders of the organization appreciated that these clinical effectiveness guidelines transcended silos and represented nearly all specialties and settings of care. At the same time, however, the leaders also noted that there were no processes in place to measure if and when these clinical effectiveness guidelines were actually being utilized, nor were there processes in place to measure the outcomes of utilization of these guidelines. The leaders sought an approach that would be data-driven.

The burning platform for improvement in patient safety and quality continues to smolder. Since the *To Err is Human* report's release in 1999 [2], more recent literature has suggested that up to 400,000 Americans die every year from medical errors, with serious harm more common than death [3]. In addition to patient harm, today's healthcare environment is under significant financial pressures, especially as healthcare in the United States remains some of the costliest in the world [4]. High reliability organizations have provided the healthcare industry with models for error reduction through process improvement and strategies for organizational culture change, and as healthcare organizations have embraced these methodologies, outcomes and quality metrics have begun to improve [5]. But in many organizations, clinical care continues to remain highly individualized with medical decision-making often tailored on a case-by-case basis [6]. Although it is unlikely that variability in healthcare will ever completely disappear, nor should this be the expectation, the high reliability organizations have taught us the importance of reducing unnecessary variability [5].

It has previously been shown that standardization of clinical care via pathways and guidelines leads to improvements in the safety and quality of care for both individual patients as well as for the population of patients with a particular diagnosis or condition [7], and it has also been shown that reduction of variability in clinical care via pathways and guidelines also leads to reduced costs of care [8]. Thus, the development of clinical pathways and guidelines needs to be a key component of a healthcare organization's efforts to improve the care experience, including quality and safety, as well as to improve the health of populations and reduce the costs of care, i.e., the Triple Aim as defined by the Institute for Healthcare Improvement (IHI) [9].

In a 2010 Cochran review, researchers examined clinical pathways and guidelines sampled from a large number of different healthcare organizations. Although they noted significant variability in definitions, settings of care, and intended impacts, they found that there were several consistencies across all of the pathways and guidelines of which they sampled. These similarities included multidisciplinary clinical algorithms that translated evidence-based guidelines for care into local organizational culture (evidence- and consensus-based care) for specific diagnoses, conditions, or populations, and the algorithms were tailored to specific settings of care [10].

Clinical pathways are more than tools to reduce variation, however. Successfully implemented pathways can also drive organizational strategy. In addition to what has been established so far as key components to clinical pathways and guidelines, it is imperative that pathways also include measurement and a data dissemination and feedback process, as well as a structured development and rollout process to ensure buy-in and support. These are the essential elements that lead to successful clinical pathways and guidelines that have widespread impact and drive improvement throughout the organization. These elements will be detailed further throughout this chapter (Key Points Box 14.1).

Key Points Box 14.1 Key Elements of Clinical Pathways and Guidelines

- Evidence- and consensus-based
- Inter- and multidisciplinary
- Integrated into the EMR and workflow
- Measurement and feedback/data dissemination process
- Education and rollout process to ensure buy-in
- Alignment with organizational strategy

Vignette 14.3

The leadership of the organization commits to measuring the adherence to and the impact of the utilization of clinical pathways and guidelines. The leadership engages its information technology experts and decides to build a process of measurement that assesses both care that is ordered and care that is actually delivered. The general surgeons have just revised their clinical pathway for the management of a common surgical diagnosis, and this provides an ideal opportunity to pilot this new measurement process. The adherence to the newly revised pathway is outstanding – the recommended perioperative antibiotic is correctly ordered nearly 98% of the time. However, an assessment of the actual antibiotic administration from the surgical records in the EMR indicates that although an antibiotic is administered prior to the incision 100% of the time, the recommended antibiotic is only administered 50% of the time. The other 50% of the time the antibiotic administered is different from the one that was ordered. Further investigation reveals that the recommended antibiotic is actually not routinely stocked on all of the anesthesia carts, and in these instances a decision is made at the point of care to administer an alternative and readily available antibiotic. Once this was identified, the leadership was able to stock the recommended antibiotic on all carts.

The traditional approach to the measurement of clinical pathways and guidelines has focused on assessing the use of and the adherence to the clinical algorithm, often accomplished by measuring the use of certain orders or of the accompanying order set, if one exists. Linking this data to the associated outcomes data (clinical, quality, and safety indicators) can indicate that the adherence to the pathway or guideline has an association with the improvement in the clinical, quality, and safety metrics. An advantage of this method is generally ease of measurement, i.e., the ability to measure the use of a particular order or orders, and/or the use of a particular pre-defined order set is often a simple task in most electronic medical records that can be done readily, quickly, and without much technical expertise. Additionally, many of the safety, quality, and clinical outcomes are already being measured via other methods for required reporting both internally and externally, so a new process does not need to be built. Association does not prove causation, however, and a significant downside to this method is that orders can and often are changed at the point of care, which may result in measurements that are not an accurate reflection of actual use of the pathway or guideline.

An alternative method for the measurement of clinical pathways and guidelines is to measure

the care that is actually delivered to the patient, as opposed to the previously described method that measures care intended. Measurement of care that is actually delivered not only provides more proof to the effectiveness of the pathway or guideline, but it also provides insight into opportunities for system improvements that may not otherwise be discovered.

Measuring care delivered enables insight into opportunities for system improvement and often exposes hidden opportunities. Measuring care that is delivered can also shed light onto other new opportunities for improvement. Length of stay and resource utilization, as well as organizational quality and safety metrics such as unplanned readmissions and opportunities to impact healthcare-acquired infections, may be related to variations in clinical care (Key Points Box 14.2).

Key Points Box 14.2 Measurement of Clinical Pathways and Guidelines

- Care intended: orders, order sets (e.g., a third-generation cephalosporin was ordered, as recommended by the clinical pathway or guideline.)
- Care delivered: what the patient actually received (e.g., a third-generation cephalosporin was ordered, as recommended by the clinical pathway or guideline, but the patient actually received a fluoroquinolone.)

Vignette 14.4

The implementation and measurement of a clinical pathway for a common surgical diagnosis yield a 40% reduction in median length of stay within 18 months, and it also nearly eliminates the patients receiving a central line for prolonged administration of antibiotics. Impressed and moved by this success, the perioperative stakeholders and providers seek to engage in the development of another clinical pathway, and they begin with a critical analysis of their perioperative data. They find that for another common surgical diagnosis, there is one provider who is an outlier from all of the others, in that this particular provider's patients are almost never admitted postoperatively. In further investigation, they find positive deviance – this provider and the anesthesia team have taken a novel approach to the preoperative education, timing of the procedure, and postoperative pain management. The group designs and implements a new clinical pathway that incorporates and makes these novel elements the new standard, leading to a 65% decrease in median length of stay. They also found a 100% reduction in 30-day unplanned hospital readmissions for patients with this particular diagnosis.

Clinical pathways and guidelines must incorporate measurement, ideally of care delivered, and this data-driven approach can drive clinical improvement that leads to subsequent improvement in organizational quality, safety, and performance metrics. An essential element of this data-driven approach, however, is the integration of clinical and information technology (IT) expertise. Formerly, clinicians in need of data communicated with the IT team via email or other formal request processes, the request was triaged and prioritized by the IT team, and once ready, the data would be pulled and delivered back to the requesting clinician. There were often discrepancies between what was requested and what was delivered, however. For example, a data pull for patients treated for an asthma exacerbation may have come back with much lower than expected volume, and upon further investigation, it is found that only patients with a final diagnosis of asthma exacerbation were extracted. The clinician intended the data pull to include all of the variants that would indicate an asthma exacerbation, i.e., status asthmaticus, wheezing, respiratory distress, etc. The clinician knew this but did not realize that this was not intuitive to the IT team who are not clinicians.

The IT team provided back to the requesting clinician exactly what was asked for, but understandably, the IT team did not appreciate the clinical nuance of the requested patient population.

Accurate and effective measurement of clinical pathways and guidelines requires an appreciation of clinical nuances. This is best achieved via a close partnership between clinical and IT expertise. The pathway and guideline development process must include both clinicians and IT team members working together at all points throughout the entire process. While the clinical experts are drafting the clinical algorithm and devising the key metrics, the IT team is concurrently developing a blueprint for the data pull and measurement logic, i.e., what defines the patient population, which patients are eligible and ineligible for the pathway, and what elements must be incorporated into the logic to ensure that the measurement is accurate and accounts for the realm of clinical care. This process is dynamic – clinicians provide the guidance for the patient population, eligibility, and metrics, and the IT team turns this into the logic. As the logic is tested and data is pulled, this is then reviewed with the clinical experts, and tweaks to the logic are made as indicated. This process happens numerous times in an iterative manner throughout the pathway development process and continues to occur following release of the pathway, as well. The measurement process becomes refined over time, and the result is pathways with adherence and impact data that are trusted by clinicians and, thus, are truly able to change behavior and affect change (Key Points Box 14.3).

Key Points Box 14.3 Integration with IT
Clinical experts and IT experts at the table together (literally!) and working hand-in-hand throughout the entire process.

Vignette 14.5
The organization has seen the success of the surgical pathways including reductions in length of stay, reductions of usage of central lines, and reductions in unplanned hospital readmissions. Demands for services and hospital census remain high, and the organization identifies a particular need for a solution to high-demand in one of the specialty ICUs where referrals are consistently outweighing capacity. Leadership embarks on a critical examination of the types of patients and diagnoses who populate this ICU, and they also benchmark against peer institutions. They find that there is one particular diagnosis of which the organization admits to this ICU at a rate nearly double that of their peer institutions. The organization embarks on a deep dive into these patients and uses a well-established risk stratification guideline for this particular diagnosis to assess whether the patients admitted to the ICU instead of an acute care unit were sicker or higher risk, and they find that this is not the case. They also find that the patients with this diagnosis who are admitted to the ICU have a length of stay that is nearly double that of those who are admitted to an acute care unit, and the patients in the ICU have higher resource utilization including more lab draws and more pharmaceuticals, despite having the same risk stratification and illness severity as those who are admitted to an acute care unit (Fig. 14.1). The organization embarks upon the development of a clinical pathway that includes guidance at the time of admission for where these patients are admitted, as well as that standardizes the management regardless of the setting of care, resulting in a 22% reduction in the median length of stay for these patients, as well as an increase in capacity of the specialty ICU.

Clinical pathways can be a key component in the implementation of organizational strategy. As previously discussed, it is important to measure care delivered and not just care intended, and successful measurement requires an integration

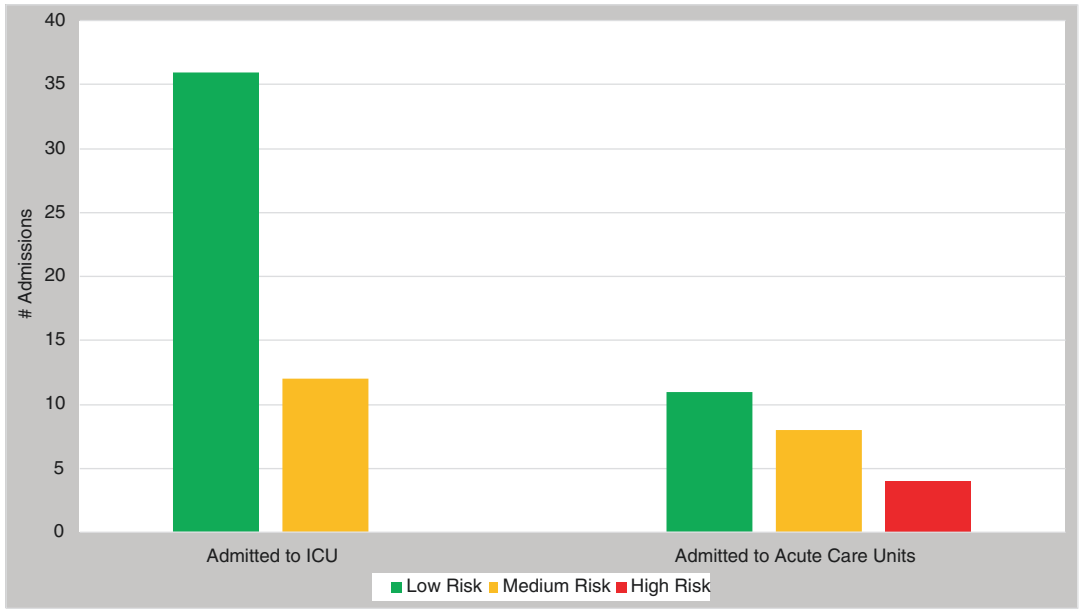

Fig. 14.1 The highest risk patients were actually admitted to the acute care units, where their management involved less lab draws and resource utilization, with a shorter length of stay

of clinical and IT expertise throughout the entire process. The process of pathway development itself, however, warrants its own discussion. Successful pathways are inter- and multidisciplinary and evidence- and consensus-based, include a robust measurement and data dissemination/feedback process, are aligned to organizational strategy, and span the continuum of care.

The process begins with the formation of the team. At a minimum, the team must consist of clinical champions who are a subset of all stakeholders. For example, a clinical pathway for the management of acute asthma exacerbations must include providers and nursing staff from the emergency department, from the inpatient services and acute care units, and from the intensive care units, as well as other stakeholders including respiratory therapists (RTs) and pharmacists. Ideally, there would also be representation from subspecialty stakeholders such as from pulmonology, as well as primary care and urgent care providers and nurses. In addition to clinical champions, the team is led by the project manager who has a combination of a clinical background and technical knowledge of the EMR. The team must also include developers who will design the logic and data pull, analysts who review and perform the analysis of the data, informaticists to edit orders and order sets, and EMR analysts to complete the changes to clinical documentation. Additional team members include a clinical education specialist to help with the buy-in and rollout process, a marketing/communications specialist to build the concomitant informational and educational materials for both internal staff and those that are patient- and family-facing, and a finance specialist to measure the cost-savings and economic impact (Key Points Box 14.4).

Key Points Box 14.4 Clinical Pathways and Guidelines Team

- Clinical champions representing stakeholders, i.e., providers, nurses, pharmacists, RTs, etc.
- IT experts (data pull, logic, order set builds, dashboards, and data analytics)
- Clinical education specialists (buy-in and rollout)

- Marketing/communication specialists (internal and patient-/family-facing educational materials)
- Finance representation (costs of care, resource utilization, financial impact)

After the team is formed, the pathway development process commences with evidence-gathering. This includes existing guidelines, perhaps from other organizations or specialty societies, as well as a thorough review of the literature with grading of the strength of the evidence. We use the GRADE methodology as our system of evaluating the literature [11]. The design and development phase begins with all stakeholders coming together to devise the clinical algorithm based on the evidence as well as group consensus and concomitant development of the data stream including the patient population, key metrics, and plan for analysis and dissemination. The clinical champions representing the stakeholders are responsible for taking the clinical algorithm back to their colleagues at multiple points along the way. This ensures that there is widespread buy-in and consensus for the pathway elements. Once the clinical algorithm has been designed, the IT team continues to work on the data elements to operationalize measurement and feedback, while the orders and associated orders sets to facilitate the use of the pathway are also developed. The rollout process is a combination of local championing by the stakeholders, as well as more targeted education by the clinical education specialist. Finally, and perhaps the most influential driver of the pathway, is the data dissemination and feedback process. Self-service dashboards can be immensely useful in providing targeted data around the key metrics for each pathway, tailored to each group of stakeholders. For example, hospital leadership receives high-level summary data around the key metrics for each pathway, while providers receive data on metrics for which they have influence, and nurses receive data on other metrics for which they are the influencers (Fig. 14.2). The stakeholder group should narrow their focus to 3–4 key metrics which are chosen by organizational leadership and the pathway clinical champions and are aligned with organizational goals and strategic priorities. Finally, it should be mentioned that every pathway is an iterative cycle – It is expected that the data after implementation will likely lead

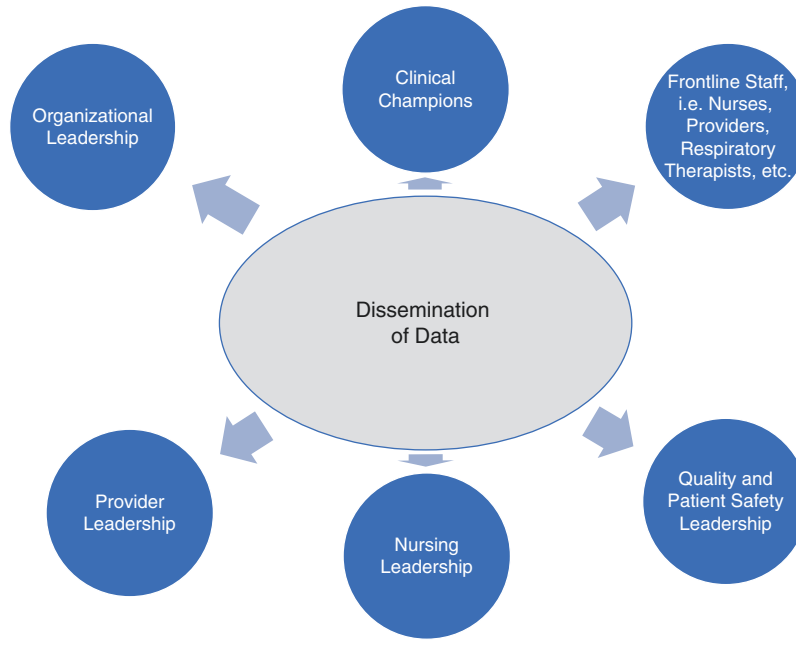

Fig. 14.2 Data dissemination is tailored to all stakeholders

to changes to the pathway and/or measurement process, and so the process described here is a cycle that intentionally does not have an end date (Key Points Box 14.5).

Key Points Box 14.5 Clinical Pathways and Guidelines Development Process

- Idea generation
- Building the team
- Evidence-gathering
- Design of clinical algorithm (evidence- and consensus-based)
- Design of data pull, metrics and measurement, and IT build including orders and order sets
- Education and rollout
- Measurement and feedback
- Dissemination of knowledge
- Repeat

Vignette 14.6

As the organization continues to see improvement in quality metrics, patient safety, clinical outcomes, and operational impact including decreasing length of stay, increasing capacity, and more efficient resource utilization, there are also notable improvements in patient and family satisfaction and staff and provider engagement. Patient- and family-facing educational materials associated with clinical pathways are leading to better engagement of patients and families. They know what care to expect, and why certain things are done, as well as why certain other things may not be done. They see the evidence behind the care that is being delivered, and they see the outcomes data. Providers feel that they are no longer siloed and are on the same page as their colleagues in other settings of care, and patients and families sense this, as well. Given these successes, the organization now embarks upon developing clinical pathways and guidelines around the management of chronic diseases that are designed to maximize health and reduce exacerbations requiring ED and hospital utilization. The organization finds that clinical pathways and guidelines that span the continuum of care are driving a healthier population.

Clinical pathways and guidelines link providers and settings of care, and in the process, they transcend silos. They enable the standardization of care that is necessary to improve safety and quality, and they reduce the variability in care that contributes to increased cost and decreased patient and family satisfaction, and that at its worst leads to medical errors. Clinical pathways and guidelines are a tool to drive change, and the impact of successful pathways is widespread, including patients, populations, healthcare organizations, and the healthcare system as a whole. Successfully implemented clinical pathways and guidelines result in improved clinical outcomes; improved quality metrics; decreased safety events; improvements in efficiency, cost of care, and workflows; and increased patient and family engagement and satisfaction. With an integrated development process, improved job satisfaction among IT team members can also be observed as they are directly connected to clinicians and see how their work has impact at the patient level. Clinical pathways are an essential piece to the implementation of an organization's strategic plan (Key Points Box 14.6).

Key Points Box 14.6 Impact of Clinical Pathways and Guidelines

- Improved clinical outcomes, including individual patients and the population of patients with this particular diagnosis or condition
- Decreased safety events
- Improved quality metrics, i.e., reduction of healthcare-associated infections and

reduction of unplanned hospital readmissions
- Improved efficiency, i.e., workflow enhancements, patient flow, and decreased costs of care
- Drive organizational strategy

Editors' Comments

The authors of this chapter are experts in clinical pathways and guidelines and have transformed the level of care in their organization by following the rubric outlined in this chapter. The authors provide the readers with a recipe for planning, implementing, and then following up (i.e., measuring) pathways and guidelines. Many organizations, due to resource constraints, chose to only do one of the above tactics with pathways and guidelines. For example, as cautioned by the authors, just implementing without monitoring pathways and guidelines will not lead to the sustained changes that can be enabled by embracing pathways and guidelines.

Furthermore, the authors elaborate on two important facets of pathways and guidelines that may not be readily appreciated by an organization that is not as well versed in the power of these improvement methodologies. The value of the team cannot be understated. This textbook has a whole chapter dedicated to understanding the value of teams in driving change; the authors similarly discuss the vital role of the team *throughout* all stages of pathways and guidelines. Many organizations involve teams haphazardly, intermittently, or without a firm conviction; the authors of this chapter outline the crucial role of the team and how to use the team concept throughout the lifecycle of pathways and guidelines.

The face-to-face collaboration between the clinical team and the information technology team cannot be mitigated. The authors of the chapter explicitly comment on how we need to move past passive communication to genuinely engage one other so that the clinicians and the information technology teams can have a shared mental model of the scope, objectives, and sustainment of pathways and guidelines.

This chapter provides a roadmap for organizations that are just beginning on their journey with pathways and guidelines to those that have matured their processes and need validation or inspiration to take their work to the next plateau in the journey of continuous quality improvement.

Chapter Review Questions

1. Describe how clinical pathways and guidelines can have impact beyond just clinical outcomes.

   Answer: Impact may include improvements in patient and family experience, reduction of hospital readmissions and/or returns to the emergency department, improvements in provider experience and reduction of provider burnout, enhancements to organizational patient flow and workflow, reduction of length of stay, as well as positive economic outcomes. Additionally, pathways and guidelines may help to drive organizational strategy.
2. What are the differences between measurement of care intended and care delivered?

   Answer: Care intended represents what is ordered and is often measured by use of an order set or by pulling specific orders from the EMR. Care delivered represents the care that actually happens, i.e., the care that reaches the patient. Examples of measurement include medication administration data (MAR) data, imaging tests completed, and labs drawn.
3. Describe how measurement of care delivered can lead to improvements in systems of care.

   Answer: Care intended may not always represent the care that actually makes it to the patient, i.e., care delivered, and thus may not

fully represent the true patient care experience. Measuring care delivered allows for discovery of opportunities for improvement when the care intended and the care delivered do not align.

4. What are the elements of successful and impactful clinical pathways and guidelines?

   Answer: Successful and impactful clinical pathways and guidelines are as follows:
   - Evidence- and consensus-based
   - Inter- and multidisciplinary
   - Integrated into the EMR and workflow
   - Measurement and feedback/data dissemination process
   - Education and rollout process to ensure buy-In
   - Alignment with organizational strategy

5. Describe the benefits of integrating clinical champions and IT expertise.

   Answer: Clinicians provide the clinical guidance, and the IT team turns this into the logic. As the logic is tested and data is pulled, this is then reviewed with the clinical experts, and tweaks to the logic are made. The measurement process becomes refined over time. The result is pathways with adherence and impact data that are trusted by clinicians and, thus, are truly able to change behavior and affect change

6. Who should be on the team for the design and implementation of a successful and impactful clinical pathway?

   Answer: Key stakeholders should be included. Some examples are the following:
   - Clinical champions, i.e., providers, nurses, pharmacists, RTs, etc.
   - IT experts (data pull, logic, order set builds, dashboards, and data analytics)
   - Clinical education specialists (buy-in and rollout)
   - Marketing/communication specialists (internal and patient-/family-facing educational materials)
   - Finance representation (costs of care, resource utilization, financial impact)

7. True or false: The success of clinical pathways is driven by measurement and data dissemination and feedback.

   Answer: True

8. Based on the discussions in this chapter, which of the following are essential for widespread impact of clinical pathways?
   A. Measurement and feedback/data dissemination
   B. Representation of champions representing all stakeholders
   C. Strategic alignment
   D. Evidence- and consensus-based
   E. All of the above

   Answer: E

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15 Accountable Justifications and Peer Comparisons as Behavioral Economic Nudges to Improve Clinical Practice

Jack Stevens

Abbreviation

EMR Electronic medical record

Chapter Objectives

- To define accountable justifications and peer comparisons
- To describe potential mechanisms of action for each strategy
- To describe important design considerations when implementing these approaches
- To assess the strengths and limitations of these approaches for improving clinical practice

Vignette 15.1

In 2011, Meeker and colleagues found that antibiotics were ordered inappropriately for nearly 25% of primary care visits with diagnoses of nonspecific upper respiratory tract infections, influenza, and/or acute bronchitis across 47 different practices in Los Angeles and Boston [1]. Such problematic prescribing is hardly unique to those locales. Annually across the United States, tens of millions of antibiotic prescriptions are likely not warranted; they are ordered for indications (e.g., viral infections) that do not respond to these medications [2]. Inappropriate antibiotic prescribing leads to unnecessary side effects, antimicrobial resistance, and avoidable healthcare expenditures. Strategies to improve antibiotic stewardship are greatly needed.

In 2016, Meeker et al. published results in the *Journal of the American Medical Association (JAMA)* of a randomized cluster trial to reduce inappropriate antibiotic prescribing among those 47 primary care practices [1]. Those investigators found that two behavioral interventions – accountable justifications and peer comparisons – successfully achieved that objective. Both interventions are consistent with behavioral economics, an interdisciplinary field that utilizes insights from economics, marketing, and psychology to enhance individual

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decision-making. Applied by healthcare teams [3], governmental agencies [4], and academic institutions [5], behavioral economics features low-intensity interventions often known as "nudges." While these interventions are not heavy-handed mandates or bans, these nudges are not neutral. These nudges intentionally encourage decision-makers to make particular choices (Key Points Box 15.1).

Key Points Box 15.1 Design Considerations for Accountable Justifications

Phrasing – Neutral versus strongly worded

Timing – Early during the clinical encounter versus later in the clinical encounter

Acceptability – Framing this intervention as (1) promoting adherence to best practices, (2) gathering information regarding when guidelines are not followed, and (3) allowing professional autonomy

Through three key events in 2018, behavioral economic nudges received their greatest attention to date for promoting patient safety and quality. To begin with, a commentary about the first behavioral economics team embedded within a healthcare organization – the Penn Medicine Nudge Unit – was published in the *New England Journal of Medicine* [3]. Next, leaders from 22 North American organizations attended the inaugural "Nudge Units in Health Care" symposium in Philadelphia [6]. Finally, the topic for the single keynote speech at the Institute for Healthcare Improvement (IHI) scientific symposium was behavioral economics [7].

The novel contribution of this chapter is to highlight specific design considerations when implementing two behavioral economic nudges – accountable justifications and/or peer comparisons – to improve clinical practice. This chapter is intended to provide more explicit detail on these design considerations relative to previous commentaries [8, 9]. While the context for these strategies in the present chapter is antibiotic stewardship, these two behavioral economic interventions could be applied for a wide range of clinician behaviors. Each of these two behavioral economic strategies will be discussed in turn. The Meeker et al. study was chosen as an exemplary vignette to demonstrate a real-world application of behavioral economics in healthcare [1].

Accountable Justifications

Description

Accountable justifications feature asking healthcare providers to document a rationale for making questionable clinical decisions. In regard to the Meeker et al. study [1], clinicians were asked to write a justification in a free text box in an electronic medical record (EMR) system when ordering an antibiotic (e.g., penicillin) for a condition that would not respond to that medication (e.g., a viral infection like influenza). Clinicians could click a button to cancel the antibiotic prescription after the presentation of the accountable justification request. However, clinicians were notified that if they continued to order the antibiotic and failed to provide an accountable justification in the EMR system, the words "NO JUSTIFICATION FOR PRESCRIBING ANTIBIOTIC" would be placed in the patient's record. Those cautionary words featured both capital letters and red font as part of an actual justification request.

Potential Mechanisms of Action

This successful intervention is consistent with EAST framework posited by David Halpern from the United Kingdom [4]. His group established one of the first formal behavioral economics teams embedded within a governmental agency to address diverse public policy objectives (e.g., promoting organ donor registration, increasing tax collections). The acronym EAST stands for Easy, Attract [Attention], Social, and Timely.

Regarding Easy, behavioral economics suggests that optimal decisions can be achieved by making the desired behavior as natural and automatic as possible while making the opposite

behavior difficult to complete. In the present antibiotic example, an accountable justification requires extra documentation time for clinicians when making questionable prescribing choices.

Regarding Attract [Attention], behavioral economics recognizes that everyone has cognitive limits in attention and memory. Therefore, behavioral economics posits that salient information is sometimes needed to encourage optimal behavior. The EMR message asking clinicians to enter an antibiotic justification and particularly those cautionary words about failing to provide this rationale are examples of novel and vivid content.

Regarding Social, behavioral economics suggest that sometimes interpersonal influences, as opposed to basic scientific information, might promote optimal decisions. The accountable justification did not remind clinicians of biological facts they already knew, such as viral infections do not respond to antibiotics. Rather, this behavioral economics intervention relied on clinicians' evaluation concerns about being judged by others who could access these rationales.

Regarding Timely, behavioral economics posits that optimal decisions can be fostered by providing people with critical information at key moments. The long gap in time between information provision and decision-making may be one of the leading drawbacks of traditional continuing education initiatives. While widely utilized, such continuing education programs often have small effects on clinical practice [10]. In contrast, the accountable justification draws clinician' attention to the importance of antibiotic stewardship just as treatment decisions are being made. A close temporal relationship between information provision and decision-making may enhance outcomes.

Important Design Considerations

The Phrasing of the Request for the Accountable Justification

Simply asking clinicians in a neutral fashion to "please comment" on a particular clinical decision may not be a sufficient nudge to improve practice. Therefore, more strongly worded language can be tailored to remind clinicians of the importance of specific standards (e.g., advantages of best practices, disadvantages of alternative approaches) and the consequences of not providing a justification. Similarly, allowing clinicians to click a selection on an EMR screen with a predetermined list of potential reasons for disregarding a particular guideline may not promote thoughtful reflection. Instead, requesting a more complicated and time-intensive response, such as a free text justification, might facilitate more deliberative thinking.

The Timing of the Request for the Accountable Justification

Asking clinicians to provide an accountable justification as they are writing a questionable order seems like the most logical time for this strategy. In the Meeker et al. study, an encounter could not be closed until the prompt for the justification was acknowledged [1]. However, if clinicians have already orally informed patients of particular decisions before placing the order in the EMR system, the accountable justification may be too late to change practice for the current patient. Nevertheless, the accountable justification may change future practice if clinicians become aware that particular decisions will again be called into question. Therefore, if there are opportunities for accountable justifications to appear earlier in the clinical encounter (e.g., while practitioners are reviewing particular presenting problem in the EMR based upon a triage nurse's assessment), this behavioral economics strategy might have even a more significant impact.

Clinician Acceptance of this Behavioral Intervention

An accountable justification could create slightly more documentation for busy clinicians. This strategy should be framed in a non-punitive fashion. Accountable justifications have two purposes: (1) encouraging adherence to best practice standards and (2) an opportunity for organizations to learn more about the circumstances under which clinicians decide against following guidelines. Regarding the lat-

ter, organizations can learn when clinicians view guidelines as inappropriate for particular subgroups of patients. Original research or a review of the scientific literature can subsequently be conducted to ascertain if those exceptions are warranted. Alternatively, clinicians may document in an accountable justification that certain guidelines are impractical, thereby encouraging organizations to develop strategies to improve workflow.

Clinicians May Also View Accountable Justifications as Interfering with Their Professional Autonomy

Clinicians should be reminded that an accountable justification is not a hard stop. In the Meeker et al. example, clinicians could still prescribe antibiotics for viral infections when they wished to do so [1]. If the accountable justification had mandated that an antibiotic could not be prescribed for certain diagnoses, one could envision greater clinician resentment and perhaps some gaming of the system (e.g., coding a viral illness as a bacterial infection to obviate the need to write a justification). Interestingly, Meeker and colleagues found no evidence of such gaming as a result of accountable justifications relative to a control condition [1].

Peer Comparisons

Description

Peer comparisons feature giving a clinician periodic feedback regarding his/her performance relative to the behavior of similar healthcare providers. This performance may be based upon different sources (e.g., direct observation, review of EMR documentation). Peer comparisons are often referred to as social norms or descriptive norms because the targeted individual is informed about the routine behavior of similar people (peers). Peer comparisons have empirical support for a wide range of outcomes in the behavioral economics literature, from increasing voter turnout [11] to promoting energy conservation [12].

Peer comparisons should be distinguished from widely utilized "audit and feedback" interventions due to the different types of performance profiles. Audit and feedback interventions feature giving a target clinician a periodic summary of her/his performance; audit and feedback interventions sometimes, but not necessarily, feature performance feedback relative to a peer comparison base. Therefore, essential design considerations for audit and feedback interventions [13] may not necessarily apply to peer comparisons. Furthermore, peer comparisons should be distinguished from peer review. In the latter, a clinician is assessed by a similar healthcare provider who may not necessarily provide a performance evaluation relative to a peer comparison base. There are also medical staff and potential medicolegal implications of referring to this as "peer review" which is beyond the scope of this chapter (Key Points Box 15.2).

Key Points Box 15.2 Design Considerations for Peer Comparisons

Benchmarks – Superstar versus top-tier versus all practitioners versus average practitioner versus slightly high-performing group

Social approval for high achievers – preventing deterioration for top performers

Frequency of peer comparison feedback – annual versus monthly versus daily/weekly

Modality of peer comparison feedback – by person or through electronic means

Audience of peer comparison feedback – private versus public

Target behavior – selecting an action that would require only short-term intervention

Target clinicians – characteristics of responsive versus nonresponsive practitioners

Target unit – individual clinician versus larger unit (e.g., floor, healthcare organization)

In the Meeker et al. study, clinicians received peer comparison feedback on a monthly basis [1]. Each clinician from the top decile – those prescribers who rarely wrote an inappropriate antibiotic prescription relative to their peers – received an e-mail message informing them that "You are a top performer" with a summary of how often she/he wrote an inappropriate prescription in that month. The remaining 90% of clinicians received an e-mail message informing them that "You are not a top performer" with a summary of how often he/she wrote an inappropriate prescription in that month and how that compared to the top decile.

Potential Mechanisms of Action

Peer comparisons may exert positive effects through three psychological mechanisms. First, peer comparisons may provide social proof to the target individual [14]. A clinician may recognize the importance of antibiotic stewardship when learning that other practitioners judiciously prescribe these medications. Second, peer comparisons may enhance the self-efficacy of the target individual [15]. A clinician may be convinced that a low inappropriate antibiotic prescribing rate is feasible when learning that other prescribers have already demonstrated this target behavior. Third, peer comparisons may motivate a clinician to improve his/her standing relative to other practitioners [16]. Many people view themselves as above average in a variety of domains. Therefore, receiving feedback on suboptimal performance levels may motivate a prescriber to order antibiotics more appropriately so that these positive self-perceptions can continue to be held.

Important Design Considerations

Benchmarks for Comparisons

A clinician could receive feedback relative to five different standards: the superstar, the top tier, all practitioners, the average practitioner, or a slightly higher-performing group. The advantages and disadvantages of each standard are discussed in turn.

Allowing a target clinician to receive feedback on what the superstar – the highest-performing healthcare provider – is achieving may promote change as he/she learns there is room for improvement. However, such feedback may be disheartening when the performance gap is quite large. Alternatively, she/he may view the superstar's performance with skepticism, concluding that there is something atypical about this highest performer's patient population.

Allowing a target clinician to receive feedback on what the top tier of clinicians is exhibiting may be more beneficial. People may not view themselves as the best performer, but they may view themselves as part of the top 10–20% in a particular category and indeed may strive for this categorization. The performance of this tier may be considered to be an "achievable benchmark" and may motivate him/her to bolster performance. This top decile was successfully utilized in the Meeker et al. study [1] as well as an earlier study on diabetes care [17]. Again, clinicians in the lowest tier of performance may still view a goal of being in the top group as unattainable.

Allowing a target clinician to receive rank-order feedback, in which he/she is shown his/her relative standing on the continuum from lowest performing to highest performing, provides readily understandable peer comparisons. This rank-order feedback was more effective than average feedback in a nonclinical domain [18].

Allowing a target clinician to receive feedback on what the average clinician is exhibiting may be the simplest option for implementation. However, an average may not sufficiently motivate improvement if a clinician cannot easily ascertain what levels of performance are inside and outside of the normal range and may unintentionally reinforce complacency.

Allowing a target clinician to receive feedback on a slightly higher-performing group of providers may motivate small but realistic levels of improvement. However, providing many different tiers of feedback depending upon a target clinician's recent performance level may be logistically unwieldy for organizations.

Social Approval for High Performance

Peer comparisons are primarily designed to improve the performance of low achievers. However, careful consideration is needed regarding how to prevent deterioration of the performance of high achievers when peer comparisons are given. High achievers may subsequently lower their performance if they learn that others are not exerting the same effort in a particular domain. If both low and high achievers gravitate towards average performance after receiving peer comparisons, there may not be an overall improvement in the target behavior. An example of such an unintended effect occurred in an energy conservation study [12]. When low initial energy users received feedback that they were below the neighborhood average, many subsequently increased their usage. Only a signal of social approval – a smiley face icon on their energy bills – helped low initial energy users to continue to conserve over time.

Referring back to the case vignette from the Meeker et al. study, the top tier of clinicians received a message of social approval known as an injunctive norm [1], which refers to signaling praise or displeasure for someone else's behavior. They were informed that "You are a top performer." This message was intended to encourage those prescribers who rarely wrote an inappropriate prescription to maintain their high level of antibiotic stewardship.

Frequency of Peer Comparison Feedback

Finding the right balance between infrequent and overly frequent feedback is important. Infrequent feedback (e.g., yearly) gives clinicians rare opportunities to observe improvements in relative standing. Overly frequent feedback (e.g., daily or weekly) would likely be affected by normal variations in patient characteristics or clinician behavior, as opposed to more stable changes in practice patterns. In the Meeker et al. study, monthly feedback was utilized [1]. Similarly, Kiefe and colleagues provided peer comparison feedback once every 3–6 weeks in order to promote better diabetes care [17].

Modality of Peer Comparison Feedback

Receiving feedback from an administrator or another clinician – either face to face or over the telephone – may make the peer comparisons very noticeable. However, such feedback may not be realistic to deliver on a large scale and may naturally engender feelings of defensiveness. In contrast, feedback delivered electronically (e.g., e-mail), as was implemented in the Meeker et al. study [1], may require fewer resources to implement but may not be as salient to target clinicians.

Audience of Peer Comparison Feedback

Peer comparisons can be presented to a variety of audiences ranging from the individual practitioner to a clinical division to the general public. While public presentation might optimize improvement as clinicians seek to protect and enhance their reputations, such a display may have unintended consequences (e.g., leading clinicians to select own those patients with the most promising prognoses). Furthermore, if peer comparisons are presented publicly, extra steps may need to be taken to allow clinicians to correct any errors in individual performance profiles before release.

Target Behavior for Peer Comparison Feedback

Considerable resources in data collection and analysis may be required to periodically provide clinicians with peer comparisons. Long-term provision of peer comparisons may be cost-prohibitive. Ideally, the target behavior should be initially enhanced by peer comparison feedback, but longer-term improvement should be maintained by other factors. In a follow-up to the original Meeker et al. randomized trial, Linder and colleagues found that improvement in antibiotic stewardship persisted for those primary care clinicians receiving peer comparison feedback even during the year after that intervention was stopped [19]. Peer comparisons may have made routine responsible antibiotic prescribing. Information on relative standing and social approval may not

be necessary for the long run once a clinician has established a particular practice pattern.

A potential unintended consequence of peer comparisons is deterioration in nontarget behaviors. If practitioners focus their attention on domains featured in peer comparison reports at the expense of other important clinician behavior, there may be no overall improvement in healthcare delivery. Therefore, developers of peer comparison interventions may wish to monitor nontarget behaviors to examine if negative spillover effects occur.

Target Clinicians for Peer Comparison Feedback

As described in the previously mentioned mechanisms of action section, clinicians may respond if they are ambivalent about the utility and feasibility of a particular guideline and/or if they want to compare favorably relative to their peers. However, some clinicians may not fit those characteristics. Clinicians who adamantly disagree with a particular clinical guideline are unlikely to change based upon peer comparisons. Alternatively, clinicians who do not care about relative standing or pride themselves on practicing differently from their colleagues are also unlikely to be positively influenced by peer comparisons. Finally, clinicians who have other priorities (e.g., preventing long discussions with patients during hectic schedules about the futility of antibiotics for certain infections) may not be influenced by peer comparisons. As can be predicted, clinician characteristics may moderate response to peer comparisons.

Target Unit for Peer Comparison Feedback

Many clinical outcomes are the result of teamwork as opposed to the efforts of an individual practitioner. Therefore, sometimes comparisons between larger units (e.g., hospital floors, entire healthcare facilities) are appropriate. On the one hand, such comparisons may instill cross-group competition to harness overall system improvement. On the other hand, such comparisons may diffuse responsibility for a particular outcome and fail to precipitate accountability and change at the individual level.

Conclusion

The present chapter highlighted important design considerations in implementing accountable justification and/or peer comparisons to change clinical practice. Based upon their considerable success in the Meeker et al. study and their cost-effectiveness [20], these strategies appear worthy of consideration. However, readers should be cognizant that much remains unknown about these strategies.

To begin with, accountable justifications have not been extensively evaluated in other healthcare clinical domains besides antibiotic stewardship. However, in non-randomized studies, similar accountable justifications have been part of multicomponent programs aimed at reducing inappropriately scheduled births at 36–38 weeks' gestation [21] and promoting adherence to bronchiolitis guidelines [22]. In addition, peer comparisons have often had unsuccessful results in the medical literature [23]. Furthermore, little empirical research has been conducted on which parameters maximize the effectiveness of these two strategies. Finally, accountable justification and peer comparisons should be evaluated head to head versus other behavioral economic strategies like the ones listed in Key Points Box 15.3. Careful evaluation is warranted when utilizing the promising approaches featured in this chapter.

Key Points Box 15.3 Empirical Examples of Successful Behavioral Economic Strategies Not Featured in the Present Chapter

Public Commitments

Definition: Have clinicians (or other similar physician leaders or influencers in an organization) make public declarations of their pledges to follow evidence-based practice guidelines

Example: Posters containing photographs of primary care clinicians placed in

their examination rooms with text proclaiming their commitment to prescribe antibiotics only when necessary [24]

Loss Aversion

Definition: Utilizing people's strong dislike of losses to encourage target behaviors

Example: Giving financial bonuses upfront to clinicians at Massachusetts General Hospital that could be deducted from future compensation if performance standards were not met [25]

Changing the Default

Definition: Altering an EMR field to make the preferred pathway occur as automatically as possible

Example: Changing the number of postoperative pills for an opioid prescription from 30 to 12 in a pre-populated EMR field but allowing clinicians to override this lower recommendation and prescribe a different number of pills [26]

Framing

Definition: Changing the phrasing of an option to encourage optimal behavior

Example: Messages reminding clinicians that hand hygiene prevents "patients," as opposed to "you [clinicians]," from catching infectious disease [27]

Editors' Comments

The author of this chapter is a pioneer in the application of behavioral economics to quality improvement and safety. He has been embraced by his organization to use novel strategies extrapolated from other industries to drive improvement past the inevitable plateaus. In a textbook of this nature, it is impossible to cover the topic of behavioral economics in healthcare in a complete manner; rather, the author chooses to expound on two tactics that are particularly pertinent to healthcare: accountable justifications and peer comparisons.

The opening vignette and introduction cite a few of the seminal works in the field of behavioral economics and healthcare. The reader, once seeing the value of incorporating accountable justifications through the author's examples, will suddenly see the potential applications of accountable justifications throughout the clinical realm. Indeed, this is the value of this chapter by Dr. Stevens. Once the improvement scientist understands the role of accountable justifications, peer comparisons, and other behavioral economic strategies, the world of continuous quality improvement and improvement science becomes logical and less mysterious.

Peer comparisons are already a crucial part of a provider's thought process – however, Dr. Stevens helps provide the understanding and tools for improvement scientists to consider how to best use peer comparisons on a macro-level within a hospital or healthcare organization to drive towards an intended result.

It is not fathomable for Dr. Stevens to cover in depth the myriad techniques and strategies of incorporating behavioral economic approaches to quality improvement in healthcare, especially since the applications are relatively new and constantly being updated. The reader should be left with a deep appreciation of how the next significant gains in quality improvement and patient safety will be from incorporating strategies such as those from behavioral economics.

Chapter Review Questions

1. Describe accountable justifications and peer comparisons.

   Answer: Accountable justifications feature asking healthcare providers to document a rationale for making questionable clinical decisions. Peer comparisons feature giving a target clinician periodic feedback regarding his/her performance relative to the behavior of similar healthcare providers.
2. Discuss why each of these strategies might improve clinical practice.

   Answer: Accountable justifications may work because they make inappropriate behavior more difficult, attract attention to desired behavior, use social influences, and/or provide timely reminders. Peer comparisons may work because they demonstrate that target behavior is acceptable and feasible. Additionally, peer comparisons may work because people want to compare favorably relative to others.
3. What are three important design considerations for accountable justifications?

   Answer: Timing, phrasing/content, and acceptability.
4. What are some important design considerations for peer comparisons?

   Answer: Benchmarks, signaling approval for high achievers, frequency of feedback, modality of feedback, audience for feedback, target behaviors, target clinicians, and target unit (individual clinicians versus teams).
5. From an empirical perspective, describe the limitations of the two behavioral economic strategies discussed in this chapter.

   Answer: Accountable justifications have little empirical data. Peer comparisons have often not been successful in other studies. Both interventions should be evaluated relative to other behavioral economic strategies.

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Diagnostic Errors and Their Associated Cognitive Biases

16

Jennifer E. Melvin, Michael F. Perry, and Richard E. McClead Jr.

Chapter Objectives

- To introduce the current understanding of the diagnostic process
- To describe common cognitive biases that contribute to diagnostic errors
- To illustrate how cognitive biases impact the diagnostic process and patient care through a case-based approach

Introduction

In the fall of 2016, the National Academies of Sciences, Engineering, and Medicine (NASEM, formerly the Institute of Medicine) published a third book in the *Quality Chasm Series*. The first two books were *To Err Is Human: Building a Safer Health System* [1] and *Crossing the Quality Chasm: A New Health System for the 21st Century* [2]. Diagnostic error was finally introduced in this third book, *Improving Diagnosis in Health Care* [3].

Diagnostic errors, whether resulting from an inaccurate or delayed diagnosis, are common in healthcare, although they are largely underappreciated. The NASEM report [3] estimated that "5% of U.S. adults who seek outpatient care each year experience a diagnostic error." For years, we have known that 10% of autopsies reveal a prior clinical diagnostic error. A careful review of hospital adverse events reveals that 6–17% of these events involved a diagnostic error. Diagnostic errors are the causal factors in the majority of paid malpractice claims. They represent the highest proportion of total malpractice payments and are twice as likely as other errors to result in the claimant's death. Most concerning is the fact that each of us, as patients, will experience at least one diagnostic error in our lifetime [3].

Diagnostic errors result from a variety of failure modes. These failures result from inadequate collaboration or poor communication among members of the healthcare team, their patients, and the patients' families; a healthcare system that does not support the diagnostic process; a

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lack of feedback to clinicians regarding their diagnostic performance; and a culture that is punitive and nontransparent regarding medical errors.

The NASEM report presents a conceptual model of the diagnostic process that emphasizes its complexity and iterative nature (Fig. 16.1) [3]. This model describes how a patient with a health problem engages with a medical practitioner and the healthcare system. The medical practitioner working within the system gathers information from the patient, and in collaboration with other members of the healthcare team, integrates and interprets the information to arrive at a working diagnosis. The practitioner communicates this preliminary diagnosis to the patient, and a treatment plan is initiated. The clinical response to the treatment is then entered into an iterative feedback loop at the information gathering step, and the working diagnosis is confirmed or modified accordingly. Eventually, patient and system outcomes result, and learning from the diagnostic process occurs.

The NASEM report defined a diagnostic error as *the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient* [3]. This definition is patient centered and reflects the iterative and complex nature of the diagnostic process. However, this definition is not without problems. How far amiss from the patient's true diagnosis must a practitioner's diagnosis be for it to be inaccurate? Additionally, a timely diagnosis refers to a diagnosis that is not meaningfully delayed, but since the diagnostic process is iterative, some time is required to reach a final diagnosis, indicating that timeliness is context specific. For example, a patient who presents with abdominal pain in the right lower abdominal quadrant may have appendicitis, but the supportive information (e.g., abdominal ultrasonography) may be initially inconclusive. A patient can present so early in the course of appendicitis that the clinician cannot make the diagnosis. The patient may then be discharged with nonspecific abdominal pain and advised to

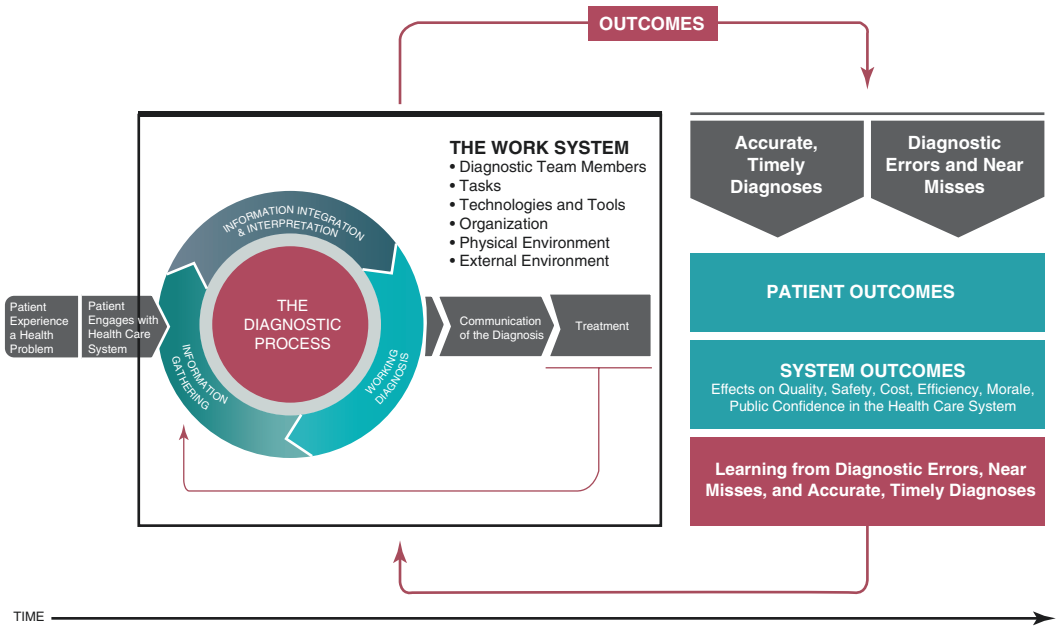

Fig. 16.1 Conceptual model of the diagnostic process [3]. (Reprinted from Balogh E [3]. Reproduced with permission from the National Academy of Sciences, Courtesy of the National Academies Press, Washington, DC)

follow-up if the pain does not improve. If the patient then presents with persistent abdominal pain that leads to a conclusive diagnosis of appendicitis and subsequent appendectomy, did the original practitioner make a diagnostic error?

In this chapter, we will present a clinical vignette that resulted in a delay in diagnosis and, initially, the incorrect management of a patient. We will then discuss the systems of thinking involved in the diagnostic process and the cognitive biases that influence the diagnosis. Finally, we will present a diagnostic autopsy of the clinical vignette and the failure of critical thinking that may have contributed to the cognitive biases involved with the case.

Vignette 16.1

A teenage girl presents to an emergency room with a history of abdominal pain and vomiting. Her physical exam is unremarkable. She is given the diagnosis of gastroesophageal reflux disease (GERD) and discharged with medication to treat her symptoms. Despite medication compliance, her symptoms persist. She is subsequently evaluated by multiple providers, all of whom confirm the diagnosis of reflux and further intervene only to expand her pharmacotherapy. When her symptoms continue to persist, a practitioner ultimately diagnoses her with a psychosomatic disorder. Subsequently, she is lost to follow-up. When she presents months later to the healthcare system for worsening of her symptoms and significant weight loss, a more thorough clinical history is obtained, and the correct diagnosis and treatment are established.

How Cognitive Bias Impacts the Diagnostic Process

Many factors contribute to diagnostic error. In a review of 122 closed malpractice claims, Kachalia et al. described four categories of failures that contribute to diagnostic errors [4]. These categories of failure include patient-related factors such as an atypical presentation or a poor historian, system factors such as workload and interruptions, communication factors such as handoffs and conflict, and cognitive factors such as judgment and knowledge. While recognizing that multiple categories often play a role in any given case, these authors demonstrated that cognitive factors contributed to diagnostic error in 96% of these cases. Another approach to assess diagnostic errors is to categorize them into the following two main domains: those resulting from cognitive errors and those related to system-based errors [5]. Although many cases may have overlap between these two domains, diagnostic errors stemming from cognitive errors present a unique problem compared to those related to system process errors, as cognitive errors are difficult to measure and therefore more challenging to improve. Both of these approaches highlight the importance of the cognitive processes in diagnostic errors. Toward a deeper understanding of these processes, Graber et al. published a literature analysis that characterized three main types of cognitive errors: faulty clinical knowledge, faulty reasoning and/or decision-making, and failure to employ appropriate help when needed [6]. Cognitive biases underlie and often drive these categories of cognitive errors. (Key Points Box 16.1)

Key Points Box 16.1 Diagnostic Error

As defined by the National Academy of Medicine, a diagnostic error includes a failure to (1) establish an accurate and timely diagnosis or (2) communicate that diagnosis to the patient.

Diagnostic reasoning is complex, and cognitive biases play an integral role. Often studied in psychology and behavioral economics, cognitive biases are also prevalent in the medical profession. The automatic acceptance of cognitive biases, or "rules of thumb," often leads to predictable and recurrent results. These biases are fre-

Table 16.1 Cognitive biases

Cognitive biases	Description
Anchoring bias	The tendency to lock onto salient features and fail to adjust the initial impression after further studies
Availability bias	The tendency to initially think about whatever diagnosis most readily comes to mind
Bandwagon effect	The more other people draw similar conclusions or have comparable perceptions, the more likely subsequent individuals come to the same conclusions
Confirmation bias	A self-perpetuating cycle in which there is a tendency to look for confirming evidence to support an initial diagnosis, sometimes at the expense of reviewing disconfirming evidence
Diagnostic momentum bias	When a potential diagnosis is passed from one provider to another and as such becomes more "sticky," until it finally is accepted as the true diagnosis despite an incomplete evaluation
Framing effect bias	The tendency to be influenced by the way the problem presents
Overconfidence bias	The tendency to act on incomplete information due to overconfidence in judgments, which may result in incomplete differential diagnoses
Premature closure	Once a clinician makes a diagnosis, less effort is put into trying to disprove it
Representative bias	Making judgments about events based on personal experiences and preconceived notions rather than based on their actual likelihood
Unpacking principle	A failure to elicit all relevant information; therefore, the differential diagnosis may be left incomplete
Visceral bias	May result in missed diagnosis due to countertransference of positive or negative feelings toward patients

quently employed when making quick, snap judgments in the face of uncertainty. In the appropriate setting, cognitive biases enable rapid and efficient decisions and actions and are therefore valuable when timeliness is imperative or during cognitively demanding tasks. However, at times, cognitive biases result from a limited capacity for information processing and may therefore lead to inappropriate or wrong conclusions. Over one hundred cognitive biases relating to decision-making, behavior, memory, and social biases have been described, and many of them play a critical role in diagnostic errors. Some of the more recognizable biases that operate in the diagnostic process are reviewed in Table 16.1.

System 1 and System 2 Thinking

When faced with a problem, decision-making often takes one of two forms of thinking. Fast, quick thinking allows a person to jump to a conclusion automatically. Slower or more focused thinking involves paying close attention to the thought process, the possible solutions, and the possible outcomes. Psychologists describe these dual forms of thinking as System 1 and System 2 thinking. System 1 thinking refers to the faster, automatic, and unconscious model, whereas System 2 thinking refers to the slower, conscious, and effortful model [7, 8]. System 1, therefore, can be compared to an intuitive track, as it operates rapidly and with little voluntary control. Information processed along this track includes reading a simple sentence or reading 2 + 2 =? and automatically knowing the answer is 4. System 2 thinking, however, is more deliberate and slow. Thinking along the System 2 track is useful when concentration is required, such as in filling out a tax form or solving the equation 48 × 36 =? [7].

This dual process theory of thinking and decision-making is also employed when clinicians are faced with a diagnostic challenge [8, 9]. System 1 thinking often defaults to utilization of cognitive biases to reach a conclusion. Clinicians are constantly encountering new patients and presentations throughout their training and clinical experience. Over time, clinicians learn symptom patterns, also known as illness scripts. With repetition, quick pattern recognition allows clinicians to utilize System 1 thinking and effortlessly categorize certain illness scripts into the correct diagnostic category. This quick, automatic think-

ing may be particularly beneficial in emergent situations such as those that present to the emergency department. For example, rapid recognition of Cushing's triad in a trauma patient allows for immediate lifesaving interventions instead of a delay in care due to evaluation for other potentially non-emergent etiologies. However, this quick System 1 thinking can fail both the clinician and the patient in several ways. If a bias clouds the initial patient presentation such that the clinician fails to elicit the entire story or if the workup is prematurely or inappropriately completed, the clinician may place the patient into the wrong diagnostic category. In this way, reliance on System 1 pathways and, indirectly, cognitive biases may lend itself to a diagnostic error [10]. (Key Points Box 16.2)

Key Points Box 16.2 Dual Process Theory
System 1 Thinking – quick, automatic, unconscious mode of thinking
System 2 Thinking – slow, deliberate, purposeful mode of thinking

In contrast, thinking slower and therefore forcing utilization of the System 2 pathway may improve decision-making in certain circumstances. This approach employs deliberate, logical thinking and therefore allows for deeper thought and reflection. This method may be beneficial in a medically complex patient or in a patient that does not neatly fit into an illness script. In medicine, however, slow and deliberate thinking is neither always necessary nor required. A large proportion of patients do fall into easily recognized patterns and diagnoses, and recognizing these patterns decreases unnecessary testing and utilization of resources [11]. It is unreasonable then to suggest that System 1 thinking should never be utilized in medicine. More importantly, clinicians should recognize and acknowledge their biases and knowledge deficits. If these biases and deficits are recognized and acknowledged while thinking about the patient, System 2 thinking can also be activated, and diagnostic errors due to cognitive bias may be prevented.

Teaching Diagnostic Reasoning

Conscious utilization of the System 2 pathway is an important step in the improvement of clinical reasoning. Royce et al. have described clinical reasoning as "the process of applying cognitive skills, knowledge, and experience to diagnose and treat patients" [12]. Therefore, to improve clinical reasoning, a practitioner needs to develop an understanding of their underlying cognitive skills and biases, improve their knowledge base, and increase their diagnostic experiences. Experiences often come with time and volume, while knowledge, although a lifelong process, starts early in a physician's career. Methods for teaching cognitive skills are not well described but may be less effective until a physician has a solid foundation of medical knowledge.

Improved recognition and teaching of clinical reasoning skills are important in the overall goal of improving diagnostic accuracy. In several malpractice cases attributed to diagnostic error, the errors were found to be secondary to a "failure to consider the correct diagnosis" and not due to ignorance of the correct diagnosis [12, 13]. Often, recognizing where the clinical reasoning went wrong when a diagnostic error occurred is difficult. An important and fundamental component of clinical reasoning is cognitive bias. Therefore, if we teach critical thinking and debiasing techniques, we will improve the overall diagnostic process.

Teaching metacognition, or "the capacity for self-reflection on the process of thinking and self-regulation in monitoring decision making," works synergistically with critical thinking and debiasing technique education [12]. Together, these skills encourage the provider to think slower and spend more time utilizing the System 2 logical thinking track. Awareness of the automatic acceptance of results provided by a cognitive bias brings those biases to the forefront. This recognition allows the bias to be observed and critically considered and can lead to a conscious decision to either accept or reject the diagnosis that the bias has led the provider to. (Key Points Box 16.3)

Key Points Box 16.3 Metacognition

The ability to critically evaluate one's own thinking, commonly referred to as "thinking about thinking." It is considered a critical component of learning.

However, reviews of studies teaching metacognition and debiasing strategies have led to a variety of outcomes. Understandably, teaching debiasing techniques to medical students has not demonstrated a benefit for improving diagnostic accuracy. This observation is likely related to overall knowledge deficits in medical students. If knowledge is lacking, certain cognitive biases are likely not present, and diagnostic accuracy will suffer, regardless of biases [14–16]. Similarly, in diagnoses with classic presentations, the clinician often knows the diagnosis with a high degree of certainty, and teaching debiasing strategies and critical thinking will not likely alter their (correct) diagnosis. Encouraging critical thinking or analytical reasoning is, therefore, most beneficial for complex or atypical cases. In one study [17], medical residents evaluated computer-based cases of varying complexities. In cases with classic presentations in which the diagnosis was clear, the authors found that no amount of analytical reasoning would change the clinicians' minds. However, when the cases became more complex with conflicting data, cognitive biases such as *premature closure* and subsequent diagnostic errors were more prevalent. Therefore, in complex or unusual cases, they noted that "physicians would benefit from better awareness of cognitive processes and the application of rigorous analytic reasoning" [12]. Several other studies have demonstrated that providing training in reflective practice, reasoning skills, and probabilistic decision-making do improve diagnostic accuracy, often by decreasing cognitive biases [18–20].

Diagnostic Autopsy

Vignette 16.2

"Jessica," a 17-year-old female with no significant past medical history, presents to a pediatric urgent care facility with 1 month of epigastric pain and vomiting. She describes the pain as daily, dull, and non-radiating. She has not been able to achieve any relief from her symptoms. Given the clinical history and unequivocal physical exam, the urgent care physician transfers the patient to a large quaternary pediatric emergency department for ongoing evaluation. In the emergency department, further clinical history reveals that the pain seems to be worse in the morning and after meals. Symptoms were consistent with GERD, so no further laboratory or radiographic evaluation was obtained. Review of the electronic health record (EHR) did not reveal a documented differential diagnosis in the physician's note, so it is unclear if the physician considered other diagnoses. Jessica was discharged home with parental reassurance, a prescription for ranitidine, and follow-up with her primary care doctor.

Two of the more commonly encountered cognitive biases are *anchoring bias* and *premature closure bias*. As described by Daniel Kahneman [7], the quick, autonomous style of System 1 thinking depends on pattern recognition to make an accurate diagnosis. However, this system of thinking is prone to cognitive bias as noted above. *Anchoring bias*, the tendency to lock onto salient features and failure to adjust this initial impression, may be particularly apparent when patients present from other facilities, as they often arrive with a labeled diagnosis. Likewise, documented triage chief complaints may also provide the physician with a "pre-diagnosis." Anchoring from this initial diagnosis may lead to inappropriate

diagnostic conclusions. Similarly, the *premature closure bias*, in which a provider fails to consider alternative diagnoses once a primary diagnosis is assigned (either by that provider or another), may occur in these situations. Applying this principle to the conceptual model of the diagnostic process as outlined in Fig. 16.1, a clinician's information gathering will be limited by the *premature closure bias*. This limitation can unintentionally result in failure to complete a thorough clinical history, failure to consider necessary diagnostic tests, and failure to consult pertinent sub-specialty services in appropriate clinical scenarios. The failure to consider a more thorough differential diagnosis likely led the clinician to obtain no additional documented clinical history or evaluation in this case presentation.

Vignette 16.3
The next day, Jessica returns to the same emergency department with continued epigastric pain, nausea, and vomiting. The emergency room physician assessing her in all likelihood has seen numerous adolescent patients with a similar presentation who were diagnosed with GERD and successfully treated. In the medical record, the provider comments on the patient's reassuring clinical appearance and recent diagnosis of GERD, so a prescription for a cytoprotectant, sucralfate, is added to her regimen. She is discharged home with a continued emphasis on supportive care.

During a busy emergency department shift, providers can see dozens of patients with similar symptoms, so they must often rely on illness scripts to help identify, triage, and treat patients. If a provider frequently sees patients with reflux symptoms, he or she would be more likely to make that diagnosis when a teenager with epigastric pain and vomiting presents to the emergency department. This tendency to diagnose based on previous experiences with illness scripts with similar symptoms is called the *availability bias*. This bias can occur when healthcare providers make decisions based on perceived frequency or likelihood of a condition due to the ease of recall rather than actual probabilities [21]. One study found that only 27.9% of 10- to 17-year-old children with symptoms of gastroesophageal reflux reported experiencing abdominal pain [22]. Therefore, although abdominal pain occurs with reflux, it is unlikely that every patient presenting to the emergency department with epigastric pain has GERD. This bias tends to lead to the overdiagnosis of the more common conditions and underestimation of the true prevalence of rare diseases. The *availability bias* inherently lives in the common medical aphorism, "when you hear hoof beats, think horses, not zebras." In Jessica's case, multiple providers were quick to attribute chronic epigastric pain and vomiting to GERD, a routine diagnosis in pediatric and adolescent medicine. However, her actual diagnosis was less common and required more thoughtful consideration to make an accurate diagnosis.

Vignette 16.4
The following day, Jessica sees her primary care doctor to discuss these symptoms. At that visit, the physician completes the first fully documented adolescent psychosocial screen. Jessica endorses occasional drinking and trying marijuana "a couple of times." There is a concern for a possible "psychosomatic" etiology to her symptoms; however, the patient is told to continue supportive care with a new prescription for ondansetron and to follow-up in 1 week.

The patient followed up with her primary care provider as instructed to re-evaluate her complaints. She continued to endorse abdominal pain, nausea, and vomiting despite treatment with two prescription medications for reflux. During this visit, her high-risk adolescent behaviors are commented upon in the physician documentation, but the connection to the primary complaint was not established. The physician appropriately took a more detailed clinical history but concluded that the patient was likely suf-

fering from psychosomatic symptoms. This tendency to use evidence that supports your working diagnosis (e.g., benign abdominal exam) but ignore other evidence that may contradict it (e.g., history of marijuana use, no improvement on appropriate medications) is known as the *confirmation bias*. This bias likely impaired the provider's diagnostic thinking and inhibited the acquisition of a more detailed history.

As mentioned, this patient was a healthy, well-appearing teenager with a history of marijuana use who, despite persistent symptoms, had a benign abdominal exam. This benign exam led multiple providers to assume that this patient's symptoms were more representative of functional abdominal pain rather than a more complicated diagnosis. Tversky and Kahneman discussed this inherent tendency to make a judgment based off something being more representative rather than more likely and labeled it the *representativeness bias* [21]. They illustrate this bias through an example. They describe a shy and timid individual who is meek, tidy, and introverted and has exceptional attention to detail. They then ask subjects to assess the probability of this individual's profession when given the choices of farmer, physician, librarian, or pilot. The *representativeness bias* would stereotype this individual as best fitting our preconceived notions of a librarian. In our clinical vignette, providers stereotyped a well-appearing, healthy adolescent female with intermittent marijuana use as more likely to have functional abdominal pain than a more complex diagnosis.

The 2002 NASEM report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, highlighted these inherent stereotypes and implicit biases [23]. While this chapter will not go into the complex nature of current healthcare disparities, it is important to note that stereotypes and implicit bias can alter the diagnostic process. When stereotypes compromise the healthcare system and its providers, they may detrimentally affect the entire conceptual model of the diagnostic process. These biases negatively impact the way patients and families engage in the healthcare system. They also adversely impact how providers formulate a working diagnosis and how they communicate the diagnosis and treatment options. Patient outcomes can also unfortunately be negatively impacted.

Vignette 16.5
After the patient's visit, the physician completes documentation in the EHR. The clinical indication for this visit is "follow-up exam," with no other documented diagnosis of marijuana use.

In addition to cognitive biases, other system processes can contribute to diagnostic errors. The leading paradigm of thinking that illustrates this concept is James Reason's Swiss Cheese analogy [24]. In his model, potential hazards can reach victims when the holes (latent failures) in many different processes are perfectly aligned to result in preventable patient harm. These holes include both active failures, such as unsafe acts committed by individuals in direct contact with the patient or system, and underlying conditions, such as inherent flaws within a system that can contribute to harm [24]. In medicine, the EHR is a potential hazard that can contribute a latent failure as described by Reason's Swiss Cheese analogy.

The inherent flaws in EHRs are demonstrated in our clinical vignette, as provider interaction with the EHR contributed to delayed recognition of the patient's diagnosis. One of the most widely used EHR features is its ability to highlight a patient's medical and social histories. The provider who first discovered Jessica's history of marijuana use failed to document this history. Subsequently, multiple following providers also failed to complete this social history, and the EHR system failed to alert the providers that the social history section was incomplete. This information may have triggered future providers to either obtain a more detailed social history or consider marijuana use as a contributory factor in her diagnosis. Instead, the providers committed an error of omission, which supported the prevailing theory that her pain was secondary to GERD.

Other inherent flaws with EHRs that require consideration are the use of highly focused ordersets and the enormous volume of documentation that EHRs create. Pre-templated ordersets, while helpful for efficiency, may bias the clinician toward *premature closure*, as ordersets are often very narrow in their diagnostic focus. The volume of documentation in EHRs must also not be underestimated. Large quaternary medical centers will generate tens of millions of notes in a given year. This staggering statistic makes it nearly impossible for medical providers to review all documentation, especially when patients have numerous prior encounters. With increasing external pressures from administrators and insurance companies to expedite patient care and reduce the length of stay, providers are often unable to dedicate the necessary time and resources required for detailed chart review.

Vignette 16.6
Twelve days after her initial clinic appointment, Jessica is seen again for a follow-up visit. Her symptoms continued to be attributed to underlying GERD; yet, there is no discussion or documentation at this visit of her previously identified high-risk adolescent behaviors. The patient is sent home with education about GERD prevention.

Upon receiving the diagnosis of GERD, the patient had several subsequent encounters with medical providers who continued to attribute her symptoms to reflux. Her ongoing complaints of nausea, vomiting, and epigastric pain that were refractory to medications should have been a warning sign that GERD was not the correct diagnosis. At the core of the conceptual model is the question "has sufficient information been collected?" This question challenges providers to regularly reflect on whether key components of a proposed working diagnosis are missing. In this instance, medical providers had tunnel vision, failed to seek new information, and failed to consider an alternative diagnosis. Provider assumption of the correctness of the initial diagnosis to make subsequent medical decisions is known as the *anchoring bias*.

Also, this mode of thinking perpetuated a secondary cognitive bias, the *bandwagon effect.* The more other people draw similar conclusions or have comparable perceptions about a case, the more likely subsequent individuals are predisposed to those same biases and come to the same conclusions. Encounter after encounter, this patient was labeled as suffering from GERD. Minimal diagnostic evaluations were completed on each subsequent encounter, and less attention was paid to the fact that her symptoms persisted despite being on the appropriate treatment for GERD. Rather than stopping to take a "diagnostic time-out" and to consider other possible explanations, the clinicians continued to treat Jessica for GERD. (Key Points Box 16.4)

Key Points Box 16.4 Common Types of Cognitive Biases
Representativeness – probability that an event or object belongs to another category based on the characteristics it shares with the category

Availability – making a judgment about likelihood based on how easily the event or object comes to mind

Anchoring – heavily relying on an initial impression to make subsequent judgments

Vignette 16.7
Jessica is then lost to follow-up for several months until she finally returns to the clinic with 12-pound weight loss, persistent abdominal pain, and near-daily vomiting. For the first time, a provider documents in the EHR a detailed differential diagnosis including irritable bowel syndrome, inflammatory bowel disease, hyperemesis from marijuana, bowel perforation, and appendicitis. The patient is transferred to the same quaternary pediatric emergency depart-

ment, where an extensive workup including complete blood count, chemistry panel, hepatic function panel, and inflammatory markers are unremarkable. An acute abdominal X-ray series is obtained and unremarkable. The only pertinent positive test result is a urine drug screen, which is positive for marijuana. At that time, the emergency department provider takes a more directed and detailed drug abuse history and discovers that the patient has been chronically using marijuana several times a day for the past 12 months. Upon admission to the pediatric general medicine service for intravenous fluid resuscitation, it was discovered that warm showers relieved her symptoms, and her family confirmed her history of taking numerous hot showers every day over the last few months. Many months after her initial presentation for epigastric pain and vomiting, Jessica is correctly diagnosed with cannabinoid hyperemesis syndrome. She established care with the Psychology Department, and symptoms resolved after cessation of marijuana use.

Cannabinoid hyperemesis syndrome (CHS) is a well-documented sequela of chronic abuse of marijuana that consists of recurrent abdominal pain with unrelenting nausea and vomiting. One of the most pathognomonic characteristics of CHS is the relief of symptoms by hot showers. While the true incidence of CHS is unknown, multiple case reports have been published in both the pediatric and adult literature [25–27].

Mitigating Cognitive Bias

As discussed, cognitive biases play an integral role in many diagnostic errors. There are over one hundred such biases that can impair our thinking. These biases are inevitable, but through debiasing and mitigation strategies, we may be able to temper their effect.

Mitigating cognitive bias involves a change in behavior and thinking. The first step is to recognize and accept the facts that thinking is prone to bias and that everyone makes diagnostic errors. When a clinician recognizes that a cognitive bias is impairing their diagnostic process, they can adjust their thinking to mitigate the effect of that bias on their reasoning. However, recognition of the effect that these cognitive biases have on the quality of our diagnostic thinking is influenced by other factors and conditions in which we operate. These factors include the environment in which we function, the people and patients with whom we work, and our emotional state and physical well-being [28]. Sometimes it takes a string of serious safety events due to diagnostic errors or the publication of a major report such as *Improving Diagnosis in Health Care* to foster awareness and acceptance of our error-prone diagnostic processes. Unfortunately, some cognitive biases are more resistant to mitigation, and a more structured mitigation strategy is required. (Key Points Box 16.5)

Key Points Box 16.5 Mitigating Cognitive Bias

To lessen the frequency of cognitive bias, individuals must first recognize the existence and prevalence of these lapses in thinking. Different strategies to mitigate cognitive bias have been identified, including processes such as a diagnostic time-out, formulating a differential diagnosis, checklists, etc.

Croskerry [28] describes several strategies that may mitigate cognitive bias. The clinician must obtain a thorough history and physical and must develop a comprehensive differential diagnosis that is appropriate for the clinical presentation. These two seemingly simple strategies alone may mitigate several cognitive biases, including the *unpacking principle* and the *ascertainment*, *anchoring*, *premature closure*, *availability*, and *representative biases*. Unfortunately, in the rush to see an increasing number of patients, in our

effort to be overly efficient with documentation and coding, and in our frustration with EHRs, we may cut corners when reviewing a case and developing a differential diagnosis. For hospitalized patients, we think a diagnostic time-out can help enhance the breadth and quality of differential diagnoses. This time-out is utilized during the initial inpatient assessment, at which time the patient care team is asked to address three questions: (1) What do we think the patient has? (2) What else might the patient have? (3) What diagnosis can we not afford to miss? The diagnostic time-out also addresses two other mitigating strategies identified by Croskerry, Rule Out the Worst Case Scenario (ROWS) and Until Proven Otherwise (UPO).

Other mitigating strategies include a checklist as described by John Ely et al. [29]. A checklist for a variety of chief complaints may mitigate *anchoring bias* and *availability bias* and minimize memory failures. Mnemonics to aid the development of differential diagnoses are often learned in medical school, but practicing clinicians may abandon these tools in the busy clinical environment. Table 16.2 demonstrates several inclusive mnemonics helpful for a variety of conditions. Each of the mnemonics are derived from a list of clinical systems from which a clinician can develop a differential diagnosis consistent with a chief complaint. The first letter of the mnemonic corresponds to a clinical system to consider.

Measuring Diagnostic Error

Peter Drucker (1909–2005), a business management consultant, coined the axiom among quality improvement experts "if you can't measure it, you can't improve it." Increasing awareness of diagnostic error and the cognitive biases that contribute to their occurrence are important; however, in order to act on that increased awareness, i.e., in order to decrease the frequency of diagnostic errors, diagnostic errors first need to be made measurable.

To measure diagnostic errors, detailed chart reviews can be conducted. If the NASEM report is accurate, there are multiple diagnostic errors occurring daily, and they should not be hard to find. In reality, not all diagnostic errors result in patient harm, and patients' symptoms often resolve despite a diagnostic error. Detailed chart reviews can be time-consuming and involve multiple practitioners to validate the diagnostic error identified. A more practical approach to measuring harmful but potentially preventable diagnostic errors may be the use of a diagnostic error index [30]. A mature patient safety program may identify diagnostic errors from established institutional sources. For example, quality improvement staff can monitor diagnostic errors from reliable sources such as autopsy data, morbidity and mortality reports, adverse event reports, root cause analysis investigations, and medical record triggers. We have used the diagnostic error index

Table 16.2 Differential diagnosis mnemonics

Vindicate psychology	Victims	Vitamin D	Vin di catem-p
*V*ascular	*V*ascular	*V*ascular	*V*ascular
*I*nfectious	*I*nfectious	*I*nfectious	*I*nfectious
*N*eoplastic	*C*ongenital	*T*rauma	*N*eoplastic
*D*rug	*T*umor/*T*rauma	*A*utoimmune/inflammatory	*D*egenerative
*I*nflammatory	*I*mmunologic	*M*etabolic	*I*mmune/*I*ntoxication
*C*ongenital	*M*etabolic	*I*nherited/congenital	*C*ongenital
*A*utoimmune/*A*llergic	*S*eizures/p*S*ych	*N*eoplasm	*A*utoimmune/*A*llergy
*T*raumatic		*D*rug toxicity	*T*rauma
*E*ndocrine			*E*ndocrine
*P*sychology			*M*etabolic
			*P*sychological

as a measurement tool and have shown a decrease in significant patient harm events.

Culture of Safety and Transparency

Over the last 20 years, the importance of diagnostic error recognition within the patient safety culture has come to the forefront. In its purest form, patient safety culture was conceptually defined in the 1999 NASEM report *To Err Is Human* as an environment that prioritizes reduction of patient harm and improvement in clinical outcomes [1]. For a complex and sophisticated system such as a healthcare organization, a safety culture entails the attitudes, beliefs, and patterns of behaviors of the group and its constituents that relate to the organization's commitment to safety [31]. These definitions highlight the fact that safety culture is an active and dynamic notion that requires the engagement of both individuals and leaders.

Before an organization can improve safety, its constituents must have a work environment in which there is not a fear of retribution. A transparent and open culture directed toward safety is essential to healthcare and is a necessary component for the reduction of diagnostic errors and preventable patient harm. Creating this psychological "safe space" is vital to successful patient safety cultures but can be very difficult to achieve. Many organizations, including the Institute for Healthcare Improvement (IHI), have long recognized the importance of a culture of safety in healthcare. To assist institutions who are seeking to establish or solidify their culture of safety, the IHI outlined six specific domains to guide safety endeavors [32]:

1. Establish a compelling vision for safety
2. Value trust, respect, and inclusion
3. Select, develop, and engage your board
4. Prioritize safety in selection and development of leaders
5. Lead and reward a just culture
6. Establish organizational behavior expectations

Whether utilizing these six principles or other similar concepts, healthcare organizations must first have a foundational basis which supports a positive safety culture. It is from this open and transparent safety culture that organizations can address diagnostic error and eliminate preventable harm occurring in their healthcare system.

Summary

In this chapter, we provide background regarding the problem of diagnostic error. We describe the diagnostic process and the types of diagnostic thinking involved. We present a case of a diagnostic error that involved several cognitive biases and discuss the more common biases. We then perform a diagnostic autopsy and demonstrate how cognitive biases likely led multiple physicians to the same erroneous diagnosis. Finally, we suggest ways that diagnostic errors can be measured and that the associated cognitive biases can be mitigated.

Editors' Comments

Medical diagnosis has long been looked at as an art which was presumed to have been mastered during a clinician's training years and is the very basis of the business of and presumed need for expansive healthcare delivery systems. Over the past two decades, the vulnerability and pitfalls of these systems have been exposed by multiple studies, most mentioned in the bibliography of this chapter. Our healthcare systems have become more complex and lack the framework for sustained improvement, accountability, communications, and other qualities seen in high functioning and high reliability organizations.

Diagnostic errors appear to be focused on individual errors when they actually often reflect system issues that create situations that place healthcare team members

and our patients at risk. The story of *The Tortoise and the Hare* [33] comes to mind when reading about fast (type 1) and slow (type 2) thinking. Time pressures due to financial constraints, staffing shortages, changing clinical acuity, and seasonality force providers to see more patients rapidly, a situation that does not foster slow and deliberate thinking. There are times when we want the hare to win the race such as during a resuscitation, but the tortoise needs to be in the room. If we want tortoise-type thinking to dominate daily medical activities, our systems need to be better designed and more efficient; problems and errors need to be brought to the surface quickly; organizational cultures need to be aligned for continuous improvement, transparency, accountability and change; and finally, regulations and financial incentives need to be realigned to promote type 2 thinking. We need to be aware that clinical pathways, while necessary for standardization and efficiency, can also foster cognitive biases.

Diagnostic errors and their associated cognitive biases represent the fallibility of medicine. With their acknowledgment, our patients, families, and team members ask how we are redesigning our systems to improve detection and reduce diagnostic error occurrence. Unfortunately, our systems with the many mergers of healthcare entities are becoming more complex, not less. We need to consider educating our students, active workforce, patients, and their families about the nature of such errors and biases and how we can together reduce their incidence. We need to understand the diagnostic process and the methods by which we can overcome its pitfalls. Diagnostic errors represent one of the biggest challenges for patient safety, especially with the difficulty surrounding their measurement. This field will likely be receiving much more attention in the upcoming years. In 2009 David Newman-Toker and Peter Provonost [34] once eloquently stated that: "as with most scientific advances, this will be a long and arduous journey, but the next frontier for patient safety is in plain view." Despite the passage of 10 years, the challenges of diagnosis and critical thinking have not changed. We will need to work harder and smarter to assuage the harm caused by diagnostic errors.

Chapter Review Questions

1. What are the two characteristics that define a diagnostic error?

   Answer: A diagnostic error is defined as a failure to either establish a timely and accurate explanation of a patient's health problem or a failure to communicate that diagnosis to the patient.
2. What is a cognitive bias?

   Answer: Cognitive bias refers to a cognitive strategy or mental shortcut that fails, leading an individual to deviate from the standard norm of decision-making based on the way information or a situation is presented.
3. True or False: System 2 thinking involves the quick, autonomous way of thinking, which often happens below our level of consciousness.

   Answer: False
4. What are the three core elements to the diagnostic process, as outlined by the conceptual model of the diagnostic process?

   Answer: The three core elements include gathering of information, information integration and interpretation, and formulation of a working diagnosis.
5. A primary care doctor evaluates a 64-year-old female complaining of chest pain. Her symptoms are very similar to those of another patient who was seen in the office yesterday with pneumonia, so the physician prescribes an antibiotic and discharges today's patient home with a diagnosis of pneumonia and no further testing. This event may be an example of which type of cognitive bias?

A. Bandwagon effect
B. Overconfidence bias
C. Visceral bias
D. Availability bias
E. Selection bias

Answer: D. Availability bias

6. True or False: Marijuana is the second most commonly used substance by adolescents.

   Answer: True

7. What strategies can be implemented to mitigate cognitive bias and reduce the potential for diagnostic error?

   Answer: Cognitive biases are an inevitable part of human decision-making. While these biases may impair our judgment and lead to diagnostic error, several strategies have been outlined to help individuals minimize their impact. These strategies include but are not limited to the creation of checklists, development of a differential diagnosis, utilization of mnemonics, and use of a deliberate pause in thinking, called a diagnostic time-out.

8. Describe concepts that have been outlined to help organizations, leaders, and individuals establish a culture of safety at their institution.

   Answer: A transparent and open safety culture is imperative to reduce diagnostic error and preventable harm in healthcare. Institutions can work toward establishing this culture by following the six domains outlined by the Institute for Healthcare Improvement. These core domains include objectives such as establishing a compelling vision for safety, actively engaging the administrative board, prioritizing safety in the development and selection of leaders, and placing a value on trust, respect, and inclusion.

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17

An Improvement Operating System: A Case for a Digital Infrastructure for Continuous Improvement

Daniel Baily and Kapil Raj Nair

Chapter Objectives

- Share common quality and safety improvement challenges in healthcare systems
- Define an improvement operating system, its aspects, and how it can drive safety and quality improvement
- Use patient safety culture improvement case as an exemplar, to demonstrate how an improvement operating system gets operationalized
- Share a vision for how an improvement operating system should evolve over time to be used as a broad-spectrum operational infrastructure

Vignette 17.1

A hundred-bed local community hospital has struggled with sustaining patient safety culture improvement. The hospital board is also aware of the sustainability challenges and has asked the VP of Quality to address and build patient safety culture as a foundational tool for improving quality and safety. The organization has achieved safety culture improvement in the past but is unable to connect microculture level actions to outcomes. As part of setting the strategy for improvement, the leadership distilled their case into a probing question: "How do organizations leverage the current momentum in safety culture improvement while improving or sustaining all other quality and safety metrics they are responsible for?"

Opening Question

In 2012, CMS reported on 43 quality measures in their National Impact report [1]. This past year (2018) CMS reported on 762 different measures [2]. That's an average of ten additional metrics per month, for 6 straight years – just from CMS, let alone the requirements from private payors and watchdogs! As the list of requirements grows and resources to spend on meeting these requirements shrink, health system leaders are constantly challenged to maintain priority and focus. Even with the best intentions and commitment,

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safety and quality leaders have found the ability to create and maintain the needed focus on improvement a significant challenge with little to no capability of systematization, sustainability, or evolution of improvement efforts at scale. In such an era of intense regulatory and performance requirements combined with dynamic change, how can quality and safety leaders fathom or even envision sustainable improvement?

This chapter shares an approach that helps organizations direct improvement programming in a different way. What if, we can do more with less?

Introduction

It's no secret that healthcare is facing pressure from many sides. In an era of value-based purchasing, system consolidation, and changing delivery models, healthcare organizations are mandated to reduce all cause patient harm, increase patient satisfaction scores, engage a changing workforce, and comply with an ever-growing number of reporting requirements from regulators and public advocacy groups. As the list of requirements grows, our resources to spend on meeting these requirements are shrinking. Reimbursements are shrinking – often made even more painful by penalties due to underperforming on quality, safety, and satisfaction metrics. We also face severe and growing workforce shortages that are undermining any improvement initiative, leading to disengagement and burnout, and chipping away at our workforce's most valuable resource: time. Through all of this, our patients continue to get harmed at unacceptable rates.

The organizational stakes are high!!

We have to become nimble and resourceful, or yield to disruption, as the healthcare market [3] is evolving at an ever-faster pace. We have to find ways to significantly reduce workforce burnout as we are constantly losing qualified healthcare providers [4]. We have to dramatically strengthen patient safety efforts as we continue to harm our patients at unacceptable rates.

Unfortunately, we face some significant internal gaps preventing most organizations from successfully navigating these tumultuous waters and creating the needed improvement.

Common Internal Gaps

Leadership Gap

Although highly educated and well-intentioned leaders – especially at the mid-level – struggle to execute on dozens of improvement targets, the successes that do occur are usually the result of heroic efforts that rarely spread across the organizations. Most critically, on improvement initiatives, the perspective of leaders of all levels usually varies dramatically from the frontline caregivers who must ultimately make the needed change. This creates a misunderstanding of enablers and barriers of improvement ultimately stalling improvement actions. A qualifying example would be Agency for Healthcare Research and Quality (AHRQ) Surveys on Patient Safety Culture (SOPS) [5] which is used to measure perceptions of healthcare employees, including frontline staff and organizational leaders, on patient safety and quality of care. The SOPS national benchmarks consistently show organizational leaders as having a higher perception of quality and safety than frontline staff. This could be triggered by leaders lacking operational sensitivity. In their famous book, *Managing the Unexpected*, the authors Karl E. Weick and Kathleen Sutcliffe refer to "sensitivity towards operations" [6] as a core principle to create sustained performance.

Information Gap

Healthcare leaders lack real-time, actionable information about the improvement efforts going on across their organization. This problem is exacerbated by lack of strong clinical analytics and compounded by the nonexistence of a digital infrastructure to consistently track improvement actions and progress. This leads to an overwhelm-

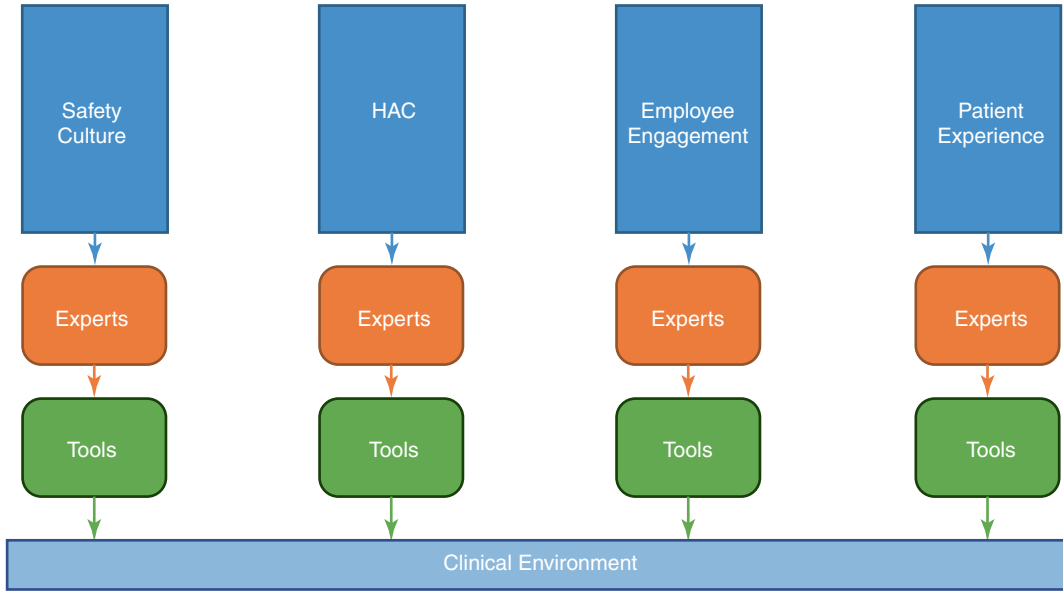

Fig. 17.1 Various siloed data streams applied in a clinical environment

ing number of improvement initiatives whose success can only be evaluated retrospectively. These retrospective analyses are more opinion-based than data driven. This is primarily driven by lack of continuous improvement activity data which typically helps organizations to know what worked and what did not work and why certain activities or tasks were dropped. Therefore, we fail to learn iteratively, or course correct at the rate needed to be successful.

Improvement Silos

Most improvement efforts are siloed and are addressed as work streams driven by data sets. The experts who are leading these improvement efforts each own these data streams independently of each other, forcing frontline leaders to operate on the improvement initiatives independently. For example, a hospital system will have patient experience measures and improvement experts similar to how they have quality and safety improvement experts. This approach significantly dampens systematic improvement (Fig. 17.1).

All of the above lead to a *gap in execution* – we ultimately fail to see the rates of improvement we both expect and need.

Vignette 17.2

In context of their probing question, the organization decided to dig further deep into understanding the root causes of their sustainability challenge.

They lacked local ownership of improvement efforts. They had significant variability in performance. While the top performers were lifting the overall results above benchmarks, more than half of their units statistically trailed the benchmarks concerning patient safety culture. This problem was compounded by the fact that about one in five units/outpatient areas had new managers. The organization's improvement efforts did not leverage cross cutting strategies such as safety culture to their advantage.

They also experienced a significant difference between leadership and frontline's

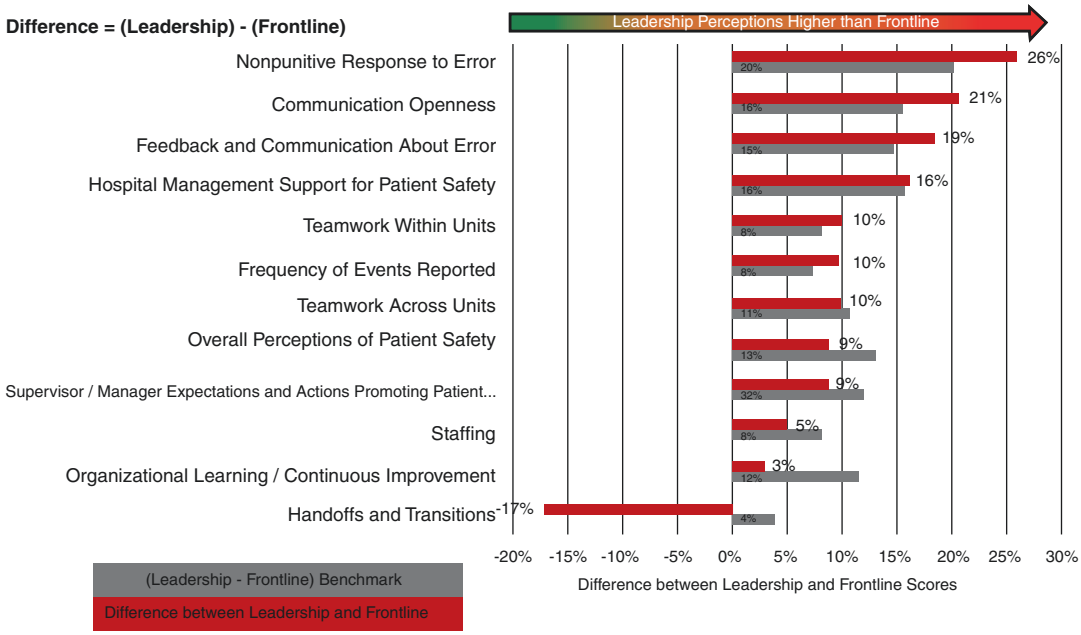

Fig. 17.2 Difference in leadership to frontline perceptions measurement

view of safety culture. This gap is depicted using patient safety culture measures through a standardized measurement instrument such as AHRQ Surveys on Patient Safety Culture (SOPS). In the graph shown in Fig. 17.2, we consider the scores of leaderships vs. frontline for the same composite (Fig. 17.2).

Key Point Box 17.1

Operating System (noun): software that controls the operation of a computer and directs the processing of programs as by assigning storage space in memory and controlling input and output functions [7].

First known use: 1961

[Source: Merriam-Webster Dictionary]

A Way Forward

To fix these above challenges, healthcare leaders should acknowledge that their organizations simply *lack an improvement operating system*. One could think of an improvement operating system as a combinatory set of core values, robust management processes, and a proactive prioritization method through which the organization iteratively accomplishes its targets while building a strong and vibrant team-based culture. Every organization is unique and therefore has the potential to have its own unique operating system. But there are certain common attributes especially when considering the core values (Key Points Box 17.1).

What Are the Core Values of an Operating System for Improvement?

We describe an improvement operating system that will ensure microculture (unit, department, or a clinic)-based improvement, visibility into improvement actions, and leadership engagement. These three components will increase visibility, scalability, and sustainability of improvement efforts.

- *Visibility*. An improvement operating system will ensure leaders have clarity around the broad state of improvement efforts across the microculture-based teams, both inpatient and

outpatient, working on improvement initiatives. In contrast to typical, stagnant action plans, improvement team leaders will regularly provide simple progress reports that include activities, barriers, and enablers towards improvement. An improvement operating system should also aggregate the activity and performance data to ensure that senior leaders consistently have the pulse of improvement rather than waiting for long improvement cycle feedback. This aggregation of data should also lay the foundation for connecting the improvement actions to outcomes data to create visibility into the effectiveness of various efforts.

- *Scalability*. The improvement operating system will enable leaders to scale improvement efforts without adding additional quality and safety personnel. Furthermore, these efforts will provide leaders with the ability to identify internal best practices and scale those practices across the facility and system. This approach ensures appropriate leaders and champions are given relevant information for the teams they support and the barriers they face in order to work towards removing them, regardless of the number of teams or improvement aims.
- *Sustainability*. Within an improvement operating system, improvement plans and priorities are based on leadership's vision. These are also informed by the current data. This ensures organic, sustainable improvement rather than a reliance on external expertise and resources. This approach also detects when barriers are preventing local teams from making progress on local goals, enabling leaders to intervene far sooner than waiting for lagging metrics to change. As the improvement teams grow their improvement capabilities, they will increasingly rely on this operating framework to provide insights and accountability towards their own plans.
- *Integration*. An improvement operating system should integrate the improvement initiatives, performance data, and toolkits. This will mitigate the "initiative fatigue" that frontline leaders face. The integrated method could also accommodate new feedback and support mechanisms without draining the organizational capacity.

Operationalizing an Improvement Operating System

Putting an improvement system into action requires careful thought, attention, and execution. Quality and safety improvement is not just a technical business of best practices and advanced data analytics to manage process and quality improvement (PI and QI) projects. It is also an adaptive challenge [8]. It requires behavior and attitude changes at all levels of the organization. Hence an operational plan that does not maintain significant interest into the foundational aspect of organizational culture improvement will not succeed in putting an improvement operating system in place. Hence, we propose a four-staged action framework for iterative and continuous improvement for organizations starting with patient safety culture. The four-staged action framework is similar to the Deming's cycle (also known PDSA cycle) introduced by Dr. Edwards Deming. This iterative cycle forces a rhythm into an organization which is really important as healthcare organizations constantly struggle to prioritize (Fig. 17.3).

The critical initial stage of the safety culture improvement cycle, PLAN, requires creating clarity of purpose and shared language across the core improvement team and executives for systematic improvement of patient safety culture. This stage requires leaders to articulate the strategy, support infrastructure, and timelines for their improvement journey. Organizational leaders should clearly understand the current improvement initiative inventory and the organizational approach towards improvement. This will not only paint the picture of the current state and its efficacy but also will provide significant input towards creating the

Fig. 17.3 12-month improvement cycle phases

vision towards advancing the organizational strategy regarding patient safety culture. Leaders should consider this stage as a forming stage [9] and develop messaging that clarifies purpose, timelines, and expectations while creating the alignment among themselves. Most importantly, they should ensure that the latest safety culture data is rolled out to all levels of the organization including frontline staff. One could use a standardized safety culture measurement tool such as prior mentioned AHRQ Surveys on Patient Safety Culture (SOPS) Measurement and associated best practices on distributing results.

Vignette 17.3
In order for them to be successful, the leaders of all levels jointly decided a course of action with the following high-level core objectives that aligned with their 5-year plan to be able to provide the best care and health outcomes to the population they served.

The leadership team through thoughtful deliberation realized that they have to first tighten their patient care operating model. To achieve this, they have to improve patient experience, patient safety, care quality, and staff engagement at all levels. The leadership team decided to create an infrastructure that is feedback rich so that they can lay the foundation for engaging their mid-level leaders and frontline staff. With commitment from all executive leaders, they decide to embark on a safety culture improvement journey. To that end, they articulated the following core objectives:

1. Maintain forward momentum with safety culture improvement
2. Improve and cultivate local ownership of improvement
3. Reduce the leadership gap

The objective of the ORGANIZE phase is to prepare for systematic improvement of patient safety culture. This phase of the improvement cycle involves organizing the improvement infrastructure as well as establishing the improvement plans that align with other organizational strategy, metrics, and plans. Organizational leaders should create clarity and alignment towards a shared success. Accomplishing a shared success requires a significant amount of attention, focus, and cascading communication.

A common set of core activities during this normative stage should include:

- Establishing an improvement infrastructure, both globally and locally. Leaders could use models such as Comprehensive Unit-based Safety Program (CUSP) [10] for helping clinical teams while establishing an executive engagement network within the organization.
- Gathering frontline teams and local leaders input on the set improvement actions is extremely important to create not only buy-in but also continued engagement in the process. Existing organizational engagement modalities that could trigger appreciative inquiry [11] such as structured discussions, focus groups, structured leadership rounds, or table top discussions could be proven useful for getting the needed bidirectional feedback.
- Aligning the safety culture action plans with other organizational strategies and metrics by connecting with the "why" behind our actions can significantly improve the odds of success. It provides the existential connection between organizational core values and the work, increasing employee engagement and satisfaction which is shown to have direct correlation to patient safety.
- Cascading the targeted and brief action plans throughout the organization creates not only clarity on what needs to be done but also lays the foundation for accountability on the plans.

Vignette 17.4
The organization established a core team led by the Chief Operating Officer (COO). In this organization, the VP of Quality and

CNO directly reports to the COO. The core team also included the Chief Medical Officer, a data analyst, and select frontline leaders. This team conducted an initiative inventory along with a key stake holder analysis finally forming an improvement roadmap. The core team also spent significant amount of energy in crafting the right messaging to the frontline leaders and staff.

The core team also articulated the role of the senior leadership team:

- Lead improvement effort (quarterly)
  - Initial input on goals and processes
  - Quarterly meetings to review overall progress
  - Sharing experiences and feedback from rounding
- Serve as improvement team sponsors (ongoing)
  - Direct coaching/rounding on improvement teams – (monthly)
  - Review Improvement Team Progress

The core team assigned themselves to the following:

- Operationalize the improvement operating system (monthly)
  - Manage and adjust improvement roadmap
  - Monitor overall progress
- Support Improvement Teams (ongoing)
  - Provide tools and resources (i.e., be the experts)

The most important phase is the USE phase. The purpose of the *USE* phase is to materially improve the culture of safety. The majority of healthcare organizations fail to see significant improvement in patient safety culture, in part because the prior phases were poorly implemented and in part because execution of improvement actions is weak. The few organizations that do execute and monitor action plans successfully are able to see significant improvement in patient safety, quality, and staff engagement.

This action-focused portion of the improvement cycle requires leaders to "walk the talk" by embedding themselves with the improvement teams through rounding, adopting, and coaching an improvement team. This will help maintain high levels of accountability throughout the organization as leaders will be able to monitor progress, remove barriers, encourage enablers, and share internal best practices throughout the improvement cycle. It also helps leaders understand the volume of activity, creating an operationally sensitive environment which is really important to create focus and elevate priority. In order to be successful, local leaders should be equipped with executable safety science knowledge, skills, and attitudes to lead change.

The main purpose of the EVOLVE phase is to course correct or advance current work based on three sets of data (a) *performance data* based on improvement actions, (b) *feedback data* on enablers and barriers, and (c) actual *outcomes data*.

While considering safety culture improvement, unit-based performance data should include insights into actions. A shared understanding of organizational performance on the improvement cycle can be created. Momentum can be measured using simple metrics around goal completions such as percentage of goals completed, percentage of goals and actions dropped, etc. Engagement can be measured using number of teams completing improvement actions at various completion rates. Feedback data can be demonstrated by describing top three barriers and enablers, etc. A Kurt Lewin's force field analysis [12] with appropriate ranking order could be used here to create a consumable view of the data. A sample is given in the case vignette.

Vignette 17.5

As the microcultures started working through their improvement cycle. The microculture leaders started to identity the enablers and barriers which helped the leadership team tremendously.

A sample of an organizational force field diagram is shown in Fig. 17.4 based on their feedback from the progress reports (Fig. 17.4).

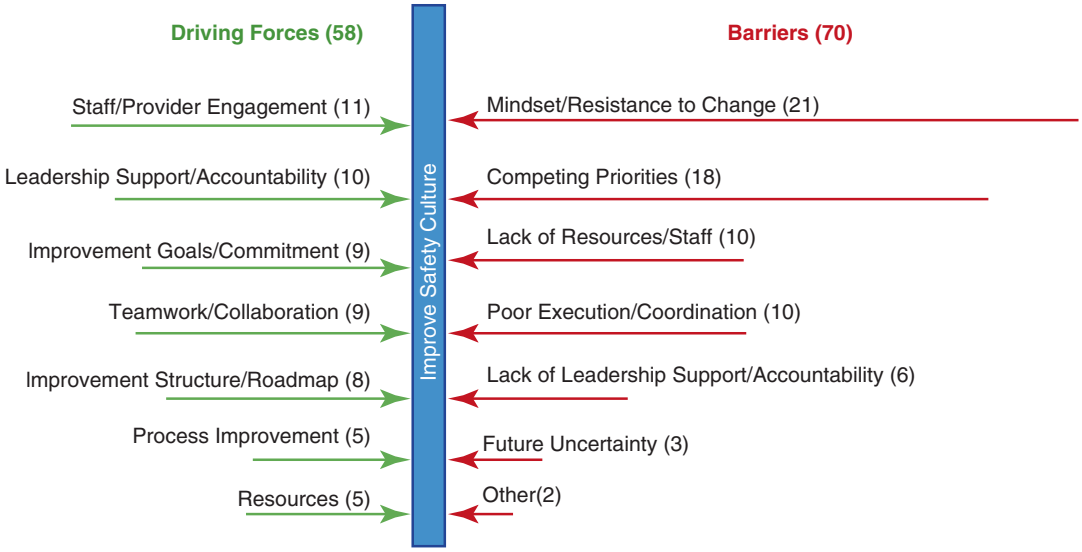

Fig. 17.4 Organizational force field diagram

Ultimately, as the outcome data becomes available through safety culture measurement at the end of the improvement cycle, organizations will be able to connect actions to outcomes. This marriage of outcomes data with performance and feedback data provides a data-driven contextual report rich with output that should set the new improvement cycles directionality. Though this evolutionary process may be sound in analytical rigor, it should be grounded in process celebrations of successes and course corrections on missed opportunities, all the while connecting the work all back to the organization's vision.

Vignette 17.6
The core team measured performance data on improvement actions.

Metrics such as goals set versus goals met, number of teams updating progress reports on a regular cadence, percentage of local goals sources to overall, etc. helped the organization to easily communicate organizational performance to senior leaders as well as the board.

By the end of a 12-month improvement cycle, the organization was able to improve overall safety culture and local ownership of improvement actions. They were unable to close the leadership gap as they desired. In fact, the gap increased.

The organization was most excited not by the safety culture improvement but by the power of the improvement infrastructure that they built. They are using the same operational approach, information system, and leadership engagement model to further advance patient safety culture and improve patient experience in their current improvement cycle.

Considerations

Improving organizational performance is no easy feat. It requires a rare multifactorial combination of vision, leadership, capacity, capability, and a willingness to change. As organizations plan their improvement journey, we recommend a few areas to keep in mind.

1. Maturity levels: It is imperative to consider the maturity level of an organization's capability for each improvement data set as an organization embarks on operationalizing integrated improvement. After working with myriad hospitals systems across the world, we developed the framework (Fig. 17.5) to convey organizational maturity.
2. Broad-spectrum approach: It is important to build and flex the organizational muscle of integrated improvement programming with a couple of data sets before using it as a broad-spectrum approach throughout the organization (Fig. 17.6).
3. Digital environment: A digital improvement operating system unleashes the power of data science. Digitization of improvement programming and tracking will help organizations maintain data integrity and data deliverability, freeing up subject matter experts to facilitate improvement rather than spending their time and resources on simply collecting and analyzing data.
4. Feedback-rich environment: A fundamental assumption for a successful long-term deployment of an integrated improvement environment is the organization's commitment towards creating a feedback-rich "just culture."

Journey	Crawl	Walk	Run
Role of Subject matter or Improvement Experts	Drive the improvement program, engage and educate leaders ***Owner***	Collect and share data, support senior leadership understanding and engagement	Act as expert resources, guides, and consultants
Role of Senior Leaders	Begin rounding on and communicating about improvement initiative	Develop org. - wide action plan and implement "adopt a team" ***Owner***	Set strategic direction and directly support team based improvement
Role of Local Leader	Follow simple outlined structures for team based based action plans	Leading local team and iterating approach as needed	Lead the local improvement effort ***Owner***
Areas of Focus	Organization wide focus, some local team based differences (e.g. safety culture survey)	Cascading areas of focus based on safety culture and other metrics.	Driven by strategic focus. Metrics are integrated and local (safety, quality, satisfaction, etc.)
Outcomes	Limited Success	Pockets of Improvement	Year after year of methodical improvement

Fig. 17.5 Journey to organizational maturity

Improvement Cycle	Teams	Sponsors	Initiatives	Outcomes	Summary
Cycle 1: Foundation	Limited to select, organizational teams (usually well formed teams such as nursing to aux units)	Small group of highly engaged senior leaders	Limited to a key area of quality or patient safety performance	Focus is on process more than outcomes	**Foundation** laid for systematic improvement infrastructure
Cycle 2: Engagement	More teams included, starting to see "ad hoc" improvement teams	Expanded group of leaders. Begins to better reflect natural hierarchy	Expanded to multiple key areas {such as patient experience or employee engagement)	Begin to see consistent connections between actions and outcomes	**Engagement** increased and lessons applied to better configure infrastructure
Cycle 3: Hardwiring	All improvement teams engage through the improvement system	All leaders have some role as sponsor/team leader	Improvement System used to organize and simplify expansive list of initiatives	Ongoing connection of actions and outcomes	**Hardwired** improvement infrastructure

Fig. 17.6 Broad spectrum approach to improvement cycle

Conclusion

The organizational impact of an improvement operating system can be very positive. With an improvement operating system, organizations have the ability to set a direction and follow through with intended actions. Senior leaders have meaningful input from local leaders and frontline staff about what type of support is needed in order to achieve the stated goals (cascaded from the organizational vision). Middle managers confidently lead their teams forwards – directly with the support of senior leaders – and generate new ideas and approaches. Frontline staff of these organizations are engaged, they speak the language of high performance, and they work together as highly performing teams. New efforts to improve are not shunned; they are adapted with constant feedback from the frontline. This not only creates a psychologically safe environment for iterative learning but also paves the way for a generative culture.

An intentionally crafted, supported, and executed improvement operating system will ultimately help an organization break down silos between various improvement efforts and teams, promoting rapid learning across various levels of the organization and creating a data-driven accountability system.

Editors' Comments

What is an improvement operating system? This term is certainly new to the Editors and we believe to many in healthcare. The authors of this innovative chapter are cofounders of a company that creates Improvement Operating Systems for healthcare. We could not think of a more forward-reaching topic that has the potential to transform healthcare improvement science than this chapter. The authors describe the tenets of operating systems and the current state of continuous quality improvement. The logical leap, which admittedly has taken the Editors some significant time and reflection to fully understand and appreciate, is that the authors then use the fundamentals of operating systems and apply these to healthcare. Once the reader understands how to bring together a traditional operating system with the values of healthcare into a continuous quality improvement glide-path, the next step is to make it happen. They adroitly have created a four-step pathway that organizations can actually follow prescriptively (Fig. 17.3) to embark upon an improvement cycle with an improvement operating system. The steps of plan, organize, use, and evolve are well described in the middle of the chapter. Once the data (i.e., results) are obtained from an improvement operating cycle, the authors use an organizational force field model (Fig. 17.4) to demonstrate who to use the feedback to demonstrate driving forces compared to barriers. As cofounders of a digital improvement science company, the authors bring unique perspective. The figures that describe the journey to organizational maturity and a broad-spectrum approach to an improvement cycle are crucial messages for the reader to understand and potentially use to communicate the value proposition of an improvement operating system within their organization. The Editors suggest the reader pausing to ask themselves, "Where is my organization in their maturity"? Using this as a starting point, the reader can then consider if an improvement operating system is within their scope and possibilities. The question should not be "if," but rather "how soon." Fortunately, this chapter provides a framework to start and accelerate the readers' organizational journey to an improvement operating system.

Chapter Review Questions

1. Describe common internal gaps faced by healthcare leaders.

   Answer: Common internal gaps include:

Leadership Gap: A gap in perception of organizational culture around improvement efforts or organizational culture between leadership and frontline

Information Gap: A gap between real-time actionable information on improvement efforts

2. How will an improvement operating system create visibility within an organization?

   Answer: An improvement operating system will create visibility through simple progress reports that contain organizational activities as well as drivers of change around these improvement activities.
3. True or False: Solving for patient safety is just a technical challenge.

   Answer: False. A strong culture of engagement and commitment for improvement of patient safety at all levels of the organization is also needed.
4. What are the core value elements of an operating system?

   Answer: Visibility, scalability, sustainability, and integration of improvement efforts are the core value elements of an operating system.
5. What are the different stages of a safety culture improvement cycle? How does it relate to Deming's cycle?

   Answer: The various stages are Plan, Organize, Use and Evolve. It is a variant of the Deming's cycle or Plan, Do, Check/Study, Act (PDCA or PDSA) cycle.
6. Provide a set of metrics that you could use to measure engagement of improvement teams during an improvement cycle.

   Answer: Metrics that could measure team engagement rates based on number or percentages of teams regularly updating progress reports, percentage of goals that are set at grass root level vs. organizational level, etc.
7. What are certain considerations that you should make while designing an improvement operating system?

   Answer: Organizational maturity in terms of improvement infrastructure and organizational culture should be considered. Also, when an organization is willing to introduce digital transformation towards improvement, programming needs to be considered as well.

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Patient Flow in Healthcare: A Key to Quality

18

Karen Murrell

Chapter Objectives

- To introduce the concept of "flow" in healthcare as a quality measure
- To describe concrete methods to create operational improvement using Lean methodology
- To discuss the role of leadership in improving a system and setting a vision to jumpstart any project
- To use a case-based approach to illustrate the role of flow to either impede or improve patient care

Introduction

In the current healthcare system, inherent delays and frustration have come to be expected. These same delays impact the quality of care throughout the system [1]. In the white paper "Achieving Hospital-Wide Patient Flow," Pat Rutherford from IHI discusses the impact of hospital flow on quality and patient care [2]. She describes the need for interdependent, interconnected systems to improve patient outcomes but also describes the challenges of such a system. With leadership and specific strategies, smooth patient flow is possible. Imagine the hospital of the future where diseases are identified at their earliest stages in the primary care office, and when evaluation or treatment is needed, it is carried out seamlessly in the hospital without time delays and interruptions between each step. A hospital where specialists are available at a moment's notice and all caregivers are focused on getting the patient well and home to family. This can be created – but will require a shift in how system-wide operational strategies are designed. In this chapter, principles will be illustrated with actual case studies about journeys to improve patient flow and discuss how system-wide spread of best practices can occur.

Vignette 18.1

In 2010, there was a case that spread across the news in Northern California. It describes the case of a little girl who required multiple amputations after waiting 4 hours to see a physician in the ED. Her father describes his despair as he waited to see a physician with his sick little girl. One cannot know if the outcome would have been different if she had been seen quickly, but this delay could not have helped. At another Northern California hospital in 2007, there was an impending crisis. A per-

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fect storm was developing that started in the ED and continued on the inpatient side. There were long delays for patients that often led to quality issues because of poor flow. At the same time, the hospital was seeking trauma center designation, volumes were increasing at double digit rates annually, and the county psychiatric unit closed their crisis stabilization unit and half of the inpatient beds. Boarding in the ED was a frequent problem. New leadership in the ED did not know what to do to improve care and patient flow. Leaders in the ED and hospital read about a course in "Lean Healthcare" and attended and began to spread the basic principles throughout the hospital. They methodically set about changing how healthcare was delivered and transformed healthcare delivery. They found that excellent flow dramatically improves quality for patients. These general principles apply across the health system both in the USA and around the world. The general flow principles learned can be replicated in any healthcare system but will require process changes and cultural transformation.

In 2011, another little girl came into the transformed emergency department with her father. She had a complaint of nausea and vomiting with normal vital signs. Previously, she easily could have waited 4 or 5 hours, but with improved flow, she is immediately seen by a doctor. He decides she is ill, does a spinal tap, and discovers she has meningococcal meningitis – a very time sensitive disease. She is immediately treated and admitted and makes a full recovery. For many years, the ED physician gets updates from her mother about how well she is doing, how she has started school on time, and most importantly she says: "without you my life would have been very different." This is the impact of flow in a hospital, consistent, reliable care that allows doctors to treat and save patients. This chapter will discuss general principles to improve operations and flow as well as change management and lean principles learned.

Background

There is much data that supports the adverse health outcomes associated with poor patient flow [3]. Studies show that ED boarding increases both mortality and patient length of stay once they are admitted – further compounding the problem [4]. On the inpatient side, studies show that for every added patient with heart failure, pneumonia, or heart attack given to an overworked nurse, odds of readmission increase from 6% to 9%. For the ICU, every patient discharged early because of overcrowding has double the chances of being readmitted to the ICU. While this is a well-known phenomenon, very few hospital systems have been able to strategically address solutions to the problem. In the USA, the most common strategy is building additional space for care without looking at waste and poor flow as an etiology for problems [5].

Historically, the US healthcare system payment model has not rewarded patient flow. Hospitals depended on hospital admissions for reimbursement, and this translates to the more procedures the better for the hospitals' financial bottom line. Physicians in many areas have been compensated per patient, leading to multiple consultations per admission. The idea that hospital admission equals quality was widespread in the culture of patients. This system resulted in many unnecessary admissions to the hospital, with multiple consultations and procedures that could have been safely delayed but were often performed. The new current bundled payment model and payment for quality means hospitals now have a new focus on decreasing length of stay and avoiding readmissions. If designed well, this can improve patient care and encourage interdependence across the system from outpatient through the hospital. It also means that now a few smart, strategic, and unique hospitals are consid-

ering flow a top priority. There is hope that this will increase even more in the future.

Leadership

Without top-level hospital leadership support, system-wide change is difficult [6]. The first step in any change management strategy is setting a clear vision. This vision must be simple and clear and able to be articulated by all employees. No change is easy, and without this leadership support and direction, new processes that are developed will quickly regress back to the status quo. Employees must know the "why" behind decisions that are made in order to stand behind them. Intermountain Healthcare is an example of one organization where visible leadership has helped to transform the organization. Leaders have set a clear vision that the goal is to "be a model health system by providing extraordinary care and superior service at an affordable cost." All employees understand this goal, and each department has goals that align with this vision. These goals are discussed at rounds where daily metrics are discussed. Frontline staff can escalate concerns to their manager. There are cascading reports up the chain to a daily report out at the highest leadership level, and each employee feels that their concerns are addressed in a timely manner. Successes on the department level are recognized by top leadership. This high-level leadership support is critical for system-wide flow improvement. Successful leaders are visible, break down barriers for the team, and create the inspiration necessary for success [7].

Vignette 18.1 (Continued)
Flow improvements at the California Hospital described earlier started in the emergency department. After coming back from Lean Training, a multidisciplinary "flow team" was established in the ED. This team had representatives from physician, nursing, tech, and clerical staff. They did an extensive redesign of the process for low-acuity patients. This project was picked because all care was under the control of the ED. Operational improvements for this cohort of patients immediately decreased "left without being seen" rates and markedly improved patient satisfaction. What was most important was that the hospital CEO was very supportive of the work and came to the ED and recognized each of the employees involved and the department. This began the cultural transformation and increased support for the next flow projects. Other employees were eager to participate and join further projects. Without this executive level support, sustained change would have been difficult.

Flow Principles

It is well-known that having satisfied, engaged employees leads to optimal healthcare for patients. Job satisfaction in healthcare is related to many factors: optimized workflows, autonomy and the ability to participate in decisions that are made, and excellent communications and the ability to have a voice without risk of repercussion. Job burnout in healthcare is rampant, and healthcare workers mention that the hours of data entry required in the era of electronic medical records lead to stress and anxiety. While these factors are well-known, it is also very common in healthcare to have a reactive approach to problems instead of really considering the impact of decisions on workers. When a sentinel event occurs, it is common that new procedures are layered on a process and on workers who are already living at the high end of the utilization curve. (Fig. 18.1)

As illustrated by Dr. Chuck Noon in his book *The Definitive Guide to Emergency Department Operational Improvement*, the curve shows that when any system is utilized over 80%, wait times increase exponentially [8]. There is no doubt that procedures and standard work are necessary to

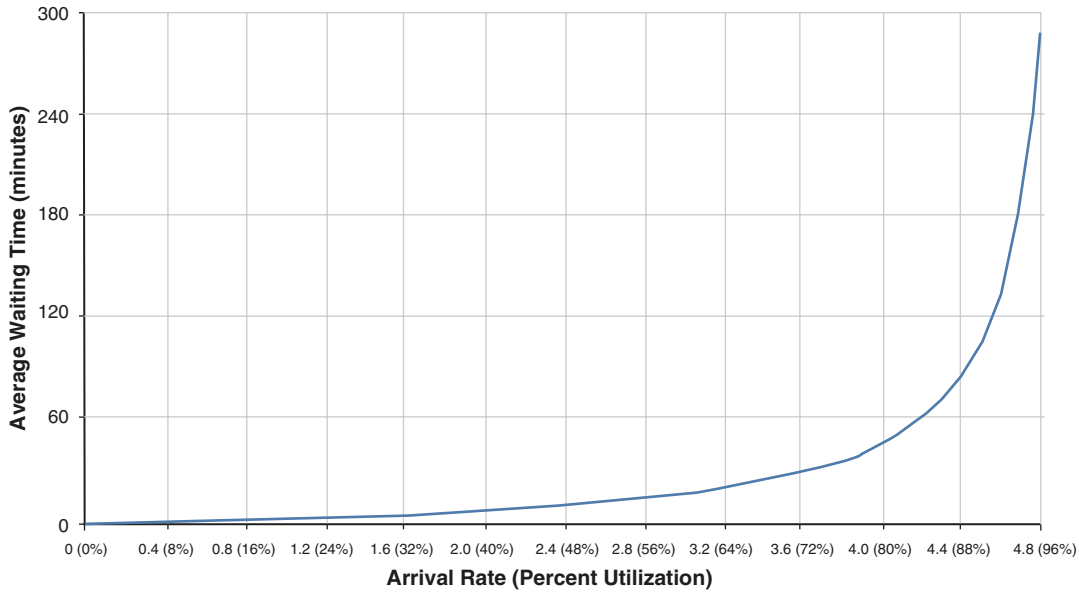

Fig. 18.1 Utilization curve. (Image courtesy of Charles E. Noon)

avoid patient harm but should be done thoughtfully with consideration of what the new procedure does to workers and after a deep dive into the root cause of the problem. It is not uncommon for an unusual and non-preventable patient case to generate new procedures for every other patient in a system. This work may be non-value-added and take away from high-value procedures. When just a few minutes are added on to each patient in a busy system, wait times can increase exponentially. If a new policy or procedure must be incorporated by a busy server, it is critical to look at all steps in the process and either take away another task or redesign the system. Involving the frontline workers in decisions contributes to feelings of autonomy and improved patient satisfaction.

How does patient flow improve quality for patients and worker satisfaction? There are two critical principles of redesign: (1) do "this hour's work this hour" and (2) create systems that are better for patients but easier for people doing the work.

As stated in the IHI white paper on patient flow, the goal is to give patients "the right care, in the right place, at the right time" [2]. Healthcare is full of faulty systems that are done because of legacy designs. An optimal system allows the patient to seamlessly arrive, tell their story once to the healthcare team, get treatments and testing without delay, and go home or be admitted to the hospital. A system like this promotes quality healthcare and also allows healthcare workers to focus on doing what they like best: caring for patients. On the emergency medicine side, this means an even length of stay for patients across the 24 hours of arrivals. On the hospital side, thinking about a 24/7, 7-day a week hospital is ideal. Obviously, this cannot be attained overnight but should be the goal of anyone looking to improve flow in healthcare.

The second principle is creating systems that are better for patients but easier for people doing the work. There are only three ways to create capacity in a healthcare system: decrease length of stay, decrease arrivals to a system, or build more beds. Building beds is not an optimal plan in today's financial climate, so the ideal place to start is thinking about how to decrease length of stay. Decreasing length of stay does not mean decreasing patient care time. Each patient should receive compassionate, customized care with ample time with the healthcare team. This is considered "value-added" work in Lean Healthcare

[9]. Where length of stay can be decreased is in all of the non-value-added activities that occur in medicine. Examples are waiting for care, excess movement and transportation, equipment not available, poor communication and defects, and rework. Improving flow in the ED is a "war won in minutes," and on the hospital side, it is a "war won in hours." When looking at ED flow projects, the goal should be to decrease length of stay by minutes at a time. On the hospital side, the goal should be to decrease total length of stay by several hours at a time. Surprisingly, these small incremental improvements can drive bed utilization down and eliminate waits for patients. This defined means to look at every step in a process critically and redesign patient-centered flow systems that decrease length of stay. (Key Points Box 18.1)

Key Points Box 18.1

Lean Healthcare uses some of the same operational principles originally developed by the Toyota Production Company. Lean Healthcare is a set of operating philosophies and methods designed to create maximum value for patients. It uses basic tools and methods to systematically reduce waste and therefore waits for patients. It emphasizes what is value-added from the patient perspective, employee involvement, and continuous improvement. Waste in the system is considered and removed whenever possible. Waste in Lean Healthcare includes excess transportation, inventory, motion, waiting, overproduction, overprocessing, and defects. Examples include waits for transport, blood hemolysis, cardiac monitoring when not required, and hospital readmission.

Vignette 18.2

Imagine a patient arriving in an emergency department with a wrist injury after snowboarding. The patient signs in at registration and her verbatim chief complaint is entered. She is immediately brought into a treatment room chair and assessed by a physician assistant and a nurse together. The history is taken just once, and all necessary information is gathered. Vital signs are obtained, and pain is treated on the way to radiology. After the x-ray is taken, the physician assistant immediately shows the x-ray to the patient who is reassured there is no fracture. A splint is applied, and discharge instructions are discussed by the team, and all questions are answered. Within 30 minutes the patient is heading back home to their family. The patient cannot stop talking about the excellent care, and the healthcare team has the ability to spend even more time with patients because much of the waste is removed from the system.

There is an old saying "there is only one way to eat an elephant: a bite at a time." The above described care pathway was not developed overnight. It occurred after a systematic redesign of each aspect of patient care. First, triage was eliminated when possible or markedly shortened for all patients. Then, care teams were developed for low-acuity flow. Initially there was a separate office for providers and nurses, but the team recognized this created waste for the patient since the history was repeated. Every step in the process was carefully considered and redesigned after multiple trials with input from all workers and patients. Every step was measured, equipment was standardized and optimized, and care teams were developed. No detail was too small. An example was treating patients in chairs instead of lying on a gurney. A gurney was available if needed, but if not, a chair could be cleaned in 30 seconds, while a gurney took 3 minutes to turnover. This small step multiplied over hundreds and thousands of patients makes a huge difference. The new seamless

process created high-quality care, the highest patient satisfaction, and job satisfaction that was unmatched. Because the team had more time and care was standardized, patient complaints were essentially eliminated. With the new system, the teams were much more productive but still had time to talk with their paired colleague and "make a new friend" as a department leader often stated. These changes were both better for patients in both quality and experience and easier for people doing the work with higher job satisfaction.

Segmentation for Quality

We can infer in medicine that waiting and boarding lead to adverse outcomes for patients simply due to the lack of immediate attention and care. Mathematically, it would seem that pooling of resources to care for patients would optimize care and flow through a hospital system. Considering and optimizing workflows with the main idea of preserving high-acuity beds in both the ED and the hospital can jumpstart flow through the entire system. This segmentation allows care providers to standardize care based on evidence-based best practices. Starting in the ED, the most common type of segmentation is a fast-track area for low-acuity patients. One excellent model locates the fast track near the front door. The goal of design is to minimize movement of the patient and the care team and be sure all equipment needed for the team is at their fingertips. This optimized model has the physician or advanced care provider and the nurse sitting together. The patient tells their story one time to the care team, and all necessary information and data (vital signs, exam) are collected in the one room. If no testing is necessary, discharge instructions and prescriptions are printed in the room and given to the patient. If studies are necessary, a clearly defined area in view of the care team is established as a visual signal that the x-ray is completed. With this model, only two rooms are necessary for care: the assessment room and a procedure room. This system maximizes team work and eliminates most of the motion waste and poor communication of other systems. Improving flow is a war won in minutes, and this method eliminates much of the unnecessary flow. The team can see three to four patients per hour but usually only have one to two active patients because it is a flow-based model. When care is done, the patient is discharged home quickly and efficiently. All members of the care team have more time to spend with patients and less on wasted motion.

Another idea utilizing operational redesign is a vertical treatment area in the emergency department. Traditionally, most patients are treated on a gurney in the ED. These beds become the scarcest resource, and lack of beds creates long waits and delays in care. Almost every ED has over 50% of patients who are categorized as "mid-acuity" and are not differentiated more than that. Many of these patients are well-appearing patients who need more testing to determine the diagnosis. These are the patients that can rapidly occupy all the high-acuity beds and create long delays for patients. There are many workflows done in emergency medicine that continue just because historically they have always been done a specific way. Starting IVs on all patients getting a blood draw is one such procedure. When interviewed, most patients would prefer to just know what is wrong and not have an IV unless medications are needed. There is also much evidence that many medications are safer and as effective when given orally. If a patient presents with a complaint such as abdominal pain and looks well, a vertical treatment space may be ideal. In this system, the patient would again be seen by the care team of a provider and nurse together. An assessment is done including history and physical exam and tests are ordered. A nurse or phlebotomist draws blood, all radiology studies are ordered, and oral medications are given. Instead of lying on an uncomfortable gurney, the patient waits in a "results waiting room." When all tests are completed, the provider brings the patient back into the assessment room to discuss the results and a plan for care. If results reveal something that requires admission, then at that time, the patient can be transferred to the main ED for further treatment. This is a very small percentage of patients. This requires system redesign and

thinking in a different way and considering every step in a process. Each time an unnecessary IV is established, it adds to the nursing workload. Every IV that is inserted must be removed as well. IVs are generally safe but are not completely without risk as well. Peripheral IV infiltrates and extravasations, site hematomas, phlebitis, and air embolism are all known rare complications. Care is improved when the care team is trained to think differently – if a patient is dehydrated and needs fluids, an IV is established, but if it is not needed avoiding this procedure can decrease workload, preserve high-acuity beds, and improve patient quality and satisfaction.

On the hospital side, these same principles hold true. Creation of a low and mid-acuity observation unit will preserve high-acuity beds and prevent boarding for patients. Many hospitals cohort observation patients based on CMS rules that were developed and state that any patient who does not stay "two midnights" should be put into observation status. This has broadened the number of patients on observation status. Cohorting of these patients is faulty and will not improve hospital flow. Observation should be created around standard diagnosis-based care plans with the idea for 24-hour and 48-hour care plans. There is much evidence available about optimal care and quality for various diagnoses. A perfect example is transient ischemic attack (TIA) or stroke without deficits. Often these patients are in the hospital for several days. With careful planning all evidence-based care can be completed within 24 hours. Often, patients are observed on a cardiac monitor for long periods of time even when they do not require it. Patients can have all imaging done, see a consultant, and get an evidence-based treatment plan in under 24 hours. Again, a system that is better for patients, delivers higher quality care, and is better for the healthcare system. There are many diagnoses that are amenable to this kind of care, and a system can be created to optimize both quality of care and flow. Chest pain, syncope, asthma, head injury, and TIA as noted above are all diagnoses that are amenable to a 24-hour observation unit, but any diagnosis that can have a protocol established with clear pathways can be placed in observation. An example of a new process to improve flow is a procedure room co-located within the observation unit. This can allow GI and pulmonary specialists to do procedures easily and allows many more patients to be placed in the unit. Most 24-hour observation units are staffed by emergency physicians or supervised advanced practitioners and nursing staff with hospitalist consultation as needed.

Several other segmented units are possible in the hospital to improve flow. For example, a rapid surgical unit with agreed-upon protocols can provide high-quality, patient-centered care. Patients can understand what needs to happen postop to progress to discharging home before the surgery even happens. Technology can be used to record walking, PO intake, and pain control. These rapid surgical units can decrease length of stay by 24 hours or more – especially if patients are given the discharge information pre-op. Another segmented unit is a medical "48-hour" unit staffed by hospitalists. This is ideal for diagnoses like congestive heart failure and pneumonia that require therapies but are well-defined and have outcome measures for discharge.

There are two primary goals of segmentation: provide protocol driven, patient-centered high-quality care *and* preserve high-acuity beds in the ED and hospital for admitted patients. There is risk with segmentation, however. Queueing theory can help to illustrate this problem. Queuing theory is the mathematical study of waiting lines or queues. It is considered a branch of operations research and originated with research by Agner Erlang when he created models to describe the Copenhagen telephone exchange [10].

Using this mathematical model, in general systems should pool resources, which means sharing patient load among all physicians and nurses to prevent one server sitting idle while the other is overwhelmed. In the ED, an example would be when physicians pick up patients when they feel they are ready in any area and work with all nurses. Despite this general principle, segmented care improves quality and flow when there is an assigned team and clear workflows [11]. The power of each of these segmented care pathways is in the teamwork and how the well-defined workflows are designed to decrease the length of stay. These areas must be designed to

not become the safety net when things are going wrong and prior to initiating volumes must be assessed so each area is highly productive. Using data to design workflows will determine the hours of operation for each segment and help to decide if segmented areas should be combined (combination low and mid-acuity patients in one area) and also the number of observation unit beds in the hospital. Well-defined segmentation can jumpstart flow of the entire hospital system.

Vignette 18.3
A 75-year-old woman comes in with a lower GI bleed at 10 pm. She is rapidly seen by an ED physician. An IV is established, baseline labs are drawn, and her vital signs and hemoglobin are stable. The observation unit is contacted and care is transferred. A standardized bowel prep is started, serial hemoglobin levels are drawn, and a message is left for the GI physician. At 7 am, the GI physician checks the phone and prioritizes patients in the observation unit. The procedure is done in the unit, and bleeding has stopped. Results are discussed with the patient, and she is very happy to go home 14 hours after admission to the ED. The GI doctor states "he can do twice as many procedures easily because he is not waiting for patients to be transported." The patient raves to her neighbors about the timely high-quality care she received.

Teamwork and Communication

In the book *Team of Teams*, General Stanley McChrystal [12] describes two case scenarios: the first in which a plane crew with an hour of fuel, no incapacitating technical issues and clear protocols in place to deal with small technical issues crashed in 1978, and the second and very famous scenario where Captain Sullenberger landed a plane in the Hudson River in 2009 after complete engine failure 2000 feet above the ground. General McChrystal describes how a primary difference in the two scenarios was how the airline crews were structured. In 1978, airline crews were structured as a command. All team members looked to the captain for instructions, orders, and guidance. By 2009, airline crews were structured as teams, and each crew member knew their role and had the autonomy to make decisions under pressure.

Atul Gawande describes this same concept in *The Checklist Manifesto* [13]. He describes the importance of standard work in the form of checklists while still having communication and teamwork to allow each team member to feel comfortable identifying and solving identified problems. In order to improve operations, each team member must understand their individual role in the patient care system. In our current healthcare system, this lack of standard work and role clarity can lead to delays and quality issues throughout the system.

A clear recommendation to improve flow and quality in healthcare is the establishment of care teams. In the ED, the pairing of low and mid-acuity providers with a nurse while minimizing movement improves flow, communication, and quality. For high-acuity ED patients, establishing care teams in the main ED will improve all metrics. When the high-acuity teams are sitting in close proximity and processes are implemented where all team members greet patients on arrival, there are clear communication and expectations set with the care team. Patients are also aware immediately about the treatment team and can be involved in decisions at the outset. This close proximity allows the team to round on patients together multiple times in a shift. This improves communication and balances the workload for nursing as well. Close communication prevents missed orders and clarifies the care plan for the team. On the hospital side, a similar situation is the geographic assignment of hospitalists on the floor. When this is possible, communication is markedly improved and nurses can prioritize work after rounding with the physician. Whether implemented or not, daily multidisciplinary rounding as standard work involving the patient and family has been shown to improve communication, assure all care activities are completed

(checklist), and involve patients and families in decision-making.

Vignette 18.4

In a high-volume ED with a footprint as large as a football field, prior to any operational changes, physicians cared for patients in any area of the department. It was very common for physicians to have patients on each end of the department. It was difficult for nurses to know which physicians were treating patients, and no communication system was in place. One day, the treating physician was sitting at one end of the department, while a patient located on the opposite side had a systolic blood pressure of 70. The nurse did not want to leave the critical patient but was unsure how to find the physician.

The ED leadership team recognized that the system that was in place impeded communication and created uneven workflows. They created care teams of one MD and several nurses who sat together and cared for patients in a pod. A patient came in with a fever and low blood pressure. The team recognized that the patient likely had sepsis, and timely antibiotics and fluids were important to decrease mortality. The team had standard work where the entire team met the patient on arrival. While the physician spoke to the patient and family and got history and placed orders, one nurse completed all tasks and started IV fluids and obtained labs. The other nurse documented the care and obtained timely antibiotics. With timely care, the patient's blood pressure stabilized, and the patient received antibiotics within 1 hour of arrival. The patient was quickly admitted to the hospital.

Performance Improvement in Healthcare

(Key Points Box 18.2)

Key Points Box 18.2

Servant leadership is a leadership philosophy in which the leader embraces care of employees. This varies from traditional leadership where the leader's focus is organizationally driven. A servant leader shares power, puts the needs of the employees first, and helps people develop and perform as highly as possible. The focus is on employee personal growth. The benefit is in increased employee engagement and commitment to the organization [14].

Creating a healthcare system with optimal flow and quality starts with a passion for excellence initiated by a determined leader. This leader creates the vision for either the organization or department and shares it on a daily basis with the healthcare team. Servant leadership means that the professional development of the team is a high priority. The vision of the leader is considered the "true north" and guides project development. The basic principles of Lean Healthcare mean that leaders "go to the Gemba" to see the work, and workflows are not top-down driven but involve frontline workers and a "Kaizen" mindset of continuous improvement. "Kaizen" is a Japanese term that means continuous improvement. This leadership vision combined with a Kaizen mindset leads to a culture of respect that runs through the entire organization.

This leadership and vision can jumpstart a process improvement project. It lets frontline staff know that leadership considers consistent improvement a priority. Leadership commitment to the monetary costs of training staff on basic principles of process improvement and the tools needed for a disciplined approach emphasizes this organizational prioritization. This training allows staff to look at processes with an engineering mindset and a critical thinking approach. The goal of any process improvement project is to create systems that are better for patients but easier for people doing the work. This essential principle guides the selection of frontline staff involved in each project. Process improvement is

a long-term strategy. The goal is continuous improvement with clearly measurable metrics determined at the outset that are visible to all employees. A several day Kaizen event has been shown to change faulty processes that have been in place for years, and the rewards will be in improved quality care, engaged staff with higher satisfaction, and improved organizational financial performance. The staff becomes a "community of scientists."

One option to start the journey is at the department level. After the vision is set by senior leadership, focused Lean training can begin on the unit level. A multidisciplinary team is identified to work on a predetermined problem that creates a bottleneck in the department. Pre-work is done to determine the scope of the project and to develop metrics that will show improvement. During the event, the current process is mapped out with each step written down from the patient perspective. This opens the eyes of the team to problems. Each step is determined to be "value-added" or "non-value-added" from the patient perspective. This creates a framework for the development of a new improved process that is then trialed and a system is put in place to trial along with a plan for complete implementation. At the end of the event, the team presents to upper leadership who relate the project to the overall organizational vision. This validation by leadership begins to create a flow-based culture focused on patient-centered continuous improvement. This step-by-step approach is repeated over and over and when combined with daily operational boards with escalation to senior leadership results in a recipe for high-quality, cost-effective patient care without delays. There are several healthcare organizations in the USA that are well-known for their implementation of Lean Healthcare systems.

Virginia Mason

Virginia Mason, a healthcare system based in Seattle, is known throughout the world as a leader in patient safety and quality by using the principles described above. The journey started in 2002. In 2000, Dr. Gary Kaplan took over as CEO. The company had suffered financial losses that threated long-term survival. He was a visionary leader who told his team: "we change or we die." The entire executive team flew to Japan to observe Lean management techniques and the Toyota Production System and then developed a new strategic plan that was patient-centered and focused on four pillars: people, quality, service, and innovation. They created a program of continuous improvement that also involved patient input. This vision has not varied, and now the medical group has integrated the philosophy throughout the entire system. They now teach process improvement and training to healthcare leaders and are known throughout the world as a patient-centered quality leader because of their search for a perfect patient experience that eliminates errors and defects [15].

Intermountain Healthcare

Another well-known health system that has applied process improvement principles to healthcare is Intermountain Healthcare. They are based in Salt Lake City, Utah, and have visitors from around the world who come to learn how they have developed and sustained improvement. Intermountain started their improvement journey with their frontline team members. They recognized that there was no standard work for frontline managers and employees. They redeveloped charge nurse positions with coaching and clear expectations. Charge nurses were required to round on frontline staff to see if standard tasks were completed. Starting here allowed the organization to spread the culture of improvement both up and down the chain of command. Daily rounds were initiated on each unit with an escalation up the leadership chain including to the CEO, allowing upper leadership to understand problems at the frontline daily [16].

Each of these health systems has made the commitment to strive for perfection using process improvement methodology.

Open Data to Drive Performance

Physicians are often skeptical about data, particularly unblinded data. This is related to a number of concerns. Physicians question the accuracy and relevance of data. Most importantly physicians are skeptical about the intent behind the release of unblinded data. There is general concern that data will be used punitively or that data will be released to the public. Usually, the goal of data release is to influence physician behavior or increase physician productivity.

Vignette 18.5
A study was done looking at two individual EDs. One ED shared blinded data with the group. The second ED shared unblinded data in a different way. The data was combined with identification of high performers and discussion of best practices that were validated with the group. The study found that the first ED had no significant improvement in physician metrics, while the second ED that combined sharing data with education around best practices had a 10.9% improvement in physician productivity with significant reduction in variation across providers. This improvement was not associated with any declines in quality or service scores. The data that was shared was done in a nonpunitive way and was combined with a discussion around the vision for improved patient care and eliminating waits.

When implementing multiple changes to improve flow, it is critical to have well-defined metrics to show that the system is improving. Having a discussion with the staff involved in the process about which metrics will be tracked and addressing concerns about data validity at the onset will improve buy-in and avoid controversies later. When the data is used in context with the vision for high-quality and improved patient care, physicians are less likely to feel individually attacked.

Many organizations make the mistake of sharing multiple metrics without context with workers. Most workers will not look closely at the metrics, and even more importantly many times, this will create a defensive culture and not lead to any organizational improvement. Instead of this, a few well-targeted metrics shared in the context of the vision for improved patient care and flow can engage the entire team. When these metrics are shared with advice on best practices from peers, data can be used to drive performance. Physicians and other healthcare professionals are much more likely to respond to active sharing and a collaborative approach in contrast to passive sharing [17].

Vignette 18.6
At a monthly staff meeting, unblinded data was shared by the radiology champion on CT scan utilization for all providers. Prior to sharing, there was a discussion about possible concerns of the physician group and because of this the data excluded trauma patients where ordering was not under the ED control. When the data was shared, lower utilizers gave their own tips and strategies to the group in a fun and entertaining way. The newest research was also shared including the PECARN (Pediatric Emergency Care Applied Research Network) study with best practices for children with head injuries. One physician reported to the group "I had no idea I was the highest utilizer of head CT's in the department!" She reported later that the positive attitude of the group and the education she received allowed her to comfortably change her practice. The next month, her CT utilization was at the 50th percentile with no quality issues. This improvement was sustained the following year.

Technology to Improve Flow

In the book *Punish the Machine* [18], Dr. Uli Chettipally states that 50% of what physicians do in American healthcare is unnecessary, ineffective, or dangerous. This waste can be categorized as excess movement, waiting, unnecessary steps, unnecessary procedures, and errors. To improve medical care and reduce cost, Lean operations' management with a critical eye and embracing technology are necessary. Currently the electronic medical record is not being used to its fullest potential. At the present time, the computerized medical record is a crude instrument used for documentation, reimbursement, and regulatory compliance. There are two areas in particular that technology could improve flow and quality: operational flow and clinical care.

For operational flow, there is a wealth of opportunity. In Silicon Valley, there are a group of engineers engaged in improving healthcare operations. This markedly different approach uses predictive analytics and machine learning to predict when crowding and surge are about to occur and offers possible solutions. In real time, the analytics can help with flow by deciding which patients should get testing first when a test is the only barrier to discharge. It can schedule the hospital stay so patients know what to expect, and it can notify the physician when all testing is completed and even predicts the probability the patient will be admitted and request a bed much earlier in the process. On the retrospective side, software allows a manager to perform root cause analysis of problems quickly and efficiently. An example is when it is noted that the length of stay was longer during a particular part of the day. The manager can simply click on that period and find out the cause. Perhaps the lab was slower than normal, or radiology turnaround time was not optimal, or there was an influx of patients that overwhelmed the treatment team. This allows targeted improvement to occur. These examples are only the tip of the iceberg for what artificial intelligence can do for operations. Imagine if the second patient walks into the ED, it is predicted that the patient is at risk of a serious outcome. The patient is pulled in front of other less serious patients and immediately seen by a treatment team and care is initiated.

On the clinical side, artificial intelligence is even more promising. New medical research is released daily, and it is impossible for the individual physician to keep abreast of all new trends. There is a widely quoted article that it takes 17 years for a new best practice to be implemented broadly [19]. Programs are being developed to put best practice healthcare recommendations in front of the physician while treating the patient. This allows patients and their families to be involved in the clinical decision-making. While this has much promise and is markedly better than what is available now, the future holds even more promise. Imagine if after seeing a patient, the physician is able to see what the outcome was for the last thousand patients with the same diagnosis and if treatments could be targeted to patient's specific characteristics.

The future is bright for the use of technology to improve both patient clinical care and flow through the hospital system. It will require a new mindset and a partnership between clinicians and engineers to put this in practice. The emphasis must be on helping the clinician deliver high-quality clinical care while eliminating waste and unnecessary cost in the system. The case study below illustrates how data can be used with patients for shared decision-making utilizing best practices.

Vignette 18.7

A 7-year-old girl is brought into the ED after a head injury while playing soccer. She hit her head on another player and fell to the ground. There was no loss of consciousness, but she has a mild headache and nausea. The mother is very concerned and wants a cat scan. As the physician opens the chart, the PECARN rules open, and the physician explains the significance of the study and goes through each of the questions together. At the end, the computer states the risk for serious head injury is under 1/2000, and the physician and

mother have an informed discussion about the risks and benefits of CT. They decide to forgo the CT for now, and head injury instructions are given. They are discharged within 30 minutes of arrival, costs are minimal, and the child has an excellent outcome without the radiation risk associated with an unnecessary CT scan usage. Both physician and mother are very happy with the clinical interaction. (Fig. 18.2)

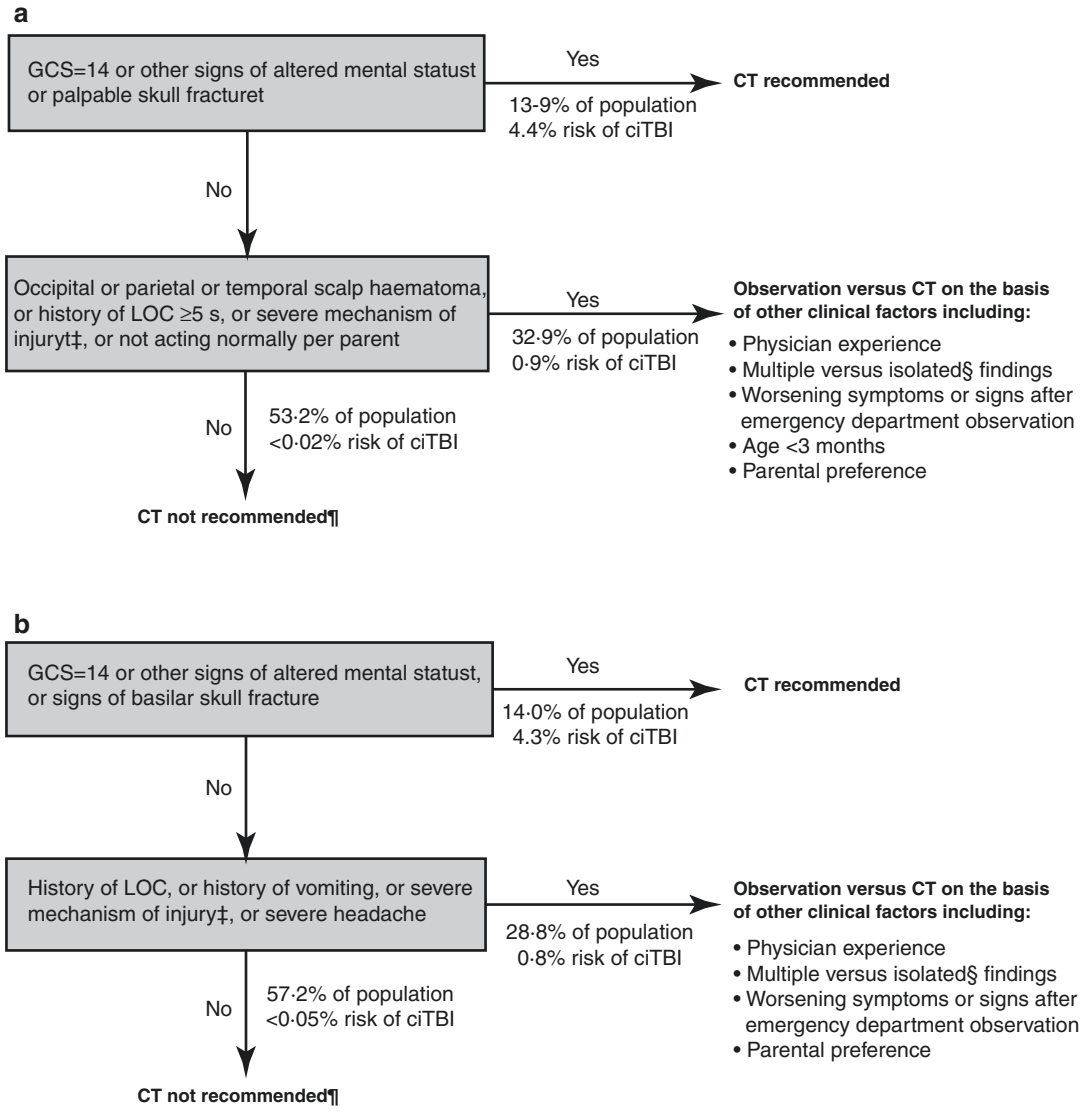

Fig. 18.2 **a** children <2 years of age and **b** is for children ≥2 years of age [20]. Reprinted from The Lancet, Vol. 374/Edition Number 9696, Kuppermann N, Holmes JF, Dayan PS, et al., Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study, p. 1160–11770, Copyright (2009), with permission from Elsevier)

Conclusion

In the USA, about 17% of GDP is currently spent on healthcare. On average, other wealthy countries spend about half as much per person on healthcare. Even more importantly, the quality of care delivered is poor in many instances. A 2014 report from the Commonwealth Fund stated that the USA "ranked last overall among 11 industrialized countries on measures of health system quality, efficiency, access to care, equity and healthy lives" [21]. While the USA has the highest costs, it also has the lowest performance.

Changing this alarming pattern will require a paradigm shift in how medical care is delivered across the system. Excellent patient flow across a system utilizing technology and best practices will deliver the highest quality care. There are bright spots across the country. These must be embraced and used as a stepping stone to even further improvement.

To make this fundamental shift, leadership will be key. These leaders will set the vision for delivering high-quality, cost-effective care while recognizing how important timely care is for both patient and caregivers. This respect for time and elimination of waste will improve patient and family satisfaction and prevent physician burnout. Thinking about how every decision impacts flow is fundamental. Real change will come when the frontline staff doing the work understands the vision and are engaged to solve problems. High-quality care and operations will always be intertwined. While this is not a small undertaking, this vision combined with a mindset of continuous improvement will assure improved high-quality patient care [22].

Editors' Comments

The most important facet impacting the business of healthcare is probably patient flow; having patients move throughout the system in a safe, expeditious manner is crucial for optimizing operations while simultaneously enhancing the finances of the organization. As such, this chapter presents excellent strategies on how to ensure the patient flow in your healthcare system drives quality.

The concept of patient flow is relatively new and may not be fully understood by all of our readers. The author begins the chapter with striking case studies that demonstrate through the vignettes the impact of patient flow on quality, safety, and outcomes; indeed, those of us in healthcare settings have seen this replayed – sometimes on a daily basis. Once the reader understands how patient flow contributes to overall quality and safety not only for that one patient, but for patients within the entire system, then we have reached common ground.

The author builds on the burning platform of patient flow by delving into the science of flow. For the sophisticated reader, the chapter explores how improvement science can lead and support patient flow efforts and how to best consider patient flow from a scientific approach. Through the vignettes, the author highlights specific scenarios such as "low-acuity flow" and "segmentation for quality." Both are explained thoroughly by the author that it is not unreasonable for the reader to pilot some of the strategies that may apply in their healthcare system.

As seen throughout the prior chapters in this textbook, success in managing and optimizing patient flow comes down to teamwork and communication. Teamwork and communication are the keystones for any successfully change endeavor that is of the magnitude and significance as patient flow. The teamwork and communication can be microunit based or can be organizational; depending on the scope of the patient flow initiative, the improvement scientist will have to build the right team and utilize the proper communication channels.

Ultimately, success in managing patient flow will come down to data and technology, the two final areas discussed in the chapter. This chapter serves as an excellent primer to introduce readers to patient flow and to simultaneously guide the advanced improvement scientists on the best strategies to incorporate improvement methodologies to patient flow.

Chapter Review Questions

1. What is the definition of Lean Healthcare?

   Answer: Lean Healthcare is a set of operating philosophies and methods based on the Toyota Production System principles designed to create maximum value for patients. It uses basic tools and methods to systematically reduce waste and therefore wait times for patients. It emphasizes what is value-added from the patient perspective, employee involvement, and continuous improvement.
2. What are the two known impacts on patient care and hospital operations found with boarding patients in the emergency department?

   Answer: Increased mortality and longer length of stay after admission.
3. Describe two examples of segmentation in the emergency department and one example for the inpatient units.

   Answer: (a) In the ED, a streamlined low-acuity treatment area and a vertical treatment area for mid-acuity, well-appearing patient, and (b) on the inpatient unit, an observation unit with defined patient pathways.
4. True or False: The role of a leader is to direct frontline staff on their daily work.

   Answer: False. The role of the leader is to create a vision for the staff and support the process improvement work in process.
5. Does transparent data improve physician performance?

   Answer: It depends. If transparent data is paired with sharing of best practices, physician performance can improve. Sharing of transparent data is not a panacea, but there is broad subjective sentiment that transparency drives improvement.
6. What is the definition of Kaizen?

   Answer: Continuous improvement. A Kaizen event brings a group of people together in a structured way to solve a well-defined problem.
7. Describe two ways that analytics will help improve flow and patient care in the future.

   Answer: Analytics can help with retrospective review of issues, real-time "pushes" to staff to assist with workflow, and prospective predictions of high volume with recommendations to plan for it. On the clinical side, analytics can bring best practices up to the clinician and allow shared decision-making with patients and family.
8. Describe a basic framework for process improvement in healthcare

   Answer: Process improvement is best when leadership sets the vision. Lean education of frontline staff ensures everyone uses the same methodology for projects. This combined with multidisciplinary teams for process improvement, Kaizen events, and clear metrics using technology create a robust framework for improvement.

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19 It Takes Teamwork: Consideration of Difficult Hospital-Acquired Conditions

J. Wesley Diddle, Christine M. Riley, and Darren Klugman

Chapter Objectives

- To explain the high risk ICU environment and the associated impact on patient safety
- To define hospital-acquired conditions, using unintended extubations as an exemplar
- To highlight the importance of interprofessional collaboration and system redundancy in quality improvement processes
- To understand the impact proactive process maintenance has on assuring sustainable gains

Vignette 19.1

In a tertiary care free-standing children's hospital, an unintended extubation occurs in an infant in the cardiac intensive care unit (CICU). The patient experienced a brief cardiac arrest during the efforts to re-secure the airway, and she received cardiopulmonary resuscitation (CPR) for 3 minutes before return of spontaneous circulation (ROSC). Because of the serious nature of this safety event, a root-cause analysis (RCA) was convened to explore factors contributing to the inadvertent airway loss. That process identified several factors that potentially increased the likelihood of an unintended extubation: the event occurred during nursing sign out; the endotracheal tube (ETT) was noted to be high by radiology on the morning X-ray; the patient has been in the CICU, intubated, for more than 3 weeks, and she was described as "difficult to sedate" by several bedside providers; the respiratory therapist (RT) involved in the case typically works in another unit in the hospital but was "cross"-covering the CICU during this shift. Unit leadership, with the support of hospital leadership and the assistance of the Quality and Safety Team, has been charged with reducing the chance of similar future events.

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Opening Problem

Hospital-acquired conditions (HACs) can result in additional, preventable harm to patients in any milieu, but patients in an ICU are particularly vulnerable because of their disease complexity, level of invasive monitoring and support devices, and frequent procedures and blood draws, multiplying the opportunities for lapses in safety and subsequent harm. This chapter uses one type of preventable event – unintended extubations in a pediatric CICU – to explore the unique challenges to patient safety and quality improvement inherent in the ICU environment. This chapter is not about unplanned extubations per se; rather it uses this hospital-acquired condition as an exemplar to demonstrate the generalizable principles necessary for achieving and sustaining improvement in this setting.

Introduction

While an intensive care unit typically accounts for only a fraction of the total bed spaces in a hospital, it accounts for a disproportionate share of hospital activity, whether viewed in terms of hospital charges, acuity, or utilization of hospital resources (laboratory, pharmacy, nursing, engineering, etc.) [1–3]. In addition, hospitals are characterized by more than just numbers of beds, or revenue; they are the backdrop for stories about patients' lives. The stories that unfold in the ICU are among the most dramatic, whether they detail a miraculous recovery or a tragic loss, and they impact patients, families, the hospital community, and the local community, to a degree out of proportion to the number of beds they represent.

The pediatric cardiac intensive care unit has emerged as a separate ICU in many children's hospitals over the course of the last two decades. Improvements in surgical and cardiopulmonary bypass technique have led to the performance of palliative and corrective surgeries in progressively younger and more complex patients, such that even the most complex lesions are now routinely operated on in the neonatal period. Patients who were previously considered to have nonsurvivable congenital cardiac anomalies or to carry a prohibitively high risk for operative mortality now routinely undergo complex operations in spite of gestational age or weight and often while still in the midst of the physiologic transition from fetal life. Such patients can be quite fragile due to their cardiovascular pathophysiology prior to operative intervention, but they are often even more so in the immediate postoperative period, when the vulnerabilities secondary to an inefficient circulation are magnified by the systemic effects of cardiopulmonary bypass. This combination of underlying circulatory pathophysiology and transient bypass-related instability leads to a low level of resiliency in this patient population. This has helped drive the creation of dedicated cardiac intensive care units and a concomitant sub-specialization of training for medical, nursing, and ancillary staff.

The expansion of pediatric cardiac intensive care units has led to new challenges and considerations for care delivery. The benefits of subspecialization in the CICU are widely accepted, but this a level of expertise requires extensive education, additional training, and significant practical experience. The opening of CICUs at pediatric centers around the country over recent years, coupled with a high-intensity work environment which is associated with elevated levels of burnout [4–7], means that there simply are not enough experienced nurses to fill the available positions. As a result, in any given CICU, during any given shift, there is a growing number of novice providers at the bedside. Additionally, trends such as the prolongation of medical training, in-house 24/7 attending coverage, and assignment of higher-risk patients and procedures to specialized staff mean that residents and fellows show up to the CICU with less experience and comfort with complex physiology and procedural expertise than in the past. Consequently, hospitals and training programs have had to devise educational models that aim to rapidly get junior staff the knowledge and skills they need to perform their jobs optimally. One means of addressing the wide variability in experience levels is protocolization of care. Formal protocols enhance safety and decrease practice variability among providers, optimizing patient safety even when provider experience level is varied [8].

Vignette 19.2

Following the RCA, local nursing, physician, and respiratory care leadership identified several strategies to better understand and address the problem of unintended extubations (UEs). The first was the decision to identify UEs as a modifiable problem; although UE had been tracked for years, it had not previously been given the rigor of other quality metrics such as central line-associated blood stream infections (CLABSIs) or catheter-associated urinary tract infections (CAUTIs). After making the cognitive leap to characterize the issue as a modifiable metric rather than an accepted risk, a prospective registry for UEs was created, with a plan for data collection to better understand the scope of the problem. Concurrently, the following immediate interventions were put in place, based on suggestions generated during multidisciplinary brainstorming sessions:

- The RN and RT would measure the ETT position each morning before the chest X-ray was taken and document that position in the patient record and on the ventilator at the patient bedside.
- As an additional safety check, the RN would explicitly verbalize the ETT position at morning rounds with the medical team.
- ETT manipulation would always be performed with two providers. If ETT malposition was recognized and needed to be addressed during sign out, a minimum of two people would complete the task, and sign-out would be paused until the security and proper positioning of the airway was assured.
- Repositioning of the ETT first requires a discussion regarding the need for additional sedation or neuromuscular blockade, empowering nursing and respiratory staff to advocate for these to be ordered if needed.

Framing the Problem

Local, multicenter, and nationwide efforts to identify best practices and reduce unwanted practice variation have led to increased use of protocols or guidelines to help standardize care [9, 10]. Initially, guidelines may be based on expert consensus; however, over time, the data should be accrued to inform and refine best practices. The unit leadership in the vignette is following the business management adage "if you can't measure it, you can't improve it," in establishing a registry to characterize the problem of UEs. The model for improvement provides a simple framework to guide improvement efforts, and the necessity of good data in those efforts is evidenced by the model's questions. After first identifying what we are trying to accomplish (i.e., reduce unintended extubations in the CICU), the second question in the model is "How will we know a change is an improvement?" A dramatic event such as the airway loss leading to cardiac arrest described above may well motivate changes in unit practice that will result in improvement, but cognitive biases towards dramatic or recent events can result in an incomplete or inaccurate picture of the scope of a problem. Objectively recorded data over time can inform more logical, thoughtful responses to problems, and it enables a unit to measure the impact of their interventions. Sometimes what "feels" like the right way to address a problem is an appropriate and effective solution, but just as often it may not have the intended effect in practice; data allow for the distinction to be made and corrective actions to be taken.

Data Collection

Both multicenter data and local data have value. Multicenter registries leverage the statistical power of the greater number of events to identify predictors and patterns which might not be evident in the data from a single center and may identify patterns which persist across a variety of practice patterns and patient populations. Such registries may also enable comparison of local practice and outcomes to other centers, identifi-

cation of best practices, and the establishment of benchmarks that individual centers can strive for.

Frontline Investment and Stakeholders

It is critical to seek input from frontline staff when planning and implementing performance improvement initiatives, as showcased in this vignette. Frontline staff interact with the system in a very different way than those in leadership. Charging the staff to address the problem rather than dictating interventions to them grants staff buy-in and ownership in the improvement process. This sense of ownership promotes engagement and increases the likelihood of the long-term investment necessary to produce sustainable gains. Involvement of frontline staff also leverages their detailed knowledge of day-to-day unit operations, making it more likely that new interventions will fit seamlessly into established practice patterns. When planning interventions, the "hassle factor" should be considered. Even well-intentioned providers may be unlikely to participate in interventions that dramatically increase the time or cognitive burden required to complete a task. Streamlined interventions that are built into current practice patterns and workflow are more successful over the long term.

Background of Hospital-Acquired Conditions

Introduced as a concept by the Center for Medicare & Medicaid Services (CMS) as part of Medicare reform in 2008, HACs were defined as an undesirable situation, condition, or complication that a patient develops during a hospital stay that was not present at admission [11]. Traditionally, many HACs have been characterized as infections secondary to devices or procedures, but the list is updated by the CMS on an ongoing basis (see Table 19.1 for a complete list of 2008 and 2018 HACs). Great strides have been made in decreasing HAC rates through the utilization of care bundles [11, 12]. Expanding this definition and classifying UE as a HAC was novel and allowed new interventions to be rolled out utilizing a vocabulary and paradigm of improvement that staff was familiar with.

Table 19.1 2008 and 2018 hospital-acquired conditions per Center of Medicaid Studies [13]

Hospital-acquired conditions per CMS	
2008	2018
Foreign object retained after surgery	Foreign object retained after surgery
Air embolism	Air embolism
Blood incompatibility	Blood incompatibility
Stage III and IV pressure ulcers	Stage III and IV pressure ulcers
Falls	Falls
Manifestations of poor glycemic control	Manifestations of poor glycemic control
Catheter-associated urinary tract infection	Catheter associated urinary tract infection
Vascular catheter-associated infection	Vascular catheter-associated infection
	Deep vein thrombosis/ pulmonary emboli following hip replacement
	Surgical site infection
	Iatrogenic pneumothorax with venous catheterization

Vignette 19.3

It is 1 year later, and the rate of UEs is being reevaluated at an annual review of unit data. After a dip in the frequency of UEs following the sentinel event the previous year, the incidence has increased over the last 2 months. A detailed review of cases reveals that several of the UEs occurred when the ETT was in a higher position than ordered by the physician – i.e., it was measured and documented by the RT and RN as being higher than ordered, but no intervention was taken to remedy the situation. It is also noted that the use of PRN sedation prior to re-taping of ETT's has decreased, in part because of a national shortage of the most frequently used medications for sedation. The unit reviews the current care bundle in light of these recent changes in local practice and

decides to implement the following interventions aimed at hardwiring best practices and creating visual reminders for staff:

- Incorporate a mandatory field for ETT position into the ventilator order set, forcing the medical team to be explicit about the desired ETT position.
- ETT position will be included as a quality/safety metric on the unit quality dashboard, which will auto-populate the ETT position once entered by the RT and automatically highlight if it differs from the ordered position.
- When weekly medication shortage updates are sent out to the unit, alternative sedation medications with suggested dosing regimens will be included in the emails, and the unit-based pharmacist will highlight the readily available options appropriate for a patient during rounds, in order to anticipate potential sedation needs.

Sustaining Initial Gains

Interval review of processes and data with practice audit and feedback to local teams is essential in order for quality improvement efforts to sustain a positive impact over the long term. Continued surveillance and audit may identify unintended effects and/or cross talk of various QI efforts in the complex environment of the CICU. In the case described, well-intentioned efforts to address drug shortage issues had the unanticipated downstream effect of frontline staff reducing their use of sedatives in some cases where their use would have been appropriate, perhaps contributing to an environment where an unintended extubation was more likely. Purposeful solicitation of input from frontline staff, as part of the continual assessment and refinement of the QI efforts, allowed for the identification of this unintended consequence. In addition, it helped elucidate the reasons that a bundle element was difficult to implement during this time period. While bedside staff was measuring the ETT position daily, as specified in the bundle, this was not effectively triggering appropriate action by the medical team. To effect changes in provider behavior, additional interventions were required. Involving the unit-based pharmacist to not only provide information regarding drug shortages but also provide anticipatory guidance on alternatives helped ensure that sedation was being given when appropriate. Introducing an automatic trigger for medical providers to verify ETT position when placing respiratory care orders ensured that when this information was provided by bedside staff at rounds, it would prompt an action by the medical team to reconcile any differences between the ordered and actual endotracheal tube positions. This set up a "call and response" or "push and pull" dynamic, wherein different provider roles reinforce one another towards a shared goal. This example reinforces the need for the presence and active participation of multiple stakeholders in the planning process (see Fig. 19.1 for a cause-and-effect diagram), prospective data collection with planned periodic data review (see Fig. 19.2 for run chart), and ongoing involvement of stakeholders representing the entire spectrum of providers who would be implementing or affected by the efforts.

Sharing data within organizations also provides opportunities to learn and discover new ways to tackle problems that may not be unique to a single unit or environment. As part of the broader organizational approach to HACs and specifically UE, the CICU UE team began meeting regularly with other ICU team members who were also working on reducing UE in their respective areas. Meetings included data sharing from each unit with sharing of successes and challenges. These meetings, which include data and process sharing across ICUs, are powerful venues to translate successes from one area to another and also to learn from experiences of others who faced similar challenges. Critical in sustaining success is the ability to share data with frontline staff and more broadly across an organization. Knowledge of the data should be universal and is an important tool to maintain momentum and ensure long-term success.

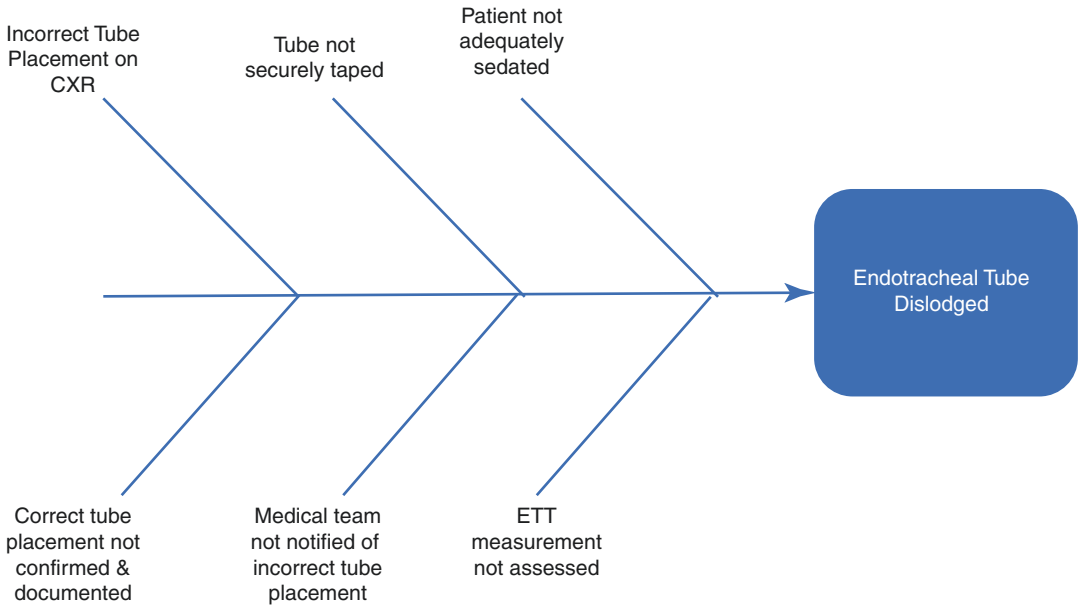

Fig. 19.1 Cause-and-effect diagram

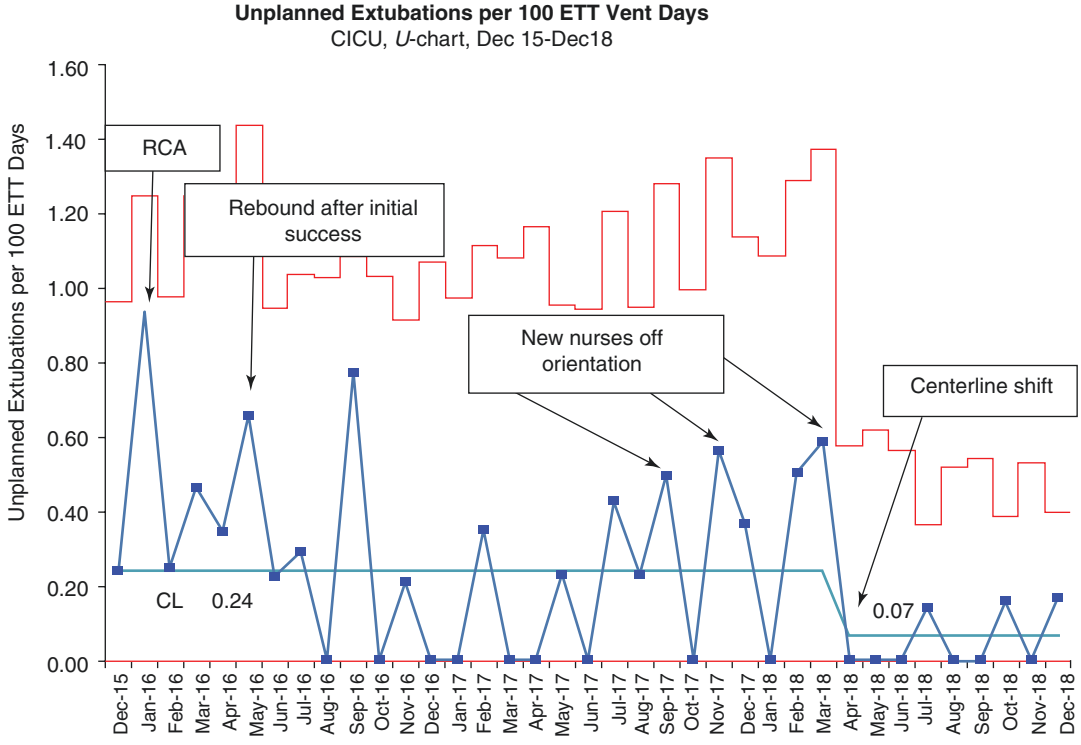

Fig. 19.2 Sample run chart

Redundancy

Redundancy is necessary to embed a practice change, and it will be most effective if actions are reinforced at multiple levels across professional roles. In this case, order set modification to create a field that triggers a mandatory prompt for medical staff supplements and supports the efforts by the bedside nurse and respiratory therapist to ensure appropriate ETT position. It ensures that their efforts of measurement, documentation, and announcement are acknowledged by the medical team. Based on review of the X-ray and the patient's trajectory, the most appropriate action may be to adjust the order to reflect the reality of the current ETT position, or it may be to provide additional sedation, adjust tube position, and repeat an X-ray. The redundancy built into the architecture encourages the necessary data acquisition to facilitate decision-making and creates a trigger for the dialogue to come to a decision. Ideally, such redundancy supports the overall goals of the QI efforts without significantly increasing the cognitive burden of the staff involved. Optimizing technology to support the staff efforts is one way of creating redundancy without assigning more "tasks" to the bedside staff. In this ICU, a quality dashboard pulled data automatically from the electronic medical record to a flat screen monitor mounted on the wall, prominently displaying a number of important quality and safety metrics for each patient. This dashboard was an accepted fixture of the unit's culture, and the care team begins rounds at the quality board during morning and evening rounds. Working with the information technology (IT) department, ETT position data was added to the dashboard, with color-coding of the data when a discrepancy existed between documented and ordered positions. This intervention built upon a familiar landmark and workflow in the unit, and it created a visual reminder that could be quickly appreciated by the team before rounds even began. As the available technology in our hospitals continues to be updated, revamped, or overhauled, we must seek out opportunities for the technology to support our work, rather than add to the burden. IT services can be a crucial ally in creating and supporting successful QI efforts.

Small Tests of Change

QI in complex care environments may be more accepted by staff, and ultimately more successful, when done as small tests of change rather than attempting a dramatic process overhaul. Small tests of change are mini-interventions that allow teams to quickly and effectively test new ideas. These changes, undertaken as Plan-Do-Study-Act cycles, allow for change to be grafted onto existing practice, where they can be viewed as modifications of the familiar rather than seen as a new burden to be added to the existing task load. Incorporation of provider feedback early and often can help inculcate a culture that is accepting of change and expecting to have a say in the details of that change. This culture can lead to a unit which is more engaged in the QI efforts and which understands QI as a continuous process rather than a project with discrete endpoints. Internal data review assures that interventions remain pertinent and effective accounting for unexpected variations in local practice patterns. Feedback from frontline staff should be frequently solicited, resulting in modification or even elimination of interventions that don't enhance team performance or have a high "hassle factor."

Vignette 19.4

It is 2 years later, and the overall rate of unintended extubations has remained low, but a pattern has been noted in the occurrence of UEs – they tend to increase when there is an influx of new bedside nursing staff. The unit is a high-intensity environment, with high turnover among staff. In addition, significant variability has been noted among the medical staff in terms of use of the safety dashboard as a resource on

rounds. Several tests of change are implemented:

- Best ETT re-taping practice is incorporated into the onboarding of new nurses and RTs when joining the unit, and an electronic copy of the practice is made available on the unit website.
- A joint review of the unit dashboard by the medical teams, charge RN, and RTs is to be performed each morning prior to the initiation of bedside rounds to ensure that ETT malposition is recognized and a plan is put in place to address them.
- Unintended extubation data will now be incorporated into a periodic summary of key unit quality metrics that will be shared with all members of the unit on a quarterly basis, in order to help staff move from personal anecdotal experience to a more global understanding of the state of safety in the unit from a data-driven perspective. When UEs remain low, this success will be highlighted and the importance of the coordinated efforts of the members of the team reinforced; when there are spikes in the frequency of UEs, these data will be broadcast along with reminders to adhere to best practices and solicitation for input regarding creative solutions.

As this case study has highlighted, quality improvement is a dynamic process, not a project with a discrete beginning and end. Evaluation and modification must be ongoing to create sustainable gains in a complex care matrix like the CICU. QI is also a team effort. Stakeholder representative of the broad spectrum of providers in the unit should not only be involved in process planning but also in process maintenance, and their dual roles as effectors of change and providers affected by change should be explicitly recognized. Good data is essential to inform ongoing efforts, and it should be anticipated, reported transparently, and the results should be reported at routine intervals for iterative data analysis and feedback. Interventions must be streamlined and easily incorporated into current practice, avoiding undue complexity which might lead them to be abandoned, challenged, or ignored. Whenever feasible, interventions should be hardwired and redundancy created, so that the various silos in the care hierarchy support one another in common purpose. Education needs to be on a continuous cycle to re-educate existing staff, ensure ongoing competency, and maintain awareness of guidelines and practice expectations. Ultimately, culture change cannot be achieved unless staff are engaged, educated, and motivated, which requires active participation by empowered stakeholders and positive meaningful leadership investment.

Editors' Comments

Hospital-acquired conditions (HACs) originally described as a term in 2008 by CMS, but implied in the 1999 Institute of Medicine report [14], are a major focus for healthcare organizations globally. No healthcare worker comes to work planning to cause harm – but few healthcare systems are well designed to help their team members completely prevent HACs from occurring. As discussed in the preceding chapters, their inherent complexity makes the pursuit of zero harm challenging, but these challenges are no more insurmountable than those faced by high reliability organizations (HROs). The authors of this chapter have successfully embedded HRO principles in their HAC reduction efforts in their cardiac intensive care unit, especially pre-occupation with failure, sensitivity to operations, and reluctance to simplify. Their use of automated boards, or andons, that point out patients at risk of unplanned extubation are consistent with the Toyota Production System principle of *jidoka* or building quality into their processes discussed in earlier chapters. The authors and

their organization have made HAC reduction and their prevention into a team sport, a success that many organizations will want to emulate. Team building and engagement are key points emphasized in this chapter to build a learning system that will help all health systems drive to "zero harm." Their admirable focus on sustaining their gains, building redundancy, and small tests of change only further encourage their teams' engagement. The authors have demonstrated the practical application and alignment of many of the key improvement and safety science principles mentioned in the earlier chapters. Steven Spears [15] in *The High Edge Velocity* described four capabilities of successful complex organizations: (a) visualizing problems as they occur; (b) timely problem solving; (c) spreading new knowledge learned; and (d) leading by developing capabilities a, b, and c. Our authors' cardiac intensive care unit is an excellent example of a system designed for success which captures all of the aforementioned capabilities. In the spirit of continuous process improvement, their work continues to even further improve their outcomes for their critically ill, mechanically ventilated patients.

Chapter Review Questions

1. What is a hospital-acquired condition?

   Answer: Introduced as a concept by the Center for Medicare & Medicaid Services (CMS) as part of Medicare reform in 2008, HACs were defined as an undesirable situation, condition, or complication that a patient develops during a hospital stay that was not present at admission [11].
2. Define "small test of change"

   Answer: Small tests of change are mini-interventions that allow teams to quickly and effectively test new ideas. These changes, undertaken as Plan-Do-Study-Act cycles, allow for change to be grafted onto existing practice, where they can be viewed as modifications of the familiar rather than seen as a new burden to be added to the existing task load.
3. True or false. Frontline buy-in isn't necessary to sustain culture change as long as strong leadership is present.

   Answer: False
4. Why is redundancy important when planning and maintaining QI initiatives?

   Answer: Redundancy is necessary to embed a practice change, and it will be most effective if actions are reinforced at multiple levels across professional roles. In this case, order set modification to create a field that triggers a mandatory prompt for medical staff supplements and supports the efforts by the bedside nurse and respiratory therapist to ensure appropriate ETT position.
5. True or false. QI is a discrete process with defined start and endpoints.

   Answer: False. QI embraces the principles of continuous process improvement, wherein each small test of change, whether defined as successful or not, provides a new opportunity to evaluate the system for opportunities for improvement.

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Human Factors in Healthcare

20

Laurie Wolf, Sarah Henrickson Parker, and Jonathan L. Gleason

Chapter Objectives

- Provide a brief introduction to the science of human factors.
- Discuss applications of human factors to complex clinical problems.
- Provide readers with resources to integrate human factors into their clinical practice.

Grounding Question

Healthcare is a complex adaptive system of humans and technology. To ensure optimal performance, the system must be designed to account for human limitations and augment human capabilities. In healthcare, we often struggle because human-machine interactions are not designed as such. Our grounding question is how can a healthcare system integrate human-centric systems design into daily operations? What is human factors science, and how does it impact patient and provider safety in healthcare?

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Introduction

Definition of Human Factors (HF)

The International Ergonomics Association defines human factors (HF) as "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance" [1]. The term "human factors" can be a misnomer that attributes the cause of the error to a human action [2]. The science of human factors takes a systems approach to fully understand all the circumstances that contributed to the error. A "systems approach" indicates the entire work system in which a specific job or healthcare function is executed. A system approach is focused not just on single system elements or single processes but the overall function and interactions of component parts within a system. "…[To] improve safety, quality, performance and comfort, a good place to start is by analyzing the involved systems so they can be improved" [3] (p. 337). Historically, healthcare has adopted the

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perspective that the system is well designed and the human operators are to blame when something goes awry. This approach leads to attempted "redesigning" (training) of the humans within the system, rather than exploring *why* or *how* the design of the system might've influenced the human working within the system. As healthcare organizations continue to build and seek new tools to address patient safety challenges, human factors engineering (HFE) has become a prominent science to provide tools and methods for application within healthcare. HF and HFE are used alternately throughout this chapter for sentence structure with the same content intention.

Vignette 20.1
HF is sometimes best explained by understanding case studies as examples to illustrate important principles. The following hypothetical case illustrates an event in which a chest tube is inserted into the wrong lung due to misinterpretation of an x-ray during a code event in an intensive care unit. Clinically informed HF analyses typically reveal a complex array of contributing factors. The visual display on the portable x-ray machine can be confusing and exceed human capabilities in the context of a code event. For example, multiple colors on the interface that are barely distinguishable from one another yet are supposed to direct visual attention can be ambiguous. In addition, the orientation of the image as it is designed to be captured is backward (again, by design), only to have to be flipped by the x-ray technician. The only way this default orientation is rapidly identifiable is by the small lettering in the corner of the display. This small lettering is difficult to read and could be missed in any situation, particularly an emergency. The images are small, and it is difficult to determine which image is highlighted. A strong intervention would be to purchase an adaption to the x-ray machine that would improve the user interface and enhanced the display to reduce the risk of error.

History of Human Factors

In its early incarnations, the study of humans at work was focused on physical (not intellectual) work. The term "ergonomics" (the study of work) was most frequently used to explain the science of understanding humans at work. Early studies explored time and motion of humans in a work setting, showing that industrial workers were neither as safe nor productive as possible, because of mismatches between the physical layout and design of the work setting and human capabilities [4]. Initially, it was conceptualized that only selected individuals would have the aptitude or capability to interact with complex new machines, such as cars or airplanes. In the military, psychologists were recruited to develop and administer tests to identify individuals with the natural skills to perform such tasks. However, with the proliferation of technology, only selecting individuals with specific aptitudes became untenable. At this point, the idea that technology needed to be designed for its user, rather than the user adapted to the technology, began to take root [5].

Human factors engineering (HFE) began as a formal discipline after World War II, primarily in the military and aviation domains before moving into other industries in the 1970s. Events in other industries such as the "Three Mile Island" nuclear accident in the USA and the "Bhopal gas tragedy" in India resulted in several regulatory documents, outlining how HFE must systematically be incorporated in system design. HFE has been utilized in healthcare to a small degree since the 1980s; however, HFE became more prominent in healthcare during the 1990s with the shift in culture away from "blaming the user" and identification of active (user) and latent (systems) failure [6].

In the original incarnation of HFE in the USA, the focus was on making humans faster and more productive. Industrialists such as IBM's T.J. Watson were discussing how to integrate support for humans into work to increase efficiency and productivity. Fitt's list [7] attempted to develop a list of functions that were better allocated to humans and those that were better allocated to machines. This type of thinking – to

design the inefficient and error-prone human out of the system – still proliferates today. In many systems, taking the human out of the loop is desired. However, as the field of HFE has matured and the complexity of work has grown exponentially, there are many other perspectives to appropriately integrate human capabilities and limitations into work.

Initially, the study of human factors was largely focused on optimizing the performance of one individual during specific tasks (e.g., pilot stick and rudder skills during landing). Therefore, many interventions were focused on the design of individual interfaces or dealing with issues such as individual memory capacity or acute stress performance or fatigue. In recent years, the research trajectory has evolved to consider the influence of work context (e.g., its social and environmental setting) on human performance. For example, the study of cognitive systems integration evolved because of the need to manage dynamic function allocation between humans and computers [8]. HF practitioners now consider context at least as, if not more, important to understanding how humans conduct their work.

In its recent iterations, HFE has evolved to consider the much more complex evaluation of sociotechnical systems [9, 10]. In addition to the environmental context of work, the tools with which work is performed and the technology that is becoming ubiquitous, there has been an increasing emphasis on the social conditions of work settings. Often, people work in teams, and the productivity of a team is contingent upon more than simply the action of each of its individual members. Now, HF must consider not just the individual dynamics but how teams engage in leadership and coordination and back up behaviors among others [11, 12].

To date, HFE professionals within healthcare are largely working on individual reactive use cases or within industry they are designing technology for use within health systems. The opportunity remains for clinically informed translational HF teams to be fully integrated into the proactive continual redesign of clinical operations. That is, a realistic understanding of clinical challenges and early integration of HF contributions into research and design will enhance usability, efficiency, and error prevention of medical equipment and environments.

Domains of Human Factors

The foundation for HFE is based on three general domains of specialization: physical, cognitive, and organizational [1, 10].

- Physical domain – Includes human anatomical, anthropometric and biomechanical characteristics, material handling, posture, repetition, workplace layout, and physical capabilities (for all senses). These concepts can be used in healthcare to reduce worker and patient injuries and achieve optimal workplace layout and environment (sound, lighting, glare, floorplan).
- Cognitive domain – Includes mental workload, perception, memory, reasoning, decision-making, human-computer interaction, human reliability, and stress. These concepts can be used in healthcare to evaluate usability of technology, design training systems, and develop user interfaces. Cognitive issues are critical when understanding incident or event reporting system and analysis process.
- Organizational domain – Includes sociotechnical systems, organizational structures, policies, communication, job/work design, shift work, participatory design, and teamwork. These concepts can be used in healthcare to design jobs that will reduce stress and burnout and improve patient and staff satisfaction. Organizational issues must be considered when designing patient care models to achieve appropriate work schedules and enhance worker performance and processes.

It is a misnomer to think of HF in the context of focus on one individual or to change that person's behavior or even to eliminate error. On the contrary, the science of HF is based on a systems approach that considers environment, task, organization, culture, workflow, and physical/mental

capabilities and limitations of groups of users. The goal is to optimize the system for humans so that they can accomplish a goal efficiently and with minimal risk of error. That is, design a system for human use, not to change the human to adapt to the task.

Human factors is a scientific discipline that requires an academic degree. It is not simply a set of tools or methods that can be learned in a certification class. We acknowledge this difference because there is a proliferation of certification courses in lean and six sigma, specifically for healthcare. While these are critically important to advancing patient safety and process improvement in healthcare, the HF approach requires additional training. There is a board certification process offered by the Board of Certified Professional Ergonomists (BCPE) that requires a degree, several years of experience, approval of a body of work, and successfully completing a proctored examination. There is also a society called HF and Ergonomics Society (HFES) with annual, international conferences, and resources available on the website (https://www.hfes.org/home) [13].

Key Points Box 20.1 Introduction

- Human factors is a scientific discipline.
- Human factors is ideal to apply to complex, dynamic systems that are prone to human error.
- Human factors research is translational to clinical practice and implemented to benefit patients, employees, and the community.

Human Factors, Design, and Implementation Science

For any best practice to be implemented into care, they must be translated from idea into action. In healthcare, this translational timeline has been estimated to be 17 years for 14% of original research to result in patient benefit [14]. An editorial from 2006 stated "the promise of a cure requires an additional step: patients must receive treatments promptly and properly… we spend far more money on inventing new treatments than on research into how to deliver them…" [15]. This elongated timeline, alongside of a historical lack of investment in the science of healthcare delivery, has resulted in the relatively new field of implementation science.

There are two translational opportunities in the clinical research continuum: (1) translation from basic science to human studies and (2) translation from human studies into clinical practice and health-related decision-making. This second stage – from human studies into clinical practice, represents a significant opportunity for human factors. Clinical practice translation often requires humans to change their behavior or to use a new device or technology in their work.

As previously stated, the design of the work system is highly influential on how humans behave in practice. The heart of HF is to design an implementation of a process change or a new technology with the specific needs of the human in mind. By considering the human who is doing the work, within their specific work context and within the complex sociotechnical system, there are opportunities to identify gaps in design, which can result in better interventions. (Key Points Box 20.1)

Systems Approach

A complex system like healthcare must take a systems approach that considers human capabilities and limitations for an understanding of process issues because humans are fallible. Healthcare is a microcosm of constant change (nonlinear, chaos). Many disciplines must collaborate to develop a systems approach to achieve safe interventions in healthcare [16, 17]. HF explores a problem by looking at the people within a system, their interactions with each other, the environment, and organizational components. The goal is to redesign tasks, equipment/environments using a systems approach to achieve a safe environment or process where the human can succeed by working efficiently with

minimal risk of error and, perhaps more importantly, minimizing the risk of harm when errors do occur. The following is a sample of some common models to ensure HF achieves a systems evaluation/design approach.

Work as Imagined Versus Work as Performed

The healthcare environment today is dynamic and complex due to technologies, equipment, patient acuity, healthcare staff changes, teaching and research challenges, and complicated team relationships. With all these constantly changing factors, it is inevitable that the way we imagine the work should be done (according to policy and best practice) may be very different than the way the work is actually performed on a daily basis. It is imperative that we understand the gap between work as imagined and work as performed, so we can address the barriers and achieve alignment of the two perspectives. People come to work to do the right thing. If they don't do the right thing, the job of quality and patient safety teams is to figure out why. HF observations are focused on identifying deviations, not for the sake of identifying deviation alone but to determine the underlying reasons for the deviation [18].

Social and technical subsystems are tightly coupled, meaning that movement in one subsystem results in a corresponding response in the other subsystem. If variation occurs in any one of the components making up a complex system, its effect ripples throughout the entire system. The design of a system must consider all aspects of the task at hand, from specific instrumentation and work environment to more abstract HF such as shared team awareness. Interventions that are not inclusive of larger system influences will be difficult to sustain. For example, the surgical safety checklist was designed to address a critical task at the point of care delivery. However, multiple studies have shown that the organizational context in which the checklist is implemented has significant influence on its sustainability [19–23]. Creating an intervention that only addresses one aspect of a complex work system can result in frontline staff creating workarounds or decreasing the use of the intervention or tool [24, 25]. For example, implementing a sepsis screening procedure in the emergency room that requires a lab draw that is sent outside of the ER is likely to produce alternate shortcuts because the procedure is not feasible within the context of a busy ER.

The difference in taking a linear vs. a complex adaptive approach has been codified by safety experts as either a safety-1 (linear) perspective or safety-2 (complex adaptive system) perspective. Healthcare is only recently developing a more safety-2 perspective to address complex challenges. There are many opportunities within healthcare to integrate safety-1 approaches to improve care, for example, focusing on adverse outcomes and trying to reduce variability, thus reducing errors or mitigating their impact [17]. This type of approach is most applicable to the more predictable aspects of healthcare work (e.g., management of quality of blood products in a blood bank, sterilization procedures). Checklists have been most successful in those settings in which the work occurring is more linear, with safety achieved with decreased variability through stricter regulations and constraints [26].

Hands-on clinical work, at the sharp end of care, is delivered by a complex system of interacting parts that are tightly coupled to one another and must respond, flex, and continually adapt to meet clinical goals. The success of any safety intervention for a complex system cannot only address one part of the system; it must also reflect the complexity of the system as a whole [27]. Therefore, safety-1 interventions, though often applied, are difficult to sustain, as they do not meet the requirements of the system in which they are applied [17]. To adopt a systems perspective, we must acknowledge the large interdependent sociotechnical systems that tackle complex clinical challenges. Each system in turn has several complex subsystems. These interactions result in complex work that is difficult to examine linearly. Without a shift to a systems framework, each intervention can be individualized to a specific clinical issue, resulting in near constant "up to the minute" patient safety adjust-

ments, and ultimately workflow paralysis [28]. In light of the myriad of competing goals facing clinical workers, i.e., patient care, electronic documentation, productivity and throughput, infection control, etc., safety and risk mitigation interventions require deliberate crafting to meet the needs of as many stakeholders as possible to reduce unwanted/unexpected consequences and tradeoffs.

Systems Engineering Initiative for Patient Safety Model

The Systems Engineering Initiative for Patient Safety (SEIPS) can provide insight into the influencing components for safety within a complex system [9]. Opportunities for safety or harm are created at multiple critical points in a system, through organizational pressures, technology design, physical environment design, individual human cognitive and team capabilities and limitations, and the structure of tasks, all of which are influenced by the external environment (e.g., regulatory or payment) within the system [29–32]. This model offers theoretical grounding and insight into how to conceptualize system influences.

Developed alongside healthcare providers by systems engineers at the University of Wisconsin, this model is frequently used to provide a framework to understand system influences on provider and patient performance. In the model, five aspects of a system (organization, people, task, technology, and physical environment) influence process and outcome measures. SEIPS can be utilized to ensure all aspects of a work system are examined.

Proactive Versus Reactive

HF has a role in reacting to events that have already occurred (understanding systems contributions and human abilities) as well as proactive prevention (predicting where errors are likely to occur due to exceeding human capabilities) to address challenges in healthcare. In 1999, the Institute of Medicine published *To Err is Human* as a call to action to address preventable harm and medical error in healthcare [33].

Proactive HFE can be utilized to predict where errors are likely to occur based on task requirements in comparison to human capabilities and limitations. Identification of trends and potential problems can be predicted regardless of the severity of event outcome. Consideration of HF in equipment/environment and process design is critical to reducing errors and sustaining improvement.

Reactive After an adverse event has occurred, HFE can be utilized to perform an accident investigation to determine contributing factors and root causes. Due to the complexity and temporal changes in healthcare, it is often impossible to determine a single, linear root cause to an event. A multidisciplinary systems approach can implement strong interventions on several contributing factors to prevent reoccurrence.

Usability (UX)

UX is the acronym for understanding the user experience. Usability testing is an evaluation method based on HF principles. The purpose of a usability study is to understand what a user wants and needs as well as identifying capabilities and risk for mistakes. Aligning expectations and abilities will improve the user's perception and the quality of the interaction with the product or process to achieve the desired tasks. It is critical to test a product or process with a representative sample of actual users performing realistic scenarios. The proper design of a usability study is critical to achieving realistic results [34].

The benefits of usability studies are threefold: (1.) identification of design flaws, (2.) identification of process or workflow enhancements that will be needed prior to implementation, and (3.) identification of issues to optimize educational content. Usability studies can help evaluate new technologies or equipment prior to purchase, to help ensure that they work well with existing systems and that hospital workers won't find them

burdensome to use. When a design flaw is identified in a usability study, it allows transparency of a problem and will prevent a user from blaming themselves. (Key Points Box 20.2)

Key Points Box 20.2 Systems Approach

- Healthcare is a complex system – HFE is an essential component of the multidisciplinary approach.
- Humans are a critical part of the system as both patient and provider.
- Proactive and reactive HFE approaches are necessary.

Vignette 20.2

A new defibrillator may be a wonder of engineering, but if a trauma team gets confused by the control panel and accidentally turns the machine off at the wrong time, the impact on a patient in distress could be disastrous [35, 36]. Watching teams test equipment under simulated emergencies helps get closer to the context in which work is actually performed while remaining in a safe environment.

Imagine a situation in which an electrical issue caused a device to shut down unexpectedly, even during lifesaving activities. In order to mitigate the risk of device failure, a short-term fix could be to place a sign on the defibrillator to warn that the machine should remain plugged in the wall during use (Fig. 20.1). A sign communicating this information is a stronger intervention than sending out mass communications (e.g., email) about the risk mitigation plan. That is, communicate what is needed at the point where and when it is most critical!

A long-term (or permanent) solution could be to purchase an alternative defibrillator that did not have this electrical issue. If new devices are being considered, bring them into a safe environment (like a simulation laboratory) for UX evaluation. The HF engineering team can work with nursing and simulation colleagues to develop dynamic lifesaving scenarios (such as synchronized cardioversion and ventricular tachycardia for defibrillation). It is important to get "realistic" volunteers like frontline nurses and EMT staff to participate in the UX evaluations. They will use the devices in scenarios and engage with a real defibrillator machine and a manikin to deliver appropriate shocks to the simulated patient. Video-recorded scenarios and data from semi-structured interviews should be evaluated for results such as reaction times, accuracy, button presses, errors, and the system usability scale (SUS).

Assume further that even if the device functions well and complies with basic usability principles, additional issues can still be uncovered, for example, a mismatch in intention and effect (turning on the device is challenging because of the limited tactile feedback) or a lack of visible feedback (the "ready to shock" is tonal and has a visual icon, but the icon was too small to see). It is also important to include unfamiliar users in testing if there is a chance the device must be used in an emergency. For example, users could be "float pool" nurses who are not common users of defibrillators. These individuals may struggle to use the devices and to understand the flow of the defibrillation. This is concerning because these individuals may rarely need this device and if the device is not intuitive, there is a significant increase in the chance of an error or delay in the lifesaving intervention for the patient.

Errors made with the device during novice simulation scenarios can be used as training opportunities for frontline users. It is important for users of the defibrillator to understand common errors and pitfalls with the machine. This vignette illustrates how usability can be integrated into device evaluation. In addition, usability issues such as these can also be integrated into ongoing code blue simulation trainings [37].

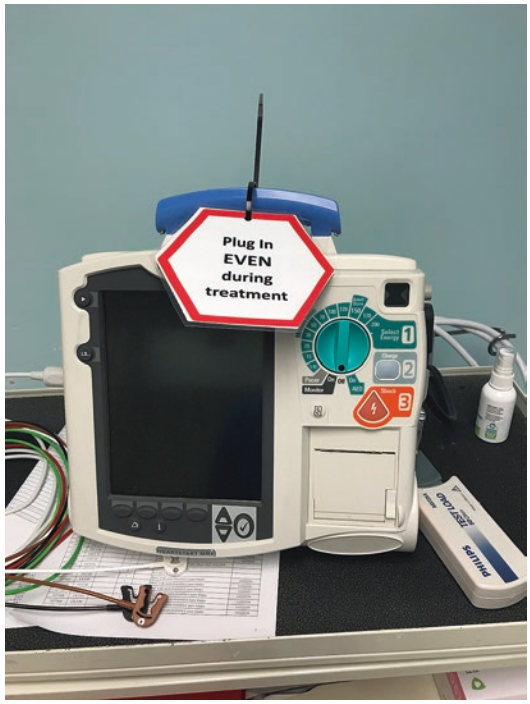

Fig. 20.1 Placing a sign on devices can be a short-term "quick fix" intervention

Human Error

A critical application of HF in healthcare is reactively determining the causes of human error [38]. Within the human error literature, there are a few important concepts. First, most accidents could be considered to be a "normal accident" [39]. A normal accident is one that occurs in a complex system, not entirely due to a single source but to broader system factors (organization). Normal accidents are often seemingly large but have small beginnings.

The second concept that is important for understanding human error from a systems perspective is the difference between errors, violations, and within the category of violations and the difference between accepted and unaccepted violations. An error is a mistake or slip or lapse or mishap. Errors are unintentional. Forgetting your keys is an error, for example. A violation is something entirely different. A violation is an intentional breach of rules or protocols. However, within violations there are both acceptable and unacceptable categories. For example, most people drive 5–7 miles above the speed limit. This is a violation. However, it is a universally accepted violation (in Western culture). However, crossing the double yellow lines to pass a slow car on a two-lane road would be an unacceptable violation. It is a violation, same as speeding, but it is outside of normal protocol. Another example is going 10 miles an hour above the speed limit in a school zone. Although going above the speed limit is accepted in many places, it is not in particularly risky situations [40, 41].

Finally, the concept of active vs. latent failures is important to understand. Active failures are those that are visibly manifested – they are seen and identified and often persist at the frontlines of care. However, the origin of these errors is frequently much further back in the system of care. For example, in the SEIPS model, errors do not just result from an individual making a mistake but rather from organizational influences such as the choice of a device or technology that is not well designed for human use (e.g., defibrillator example above).

Each of these concepts – errors are banal, that there are different genesis points for error, and that examining only the visible output from an error, rather than the underpinnings, leads to false conclusions, are critical concepts to both proactive and reactive application of human factors in healthcare. First, in healthcare, we treat errors as if they are completely unexpected deviations. This is often not the case. We have heard about risky situations from frontline workers via complaints or near-miss reporting systems for years prior to an actual error occurring. Second, we mistakenly treat every error as if it were an unacceptable, intentional violation. Again, this is rarely the case. Third, in healthcare, we tend to address only the active failures, rather than proactively assessing the latent failures.

The following frameworks for understanding errors when they happen and/or for anticipating high risk situations will be discussed: HFACS and HFIX. These are by no means the exclusive frameworks for understanding error in healthcare or human error in general. However, these two frameworks have been applied with success in

healthcare settings and are theoretically grounded in the human error literature [38, 42].

Human Factors Analysis and Classification System (HFACS) – As an enrichment of James Reason's work in 1990 [43] that helped to understand active and latent errors, the Federal Aviation Administration (FAA) developed Human Factors Analysis and Classification System (HFACS) [44] to identify the human factors issues in aviation accidents. HFACS provides a framework for accident/incident investigation. Categories in the framework include:

- Unsafe acts (including all types of errors – decision errors, skill-based errors, perceptual errors and violations)
- Preconditions for unsafe acts
  - Environment (physical, technical)
  - Condition of operators (mental state, physiological state, physical/mental limitations)
  - Personnel (crew resource management, personal readiness)
- Unsafe supervision (inadequate supervision, planned inappropriate operations, failure to correct a known problem, and willful disregard for rules or policies)
- Organizational influences (prevailing atmosphere within the organization, formal process by which the organization's vision is carried out, and resource management)

The HFACS framework allows information collected from event reports to be systematically reviewed and categorized according to pertinent HF issues that may have contributed to the event. Learning from events is most powerful if aggregate information can be reviewed to identify themes or trends. Although HFACS was originally developed in the military environment, it has been adapted for healthcare and has successfully provided focus for effective use of resources to achieve patient safety improvements [38].

Human Factors Intervention Matrix (HFIX) – This method was originally created to help develop interventions in aviation. The method arranges error types into a matrix (decision, skill-based, perception, violation) and aligns each category with the following dimensions:

- Human/crew: How to clarify understanding of responsibilities and align to human capabilities/limitations
- Technology/engineering: Technology that can replace or help human performance
- Technical/physical environment: Threats to personal safety by a hazard or event
- Task/procedure: How to change the nature of a task to reduce errors
- Organizational/supervisory: How to alter the organization to improve performance and reduce errors

This approach is a broad overview that looks at all the components to get a quick understanding of the strengths and weaknesses of a safety program. A recent study used HFIX to generate interventions for issues involving training nurses in a trauma center. Developing interventions within a framework such as this ensures that a systems perspective is considered, and resources can be allocated most efficiently and effectively [42]. (Key Points Box 20.3)

Key Points Box 20.3 Human Error

- To err is truly human [33].
- Human error is never the final cause for an accident.
- There are many models to assist in understanding contributing factors to human error.

Strength of Interventions

After contributing factors are understood, it is critical to implement strong interventions to prevent reoccurrence. Interventions that are based on humans may be necessary to increase awareness but will always be weaker and have a higher failure rate. Health systems cannot teach their way to "safe." For example, training and education are necessary but are not resilient to staff

turnover or human nature to drift toward risky behaviors. Stronger interventions will rely on a more resilient system-based approach to "design out" any potential for the error to occur again. System-based interventions can take more resources to achieve error proofing, but the expense/time can be warranted if the severity or consequence of reoccurrence is severe.

In 2016, the National Patient Safety Foundation (NPSF) published a landmark document that encouraged the healthcare industry to think differently about getting to zero preventable harm[45]. Recommendations focused heavily on what they thought the industry was missing in response to serious safety events and why preventable events continue to occur far too often across the nation. Root cause analysis and action (RCA^2) was an improvement with a focus on achieving strong corrective interventions and coordinated action plans to prevent recurrence.

Interventions should be aligned to address contributing factors or predicted human deficiencies. Figure 20.2 illustrates some common interventions categorized on a continuum of weak to strong based on VA National Center for Patient Safety scoring methodology. Rating the strength of interventions can provide insight to sustainment of improvements. The strength of intervention rating allows teams and executives to prioritize resources.

Typically, one event will require a combination of weak to strong interventions to address the full gamut of issues. Even with the ideal of a system forcing function that reduces the risk of an error, some training may be needed to increase awareness and set behavior expectations.

Vignette 20.3

An adverse event involving a portable ventilator that rolled into an MRI machine resulted in seven interventions (two strong, three intermediate, two weak) (see Fig. 20.3). Meetings were held to determine contributing factors that were part of a systems approach that considered environmental, organizational, equipment, physical layout, and tasks. A multidisciplinary team developed action items to encourage strong, independent, system-oriented interventions. The strongest intervention was to bolt the ventilator directly onto the wall, making it impossible for it to ever roll into the MRI machine again.

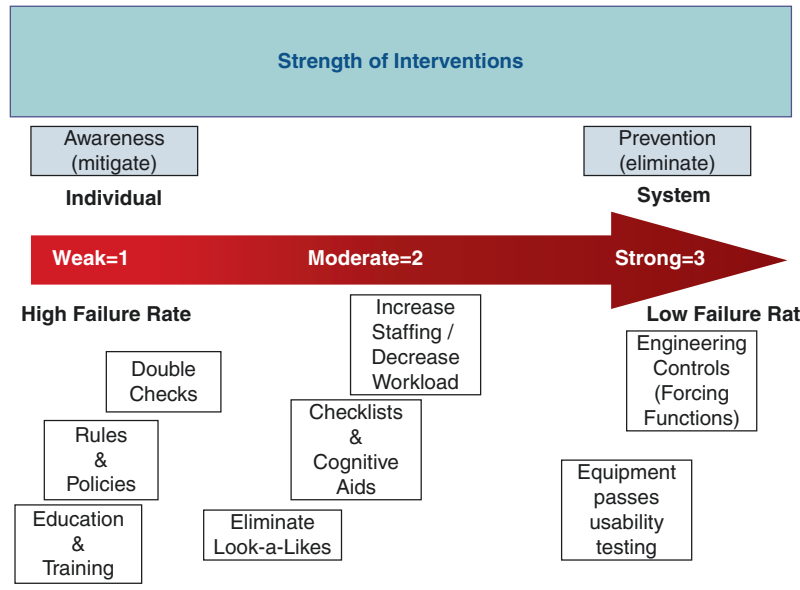

Fig. 20.2 Strength of Interventions. Adapted from National Patient Safety Foundation: Root Cause Analysis & Action [45]

a

Intervention	Description of intervention	Score
1	Education for non-MRI staff	weak
2	Report event to FDA	weak
3	Workflow evaluation & changes	intermediate
4	Remove 2/3 ventilator batteries	intermediate
5	Staffing evaluation	intermediate
6	Place gauss alarms	strong
7	Mount vent to wall	strong

b

Fig. 20.3 Action item/intervention and strength score (**left/a**) and photo of ventilator attached to a wall in MRI room (**right/b**)

The primary goal of an RCA[2] is to do everything possible to prevent the adverse event or near miss from ever happening again. Action items should improve patient and staff safety with a focus on strong interventions to solve all types of safety concerns. The types of issues investigated and resolved using RCA[2] methods include medication errors, patient falls, alarm fatigue, communication issues, hand-off transitions of care, restraints, etc. Equal attention is given to investigations of adverse events (reactive) as to predictive trends or near miss (proactive). (Key Points Box 20.4)

Key Points Box 20.4 Strength of Interventions

- Stronger interventions are system-based and do not rely on human training and behavior.
- A combination of strong and weaker interventions needs to be implemented to reduce risk of reoccurrence.
- We need to design systems to anticipate and mitigate errors when they occur. They will occur.
- Rating of interventions following serious safety events is essential.
- Strong, independent interventions are needed to reduce risk of reoccurrence.

Summary

HF should be integrated into a well-supported multidisciplinary team that is responsible for the design of care delivery and the prevention of harm. This tactical team should include clinical experts, analytics, process improvement, and human factors. In order to achieve the maximum impact, executive support is essential.

Inclusion of HF into the following areas is beneficial.

- Root cause analysis and action (RCA[2]) (e.g., Vignette 20.3)
- Intense analysis
- Human-machine interfaces (alarm fatigue)
- Failure mode effects analysis (FMEA)
- Usability for purposes of efficiency
- Simulation
- Assessment of new technology during procurement

Leadership can impact sustainability of improvements by providing time, resources, and support. Hospital and health system boards should become familiarized with basic HF principles. The schedule for implementation of strong solutions may require short-term (stopgaps) as well as long-term customized interventions (e.g., software changes, mounting ventilators to the

wall). Collaboration to develop a customized process is essential for sustainment.

The primary challenge to incorporating HF into health systems is the scarcity of HF experts. As opposed to process improvement competence which can be achieved through various training programs, there is no abbreviated pathway to competence in HF. Therefore, few health systems have HF resources that are primarily dedicated to proactive and reactive design of clinical operations. Partially due to the scarcity of HF experts, HF teams within healthcare are often primarily academic and/or entrepreneurial.

The healthcare industry should focus on identification of contributing factors to error and improving the strength of interventions to improve patient safety. The following components are important for success:

- Complex events may have critical contributing factors without a singular root cause.
- Creating a culture of reporting events and near misses is essential.
- Supporting staff to implement strong action plans encourages awareness that the status quo can be changed.
- Extrapolate event reports to include similar system risks.
- Leadership support is essential to reduce barriers and ensure resources to implement strong action items.

Editors' Comments

There are human factors experts, and then there are the authors of this chapter. The authors deftly introduce the concept of human factors and how this thinking can be transformative in healthcare. The striking fact about their first vignette is that on some level, we have all experienced a similar situation or at the least have heard of such an issue happening in other organizations. The question then arises, if issues are omnipresent as detailed in the vignette, what we are as improvement scientists doing to address these issues. There are myriad workarounds that we all have suggested and implemented for such a vignette; however, where are the real tangible solutions? This is the authors' point – we need to reframe issues within the construct of human factors.

The historical evolution of human factors is interesting as it shows that over the next decade, we can potentially make significant strides in bringing human factors thinking and applications to our standard workflows, just has been done in myriad other industries such as automobile, aircraft, and ship manufacturers. For the novice reader, the domains of specialization of human factors as outlined by the authors – cognitive, physical, and organizational, provide the overarching framework to consider human factors integration into healthcare.

Our teams have ardently attempted to incorporate the concepts of work as imagined and work as performed. The authors excel, however, compared to many of our organizations in that they use human factors concepts to understand the deviation from work as imagined, which is an area where other healthcare organizations have not yet appreciated.

The concept of user experience and the accompanying vignette is an area that many healthcare systems have yet to delve into. The sophistication of the authors' commitment to human factors is evident in the vignette; however, the rest of us should not be intimated – knowledge of human factors as shared by the authors certainly moves our thinking and perhaps our organizations further on the quality improvement journey. The middle section of the chapter involves understanding human errors, active and latent failures, and classification systems for human factors. It is these sections where the reader can gain a significant understanding and appreciation of the role of human factors thinking in one's

improvement efforts. There is much to be gained in understanding the strength of interventions and how we can apply this rubric to the outcomes of our causal analyses, for example.

The authors have created what we believe is one of the most definitive chapters on human factors in healthcare using a case-based approach to imbue the reader with a realization of the value of human factors and how the next advancements in patient safety and quality improvement will be within the construct of human factors.

Chapter Review Questions

1. Which of the following components should be considered during a human factors analysis?
   A. Organization
   B. Human capabilities
   C. Environment
   D. All of the above*
   Answer: D
2. Human error can be completely designed out of a system.
   A. True
   B. False*
   Answer: B
3. Select the following types of error proofing from Weakest to Strongest.
   A. (Weakest) training….checklist…..automation (strongest)*
   B. (Weakest) forcing function…..training…..rules/policies (strongest)
   C. (Weakest) simplification…..rules/policies……training (strongest)
   D. All of the above
   Answer: A
4. Human error is an acceptable final cause of an accident.
   A. True
   B. False*
   Answer: B
5. Human Factors should be considered in which of the following activities?
   A. Root cause analysis and action (RCA^2)
   B. Failure mode effects analysis (FMEA)
   C. Usability assessments
   D. Simulation
   E. All of the above*
   Answer: E

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Workforce Safety

21

Joel T. Bundy and Mary M. Morin

Abbreviations

DAFW	Days away from work
DART	Days away, restricted, or transferred
HRO	High-reliability organization
MSD	Musculoskeletal disorder
MSI	Musculoskeletal injuries
NSI	Needle stick and sharp injuries
PCP	Primary care provider
PPE	Personal protective equipment
RCA	Root cause analysis
SPHM	Safe patient handling and movement
STF	Slips, trips, and falls
TCIR	Total case incident rate

Chapter Objectives

- Review of various functions of an employee health program as it relates to worker safety, including:
  - Overview of workforce safety
  - Methods of measurement
  - Patient handling
  - Slips, trips, and falls
  - Exposures
  - Workplace violence
  - Burnout and resiliency

Vignette 21.1

Dr. Murphy is an experienced pulmonologist who is sought out for her expertise in the diagnosis and treatment of lung diseases such as chronic obstructive pulmonary disease; she is known for her fast turnaround times on consults and completion of interventional procedures. After a long day of planned and unplanned bronchoscopies, hospital consults, and outpatient visits, Dr. Murphy was feeling more fatigued than usual and felt pruritic; she also felt like she had a fever. When she finally got home, she noticed a red rash with blisters over her body, including on her scalp, and had a fever. The next morning her symptoms were worse, so she made an appointment with her primary care physician (PCP) for later in the day after she finished her hospital rounds and planned procedures. After completing registration

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at her PCP's office, she took a seat in the full waiting room, was soon called back to the treatment room, and checked in by the medical assistant. Upon entering the treatment room, her PCP quickly diagnosed the red, itchy, and blistery-looking rash as varicella. Dr. Murphy, who had always completed her annual health screenings, had always declined the offer of the varicella vaccine because her titer was "low," but not "negative," and did not think she was at risk for exposure. What Dr. Murphy didn't think about either, when declining the vaccine, was the risk of exposure to others (i.e., patients, co-workers, community members, and family members) who may not have immunity. All patients and staff members with whom Dr. Murphy had close contact were notified of their exposure and evaluated for immunity by obtaining blood titers. Several patients and staff members had negative titers and required the administration of the immune globulin for varicella (VZIG) at $15,000/dose and treatment of associated symptoms; these expenses were incurred by the hospital which employs Dr. Murphy and the exposed staff. In addition, Dr. Murphy and the staff with negative titers were placed on medical leave for at least 21 days causing further impact on patient care (as well as outpatient and inpatient revenues) and staff member workloads due to required absences. Total cost due to lost revenues, paid sick time, lost wages, overtime for coverage of the physician and staff, and medical treatment (staff and patients) was over $400,000.

Introduction

Patient safety has been a high priority for healthcare organizations since the publication of *To Err is Human* [1]. This seminal paper is widely discussed by clinicians and healthcare systems alike. From this came the impetus to save 100,000 lives and with it the birth of the modern patient safety movement. Much has been learned from other industries and their accidents, including the airline industry, in how we can protect patients from harm.

Building on those ideas is the high-reliability organization (HRO) concept, or how we, in healthcare, can learn from other organizations with fewer accidents than would be predicted. Kathleen Sutcliffe and Karl Weick [2] describe the attributes of HROs, reviewing the important ideas of both prevention and also resiliency, as both should work in concert for an organization to be able to provide safe care. Preventing harm is much more than writing and rewriting policies.

Because HROs demonstrate success by the avoidance of accidents, how this occurs is necessarily harder to detect. Sutcliffe posits successful systems organize around three high-arching concepts which she describes as essentially creating a mindful infrastructure: interacting respectfully between members of the team, interrelating heedfully across the system, and emphasizing principles forcing those within the organization to pay attention to the details. This is a prerequisite for obtaining the behavior and culture changes needed to achieve the outcomes desired for learning healthcare systems to become safer.

Running parallel to this emphasis on high-reliability organizing has been an attempt to deliver healthcare through the framework of the Triple Aim, a single aim with the three dimensions of high-quality care for patient populations, delivered with patient-centered experiences and with reduced costs. As Hamlet pondered on humanity, he specifically mused, "How noble in reason" (Shakespeare, 1600, Act 2, Scene 2) [3], the same could be said for the Triple Aim.

For those leading change in healthcare systems, there is an attempt to inculcate these principles in the development of policies and programs for the populations served, especially when considering their safety and quality. But how to achieve all three aspects of the Triple Aim? Having success with two legs of the stool is easier; having all three remains a challenge. Being a learning organization is a foundational

principle which allows for the achievement of this goal [4].

With the changes in healthcare delivery during the last century (e.g., group practices, HMOs, managed care, etc.), there was a hope these models would further improve efficiency, thus providing better quality for the community and at a lower cost. Over the past decade, national healthcare reform continued with the passage of the Affordable Care Act. Regardless of reform initiatives over the past decade, healthcare expenses have continued to rise, with total expenses for the top ten largest spending conditions nearly doubling, with an annual growth rate of 6.1% [5]. Therefore, the importance of improved cost controls, whether it be through the ACA or some other model, is paramount.

Over time it has become clear provider purpose needs to be considered in our equations of how we deliver care. Adding "provider purpose" as a fourth leg to the stool establishes the well-described Quadruple Aim [6]. Provider purpose, with the emphasis on well-being, aligns with the resiliency component of HROs. It is through this lens that we focus on worker safety, those very workers who are at the sharp end of care delivery, as the undergirding for the building of a highly reliable healthcare system – having an appropriate foundation to build on, scaling through Plan-Do-Study-Act, and learning from errors.

Humans, and that certainly includes the workforce, will make errors. To understand how we can impact workforce safety, it is imperative that there is an understanding of human performance. The Department of Energy (DOE) *Human Performance Handbook Volume 1: Concepts and Principles* lays out five principles that set the stage for how we can tackle errors in our employees. These principles state:

1. People are fallible, and even the best people make mistakes.
2. Error-likely situations are predictable, manageable, and preventable.
3. Individual behavior is influenced by organizational processes and values.
4. People achieve high levels of performance because of the encouragement and reinforcement received from leaders, peers, and subordinates.
5. Events can be avoided through an understanding of the reasons mistakes occur and application of the lessons learned from past events (or errors) [7].

If people are fallible and indeed to err is human, then it will take more than additional education to prevent errors from occurring and producing harm. These errors may touch the patient in addition to the worker. Since errors are inevitable, it requires building capacity and resiliency into the system with an underpinning of just culture principles when dealing with mistakes and harm.

Those same workers continue to experience harm at an alarming rate, whether it relates to burnout and depression, physical injuries in the doing of normal work, or being the recipient of violence. As we will see later, these injury rates are greater than seen in most other industries [8], and burnout remains high across multiple physician specialties [9], as well as other healthcare workers and support staff members (e.g., nursing, environmental services, therapists, advanced practice clinicians/providers) [10].

Hamlet, and those in the safety profession, would encourage us to continue to "take arms against a sea of troubles" that remains within our US healthcare system [11].

Measuring Defects

Upton Sinclair published his book *The Jungle* in 1906 to a shocked and appalled public [12]. Death, disease, and injury fell on the immigrant workers in Chicago due to unsafe working conditions. The federal response to protect the public led to what would eventually become the Food and Drug Administration. Fast forward to the 1960s where worker injuries were increasing, with disabling injuries increasing by 20%. William Steiger's house bill to protect these workers was signed into law in 1970 and with it the development of the Occupational Safety and

Health Administration (OSHA) set standards for workplace safety.

Injuries in the workplace are measured in various ways. On learning boards, in real time, it may be recorded as days since last injury. At an organizational level, metrics to understand the impact of worker injuries include the total case incident rate (TCIR); the number of days away, restricted, or transferred (DART); the raw number of injuries; and days since last injury (at the unit, department, and/or organization levels). TCIR is defined as the number of injuries and illnesses per 100 full-time workers during a 1-year period. DART represents the time away from work for employees for those same injuries.

For those who work in healthcare, these metrics are alarming. Although the TCIR for acute care facilities has improved from 9.1 in 2000 to 5.7 in 2017, this rate is still much higher than most other industries, including construction, utilities, or hazardous waste collecting [8].

In addition, the impact on an organization can be measured in other ways, such as financial. OSHA estimates that employers pay $1 billion per week simply in workers' compensation costs [13], and within healthcare this amounts to $14 billion per year [14]. In addition to workers' compensation costs, there are productivity losses, turnover, and even overtime costs to consider. Our case vignette to open this chapter gives a clear example of the impact to an organization from worker injuries and illnesses and reminds us of the ripple effect across a hospital unit, medical group, or for delivery of services to patients.

When considering injuries, it remains important to trend leading indicators such as safety culture and other precursor events in an attempt to mitigate future events. The reporting of near-misses is an important component of our overall safety culture and should be for our workers as well. Long debated has been the overproportion of serious events of harm in relation to precursor events and near-misses. Sidney Dekker, in his book *The Safety Anarchist*, Chap. 5 "What gets measured, gets manipulated" [15], describes the disconnection between calamitous events and the safety records of several organizations, including the BP Deepwater Horizon disaster. Diving deeper into that example will help us to better understand these concepts.

It was April 20, 2010. The oil rig Deepwater Horizon was 27 stories, 25 stories above and 2 floors below. The rig punctured the ocean floor an additional 350 stories below for the oil. Despite their excellent safety record, gas and oil blew past the first blowout preventer on the way to the rig itself. There were only minutes until the first explosion.

How could this happen given their impressive safety record? Where were the innumerable precursor events prior to this tragedy? It was truly ironic that BP executives were there on the rig the very day of the explosion celebrating 7 years without reporting a lost time accident [16]. Think of it, *7 years*. In fact, they had just won two awards for safety in the year prior, one of them the OSHA Star Award!

To understand this better, and why we still get it wrong, Dekker would have us take a trip back to the 1930s and the Travelers insurance company. Looking for practical applications to prevent accidents, Herbert William Heinrich, the assistant superintendent of their engineering and inspections division, "scientifically" reviewed 75 000 cases from insurance claims spanning the decade prior. What did he find? In his work, unsafe acts accounted for 88% of accidents, with 10% being from the factory layout and conditions and only 2% being unpreventable. With this data he developed his model where for 330 occurrences, 300 produced no harm, 30 minor harm and 1 serious harm or death [15]. What then to do? It seems simple – prevent unsafe human behaviors and accidents will markedly decrease. This is the typical triangle we so often see in safety today and which we have adopted in healthcare. It now teaches for every 1 serious safety event, there are 100 precursor events and 1000 near-misses (Fig. 21.1).

Several studies show that fatality rates have not decreased at the same rate as minor injuries. In fact, in the construction industry, sectors with "high rates of fatal injuries had low rates of minor (nonfatal) injuries" [18]. Heinrich's model should predict that less common high-consequence injuries such as a mortality would follow patterns

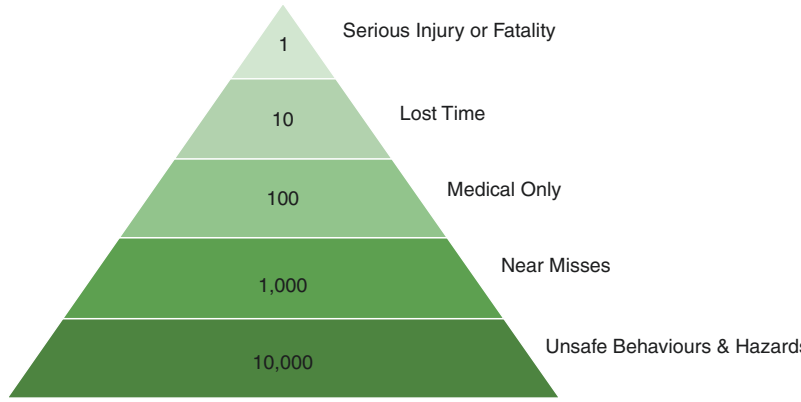

Fig. 21.1 Unsafe behaviors and injuries [17]. (Adapted from Heinrich HW [17])

similar to the more common low-consequence injuries such as a slip on a wet floor, but it does not. What do we see in healthcare? Is it common low-consequence injuries or less common high-consequence injuries? Yes, it is both and in combination. Anesthesia in low-risk patients is now six-sigma safe, meaning less than 3.4 defects in one million opportunities. What things are high-consequence but less common events? Management of central lines, perhaps, as they are low frequency when compared to the legion of simple peripheral IVs. How about high-consequence *and* common events? That seems to fit much of what we see and do in healthcare – medication administration, surgery, mobility in frail patients, and on and on.

So, if the model isn't completely relevant, can it still work for us? Should we look at precursor events and unsafe behaviors even though they do not fit the evidence we understand today? Yes of course, and we need to measure them, trend them, and learn from them. Heinrich's triangle is a model, and as such, it has uses to uncover unsafe workarounds that may permeate our neat designs. In the just culture world, we recognize people *will* make mistakes. With that said, it is up to us to create a system that mitigates those errors to keep them from touching and harming a patient. The Heinrich's triangle would predict that removing unsafe behaviors in people would prevent accidents/harm, but clearly it is much more complex within the systems in which we care for patients. If we simply "fix" our workers, the system remains broken.

What then to do? Identifying unsafe behaviors and precursor events is important, and there is much learning to be gained, but that is not enough. Solving for system failures is the new "key" in patient safety, which itself remains the keystone in everything we do. If Heinrich's triangle isn't the total framework from which to begin, how else to tackle these ever-elusive problems? We can posit that the concepts of high reliability should be the new framework we use to build our house. From Weick and Sutcliffe's *Managing the Unexpected: Sustained Performance in a Complex World*, there are five overarching principles seen in highly reliable organizations [19].

1. Preoccupation with failure: ask others how processes are going to break down.
2. Reluctance to simplify problems that are complex: be willing to challenge dogma.
3. Sensitivity to operations: use rounding to get out on the "factory floor."
4. Commitment to resilience: help others to remember their "purpose" in work.
5. Deference to expertise: learn from our experts at the sharp end of care.

If these concepts are followed, starting with recognizing that some processes are broken (or will break in the future), we can proactively determine what risks through which to work.

It remains imperative to risk-assess these high-consequence events against the probability of occurrence. What is the risk of failure? What is the risk to the patient, the staff, or the organization when that failure occurs? What action do we then take to mitigate against the next failure? From the flaws in Heinrich's triangle, we can recognize that we cannot allow the lack of recorded events or unsafe behaviors give us a false sense of achievement. We *must* keep digging to prevent the next Deepwater Horizon explosion, or the fall of the confused man in the room at the end of the hall, or an HIV+ needle stick to one of our workers. The same principles of safety differently apply to our workforce as well as our patients. The wolf is always at the door, and disaster can occur even with a good-looking red-light green-light dashboard.

Vignette 21.2
Kristen Brown, a RN with 25 years of experience, was caring for a stroke patient who was not able to push himself up in bed. During her start of shift rounds, she went into his room and noticed he needed to be repositioned in bed. Instead of calling for assistance or using the patient lift device on the unit, she used the sheet underneath of him. While pulling him up, she felt something "pop" in her back, and she immediately felt excruciating pain. Kristen was sent to the Emergency Department (ED) by her Nurse Manager for immediate evaluation and treatment, and her patient assignment had to be covered by the other RNs on the unit. During her ED visit, Kristen was informed she had a herniated lumbar disc requiring medication and neurosurgical follow-up. Kristen was placed on medical leave for 4 weeks and was able to return to limited duty with restrictions such as no prolonged standing or sitting and no lifting or pulling. She was not able to return to bedside nursing practice due to the severity of her back injury and was eventually placed on long-term disability and worker's compensation. The full cost of her injury was over $350,000 and the quality of her life was negatively impacted.

Safe Patient Handling and Mobility (SPHM)

What would you do if a you are performing neurological assessment requiring a patient to stand and they started to fall – would you let them fall, possibly incurring an injury? Would you try to "catch" them to either prevent or lessen the impact of a fall and possibly injure yourself? (Vignette 21.2). What if you know they are on anticoagulant therapy for an embolic stroke? Would this change your willingness to risk your safety to protect them? What if you are a nursing assistant on a busy medical-surgical unit and you hear a loud thud and find an elderly patient on the floor, and the patient tells you they can get up if you can help them to stand? Do you try and assist them to standing, do you call for another staff member to help, or do you get other staff members to help and take the time to use a lift device? Both of these scenarios are very real, and as you will read later in this chapter, being present in the moment and using critical thinking skills to solve for the unexpected are an important safety behavior.

Musculoskeletal injuries and musculoskeletal disorders (MSDs), injuries and disorders of joints, muscles, tendons, cartilage, spinal discs, and nerves [20], occur at high rates in healthcare workers and can be a result of patient handling tasks (e.g., lifting, transferring, ambulating, and repositioning patients). Continuous performance of these tasks places patient care providers at risk for the development of MSDs. MSDs affect healthcare organizations financially and can impact operational functions in any setting (e.g., acute care, home health, skilled nursing, etc.). In 2017, hospitals had 51,380 new days away from work (DAFW) related to workplace injuries and illnesses [21]. This resulted in an incidence rate of 129.8 cases/10,000 full-time workers (FTE) – a decrease from 134.3/10,000 FTE in 2016. Specifically, the incidence of DAFW cases due to MSDs decreased in 2017 to 56.7 cases/10,000 FTE as compared to 62.1/10,000 FTE in 2016. Regardless of overall decreasing hospital worker trends in DAFW and incidence rate, RNs and nursing assistants continue to be the two groups most impacted by MSDs. In 2016, RNs ranked

highest with an MSD incidence rate of 46.0/10,000 FTE followed closely by nursing assistants at 41.3/10,000 FTE [22]. The number one reason why MSDs are high for nursing staff is the result of their everyday jobs which require frequent patient handling tasks. More than two decades ago, studies started showing that teaching nursing staff to move or lift patients using "proper body mechanics" is not a safe practice, as there is no way to manually lift a patient safely [23–25].

Patients are the greatest source of strains, sprains, and tears. In 2016, strains, sprains, and tears due to excessive bending, lifting, repetitive movements, bending, and physical effort accounted for 51.0% of all injuries to RNs and resulted in a median of 7 DAFW [26]. Since patients are the largest cause of these types of injuries in nursing staff, some hospitals have successfully decreased lift-related injuries by 80% through the implementation of equipment and devices designed to safely lift and move patients. The use of assistive equipment and devices should be the core component of a hospital, home health, or long-term care facility's "safe patient handling and movement" program [27]. Adam Rubinfire, in an article for Modern Healthcare [28], noted many healthcare facilities have invested in assistive devices to reduce MSDs, though he notes the cost to purchase equipment and/or install lift equipment is challenging. For example, the average cost of installing an overhead lift is $16,000/patient room, and the average cost per mobile device is $6000. Regardless, the investment is critical to reducing healthcare-related MSDs, and according to the 2015 American Nurses Association (ANA) President Pam Cipriano, "It is one of the key areas where nurses fear injury in the workplace that could be career-ending" [28]. Additionally, most states do not require healthcare facilities to have SPHM programs, with only eight states passing legislation for safe patient handling in healthcare settings as of 2014 [27, 29]. Only in the past few years has OSHA increased its enforcement of protecting healthcare workers from MSD, as almost all are preventable.

Vignette 21.3

John Price, a certified surgical technician (CST), was called into the hospital, at 0300, for an emergency surgery. At the end of the surgical procedure, the needle count was off (or short) by one – a needle was missing. As per hospital protocol, a flat-panel X-ray was ordered, and John went behind the radiation protection screen as required for his safety [radiation exposure]. After the X-ray was taken, John tripped over the protruding legs of the screen and falling on his right hip sustained a displaced fracture of femoral neck requiring urgent surgical repair. John's road to recovery was long as it was complicated by several post-operative complications requiring prolonged hospitalization, inpatient rehabilitation, and months of medical leave which required him to go on long-term disability. A root cause analysis (RCA) was completed, and other types of injuries related to staff tripping on the radiologic screen legs were identified as part of the RCA process. Immediate action was taken to educate staff across the system on the trip hazard until new, trip-free screens could be implemented. The costs associated with John's injuries were over $1,000,000, including worker's compensation for time lost.

Slips, Trips, and Falls

Imagine dedicating your life to caring for people in need, specifically those acutely ill and hospitalized, and then becoming the patient while caring for others (Vignette 21.3). This chapter describes the occupational hazards of healthcare employees that turn caregiver to patient. The category of slips, trips, and falls (STF) has alarming statistics associated with it within healthcare. Slips, trips, and falls on the same level (STFL), according to both the European Commission and the Bureau of Labor Statistics, count for about one in five of the reported nonfatal work injuries

[30]. Based on the most recent data available for 2017, the incidence rate of lost work days due to STF injuries was 25.2 per 10,000 healthcare employees, while the average for all industries was only 14.5. At least these injuries are improving, as the rate in healthcare has decreased by 34% since 2009 when the incidence rate was 38.2. It remains a leading cause of lost work day injuries in healthcare workers, second only to injuries from overexertion [31].

In addition to the impact on the individual and the team, STFL injuries have a substantial effect on direct costs, with recent data demonstrating this to be approximately $9.19 billion [30]. Bell showed that sprains, strains, dislocations, and tears were the largest percentage of workers' compensation claims after STF in acute care hospitals, with emphasis on the increased risk of fracture (8.4%) [32].

On a positive note, the hazards associated with STF have been studied extensively, and safety experts agree that this type of occupational injury is preventable. We know that the foundation for the prevention of STF is good housekeeping [33]. The Department of Health and Human Services has marked out the top ten causes of STF and ways to prevent each [34].

As you might expect, contaminated floors with slippery fluids are the number one cause of STF in healthcare [32]. This important study, with research involving three US hospitals, looked at intervention measures over 3 years, then with a 3-year post-evaluation monitoring period. Workers' compensation claim rates during the post-intervention period decreased by 58%. Components to mitigate risk included keeping the floors clean and dry, preventing entry into areas with wet floors, and the use of slip-resistant shoes. In addition, Haslam and Stubbs divided measures for prevention of STF into primary prevention, risk reduction, and maximizing capacity [35]. Again, looking at contaminated flooring, and with this in mind, primary prevention could be to cover the hospital entryway in anticipation of inclement weather, risk reduction might be to provide warning signs of damp floors, and maximizing capacity would be to encourage suitable footwear by employees.

In addition to wet floors, other common causes of STF include poor drainage from pipes and drains; irregular surfaces, both inside and outside; ice and snow; inadequate lighting, improper maintenance of stairs and handrails; improper use of ladders; clutter leading to tripping hazards; and improper use of floor mats and runners [34]. As these accidents are preventable, reviewing the history of STF in the organization is an important place to start, putting efforts in areas of prior injuries. Once discovered, focused communication with the employees is paramount. Efforts should include communication in unit and safety huddles, leadership rounding, department and town meetings, skill fairs, and any other areas where communication to staff occurs. Communication should include environmental services, nursing, medical staff, vendors, and everyone in between. Learning has to be deliberate in the organization. Preventable accidents are everyone's business and include those injured, the teams impacted by the loss of their teammate, and the organization that has to cover for the lost worker, as well as pay the workers' compensation bill.

Vignette 21.4

Samantha Wilson, RNFA (First Assistant), was working with a vascular surgeon performing a femoral-popliteal bypass on a patient with known hepatitis B; Samantha had not started the hepatitis B series. When she was assisting the surgeon, she was accidentally stuck with a suture needle. The puncture site was immediately cleaned, and she was evaluated by Occupational Health and counseled on the need for ongoing lab work and infectious disease visits. Within 6 weeks she started to develop signs and symptoms of hepatitis B infection, including elevated liver enzymes. Blood testing confirmed she had hepatitis B infection. Since there is no cure for hepatitis B, Samantha will continue to be monitored by infectious disease. The lifetime cost of her care and monitoring will be covered by the employer.

Exposures

As you have already read, healthcare workers face many serious health and safety hazards (Vignette 21.4). Exposures are not inclusive of only those healthcare workers in direct patient care (e.g., physicians, nurses, dentists, etc.). Anyone working in a healthcare setting is at risk of exposure hazards to include workers in environmental services, laundry, laboratories, radiology, and even administration. What types of healthcare-related exposures are there? Exposures include hazards from blood/body fluid-borne pathogens (e.g., hepatitis B, hepatitis C, HIV) and biological risks (e.g., influenza, measles, varicella), drugs (e.g., antineoplastic, aerosolized medications) and chemicals (e.g., peracetic acid, formaldehyde, ethylene oxide), waste anesthetic gases (e.g., halothane, isoflurane), respiratory borne pathogens (e.g., tuberculosis), radioactive materials (e.g., ionizing), and others. OSHA has standards, regulations, and guidelines for the protection of healthcare workers from exposure hazards, and the CDC has numerous resources available to assess and decrease healthcare worker exposure risks [20, 36]. What are the mechanisms of exposures? Several will be highlighted as they pose serious health hazards to workers in healthcare.

A worldwide problem, needle stick and sharp injuries (NSIs), is avoidable and presents the greatest risk of transmission of dangerous blood/body fluid-borne pathogens such as HIV, hepatitis C, and methicillin-resistant *Staphylococcus aureus* (MRSA) to healthcare workers, with nurses and physician most impacted. OSHA estimates there are 800,000 to over a million NSIs annually in the United States and many go unreported [37].

In a September 5, 2018, report from the International Safety Center (ISC) [38], physicians for the first time, in 2016, reported the highest percentage (34.2% of NSIs instead of nurses (33.4%)); these NSIs are occurring mainly in the OR. In 2019, the ISC reported in 2017 nurses and physician NSIs were almost the same at 32.9% and 32%, respectively, and due to "unsafe practices" [39]. There are three major categories NSIs fall into: "failure to use a safer medical device; failure to activate safety mechanisms when devices with sharps injury protections are used; and unsafe work practices during multi-step processes (e.g., passing instruments by hand during surgical procedures)" [38]. OSHA reported the three main reasons of NSI occurrences, after use and before disposal (40%), during use on patients (41%), and during or after disposal (15%), and states work practice control and engineering are the primary ways to eliminate or reduce blood/body fluid-borne pathogen exposures [36]. It is estimated NSIs in US hospitals alone cost $1 billion in post-exposure care. As highlighted in the CDC's Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program, there are other costs more difficult to quantify: emotional costs associated with anxiety and fear from the possible consequences of an exposure; direct costs related to medication treatment toxicities, DAFW, and those associated with a positive HIV or HCV infection; and the indirect costs of a healthcare worker not returning to their job, as well as the financial liabilities for both worker and employer associated with medical care and possibly worker's compensation [36].

Exposures of healthcare workers to blood and body fluid splashes and splatters can occur in patient rooms, procedure and treatment rooms, and ORs. Just like NSIs, these types of exposures are mostly preventable through the use of personal protective equipment (PPE). PPE includes face shields, eyewear, respirators, gowns, and gloves. The ISC reported on January 22, 2019, there are "unacceptably high incidence of blood and body fluid splatter to unprotected eyes (48.1%)" and in only 3% of the incidences were the healthcare workers wearing protective eyewear [40]. Blood splashes and splatters have significant risks for not only blood-borne pathogens but other infectious diseases including MRSA, TB, and influenza. Since 2008, OSHA has required healthcare employers to provide and pay for PPE to minimize exposure risks and for several decades has required them to offer and provide the vaccine for hepatitis B [40].

In addition to PPE, OSHA requires healthcare employers to have a respiratory prevention program and include strategies such as isolation rooms, laboratory hoods, vaccines, and respirators to reduce employee exposure to infectious diseases, chemicals, and other products. In May 2015, OSHA published a respiratory protection "toolkit" as healthcare workers may potentially be exposed to diseases or chemicals transmitted via particles or droplets either present or suspended in the air, which, without protection, are inhaled or come into contact with mucous membranes [41].

Though OSHA requires the employer to protect its healthcare workers, regardless of the setting (e.g., hospital, long-term care facility, home health, medical practices), every individual must actively engage in protecting themselves and others from unnecessary exposures through preventive measures, including immunizations. Additionally, workers need to immediately report all exposure and complete the post-exposure treatment requirements.

In *Zero Harm: How to Achieve Patient and Workforce Safety*, Emily Halu and Joseph Cabral make the case that healthcare worker safety will not be realized until healthcare employers fully "understand the value of safety-first decision making, even in the face of serious financial pressures" [42]. Halu and Cabral challenge healthcare organizations to establish a zero-injury goal and commit to zero harm for their staff, as employee safety leads to patient safety.

Vignette 21.5

As a double-boarded physician in internal medicine and psychiatry, Dr. Rogers was well-respected by his medical peers and other healthcare team members for his approach of determining (ruling out) pathophysiological reasons for patients presenting with severe mental health issues. One evening, while making rounds on an inpatient psychiatric unit, he was attacked by a violent 250-pound male patient who charged him and wrapped his arm around his neck. Dr. Rogers was strangled to unconsciousness before hospital security could get to the unit. He suffered a hypoxic brain injury which left him severe speech and motor disorders. Dr. Rogers was not able to resume to practice medicine after his injury, and he and his family suffered significant and long-term emotional and financial issues.

Workplace Violence

Imagine going to work where keeping safe from violence requires special access badging with limited hours for guests, fences, police presence, panic buttons, metal detectors, and security cameras (Vignette 21.5). Imagine going to work and only having your first name on your badge out of concerns you and your family will become a target. Imagine feeling threatened so often that it becomes a normal part of work and new threats often go unreported. This is the world of healthcare. According to the Bureau of Labor Statistics, injuries in 2017 from violence in the healthcare setting requiring time away from work was four times over the national average for private industries; 71% of such injuries occur in the healthcare and social service setting [31].

The National Institute for Occupational Safety and Health (NIOSH) defines workplace violence as "violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty" [43]. In their revised Sentinel Event Alert, the Joint Commission states, "Once considered safe havens, health care institutions today are confronting steadily increasing rates of crime, including violent crimes such as assault, rape and homicide" [44]. Workplace violence is more than physical violence as it also includes harassment, bullying, intimidation, and stalking [33]. What is clear is that workplace violence is a national problem with a disproportionate impact on those who are offering care to their communities.

The costs are both tangible and intangible as described in an International Labour

Organization report from 2001 [45]. More obvious are the costs related to missed work, decreased productivity, turnover, compensation, and litigation costs. Other intangible costs include loss of reputation and goodwill to the organization. There may be a heavy emotional impact on the individual with social isolation and suffering.

There are four types of workplace violence depending on the relationship between the workplace and the perpetrator: a person with criminal intent and without any relationship (Type I); a former patient or customer (Type II); a former employee (Type III); or someone who has a personal relationship with a current employee (Type IV) [46, 47]. Although acts of violence can occur in the hospital proper, they can also occur in a provider's office, in the patient's home during a home healthcare visit, or in the emergency department. Sadly, one study focusing on the emergency department documented a career prevalence of physical violence of 80%, but with only 49% of these incidents being reported to the police and medical care infrequently sought after an injury [48]. As nurses spend more time with patients, they have the highest rates of assault; up to 46% nurses surveyed had experienced violence in the past five shifts worked according to one study [49].

What to do? OSHA would recommend a formal program involving leadership as well as those at the sharp end of care delivery [50]. For leadership this involves setting the expectation for a safe work environment, allocating appropriate resources, designating responsibility to specific leaders toward execution, formulating effective policies, and establishing a comprehensive program around medical and psychological counseling following an assault or other act of violence.

A recent randomized controlled study demonstrated that interventions that were data-driven and focused on specific worksite concerns were effective in decreasing Type II (patient to worker) violent events and injuries [51]. Strategies were environmental, administrative, and behavioral. Environmental strategies included more frequent rounding by security, installation of panic alarms on nursing units, and increased lighting in the parking lot. Administrative strategies included more timely psychiatry consults, improved staff-patient ratios, security drills with staff, and safety monitoring policies for non-employees entering the unit. Behavioral strategies included de-escalation training, team building, and customer service classes for staff.

Further improvement will require a multidisciplinary approach. The impact of workplace violence at the hands of an angry or confused patient is too important to do otherwise, with the specter of worker fear, job dissatisfaction, burnout, and missed work as outcomes. This becomes all the more poignant for caregivers who have dedicated their lives to the healing profession, then to meet a violent injury in the giving of themselves to others, and sometimes all of themselves.

Vignette 21.6

Dr. Jeffers was a well-respected surgeon at his hospital and with his patients. He was efficient, a great communicator with his patients and the staff, and his quality had always been top-notch. The patient was like hundreds before. Put the laparoscope into the abdomen, do the surgery, solve the issue at hand, and help the patient and family transition to the next part of their journey.

Everything went according to plan that morning. Anesthesia was uneventful and the patient tolerated the procedure well. The only problem was that the wrong surgery was performed. The patient was harmed and because of this would have a life-long impairment.

The entire clinical team was devastated, especially Dr. Jeffers. He openly wept and strongly considered walking away from his life as a physician. It took time, and especially with help from therapy, for Dr. Jeffers to feel comfortable seeing a patient again, much less operate. The caregiver needed to be cared for.

Burnout and Resilience

The scenario above is all too common (Vignette 21.6). It is estimated that over 4000 surgical never events occur every year in the United States. This ranges from retained foreign objects such as sponges, performing surgery on the wrong site or on the wrong patient or even doing the wrong procedure, to death in over 6% of patients [52]. This section isn't about patient harm; each of these cases has a physician and a care team behind the event, and that team is often profoundly affected, feeling personally responsible, even when the error was due to system failures. When there is a direct correlation between the delivery of care and the harm to the patient, that individual delivering the care often needs help as well as the patient harmed. Emotions range from chaos to intrusive reflections and a journey to restoring integrity to moving forward in life – but that does not always mean remaining in healthcare [53]. The Joint Commission has developed a toolkit with modules to be implemented for successful staff emotional support programs [54].

Unfortunately, medical errors are among a legion of problems besetting workers in healthcare; concerns over burnout, depression, and suicide are making headlines. Those in healthcare struggle to deal with anxious or angry patients and families, threats both verbal and physical, and the physical requirements, as discussed, which can push the body and mind into decay. In a survey of over 2000 physicians, there were other factors contributing to burnout including healthcare reform and administrative demands, work-life imbalance, the economy – including lower reimbursement – and not enough time for relaxation or other wellness activities [55].

Today, ubiquitous programs are available to deal with burnout, or resiliency, depending on your vantage point. What is clear is that we have a long way to go to win the war on provider burnout. In a recent 2019 Medscape article, 44% of physicians feel burned out across the spectrum of medical practices, whether hospital or office-based or surgical or medical [9]. Too many good clinicians are leaving clinical practice. Wellness and morale are plaguing the field of healthcare, making the complex task of care all the more difficult. At the foundation of almost every improvement effort is the aspect of culture – getting it right to drive change. Unfortunately, if the providers of care are struggling, the ability to help others in need can seem like a bridge too far. For many, the Pennsylvania nurses' study was a wakeup call for action where burnout was associated with an increase in CAUTIs and surgical site infections [56]. The Advisory Board speaks of the cost to organizations, referencing a 16% decrease in patient satisfaction scores coupled with an 11% increase in medical errors in burned-out physicians [57].

Many might ask whether this is due to the authoritarian high modernistic ideals of forcing physicians and nurses into a rigid structure of work (the electronic medical record, being an example) and whether with this, work loses purpose and meaning and becomes purely task-driven…too many clicks on the computer, yet another alert, pushing through an order set, or adding a smart phrase.

This is why the Quadruple Aim has taken on new meaning – to add purpose and meaning to the equation of work. Researchers today are devoting entire careers to the concept of wellness and burnout across all areas of care delivery, from attending physicians to residents to students, nurses, administrators, pharmacists, and so on.

It is imperative that we solve this growing issue with comprehensive solutions. Recognizing this problem as conditional is imperative before moving forward. This requires expertise in the field of positive psychology to understand resilience and emotional thriving. It requires specific and sustainable interventions, as well as the ability to implement across inpatient and ambulatory practices, for employed and independent providers, and the other caregivers in our delivery system.

To combat the pervasive problem of burnout, leaders need to improve operational inefficiencies and create a culture of wellness within an organization. It takes a resilient workforce to tackle the needs demanded from a complex inpatient census and the surrounding underserved

community. With that being said, it is also about professional fulfillment and better self-care. In *Leading Well from Within*, Dan Friedland espouses a framework for personal resiliency that deals with how we manage our reactivity and both our stress and self-doubt mindset. He emphasizes personal creativity for connecting, learning, and focusing on what is truly important and, finally, catalyzing growth in a call to action toward an inspired life [58]. Many providers still have a long way to go toward resiliency.

According to a study published in 2012, people are actually happier when they *do* slow down, appreciate the people they love, find meaningful things in their lives, and feel gratitude toward others. The author writes, "The challenge in fostering appreciation is that we want to periodically reflect on the positive aspects of our lives, value our friends and family, relish and savor the good times [59]."

There is another powerful study to share with you about slowing down. This was from 1973 and titled "From Jerusalem to Jericho" and was a study on situational and personality variables on what we do [60]. Ostensibly, the study was designed to test seminary students on whether they would stop to help someone in need – a planted "victim," similar to the Good Samaritan who helped the man on the side of the road who had been mugged while traveling from Jerusalem to Jericho. Would these students stop to help a "victim" because they were in seminary or perhaps because they had been briefed on the importance of ministering or maybe since they were actually going to give a talk on the Good Samaritan. No, no, and no! The only thing that made a difference in the overall helping behavior was whether the person was in a hurry or not. People in a hurry were focused on the task at hand, some of them even stepping over the person in need to hurry off to their assignment. Those with extra time were able to be present in the moment and, shall I say, use their critical thinking skills to solve for something unexpected.

How can we interpret these results for those of us in healthcare? We came into healthcare to help others who are suffering and in need. In this, we are no different from those seminary students. What then happens when *we* get busy? Do we also focus on the tasks at hand? Are we unable to see the forest for the trees? The safety literature would say yes; we too make errors because we do not give ourselves time to cognitively refocus [61]. If we take the time to be present in the moment, we are more likely to be happier, especially when we are appreciative and grateful for what is there right in front of us. By doing this we help to achieve the fourth pillar of the quadruple aim, the taking care of "us," remembering our purpose in work and the passion and joy that comes with it. Will we be busy? Of course, and being aware of that reminds us to pay attention to the details around us and to use the STAR tool in the doing-Stop*-Think*-Act*-Review*.

Let's stop and smell the roses, for us and those all around us, whether at the end of our stethoscope, across from us in a meeting, on the receiving end of an email, or tonight, or across the dinner table with our family in the balance…

Editors' Comments

Employee and staff safety, workplace safety, or taking care of our own; however, we choose to refer to this mission critical part of hospital safety and quality initiatives; the indisputable fact is that harm occurs to our employees. The authors of this chapter create the burning platform by demonstrating work that shows employee harm occurs at an alarming rate in our organizations. Many health systems erroneously focus on patient safety, hospital-acquired conditions, hospital-associated infections, etc. and lose sight of perhaps the most important part of hospitals – the employees.

Workplace safety is broadly encompassing. This chapter, through the vignettes, focuses on a few of the themes of workplace safety that can be generalizable to other specific workplace safety initiatives. The methodology to approach workplace

safety is no different than the methods to approach patient safety, hospital quality, or even educational paradigms for that matter (Chap. 22). Indeed, our organizations have seen significant gains in employee and staff safety (workplace safety) by utilizing the model for improvement, identifying key drivers, implementing P-D-S-A cycles, and measuring our data. Admittedly, we were pleasantly surprised to see the excitement and engagement from our employees when we embarked upon these initiatives in our organizations – and we have just begun to target the low-hanging fruit. A frontline environmental services employee stated, "I am glad the hospital is looking out for my safety, so I can look out for my patient's safety." This quote epitomizes the value of this work and the need to ensure that we broaden our improvement lens past solely patient and hospital safety to ensure we apply the same rigor and passion toward employee safety.

Chapter Review Questions

1. What aspect was added to the Triple Aim to create the Quadruple Aim?
   A. Patient safety
   B. High reliability
   C. Provider purpose
   D. Physician satisfaction

   Answer: The correct answer is C. The addition of the fourth aim is to emphasize the importance of improving the experiences of those providing healthcare – specifically joy and meaning. Challenges in the work environment, such as staffing, productivity, risks of psychological and physical harm, and non-value added work, are leading to job dissatisfaction and burnout.
2. Patient safety leads to healthcare worker safety?
   A. True
   B. False

   Answer: False. Evidence shows safe employees lead to safe patient and care.
3. What is the primary role of OHSA?
   A. Protect public health and safety through the control and prevention of disease, injury, and disability in the United States and internationally
   B. Provide oversight and ensure safety of workers in the United States
   C. Protecting the health of all US citizens and providing essential human services
   D. None of the above

   Answer: The correct answer is B. The importance of OSHA in the workplace is to establish workplace-specific safety standards to protect both employees and employers from occupational injuries/harm.
4. Which healthcare workers are at risk for exposures to infectious diseases in the work environment?
   A. Nurses
   B. Physicians
   C. Lab technicians
   D. Anyone who works in a healthcare setting

   Answer: The correct answer is D. Workers in all healthcare settings are at risk of being occupationally exposed to a variety of infectious diseases during performance of their work-related responsibilities.
5. RNs and nursing assistive staff are at greatest risk for patient handling-related injuries?
   A. True
   B. False

   Answer: True. RNs and nursing assistive staff are responsible for performing repetitive and routine task such as manually lifting, moving, transferring, and ambulating patients. There are many risk factors, including the patient population is aging and their mobility is compromised, 1 in 5 adults are disabled, long shifts, lack of adequate staff and lift equipment/device resources, and rising obesity rates, creating challenges for safe patient handing in healthcare settings.
6. Patient handling injuries can be prevented by using which of the following?
   A. Face shield, gown, and gloves
   B. Lift and ambulation assist devices
   C. Safety needles
   D. Proper body mechanics

Answer: The correct answer is B. Using lift and assist devices, such as ceiling lifts, gait belts, slide sheets, hoist slings, wheel chairs, lift stand, and wheelchairs, can prevent work-related and patient injuries.

7. Slips, trips, and fall (SLF) injuries in healthcare workers are?
   A. A leading cause of lost workdays
   B. Are preventable
   C. Are considered an occupational hazard
   D. All of the above

   Answer: The correct answer is D. Slips, trips, and falls in healthcare settings are one of the leading causes of work-related injuries with the majority due to contact with a liquid [e.g., cleaning or body fluids, water, etc.] and can be prevented by the use of slip-resistant footwear.
8. Exposures for healthcare workers can include?
   A. Needle and sharps
   B. Chemicals/gases/drugs
   C. Airborne pathogens
   D. All of the above

   Answer: The correct answer is D. Workers in healthcare settings encounter a wide range of hazards on the job. Although it is possible to prevent or reduce, healthcare workers continue to experience injuries and illnesses due to exposure hazards in the workplace.
9. Who is ultimately accountable for using personal protective equipment (PPE)?
   A. The healthcare worker
   B. The employer of healthcare workers
   C. OSHA
   D. No one person

   Answer: The correct answer is A. Ultimately, the healthcare worker is accountable for using PPE and for using it correctly. Healthcare facilities are responsible for meeting the OSHA requirements for providing and ensuring workers know how to correctly use PPE.
10. Workplace violence in healthcare can occur in any setting (e.g., hospital, physician's office, skilled nursing facility, etc.)?
    A. True
    B. False

    Answer: True. Workplace violence is significantly more common in healthcare industries and is not just a hospital issue as it can occur in any healthcare or non-healthcare setting). Patients account for 80% of workplace violence injuries to workers.
11. Which healthcare workers experience the greatest incidence of workplace violence?
    A. Physicians
    B. Technicians (e.g., lab, radiology, etc.)
    C. RNs and nursing assistants
    D. Therapists (e.g., respiratory, physical, etc.)

    Answer: The correct answer is C. RNs and nursing assistants are more vulnerable as they are the largest sector of the healthcare workforce, and their rates of workplace injuries due to violence are continuing to rise steadily.
12. Which statement is true about the four *types* of workplace violence?
    A. They include rape, homicide, harassment, and stalking.
    B. They are based on the relationship between the workplace and the perpetrator.
    C. They only occur only in the hospital setting.
    D. All of the above.

    Answer: The correct answer is B. OSHA/NIOSHA has defined four types of workplace violence based on research to better understand risks and prevention strategies.
13. Burnout occurs only in those physicians working in hospitals?
    A. True
    B. False

    Answer: False. Burnout can affect any healthcare worker and in any healthcare setting.
14. STAR, an error prevention technique, is an acronym for?
    A. Stop, Think, Act, Review
    B. Stop, Think, Ask, Repeat
    C. Speak up, Think, Act, Review
    D. Stop, Time-out, Ask, Review

    Answer: The correct answer is A. STAR is a high reliability safety tool used to prevent

errors – especially in preventing errors while performing actions that are so highly practiced, they are automatic.

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Changing the Improvement Paradigm for Our Kids

22

Daniel B. Wolfson, Jeffrey Scott Warshaw, and Julianne C. Coleman

Chapter Objectives

- To demonstrate the value of improvement science and its utility for improving efforts across non-healthcare social enterprises; lessons learned and novel insights are broadly generalizable.
- To introduce other approaches to improvement that draw on quality improvement methodology and principles.
- To build an understanding in the application of improvement methodology, including tools and best practices for diagnosing problems, understanding systems, theory-building, and testing and building evidence.
- To provide examples of frontline-driven improvement efforts that build a culture of collective learning and reflective problem-solving within complex organizations.

Vignette 22.1 The Moral Imperative

Good relationships impact learning. My school matters because it provides opportunities and is like a family to me…. there's a bond that's so strong with each other …I don't like to see my parents suffer…I want to be on top of my game…I want to be able to spread my wings and fly…I want to take a better step ahead of me because I want to make my parents proud. Ever since we have had to live in a van- they do anything to get us food…I appreciate that…sometimes our parents wouldn't eat to give us food. I appreciate them and my teachers who work to help us improve and be able to take the next step. – Unnamed homeless student (senior in high school)

Opening Question/Problem

This chapter is designed to provide a different view of quality improvement through the lens of education, specifically in PreK-12 grades. The examples and discussion provide insight to the utilization of key improvement principles by practitioners to target efforts to improve outcomes for those that both healthcare and schools serve. For the longest time, social sector enter-

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prises have implemented solutions or initiatives without a systematic approach to improvement, often leading to mixed results. This chapter attempts to demonstrate how this problem of "solutionitis" [1] is beginning to be addressed in education through improvement science.

Introduction

The opening vignette provides an example of the moral imperative for how our educational system must work to serve the needs of all of our students regardless of their context and who they are; healthcare's moral imperative is strikingly similar. School systems are challenged to provide not only the academic support but also the social, emotional, and behavioral support in a way that develops and fosters students' strength and potential at the highest levels. In meeting these challenges, school leaders and teachers constantly work to improve their system to better meet the needs of each and every student. Often across the educational enterprise, improvement reflects an approach that is based on the premise that programs and people are the formula for getting results through improvement. This is often reflected in how school systems tend to roll out new programs at scale with no real plan for understanding how their improvement is working along the way. In schools, we often scale implementation quickly but poorly implement. School systems also tend to view improvement in terms of adding more of something. For example, schools often add more staff or more resources or more time to an improvement effort. These types of improvement efforts tend not to produce the results desired as these efforts typically do not change the way work is accomplished in the system [1]. School systems also tend to look for hero leaders who they believe can turn a school around. Again, the flaw in this approach is that unless the design of the system changes, the results will likely be more of the same. Furthermore, a common approach schools often use for improvement is that they tend to rely on training. All training has the potential for changing standard work of the classroom practitioner; however often times there is no embedded support or cycle of reflective inquiry that assists the practitioner in implementing the training in a way that results in measurable improvement. Finally, school systems tend to believe that if they say things louder [1], making sure that people are explicitly told about the change, then it will be implemented in the way that gets the desired results.

The dilemma for the improver is that all improvement requires change; however not all change is an improvement [2]. Improvement science holds great promise in providing tools, mindsets, and a methodology that empowers practitioners to collaboratively solve problems of practice. Improvement science helps us to attack the knowing-doing gap [3] as it helps to discipline our improvement efforts to be able to sort out what works for whom and under what conditions. The improvement paradigm is the key to unlocking the best ways to change educational systems in our schools that will result in actual improvement, eliminating equity gaps among historically underserved students, and empower frontline practitioners to drive improvement efforts.

The case vignettes provided in this chapter will provide the reader with opportunities to build an understanding of the utility of improvement science to engage practitioners in a systematic approach that is driven by deep learning and reflective inquiry. The vignettes represent real stories of improvement teams and their efforts; however, the names have been changed for the purpose of presenting learning opportunities that demonstrate the potential and value of improvement science. Improvement is the core of quality, and these lessons can be extrapolated to other industries.

Improvement Science and the Knowing-Doing Dilemma

In education, there is an emphasis on the utilization of research evidence-based practices. We often organize ourselves in education around the resources that will provide buckets of what

works. However, there is a well-documented tension which we call the knowing-doing gap [3] in which educational practitioners struggle with getting good ideas to work in practice with measurable improvement [4]. This lack of understanding around the knowing-doing gap helps to exacerbate the dissatisfaction in system performance that we currently see in our educational systems (Key Points Box 22.1). And it is the assumption that school systems make around how to address the knowing-doing gap that often follows a path that does not result in the desired improvement. What typically happens is that a school system invests resources and professional capital to scale a program or initiative based upon the assumption that if implemented it would result in an improvement in performance at some point in time. Moreover, if the performance outcome is not improved as anticipated, then the system tends to do more of the same program or initiative by increasing additional resources toward the implementation. It is this paradigm that has unintentionally hindered efforts to address the knowing-doing gap to get the meaningful improvement that is needed for our kids. In California our school systems only work well for about half our students in meeting academic standards [5]. The current challenge is how do we change and shift the paradigm to improve, especially as an approach that fosters equity in a way that ensures all of our students have access to high-quality educational experiences that provide them with the most opportunities with the most choices for advanced learning and career when they graduate high school.

Key Points Box 22.1 Knowing-Doing Gap
The knowing-doing gap is a well-documented tension in which practitioners struggle with getting good ideas to work in practice with measurable improvement. Improvement science addressees the knowing-doing gap as it helps to discipline our improvement efforts to be able to sort out what works for whom and under what conditions.

Teaching and learning is a sophisticated endeavor representing the complex work of teachers and students in the presence of content [6]. The pedagogical considerations along with the content knowledge or subject matter expertise must be engineered by the teacher to engage the student in order to create high levels of learning that results in increased performance. This knowing-doing gap has been particularly challenging as research-based knowledge provides the gold standard through randomized controlled trials (RCT) [4]; however the implementation of these across varying contexts found in schools and classrooms is extremely difficult.

We now recognize that understanding variation is a key driver for implementation in the school context [1]. In other words, educators have access to "what works" research; however getting these good ideas to work in a specific context that increases student outcomes is the primary challenge. Improvement science has helped to mitigate this knowing-doing gap by introducing a disciplining methodology with tools and resources that can be applied at the classroom, school, or district level to make a program or practice work reliably and across contexts [1, 7].

The Carnegie Foundation for the Advancement of Teaching and Learning [8] is the key organization that has adapted and provided expertise for the utilization of improvement science across the educational enterprise. Carnegie has drawn upon quality improvement research and practice in identifying six core principles of improvement that are seminal to the building of improvement knowledge, including (1) make the problem specific and user-centered; (2) variation in performance is the core problem to address; (3) see the system that produces the current outcomes; (4) measurement is key to improving at scale; (5) anchor improvement in disciplined inquiry; and (6) accelerate improvement through networked communities [1]. Table 22.1 shows these core principles of this learning-by-doing approach to solving problems.

These core principles represent a process that is potentially messy and non-linear, drawing on a theory-based approach to learning (Key Points Box 22.2). Moreover, such a

Key Points Box 22.2 Theory-Based Learning
Improvement efforts represent a learning journey in which the improvement team engages in itinerate phases of the work and continually learns along the way to refine their theory of improvement. The team exhibits a learning stance, acknowledging that there are gaps missing in their theory, and knows that the theory will evolve as they continue to learn.

Table 22.1 Abbreviated view of Carnegie's core principles of improvement [1]. These are the core principles that teams should pay attention to in an improvement effort

Be problem-specific and user-centered	What is the gap we are trying to close? What specifically is the problem we are trying to solve? Engage users who are close to or experiencing the problem
Variation in performance	What works for whom and under what conditions? Key to reliably scaling improvement
See the system	Build a picture of the system by considering all views Causal system analysis to address why we are getting the current outcomes Utilize tools such as process maps to make the system visible
Measurement	How do we know a change is an improvement? Build a family of measures that includes outcomes, drivers, processes, and balancing measures
Engage in disciplined inquiry	Highly reflective learning cycles to accelerate learning to improve quickly Use of rapid Plan-Do-Study-Act (PDSA) cycles
Networked communities	Communities of "common accomplishment" for a clearly defined measurable outcome Leverages the characteristics of learning networks

problem-solving approach also requires a culture where the improvers exhibit a learning stance that will make it more likely that measurable improvement will occur. A learning stance actualizes the potential for improvement and includes key mindsets such as humility, discipline, curiosity, and willingness [9]. There is a mantra that is frequently used in improvement work by teams to articulate the seminal idea that we are learning our way into improvement: "possibly wrong, definitely incomplete" [10]. With this stance, we acknowledge that our current best thinking will have gaps in knowledge and by explicating our mental models of how things work, we will be more likely to realize reliable improvement at scale.

California has made a series of significant shifts in public education for improving education. A key shift was the movement from "test and judge" to a "support and improve" approach, with the intent to transition school districts into learning organizations driven by continuous improvement [11]. As a result of the policy shift toward a continuous improvement model, a system of support was developed leveraging improvement science. There is a supporting idea that we want to explicitly call out that are tied to assumptions about how people should work together when engaged in improvement efforts. As an improvement team, the approach moves from "doing to people" to "doing with people" because it is more likely to lead to sustained improvement. For change to be sustainable, it must be developed and directed by individuals within the system who will be doing the hard work of continuous improvement. This includes a focus on a frontline approach that acknowledges the expertise of those closest to the problem and views these practitioners as primary drivers in getting good ideas to work [12] (Key Points Box 22.3).

Key Points Box 22.3 Key Ideas
- A learning stance is essential.
- It's about systems, which are complex and by nature hard to see.
- Deliberately engage in a deep understanding of the problem.
- Theory-based learning.
- Discovery "by doing" through reflective inquiry cycles.
- Frontline engagement and ownership.

Vignette 22.2 Theory-Based Learning and the Driver Diagram

The College and Career Technical Education (CTE) teacher from Gravel Springs High School is responsible for designing and teaching the "Clean Energy" course sequence as a career pathway at the school. The teacher often struggles to find work-based learning experiences for her students as she has traditionally relied on her relationships with industry in the local area, which has limited access to companies in the clean energy sector. At a recent county-wide conference, she runs into a colleague who teaches a similar course sequence for a clean energy career pathway in an affluent area. She learns that the Solarium Corporation, working in partnership with the local community college, provided a 5-day summer solar energy academy internship experience for his students. This was exactly the type of work-based learning she was hoping to find for her students – hands-on activities, field visits, and lectures from solar professionals. Unfortunately, she grows concerned about bringing this opportunity to fruition at her school knowing that her students would likely not be exposed to this type of experience based upon the location of the high school and its more traditional local industry connections.

Context

The vignette above (Vignette 22.2) provides insight into the dilemma that exists in the current reality across the local region. The current reality for many students in high schools is that student access to work-based learning experiences is driven by the local classroom teacher and the relationships that he or she has with local industry in the area. Unfortunately, depending on where a student attends high school, they may have limited access to work-based learning opportunities that are key to preparing them for post-secondary advanced learning and career readiness. In order to address this issue of equity, a regional consortium was formed funded through a major grant effort to develop a web-based platform that would serve as a connector between high school students and local industries. This web-based platform, also called the e-portal, would potentially level the playing field across the region as it would serve as a hub for industry to connect work-based learning experiences with career technical education teachers across the 111 high schools in the county. In this way, students in less affluent areas would have increased access to opportunities that would better prepare them for options after graduation.

Utilizing Improvement

After the initial first year of the e-portal, baseline data indicated that only approximately 8.5% of all work-based learning experiences were accessed through the e-portal. As this represented a dissatisfaction with the status quo, the Career Pathway Team utilized improvement science to assist them in optimizing the potential of the e-portal in order to provide greater access of work-based learning opportunities. Through the use of improvement methodology, an improvement charter was established, with the aim to increase the number of work-based learning experiences accessed through the e-portal to 20% after 2 years. This aim directly supported the regional infrastructure for career pathway development in high schools and addressed the disparity between schools by increasing access to work-based learning for all teachers and students regardless of the location. Based upon the aim, this improvement project developed a theory of improvement which addressed the following project goals: (1) increase the number or baseline experiences completed through the e-portal, (2) increase the number of teacher requests for work-based learning, (3) increase the number of teachers trained to use the e-portal, (4) increase the number of work-based pathways, and (5) increase the number of industry business

partners offering opportunities through the portal. The Career Pathway Team used an improvement tool called a driver diagram to organize a coherent theory to explain the "why we are doing the things we are doing" and "how are we doing them" to be able to move the needle on the aim (Key Points Box 22.4).

The power of the driver diagram is the visualization of a shared belief and model of what the team thinks is needed to accomplish measurable improvement. Figure 22.1 depicts the driver diagram and shows the primary drivers, secondary drivers, and change ideas that were tested.

Key Points Box 22.4 Driver Diagram
An organizing tool is used to visualize a shared theory of improvement. It serves to coherently build understanding of an improvement team's current best thinking of the high-leverage areas in the system to target for moving the needle on the aim.

What makes the driver diagram different from other types of logic models is that the improvement team acknowledges that the theory of improvement is "possibly wrong and definitely incomplete." In other words, we exhibit a learning stance throughout the problem-solving process and understand that our initial theory has gaps in it. Thus, as the improvement team works to conducting rapid inquiry-driven PDSA learning cycles of its change ideas, the driver diagram is iteratively updated to represent the learning and current best thinking of what will move the aim. One of the key ideas of improvement science is the commitment to test ideas in practice and use that learning to update one's current theory that builds evidence overtime of what it is an improvement and what is not.

Lessons Learned

After 1 year of improvement work, notable lessons were documented by the Career Pathways Team in applying improvement methodology to inform ongoing work, thus resulting in growing

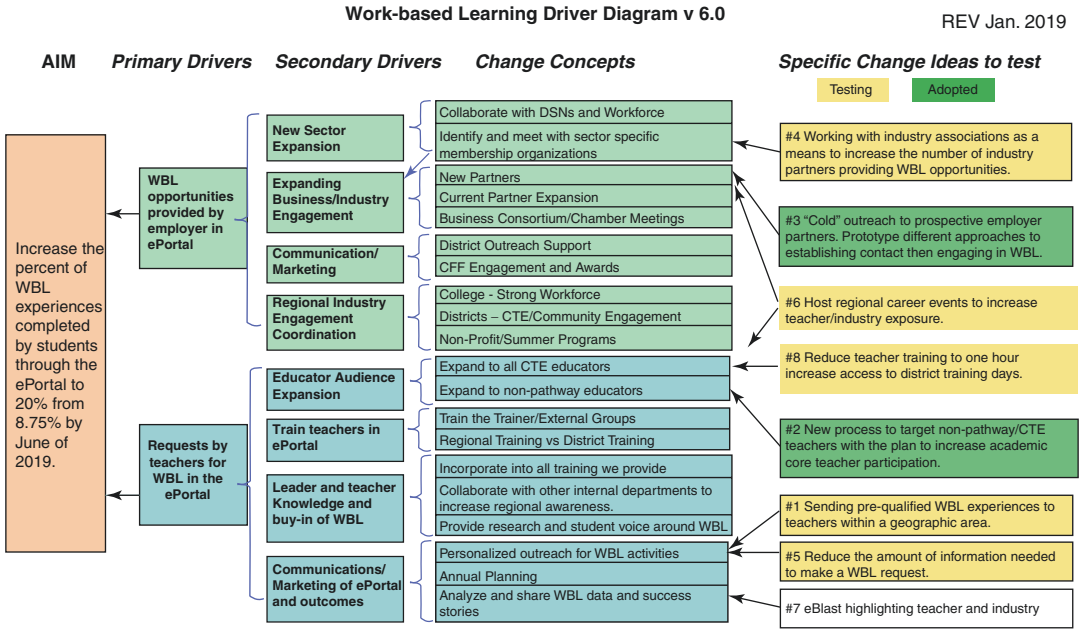

Fig. 22.1 Driver diagram that depicts the team's shared theory. This is the driver diagram utilized by the improvement team to visually represent the current shared theory of how to accomplish the AIM

the improvement efficacy of the team. The team found that as it tested change ideas and its theory of improvement, the rapid inquiry-driven PDSA learning cycles accelerated their learning, driving frequent iteration of the driver diagram as they refined their theory. Likewise, the team also found that in running PDSAs, the more concrete they were in predicting the outcomes, the greater the degree of learning influenced their working theory. In other words, the act of explicating their theories about what they believe would occur as part of the PDSA learning cycle increased the richness of the team's learning about how the changed idea worked. Moreover, as the team developed its theory of improvement, they discovered the importance of accurately determining the cause of variation found within the system as a way to inform its approach to problem-solving. For example, what typically can occur is that the improvement team believes that most of the changes that need to happen are in response to special-cause variation found within the system. Special-cause variation means that the outcome to improve is a result of the system not performing optimally as it was designed; requiring improvement that specifically addresses an isolated problem, and by fixing it, would return the system to its performance (Key Points Box 22.5).

Key Points Box 22.5 Variation of Performance

Variation found in performance is the primary challenge to address throughout the improvement journey. For understanding current performance of systems, improvement teams pay attention to the type of variation – "common cause" or "special cause" – to inform their approach. The improvement team also thinks about variation as it builds and tests evidence through the PDSA process to reduce variation and improve predictability of outcomes.

However, the understanding of common cause variation or "natural variation" provides a powerful implication for improvement teams in building their theory of what to do to move the needle on the aim. A team that pays attention and can identify whether performance is due to natural variation requires the team to determine if they are satisfied with the performance of the system. If the answer is dissatisfaction with the system performance, then a redesign of the system is necessary in order to get improvement at a higher level of performance rather than simply mitigating a problem in isolation as it is "special-cause." Finally, a key takeaway was the realization by the team that this work is complex and messy, and it's important that a disciplined methodology that engages the frontline be used to help a team navigate in a way that results in measurable improvement.

Vignette 22.3 Addressing Variation in the System

A high school district continually sees low outcomes in terms of academic achievement, graduation rates, and college and career readiness among students with disabilities. Among their ten school sites, strategies and processes for supporting struggling students vary greatly and produce inconsistent (but below district average) results. The district recognizes the interconnected relationship between academic achievement, graduation rates, and college and career readiness and seeks to improve all three indicators by calibrating the prescription and documentation of interventions for struggling students.

Context

During the 2017–2018 school year, state test results revealed district-wide student performance in English Language Arts (ELA) among all students to be 18.1 points above the state's standard threshold for proficiency. In contrast, ELA results among the district's students with disabilities showed a performance level of 93.1 points below the state's standard of proficiency. A similar discrepancy existed in the area of graduation rate,

with an 82.1% graduation rate among all students compared with 62% among students with disabilities. Finally, the state's College and Career Readiness Indicator showed that 44.2% of all students met state criteria for college and career readiness, while just 4.9% of students with disabilities met such criteria upon completion of their high school program of study. Vignette 22.3 above is an example of addressing variation in the system.

Based on learning from previous improvement efforts, district leaders were aware of the importance of a thoughtful approach to engaging a team in taking on their improvement work. Past teams had either been too large to be productive, leading to frustration and waning participation due to a perceived lack of progress. or had lacked site representation, which led to a lack of investment in the implementation of improvement ideas due to a perception that district leaders were imposing solutions without considering the perspective of the site stakeholders. Thus, the district assembled a team of district and site leaders to develop an improvement plan. The team consisted of an assistant superintendent of educational services, two directors of college and career, a special education director, a data scientist, and two site principals. The site principals were chosen from schools with the most significant gap in the achievement, graduation, and college and career indicators.

Utilizing Improvement

The district team, with guidance from an improvement coach, explored relevant data [5] and current programs and efforts in place to support students with disabilities in order to clarify the context of their improvement work and assess needs (Fig. 22.2).

The goal of the needs assessment process was to delve beyond the outcome data (which merely serves as a symptom of systemic weaknesses) in order to identify systemic causes as viable contexts for improvement efforts.

The process revealed a need to better cultivate and support human capacity in prescribing and

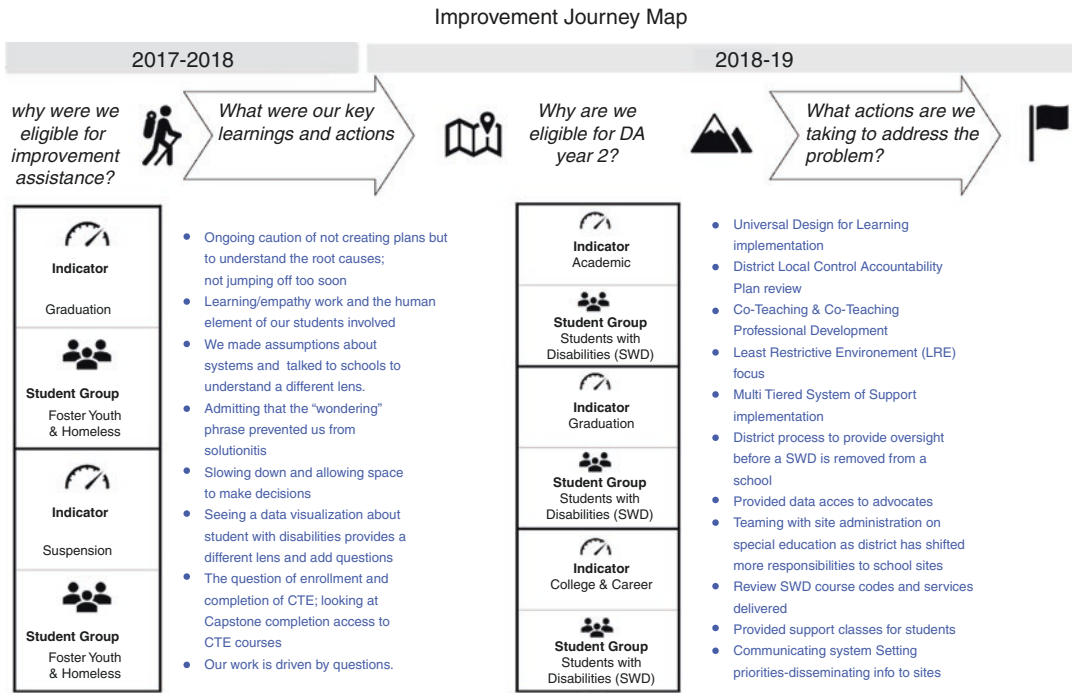

Fig. 22.2 Improvement journey map. A journey map is a tool that was utilized to increase understanding of the support provided and experienced by students with disabilities

What is our theory of action? *(If we..., then we will improve our systemic weakness)*		
Theory Sentence: If we allocate resources using data driven decision making, to provide professional development with monitoring, thet supports site based ownership, both in and out of the classroom, with site administration using reciprocal accountabiity, then we will build and improve human capacity in our organization to increase outcomes for students with disabilities.		
What are we trying to accomplish? *(Aim Statement)*	What changes will we make to get improvement? *(Change ideas)*	How will we know the change is an improvement? *(Process & outcome measures)*
We will improve leadership capacity for reciprocal accountability	Calibrate site definition of student need indicators and criteria at principals leadership meetings	Students with Disability data Grades/Attendance/Behavior

Fig. 22.3 Theory of action. The improvement team developed an overarching shared theory of action that represented the key lever points in the system that they believed needed to be addressed to improve outcomes

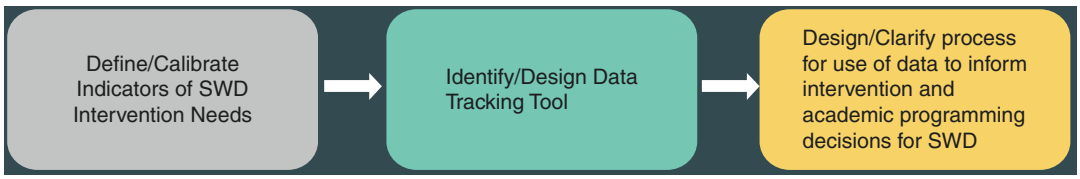

Fig. 22.4 Improvement process design diagram. This diagram represented the improvement team's design for standardizing the process for identifying interventions for students with disabilities (SWD)

implementing interventions for students with disabilities and surfaced a lack of coordinated accountability systems between site and district leaders.

The team's next steps included articulating a theory, driven by an essential question: How do we build and improve human capacity of individuals in our organization to improve outcomes for students with disabilities? By mapping their system with input about intervention efforts from both site and district leaders, the team developed a theory of action from which to draft an initial aim and change ideas (Fig. 22.3).

Ultimately, the team recognized the need to better calibrate their processes for identifying student needs, documenting intervention efforts, and leveraging information to inform decisions about supporting student success (Fig. 22.4).

The two school sites began a series of Plan-Do-Study-Act (PDSA) cycles to learn about how to improve their curation of intervention data in service of student needs. The learning from these PDSA cycles helped to inform district adjustments to the student intervention tracking system. While this work is ongoing, next steps include continued refinement of the intervention tracking tool and district level support for the development of a data use protocol during the academic programming process for students with disabilities, with the intention of reducing the variation in both the technical application of the intervention tool and the role that student intervention data and histories play in student support and academic planning processes.

Lessons Learned

This improvement journey generated substantive learning and positioned the district to scale up their efforts across each of their high schools. Chief among the lessons learned was the recognition of the impact of variation in site-based processes on student outcomes. Specifically, the lack of calibration between sites around intervention criteria and documentation produced significant inconsistencies in the experiences, success, and achievement of all students, with a magnified neg-

ative impact on historically underserved student populations such as students with disabilities. Examining the impact of variation led to additional lessons about the importance of district level coordination across the system as a means of reducing variation. While the district had made a conscious effort to empower sites through a "hands-off" approach, the sites had actually found themselves developing internal processes in a vacuum, with detrimental impact on student experiences and district-wide outcomes. This improvement journey brought to light the value of reciprocal accountability between the district and school sites, driven by a spirit of support and a commitment to continuity in processes, leadership, and student experiences.

The team recognized that the complexity of the system, including challenges such as ongoing changes in district and site staffing, underscores the need for systems of support to better ensure consistent implementation of district processes and policies that honor the district's vision for supporting all students in accessing a meaningful high school course of study that equips them for advanced learning and productive careers.

Vignette 22.4a Launching an Improvement Effort

A kindergarten through eighth grade school district has a problem with suspension rates among students with disabilities. School staff suspends students with disabilities, removing them from the instructional environment, at a significantly disproportionate rate when compared to their general education peers. While historical data indicates that this problem has been pervasive over time, a review of data through the lens of the new state accountability system prompts both a sense of urgency and access to support for improvement efforts via a partnership between the district and their local office of education.

In 2017, the district saw an overall suspension rate of 4.2% among its approximately 13,000 students [5], which indicated an increase of 0.5% from the previous year (Fig. 22.5a). Disaggregated data showed a suspension rate of 8.5% and an

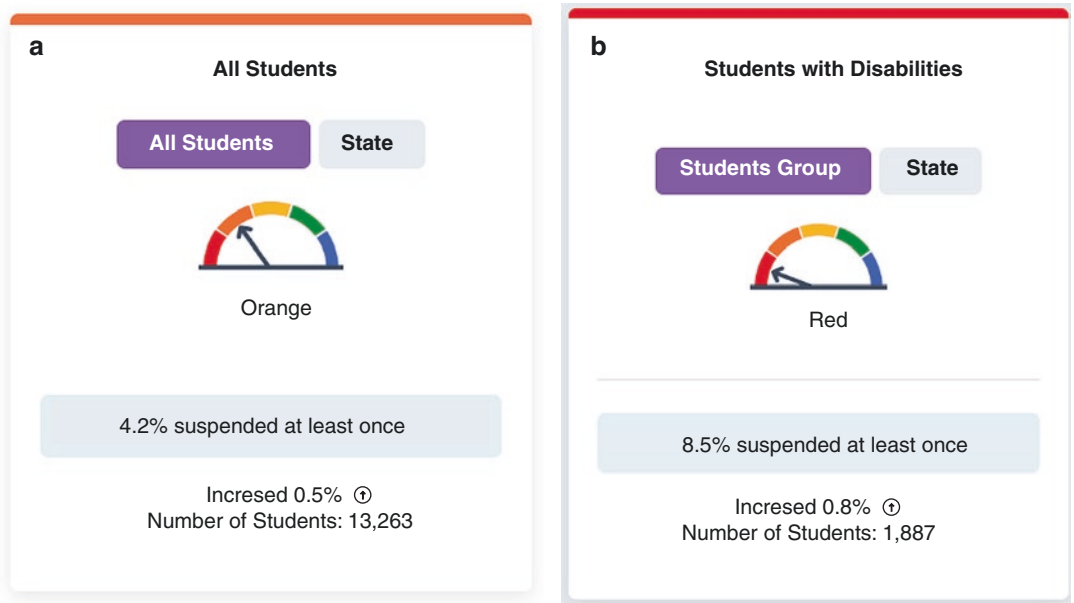

Fig. 22.5 Dashboard indicator for district suspensions. This depicts the annual suspension rate for all students (**a**) and the students with disabilities student group (**b**)

increase of 0.8% among the district's nearly 2000 students with disabilities [5] (Fig. 22.5b). Vignette 22.4a shows inquiry mindset and the interconnectedness of the system.

District leaders recognized the disparate outcomes as a reflection of inequitable practices within their system and also expressed trepidation about staff reaction to a perceived effort to limit the use of suspension as a consequence for inappropriate student behavior.

Vignette 22.4b Assembling an Improvement Team

Preliminary conversations between the support team and district leadership emphasized the value of well-informed, small-scale improvement efforts in order to maintain a nimble approach to change while accelerating learning that could be scaled after refinement. As a result, the district identified one elementary (kindergarten through fifth grade) school site and one middle (sixth through eighth grade) school site to participate in an improvement project, with an initial goal of exploring contributing factors to suspension rates in service of reducing suspensions among students with disabilities at these two schools and eventually across all district schools. The two schools were chosen because they had the highest suspension rates for students with disabilities among the district's elementary and middle schools, respectively.

The district's consciousness of perceived hierarchical authority among staff members was an important consideration in assembling an improvement team (Vignette 22.4b). Participating district office leadership included an assistant superintendent of learning support, a special education director, and a district resource teacher assigned to support special education classroom teachers. In addition, the two school principals, a middle school dean of students, and a special education teacher from each site joined the team, providing site-based voice and perspective about the beliefs and processes surrounding student suspensions. Integrating site representation with district level perspective and expertise about special education due process and district coordination of services, the team launched their improvement project confident that the diversity of roles and voices among team members would be an asset to their learning and would promote responsiveness to student needs. A contingent of three improvement coaches provided support and guidance to the district team throughout their improvement journey.

Vignette 22.4c Improvement Through an Inquiry Mindset

Traditionally, improvement efforts in education involve a semi-informed leap to a "quick fix." Predictably, this leads to ineffective strategies, implemented without fidelity, producing insufficient (or in some cases, regressive) results. The early stages of improvement learning required the district to adopt an inquiry mindset, with a focus on understanding their system and how the nuances within that system were contributing to their disproportionate suspension rate among students with disabilities. Review of site and district data raised a series of learning questions: What are the categories of offenses that result in suspensions? Do we see trends in the location of incidents (e.g., classroom vs. playground)? How much inconsistency in suspension rates exists across grade levels? How developed (and supported) is staff capacity to de-escalate student behavior and implement alternative consequences? In order to learn more about their system, the two site teams analyzed local data and sought a deeper understanding of user experiences by conducting empathy interviews with students and teachers.

Findings from these interviews revealed a lack of familiarity with progressive discipline procedures among teachers, which had prompted many of them to see suspension as their only recourse for addressing student misbehavior. Thus, while district and site administrators had perceived that teachers exercising their right to suspend was largely driven by a punitive mindset about student behavior, empathy interviews revealed that reluctance to apply alternative measures was more commonly driven by lack of teacher knowledge about their students' needs and viable alternatives for addressing behaviors. Student interviews corroborated this finding, as students shared that they felt they had sometimes been suspended without first exhausting other means of discipline and correction. Vignette 22.4c is an example of utilizing improvement with an inquiry mindset.

Vignette 22.4d Understanding the Interconnectedness of the Problem

Evaluating local data and gaining user perspective via empathy interviews provided a foundation of learning from which to explore root causes of suspensions among students with disabilities within each site as a manifestation of the district system. Their root cause analysis led to recognition of the need to improve calibration and continuity among staff responses to student behavior. Ongoing team conversations surfaced a second round of learning questions, focused on the degree of variation in student discipline procedures that existed across classrooms and school sites. The team engaged in a process mapping exercise to illustrate their understanding of how student discipline was addressed and what aspects of the process were implemented inconsistently or ineffectively.

Each school site and two factions of district office team members drafted a process map of their student discipline procedures. With facilitation from improvement coaches, the four process maps were then consolidated, revealing drastic differences in the steps and sequencing of each team's process. Figure 22.6 shows the resulting illustration which, while appearing chaotic, illuminated key areas of process variation and ultimately prompted discussion about change ideas that could better standardize practice while building teacher capacity with alternatives to suspension.

Vignette 22.4e Change Ideas and Plan-Do-Study-Act Cycles

Both the elementary and middle school teams (and district leaders) agreed that pursuing change ideas in close proximity to negative student behavior, rather than further "downstream" in the discipline process, presented the most promising opportunity to avert suspensions. Each site developed a preliminary aim statement centered around reducing the incidence of suspension among a small group of students with disabilities during the final 6 weeks of the school year. Using a collection of best practice research and each site's knowledge of local context, the team generated an initial list of change ideas, which they plotted in quadrants based on the expected impact and required effort (including necessary human and fiscal resources) associated with each idea (Fig. 22.7). Each site team then selected a change idea from the "high impact, low effort" quadrant that they believed to be viable, accessible, and promising for improving outcomes for their students and staff. Their change ideas were implemented in rapid Plan-Do-Study-Act (PDSA) cycles with a small group of students at each site.

The elementary site developed a process for helping students to self-regulate in response to escalating behaviors and established a de-escalation station in the special education classroom of the teacher participating on the improvement team. Vignette 22.4e shows PDSA cycles. In the event of negative student behavior, the teacher referred the student to the de-escalation station in lieu of removal from the classroom, and either she or an instructional aide facilitated the self-regulation strategies, resulting in most students

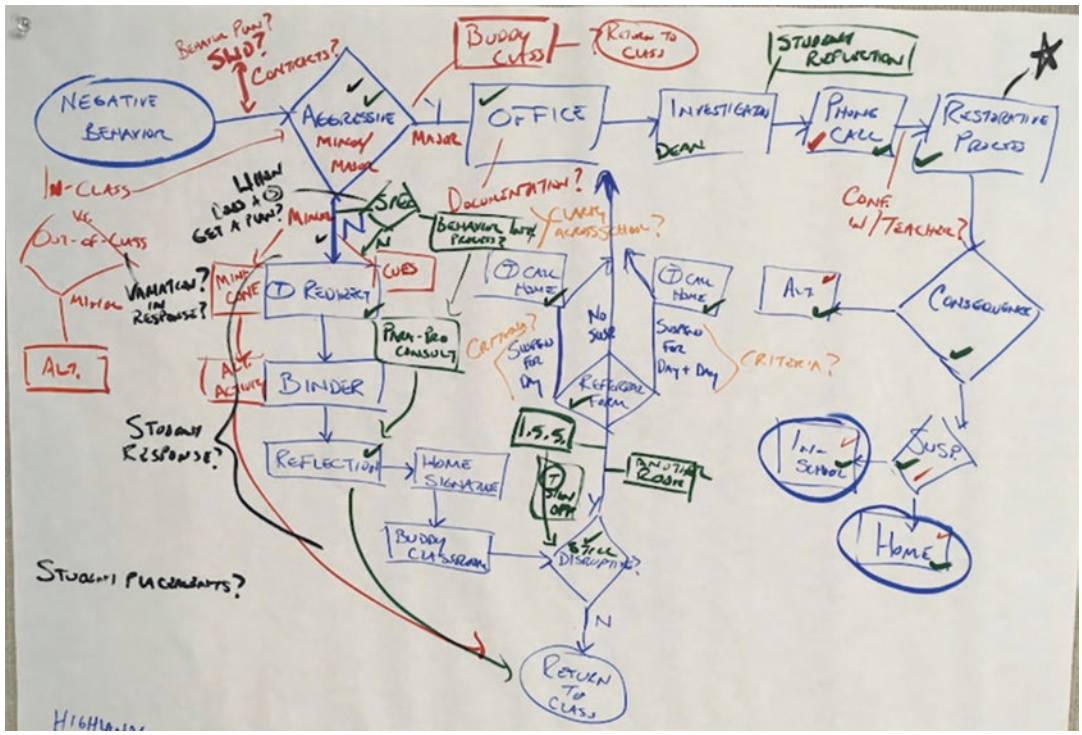

Fig. 22.6 Process map of student discipline processes

correcting their behavior without the need for suspension. By the third testing cycle, they found that nearly all students had gained familiarity with the process and were equipped to engage in self-regulation strategies without direct adult facilitation, which in most cases allowed the teacher to simply refer students to the de-escalation station as needed and minimized the impact of the teacher or instructional aide disrupting the instructional process to intervene with the misbehaving student.

The middle school engaged in testing of individualized behavior support "menus" for six of their most frequently suspended students with disabilities. Site administrators met with each student to collaboratively develop a list of strategies that teachers could use to address behavior concerns prior to resorting to suspension; administrators then created behavior support cards for each student and held brief conferences with teaching teams to share the document and begin testing their use. After the first testing cycle, the site team recognized the need to include campus supervisors and lunchroom staff in the change in order to support and correct student behaviors outside the classroom. Beginning with the third testing cycle, the team expanded the student group to include three general education students with recurring discipline issues.

Vignette 22.4f Improvement and Lessons Learned

Prior to engaging in their Plan-Do-Study-Act cycles, each school site gathered baseline data about the number of weekly suspension referrals among the selected group of students. During the 6 weeks preceding the first PDSA cycle, the participating elementary school students had been suspended an average of more than 12 times per week. Suspensions of the same group of students fell to six incidents during the first week of PDSA testing and continued to decline during subsequent testing cycles throughout the remaining weeks of the school year, with just two incidents

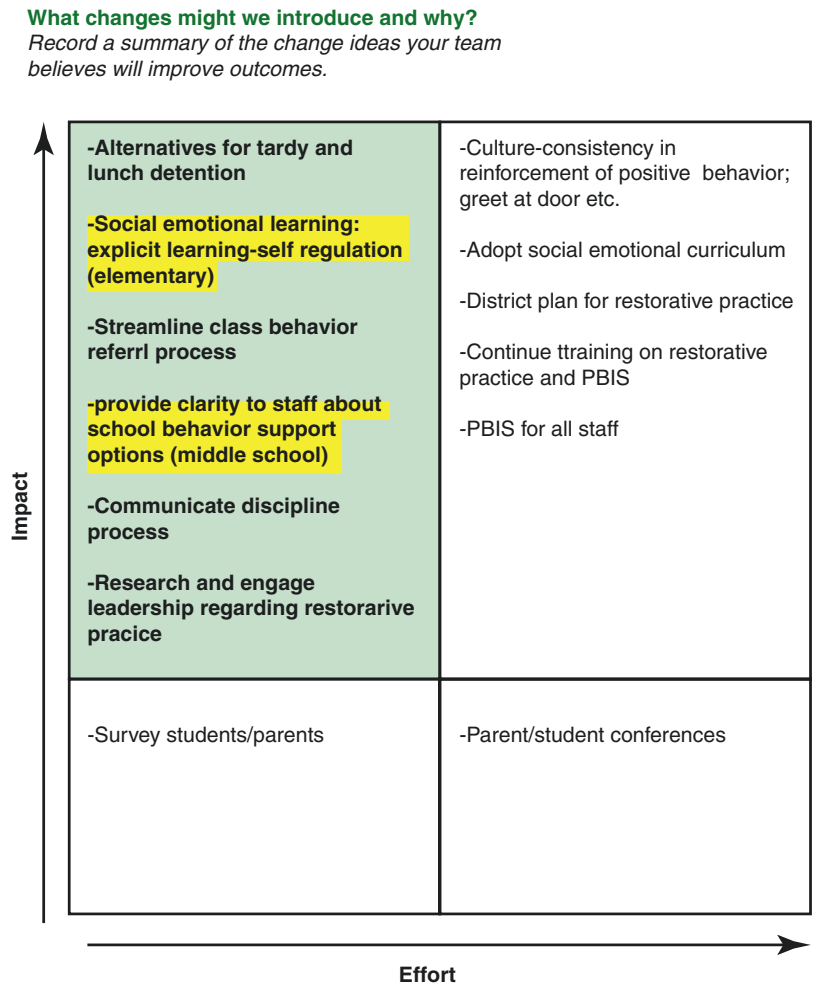

Fig. 22.7 Effort vs. impact matrix. The improvement team mapped potential change ideas, comparing effort and impact, to identify the most viable to test

recorded in each of the final 2 weeks (Fig. 22.8).

At the middle school, the selected students had averaged six suspension incidents per week during the 2 months leading up to launching the first PDSA cycle. During the first 2 weeks of testing, the same students averaged four suspensions per week; after which suspensions fell to an average of two per week (Fig. 22.9).

In reflecting on their improvement efforts, the team recognized some limitations in terms of the proficiency of staff when considering how best to implement change ideas at scale. As a result, the pace of implementation continues to be slow, as the team has prioritized fidelity of implementation through incremental professional learning for staff over rapid, but likely ineffective, application of changes. Vignette 22.4f is an example of results and lessons learned.

Throughout the improvement journey, the team embraced opportunities to learn and freed themselves from expectations of instantaneous results, which allowed the process of pursuing improvement to be one of authentic inquiry and growth, rather than a compliance-driven exercise. As a result, conversations and efforts remained focused on improving student outcomes and established appreciation for the interconnected elements of the disciplinary and instructional

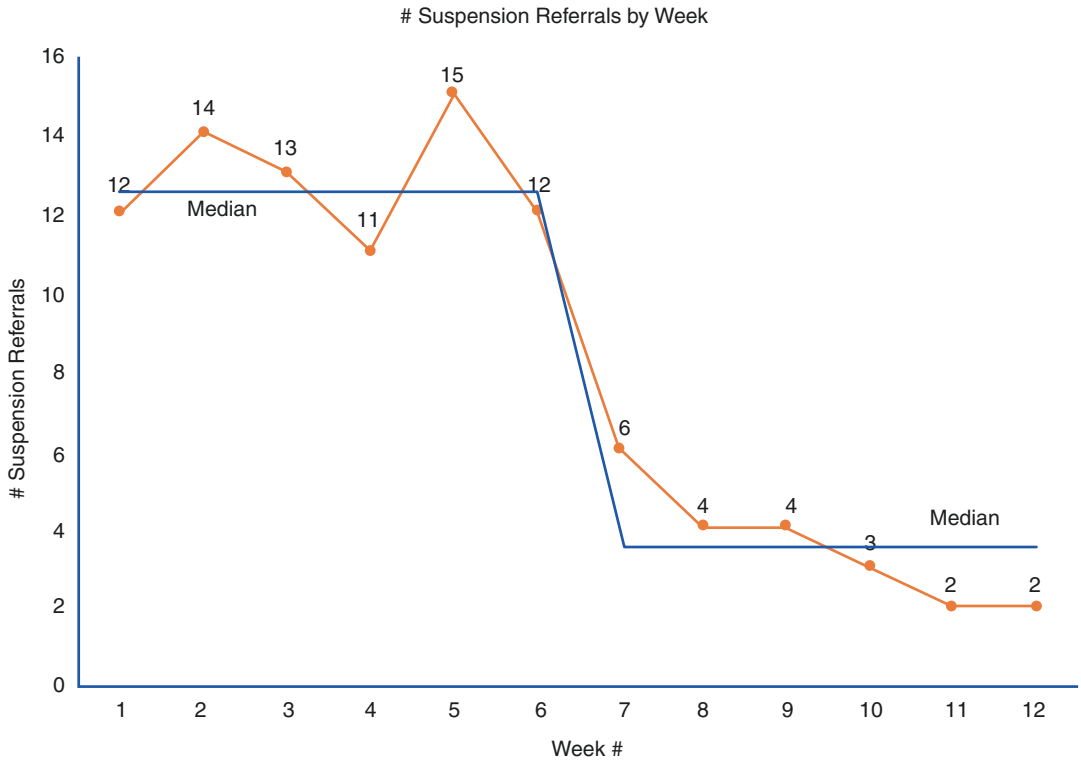

Fig. 22.8 Run chart showing suspension referrals for the elementary school. This run chart depicts the number of referrals by week, showing a significant decrease during the first week of PDSA testing (Week 7)

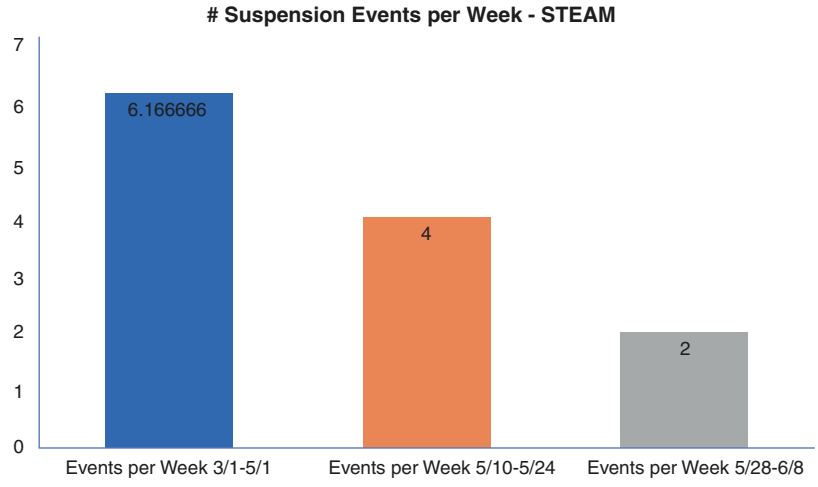

Fig. 22.9 Suspension events for the middle school. This chart depicts the number of weekly suspension events, showing a decrease over the course of PDSA testing

models in their system, specifically the impact of suspensions on student learning. In the context of the state accountability system, this allowed the district to recognize and leverage the relationship between suspensions and student achievement in communicating with stakeholder groups about

the collective learning of the improvement team. While initial improvement goals and aim statements had been focused on reducing suspensions, the focus of the work evolved to prioritizing the value of preserving and protecting instructional time for students with disabilities in order to maximize student learning experiences.

Vignette 22.5 Engaging the Frontline
River Flat Community School is a small K-5 elementary school in south central LA serving a significantly diverse community where about half of the students are African American and half are Latinx students. State accountability achievement has shown that there are significant achievements gaps in mathematics, particularly in grades 4 and 5. About 80% of those students are working below grade level in mathematics. The school has worked over the past 2 years to address the achievement issues in mathematics by providing professional learning for teachers. However, the learning has been highly complex and theoretical, and as a result, there has been a struggle in translating adult learning into practice in a way that increases math achievement for students.

Context

The teachers at River Flat Community School have recently engaged in professional learning for a new mathematics instructional adoption called Cognitively Guided Instruction (CGI) [13], to improve mathematical performance through a set of tools and pedagogies that helps students think about conceptual problem-solving. The school also participates in a network community focused on the application of improvement science to improve student outcomes with a focus on mathematics. As part of this network, a school improvement team was created, which included three classroom teachers from grades 4 and 5, a district office curriculum administrator, school principal, math coach, and an improvement coach. The team was tasked to specifically address the lack of improvement in grades 4 and 5, despite the best efforts to improve mathematics instruction through teacher professional development. The team worked from February to May through an improvement methodology. Vignette 22.5 shows engaging the frontline to improve teaching and learning (Key Points Box 22.6).

Key Points Box 22.6 Engaging the Frontline
Frontline-driven improvement efforts utilize those practitioners closest to or experiencing the problem in the improvement work. This approach acknowledges the practitioner's expertise in understanding the problem and testing change ideas in practice.

Utilizing Improvement

The improvement team began its work by investigating their current levels of performance in mathematics available through state test data, local district measures, and classroom formative assessments. Based upon this initial look at the data, the team worked to understand the problem (and how it was situated in the system) by identifying how they might gather other information to gain insight into current student performance. For example, the team asked such questions as "how did students see themselves in mathematics" and "how did they come into the classroom each day"; and so they began to frame questions about what they wanted to know. They formulated an investigation into the problem driven by these learning questions, which included empathy interviews with students to understand how students thought about themselves in learning mathematics. The investigation also included conferencing with students and analysis of student work samples. The findings from the investigation were powerful as it showed the team that the original assumptions about how students thought about themselves were wrong as students

indicated that they really felt like mathematics was something they believed they could learn (Vignette 22.5).

Based upon the learning from this deeper dive into the problem, the improvement team initially decided to focus on student grouping and discourse to target for improvement. As the teachers began to work to address student groups, they realized that students worked in groups well, but rather it was the intellectual nature of the student talk that was not substantial enough to solve mathematical problems. As a result, the team with the assistance of the math coach moved to target their improvement efforts around the student's utilization of strategies to solve math problems. The team's project aim was developed: increase the number of valid strategies students use to solve a problem. In other words, they wanted students to demonstrate multiple ways of using valid problem-solving strategies in their approach to solve a math word problem. The team adapted the three questions from the Model for Improvement [7] to guide their improvement effort (Table 22.2).

The improvement team identified two measures to collect data to inform the improvement effort, including (1) percent of students using two or more valid strategies and (2) percent of students using invalid strategies. Teachers created a weekly routine to (1) collect student work for all word problems, (2) meet together to assess and sort student work, (3) review the data and consolidate learning from the last PDSA testing of change idea, and (4) determine the next steps.

Initially, the baseline showed that 31% of students were able to use two or more valid strategies with 47% of students demonstrating use of invalid strategies in solving a word problem. Figure 22.10 depicts the data over time (run chart) in tracking the PDSA testing of the change ideas. (Key Points Box 22.7).

After the introduction of the first change idea (students draw a picture in solving a problem), a significant reduction (23 percentage points) occurred for "use of invalid strategies" (Fig. 22.10a). Interestingly, the first change idea resulted in only a slight increase in the "use of two or more strategies" as shown in Fig. 22.10b. A further review of Fig. 22.10 showed a significant decrease in student use of invalid strategies after the introduction of the second change, reaching a low of 5% at time five. Similarly, an increase in the utilization of two or more valid problem-solving strategies reached a high point of 81% (Time 5). The final change (Strategy #3) was implemented by the team at time period nine, resulting in a continued sustaining of increased

Table 22.2 Improvement charter. The chartering process is utilized by teams to collectively focus on the improvement effort by addressing the three questions from the model for improvement

What do we want to accomplish?	Increase the number of valid strategies students (grades 4 and 5) used to solve a math word problem (valid strategies defined as the logic needed to lead to a correct answer)
How will we know a change is an improvement?	1. Percent of students using two or more valid strategies 2. Percent students using invalid strategies
What changes might we try?	1. Model with a picture that is representative of the word problem to solve 2. Elicit moves to pull out student thinking (verbally share with class individual student use of valid strategies) 3. Create anchor posters with student-generated valid strategies

Key Points Box 22.7 Data Visualization (e.g., Run Charts)

The use of data to inform improvement efforts helps to maintain a focus on the impact of changes in terms of both processes and outcomes while reducing emotionally driven responses to experiences and results. Representing findings through data visualizations such as run charts provides a view of data collected over time, which is especially valuable when the data includes annotations that allow improvement teams to see connections between changes to the system and the outcomes those changes produce.

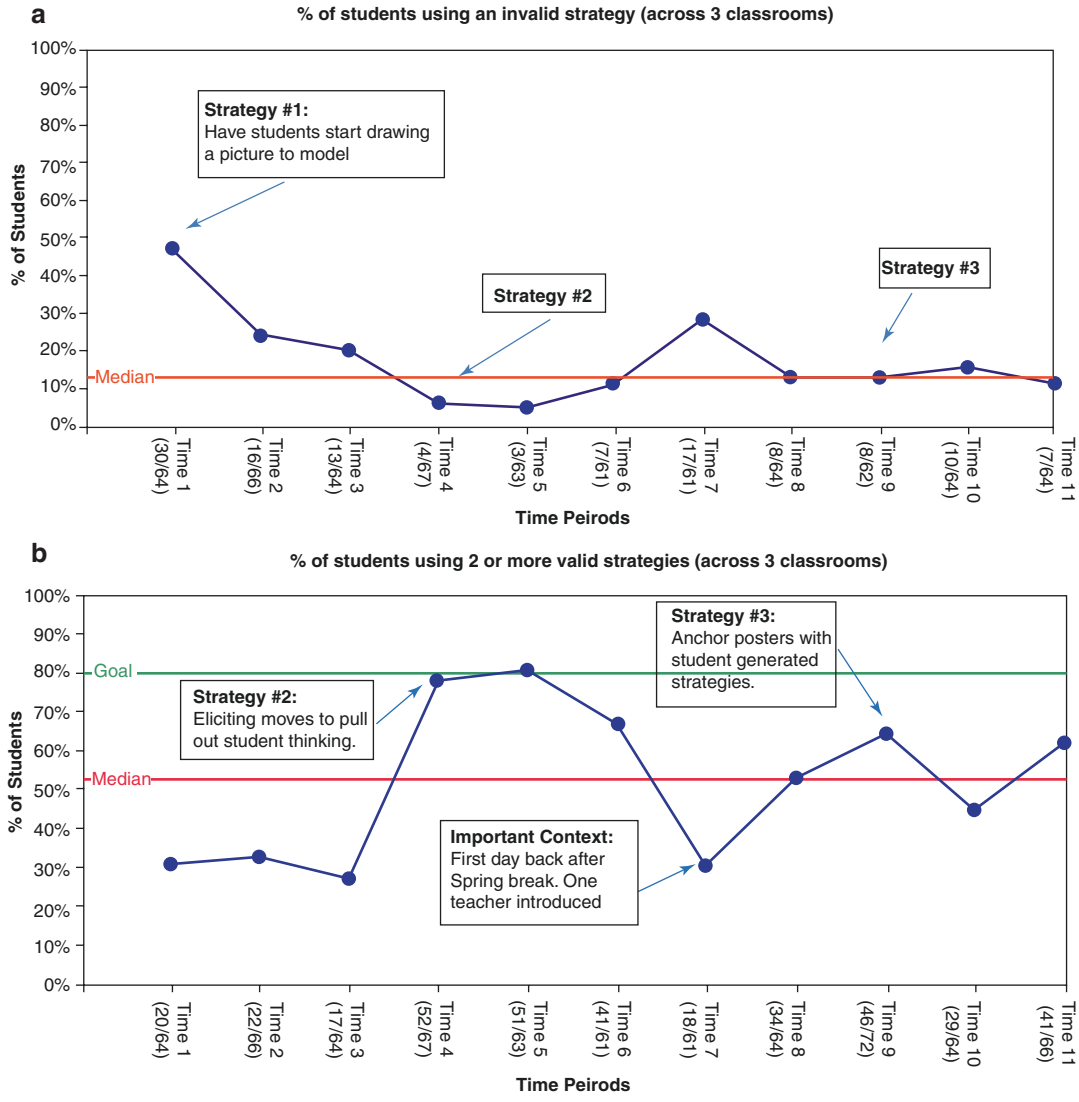

Fig. 22.10 Run chart. This figure depicts (**a**) the percent of students using an invalid strategy and (**b**) the percent of students using two or more valid strategies

utilization of two or more strategies from the baseline.

As a result of implementing all three change strategies (time periods 9–11), the improvement team continued to realize an increase above the baseline in the percent of students utilizing two or more strategies. Based upon these data, the improvement team had a high degree of belief that these change ideas moved the needle on the aim. Moreover, the frontline nature of this work provided the opportunity for their grade-level colleagues to learn and adopt these into practice in a way that potentially impacted all students.

Lessons Learned

The improvement methodology utilized provided a pragmatic approach that enabled teachers to take strategies from their professional learning and test them in practice to obtain measurable

improvement. Using this approach allowed teachers to take complex evidence-based ideas and break them down into manageable pieces to try and adapt. One important lesson realized was that launching an improvement team is uniquely hard work in any context as it requires a different way of collectively working together and publicizing practice. Defining roles and responsibility and organizing and managing work in a routine rhythm are critical. Teams that do not establish an improvement rhythm and routines often have a difficult time on making any movements in their improvement efforts. In this example, the improvement team was able to establish a rhythm that built teacher efficacy, generating momentum to propel the work forward. A second lesson learned was that the improvement team created the conditions for internal accountability. The accountability was significantly stronger as the teachers, as the frontline, owned the work.

Teachers shared that they felt like they had to try these things because they were accountable to their team to come with the data. A final lesson learned was that the run chart was a powerful tool in making the improvement efforts visible. Utilizing the run chart to look at data in real time lends itself to increasing teacher efficacy as they could see themselves in terms of direct connections to the changes they were testing in practice – "I did this, and this was the result of my actions." For the teachers, it was the first time they saw evidence of their theory playing out in practice.

Conclusion: Key Summary Points

Improvement science provides a thoughtful and disciplined approach to problem-solving that has tremendous potential to empower those that serve kids (in both the education and healthcare sectors) to pragmatically improve outcomes. The practice of improvement changes the paradigm of past approaches, requiring expertise to work collectively through new mindsets, requiring humility to learn one's way into improvement. Improvement work is hard, and teams should be mindful of the following key points as they progress through their improvement journey (Key Points Box 22.8).

Key Points Box 22.8 Summary

- Improvement science addresses the knowing-doing gap as it helps to discipline our improvement efforts to be able to sort out what works for whom and under what conditions.
- Improvement work represents a learning journey in which the improvement team engages in itinerate phases of the work and continually learns along the way.
- Improvement teams need to pay attention to variation found in performance as it is a key challenge to address throughout the improvement journey.
- Improvement empowers frontline-driven practitioners closest to or experiencing the problem to collectively work to understand the problem and test changes in practice.
- The use of data is a powerful tool in making the improvement effort visible, informing, promoting, and maintaining the focus on the impact of changes in terms of both processes and outcomes.
- Improvement work is hard! Learning improvement requires doing improvement!

Editors' Comments

Notwithstanding, this chapter's vignettes bespeak the merit of partnering with our fellow preK-12th grade education improvement specialists as we jointly try to address the needs of our respective communities. Our authors are addressing the variation in the educational approaches across their system, especially with their at-risk students, while ensuring that no child in need is left behind. Across the USA, hospital emergency departments (EDs) and primary care offices have had an ongoing surge in the number and acuity of behavioral health patients. We need to be pro-active about this issue – as when such a patient arrives at an

ED in crisis, there are likely to have been multiple missed opportunities to intervene. This chapter exemplifies the significant value of the systematic improvement work being done by the authors. The potential of a continuous dialogue and shared learning between public education and healthcare institutions is limitless and can have many yet unrealized benefits for our shared obligation to the most vulnerable members of society, the children. We want to thank the authors for enlightening us!

Chapter Review Questions

1. Describe "solutionitis" and its implications for improvement.

   Answer: Solutionitis is a descriptive term that describes the tendency of organizations to implement solutions or initiatives without a systematic approach to improvement, leading often times to mixed results. Improvement teams should work to deeply understand the problem so as to strategically target improvement resources and efforts.
2. What is the knowing-doing gap and how does improvement science address this?

   Answer: The knowing-doing gap is a well-documented tension in which practitioners struggle with getting good ideas to work in practice with measurable improvement. Improvement science addresses the knowing-doing gap as it helps to discipline our improvement efforts to be able to sort out what works for whom and under what conditions.
3. What is the utility of a driver diagram?

   Answer: An organizing tool to build a shared theory of improvement. It helps the improvement team to develop and refine a coherent theory that addresses the aim.
4. Why is a learning stance critical to the improvement journey?

   Answer: A learning stance actualizes the potential for improvement and includes key mindsets such as humility, discipline, curiosity, and willingness. With this stance, we acknowledge that our current best thinking will have gaps in knowledge, and by explicating our mental models of how things work, we will be more likely to realize reliable improvement at scale.
5. What are Carnegie's six core principles of improvement?

   Answer: (1) Be problem-specific and user-centered, (2) variation in performance, (3) see the system, (4) measurement, (5) engage in disciplined inquiry, and (6) networked communities
6. What is a frontline approach, and how does it contribute to the learning of an improvement team?

   Answer: A frontline approach utilizes those practitioners closest to or experiencing the problem in the improvement work.
7. In reflecting on the case studies and the ways in which these examples utilized improvement science, which elements of quality improvement methodology are similar or different from other approaches? What "squares" with your thinking, and what is still "circling" in your head?

   Answer: The purpose of this question is to engage the reader in reflective thinking about the examples presented in this chapter and to identify common elements that resonate and those ideas that they are curious about.

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Afterword

Our intent for this book is to provide an exemplar for understanding the, at times, abstruse field of improvement and safety science through the use of stories, vignettes, and shared experiences. We have been fortunate to have leaders from healthcare and non-healthcare organizations share their experiences and offer readers guidance from their lessons learned.

Dr. Richard Brilli (who currently occupies the first inaugural Endowed Chair of Patient Safety and Quality at Nationwide Children's Hospital), an accomplished leader, clinician, coach, and mentor, grounded this book in the Foreword by reminding us of our ultimate commitment to our patients and their families.

We (the Editors) are fortunate to be parents, husbands, clinicians, leaders, community members, and lifelong learners. We stand on the sidelines in public areas, including at our children's events – and hear the conversations. We become involved either indirectly or directly in these conversations where experiences with various healthcare interfaces are shared – most positive, many not.

These commentators often work in other industries, e.g., aviation, manufacturing, service, etc. They often ask why healthcare does not change with the same speed as their respective industries. So why is healthcare lagging?

This answer to this question needs to be a discussion among all team members of a healthcare organization from leadership to the frontlines. The answer might be different based upon the lens and experience of the observer. At times, healthcare leaders and team members feel overwhelmed by competing priorities and heterogeneous patient populations, but similar challenges have been overcome in other industries. So is healthcare that much different? What is healthcare's top priority? Clearly it must be the safety of our patients and team members!

However, there is considerable variation in clinical practice which affects healthcare safety and quality. Patients, families, insurers, and our communities often are looking for the best outcomes and value. They want to go to healthcare organizations that strive for Zero Harm. Do we ask who the pilot is before we board a commercial plane? Usually not, but some patients may spend inordinate amounts of time researching the experience and outcomes data of their various choices for the delivery of services.

We need to develop a common, shared perspective and permanent solutions for many of these recognized challenges. We are not only the providers of care but at some point will be consumers as well. Our patients in both hospital and ambulatory settings rightfully expect only the best and safest care from their local providers and systems. We must establish partnerships with our patients, families, and communities as we "problem solve" these challenges together.

Every chapter in this text can further an organization's high-reliability journey and increase overall organizational mindfulness (the quality of attention and awareness, as defined by Weick and Sutcliffe

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[1]). This text can easily be renamed "The Journey to Increased Organizational Mindfulness: A Case-Based Approach." Moving forward, we need to accelerate our learnings and drive to zero harm.

Reference

1. Weick KE, Sutcliffe KM. Managing the unexpected: resilient performance in an age of uncertainty. San Francisco: John Wiley and Sons; 2007.

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