

Comparing Lean and Quality Improvement



AN IHI RESOURCE

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In their role as consulting Improvement Advisors to IHI, the authors are long-standing practitioners of the IHI approach to quality improvement who recognize the fundamental compatibility and potential synergies between the IHI approach and Lean as ways of perceiving, understanding, and influencing the progress of health care systems seeking to provide excellent patient care in a fast-changing environment.

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The Institute for Healthcare Improvement (IHI) is a leading innovator in health and health care improvement worldwide. For more than 25 years, we have partnered with a growing community of visionaries, leaders, and frontline practitioners around the globe to spark bold, inventive ways to improve the health of individuals and populations. Together, we build the will for change, seek out innovative models of care, and spread proven best practices. To advance our mission, IHI is dedicated to optimizing health care delivery systems, driving the Triple Aim for populations, realizing person- and family-centered care, and building improvement capability. We have developed IHI's white papers as one means for advancing our mission. The ideas and findings in these white papers represent innovative work by IHI and organizations with whom we collaborate. Our white papers are designed to share the problems IHI is working to address, the ideas we are developing and testing to help organizations make breakthrough improvements, and early results where they exist.

Contents

Executive Summary	4
Overview	5
Describing the IHI Approach to Quality Improvement and Lean	7
Comparing IHI-QI and Lean	16
Summary and Implications	18
Appendix A: Origins and Historical Linkage of the IHI Approach to Quality Improvement and Lean	21
Appendix B: Glossary of Common Lean Terminology	24
References	26

Executive Summary

In the past 25 years, improvement in health care has grown from demonstration projects into a worldwide movement. Dominant in this movement has been an improvement approach grounded in the work of Walter Shewhart, W. Edwards Deming, Joseph Juran, and Associates in Process Improvement, and shaped in practice by the staff and faculty of the Institute for Healthcare Improvement (IHI). Today, this “IHI approach” to quality improvement (referred to as “IHI-QI” throughout this paper) provides a framework for thousands of improvement practitioners around the globe. Meanwhile, many people in health care have heard about Lean and the Toyota Production System (TPS) as a powerful method for improvement and cost reduction in manufacturing, and about its notably successful application in health care by influential organizations such as Virginia Mason Medical Center and ThedaCare.

People often want to know about the relationship between IHI-QI and Lean, and how they can best utilize one or both approaches to improve their own care systems. This white paper aims to address these issues, and argues that because IHI-QI and Lean are complementary ways of approaching improvement, it is not necessary to choose one over the other as a guide to action.

Furthermore, integrating perspectives and lessons from the two approaches has the potential to strengthen both Lean and IHI-QI. As practitioners of IHI-QI, the authors see specific Lean lessons worth adopting, like the Lean requirement to ground analysis and improvement in the workplace, with expectations for all levels of a management hierarchy to engage in standard work and continuous improvement. For practitioners of Lean, we believe that IHI-QI offers diverse conceptual frameworks for managing change, techniques for implementing changes in complex systems, program formats for spreading change, and learning models that have been developed and implemented in a broad array of health care settings.

This paper begins with a brief overview of the issues and some key definitions, followed by more detailed descriptions of Lean and IHI-QI. For each approach, we discuss the key conceptual foundations, the principles that lead the way to improved system performance, the project roadmaps typically followed under each approach, and the tools that characterize them in practice. We also point out the fundamental congruence between the two approaches, as well as key differences. Finally, we suggest ways that practitioners of both Lean and IHI-QI can use the principles and methods of the other to extend their capabilities. Appendix A provides additional detail about the intertwined histories of Lean and IHI-QI.

After reading this paper, you will have clear answers to the following questions:

- What are the basic concepts and principles of IHI-QI and Lean?
- How are they similar (in history and approach)? How are they different?
- For what purposes is IHI-QI the most appropriate approach? For what purposes is Lean the best approach?

Overview

*“Do not seek to follow in the footsteps of the old masters.
Seek instead what the old masters sought.” –Basho (1644-1694)*

In her 2012 keynote presentation at the Institute for Healthcare Improvement (IHI) National Forum on Quality Improvement in Health Care, IHI CEO Maureen Bisognano said that everyone in health care should have two jobs: to do the work and to improve how the work is done.

In that simple statement, Bisognano posed a transformational challenge to health care organizations struggling to meet the increasing demands of the marketplace to provide excellent patient experience, and make a meaningful impact on the health of the patients they serve. Following in the footsteps of other industries, they must somehow figure out ways to define the work — of everyone, including senior executives, point-of-care staff, clinicians, and those in support roles — to deliver excellent care and services (“doing the work”), while simultaneously designing systems and processes that build in continuous improvement (“improving how the work is done”).¹

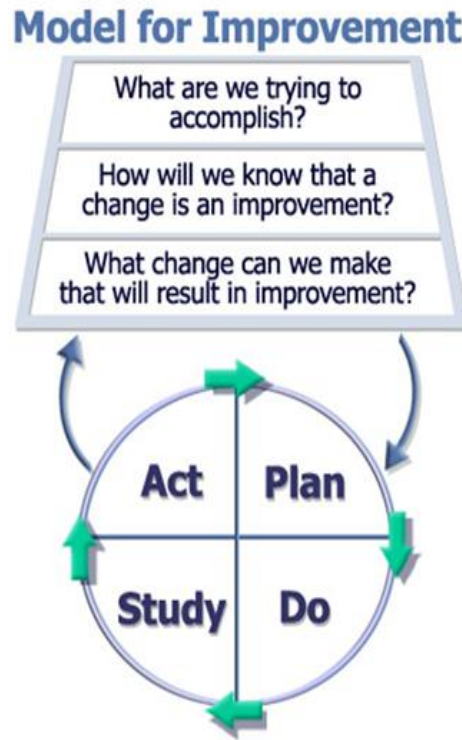
How can this be accomplished?

This white paper describes two distinct but related approaches to Bisognano’s challenge. We refer to these approaches as the “IHI approach” to quality improvement (which, for the purposes of this paper, we shorten to “IHI-QI”) and “Lean.” We take “IHI-QI” to mean the approach to quality improvement developed by Associates in Process Improvement and promulgated by IHI, grounded in the work of Walter Shewhart, W. Edwards Deming, and Joseph Juran. IHI-QI emphasizes rapid-cycle testing in the field in order to learn which interventions, in which contexts, can predictably produce improvements. By “Lean” we mean the integrated principles, methods, and tools that have developed from the Toyota Production System to optimize the performance and management of value-producing systems.

The effort to improve quality in US health care has spread well beyond the “early adopter” phase of the 1990s. At that time, the Institute for Healthcare Improvement took the lead in promoting and translating industrial quality improvement methods to health care practitioners in a determined effort to close the “chasm” between unreliable common care practices and the evidence-based guidelines emanating from medical science.² In the 25 years since the seminal book *Curing Health Care* was published,³ health care quality improvement has become a worldwide movement, and in the US has gained urgency from policy reforms by payers, governments, and professional standards bodies that increasingly insist on management of outcomes and documented efforts to constrain costs and improve value. These trends show every indication of accelerating in coming years.

IHI has been guided by a close relationship with Tom Nolan, Ron Moen, Lloyd Provost, and their colleagues at Associates in Process Improvement (API) that began in 1992.⁴ That collaboration has resulted in wide-scale application of IHI-QI in health care worldwide. The IHI approach is informed by the work of Shewhart and Juran and is based on the application of Deming’s System of Profound Knowledge. The specific methods of IHI-QI have evolved, based on learning from their application within health care by API, Improvement Advisors, IHI Fellows, faculty and staff, strategic partners, as well as thousands of participants in IHI projects and initiatives. IHI’s clinical and technical leaders learned quality improvement from API, who in their turn worked closely with Deming.

Figure 1. The Model for Improvement



Developed by Associates in Process Improvement

IHI-QI is a vibrant discipline. It has not ossified into dogma, thanks in good measure to the diversity, energy, and idealism of its adherents, and to the “open source” approach that IHI has promoted with regard to methods and content. IHI faculty have been encouraged to candidly share their best ideas, in the belief that the field can most rapidly and effectively advance health care quality through collaboration. Together, the IHI community has grown in an atmosphere of transparency and a spirit of “all teach, all learn.”

IHI-QI is often confused with one of its core elements, the Model for Improvement (see Figure 1).⁵ The Model — three clarifying questions and the Plan-Do-Study-Act (PDSA) cycle — has formed the mainstay of IHI’s teaching and improvement methodology over the years. But despite its fame, and despite its manifest utility in almost any life situation, the Model for Improvement is not synonymous with IHI-QI.

The Model for Improvement, developed by Associates in Process Improvement, is a general-purpose heuristic for learning from experience and guiding purposeful action. More simply, it is an

“algorithm for achieving an aim” at any scale. As a tool for gaining practical knowledge, it represents a radical distillation of pragmatic epistemology into a habit of immediate, sequential testing of changes. One objective of this paper is to reconsider the Model for Improvement in its proper place, as a pervasive guide for action within the larger context of IHI-QI.

At present, Lean tools and methods are rapidly gaining adherents among aspiring health care improvers. As health care leaders have embraced the results-oriented discipline of industrial quality improvement, interest in more effective management systems has increased. The Toyota Production System (TPS), in particular, has received much attention. TPS is rooted in the innovations of Taiichi Ohno and colleagues in Toyota factories starting soon after the end of World War II. Adaptations of TPS are widely known by reference to one of its key principles of practice, “Lean” — the drive to devise nimble tasks, processes, and enterprises that maximize value and minimize waste in all its forms. Leading health care organizations, notably Virginia Mason Medical Center in Seattle,⁶ ThedaCare in Wisconsin,⁷ and the Pittsburgh Regional Health Initiative in Pennsylvania,⁸ have adopted TPS as their model for management and improvement, with widely recognized success.

Which Is “Better”?

The recent upsurge in adoption of Lean methods in health care settings, following on the wide dissemination of IHI-QI over the past 25 years, has led some people to ask, “Which is better, the IHI approach or Lean?” Certainly, the choice of methodology can be challenging for organizational leaders with limited knowledge of both approaches, who look to the literature, the testimony of colleagues, or current fashion to decide how to build their organization's improvement capacity. The choice of Lean or IHI-QI may well be seen as a Big Decision, with serious risks and expensive

consequences. The decision is made no easier by the narrow interests and elaborate technical language of consultants and vendors promoting their own particular approaches and skill sets.

But the question is a canard, equally contrary to the spirit of both traditions. A critical comparison of the origins, core principles, methodological roadmaps, and tool sets of IHI-QI and Lean reveals them to be harmonious in conception and complementary in practice. Instead of an “either-or” choice, we suggest that there is much for leaders to gain by considering both IHI-QI and Lean in light of the needs of the new health care marketplace, with a clear view of the complementary strengths and applications of each, appreciating the profound compatibility of their philosophies and approaches.

Describing the IHI Approach to Quality Improvement and Lean

Methodologies, like children, are ultimately shaped by their parents and by the tasks they are set to accomplish. IHI-QI and Lean share a close family history, arising out of pragmatic philosophy, the scientific method, statistical process control, and practical line-level industrial engineering. However, these siblings were separated at birth and reared by practitioners from different cultures and neighborhoods — the Japanese factory floor versus American industry. They have enjoyed frequent family visits along the way.

Lean and the Toyota Production System

A journey to discover the origins of Lean might begin with a tour of Henry Ford’s automobile assembly plant in Highland Park, Michigan, in 1914, where the system he called “flow production” incorporated many features we now associate with Lean and TPS.^{9,10} Or, one might pinpoint the moment in Nagoya, Japan, in 1946, when Taiichi Ohno assumed control of the machine shop at Toyota’s Honsha assembly plant and began to assemble the elements of what would become the Toyota Production System (TPS). Ohno detailed standardized work for each job in the shop, and began to experiment with physical configurations and job pacing that minimized queues and time between operations, signaling systems that allowed upstream operations to respond quickly to downstream conditions, and worker training that emphasized awareness and individual responsibility for quality and problem solving.¹¹ Under Ohno’s leadership over the following decades, the core principles and techniques that became TPS were elaborated and codified.

In a profound sense, TPS embodies an aim — an ideal of how a value-focused production system should behave, and the components, connections, and attributes it must have in order to behave that way. Steven Spear (IHI Senior Fellow, MIT Sloan School faculty, and noted Lean expert) summarizes the ideal production system in terms of outcomes:¹²

- The output is defect free.
- The product or service is delivered in response to customer need (i.e., on demand, “pull” system).
- The response is immediate.
- Products or services are provided one by one, in the unit size of use (i.e., tailored to the identified needs of the consumer).

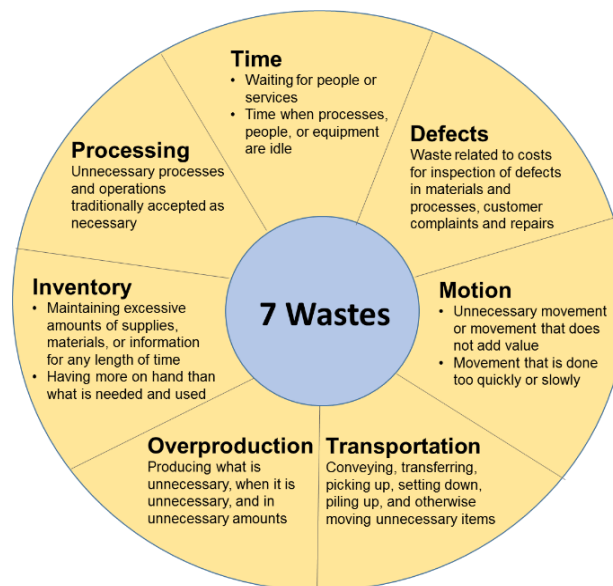
- Work is done without waste.
- Work is done safely.
- Work is done securely.

The core principles of TPS are apparent in Lean production systems that approach this ideal. Toyota’s website says that TPS is built on two concepts: *jidoka* (“automation with a human touch”) and *Just-in-Time*. *Jidoka* means “when a problem occurs, the equipment stops immediately, preventing defective products from being produced.” By extension, *jidoka* signifies continuous inspection built into every process — automated when possible, but always foremost in the awareness of operators, who are charged with recognizing and addressing problems immediately by means of *kaizen*. (See Appendix B for a glossary of common Lean terminology.)

Kaizen means “continuous improvement”; it also refers to the local experimentation (aka “PDSA testing”) undertaken to mitigate production problems at the front line.¹³ Detailed standardization of tasks refined via *kaizen* means that ever smaller deviations in methods and quality can be discerned as problems, then quickly corrected, thus leading to ever greater consistency of product and conformance to specifications.¹⁴

Just-in-Time (JIT) describes the ideal functioning of the production system. It means that “each process produces only what is needed by the next process in a continuous flow,” reducing to an absolute minimum the time between recognition of customer desire and its fulfillment by the process. “Customers” in this sense include the next process in the production chain as well the ultimate consumer of the product or service.¹⁴ Pursuit of JIT production engages a set of principles for standardizing, integrating, and coordinating operations within and between processes across the entire enterprise. Fundamental among these are *value* and its converse, *waste*.

Figure 2. Toyota Production System Seven Wastes



Value is “expressed in terms of a specific product (i.e., a good or service) that meets the customer’s needs at a specific price at a specific time.”¹⁵ Value is created by the production system; any aspect of production that does not contribute to value is *waste*: wasted material, wasted time, items held in queues or inventories, wasted human effort, and so on (see Figure 2 for the TPS Seven Wastes¹⁶: time, defects, motion, transportation, overproduction, inventory, processing). Maximizing value requires minimizing waste. The term “Lean” acknowledges the drive to eliminate waste from the system, and thus produce maximum value at minimum cost.¹⁷

The production process — from the customer’s signaled need to production to consumption — is called the *value stream*, and includes both the production process and the information flows that control it. The ideal value stream behaves as a single “super-organism,” responding rapidly and flexibly to customer demand and changes in external conditions (though poorly designed Lean systems are prone to disruption if too tightly adapted to anticipated conditions¹⁷).

Key principles such as *standardized work*, *flow*, *heijunka* (load leveling), and calculating *takt time* and *cycle time* guide system improvements to increase integration, coordinate activity, and minimize waste. *Poka-yoke* (mistake-proofing) devices, beginning with simple checklists, integrate error prevention and real-time inspection into standard work in order to make errors less likely and, when they occur, instantly visible before they become defective products.¹⁸

Communication within and among processes is the nervous system for rapid, responsive action. A *kanban* is a token that signals to an upstream process that product is needed, and to a downstream process that it has been delivered, thus enabling the customer to “pull” product in single units from the producer. *Visual controls* allow operators and supervisors to sense the current state of the system, so that they can coordinate their actions in real time with upstream and downstream conditions and resolve discontinuities. An *andon* is a signal that a problem has occurred, and may halt the process (even an entire factory) while a remedy is found, thus avoiding the waste that would result from sending a defective product down the line.¹⁵

The TPS features and principles noted above constitute an integrated “template” for designing a production system that conforms to the Lean ideal. In IHI-QI terms (described in further detail below), they are *change concepts* that serve to prompt improvers to identify specific ideas for designing processes and addressing problems using disciplined empirical techniques.

It is important to note that TPS is a *production* system. Its ideal outcomes, change concepts, and tools are adapted to reduce waste and variation in systems where the concept of a value stream applies. Certainly, health care systems include a great many production processes, from clinic visits to medication administration in hospitals to support functions such as pharmacy management. However, it is prudent to recognize the degree to which the TPS template must be altered to fit the very diverse and complex world of health care, where prevention, patient care, and payment are typically the responsibility of multiple business entities, and where patients themselves are intrinsic “producers” of their own outcomes.

For example, Spear employs the principle of “reducing ambiguity” as a key Lean change concept for standardizing care processes to improve safety.¹⁹ In its efforts to apply TPS, Virginia Mason Medical Center (VMMC) found that translating the concept of *jidoka* into the realm of medication errors and adverse events presented a host of definitional problems that resulted in the Patient Safety Alert, a declared signal of an error that could endanger patient safety and a set of procedures for rectifying the error without actually halting patient care.²⁰ Similarly, VMMC invented the “flow station” to help eliminate waste and improve flow in the hospital workplace where, in contrast to an assembly line, the providers, not the patients, are constantly on the move.²⁰

Even the concept of “value” must shift when transposed into health care.²¹ In TPS, value is defined in terms of customers’ willingness to pay.²² In health care, John Toussaint, former CEO of ThedaCare, writes that “looking for what is truly of value in a process is an emotionally loaded exercise. Not only do physicians embrace different methods and measures, there is often a good deal of ego invested in those methods. At ThedaCare, therefore, teams examining a process for improvement are continually reminded to consider the patient first.”⁷

Jim Womack, founder of the Lean Enterprise Institute, stresses that the core health care value stream is the individual patient’s “journey” over the course of an illness, surgery, chronic disease, pregnancy, end of life, or myriad episodes or conditions. The similar journeys of many patients call for “service line” value streams that flow across traditional departmental and organizational boundaries, supported by common resources and infrastructure. Since “value” depends in part on the unique circumstances and needs of each patient, such standardized processes of care must

include features that allow them to adapt in real time to individual patient needs throughout the journey, while maintaining the reliable consistency required by evidence-based practice. Care systems that are responsive at this level require tightly integrated care teams for whom continual awareness of individual patients' needs and front-line *kaizen* are essential.¹

Lean follows a “roadmap” for bringing a production system into conformance with an ideal state like that defined in TPS. As described by Womack and Jones in *Lean Thinking*, the route has five waypoints:¹⁵

1. Specify the value desired by the customer.
2. Identify the value stream for each product providing that value and challenge all of the wasted steps (generally nine out of ten) currently necessary to provide it.
3. Make the product flow continuously through the remaining value-added steps.
4. Introduce pull between all steps where continuous flow is not possible.
5. Manage toward perfection so that the number of steps and the amount of time and information needed to serve the customer continually fall.

As they follow the roadmap, practitioners use the Lean “toolkit” to guide their journey. *Value stream maps* detail the steps in a process along with the associated information flow and data to quantify waste, cycle time, and other process characteristics. A supervisor seeking to rectify a production problem “goes to the *gemba*” (workplace) for a firsthand view of the situation before undertaking any *kaizen*. *Spaghetti diagrams* reveal wasted physical motion; *5-S* is a set of ideas for organizing tools and materials to eliminate the waste of excess inventory and searching for needed items. A team seeking to improve a process beyond incremental changes may engage in a *kaizen event* (aka “rapid improvement event”), an intensive sequence of value stream mapping, process redesign, data collection, and testing intended to generate rapid, radical improvement.

Similar to the Model for Improvement used in IHI-QI, the A3 approach used in Lean is a general method for defining a problem and goal for improvement, targeting candidate changes, and planning a series of tests to settle on workable “countermeasures.” A3 and the Model for Improvement share a common motivation: to provide a method for everyone, not just staff specialists, that is as simple as possible and can be applied anywhere in an organization.²³ The method takes its name from an A3 (297 x 420 mm) size sheet of paper, which must fit the entire plan. A3 was devised by Toyota engineers as part of their preparation at Toyota Motor Company to compete for the JUSE Deming Prize, awarded in 1965. They needed a way to demystify the work of the quality expert so that problem solving could become an integral part of everyone’s daily work, at all levels of the organization.¹ By relying on a standard format with diagrams that everyone can understand, A3’s requirement of a single page forces succinct summary and focus on the most important aspects of the problem and its resolution. In similar fashion, improvement science practitioners often employ structured forms to guide PDSA planning and execution. Table 1 matches elements of the A3 approach with the components of the Model for Improvement.

Table 1. Lean A3 Problem-Solving Approach Mapped to the Model for Improvement

Component of Model for Improvement	Component of A3 Problem Solving
<p>AIM: What are we trying to accomplish?</p>	<p>Eliminate or at least reduce the gap between current state and standard performance or between current state and ideal state.</p>
<p>MEASURES: How will we know that a change is an improvement?</p>	<p>Specify one or more measures that characterize the current state and the ideal state (e.g., with respect to quality, cost, timing or safety). Specify the goal as target level(s) of the measure(s).</p>
<p>CHANGES: What change(s) can we make that will result in improvement?</p>	<p>Develop one or more changes from investigation of current state combined with Lean concepts (e.g., eliminate waste).</p>
<p>PDSA: Carry out Plan-Do-Study-Act (PDSA) test cycle(s) to increase the degree of belief in the change(s) that can improve performance (i.e., get closer to the aim). Revise the change(s) or the method, or abandon the change(s) based on data.</p>	<p>Test the changes to confirm that they reduce or eliminate the gap between current state and ideal state (Plan-Do-Check-Act). Revise or augment the changes as needed to achieve the goal.</p>

At its highest level, Lean extends the concepts and methods of the production system into a holistic conception of the organization, its context, culture, and management. In *The Machine That Changed the World*, Lean is described as a product development process, a fulfillment process from order through production to delivery, a supplier management process, a customer management process, and a general management process. John Toussaint, former CEO of ThedaCare, calls Lean an “operating system.”²⁴ In this view, TPS principles extend outward from the core value stream to shape management, support functions, supply chains, and customer experience beyond the mere receipt of a product or service.

In a Lean enterprise all levels of management, from line supervisors to the CEO and board of trustees, must conform their own work to the key principles of TPS, including standardized daily work, sensitivity to operational quality, constant readiness to detect and address problems in real time, and providing coaching and leadership in Lean thinking and methods to staff.²⁵ In this way improvement becomes integrated into the daily functions of all staff, not just managers and quality specialists. In their 2013 article, Toussaint and Berry say that Lean applied to health care reflects “an organization’s cultural commitment to applying the scientific method to designing, performing, and continuously improving the work delivered by teams of people, leading to measurably better value for patients and other stakeholders.”²⁶

The IHI Approach to Quality Improvement

For the purposes of this paper, we refer to IHI-QI as the approach to improvement developed by Associates in Process Improvement and promulgated by IHI, grounded in the work of W. Edwards Deming, with roots reaching deep into pragmatic philosophy, systems theory, Walter Shewhart’s statistical treatment of quality, human psychology and logic, and the scientific experimental method.²⁷

IHI-QI draws a fundamental distinction between the system to be improved and the techniques and methods used to improve it. IHI-QI seeks to formulate and codify generalizable knowledge that, when applied in other systems, can yield predictable improvements.²⁷⁻²⁹

All improvement requires that changes be made in the system (though to be sure, not all changes are improvements). Building on the knowledge of subject matter experts, improvers target changes that are predicted to lead to improvement in a specific system. These changes are then tested and amended through iterative Plan-Do-Study-Act (PDSA) cycles to produce sustainable improvement. Such changes comprise the “content” of improvement.

In health care, a primary source of content is clinical science: the body of theory and evidence that links clinical assessments and treatments with desirable outcomes. Content knowledge is exercised by those who work in the system with firsthand knowledge of its purpose, processes, and dynamics. IHI-QI in a particular system is guided by a content theory that justifies particular changes by their anticipated impact on results.

IHI-QI does not confine itself to any particular content area or production system. Its chief concern is with how theories and techniques offered by various disciplines can be brought to bear on a given system under specific conditions with a sufficient degree of belief that they will achieve the desired improvements.^{30,31} Success in such endeavors requires *will*, the moral engagement and energetic action to improve; *ideas* for changes that can be tested, adapted, and ultimately implemented; and *execution*, the techniques and methods that translate theory into actual improvement.³² In Deming’s terminology, the knowledge that builds will, generates ideas, and guides execution is “Profound Knowledge.”

Profound Knowledge stresses that predictably successful improvement requires skills and knowledge that extend across a wide range of disciplines in four interdependent domains: Appreciation for a System, Theory of Knowledge, Psychology, and Understanding Variation.³³ In Deming’s words, Profound Knowledge “provides a map of a theory by which to understand the organizations that we work in.”³⁴

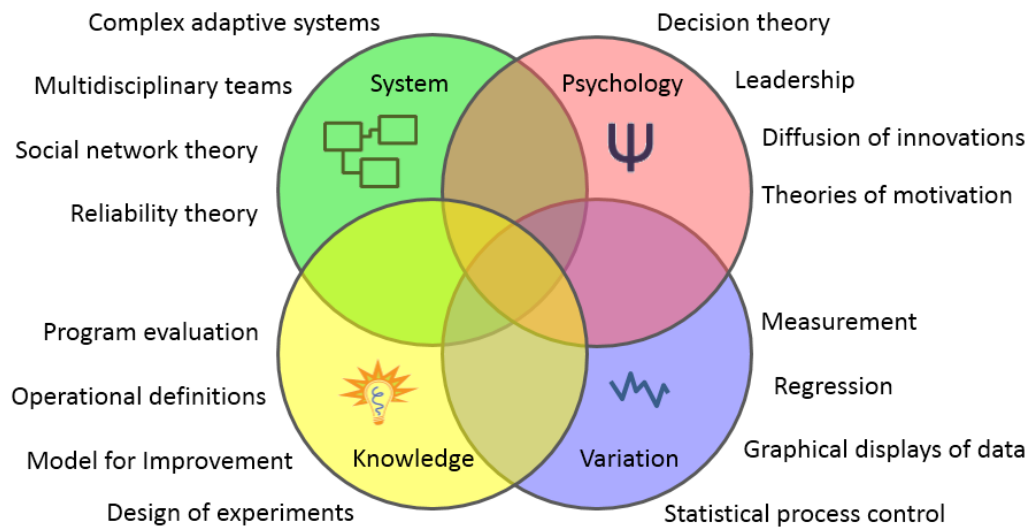
- *Appreciation for a System* is a matter of understanding the purpose of the enterprise and the interoperations among its parts — physical, social, and functional.³⁵ Systems thinking embraces the causal influences and feedback loops that enable (or impede) enactment of the organization’s aim, its capacity for improvement and propensity to change, and the qualities it must exhibit in order to achieve its aim. Such systems, animated by human beings, are by nature complex and adaptive, and thus resist efforts to improve them through simplistic “top-down” directives.³⁶
- *Theory of Knowledge* refers to the development of practical knowledge of “what works.” It is grounded in predictions about the results to be achieved through system changes. Knowledge is gained through a process of stating a theory, making a prediction based on the theory, comparing observations with predictions, and revising or abandoning the theory accordingly.³³ Thus the science of improvement is deeply concerned with the nature of learning and with ways to foster, maintain, and accelerate learning in practice. The Model for Improvement is both an expression of the theory of knowledge and its most fundamental technique. The explicit goal of the science of improvement is to increase such knowledge.
- *Psychology* deals with the behavior of humans as social actors, their interactions with one another, and their interactions with the systems of which they are a part. Intrinsic personal motivation is fundamental to improvement, and the factors that mobilize and sustain the will to improve are vital for successful initiatives. Biases in people’s perception and interpretation

of others’ behavior, for example, “attribution error,” have important implications for leaders working to develop a blame-free culture of improvement.³⁷ Care systems, to be truly reliable, must compensate for the shortcomings of human memory and attention, and for people’s naïve decision-making “heuristics.”³⁸⁻⁴¹ Techniques to assess and balance factors such as temperament, motivation, and emotion are critical for the operation of well-functioning teams.⁴²

- *Understanding Variation* requires the recognition that variability — both among entities and over time — is an inherent characteristic of any system. Measures and data are useful to guide future action, provided we can discern patterns in such variation and respond appropriately. Shewhart’s theory of variation, made operational by control charts, provides the foundation. The key concept of Shewhart’s theory is the distinction between common cause variation produced by a stable, predictable process and special cause variation that results either from unstandardized, uncontrolled operations or from intentional process changes.⁴³

In working to improve a system, IHI-QI practitioners employ an array of conceptual frameworks and methods drawn from many disciplines in order to understand and influence complex adaptive systems such as health care organizations. Selection of methods will vary greatly depending on the scope, scale, and context of the work. Figure 3 matches a few of these frameworks with the domains of Profound Knowledge to which they mainly pertain, with the caveat that there is much overlap; for example, a framework such as “leadership” finds relevant principles in all four domains.

Figure 3. Conceptual Frameworks Associated with Deming’s Four Domains of Profound Knowledge



The search for conceptual frameworks that can be usefully brought to bear on improvement is ongoing. Emerging fields such as social network analysis, predictive modeling based on large data sets, and decision theory offer tantalizing frameworks for innovation not only in care processes, but also for informing execution models that are increasingly effective for improvement.

The Model for Improvement is the engine that propels Profound Knowledge from a static catalog of interesting ideas into a dynamic program of learning and action. The Model represents a

ceaseless quest for practical, functional knowledge gained from hands-on experience in execution. Set a goal and measure it. Select a change idea, make a prediction, and try it out. What worked? Why? Under what circumstances? Will it work next time? Revise and try again. The Model drives improvement at all levels of scale, from the most minute adjustment of standard work, to the process redesigns of improvement teams, to the initiatives that aim to transform the health care systems of entire countries.

Productive testing requires good ideas about how to change the system. Such ideas may arise from the insights of those who work in the system (especially those with line-level point-of-care experience), or they may come from observation of another system that has demonstrated a better approach to the problem. Directed creativity techniques like those of Edward deBono⁴⁴ or the IDEO Corporation⁴⁵ can help teams generate innovative ideas for changes.

The authors of *The Improvement Guide* advocate for *change concepts* as a way of targeting ideas for change related to an improvement aim. They explain that “a change concept is a general notion or approach found to be useful in developing specific ideas for changes that lead to improvement.”⁵ Improvers are prompted to think of an aspect of the system that needs change, then select a change concept that describes the needed improvement and use it to provoke an idea. For example, a data team working to increase their efficiency might consider the change concept “eliminate things that are not used,” review its current work process, and discard a monthly report that is no longer needed by its original consumer. Such change concepts are represented by TPS principles such as *eliminate waste*, *Just-in-Time*, *jidoka*, and *poka-yoke*. A number of TPS change concepts appear in *The Improvement Guide*’s Appendix A.

IHI-QI initiatives are designed to fit the topic, scope, and scale of work at hand. Based on the design of IHI educational offerings, Collaboratives, and spread initiatives, and much hands-on experience, the authors of this white paper have outlined a series of steps that describe a “generic” IHI-QI initiative (see Table 2). This sequence is a bit of a “deli menu” — no diners are expected to consume all the items, and the sequence of dishes is certainly not obligatory. No improvement team would execute these steps in a fixed order, but instead would work up and down the list as the initiative is planned and enacted.

Table 2. Steps in a “Generic” IHI-QI Initiative

Step	Elements
1. Plan the initiative	<ul style="list-style-type: none"> • Create an explicit theory of what improvement you intend to obtain in the system and how you intend to go about it.
1a. Content theory and aim	<ul style="list-style-type: none"> • Identify the system to be improved (e.g., patient population, sites, unit of adoption). Assemble evidence, develop guidelines and protocols, identify key outcomes, and express the desired future state of the system. • Assess the gap in current performance. • Use a driver diagram to capture the content theory and target key processes needed to achieve the aim. • Develop a formal aim statement: “how much, by when, for whom.” • Identify and operationalize outcome and process measures.

Step	Elements
<p>1b. Execution theory and plan</p>	<ul style="list-style-type: none"> • Select a format for the initiative (e.g., “fast-track improvement,” single-process improvement, Breakthrough Series Collaborative, spread initiative) based on aim, scope of the system, and specificity of content. • Plan for data collection, analysis, and feedback. • Assess the internal and external contexts, and figure out how to influence them. • Assemble a team. • Plan activities (e.g., webinars, site visits, <i>kaizen</i> events, coaching). • Assess the needs of customers and staff. • Develop an evaluation plan and metrics that can provide concurrent feedback and track the inevitable adaptations of methods that occur in every initiative. • Develop a timeline and tactical plan.
<p>2. Develop, test, and pilot changes</p>	<ul style="list-style-type: none"> • Assess the current system structure and performance using control charts, system diagrams, Pareto charts, process maps, or other tools. • Identify relevant change concepts and exemplar systems. • Use change concepts or directed creativity to develop and prioritize change ideas. • Use PDSA cycles to develop, test, and pilot changes under diverse conditions, to gain confidence that they will work as predicted and refine where necessary. • Use measurement to monitor progress, identify problems, and promote adoption.
<p>3. Implement, sustain, and control</p>	<ul style="list-style-type: none"> • Implement successful changes throughout the local system. • Test and implement necessary support functions, including training, job descriptions, human resources, information technology, etc. • Establish a long-term measurement plan to monitor for sustainability. • Institute a quality control regime.
<p>4. Spread changes throughout the extended system</p>	<ul style="list-style-type: none"> • Define the scope and unit of spread. • Devise measures of spread. • “Package” content for easy implementation by new teams. • Develop communication and measurement systems and technical support. • Monitor and adapt.
<p>5. Evaluate and “pass forward”</p>	<ul style="list-style-type: none"> • Use statistical analysis, after-action reports, surveys, etc., to evaluate the effectiveness of the initiative, its interventions, team operations, and the role of context. • Celebrate success. • Codify learning to inform future improvers.

IHI-QI has flourished in the complex world of health care, with its many independent constituencies, disparate traditions, and often competing institutions. Its eclectic, overarching approach to improvement has fostered a generation of innovation and adaptation. Over the years, practitioners working across the broad IHI-QI field have extended the range of tools and methods to include driver diagrams, Failure Modes and Effects Analysis,⁴⁶ the MUSIQ survey of project

context and organizational QI readiness,⁴⁷ Elias Porter’s SDI psychological profile inventory,⁴⁸ and many others. In the spirit of Deming’s Profound Knowledge, they have assimilated useful constructs and methods from a wide array of other disciplines, including aviation, reliability science, social psychology, social network theory, Everett Rogers’ *Diffusion of Innovations*,⁴⁹ and behavioral economics.⁵⁰

IHI has led the development and adaptation of program formats for organizing people to engage in improvement, including the Breakthrough Series Collaborative,⁵¹ R&D methods for developing new processes (e.g., 90-Day R&D projects), the IHI Framework for Spread,⁵² as well as campaigns designed for large-scale dissemination of evidence-based clinical practices (e.g., the 100,000 Lives Campaign). The IHI Open School, with its online curriculum, an international network of local chapters, and web-based resources, is designed to inculcate IHI-QI in the next generation of practitioners.

Comparing IHI-QI and Lean

The above descriptions reflect strong congruence between Lean and IHI-QI:

- Both approaches recognize the purpose of the system — defined from the customer’s perspective — as the starting point for improvement.
- Both approaches take the well-being, morale, and dignity of people working in organizations as both ethical and instrumental objectives.
- Both approaches emphasize the design and continual refinement of processes as the way to reduce variation and increase value in outcomes.
- Lean and IHI-QI both rely on general principles (in IHI-QI terminology, “change concepts”) to guide the identification of candidate changes and solutions. They share many improvement tools and methods.
- Both emphasize the use of error proofing and inspection (including probabilistic sampling) in process design in order to improve reliability and reduce the rate of defects.
- Both approaches provide a simplified heuristic for defining quality problems on small and large scales, identifying candidate changes, and testing them to arrive at workable solutions. For IHI-QI, the heuristic is the Model for Improvement; for Lean, the A3 approach to problem solving.
- For both, the daily application of experimental methods by line-level staff to recognize workplace problems and identify useful changes (*kaizen*, PDSA) is the driving mechanism of sustainable improvement.
- Both recognize that measured feedback is an essential component of successful improvement efforts.
- Both see the ultimate work of improvement as transforming the culture of the organization from one based primarily on personal accountability to one based on cooperative understanding of system purpose, dynamics, and operation.

To be sure, there are differences between Lean and IHI-QI as these approaches are typically employed in health care. Table 3 highlights aspects of Lean and IHI-QI where the two approaches diverge. Appendix A provides additional detail about the intertwined histories of Lean and IHI-QI.

Table 3. Key Differences Between Lean and IHI-QI

Aspect	Lean	IHI-QI
Purpose	<ul style="list-style-type: none"> • Maximize customer-specified value of products or services. • Value includes cost, timeliness, absence of defects, and produce or service features. 	<ul style="list-style-type: none"> • Formulate and codify generalizable knowledge that yields predictable improvement in outcomes when applied in diverse systems. • When applied in health care, aims ideally balance patient experience, cost, and population health.
Origins	<ul style="list-style-type: none"> • Originated by engineers and managers working within an automotive manufacturing system. • Lean has since been extended with methods and principles for application in other contexts, including more recently in health care. 	<ul style="list-style-type: none"> • Developed primarily by consultants working first in automotive and electronics manufacturing, and elaborated in health care systems by the IHI community.
Focus and scope	<ul style="list-style-type: none"> • Methods are specialized for repetitive product production within a single enterprise (including suppliers and customers); generalized to services and clinical care (with adaptations). 	<ul style="list-style-type: none"> • Approach is abstract, includes methods for problem/aim definition applicable to any system. • Many initiatives are concerned with spread of evidence-based practices across health care systems and coalitions of enterprises.
Key principles guiding improvement	<ul style="list-style-type: none"> • “Value” definition provides criteria; value stream describes process. • Ideals and change concepts inherent in TPS form an integrated “template” that prompts ideas for problem mitigation and guides <i>kaizen</i> (continuous improvement). 	<ul style="list-style-type: none"> • Profound Knowledge and the Model for Improvement apply to any system. • Program theory provides the aim and change concepts to guide testing. • Metrics provide criteria. • Iterative PDSA cycles are used in diverse conditions to develop, test, implement, and spread robust changes.
Measurement and data	<ul style="list-style-type: none"> • Data relevant to the process operations are embedded in the value stream as visual controls and charts showing performance over time. • Qualitative data, rooted in direct observations, is the basis for problem mitigation. 	<ul style="list-style-type: none"> • Measures are defined as a component of content theory. • Organizational dashboards monitor performance at all levels. • PDSA-level measures evaluate changes. • Common vs. special cause variation distinctions help guide management decisions. • Run and control charts with decision rules are used to evaluate the significance of changes.

Aspect	Lean	IHI-QI
		<ul style="list-style-type: none"> Qualitative data are essential for interpreting changes in context. Data provides feedback to teams, typically tracing improvement over time.
<p>Integrating improvement into daily work</p>	<ul style="list-style-type: none"> <i>Jidoka</i> requires constant detection and remediation of defects at the lowest possible level of the organizational hierarchy. Managers at all levels have a key role as teachers of improvement. Standardization and visual controls reduce complexity, thus increasing mental capacity of people to improve. 	<ul style="list-style-type: none"> Improvement efforts are organized around projects with time-bound goals. Methods for implementing changes as standard work describe adoption, scale-up, and adaptation of support processes.
<p>Primary approach to reducing variation</p>	<ul style="list-style-type: none"> Standardized work is developed by line-level staff and supervisors. Continuous <i>kaizen</i> based on Lean change concepts to incorporate <i>poka-yoke</i> features refines standard work to reduce process variation empirically. 	<ul style="list-style-type: none"> Statistical process control retrospectively identifies special causes to be eliminated, to stabilize the process; redesign a stable process using the Model for Improvement based on change concepts. Reliability theory provides change concepts to reduce errors and defects in real time.
<p>Role of managers and executives in improvement</p>	<ul style="list-style-type: none"> Managers and executives have standard work processes, and the primary role as coaches for frontline staff. Improvement is integrated with standard work. 	<ul style="list-style-type: none"> Executive sponsors are seen as necessary for initiative success. They remove barriers and support the frontline project team.

Summary and Implications

Lean and the principles of TPS are in no way antithetical to the IHI approach to quality improvement, and vice versa. Lean is, in a sense, a complex and deep “application” of Profound Knowledge, a particular deployment of improvement in the realm of production systems, though it was not purposely conceived as such.

IHI-QI is a general approach that guides the development and application of execution theories across a range of specified contexts to realize clearly stated goals. We can consider Lean and TPS to be an example of such an execution theory. The TPS package of interdependent change concepts was originally developed to optimize manufacturing production systems. It represents a “template” for improving such systems, with a set of predefined aims, change concepts, implementation roadmap, and tools. Its validity has been empirically well established in the marketplace by

competitive manufacturing firms seeking to maximize value. Lean extends the principles of TPS into a general system of distributed management.

The application of TPS and Lean in other types of systems such as health care requires adaptation of the original template to divergent organizational structures whose aims, customers, contexts, and cultures may range very far indeed from Ohno's machine shop at Nagoya. Each new application subjects TPS/Lean to a new test of its validity, where the domains, principles, and methods of improvement science come into play. The further the system of application diverges from manufacturing production, as in health care, the more the template must be adapted to yield predictable improvements.

Lean is well on its way to being validated in health care, in the sense that we can identify systems that have deployed and adapted Lean systematically and demonstrated improved performance, sustained over a period of years, that they attribute to the use of Lean principles. Practitioners of IHI-QI should recognize Lean thus applied as a success story in the larger improvement mission to develop and spread successful execution models. Improvement practitioners should seek to recognize the range of systems and contexts in which Lean is useful, and the modifications needed to adapt it when context requires.

In the view of the authors, a major lesson that IHI-QI practitioners can take from deployments of Lean in health care is its insistence that the *gemba* (the workplace) is the fundamental locus of sustainable improvement, and that point-of-care preoccupation with continuous improvement based on standard work is essential for success.

This is where the “two jobs” of everyone in health care — to do the work and to improve how the work is done — come together.

- Every person in the organization has a necessary role to play. IHI-QI initiatives typically focus on line-level processes, but too often fail to develop and integrate standard work for supervisors and executives that, in Lean, are essential to transforming the organizational culture.
- In Lean, improvement is the responsibility of the line-level work team, not specialized quality professionals or consultants. An essential component of Lean transformation is process definition and improvement by the work team in the workplace; IHI-QI initiatives typically advocate the use of cross-functional teams. IHI-QI practitioners struggling to achieve sustainable change would be well advised to explore ways to bring the improvement initiative to the workplace, instead of (or in addition to) using a quality department staff person to “drive” the project or bringing team members offsite for training and coaching. The microsystem school of health care improvement has heard this message loud and clear; it describes an improvement roadmap that concentrates on work team assessment, development, and continuous improvement.⁵³
- IHI-QI practitioners should insist that they themselves, along with the leaders of the organizations with whom they work, go to the *gemba* to observe. Leaders will observe their teams in action. IHI-QI practitioners will observe the viability of their execution theory in action. Both will be better prepared to coach about improvement, and better able to adapt improvements as required.
- In complementary fashion, Lean practitioners can benefit from the diverse conceptual frameworks, program formats for spreading change, evaluation models, and practical

experience that IHI-QI offers regarding the deployment of improvement initiatives across a broad array of complex settings.

Creating a truly Lean health care organization requires a transformational commitment by leadership, followed by a steadfast, long-term commitment to building improvement capability throughout the management hierarchy. And not only capability — Lean also demands that roles, attitudes, and job descriptions are redefined at all levels of the organization. This kind of large-scale change is formidable. It is the kind of work that practitioners of IHI-QI have engaged in for the past quarter century and more. From the viewpoint of IHI-QI, a Lean deployment represents an organization-level improvement initiative that embraces a particular execution model. Planning and evaluation of Lean deployments from the IHI-QI perspective can lead to principles and practices that may accelerate the adoption of Lean in new environments, and suggest testable ideas for adapting of the Lean/TPS “template” to the unique challenges of complex health care systems.

For example, with adapted change packages and team support methods, the Breakthrough Series Collaborative model could provide a workable platform for the deployment of Lean among frontline staff and supervisors. Principles and tactics of adoption and spread could subsequently inform the systemwide transformation of organizations to a Lean culture. The design and implementation of theory-driven measurement systems can inform initiatives promoting the adoption and impact of Lean practices. Ultimately, it may be that models such as the Learning Healthcare Organization, and related principles such as the IHI Triple Aim, can extend the TPS template and change concepts to better apply in health care.⁵⁴

For both traditions, the future is about learning what works to improve value for patients. This mutual goal, pursued with a pragmatic spirit of shared learning, can help health care practitioners and improvers work together toward “doing the work and improving the work.”

Appendix A: Origins and Historical Linkage of the IHI Approach to Quality Improvement and Lean

Lean and the “IHI approach” to quality improvement (IHI-QI) share common roots in the industrializing world of the early 20th century, and have traced intertwined histories ever since.

Toyota Corporation was first established in 1918 as Toyoda Cotton Spinning and Weaving Company by Sakichi Toyoda.⁵⁵ Key principles of the Toyota Production System, including *flow* and *jidoka* — which originally denoted a loom that would stop automatically if the thread broke — had their origins in these early textile operations.²² Toyota Motor Company, Ltd., was established as a separate entity out of Toyoda Automatic Loom Works in 1937.⁵⁵

In the first half of the 20th century, Toyoda leaders, in keen competition with American and British textile firms, observed and creatively adapted methods from foreign manufacturing. Sakichi Toyoda, and later his son Kiichiro, regularly toured factories in Europe and the US.⁵⁵ A translation of *Principles of Scientific Management* by Frederick Taylor, the first celebrity management consultant, appeared in Japan in 1913.⁵⁶ Taylor’s methods focused on process standardization, careful measurement, and field experimentation as keys to improving production efficiency. Taylor trained Japanese managers in his seminars in the US, while scientific management was popularized in Japan by Ueno Yoichi, a consultant for Kyochokai, a semi-governmental think tank. Ueno’s concepts of waste — *muda*, *mura*, and *muri* — were anathema to the ideal of efficiency, and later appeared as key concepts of the Lean value stream.⁵⁶ Henry Ford’s innovation of the moving assembly line, which enabled production to flow, was an important feature of Toyota’s initial automobile venture. Taiichi Ohno even drew inspiration from the American supermarkets of the 1950s for the *kanban* control method that is an essential feature of Just-in-Time production.²²

Meanwhile, Walter Shewhart, a physicist working at Western Electric Bell Labs in the 1920s, was creating a functional conception of quality based on statistical distributions and the pragmatic principles of prediction and experimentation. Shewhart defined the quality of a product in terms of its future utility:

“The judgment that the quality of any thing is such and such is from a practical viewpoint equivalent to a judgment that it will be such and such. Moreover, such a judgment is based upon... evidence obtained through certain operations on the thing or similar things in the past and implies that certain experience will result if certain operations are carried out on the thing in the future... Hence we shall consider the first origin of standards of quality... as relating past to future experience.”⁵⁷

W. Edwards Deming, a statistician, was a colleague and student of Shewhart at Western Electric. In his work at the US Department of Agriculture, Deming combined Shewhart’s ideas with emerging principles in experimental design that he had absorbed while studying with R.A. Fisher at University College in London; a job at the US Census Bureau provided the opportunity to extend Shewhart’s thinking beyond production systems into service operations. Following World War II, Deming was recruited by General Douglas MacArthur’s occupation administration to advise the

Japanese census. While there he established relationships with engineers, who later founded the Japanese Union of Scientists and Engineers (JUSE).⁵⁸

Shewhart invented statistical process control (SPC) charts, and with them the notion of common and special cause variation that related process standardization to the discovery of defects. Quality control could now cease to be a matter of merely inspecting for defective product, and become a continuing search to identify and eliminate the underlying causes of poor quality. Improvement for Shewhart progressed in an iterative cycle of “specification, production, inspection”; Deming refined the cycle into “design, production, sales, and market research.” Deming introduced the cycle in Japan in 1951, where it became “Plan-Do-Check-Act,” the essence of *kaizen* (continuous improvement) and a fundamental principle of both Lean and, as “Plan-Do-Study-Act,” the Model for Improvement.^{13,59}

Development of the Toyota Production System beginning in the 1950s took place in a vigorous, rapidly expanding industrial environment. While American industry, unchallenged in the postwar era, concentrated on economies of scale and cultivation of worldwide markets, Japanese companies re-engaged in broad adoption of quality control and improvement methods under the leadership of JUSE, with the aim of closing a perceived nine-fold productivity gap between American and Japanese industry.^{9,60}

Both Deming and Joseph Juran, another student of Shewhart at Western Electric, took part in lectures and visits sponsored by JUSE starting in the 1950s. Deming’s 1951 lectures focused on Shewhart’s statistical methods. JUSE engineers soon concluded that a more comprehensive approach to quality improvement was required, and in 1954 invited Juran to deliver lectures on quality management. In subsequent years JUSE promoted education, research, and applications of quality, out of which emerged a general body of methods and concepts that JUSE called Total Quality Control (TQC), later modified and renamed Total Quality Management (TQM).⁶¹ TQC was actively practiced at Toyota during the postwar years, and formed the ground in which TPS took root.^{22,62} Deming’s legacy in Japan derives from his 1950s interactions with JUSE. In 1951 JUSE established the Deming Prize, awarded annually for excellence in quality improvement. In a 1991 speech Shoichiro Toyoda, then Chairman and former President of Toyota, remarked that “every day I think about what he meant to us. Deming is the core of our management.”⁶³

Anxiety over the ascendancy of Japanese industry in the 1970s, due in large measure to the superior quality of Toyota automobiles and other Japanese products, led to a renewed interest in quality methods among American manufacturers. In 1980, a TV special, “If Japan Can, Why Can’t We?,” launched Deming on a late-life career of consulting to US firms.

In Fremont, California, the New United Motor Manufacturing, Inc., a joint venture between Toyota and General Motors, brought Toyota know-how to running a car factory in the United States in 1984. Two years later, Toyota opened an assembly plant in Kentucky. Knowledge of the Toyota Production System began to spread among Americans, who gained firsthand experience with Toyota and its supply chain. Toyota attracted the attention of researchers, including James Womack, at the International Motor Vehicle Program at MIT. Womack led the research team that coined the term “lean production” to describe Toyota’s business system. Womack left MIT in 1991, and in 1997 established the Lean Enterprise Institute, which is today a leading purveyor of TPS philosophy and methods.

In 1987, Dr. Donald Berwick, then a Boston pediatrician, and A. Blanton Godfrey, then CEO of The Juran Institute, launched the National Demonstration Project on Quality Improvement in Health Care (NDP) with funding from the John A. Hartford Foundation. Twenty-four health care

organizations joined with industrial engineers in an attempt to answer the question, “Can the tools of modern quality improvement, with which other industries have achieved breakthroughs in performance, help in health care as well?”³ The QI methods taught in the NDP were from the Total Quality Management tradition of Joseph Juran.³ One outcome of the NDP was the founding of the Institute for Healthcare Improvement in 1991, the same year that Tom Nolan, an original member of Associates in Process Improvement (API), assumed what was to become a guiding role in IHI’s mission of spreading improvement techniques in health care. IHI’s early focus had been on general QI methods and tools education for health care professionals; in the mid-1990s, with the support of Nolan, attention turned to setting specific aims for improvement of the health care system⁶⁴ and developing methods to pursue them. Notable among them is the Breakthrough Series Collaborative, a multi-team project format for spread originally conceived by Berwick and Paul Batalden. The first Collaborative, focused on reducing the rate of cesarean sections, kicked off in 1994.

Tom Nolan, Ron Moen, and Lloyd Provost met when the three worked as statisticians for the US Department of Agriculture in the early 1970s. All three then pursued careers in the private sector. In 1981 Moen was hired by General Motors (GM) to be the point of contact with Deming, who had been retained as a consultant to the automaker. Nolan and Provost left their employers to consult with GM at this time and, with Moen, began working together as Associates in Process Improvement. Eventually, all three worked with Deming in his national seminar series from 1980 until Deming’s death in 1993.⁶⁵ During the 1990s Moen, Provost, and Tom Nolan were joined in API by Kevin Nolan, Jerry Langley, and Cliff Norman. Together they continued to develop Deming’s “Plan-Do-Study-Act” cycle into the Model for Improvement, adding the three guiding questions and insisting on prediction as a necessary starting point for useful tests.⁵⁹ API had observed that frequent, rapid testing was a characteristic of successful improvement efforts; in refining the Model for Improvement, they sought to simplify the core approach to its absolute essentials — aim, feedback, changes, and testing loop — to make it applicable in any setting, by anyone.⁴ *The Improvement Guide*, written by API authors and first published in 1996, presented the Model for Improvement, a core element of IHI’s approach to quality improvement.^{4,5}

Since 1995, API has worked closely with IHI to extend and adapt the IHI approach to quality improvement to the distinctive needs of the health care industry. An important focus of this work has been developing program formats (e.g., Breakthrough Series Collaborative, spread initiatives, Campaigns, deep dives, educational and professional development training programs) in order to support the many health care systems implementing their own local improvement initiatives with whom IHI and API work. In the process, IHI and API have adapted a wide range of conceptual frameworks as a source of program interventions. For example, Everett Rogers’ theory of the diffusion of innovations⁴⁹ informed the program strategies that appear in IHI’s spread models. Political campaigns were a source of inspiration for the IHI 100,000 Lives Campaign.

Appendix B: Glossary of Common Lean Terminology

This list of terms is adapted from the IHI white paper, *Going Lean in Health Care*.⁶⁶

5-S	Sort, Simplify, Sweep, Standardize, Self-Discipline: A visually-oriented system for organizing the workplace to minimize the waste of time.
Andon	A system that signals process defects as they occur, and empowers the operator to halt production until the problem is corrected.
Flow	The progressive achievement of tasks along the value stream so that a product proceeds from design to launch, order to delivery, and raw materials into the hands of the customer with no stoppages, scrap, or backflows.
Gemba	The “workplace,” where value is created (e.g., managers “go to <i>gemba</i> ” to observe production firsthand; the best ideas for improvement come from direct observation).
Heijunka	“Load leveling,” or reducing the wasted overcapacity required to accommodate fluctuations in demand by managing demand or increasing the flexibility of production.
Jidoka	“Automation with a human touch” (involves appropriate use of automation, continuous inspection, and a halt to the production process when a defect is detected).
Just-in-Time	A system for producing and delivering the right items at the right time in the right amounts. The key elements of Just-in-Time are flow, pull, standard work, and <i>takt</i> time.
Kaizen	Continuous, incremental improvement of an activity to create more value with less waste.
Kanban	A signal, often a card attached to supplies or equipment, that regulates pull by signaling upstream production and delivery.
Poka-yoke	“Mistake-proofing”: Process features that prevent, signal, or correct human errors as they occur, before they cause a process defect.
Pull	A system of cascading production and delivery instructions from downstream to upstream activities in which nothing is produced by the upstream supplier until the downstream customer signals a need; the opposite of push.
Standard work	A precise description of each work activity specifying cycle time, <i>takt</i> time, the work sequence of specific tasks for each team member, and the minimum inventory of parts on hand needed to conduct the activity.
Takt time	Sets the pace of production to match the rate of customer demand; the “heartbeat” of the production system. <i>Takt</i> time is the available production time divided by the rate of customer demand. For example, if customers demand 240 widgets per day and the factory operates 480 minutes per day, <i>takt</i> time is two minutes.

Value	Value is expressed in terms of a specific good or a service which meets the customer's needs at a specific price at a specific time. ¹⁵ Value is created by the production system; any aspect of production that does not contribute to value is waste.
Value stream	The specific activities required to design, order, and provide a specific product or service — from concept launch, to order, to delivery into the hands of the customer.
Visual control	Signals placed in the workstream or environment that indicate the current state of the process, used to guide actions to be taken.
Waste	Anything that does not add value to the final product or service, in the eyes of the customer; an activity the customer wouldn't want to pay for if they knew it was happening.

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