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Management Systems to Structure Continuous Quality Improvement

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KEY POINTS

- Management systems are critical linchpins that align performance of people, processes, and technology to achieve improvement goals and quality outcomes.
- Management systems provide structure and support people at all levels who are responsible for quality improvement efforts, including leaders (top-down) and managers with employees (bottom-up).
- The outcome is a laboratory system founded on educated, empowered people who are charged with and supported in continuously making service and production improvements as a basic work expectation.

KEY WORDS

Quality improvement; Continuous improvement; Lean

ABSTRACT

Objectives: This review describes the processes and effectiveness of the primary management systems that structure and sustain consistent behaviors and result in a transformed culture of continuous quality improvement (CQI) from top to bottom throughout the Henry Ford medical laboratory enterprise.

Methods: Through a 17-year focus to achieve a functional CQI enterprise, quality management systems were developed and continuously improved by teams of laboratory leaders, managers, and quality specialists to coordinate and standardize human efforts, and provide actionable knowledge and data to engage improvement efforts at all levels of work. Lean and ISO 15189 discipline and requirements were addressed in annual management review of functionality and effectiveness to close gaps and further refine the management systems.

Results: Improvements in the use and effectiveness of 4 management systems are illustrated.

Conclusions: The 4 primary management systems that provide structure and support transformation to a culture of CQI are the team leader, Plan-Do-Check-Act problem-solving, deviation management, and daily management systems. These management systems are designed to deepen the effectiveness of the continuous improvement culture by helping managers understand variation in the work they oversee and providing guidance for more effective employee engagement in the daily processes of quality improvement.

INTRODUCTION

In the large, integrated Henry Ford Health System laboratories, we have come to appreciate that business management systems are required to develop a culture that consistently produces continuous quality improvement (CQI) at all levels of the work. These are the critical supporting linchpins that align performance of people, processes, and technology to achieve improvement goals and quality outcomes. Key to long-term success have been the 10 primary quality management systems developed and refined since 2006 in our lean CQI enterprise, the Henry Ford Production System. These management systems are aligned in the lean enterprise to promote problem-solving, with continuous improvement cycles and to foster compliance, competence, and performance excellence under our International Organization for Standardization (ISO) 15189 accreditation.[1] The primary systems that form the support structure of the continuous improvement cycle methodology of the Henry Ford Production System are illustrated in FIGURE 1.

These management systems provide structure and support people at all levels who are responsible for quality improvement in our business enterprise—not only leaders and managers (top-down) but, more importantly, supporting systems designed to integrate improvement efforts from the level of the work (bottom-up), as shown in FIGURE 2.

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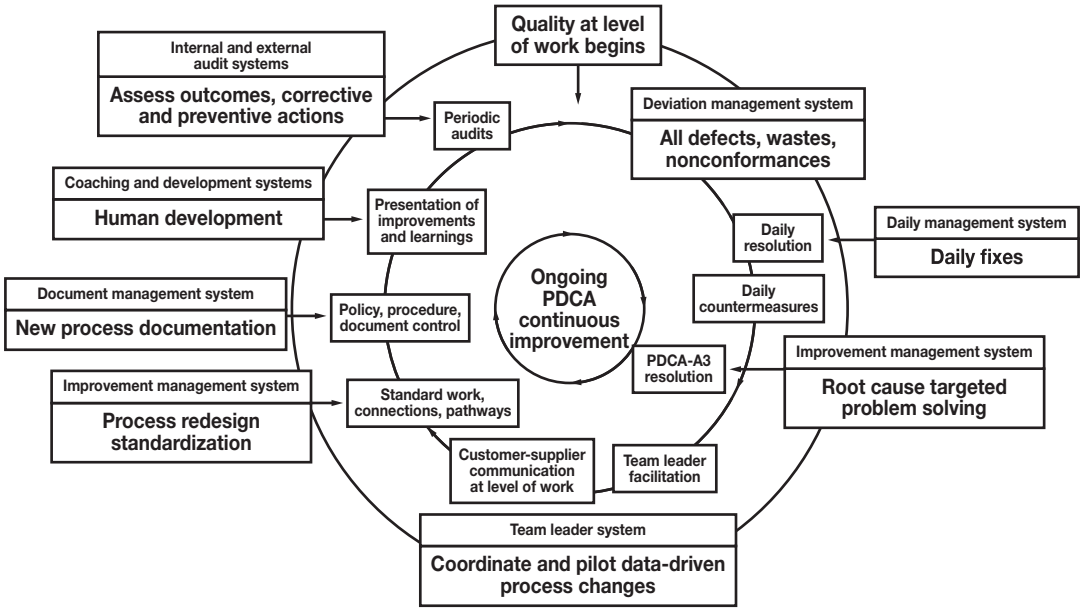

FIGURE 1 Continuous improvement cycle and supporting management systems. PDCA, Plan-Do-Check-Act.

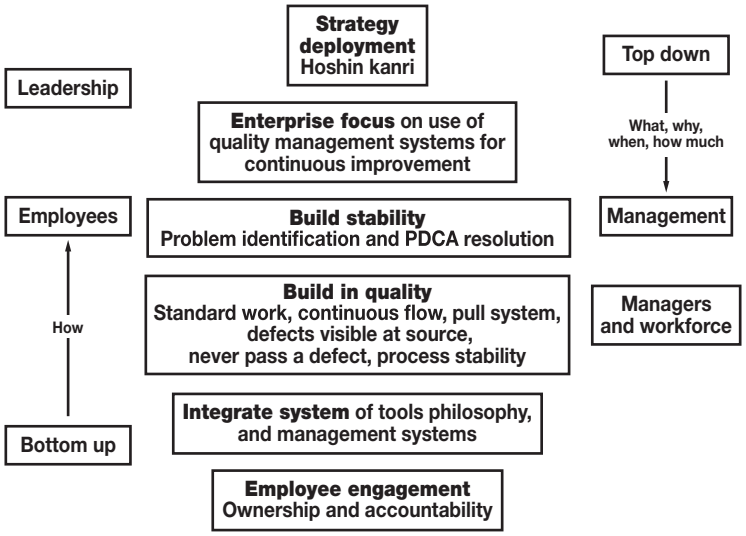

FIGURE 2 Roles in top-down and bottom-up continuous improvement. PDCA, Plan-Do-Check-Act.

It is said that systems do not produce quality, people do. In our experience, however, management systems are required to guide people in their daily focus to lead, manage, and work toward consistent execution of CQI and quality goals. These management structures hardwire human intention and consistency of CQI behaviors at all levels of the enterprise because they form the underlying business system for leaders, managers, and employees. In this way, culture is transformed so that quality is the basis of management and CQI becomes *the only way we work here.*

In this article, I describe the primary quality management system structures that coordinate and standardize human efforts for consistent execution and achievement of work-level (bottom-up) and leader-level (top-down) CQI activities and outcomes.

TEAM LEADER SYSTEM: BOTTOM-UP FORCE MULTIPLIER

First, there are 3 required elements to consider in transforming the cultural expectation that everyone is engaged in continuous improvement: (1) cultural philosophy that fosters participation and makes identification of errors blameless, (2) educational structures for human development and support for engagement, and (3) management systems for consistent execution of continuous improvement activities at all levels. These tripartite elements of a culture of continuous improvement are shown in FIGURE 3.

Because our initial CQI focus was to achieve employee engagement in improvement at the level of the actual work, we recognized the need for a more granular work-level quality leader of small

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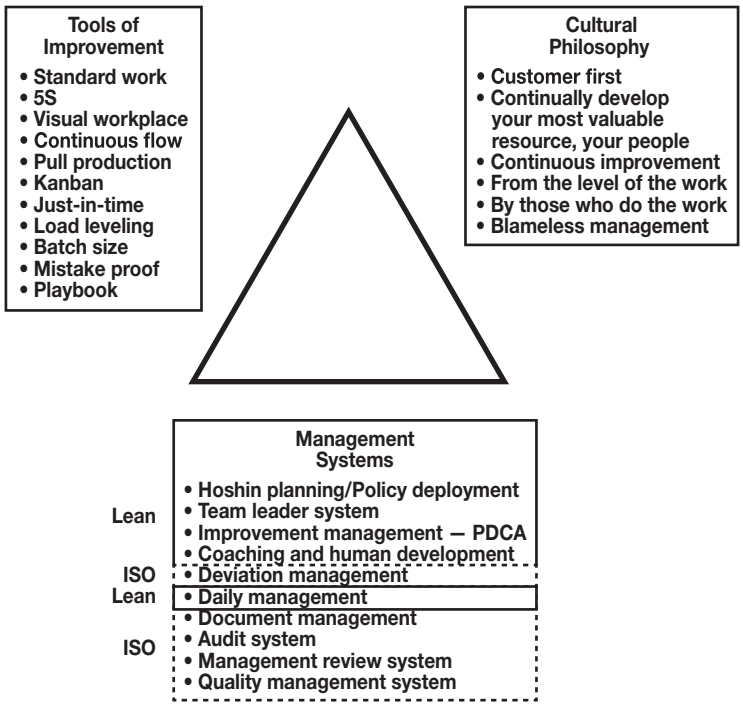

FIGURE 3 Lean and International Organization for Standardization (ISO) 15189 management systems for continuous improvement. PDCA, Plan-Do-Check-Act.

teams who produce components of value. This team leader is key to an effective team-based focus on improvement and local use of the supporting management systems, as illustrated in FIGURE 4. At this micro level, a bottom-up engagement of the workforce can achieve CQIs where thousands of nonstandard practices may result in many nonconformances that the users (customers) of that product or service experience.

The team leader system is the structure we created to use coordinated CQI efforts by those who do the work in numerous work areas aligned to the path of work flow.[2] In doing so, we recognize as subject matter experts those who do the actual work. Their participation fosters coordination of knowledge and process changes across multiple work areas in synchrony with the flow of that work to its final state as a product or service.

The team leader structure requires designation of a work-level team champion or leader for a work area that produces a product or service that others use. This person takes responsibility for assuring the team's daily capture and analysis of quality issues, team communications, coordination with upstream suppliers and downstream customers, pilot implementation of changes that the team proposes, effectiveness assessment of the process change using data, and rollout of the new standard work.

The team approach provides (1) responsible voices for each work area that are experienced and authorized to investigate defects and modify processes, (2) an aligned view of the flow of work rather than isolated efforts, and (3) coordination of agreed-upon interventions and countermeasures that are planned to eliminate problems. When designed as the focus of a daily huddle and structured as daily management, this approach sets the expectation and cadence of continuous improvements.

The team leader system is the force multiplier that structures local work area representation and broad work-level participation in team thinking, identification of process defects, and root cause analysis. This process eventually results in testing of proposed countermeasures and assessment of effectiveness by the team. This system was developed to achieve Toyota's Rule in Use #4, as described by Spear and Bowen,[3] whereby improvements are made at the lowest level of the organization by those who do the work. Employees are expected to improve their own work, guided by a teacher, based on a data-driven, scientific approach.[3] This approach requires granting authority to people who do the actual work over their work environment. It also requires that teams be educated and trained in CQI so that they will have sufficient knowledge and ability to influence processes and achieve desired goals as they continuously meet the challenges of perfecting work processes so that the work flows smoothly.

Team leaders are encouraged to arrange customer-supplier meetings that bring workers together to discuss their expectations and customer requirements as the product or service is sequentially produced and passed from one work area to another. The purpose of these meetings is to understand more deeply and discuss highly specified requirements to aid in the direct hand-offs between customers and suppliers to eliminate the main types of waste in processes. Meetings of aligned teams designed solely for improvement purposes remove barriers between work areas and promote enhanced understanding and knowledge geared toward mutual ownership of solutions rather than presenting a forum for the typical "blame game." Additional insights focus on process standardization and elimination of non–value-added waste in its many forms as keys to moving continuously toward the ideal condition,

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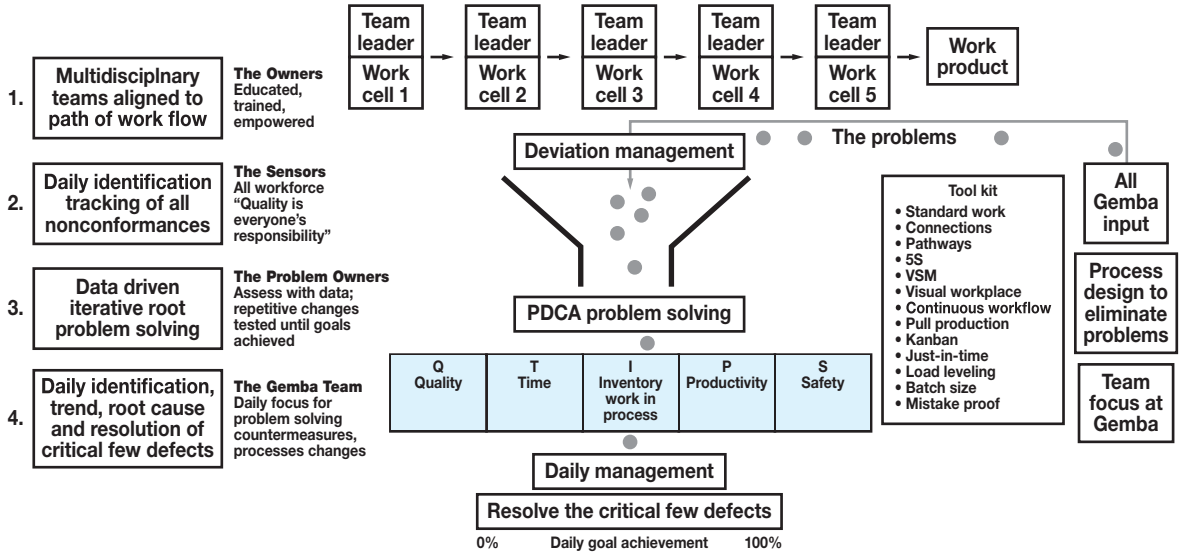

FIGURE 4 Management systems for bottom-up continuous improvement. PDCA, Plan-Do-Check-Act; VSM, value stream mapping.

and flow can be achieved. Weekly customer-supplier interactions set a cadence, with the direct outcome of a rapid pace of continuous improvements toward these goals.

The team problem-solving approach is often "Go and See," in which subject matter experts observe the problem to understand better the current condition before suggesting process improvements. This understanding requires analysis of workflow, standardized work procedures, and further evaluation to analyze and detect the root cause of defects. In comparison, other quality improvement methods often are limited to the review of data from reports created by individuals external to the work itself.

The team leader is a necessary position in driving quality from the level of the work because this person is responsible for assuring that ongoing small improvements in segments of the process under the team leader's control continue to move the entire process toward perfection.

Respecting people and recognizing their contributions is key to employee engagement in CQI. The importance of investing time in developing and valuing people cannot be overstated: it is the people in the organization who are expected to drive continuous improvements, and this now defines the foundation of work. The need to continually improve is woven into the fabric of the people and not viewed as a time-consuming inconvenience, option, or an additional potential reward.

We have found that a monthly departmental meeting of all team members and their team leaders that is structured to present and update improvement projects is an opportunity to set and reinforce the cadence of change and share the lessons *learned by doing* from the numerous process improvement initiatives, both failed and successful. Important outcomes of meeting regularly for this purpose are to solidify the self-confidence and empowerment of employees as they engage in making change, to enhance team bonding, and to lend an appreciation of the interdependence of the work that they perform as they work together to reach common goals.

Departmental leaders should take this opportunity to lend the most important reinforcer: public recognition of individuals and teams for their engagement, creativity, and important contributions to quality improvement. Our experience demonstrates that teamwork is the foundation of process improvement and that individual performers will extend themselves to make the enterprise successful if they are granted ownership and included early in the decision-making process. We have used the team leader structure to systematize the culture of continuous improvement to model behaviors and expectations in *learning by doing* across all our Henry Ford laboratories since 2006.[4] At Henry Ford, this discipline has resulted in a consistent pace of 1,000 annual process improvements accomplished in the laboratories of the acute care hospitals **FIGURE 5**.

SENIOR LEADER SYSTEM: TOP-DOWN STRATEGY IMPROVEMENT

Senior leadership is charged with focusing on the corporate mission by forming a vision and developing multiyear strategies with their direct reports to implement and achieve significant business goals. More often, these large stretch goals relate to growth and profitability from new or expanded business processes or endeavors. In a lean business system, this approach by leaders is also visual, documented, and measurable, with intent to continually improve the delivery of key strategies. This system, used by senior leaders, directors, and managers, is known as *hoshin kanri,* or policy deployment. The strategies and actions can be visually represented by an X-matrix and progress documented using key performance indicator (KPI) and action plan trackers. Detailed are 3-year goals, 1-year breakthrough objectives, and high-priority actions and personal accountabilities. KPIs are usually reviewed monthly. Action plan progress and problem-solving by implementation teams is usually addressed weekly. In a sense, the executive- and manager-level

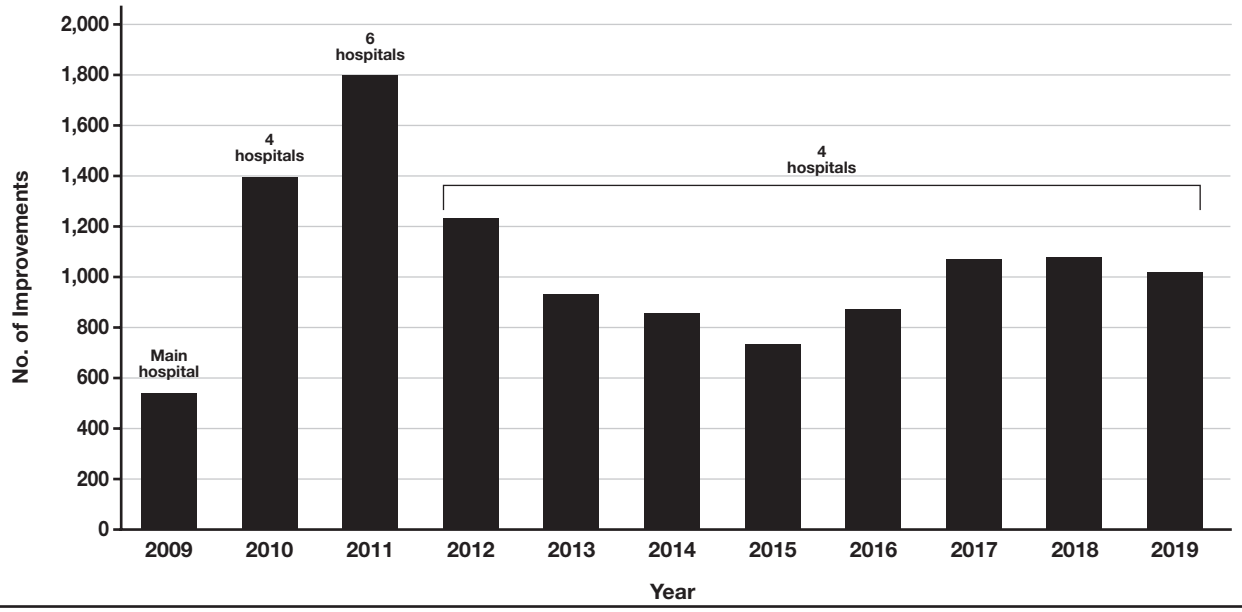

FIGURE 5 Annual process improvements at Henry Ford Health System Laboratories of acute care hospitals.

leaders are also a team that uses data-driven problem-solving approaches to refine their strategy and its execution throughout the year. In this way, leaders can break down complex problems into small, manageable solutions from the team. The management systems that support this approach to top-down continuous improvement are illustrated in FIGURE 6.

PLAN-DO-CHECK-ACT SYSTEM: ROOT CAUSE–TARGETED PROBLEM-SOLVING

Unlike the historic "sounds like a good idea" approach to improvement, we rely heavily on a data-driven approach to problem-solving. This approach requires testing and proving the effectiveness of each process change. Adhering to the data-driven Plan-Do-Check-Act (PDCA) discipline is effective but challenging. Human nature often reverts to making fast, automatic, or emotional suggestions in problem-solving rather than using the controlled, methodic, rule-governed, and slower PDCA process, which is designed to identify interventions that target the root causes of problems. This challenge in human thinking is well described by Daniel Kahneman in his book *Thinking, Fast and Slow* and lends insight into the need for ongoing education and training in PDCA thinking and problem-solving.[5]

We have systematized PDCA problem-solving in a standardized storyboard framework by using A3-sized paper that defines the methodology of each required element so that teams dig deeper into problem analysis to arrive at a deeper understanding of the root causes of the problems, thereby creating an intervention that focuses on the root of the problem. Note that the PDCA process of planning the change is more involved, with 7 steps rather than the 3 steps for implementing, checking for effectiveness, and stabilizing the new process FIGURE 7. It is our expectation that those who do the work see their daily work in the context of continually making effective process improvements that are designed and tested using the scientific method. Therefore, problem-solving begins by defining the problem through data collection to establish a baseline by which to gauge the success of any proposed changes.

From our ISO 15189 discipline of problem elimination through process change, we have added an additional element of process standardization that requires creation of standard work documents under document control and an effectiveness check, with a daily metric to assess process stability and an audit to assess long-term process stability. These elements are not seen in typical lean PDCA storyboards and derive from long experience in CQI.

DEVIATION MANAGEMENT SYSTEM: FILLING THE DIAGNOSTIC PROBLEM FUNNEL

How do leaders and managers gain knowledge of the daily reliability and consistency of the work they are charged with overseeing? What is going well and not going well, meeting the customer requirement or producing dissatisfaction? How does one know what to tackle next and specifically how to make effective change to eliminate problems?

Knowledge of deviations and feedback to leaders—and rarely to those who do the work—may include customer complaints, departmental or system incident reports, manual recording of issues on white boards, or (rarely) electronic capture of errors or amended reports. We have used all of these methods with varying success. We began with whiteboards as an opportunity for the workforce to document variation and waste. The unstructured format, however, commonly led to inconsistency of defect capture and documentation, with sporadic employee participation. Whiteboards often degraded to "whining" boards. Customer complaint, although important, is a sporadic and

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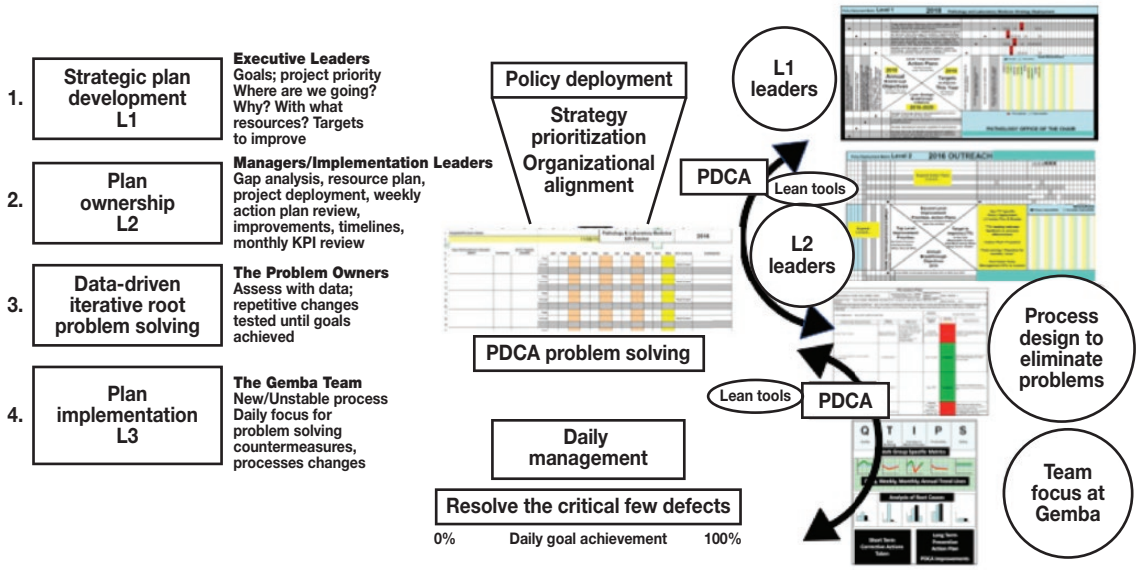

FIGURE 6 Management systems for top-down continuous improvement. KPI, key performance indicator; PDCA, Plan-Do-Check-Act.

Plan	Do-Check-Act
1. A3 Team Represent those affected by the problem	8. Do - Implementation of New Plan Schedule roll out specifics of new action plan Define: what, how, who, when, where Assign responsibility and completion dates
2. Problem Background Define the problem to be resolved without assumptions; narrow down to the specifics and write the problem statement	9. Check - Results Postimplementation, re-collect same data points that defined the current condition to assess effectiveness of the changed process Target met? If yes, accept new plan and modify process If no, investigate further; identify correct or additional root causes; modify plan; go through second PDCA cycle
3. Hypothesis The proposed intervention guess; if we adopt "x" the problem should be reduced by (# or %)	
4. Current Condition What is occurring currently; collect data to confirm the problem statement and show the magnitude; tabulate and prioritize	
5. Problem Analysis Use "5 Why" analysis to understand root causes or use cause and effect diagrams	
6. Target Condition The expected improvement goal to be reached	10. Act - Standardization Adopt the new process Create standard work documents Assess effectiveness by using a daily metric Design periodic audits to assure gain is held
7. New Action Plan (New Process) Describe the new improved plan to be adopted after considering root causes	
The way things are now — current state	The better way of work — ideal state

FIGURE 7 Plan-Do-Check-Act (PDCA) problem-solving A3 storyboard

inconsistent means of assessing and temporally intervening in process instabilities.

In 2012, we began to pursue the goal of creating a Deviation Management System (DevM) for the robust, real-time identification and knowledge of improvement opportunities in the work.[6] The aim was to provide managers with enhanced surveillance of nonconformances; because these nonconformances were detected daily, the system has become a much more powerful way to continually fill the diagnostic funnel of knowledge about problems to guide process improvement. The system was designed to capture deviations from the entire workforce at the level of the work, fostering real-time defect capture, with structured, deeper knowledge related to the deviation causes and parameters as they are encountered (case, source, type, person, cause). This DevM system arms managers with diagnostic analysis and knowledge for prioritizing problem-solving. In contrast to the free-form whiteboard approach, the power of DevM is structured behaviors that identify quality defects at the source, with root causes and interventions accomplished temporally closer to the actual event.

We integrated into this process the opportunity to begin the root cause analysis and documentation of the corrective action taken. This system reinforces local ownership for documentation and follow-through, pushing solutions down to the level of the work, where expertise lies. We continuously improved the robustness of this DevM system to feed collection and documentation of work-related nonconformances with development of a taxonomy of more than 300 defect types that may be encountered in our large system of quaternary-tertiary, specialized, referral, and community hospital laboratories. Moreover, the DevM system is designed to incorporate documentation of actions taken to correct and eliminate nonconformities, as required by ISO 15189. Data entry is a simple but robust Excel-based system in the manual laboratories, supplemented by electronic capture of order, specimen, and report defects in the automated laboratories.

Given our adherence to the ISO 15189 requirement for occurrence or nonconforming event management, we have taken a broad view in defining a *nonconformance* as any deviation from a standard; a defective work product or process that is defective, nonideal, or imperfect in form; a product or service not done right the first time; or any person not following policy or procedure as a root cause of the nonconformance. This definition of workplace defects includes any deviation from expected work process outcomes by instrument or human and any identified process wastes and inefficiencies.

From this DevM system, we consistently document knowledge of roughly 70,000 work nonconformances annually in a laboratory system that performs more than 35 million tests each year. Knowledge of nonconformities from the deviation management process effectively assists managers and supervisors in prioritizing and directing corrective actions and process changes at the level of the work with their teams **FIGURE 8**. Nearly three-fourths of the documented deviations are handed to the laboratory by individuals external to the laboratory who perform specimen ordering and collection. Much of this variation represented in the nonconformances that we have identified using the DevM system can be traced back to a human action or lack of action from these external suppliers as well as our own internal employees. Armed with focused knowledge, many interventions call for extending beyond the laboratory to standardize the supplier with innovative approaches to guide and standardize human behaviors and make work actions more reliable, often in a highly visual and accountable work environment.

The DevM system is critical to informing leaders and teams of the potential totality of work-related nonconformances or deviations as a knowledge base to target process improvements. Broad and consistent DevM participation by the workforce creates the foundation

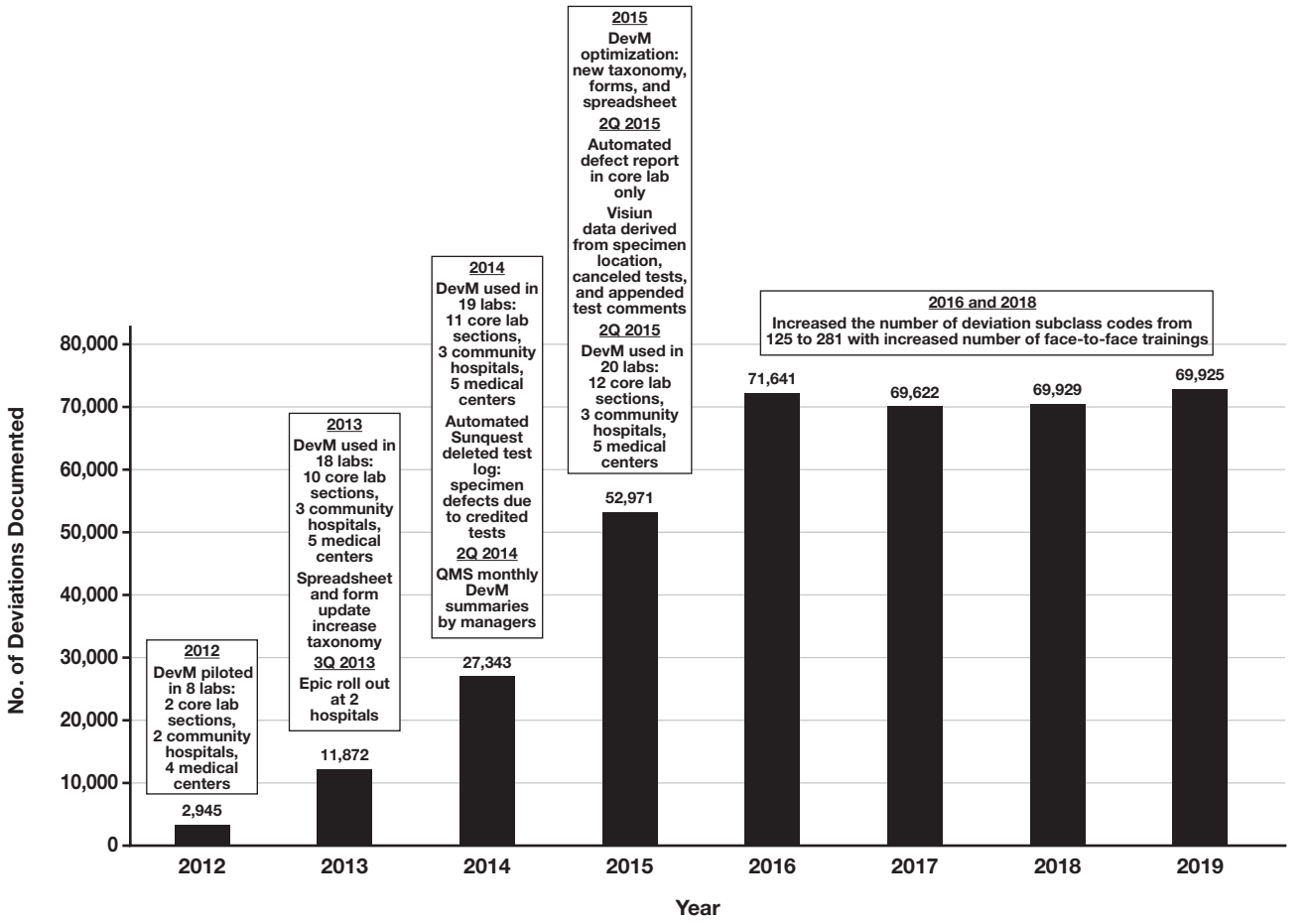

FIGURE 8 Continuous improvement of Deviation Management (DevM) capture, 2012-2019. Q, quarter; QMS, quality management system.

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of knowledge to enable continuous improvement, thereby addressing Deming's call for "profound knowledge" for leaders to affect change and improvement.[7] This knowledge and opportunities for work improvement from analysis of nonconformities identified in the DevM system have become the standard work of the manager to effect consistency and reliability in the work they are charged with overseeing. We derive 3 modes of tight managerial function from using the DevM system—namely, surveillance for defect detection, monitoring for assessment of control of nonconformities and effectiveness in their elimination, and employee engagement in detection and process improvement.

DAILY MANAGEMENT SYSTEM: SOLVING THE CRITICAL PROBLEMS DAILY

Daily Management (DM) is a powerful management problem-solving structure that functions on a 24-hour basis for continuous improvement from the base of the organization up using a daily visual management system.[8] DM is owned by the team and provides structure, alignment, focus, and accountability in continuously improving the group's work effort, be it a product or a service. DM focuses on implementation of immediate and urgent countermeasures (short-term corrective actions) to bring the work system back to stability that are then followed by a data-driven root cause analysis, with the intent of preventing recurrence with a well-thought-out preventive action plan. The broad approach, with the identification of defects in failed processes from the previous 24 hours, provides for visual management at a glance and prioritized focus for the manager and team **FIGURE 9**.

Lean does not progress beyond consultant-led efforts until midlevel managers buy into the culture change and model new behaviors that result in problem-solving with their staff. This is why DM is such an effective management approach for the conversion and continued education of midlevel managers in securing Lean from top to bottom in the organization.

For a lean leader, DM metric boards serve as the data-rich conversational focus of their Gemba walk, where probing questions can develop team members and reinforce lean thinking and behaviors for continuous improvement. In a lean culture, the role of leaders is to support daily improvement—to add energy, ask questions, encourage, and coach without taking over. In this manner, the leader, by coaching the team through the improvement process and recognizing that the answers lie with those doing the work, develops the abilities of his or her people and reinforces the approach to problem-solving. The conversations of effective coaching become easier for leaders who understand the work, and we have found that daily rounds at the DM board are the perfect place for leaders to gain that deeper understanding and support the daily improvement efforts of staff. According to Liker:

> The more clear it is in the work-place what the standards are (reflecting what should be) the more easily the manager can see the gaps and have productive discussions with people in the process. If there is a chart it should be clear if the process is in control (green) or out of control (red). It should be clear where inputs used should be, how much should be there, and when they should be arriving. It should be clear (without flipping through many computer screens) what the technical worker should be working on versus what they are working on. This is called a "visual workplace" and the more it is clear visually what should be happening versus what is happening the more productive the Gemba walks will be. (J. K. Liker, PhD, written communication, 2011).

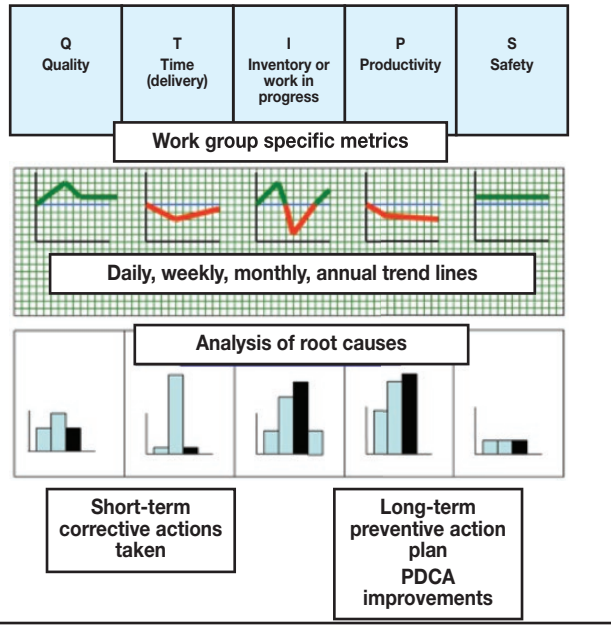

FIGURE 9 Daily management system, Quality, Time, Inventory, Productivity, and Safety (QTIPS). PDCA, Plan-Do-Check-Act.

The vital role of DM in continuous improvement is best grasped by understanding the culture of Toyota. According to Liker and Convis:

> Toyota believes that improvement cannot be continuous if it is left to a small number of process improvement experts working for senior management. Continuous improvement is possible only if team members across the organization are continually checking their progress relative to goals and taking corrective actions to address problems. Continuous improvement starts at the work group level, where value-added work is done. At Toyota, that is at the level of work teams, where group leaders and team leaders facilitate daily kaizen.[9]

In the Toyota Floor Management Development System, the focus is on the current performance of the work group relative to expected targets, organized by the major key performance indicator categories Safety, Quality, Productivity (delivery, service), Cost, and People (human resource development, engagement).[9] In the

Danaher Business System, metrics revolve around Safety, Quality, Delivery, Inventory, and Productivity. Our Henry Ford Production System laboratories focus process improvements in the categories of Quality, Time (delivery), Inventory (work in process, batch size, instrument availability), Productivity, and Safety. These DM categories are represented by the acronym QTIPS.[8] We have also designed our DM system to incorporate documentation of frequency trending, root cause analysis, corrective/preventive actions, and resulting process improvements derived from data-driven problem-solving by teams **FIGURE 9**.

DM is not a display of stable production, operational efficiency numbers, rare events, or a posting of weekly collected data. Rather, DM metrics reflect a daily update of the consistency and reliability of new or unstable processes that are being monitored because they are failing and need further adjustment. When DM boards are aligned by sequential workstations along the path of workflow, DM can make visible any defective work processes from hand-offs that result in substandard quality. In this way, DM can break down barriers of control and isolation between groups that preclude the achievement of continuous flow, the goal at the core of Lean efficiency.

The DM metrics that are refreshed and reviewed daily are the gauge of success as teams identify opportunities, understand root causes, propose and implement countermeasures, and bring unstable situations under control. The visual trend of "red" days transitioning to "green" is the simplistic signal to all that strategically aligned goals have been achieved in a stable work system. This simple color-coded designation of a successful green day enables the team and leaders to know immediately at a glance that the operation is stable and meets the performance expectation. If a red day, the team must understand the situation at a deeper level by further exploring root causes and interventions. The structured board approach guides teams to study the process from daily countermeasures to propose process change opportunities that are tested by using data to eliminate work problems. DM is an effective tool for teams to own and foster data-driven problem-solving at the level of the work, and we have continually evolved and annually trained our employees in effective use of DM. We began DM in 2014 with 8 core laboratory divisions employing 64 DM metric boards that derived 42 PDCA-driven process improvements.[8] By 2018, 126 DM metric boards were in use by 16 core lab divisions and hospitals. As a measure of its importance, DM was used effectively in the COVID-19 crisis year 2020 by 17 core lab divisions and hospitals that monitored their processes with 132 DM metric boards despite staff furloughs and medical absences **TABLE 1** and **TABLE 2**. The average meeting time expended in DM is 2 to 10 minutes per day per DM board. Unstable and failed processes may require further time to share information or questions about next steps or subsequent root cause analysis or interventions to be tested.

DM is the key accountability system for managers to continually improve their operations in a structured and visible manner with their implementation teams. Strategy and policy can only go so far without quality delivered every day at the level of the work. We have found DM to be an essential means of delivering on our daily quest to achieve ever higher levels of performance quality.

SUMMARY

In the large, integrated Henry Ford Health System of Laboratories, the inspiration for our approaches to CQI have been the

TABLE 1 2018 Daily Management Board Metrics (126 Boards; 16 Divisions and Hospitals)

	Quality	Time	Inventory	Productivity	Safety
Chemistry	2	3			2
Cytology	3				1
Cytogenetics		1	1	1	
Hematology/Coagulation/UA	3	5			3
HFMG 27/7 OPD Labs	2	2		1	2
HLA	1	1		1	1
HWH Hospital	3	1	3	1	2
MCT Hospital	7	4	3	3	6
WBH Hospital	3	2		2	
Transfusion Medicine	1		3		
Surgical Pathology	2	4	3		6
Molecular Pathology				3	
Microbiology/Serology			1		3
Pathology Informatics	11				
Outpatient Lab K1	1		1	1	1
Lab Customer Service	2	6	1		
Total DM boards	41	29	16	13	27

DM, daily management; HFMG, Henry Ford Medical Group; HLA, human leukocyte antigen laboratory; HWH, Henry Ford Wyandotte Hospital; MCT, Henry Ford Macomb Clinton Hospital; OPD, outpatient; UA, urinalysis laboratory; WBH, Henry Ford West Bloomfield Hospital.

TABLE 2 2020 Daily Management Board Metrics (132 Boards; 17 Divisions and Hospitals)

	Quality	Time	Inventory	Productivity	Safety
Chemistry	4	2			1
Cytology	1	1			1
Cytogenetics	4	3	2		1
Hematology/Coagulation/UA	2	3			
HFMG 27/7 OPD Labs	1	3		3	3
HFMG Non 24/7 h Labs	2	1	1	2	1
HLA	2	1	1	1	1
HWH Hospital	3	2	2	1	1
MCT Hospital	5	4	2	3	7
WBH Hospital	2		1		
Transfusion Medicine	1		3		1
Surgical Pathology	1	5	2		8
Molecular Pathology	4	3			
Microbiology/Serology	3				
Pathology Informatics	9	4			
Outpatient Lab K1					
Lab Customer Service	3	4			1
Total DM boards	47	36	14	10	25

DM, daily management; HFMG, Henry Ford Medical Group; HLA, human leukocyte antigen laboratory; HWH, Henry Ford Wyandotte Hospital; MCT, Henry Ford Macomb Clinton Hospital; OPD, outpatient; UA, urinalysis laboratory; WBH, Henry Ford West Bloomfield Hospital.

management philosophy of Dr W. Edwards Deming and the people-focused business management systems and production process improvement approaches of the Toyota Production System (TPS), also referred to as Lean.[7,10-12] Our goal has been to mirror the TPS, which is a sociologic and technical system that results in highly efficient just-in-time or lean production.[13] Since 2006, we have adopted these philosophical, production, and continuous improvement principles in our health care medical laboratory environment.[4] Moreover, we have focused on the important guiding principle of respect for our people, with human development systems to achieve CQI engagement at all levels of employment but most importantly from the lowest level of the operations. This Henry Ford laboratory continuous improvement system, founded on our educated and empowered people charged with continuously making service and production improvements, is illustrated in FIGURE 10.

Our TPS training began in 2004 through the Pittsburgh Regional Health Initiative.[14] Since 2005, we have adapted and used these inspirations in our medical laboratory environment across the Henry Ford Health System to achieve Dr Deming's mandate that "quality is everyone's responsibility," recognizing that "quality starts in the boardroom."[7] That constancy of purpose has transformed this laboratory system into a CQI work culture that is highly effective because all employees essentially have 2 jobs: to do the work well and to improve the work continuously. As has been described before, the early quality journey and learning in transforming culture are designed to meet the expectation of achieving CQI at the level of the work (bottom up), creating team communication pathways, identifying sources and metrics for work improvement opportunities, and relating these efforts to improvement outcomes with integration of supporting technology.[2,4,11,15-17]

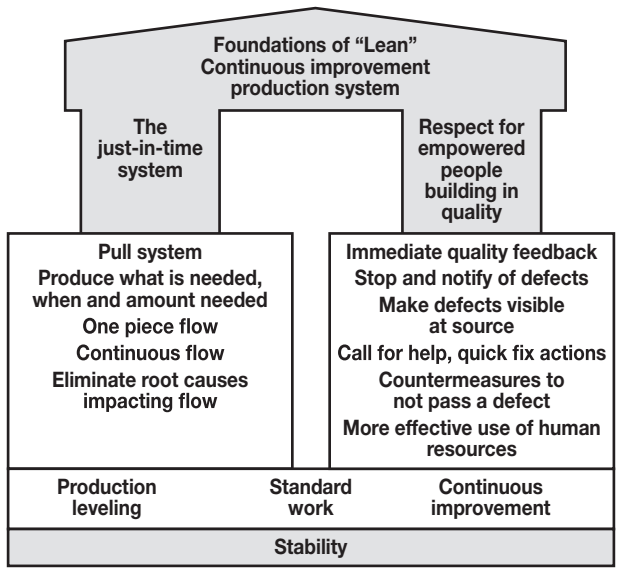

FIGURE 10 Henry Ford laboratory continuous improvement system.

Our pursuit of ISO 15189 accreditation began in 2010 as a higher quality goal for this system of laboratories.[1] In this process, we identified opportunities to create new management systems and to incorporate a more disciplined managerial focus aligned with our lean systems. We achieved ISO 15189 accreditation in 2013 as the largest multisite system of hospital laboratories in the United States. During this time frame, we engaged with the disciplined global lean practitioner, Danaher Corporation, through Beckman Coulter Life Sciences. These further learnings from ISO 15189 and the Danaher Business System evolved our subsequent journey to fortify our quality management approaches both at the level of the work and at the level of top leadership.

Expanding beyond our initial approaches to improving the process of work, we now focus on deeper integration of new management systems for consistency in CQI behaviors and actions at all levels. In this manner, our routine is now to standardize and measure the behaviors, actions, and effectiveness of our leaders (top down) in strategy deployment and of our managers in action plan execution and problem-solving aligned with daily improvement activities at the level of the work.[6,8,12]

At its core, CQI and the management systems that structure and support the expected outcomes of employee engagement in continuous improvement require continuous education and human development. Systems are not enough. In the words of Deming from his last 2 of 14 management principles, "Institute a vigorous program of education and self-improvement. Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job."[7]

Continuous improvement also applies to the management systems themselves described here and the others illustrated in FIGURE 1. Management Review System is the systematic approach to the annual assessment of the use and effectiveness of the management systems stratified by hospital, division, manager, and team. These critiques often result in improvement changes and more effective use of the management systems themselves, as illustrated for DevM through improved capture of deviations over 8 years, from roughly 3,000 to 70,000 per year, and for DM beginning with 64 metric boards expanding to 136 DM boards per year over 6 years. The additional management systems in use that contribute to the improvement of the management systems themselves include the Internal Audit System and integration and analysis of the results of DevM and DM within the Quality Management System plan itself.

I strongly believe that for health care to become highly reliable, a marked culture change is required in how we do and improve this important work.[2,4,17] We can mostly agree on the perfect state, but achieving that goal requires continuous improvement based on knowledge of current unreliability or deviations from the expected by those doing the work, as it arises, so that managers can work with teams in a structured process to continually improve the work. This improvement is critical in health care because our process defects may readily escalate to medical errors, currently the number 3 cause of death in the United States. The Joint Commission recognizes that the approach to continuous improvement described here, or "robust process improvement" in its parlance, should be the basis for health care to be effective in achieving high reliability, as manifested in consistency and excellence in quality and safety.[18] Demonstrated in this paper is the Deming-style philosophy of management, with workforce education and engagement in the work of improvement, supported in this transformation by new business quality management systems. In our view, these elements are essential for pursuing the new condition in which all health care processes are highly reliable.

The manner in which we have successfully maintained our focus on continuous improvement is both top down and bottom up. At the leadership level, we review the effectiveness of the management systems in a formal management review process, performed by our quality manager with the chair. At the level of the work, we build assessment into the standard work expectations of managers, supervisors, and employees. It is said that what is measured improves. So, we measure managers in a monthly KPI cadence meeting.

Managers are charged with reporting to leadership their own quality engagement and performance in the monthly KPI review process by monitoring their own discipline in using deviation and daily management to engage their direct reports and teams in consistent execution and quality improvement outcomes. This assessment focuses on the effectiveness of the 2 main management systems in producing improvements at the level of the work. These monthly reviewed metrics focus on the managers' role in employee education and engagement in DevM and DM. The metrics include (1) defined and updated work performance metrics, with root causes of misses; (2) employees trained in lean new-hire orientation and annual lean refresher training; (3) effectiveness of lean training as a percentage and number of employees involved in PDCA improvements; (4) outcomes of lean team training as a number of process improvements presented by teams monthly; (5) use of DevM summarized as monthly data analysis, with root causes and summary; (6) engagement of employees as a percentage contributing to DevM; (7) use of DM as a number of metric boards followed monthly; and (8) team engagement in DM as a percentage of daily board huddles conducted.

Based on our experiences in adaptation of Lean and ISO 15189 in this large, integrated system of laboratories, I strongly believe that the one critical aspect of this transformation is a requirement for quality management systems to structure and guide the behaviors and consistency of midlevel managers in achieving CQI. This is so often the missing link, an alignment of managers' standard work through management systems that structure and facilitate the expectation of a continuous focus on improvement and human development and engagement toward that end.

In this paper, I have illustrated the importance of the main management systems that we rely on to achieve and sustain that transformation to a CQI work culture from top to bottom throughout this medical laboratory enterprise. These management systems are designed to deepen the effectiveness of our continuous improvement culture by arming managers with knowledge of the variation in the work they oversee and providing guidance for more effective employee engagement in the daily processes of quality improvement.

REFERENCES

1. International Organization for Standardization. *ISO 15189:2012: Medical Laboratories—Requirements for Quality and Competence.* Geneva, Switzerland: International Organization for Standardization; 2012.
2. Zarbo RJ. Creating and sustaining a Lean culture of continuous process improvement. *Am J Clin Pathol.* 2012;138:321-326.
3. Spear SJ, Bowen HK. Decoding the DNA of the Toyota Production System. *Harvard Bus Rev.* 1999:96-106.
4. Zarbo RJ, D'Angelo R. Transforming to a quality culture: the Henry Ford Production System. *Am J Clin Pathol.* 2006;126(suppl 1):S21-S29.
5. Kahneman D. *Thinking, Fast and Slow.* New York, NY: Farrar, Straus and Giroux; 2011.

HTTPS://DOI.ORG/10.1093/AJCP/AQAB109

6. Zarbo RJ, Copeland JR, Varney RC. Deviation management: key management subsystem driver of knowledge-based continuous improvement in the Henry Ford Production System. *Am J Clin Pathol.* 2017;148:354-367.
7. Deming WE. *Out of the Crisis.* Cambridge: Massachusetts Institute of Technology Press; 1986.
8. Zarbo RJ, Varney RC, Copeland JR, et al. Daily management system of the Henry Ford Production System: QTIPS to focus continuous improvements at the level of the work. *Am J Clin Pathol.* 2015;144:122-136.
9. Liker JK, Convis GL. *The Toyota Way to Lean Leadership: Achieving and Sustaining Excellence Through Leadership Development.* New York, NY: McGraw-Hill; 2011.
10. Liker JK. *The Toyota Way: 14 Management Principles From the World's Greatest Manufacturer.* New York, NY: McGraw-Hill; 2004.
11. Liker JK, Franz JK. *The Toyota Way to Continuous Improvement: Linking Strategy and Operational Excellence to Achieve Superior Performance.* New York, NY: McGraw-Hill; 2011.
12. Liker JK, Ross K. *The Toyota Way to Service Excellence: Lean Transformation in Service Organizations.* New York, NY: McGraw- Hill; 2016.
13. Toyota Motor Corporation. *The Toyota Way 2001.* Toyota City, Japan: Data on file; 2001.
14. Grunden N. Culture change transforms Henry Ford Pathology Department. In: *The Pittsburgh Way to Efficient Healthcare: Improving Patient Care Using Toyota Based Methods.* New York, NY: Healthcare Performance Press; 2008:166-182.
15. D'Angelo R, Zarbo RJ. The Henry Ford Production System: measures of process defects and waste in surgical pathology as a basis for quality improvement initiatives. *Am J Clin Pathol.* 2007;128:423-429.
16. Zarbo RJ, D'Angelo R. The Henry Ford Production System: effective reduction of process defects and waste in surgical pathology. *Am J Clin Pathol.* 2007;128:1015-1022.
17. Zarbo RJ. Leaders wanted: a call to change the status quo in approaching health care quality, once again. *Am J Clin Pathol.* 2010;134:361-365.
18. Chassin MR, Loeb JM. High-reliability health care: getting there from here. *Milbank Q.* 2013;91:459-490.

HTTPS://DOI.ORG/10.1093/AJCP/AQAB109