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# ISO MEETS PROCESS IMPROVEMENT

The Next Level of Evolution for the Healthcare Quality System

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## Introduction

The Healthcare Improvement Model is a framework to help a healthcare system strategically improve its processes, policies and procedures. Through the adoption of this model, the system continuously improves the way it cares for its patients, while positively impacting its bottom line. The Healthcare Improvement Model also allows ISO (International Organization for Standardization) and PI (Process Improvement) to integrate into a platform that promotes continuous improvement within a healthcare organization. The model starts at the system level and permeates through the individual hospitals and or its affiliates within the healthcare system.

## What is ISO?

In 1946, a group of 65 delegates from 25 countries discussed the future of International Standardization. By 1947, ISO was formed, employing 67 technical committees to focus on specific subjects. Now, ISO includes 163 members with a total of 21,000 standards, covering almost all aspects of business, healthcare, and technology. Out of the 21,000 standards published, more than 1,300 focus on health care issues.

ISO published its first standard for the healthcare sector on September 20, 2001. By 2013, health care reached 9% of the monetary value of all finished goods and services produced globally. <sup>1</sup> The ISO 9001 Standards employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. <sup>2</sup> Implementing ISO allows the healthcare system to ensure patients receive the highest level of quality care.

## ISO is a Foundational Model, Helping Organizations Achieve Excellence

ISO isn't an award of excellence. It is a set of requirements to provide guidance to an organization seeking to implement a high-performing, quality management system. In health care, ISO promotes the adoption of a process approach when developing, implementing and improving patient care. Often compared to an award, such as Baldrige Criteria for Performance Excellence or Shingo Prize for Operational Excellence, ISO is a framework for excellence in quality.

Baldrige is a national award given to U.S. organizations occupying the business, education, nonprofit and health care sectors.<sup>3</sup> The purpose of this award is to promote the importance of performance excellence with the intent to increase competitiveness

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<sup>1</sup> The ISO Story – [www.iso.org](http://www.iso.org)

<sup>2</sup> ISO 9001 Fifth edition -2015-09-15

<sup>3</sup> Baldrige FAQs – [www.nist.gov](http://www.nist.gov)

within consumer markets. Organizations that receive the Baldrige award exemplify the following characteristics:

- Quality management system;
- Continuous improvement; and
- Demonstrate effectiveness and efficiency in resource utilization, process and system optimization.

The Shingo Prize is a global award created to drive excellence through the application of universally accepted principles.<sup>4</sup> These principles encompass operational excellence, alignment of management systems and the application of improvement techniques across the entire enterprise. The award focuses on organizational transformation creating a culture that thrive on continuous improvement at all levels. The Shingo Prize considers the four below dimensions when assessing an organization.

- **Cultural Enabler:** Make it possible for employees within the organization to engage in the transformation journey, progress in their understanding and ultimately build a culture of operational excellence.
- **Continuous Process Improvement** – begin by clearly defining value based on the customer requirements. Based on the customers’ expectations, systems are designed to meet their needs. Every employee understands and owns their part of the process and diligently seek ways to improve it.
- **Enterprise Alignment** – execution is the most valuable tool when it comes to organizational transformation. To succeed in this transformation, it is imperative for organizations to develop management systems that align behaviors and work with principles and direction that are simple, comprehensible, actionable, and standardized.
- **Results** – driven by value and seek ways to improve quality, cost, delivery, safety, and morale. Widespread involvement is essential for continuous improvement. Every employee responsible for the expected results are consider equal owners of the process.

Both Baldrige and Shingo focus on strong customer performance, workforce effectiveness and future growth potential for the organization. ISO is the vehicle used to help organizations obtain either designation of choice.

## ISO in Healthcare

ISO provides a clear direction of what needs to take place to achieve operational excellence. It is imperative for healthcare organizations to understand and deploy a

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<sup>4</sup> [www.shingoprize.org/model](http://www.shingoprize.org/model)

high performing Quality Management System (QMS) such as ISO. The definition of a high performing quality management system is a collection of processes that consistently meet patient requirements while augmenting patient and family satisfaction. In order for a health care system to implement a high performing quality management system, a structured safety and quality team must be identified and commissioned at the system level.

Furthermore, ISO has requirements that deal with systems, processes, procedures, and policies, within the healthcare organization. Employing these requirements allows the hospital to standardize and deliver quality care. From a quality management system perspective, the hospital is able to identify key performance indicators to measure the effectiveness of patient care. By executing internal audits, the high performing quality management system is able to identify nonconformities or broken processes using key performance indicators as its process control mechanism.

### What is Process Improvement (PI)?

Process Improvement is the continuous and ongoing effort to achieve measurable improvements exploiting an efficient and effective technique. PI uses performance, accountability, outcomes and other indicators of quality to improve efficiency and effectiveness of an organization. It is a scientific methodology for leaders to address, resolve and eliminate complex issues driving negative quality performance.

PI provides tools for staff to develop and implement corrective/preventive action plans used to resolve and prevent nonconformities. As failures occur within processes, process improvement tools help define and understand the root cause of the failures. The most commonly used PI tools are DMAIC and PDCA cycle. Many organizations use these two methods to instill controls and continuous improvement of processes, products, and services.

For example, a large healthcare system pursued its ISO certification; it discovered there were nonconformities that must be addressed prior to obtaining its certification. After further investigation, the administration launched a system-wide task force trained in quality and process improvement to resolve the nonconformities. The team needed to use the appropriate PI tools to identify the root cause, create a future state process, test the process and standardize. Practicing PI helped standardize, reduce and eliminate future similar nonconformities and obtain their ISO certification without further delay.

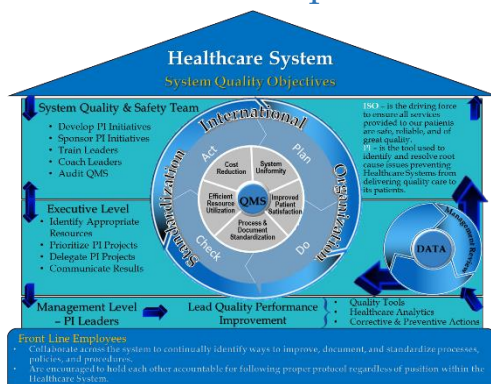
## ISO Meets PI

ISO creates the foundation to develop a structure to provide resources and support through inputs and outputs of a robust quality management system. PI is the tool used to reduce or eliminate the potential failures within the quality management system.

When PI and ISO are integrated, hospitals should expect to produce the following results:

- Significant decrease in the number of patients harmed;
- Increase in patient and employee satisfaction;
- Reduced administrative cost;
- Standardization of processes and documentation;
- System uniformity and optimization;
- Continuous improvement;
- Quality improvement projects to produce positive impacts on revenue.

## The Healthcare Improvement Model



The Healthcare Improvement Model was created to visualize the integration of ISO and PI. The model uses a five-tier approach to infuse continuous improvement at all levels of the system. As the model shifts from tier to tier, the requirements and responsibilities for PI intensifies. This places the burden of responsibility for sustained improvement and financial growth at the local as well as the system level.

The Healthcare Improvement Model continues to rotate feedback throughout the system. This ensures that everyone understands the main objectives created to promote patient safety first, followed by continued financial growth.

### Top of the House – Tier I:

At the system level, executive leaders set the vision and quality objectives for the entire health care system. The quality objectives are tracked through a balanced scorecard or similar tracking tool at the system level. The metrics are determined by national best practices, benchmarks and health care analytics. At the system level, transparency is vital to improving the health care organization. The health care system's vision and objectives filter throughout the entire healthcare model thereby creating a culture of continuous improvement.

## System Quality and Safety Team – Tier II:

To achieve cultural transformation with sustainability, the system must create and leverage a quality and safety team to develop, guide, control and execute a high performing quality management system. Along with this robust QMS, a strategic approach must be developed for how the system is audited with proper protocol for resolving nonconformities. Tier II develops the PI strategy, facilitates training and coach local level executives and PI resources.

The PI strategy dictates training requirements, certifications, project development and execution as well as sets parameters for project success. Through PI education, the team is able to dispatch future subject matter experts to manage projects at the system and local level. While PI isn't new to health care, integrating ISO and PI is a fairly new approach. A team of experts will be needed to manage its implementation and success. Having a systematic approach to improving and sustaining quality requires a high performing quality management system.

To continually execute the standards of this robust system requires tools that can identify and resolve root causes to all nonconformities. This is where ISO and PI are amalgamated to produce system optimization and process sustainability. At the Tier II level, the system quality and safety team ensures all services provided to our patients are safe and reliable.

To achieve this goal with excellence, metrics and tools must be in place to continually audit the process and effectiveness of the staff. In addition to resolving nonconformities, the integration of ISO and PI gives the system quality and safety team the ability to predict and solidify financial gains for the system.

## Executive Level – Tier III:

The executive level tier III is responsible for the top leadership of the local hospitals within the health care system. The role of the executive level is to assess, prioritize and delegate quality improvement projects including a strategic plan.

Data is reviewed from across the organization and top leadership provides resources, promotes improvement and establishes accountability for the effectiveness of the quality management system. In addition, they are required to perform a management review of all the nonconformities, identify risk and opportunities to ensure safe delivery of quality care. The executive level will be the liaison between tier IV and tier II. There should also be some form of local quality and safety support personnel to assist in meeting the system's quality objectives. The executive level will consider all financial ramifications to determine what PI projects will best improve and sustain the overall quality management system (ISO). Through these efforts, the executive level

disseminates the most important projects to tier IV to complete and report results back to the executive level tier III as well as the foundation (i.e., frontline) tier V.

### Management Level – Tier IV:

Most of the quality performance improvement work will take place at this level. Managers trained in PI should execute the performance improvement projects for their respective department or service line. The trained PI leaders will use PI tools to identify, validate and resolve the root cause of nonconformities and other identified risk.

This level must be the voice for continuous improvement throughout the culture. This will assure the quality management system (ISO) operates at its highest efficiency. The management level will ensure standardized processes, policies and procedures are implemented and effective. This level alongside tier V will constantly look for opportunities to improve the experiences and outcomes of all patients served. Collaboration and communication with both tier III and tier V will be the key to success. This level is the quality champion for the health care system.

### The Foundation – Tier V:

When you think about the foundation of any organization it is impossible to believe that success is achievable without frontline employees. Frontline employees are the foundation of every process improvement project. They are the true subject matter experts and catalyst for change. Their support, buy-in, and ownership will be needed to improve any process, policy, procedure or system. In order for ISO and PI to work in unison, frontline employees must be trained and empowered to identify and resolve nonconformities. This requires a cultural shift in behaviors, roles and responsibilities.

At this level, front-line employees will be the gate-keepers for processes, policies and procedures. Any improvement work filtered down from tier III and tier IV must be methodical and purposeful for this group to commit to the change. In addition, this group must feel valued by tiers I through tier IV to guarantee sustainability and continuous improvement. Tier V will need to receive basic PI training to support improvement and lead small projects within their service lines.

Toyota continues to have great success because management realizes that their employees are the key to success. Top level executives empower their teams to consistently identify and resolve nonconformities on a daily basis. What is so awesome about the Toyota Production System is that it is not a respecter of position. All of Toyota's employees have the authority to stop the flow of work to resolve any and all nonconformities identified.



Small scale PI is not always a project to project basis at this level of the model. It is a continuous effort to identify nonconformities within the tier V sphere of influence. This creates a culture that believes in completing work at the highest level of efficiency and keeping safety first. Therefore, the health care improvement model considers frontline employees the foundation of the model.

### The Flywheel and Gear – The Integration of ISO and PI:

It is imperative to integrate ISO with the tools used to develop and execute a process improvement initiative. It is true that both ISO and PI can stand alone and operate in silos. However, this will make it very difficult to drive continuous improvement and sustainability throughout the entire healthcare system. ISO creates the framework through systematic definitions and management of processes and their interactions.<sup>5</sup>

Process improvement provides the tools needed to reveal root causes, create standardized processes and resolve identified nonconformities. Both ISO and PI require great commitment and understanding and can yield immense high-quality care in any health care system.

The Flywheel of the model is ISO driven and therefore provides the requirements needed to reduce cost, create system uniformity, standardize processes and documentation, and promote efficiency in resource utilization.

In addition, ISO provides a framework on how to identify nonconformities through internal audits and risk based thinking. However, it does not provide the tools needed to resolve the opportunities for improvement. PI is the check and balance for the quality management system. Its main purpose is to monitor and resolve nonconformities in the quality management system. It uses data received from what the model calls the gear to process and analyze root causes to process and system failures. It then creates corrective and preventive action plans for implementation at the local and system levels. PI is the workhorse of the two that yields the results of a high



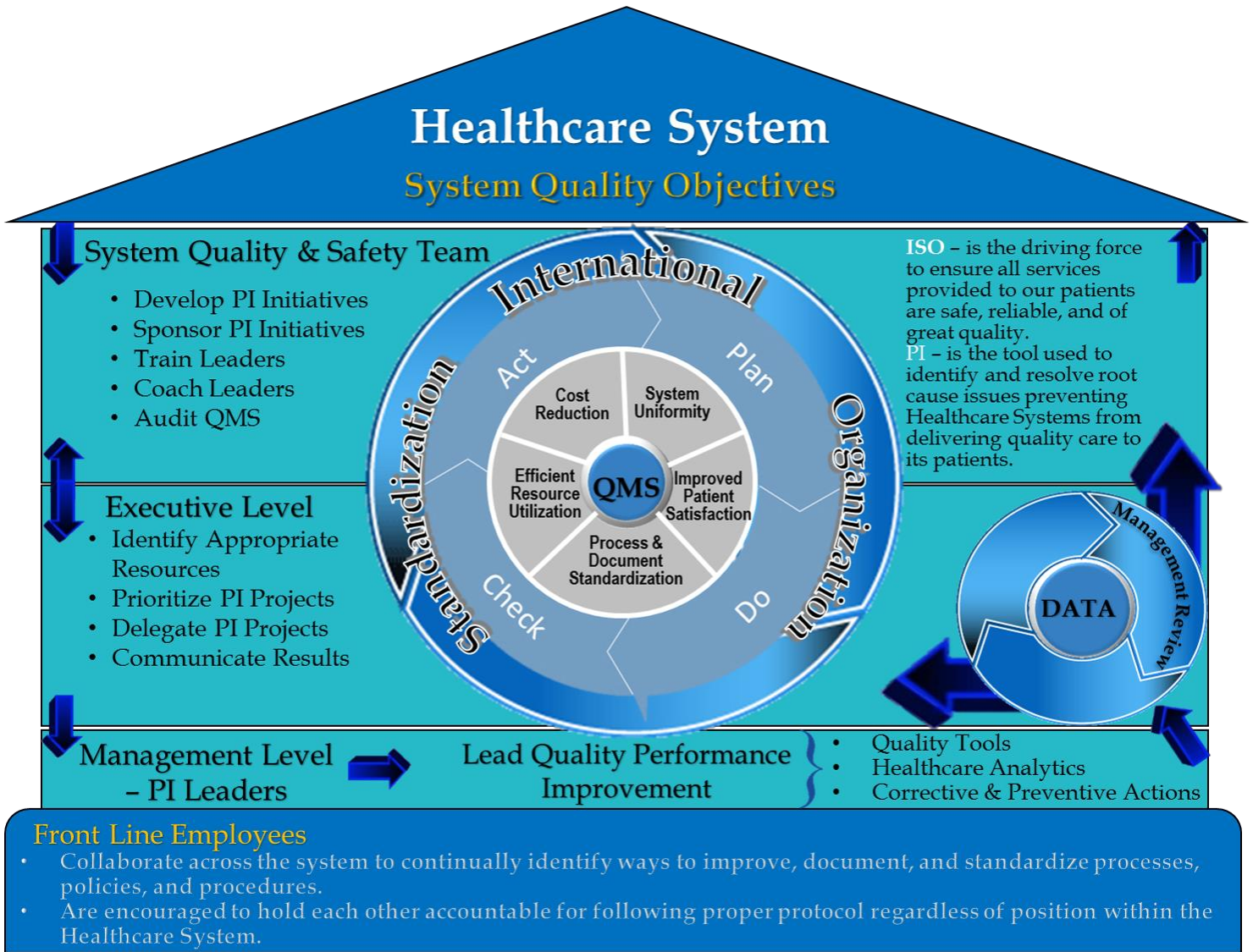
<sup>5</sup> ISO 2015 – Reference number ISO 9001:2015(E)

performing quality management system. ISO and PI both drive continuous improvement. By constantly focusing on action plans through monthly, quarterly or even annual updates, leadership is able to track the progress at the local and system level ongoing.

Data is the gear that drives the impact of the flywheel. It rotates and provides the information needed for the local and system to complete risk assessments, strategic planning and management review. All of this information is filtered back up through the entire health care system impacting quality and financial results.

## Conclusion

The integration of ISO and PI will be the catalyst to launch every health care system to the next evolution in its pursuit of excellence in patient care. This is a continuous improvement journey. Determination is the key factor in standardizing processes, policies, and procedures. Once adopted, the health care system's financial blueprint will consistently exceed expectations. This is due to its insatiable appetite to constantly look for ways to eliminate waste within its processes. Implementing the health care improvement model will not only position your organization to apply for any top quality prestigious award, it will act as a constant reminder of our promise to always do what is best for our patients.



## Reference Materials:

- The Essential Guide to Health Care Quality by National Committee for Quality Assurance
- The ISO Story - [www.iso.org](http://www.iso.org)
- Baldrige FAQs - [www.nist.gov](http://www.nist.gov)
- Shingo Prize - [www.shingoprize.org](http://www.shingoprize.org)
- Lean Enterprise - [www.lean.org](http://www.lean.org)
- Six Sigma - [www.isixsigma.com](http://www.isixsigma.com)
- Six Sigma Certification - [www.iassc.org](http://www.iassc.org)