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Achieving Breakthrough Improvements With the Application of Lean Six Sigma Tools and Principles Within Process Excellence

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- Medical errors that result in patient deaths account for 17 to 29 billion dollars in the United States. These are not errors in which the patient lived but suffered, these are only the errors that resulted in death.
- Conservatively, the actual number of patient deaths due to medical errors is around 43,000 per year.
- Most organizations have experienced some type of quality improvement program in the last few years, programs such as total quality management, continuous quality improvement, or even Six Sigma.

After reading this article, the reader should understand the application and synergy of Lean and Six Sigma as quality improvement programs.

Compliance 110501 questions and corresponding answer form are located after the CE section on p. 243.

Has your organization implemented improvement initiatives or quality programs in the last 5 years? Have you been able to achieve exponential improvements, such as over 50% increase in productivity, 75% to 80% decrease in turnaround times for test results in the clinical laboratory, or 30% to 50% reduction in the physical space required to do the testing? AND have the improvement gains been sustainable over time? If you answered "Yes" to the last 2 questions, you need to put your experience in writing and share that information with your colleagues. The expectation is that you are in the minority of readers.

Most organizations have experienced some type of quality improvement program in the last few years, programs such as total quality management, continuous quality improvement, or even Six Sigma. Many of these programs have been adopted as the "latest and greatest flavor of the month" with little thought, planning, or expectations for implementation. In fact, these "flavors of the month" have created cynicism among many organizational leaders, causing these leaders to dispute the value of more quality initiative flavors.

Market Dynamics

What is not disputed is that health care providers must radically change their business environments if they are to remain competitive. Health care continues to face:

- Declining reimbursement
- Personnel shortages
- Increased costs
- Intensified competition
- Regulatory requirements
- Physical space constraints
- Increased testing volumes and complexity of services
- Demands for technological enhancements
- Intensified focus on customer service levels and medical errors

Key words for health care are "costs," "customer focus," "quality," and "errors." These are not exclusionary. In fact, it is the cost bucket that is most controllable and that is directly and adversely impacted by poor customer service and poor quality products, services, and work processes. What is not appreciated is that 70% to 80% of costs are embedded in processes, the processes responsible for producing the products and services provided customers.

These same processes create other costs in terms of medical errors. Medical errors that result in patient deaths account for 17 to 29 billion dollars in the United States.[1] These are not errors in which the patient lived but suffered the wrong limb or other body part being amputated; these are only the errors that resulted in death. Conservatively, the actual number is around 43,000, ahead of deaths due to automobile accidents or even breast cancer and AIDS (**Figure 1**).[1] Nearly all of these errors are due to process or system problems, problems that throwing more people at or more money at without a systematic process review will not resolve.

For success in this environment, health care facilities must be able to provide their customers with reliable products and services of reproducible quality. These products and services must be provided in a timely fashion, meaning on time, every time, and at a competitive price that is profitable. Yes, facilities want to strive for low costs but not at a cost that is causing a net loss of income. The good news is that there are tools and principles that hold the keys to identifying, achieving, and sustaining exponential improvements in the form of Lean Six Sigma, within Process Excellence™.

Process Excellence (PEx)

PEx is structured methodology that is:

- Results oriented
- Project focused
- Customer value driven

It is a methodology that seeks to eliminate process variation and waste and deliver value to customers faster with appropriate resources. PEx includes the principles and toolsets of Lean, Six Sigma, and Design Excellence, the latter of which is used to drive the design of a new product, service or work space to optimize process flow and meet customer expectations with minimal waste and defect opportunities. The focus for this article will rest primarily with Lean and Six Sigma applications.

Six Sigma

Six Sigma means several things. By definition, Six Sigma means 3.4 defects per million opportunities and a process yield of 99.9997%. Six Sigma is also a philosophy of continuous improvement to eliminate process variation in all operational areas, a philosophy that supports a structured and rigorous methodology often referred to as the DMAIC roadmap. This DMAIC roadmap follows specific steps that include: **D**efine, **M**easure, **A**nalyze, **I**mprove, and **C**ontrol. At each step there are specific statistical tools and quality tools that are applied, with the ultimate goals of the DMAIC process being 2-fold: to uncover baseline process capabilities and root sources of variation, and to design and test process improvements that will increase process capabilities and reduce or eliminate process defects and variation.

To increase process sigma, process variation must be decreased and customer specifications met more often. As process sigma is increased, customer satisfaction improves with higher quality products and services, with less rework and defects, and with delivery times that are closer to customer requirements.

Some of the statistical and process improvement tools used at each step in the Six Sigma approach are:

- Define
  - Stakeholder analysis (or Voice of the Customer)
  - SIPOC (high level process map that lists major suppliers, inputs, process, outputs and customers)
  - RTY or rolled throughput yield
  - Affinity diagram
  - Kano model
  - Critical-to-Quality tree
- Measure
  - Control charts and run charts
  - Frequency plots and time series plots
  - Gage R&R
  - Pareto charts
  - Prioritization matrix
  - FMEA (Failure Modes and Effects Analysis)
  - Process Sigma and capability
- Analyze
  - Affinity diagrams and case and effect diagrams
  - Control charts and Pareto charts
  - DOE (Design of Experiments)
  - Flow diagrams, frequency plots, scatter plots, and stratified frequency plots
  - Hypothesis testing
  - Regression analysis
- Improve
  - FMEA or FMECA (Failure Modes, Effects and Criticality Analysis)
  - Stakeholder analysis
  - Flow diagrams
  - Hypothesis testing
- Control
  - Control charts and other charts
  - Flow diagrams

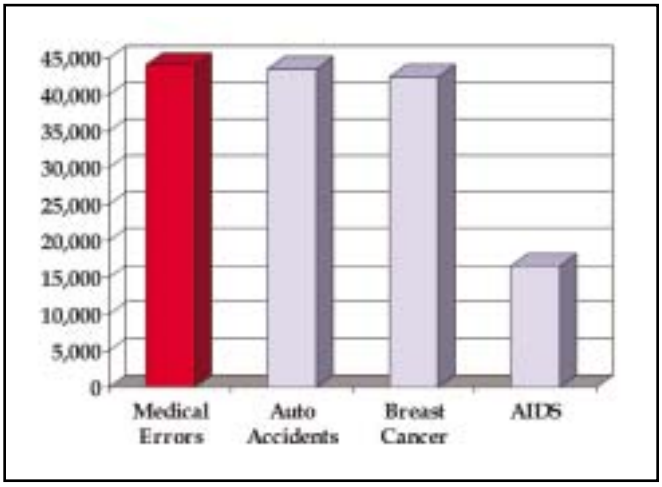

Figure 1_Deaths due to medical errors in the United States. *IOM Report* To Err is Human: Building a Safer Health System, *National Academy Press, 2000*

Lean

Lean is a methodology that is aligned similarly to Six Sigma. The goals of Lean are to improve process flow, eliminate waste, and deliver value to customers faster. Value is determined from the customer's perspective and is defined as any activity that changes the fit, form, or function of the raw material (the first time the activity is applied) to meet customer requirements. Non-value-added activity is defined as anything that takes time or resources but do not add to customer requirements or change the fit, form, or function of the raw materials. Non-value-added activities can also be thought of as those activities for which customers are not willing to pay.

All non-value-added activities are termed "waste" with Lean. Where variation is the enemy of Six Sigma, waste is the enemy of Lean. Waste can be found in any of the following, classic categories of waste[2]:

- Over production – producing more than what was requested
- Waiting – time wasted when the raw material is sitting, with no value being added
- Transportation – time wasted moving the raw material through the process
- Inventory – wasted direct and indirect costs of excess inventories of supplies, reagents and disposables or of non-productive items
- Processing – cost of unnecessary or wasteful processing
- Motion – cost of unnecessary or inefficient motion during processing
- Defects – cost of rework and actual defects as well as the associated costs of losing customers

An 8th category of waste exists as "intellectual capital." This is the cost of wasted talent or unneeded labor. This last category

of waste is not inconsequential, with the shortage of personnel in health care service areas approaching 15%.

All waste represents costs to organizations, with time at the heart of most waste. Facilities can always rework a customer order or replace defective products. More inventory can be ordered if outdated or non-productive items are discovered. More space can be found in various nooks and crannies if inventory levels are not well controlled or visually managed. What cannot be replaced, however, is misplaced talent or lost time because of poor quality, non-value-adding processes.

Some examples of Lean tools are:

- Stakeholder analysis
- Value stream mapping
- 5S (Sort, Segregate, Shine, Strengthen, and Standardize)
- Standard work
- Point-to-point diagrams
- Value added analysis
- Visual management
- Inventory management using Kanban system
- Leveled scheduling
- Process capability improvement
- FMEA
- Pilot

Synergy Between Six Sigma and Lean

Six Sigma by itself is not able to impact exponential improvement without incorporating principles from Lean. Lean drives optimal efficiencies by identifying and eliminating as much waste or non-value-adding activities as possible and establishing standard work. Standard work is more than standard operating procedures. Standard work identifies the minimal resources required to do the work in a first-in-first-out, single-piece flow fashion. Standard work dictates what tools and other factors of production are used for the work and in what order, using visual management tools, so that the work is done the same way every time with the same number of resources and in the same amount of time every time. Until this level of process control is established and this level of waste is eliminated, it is nearly impossible to attack process variation with Six Sigma tools and methodology. Variation is much easier to identify and resolve with a Lean process.

The Six Sigma methodology by itself takes a long time, usually between 6 and 9 months. At the end of that application, the improved process may include non-value-added activities that could have been eliminated.

Lean implementation takes only 8 to 14 weeks, depending on the scope of the process review and physical plant improvements required. Lean increases the velocity of improvement implementation and helps identify process improvements that require Six Sigma tool application.

By combining the toolsets and methodology with PEx, both the velocity and success rate of exponential, not incremental, operational improvements are impacted. Significant savings can be found in any size or type of health care facility. Typical results when PEx, specifically Lean Six Sigma tools and principles are applied, follow:

- 75% to 80% Reduction in cycle time
- 50% to 70% Increase in productivity
- 50% to 90% Reduction in inventories
- 75% to 80% Reduction in test result turnaround times
- 30% to 50% Reduction in physical plant requirements (space and equipment)
- 75% to 80% Reduction in distance traveled
- 10% Minimum reduction in errors

Results in clinical laboratories have generated annualized savings between $600,000 and $2,275,000. Other savings have been realized in terms of risk or cost avoidance. For example, a facility found that it was unnecessary to continue with plans to expand into a new facility, at an estimated cost of $10 million. Sufficient physical space was found after a Lean implementation project that consolidated core laboratory functions and uncovered additional process capability, which allowed an approximate 40% increase in test volume to be absorbed with fewer resources.

Similar results have been reported in applying Lean and Six Sigma in other areas of health care, such as surgical units, anatomic pathology, microbiology, radiology, food services, emergency room services, blood donor centers' testing, donor collections, and component production. These health care functional areas realized the power of Lean plus Six Sigma to remove emotions from decision-making and establish a new cultural direction.

Summary

Lean coupled with Six Sigma tools drives decision-making by data and metrics and provides a mechanism to quantify the potential for variation, defects and risk as well as value-added and resource optimization BEFORE implementing actual changes. Lean and Six Sigma provide a common language that can be used to compare very different functional areas and even technology enablers.

There is no magic bullet or magic wand that can ensure the success and sustainability of health care facilities. There is not one big thing that can be done to improve operations, or it would have been done already! Exponential improvements, the kind that are required to really put costs in order and assure product and service reliability, reproducibility and quality, will only be found in thorough process review within a structured, robust methodology, and supported by actual data. There is a saying in the PEx community that "You get what you expect, and you deserve what you tolerate."

It is within this environment that many facilities currently find themselves. There never seems to be enough time to step back and apply the principles of Lean and Six Sigma, but there always seems to be enough time for that rework. It should not be surprising that most facilities have to deal with the same problems over and over again.

There are tools and methods that can help facilitate the degree of transformation that is needed for organizations to be more successful, be sustainable, and be more strategically positioned. The tools and methods lie within PEx, particularly Lean and Six Sigma.

It is imperative that facilities make the time to significantly change the way processes and systems are reviewed, the way work is done and decisions made, and the type of behaviors that are tolerated and/or rewarded. It is similarly imperative that leadership and commitment be in place for significant and lasting change to become part of the operational strategy and for continuous improvement to be inculcated. Progress requires change; facilities that are unwilling to change will never progress. LM

1. Kohn LT, Corrigan JM, Molla S. To err is human: Building a safer health system. The National Academies Press, 2000.
2. Womack JP, James DT. *Lean Thinking*. New York: Simon & Shuster, 1996.