Six Sigma Applications in Healthcare

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“Insanity is continuing to do things the way you’ve always done them and expecting the results to be different.”

Albert Einstein
"Success should be judged by results, and data is a powerful tool to determine results. We can't ignore facts. We can't ignore data."

President Barack Obama
July 24, 2009
THE CENTURY OF QUALITY

“We are headed into the next century which will focus on quality...

Dr. Joseph M. Juran
“We should work on our process, not the outcome of our processes.”

Deming
Objectives

- Explore six sigma philosophy
- Learn some of the six sigma principles and tools
- Examine the component parts of a Continuous Improvement Process (CIP) and how Six Sigma, and Lean methodologies work together within the DMAIC problem solving process.
- Examine the importance, benefits and integration of ‘Lean Thinking’ to help achieve Company objectives and operational strategies.
- Identify how Six Sigma is used in healthcare
- Explain the need for providing more detailed Lean tools.
Is 99% Good?
If 99.9% were good enough

Every year there would be:
- 20,000 prescription errors made
- 15,000 newborn babies dropped during delivery

Every week there would be:
- 500 incorrect surgical procedures performed

Every hour there would be:
- 16,000 pieces of mail lost by the US Postal Service
$6 \sigma$ – The Measurement

$99.0\% = 3.85 \sigma$

$99.99996\% = 6 \sigma$
WHAT IS SIX SIGMA QUALITY?

Product/Service Features

That Customers Want

Design for Six Sigma

Freedom from Deficiencies

At Six Sigma Levels

Improve to Six Sigma
Process and Its Variables
Six Sigma Philosophy

Anything the customer will not pay for is Non-Value Added

80% of Non-Value Added is waste

Customer Focus/Customer Centered

Customer satisfaction and loyalty ...
Improve Quality Process

**Lean: Optimize Process Flow**
- Document *how work gets done*
- Examine and improve *work flow*
- Eliminate waste and non-value added

**Six Sigma: Minimize Variation**
- Variation, variability and variance
- Identify factors / processes that increase variation
Linking Lean with Six Sigma

**Six Sigma**
- A philosophy of *continuous improvement* focused on eliminating poor quality and process variation
- Attack Variability
- Eliminate Errors
- Utilize the DMAIC Problem Solving Model
- Delivering *what is expected when it is expected*

**Lean**
- A methodology focused on *process speed*, efficiency, and elimination of waste — *non value added activities*
- Properly Configure Work flow
- Add Value with Every Step of any Process
- Move to *Single Piece Flow (assembly line)*
Six Sigma Methodology is Change

Six Sigma Is...
- Structured Problem Solving
- Improve profit through increased revenue and reduced costs.
- Fact Based Decision Making
- Rigorous Methodology
- Management By Fact
- Statistically Based
- Team Driven

“Six Sigma Is Not...
- Intuition
- About “Best” Customer
- That Won’t Work Here”
- Opinion
- “We’ve Tried That”
- Firefighting
1736: French mathematician Abraham de Moivre publishes an article introducing the normal curve.

1924: Walter A. Shewhart introduces the control chart and the distinction of special vs. common cause variation as contributors to process problems.

1960: Kaoru Ishikawa introduces his now famous cause-and-effect diagram.

1986: Bill Smith, a senior engineer and scientist introduces the concept of Six Sigma at Motorola.
Normal Distribution

• A normal distribution shows the theoretical shape of a normally distributed histogram.

• The shape of the normal probability curve is based on two parameters: mean (average) and standard deviation (sigma).

• For Six Sigma projects it relatively easy by using normal probability tables (commonly known as z-tables)
Example...

We are actively doing things to improve patient safety

Mean = 3.94
Std. Dev. = .771
N = 123
Z-Score

The Bell Curve

Mean/Avg

Mean minus 1 St Dev

Mean plus 1 St Dev
Normal Distribution

- Sigma is a measure of variation (the data spread)
A Six Sigma Process Has at Least Six Standard Deviations Between the Mean and the Nearest Spec Limit

When dealing with short-term data, this 1.5σ “buffer” is reserved for future mean-shift.
Mean Vs SD

Areas Under the Normal Curve

<table>
<thead>
<tr>
<th>Sigma</th>
<th>DPMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>308,537</td>
</tr>
<tr>
<td>3</td>
<td>66,807</td>
</tr>
<tr>
<td>4</td>
<td>6,210</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
</tr>
<tr>
<td>6</td>
<td>3.4</td>
</tr>
</tbody>
</table>

99.99%
Mean ± Six Sigma
Data Variation

BEFORE 3s

6.6% Defects

AFTER 6s

No Defects

Patients don’t feel the averages, they feel the variability
Understanding Variability

- Variation exists in everything.
- Improved capability, becomes a necessity, due to the need of:
  - improved designs
  - lower costs
  - better performance
- All of this leads to the need of tighter tolerances
- This means that the ability to operate to a tight tolerance, without producing defects becomes a major advantage
Basic stat.

Let’s Look at Some Basic Statistics

Mean diameter = 2.50 mm
Standard Deviation = 0.125 mm

On Average it’s OK
It’s a Variation issue

The number of Sigmas between the mean of a process and the nearest specification limit
Basic stat.

Reducing Variation is Clearly the Key to Improving Process Capability

Spec Width
0.5 mm

Std Dev
0.083 mm
Basic stat.

Reducing Variation is Clearly the Key to Improving Process Capability

Lower Specification Limit

Upper Specification Limit

Spec Width 0.5 mm

Std Dev 0.05 mm

5σ
Basic stat.

Reducing Variation is Clearly the Key to Improving Process Capability

Spec Width
0.5 mm

Std Dev
0.041 mm
Sigma Capability
The number of Sigmas between the mean of a process and the nearest specification limit

3 σ Process

Lower Specification Limit

Determined by the customer

Upper Specification Limit

Determined by the customer

WASTE Complications and the Wows

3 σ Process Centered
• We make more than customer needs because some of what we make is waste
• Process is WIDER than the specifications

6 σ Process

3 σ Process has 66,807 dpm vs 3.4 from a 6 σ process

6 σ Process Centered
• We make as much as the customer needs and have very little waste
• Process FITS within the specifications
Measuring Process Performance

- Patients want their pain medications to be delivered fast!
  - Guarantee = “30 minutes or less”

- What if we measured performance and found an average delivery time of 23.5 minutes?
  - On-time performance is great, right?
  - Our patients must be happy with us, right?
How often are we delivering pain medication on time?

*Answer: Look at the variation!*

Variation in pain medication process

- Managing by the average doesn’t tell the whole story. The average *and* the variation *together* show what’s happening.
Reduce Variation to Improve Performance

How many standard deviations can you “fit” within customer expectations?

- Sigma level measures how often we meet (or fail to meet) the requirement(s) of our patient(s).
Mean and SD

- Positive skew: mean > mode
- Negative skew: mean < mode
What does variation mean?

- Variation means that a process does not produce the same result (the “Y”) every time.

- Variation directly affects customer experiences.

Customers do not feel averages!
Common vs Special Variation

• **Common cause** variation is intrinsic to the process.

• It is random in nature and has predictable magnitude. Process noise is another name for it. An example would be the variation in length of the surgery with the absence of accidental

• **Special cause** variation is the variation that is not a normal part of process noise.

• When special cause variation is present, it means that something about the process has changed.

• Special cause variation has a specific, identifiable cause.

• When special cause variation exists due to the effect that special cause variation has on inferences about central tendency (average) and standard deviation (spread in the data).
How special variation look like in your data

Special cause variation:
7 or more consecutive ascending or descending points
Special Variation

Signal of special cause variation:
9 or more consecutive data points on the same side of the centerline
Special Variation

Signal of special cause variation:
Repeating patterns
Design of Experiments: Measure and Process

Controllable Inputs

X1  X2  X3

Quality Characteristics: Outputs

Y1, Y2, etc.

Establish the performance baseline

Inputs:

Raw Materials, components, etc.

Uncontrollable Inputs

N1  N2  N3
Design of Experiments: Measure and Process

Inputs:
- Raw Materials, components, etc.

Controllable Inputs:
- X1
- X2
- X3

Uncontrollable Inputs:
- N1
- N2
- N3

Quality Characteristics: Outputs
- Y1, Y2, etc.

Process:
- LSL
- USL

Graphs and charts illustrating the flow of inputs through the process, leading to quality characteristics, with control limits (LSL and USL) for output variability.
Sources of Process Variation

- Variation in measurement systems due to improper calibration and implementation
- Variation in a manufacturing process: varying manpower levels, work methods and ethics, environmental factors
- Poor design: bad design practices
- Variation in inputs (parts and supplies) from vendors and subcontractors
Sources of waste and variation in health care
## Waste Defined in Healthcare

<table>
<thead>
<tr>
<th>Wastes</th>
<th>Healthcare Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transport</strong></td>
<td>1. Moving patients from room to room</td>
</tr>
<tr>
<td></td>
<td>2. Poor workplace layouts, for patient services</td>
</tr>
<tr>
<td><strong>Inventory</strong></td>
<td>1. Overstocked medications on units/floors or in pharmacy</td>
</tr>
<tr>
<td></td>
<td>2. Unnecessary instruments contained in operating kits</td>
</tr>
<tr>
<td><strong>Motion</strong></td>
<td>1. Leaving patient rooms to get supplies or record or to document care provided</td>
</tr>
<tr>
<td><strong>Waiting</strong></td>
<td>1. Early admissions for procedures later in the day</td>
</tr>
<tr>
<td></td>
<td>2. Waiting for internal transport between departments</td>
</tr>
<tr>
<td><strong>Over-Production</strong></td>
<td>1. Multiple signature requirements</td>
</tr>
<tr>
<td></td>
<td>2. <a href="#">Multiple information systems entries</a></td>
</tr>
<tr>
<td><strong>Over-Processing</strong></td>
<td>1. Asking the patient the same questions multiple times</td>
</tr>
<tr>
<td></td>
<td>2. Batch printing patient labels</td>
</tr>
<tr>
<td><strong>Defects</strong></td>
<td>1. Hospital-acquired conditions</td>
</tr>
<tr>
<td></td>
<td>2. Wrong-site surgeries</td>
</tr>
<tr>
<td></td>
<td>3. Medication errors</td>
</tr>
<tr>
<td></td>
<td>4. Dealing with service complaints</td>
</tr>
<tr>
<td><strong>Skills</strong></td>
<td>1. Not using creative and smart employees or people with physical abilities</td>
</tr>
<tr>
<td></td>
<td>2. Staff not involved in redesigning processes in their workplace</td>
</tr>
</tbody>
</table>
Six Sigma Basic Premise

\[ Y = f(X) \]

**Outputs** (customer and quality (CTQ)) = **Functions**

- Mortality = \( f(x) \)
- Surgical Site Infections = \( f(x) \)
- Beta Blocker Compliance = \( f(x) \)
Improvement methodology

DMAIC

Define
Measure
Analyze
Improve
Control
DMAIC Project Roadmap

**Define Phase**
- Define the Situation
- Define the Situation
- Defect Rate per Step
- Calculate Financial Impact ($$)
- Check Gauges & Data Collection Devices & Procedures

**Measurement Phase**
- Identify: process inputs process outputs
- Cause and Effects Matrix
- Establish Measurement System
- Establish Baseline
- Evaluate Control Plan*

**Analysis Phase**
- Gather Historical Data or Sample
- Perform FMEA
- Perform Multi-vari Analysis (T test, ANOVA)

**Improvement Phase**
- Build Cause-Effect model/ regression/ correlations
- Identify and Test Improvements/ suggest a plan

**Control Phase**
- Isolates Parts of Data from other Parts
- SPC

*Control Plan Indicates if Process is Operating as Expected
DMAIC Project tools

Define Phase
- 5 why’s
- VOC
- Pareto Chart
- Flowchart
- Affinity Diagram
- Spaghetti Diagram

Measurement Phase
- ANOVA, ANCOVA,
- Cross tables, Mean,
- T test
- VOC

Analysis Phase
ANOVA, Multiple Linear Regression
Fishbone, FMEA, flowchart Kaizen/ rapid change
Design of Experiments

Improvement Phase
Kaizen,
PDCA,…Kaizen/ rapid change
Design of Experiments

Change Acceleration Process

Total Productive Maintenance, PDCA
Pilot testing, Statistical Tolerancing
Design of Experiments

*Control Plan Indicates if Process is Operating as Expected
Fall Prevention Toolkit Facilitated Through DMAIC For Rapid Quality Improvement

Medical Center
Fall Reduction Team

Define

Introduction
The report “To err is human” of the Institute of Medicine (IOM) published in 2000 estimated that healthcare errors and adverse events may account for up to $4.5 billion in annual costs in the USA. Patient falls in the hospital care setting are recognized as a serious health problem since they are common and may result in injuries and complications which prolong hospitalization, decrease patients functional capacities and leads to increased health care costs. The impact a fall can have on a patient’s perception of safety and well-being may impact the patient’s ability and willingness to participate in activities of daily living and rehabilitation due to fear of falling again any process improvement a challenge.

Problem
Patient falls in the hospital care setting are recognized as a serious health problem since they are common and may result in injuries and complications which prolong hospitalization, decrease patients functional capacities and leads to increased health care costs. The impact a fall can have on a patient’s perception of safety and well-being may impact the patient’s ability and willingness to participate in activities of daily living and rehabilitation due to fear of falling again.

Objectives
The objective of this project were to:
1. Reduce average cost per case for patients who have a fall with injury
2. Reduce average length of stay for patients who have a fall with injury
3. Describe characteristics of in-patient falls across clinical departments at CRMC
4. Examine in-patient fall rates and consequent injuries before and after the implementation of an interdisciplinary hospital fall prevention program

Strategic Plan
Leadership plays an instrumental role in understanding the problem, establishing a safety culture, and improving the environment of care for those that need direct nursing care for patient care can be increased. Therefore to ensure organizational involvement the following steps included:
• A multidisciplinary Steering Team was set up to devise a strategy for reducing patient falls in CRMC, the team included nursing staff and other professionals using Quality Management process.
• We evaluated our fall reduction policy program.
• We implemented a national strategy promoted by national regulatory agencies.

Measure

Locations contributed to the Problem

Significant of the Problem
It is generally accepted that patient falls are caused by multiple factors. Another popular classification scheme of falls is based on the assumption that they result from a complex interaction of intrinsic and extrinsic risk factors as illustrated in the figure below explain the contributing factors for fall in CRMC in 2010. The summary list of factors derived from many studies incorporating different methodologies, settings, and samples.

Analyze

Root Cause Analysis
To understand the causes of the fall, the steering fall team conducted a root cause analysis to identify the fall causes at CRMC.

Fall Prevention Interventions
The fall team at CRMC included the following interventions:

Identification
1. Placing a falling star sign outside these doors
2. A fall precaution is hard to modify other departments’ patient at a fall risk
3. A fall precautions care plan order entered into patient record
4. Communicate fall risk status and fall prevention interventions as part of the hand-off procedures

Monitoring
1. Hourly rounding to focus on the 3 Ps - Pets, Potty, and Positioning
2. Encouraging patients to call for help
3. Frequent toileting
4. In the I.A.R.I.F. the pharmacy identifies for the nurses all medications that can contribute to patient fall risk

Physical Environment
1. Call light for patient
2. Low beds
3. Use of IVs for elderly patients

Patient Specific Interventions
1. Increase staff support at all times
2. Remove intervention times when not longer medically necessary
3. Avoid sedative use

Control

Challenges
Even though, there was enough time to fully assess the impact of the interventions. Given the frequency of serious injury falls, even for the first 10 months would have been insufficient. Several challenges confronted the team. However, the greatest challenge for fall team is the translation of knowledge into evidence-based programs and policies.

2011 Improvement
After instituting several changes in our fall program, the data indicates a significant reduction in fall numbers.

Learned Lessons
1. Comfort rounds: The nurse checks patients for the safety needs
2. Monitor patients in the bathroom to avoid risk of fall and injury
3. Integrate the instructional techniques for patients and family
4. Do not automatically deny the young patient as a low-risk for fall or injury
5. Customize interventions based on changing patient conditions throughout the hospital stay
6. Using technology might be significant in fall
Six Sigma Tools
Change Acceleration Process

- **Leading Change**
  - Share Need
  - Shape Vision
  - Get Buy-in
  - Make it last

- **Changing Systems & Structures**
  - Current State
  - Transition State
  - Improved State

- Monitor Progress
Statistical Process Control

A key control and monitoring tool. Control charts are used to distinguish between common and special cause variation and use that understanding to control and improve processes.
Pareto charts

To identify critical factors that have the greatest influence on performance, recognizing that most problems are created by a few causes (Referred to as the 80/20 rule). The analyze step continues with cause and effect, or fishbone diagrams to identify potential causes of problems.
The fishbone diagram is an analysis tool that provides a systematic way of looking at effects and the causes that create or contribute to those effects.
Correlations

Descriptive Statistics

<table>
<thead>
<tr>
<th>I would rather stay</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.11</td>
<td>.000</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>2.52</td>
<td>1.005</td>
<td>46</td>
</tr>
</tbody>
</table>

Correlations

<table>
<thead>
<tr>
<th></th>
<th>I would rather stay</th>
<th>I am an extravert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation</td>
<td>1</td>
<td>-.310*</td>
</tr>
<tr>
<td>Sig. (1-tailed)</td>
<td>.</td>
<td>.018</td>
</tr>
<tr>
<td>N</td>
<td>46</td>
<td>46</td>
</tr>
</tbody>
</table>

*. Correlation is significant at the 0.05 level (1-tailed).

Graph showing trends and data points for various metrics over the months of the year.
Regressions

```
<table>
<thead>
<tr>
<th></th>
<th>Chlamydia</th>
<th>Gonorrhea</th>
<th>Syphilis</th>
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<tbody>
<tr>
<td>2004</td>
<td>10,000</td>
<td>8,000</td>
<td>6,000</td>
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<tr>
<td>2005</td>
<td>11,000</td>
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<td>7,000</td>
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<td>2006</td>
<td>12,000</td>
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<td>13,000</td>
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<tr>
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<tr>
<td>2011</td>
<td>15,000</td>
<td>13,000</td>
<td>12,000</td>
</tr>
</tbody>
</table>
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Staffing Falls
Path Analysis

Diagram showing the relationships between workplace stress, stress of conscience, coping strategies, and moral distress.
Spaghetti Diagram
Kaizen – Utilization Review

Standardizations eliminating waste to increase efficiency. Six Sigma is a more specific form of process improvement that narrows its focus on improving the quality of the final product. This is done by examining the potential causes for failure in quality and eliminating the reasons for these defects. Instead of examining ALL the processes of a particular business

http://www.antolambert.blogspot.co.uk/
What are some Six Sigma Tools?

- Process Map
- X - Y Matrix
- Measurement System Analysis
- Capability Analysis
- Descriptive Statistics
- Graphical Techniques
  - Box Plots
  - Histograms
  - Scatter plots
  - Time Series Plots
  - Run Charts
  - Pareto Charts
  - Check Sheets
- Analysis of Variance
- Correlation
- Regression
- Inferential Statistics
  - Central Limit theorem
  - Confidence Intervals
- Failure Modes and Effects Analysis
- Multi - vari Studies
- Design of Experiments
  - Fractional Experiments
  - Full Experiments
- Response Surface Methods
- Analysis of Means
- Transformations
- Sample Size Selection
- Fishbone Diagrams
- Hypothesis Testing
- F - test. T - test
- Chi - square test
- Tests for Normality
- Tests for Equal Variances
- SPC Charts
- Control Plans
- DFSS
- Statistical Tolerancing
Wrap up

“A comprehensive and flexible system for achieving, sustaining and maximizing business success. Six Sigma is uniquely driven by close understanding of customer needs, disciplined use of facts, data and statistical analysis, and diligent attention to managing, improving and reinventing business processes.” (patient safety)

-- The Six Sigma Way, by Pande, Newman and Cavanaugh
References

• George, L. (2002). Lean Six Sigma