Applying Lean Six Sigma to your Compliance Program

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Kootenai Health

Content

• Lean Six Sigma’s goals of reducing waste and variation can help improve organizational compliance
• An overview of the application of the methodology to understand how it supports a culture of compliance
• Learn specific tools that can be applied throughout your organization to increase standardization and compliance

Lean Six Sigma Leadership Culture

• Honor and Respect People – your people have good ideas – recognize and reward them for that – allow them to contribute through collaboration and empowerment
• Honor The Customer – they are the reason we exist – figure out what they want and make improvements and create standards around what they want
• Honor Standards – it is the “sustain” plan to keep things in compliance - document what you do, do what you document and prove it in practice
  • Error proof practices to ensure minimal regulatory intervention
The Lean Six Sigma Difference – Change in Culture

LSS System Focus
• People are not perfect and will make mistakes
• System factors cause many negative events/issues
• Reliable outcomes are obtainable with the right mix of people and processes

Traditional Individual Focus
• People who make mistakes are poor performers
• Systems performance will improve by removing poor performers

The Lean Six Sigma Difference – Change in Culture

So, What Are Some Of The Barriers To Compliance?
• Poor Communication
• Flawed Teamwork
• No collaboration
• Rushed Procedures
• Time Pressure
• Policies that are hard to follow
• Inadequate Interfaces
• Lack of error prevention expectations or accountability

Overview of Lean Six Sigma Methodology

**Lean**
- Eliminate Waste/ Improve Flow
- Reduce cycle time
- Lower complexity
- Analysis of physical layout
- Known Solutions
- 3 – 5 day deployment/implementation

**Six Sigma**
- Reduce defects & variability
- High complexity
- Unknown root causes/solutions
- Data driven control Strategy
- 4 – 8 month projects
Benefits of Lean Six Sigma

Process Improvement

Before

After

Same value, Less time and Resource!

Business Improvement

Eliminate waste in and around Processes

→ Lean

Eliminate defects in Processes

→ Six Sigma

Lean Processes that Operate at Six Sigma

Lean – reduce steps & waste

Flow

Improvised outcome

Repeatability

Six Sigma – reduce defects & variability

How reducing steps reduces defects

Rolled Throughput Yield

Patient A is treated in 3 steps:

Triage \( Y_p = 80\% \)

Diagnostic Testing \( Y_p = 70\% \)

Diagnosis \( Y_p = 90\% \)

Patient A Treatment

Rolled Throughput Yield = Product of the First Pass Yields

\[ Y_R = Y_p \times Y_p \times Y_p \]

\[ Y_R = (0.80) \times (0.70) \times (0.90) \]

Rolled Throughput Yield is the Probability That the Process to treat the Patient Will Produce Zero Defects

\[ Y_R = 0.504 = 50.4\% \]
A Brief History of the Toyota Production System - Lean

It started in Japan at the Toyota Motor Company

1902: Sakichi Toyoda, founder of the Toyota group, invented an automated loom that stopped anytime a thread broke.

1908: Henry Ford invents the moving assembly line and raises the daily wage to $5.00; continuous flow as a production method is created.

"The thing is to keep everything in motion and take the work to the man and not the man to the work. This is the real principle of our production and conveyors are only one of many means to an end." - Henry Ford: Today and Tomorrow

Several decades later Taiichi Ohno, a production engineer at the Toyota Motor Company applied the same concept as he sought to eliminate waste, or non-value added activities, within the Toyota organization.

In addition to stopping production at every defect (Jidoka), he employed another key concept, JIT (just in time). Together, Jidoka and JIT are the pillars of the Toyota Production System, supported by a foundation of Heijunka (level loading) ... the basis of Lean.

Where Does Lean Come From?

1943 - 1978

1978

1996

Lean

Shingijutsu

TOYOTA

- The basic philosophy of Lean is to provide the customer with:
  - What they want
  - When they want it
  - Using the absolute minimum resources

Key Terms

- **Value** - an activity that administers care or provides a service or information to meet customer/patient needs and requirements (usually something that the customer/patient is willing to pay for)
- **Value Stream Map** - A graphic map of steps that occur from a request for a product or service to delivery of the product or service. Similar to a process map but with greater amount of detail – such as time taken, resources consumed, inventory etc.
  - **Value-added** - a step, activity or a process that is perceived to add value to the customer/patient; it transforms the product or service
  - **Non-value-added** - a step, activity or process that takes time, resources and/or space but does not contribute to adding value or satisfying customer/patient needs
  - **Value Enabling or Non-Value-Added Essential** - a step, activity or process that does not add value but must be done, usually required either because of regulations or as a pre-requisite to completing a value-added step
- **Muda** = Waste – anything that takes resources but creates no value for the customer, usually an excessive or unwanted step, resource, or activity
- **TAKT Time** – the rate at which a customer/patient demands a product or service
  - **TAKT Time is NOT Cycle time**
- **Pull** – used to describe the customer/patient generating the demand for service / product as opposed to the producer ‘pushing’ to the customer/patient
- **Kaizen / Kaizen-event** - a Rapid Cycle Improvement - 3-5 days where actual changes are made (Action) i.e. processes are changed, equipment is moved etc.
Lean Thinking Process

1. Specify Value
   Define value in terms of a specific product

2. Map the Value Stream
   Map all of the steps, value added, non-value added, that bring a product of service to the customer

3. Work to Perfection
   The complete elimination of waste, all activities create value for the customer

4. Implement Pull
   The continuous movement of products, services and information from need to end through the process

5. Establish Flow
   Nothing is done by the customer process until the downstream customer signals the need

Four Rules of Lean

1. Work activities are specified to:
   - Content – what is being done
   - Sequence – in what order
   - Timing – how long should it take
   - Outcome – what are the expected measurable results

2. All connections must be simple and direct

3. Pathways are simple and involve as few steps and people as necessary

4. Continuous Improvement by those doing the work and as close to the problem as possible
   - Assign corrective action and improvement
   - Follow up on the previous day’s action items

Toyota Production System

- Single Piece Flow
- Pull Production
- TAKT Time Production
- Level Loading
- Sequencing
- Automation
- Stopping at Abnormalities
Toyota Production System: Jidoka

Reasons to Stop a Process:
- Defective Material (Rapid Response Team)
- Material Shortage (Flash Sterilization)
- Equipment Breakdown

Andon Boards (Call Lights) Sounds (Machine warnings)

Make everything visible to everyone:
- Expose waste
- Make standards clear
- Improve efficiency

The Lean Toolkit – Basic Lean Tools

- Identifying and Eliminating Waste
- Value Stream Mapping (VSM)
- Root Cause Analysis Using 5 Whys
- 5S
- Spaghetti Mapping
- Takt Time
- Standard Work
- Level Loading & Sequencing
- Single Piece Flow
- Daily Action Review

The 8 Types of Muda (DOWNTIME)

<table>
<thead>
<tr>
<th>Muda Type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overproduction</td>
<td>Defective work that does not add value to the customer.</td>
</tr>
<tr>
<td>Waiting</td>
<td>Work that waits for material, information, people, or equipment to be available.</td>
</tr>
<tr>
<td>Non-Utilized Resources</td>
<td>Resources that are not used at all or not being used to their full potential.</td>
</tr>
<tr>
<td>Transportation/Motion</td>
<td>Movement of people or materials that does not add value to the customer.</td>
</tr>
<tr>
<td>Inventory</td>
<td>Materials, parts, or products that are not used to create value for the customer.</td>
</tr>
<tr>
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<td>Materials, parts, or products that are not used to create value for the customer.</td>
</tr>
<tr>
<td>Extra Processing/Research</td>
<td>Activities that do not add value from the customer's perspective.</td>
</tr>
</tbody>
</table>
Waste examples that lead to compliance concerns:

- Data collection – process steps that do not add value for the patient. For example when in clinical trails there is the collection of extraneous data that will not be utilized in the study. This creates waste, risk and liability.
  - Can the data collection be streamlined to remove the collection and retention of unused data?
- When communication of information and ideas is isolated or siloed within a company and/or departments.
- When the same information needs to be submitted separately to different regulatory agencies – and if they have different data definitions.
- Underutilization of staff to identify and help prevent defects

### Clues to Waste & Non-Value Added Work

- Remeasure
- Reevaluate
- Remake
- Redo
- Recall
- Recheck
- Rework
- Repeat
- Redesign
- Revise
- Reject
- Retest
- Reship
- Return
- Reissue
- Retype

### Waste Observation Tool

<table>
<thead>
<tr>
<th>VALUE STREAM/PROCESS NAME</th>
<th>DATE</th>
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<tbody>
<tr>
<td>_________________________</td>
<td>______</td>
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<table>
<thead>
<tr>
<th>No.</th>
<th>Process Name</th>
<th>Waste Description / Observation</th>
<th>Time (sec)</th>
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</thead>
<tbody>
<tr>
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<td>20</td>
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</tbody>
</table>

In the next 24 hours I will remove the Waste No. _________ and communicate to the affected people.

Signature: __________________________________________
Ohno Circle Tool

- Explain the 8 wastes
- Stand in the same spot every day in the center of the workplace (gemba)
- Find wastes every day
- Identify Root Causes
- Remove at least 1 waste everyday

Which of these add value for the customer

- Preregistration process call prior to procedure
- Arriving and waiting for the nurse to call for you
- Being walked to the exam room
- Taking vital signs
- Waiting for the doctor
- Getting directions to the hospital
- Finding your way to the lab to get blood drawn
- Filling out billing information
- Correcting the bill

Which of these are compliance concerns

- Preregistration process call prior to procedure
- Arriving and waiting for the nurse to call for you
- Being walked to the exam room
- Taking vital signs
- Waiting for the doctor
- Getting directions to the hospital
- Finding your way to the lab to get blood drawn
- Filling out billing information
- Correcting the bill
Value Stream Mapping

Why Value Stream?

- Understand current situation - Big picture
- Ratio of Non-Value to Value Added Time
- Exposes sources of waste - not just waste
- Shows & linkages between the 7 types of flow

Guidelines for Mapping

- Start at the customer and work backwards
- Walk the actual flows
- Don’t map the organization but map the flow through it
- Identify value added and non-value added steps (muda or waste)
- Identify where to focus analysis of activities
- Don’t be too detailed this is an overview
- Use pencil not power point...quick and crude

The 7 Flows

1. Patients
2. Communication
3. Supplies
4. Information (What and When)
5. People (Std. Work, Takt Time)
6. Equipment (Portable X-Ray, EKG, etc)
7. Specimens

Example: Cath Lab Value Stream Map

Value Stream Mapping

Three Versions of Value Stream Map Processes

Current State VSM is created from the patient/customer’s perspective (i.e. walk the process). The process to develop and map concepts for the Future State provides a gap analysis between where you are and where you need to go and helps to determine the improvement strategy.
Root Cause Analysis (RCA)

A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a defect.

Why Conduct an RCA:
• To identify the processes and systems related to the occurrence as well as the proximate cause of the event
• Leads to an improvement in processes or systems
• Decreases the likelihood of similar events in the future

Root Cause Analysis (RCA) – 5 Whys Tool

• A simple and widely used tool
• Team asks/considers “why” at least five times
• Agree on root cause
• Develop action plan for improvement
Root Cause Analysis (RCA) – 5 Whys Tool

Department/Area: Initiator: Date:

Issue/General Information: Occurrences:

Why #1: Why #2:

Why #3: Why #4:

Why #5: Temporary Countermeasure:

Final Countermeasure:

Ask WHY a final time:

Read backwards after completion. Does the analysis make sense?

Circle One: Yes No

5S

What is 5S?

Sort

Arrange & Prioritize - Distinguish needed and unwanted items

Prevent Problems from occurring - ensure arrange and identify needed item for ease of use

Simplify

Shine

Inspect and Clean up area daily

Establish Orderliness/ Standards/ clearly define tasks

Standardize

Sustain

Discipline to maintain established procedures – audit area

Keys to Success

• Get everyone involved.

• Integrate 5S Principles into daily work.

• Communicate need for 5S, roles of all participants.

• Be consistent in following 5S in all areas

• Leadership involvement at all levels

• Follow through - 5S takes effort & persistence.

• Link 5S activity with all other initiatives.

5S

Create Standards ... Detect Abnormalities

Look Here ...

• 5 cowboys to drive 1000 cattle

• Should take one look and understand the situation

• Clearly differentiate between what is “Normal” and “Abnormal”

• Detect what is “Abnormal”

Not Here ...
### 5S Tool

<table>
<thead>
<tr>
<th>Item</th>
<th>Issuance</th>
<th>5S Evaluation Form</th>
<th>Score</th>
<th>What is the team doing to improve the 5S level?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equipment Maintenance</strong></td>
<td>All machines and equipment are kept clean, by their operators.</td>
<td>0 - 5</td>
<td><strong>Medium</strong> (10% or more)</td>
<td><strong>High</strong> (1% or less)</td>
</tr>
<tr>
<td><strong>Toolboxes</strong></td>
<td>All toolboxes are arranged in a neat, organized manner.</td>
<td>0 - 5</td>
<td><strong>Low</strong> (1% or less)</td>
<td><strong>Medium</strong> (10% or more)</td>
</tr>
<tr>
<td><strong>Cleanliness</strong></td>
<td>Tools are kept clean, and any necessary cleaning is performed daily.</td>
<td>0 - 5</td>
<td><strong>High</strong> (1% or less)</td>
<td><strong>Low</strong> (1% or less)</td>
</tr>
<tr>
<td><strong>Mark and Task Control</strong></td>
<td>All markings and task controls are clearly visible and easily understood.</td>
<td>0 - 5</td>
<td><strong>Medium</strong> (10% or more)</td>
<td><strong>Low</strong> (1% or less)</td>
</tr>
</tbody>
</table>

**After 5S is with 5** Being the Highest:

**Footer**: For Page 2
**Guidelines for Mapping**

- Obtain / draw a layout of the care area
- Observe first the patient as he/she goes from one station to another and draw on the layout
- Do not lift your pencil from the paper – continuous flow
- Repeat for care-giver & family
- Measure the total distance traveled and note

---

**Spaghetti Mapping**

- A diagram that shows the motion of the patient / family / care-giver throughout the care experience

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**Mission: Go to Gap, Buy a Pair of Pants**

- **Shopper**
  - Time: 6 min
  - Cost: $33

- **Non-Shopper**
  - Time: 3 hrs 26 min
  - Cost: $876

---

**Takt Time**

Takt = Rate at which the Patient/Customer PULLS from you (the heartbeat of the org).

\[ \text{Takt} = \frac{\text{Total Available Time (in seconds)}}{\text{Total Patients seen in that time frame (Demand)}} \]

Ex. If there are 60 patients that come into an ED during a given shift, Takt time can be calculated as:

\[ 60 \text{ sec.} \times 60 \text{ mins.} \times 8 \text{ hrs.} \]

60 patients

In order to ‘keep up’ at the rate at which a patient walks into the ED, you would need to complete a patient treatment every 480 seconds

\[ \text{480 sec.} \]

Every 480 seconds there is a patient walking into the ED, so every 480 seconds, there should be one being discharged – or else there will be a wait

**NOTE:** This does not mean it only takes 480 seconds to treat a patient! It means that the slowest step in the process should not exceed 480 seconds, and if it does, there will be waits and bottlenecks.
Standard Work

- Standardizes the way everyone does specific tasks
- Best process for quality, safety, compliance and efficiency
- Helps maintain control
- Makes it easier to expose and solve problems

“Everything should be made as simple as possible, but not one bit simpler”
-Albert Einstein

Standard Work Sequence

Standardized Work Job Instructions (SWJI)

easy to follow displays, placed where the work gets done, to ensure consistency

standardized work job instructions (SWJI)
Level Loading & Sequencing

Ensures that all steps in a Value Stream operate at or below Takt.

By redistributing some of the tasks in Step D to A, B, and C...

...we can easily identify our target for improvement. If we reduce the cumulative Cycle Times for all the steps by 12 seconds, we can potentially reduce from four steps to three.

Single Piece Flow

Catches Defects too Late
- How many more do you have?
- Where are they in the process?
- What is the root cause?

Catches Defects Immediately
- You only have one
- You know where it occurred
- Resolve the root cause immediately
Daily Action Review

- Series of interconnected, brief and structured daily meetings that:
  - Compare actual to expected performance
  - Assign corrective action and improvement
  - Follow up on the previous day’s action items

What is Six Sigma

- Measure of Quality
- Process For Continuous Improvement
Understanding of Six Sigma

Statistically
Six Sigma refers to a process that produces only 3.4 defects per million opportunities.

<table>
<thead>
<tr>
<th>Sigma</th>
<th>DPNO</th>
<th>Most U.S. Businesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>306,537</td>
<td>Goal</td>
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<tr>
<td>3</td>
<td>66,807</td>
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<td>4</td>
<td>6,210</td>
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<td>5</td>
<td>233</td>
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<tr>
<td>6</td>
<td>3.4</td>
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</tbody>
</table>

Business Strategy
An overall strategy that encompasses an organization's quality philosophy. It sets the vision for achieving Six Sigma levels of quality in key processes and services.

Tools and Tactics
A set of statistical tools and a disciplined methodology used by specially trained individuals to improve processes by reducing variation and defects.

Measure of Quality

Reducing variability is the essence of six sigma.

Measure of Quality

What is Sigma?

Patients don’t feel the averages, they feel the variation.
• 68% of data falls within 1 standard deviation of the mean
• 95% of data falls within 2 standard deviations of the mean
• 99.7% of data falls within 3 standard deviations of the mean

Let's look at our “average” LOS for a procedure. Looking at the last 30 patients we had an average LOS of 5 days. What is the problem?

Is this what our patients are feeling? Is everyone getting out in 5 days?

No!

Let's look at a distribution of the actual data.

It probably looks more like this with the average being 5 days.
We can see that there are a significant number of patients getting out later and earlier. Either way this can be a source of customer dissatisfaction & regulatory inquiry.

Let's say that our patients & regulators are OK if they are out between 1 day early and 1 day late. These are our spec limits.

Where are our defects, or, where are our dissatisfied patients?

If our standard deviation was 1 day, then we would have 68% of our patients getting out between 4 and 6 days AND 32% not.

If we can reduce variation, we can reduce dissatisfied patients & regulators.

If our standard deviation was reduced to .5 day, then we would have 95% of our patients getting out between 4 and 6 days.
Six Sigma Quality

### Patient Wait Times (mins)

<table>
<thead>
<tr>
<th>Starting Point</th>
<th>After Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>29</td>
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<tr>
<td>18</td>
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</tbody>
</table>

**Average**: 17, 13

**Mean**: 25% improvement

### What We See

#### What Patients Feel

- Variability
  - No Significant Change!

### Process for Continuous Improvement

Six Sigma provides a process-based approach to continuous improvement. It can be used to improve any process... business, transactional or healthcare.

### Process for Continuous Improvement

#### Six Sigma Methodologies

**DMAIC**: To improve any existing product or process

- **Define**: Who are the customers and what are their priorities?
- **Measure**: How is the process performing and how is it measured?
- **Analyze**: What are the most important causes of the defects?
- **Improve**: How do we remove the causes of the defects?
- **Control**: How can we maintain the improvements?
Case Study – Surgical Services Equipment Availability

Pictures of Before State:

- Blocked doorways/ clutter
- Equipment in non-sterile hallway

- Expensive equipment in vulnerable location
- Egress blocked by equipment
Case Study – Surgical Services Equipment Availability

Improvements:

• Equipment moved to storage room on first floor
  — Relocated 2 pharmacy employee offices
  — Removed expired equipment & supplies
  — Moved vendor items to one location, initiating consignment process which vendors had been resistant to
  — Added wall boards for more efficient storage
  — Taped floor for access to door and where equipment goes
  — Put pictures of items on wall to indicate where it goes in room; also put picture in old location with note indicating where it is now located

• Created equipment transport process
  — Tagging process so equipment is no longer just left in elevator due to not knowing the clean or dirty status of equipment
  — Now know what equipment is going up (clean) and going down (dirty)
  — Included involvement of Patent & Equipment Transport Team and Central Sterile team, in addition to Surgical Services Staff

• Renovated and reconfigured an exiting “work” (storage) room:
  — Large 248 sq foot space with a lot of extra room that was underutilized
  — Dropped par levels on supplies by over $3,000
  — Removed cabinets and sinks, and expanded the doorway
  — New open space allowed storing $3M of equipment that was formally stored old hallway—expensive, easily damaged equipment now in a protected area
  — Able to outline floor to ensure storage locations are maintained

Case Study – Surgical Services Equipment Availability

Pictures of After State:

Cleared Egress  Hallway cleared of clutter
Tenants of Successful Lean Six Sigma Management

- The basis of management decisions should be long-term vision and strategy, even if that is at the expense of short term gains
- Create a process to continuously bring problems to the surface
- Level out the work (The tortoise and the hare)
- Build a culture of stopping to fix problems and getting things right the first time
- Standardize processes and tasks to get to and maintain continuous improvement and front line empowerment
- Implement visual controls so problems will not be concealed

Tenants of Successful Lean Six Sigma Management

- Use technology that serves your people and processes – do not become subservient to technology
- Develop leaders who understand the work, live the vision, strategy and values and teach it to others
- Develop excellence in your people and teams
- Respect your extended network of partners and help them improve
- Go to the work (gemba) and understand the problem
- Make decisions slowly, considering all your options, but implement decisions rapidly
- Become a learning organization

Ending Thoughts

- Tracking and trending data and issues will highlight issues that need to be brought better into compliance
- Standardized work and documentation will improve by involving the stakeholders
- Bringing a cross functional team together to resolve issues ensures a common approach and culture throughout the organization
Self Assessment
What is your experience?

Lessons Learned | Successes
---|---
|||
|||
|

Good judgment comes from experience, and a lot of that comes from bad judgment

- Will Rogers

Application of Learnings

One Thing Learned

One Thing to Apply

Ending Thought

It’s easier to behave ourselves into a new way of thinking than to think ourselves into a new way of behaving.

Managing on the Edge, R. Pascale
Questions

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