Using Lean Six Sigma in Process Improvement

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Objectives

• Describe how Lean Six Sigma tools such as Robust Process Improvement™ (RPI) can be applied to laboratory process improvement and initiatives such as improved hand hygiene.
• Identify how a formalized methodology like Lean Six Sigma assists in meeting The Joint Commission accrediting requirements.
• Define “high reliability” as it applies to health care organizations.
• Identify Clinical and Laboratory Standards Institute (CLSI) resource documents that can be used as references for process improvement activities.
Lean Six Sigma History

- Developed by Motorola 1987
- Allied Signal (Larry Bossidy) 1993
- General Electric (Jack Welsh) 1995
- Health Care 2000
- 99% quality (3.8 Sigma) 5000 incorrect surgeries per week but 6 sigma quality 99.9996% 1.7 per week

Six Sigma Methodology - DMAIC

- **Define** in numerical terms problems or opportunities
- **Measure** current levels of performance
- **Analyze** and determine root cause analysis (RCA) of the problem
- **Improve** the current situation
- **Control** the new process

Define

- Select project and team
- Define project scope
- Identify problem statement
- Develop project charter, ie, A3
- Develop a SIPOC map (suppliers, inputs, process, output, customers)
- Listen to voice of the customer (VOC)
Measure

• Collect baseline data

• Determine tools to monitor project: descriptive statistics, run chart, control chart, check sheet, Pareto chart, cause and effect diagram, tree diagram, 5 why’s, failure modes and effects analysis (FMEA), process flowchart

Analyze

• Questions about data (confidence intervals, hypothesis testing), variation analysis

• Gap analysis

• Process map, cause and effect diagram, RCA, FMEA

• CLSI documents

• Westgard QC- Six Sigma Calculators

• The Joint Commission
Control Charts

Run Chart

Ishikawa Diagram

Fault Tree Analysis

Related CLSI Documents

- I/LA28-A2 - Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline - Second Edition
- GP35-A - Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline
- HS1-A2 - A Quality Management System Model for Health Care
Other References

- Westgard, James O., *Six Sigma Risk Analysis*
- The Joint Commission, *Failure Modes Effects Analysis in Healthcare, a Proactive Risk Analysis*

Improve

- Develop a solution and action plan
- Implement solution
- Perform creative thinking, brainstorming
- Reduce variability, Error proof
- Change management
- Work-Out™ sessions
Control

- Standardization
- Acceptance
- Accountability
- Continued success

RPI, DMAIC, and The Joint Commission Survey

- The Joint Commission Center For Transforming Healthcare is using Robust Process Improvement™ (RPI) internally and externally as we work with hospitals and health care systems to improve quality, safety, and efficiency.

- RPI combines Lean Six Sigma, Work-Out, Change Management, and other improvement tools to improve quality and efficiency.
The Joint Commission Laboratory Standards: Performance Improvement

- PI.01.01.01 The laboratory collects data to monitor its performance.
- PI.02.01.01 The laboratory compiles and analyzes data.
- PI.03.01.01 The laboratory improves performance.

The Joint Commission Laboratory Standards: Leadership

- LD.03.01.01 Leaders create and maintain a culture of safety and quality throughout the laboratory.
- LD.03.02.01 The laboratory uses data and information to understand variation in the performance of processes supporting safety and quality.
- LD.03.03.01 Leaders use laboratory-wide planning to establish structures and processes that focus on safety and quality.
The Joint Commission Laboratory Standards: Leadership

• LD.03.04.01 The laboratory communicates information related to safety to those who need it.

• LD.03.05.01 Leaders implement changes in existing processes to improve the performance of the laboratory.

• LD.03.06.01 Those who work in the laboratory are focused on improving safety and quality.

The Joint Commission Laboratory Standards: National Patient Safety Goals

• NPSG.01.01.01 Use at least two patient identifiers when providing laboratory services.

• NPSG.02.03.01 Report critical results of tests and diagnostic procedures on a timely basis.

• NPSG.07.01.01 Reduce the risk of health care associated infections. Comply with either Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO) hand hygiene guidelines.

The Health Care Quality Challenge

• More than 400,000 harmful, preventable outcomes occur in hospitals every year.

• The costs associated with unsafe care and poor quality in hospitals are unacceptable.

• There is a strong demand from health care organizations for specific guidance on how to solve these problems.

• Health care organizations want highly effective, durable solutions and are ready to implement them.
Why the Center Was Created

• In keeping with its objective to transform health care into a high reliability industry and to ensure patients receive the safest, highest quality care they expect and deserve, the Joint Commission Center for Transforming Healthcare was established in 2009.

• The Center presents a new approach to address critical safety and quality problems sought by The Joint Commission, health care organizations, patients and their families, physicians and clinicians, and other public and private stakeholders.

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Why Hand Hygiene?

In the United States, one in 15 hospital patients becomes seriously ill as a result of acquiring an infection in the hospital. This is equivalent to six million cases a year.

And the costs... the estimated annual medical cost of HAI to U.S. hospitals is over $30 billion, the benefits of prevention could save $6 billion annually, or a reduction in HAI could save up to 17,000 deaths a year.

Every day, 247 people die in the USA as a result of a health care-associated infection. This is equivalent to a 767 aircraft crashing every day or more than 90,000 deaths annually.

World Health Organization

SAVE LIVES

Health Care Associated Infections (HCAIs) affect hundreds of millions of people worldwide and are a major global cause of preventable death.

"Hand hygiene is not a new concept, long lasting improvements remain difficult to sustain... until a comprehensive one-size-fits-all approach is developed.

Hand Hygiene Improvement Strategies"
Health Care Associated Infection Statistics

• Nearly 2 million patients in the United States contract a health care associated infection (HAI) annually.

• With nearly 100,000 deaths each year, HAIs are the fourth largest killer in the United States and cause more deaths every year than AIDS, breast cancer, and auto accidents combined.

• Two-thirds of those deaths result from bloodstream infections and ventilator-associated pneumonia.

• HAIs add nearly $9000 in expenses per infected patient in hospitals and cost US hospitals between $4 to $29 billion.

Main Causes of Failure to Clean Hands (across all participating hospitals)

Main Causes for Failure to Wash Hands

• Ineffective placement of dispensers or sinks

• Hand hygiene compliance data not collected or reported accurately or frequently

• Lack of accountability and just-in-time coaching

• Hand hygiene not stressed enough by safety culture at all levels
Main Causes for Failure to Wash Hands (cont)

- Ineffective or insufficient education
- Hands full
- Perception that wearing gloves interferes with process
- Perception that hand hygiene is not needed when wearing gloves
- Forgetfulness on the part of health care workers
- Distractions

Hand Hygiene Compliance Aggregated

Identifying Causes, Targeting Solutions

Causes
- Hand hygiene compliance data are not collected or reported accurately or frequently
- Safety culture does not stress hand hygiene at all levels
- Ineffective placement of dispensers or sites
- Hands full

Solutions
- Define a framework for a systematic approach for improvement
- Implement a hand hygiene improvement system to determine the real reason for poor compliance
- Develop and implement the plan
- Improve the patient, health care staff, and visitors’ hand hygiene compliance
- Incorporate hand hygiene into patient care and education
- Develop a feedback mechanism for hand hygiene
- Increase awareness, education, and communication
- Provide easy access to hand hygiene equipment and dispensers
- Create a policy for everything, for example, a healthcare worker will not enter a patient’s room if hand hygiene is not practiced prior to entering the room

Hand hygiene compliance improvement in global sites
**Targeted Solutions**

- Targeted hand hygiene solutions from the Center use the acronym “HANDS” to ensure
  - Habit
  - Active Feedback
  - No One Excused
  - Data Driven
  - Systems

**Effective Hygiene is in Our HANDS**

- Habit
  - Always wash in and out properly
  - Wash hands in and out
  - Use alcohol-based hand rubs
  - Use hand sanitizer
  - Wash hands

- No One Excused
  - Personalize the patient experience
  - Encourage hand hygiene

- Active Feedback
  - Coach and train to instill staff to wash
  - Create a feedback system

- Data Driven
  - Effort provides a framework for a systematic approach to improvement
  - Use a standard measurement system to track hand hygiene
  - Use-based automated hand hygiene equipment

- Systems
  - Establish accountability and responsibility
  - Establish a systems approach
  - Establish a systems approach
  - Establish a systems approach

**Targeted Solutions Tool™**

- The Targeted Solutions Tool (TST) was developed by The Joint Commission Center for Transforming Healthcare to:
  - Enhance the efforts of The Joint Commission-accredited health care organizations, which are already tackling these difficult and pressing problems.
  - Facilitate the spread of the learnings from the Center’s projects, including identification of root causes and the targeted solutions that address causes of failures.
Targeted Solutions Tool Process

• The TST application is a step-by-step process that encapsulates the work of the Center to bring solutions to accredited health care organizations by:
  – Measuring an organization’s actual performance
  – Identifying specific causes to breakdowns in care
  – Directing organizations to proven solutions that are customized to address their particular barriers to excellent performance

Targeted Solution Tool Steps

• The TST has six steps designed to provide users with a step-by-step guide through a project:
  
  Step 1: Getting Started
  Step 2: Training Observers
  Step 3: Measuring Compliance
  Step 4: Determining Factors
  Step 5: Implementing Solutions
  Step 6: Sustaining the Gains

Hand Hygiene/Targeted Solutions Tool Utilization Update

• As of August 6, 2011, there were:
  – 245,831 hand hygiene observations in the database
  – 67,743 unique visitors to the Targeted Solutions Tool
  – 1,979 projects with “In Progress” status in the database
  – 758 projects entered hand hygiene observations
  – 175 distinct organizations have projects with observation data (one organization can have multiple projects)
Additional Information About the TST

• Joint Commission Customer Service at (630) 792-5800

• E-mail: tst_support@tcthc.org (include your name, your organization’s name, and your organization’s ID number)

Road to High Reliability

• Leadership
• Safety culture
• Capacity to execute
Robust Process Improvement

Chassin, Mark and Loeb, Jerob; “The Ongoing Quality Improvement Journey, Next Stop, High Reliability”, Health Affairs, April 2011

High Reliability

Leadership
• Commitment of management
• Reflected in vision/mission statements

Safety culture
• Trust
• Report
• Improve
• Capacity to execute robust process improvement
Lean as a Quality Improvement Tool

This Session Will:

- Discuss basic Lean concepts.
- Teach the use of an A3 template as a Tool for Tracking Lean quality improvements.
- Demonstrate A3 using blood culture contamination rates as the improvement activity.
- Understand the importance of observations in the “gemba” to find the least wasteful improvements

What is Lean?

“Is a systematic approach of continuous improvement used for the identification and elimination of waste to provide value to the customer.”
A Little Lean History

- **Ford Production**
  - In 1913, Ford combined consistently interchangeable parts with standard work and moving conveyance to create what he called flow production.

- **Toyota Production System (TPS)**
  - Just after World War II, Toyoda and Ohno, engineers at Toyota, believed that a series of simple innovations might provide continuity in process flow. The Japanese engineers visited Ford’s plant in Michigan, and invented the TPS/LEAN systems.

  — and [Taiichi Ohno](https://www.toyota.com/)

Toyota Philosophy

- Create continuous process flow to bring problems to the surface
- Use “pull” to avoid overproduction
- Level out the workload (heijunka)
- Get quality right the first time
- Standardize tasks
- Use visual controls so no problems are hidden
- Use only reliable, thoroughly tested technology that serves your people and processes

Value Added

- Service value: An aspect of a product or service that a customer is willing to pay for
  - STAT courier pick-up in an outreach program
  - Results for treatment by physician are value added
- Value Added: Service that increases value to the patient, physician or patient care staff
  - Turnaround Times
  - Result Accuracy, as in blood cultures with no contaminations
- Non-value added service is one that is required by process but has no direct impact for the patient
  - Processes to get results are non-value added but required by regulations
  - Calibrations of equipment
  - Quality control (QC) prior to running and reporting test
Waste

- The original seven muda (wastes) are:
  - Transportation (moving product not actually required to perform the processing)
  - Inventory (all components not being processed)
  - Motion (moving or walking more than is required to perform the processing)
  - Waiting (waiting for the next production step)
  - Overproduction (production of tests outside of need or protocols)
  - Overprocessing (Poor equipment tooling)
  - Defects (the effort involved in inspecting for and fixing defects)
- An eighth waste was defined by Womack et al. (2003): as manufacturing goods or services that do not meet customer demand or specifications.
  - Tests performed but not ordered
  - Direct patient impact of service level

A3 Outline

- How does one capture Lean activities?
- One-page report called an A3
- Nine boxes in which one records:
  - Reason for action
  - Current state
  - Future target state
  - Gap analysis
  - Solution approach
  - Rapid experiments
  - Completion plan
  - Confirmed state
  - Insights

What is an A3?

- Method for reporting LEAN activities
- A3 is actually the size of sheet of paper 11" X 13"
  - It was the “order name” of paper that went into a copier
  - The A3 has nine blocks utilized to record LEAN efforts
- The A3 is a simple way to track a LEAN project for timeline completion and metric outcomes
- In a glance once can:
  - Understand the problem and the scope of the LEAN activity
  - See process change with metric outcomes to record improvements
  - See solutions and the scheduled changes with assigned responsibilities

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Reason for Action

- Reason for Action
  - Why is this LEAN improvement important?
  - Motivate for participation in the changes
- Create a problem statement
- Set the boundaries
  - Resist creep
- Ensure data speaks to the problem

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Reason for Action

- Denver Health blood culture contamination rates exceed the national benchmarks of 3%:
  - Leading to increased length of stay (LOS)
  - Use of costly antibiotics, expensive testing, and supply costs
  - High contamination rates have led to lack of physician confidence in testing results
- Emergency department contamination rates are the highest in the health system and will therefore be the focus improvements.

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Current State

- Blood culture contamination rates exceeded national benchmark of 3.0%:
  - Emergency Department (ED) contamination rates ranged from 2.6% to 9.4% in 2009, overall contamination rates were 5.9%
  - Phlebotomy rates remained at or below 3% in 2009
- ED staff drew 250-300 cultures per month
  - Over 100 ED staff performed Blood Culture draws
  - Up to 80% of the ED staff drew fewer than 3 Blood Cultures per year
  - ED staff turn-over averaged 25% yearly
  - Competencies were not on record for all staff drawing Blood Cultures
Current State

Waste Walk in the ED “Gemba” (contd)

• Tops of the culture bottles were not cleaned
• Needles were stabbed through alcohol swabs lying on tops of vials
• Cultures drawn without physician order then discarded
• Cultures were drawn but not labeled at bedside
• Cultures were not drawn in appropriate draw order
• Labeling often obstructed barcoding on vials causing issues with reads on instrumentation in Microbiology
• Bottles were not filled to provide optimal blood volumes for bacterial growth
• Culture bottles were found in excess of 20X the need based on volumes
**Current State: Physician’s “Gemba”**

- Physicians did not feel they could rely on results when drawn in the ED
  - Cultures were immediately ordered and redrawn upon admission when sepsis suspected
- Contaminations led to increased LOS until two consecutive cultures were negative
- Contaminations led to expensive antibiotic therapy which was often unnecessary
- Additional LOS inflated the cost of the patient stay by an estimated $5000/day

**Future State for ED & Physicians**

- Phlebotomists draw Blood cultures in ED
  - Use experts to ensure procedural requirements followed
- ED can ensure coverage for protocols when phlebotomy cannot arrive within hour (10-15 X/mo)
  - Provide Health Care Techs education module used in MICU
  - Keep number of staff trained to minimum (10-20)
  - Report statistics monthly in update with ED
- Broadcast to physicians the changes in draw protocols in ED and statistical updates
  - Alleviate unnecessary blood culture orders
- LOS will decrease, supply costs & FTE effort

**Gap Analysis**

- The goal of gap analysis is to identify the difference between the optimal use of resources and the current level
- The gap analysis process involves determining, documenting and agreeing about the variance between current capabilities and change for future
- **Benchmarking** and other metrics are important to this analysis.
Gap Analysis

- Lack of consistent documented education for ED staff
  - Low volume of Blood Culture draws across large volume of ED staff
- Lack of orders when Blood cultures drawn
- Poor inventory management of culture vials
- Lack of consistent communication and information sharing regarding laboratory-collected contamination rates

Solution Approach

<table>
<thead>
<tr>
<th>Phlebotomy performs Blood Culture Draws in the ED</th>
</tr>
</thead>
<tbody>
<tr>
<td>A small team in ED is trained and competent</td>
</tr>
<tr>
<td>Par rates for Blood Cultures vials are set</td>
</tr>
<tr>
<td>Education modules are loaded into staff member MC Strategy files</td>
</tr>
<tr>
<td>WT and ED staff meeting</td>
</tr>
</tbody>
</table>

- Expert technique will decrease ED Blood Culture contamination rates
- Protocols requiring draws that phlebotomy cannot attend will meet requirements for loading antibiotics
- The smaller ED team will gain experience and expertise
- Mediation for problem solving is more immediate
- Vials can be adjusted to required supply volumes based on utilization statistics
- Supply chains can track stock across the facility
- There will be decreased supply costs
- Competencies can be addressed immediately
- Accountability can be assigned for education and follow-up
- Statistics will speak for themselves

Rapid Experiments

- Rapid experiments trial the future state
  - Anticipate innovative “out of the box” thinking and processes
  - Experiment to discover and tweak based on discovery
  - Integrate new and traditional technologies to unlock performance
  - Educate early about rapid experimentation
  - Fail early and often but avoid ‘mistakes’
  - Listen and understand the angst of doing something new
Rapid Experiments in ED

- Placed phlebotomist in ED to draw
  - Successful, but waste apparent as Phlebotomist not busy 90% of the time
    - Need method to “pull” phlebotomist to ED for culture draws
- Orders placed for Blood Cultures
  - Need to centralize location for pick-up
  - Need room number on requisition
- 6S to reduce inventory and centralize location of ED Blood Culture vials
  - One person responsible for inventory
  - CS agreed to centralize distribution of vials

Completion Plan

- **Actions to be taken**
  - Responsible person/s
- **Times, dates to complete plan**
  - This work plan takes into consideration:
    - Project objectives
    - Budget
    - Purchasing
    - Schedule
    - Materials
    - Personnel
    - Mitigation
    - Communication/Training

### Completion plan

<table>
<thead>
<tr>
<th>Task</th>
<th>Timeframe</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sr. Phlebotomist obtain pagers</td>
<td>Within next 3 days</td>
<td>Done</td>
</tr>
<tr>
<td>Sr. Phlebotomist/ED RN educator script calls</td>
<td>Within next 2 wks</td>
<td>Done</td>
</tr>
<tr>
<td>RN educators will educate staff about change</td>
<td>Within next 2 wks</td>
<td>Done</td>
</tr>
<tr>
<td>ED education to physicians and PAs reporting changes through ED Administrative Committee</td>
<td>One month</td>
<td>Done</td>
</tr>
<tr>
<td>Room numbers in ED suites must be on requisitions to expedite draws</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location of centralized regulations and no Blood Culture draws without orders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbiology Supervisor and CS Manager meet to determine ordering and distribution of vials and responsibilities</td>
<td>Within next week</td>
<td>Done</td>
</tr>
<tr>
<td>Develop tracking report for Blood Culture vials inventory and where distributed</td>
<td>Within next week</td>
<td>Done</td>
</tr>
</tbody>
</table>
Metrics to Report and Track

- Reported in categories
  - Quality
  - Financial Impact
  - Human resources impact

- Confirmed state
  - Statistical tracking of metrics or quality outcomes
    - Numerator
    - Denominator
  - Numbers that are easy to retrieve, obtain
  - Accuracy of the data
  - Reproducibility and ease of gathering the data
  - Method for re-evaluation when metrics not met

Confirmed State

<table>
<thead>
<tr>
<th>Measure</th>
<th>Initial</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of total Blood Cultures drawn by ED</td>
<td>250-300/month</td>
<td>Less than 20/month</td>
</tr>
<tr>
<td>Number of contaminated Blood Cultures drawn by ED (Averaged 5.9% overall 2009)</td>
<td>Average of 15/month</td>
<td>1-2 contaminated Blood Cultures/month</td>
</tr>
<tr>
<td>Denver Health Blood Culture Contamination Rates</td>
<td>3.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cost Savings</td>
<td>0</td>
<td>$150,000/Qtr</td>
</tr>
</tbody>
</table>

ED Blood Culture Draw Data

[Graph showing number of blood cultures drawn by ED and number of contaminants by month from January to July 2011]
Insights or Lessons Learned

- Laboratory took the lead on designing education and providing immediate feedback
- ED was surprised at the lack of confidence physicians placed on Blood Cultures drawn in ED
- Denver Health recovered nearly $205,000 to $350,000 each quarter following implementation of the LEAN Improvement
- ED push-back from health care techs was an obstacle in getting program started.
  - Nurses support removed the angst as nurses felt patient’s care time was increased.

Conclusions

- LEAN tools provide processes for quality improvements
- The A3 is a dynamic tool for recording on one page the improvement metrics
- Walking in the Gemba is a must for understanding process breakdowns, the waste and where to focus efforts
- Narrowing the scope of the project requires good, easy to pull data

Summary

- LEAN Improvement activities can be summarized in a single 11” X 13” document with nine blocks of information
- In a single glance one can understand the scope of the improvement activity, see the plans, the processes being addressed and note the improvements through metric reporting
Questions?