Adding value to clinical laboratory services through use of Six Sigma Metrics

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IFCC Committee on Clinical Laboratory Management
http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Symposium on Improvement in Clinical Laboratory Services: Approaches to Adding Value

IFCC WorldLab Durban
Durban International Convention Centre
Durban, South Africa - October 25, 2017
“No human investigation can claim to be scientific if it doesn’t pass the test of mathematical proof.”

Leonardo da Vinci
Continuous Improvement Models

Systematic strategies:
• Root Cause Analysis (RCA)
• PDCA
• LEAN
• Six Sigma (DMIAC)

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Continuous Improvement Models

Reactive:
- Determine why a failure occurred.
- Eliminate the problem.
- Minimize probability of recurrence.

Proactive:
- Forecast probable events.
- Identify gaps between desired & actual.
- Determine what to change and how.

Edward Randell/ Control of laboratory error through “Corrective and Preventive Actions”
Continuous Improvement Models

Developed during World War II by Walter A. Shewhart (and promoted by his student W. Edwards Deming). Best suited for non-complex problems.

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## Continuous Improvement Models

<table>
<thead>
<tr>
<th>LEAN</th>
<th>Sigma</th>
</tr>
</thead>
</table>
| • Developed by Toyota during 1970’s to help streamline production plants.  
• Optimize equipment, time and people to superior performance.  
• **5S** (Sort, Simplify, Sweep, Standardize, Sustain)  
• Kaizen teams for rapid improvement | • Developed by Motorola Corp. to make improvements by identifying errors and mistakes.  
• Uses measurable and quantifiable STATs to select and conduct improvement projects to improve quality. |

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Continuous Improvement Models

### Lean
- **Value**: Specify value to the customer
- **Map**: Value stream
- **Eliminate**: Waste and variation
- **Flow**: Make value flow to the customer
- **Iterate**: Continuously improve

### Six Sigma
- **Define**: the problem
- **Measure**: baseline performance
- **Analyse**: Performance and identify root cause
- **Improve**: Implement solutions
- **Control**: Ensure improvements are embedded

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Continuous Improvement Models

LEAN & Six Sigma organizations are based on hierarchal belt systems

Master Black Belts – >2 years experience and train others
Black Belts – Train and oversee projects
Green Belts – Lead projects
Yellow Belts – Familiar and participate
White Belts – Familiar with processes
Presentation Outline

• A Primer in Six Sigma
• Why six sigma in laboratory medicine
• Six Sigma and the Total Testing Cycle
• Six Sigma and Adding Value
• Getting it started and making it stick.
Evolution of Six Sigma

• **Carl Fredrich Gauss** (1777-1855) – The normal Curve
• **Walter Stewhart** (in 1920s) – three sigma standard
• **Bill Smith** (Motorola Engineer; 1980’s) – Coined the term
• Today – Six Sigma has evolved to a quality system and more…

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What is Six Sigma?

‘a disciplined method of using extremely rigorous data gathering and statistical analysis to pinpoint sources of errors and ways of eliminating them’

Harry and Schroeder (1999)

Focus: Creating value for Customers
What is Six Sigma?

- Data driven process improvement system.
  - Relies on measuring processes and making improvements
  - Based on statistical concepts
  - Reduces errors and defects

<table>
<thead>
<tr>
<th>Sigma level</th>
<th>Defect Rate (dpm)</th>
<th>Yield (%) or Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1σ</td>
<td>690,000</td>
<td>30.8</td>
</tr>
<tr>
<td>2σ</td>
<td>307,770</td>
<td>69.1</td>
</tr>
<tr>
<td>3σ</td>
<td>66,811</td>
<td>93.3</td>
</tr>
<tr>
<td>4σ</td>
<td>6,210</td>
<td>99.4</td>
</tr>
<tr>
<td>5σ</td>
<td>233</td>
<td>99.98</td>
</tr>
<tr>
<td>6σ</td>
<td>3.4</td>
<td>99.9997</td>
</tr>
</tbody>
</table>
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**Define problem, select & train team, CTQs defined.**

**How do we measure the problem**

**Analyze process & determine causes**

**Improve**

**Assure improvements sustained**

**Control**

**Design**

** DMAIC: Six Sigma in action.**

**Assemble Team**

**Project Charter/Management Plan**

**Develop & implement measurement system**

**Collect & analyze data on process, root causes, and gaps**

**Generate and test solutions – Implement the best**

**Document/standardize/monitor/transfer ownership**
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Medical Error: Laboratory Medicine Perspective

Six Sigma
- Applicable to any process
- Inerrant tolerance limits
- Identifies and removes defects
- Decreases inefficiency
- Increases quality

Ref:
Coskun CCLM 2007;45:121
Stroobants et al. CCA 2003;333:169

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Defects are:
• Anything causing dissatisfaction:
  • Unnecessary costs
  • Unnecessary steps
  • Unnecessary services
  • Time loss
  • Errors
  • Medical errors
  • Patient morbidity
  • Patient mortality
What value can the laboratory create?

Patients, friends and family
- Minimized wait times
- Minimized discomfort
- Minimized cost
- Rapid Diagnosis and Treatment

Health Care Staff
- Appropriate TAT
- Reliable Results
- Relevant Information to direct decisions

Laboratory Staff
- Clear Expectations
- Minimized wasted time
- Respect & Appreciation
- Manageable workload and workflow

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From value outcome to metric and target

Pre-Analytical
- Mis-IDed Samples
- Transcription errors
- Unsuitable samples
- Phlebotomy wait-times

Analytical
- EQA results outside limits
- QC failures
- Valid Complaints
- Analytical cost/test

Post-Analytical
- TATs
- Results delivered outside target
- Critical results outside target time
- Erroneous Reports

Refs:
CCLM 2011;49:463
CCLM 2015;53:1653
CCLM 2015:53:943
CCLM 2016;54:1169
From value outcome to metric and target

Superior Performance

Quality Goals

Best in class

Performance Goals

Refs:
CCLM 2011;49:463
CCLM 2015;53:1653
CCLM 2015;53:943
CCLM 2016;54:1169

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Metric Calculations

Accuracy and Precision

- \[ \text{Sigma Metric} = \frac{TEa - \text{Bias}}{\text{Precision}} \]
- \[ \text{Sigma Metric} = \frac{TEa - |\text{Bias}|}{\text{Standard Deviation}} \]
- \[ \text{Sigma Metric} = \frac{\%TEa - |\%\text{Bias}|}{\%CV} \]

Other specifications

- \[ \text{Sigma Metric} = Z = \frac{\text{Specification Limit} - \text{mean}}{\text{Standard Deviation}} \]
- For DPMO
  - Use conversion tables
  - Calculation

Sigma metric is directly related to safety, efficiency, and cost of quality.

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Applications

Selecting QC Procedures
Higher Sigma associated with:
- Lower reagent supply
- Lower labor costs
- Fewer QC failures
- Between laboratory reproducibility

<table>
<thead>
<tr>
<th>Sigma Metric</th>
<th>QC Rules Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Sigma</td>
<td>1-3.5s</td>
</tr>
<tr>
<td>5 Sigma</td>
<td>1-3s</td>
</tr>
<tr>
<td>4 Sigma</td>
<td>1-3s, R4s, 2 of 2-2s, and 2 of 3-2s</td>
</tr>
<tr>
<td>3 Sigma</td>
<td>1-3s, R4s, 2 of 2-2s, 2 of 3-2s, 4-1s and 12x</td>
</tr>
</tbody>
</table>

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## Applications

<table>
<thead>
<tr>
<th>Value</th>
<th>Six Sigma Metric/Process</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>6σ process reduced pathology lab error rate</td>
<td><em>Turk. Patol. Derg 2016:32:171</em></td>
</tr>
<tr>
<td>Efficiency &amp; timeliness</td>
<td>6σ process reduced STAT TAT and elimination of process steps leading to error</td>
<td><em>J. Clin. Lab. Anal. 2017:e22180</em></td>
</tr>
<tr>
<td>Timeliness</td>
<td>6σ process reduced hemolysis in ED</td>
<td><em>JCQPS 2015;41:99</em></td>
</tr>
<tr>
<td>Timeliness &amp; Efficiency</td>
<td>6σ process reduce TAT and LOS in ED</td>
<td><em>AJCP 2013:140:193</em></td>
</tr>
<tr>
<td>Timeliness &amp; Efficiency</td>
<td>6σ process reduces data entry errors with improved process and cost savings</td>
<td><em>IJHCQA 2011:26:496</em></td>
</tr>
<tr>
<td>Safety</td>
<td>6σ process reduces analytical errors in automated lab</td>
<td><em>MLO 2005:37:20</em></td>
</tr>
</tbody>
</table>
Getting it started

Educate Self & then just do it!

DESIGN
- Prepare a team
- Select a project
- Stakeholder Requirements
- Project Charter
- Process Maps

6σ Project: Expanded auto-verification at 3 regional hospital laboratories
- <5% of samples held require no intervention by MLT.
  - 61% critical values
  - 10% hemolysis
  - 9% other reasons
- Objectives
  - Expand to all serum tests.
  - Fine tune to reduce false flags.
  - Implement Monitoring System
Getting it started

Value to Stakeholders

- Safer and Higher Quality Health Care
- More accurate, timely and useful information to inform decisions.
- Better tools to work towards better service.
- Higher profile in the health care team.
- Champions for high quality care.

Sites

Sample AV rate

<table>
<thead>
<tr>
<th>Sites</th>
<th>Sample AV rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSC (Automated Chemistry)</td>
<td>52%</td>
</tr>
<tr>
<td>WMH (Automated Chemistry)</td>
<td>40%</td>
</tr>
<tr>
<td>SCH (Not automated)</td>
<td>38%</td>
</tr>
</tbody>
</table>

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Mapping and measuring

MEASUREMENT
- Measurement System
- Detailed Mapping
- Metric Identification
- Collecting Data

<table>
<thead>
<tr>
<th>MLT</th>
<th>Number of Samples</th>
<th>Seconds per sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>72</td>
<td>6.57</td>
</tr>
<tr>
<td>2</td>
<td>123</td>
<td>7.83</td>
</tr>
<tr>
<td>3</td>
<td>213</td>
<td>6.01</td>
</tr>
<tr>
<td>4</td>
<td>100</td>
<td>16.58</td>
</tr>
<tr>
<td>5</td>
<td>204</td>
<td>4.90</td>
</tr>
<tr>
<td>6</td>
<td>42</td>
<td>5.00</td>
</tr>
<tr>
<td>7</td>
<td>109</td>
<td>5.10</td>
</tr>
<tr>
<td>8</td>
<td>100</td>
<td>5.05</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>7.13 ± 3.95</td>
</tr>
</tbody>
</table>
Analysis and baseline

ANALYZE

• Analyze gaps
• Determine sources of variation
• Factors influencing process
• Benchmarks

Table 5. Summary of metrics and benchmarks pre-implementation of new AV rules.

<table>
<thead>
<tr>
<th>Performance Metrics</th>
<th>Definition/Units</th>
<th>Baseline</th>
<th>Benchmark or Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample hold rate</td>
<td>Proportion of total</td>
<td>0.396 ± 0.037 (n=6)</td>
<td>&lt;0.10</td>
</tr>
<tr>
<td>Test hold rate</td>
<td>Proportion of total</td>
<td>0.225 ± 0.009 (n=6)</td>
<td>&lt;0.10</td>
</tr>
<tr>
<td>MOL hold rate for potassium</td>
<td>Proportion of tests held</td>
<td>8.7%</td>
<td>&lt;2.5%</td>
</tr>
<tr>
<td>Delta hold rate for potassium</td>
<td>Proportion of tests held</td>
<td>3.7%</td>
<td>&lt;2.5%</td>
</tr>
<tr>
<td>High/Low hold rate for potassium</td>
<td>Proportion of tests held</td>
<td>12.5%</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>Sample hold rate</td>
<td>Proportion of tests held</td>
<td>3.8%</td>
<td>&lt;2.5%</td>
</tr>
<tr>
<td>Process time</td>
<td>Median time (min) from placement on back to result release to electronic medical record</td>
<td>9.58 ± 1.00 (n=6)</td>
<td>Baseline</td>
</tr>
<tr>
<td>Process time-cost</td>
<td>Weekly labor time-cost associated with review of test held for manual review</td>
<td>1678 ± 5461 seconds</td>
<td>&gt;50% reduction</td>
</tr>
<tr>
<td>Test manual verification time</td>
<td>Average time (seconds) spend reviewing held sample</td>
<td>7.1 ± 4.0 (Mean ± SD)</td>
<td>2 baseline</td>
</tr>
<tr>
<td>50th percentile TAT for STAT potassium level</td>
<td>Average weekly time in minutes</td>
<td>51.9 ± 1.0 (n=6)</td>
<td>Baseline</td>
</tr>
</tbody>
</table>

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Improve and implement

**IMPROVE**
- Prioritize OFIs
- Optimize settings for improved system
- Risk Assessment
- LEAN concepts
Control

CONTROL
• Validate Improvements
• Institutionalize
• Close out project

Gains:
• Manual verification time/sample increased 3x
• Total manual verification time/week decreased to ~1/3
• Median Analytical processing time significantly decreased by 1 to 3 minutes
• Test AV rate increased to ~95% at all 3 sites
• Sample AV rate increased to >90% at all 3 sites

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>AV Rate</th>
<th>Sigma¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSC test</td>
<td>8</td>
<td>0.962 ± 0.005</td>
<td>13.6</td>
</tr>
<tr>
<td>HSC sample</td>
<td>8</td>
<td>0.947 ± 0.014</td>
<td>3.4</td>
</tr>
<tr>
<td>WMH test</td>
<td>8</td>
<td>0.983 ± 0.003</td>
<td>28.1</td>
</tr>
<tr>
<td>WMH sample</td>
<td>8</td>
<td>0.911 ± 0.009</td>
<td>1.2</td>
</tr>
<tr>
<td>SCH test</td>
<td>5</td>
<td>0.977 ± 0.002</td>
<td>31.6</td>
</tr>
<tr>
<td>SCH sample</td>
<td>5</td>
<td>0.925 ± 0.003</td>
<td>8.5</td>
</tr>
</tbody>
</table>

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## Making it work

### Challenges
- Completing Projects
- Mentors
- Training and Certification
- Commitment
- Culture

### Strategies
- Project Charters
- Mentor and Sponsor involvement throughout
- Leadership Commitment and Involvement

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**Attention to the human element is critical to success!**

Attention must be balanced across technical, process and human elements.

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Summary

- Six Sigma is a data driven process improvement scheme focusing on adding value by removing defects.
- Six Sigma metrics and process are easily adaptable to Laboratory Medicine and moves the laboratory toward:
  - Proactivity
  - Metrics driven performance
  - Continuous Improvement
  - Quality Minded Culture