Lean and Six Sigma in the Clinical Laboratory

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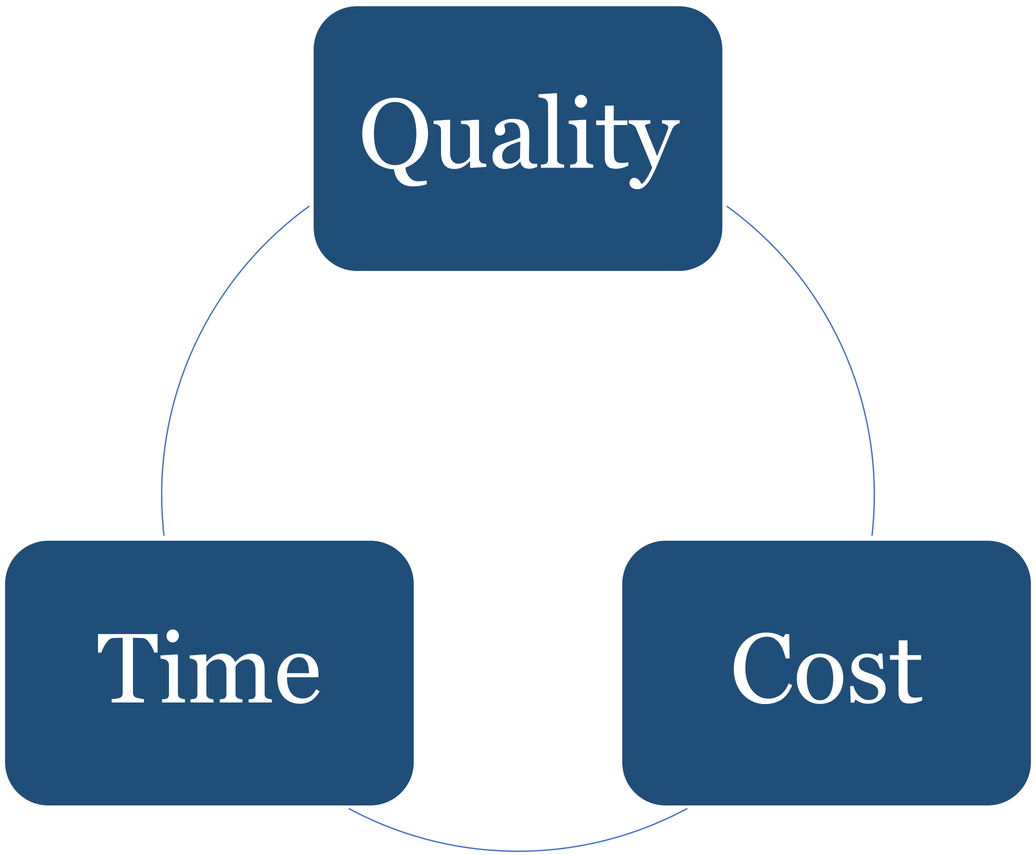
Improving Laboratory Performance

The 3 Keys – The 3 Ps

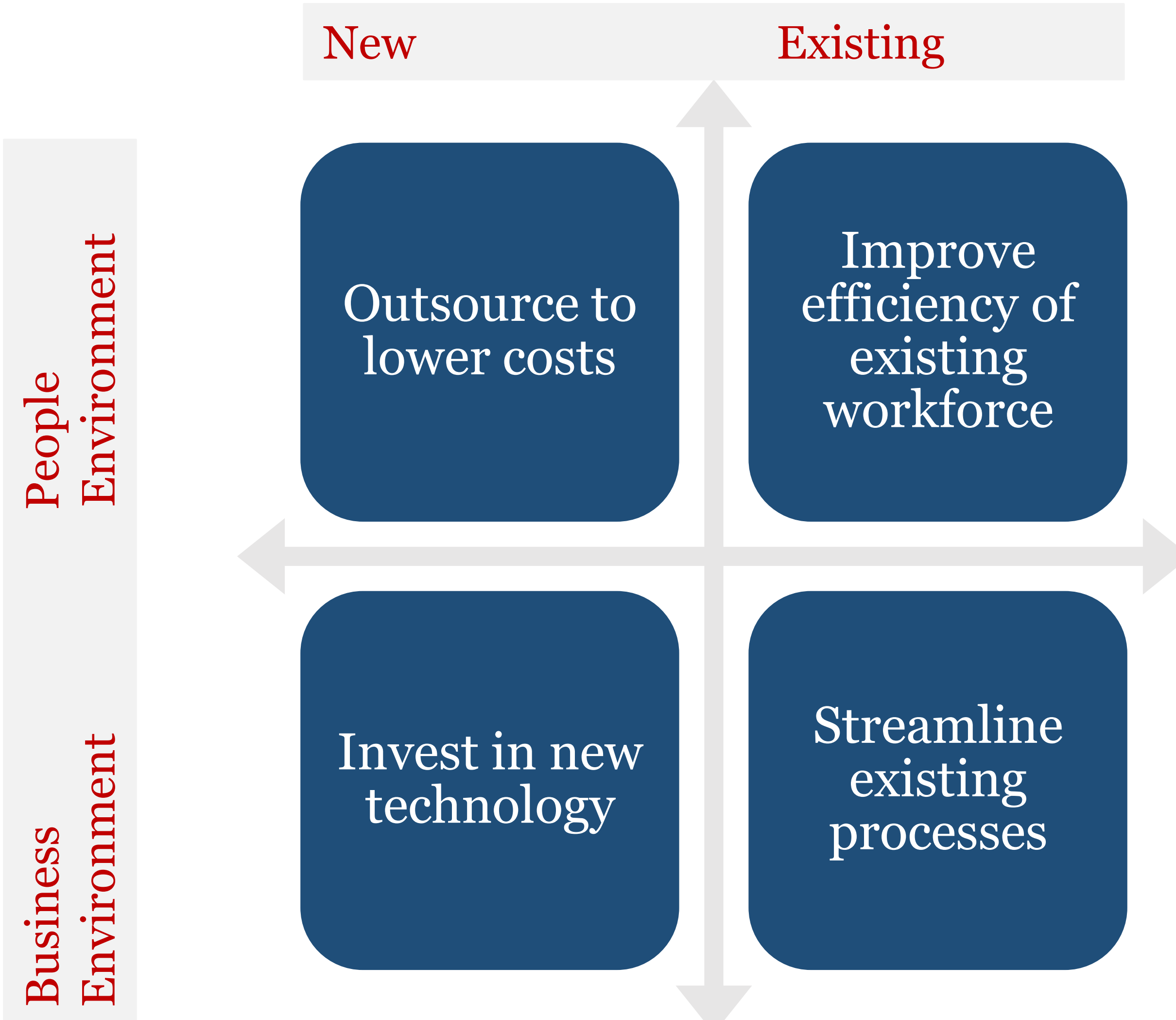
- People
- Product
- Process

Improving Laboratory Performance



Change the System to Improve all Three

Changing the System



ISO 15189:2012

Requirements for Quality & Competence in NABL

4.12 – Continual improvement

- The laboratory shall continually improve the effectiveness of the quality management system, including pre-examination, examination and post examination processes

4.14.7 –Quality Indicators

- The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination.

3.19 Quality Indicator

- Measure of the degree to which a set of inherent characteristics fulfils requirements
- NOTE 1:

  Measure can be expressed, for example, as

  - % yield (% within specified requirements)
  - % defects (% outside specified requirements)
  - Defects per million opportunities (DPMO)
  - Or on the Six Sigma scale

Quality Improvement Tools

Conventional Tools

- Internal audits
- External quality assessment
- External audit and accreditation
- Management review
- Opportunities for improvement
- Quality indicators

Newer Trends

- Lean
- Six Sigma
- Plan Do Study Act
- Root cause analysis
- Failure Modes and Effects Analysis

Lean Methodology

Lean Methodology

- Application of the Toyota Production System
- Driven by identification of customer needs and aims to improve processes by removing activities that are non value-added (waste)
- Steps involve maximising value-added activities in the best possible sequence to enable continuous operations
- Depends on Root Cause Analysis (RCA) – improve quality – prevent similar errors (4.10 and 4.11 of ISO 15189:2012)

Clinical Lab – Process Driven

Pre-examination

- Request form
- Primary sample collection and handling
- Sample transportation
- Sample reception

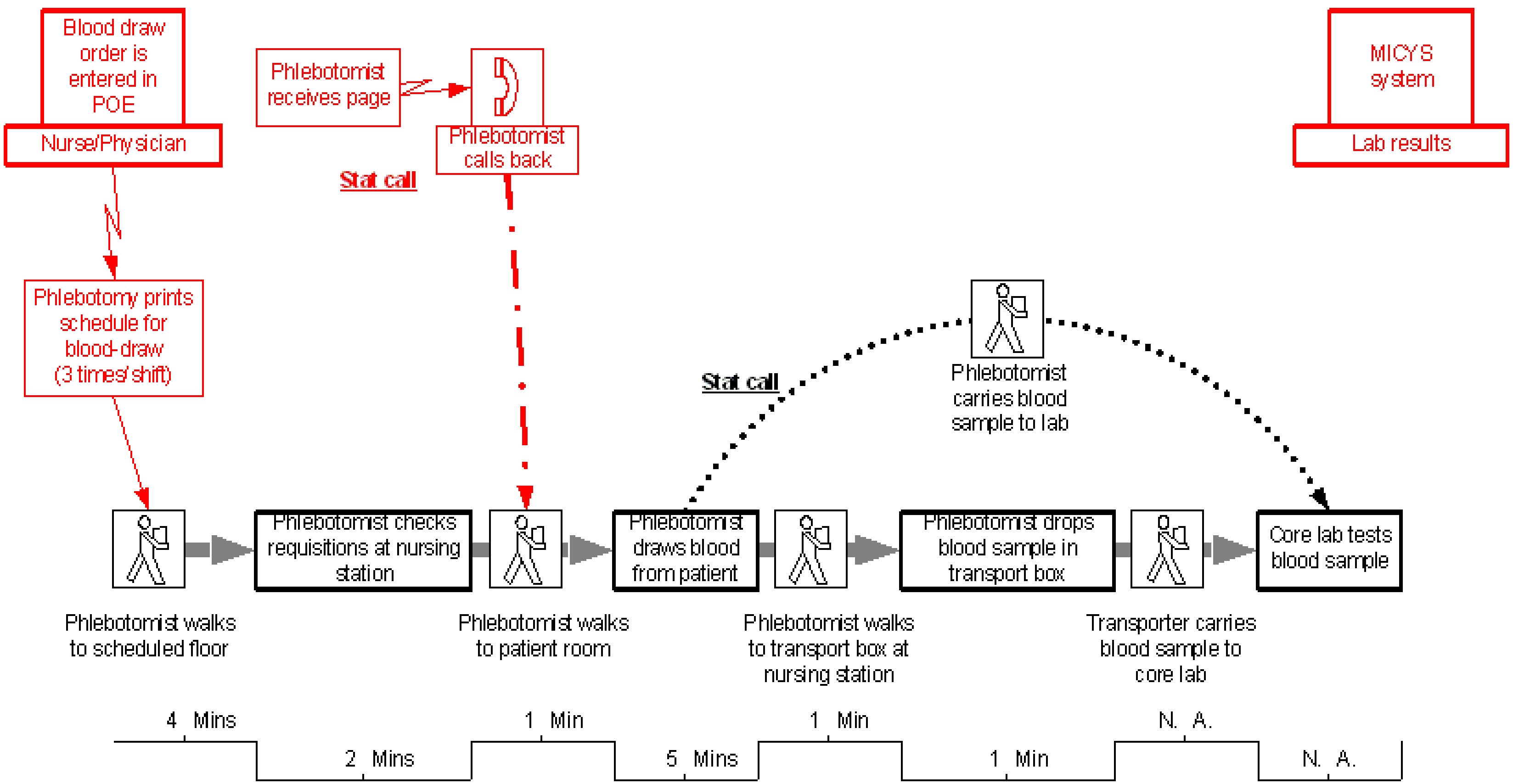
Examination

- Examination procedure
- Quality control

Post-examination

- Review of results
- Storage, retention and disposal of clinical samples
- Reporting of results
- Release of results

VSM of Phlebotomy



Lean Laboratory

- Improve the process
  - Identify and map the value stream, streamline the process
  - Make value flow, create pull and eliminate non- value adding activities
- Improve sample and test scheduling
  - Prioritise samples
  - Smooth sample flow
  - Optimise resource use - level the load and mix
- 2 key activities in lean lab (80% of cost and efficiency gains)
  - Process improvement
  - Test scheduling

Kaizen Changes

Heijunka

- Levelling and sequencing an operation
- Level loading work and sequencing the operation of phlebotomists decreases sample waiting time
- Reduces batching of samples

5S Approach

- Reduces steps
- Increases touch time
  - Sort
  - Set in order
  - Shine
  - Standardise
  - Sustain

Case Study – 450 sample collections / day

Customer Need

Faster results	Average TAT: 4 hours

Time Value Analysis

Phlebotomy Chemistry Analysis	Upto 1 hour Upto 30 minutes

Kaizen Changes

Levelling and Sequencing Changes in shifts and responsibilities	5S Layout changes, SOPs and training

Results – TAT reduced to less than 3 hours

Six Sigma

Six Sigma Methodology

- DMAIC – DMADV – DFSS
- DMAIC – data driven quality strategy for improving processes – used to improve existing business processes
- **D**efine the problem or project goal
- **M**easure the problem or process from which it was produced
- **A**nalyse data and processes to determine root cause of defects and opportunities
- **I**mprove the process by finding solutions
- **C**ontrol – implement, control and sustain improvement solutions

Practical Application of Six Sigma

- Insufficient sample volumes
- Haemolysed specimen
- Inadequate anticoagulant ratio
- Patient ID errors
- Lost samples
- Unacceptable IQC
- Unacceptable EQA
- Evaluating manufacturer for new analytical equipment

How to Measure Sigma Metric

Measure Outcome

Inspect outcomes and count defects

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Calculate Defect Per Million (DPM)

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Convert DPM to SIGMA metric

Useful for pre- and post-examination processes

Measure Variation

Measure variation (Bias, CV)

↓

Calculate SIGMA

SIGMA=(TEa – bias)/CV

↓

Implement "Right QC"

Useful for examination processes

Define Phase

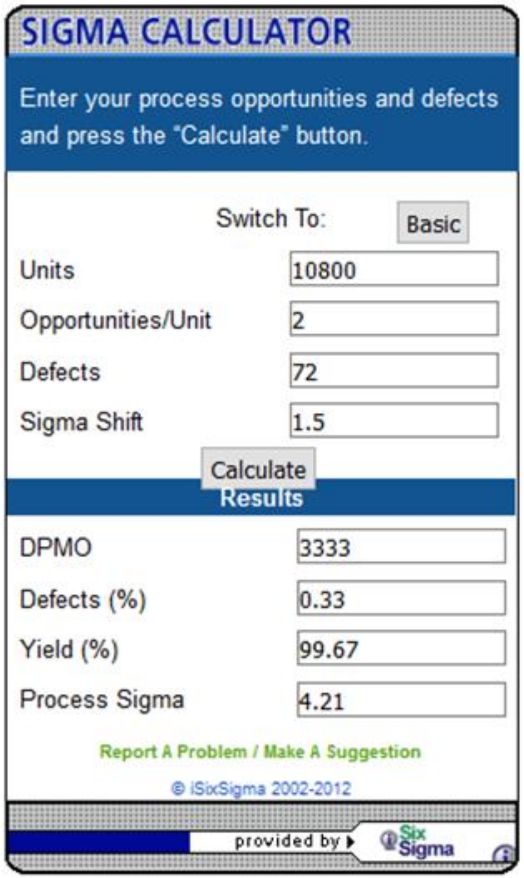
Measurement of Outcome:

Pre-analytical errors

- Insufficient sample volume
- Haemolysed samples
- Inadequate anticoagulant ratio

- Project team
- Document customers and core business processes
- Develop a project charter
- Develop SIPOC process map (suppliers – input – process – output – customers)
  - Identifies the current processes
  - Identifies how the processes should be modified and improved

Measure Phase



Sigma metric = 4.2

- Data collection
- Data evaluation
  - Calculate Defects Per Million Opportunities (DPMO) from existing data using:

$$\text{DPMO} = \frac{\text{(Number of defects)}}{\text{(No of opportunities)} \times \text{(No of units)}} \times 1{,}000{,}000$$

- Convert DPMO to Sigma metric using
  - Six Sigma table
  - Excel software

Six Sigma Scale

Sigma	Error (%)	Error (DPM)
1	69%	691462
2	31%	308538
3 (Minimum acceptable)	6.7%	66807
4	0.62%	6210
5	0.023%	234
6	0.00034%	3.4

Analyse Phase

Root Cause Analysis

- Brand of tubes used
- Inadequate training in phlebotomy
- No SOPs
- High turn over of staff

- 5 specific types of analysis
  - Source
  - Process
  - Data
  - Resource
  - Communication

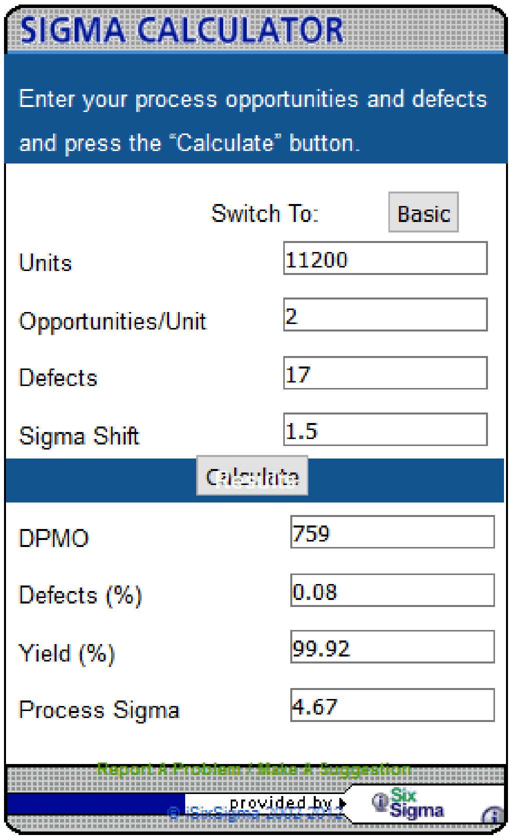
Improve Phase

Improvement Plans

- Changed sample tubes to a reputed brand
- Phlebotomy training to staff
- Training on SOPs

- Identify improvement breakthroughs
- Identify and select high gain alternatives
- Select preferred approach
- Design the future state
- Determine new Sigma level
- Perform cost/benefit analysis
- Design dashboards / scorecards
- Create preliminary implementation plan

Control Phase



Sigma metric = 4.7

- 4 specific aspects of control
  - Quality control
  - Standardisation
  - Control methods and alternatives
  - Responding when defects occur

Sigma Metric for Process Performance

- To achieve 3 sigma, usually only obvious changes and corrections are required
- To achieve 4 sigma, processes must also be improved
- To achieve 5 sigma, the design of the processes must be improved
- To achieve 6 sigma requires rigorous tools and a design for perfection

Realistic goal is to cut number of defects by half rather than trying to achieve 6 sigma for every process

In conclusion .....

- Lean and Six Sigma are both extremely powerful tools for quality improvement
- Lean – Used to enhance speed or reduce waste
- Six Sigma – Used for quality improvements
- Challenges to be expected
  - Data collection
  - People
  - Communication

Thank You