

Does Lean and Six Sigma Make a Difference to the Business of Providing Laboratory Services?

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Agenda

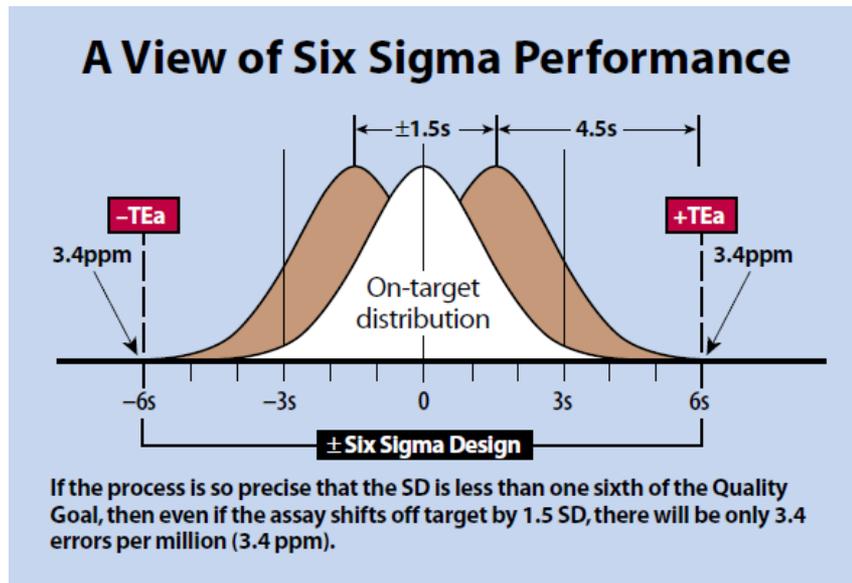
- Six Sigma
- Lean
- Lean and Six Sigma
- Lean Six Sigma Strategy
 - Problem solving methods (DMAIC)
 - Statistical evaluation of laboratory performance (Sigma Metric or DPMO)
- Applications of Lean Six Sigma Methodology in Clinical Laboratories
- Case Studies
- Conclusion

Six Sigma

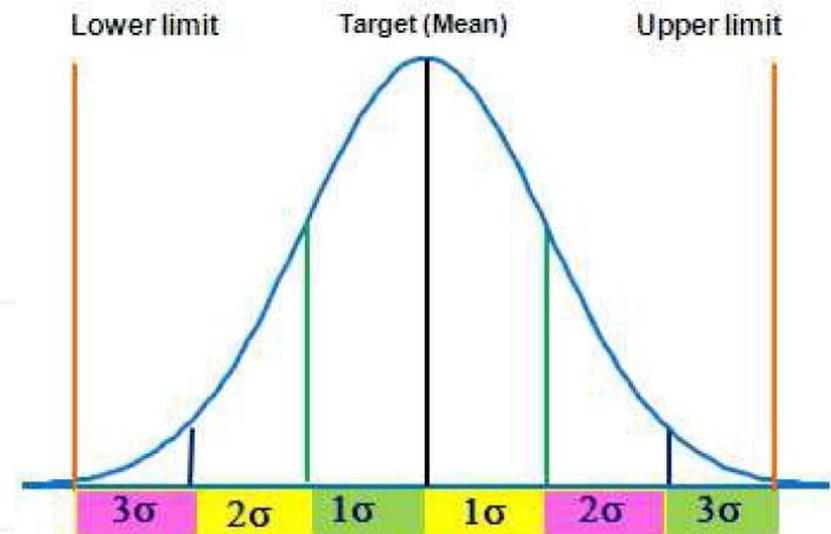
- Six Sigma is **the latest version** of total quality management (TQM) and **represents an evolution in quality** that is being implemented widely, particularly **in business and industry**, in the new millennium.

Six Sigma

A 6 sigma process



A 3 sigma process



- Six Sigma is not only a tool to quantify quality on a specific scale such as Sigma Metric
- **It is a powerful methodology applicable to virtually every human enterprise**
- The ultimate goal of Six Sigma breakthrough methodology is to set up processes achieving **Six Sigma performance**

Lean

- Lean is a discipline, that focuses on **process speed and efficiency**
- The “lean concept” means creating greater value for patients with fewer resources.
- A lean organization focuses on creating processes that need
 - less space,
 - less capital,
 - less time, and
 - less human effort by reducing and eliminating waste.
- By “waste,” we mean anything that adds no value to the process.
- The slogans of the lean concept “do it right the *first time*.”

- **Six Sigma** focused more on quality than speed
- **Lean** are better at improving process flow and speed than on improving quality

Lean + Six Sigma

- Quality, speed and low cost
 - Laboratory test results should be released as quickly as possible and on time **(SPEED)**
 - With no (or minimum) errors **(HIGH QUALITY)**
 - And at a lowest possible price **(LOW COST)**

Lean Six Sigma or 3M

- **M**aximum quality
- **M**inimum time
- **M**inimum cost

3M

Maximum Quality

- A process that makes a lot of errors cannot keep up its speed
- High quality increase the speed of the process

Minimum Time

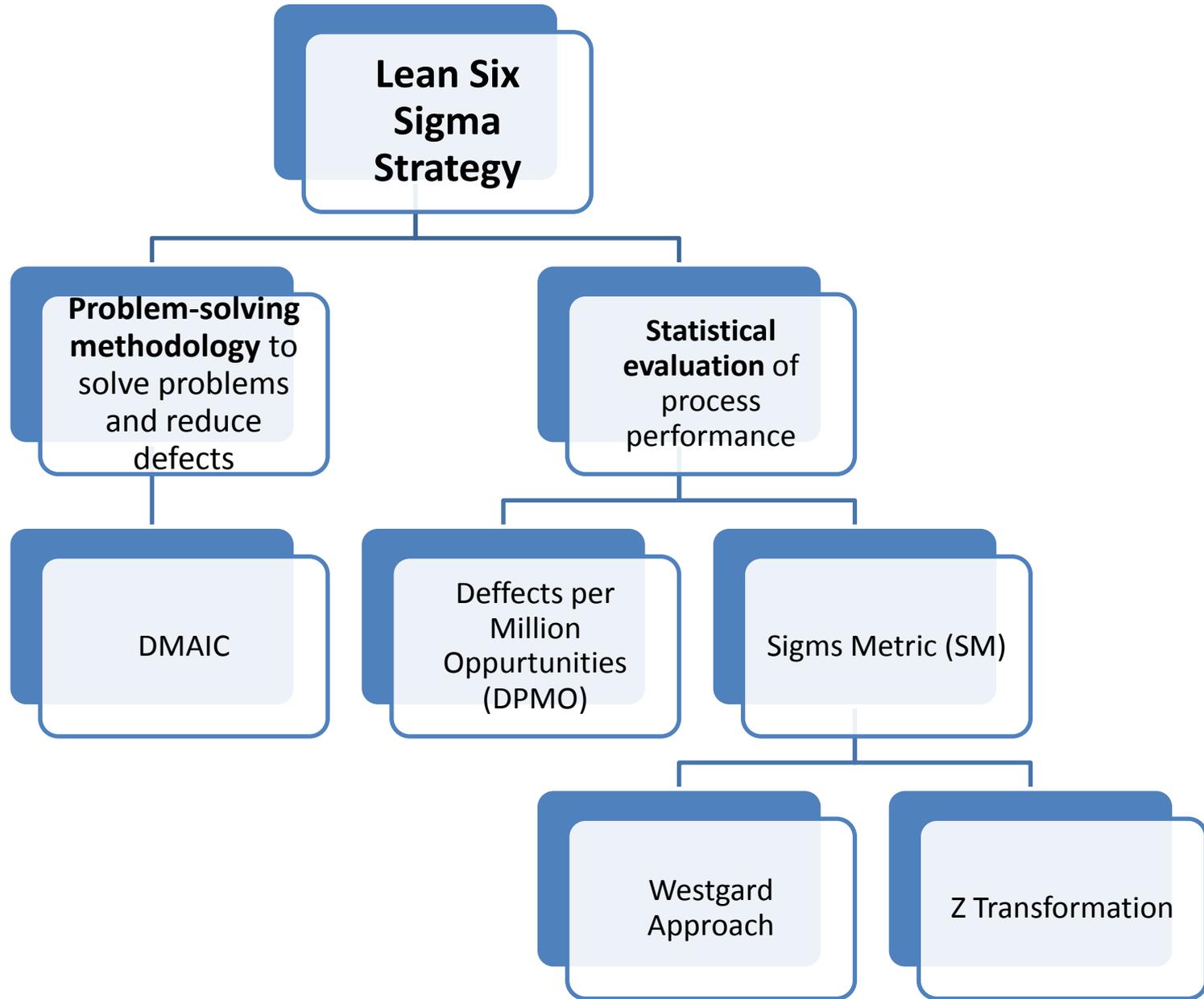
- If the process works slowly it is prone to errors

Minimum Cost

- High quality and high speed decrease the cost of clinical laboratories

- Lean Six Sigma strategies are based on two important principles:
 - (a) **Problem-solving** methodology and
 - (b) **Statistical evaluation** of process performance

Lean Six Sigma Strategies



Problem-solving Methodology

- The **Problem-solving** or **Lean Six Sigma methodology** is often summarized as the acronym **DMAIC**, for

- **D**efine
- **M**easure
- **A**nalyze
- **I**mprove and
- **C**ontrol



8 Steps of Methodology

Order	Step	Phase
1	Recognize	Identification
2	Define	
3	Measure	Characterization
4	Analyze	
5	Improve	Optimization
6	Control	
7	Standardize	Institutionalization
8	Integrate	

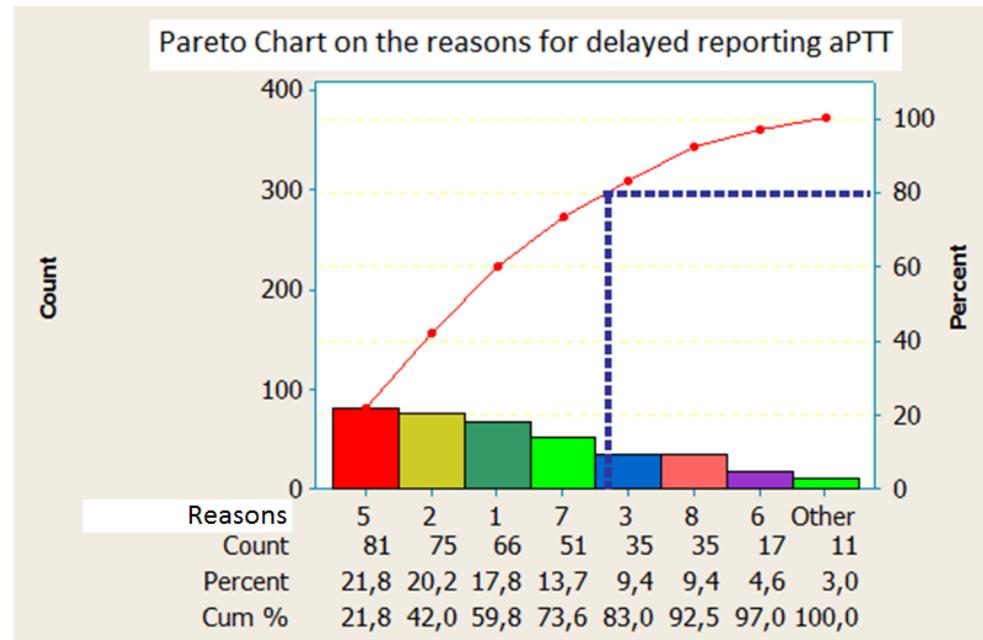
- DMAIC has proven itself to be one of the **most effective problem-solving methods** ever used because it forces teams to use data

DEFINE-M-A-I-C

- In the first step of DMAIC we have to define ‘what is the project’ in detail?
- In this step we have to
 - Set the team
 - Draw a road map for success
 - Discuss the project with the team in detail and reach agreement with management on a realistic scope

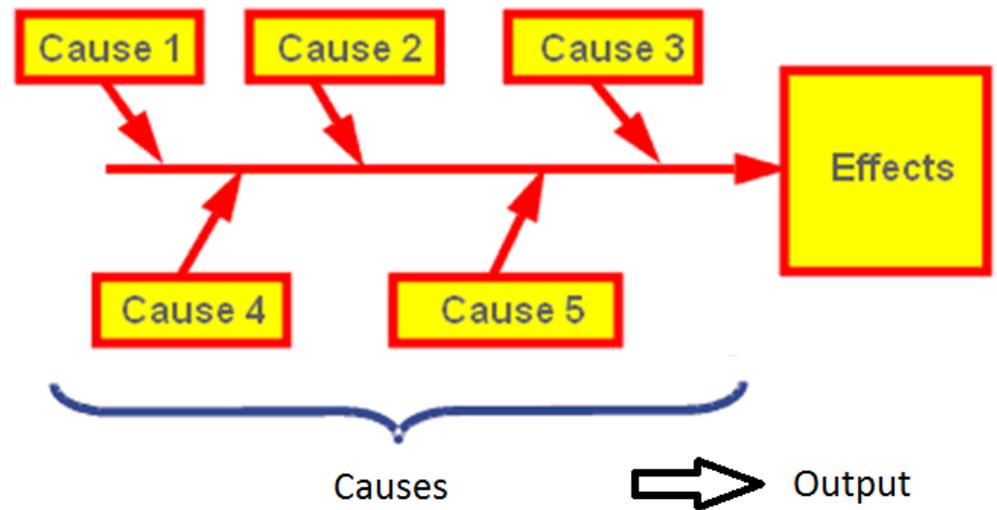
D-MEASURE-A-I-C

- 'Measure' is the heart of Lean Six Sigma projects
- Various tools can be used in MEASURE step such as
 - Time Value Maps
 - Pareto Charts
 - Time Series Charts



D-M-ANALYZE-I-C

- In this step we have to analyze and determine the root cause(s) of the problems

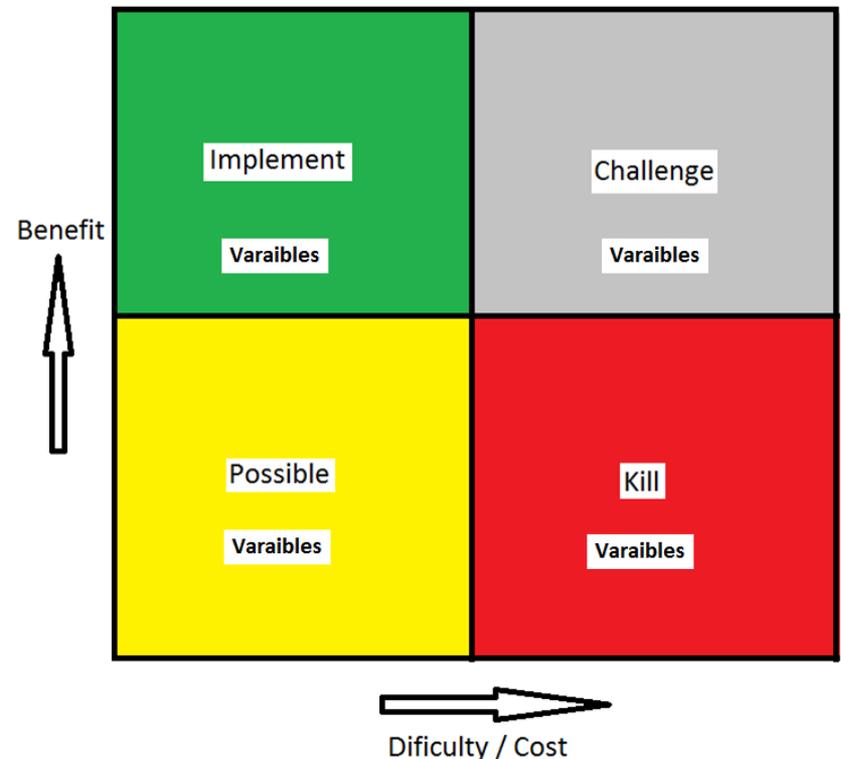


D-M-A-IMPROVE-C

- In this step we have two main purposes:
 - To **eliminate variation** in quality and speed
 - To **improve process flow and speed**
- We have to eliminate everything that interrupts or hinders laboratory productivity

- We have to eliminate the defects, waste, costs and so on, that are linked to the test results and physicians need
- We can use PICK chart to evaluate alternative solutions

PICK Chart

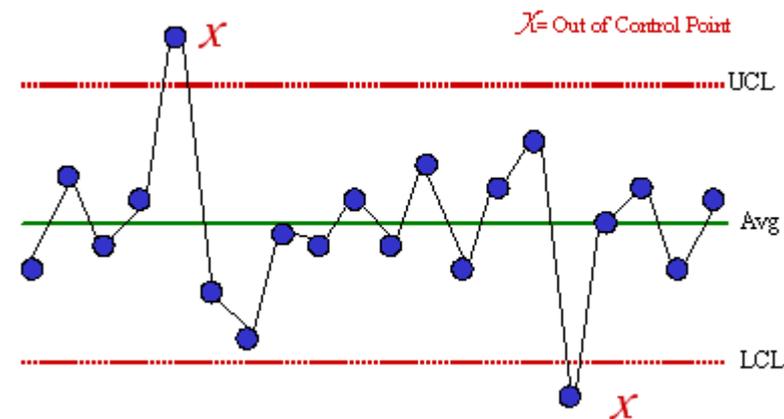


D-M-A-I-CONTROL

- This step is specific to Six Sigma methodology and intended to prevent defects from returning to the process.
- It means ongoing assurance that performance meets the goals and objectives defined for the process.

Control Charts

- In control step we have to
 - Document the improved new procedure and
 - Train our team
- Note that **Changing habits is harder than changes the switches** on a laboratory instrument
- To monitor the process we usually use control charts



Statistical Evaluation of Laboratory Performance

- Sigma Metric
 - Westgard Approach
 - Z Transformation
- Defects Per Million Opportunities (DPMO)

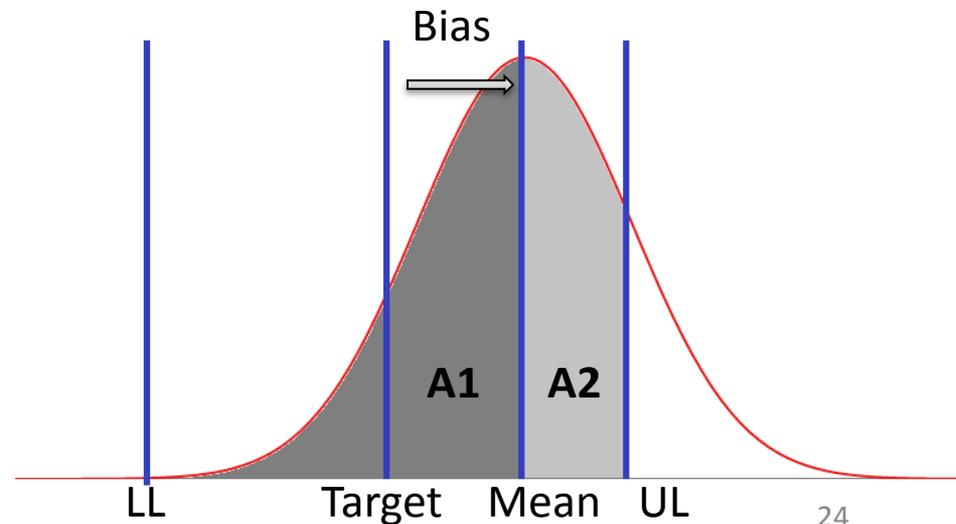
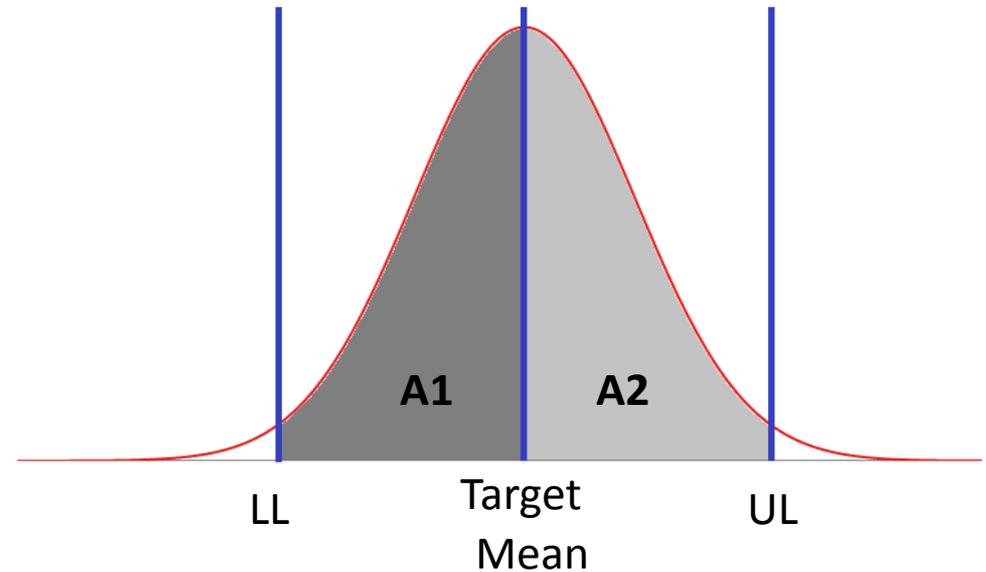
Sigma Metric (Westgard Approach)

- $SM = \frac{TEa-B}{\sigma}$

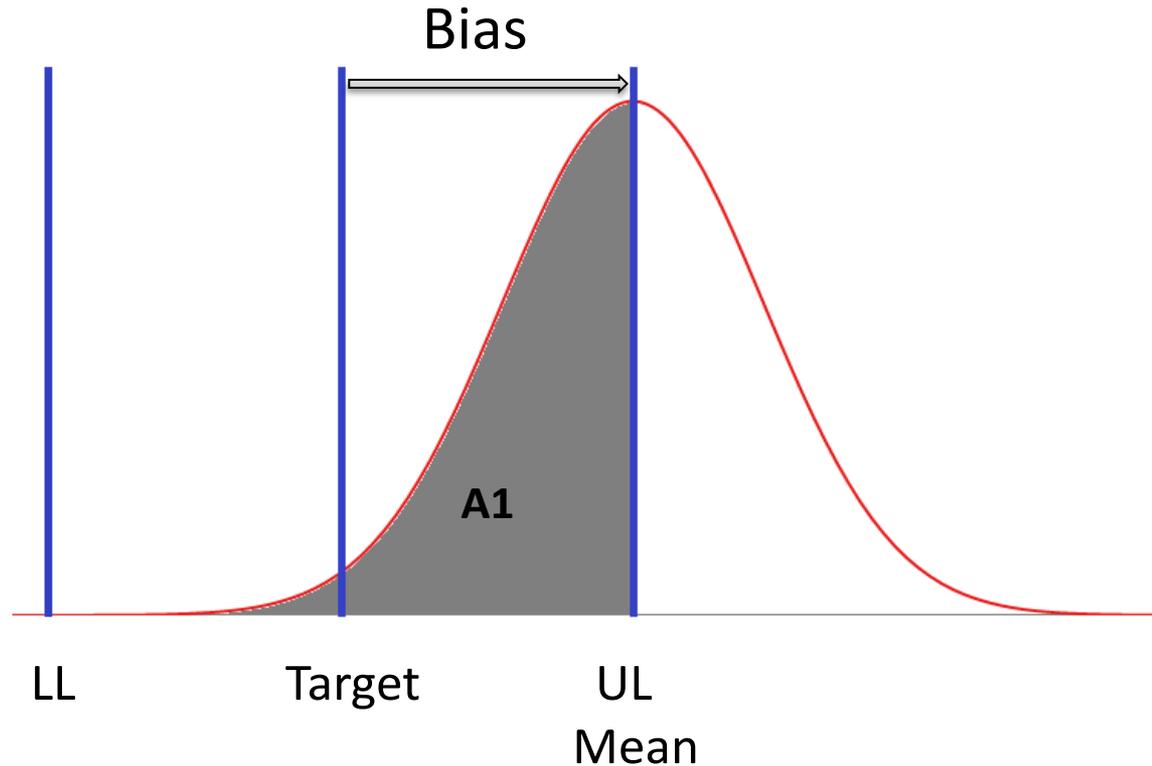
or

- $M = \frac{TEa-B}{CV}$

- Westgard approach overestimates laboratory errors and underestimates laboratory performance both in internal and external QC procedures.



- According to Westgard approach the SM of this process is zero
- However %50 of data produced by this process is located between LL and UL.



Z Transformation

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DISCUSSION FORUM

A new approach to calculating the *Sigma Metric* in clinical laboratories

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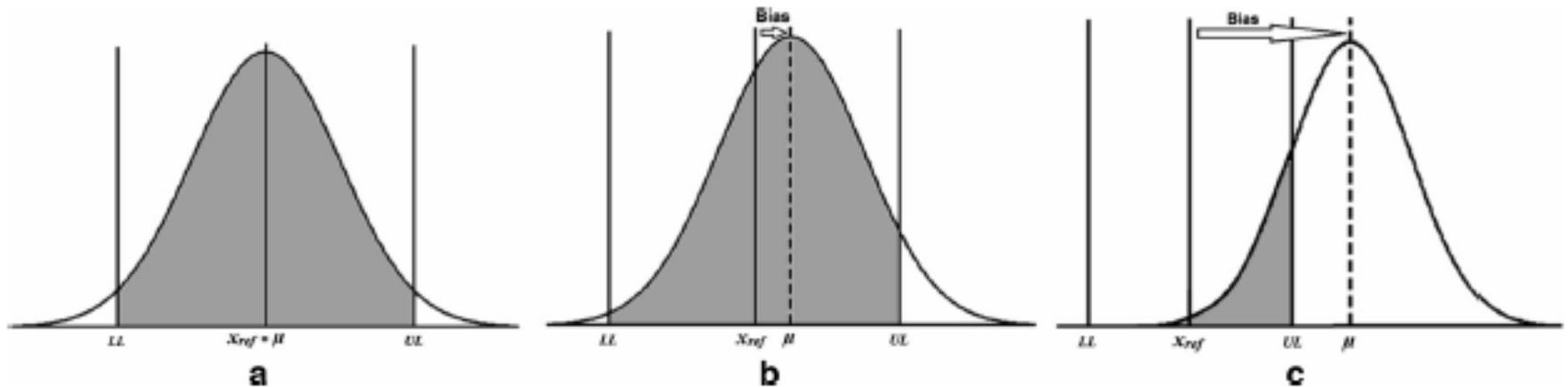
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Abstract In clinical laboratories, the performance of a process as *Sigma Metric* (*SM*) is calculated by the equations derived by Westgard. In the present study, we found that the Westgard equations do not reflect the real performance of the process and that the *SM* calculated using these equations is lower than the real *SM*. We measured the

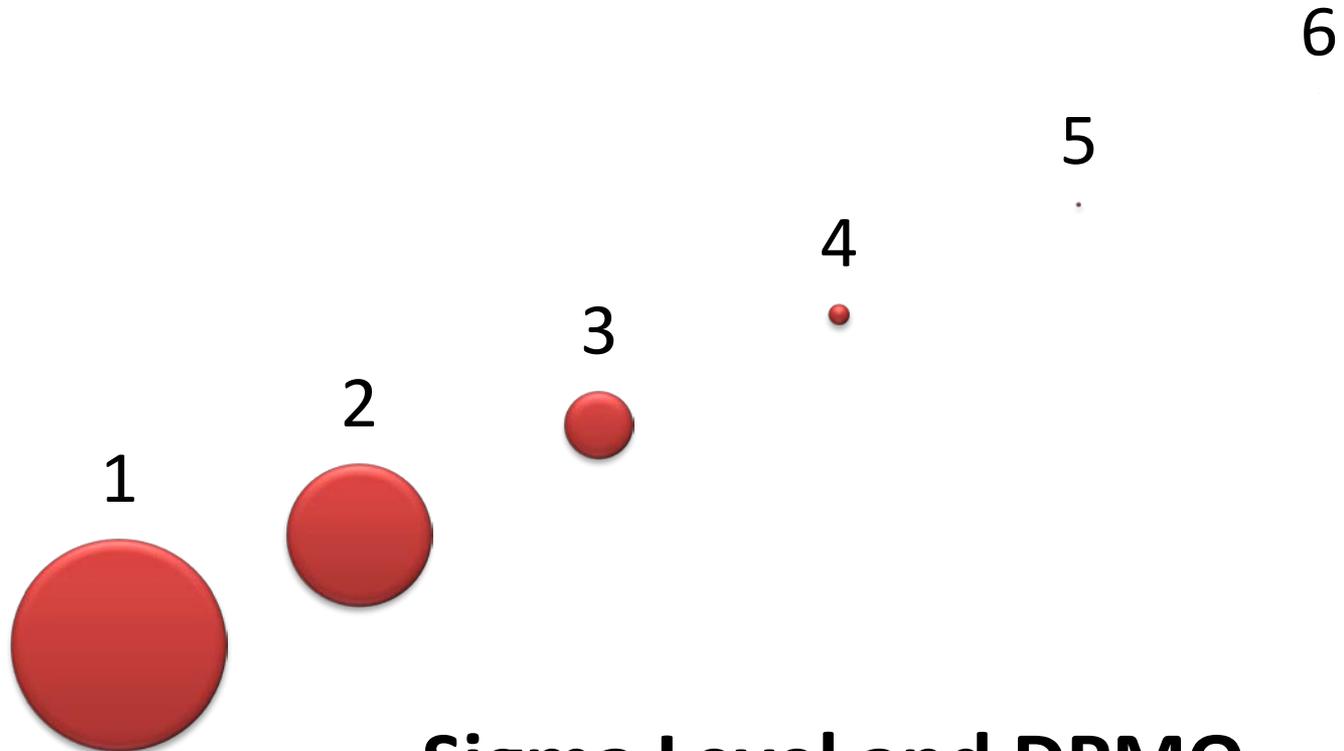
Introduction

The Six Sigma methodology represents an evolution in quality management that is being implemented widely, particularly in business and industry, in the new millennium. The principles of Six Sigma are linked to Motorola's

Z Transformation is the Gold Standard in Sigma Metric Calculation



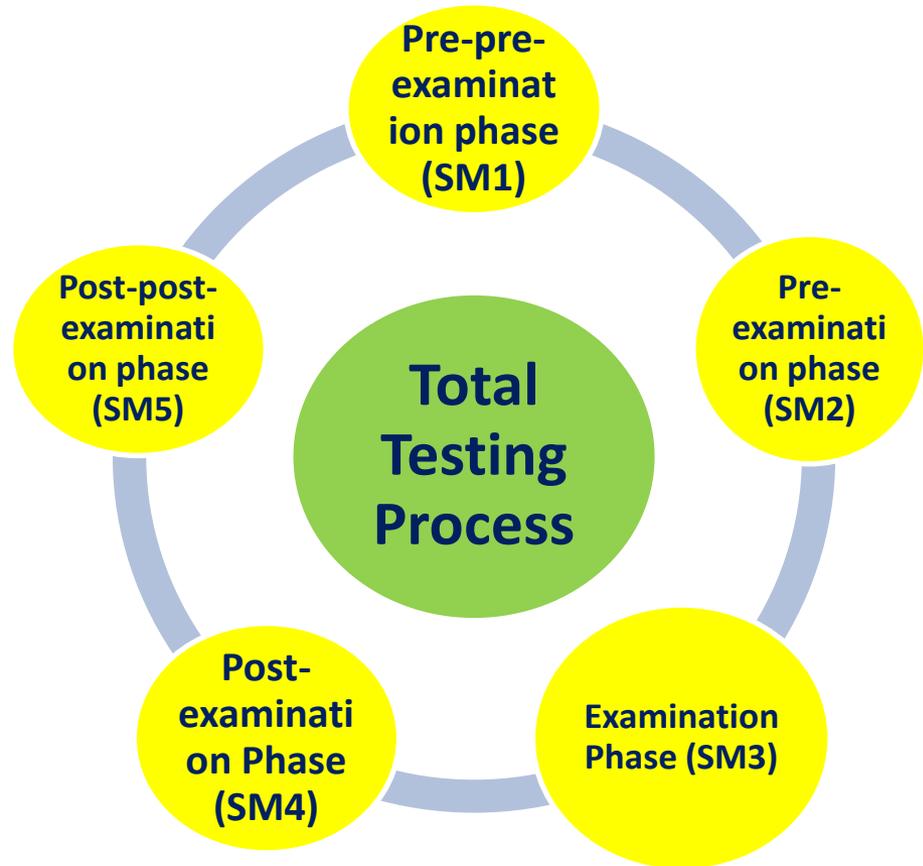
DPMO



Sigma Level and DPMO

Applications of Lean Six Sigma Methodology in Clinical Laboratories

- In clinical laboratories most errors (Approximately %90) are linked to pre- and post-examination phases.
- In the first step we should apply Six Sigma Methodology to pre- and post- examination phases



Statistics in Total Testing Process

Total Testing Process	SM or DPMO	Lean Six Sigma Methodology
Pre-pre-examination Phase	DPMO	
Pre-examination Phase	DPMO	
Examination Phase	SM	
Post-Examination Phase	DPMO	
Post-post examination phase	DPMO	

Letter to the Editor

Six Sigma and laboratory consultation

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Keywords: laboratory consultation; laboratory errors;
quality control; Six Sigma.

implemented in business and industry in the new millennium. In all projects and process improvements with Six Sigma tools, the road map that should be followed is expressed as: “define, measure, analyze, improve and control stages” (DMAIC) (5). The Six Sigma strategy measures the degree to which any process deviates from its goal. The sigma value indicates how often defects are likely to occur; the higher the

Case Studies

Case 1

Improving Preanalytic Processes Using the Principles of Lean Production (Toyota Production System)

Thomas J. Persoon, MS,^{1,2} Sue Zaleski, MA,¹ and Janice Frerichs¹

Key Words: Preanalytic; Process improvement; Lean production; Turnaround time

DOI: 10.1309/865V7UMFPUKGC8D

- The authors used principles of lean production (the Toyota Production System) to redesign preanalytic processes.
- At the end of the project the median preanalytic processing time was reduced from 29 to 19 **(34%)** minutes, and the laboratory met the goal of reporting 80% of chemistry results in less than 1 hour

Case 2

- **Define**
- DSI Laboratories has used Lean and Six-Sigma methodologies to eliminate waste and reduce variation in its hospital clinical laboratory.
- **Measure and Analyze**
- After mapping its process, the laboratory found that phlebotomists were submitting samples in large batches, which created an early-morning flood of specimens.
- Sunyog M. Lean Management and Six Sigma yield big gains in hospital's immediate response laboratory. Quality improvement techniques save more than \$400,000. Clin Leadersh Manage Rev 2004;18:255–8.

Case 2

- **Improve and Control**
- Switching to single-piece workflow and distributing the workload more evenly allowed DSI to cover the same number of patients with two to three phlebotomists instead of 12.
- By establishing a more efficient workflow process within the laboratory, a single technologist could quickly move between stations and perform those tests that made up 80% of the work volume.
- The net result was a savings of more than **\$400,000** in the first year.

Case 3

- Six Sigma project to **reduce access errors**
- **Define**
- Access errors consist of errors occurring when entering patient data, ordering tests and labeling samples.
- A multidisciplinary team was assembled to lead this Six Sigma project, aiming to reduce access defects by 50% and increase staff productivity.
- Riebling NB, Condon S, Gopen D. Toward error free lab work. ASQ Six Sigma Strategy Forum Magazine 2004;4: 23–9.
- **Gras JM**, Philippe M. Application of the Six Sigma concept in clinical laboratories: a review. Clin Chem Lab Med 2007;45:789–796

Case 3

- **Measure**
- They identified that 5% of laboratory examination requests were inaccurate or incomplete: this was defined as a defect. The resulting DPMO was 7210, or 3.9 sigma.
- **Analyze**
- In the Analyze step, they discovered that 50% of errors were due to wrong entry of the patient's social security number.

- Riebling NB, Condon S, Gopen D. Toward error free lab work. ASQ Six Sigma Strategy Forum Magazine 2004;4: 23–9.
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Case 3

- **Improve**
- The Improve step of the project involved replacing addressographs (that were commonly misread) by barcoded labels to be put on laboratory requests and in designing a new training program for accessioners.
- **Control**
- In the Control phase, DPMO frequencies were routinely monitored.
- At the end of the project, the performance of the accession department increased from 3.9 sigma to 4.2 sigma, resulting in **\$339,000/year** in cost savings and increased benefit.

Case 4

- Six Sigma project concerning the post-analytical phase of laboratory testing
- **Define**
- In this project, a defect was defined as the need to modify a laboratory test result for any reason after the verification process had been completed by a laboratory technologist.

- Riebling N, Tria L. Six Sigma strategy project reduces analytical errors in an automated lab. *Med Lab Obs* 2005;37:20, 22–3.
- **Gras JM**, Philippe M. Application of the Six Sigma concept in clinical laboratories: a review. *Clin Chem Lab Med* 2007;45:789–796

Case 4

- **Measure**
- During the Measure step, they defined the DPMO as being 355, corresponding to a high performance level of 4.8 sigma.
- The project objective was to reduce post-analytical errors by 35% to obtain a performance level of 5 sigma.
- **Analyse**
- Statistical analysis revealed that 86% of errors were caused by only two types of mistakes: 52% were due to procedural errors committed by employees while reviewing results, while 34% were caused by auto-verification errors in the Laboratory Information System (LIS).

Case 4

- **Improve**

- In the Improve phase, the Six Sigma team designed a simplified result-review guideline tool to decrease errors due to laboratory technicians.

- IT department personnel created new software that allowed real-time monitoring of results coming from the analyzers, coupled to audio alarms triggered when a potential problem occurred.

- **Control**

- In the Control phase, they monitored DPMO for corrected results on a regular basis.
- The number of corrected results significantly decreased and the performance level reached the goal of 5.0 sigma.

- Riebling N, Tria L. Six Sigma strategy project reduces analytical errors in an automated lab. *Med Lab Obs* 2005;37:20, 22–3.
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The Cost of Lean Six Sigma

- If you invest 1 Euro for well organized Lean Six Sigma Project you will save (gain) approximately 5 Euros

Conclusion

- Laboratory services require systematic innovation efforts to remain competitive, up-to date and more cost-effective.
- The key is Lean Six Sigma
- It increase quality, speed and decrease cost of clinical laboratories





THANK YOU