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

Edward Randell

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

Quote

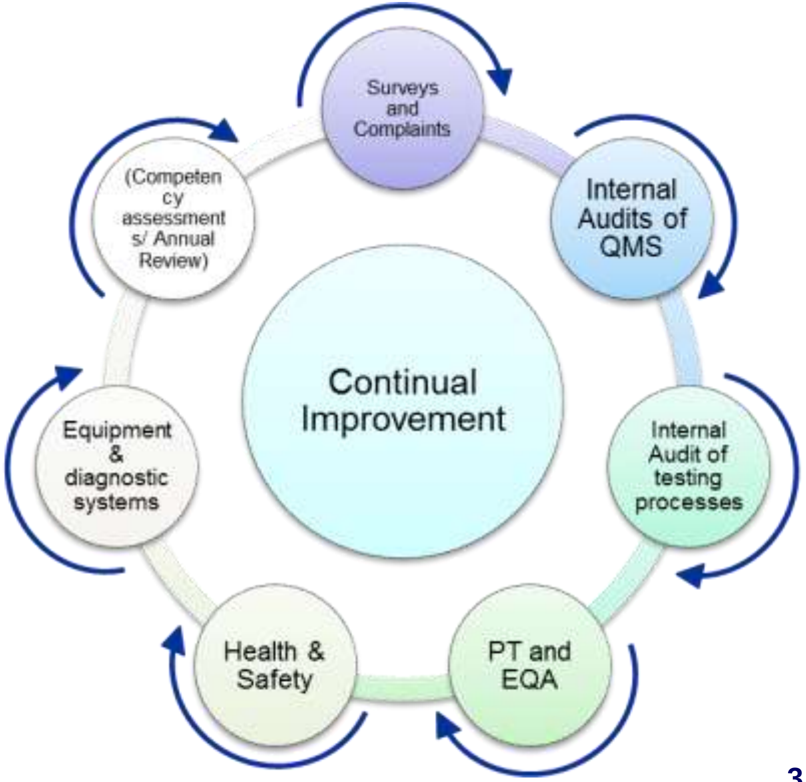
"No human investigation can claim to be scientific if it doesn't pass the test of mathematical proof."

Leonardo da Vinci

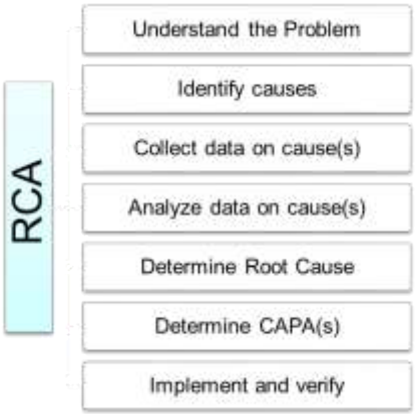
Continuous Improvement Models

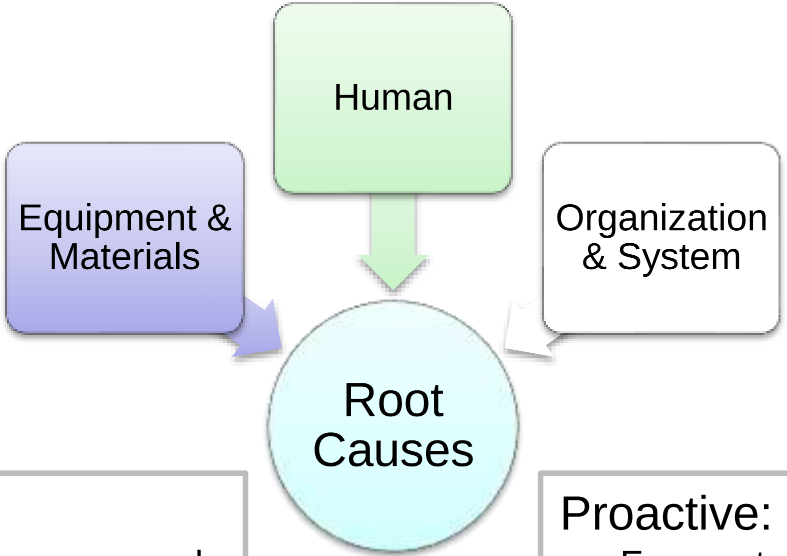
Systematic strategies:

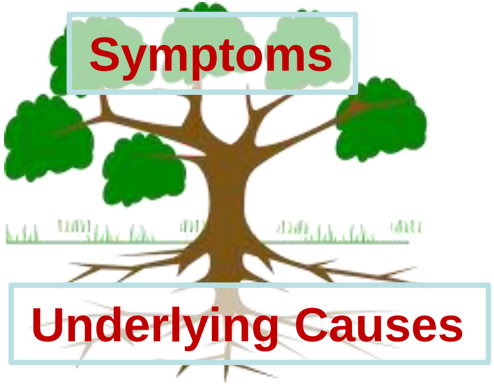
- Root Cause Analysis (RCA)
- PDCA
- LEAN
- Six Sigma (DMIAC)



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.

Continuous Improvement Models

Developed during World War II by *Walter A. Shewhart* (and promoted by his student *W. Edwards Deming*).

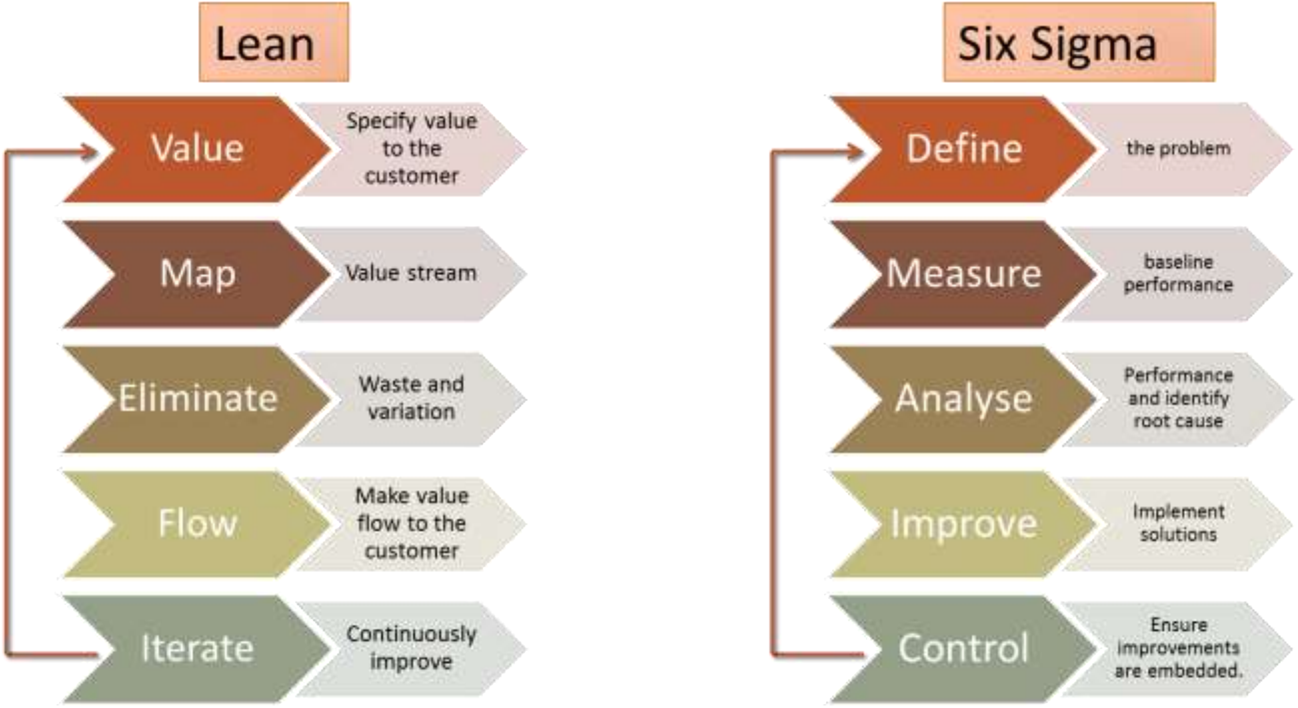
Best suited for non-complex problems

Edward Randell/ From provider of results to contributor of value: Adding value to clinical laboratory services through use of Six Sigma metrics.

Continuous Improvement Models

LEAN	Sigma
• 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.

Continuous Improvement Models



Continuous Improvement Models

LEAN & Six Sigma organizations are based on hierarchal belt systems

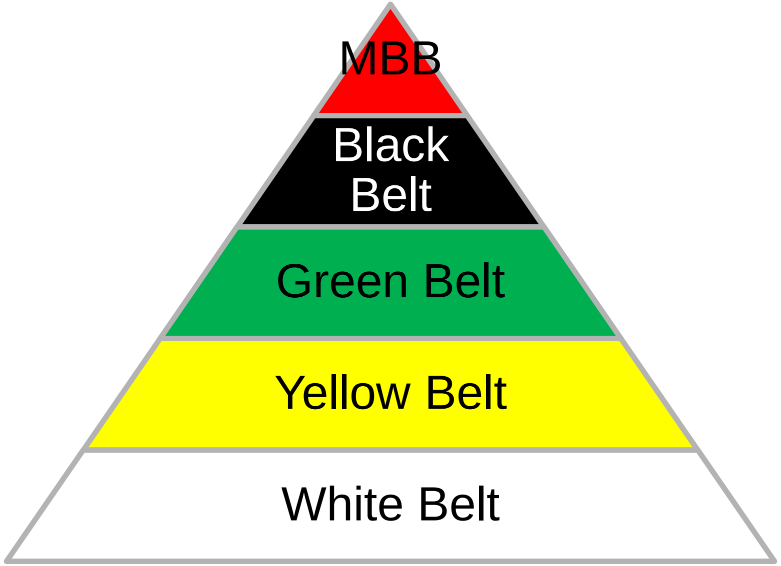
Master Black Belts – >2 years experience and train others

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.

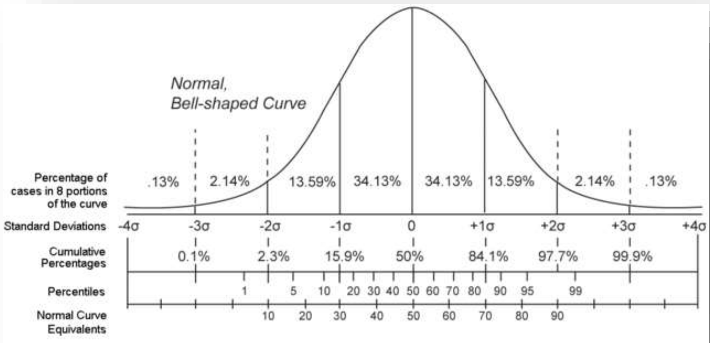
Evolution of Six Sigma

- *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…

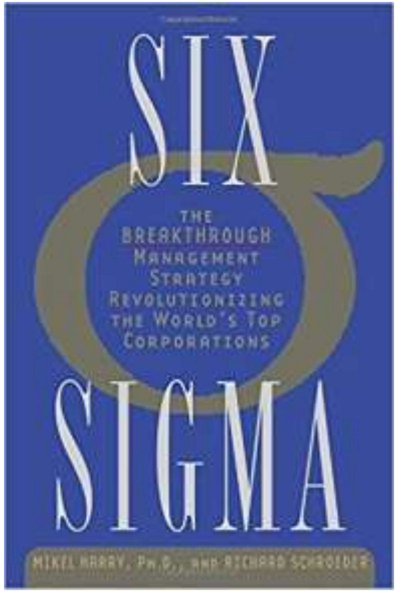
Gauss

Stewhart

Smith

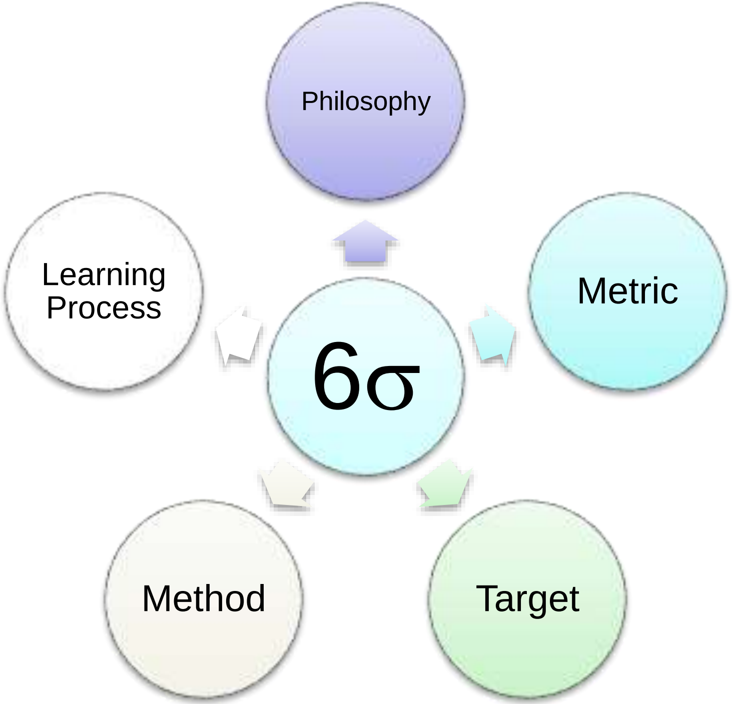


What is Six Sigma?



‘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)



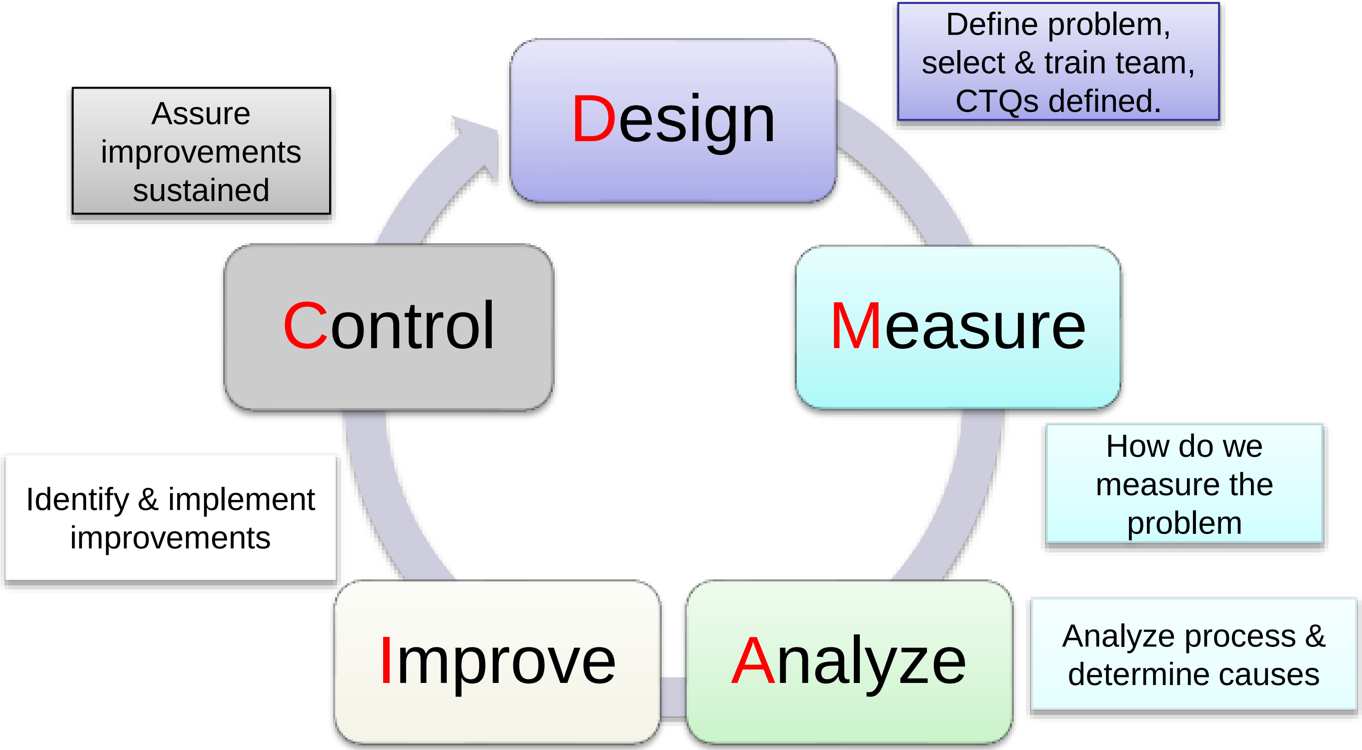
Focus: Creating value for Customers

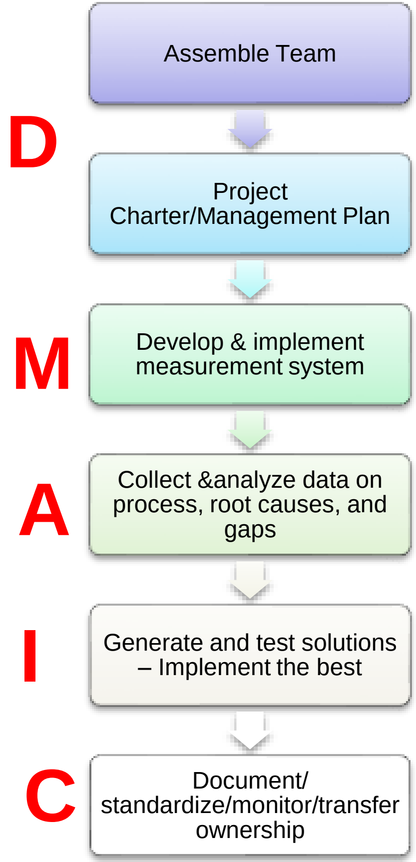
What is Six Sigma?

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

Sigma level	Defect Rate (dpm)	Yield (%) or *Accuracy*
1σ	690,000	30.8
2σ	307,770	69.1
3σ	66,811	93.3
4σ	6,210	99.4
5σ	233	99.98
6σ	3.4	99.9997

DMAIC: Six Sigma in action.





Edward Randell/ From provider of results to contributor of value: Adding value to clinical laboratory services through use of Six Sigma metrics.

The Six Sigma Focus

Value to Customer

- Patients, friends and family
- Health Care Staff
- Laboratory Staff

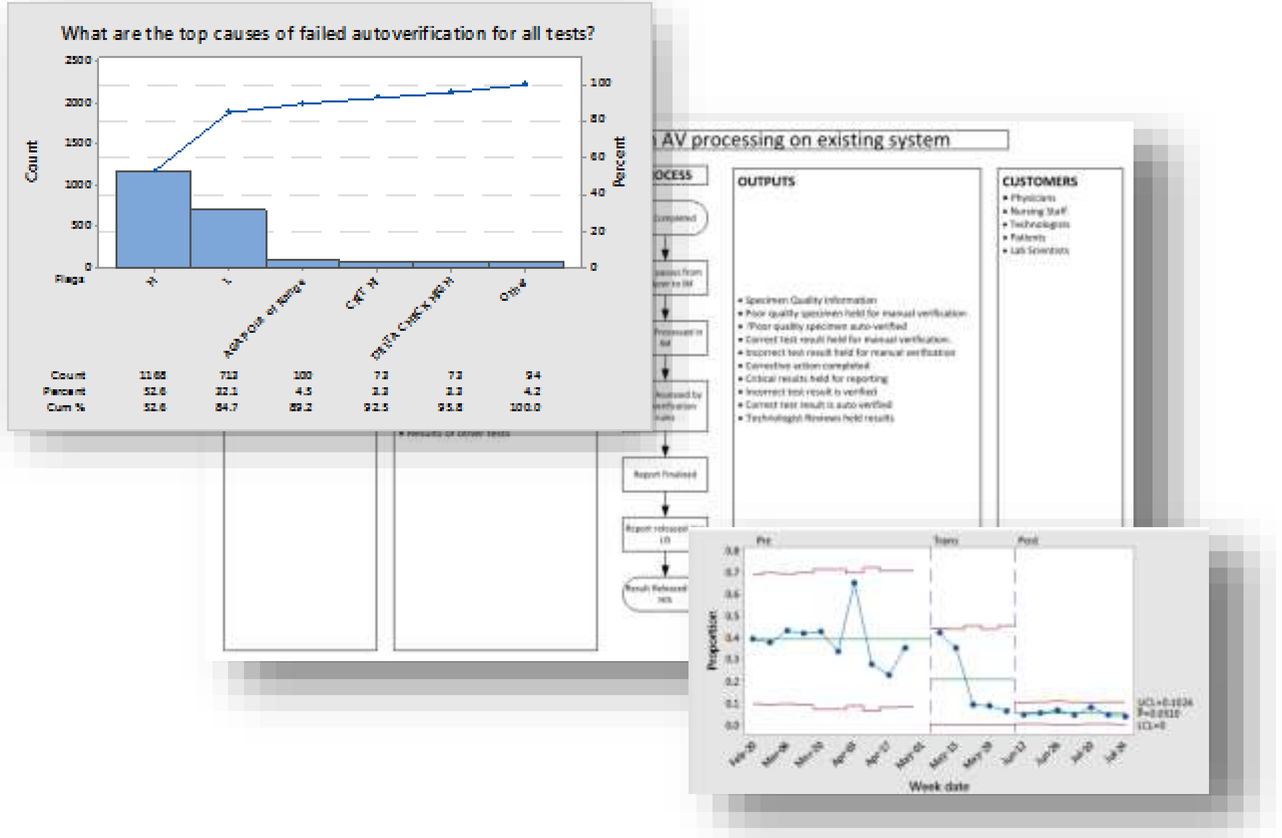
Optimizing processes for value

- Quality & Costs & Timeliness
- Patient and Employee Satisfaction
- Safety

Continuous Process Improvement

Six Sigma Tools

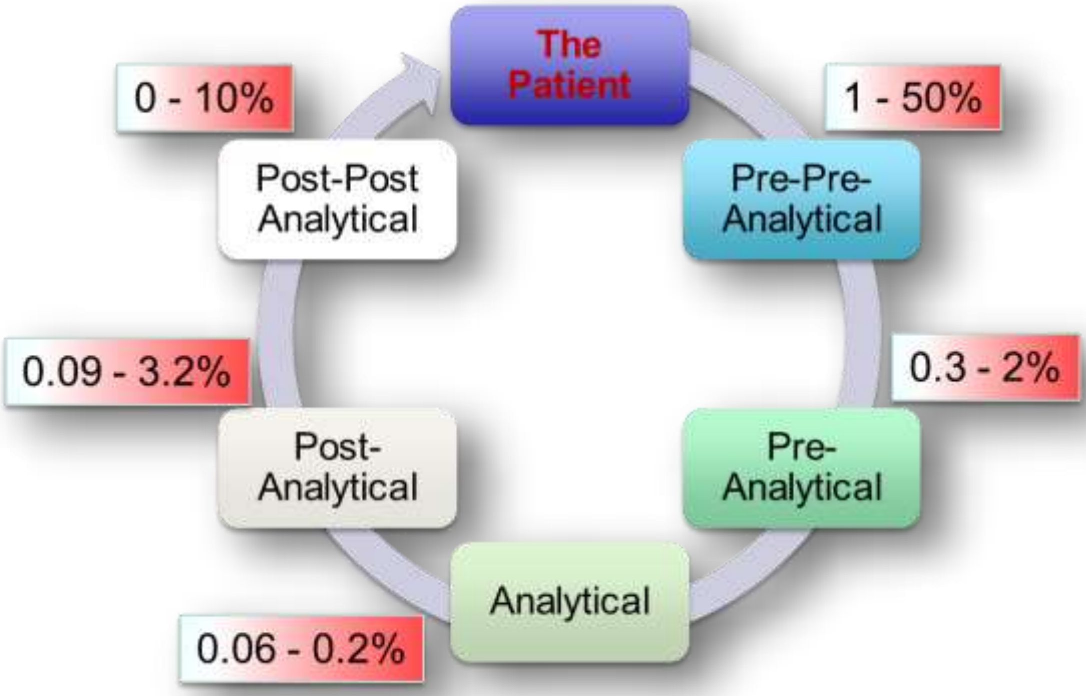
- Project Charters
- Process Flow Charts
- SIPOC Diagrams
- 5 Whys
- Brain Storming
- Pareto Charts
- Control Charts
- Statistical Analysis
- Fish-bone and RCA
- FMEA
- Sigma Calculations
- Plus many others



Medical Error: Laboratory Medicine Perspective

Six Sigma

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

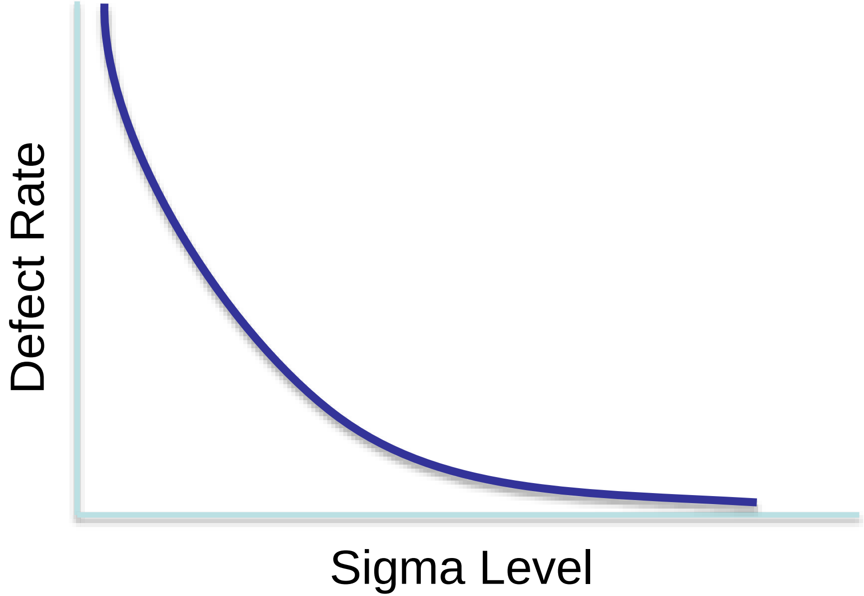


Ref:
Coskun CCLM 2007:45:121
Stroobants et al. CCA 2003;333:169
Plebani et al. Clin Chem 1997;43:1348

Medical Error: Laboratory Medicine Perspective

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

From value outcome to metric and target

Pre-Analytical	Analytical	Post-Analytical
Mis-IDed Samples	EQA results out side limits	TATs
Transcription errors	QC failures	Results delivered outside target
Unsuitable samples	Valid Complaints	Critical results outside target time
Phlebotomy wait-times	Analytical cost/test	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

Metric Calculations

Accuracy and Precision

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

Other specifications

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

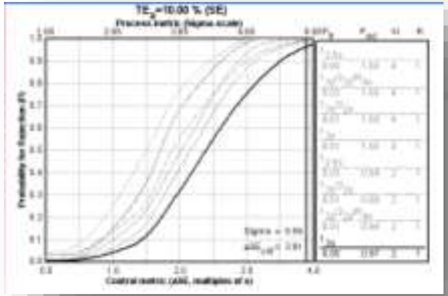
Sigma metric is directly related to safety, efficiency, and cost of quality.

Applications

Selecting QC Procedures

Higher Sigma associated with:

- Lower reagent supply
- Lower labor costs
- Fewer QC failures
- Between laboratory reproducibility



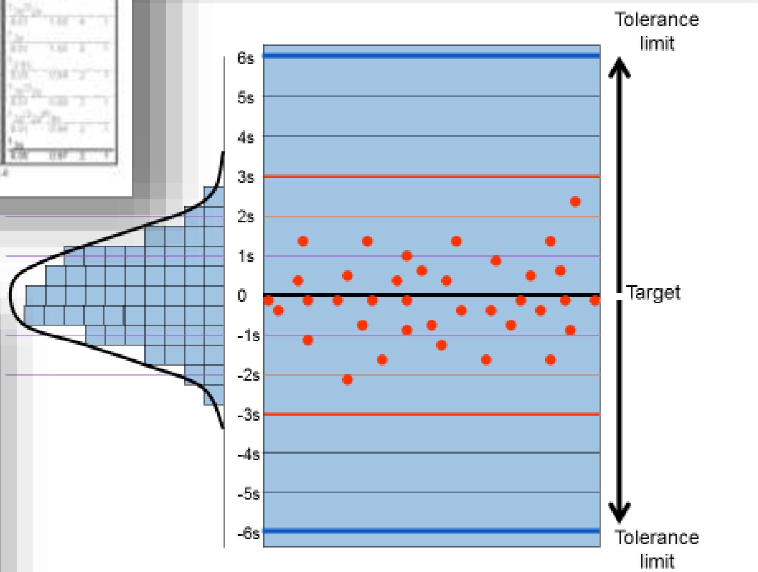


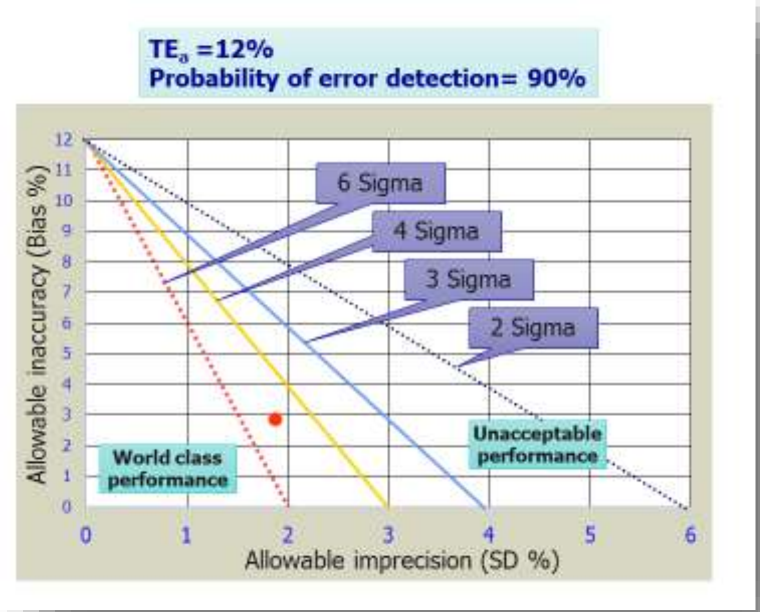
Table 4
Quality control rules used for sigma metric of method

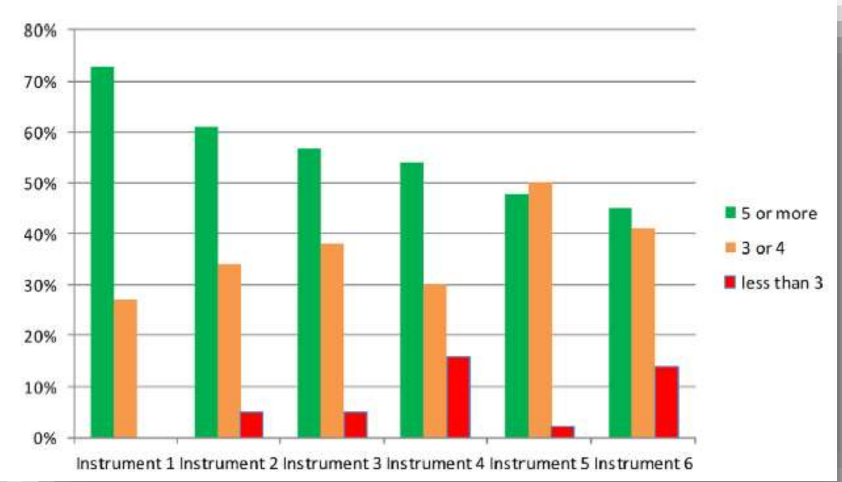
Sigma Metric	QC Rules Used
6 Sigma	1-3.5s
5 Sigma	1-3s
4 Sigma	1-3s, R4s, 2 of 2-2s, and 2 of 3-2s
3 Sigma	1-3s, R4s, 2 of 2-2s, 2 of 3-2s, 4-1s and 12x

Ref:
Clin Lab Med 2017:37:85
Clin Lab Med 2017:37:117

Applications

Selecting & Evaluating Instruments and Methods





Refs:
Clin. Biochem. 2015:49:599-707
Clin Lab Med 2017:37:117

Applications

Value	Six Sigma Metric/Process	Reference
Safety	6σ process reduced pathology lab error rate	*Turk. Patol. Derg 2016:32:171*
Efficiency & timeliness	6σ process reduced STAT TAT and elimination of process steps leading to error	*J. Clin. Lab. Anal. 2017:e22180*
Timeliness	6σ process reduced hemolysis in ED	*JCJQPS 2015;41:99*
Safety & Efficiency	6σ metrics and rule selection reduced QC costs	*Vet. Clin. Path. 2014:43:164*
Timeliness & Efficiency	6σ process reduce TAT and LOS in ED	*AJCP 2013:140:193*
Timeliness & Efficiency	6σ process reduces data entry errors with improved process and cost savings	*IJHCQA 2011:26:496*
Safety	6σ process reduces analytical errors in automated lab	*MLO 2005:37:20*

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*

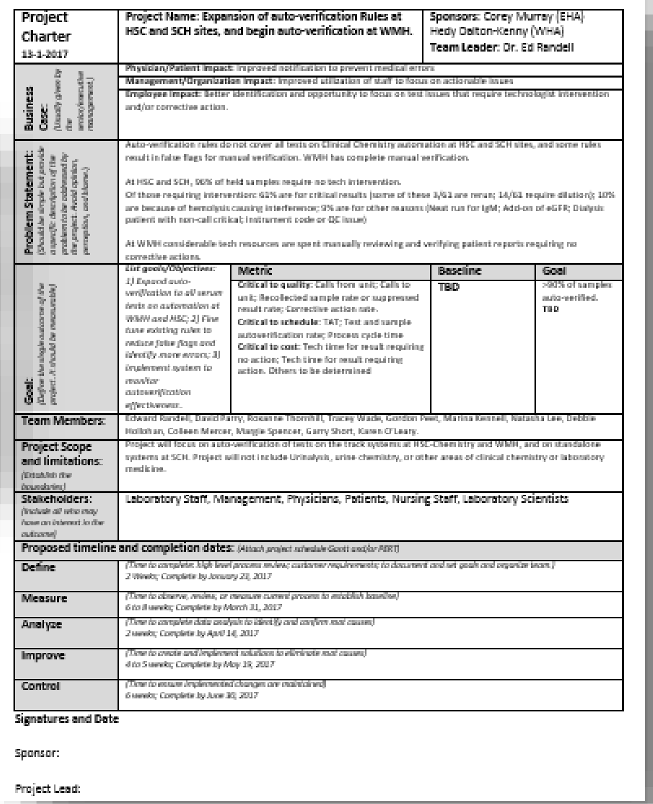
- <5% of samples held require no intervention by MLT.
  - 61% critical values
  - 10% hemolysis
  - 9% other reasons
- Objectives
  - Expand to all serum tests.
  - Fine tune to reduce false flags.
  - Implement Monitoring System

Getting it started

Value to Stakeholders

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

Sites	Sample AV rate
HSC (Automated Chemistry)	52%
WMH (Automated Chemistry)	40%
SCH (Not automated)	38%



Project Charter 13-1-2017	Project Name: Expansion of auto-verification Rules at HSC and SCH sites, and begin auto-verification at WMH.			Sponsors: Corey Murray (EHA) Hedy Dalton-Kenny (WHA) Team Leader: Dr. Ed Randell
Business Case: (Usually given by the senior/executive management.)	Physician/Patient Impact: Improved notification to prevent medical errors Management/Organization Impact: Improved utilization of staff to focus on actionable issues Employee Impact: Better identification and opportunity to focus on test issues that require technologist intervention and/or corrective action.			
Problem Statement:	Auto-verification rules do not cover all tests on Clinical Chemistry automation at HSC and SCH sites, and some rules result in false flags for manual verification. WMH has complete manual verification. At HSC and SCH, 90% of held samples require no tech intervention. Of those requiring intervention: 61% are for critical results (some of these 3/61 are rerun; 14/61 require dilution); 10% are because of hemolysis causing interference; 9% are for other reasons (Next run for IgM; Add-on of eGFR; Dialysis patient with non-call critical; Instrument code or QC issue) At WMH considerable tech resources are spent manually reviewing and verifying patient reports requiring no corrective actions.			
Goal:	List goals/Objectives: 1) Expand auto-verification to all serum tests on automation at WMH and HSC; 2) Fine tune existing rules to reduce false flags and identify more errors; 3) Implement system to monitor autoverification effectiveness.	Metric: Critical to quality: Calls from unit; Calls to unit; Recollected sample rate or suppressed result rate; Corrective action rate. Critical to schedule: TAT; Test and sample autoverification rate; Process cycle time. Critical to cost: Tech time for result requiring no action; Tech time for result requiring action. Others to be determined	Baseline: TBD	Goal: >90% of samples auto-verified. TBD
Team Members:	Edward Randell, David Parry, Roxanne Thornhill, Tracey Wade, Gordon Peet, Marina Kennell, Natasha Lee, Debbie Hollahan, Colleen Mercer, Margie Spencer, Garry Short, Karen O'Leary.			
Project Scope and limitations: (Establish the boundaries)	Project will focus on auto-verification of tests on the track systems at HSC-Chemistry and WMH, and on standalone systems at SCH. Project will not include Urinalysis, urine chemistry, or other areas of clinical chemistry or laboratory medicine.			
Stakeholders: (Include all who may have an interest in the outcome)	Laboratory Staff, Management, Physicians, Patients, Nursing Staff, Laboratory Scientists			
Proposed timeline and completion dates: (Attach project schedule Gantt and/or PERT)				
Define	(Time to complete: high level process review; customer requirements; to document and set goals and organize team.) 2 Weeks; Complete by January 23, 2017			
Measure	(Time to observe, review, or measure current process to establish baseline) 6 to 8 weeks; Complete by March 31, 2017			
Analyze	(Time to complete data analysis to identify and confirm root causes) 2 weeks; Complete by April 14, 2017			
Improve	(Time to create and implement solutions to eliminate root causes) 4 to 5 weeks; Complete by May 19, 2017			
Control	(Time to ensure implemented changes are maintained) 6 weeks; Complete by June 30, 2017			

Signatures and Date

Sponsor:

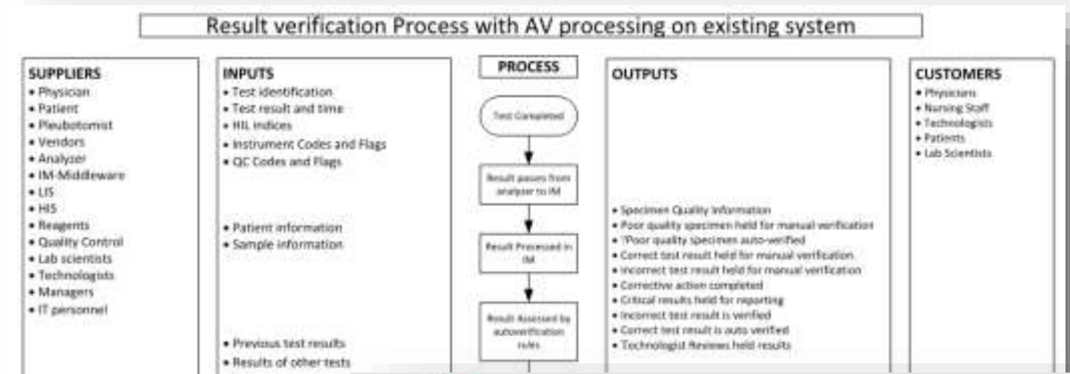
Project Lead:

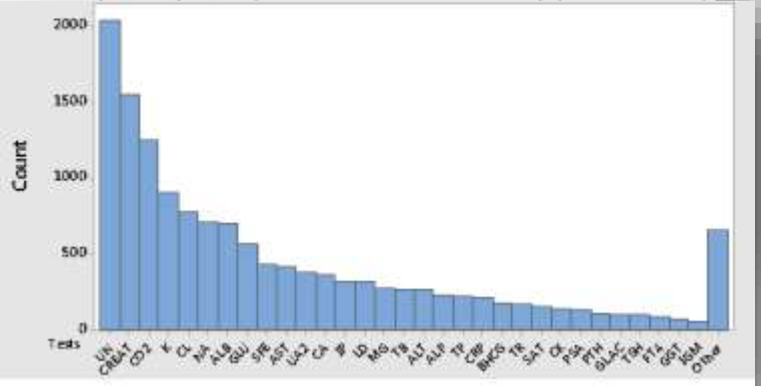
Mapping and measuring

MEASUREMENT

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

MLT	Number of Samples	Seconds per sample
1	72	6.57
2	123	7.83
3	213	6.01
4	100	16.58
5	204	4.90
6	42	5.00
7	109	5.10
8	100	5.05
All		7.13 ± 3.95





Analysis and baseline

ANALYZE

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

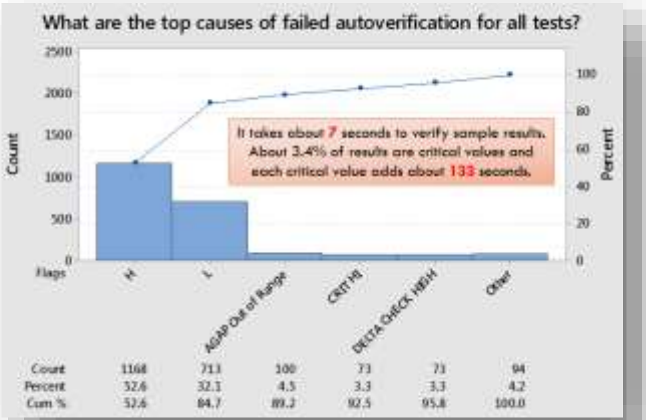


Table 5. Summary of metrics and benchmarks pre-implementation of new AV rules.

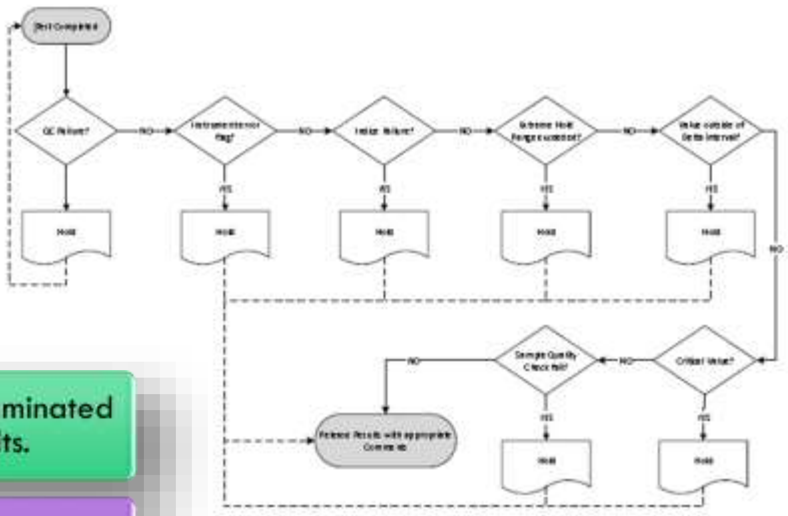
Performance Metrics	Definition/Units	Baseline	Benchmark or Target
Sample hold rate	Proportion of total	HSC: 0.398 ± 0.037 (n=6) WMH: 0.650 ±0.014(n=6) SCH: 0.604 ± 0.036(n=6)	<0.10
Test hold rate	Proportion of total	HSC: 0.225 ± 0.009 (n=6) WMH: 0.209 ± 0.009(n=6) SCH: 0.223 ± 0.012(n=6)	<0.10
HIL hold rate for potassium	Proportion of tests held	3.7%	<2.5%
Delta hold rate for potassium	Proportion of tests held	3.7%	<2.5%
High/Low hold rate for potassium	Proportion of tests held	12.8%	<1%
Special Rule hold rate for potassium	Proportion of tests held	1.6%	<2.5%
Process time	Median time (min) from placement on track to result release to electronic medical record.	HSC: 41.3 ± 1.00* (n=6) WMH: 32.8 ± 1.2* (n=7)	≤baseline
Process time-cost	Weekly labor time-cost associated with review of tests held for manual review.	16785 ± 5461 seconds	>50% reduction
Test manual verification time	Average time (seconds) spend reviewing held sample.	7.1 ± 4.0 (Mean ± SD)	≥baseline
90th percentile TAT for STAT potassium levels	Average weekly Time in minutes	HSC: 51.9 ± 1.0*(n=6) WMH: 66.6 ± 5.1*(n=11)	≤baseline

* Based on time specimen on automated track system at HSC, but from time of receipt in the laboratory at WMH. Expressed as average weekly median and standard deviation.

Improve and implement

IMPROVE

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



Quality check failures: Fibrin, Mix-up, old samples, contaminated samples, poor quality, impossible results, rare results.

HIL flags that require action

Extreme results

Delta Checks

Instrument & QC errors

Critical Results

Control

CONTROL

- Validate Improvements
- Institutionalize
- Close out project

Parameter	N	AV Rate	Sigma[1]
HSC test	8	0.962 ± 0.005	13.6
HSC sample	8	0.947 ± 0.014	3.4
WMH test	8	0.983 ± 0.003	28.1
WMH sample	8	0.911 ± 0.009	1.2
SCH test	5	0.977 ± 0.002	31.6
SCH sample	5	0.925 ± 0.003	8.5

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

Making it work

Challenges

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

Strategies

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

Attention to the human element is critical to success!

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

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