The business case for optimized quality control practice

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Purpose of the Study

Background

Clinical Laboratories commonly monitor their testing procedures by repeatedly analyzing quality control materials and assessing the results to determine acceptable performance. In most jurisdictions this requirement is regulated and results in a significant volume of testing and cost to the healthcare system.

It is recognized however that most laboratories do not follow generally accepted standards of practice concerning Quality Control practices.
The negative impact of this, inside and outside the laboratory, is not well understood or easily quantified.

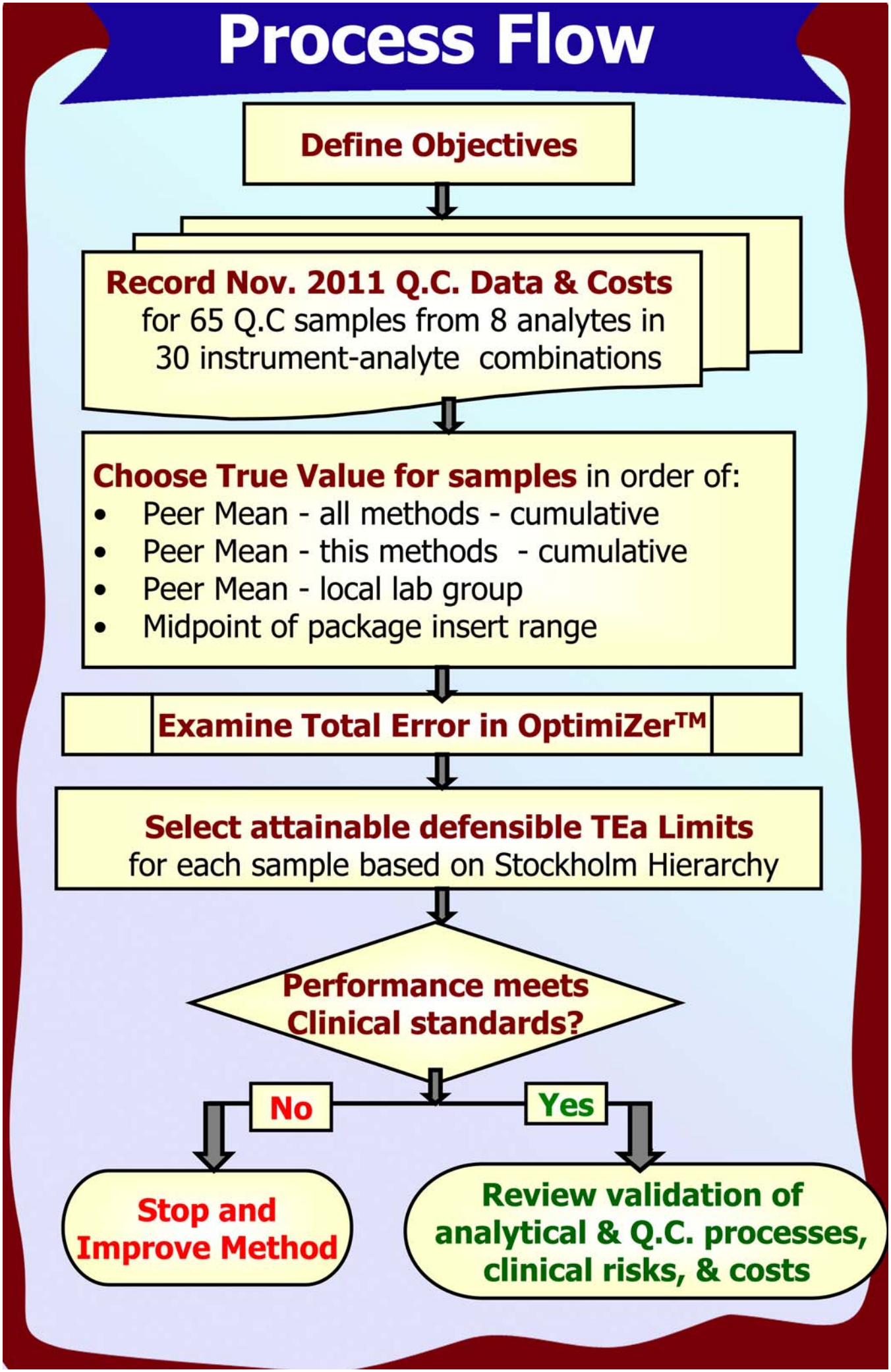
In the current environment of limited resources laboratories need to ensure that their quality control system design maximizes both efficiency (lowest possible costs in the laboratory) and effectiveness (best possible protection of patients from clinical harm of misleading laboratory results.)

The Study

To understand this better, we analyzed our current Quality Control practices for 30 tests across 6 laboratories and compared our practices with Q.C. processes recommended by a prototype version of Quality OptimiZer™ Software (Awesome Numbers Inc.) to determined:

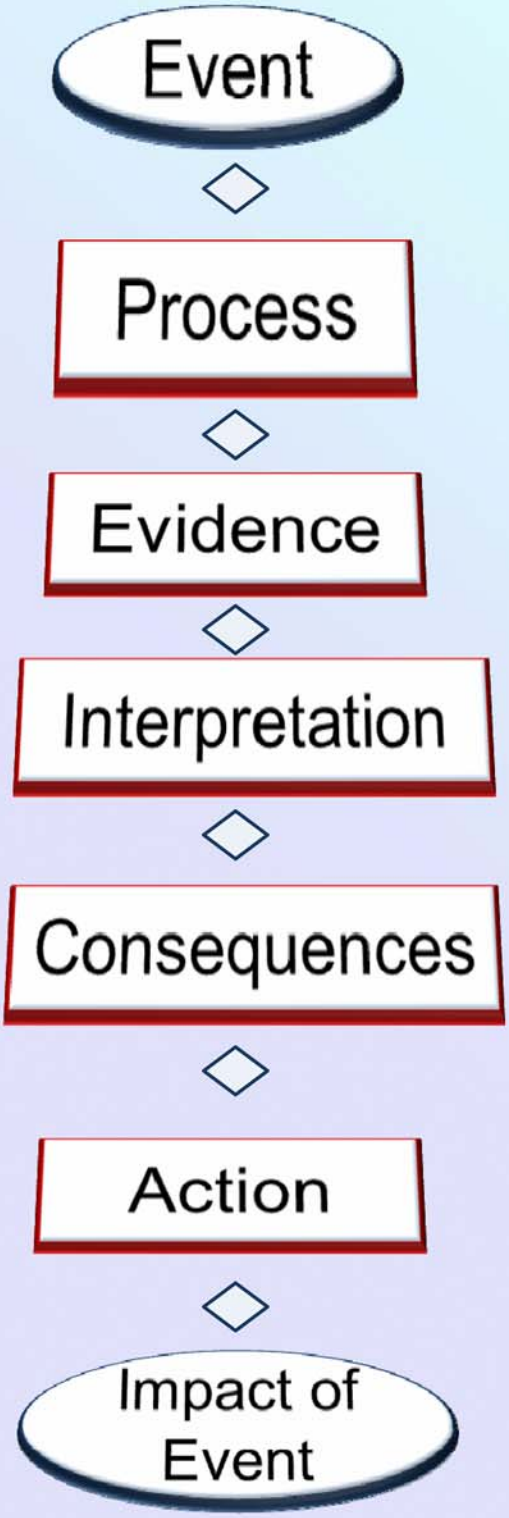
- the gaps in practice, and
- the impact of the identified improvements to overall healthcare system reliability and costs.

Process Flow



Q.C. in Theory

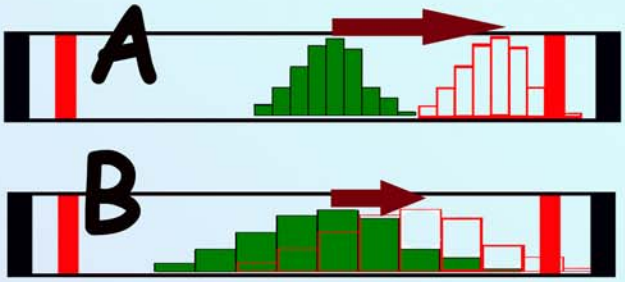
Routine Quality Control practices detect change from stable acceptable performance that produces clinically-meaningful results



1. **Events** that change method performance can & do happen frequently in labs.
2. Scientifically-referenced Q.C. **processes** vary Q.C. rules & actions to match method performance (Margin for Error.).
3. **Evidence** (Q.C. Flags) alert staff to clinically-significant change.
4. Staff **interpret** the evidence consistently. Q.C. flags are evidence of change, not failure. Change can be for the better or worse!
5. Staff understand the **consequences** of misleading patient results;
6. Take the right **action**.
7. **Report results only when performance meets clinical goals.**

OptimiZed Quality

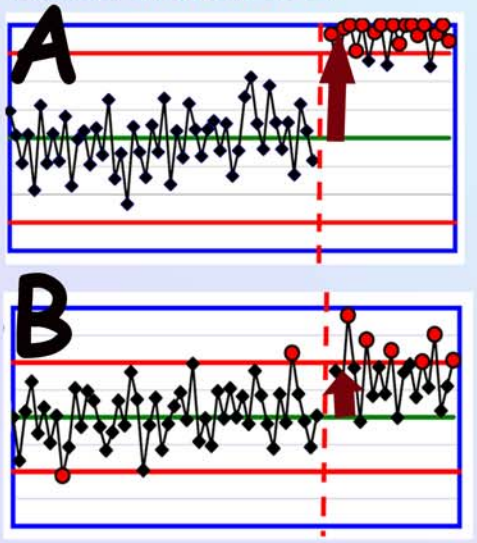
Q.C. rules are selected to match the size of shift tolerated before results become clinically misleading: - the 'Margin for Error.'



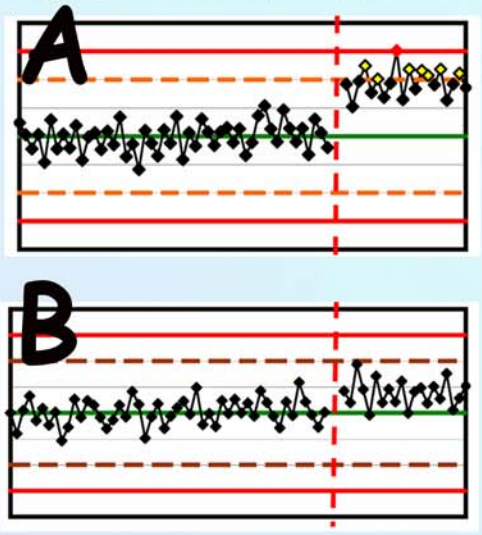
Example 'A' can shift 3.3 SD.

Example 'B' can only shift 1.3 SD.

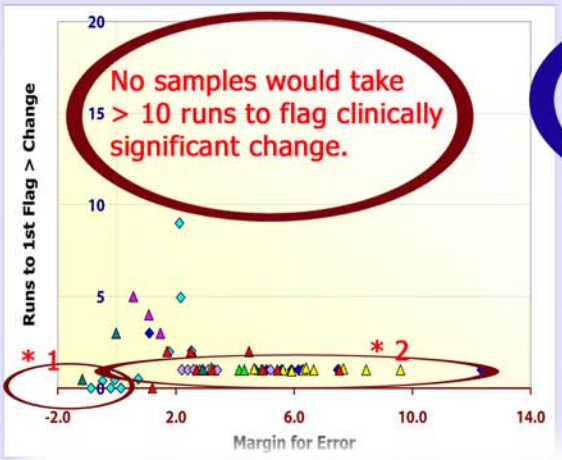
OptimiZed Q.C.
Asg mean & SD = Meas
Rules match ME



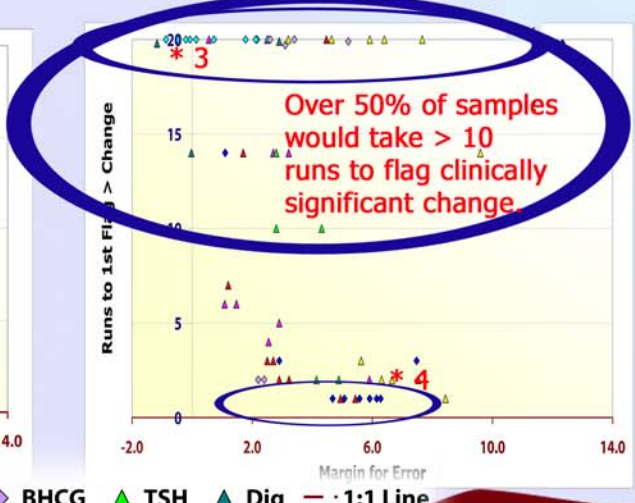
Q.C. Practice Example
Asg SD = 2x Meas SD.
Rules '1-2s' & '1-3s'



OptimiZed Q.C.
Asg SD = Meas SD
Rules vary with Margin for Error



Q.C. Practice; Stop & Act for '1-3s' reject.
Asg SD = 0.8 to 3.7x Meas SD



◆ APTT ▲ PT ◇ Na △ Ca ▲ Chol ◇ BHCG ▲ TSH ▲ Dig — 1:1 Line

Example

Bottom Line

Quality OptimiZer™

Efficient, Effective, Reliable Quality

MY LAB | Sunshinometer | Serum Sunshine | 06/01/2012 To 06/30/2012

Validation of Analytical Process:	Validation of Effectiveness:	Validation of Efficiency:
Pass - A. All OK	Fail - Stop & Fix	Pass - A. All OK

Opportunities for Improvement: OptimiZe Q.C. process to improve patient care and reduce laboratory costs.

Q.C. Sample	Performance BarZ©	Analytical	QC Rating:	Effectiveness	Efficiency	Reliability	Q-Score
Level 1 Lot: QC1111 ME: 3.0		★★★	Optimized Quality	★★★★★	★★★★★	★★★★★	100%
			Lab Practice	●	☆☆☆☆☆	No Flags	40%
Level 2 Lot: QC2222 ME: 4.0		★★★★	Optimized Quality	★★★★★	★★★★★	★★★★★	100%
			Lab Practice	☆	★☆☆☆☆	●	43%

Quality Metric What it means	How It Is Measured Impact to patients & lab	Level 1 Quality Optimizer	Level 1 Lab Practice	Level 2 Quality Optimizer	Level 2 Lab Practice	Level 3 Quality Optimizer	Level 3 Lab Practice
Q.C. Design Assigning the right QC values; Using the right rules	Actual QC rule used	2.5	6.0	3.5	5.3		
	Ratio of Actual QC rule used to theoretical QC rule.	1.0	2.0	1.0	1.8		
Q.C. Effectiveness Ability to flag clinically significant change that can cause >5% of patient results to be clinically misleading.	Probability of error detection	78%	0%	78%	16%		
	Runs to first Flag	1	20	1	6		
	Patients at risk/year	10	200	10	60		
	Patients harmed	1	10	1	3		
	Clinical Cost	$20	$300	$20	$90		
Q.C. Efficiency Ability of the QC process to NOT flag results that are clinically acceptable (few false positive QC flags.)	Probability of false rejection	0%	0%	0%	0%		
	False pos runs/year	0	0	0	0		
	Reagent & Supply Costs	$0	$0	$0	$0		
	Staff Costs	$0	$0	$0	$0		
	Total Lab Costs	$0	$0	$0	$0		
Q.C. Reliability Probability that a QC Flag signifies significant change.	True Positive Flags per Year / True + False QC Flags	100%	No Flags	100%	100%		

Actions to improve QC Design, Effectiveness, Efficiency and Reliability

Analytical Process: Lev 1 2 3

- Low Quality Rating
- Improve precision
- Improve accuracy
- Improve BOTH

QC Process:

Compare the Consequences of the OptimiZed and Laboratory processes.
1. What is the clinical impact of OptimiZed Q.C. (patients risk & cost)?
2. How would OptimiZed QC imact time & costs in the laboratory?
3. Would the change in reliability improve staff confidence in Q.C

- ☐ Stop reporting / improve
- ☐ OptimiZe Q.C. Process
- ☐ Other Process

The Bottom Line

The clinical cost of patients at risk:

Optimized Quality could prevent risk to up to 190 patients; and up to 9 patients could be saved from potential harm. Clinical savings could total $280.

OptimiZed Quality will cost $0 more for reagents and supplies and $0 more for staff. Total = $0 per year.

Combined financial impact to clinical and laboratory: Savings of $280.

Financial Assumptions

The clinical cost of patients at risk:	$1.00
Cost of clinically misleading results:	$10.00
Reagent and Supplies cost/test:	$1.00
Salary with benefits modeled at:	$50.00

Average = 100 runs per month with 10 patients per run

Simulated change would cause 5% of results to exceed TEa limits, with this significant change 1 x in a year.

Chart Comparison

Quality OptimiZer™

Efficient, Effective, Reliable Quality

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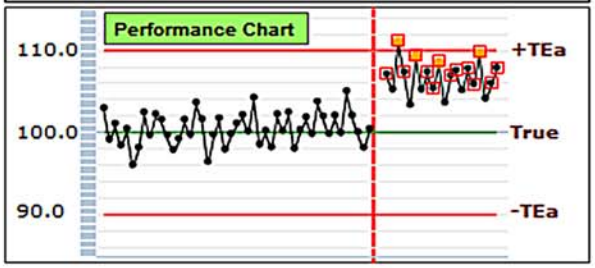
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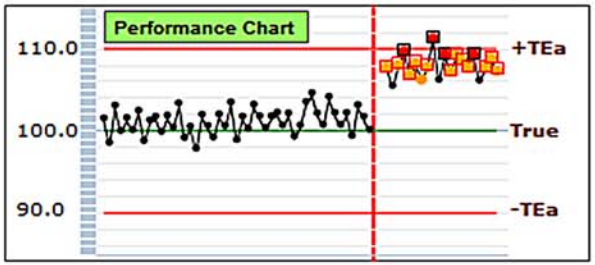
Lab practice = Check QC after reporting patients. Repeat for Reject or 2 consecutive warnings.

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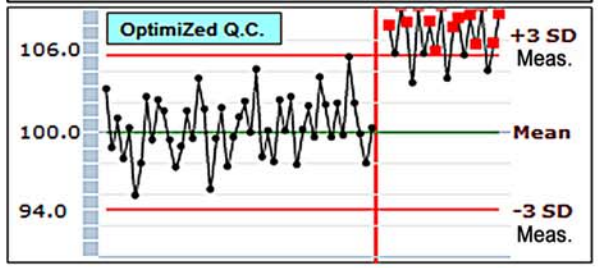
	Where You Are (and expect to be)		Where You Want To Be		Assessment of Analytical Quality — Ability to produce clinically meaningful patient results.				Where you say you Expect To Be — Assigned Chart Values		The Asg Mean is ____ SD from the Meas Mean	The Asg SD is ____ x Meas SD	"Stop & Act Rule" Optiimized Quality	"Stop & Act Rule" Lab Reject
	Mean	SD	True	TEa	Bias	TE	ME	OK?	Asg Mean	Asg SD				1-3s
Level 1	100.0	2.00	100.0	10.00	0.0	4.0	3.0	OK	100.0	4.00	0.0	2.00	1-2.5s	1-6.0s
Level 2	101.0	1.50	100.0	10.00	1.0	4.0	4.0	OK	100.0	3.00	-0.6	2.00	1-3.5s	1-5.3s
All Levels	Facts: Measured		From Opinion (Policy)		Mean-True	(Bias + 2 SD)	(TEa - TE)/SD	TE < TEa?	Asssigned Chart Values		(Asg-Meas)/SD	Asg/Meas	Asg Rule	Modeled

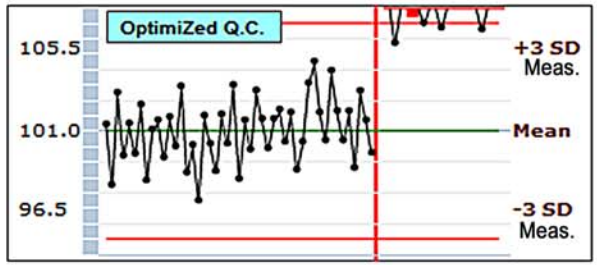
Performance Charts plot QC values against True Values and Performance Standards (TEa Limits)



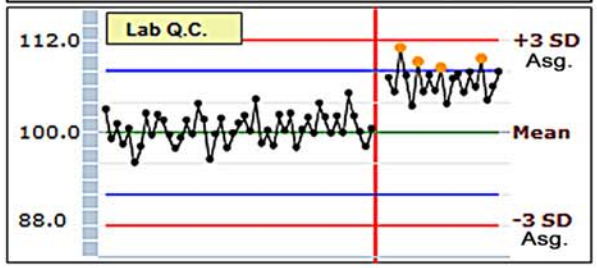


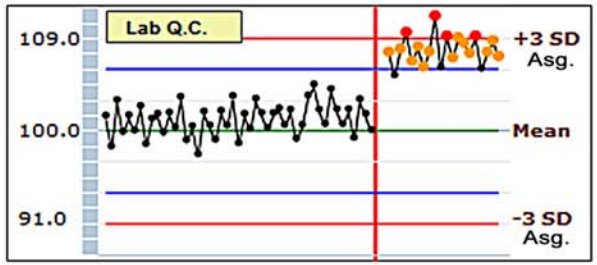
Optimized Quality assigns the measured mean & SD; selects QC rules based on Margin for Error





Lab QC practice may assign other mean & SD values, modifying QC rules from theory.





Example

● Lab QC Warning (without a Reject Flag in the same run.) ● Lab Reject ■ Optimized Quality Action Flag

Charts show 50 simulated QC results based on your measured mean and SD. After the red line, 20 points show a shift with 5% of results >TEa (clinically misleading.)

Real

Bottom Line

Quality OptimiZer™

Efficient, Effective, Reliable Quality

LAB 2 INSTRUMENT B PT 11/11/2011 To 12/21/2011

Validation of Analytical Process:	Validation of Effectiveness:	Validation of Efficiency:
Pass - B. Review	Fail - Stop & Fix	Pass - A. All OK

Opportunities for Improvement: OptimiZe Q.C. process to improve patient care and reduce laboratory costs.

Q.C. Sample	Performance BarZ©	Analytical	QC Rating:	Effectiveness	Efficiency	Reliability	Q-Score
Level 1 Lot: 1111111 ME: 3.0		★★★	Optimized Quality	★★★★★	★★★★★	★★★★★	100%
			Lab Practice	●	☆☆☆☆☆	No Flags	0%
Level 2 Lot: 2222222 ME: 1.6		★	Optimized Quality	★★★★	☆	●	30%
			Lab Practice	☆	★☆☆☆☆	★★★★★	43%

Quality Metric What it means	How It Is Measured Impact to patients & lab	Level 1 Quality Optimizer	Level 1 Lab Practice	Level 2 Quality Optimizer	Level 2 Lab Practice	Level 3 Quality Optimizer	Level 3 Lab Practice
Q.C. Design Assigning the right QC values; Using the right rules	Actual QC rule used	3.0	5.7	2.0	3.0		
	Ratio of Actual QC rule used to theoretical QC rule.	1.0	1.9	1.0	1.0		
Q.C. Effectiveness Ability to flag clinically significant change that can cause >5% of patient results to be clinically misleading.	Probability of error detection	66%	1%	49%	16%		
	Runs to first Flag	1	20	2	6		
	Patients at risk/year	33	661	66	198		
	Patients harmed	2	33	3	9		
	Clinical Cost	$53	$991	$96	$288		
Q.C. Efficiency Ability of the QC process to NOT flag results that are clinically acceptable (few false positive QC flags.)	Probability of false rejection	0%	0%	5%	0%		
	False pos runs/year	0	0	36	0		
	Reagent & Supply Costs	$0	$0	$648	$0		
	Staff Costs	$0	$0	$675	$0		
	Total Lab Costs	$0	$0	$1,323	$0		
Q.C. Reliability Probability that a QC Flag signifies significant change.	True Positive Flags per Year / True + False QC Flags	100%	No Flags	3%	100%		

Actions to improve QC Design, Effectiveness, Efficiency and Reliability

Analytical Process: Lev 1 2 3

- Low Quality Rating — X
- Improve precision — X
- Improve accuracy
- Improve BOTH

QC Process:

Compare the Consequences of the OptimiZed and Laboratory processes.
1. What is the clinical impact of OptimiZed Q.C. (patients risk & cost)?
2. How would OptimiZed QC imact time & costs in the laboratory?
3. Would the change in reliability improve staff confidence in Q.C

- ☐ Stop reporting / improve
- ☐ OptimiZe Q.C. Process
- ☐ Other Process

The Bottom Line

The clinical cost of patients at risk:

Optimized Quality could prevent risk to up to 628 patients; and up to 31 patients could be saved from potential harm. Clinical savings could total $938.

Until analytical quality is improved, OptimiZed Quality will cost $648 more for reagents and supplies and $675 more for staff. Total = $1,323 per year.

Combined financial impact to clinical and laboratory: Cost of $385.

Financial Assumptions

The clinical cost of patients at risk:	$1.00
Cost of clinically misleading results:	$10.00
Reagent and Supplies cost/test:	$1.00
Salary with benefits modeled at:	$37.50

Average = 60 runs per month with 16 patients per run

Simulated change would cause 5% of results to exceed TEa limits, with this significant change 2 x in a year.

Chart Comparison

Quality OptimiZer™

Efficient, Effective, Reliable Quality

LAB 2 INSTRUMENT B PT 11/11/2011 To 12/21/2011

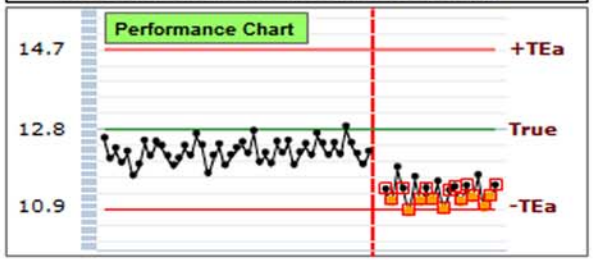
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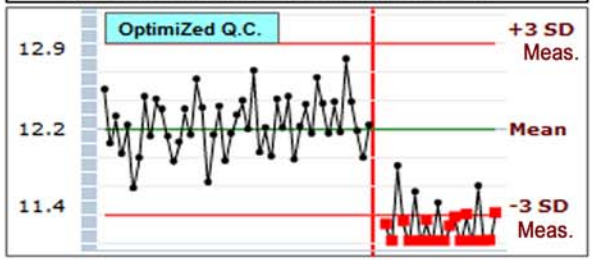
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	Mean	SD	True	TEa	Bias	TE	ME	OK?	Asg Mean	Asg SD				1-3s
Level 1	12.2	0.26	12.8	1.90	-0.6	1.1	3.0	OK	12.2	0.50	0.0	1.92	1-3.0s	1-5.7s
Level 2	37.9	1.48	38.2	5.70	-0.3	3.3	1.6	REVIEW	37.9	1.50	0.0	1.01	1-2.0s	1-3.0s
All Levels	Facts: Measured		From Opinion (Policy)		Mean-True	(Bias + 2 SD)	(TEa - TE)/SD	TE < TEa?	Asssigned Chart Values		(Asg-Meas)/SD	Asg/Meas	Asg Rule	Modeled

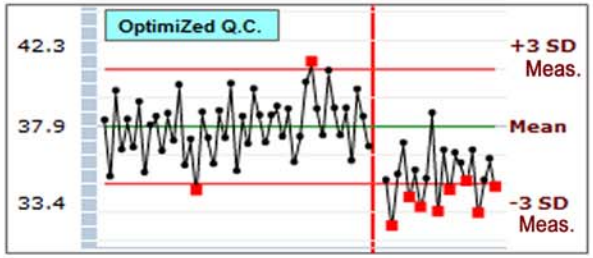
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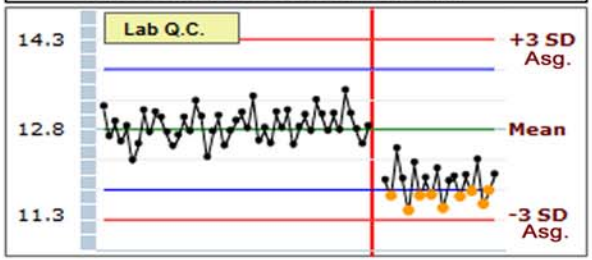


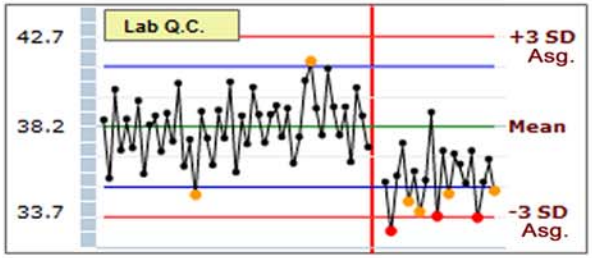
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Lab QC practice may assign other mean & SD values, modifying QC rules from theory.





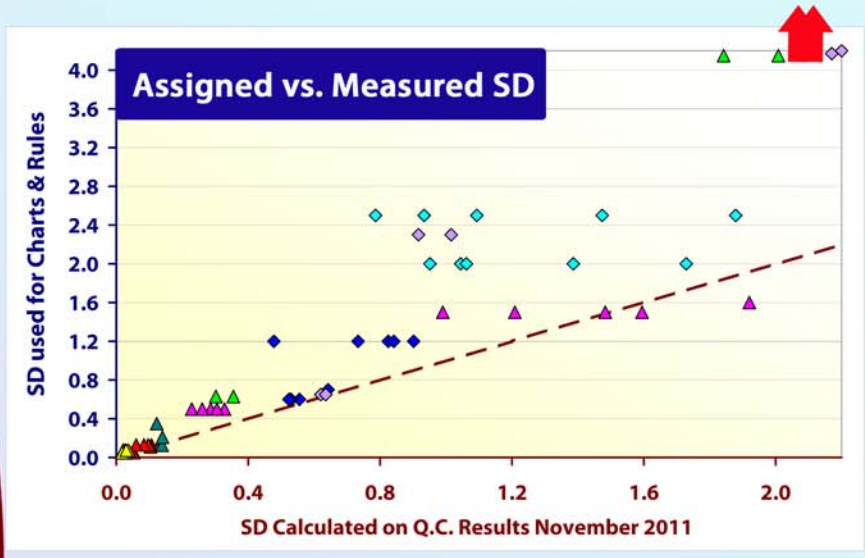
Real Data

● Lab QC Warning (without a Reject Flag in the same run.) ● Lab Reject ■ Optimized Quality Action Flag

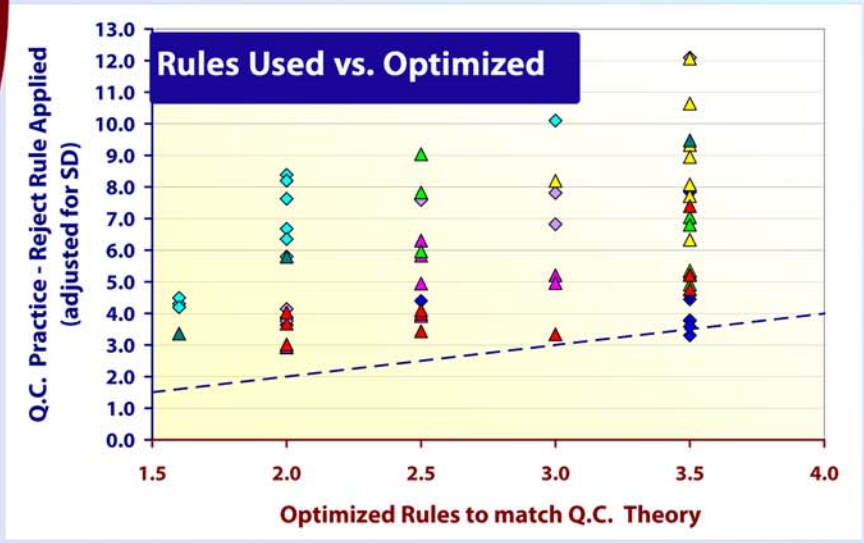
Charts show 50 simulated QC results based on your measured mean and SD. After the red line, 20 points show a shift with 5% of results >TEa (clinically misleading.)

Root Cause: The Q.C. Gap

Q.C. practice diminished Q.C. effectiveness and efficiency.

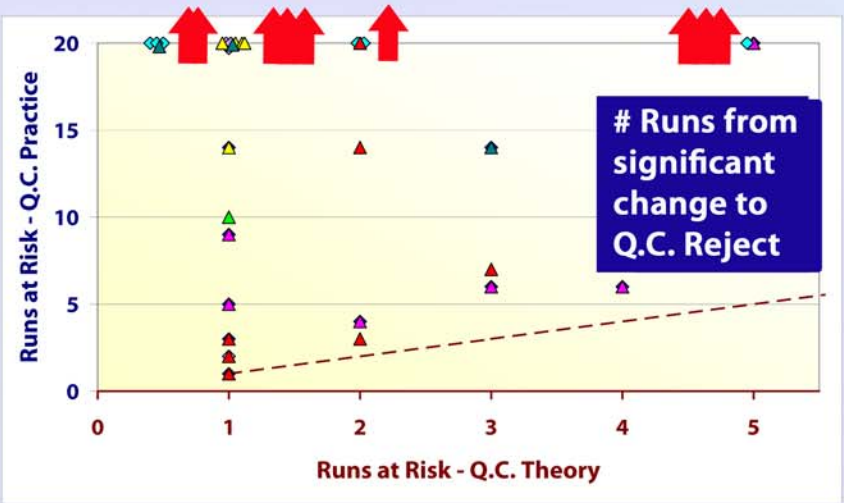


Assigning chart mean & SD at values NOT measured by each lab & method cripples Q.C. rules.
No SDs were assigned at actual values.



Meas SD = 2.0
Asg SD = 2.0
1-3s rule flags at +/- 6.0 units

If Asg SD = 4.0
'1-3s' rule flags at +/- 12.0 units
Rule Used =1-6s



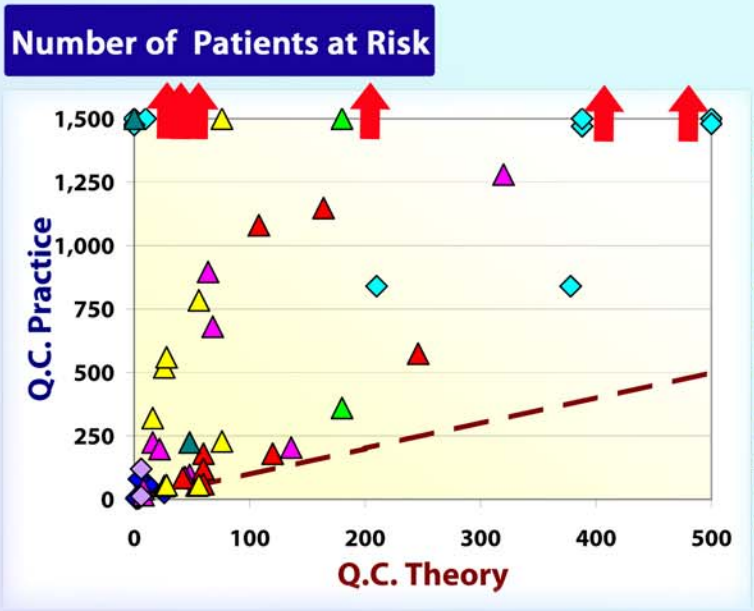
Labs used a 1-3.5s rule (or higher) for 89% of controls.

Only 40% had Margins for Error high enough to flag significant change with a 1-3.5s rule.

APTT PT Na Ca Chol BHCG TSH Dig 1:1 Line

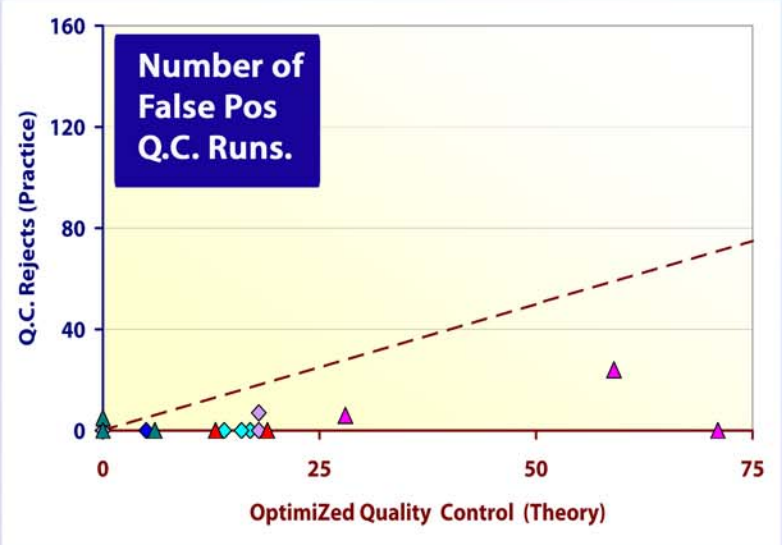
Impact on Reject Rule

Inflated Q.C. rules delay flagging significant change & put more patients at risk of harm from misleading results.



Inflated rules create few true positives. Lab practice to stop and act for a '1-3s' reject or two '1-2s' warnings placed more patients at risk than optimized Quality Control.

Inflated reject rules generate fewer false positives than Optimized Quality.



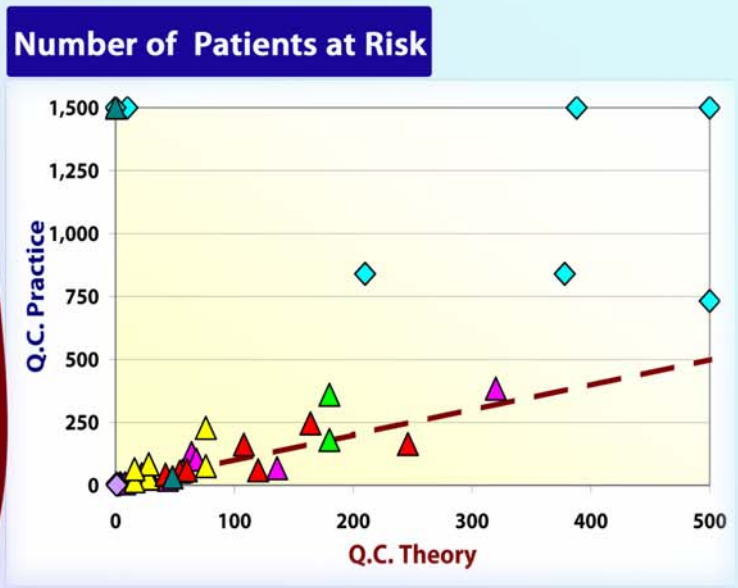
Lab practice created fewer false positive Q.C. flags than optimized Q.C.. OpitimiZer™ uses tighter Q.C. rules to detect change sooner in methods with low Margin for Error.

The number of false positive runs is determined by the Q.C. rule. Incorrect means and inflated SDs caused lab '1-3s' reject rules to flag results at 2.9 to 12.1 SD from the mean.

◆ APTT ▲ PT ◆ Na △ Ca ▲ Chol ◇ BHCG ▲ TSH ▲ Dig — 1:1 Line

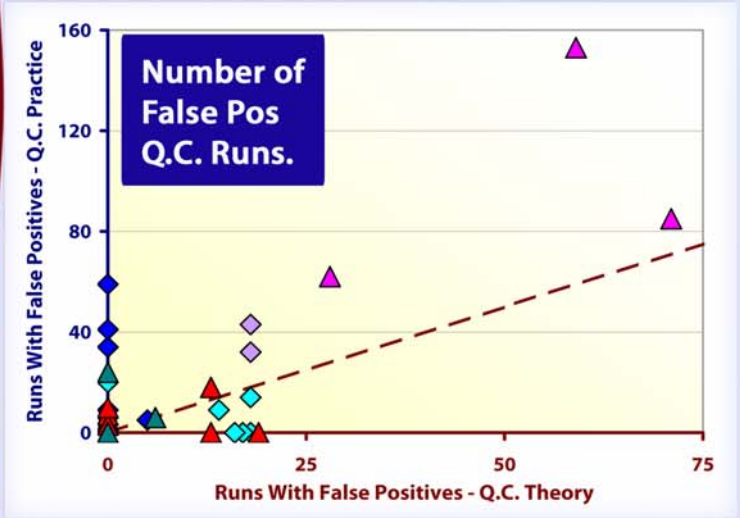
Impact on Warning Rule

Wrong mean and SD values caused the lab '1-2s' rule to actually flag results at +/- 2.0 to 8.7 SD from the mean.



If staff had acted on every single '1-2s' flag, there would still be thousands more patients at risk than with optimized Q.C. reject rules.

OptimiZer™ simulated a shift in the mean that would cause 5% of results to exceed TEa limits. The number of patients at risk is based on the number of runs to the first Q.C.flag after this change, and patients/run.



Lab practice created twice as many false positive Q.C. flags as optimized Q.C..

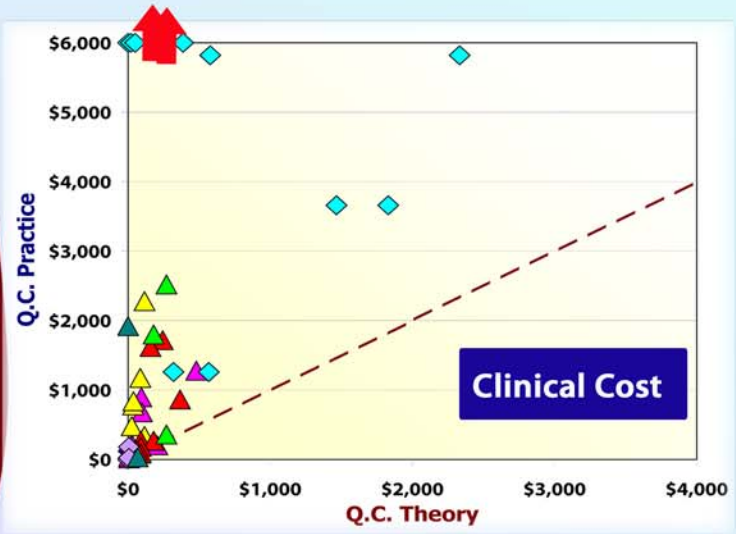
You cannot fix this problem by just assigning the real mean and SD on charts.

Effective, efficient quality control requires using the right mean & SD AND the right Q.C. rule.

◆ APTT ▲ PT ◇ Na △ Ca ▲ Chol ◇ BHCG ▲ TSH ▲ Dig — 1:1 Line

Costs with Reject Rule

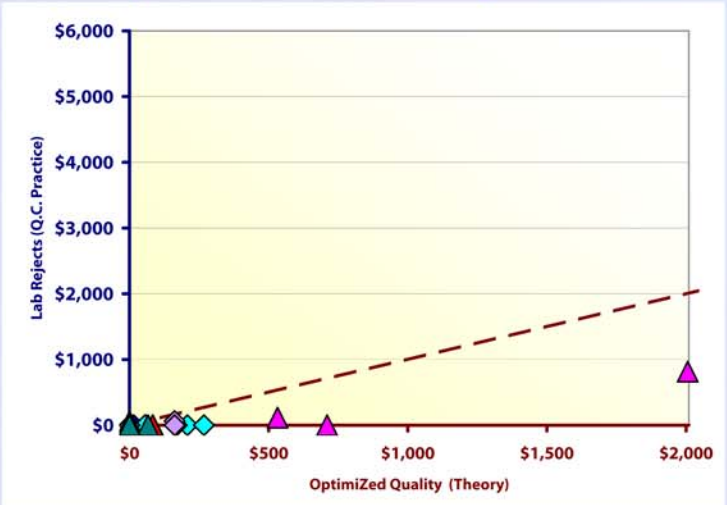
Clinical Costs were 6.5 x times higher with the current lab '1-3s' rule than with optimized quality. Three methods failed to meet TEa at the time of the study.



These 3 methods were already producing misleading results - results that failed to meet TEa limits.

If that significant error remained undetected for the full upcoming year, clinical costs would be 20x as high, with 20x as many patients at risk and potentially harmed, compared to OptimiZed Q.C..

We assigned a cost of $1.00 for each patient at risk and $10.00 for each patient receiving a misleading result. Clinical costs of missed or delayed diagnosis, or incorrect treatment changes can be much higher. Actual costs depend on the analyte and its impact on clinical decisions.

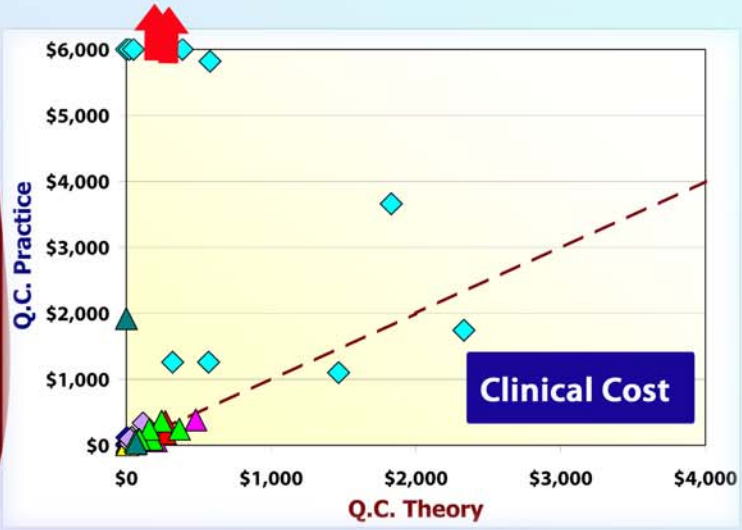


Laboratory costs were lower with inflated Q.C. rules.

◆ APTT ▲ PT ◇ Na △ Ca ▲ Chol ◇ BHCG ▲ TSH ▲ Dig — · 1:1 Line

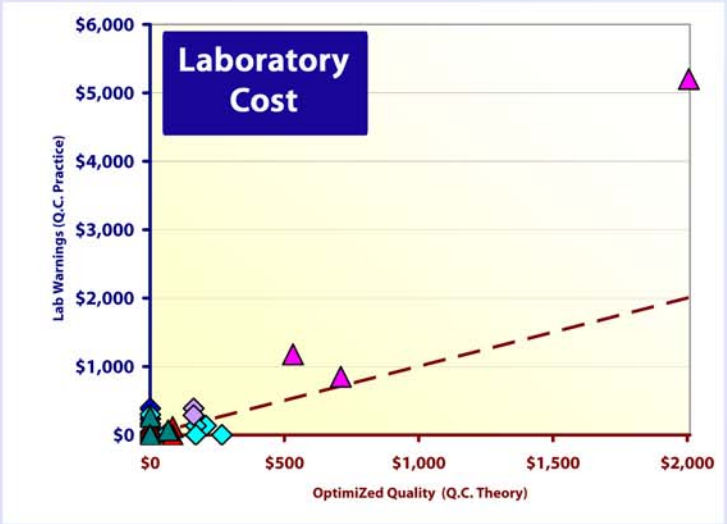
Costs with Warning Rule

Clinical Costs would be 3.6 x times higher, even if staff had stopped and acted for every '1-2s' flag. Lab costs would double compared to OptimiZed quality.



Costs were almost 17x higher, if we included the failed tests that were currently producing results with clinical impact to patients & cost to the system now.

The question remains: if unacceptable performance was not detected to date, when would it be?



Lab costs were based on actual cost/test for repeat tests. Labour was calculated based on the time spent for Q.C. flags.

If the labs had chosen to use their '1-2s' rule, that would cost $5300 more than OptimiZed quality. It would also cost more for clinical care by placing more patients at risk of misleading results.

◆ APTT ▲ PT ◇ Na △ Ca ▲ Chol ◇ BHCG ▲ TSH ▲ Dig — · 1:1 Line

Results

Quality OptimiZer™ Software validated current analytical quality, quality control effectiveness and quality control efficiency for each method.

Current practice was to stop and act only for reject flags.

Analytical Process	Criteria	APTT	PT	CHOL	Ca	Na	BHCG	Dig	TSH
Pass - A. All OK	All levels ME > 2.5	4	2	3	5				2
Pass - B. Review	1 or more levels ME > 1.0 ≤2.5	1	2	2		2	2		
Pass - C. Check NOW	2 or more levels ME > 0.0 ≤1.0		1						
Fail - Stop & Fix	1 or more levels ME <0					3		1	
Q.C. Process - Effectiveness									
Pass - A. All OK	Change detected in 1 run	2	0						
Pass - B. Review	Change detected in 2 runs			2					
Pass - C. Check NOW	Change detected in > 2 runs	2	2	1					
Fail - Stop & Fix	Change NOT detected for > 10 runs	1	3	2	5	5	2	1	2
Q.C. Process - Efficiency									
Pass - A. All OK	0% false positives	5	3	5	5	5	1	1	0
Pass - B. Review	0-≤2% false positives		2				1		
Pass - C. Check NOW	2-5%% false positives								
Fail - Stop & Fix	>5% false positives								

Effectiveness and Efficiency of Current Q.C. Practices compared to OptimiZed Quality	OptimiZed Quality	Current Process	Current Process
		If staff react only to Reject '1-3s' Flags	If staff react to every single Warning '1-2s' Flag
Actual Q.C. Rules Applied	(1-2s to 1-3.5s)	(1-2.9s to 1-12.1s)	(1-2.0s to 8.7s)
Maximum number of runs with patients at risk	68	418	166
Maximum number of patients at risk	4,046	63,966	53,080
Maximum clinical cost	$5,648	$111,454 *	$94,638 *
Maximum number of false pos runs	304	42	655
Maximum cost for false pos runs	$4,524	$1,049	$9,809

* includes $72,000 for tests that currently failed TEa & errors were undetected by curent Q.C. practice.

Discussion

Analytical Process → If the analytical process produces clinically-misleading results .....

Q.C. Process → ... and the Q.C. process does not flag the change (or staff do not react appropriately) ...

Patient Results → ... incorrect patient diagnosis or treatment decisions can be made. Patients & healthcare suffer.

By simulating clinically-significant change, we discovered that over 50% of current Q.C. failed to detect this change in less than 10 runs.

The Gap between Q.C. Theory and Practice

1. Staff designing Q.C. processes were not familiar with expert publications & recommendations.
2. There was no process to ensure that analytical processes meet performance standards.
3. Staff used consistent Q.C. processes for analytical processes with very inconsistent performance.
4. The mean and SD values that were assigned on Q.C. charts, and used to generate Q.C. rule violations, were set at values that did not reflect the analytical processes they were meant to control.

Laboratories collectively spend billions of dollars on 'quality control' to (theoretically) ensure that patients receive clinically meaningful results. Q.C processes should be validated for effectiveness & efficiency.

Conclusion

Based on our analysis, we estimate that with these current Quality Control practices as many as 63,966 patients are at risk annually of clinically-unacceptable results, which is a significant patient safety issue. Based on our assumptions, this could result in unnecessary healthcare system costs for the 30 instrument-analyte combinations of approximately $111,454.

When we extrapolate the impact of this to all 327 analytical tests across 7 Laboratories in our District Health Authority the potential avoidable clinical cost could be as high as approximately $1.2 million per year. With optimized Q.C practices, we estimate that this cost will reduce to approx. $110,874 annually. This represents a significant opportunity for improvement.

Closing the gap between knowledge and practice would require a commitment by Laboratory Administration to recognize this opportunity to improve the efficiency and effectiveness of their laboratories. This could be achieved by adopting generally acceptable standards of practice and considering relatively minimal investments such as developing dedicated Quality Control deep-knowledge experts, wide spread technical staff education and training appropriate to their role, and software capable of easily analyzing performance and automating a customized approach to Quality Control for each test in their Laboratories.