Evaluation of Quality OptimiZer™ software

(Awesome Numbers Inc.)

to simplify application of CLSI EP 23-A, minimize patient risk and reduce clinical cost

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Objectives

1. to evaluate the efficacy of Quality OptimiZer™ software to assess analytical process quality, verify clinical effectiveness of Q.C. processes and recommend a comprehensive Q.C. strategy,
2. to quantify the impact of OptimiZer Q.C. processes on patient risk, clinical and laboratory costs, and
3. to compare Quality OptimiZer reports to EP 23 recommendations.

Relevance:

Ineffective quality control practices expose patients to the risk of incorrect or delayed diagnosis and/or treatment.

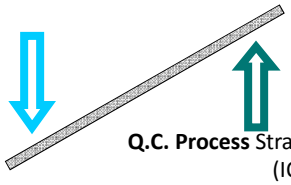
Both CLSI EP23 and CMS Individualized Quality Control Plan (IQCP) require labs to "ensure test result quality is appropriate for clinical use;" validate "the ability of the QC procedures to detect medically allowable error;" and assess "potential costs both in terms of the patient's well-being and financial liability."

Methodology:

We examined analytical processes, Q.C. processes, patient volumes and costs from five analytes, from two instruments in two laboratories.

For each Q.C. sample, we gathered
7 'stats' (verifiable facts)

Analytical Process Quality



Q.C. Process Strategy (IQCP)

	Sodium November 2013 Level 2	
1	Measured Mean	145.3
2	Measured SD	1.06
3	True Value	144.8
4	Medical Goal	4.0
5	Assigned Mean	146.0
6	Assigned SD	1.46
7	QC 'Stop & Act Rule'	1-3s

Determine **Analytical Process** Quality

Determine **Q.C. Process** Effectiveness

4 Numbers determine analytical process ability to meet medical goals defined by the Lab Director

	Where You Are (and expect to be)		Where You Want To Be	
	1 Mean	2 SD	3 True	4 TEa
Level 1	145.3	1.06	144.80	4.00

Validation of Analytical Process:
Pass: Meets Clinical Need

Patients OK Now? ✓

Performance BarZ©

Vitros 350 Sodium

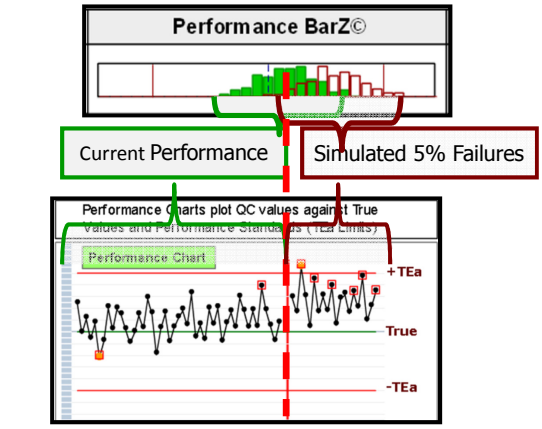
	Perform	BarZ	Analytical	Grade	ME
1	4 3 4		★	B-	1.3

ME = Margin for Error
= (TEa-TE)/SD
= How close to failure
= Zero ME means STOP!

Green BarZ show the current measured mean & SD

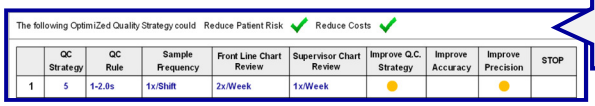
Red BarZ show distribution if 5% of results exceed the medical goal (Tea)

Quality OptimiZer™ simulates a clinically significant change



After the simulated shift,
all patients are at risk;
5% will receive medically-invalid results.

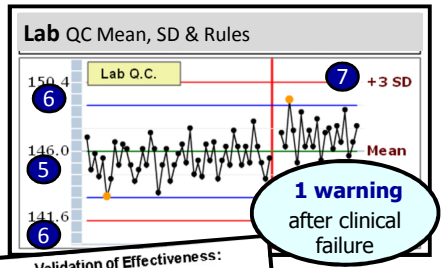
Patients will be at risk
(or harmed) until QC flags the error and staff stop reporting until acceptable performance is restored.



Quality OptimiZer™ recommends and evaluates an individualized 5-part QCP to minimize the number of patients exposed to risk if the method fails.

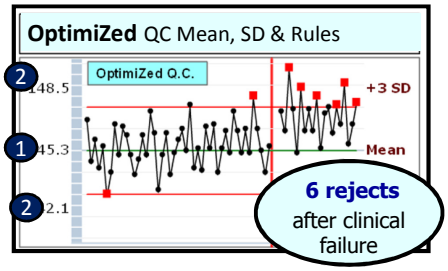
3 Numbers determine Q.C. process effectiveness

Laboratory QCP
Assigned mean & SD



Validation of Effectiveness:
Fail: Requires Action

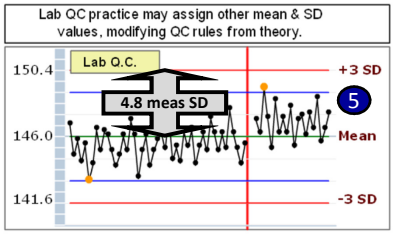
OptimiZed Q.C.
Measured mean & SD



IQCP impacts patient risk & cost	Optimized QCP	Existing QCP
Probability of error detection	38%	0%
# Runs to first Flag	3	20
# Patients at risk / year	210	1400
# Patients potentially harmed / year	11	70
Clinical Cost	$320	$2,100

The root cause of ineffective QC

Arbitrarily assigned Q.C. chart values are applied on the QC Chart. What staff perceive as a '1-3 s rule failure' does not occur until a point falls 4.8 meas SD from the meas mean.



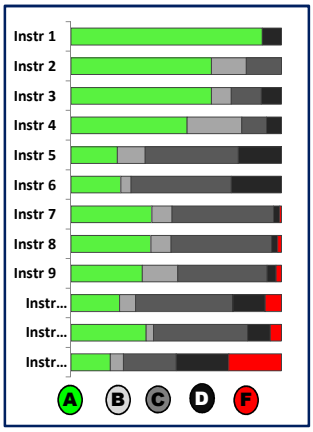
	Measured	Assigned	Chart mean is 0.7 SD < meas mean (0.7/1.06)	
Mean (1)	145.3	(5) 146.0		
SD (2)	1.06	(6) 1.46	Chart SD is 1.38 x Meas SD (1.46/1.06)	
			Actual QC Rule (148.5 -145.3)/1.06	Assigned QC Rule (150.4 -145.3)/1.06
+ 3 SD Flag at	148.5	150.4	3.0	**4.8**
+ 2 SD Flag at	147.4	148.9	2.0	3.4
Mean	145.3	146.0	0.0	0.7
-2 SD Flag at	143.2	143.1	-2.0	-2.1
-3 SD Flag at	142.1	141.6	-3.0	-3.5

Assigned Reject Rule

Quality OptimiZer's Risk-Based Quality Grade™ evaluated both the analytical process quality and QC process effectiveness

The R-B-Q Grade™ provided a quick summary for each QC sample, and could be summarized to represent multiple instruments or sites.

	A	B	C	D	F
Does this method meet clinical standards now?	Y	Y	Y	Y	N
Would Q.C. detect a clinically-significant failure?	Y	Y	N	N	N/A
Does existing Q.C. minimize false positives?	Y	N	N/A	N/A	N/A
Action Required					
Improve Q.C. Process		✓	✓	✓	✓
Improve Analytical Process				✓	✓
Stop reporting, improve the analytical process, repeat patients					✓



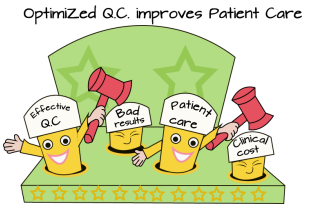
Discussion

1. Error detection is impeded by the common practice of assigning mean and SD values from inappropriate sources, and failing to individualize QC processes in response to analytical process quality.

2. Laboratory quality would benefit from increased staff focus on clinical quality and the interaction of the seven numbers that drive and assess quality.

3. OptimiZed Q.C. processes were consistently more effective to detect clinically-significant error.

4. The R-B-Q Grades, star ratings, and recommended action flags are useful to guide consistent practice.



Conclusions

Quality OptimiZer reports satisfied EP 23-A recommendations:

- ensures test result quality is appropriate for clinical use
- provides suggestions on the frequency of QC sample procedures to have a high probability to detect a stated medically allowable error.
- at the least, provides the ability to check if QC procedures can detect medically allowable error.

The QC strategy using QC samples should include the following for each method:

- The frequency of QC sample test events
- The type and number of QC samples tested per test event
- The statistical QC limits used to evaluate the results
- The frequency of periodic review for detecting shifts and trends
- The actions taken when results exceed acceptable limits

Decisions are based on evaluation of potential costs both in terms of the patient's well-being and of financial liability of the treating parties vs benefits to the patient.

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