Risk-Based Quality Grades© – An Alternative to Sigmametrics

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ABSTRACT

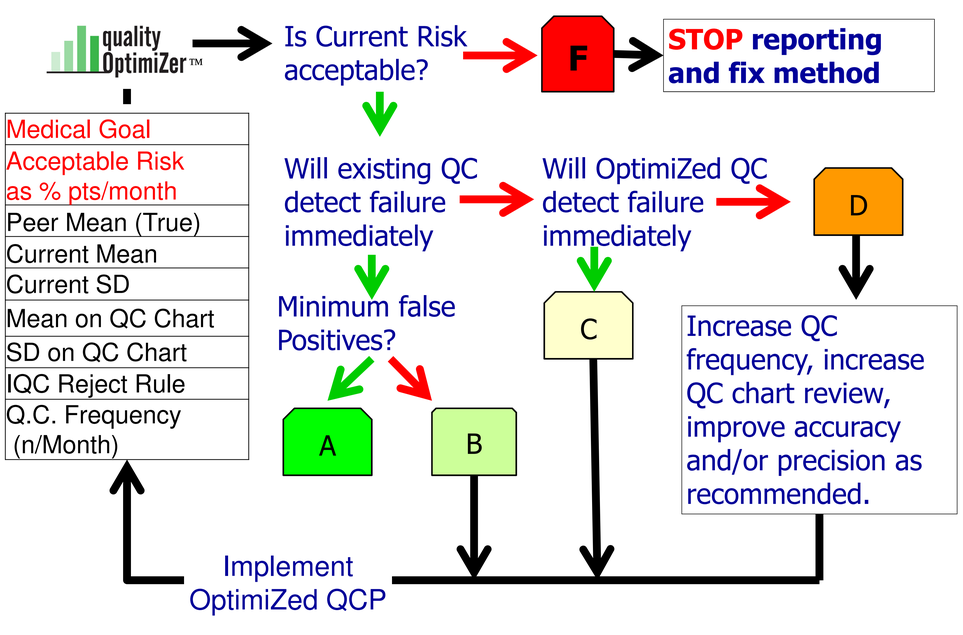
Objectives:
1. **to introduce the Risk-Based Quality Grade© (R-B-Q Grades©) as a metric to:**
   a. combine the current risk of the analytical process producing a medically-unreliable result with
   b. the potential risk of the quality control (QC) process failing to detect a clinically significant error
2. **to compare the R-B-Q Grades© to Sigmametrics for managing patient risk**

Methodology:
1. We examined analytical process quality and quality control practices from three distinct groups separated by dates and QC practice, with a total of 46 laboratories, 274 methods, and 612 QC samples for a total of seven analytes.
2. For each QC sample, we gathered: Measured mean; Measured SD; Peer mean; TEa limit; QC chart Assigned mean; Assigned SD; and QC rule(s).
3. We used **Quality OptimiZer™ software** to:
   a. measure the Current Risk Level as the percent of results that currently fail TEa limits and may be medically-unreliable;
   b. simulate a shift that would cause 2.3% of results to fail TEa limits;
   c. recommended a mathematically-optimized 5-part Q.C. process;
   d. measure the Potential Risk Level as the probability that a patient tested after the simulated error will be exposed to unacceptable risk;
   e. compare the effectiveness of current and recommended QC processes to detect this significant shift;
   f. grade patient risk based on current and potential risk;
   g. measure Margin for Error (to calculate sigma);
4. We compared the interpretation of acceptability of quality and probable action based on R-B-Q Quality Grades© and sigma.

Results:
Sigmametrics would indicate that 3% of methods require attention; however, R-B-Q Quality Grades© would indicate that 89% of methods have unacceptable potential risk.

Conclusions: **The Risk-Based Quality Grade© should be further investigated as a metric to manage patient risk.**

Introducing … Risk-Based Quality Grades©



More info on R-B-Q Grades© and their automation: zoe@awesome-numbers.org

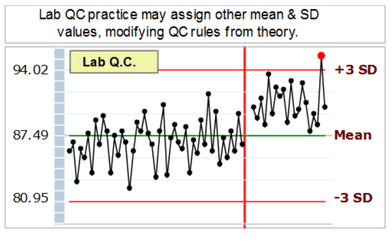
INTRODUCTION

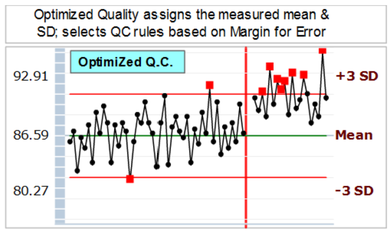
Quality control can be simplified for laboratory professionals. Software has been developed to grade an assay's performance based on only a few statistical values. The new **R-B-Q Quality Grades©** uncovered unacceptable risk in 89% of the assays reviewed compared to only 3% of the assays when Sigmametrics was utilized.

Risk-based Quality Grades© show that 89% of the methods in the study had unacceptable potential risk levels, while Sigmametrics showed only 3% of the methods had unacceptable potential risk levels.

Sigmametrics	R-B-Q Grades©
Definition: A numeric value that characterizes method performance in terms of the number of standard deviations or sigmas that fit within the tolerance limit or quality requirement of a test.	Definition: A grading system A to F that combines [1] current risk of patients receiving medically-unreliable results (MURs) based on measured ability of the analytical processes to meet medical goals and acceptable risk levels and [2] effectiveness of QC processes to detect unacceptable risk levels and [3] opportunity to avoid unnecessary false positive QC flags.
Acceptable 3 sigma level is minimum for any business or manufacturing process (66,807 dpm) (**6.7%** long term error rate)	Acceptability is based on ability to meet locally-defined medical goals and acceptable risk levels as % acceptable MURs/month. Acceptable goals and risk levels are adjusted to meet clinical need.

This 3.6 sigma method illustrates how impossible it is to guarantee error detection in 1 run – even with a 1-2s QC Rule. The inflated SD of current lab practice may take 20 runs.

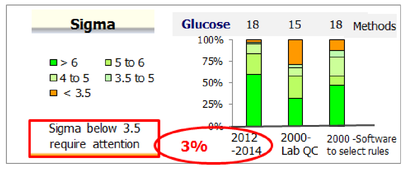


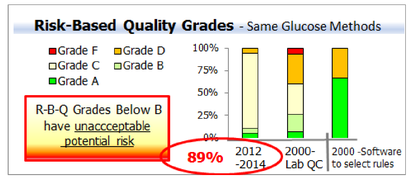


METHODS

The QC data from the three groups of laboratories was uploaded into the Quality Optimizer™ software. The data were independently reviewed by both authors, whose conclusions were identical. These statistics were reviewed: current number of data points that fail TEa; TE vs. simulated TEa failure; Margin for Error vs. sigma; current QC practice vs. optimized QC practice; and current patient risk vs. potential patient risk.

RESULTS





SUMMARY/CONCLUSION

Risk-Based Quality Grades© identified potential patient risk associated with QC design.

Risk-Based Quality Grades© should be further investigated as a metric to manage patient risk.

CONFLICTS OF INTEREST

Zoe Brooks is director of research and innovation at AWEsome Numbers, Inc. and developer of Quality Optimizer™ software. Kim Przekop has no financial interest in AWEsome Numbers or Quality Optimizer™ software.