Mathematically-OptimiZed Risk Evaluation™

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Laboratories have used quality control (QC) concepts and theories based on the same statistical calculations and assumptions for decades. Risk management, as stated in Clinical & Laboratory Standards Institute's (CLSI) EP23A Guideline, adds an 'acceptable risk criteria.'

Now there is a way to comply with EP23A and also save time, reduce risk to patients, and diminish analytical lab errors and their costs.

The Mathematically-OptimiZed Risk Evaluation™ (M.O.R.E.) method enhances existing QC concepts, while risk metrics unveil a wealth of new understanding - just 'beyond sigma.' M.O.R.E. is an Excel-based software that can consistently evaluate QC results and propel the QC process to meet locally-defined quality standards. The M.O.R.E. method begins with basic QC values: target and current mean, the QC chart mean, target and current SD, frequency of QC runs, and any QC rules applied.

Then, the medical director and/or clinicians sets medical goals and acceptable risk levels for quantitative analytes, while the administrative director sets costs/test and the average cost of harm to the patient if a medically-unreliable result (MUR) is released from the laboratory for those analytes. Medical goals are similar to allowable error limits; however, clinicians set the goals with their patients in mind.

The acceptable risk level drives the number of patients a laboratory is willing to expose to an MUR. Currently, SQC (Statistical QC) reports a numerical indicator of the level of quality which is subject to variations in calculation and interpretation. The new M.O.R.E. method answers the question, "Is risk acceptable?" with a clear "Yes" or "No."

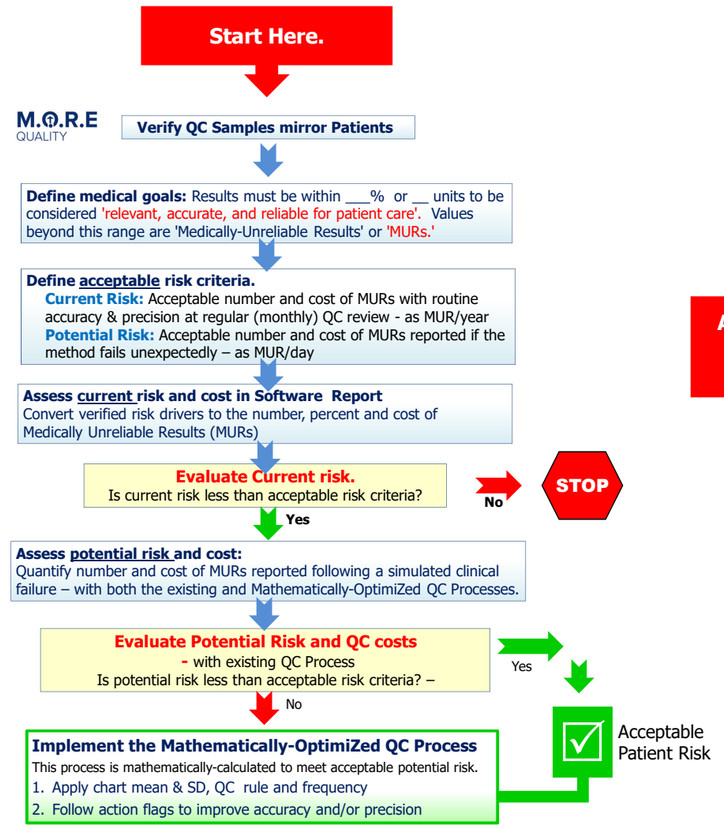
The M.O.R.E. method increases the effectiveness of the QC process and its ability to reduce the number of MURs, and also alerts the laboratorian immediately when the analytical process changes enough to allow more than the acceptable number of MURs to be released.

Risk evaluation
-process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk (ISO 14971)

CARL – the locally-approved Current Acceptable Risk Level – defined as the acceptable number of medically-unreliable results (**MUR**s) per year for each analyte/ analytical process and QC sample.

CARL is typically set at 1 MUR/Year, replacing the statistical QC assumptions such as 5%, or 2 sigma (2.75% error), or 3 sigma (0.135% error).

Acceptable risk – "A state achieved in a measuring system where all known potential events have a degree of likelihood for or a level of severity of an adverse outcome small enough such that, when balanced against all known benefits—perceived or real—patients, physicians, institutions, and society are willing to risk the consequences." CLSI EP23-A



"At the least, the ability of the QC procedures to detect medically allowable error should be evaluated."

Risk Drivers: The path to M.O.R.E.

	Example
Patient Results / Month	9,000
CARL: Current Acceptable Risk Level # MUR / YEAR	1
PARL: Potential Acceptable Risk Level # MUR / Day of Failure	1
True Value (Peer Mean preferred, or package insert target)	100.0
Locally-Approved Medical Goal (or enter TEa limit to model)	30.0
Current Measured Mean	95.0
Current Measured SD	5.00
Existing Q.C. Chart Mean	95.0
Existing Q.C. Chart SD	8.0
Existing QC Reject Rule 1-	3
QC sample frequency / Month	30
Estimated average cost/MUR	$100.00
Cost/test for each QC or patient result	$1.00

Auto-evlauate risk. Verify QCP Effectiveness.

C. Improve QCP	Current Risk Level OK?	Margin for Error	Ability of the QCP to detect medically allowable error (TEa)	
			Detect Failure in One Day?	Avoidable False Pos?
	PASS	0.72		
Existing QCP: Chart values, QC rule and frequency			FAIL	N/A
Mathematically-OptimiZed QC Process			PASS	UNAVOIDABLE

Example of potential savings with M.O.R.E.

Quantify the impact of QC design on patient risk & clinical/legal cost			Existing	M.O.R.E.	Savings
Difference in cost to control Quality / MONTH			$30	$60	($30)
# Patients exposed to unacceptable Risk > simulated failure			6,000	300	**5,700**
# MUR before QC Flag =			**20**	**1**	**19**
If failure rate =	**5.0%**	# MURs =	300	15	**-285**
Potential net healthcare saving, if method fails =			$30,000	$1,500	**$28,500**

References:

CLSI. Laboratory Quality Control Based on Risk Management; Guideline. CLSI document EP23 Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

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Conflict of Interest Disclosure:
Zoe Brooks is CEO and Director of Innovation and Research at AWEsome Numbers, Inc., and creator of the process of Mathematically-OptimiZed Risk Evaluation