

Risk Management means
knowing when to stop.



Introducing

Mathematically-**O**ptimiZed **R**isk **E**valuation™

Improving Patient Care through better laboratory quality

Introduction

Zoe Brooks is the e-book author and creator of the process of M.O.R.E. Quality™, Mathematically-OptimiZed Risk Evaluation™.

"After decades of studying, modeling, testing, teaching, refining quality control processes (and acquiring some good old fashioned horse sense) I discovered that an entire new world of understanding exists beyond the usual QC statistics. The trick is to have a practical process to implement the very specific definitions and recommendations of risk management from ISO, CLIA and CLSI EP23-A." With 'limits of medical utility' based on clinical need, and 'acceptable risk criteria' as the number and cost of lab errors reported, the design, validation and (soon) implementation of verified-effective quality control processes can be automated.



This e-book contains quite a lot of information for an 'overview.' I tried to anticipate your questions and the content grew. Focus on the headlines and read what pertains to you. Parts of this will look much like traditional statistical QC; look closely at the new risk drivers and risk metrics. Some people will zoom in on the numbers, graphs and stats; others will zoom right past them. That's OK, much of this story is visible in the images.

Please feel free to contact me with questions or comments.

NOTE: Mathematically-OptimiZed Risk Evaluation™ applies only to methods that:

[A] create numerical results, and

[B] use stable sample/surrogate/external QC samples to monitor acceptability of analytical accuracy and precision.

What is M.O.R.E. Quality™?

Month after month, staff diligently plot the QC results, track and review results - but how do you know what is acceptable? What are the consequences of medically unreliable results? How often do lab tests cause an additional test, referral for MRI? Incorrect treatment? Each of these has an associated cost, and a risk to the patient, perhaps both.

Mathematically-OptimiZed Risk Evaluation™ is a software-driven risk management process that gives the Laboratory Director the ability to ensure acceptable patient risk - from analytical errors in numerical results (approx. 80% of results) - across multiple departments and sites.

Q&A:

Where does it fit?

- M.O.R.E. Quality works WITH (does not replace) existing QC software to upgrade its capabilities from statistical QC to verified risk management
- **When and why would you use M.O.R.E. Quality?**
 - Export summary data from your existing QC software and upload it for every regular/monthly QC review to
 - Evaluate acceptability of risk of each QC sample
 - Recommend corrective action to reduce risk
 - Design a verify a full QC Process to detect failure of acceptable risk criteria
 - Follow troubleshooting reports to correct faults
- **How much time will this take?**
 - Far less than the time you save by:
 - condensing method review from hours to minutes
 - eliminating warnings and false positives in daily QC
 - providing troubleshooting and method improvement recommendations
 - Set up quality standards, then export data from your QC software to an Excel spreadsheet
 - Upload files for each regular/monthly review
 - If method accuracy or precision has changed since the previous review, reports will recommended changes in QC frequency, rule applied, QC chart review frequency corrective action and corrective action.

- **What if you see unexpected shifts or QC flags?**
 - A regular report provides ranges for the new mean value with corresponding recommended action and changes in QC process
- **What QC rules would you use?**
 - Front line staff will see a single "Stop and Act" rule
 - No warnings; No avoidable false positives
- **What if your software only applies Westgard rules?**
 - If I can only use single rules with this software, doesn't the 1:2s have a high false positive rate?
 - We provide a factor to convert 1-2s or 1-3s rule the Stop & Act rule
- Is there a risk-free, trial period where I can use the software in my laboratory?
- **Staff will not want to change QC processes**
 - Accept that fact. Involve front line supervisors and staff in the process.
 - Show them how much simpler their lives can be, and how much difference they can make to patient care.

Update the mathematics and assumptions:

Compared to existing statistical QC with sigma metrics and Westgard rules, the mathematical formulae and algorithms of M.O.R.E. Quality™:

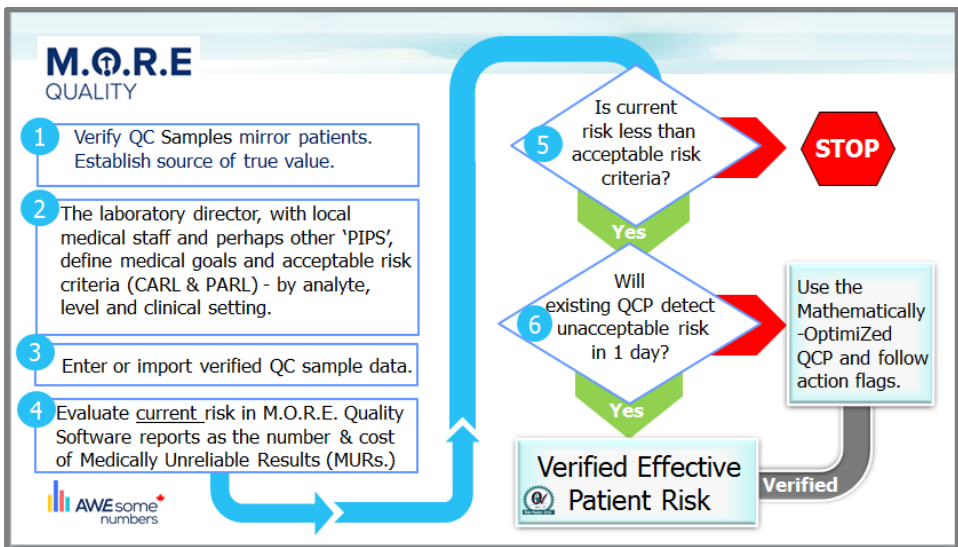
1. is based on medical goals and acceptable risk criteria to your laboratory director – and patients, institutes, physicians and society (“The PIPS”)
2. consider more variables (risk drivers)
 - a. sigma does not respond to changes in patient test volume and acceptable risk criteria
3. provides more information (risk metrics, graphics, action flags and recommendations)
 - a. quantifies opportunities to reduce:
 - i. patient risk exposure,
 - ii. clinical cost of lab errors,
 - iii. laboratory resources to create and review quality control results.
4. advises risk levels on proven attainable risk levels, as opposed to statistical assumptions
5. meets ISO, CLIA and CLSI recommendations for risk management

M.O.R.E. Quality™ concepts and software enhance what people already know and do. NEW complex mathematical formulae and algorithms auto-direct the review, evaluation, and optimal QCP strategy (chart values, QC rules, test and review frequency).

M.O.R.E. Quality enables laboratories to:

1. Report FEWER patient errors
2. Upgrade statistical QC to verified risk management
3. Review hundreds or thousands of methods in minutes
4. Auto-identify methods that fail quality goals (e.g., TEa limits) or need improvement
5. Auto-direct troubleshooting
6. Auto-design and VERIFY effective QC Processes

**Risk Management + M.O.R.E. Quality =
A "transformational" change in technology and mindset.**



M.O.R.E. Quality™ is a clear structured verified process with only two possible outcomes:

1. Risk is unacceptable in this time period. STOP and act to mitigate any errors reported and prevent further harm, or

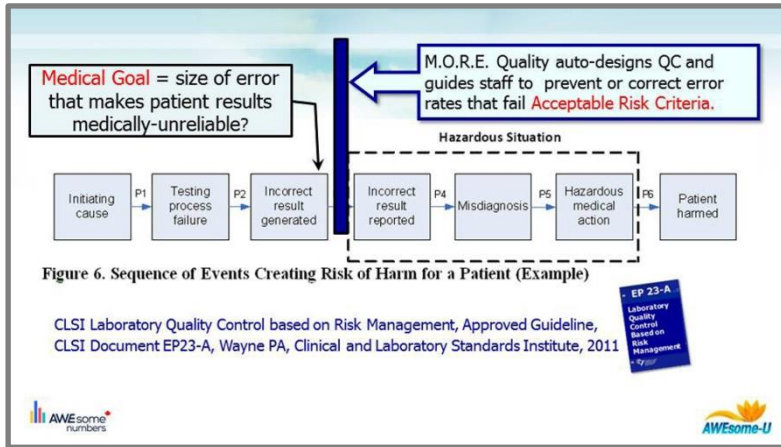
2. Risk is acceptable in this time period. If your existing QCP is not effective or not cost efficient, implement the Mathematically-OptimiZed QC process that is verified to meet your medical goals and acceptable risk criteria.

1. Verify QC Samples mirror patients.
2. Establish source of true value.
3. The laboratory director, with local medical staff and perhaps other 'PIPS', define medical goals and acceptable risk criteria (CARL & PARL) - by analyte, level and clinical setting.
4. Enter or import verified QC sample data.
5. Evaluate current risk in M.O.R.E. Quality Software reports as the number & cost of Medically Unreliable Results (MURs.)
6. Is current risk less than acceptable risk criteria?
 - a. If not, **STOP** and follow recommendations and procedures
7. Will existing QCP detect change to unacceptable risk?
 - a. Use the Mathematically-OptimiZed QCP and follow action flags.
 - b. Verified Effective Patient Risk

There are only two possible outcomes: STOP and mitigate risk now, or use QC process to assure you that risk is acceptable for every patient, every analyte, every day. Reporting unacceptable patient risk is NOT an option.

What makes it different?

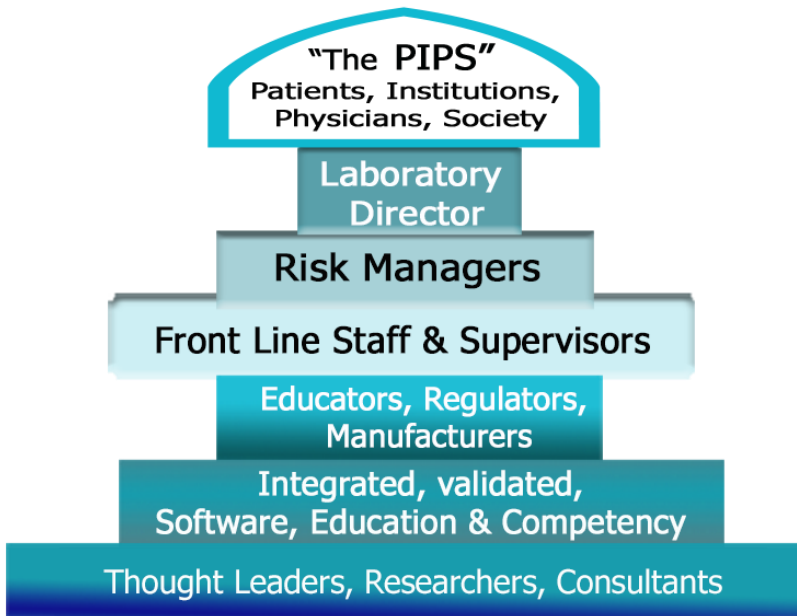
Every step of M.O.R.E. Quality™ is referenced to [CLSI EP23-A](#)



Unlike the quality control charts and rules that clinical laboratories have used for decades to detect errors in analytical processes, Mathematically-OptimiZed Risk Evaluation™ also evaluates the acceptability of risk by comparing existing analytical process quality and QC process effectiveness to acceptable risk criteria defined by the laboratory director.

Risk management concepts present an opportunity to re-think, simplify, and significantly improve medical laboratory quality. Forget statistics for now – look at risk management from a new perspective.

Risk Management is a Team Sport.



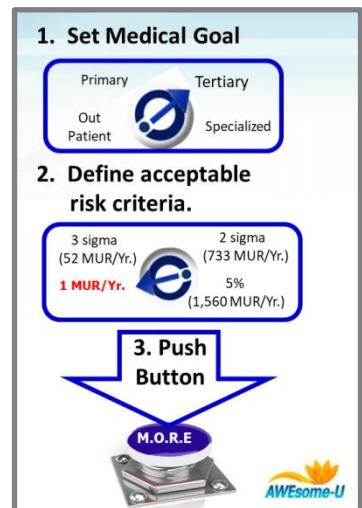
The roles and rules for everyone on the team are clearly defined.

"Risk is the combination of

[A] the probability of occurrence of harm and

[B] the severity of that harm"
(ISO/IEC Guide 51).

If the Laboratory Director sets Medical Goals and Acceptable Risk Criteria that are acceptable to 'The PIPS', the computer can manage the process and guide staff to meet these standards.



M.O.R.E. Quality™ makes QC as easy as easy as A, B, C for the laboratory director.

- A. Control *probability of harm* by setting acceptable risk criteria as the number and cost of Medically-Unreliable Results reported, routinely at method review and if the method fails.
- B. Control *severity of harm* by setting limits of medical utility (medical goals) – and the associated cost of failure to meet those goals - for each analyte by clinical setting.
- C. M.O.R.E. Quality™ will design a QC process and guide staff to meet these standards or act as per your procedures.

Zoe: Why teach the smartphone generation the same old statistics and QC rules, when software can just tell them what those stats mean and what they should do to mitigate or improve standards of patient risk?



That's like teaching someone to make their own personal digital alarm system. It is far more effective to program the alarms and teach people to react to the alarms from their 'digital watches.' Then just synchronize the watches.

Would you like to know M.O.R.E.?

1. Download [The Checklist of Best Practice for Risk Management in Statistical QC](#)
2. Join the team as a Participant, Analyst or Panelist [at AWEsome-U](#) to:
 1. research best practice to manage patient risk in medical laboratories;
 2. measure existing patient risk against regulated, evidence-based or clinical allowable error limits for calcium, glucose and sodium
 3. compare key features of existing and proposed statistical quality control processes;
 4. evaluate the ability of existing statistical quality control (SQC) processes and "Mathematically-Optimized™" SQC processes to
 5. meet best practice recommendations
 6. detect simulated method failure
 7. quantify potential reduction in:
 8. financial risk exposure from medical laboratory errors
 9. in-lab costs to perform quality control

Contact zoe@awesome-numbers.org