B-156

Impact of Seven Incremental Scenarios of QC Strategies

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Background

CLSI EP23A states that **"At the least, the ability of the QC procedures to detect medically allowable error should be evaluated."** It also defines that "The QC strategy using QC samples should include the following for each measuring system:

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

Methods

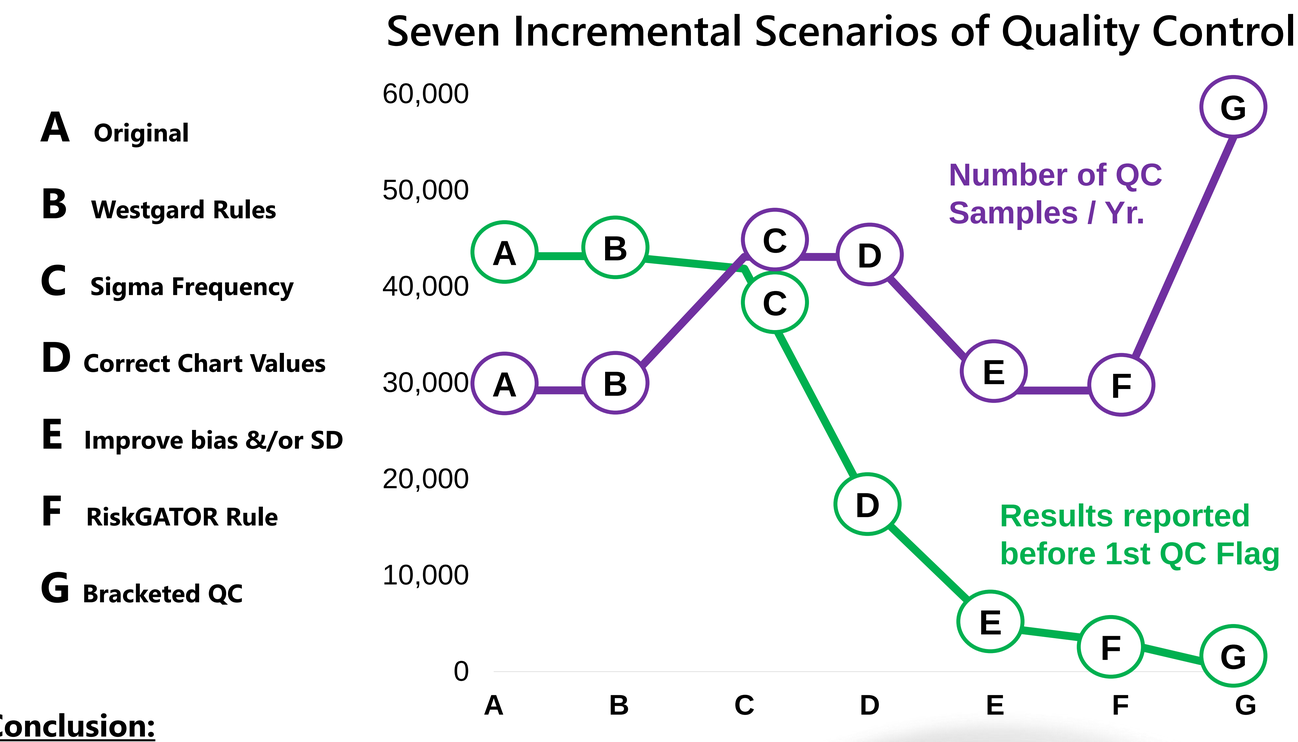
Eighty QC sample mean and SD values were compared to Peer Means and TEa limits for 14 routine chemistry analytes and four cardiac markers tested in December 2022. The number of patient results was normalized to 200 and 60 per day for routine and cardiac; the number reported before the first QC flag after a simulated shift to a 5% error was calculated using RiskGATOR software for seven incremental scenarios of quality control beginning with

[A] Original QC rules (1-3s/2-2s), chart limits, frequency (once per day), analytical bias & SD;
[B] Westgard Rules based on sigma values;
[C] Westgard QC frequency;
[D] Chart means & SDs set to measured values;
[E] Improved bias and/or SD where advised by RiskGATOR software;
[F] Single RiskGATOR rules;
[G] QC bracketed at the end of each day.

Results

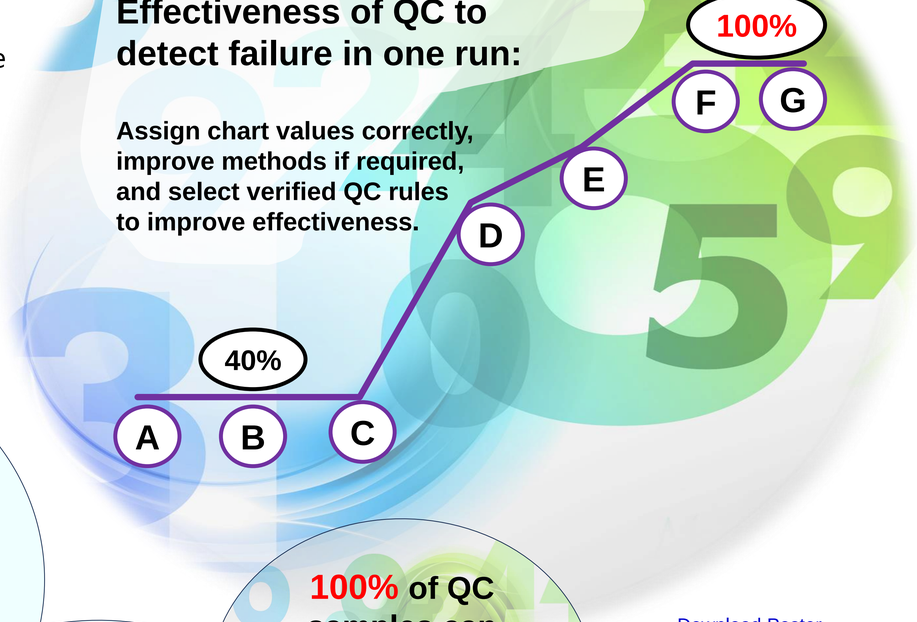
The number of patients at risk decreased with each component of the QC process. Observed and advised number of QC samples per year was inconsistent.

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Conclusion:

1. Selecting Westgard rules and frequency alone will not reduce patient risk significantly.
2. Assigning QC chart values to recent mean and SD and improving analytical bias and SD have the most impact on reduction of patient risk.
3. RiskGATOR single rules are more effective than Westgard rules.
4. Bracketing QC with verified-effective QC will reduce patient risk to zero



60% of original QC processes failed to detect simulated failure in one run.

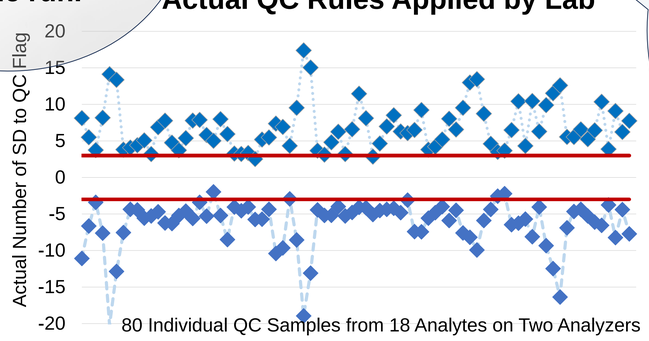
A, B. Why were so many patients reported before the first QC flag originally – and why do Westgard rules not help?

Because their perceived 1-3s rule is usually higher than a 1-6s rule, many QC samples would NEVER detect failu

15% of QC samples could not detect failure in a single run with 1-3s/2-2s rules, even with improved quality.

It would take two replicates, often two days, to detect failure.

100% of QC samples can report zero errors by using a 1-2.5s rule when required.



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24 analytical processes required improvement in accuracy and/or precision
To meet an CLIA allowable error limits with an acceptable error rate of 3 sigma,
- or to enable error detection in a single QC run with a 1-2.5s rule, as this example..

