In Favor of "Full QC"

Back in November 2012, MLO ran an article titled "Empty QC" where the author suggested that some of our current QC practices are not adding value, or even supplying any useful function. This article prompted a response in our blog, Is QC "running on empty"? But more recently, one of the website readers offered his own response.

**I’M AGAINST THE IDEA OF QC BEING “EMPTY!”**

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As a laboratorian interested in QC and studying different materials about the issue of controls, QC, and QC frequency, I think honest and intended people, especially Professor J. O. Westgard, have tried a lot to improve the QC field and provide us with more efficient QC rules and devices. Many others are trying to produce QC materials, and some are inspecting laboratories to help us do better. It would be unfair to accuse everybody related to the issue having just a financial interest in the running of controls.

As with any other warning system, QC is just an alarm that should be used correctly and mindfully to produce good results. Certainly, “financial interest” is one motive for the control manufacturers, but this doesn’t necessarily means that we don’t benefit from QC; when we provide fire-alarms for our houses, both we and the manufacturer of that alarm benefit.

No doubt, “If our latest healthcare laws are supposed to be primarily concerned with patient outcomes, certainly the regulations of inspecting agencies should be geared towards patient outcomes as well”, but this doesn’t necessarily mean we should reduce or eliminate QC. Look at the CAP criteria for HbA1C: From 2008 to 2012, TEa has been reduced from 15% to 12% and then to 7%; and it’s supposed to be reduced to 5% in the near future. Why? Because tightening the TEa limits support more sensitive patient diagnoses and treatments, improving patient outcomes. Mandating a smaller TEa means that manufacturers must develop better performance or risk losing their market share. Laboratories, in turn, must seek out better performing assays, or, if not, they must employ more stringent QC procedures and expend more money and effort on running QC. For example, with an A1C assay having bias 1% and CV 1.5%, the appropriate QC rules for different TEa is:

- For TEa 15%: $1_{3.5S}$ (N=2, AQA=90%, Pfr=0); Sigma metric=9.3 (World class);
- For TEa 12%: $1_{3.5S}$ (N=2, AQA=90%; Pfr=0); Sigma metric=7.3 (still World class);
- For TEa 7%: $1_{2.5S}$ (N=4, AQA=90%; Pfr=3%); Sigma metric=4 (Marginal);
- For TEa 5%: No statistical QC even with N=6 and AQA=50%; Sigma metric=2.7 (Poor)."

As we see, when we desire better patient outcomes, but don't have improved performance, we have to apply more robust QC procedures. In the future, some of our HbA1c assays that are acceptable at present will be considered poor or unacceptable by future quality requirements. In HbA1c, we need these improvements to tackle the growing burden of diabetic patients. Better performance will help us support better care by clinicians.