

# Rhetoric Versus Reality? Laboratory Surveys Show Actual Practice Differs Considerably from Proposed Models and Mandated Calculations

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## KEYWORDS

- Measurement uncertainty • Individualized quality control plans • Allowable total error
- Total error • Performance specifications

## KEY POINTS

- There is a large difference between the scientific debate about goals, measurement uncertainty, and analytical goals and the reality of how laboratories routinely operate.
- Online surveys of laboratory professionals in the United States and around the world were conducted in 2014, 2015, and 2016.
- Most laboratories that implement measurement uncertainty do so only because of regulatory mandate by ISO (International Organization for Standardization) 15189. They do not have a practical use for the calculation.
- Most US laboratories that implement individualized quality control (QC) plans (IQCPs) did so only to fulfill the US regulatory mandates. The IQCPs did not substantively change their QC practices. In particular, most laboratories made no change to their QC frequency after completing their IQCPs.
- Most laboratories use allowable total error to set their analytical goals, along with other goals from a variety of resources. Only a small percentage of laboratories set their goals using target measurement uncertainty.

Although the scientific literature is full of publications proposing new models for errors and new statistics to calculate, the real world of laboratory practice is different. The academic debates often seem to take place in a separate reality, arguing over what is the perfect, pure expression, while ignoring the economic and work-flow pressures that drive the current practice of laboratory medicine.

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Over the past 3 years (2014–2016), the authors have conducted 3 online surveys on analytical goals,<sup>1</sup> measurement uncertainty,<sup>2</sup> and individualized QC plans (IQCPs)<sup>3</sup> that attempted to capture the real-world practices of laboratories all over the world. The findings of these surveys are different than what is recommended or condemned in the literature. The contrast between reality and theory is stark. When the 3 surveys are summarized, a very different picture of laboratory practice is revealed than what the literature describes, debates, or recommends.

That the scientific literature should differ so considerably from reality is to be expected, particularly for new models that are being introduced. Novel approaches are by definition previously unknown. However, in the measurement uncertainty (MU) and total error (TE) debate, both approaches have been around for decades, and most laboratories are already applying one if not both of these models. The difference between the scientific literature and reality therefore should not be large, but it is.

For IQCPs,<sup>4</sup> this is a new approach, in which US laboratories are in effect “guinea pigs” in a kind of regulatory experiment. After an unsuccessful attempt in the early 2000s to justify reduced quality control (QC) frequency through the equivalent QC (EQC) protocols,<sup>5,6</sup> the Centers for Medicare and Medicaid Services asked the Clinical Laboratory Standards Institute to develop an alternative justification for running QC only once a month or once a week. Although the motivation espoused for this regulatory initiative was that the advanced engineering of modern instrumentation no longer requires the traditional regulatory default minimum of daily QC (ie, running controls once every 24 hours), the more honest reason for this approach was the proliferation of point-of-care (POC) devices that are not designed for practical daily QC. For institutions using POC devices for which operators are not well versed in QC, with devices that are not well designed to mimic operations with daily QC, and in situations in which the number of devices and operators can run into the hundreds, the traditional QC approach was daunting and a reduced application of QC was desirable.

There is always a need for scientific debate that is separate from market realities; a discussion that envisions the future ideal state of the marketplace and that shows the optimal possibilities and urges both the diagnostic industry and laboratories to innovate and improve to make those possibilities into practical realities. However, if the discussion is so lofty as to be unrealistic, the debate has little relevance to industry or laboratory. It is a tragic waste of scientific focus if research concentrates on issues that have no practical impact on laboratories and the diagnostic industry. In addition, if there is an ideal state that laboratories and industry need to achieve but is currently beyond their reach, then, at least in the interim, a model is needed that is practical and achievable.

## MATERIALS AND METHODS

In late 2014 through 2016, Westgard QC sent out invitations to online surveys on MU, analytical goal setting, and IQCPs. The survey requests were sent to more than 24,000 laboratory professionals who had voluntarily joined the electronic newsletter list of [westgard.com](http://westgard.com) and nearly 15,000 LinkedIn connections who had voluntarily connected with one of the authors. Surveys were conducted on the SurveyMonkey site and consisted of a variety of single-choice, multiple-choice, and free-form comments. Results were downloaded from the site and saved as Microsoft Excel files. Survey results were initially posted on Westgard Web.

## LIMITATIONS

The surveys were subject to several biases common to voluntary polling. Although the authors sent out survey requests to more than 24,000 laboratory professionals and

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