Six Sigma Quality Management System and Design of Risk-based Statistical Quality Control

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KEYWORDS

• Six Sigma • Quality management system • Process capability • SQC
• Analytical run • Frequency of QC

KEY POINTS

- The traditional error model provides the basis for development of a scientific quality management system (QMS) that adheres to the Deming Plan-Do-Check-Act process for objective decision making based on data.
- Incorporation of Six Sigma concepts and metrics provides a QMS that supports analytical quality management with tools for specifying quality goals, judging the acceptability of performance of examination procedures, designing statistical quality control (SQC) procedures to detect medically important errors, and evaluating quality from external quality assessment and proficiency testing surveys.
- Design of risk-based SQC procedures is practical using the traditional criterion of achieving 90% detection of the critical medically important systematic errors, P_{edc} (probability of detection of medically important systematic errors), along with the documented relationship between P_{edc} and the Parvin measure of the maximum expected number of final unreliable test results, which can be understood as the maximum number of unreliable final test results that might be reported in an analytical run.
- The number of patient samples in an analytical run bracketed by quality control (QC) events, or frequency of QC, can be optimized from information on P_{edc} to minimize the risk of reporting erroneous test results.
- Practical tools for daily quality management are the strength of the error model and show why the uncertainty model has yet to be widely accepted in medical laboratories.

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INTRODUCTION

Metrology challenges some of the traditional concepts and practices that have been developed for quality management in medical laboratories, as discussed in some of the earlier articles in this issue (See Theodorsson's article, "Uncertainty in Measurement and Total Error – Tools for Coping with Diagnostic Uncertainty"; and James O. Westgard and Sten A. Westgard's article, "Measuring Analytical Quality: Total Analytical Error vs Measurement Uncertainty", in this issue) as well as other recent articles in the literature.[1–6] Nevertheless, medical laboratories now depend on practices that have evolved from the initial establishment of statistical quality control (SQC) and the evolution to Total Quality Management and Six Sigma quality management. The theoretic rigor of metrology and the practical needs in medical laboratories must be reconciled and will likely require that the uncertainty model of metrology and the error model, now considered traditional practice, coexist for the foreseeable future.

TRADITIONAL ERROR MODEL IS THE FOUNDATION FOR SIX SIGMA QUALITY MANAGEMENT SYSTEM

First and foremost, the concept of total analytical error (TAE) and the related quality goal in the form of allowable total error (ATE) seem to be contentious issues, even though they are well-established concepts with more than 40 years of widespread application in medical laboratories.[7,8] The practice of making a single measurement to report a test result is almost unique to medical laboratories, as opposed to metrology laboratories. That practice means that any test result may be in error because of both random error (imprecision, SD [standard deviation], or CV [coefficient of variation]) and systematic error (trueness, bias) and that a measure of accuracy, such as TAE, is necessary.[2] Likewise, quality goals in the form of ATE are needed for proficiency testing (PT) and external quality assessment (EQA) programs in which only a single measurement is generally performed on proficiency samples. Such ATE goals are also useful for validating method performance, selecting SQC procedures, prioritizing controls for risk-based quality control (QC) plans, and measuring and monitoring the quality achieved over time and distance.

Many tools and techniques are available to support the traditional quality management practices, as part of a Six Sigma quality management system (QMS),[9,10] whereas metrology tools and techniques are often more suitable for manufacturers of medical devices. Metrology emphasizes the use of reference methods and reference materials to provide a traceability chain that should provide comparability of test results (See Armbruster's article, "Metrological Traceability of Assays and Comparability of Patient Test Results", in this issue). The measure of quality of the traceability chain is the associated measurement uncertainty (MU), which is estimated from the components or sources of variation in the process. A bottom-up methodology is appropriate for use by manufacturers, but is too complicated for most applications in medical laboratories. A top-down methodology using intermediate-term precision data from routine SQC is recommended for medical laboratories by ISO (International Standards Organization) 15189.[11]

For quality management in medical laboratories, a Six Sigma QMS is recommended that follows the Deming Plan-Do-Check-Act cycle to implement a scientific management process, as shown in **Fig. 1** (plan, steps 1–2; do, steps 3–4; check, steps 5–9; act, steps 10–12):

- Plan: quality goals are the starting point in step 1 and ATE is the most common and useful format. The selection of an analytical examination procedure in step 2 should consider traceability and harmonization, along with the reference