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The Quality Concept and Its Specification

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Quality management science (QMS), as evolving in industry today, provides the framework that is necessary for managing quality in health care in the future (3). QMS focuses on customers, their needs and expectations, and the processes for delivering the products and services that will satisfy the customers' requirements. QMS emphasizes the "continuous improvement of quality" in order to satisfy the increasing requirements of customers. The focus on "continuous improvement" distinguishes QMS from other models for quality management.

MODELS FOR QUALITY MANAGEMENT

In health care laboratories, the traditional model for quality management includes components of quality laboratory practices (QLP), quality control (QC), and quality assurance (QA). QLP provides the foundation of policies, procedures, and protocols that define the laboratory's production processes. QC provides a way of measuring and monitoring the analytical quality of the processes within the laboratory. QA extends the measuring and monitoring to other quality characteristics, such as turnaround time, optimal test utilization, etc., that consider the extended testing process outside the laboratory.

QMS expands this model by adding components of quality improvement (QI) and quality planning (QP) (2). QI provides a mechanism for solving those difficult and chronic problems that extend across laboratory sections, hospital departments, and different health care professions. While QI leads to the replanning of processes to correct problems that have occurred, QP aims to prevent problems by implementing the correct processes

correctly from the beginning. QI adds a stronger focus on customers, understanding their needs and expectations, and quantifying those requirements in the form of quality goals. The quality goals should guide the planning of new processes (QP), the implementation of new processes (QLP), the measuring and monitoring of performance (QC, QA), the problem solving to improve performance (QI), which leads to replanning the process and repeating the whole cycle. This model provides for the continuous improvement of quality through a dynamic framework that has quality goals for central guidance.

QUALITY GOALS AND PROCESS SPECIFICATIONS

Quality goals, while of central importance for managing health care laboratories, are difficult to define. This is due, in part, to the communication difficulties between laboratories and their physician customers (8). For example, laboratories may think about turnaround time as the time when they receive a specimen to when they enter the result into the data information system, whereas a physician may think about the time from when he ordered the test to when he saw the test result on a report form. For analytical quality, laboratories think in terms of the average systematic error (bias) or inaccuracy and the standard deviation or imprecision, whereas a physician more likely thinks in terms of total error, which is the net effect of any inaccuracy and imprecision. The solution is for the laboratory to communicate its quality goals and measures of quality in the form of distributions, rather than with the means and standard deviations of those distributions.

The other difficulty that has confounded the development of quality goals is a confusion between quality goals and process specifications. It has been assumed that goals must be in the form of specifications for the process, for example, a quality goal should be in the form of an allowable CV because of our concern for the imprecision of the measurement procedures. Analytical goals should more properly be defined as total error goals; process specifications are then derived based on our further interpretation, judgment, and plan for achieving the

quality goal. Quality goals must be translated into process specifications! The same quality goal can lead to different process specifications in different laboratories.

PRACTICAL APPLICATIONS OF QUALITY GOALS

Quality goals will not impact laboratory operations unless practical approaches are developed for using them in the selection of analytical methods, internal QC procedures, and external quality assessment procedures. The inter-relationships of these steps need to be considered, more-demanding criteria need to be established for method performance (7), and practical tools need to be developed to aid the selection of QC procedures.

Examples are available that demonstrate the application of quality goals for selection of QC procedures in complex multi-test analytical systems (2), but applications are not widespread because of the need for QC simulation programs (1) which are not readily available in service laboratories. A more practical planning tool for busy service laboratories may be provided in the form of "QC selection grids" (QCSGs), which are tabular recommendations of QC procedures that are appropriate for measurement procedures having different magnitudes and frequencies of medically important errors (9). One QCSG has been provided for single-rule fixed-limit procedures, such as Levey-Jennings charts (4) with 2s, 2.5s, 3s, and 3.5s limits, and another for adaptations of the Westgard multirule procedure (5).

To use QCSGs, the quality requirement is defined in the form of a total allowable error (TE_a), the imprecision (s) and inaccuracy (bias) of the method are determined, the medically important systematic error is calculated [from the equation $SE_c = (TE_a\text{-bias})/s - 1.65$], and the instability of the method is estimated. The QC procedure is then found in the appropriate row and column of the grid. With the aid of QCSGs, it takes only a few minutes to select a QC procedure that is appropriate for the stated quality requirement and observed imprecision, inaccuracy, and instability of the measurement procedure.

With the development of tools like the QC selection grid, the limiting step for laboratories is the definition of quality goals. Practical procedures are needed that allow each laboratory to determine appropriate quality goals, or tables of recommendations should be provided by professional societies and updated frequently to maintain current goals.

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