Quality Management Science in Clinical Chemistry: a Dynamic Framework for Continuous Improvement of Quality

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Current quality assurance approaches will not be adequate to satisfy the needs for quality in the next decade. Quality management science (QMS), as evolving in industry today, provides the dynamic framework necessary to provide continuous improvement of quality. QMS emphasizes the importance of defining quality goals based on the needs and expectations (implied needs) of customers. The laboratory can develop customer-friendly goals and measures of quality by recognizing that customers' experiences are represented by a totality of results. Quality goals and measures are best communicated as "total performance" by specifying a limit and percentile of the distribution, rather than a mean and standard deviation. Application of quality goals within the laboratory will usually require partitioning the total performance goal into components and translating those components into specifications to guide the operation and management of production processes. QMS also extends beyond technical processes to people processes and provides guidance for improving the quality of worklife and caring for the laboratory's most essential resource—our people.

Quality management science (QMS) offers new opportunities for improving the quality of health care. According to Laffel and Blumenthal (1), the traditional quality assurance (QA) approaches in health care have several limitations: (a) the definition of quality is too narrow, focusing on the patient as the only customer; (b) the objective is often to achieve norms representing current performance, rather than satisfying the real needs of customers; (c) the target for improvement is primarily physician practice and behavior, rather than the performance of the organization as a whole; and (d) performance tends to be restricted to technical matters and does not adequately consider the delivery of services.

In contrast, modern industrial QMS broadens the definition of customers so that physicians and nurses are considered a laboratory's immediate customers, even though the patient is the ultimate customer. QMS emphasizes the continuous improvement of quality and targets processes rather than people as the source of problems. People are considered to be an organization's primary resource and are to be continually developed through training and education. QMS provides participatory mechanisms (project teams, quality circles, suggestion programs) to involve everyone in problem solving and quality improvement. In this way, quality becomes a pervasive issue that extends beyond technical performance to organizational effectiveness in the delivery of service. Quality becomes the culture of the organization and is reflected by all its people and all their actions.

Berwick (2) explains the need for QMS by describing our current management philosophy as the "theory of bad apples." In this approach, managers collect and analyze data and blame problems on the people who are doing the work. The strategy for improving quality is to weed out the bad apples. According to Berwick, health care organizations must abandon this approach and focus instead on the continuous improvement of quality. To implement this, he recommends that (a) managers become leaders in advocating continuous improvement; (b) investments in education and training be made to support continuous improvement; (c) respect and recognition be provided for all health care workers; (d) an open dialogue be maintained between customers and suppliers; (e) the tools and techniques of modern industrial QMS be applied; and (f) organizational structures be modified to provide a central role for quality engineers or quality management scientists. To involve all staff members in the mission of quality improvement, he strongly suggests the adoption of the "project team" as a new flexible organizational component.

Application of the principles of industrial QMS in clinical laboratories begins by focusing on customers—"customizing the clinical laboratory" is the terminology used by Schuler (3). According to Schuler, we and our staffs must be reoriented to think about customers; O'Connor emphasizes that this reorientation should start by recognizing the needs and expectations of our own "internal" customers (4). We must constantly gather information from customers to assess their needs and expectations, and to identify the level of performance they deem necessary. Our jobs are to design our delivery systems to provide the services they need.

We must recognize that our customers outside the laboratory are many; they include patients, physicians, nurses, administrators, other departments, external regulatory agencies, and payors. According to O'Connor (4), our customers judge the quality of our services not by reliability alone, but also by responsiveness, competence, access, courtesy, communication, credibility, security, understanding consumer needs, and other tangibles such as facilities, equipment, and the appearance of personnel. Therefore, the quality of our services depends on providing a " totality of features and characteristics that conform to the stated or
plied needs of [these] users or customers" (5). To do our
obs well, we must understand our customers' needs and
expectations and establish quality goals that guide the
design, evaluation, implementation, and operation of the
laboratory testing processes.

Our purpose in this paper is to describe how the indus-
trial model for QMS can be adapted to clinical laborato-
ries to provide a logical framework for managing the quality of
everything we do. We discuss meaningful measures of
quality characteristics to illustrate the differences be-
 tween our traditional perspective as a supplier of labora-
tory services and the perspective of our customers. We
suggest some general guidelines for measuring quality and
ways of formulating quality goals to facilitate communica-
tion with our customers. Finally, we describe how quality
goals should be used in managing laboratory processes and
how they redirect our scientific thinking into the realm of
planning and delivery of laboratory services.

\* Framework for Managing Quality

The traditional model for quality management in clinical
laboratories usually includes three major components. (a) Qua-
 lity laboratory practices (QLP) provided a foundation of
policies, procedures, and protocols that set forth the lab-
 oratory's production processes. (b) Quality control (QC) was
added in the 1960s to provide a statistical tool to monitor
the performance of analytical processes, to identify prob-
lems, and to correct errors before delivery of test results to
be customers. (c) Quality assurance (QA) concepts were
added in the 1980s to extend the measuring and monitor-
ing to other quality characteristics, such as turnaround
time, sample identification and labeling, test utilization,
etc.

For most of us, QA practices have tended to follow the
standards and required characteristics of the Joint Com-
m ission for Accreditation of Healthcare Organizations
(JCAHO), which unfortunately have mainly perpetuated
the "bad apple" philosophy. The stated objective of "mea-
suring and monitoring the quality and appropriateness of
services" (6) has encouraged development of paper pro-
grams. Volumes of data are collected, analyzed, reviewed,
and passed from one department and (or) committee to
another. An accumulation of stacks of paper provides
documentation of QA, whether or not the documented
problems are actually solved. Most of the problems identi-
ified by this measuring and monitoring are inherently
complex problems involving processes that cross depart-
mental lines. Industrial QMS has shown that solving such
problems requires a structured group problem-solving ap-
proach, such as a quality improvement team. No such
mechanism currently exists in most health care organiza-
tions, yet JCAHO neither checks for nor recommends the
team approach for problem solving. In our opinion, current
recommendations by JCAHO are wholly inadequate for
assuring quality. By overemphasizing documentation and
misdirecting our efforts, they may actually impose a bar-
er to the development of the quality management sys-
tems needed to improve quality.

It is essential for us to understand that QA, like QC, is
intended to measure whether the laboratory processes are
achieving their goals. The difference between QC and QA is
generally related to the particular quality characteristic
that is being measured. QC monitors performance charac-
teristics of the analytical process within the laboratory,
(i.e., imprecision and inaccuracy; QA measures perfor-
mance characteristics that extend the process beyond the
borders of the laboratory to the areas of direct and imme-
diate concern of our customers, e.g., turnaround time.
Although both QC and QA can identify problems, neither
includes a mechanism for solving the problems. Problems
identified by QC tend to be solvable because they reside
within our control in the laboratory and we, as laboratory
scientists, have the technical expertise to solve them.
Problems identified by QA are best solved by assembling
the necessary across-department expertise in the form of
the "quality team"—a missing element in our current
quality system.

In fact, two additional components—quality improve-
ment (QI) and quality planning (QP)—are needed for quality to
be properly managed (7). A fully developed framework for
quality management should include the "5 Qs" shown in
Figure 1, which should function as a continuous feedback
loop to provide the dynamic process necessary to manage
quality in today's fast-changing, competitive health care
environment.

General guidelines for development and implementation
of QI in a health care laboratory have been described (8).
The QI component complements QA by providing the
structured mechanism necessary to solve problems that
extend across laboratory sections or hospital departments,
or extend across different professional groups, such as
medical technologists, clinical chemists, clinical pathol-
gists, nurses, pharmacists, and physicians. Solving such
problems requires the quality team approach because no
one person, profession, section, or department has the
knowledge and skills to identify the cause or to develop and
implement the solution. New problem-solving techniques
are used to diagnose problems, identify remedies, and
replan the processes to prevent problems from recurring.
Implementation requires an investment in training and
education, initially for top and middle managers who steer
the improvement process, then for individuals participat-
ing in the quality teams, and ultimately for everyone in
the organization.

QI also requires a cultural change that encourages coop-
erative efforts, recognizes team accomplishments, and re-
wards individuals for being good team members. In our
present organizations, individuals tend to get ahead pri-
marily by standing out from the group, not by contributing
to a team. For teamwork to thrive, we must value the
contributions of each individual to the group effort, encour-

Fig. 1. Five-Q framework for managing quality

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age their involvement by establishing participative mechanisms for problem solving, support their efforts through training and education, and celebrate their accomplishments as team members. QI requires a people-oriented organization because everyone needs to be seriously involved and committed to solving our many problems.

Whereas QI leads to solving problems by replanning processes, the ultimate objective, of course, is to prevent problems from occurring by planning processes correctly in the first place. Thus, the QP component must be added to complete the quality management framework. QP provides the focus on customers, emphasizes the importance of understanding their needs and expectations, and leads to the definition of quality goals. These quality goals guide the planning of new processes, the implementation of operational policies and procedures (QLP), the measuring and monitoring of performance to assure that quality is satisfactory (QC and QA), and the solving of problems to improve quality when performance is not satisfactory (QI). The last step leads to replanning the process and repeating the cycle of implementation, measuring and monitoring, and improvement. This provides continuous improvement of quality through a dynamic management framework that has quality goals for central guidance.

Customer vs Supplier Perspectives on Quality

We must communicate with our customers to assess whether satisfactory quality is being achieved. However, we must not underestimate the difficulties in communication caused by the different perspectives of the customer and supplier. For example, the turnaround time of a test is often viewed very differently by the physician and the laboratory. The physician's "clock" may start as soon as he or she has written an order for a test and will not stop until the results are seen. The laboratory's clock starts only after the order to draw the specimen is received—or even later, when the specimen arrives for processing—and stops when the test result is reported (entered into the laboratory or hospital information system or called to the ordering source). There is an obvious difference in perspectives, and we should expect problems to occur just because of these different points of view.

More subtle differences in perspectives may also have an effect. Figure 2, for example, shows the within-laboratory component of turnaround time for blood gas measurements for a typical week at Hartford Hospital. The average performance for about 2500 samples is 7 min (the median of this skewed distribution). This value of 7 min represents the best single or point estimate of the time it takes the laboratory to provide this service. The laboratory staff may communicate to its customers that it takes an average of 7 min to perform this analysis. However, the customers do not experience this average performance—they experience the performance for individual samples, which are above and below the average, anywhere in the observed distribution of turnaround times. In this case, even if the laboratory achieves a goal of average performance better than say, 15 min, complaints about quality of service may be expected. The cumulative distribution shows that about 15% of the samples are not reported by 15 min and 5% are still not reported by 25 min. From the customers' point of view, performance is not adequately described by the average (or median). More important information is contained in the tail of the distribution than in the peak. From the customer's viewpoint, the times corresponding to the 90th to 95th percentiles are more appropriate for establishing a quality goal and monitoring performance than is the average turnaround time.

Analytical quality provides another example of the difference in perspective of the laboratory and its customers. According to a published recommendation from the National Cholesterol Education Program (NCEP), methods of measuring cholesterol currently should have a bias of 5% or less and a CV of 5% or less at concentrations of 2000–2400 mg/L (9). Americans have been encouraged by the NCEP to know their cholesterol concentration and are engaged in widespread testing at various testing sites, including hospitals, clinics, pharmacies; and shopping malls. Changes of 50–100 mg/L may be interpreted by the public as significant, even though such changes are well within the expected within-subject biological variation, as well as within the analytical limits allowed by NCEP's 5% goals. Figure 3 shows the distribution of results that are statistically expected for a specimen containing 2000 mg/L when analyzed by a method that just satisfies the quality goals. Assuming that the 5% inaccuracy is positive, the average concentration observed will be 2100 mg/L and 50% of the measurements will be in error by at least 100 mg/L. Because of the added effects of imprecision, 16% will have errors greater than 200 mg/L. 2.3% will exceed 300 mg/L, and 0.135% (4 of 3000) will exceed 400 mg/L.

One could argue that these individuals do not (or should not) interpret their test results—this should be done by
their physicians. Unfortunately, even though physicians are more sophisticated customers, many of them also find imprecision and inaccuracy to be foreign concepts. Physicians experience the combined effect of these errors, or the "total error" (10), which will be much larger than is immediately apparent from the 5% goals stated by NCEP. In other words, the NCEP goals are not in customer-friendly terms; communication with our customers is impaired when quality goals are stated in terms of inaccuracy and imprecision, rather than stated directly as the total error that may be observed.

Cumulative Distribution and Customer-Friendly Quality Goals

Because it is important to appreciate the customers' perspective as a collective experience with a distribution of results, it is therefore appropriate to provide collective measures of quality by presenting a cumulative distribution or by stating the limits and corresponding percentiles that describe the tail of the distribution. Furthermore, we should define quality goals for "total performance" by stating the limit and percentile of the cumulative distribution instead of figures for average performance.

For turnaround time, 90th or 95th percentile limits are probably adequate for describing within-laboratory performance. Use of higher limits, e.g., 99%, tends to focus attention on a few extraordinary problems, rather than on the performance to be expected in routine daily operations. For the blood gas data in Figure 2, for example, turnaround times >15 min were associated with batch arrival of specimens, repeat analyses, instrument problems, or heavy workload. This information is primarily of value for initiating specific quality-improvement efforts to improve performance, not for describing routine performance.

In the case of analytical quality, the errors expected under stable operating conditions are predictable from the Gaussian model. We believe it is useful to adopt a 99.7% limit (±3s limits) as the requirement for relating method performance to the "allowable total error." In other words, method inaccuracy and imprecision should be sufficiently small so that the bias together with 3s is less than the total error deemed allowable. Use of a 99.7% limit is more conservative than the usual 95% limit (±2s) that was recommended many years ago (10). However, allowing 1 of 1000 results to exceed a quality goal is not a very good guarantee of quality. It is doubtful that we ourselves would accept such a limited warranty in the products and services for which we are the customers. A minimal warranty would be to allow only 1 of 100 to exceed the quality requirement (±2.58s limits), but a better target would be to allow only 3 of 1000 to exceed the limit (±3s limits). The principle of continuous improvement indicates that we should move in this direction, a step at a time if necessary, but certainly targeting this level of performance for our fourth- and fifth-generation analytical systems.

Guidelines for other quality characteristics need to be evaluated on an individual basis. Communication with customers will generally be improved if we use cumulative distributions for presenting measures of quality and state quality goals as a limit and percentile of the distribution.

Partitioning and Translating the Total Performance Quality Goal

The preceding arguments for defining a limit of the distribution as a total performance quality goal have been based primarily on the customers' perspective. However, a total performance goal is also useful for managing production processes. The laboratory scientist must assume responsibility for partitioning the total requirement into components for different parts of the process and for translating the components into specifications appropriate for that part or step of the process. Quality goals are different from process specifications. Process specifications depend on our further professional interpretation, judgment, and plan (design) for achieving the quality goal.

For turnaround time, for example, it is useful to identify the steps in the process, as illustrated in Figure 4 (left side). Requirements for within-laboratory turnaround time may be partitioned over specimen acquisition, processing, analysis, and reporting. Individual specifications are required for each step if one is to manage the overall process; however, the specifications may vary from one laboratory to another, depending on their particular process and how they can best achieve the required performance. In all steps the component specifications are probably best formatted as maximum limits for time ($t_{max}$).

For analytical quality (Figure 4, right side), the total error requirement ($TE_{max}$) may include components from inaccuracy and imprecision of the method, calibration uncertainty, and the lack of sensitivity of the statistical QC procedure (11). Translation may be more difficult because different kinds of specifications are needed to evaluate and control different sources of error. Inaccuracy requires a specification in the form of an allowable bias; imprecision requires a specification in the form of an allowable standard deviation. Calibration generally introduces a systematic error, which may be specified by an allowable bias when calibration occurs very infrequently, or specified by an allowable standard deviation when calibration occurs daily or more frequently. For selection or design of QC procedures, it is useful to have a specification of the medically critical systematic error ($\Delta SE_c$) that needs to be detected (12). Additional components may be considered when it is necessary to allow for within-subject biological variability, sampling variability, sampling bias, and analytical bias between different routine methods operating simultaneously in a laboratory.

Discussion

Clinical laboratory scientists have a unique opportunity to provide leadership in the area of QMS for our organizat-
tions and for health care in general. The concepts of industrial QMS can probably be more easily adopted in clinical laboratories than in any other unit in a health care organization. We have a strong foundation of quality practices (QLP), extensive experience in statistical quality control (QC), and strong data-analysis skills for measuring and monitoring quality (QA). Although our training leads to a focus on analytical processes, we need to expand our view to include across-department processes and extend our scientific thinking to the management of those larger processes.

Given our current strengths (QLP, QC, QA) and our insights into the need for additional components QI and QP, we are able to develop the dynamic framework necessary to manage quality objectively. That framework is simply a logical extension of the scientific method we use in our technical work. We plan studies (QP), do experiments (QLP), collect data (QC, QA), analyze what needs to be done next (QI), and then repeat the whole cycle, again and again, until we achieve our goals. We need to apply this continuous improvement thinking to all our processes and to progressively expand the areas in which we apply the scientific method.

In applying the scientific method, we need to recognize that objectivity depends on having clearly defined quality goals to guide the whole management process. Quality goals are needed for planning new production processes, implementing new policies and procedures, measuring and monitoring performance, and assessing the need for improvements. The quality of our production processes can be managed objectively when quality goals are partitioned and translated into appropriate specifications for each component or step of the process.

Quality goals are, in effect, the "standards" needed to advance from subjective or qualitative management to objective or quantitative management. They are needed to standardize new processes so that the necessary quality will be achieved when the process is first implemented; to assess raw measurements of performance for assuring quality; to convert performance data into diagnostic information for problem solving and quality improvement; and to provide stability and consistency over time. Like standards, quality goals must be carefully prepared if they are to be useful. We believe the proper format is a total performance limit that contains a specified percentage of the distribution (expressed as percentiles). Unfortunately, many of the recommendations on quality goals now found in the literature do not readily lend themselves to laboratory applications because they are improperly formatted. A clear understanding of how goals are to be used and communicated to our customers is necessary to improve our efforts in defining them.

Although we see many implications of QMS for the technical management of testing processes in clinical laboratories, we think it is equally important to consider the implications for "people processes." Continuous improvement also means the ongoing development of our major enduring resource—people. This requires a serious investment in in-service training and continuing education, as well as a commitment to formal educational processes for clinical laboratory personnel at all levels. To attract new people to the field and to retain our present staff, we must make the laboratory an interesting and meaningful place to work, not just an efficient production line. We must provide an environment and culture that stimulate thinking, not ones that just stress physical and mental endurance. We must provide opportunities for growth and development, not just added responsibilities and frustrations. We must allow people to participate in decisions that affect the quality of their work and their working conditions. In short, we must "care" for the people with whom we work if they are to care about the quality of the services they deliver.

In a broad sense, "caring for quality" must become the central focus in what we do in the clinical laboratory. Like any philosophy, it will provide a framework of values and beliefs that will guide our actions. Like religion, it will be most meaningful when it affects our everyday activities. Like mythology, it will put us in touch with the deeper things that matter. Quality in health care matters. The personal commitment of each of us is necessary to ensure that quality is a vital force guiding our activities instead of a mere paper program diverting our efforts from meaningful work. We must care for quality today if we are to be recipients of quality care tomorrow.

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References