Quality Qorner

Lingo Lesson No. 2, or "Oh No! Here She Comes Again!"

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Maybe it's the blood banker in me; maybe it's the Virgo in me; maybe it's because I took some courses in college on the Greek and Latin origins of English words and medical terms. Or maybe it's because there are fully a dozen phrases that start with the word "quality" in the ISO 9000 Fundamentals and Vocabulary for quality management systems.[1] I can't help but be a fussbudget about using words in their correct context to achieve comprehendible communication—especially about a topic as important as quality management in medical laboratories.

Almost twenty-five years after the term "quality assurance" was first introduced into the hospital and medical laboratory environments, there are still pathologists and laboratorians who think that quality control (QC) and quality assurance (QA) are the same thing. It got even more complicated when the phrase "quality system" was introduced in the 1990s and "quality management" was introduced in 2000. Then enter "quality management system." All these phrases are continually used interchangeably, albeit incorrectly. No wonder everyone's confused and I feel like Bob Seeger in his classic song, "Runnin' Against the Wind." Sorry to say, we need another lingo lesson.

Think of *quality control* as the innermost circle of a target. The target for each and every laboratory test is accurate results. Quality control ensures we can say with a high degree of confidence that the results are accurate for the batch of samples being tested at that time. QC is method control; we test samples with known expected results and when we get those results we can say that all the patients' unknown results obtained within the specified time period (batch or shift) are likely to be accurate. However, QC does not say that those accurate results necessarily belong to the patient whose name is on the sample! All the QC you've ever done or ever will do will never prevent a patient misidentification or a sample switch. In the laboratory's path of workflow of preanalytic, analytic, and post-analytic activities, QC hits only the center—the analytic methods.

Think of *quality assurance* as the next outer ring of the target. When introduced into the health care lexicon by the JCAHO in the 1980s, quality assurance was meant to answer the question, "In these new times of diagnosis related groups (DRGs) and cost containment, how do we know we are delivering quality care to patients?" This is a very different question for the medical laboratory than whether our contribution to patient care is accurate laboratory test results. It's in QA that we start to ask questions about *how* the laboratory contributes to a patient's care. How many times did a phlebotomist attempt to collect a blood sample from an inpatient only to find that the patient was not wearing proper identification? How many samples are not acceptable upon receipt into the laboratory? How well does the collection time of the sample reflect the administration time of a therapeutic drug? How timely are laboratory results compared with physician and patient needs? How many times did the laboratory have to notify about corrections to released results found to be erroneous? How do the laboratory's results compare with those of other laboratories for the same analytic method or instrumentation? How well do final interpretations correspond to frozen section diagnoses? How well do interpretations from fine needle aspiration biopsies correlate with interpretations from the tissue biopsy? Notice that these questions— and many more that could and should be asked—measure the effects of activities in the laboratory's entire preanalytic, analytic, and post-analytic path of workflow well beyond method control. Therefore, QA is bigger than QC and covers all the preanalytic, analytic, and post-analytic processes.

What about all the other aspects of managing a medical laboratory? What about meeting design and safety requirements for your laboratory's physical facilities? What about staff training and competence assessment? What about equipment management? What about procuring, storing, and managing reagents and supplies? What about creating, approving, revising, and controlling the laboratory's documents and records? This is the next larger ring of the target, a *quality management system* (QMS) which encompasses all the management activities needed to support the laboratory's preanalytic, analytic, and post-analytic activities. A model for a generic quality management system that meets all the requirements of U.S. laboratory regulatory and accreditation organizations has been published by the Clinical and Laboratory Standards Institute (CLSI) in a guideline that describes how to use 12 Quality Systems Essentials (QSEs) as a means to organize all the policies, processes, and procedures that any laboratory needs to meet those requirements.[2] A QMS includes both QC (in QSE Process Control) and QA (in QSE Assessments), as well as the laboratory activities described above—and more—necessary to make your laboratory's best contribution to patient care.

I sincerely hope I've finally managed to convince you that QC, QA, and QMS are not the same. And I also hope you'll keep these distinctions in mind when you talk with fellow laboratorians, write papers, and give presentations on the subject of quality in the medical laboratory. My hope applies equally to those who write regulations and accreditation standards so that we can all be on the same page for the same word. Consider this your lingo lesson for this back-to-school month.

1. ISO. ANSI/ISO/ASQ Q9000-2005 Standard: *Quality Management Systems—Fundamentals and Vocabulary.* Milwaukee, WI: American Society for Quality Press; 2005.
2. NCCLS/CLSI. *A Quality Management System Model for Health Care; Approved Guideline, Second Edition.* Wayne, PA: CLSI; 2004.

This Month's Quality Quote:
"The words I use are everyday words and yet are not the same!"
—Paul Claudel, poet

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