

Quality in Health Care

How Can Labs Improve the Total Testing Process?

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Over the past decade, results from published studies and comprehensive national initiatives on quality in health care have reshaped the landscape of the nation's health care system. Of these, the largest impetus for the recent focus on quality came in 1999 when the Institute of Medicine (IOM) released a report entitled "To Err is Human" containing some alarming estimates on adverse events (1). According to the report, the number of Americans who die each year due to medical errors is between 44,000 and 98,000, numbers that exceed the eighth leading cause of death. While the accuracy of this report remains controversial, it raised the standards and expectations for patient safety improvement held by payors, providers, professional groups, and most importantly, the public.

Building on the 1999 report, the IOM's Committee on Quality of Health Care in America issued a second report in 2001 calling for a redesign of the U.S. health care system in the 21st century (2). This report called for all stakeholders to commit to a shared vision for improvement, and it included several initiatives and guiding principles to help providers redesign care processes. In another follow-up report published in 2003 as part of their Quality Chasm Series (3), the IOM once again focused on patient safety and achieving a new standard of care.

From our perspective as laboratorians, the heightened emphasis on patient safety translates into a need to improve the quality of laboratory services. While quality has always been a central focus of the clinical lab,

Taking the First Step: Creating a Quality Systems Environment

How can laboratorians respond to the need for increased patient safety? In order to meet the JCAHO patient safety goals (see box,

tory Standards Institute (CLSI; formerly the National Committee for Clinical Laboratory Standards, NCCLS) has developed an approved guideline that "defines a model for those who provide health care services that will assist organizations with implementation and maintenance of an effective quality system." This guideline, HSA1-A2 (4), describes a hierarchy of stages through which an overall quality system can be developed (see box, p. 9).

Another approved CLSI guideline, GP26-A3, addresses the application of a quality system to clinical laboratory services (5). In this guideline, all activities are organized into 12 quality system essentials (QSEs): documents and records, organization, personnel, equipment, purchasing and inventory, process control, information management, occurrence management, internal and external assessment, process improvement, customer service and satisfaction, and facilities and safety. Numerous examples for quality monitoring projects are also provided in the GP26-A3 guideline.

Mapping the Total Testing Process

When establishing a quality management system, laboratorians must consider the total testing process. Clearly, the large number of steps in each of the three phases of testing—pre-analytical, analytical, and post-analytical—can make the task overwhelming. One approach to simplify the task is to visualize each process individually. In my laboratory, we did this by laying out all of the laboratory's ongoing and potential quality monitors on a grid that lists the monitors as a function of the key activities described in GP26-A3 (See box, p. 12). Although only a limited number of our monitors are listed in this example, it illustrates how to apply a systems-based thinking approach.

Noteworthy in the most recent edition of this CLSI guideline is a change in terminology that brings it in line with quality guidelines

the IOM reports and the new annual patient safety goals set by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have raised the bar significantly for overall quality in health care. Implementing new strategies and tools to improve the quality of laboratory testing, however, is not easy in today's environment. Dwindling reimbursement and a shrinking workforce have left most labs with little free resources to spend on such initiatives.

p. 9), all laboratorians must become familiar with creating and using a quality system model. Not only is this model embraced in the final CLIA '88 regulations, but it also permeates the accreditation requirements of programs such as those offered by the College of American Pathologists (CAP).

A good way to begin creating a quality systems environment is to understand and apply the concept of a quality system to the total testing process. The Clinical Labora-



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JCAHO National Patient Safety Goals

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was one of the first organizations to increase its focus on patient safety, and it now sets a new safety agenda each year. Highlighted here are the 2005 JCAHO Patient Safety Goals. Those in boldface were new for 2005. Specific details about meeting goals 1, 2, and 5 are provided here and highlighted in red, as these goals are the most relevant to clinical laboratorians.

Goal 1: Improve the accuracy of patient identification.

- ▶ Use at least two patient identifiers (neither to be the patient's room number) whenever administering medications or blood products, taking blood samples **and other specimens for clinical testing, or providing any other treatments or procedures.**

Goal 2: Improve the effectiveness of communication among caregivers.

- ▶ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result "read-back" the complete order or test result.
- ▶ Standardize a list of abbreviations, acronyms, and symbols that are not to be used throughout the organization.
- ▶ **Measure, assess, and if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.**

Goal 3: Improve the safety of using medications.

Goal 4: Improve the safety of using infusion pumps.

Goal 5: Reduce the risk of health care-associated infections.

- ▶ Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
- ▶ Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-associated infection.

Goal 6: Accurately and completely reconcile medications across the continuum of care.

Goal 7: Reduce the risk of patient harm resulting from falls.

Source: 2005 Hospitals' National Patient Safety Goals—Joint Commission on Accreditation of Healthcare Organizations. (www.jcaho.org)

issued by the International Standards Organization (ISO). For example, 'examination' has replaced 'test,' and 'examination process' has replaced 'analytical phase.' There are a total of nine steps—four steps in the pre-examination process, three steps in the examination process, and two steps in the post-examination process—some of which are illustrated in the sample grid (see page 12).

An actual grid for a complex clinical laboratory would also list sections of the laboratory that are impacted by a specific quality monitor, as well as those individuals who are responsible for compiling the information and using it to improve the quality of services. The monitors and projects should also include indicators in other special categories such as customer satisfaction, in addition to those in all areas of laboratory testing. Because a comprehensive list of quality monitors and projects might exceed 100 items, employing a tool such as a map is important to ensure that no areas are overlooked.

Other Tools: Six Sigma and Lean

Other quality concepts receiving increased attention and application in clinical laboratories are those of Six Sigma and Lean. Originally developed in manufacturing environments,

these strategies are well suited to the delivery of laboratory services, which in many ways is identical to product manufacturing. In general, Six Sigma looks at defects per million opportunities in a process, while Lean aims to eliminate different categories of waste or non-value added services from a process.

Many resources are available to aid laboratorians in understanding the application of Six Sigma to the improvement of laboratory testing processes, including a book called *Six Sigma Quality Design and Control* by James Westgard (6). He describes the Six Sigma concept as a performance goal for a production process. The goal, as its name implies, is to achieve six sigma—or standard deviations—for any production process, "which means that 6 sigmas or standard deviations of process variation should fit within the tolerance limits for the process of the quality required for the product." To apply Six Sigma as a quality management tool, a laboratory needs to first quantitatively assess the performance of an individual testing process and then make process improvements that are designed to achieve a better level of performance and to approach that of Six Sigma level.

In contrast to Six Sigma, Lean is a set of principles and tools that can help improve

the speed of many components of the total testing process (7). Taking the waste out of selected areas of the laboratory's testing process is hardly a new concept to laboratorians. But the present environment of increasingly limited resources has made the use of the Lean approach even more significant, as described in *Clinical Laboratory News* last month (8).

Recently, our laboratory group at Loyola Medical Center applied Lean principles to how we handle and report reference lab results. To improve the quality of the process and reduce wasteful steps, our key goals were to reduce turn-around time (TAT), reduce transcription errors, increase consolidation of referred testing, and improve staff utilization. By charting the processes, we were able to reduce the number of key steps from eight to five. A key change that allowed this improvement was interfacing the lab's computers with those of the reference lab. This change allowed us to decrease the TAT on selected esoteric tests from 14% to 44%, depending on the test.

Other Tools in the Quality Bag

Laboratorians have a number of other well-known resources at their disposal for identifying new quality monitors that encompass the total testing process. One set of tools that we regularly employ is the Q-Tracks and Q-Probes quality programs. These programs are offered as part of CAP's package of quality products in conjunction with their Laboratory Accreditation Program. Q-Track projects require multiple data collections and assessments over the course of a year, while Q-Probe projects require a single data collection and assessment. Each year, we evaluate which Q-Tracks and Q-Probes are most meaningful to the present issues in our institution and selectively subscribe to those programs. We have found many of these projects useful for improving quality, as well

as for giving us a benchmark of where our quality efforts stand in comparison to peer institutions. We have also used certain Q-Track or Q-Probe metrics to establish our own internal benchmarks, and we plan to continue focusing on these in the future.

Another quality resource that should be familiar to anyone working in a hospital, clinic, or clinical laboratory setting is the incident report. In our present culture of improving patient safety and reducing medical errors, laboratory incident reports can be used to identify problems that jeopardize patient safety. In addition, Michael Astion and his colleagues at the University of Washington in Seattle recently published a new classification system that can guide the reduction of actual and potential adverse events (9). Their findings indicated that 95% of the events were potentially adverse, and that the laboratory was solely responsible for about 60% of the incidents. Not surprisingly, 71% of the incidents fell into the pre-analytic phase or the pre-examination process. Significantly, 73% of the incidents were deemed preventable.

In 2003, the Agency for Healthcare Research and Quality established the nation's first Web-based patient safety resource and journal (10). Each month, the site publishes five new interesting cases relating to medical error and patient safety problems, with one case spotlighted in a more detailed report. While to date only a small number of the cases have focused on problems in laboratory medicine, the information on this site provides some thought-provoking examples of where the health care system has opportunities for improvement.

Where Next?

Although it has been five years since the first IOM report on the quality of health care **Total Testing Process**, continued on page 12

CLSI Stages of Quality

In order to assist organizations with the implementation and maintenance of an effective quality system, the Clinical Laboratory Standards Institute has developed a guideline that provides a quality model with increasing levels or stages. While all quality stages are important, an example of the Quality Management System level (highlighted) is described in the text and presented in the box on page 12. Higher levels of the hierarchy are not achieved until the lower levels are mastered.

Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
Quality Management	Includes the stages below and also the economic aspects of "costs of quality"
Quality Management System	Systematic process-oriented approach to quality objectives
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Operational process control techniques to fulfill requirements for quality and governmental compliance

Source: A Quality System Model for Health Care: Approved Guideline. HS1-A2, Volume 24, Number 37. Wayne, Penn.: Clinical Laboratory Standards Institute, 2004.

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Total Testing Process, continued from page 9 services in the U. S. was published, a recent editorial in *The New England Journal of Medicine* highlighted the fact that much remains to be done to improve patient safety (11). In the editorial, the author raised a key question, "How can we increase confidence in health care, as we continue to address safety and quality?" One way, in my opinion, would be for each part of our health care system to assume responsibility and accountability for their role in health care delivery.

Laboratorians have already taken many steps to improve patient safety, with one of the most important being the establishment in 2003, under the auspices of the Centers for Disease Control and Prevention, of the Institute for Quality in Laboratory Medicine (IQLM). The IQLM was established to promote improvements in laboratory testing

Sample Grid of Quality System Indicators


Laboratorians at Loyola University Medical Center created a grid to visualize quality monitors as a function of the lab's key activities. This abbreviated grid shows the International Standards Organization's terminology for the processes. The Loyola group also added two additional monitors, TAT and customer satisfaction, which they want to monitor.

Monitor or Project	Pre-examination Process			Examination Process		Post-examination Process	Loyola-specific Process	
	Examination Ordering	Sample Collection	Specimen Receipt	Examination	Results Review and Testing	Result Reporting and Archiving	TAT	Customer Satisfaction
Routine CBC and Lytes TAT							X	
Blood culture contamination rate		X						
Specific nursing unit compliance with specimen container I.D. orders	X							
Specimen mislabeling		X						
Failed analytical runs				X				
Corrected or amended reports						X		
Physician Satisfaction Survey								X

and services that benefit the health of the public. At a three-day meeting this month in Atlanta (see box), clinical laboratorians will

have the opportunity to learn about practical strategies, specific to the laboratory, for improving health care.

Finally, we must ask ourselves if the cost of applying new and more comprehensive quality systems to the delivery of laboratory services is really worth it. Practically speaking, the decision all comes down to costs and benefits. At my institution, we recently analyzed the results of a multidisciplinary project and learned that the impact of specimen mislabeling on process quality and resource utilization was greater than we would have predicted. Although our defect rate for mislabeled specimens was very low, the additional charges still amounted to more than \$700 per specimen across our entire health care system.

Of course, as health care professionals, we know that the highest priority must always be the delivery of high quality, safe, and to the greatest extent possible, error-free care. If that's not sufficient motivation for us to focus on the quality of our laboratory's efforts, it's time to find another line of work. 

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