Quality Management of Pre- and Post-Analytical Processes in Laboratory Medicine

Ron B. Schifman, MD
Department of Clinical Pathology
Tucson Veterans Affairs Medical Center
Tucson, Arizona

Abstract: Quality assurance activities in laboratory medicine have traditionally focused on monitoring analytical performance. The scope of quality practices is undergoing gradual change that includes expansion toward continuous monitoring and performance improvement of pre- and post-analytical components of the total testing process. This presentation will address emerging quality management principles and procedures in laboratory medicine, emphasizing specimen quality, appropriateness of testing, results utilization, information quality, user perceptions and benchmarking.

Introduction

Quality management is a vital administrative function that serves to improve performance and add value to products, services and information.[1] Quality management is of considerable value to complex systems such as health care organizations which must integrate widely diverse functions to be efficient and effective.[2,3] Quality is an attribute that is produced and sustained by making adjustments in a system based on evaluations that come from continuously monitoring performance.[4,5]

Quality management in clinical laboratories has focused primarily on following well standardized procedures for maintaining reliable analytic functions. Most quality assessment procedures used in the clinical laboratory today consist of monitoring the accuracy and consistency of reagents, equipment and methods through internal process control, external proficiency testing and on-site inspections.[6] Accrediting organizations and regulatory agencies require adherence to these standardized procedures for laboratory certification and reimbursement. Analytical process control, while traditionally being the main focus of laboratory quality management, involves only one portion of the total testing process. Concern is growing that a disproportionate amount of time and resources is spent on analytical quality control at the expense of pre- and post-analytical factors that are known to have a considerable impact on the quality of laboratory testing and results utilization.[7,8] This paper will provide specific examples involving quality management of pre- and post-analytical components of the total testing process.

Specimen quality

The quality of a test result is only as good as the specimen that is submitted for analysis. It is important to continuously examine the quality of specimens that are received and improve processes for optimal specimen collections. Two examples are given describing pre-analytical problems arising from obtaining insufficient number of specimens and from improper timing of collections.

Laboratory diagnosis of tuberculosis

A series of three morning sputum specimens is recommended for mycobacterial culture. Submitting an insufficient number of sputum specimens has been associated with significant delays in diagnosis of pulmonary tuberculosis.[9,10] A College of American Pathologists (CAP) Q-Probes study, conducted in 1994 and involving 534 institutions, disclosed that the median number of specimens collected per patient at each institution was well below 3: 1.8 for inpatients and 1.4 for outpatients. A single positive culture was reported for 17.1 % of patients in whom 2 specimens were collected and for 12.4% of patients in whom 3 specimens were collected. While mycobacterial smear and culture turnaround time has been emphasized as one of the more important indicators of laboratory performance, findings from this study suggest that it is also important to insure that sufficient specimens are collected to achieve optimal test sensitivity.

Therapeutic monitoring of digoxin

Digoxin therapeutic drug monitoring practices were studied in 666 institutions participating in a CAP quality improvement Q-Probes study.[11] Of 280,172 digoxin levels studied, 6.7% (n=8,679) were in the toxic range (>2.6 nmol/L). While only 1.6% of specimens were collected inappropriately before steady state had occurred (less than 6 hours after oral dose), 25% of these specimens were in the toxic range. Laboratory policies not requiring the time of the last dose before measurement were associated with higher percentages of specimens drawn before the recommended time had elapsed. This study provides a good example of how improper timing of specimen collections can affect quality testing. Misinterpreting a falsely elevated digoxin level because of improper specimen collection may affect patient management and has potential for adverse clinical outcome if dosing is inappropriately modified on the basis of erroneous information.

Test utilization

Quality laboratory practices should include processes for improving appropriate test selection and utilization. Examples of quality management challenges described below include processes to control inappropriate test duplication and omissions as well as procedures to improve test selection.

Examination and improvement of test ordering processes using volume indicators

Volume indicator criteria have been used in our laboratory since 1987 to assess and improve processes associated with improper test usage.[8] For example, a substantial number of duplicate cholesterol orders were found to be caused by preprinted orders on patients receiving total parenteral nutrition. After reviewing the literature and discussing the indications for this test with clinical colleagues, we deleted these orders from the preprinted forms. A similar solution helped to reduce serum aspartate aminotransferase orders in patients with chest pain who were admitted to the coronary care unit. A substantial volume of duplicate uric acid tests was found to be caused by misinterpreting this test as part of panel because of where it was printed on the physician's order form. Revising this form produced a substantial decline in duplicate uric acid orders (Figure 1).

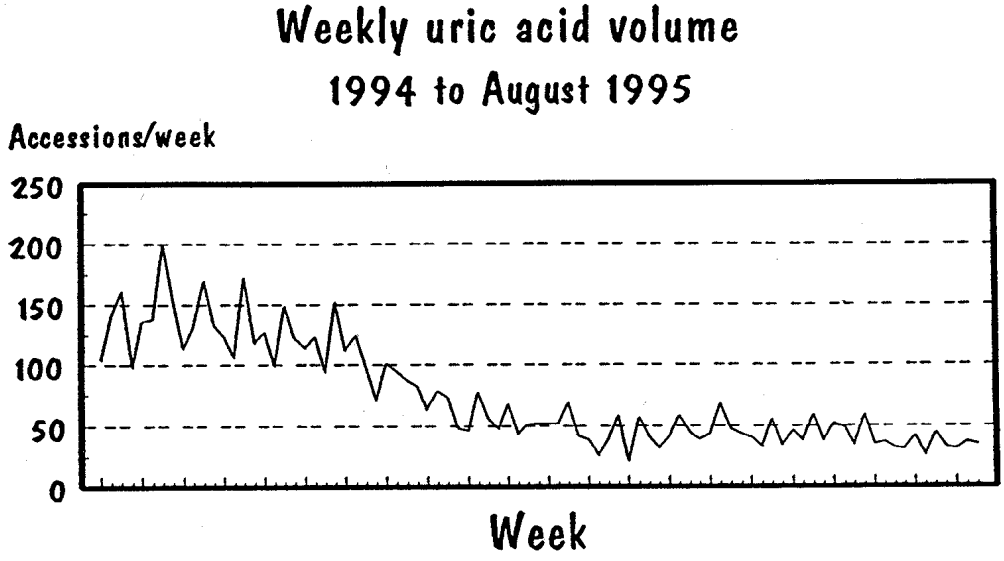

Figure 1. Effect of changing test order form on volume of orders for uric acid

Ova and Parasite Examination on Inpatients

Ova and parasite examinations and bacterial cultures on stool specimens collected from patients who have been hospitalized for 3 or more days are rarely productive.[12-15]. In this clinical setting, patients with diarrhea are more likely to have *Clostridium difficile* infection. Omitting to test for *C. difficile* in hospitalized patients with diarrhea in whom a stool specimen is submitted for ova and parasite examination or bacterial culture may represent poor test selection. When this occurs, it may be necessary to defer testing and consult the physician about indications for evaluating the patient for *C. difficile* infection (i.e., history of current or recent antibiotic or chemotherapy).

Utilizing of acute viral hepatitis A serology tests

When acute viral hepatitis A is suspected, the infection can be confirmed by measuring IgM specific antibody against hepatitis A antigen (anti-HAV IgM). Since acute viral hepatitis is nearly always associated with elevated of serum aminotransferase (AST or ALT) activity, utilization of anti-HAV (IgM) can be assessed by using the aminotransferase test as an initial indicator of appropriate test selection. In a Q-Probes study involving 625 institutions, the percentage (0.47%) of seropositive anti-HAV (IgM) results observed when aminotransferase results were normal was not significantly different from the percentage (6.27%) of reactive serologic tests reported previously in a healthy population of randomly selected adults.[16] These results show that when accompanied

by normal serum aminotransferase levels, the pretest probability of a positive IgM anti-HAV test is extremely low, and similar to that found in a healthy population. This finding supports a strategy in which serum aminotransferase is used as a prospective utilization review indicator when testing for IgM anti-HAV is ordered. Deferment of serologic testing for acute hepatitis when aminotransferase levels are normal would substantially decrease test volume and improve test selection.

Utilizing Results

One of the most important and challenging quality management goals is to insure that test results are property utilized. A test must be performed correctly and for the proper indication; the results must also be interpreted and applied properly. Failure of physicians to adequately manage patients with low serum vitamin B_{12} [17], hypercholesterolemia[18] or anemias[19] are well documented examples of this problem. Methods to insure proper utilization of test results should become an inherent part of clinical laboratory practice.

Utilizing of antimicrobial susceptibility results

When antibiotic resistance is not recognized in a timely fashion, administering appropriate antibiotic therapy may be delayed. Without active review and intervention, the average time lag between susceptibility results reporting and therapeutic modifications is about 24 hours.[20] Interestingly, a delayed response to completed results is independent of the speed at which the antimicrobial susceptibility test is performed, even when rapid methods are used.[21] Patients with serious infections are at risk for delays or failures in treatment, and given that results from antimicrobial susceptibility tests are predictive of therapeutic responses, unfavorable outcomes.[22-25]

We conducted a case-control study that examined the value of correlating therapy with final susceptibility results concurrently, using an integrated computer system. Among the non-intervention group, no changes were made within 24 hours compared with the intervention group. In the intervention group, an appropriate change in therapy was made in under 24 hours for 54% when a note was written in the patient's chart describing the discrepancy between test results and current antibiotic treatment.

Manufacturers of major automated microbiology systems, having recognized that rapid antimicrobial susceptibility test results alone are insufficient for optimal patient care, are now providing software applications that automatically link pharmacy and microbiology data for review and analysis. This is an important advance in quality management that will enable laboratories to improve their utilization of results.

Telephone results reporting

A Q-Probes study conducted in 1995 evaluated the accuracy of telephone inquires about specimen requirements and test results in 459 institutions. A questionnaire revealed that 39% and 60% of institutions had written guidelines for handling telephone inquires and dealing with security, respectively. Of 5,865 calls made about specimen requirements, 73% were correct, 13.4% were partially correct, 9.6% were incorrect and 3.9% were not completed. Of 2,948 calls made to obtain test results, 3.5% were abandoned. For all completed calls, 2.4%

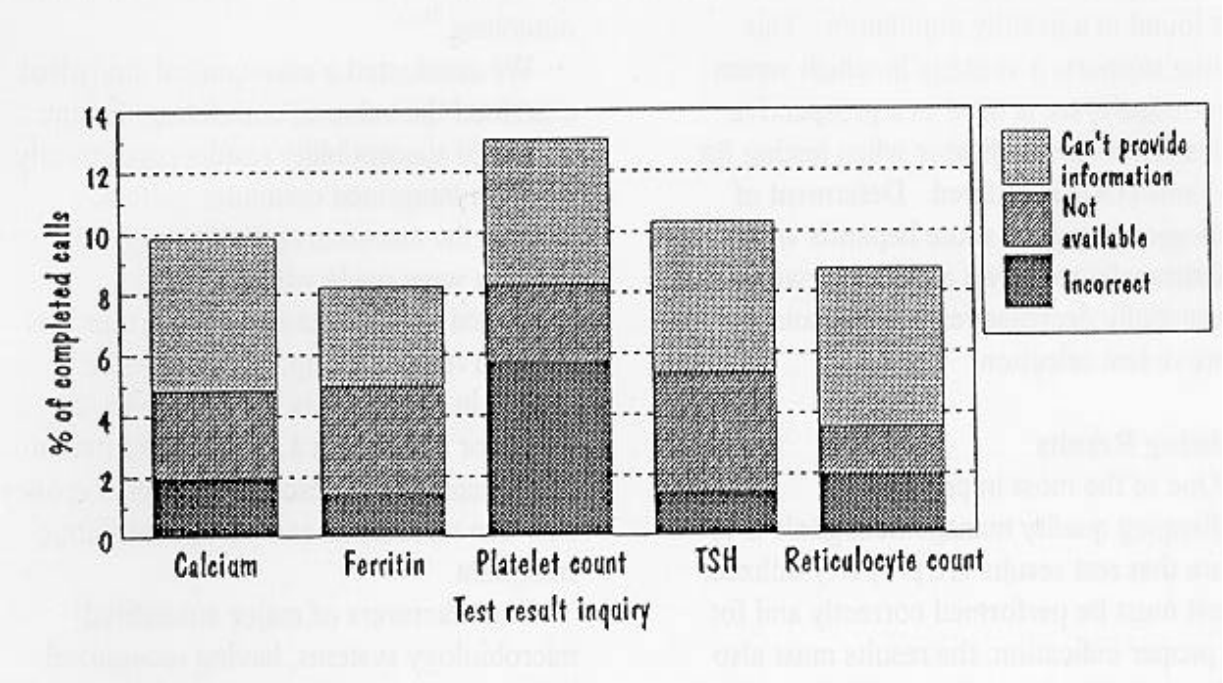

Figure 2. Accuracy of test results reporting by telephone (CAP Q-Probes study)

were incorrect, 2.7% indicated that results were not yet available, and for 4.8% of these, test results could not be given, found, or were unknown (Figure 2). Of 2,806 responses, 23.8% included correct information about tests, and 15.4% indicated that test results were abnormal (all cases selected had test results that exceeded the reference range).

Based on these results we recommended that clinical laboratories: 1) encourage use of computer systems in lieu of telephone support for providing information about test results and specimen requirements, 2) develop standards for telephone support consistent with how information is provided in written and computer formats, 3) always indicate that a test result is abnormal if it is outside the reference range when providing results by telephone and 4) develop written instructions for employees handling telephone inquires.

Benchmarking

Quality indicators gain substantial value by being interpreted in comparison with a peer group. Q-Probes is a CAP voluntary subscription improvement program for inter-institutional quality assessment and improvement.[26,27] Participants perform quality assessment studies dealing with many different types of pre- and post-analytical components of the testing process. The data collected by each facility are compared with aggregate data from other institutions as a benchmark to gauge individual performance. A critique is prepared for each study providing an interpretation of the summarized data and suggestions for improvement. While some examples of Q-

Analytical Turnaround Time	Laboratory Diagnosis of Tuberculosis
Antimicrobial Susceptibility Patters	Laboratory Quaity Assurance Programs
Autologous Blood Utilization	Laboratory Proficiency Testing
Autopsy Contributions in Quality Assurance	Lung Carcinoma Surgical Pathology Report
Adequacy	
Autopsy Report Adequacy	Lung Cancer FNAC Diagnostic
Performance	
Autopsy Timeliness and Permit Adequacy	Nosocomial Infection Rates
Bedside Glucose Monitoring	Order Accuracy
Bladder Carcinoma Surgical Pathology Report Adequacy	Pap Smear Rescreening
Blood Culture Contamination	Patient Satisfaction with Phlebotomy Service
Blood Culture Utilization	Post-analytical QA: Hypercalcemia
Blood Bank Control of Usage and Wastage	QC Exceptions
Breast Carcinoma Surgical Pathology Report Adequacy	Quality of Telephone Responsiveness
Cervical Biopsy - Cytology Correlation	Reference Test Service Quality
Cervico-vaginal Cytology Specimen Adequacy	Reporting Error
Cervico-vaginal Cytology Specimen Adequacy	Routine Test Turnaround Time
Chemistry Specimen Acceptability	Sputum Specimen Adequacy
Coagulation Test Utilization	Stool Microbiology
Colorectal Carcinoma Surgical Pathology Report Adequacy	Surgical Pathology Specimen Ident & Accessioning
Complications of Phlebotomy	Surgical Pathology Frozen Section Consultation
Critical Values	Surgical Pathology Complex Spec Turnaround Time
Duplicate Test Orders	Surgical Pathology Routine Biopsy Turnaround
Time	
Emergency Department Turnaround Time	Surgical Pathology Frozen Section Consultations
Emergency Department Turnaround Time	Surgical Pathology Frozen Section Consultations
Extraneous Tissue	Surgical Pathology Diagnosis Turnaround Time
Fine Needle Aspiration Cytohistologic Correlation (FNAC)	TDM Timing
Frozen Section Turnaround Time	The INR & Monitoring of Oral Anticoagulants
Handling of Mammographically Detected Breast Biopsy Tissue	Timeliness of Urine Specimen Analysis
Hematology Specimen Acceptability	Transfusion Appropriateness
Inpatient Phlebotomy	Transfusion Error Reporting
Laboratory Safety Practices and Policies	Viral Hepatitis Serology. Test Utilization
Laboratory Computer Availability	Wristband Identification Error Reporting

Table 1. Q-Probes Studies 1989 to 1995

Probes studies have already been provided, a complete list of studies between 1989 and 1995 is shown (Table 1).

Conclusion

As can be seen, quality management in clinical laboratories must involve examination of the total testing process. It is necessary to raise expectations and requirements for quality performance beyond analytical process control. Quality assessment and improvement in pre- and post-analytical phases of testing requires teamwork and inter-departmental cooperation. This brings new challenges as well as opportunities to solve persistent problems and improve the quality of health care.

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