Quality Assurance: Are Laboratories Assuring, Assessing, or Assuming the Quality of Clinical Testing Today?

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Abstract: Quality assurance implies making certain, guaranteeing the attainment of quality. Do laboratories actually guarantee the quality of testing services today? If not, what is the purpose of quality assurance plans, programs, and practices? Have laboratories even defined the quality to be achieved for each test? If not, how can quality be guaranteed? Do current efforts in assessing quality provide for real-time control that will guarantee quality? If not, are laboratories just assuming that measuring quality will somehow make it happen?

Even analytical quality, which is fundamental for the core production processes of any laboratory, is mainly assessed and assumed, not assured. Problems include the lack of well defined quality requirements, inadequate method performance, poorly designed statistical control procedures, misguided quality control instructions and recommendations, insufficient technical quality management skills, reduced operator skills, and delays in implementing of laboratory regulations.

Quality assurance should be understood, not as a component, but as the outcome of a quality management process that includes quality planning, quality laboratory practices, quality control, quality assessment, and quality improvement, all linked together and guided by quality goals and customer requirements, and applied to the total testing process. In the future, automation and computerization will be necessary to manage the quality of centralized and distributed laboratory testing. Analytical quality will be guaranteed through on-line or on-board quality control. Other critical quality characteristics will need real-time monitors and control mechanisms to guarantee quality if process failures cannot be prevented.

Introduction

Quality Assurance (QA) has many definitions, but the expectation of customers and consumers of health care services is that quality should be certain. This implies guaranteeing the attainment of quality. QA sounds right, but are laboratories actually doing it right? Do current laboratory QA practices guarantee quality?

Guaranteeing quality presumes that laboratories know the quality that needs to be achieved. Have laboratories even defined quality requirements for critical characteristics such as analytical quality? Do laboratories know how to use quality requirements to establish the necessary process specifications? If not, how can quality be guaranteed?

Guaranteeing quality requires measurements to assess process performance and to control process output. Do initial method validation studies and periodic verification checks assure that daily quality is satisfactory? Is the four month cycle of proficiency testing adequate for assuring daily quality? Does periodic monitoring of quality indicators and outcome measures assure that daily quality is satisfactory? Are

internal process control procedures capable of detecting problems and assuring that daily quality is satisfactory? If not, are laboratories just assuming that this periodic measuring and monitoring of quality somehow guarantees quality in daily operations?

In my opinion, current QA practices mainly emphasize the assessment or measurement of quality, assuming (maybe "hoping" is a better word) that this interest and attention will work some magic to make quality happen. Laboratories need to recognize that quality assurance is actually the outcome of a quality management process that includes quality planning, quality laboratory practices, quality control, quality assessment, and quality improvement, all linked together and guided by quality goals and customer requirements.[1] This quality management process should be applied to the total testing process whenever possible and to critical steps when necessary.

I expect that my opinion about the state of laboratory quality assurance may not agree with other views presented here, so let me identify some of the issues that concern me. I will focus on analytical quality assurance here, knowing that others will focus on pre-analytical and post-analytical problems.

Analytical Quality Assurance

Analytical quality is fundamental to the core production processes of all laboratories. Problems that prevent the assurance of analytical quality include the lack of well defined quality requirements, inadequate method performance, poorly designed statistical control procedures, misguided quality control instructions and recommendations, insufficient technical quality management skills, reduced operator skills, and delays in implementing laboratory regulations.

Lack of well defined quality requirements

What is the proper way to define quality requirements for analytical performance? As an example of the current difficulties, consider the quality goals, requirements, and specifications for cholesterol. In the U.S., a total error requirement of 10% has been defined as the acceptability criterion for CLIA '88 proficiency testing (PT),[2] whereas the National Cholesterol Education Program (NCEP) has specified an allowable coefficient of variation (CV) of 3%, an allowable bias of 3%, and a decision interval for test interpretation corresponding to 20% at a decision level of 200 mg/dL.[3] For comparison, a European group has defined a precision goal of 2.7% and a bias goal of 4.1% based on the observed individual biological variation of about 6.5%.[4]

Laboratorians are often confused by all the different types of quality goals, requirements, and specifications that are being recommended. Some of these are test outcome criteria (medically significant change, allowable total error) and others are method performance specifications (allowable standard deviations, allowable bias). They all assume a stable measurement process, i.e., there is no need for internal quality control, or analytical quality assurance, because no problems are expected. If this assumption of stable performance is not correct, then it follows that these recommendations may not be correct for applications in real laboratories where problems do occur.

I suggest that relationships do exist between these various types of goals, requirements, and specifications and that a systems approach is needed to understand

and apply them. For example: medical and analytical outcome criteria share many similarities; both can be expressed as changes that are important or significant, and both can be understood as confidence intervals that provide bounds for the maximum deviation of a test result. Both can be translated into operating specifications for imprecision, inaccuracy, and quality control to manage the daily operation of laboratory testing processes.[5,6] Thus, a system can be defined as shown in Figure 1 to relate outcome criteria to the specifications needed to manage or operate laboratory testing processes, as well as to other aspects of laboratory quality management. The bottom line in this system is the definition of operating specifications for imprecision, inaccuracy, and the control rules and number of control measurements needed at the bench level to assure the desired analytical quality will be achieved in routine service.

Inadequate method performance

Ross and Lawson recently summarized the *state of the art* precision performance based on 1500 laboratories participating in the 1990 College of American Pathologists Quality Assurance Service.[7] In comparison with the analytical goals for imprecision based on biological variation, they concluded that these goals for precision were not met for most of the analytes studied and the need for method improvements continues.

A similar comparison has been made to the operating specifications derived from CLIA PT criteria.[8] For sodium, for example, where the CLIA PT total error requirement is 4 mmol/L or 3.08% at a level of 130 mmol/L, the allowable imprecision for 90% assurance of analytical quality is 0.6% to 0.8%. Less than 20% of laboratories are able to provide that performance; hence, sodium shows up as one of the most problematic tests on PT surveys. Only potassium (of the 19 tests studied) shows the precision performance that is necessary to guarantee analytical quality in most laboratories.[8]. For many others, improvement in analytical imprecision is needed if laboratories are to guarantee the analytical quality required by CLIA PT criteria, as well as current biologic goals.

Poorly designed statistical QC procedures

The QC procedures implemented in most laboratories are based on general recommendations or practice guidelines, rather than quantitative planning that considers the quality required for each test, the precision and accuracy observed for the particular method, and the sensitivity of the particular control rules and the low numbers of control measurements per run (2-6) that are recommended today.

Problems of high false rejection (false alarms) or low error detection may occur because of the inherent performance characteristics of different decision criteria and different numbers of control measurements. Figure 2 shows power curves for commonly used control rules and numbers of control measurements (N) that are practical in laboratories today. Note that these are *S-shaped* curves that show very low probabilities of rejecting runs when errors are small (multiples of the method standard deviation of 2 or less). Note also that some of these curves indicate high levels of false rejections (shown by the y-intercepts), i.e., rejections even when there are no errors except for the inherent imprecision of the measurement procedure. Common use of 2 SD limits on Levey-Jennings charts is expected to cause a false rejection rate of about 9% when N=2 and

Figure 1. Systems view of Analytical Quality Assurance (AQA)

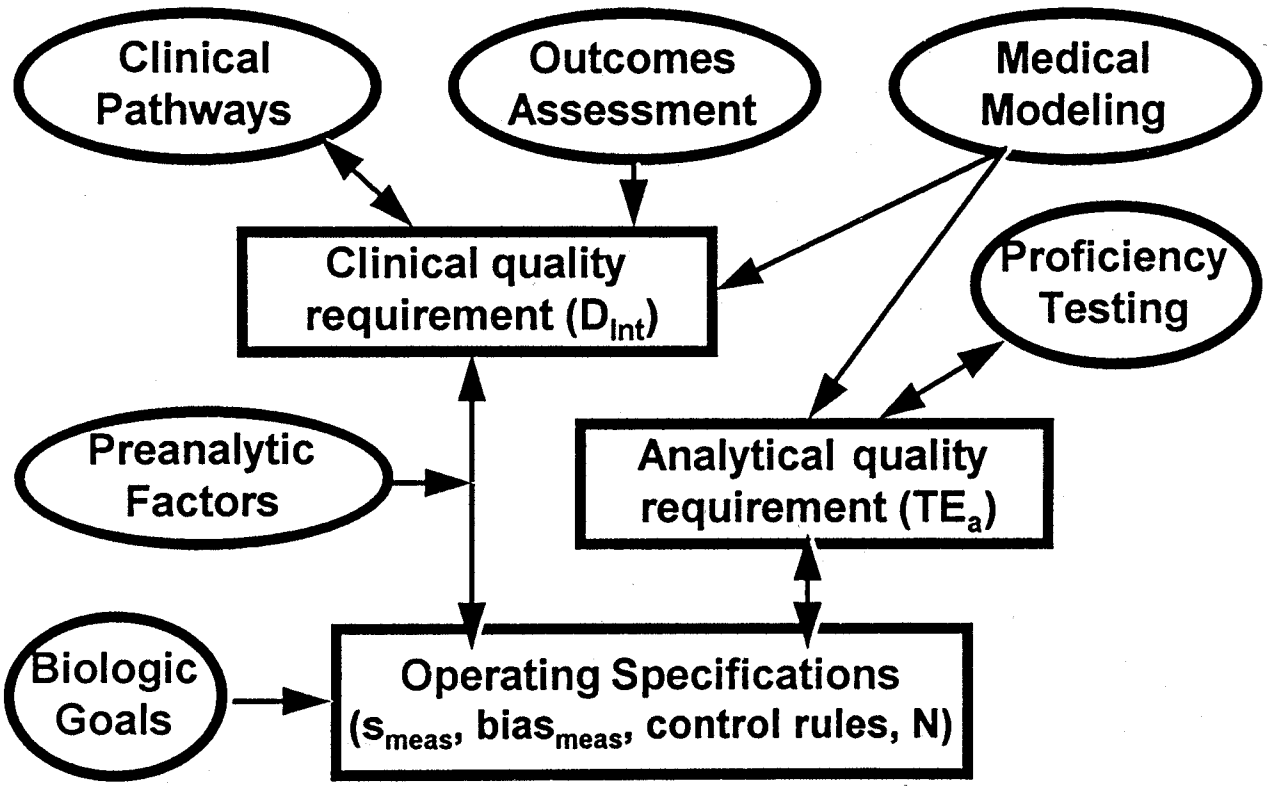

Figure 1

Figure 2. Performance of common QC procedures

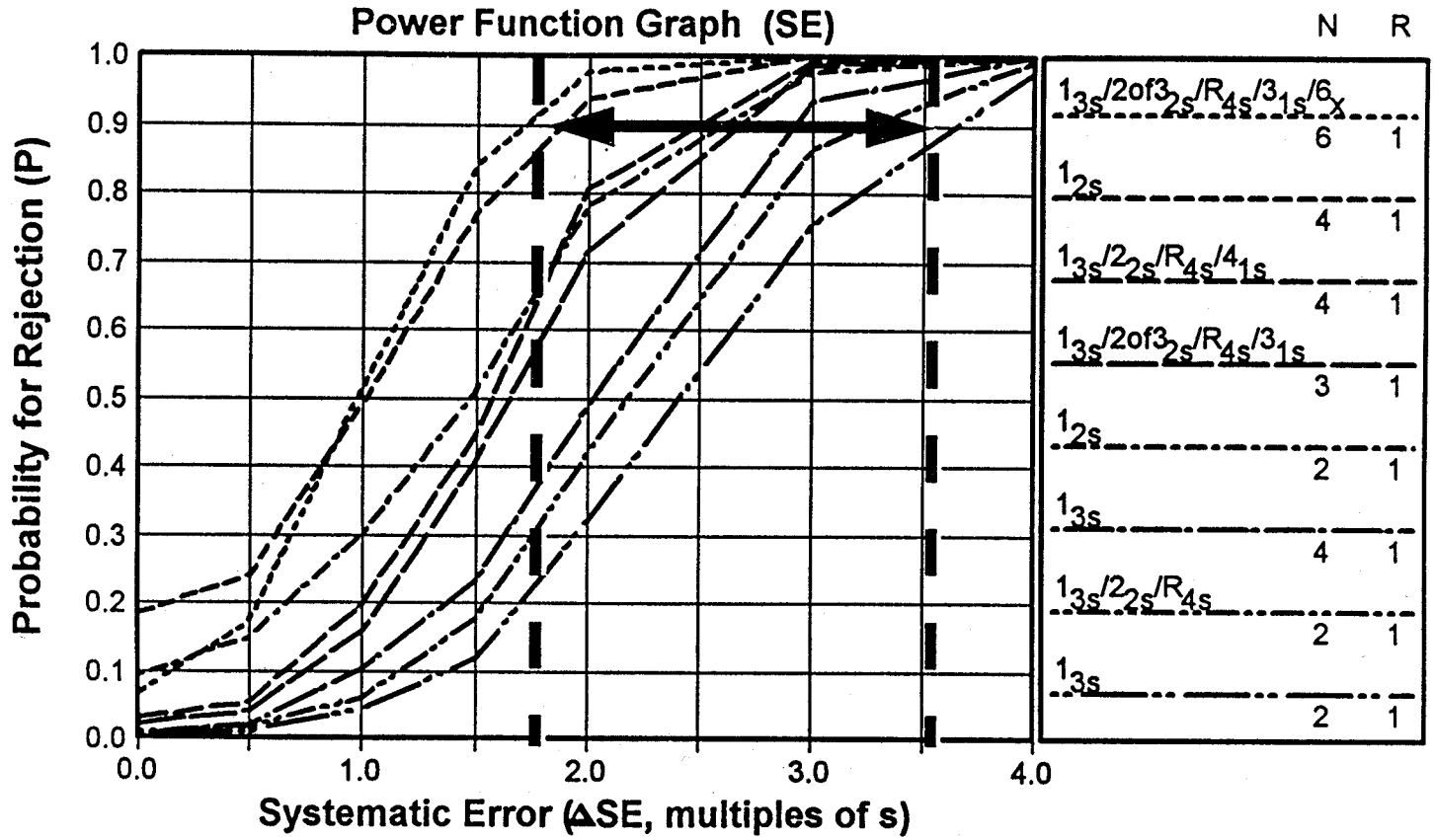

Figure 2

about 18% when N=4, i.e., nearly 10-20% of analytical runs would be falsely rejected by common QC practices. Ideally, the selected QC procedure should keep false rejections low (0-5%) and error detection high (90% or greater). For common QC procedures, this means that systematic errors may be as large as 1.8 to 3.7 times the size of the standard deviation of the measurement procedure before they are detected with the desired certainty.

Misguided quality control instructions and recommendations

Laboratories need to establish appropriate QC acceptability criteria to meet CLIA requirements for quality control. Guidelines presented in workshops, conferences, and published in the literature need to be evaluated quantitatively to validate their appropriateness for assuring analytical quality. Such guidelines may include recommendations for using statistical, fixed, and clinical control limits, without providing any information about the error detection and false rejection characteristics of the resulting QC procedure. Validation studies indicate that many current QC guidelines and recommendations are inadequate for assuring the quality required by CLIA PT criteria.[9,10]

Consider a glucose test, for example, where the method has an observed imprecision of 2.0%, the medically allowable CV is assumed to be 4.0%, the CLIA total error (TE) criterion is 10.0%. Current laboratory practices for setting control limits reveal a variety of approaches, such as statistical limits $\pm$ 2 or $\pm$ 3 times the observed method SD, clinical limits $\pm$ 2 or $\pm$ 3 times the medically allowable SD, or a fixed limit such as $\pm$ CLIA TE criterion. For a control material having a mean of 100, these various approaches would allow control limits to be set as the mean $\pm$ 4 mg/dL, $\pm$ 6 mg/dL, $\pm$ 8 mg/dL, $\pm$ 10 mg/dL, or $\pm$ 12 mg/dL, which correspond to statistical control rules of 1_{2s}, 1_{3s}, 1_{4s}, 1_{5s}, and 1_{6s}. Figure 3 shows a critical-error graph that describes the capabilities of different control rules and Ns for detecting the critical systematic error that would cause a laboratory to exceed the CLIA PT criterion. The critical systematic error here is 3.35 times the SD of the method [(10/2)-1.65].[5,6] The intersections of the critical systematic error line with the power curves for these rules with Ns of 2 show that error detection will vary from 0.99 or 99% to 0.01 or only 1%, depending on the control rule selected. Using a $1_{2.5s}$ control rule with N of 2 would give approximately 90% error detection with only 3% false rejections, which would provide a simple, cost-effective QC procedure for this application.

Insufficient technical quality management skills

Analytical quality management can be greatly improved by using simple error budgets, as represented by an analytical quality-planning model[5] that show the relationship between analytical total error requirements and performance characteristics of the measurement procedure (imprecision, inaccuracy) and control procedure (error detection, false rejection). Clinical requirements in the form of medically important changes, or decision intervals, can also be related to these same performance characteristics when pre-analytical factors are accounted for (such as within-subject biological variation) in the clinical quality planning model.[6] These models expand the total error budget to consider pre-analytical factors and QC performance, thus building in the margin of safety necessary to detect

Figure 3. Critical-error graph for glucose example

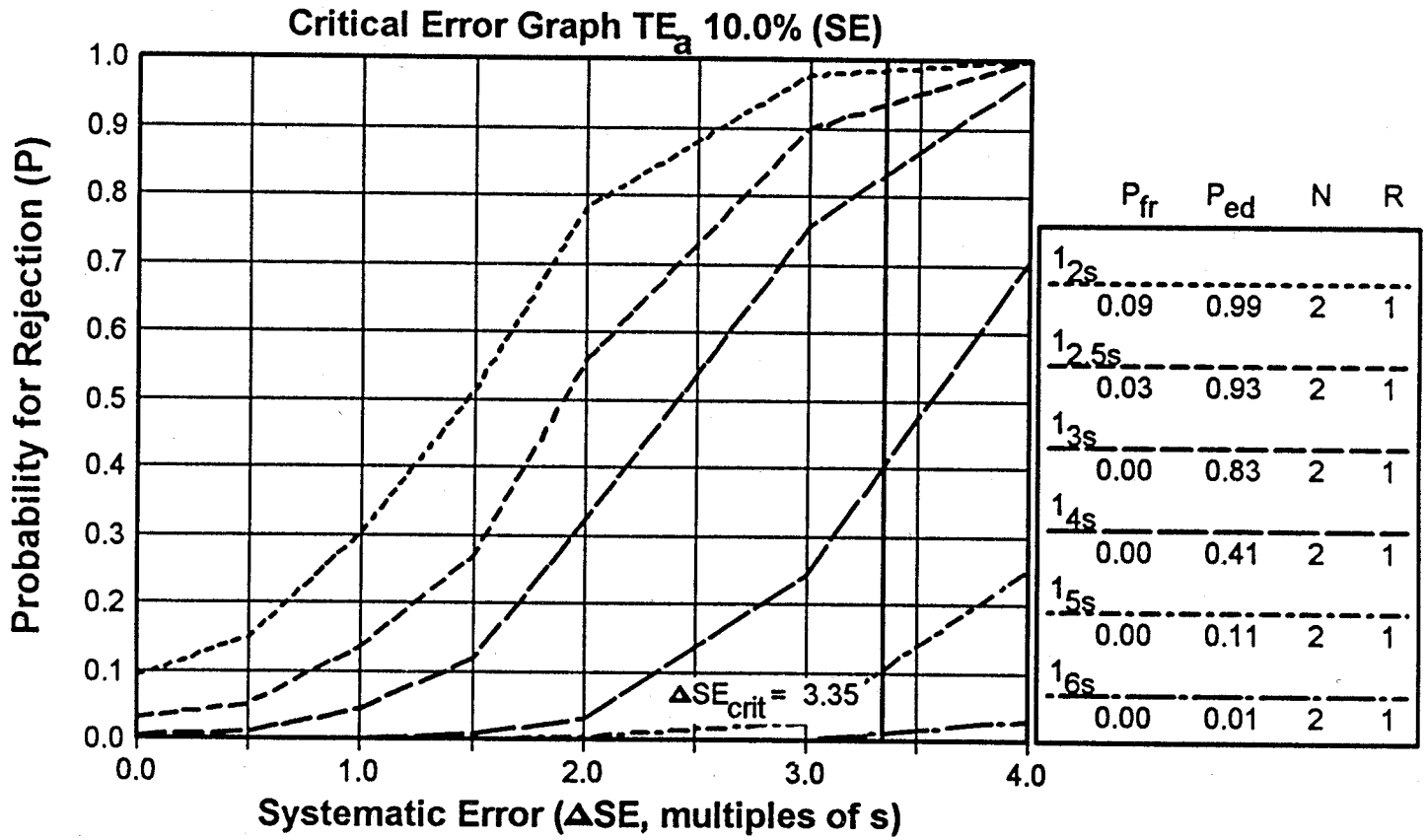

Figure 3

medically important errors.

Charts of operating specifications (OPSpecs charts)[11,12] display the relationship between allowable imprecision, allowable inaccuracy, and the necessary QC (control rules, N), as shown in Figure 4 for the glucose example discussed earlier. The different lines on the OPSpecs chart show the allowable inaccuracy and imprecision for different control rules and Ns, as shown in the key area at the right. The operating point represents the method's observed performance, in this case an imprecision of 2.0% and an inaccuracy of 0.0%. Lines above the operating point identify control rules and Ns that provide at least 90% detection of critical systematic errors. Of these candidate QC procedures, a $1_{2.5s}$ rule with N of 2 may be recommended for implementation based on its simplicity, high error detection, and low false rejection.

Managers need to understand QC planning tools, such as power function graphs, critical-error graphs, OPSpecs chart, and to apply them in planning and managing laboratory testing processes. The principles of total quality management tell us that problems occur because processes are imperfect, that process improvement is necessary to eliminate these problems, and that management is responsible for implementing appropriate processes. In laboratories, this means managers must put the appropriate measurement and control procedures in place.

Reduced operator skills

In the past, laboratories have been staffed by highly skilled analysts who were trained in laboratory technology and medical applications. These analysts generally had the skills to recognize problems and the discipline to solve them. They were dependable; therefore, the test results were dependable.

Today laboratory testing may be performed in different settings by a variety of operators who have a wide range of analytical skill and experience. Laboratories now must place a priority on having dependable processes that prevent problems from occurring and detect problems when they occur. This places a greater responsibility on manufacturers to provide highly stable measurement systems with built-in analytical quality assurance, particularly in those settings where it is known that operators will have little laboratory skill and experience. This also increases responsibilities for managers, technical specialists, and consultants who support laboratory testing in point of care settings.

Delays in implementing laboratory regulations

The delay in government implementation of a QC clearance process and the corresponding postponement of laboratory accountability for QC has resulted in a period of neglect for analytical quality assurance. Laboratories are waiting for manufacturers to provide the necessary QC instructions and, in the absence of QC clearance, are assuming that the present QC labeling will be adequate. During this time, the increasing pressure on cost control has taken priority over quality control, leaving laboratories focused on satisfying regulatory requirements and accreditation guidelines. Doing what's right to manage analytical quality may not be adequately defined by manufacturers' present QC labeling, or may not be completely identified by the lists of regulatory or accreditation requirements.

In addition, the lack of a mechanism for

Figure 4. Operating specifications for glucose example

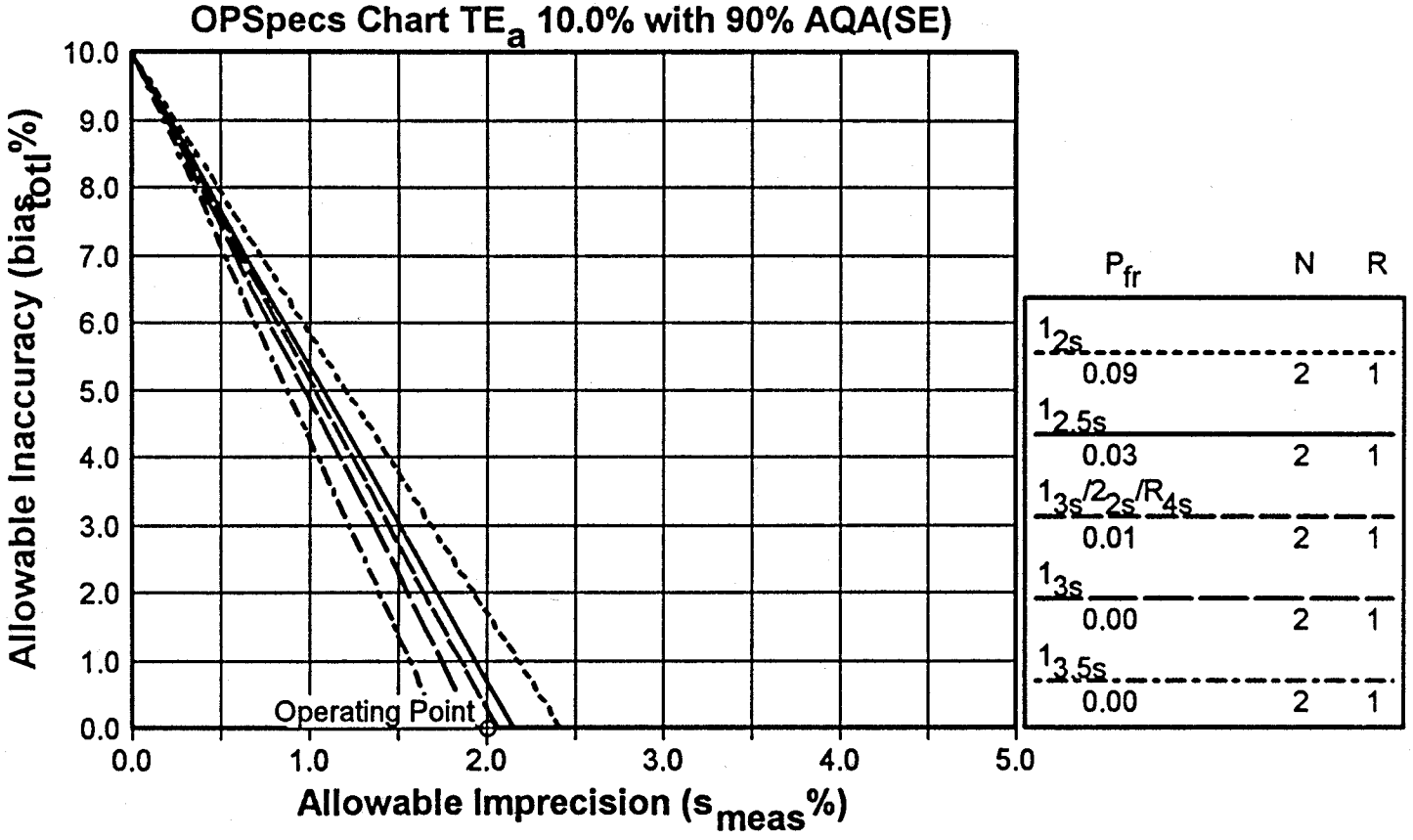

Figure 4

development and approval of new, non-traditional QC procedures may limit the potential applications of new technology. It may be more appropriate for manufacturers to make claims of defect rates for unit test devices and to provide data to substantiate low defect rates, in which case laboratories may find it necessary only to perform minimal checking when new shipments of materials arrive.

Summary

Although this discussion has focused on analytical QA, the issues identified should raise some concerns about the general *state of the practice* of laboratory QA. Are there reasons to think it's better for other quality characteristics? Are there firm data to show the relative frequency of problems and direct our attention to other areas? Are there audits of analytical quality that demonstrate a low frequency of problems in this area? Can we forget about analytical quality and move on to pre- and post-analytical problems? Can more quantitative patient management processes be built on top of our present foundation of analytical measurements? If not, how can laboratory testing be made more reliable?

I believe increased automation and computerization will be necessary to manage the quality of centralized and distributed laboratory testing processes. Analytical quality will have to be guaranteed through on-line or on-board quality control. The key inputs from laboratories or manufacturers will be the requirements for analytical quality and initial claims or initial estimates of method performance. Method performance data will then be collected, stored, and analyzed as part of an automatic QC process that selects and implements appropriate statistical QC procedures. Developing such an automatic QA process for analytical quality may also provide a model for other QA processes. Other critical quality characteristics will also require real-time monitors and control mechanisms to guarantee quality if process failures cannot be prevented.

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

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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).

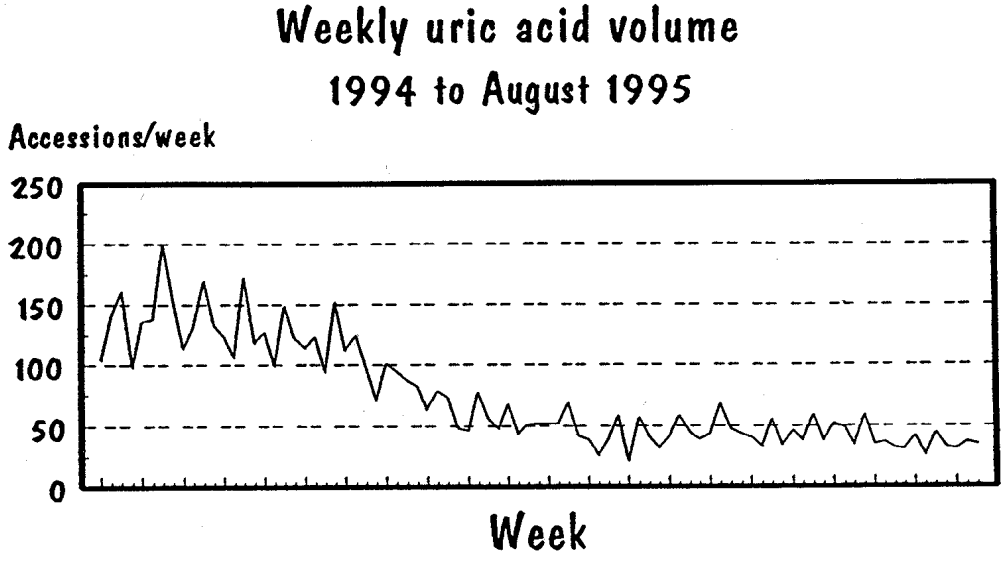

Figure 1. Effect of changing test order form on volume of orders for uric acid

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%

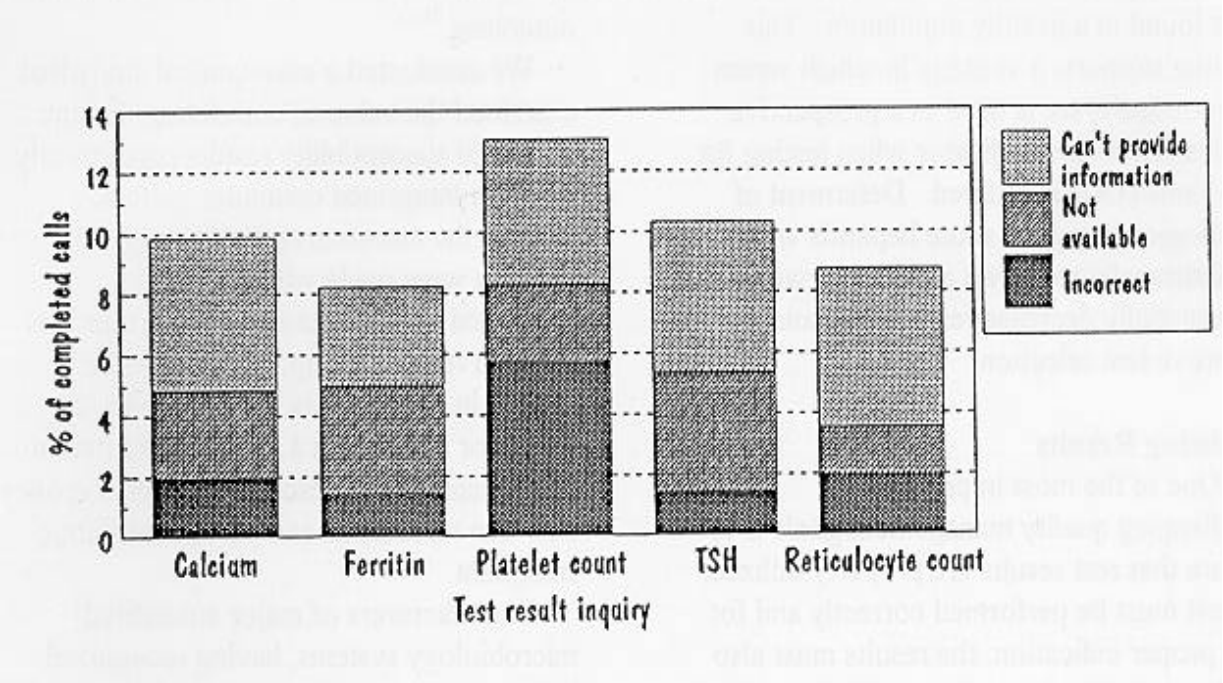

Figure 2. Accuracy of test results reporting by telephone (CAP Q-Probes study)

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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Are Phlebotomy Services Completely Satisfying Our Patient Customers?

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Abstract: In today's intensely competitive health care marketplace, it is implicit that all of the customers of any successful health care organization have their needs met, whether they be the health care purchaser, the health care user (patient), or the health care provider. The needs of each of these customers are often disparate and conflicting and are sometimes not well understood. To improve the quality of our phlebotomy services, often the only interface between the laboratory and the patient, we conducted a systematic study of the needs of outpatients who require phlebotomy services. Through the cooperation of our Health Research Department, we designed a 2 part, 3 page survey which measured patient expectations before phlebotomy and the patient experience with the phlebotomy process. We surveyed outpatient laboratories, one was a very large multi specialty group practice clinic (approximately 260 phlebotomies per weekday) and the other at a smaller primary care clinic (approximately 25 phlebotomies per weekday). 100 surveys were filled out at each laboratory. 54% of the respondents were female. Of the 18 different expectations that we surveyed, approximately one half of them scored an average of 4 or better on a rating scale of 1 through 5. The top 5 expectations and their average scores follow: cleanliness of the blood drawing area (4.84), successful blood draw with only 1 needle stick (4.64), ability of the phlebotomist to put the patient at ease (4.44), information regarding when and how results are received (4.37), and friendliness of the receptionist (4.30). While a few differences were identified between those respondents younger than the average age of 51.9 years (younger patients desiring less time in the waiting room and requiring more privacy during the phlebotomy), there were marked differences between the expectations of women and men with 14 of 18 being statistically significant ($p<0.01$) and with women usually requiring a higher service level. When patient experience was tabulated for the two different clinics, the smaller clinical had higher satisfaction for all of the 18 patient expectations, with 8 being significant ($p<0.05$). We are now using the survey results to systematically address the important differences. It is our recommendation that surveys such as that presented here be used to more intelligently initiate quality improvement efforts.

Introduction

The measurement of customer satisfaction has long been used to evaluate and improve products and services. Key to measuring customer satisfaction is identifying and prioritizing customer

expectations.[1] Satisfaction surveys which attempt to measure customer?s satisfaction without the knowledge of customer expectations can yield misleading or uninterpretable results.[1] In order to accurately assess the quality of care and services provided, customer expectations must first be determined and satisfaction with the expectations subsequently evaluated.

In today's intensely competitive health care environment, it is essential that health care organizations satisfy the expectations of their customers. From the perspective of the laboratory, phlebotomists are its most visible emissaries. Often, phlebotomists are the only personnel that patients encounter from the laboratory. As such, patients may perceive the level of care they receive during phlebotomy to reflect the quality of care provided by the laboratory or even the laboratory's clinic or hospital. Excessive delays, poor communication, bruising, discomfort, and other negative phlebotomy experiences may adversely influence a patient's perception of care. Customer satisfaction will be improved if the patient's experience is optimal. Measuring patient satisfaction with our phlebotomy service can thus be an important quality improvement tool for the laboratory.

A 1990 College of American Pathologists (CAP) Q-Probe study attempted to assess overall patient satisfaction with phlebotomy. Howanitz et al measured the complication rates of phlebotomy, based on the number of needle sticks; size and frequency of ecchymoses; length of time required for phlebotomy; and patient satisfaction.[2] This survey found that 98.6% of 23,783 outpatients were satisfied with their phlebotomy experience and only 9.8% of the 630 participating institutions had more than one dissatisfied patient. This high rate of satisfaction does not preclude opportunities for improvement. For example, 16% of the outpatients demonstrated bruising and 35% experienced more discomfort than anticipated. In a 1992 study of bruising of inpatients in a small British district general hospital, the incidence of bruising was reduced from 45% to 25% after phlebotomist training.[3]

Over the past two years, through the cooperation of our Institute for Research and Education, we developed and tested a new patient survey. Our aim was to develop an instrument to assess patient expectations of and satisfaction with the phlebotomy procedure. Patient expectations and satisfaction were surveyed for the three separate phases of the phlebotomy procedure: events before the phlebotomy, the actual blood drawing, and finally, events after blood drawing. The survey contains many more discriminatory and objective questions than the CAP survey and addresses specific patient expectations and areas of satisfaction and potential difficulty. We intend to use the survey results to identify areas for improving the phlebotomy service.

Materials and Methods

To more accurately compare patient expectations with actual experience, the patients completed the survey in two steps. While waiting to have blood drawn, patients were asked to complete and return the first part of the survey which assessed their expectations of the phlebotomy procedure. When the phlebotomy was over, the same patients were asked to fill out the second part which assessed their experience with the phlebotomy. The second part was then returned to the receptionist or phlebotomist. The patients were asked to rate a total of 18 different quality requirements on a scale of 5

Waiting Room

Privacy when talking to the receptionist
Friendliness of the receptionist
Length of time spent in the waiting room
Comfort of chairs
Current magazines
Ability of the receptionist to answer any questions or direct patient to someone who could

Blood Drawing

Privacy during blood drawing
Place to put things (jacket, purse, books)
Cleanliness of the blood drawing area
Ability of the person drawing blood to put patient at ease
Successful blood drawing with only one needle stick
Amount of discomfort from the needle of tourniquet
Cot available for blood drawing lying down
Ability of the person drawing blood to answer any questions or direct patient to someone who could

After Blood Drawing

Information regarding when and how the patient receives his/her results
Information on how to lessen the size of a possible bruise
Size of a bruise from the needle stick
Total visit time for blood drawing

Figure 1. Eighteen quality requirements of the phlebotomy procedure.

to 1, with 5 being the highest and 1 the lowest. Figure 1 shows the different quality requirements surveyed. The questions were asked twice, first in the form of: "How important is the following to you?" before the phlebotomy, and then as: "How satisfied were you with the following?" after the phlebotomy.

The survey was conducted at two outpatient phlebotomy areas, the first in a very large multi specialty group practice clinic located in a first-ring suburb (performing approximately 260 phlebotomies per weekday), and the second in a smaller primary care clinic located in a third-ring suburb (performing approximately 25 phlebotomies per weekday). The phlebotomy area of the larger clinic occupies approximately 300 sq. ft., and has seven drawing chairs (Fig 2). The chairs are located close to one another, extending into the corner. Supplies are in plain view. The other phlebotomy area occupies approximately 72 sq. ft. and has two drawing chairs (Fig 2). Supplies are stowed away out of view; here is also space for patient belongings.

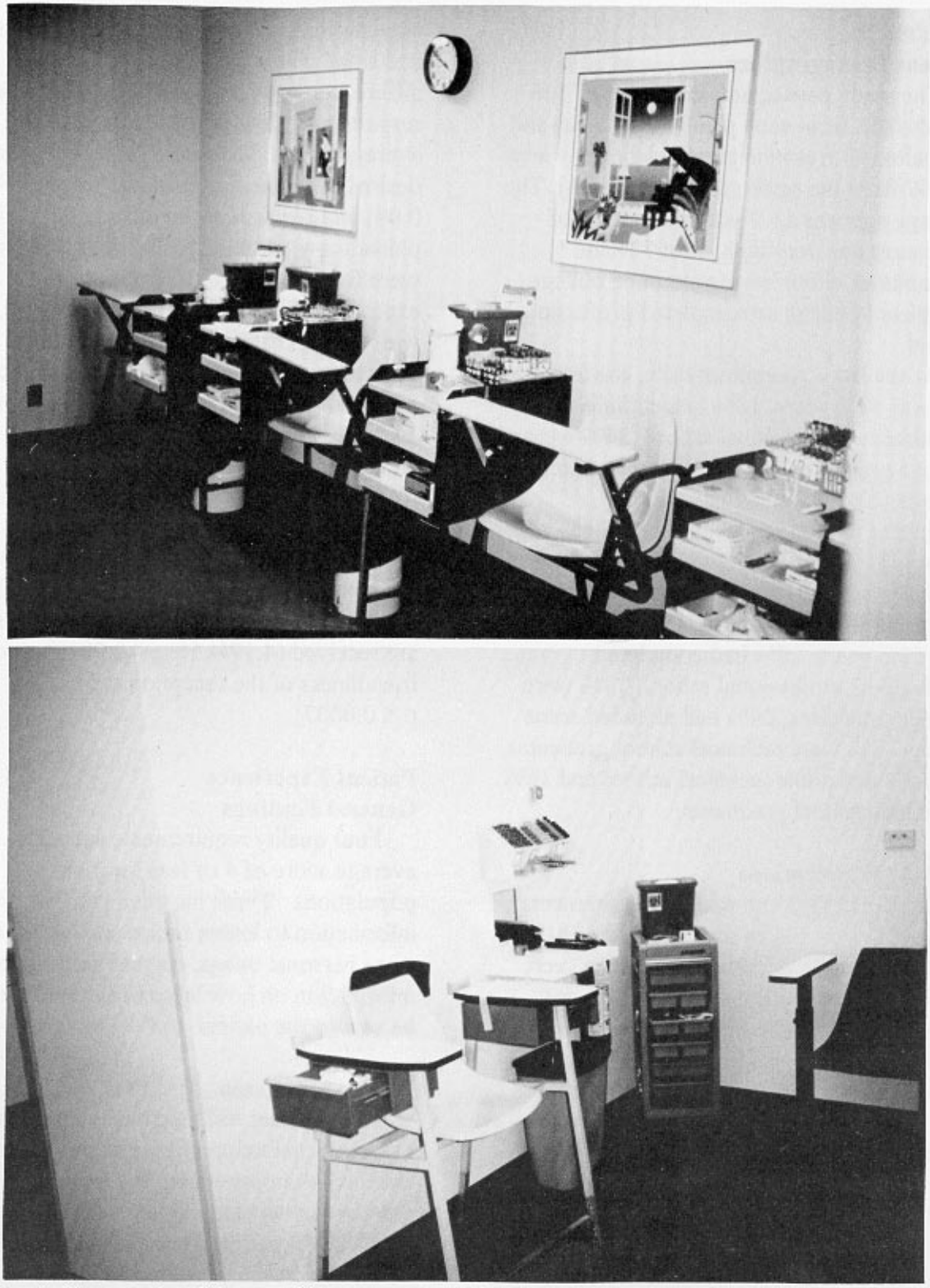

Figure 2. Photographs of the two phlebotomy areas. Top: large phlebotomy area with 7 chairs occupying approximately 300 sq. ft.; Bottom: small phlebotomy area with 2 chairs, approximately 72 sq.ft.

Results:

Patient Demographics

The study participants consisted of 106 females (53 from each phlebotomy area) and 90 males (43 from the large phlebotomy area and 47 from the small phlebotomy area). The average age was 51.9 years. The level of education was very high, with 72% of respondents either having attended college, completed college or completed professional school.

At the large phlebotomy site, the average age was 51.0 years. 16% had completed graduate or professional school, 26% were college graduates, 24% had attended some college, 10% were technical school graduates, 7% attended some technical school, 11% were high school graduates and only 6% had not completed high school. At the small phlebotomy area, the average age was 52.6 years. 20% had completed graduate or professional school, 33% were college graduates, 24% had attended some college, 3% were technical school graduates, 4% attended some technical school and 16% were high school graduates.

Patient Expectations

Of the 18 different quality requirements surveyed, 9 scored an average of 4 or better on a rating scale of 5 through 1 from "very important" to "not important" . Figure 3 shows the 18 quality requirements rank ordered by average score. The 5 most highly rated requirements and their average scores and standard deviations follow: cleanliness of the blood drawing area (4.84, 0.45), successful blood draw with only one needle stick (4.64, 0.77), ability of the phlebotomist to put the patient at ease (4.44, 0.91), information regarding when and how results are received (4.37, 0.87) and friendliness of the receptionist (4.30, 0.86). Patient expectations were very similar for the large and small phlebotomy areas. A few differences were identified between those respondents older and younger than the average age of 51.9 years (younger patients desired less time in the waiting room [$p< 0.04$] and required more privacy during the phlebotomy [$p< 0.02$]). Marked differences were found between the average expectations of men and women (Fig 4), with women having higher expectations in all 18 categories, 16 of which were statistically significant ($p< 0.01$). The top 5 were (male average /female average: p value): cleanliness of the blood drawing area (4.71/4.96: $p< 0.0001$), successful blood draw with only one needle stick (4.38/4.87: $p< 0.0001$), ability of the phlebotomist to put the patient at ease (4.08/4.75: $p< 0.0001$), information regarding when and how results are received (4.17/4.55: $p< 0.0019$), and friendliness of the receptionist (4.1/4.5: $p < 0.0007$).

Patient Experience

General Findings

Four quality requirements scored at average score of 4 or less for most populations. These included provision of information to lessen bruise size, space to store personal things, current magazines and information on how laboratory results are to be sent to the patient.

Phlebotomy Area

A significant difference was found in the average satisfaction ratings of the large and small phlebotomy areas. The smaller phlebotomy site had higher satisfaction for all of the 18 patient expectations, with 7 being significant ($p< 0.01$). Figure 5 presents the average ratings of the top nine quality requirements for the two phlebotomy

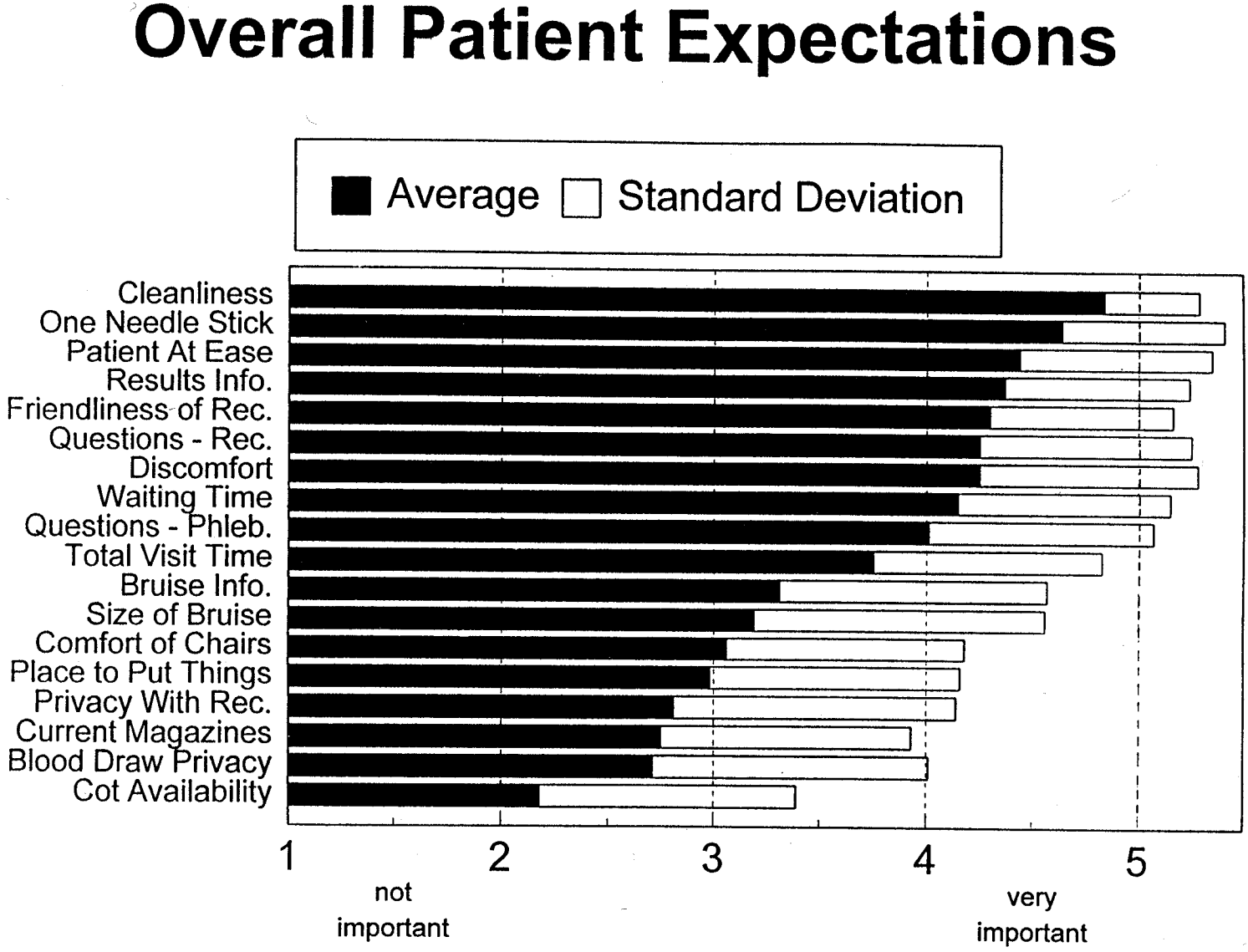

Figure 3. Average patient expectations (all patients) sorted in decreasing order. The magnitude of the white bar represents the standard deviation.

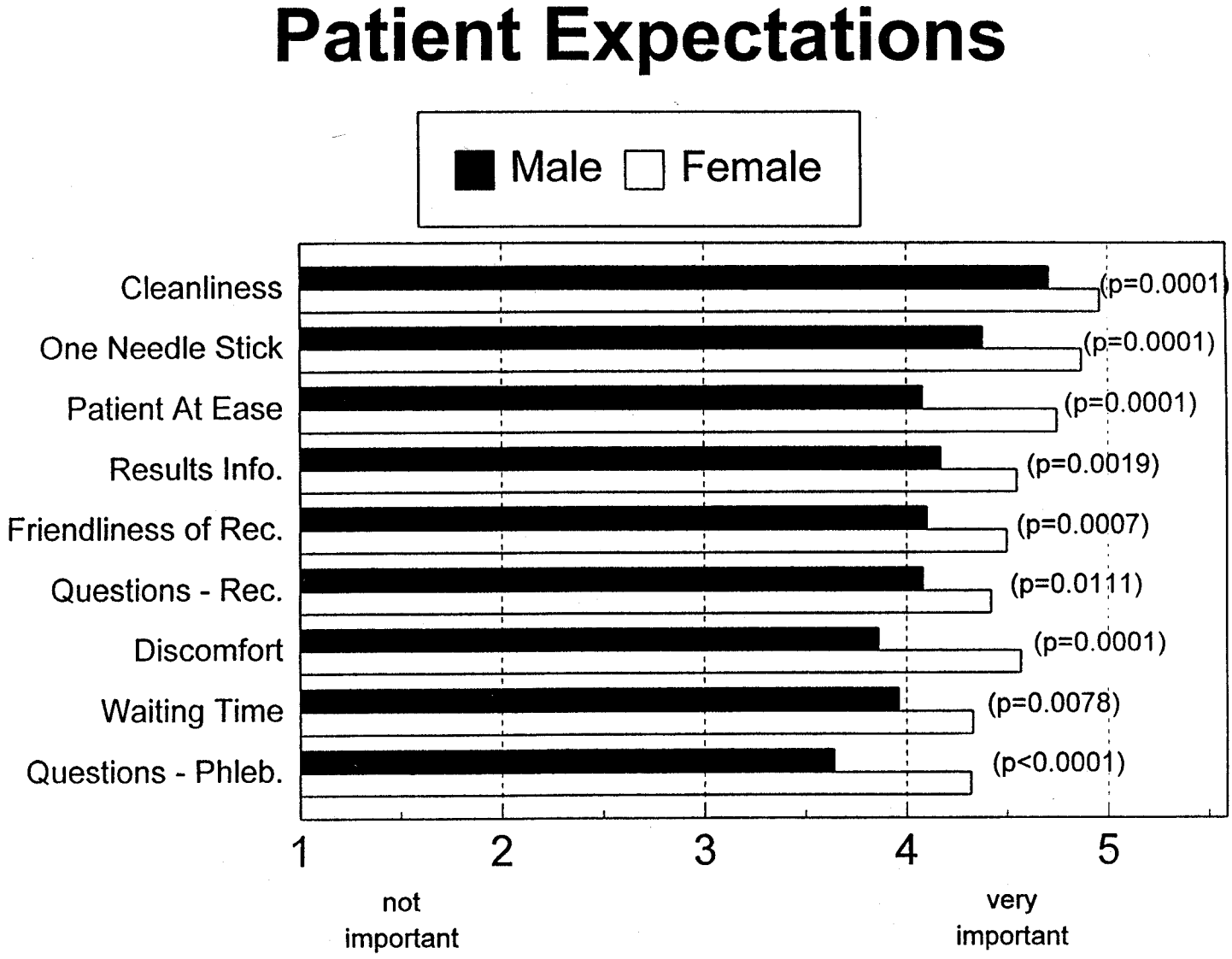

Figure 4. Average patient expectations, male vs. female for the top 9 expectations.

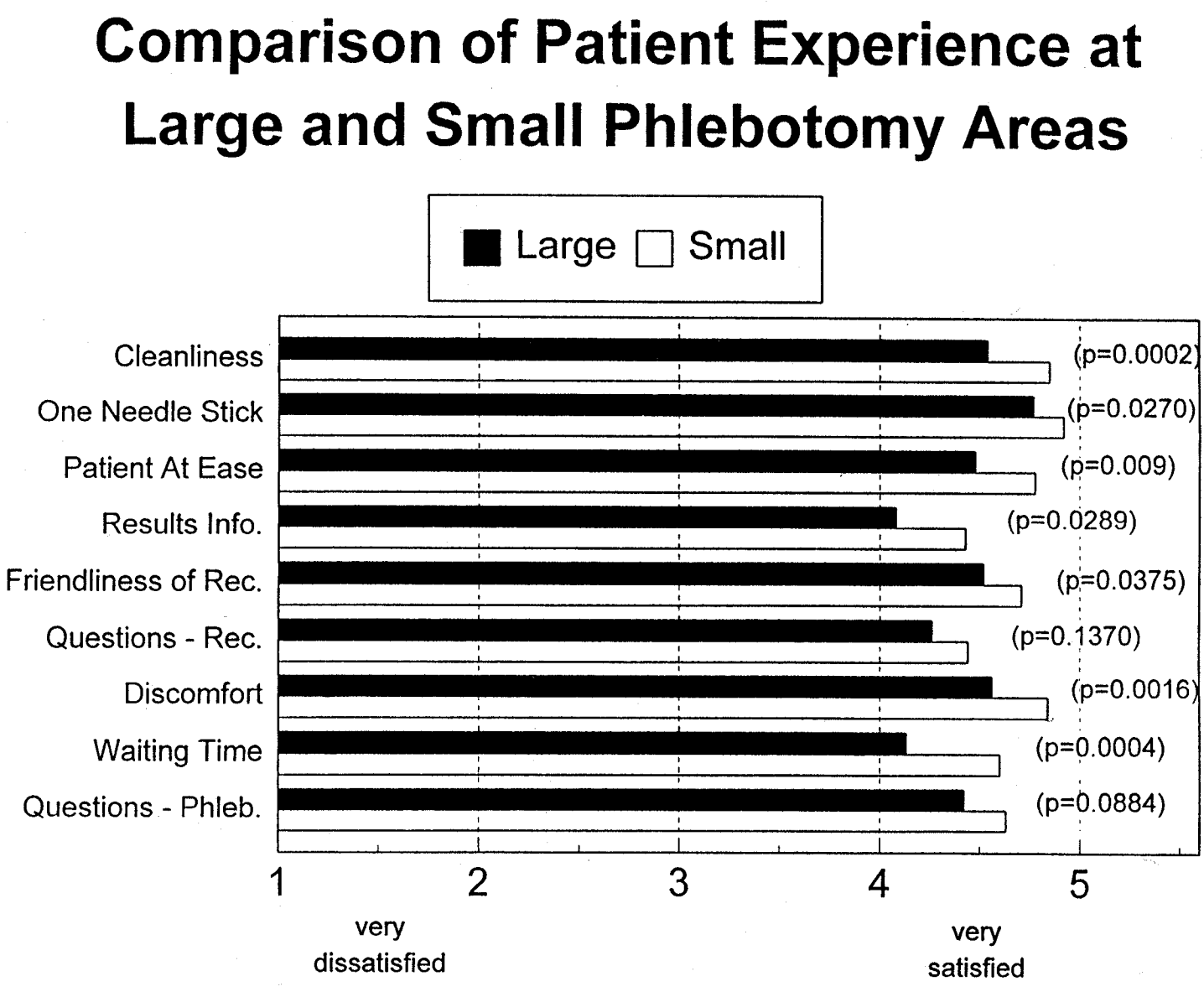

Figure 5. Patient experience, large vs. small phlebotomy areas for the top 9 expectations.

areas as well as the statistical significance of the differences. The quality requirement with the highest statistical difference was space to store things ($p<0.001$), where 48.2% at the small phlebotomy area were "very satisfied" (score of 5) versus 30.5% at the large phlebotomy area. Second highest was total visit time ($p<0.001$), where 82.5% of those at the small phlebotomy area were "very satisfied" as compared with 51.8% at the large phlebotomy area. Cleanliness of the blood drawing area ($p=0.001$) followed with 86.7% at the small phlebotomy area being "very satisfied" versus 62.9% at the large phlebotomy area Fourth was privacy of the blood drawing area ($p=0.001$), where 74.2% of those at the small area were "very satisfied" as compared with 45.4% at the large phlebotomy area. Satisfaction with time spent in the waiting room differed as well ($p=0.003$), with 70.4% of those at the small area being "very satisfied" versus 46.5% at the large phlebotomy area.

Patient Age

Patients older than the average age of 51.9 years were more satisfied with the service than their younger counterparts, with significantly higher satisfaction scores ($p < 0.01$) for 9 of the 18 quality requirements: friendliness of the receptionist, length of time spent in the waiting room, comfort of chairs, privacy during blood draw, place to store personal things, cleanliness of the blood drawing area, ability of the phlebotomist to put patient at ease, ability of phlebotomist to answer questions, and the total visit time for blood drawing.

Patient Gender

Men had an average satisfaction score of less than 4.0 only for the current magazines. Women, overall, had scores under 4.0 for a place to put things, information on how to lessen the bruise size and the current magazines. Women younger than the average age also had an average satisfaction score of 4.0 for the length of time in the waiting room.

Expectation scores can be used as a baseline for comparing satisfaction scores; dissatisfaction is indicated if a satisfaction score is lower than the expectation score. Overall female satisfaction scores were lower than expectation scores for three quality requirements, the cleanliness of the blood drawing area, ability of the phlebotomist to put the patient at ease and information regarding when and how results are received for satisfied as their expectations. On the other hand, male satisfaction scores exceeded their expectation scores for all requirements. Younger females had lower satisfaction than expectation scores for seven requirements (length of time in the waiting room, cleanliness of the blood drawing area, information regarding when and how results are received, ability of phlebotomist to put patient at ease, amount of discomfort from the needle or tourniquet, information on how to lessen the bruise size and successful blood draw with only one needle stick. Younger females at the large phlebotomy area had a total of 10 requirements for which average satisfaction was less than expectation (the same 7 categories for younger females as well as a place to store personal things, total visit time and friendliness of the receptionist).

Overall Patient Satisfaction

When asked about overall satisfaction with the phlebotomy area, 89.8% were "very satisfied" (score of 5) and 7.2% were "somewhat satisfied"(score of 4). 94.4% of those seen at the small phlebotomy area and

84.2% of those at the large phlebotomy area were overall "very satisfied" with Park Nicollet Clinic services. 87% of those at the small phlebotomy area and 69.2% of those at the large phlebotomy area said they would "definitely" return to Park Nicollet for blood drawing (score of 5) and 77.2% of patients (small phlebotomy area) versus 62.8% patients (large phlebotomy area) said they would "definitely" recommend our clinic to a friend.

Discussion

Only a few studies have attempted to systematically evaluate patient satisfaction with the phlebotomy experience. None of these has measured patient expectations which are needed to provide the base line for the assessment of satisfaction. This survey is unique in its ability to compare patient expectations and experience.

The patient population was represented by roughly equal numbers of males and females of similar age from both large and small phlebotomy areas. The high level of education observed among participants is due to the suburban location of the laboratories used for the study.

For the overall population, one half of the 18 quality requirements expectations had average scores above 4 on a scale of 5 through 1. This demonstrates the high expectations demanded by the patient population. The fact that the overall patient expectations are similar in both the large and small phlebotomy areas indicates that patients do not alter their expectations of quality of care according to the size and nature of the phlebotomy area. The significant differences between the expectations and experiences of men and women may be useful in targeting population subsets to implement improvement. The subset which showed the most room for improvement was younger women, most likely due to the higher service level that they require.

Differences in satisfaction were most apparent in patients having blood drawn in the large and small phlebotomy areas. Interestingly, the five most significant differences revealed problems that were associated with space limitations in the large phlebotomy area: a place to store things, total visit time, cleanliness of the blood drawing area, privacy of the blood drawing area and time spent in the waiting room. A larger phlebotomy area would improve the perceptions of cleanliness and privacy due to a greater separation of phlebotomy chairs and decreased clutter of the phlebotomy supplies. Additionally, a larger area would permit closer placement of patient belongings. The other two major differences dealt with long waiting room and long total visit time. More room could be made by removing one drawing chair, resulting in improved patients' perceptions of privacy and cleanliness. Since all drawing chairs can be in use at one time, removing even one would lengthen waiting times. We hope to creatively redesign our phlebotomy area so that patients' perceptions can be positively affected without increasing waiting time.

Four quality requirements did not achieve average scores greater than 4 for most population subsets. By providing information on how to lessen bruise size and when and how results will be sent to the patient, patient satisfaction can be increased. By redesigning the phlebotomy area, certain quality improvements can be implemented to positively affect the patient's perception of cleanliness and provide space to store things. Still other categories will require continuous attention, such as offering current magazines

in the waiting room.

Results indicate that our phlebotomy service can be significantly improved. According to post-survey suggestions by Cassell[4], we are reviewing these findings with all of our phlebotomists. Issues such as providing information to lessen bruise size can be addressed rather easily. Other issues, such as improving the perceptions of cleanliness, will probably require group processes to design, test and implement solutions.

We hope to take the findings of this comprehensive survey and shorten the survey so that we can use it at all of our 17 different phlebotomy areas. Self assessment through such surveys will identify further improvement opportunities.

Acknowledgments

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Point-of-Care Testing and the Critical Care Nurse: Implementation of an Effective QA/QC Program

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Abstract: Development of "user friendly" laboratory analyzers, combined with the need for rapid assessment of critical patients, has led to the performance of *in vitro* diagnostic testing at the point of care. This strategy has been well received by most physicians who want rapid turnaround times for critical laboratory tests. Since the primary caregiver in most critical care units is the registered nurse, much of POCT has been delegated to nursing personnel. A recent survey of critical care nursing (CCN) consultants found that 35% of critical care units use exclusively CCN to perform point of care testing (POCT), 32.5% jointly use lab technicians and CCN, and 25% use other personnel. Although most CCN agreed that POCT significantly improved turnaround time, they also stated that they would prefer that lab personnel operate in vitro diagnostic equipment and that laboratory testing detracted from other patient care duties. Another concern is that nurses in a busy critical care service may resist the additional time needed to implement proficiency testing, device maintenance, and an effective QA/QC program. In addition, the professional laboratorian is uniquely familiar with QA/OC issues and generally understands the specific regulatory requirements more than the CCN. Answering the concerns of laboratorians, CCN, and physicians involves (1) selecting tests from which reduction of turnaround time will have a significant impact on patient care; (2) selecting devices which are appropriate for the testing and can be efficiently used by non-laboratorians; (3) implementing a QA/QC program which is not cumbersome and which can be monitored by the central laboratory; (4) design and monitoring of a cost-effectiveness analysis with respect to the particular institution's needs; and finally (5) considering of alternative strategies such as vacuum transport, stat and/or satellite laboratories, unit-based phlebotomists or "super techs" as solutions designed to achieve the goals of bedside or near-bedside testing in the critical care setting. Forming a multi-disciplinary POCT committee has been valuable in tailoring solutions for the individual institution.

Introduction

During the past decade, new technologies and changing economics in *in vitro* diagnostic testing have increased the available instrumentation which facilitates transferring laboratory results to physicians and practitioners more quickly. One of these approaches moves testing to the patient's bedside and is known as point-of-care testing (POCT). POCT services can reduce turnaround time for certain laboratory tests and may reduce length of stay for patients.[1] Although instrumentation such as blood glucometers and portable chemistry units have been shown to be accurate even when used by operators with limited technical laboratory expertise, their training and monitoring by knowledgeable laboratory personnel, along with appropriate quality control procedures, are necessary to prevent errors.[1-4]

The advent of blood glucose testing with

micro-sample technology has rapidly replaced urine testing and the long turnaround time for glucose testing. In addition, this technology has allowed more accurate titration of insulin dosage and in most centers is used hospital-wide. Bedside glucose testing enjoyed significant success and heralded the beginning of widespread POCT. One of the most attractive sites for expanding POCT is the critical care setting. The coronary intensive care unit, surgical/trauma intensive care unit, pediatric/neonatal intensive care unit, cardiothoracic surgical recovery, emergency room, and operating room are all sites where patients are acutely ill and require rapid turnaround of laboratory data. Laboratory testing in critical care units has been shown to have a high degree of clinical relevance, most often resulting in a change of therapy.[6] The rapid turnaround time afforded by POCT provides the capability for "real time" treatment for conditions such as arrhythmias, electrolyte imbalances, hyper- or hypoglycemia, cardiac arrest, and ventilator weaning.[7] POCT also eliminates specimen transit time, which can account for as much as one third of turnaround time.[8] Using micro-sample technology to reduce phlebotomy-related blood loss has also been an important factor in introducing POCT to the critical care setting.[9] Blood loss due to phlebotomy for diagnostic testing purposes has been reported in critically ill patients as well as other groups of hospitalized patients to be as much as 944 ml for a hospital stay.[10]

Since POCT is by definition a bedside or near-bedside test, the responsibility of performing the procedure usually is given to nursing personnel. The principles of quality assurance/quality control (QA/QC) of laboratory testing are often unfamiliar to the staff nurse. In addition, there is potential for breakdown of QA/QC in a busy critical care environment where the primary caregiver is confronted with immediate life-preserving issues. Cooperation between the central laboratory and the nursing units is essential for POCT to be optimized so that the patient receives the necessary laboratory services in the time frame required for essential clinical decision making, and that these laboratory services are of the highest quality achievable under the circumstances. Answering the concerns of laboratorians, CCN, and physicians involves selecting tests from which reduction of turnaround time will have a significant impact on patient care, selecting devices which are appropriate for the testing and can be efficiently used by non-laboratorians, implementing a QA/QC program which is not cumbersome and can be monitored by the central laboratory, designing and monitoring a cost-effectiveness analysis with respect to the particular institution's needs, and finally, considering alternative strategies such as vacuum transport, stat and/or satellite laboratories, unit-based phlebotomists or "super techs" as solutions designed to achieve the goals of bedside or near-bedside testing in the critical care setting.

POCT And The Critical-Care Nurse: A Survey of Practices

In cooperation with the American Association of Critical-Care Nurses, representatives from the transplantation laboratories and biostatistics group from the Richland Memorial Hospital and the University of South Carolina School of Medicine recently conducted a national survey of critical care unit POCT practices and attitudes.[11,12] In this study, we found that most surveyed hospitals have implemented some type of near-patient

testing for their critical-care units, either by satellite laboratory or by placement of laboratory analytical equipment in the critical-care area. In the most of these units, nurses are performing either some or all the testing. This finding agrees with an independent survey performed in association with the Clinical Laboratory Management Association which found that physicians are the driving force behind POCT and that nurses perform the most of the testing.[13] When asked about the need for POCT, nurses overwhelmingly agreed that it is essential to patient care but at the same time state that current staffing patterns make its practical implementation difficult. This presents a potential conflict, since the need exists for some near-patient testing but a critical care nursing staff is already overwhelmed with responsibilities of patient care and administrative duties as indicated by the survey responses. The staffing issue, particularly with respect to the multiple tasks and decision-making responsibilities imposed on critical-care nursing personnel, has been only superficially addressed,[7] since most of the POCT literature appears to discuss technical and time management issues and not optimal test selection and QA/QC for POCT performed in nursing units. This paper will begin to broadly address some of these concerns, although ultimately the individual institution must develop a site-specific POCT program within the guidelines established by the appropriate regulatory agencies.

Test Selection

POCT is performed in critical care units because it is essential to have the laboratory values immediately if providers are make informed clinical decisions in a rapidly changing patient care situation. Reducing turnaround time, therefore, must have a significant impact on patient care. Immediate knowledge of parameters such as blood glucose, serum electrolytes, hemoglobin/hematocrit and activated coagulation time can be life saving in certain clinical situations. Bedside measurement of parameters such as CPK-MB or blood urea nitrogen may be convenient but probably not essential. It is logical that POCT performed by nonlaboratorians should be limited to a specific battery of tests essential for patient care in that particular unit. Our study referenced above showed that those CCN surveyed who performed lab testing, 95.5% performed blood glucose, 18.7% arterial blood gases, 4.5% electrolytes, 4.5% hematology profile, and 22.7% other, mostly coagulation analysis.

Device Selection

A variety of POCT instruments are currently available to fit the needs of most institutions. Reviewing these devices and their capabilities is beyond the scope of this paper, but whatever devices that institutions choose, they should be readily adapted to the needs of the specific patient care unit and the user. In addition to providing the necessary clinical information, the devices should have a mechanism for external QC as well as an independent method of testing calibration, yielding values that can be recorded and monitored. The cost per test should also be in line with the institution's needs and the demands of the patient care environment.

The QA/QC Program: Responsibility for Hospital-Based POCT

Inasmuch as a need exists for personnel performing POCT to have appropriate training, monitoring, quality control, and quality assurance (QA/QC), the question of

ultimate authority for POCT in the hospital setting should be considered. Since the hospital laboratory sets the institutional normals for its tests and is held responsible by the various regulatory agencies for most, if not all, general diagnostic laboratory testing, it is logical that POCT should be managed by the clinical laboratory medicine service. With this said, it is also very important that authority for POCT be a multi-level arrangement. Details of a suggested arrangement appear in a recent document from the National Committee for Clinical Laboratory Standards (NCCLS) which is currently in the commentary phase.[5]

Certain general principles, however, exit that will be helpful in designing a successful QA/QC program for POCT. First of all. such a program should be effective but not cumbersome and easily adapted to a busy critical care unit. Instrument controls should allow output of hard numbers from the device, and daily QA/QC should be monitored by the central laboratory for evidence of drift or out-of-range values. The program should also incorporate parallel testing with other POCT instruments as well as devices in the central laboratory that measure the same parameters.

Effectiveness Monitoring

With managed health care becoming the order of the day, several areas will need evaluation to determine the actual effectiveness of POCT. Cost of materials, time, and labor for POCT versus cost of performing the testing in the central laboratory is an important effectiveness indicator. Indeed, one study has shown POCT to be more expensive than traditional laboratory testing.[14] This must be balanced against the impact of rapid turnaround times on clinical decision making as well as the specific tests for which such a rapid turnaround time will actually affect clinical decision making on a minute-by-minute basis.[15] Other factors also have an impact, such as the status of reimbursement mechanisms, culture and tradition specific to the hospital, and the need of the clinical laboratory to meet expectations of consumers and payers of care.[16] QA/QC and cost of personnel training are also important indicators of effectiveness and should be considered in the total POCT cost.

Alternate Strategies

The institution must set clear goals for the expected outcome of POCT at the time of implementation. A combination of approaches to achieve rapid turnaround time such as those discussed above (satellite laboratories, unit-dedicated lab personnel, pneumatic tube transport) may achieve some of the institution's desired goals. Indeed, effectiveness of a POCT program should be monitored primarily by how well these goals are achieved as well as by the suggested indicators discussed above. The POCT committee is also the natural setting for this effectiveness monitoring, with necessary input from physicians and the hospital financial services.

Regulatory Agencies

A discussion of QA/QC would be incomplete without some mention of regulatory oversight. The passage of the Clinical Laboratory Improvement Act of 1988 (CLIA) resulted in sweeping changes in the manner that hospital laboratories were to be designed and managed. Specifically, CLIA sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens, affecting all laboratory testing sites including

POCT. Specific requirements are outlined in CLIA for personnel qualifications from directors to phlebotomists as well as for sample handling, QA/QC, and alternate site organization. Any institution undertaking POCT must be familiar with these regulations and develop policies and procedures which will assure compliance. Also, as stated earlier, individuals performing POCT may report to various regulatory agencies and state boards which could affect POCT. Any conflicts in regulation should be resolved through the POCT committee with the understanding that the CLIA regulations are essential for laboratory operation and must be adhered to regardless of other interests.

The College of American Pathologists (CAP) and the National Committee for Clinical Laboratory Standards (NCCLS) both have or will soon issue guidelines for POCT. These guidelines are essential reading for those setting up POCT and are written in a format with the end-user in mind to allow for the necessary information to be conveyed without a plethora of supporting legal language. Finally, it is essential for oversight of POCT programs to be located with institution's Department of Laboratory Medicine because laboratorians are most familiar with the regulations that apply.

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Summary of Workshop #3: Quality Assurance

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Key Questions

1) Are QA practices sufficiently comprehensive and focused to ensure quality laboratory service?
2) What are the methods and approaches for measuring quality assurance?

The presentations and discussion in this workshop on quality assurance focused on the following aspects of quality in laboratory testing: 1) analytical quality, 2) pre- and post-analytical quality, 3) patient satisfaction, 3) quality in point-of-care testing, and 4) future research strategies and methods.

Analytical Quality

Many laboratories today are assuming, not assuring, quality. Quality assessment is often practiced, rather than quality assurance. Quality assurance implies making certain or guaranteeing quality. Although assessment or measurement of quality is necessary, measurement alone does not assure quality. Quality control and improvement are essential. Quality assurance is not a separate component, but is an outcome achieved from a continuous quality process. The quality assurance process consists of 1) quality planning, 2) quality procedures, 3) quality control, 4) quality assessment, and 5) quality improvement.

Laboratories need to take a more systematic approach to assuring quality to be able to guarantee that results achieve the level of quality that is needed. The desired level of quality, however, is often unknown. Laboratories fail to establish analytical quality requirements and to effectively manage analytical quality. Analytical quality requirements can be defined for each assay on the basis of the allowable levels of inaccuracy and imprecision, or total allowable error. Analytical quality requirements should also account for biological variation and clinical need. Controls and control rules can be established to detect when an analytical run does not meet the allowable error level. By using more effective, systematically derived quality control evaluations for each quantitatively measured analyte, laboratories can better assure the reliability of measurements. This analytic reliability is critical for any meaningful outcome analysis program.

Analytical (process) control is a maintenance function. The laboratory is limited in its ability to improve the quality of the analytic process. Manufacturers have more capacity to produce improvement in this area. However, manufacturers do not make claims for quality, but rather for performance (accuracy, precision, etc.).

Laboratories operationally verify performance specifications on the basis of the best the method can do, rather than on the required level of analytic quality. Since manufacturers do not provide definitive information on quality, such as defect rates, it is important to test the product in the laboratory. On the other hand, if manufacturers could provide instruments and systems with sufficiently low defect rates, we could eliminate traditional quality control. Acceptable defect rates have not been defined, however, because this requires determining how often an incorrect result is allowable. Manufacturers and laboratories need to work together to define and improve analytical quality and quality control.

When we are making decisions about quality control practices, it is vital to consider cost, because cost is a major factor in our laboratories today. We may be performing some quality control to meet regulatory or accreditation requirements that is really unnecessary. In evaluating the cost of quality, we need to consider costs of prevention versus costs of failure.

Pre- and Post-Analytical Quality

We need to prioritize improvement efforts on the basis of where in the testing process improvement is most needed and most effective in order to better use resources. In order to prioritize, we should identify parts of the testing process with the highest error rates, consider ability to influence or effect changes, and take into account the interests and capabilities of the individuals involved. We do not have sufficient data to determine in which part(s) of the total testing process to focus improvement efforts. Limited data are available, however, through the College of American Pathologists' Q-probe studies and other studies that have shown pre- and post-analytical processes to be the most error prone. In this age of laboratory cost containment and cost reduction we should focus more on improving pre- and post-analysis because these processes offer the greatest need and the biggest opportunity for improvement. With pre- and post-analytic processes, the laboratory has much more control and a greater opportunity for improving processes than with analytic processes.

In addition to the Q-Probes external benchmarking process, quality can be examined by an internal system analysis within an individual laboratory. The data and information collected by either of these processes can be used to make simple administrative changes that have significant impact on pre- and post-analytic processes. For example, a change in the order of tests listed on a laboratory requisition can significantly affect test utilization. Other changes can be made to improve specimen collection protocols and processes, and, by working with clinicians, to develop test algorithms.

Before we can make these kind of changes, however, we must understand the process outside of the laboratory; we have to get out of our "laboratory box". We need to decide what questions we should be asking to determine if the right test is ordered, the specimen is collected properly, and the results are reported and used properly. We need to understand why the person who ordered a test checked it off on a requisition, for example, before we can know that the order in which tests are listed affects which tests are requested. Our challenge is to get out of our laboratory box and go to the hospital floor or physician's office, the "black hole" where laboratory test results go.

Laboratorians must provide more leadership in test result interpretation to improve the post-analytic phase.

In addition, laboratory user perceptions offer another way to evaluate and improve quality. Laboratory users should feel that their needs are understood, met, and, when possible, exceeded. User perceptions include the laboratory's ability to solve problems, avoid specimen mix-ups, meet turn-around time expectations, and to provide knowledgeable, courteous staff. These types of issues can be assessed to guide quality improvement efforts.

Although guidelines for analytical performance are fairly well defined, we need more specific guidelines for pre- and post-analytical processes. Non-traditional laboratories, however, also need specific guidelines for the analytic portion of the testing process.

Customer Satisfaction

As managed care assumes an increasingly larger segment of the medical care market, patient satisfaction becomes an important quality consideration. Information on patient or other customer satisfaction levels can be obtained through the use of carefully designed surveys. An example of a survey that was used to aid quality improvement in phlebotomy demonstrated how patients can provide useful information. Questions were grouped to provide information on both the expectations and experiences of patients during their primary contact point with the laboratory, the phlebotomy encounter. Study data showed significant differences, for example, between men and women in their expectations for phlebotomy. Both men and women, however, described having similar actual phlebotomy experiences, but differences in experience were noted when respondents were segregated by age. Using this method, the laboratory obtained information to guide change and improvement in the phlebotomy process.

The laboratory can positively affect customer opinion. Some examples are the provision of seamless phlebotomy services, tests that provide added value, like rapid Strep tests or directly measured LDL-cholesterol for non-fasting patients, and communication of test results directly to the patient. These kinds of services can differentiate laboratories when competing on managed care contracts.

Point-of-Care Testing

Developing of point-of-care testing has brought several benefits to patient care such as the reduction in phlebotomy-related blood loss and rapid result turn-around time. However, the quality control and quality assurance practices in point-of-care testing need more development. Developing an effective quality assurance program for point-of-care testing in the critical care setting provides a different set of challenges than in traditional laboratories. Institutional responsibility for point-of-care testing is needed. Quality assurance for point-of-care testing must be managed using an interdisciplinary team approach to address all concerns.

Results from a nationwide survey of 39 hospitals evaluating point-of-care testing in critical care showed some differences of opinion and further questions that need answers. One interesting anachronism from these studies was that, although critical care nurses wanted the test equipment and testing at the bedside for rapid test results, they had difficulty finding the time to perform testing. Therefore, there was a need to integrate with the laboratory to address alternative

strategies and improve the efficiency of the testing process.

The quality control and quality assurance processes must be effective but not cumbersome to non-laboratory staff, and results should be monitored by trained laboratorians. In addition, manufacturers need to help by developing point-of-care systems from which data can be downloaded directly into the laboratory or hospital information system to appropriately insert the data into the patient and control records. Better guidelines are needed on how to report results obtained at the bedside, whether they should be verified, whether delta checks should be done in a hospital setting, and whether point-of-care results should be differentiated from main laboratory test results.

More research is needed on the effectiveness of various quality control practices in point-of-care testing. Current accreditation and regulatory requirements may be unnecessary for some test systems. For example, in one situation, evaluating linearity for hundreds of new glucose meters yielded no meters that were producing non-linear results. As the use of procedural and electronic controls increases, the need to evaluate their effectiveness as compared with traditional quality control also increases. In evaluating the effectiveness of quality control, we need to consider the yield of meaningful information and how it is used. Also, the quality requirements may differ in various laboratory settings, such as physician office laboratories versus intensive care units. It is important to determine the level of quality required and develop a system for assuring it. Errors vary in the degree of their effect on patients, and we need more information to evaluate the effect of the various types of errors on outcomes.

In addition to evaluating quality practices, there is a need to evaluate the general effectiveness of point-of-care testing. Some bedside testing is essential to provide adequate turn-around time, and this alone may justify the cost. However, there may be other ways to effectively enhance turn-around time without having testing done at the bedside.

Suggested Research Strategies and Methods

The following list of suggested research strategies and methods was developed by the workshop speakers and participants:

- Research studies directed to quality improvement need to address the total testing process.
- Studies must address the parts of the total testing process where a decrease in errors will produce the greatest impact on patient care.
- Cost and benefit evaluations are vital to help make decisions regarding quality control practices.
- Questionnaires are an important tool to assess aspects of testing that are outside the laboratory.
- Studies must link quality assurance activities to patient outcomes.