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.