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

**Lawrence S. Lamb, Jr., Ph.D., R.N.**
**Division of Transplantation Medicine**
**Richland Memorial Hospital and University of South Carolina School of Medicine**
**Columbia, South Carolina**

**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.

**Acknowledgments**

The author expresses gratitude to James Reynolds, M.D., Ed Catalano, M.D., and Delores Brown, M.T. (ASCP) for their insightful review and helpful suggestions, and to Melissa Biel, R.N., M.S.N., Sue Goran, R.N., M.S.N.. and Rudolph Parriah. Ph.D. for their work on the CCN POCT survey.

**References**

1. Kurec A. Implementing point-of-care testing. *Clin Lab Sci*. 1993;6:225-227.

2. Baer D, Belsey R. Managing quality and risk of bedside testing. *Perspectives in Health care Risk Management*. 1990;3-7.

3. Zaloga G, Dudas L, Roberts P, Bortenschlager L, Black K, Prielipp R. Near-patient blood gas and electrolyte analyses are accurate when performed by non-laboratory trained individuals. *J Clin Monitoring*. 1993;9:341-346.

4. Belsey R, Baer D, Sewell D. Laboratory test analysis near the patient: opportunities for improved clinical diagnosis and management. *JAMA*. 1986;255:775-786.

5. National Committee for Clinical Laboratory Standards. Point-of-care *In Vitro* Diagnostic (IVD) Testing; Proposed Guideline. NCCLS document AST2-P. NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania, 19085, 1995.

6. Harris C, MacMillan R, Atherton S, Griffiths R. Retrospective audit of out-of-hours laboratory tests in an intensive care unit. *Clinical Intensive Care*. 1991;2:200-203.

7. Zaloga G. Evaluation of bedside testing options for the critical care unit. *Chest*. 1990-1;97:185S-190S.

8. Howanitz P, Steindel S, Cembrowski G, Long T. Emergency department stat test turnaround times. *Arch Pathol Lab Med*. 1992;116:122-128.

9. Chernow B. Blood conservation in critical care - the evidence accumulates. *Critical Care Med.* 1993;21:481-482.

10. Chernow B. Blood conservation - a critical care imperative. *Critical Care Med.* 1991;19:313-314.

11. Lamb L, Parrish R, Biel M, Goren S. The current status of in vitro diagnostic testing by critical care nurses. Proceedings of the 1994 National Teaching Institute, AACN Press, 1994.

12. Lamb L, Parrish R, Biel M, Goren S. The current status of in vitro diagnostic testing by critical care nurses. *Am J Critical Care.* (submitted).

13. Bickford G. Decentralized testing in the '90s. A survey of U.S. hospitals. Clinical Laboratory Management Association. 1994:July/August;327-328.

14. Nosanchuk JS, Keefner R. Cost analysis of point-of-care laboratory testing in a community hospital. *Clin Chem.* 1995:103;240-243.

15. Wong H. Decentralized clinical chemistry testing in the intensive care unit-. a concept whose time has come? *J Intens Care Med*. 1988;239-240.

16. Tsai W, Nash D, Last J. Point-of-care testing: barriers and facilitators to implementation. *Amer Lab.* 1994:October,14.