Plan for Quality to Improve Patient Safety at the Point of Care

Sharon S. Ehrmeyer

From the Department of Pathology and Laboratory Medicine, University of Wisconsin School of Medicine and Public Health, Wisconsin, USA

Correspondence: Sharon S. Ehrmeyer, Ph.D · Department of Pathology and Laboratory Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin USA 53706 · T: +608-262-0859, F: +608-262-9520 · ehrmeyer@wisc.edu

Ann Saudi Med 2011; 31(4): 342-346

DOI: 10.4103/0256-4947.83203

The U.S. Institute of Medicine (IOM) much publicized report in “To Err is Human” (2000, National Academy Press) stated that as many as 98,000 hospitalized patients in the U.S. die each year due to preventable medical errors. This revelation about medical error and patient safety focused the public and the medical community’s attention on errors in healthcare delivery including laboratory and point-of-care-testing (POCT). Errors introduced anywhere in the POCT process clearly can impact quality and place patient’s safety at risk. While POCT performed by or near the patient reduces the potential of some errors, the process presents many challenges to quality with its multiple tests sites, test menus, testing devices and non-laboratory analysts, who often have little understanding of quality testing. Incoherent or no regulations and the rapid availability of test results for immediate clinical intervention can further amplify errors. System planning and management of the entire POCT process are essential to reduce errors and improve quality and patient safety.

Every day our lives are bombarded with “things happening.” Most—volcanoes, earthquakes, hurricanes, fires—are acts of nature and beyond our control. “Things happen” in healthcare as well. In 2000, the U.S. Institute of Medicine reported that as many as 98,000 people die in U.S. hospitals each year as a result of preventable medical errors.1 This report alerted the public and the medical community and focused attention on ways to improve quality and eliminate medical errors to ensure patient safety. In spite of efforts to do away with these errors, errors are still widespread.2 More recent studies report that as much as 45 percent of every dollar spent on U.S. health care is related to medical mistakes and that some kind of mistake or adverse event occurs in one-third of all hospital admissions.3 The key phrases in these reports are “mistakes” and “preventable medical errors,” which means solutions can be found and implemented.

Point of care testing (POCT) is defined as any testing that is conducted outside the central clinical laboratory and near the patient. The popularity of POCT keeps increasing and is based on the assumption that test results available in a very short timeframe assist caregivers with immediate diagnosis and/or clinical intervention to benefit patient outcomes. Patient safety, in the context of the POCT process, is freedom from unintentional or preventable harm due to avoidable adverse events (medical errors) that directly impact the quality of the test result and ultimately the quality of care. Errors can occur anywhere in the entire POCT process, from deciding to order a test (pre-analytical), to ordering and collecting a patient sample, through the analytical process, to reporting and finally acting appropriately on the result (post-analytical). Patient safety potentially can be compromised whenever there is a disruption in achieving all of the necessary “correct” quality criteria throughout the process—correct test order, correct patient, correct specimen collected at the correct time, correct test result, correct patient record, and correct clinical interpretation leading to the correct and timely clinical response.

Plebani et al and others described the frequency of errors in the three phases of the total testing process.4-6 The most cited POCT deficiencies impacting the analytical phase include failure to perform and document quality control, follow the procedure and manufacturers’ directions, perform and document personnel training and ongoing competency, take appropriate corrective actions, verify accuracy of analytes tested, and document

E
results in the patient record." Meier and Jones, in their seminal papers, identified three basic sources of POCT error—operator incompetence, not following protocols and uncontrolled reagents and equipment, and also suggested that wherever POCT errors occur, the effects of these errors are amplified by incoherent or no regulation, the availability of rapid test results often reported without appropriate quality checks, and immediate therapeutic decisions and treatment based on these rapid results. "Amplifiers" as used by these authors are factors, which increase both the frequency and magnitude of the errors. Other experts advise being aware of POCT limitations, minimizing testing staff, having guidelines to lead clinicians to the right test, and timely and proper test utilization, and taking advantage of available resources, such as websites, to keep current. All of these have merit and some warrant further discussion for quality planning.

Planning for Quality

POCT is an ever increasing and significant component of hospital services and just like the central laboratory POCT requires strategic planning, management and leadership. This approach not only provides clear lines of responsibility, authority, professional expertise, oversight and accountability for the entire process, but as importantly, addresses error reduction to ensure patient safety. While the exact structure varies with the situation, typically POCT is addressed throughout the organization by a POCT committee having a common vision to best serve patient needs and meet institutional goals. A primary reason for unsuccessful POCT programs, including sub-optimal clinician utilization patterns, is a failure of the organization to take ownership of the process and involve stakeholders in the decisions for implementation and ongoing activities. Stakeholders, beginning with hospital administration, come from all areas impacted by POCT. These stakeholders form the nucleus of the "POCT committee or team" and provide the broad-based input that is essential for creating a successful program. By shifting the focus to the institution’s goals, the needs and various viewpoints of physicians and healthcare professionals and the demand for quality, medical error reduction and improved patient safety can be addressed and mostly accommodated. A key player in carrying out the directives of the team and ensuring that POCT is conducted in a quality way is the coordinator. Selecting the right one is essential, since the very visible coordinator carries out the directives of the committee and is the POCT champion, promoter, helper, resource, rule enforcer, trouble-shooter, and spokesperson.

The importance of the POCT committee and coordinator is reinforced in the International Organization for Standardization (ISO) POCT document. The ISO organization describes itself as the world's largest developer and publisher of international technical standards on many topics including medical laboratory testing and POCT. ISO 22870:2006, Point-of-care testing (POCT) - Requirements for quality and competence, gives specific requirements applicable to POCT carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. The introduction of this document includes the following statement: "risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system...” and requires that a multidisciplinary “management group” have the authority to ensure that responsibilities and authorities are defined and communicated…" The standard goes on to delineate the requirements through all phases of testing that must be addressed including personnel training and competency. It also specifies the appointment of a person, the “coordinator,” responsible for POCT quality. The approach that ISO specifies to achieve quality at POCT is very prescriptive and proactive and differs markedly from the regulatory approach of the U.S. government that is disseminated in the Clinical Laboratory Improvement Amendments (CLIA). CLIA stipulates that for methodologies classified as CLIA-waived (now over 100 analytes performed by over 1000 methodologies) and mostly performed at POC, the test site only needs to follow the manufacturers’ directions. This explains the “incoherent or no regulation” amplifier described by Meier and Jones. Fortunately, today we also have good sources of information from POCT managers who offer practical advice regarding management approaches and practices to achieve excellence and avoid common pitfalls. Dr. Paula Santrach from the Mayo Clinic named 10 key factors for creating and maintaining a quality POC program. Her key points include planning for quality, training, nurturing a patient safety culture and implementing automation whenever possible. Dr. James Nichols, Baystate Health System, suggests standardizing instruments across sites, continual quality improvement, and maximizing connectivity for improved quality and patient safety. Other experts advise being aware of POCT limitations, minimizing testing staff, having guidelines to lead clinicians to the right test, and timely and proper test utilization, and taking advantage of available resources, such as websites, to keep current. All of these have merit and some warrant further discussion for quality planning.

Buy Right

Many factors influence the method/instrument selection decision. These are based on a variety of criteria including test menu, sample volume requirements, back-
ground and number of testing personnel (ease of use), cost (instrument, reagents/supplies and storage requirements, maintenance), performance requirements (accuracy, precision, approach to quality assessment) to meet quality needs, data management and connectivity, result documentation, billing, manufacturer support, and others. Making a choice is considerably more complex than listening to a salesperson’s highly selective recitation of features and benefits.

The primary purpose of POCT is to have results quickly available to the clinician for immediate intervention. While the emphasis on immediate availability of test data is definitely a positive for most applications, it is a negative when the result is incorrect! Instrument selection must take into account the analyst, who often has less insight and knowledge of the testing process. While there are many manual and automated methods available for POCT, not all methods meet the needs of the test site and its clientele and not all are equal in terms of accuracy, precision, and reliability. It absolutely is imperative that the coordinator or designee of the POCT committee have input into the evaluation and selection of methods to ensure that testing needs can be met.29

Automation continues as a reoccurring suggestion for eliminating many POCT errors. The most common example of the evolution of POCT technology is seen with the glucose meter—the most frequently used testing device across all elements of healthcare.30 The continuing evolution of this technology demonstrates the concept of addressing error reduction by overcoming “human and process factors” that negatively impact test quality and jeopardize patient safety. For example, current test systems now prompt operators to perform the test correctly, require patient and authorized operator identification, verify correct sample handling, flag critical test results, lock the system when quality control assessments fail or are not performed, electronically transfer the result directly to the patient’s caregiver and permanent medical record once acceptance (quality) criteria are met, and maintain records on operator competence and performance for management purposes. This is a classic example of the synergy between automated, technological capabilities and medical demand.

As the evolution continues, technology will move well beyond just automating the many steps of the testing process to autonomation. Autonomation transfers a level of human intelligence to automated machinery.31 The concept encompasses the two pillars of Toyota production: “Jidoka” and “Poka-Yoke,” which translate loosely as “automation” and “mistake proofing.” The concept incorporates the Deming view that correction of mistakes must be undertaken as they occur rather than waiting to the end of the production line.32 While more sophisticated technology is being introduced, the ultimate evolution will be the development of technology that controls and ensures the quality of the entire testing process with minimal operator intervention.

Another essential component of POCT is “connectivity.” Until recently, much POCT data were simply “lost,” potentially impacting the quality of patient care. Fortunately more and more of today’s test devices have connectivity capabilities to capture data in the patients’ records and facilitate better management of the entire POCT process. Autonomation and connectivity will continue to be driving forces in ensuring POCT quality and patient safety.

Train and Check Ongoing Competency
An accurate and precise result that meets the many testing requirements is unlikely to be obtained without a well-trained, competent operator. All those involved in POCT know that a major challenge concerns the training and ongoing competency assessments of many healthcare practitioner analysts, who have a patient care focus as their primary responsibility. The increased demand for POCT that includes an extensive test menu offered 24 hours a day, 7 days a week complicates training and competency assessment. Of course, all POCT must be in full compliance with a complex set of very technical regulations and overarching professional standards usually written with the centralized laboratory in mind.

Who does the training is very situational specific and ranges from manufacturers for specific method/instrument instructions to key trainers to laboratory staff. A successful training program incorporates materials that are up-to-date, easy to understand and address all the necessary components outside the actual testing, such as — institutional policies and procedures, patient identification, patient preparation, sample collection, alert value protocol, blood-borne pathogen safety precautions, and documenting results. Face-to-face instruction by instructors with the same background as the trainee (e.g., nurses training nurses) often is considered to be the most effective approach, however, this may not be possible or practical with large numbers of analysts and/or many geographically separated POCT sites. E-learning packages developed by manufacturers, professional trainers, and/or institutional staff are becoming more widely used. Whatever the approach taken, some type of assessment as to the analyst’s competency must be carried out before actual testing is allowed. Training is not a one time activity. It needs to be undertaken with the ongoing changes in testing protocols and applicable policies and procedures.
Once trained, analysts must continue to maintain their competence to provide quality results necessary for high quality care. In the US, CLIA now mandates, at a minimum, an annual competency assessment of authorized testing personnel that includes all of the following: (1) Directly observing routine test performance, including patient preparation, if applicable, specimen handling, processing and testing; (2) Monitoring the recording and reporting of test results; (3) Reviewing, if applicable, intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; (4) Directly observing performance of instrument maintenance and function checks; (5) Assessing test performance through testing previously analyzed, internal “blind” or external proficiency testing samples; and (6) Assessing problem solving skills. Considering the amount of time, energy, and costs associated with training and competency assessment activities, the POCT coordinator/committee should consider limiting the number of analysts, when possible, and encouraging those who “do not follow the rules, and/or test infrequently” not to be involved. It is very difficult for analysts performing few tests to maintain competence.

Think Outside the Box
Traditionally, the total testing process is divided into three phases—pre-analytical, analytical, and post-analytical. Today in managing and evaluating the impact of POCT, the process needs to be viewed more broadly and include the clinicians who demand and use the rapid test results. POCT really begins with the clinician deciding to order a test, (pre-preanalytical) and ends with the clinician acting on the result (post-postanalytical).\(^1\)\(^,\)\(^3\) Meier and Jones suggest that the value of POCT may be diminished due to clinician practice paradigms.\(^9\) Medical error should be attributed to clinicians ordering the wrong test or failing to respond appropriately or in a timely manner to a test result. The degree to which these errors compromise patient safety is a function of the criticality of the test result. Consequently it is appropriate that clinician response be considered in assessing the POCT process, medical error and patient safety. While “immediate result availability,” is the major impetus behind today’s POCT, it is also the major reason for concern. The IOM study recognizes two kinds of medical POCT-related errors, which impact on patient safety: initiating the incorrect therapeutic action and/or failing to recognize the significance of the test result and failure to take the necessary action.\(^1\) Simply because advanced technology makes test results available in minutes does not mean that the clinician practice paradigms have advanced with the technology. POCT results available in “real time” must be fully integrated into contemporary patient care processes for the patient to benefit from the testing approach. As the availability of high-quality POCT results, in real time, becomes the norm, the clinician practice paradigm must change if medical errors are to be reduced. Ultimately in the POCT process, improvements may need to come from fundamentally changing the caregivers’ paradigm.

Conclusions
On a daily basis, “things happen” that impact our quality of life and safety. POCT is no exception. POCT will continue to grow and be an important segment of the modern clinical laboratory testing market. For POCT to benefit patient outcomes requires quality and quality is not automatic. Quality testing and ultimately patient safety demand planning, oversight and leadership provided by the POCT committee and coordinator. Many experts in POCT have given valuable advice and tips to achieve excellence in POCT. However in evaluating and improving POCT, the total testing process— pre-analytical phase through post-postanalytical— must be considered. Even the best test systems, analysts, and testing policies and procedures will be ineffective if the clinicians do not take appropriate advantage of POCT.
invited review

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS, editors. Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health system. Washington, DC: National Academy Press, 2000.

2. Downer K. Five Years After “To Err is Human.” Clin Lab News, 2005;31:1-2.

3. Fung A. Medical Errors Cost Health Care System Billions. April 2011. Available from: http://mobile.nationaljournal.com/healthcare/medical-errors-cost-health-care-system-billions-20110407 (accessed April 25, 2011).

4. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem 1997;43:1348-51.

5. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clin Chem 2007;53:1338-42.

6. Ross JW, Boone DJ. Assessing the effect of mistakes in the total testing process on the quality of patient care. In: Martin L, Wagener W, Essien JD, editors. Institute on critical issues in health laboratory practice. Minneapolis, Minnesota: DuPont Press, 1989 [abstract 102].

7. Plebani M. Partners in Error Prevention. Jan. 2009. Available from: http://acutecaretesting.org/frames-yes (Accessed April 25, 2011).

8. Jones BA, Meier FA. Patient safety in point-of-care testing. Clin Lab Med 2004;24:997-1022.

9. Meier FA, Jones BA. Point-of-care testing error: sources and amplifiers, taxonomy, prevention strategies, and detection monitors. Arch Pathol Lab Med 2005;129:1262-7.

10. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101-110. Not helpful? you can block实验室journals.com results when you’re signed in to search. rsmjournals.com

11. Ehrmeyer SS, Laessig RH. Point-of-care testing, medical error, and patient safety: a 2007 assessment. Clin Chem Lab Med 2007;45(6):786-73.

12. Kost G. Preventing problems, medical errors, and biohazards in point-of-care testing: using complex adaptive systems to improve outcomes. Point of Care 2003;2:78-88.

13. Nichols J. Reducing medical errors at the point of care. Lab Med 2005;36:275-7.

14. Ehrmeyer SS, Laessig RH. POCT 2003: testing environment, regulations, and technology. Adv Lab Adm 2003;12:28-38.

15. Nichols J. Medical errors: can we achieve an error-free system. Point Care 2005;4:139-41.

16. Ehrmeyer SS, Laessig RH. Quality in point of care testing: what drives the system? personnel, regulatory standards, or instrumentation? Accred Qual Assur J 2004;10:47-51.

17. Digha A, Lewandrowski K. Improving point-of-care testing with automated identification technologies. Point Care 2005;4:86-9.

18. Okorodudu AO, Petersen JR. Leveraging information technology for point-of-care testing at University of Texas Medical Branch health care system. Point of Care 2010; 9:162-64.

19. Okorodudu AO. POCT quality. Adv Lab Adm 2010;19:18.

20. Ehrmeyer SS, Laessig RH. Point-of-Care Testing and Patient Safety-A Partnership. Point of Care 2009;7:223-226.

21. Leape LL. Errors in medicine. Clin Chim Acta 2009; 404:2-5.

22. Plebani M. Errors in laboratory medicine and patient safety: the road ahead. Clin Chem Lab Med 2007;45:700-7.

23. International Organization for Standardization (ISO). Geneva, Switzerland. Available at: http://www.iso.org/iso/home.html (Accessed April 25, 2011).

24. ISO 22870:2006. Point-of-care testing (POCT) - Requirements for quality and competence. Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=35173 (Accessed April 25, 2011)

25. U.S. Department of health and Human Services. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule. Fed Regist 2003; 68:3640-3714. Available from: http://www.access.gpo.gov/nara/cfr/waisidx_04/cfr493_04.html (Accessed April 25, 2011).

26. Santrach P. Mayo Clinic’s 10 key factors for creating and maintaining a quality POCT Program. October 2006. Available from: http://acutecaretesting.org/journalscanner?TId=61290154281? (Accessed April 25, 2011)

27. Nichols J. Top 10 Planning Tips for your POCT Program. Available from: http://www.aacc.org/ SiteCollectionDocuments/Events/Expert%20Access/2005/manage/Nicholas0505.pdf (Accessed April 25, 2011).

28. Ford A. Eye the basics, not baubles, for point-of-care testing. Jan. 2010. CAP Today. Available from: http://www.cap.org/apps/cap.portal?m_ref=true&cntvwrPtt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&win dowLabel=cntvwrPtt&cntvwrPttActionForm.contentReference)=cap_today%2F1010%2F0110i_ eye_the_basics.html&_state=maximized&_pageLabel=cntvwr (Accessed April 25, 2011).

29. Okorodudu AO. Optimizing accuracy and precision for point-of-care tests. 2011 Available from: http://acutecaretesting.org/optimizing-accuracy-and-precision-for-poc-tests?frames-yes&wt.mc_id=2011-04-article1&glis=cfc25b4-8fad24d-fecad4d (Accessed April 25, 2011).

30. Ehrmeyer SS, Hausman P, Lebo R. Using technology to improve patient safety at point of care. Point Care 2005;4:46-149.

31. Ohno T. Toyota production system ? beyond large scale production. Portland, Oregon: Productivity Press, 1988.

32. Deming WE. Out of the crisis. Cambridge, MA: MIT; 1982.

33. Plebani M. Partners in error prevention. 2009 Available from: http://acutecaretesting.org/ (Accessed April 25, 2011)