In this issue: POCT – making the point

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Training and competency strategies for point-of-care testing

Sedef Yenice

Demiroğlu Bilim University and Gayrettepe Florence Nightingale Hospital, Beşiktaş-Istanbul, Turkey

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Corresponding author:
Prof. Sedef Yenice
Gayrettepe Florence Nightingale Hospital
Cemil Aslan Güder sok. No: 8
Beşiktaş, Istanbul 34349
Turkey
E-mail: sedef.yenice@florence.com.tr

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ARTICLE

The increased availability and use of POCT are being influenced by many factors, such as; industry trends to move towards patient-centered care and health-care decentralization, the increasing prevalence of infectious diseases also including the current use of Rapid SARS-CoV-2 Testing, a growing incidence of life-style diseases such as diabetes, heart disease, and hypertension, as well as advances in in-vitro diagnostic medical technologies. The use of POCT can increase the efficiency of services and improve outcomes for patients. However, the variability of the testing environment and conditions as well as the competency of staff performing the tests may have a significant impact on the quality and accuracy of POCT results.

A majority of the staff who perform POCT are not trained laboratory staff and may not be as knowledgeable about the processes involved in testing, such as

patient preparation, sample collection, management of equipment and supplies, instrument calibration and maintenance, the performance of the test, quality control, interpretation of the results, and reporting/documentation of results in each patient's context. Therefore, staff performing POCT must have the proper training and experience to ensure test results are accurate and reliable.

This short communication outlines the specific requirements for staff training based on international standards which need to be considered to ensure the quality of test results and describes competency criteria required for compliance with POCT.

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INTRODUCTION

Point-of-Care Testing (POCT) is rather broad in scope and covers any diagnostic tests performed near or at the site of a patient where a specimen is collected and outside of the conventional clinical laboratory, whether it is performed in a physician's office, emergency department, intensive care unit, operating room or an ambulatory care clinic. These tests are waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 in the US and can be molecular, antigen, or antibody tests (1). POCT ranges between three levels of complexity, from simple procedures such as glucose testing, moderate-complexity procedures (including provider performed microscopy procedures), or high-complexity procedures such as influenza testing. Health care professionals delivering POCT usually use test kits, which may include hand-held devices or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g. capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location in a hospital to read blood, saliva, or urine samples (2-4). The primary advantage of POCT is the faster turn-around time for results. They provide results within minutes (depending on the test) rather than hours leading to a possible change in the care of the patient in various settings such as physician offices, urgent care facilities, pharmacies, school health clinics, long-term care facilities, and nursing homes, temporary locations, such as drive-through sites managed by local organizations (5). An additional advantage is that these tests often require less sample volume than tests performed in the laboratory.

The recent and ongoing changes in clinical laboratory technology have a great impact on laboratory staff needs. POCT is usually performed by non-laboratory trained individuals such as licensed practical nurses, registered nurses, nurse aides, physicians, residents, students, technical assistants, respiratory therapists, emergency technicians, and pharmacists among others.

There are many "official" and professionally based standards and guidelines that define how POCT should be implemented, managed and the performance quality checked and maintained. Most professionally based guidelines follow a similar template and provide similar information which includes specific references to staff training and competency assessment (6-10). Organizations that have a central biomedical laboratory are to use these standards in POCT - specific requirements for quality and competence based on ISO 22870:2016. This standard is intended to be used in conjunction with ISO 15189:2012 and applies when POCT is carried out in a hospital, clinic, or healthcare organization providing ambulatory care. Patient self-testing in a home or community setting is excluded, but elements of this document can be applied. Table 1 lists selected International Organization for Standardization (ISO) standards to be considered associated with the POCT training and competency assessment requirements (11-18).

Table 1 International standards define or are associated with medical laboratory and POCT competency and training

Standard	Definition	Scope of the document
ISO 17593:2007	Clinical laboratory testing and in-vitro medical devices – requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy.	• specifies requirements for in *vitro* measuring systems for self-monitoring of vitamin-K antagonist therapy, including performance, quality assurance, and user training and procedures for the verification and validation of performance by the intended users under actual and simulated conditions of use. • pertains solely to PT measuring systems used by individuals for monitoring their vitamin-K antagonist therapy, and which report results as international normalized ratios (INR).
ISO 15189:2012	Medical laboratories – particular requirements for quality and competence.	• specifies requirements for quality and competence in medical laboratories. • can be used by medical laboratories in developing their quality management systems and assessing their competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities, and accreditation bodies.
ISO 15197:2013	In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.	• specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures, and the validation of performance by the intended users. These systems are intended for self-measurement by laypersons for the management of diabetes mellitus.

		• applies to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.
ISO 22870:2016	Point-of-care testing – requirements for quality and competence.	• gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic, and by a healthcare organization providing ambulatory care. This document can be applied to transcutaneous measurements, the analysis of expired air, and *in vivo* monitoring of physiological parameters. • patient self-testing in a home or community setting is excluded, but elements of this document can be applied.
ISO/TS 22583:2019	Guidance for supervisors and operators of point-of-care testing (POCT) devices.	• gives guidance for supervisors and operators of POCT services where POCT is performed without medical laboratory training, supervision, or support. It includes the key components that should be considered to provide safe and reliable POCT results.
ISO/TS 20914:2019	Medical laboratories — Practical guidance for the estimation of measurement uncertainty.	• provides practical guidance for the estimation and expression of the MU of quantitative measurand values produced by medical laboratories. Quantitative measurand values produced near the medical decision threshold by POCT systems are also included in this scope. This document also applies to the estimation of MU for results produced by qualitative (nominal) methods which include a measurement step.

		It is not recommended that estimates of MU be routinely reported with patient test results but should be available on request.
ISO 15190:2020	Medical laboratories — Requirements for safety	• specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, requirements are set forth to specify the role and responsibilities of the laboratory safety officer in ensuring that all employees take personal responsibility for their safety at work, and the safety of others who can be affected by it.

ISO: The International Organization for Standardization; PT: prothrombin time; POCT: Point-of-Care Testing; MU: measurement uncertainty.

A well-organized POCT program requires both thoughtful planning as well as ongoing oversight and supervision (19-21). Joint Commission International (JCI) specifies that a qualified individual is responsible for the oversight and supervision of the point-of-care testing program (Standard AOP.5.1.1) (22). Leadership may be involved in the planning process by identifying and approving the resources dedicated to the POCT program as well as the policies and procedures related to management and oversight of the program (23,24). When considering the tasks conducted by individuals who do not have technical skills and training, it is important to note that many countries have licensure laws that preclude the conduct of certain testing procedures by non-technical staff (25,26). CLIA requirements in the US, as they relate to moderate- and high-complexity tests, do not allow the use of non-technical staff for certain testing procedures (27). The College of Physicians and Surgeons of Alberta provides detailed recommendations for the use of POCT outside of an accredited laboratory which includes documentation, non-technical staff training, quality control, etc, in a guideline (28).

TRAINING REQUIREMENTS FOR POINT-OF-CARE TESTING

A majority of the staff who perform POCT are not trained laboratory staff members and may not be as knowledgeable about the processes involved in testing, such as patient preparation, sample collection, instrument calibration, instrument maintenance, and quality control. Therefore, staff performing POCT must have the proper training and competency assessment to ensure test results are accurate and reliable (29,30).

Alternatively, laboratory staff may take responsibility, if preferred, for some of the POCT activities, such as managing instrument maintenance and acting on instrument failures. Before training for POCT, each staff member must have qualifications verified with state or national authority requirements and accreditation agencies, if appropriate. For institutions performing POCT utilizing waived or non-waived testing, CLIA regulations require a high school diploma or equivalency in the US (31). Some state regulating agencies require a license and/or a specific level of professional qualifications for persons

performing laboratory testing in any setting, including point-of-care. Each qualified POCT user must complete initial training and orientation on each test method before initiation of testing and following any changes or update in instrumentation, kits, or test methods. Initial training must be completed before the user performing any patient testing and competence must be documented. This initial training must include direct observation, be documented, and the documentation retained in the individual's training record.

Following any changes or updates in methodology, training of personnel in the new methodology must occur and be documented before performing patient testing. All training must be performed by a qualified individual such as a certified laboratory technical staff or the manufacturer/company representative and the competency of the tester verified before performing patient testing. A qualified trainer must have been trained and demonstrated competency for all methods for which training is being conducted (32).

COMPETENCY ASSESSMENT REQUIREMENTS FOR POINT-OF-CARE TESTING

Competency confirms the effectiveness of training. Assessment of competency is an evaluation of training and verifying that training is applied to test performance. Following initial training and competency, the standards require that staff performing POCT must be re-assessed for competency at regular intervals to ensure the accuracy and reliability of results and the quality and safety of patient care. Re-training and competency re-assessment should occur if there are nonconformances or adverse events relating to patient testing. Competency assessment should include policies and procedures outlining the process for evaluating competency. As with all policies and procedures, the laboratory director must approve the process at the inception and following any major revision. All reviews and approvals are documented with signatures and dates. All policies and procedures must be periodically reviewed, annually or every two years (biennially), depending on regulatory and accrediting requirements, by the laboratory director or designee, and this review documented with the date of the review.

As with initial training, each employee that performs POCT must have competency assessed and documented after training and before performing patient testing. The documentation must be retained for each procedure the employee performs. If there is a change in test method or a new test added, initial training and assessment of competency must be completed and documented. For each employee performing POCT, an ongoing competency assessment must be completed at designated intervals for each test method that the employee performs. For CLIA compliance, competency must be assessed for each non-waived POCT at six months and 12 months following initial training and assessment annually thereafter. Evaluation of competency should include pre-analytic, analytic, and post-analytic phases of testing. For minimum compliance with POCT regulations, six procedures must be included within the competency assessment process for all employees performing non-waived POCT testing. Table 2 provides a summary of assessment procedures for POCT; including the requirement for operator training, proof of competency, quality control, and external quality assessment. Most authorities provide statements regarding POCT which include mandatory quality procedures as defined by regulation or specific policy.

Each of the required procedures will not be appropriate for every activity in a comprehensive competency assessment program. The procedures are applied as appropriate, evaluated

with an appropriate assessment tool, results evaluated, reviewed with the employee, and documentation is retained. Tools employed for competency assessment may include items such as checklists (for direct observation), case studies (problem-solving), quizzes (problem-solving), unknown sample testing (test performance), review of retained records, proficiency testing results, and any other appropriate mechanism for assessment of competency.

Like other processes in a laboratory, errors can happen at any phase of POCT. A study by Cantero, et. al. looked at the error rates during all phases

Table 2 **A staff training and education program, as appropriate, includes the following learning items of procedure and tools for assessment.**

All POCT operators must complete a comprehensive training program that includes an understanding of the purpose and limitations of the test and awareness of procedures and processes relating to all aspects of operating the device.

Procedure	Potential tools for assessment
Pre-analytic phase	
• **General background information**	
The context and clinical utility of POCT and the theoretical aspects of the measuring system	Review of the manufacturer's guides, standard operating procedure documents referring to the international and national quality standards, and training resources
• **Instrument and equipment**	
Direct observations of the use of POCT instruments and devices for ensuring readiness	Review of equipment/kit validation/verification to ensure they are performing as intended, inspection and validation of incoming materials and new lot numbers, verification of reference range for the population being tested (e.g. pediatric vs. adult)
Direct observations of the performance of instrument maintenance, calibration of equipment (instrument/reagent system) if required by the manufacturer, and function checks	Checklist and preventive maintenance records
Review of troubleshooting when an instrument fails	Checklist

Direct observations of reagent storage	Review of worksheets, inventory logs, expiration dates
• **Patient safety**	
Direct observations in the Specimen Collection and Preparation	Checklist for patient identification, patient preparation (e.g. fasting, lack of interfering drugs), proper specimen collection at the appropriate time (e.g. toxicology or therapeutic drug monitoring (TDM) tests), volume, handling, and processing by the manufacturer's instructions
Analytic phase	
• **Evaluation of the analytical performance**	
Assessment of test performance and limitations of the measuring systems	Checklist for unknown and previously analyzed specimens, internal blind testing samples, internal quality control, or external proficiency testing samples
Direct observations of routine patient test performance	Checklist
Post-analytic phase	
Monitoring the record-keeping and reporting of test results	Review of worksheets, permanent records (which may be the patient's chart or directly into an electronic medical record, if applicable) Logs for the length of time that records are retained (must comply with established best practice guidelines).
Direct observations of documentation and reporting requirements of test results	Review of arrangements/processes in place to respond to and act upon any critical POCT laboratory results. Checklist and review of worksheets
Review of response to results outside predefined limits	Checklist
Assessment of Quality Control Program	Review of quality control records, proficiency testing or EQA sample results, split samples
Assessment of problem-solving skills	Case study, quizzes, tests

Health and biosafety	
Direct observations of infection control	Review of implementation of a safety training program for employees who routinely work with blood or other infectious materials Review of worksheets related to the management of biological/medical waste disposal, logs for handwash practice, cleaning and disinfecting requirements for contaminated surfaces, supplies, and equipment Review of personal protective equipment when dealing with patients and testing of samples (e.g. gloves, gowns/coats) and evaluation and follow-up of workers after accidental exposure to blood and body fluids Review of the protocol for the management of patient adverse events/reactions (e.g. fainting),
Direct observations of risk assessment	Review of worksheets for performing a risk assessment to identify what could go wrong, such as breathing in infectious material or touching contaminated objects and surfaces. Checklist for implementing appropriate control measures to prevent these potentially negative outcomes from happening. Review of hazard assessment for the identification and mitigation of possible hazards that could be encountered when using the POCT device.

EQA: External Quality Assessment.

of testing in the central laboratory and the performance of POCT. A higher rate of pre-analytical errors was found to be associated with POCT compared to central laboratory testing (33). In this context, the organization needs to identify the risk points in the process where errors in POCT may occur and take action to mitigate those risks. Monitoring and evaluation of the risks in performing POCT are essential and must be included in the training program.

One of the biggest POCT challenges is keeping track of the training and competency assessments for a multitude of operators in different locations, many of whom are non-laboratorians (34). A list of POCT challenges is shown in Table 3. Every operator is required to have documented training on each device before reporting outpatient results. Ongoing assessments are performed at the first six months, and then annually thereafter. In a large healthcare organization,

this can include several device types and thousands of operators. Facilities that need to track a large number of POCT operators may decide to use an online training tool such as a learning management system (LMS). POCT management software can automate reminders to users who are due for their competency assessment. When devices are capable, the POCT management software can block users from using a device until their certification is valid (35).

Table 3 POCT management challenges

New instrument evaluation
Compliance of users
Testing environments
Data management
Managing inspections
Handling quality control failures
Correlations to core lab
Managing competency assessments

PERSONNEL QUALIFIED TO PERFORM COMPETENCY ASSESSMENT

Specifically, ISO 22870:2016 recommends that organizations should constitute a multidisciplinary POCT committee to oversee the PoCT service. The POCT management committee is responsible to designate staff performing POCT and implement a POCT operator training and competency assessment program. Competency assessment for personnel performing moderately complex testing (which is the majority of non-waived POCT) is the responsibility of the technical consultant. This is the requirement for CLIA compliance. The laboratory director may act as the technical consultant and may perform competency assessment if they also meet the personnel qualification requirements of education, experience, and training for the position to fulfill the responsibilities. Qualifications for a technical consultant or POCT are defined in 42 CFR §493.1411 (36). The qualified laboratory director will perform a competency assessment. Technical consultants are the only staff that does NOT require competency assessment annually.

The laboratory director bears the responsibility that all competency assessments are completed and that the testing personnel are competent and consistently report accurate test results. Competency assessment may also be performed by any person that would qualify as a technical consultant, but does not serve in that role. Testing personnel who are peers may serve in the role of assessing competency If the qualifications for a technical consultant are met.

SUMMARY

Growth in point-of-care tests which do not have to be performed by laboratorians may mean that more allied health personnel will be needed in hospitals, physicians' offices, and in organizations that do not have a central biomedical laboratory (e.g. long term care, home care, or a community pharmacy), but may have an agreement and work with a central biomedical laboratory that is offsite.

To ensure that POCT is performed safely and correctly, a clearly defined and well-structured approach to the management of POCT is required. Also, a robust strategy of training for personnel performing POCT must be in place for compliance with POCT, including specific requirements for POCT policies and procedures based on ISO 22870, staff training, and continuing education. Finally, a POCT program for training and competency assessment must be implemented and

the POCT operators must be periodically evaluated to ensure the program is meeting the educational needs of the staff performing POCT.

REFERENCES

1. www.cms.gov/clia Accessed on March 30, 2021.

2. Technology Trends in the Clinical Laboratory Industry. Institute of Medicine 2000. Medicare Laboratory Payment Policy: Now and in the future. Washington, DC: The National Academies Press. https://doi.org/10.17226/9997.

3. CAP Point-of-Care-Testing Checklist. 2012.

4. Paxton A. An uneasy dance with POC glucose in the ICU. CAP Today 2013 October issue.

5. https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html#print

6. Kost GJ. Goals, guidelines, and principles for point-of-care testing. In: Kost GJ, ed. Principles and practice of point-of-care testing. Philadelphia: Lippincott Williams and Wilkins. 2002, Chapter 1, pp3-12.

7. PD-LAB-POCT Additional Standards v1.01 Nov 2010.

8. Improving the quality of HIV-related point-of-care testing: Ensuring the reliability and accuracy of test results. CDC and World Health Organization 2015.

9. Camacho-Ryan O, Bertholf RL. Monitoring point-of-care testing compliance. Available at: aacc.org/publications/cln/articles/2016/february/monitoring-point-of-care-testing-compliance

10. CAP Point-of-Care-Testing Checklist. 2012. Accessed on March 30, 2021.

11. ISO 17593:2007 Clinical laboratory testing and in-vitro medical devices – requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy. Geneva: International Organization for Standardization; 2007.

12. ISO 15189:2012 Medical laboratories — Particular requirements for quality and competence. Geneva: International Organization for Standardization; 2012.

13. ISO 15197:2013 In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva: International Organization for Standardization; 2013.

14. ISO 22870:2016 Point-of-care testing (POCT) — Requirements for quality and competence. Geneva: International Organization for Standardization; 2016.

15. ISO/TS 22583:2019 Guidance for supervisors and operators of point-of-care testing (POCT) devices. Geneva: International Organization for Standardization; 2019.

16. ISO/TS 20914:2019 Medical laboratories — Practical guidance for the estimation of measurement uncertainty. Geneva: International Organization for Standardization; 2019.

17. ISO 15190:2020 Medical laboratories – Requirements for safety. Geneva: International Organization for Standardization; 2020.

18. Freckmann G, Schmid C, Baumstark A, Rutschmann M, Haug C and Heinemann L. Analytical Performance Requirements for Systems for Self-Monitoring of Blood Glucose With Focus on System Accuracy: Relevant Differences Among ISO 15197:2003, ISO 15197:2013, and Current FDA Recommendations. Journal of Diabetes Science and Technology 2015; 9(4): 885–94.

19. Tirimacco R, Tate J, Johnson R. Point-of-Care Testing. Clin Biochem Rev 2010; Vol 31 August, 71-3.

20. IFCC - Thinking of Introducing PoCT – Things to Consider 20 March 2014.

21. Nichols JH, Alter D, Chen Y, Isbell TS, Jacobs E, Moore N, Shajani-Yia Z. AACC guidance document on management of point-of-care testing. [Epub] J Appl Lab Med June 4, 2020, as doi:10.1093/jalm/jfaa059.

22. https://www.jointcommissioninternational.org/standards/hospital-standards-communication-center/point-of-care-testing/ Accessed on March 30, 2021.

23. CLSI POCT07-A, Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline. Clinical and Laboratory Standards Institute; Wayne, PA 2010.

24. CLSI QMS03, Training and Competence Assessment; Approved guideline — Fourth Edition. Clinical and Laboratory Standards Institute; Wayne, PA 2016.

25. Mann PA. Training Non-Laboratorians to Perform POCT. Clinical Laboratory News August 2017.

26. Khan AH, Shakeel S, Hooda K, Siddiqui K, Jafri L. Best practices in the implementation of a point of care testing program: experience from a tertiary care hospital in a developing country. eJIFCC 2019; 30 (3): 288-302.

27. https://www.cdc.gov/clia/test-complexities.html Accessed on March 30, 2021.

28. College of Physicians & Surgeons of Alberta, POCT Guidelines - Version: July 2020

29. Ehrmeyer SS. The role of training, competency assessment, and continuing education. Dec. 2002. https://acutecaretesting.org/.

30. Barabas N, Bietenbeck A. Application guide: training of professional users of devices for near-patient testing. J Lab Med 2017; 41(5): 215–18.

31. https://www.labce.com/spg1382261_training_requirements_for_poct.aspx#:~:text=Each%20qualified%20POCT%20user%20must,and%20competence%20must%20be%20documented. Accessed on March 28, 2021.

32. Kost GJ, Zadran A, Zadran L, Ventura I. Point-Of-Care Testing Curriculum and Accreditation for Public Health—Enabling Preparedness, Response, and Higher Standards of Care at Points of Need. Front. Public Health. 2019; 6:385. Published online 2019 Jan 29. doi: 10.3389/fpubh.2018.00385

33. Cantero M, Redondo M, Martin E, Callejon G, Hortas ML.Use of quality indicators to compare point-of-care testing errors in a neonatal unit and errors in a STAT central laboratory. Clin. Chem. Lab. Med. 2015 Feb;53(2): 239-247.

34. Shaw JLV. Practical challenges related to point of care testing. Practical Laboratory Medicine. 2016; 4(1): 22-9.

35. https://www.elitecme.com/resource-center/laboratory/laboratory-management-of-poct. Accessed on March 30, 2021.

36. https://www.law.cornell.edu/cfr/text/42/493.1411. Accessed on March 30, 2021.