Guidelines and Recommendations

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Point-of-care testing performed by healthcare professionals outside the hospital setting: consensus based recommendations from the IFCC Committee on Point-of-Care Testing (IFCC C-POCT)

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Abstract: The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Committee on Point-of-Care Testing (C-POCT) supports the use of point-of-care testing (POCT) outside of the hospital setting performed by healthcare professionals without formal laboratory education because of its numerous benefits. However, these benefits are associated with risks that must be managed, to ensure the provision of reliable test results and minimize harm to the patient. Healthcare professionals, local regulatory bodies, accredited laboratories as well as manufacturers should actively be engaged in education, oversight and advice to ensure that the healthcare professional selects the appropriate equipment and is able to analyze, troubleshoot and correctly interpret the point-of-care (POC) test results.

Keywords: audit; competency; instrument correlation; point-of-care testing (POCT); training

Background

Scope

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Committee on Point-of-Care Testing (C-POCT) developed this paper to address specific issues related to quality assurance (QA) for POCT performed outside the hospital setting by healthcare professionals, where heterogeneous quality management strategies exist, and to propose recommendations to ensure patient safety. The scope of this document is limited to POC tests intended for diagnosis and treatment of human disease performed

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using samples taken from a patient and does not include continuous glucose monitoring.

Methods

Consensus was achieved through review of CLSI and ISO guidelines as well as the relevant published literature published on *Pubmed.gov* on the subject matter.

Introduction

Point-of-care testing (POCT), also known as near patient testing, is defined as diagnostic testing at or near the site of patient care performed by healthcare professionals [1, 2].

The improvements in technology and miniaturization of instruments have resulted in the rapid proliferation of POC tests as important adjuncts to patient management by healthcare workers. Compared to conventional, centralized laboratory testing, POCT offers several advantages: small specimen volumes, easy to perform analysis, small instrument size, and most importantly a reduction of turnaround time (TAT), which facilitates faster decision-making in patients' diagnosis, monitoring and treatment of disease. However, these potential benefits of POCT with respect to timely medical care and improved patient outcomes can only be realised if POCT results are accurate and reliable, and which in turn is critically dependent upon adequate POCT management, oversight, regular staff assessments, POCT quality audits and proper documentation for test result accountability and correct patient management. Given its advantages, POCT is an important part of the diagnostic pathway in services within the hospital setting where urgent clinical decision-making is required for patient care (i.e. emergency units, critical care units, operating rooms, acute-care departments) as well as outside hospitals in patient disease management. With the advent of new and advanced detection methods and testing devices, POCT performed by healthcare professionals is increasingly being used outside the hospital settings in mobile facilities, primary health care facilities, physician offices, pharmacies, community centers, and nursing homes) [3] (see Figure 1).

To understand what is necessary for implementation and to reap the benefits of POCT in a primary care setting, it is important to assess the structure of healthcare operations and the lines of communication between different stakeholders. In a recent study, by Lingervelder et al. [4], it was concluded that: "… the biggest barrier to effective wide-scale implementation (of POC in primary healthcare) is a lack of communication between different stakeholders in the healthcare system and a high workload for clinicians aiming to implement POCT. Improved communication and a leadership structure dedicated to the roll-out and management POCT, could encourage its use by clinicians, and therefore positively contribute to the patient's experience in the healthcare system."

A number of international guidelines are available that address the recommended/desired features for *in vitro* POC diagnostic medical devices in order to meet regulatory requirements [2, 3, 5, 6]. The most recent ISO 15189:2022, includes management for POC testing in hospitals this replacing ISO 22870:2016 that previously had catered for POC testing. However, these standards were initially developed for hospital settings and therefore do not specifically apply to POCT in facilities located outside the hospital. The impact of POCT on patient safety is generally well managed in hospital settings, usually through a quality management system instituted and supervised by the clinical laboratory. This is often not the case when POCT is performed outside the hospital by healthcare professionals without formal laboratory education. In actual fact, these areas should be regarded as an extension of laboratory testing if quality testing is to be achieved and as such they should be subject to the same quality standards and accreditation requirements as testing in a hospital setting with oversight from the central laboratory [3, 5].

This document is organized in sections to specifically address the following areas of POCT: (1) justification for using POCT, (2) oversight and regulatory compliance, (3) device selection and method verification, (4) quality management system and key performance indicators, (5) operator training and competency assessment, and (6) result integration into patient medical records.

1 Justification for using POCT

POC tests should be implemented to improve the efficiency of the clinical pathways of how the patient's disease is managed by leveraging its strengths (ease of use, ease of patient identification, immediacy of results, smaller sample volumes, portability) when compared to centralized laboratory testing. The benefits should outweigh the risks of using POCT outside the hospital.

An evaluation of the appropriateness of the POC test and a full understanding of its role in improving the overall disease management of the patient is required before any implementation. Once incorporated into a clinical pathway, a team should be put together to oversee the operation and evaluate the impact of the POCT program on patient care by monitoring key performance indicators discussed in Section 4.

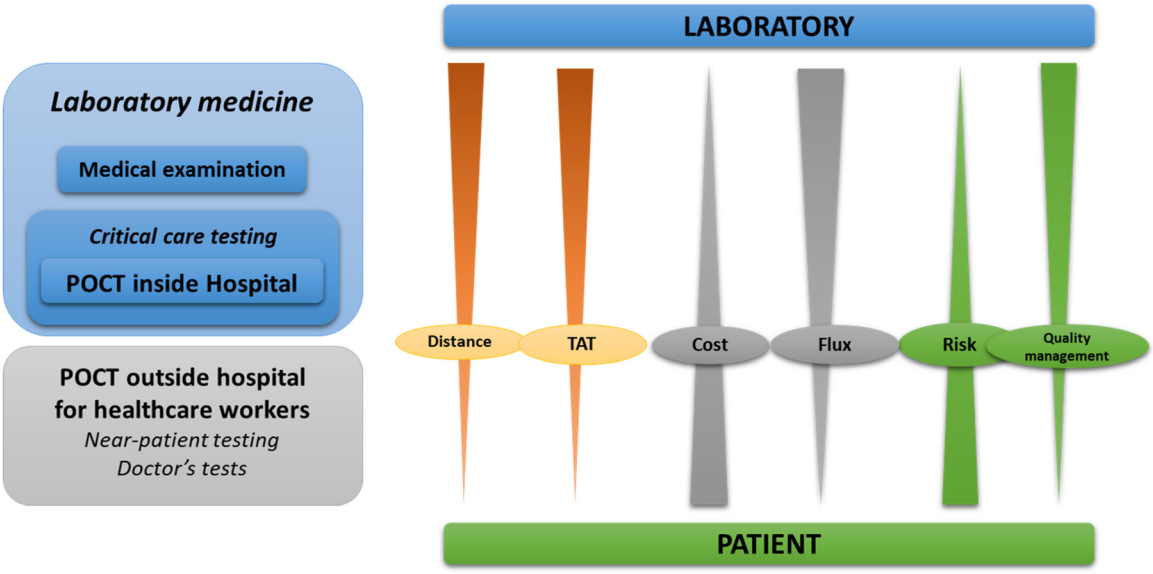

Figure 1: POCT situations and gradation in risk management. POCT perimeter is large and include three situations: POCT inside hospital, POCT outside hospital under healthcare professionals' responsibility and POCT with direct consumers. The scope of this paper includes only the second context.

2 Oversight and regulatory compliance

Appropriately trained and certified staff should supervise POC testing performed by healthcare professionals outside the hospital setting. Depending on the size of the operation, a designated person or persons (e.g. POC coordinator, POCT manager, director) should work with a POCT team or committee that should be comprised of key stakeholders that can make decisions regarding the implementation of POCT services. This person (s) together with the POCT team/committee should be responsible for the planning, implementation and maintenance of all processes involved in POCT (3). Qualified laboratory personnel that have the necessary knowledge and are best positioned to ensure safe and effective POCT oversight and regulatory compliance [2]. National regulatory requirements, where present, must be addressed and in their absence, it is proposed that local national societies and/or specialists in laboratory medicine be sought to give advice, based on the scope and complexity of any POC testing service, to achieve accreditation relative to international standards (e.g. ISO, CAP, Joint Commission International etc.).

3 Device selection and method verification

The POC coordinator, manager, director together with the POC Team (described in Section 2) are responsible for choosing the most appropriate test and/or device as well as for developing protocols and performing verification studies on the device (e.g. www.skup.org). Only POC tests that have been approved by the appropriate regulatory body should be considered for evaluation. Other stakeholders (e.g. clinical staff, infection control, education/training, information technology, and material management (inventory/supply chain), may be involved to help make the right device selection, taking into consideration the clinical environment for its usage. Evidence-based-medicine practices should steer device selection with regard to clinical utility. Device performance claims from the package insert should correlate with those obtained from verification studies that are performed by the POCT personnel. Depending upon the POCT device and intended use, these include imprecision, analytical sensitivity, specificity, linearity over the normal patient reference intervals (if quantitative results are reported) and normal patient reference intervals. If the POC device is replacing another instrument, or it will be intermittently used with another instrument, a comparability study between instruments needs to be performed to ensure the same reference intervals can be used. Analytical performance specifications (APS) should be based on one of the three models from the Milan conference, i.e. outcome studies, biological variation or state of the art [7]. The users should in cooperation with the POC coordinator establish the APS to be used and indicate if they are calculated Verification studies should in principle also assess lot-to-lot variation in results that could lead to inaccurate interpretation. This

can also be evaluated by EQA when reagent lot numbers are reported, and by having procedures for this when the user is changing a lot for example by running the same six patients samples with both the old and new lot. Device robustness, ease-of-use, sample type and size and space requirements should also be considered when selecting a POCT device. Figure 2 provides a summary of the device implementation process.

4 Quality management system and key performance indicators

A quality management system (QMS) is a documented set of processes aimed at ensuring proper analytical and clinical performance of POCT. A QMS is a key component of risk management established for any POCT service including services outside of the hospital performed by healthcare professionals. The QMS evaluates the pre-analytical, analytical and post-analytical phases of the testing process to identify opportunities for improvement. Key components of a QMS should include, but are not limited to the implementation of: (a) corrective actions in case of unsatisfactory quality control results (i.e. outside target limits) or patient results caused by for example the Hook effect or interferences; (b) audits to ensure open dates/new expiration dates are written on reagents and controls according to the manufacturer recommendations or when absent according to good laboratory practices; (c) regular and appropriate training of POC operators; (d) monitoring storage conditions (temperature and humidity for controls, reagents and instruments/kits; (e) institution and regular review of procedures for each POCT including protocols for the appropriate management of abnormal test results.

4.1 Quality control

Performing internal quality controls (IQC) at regular intervals is key to ensuring that POCT instruments are functioning properly and that POCT reagents are providing accurate patient results. This is particularly important when instruments are needed to be kept in storage in a "continuous ready" mode, such as needed in crisis response centers [8, 9] (Figure 3). In a study by Price and co-workers [10]. It was shown that analyzing IQC once a week for haemoglobin, C-reactive protein, and glucose was associated with better analytical quality [10]. A recent paper lists a scoring system to decide the frequency of IQC [11] and in the United States, IQC frequency is dependent on how the device is classified by the Food and Drug Administration

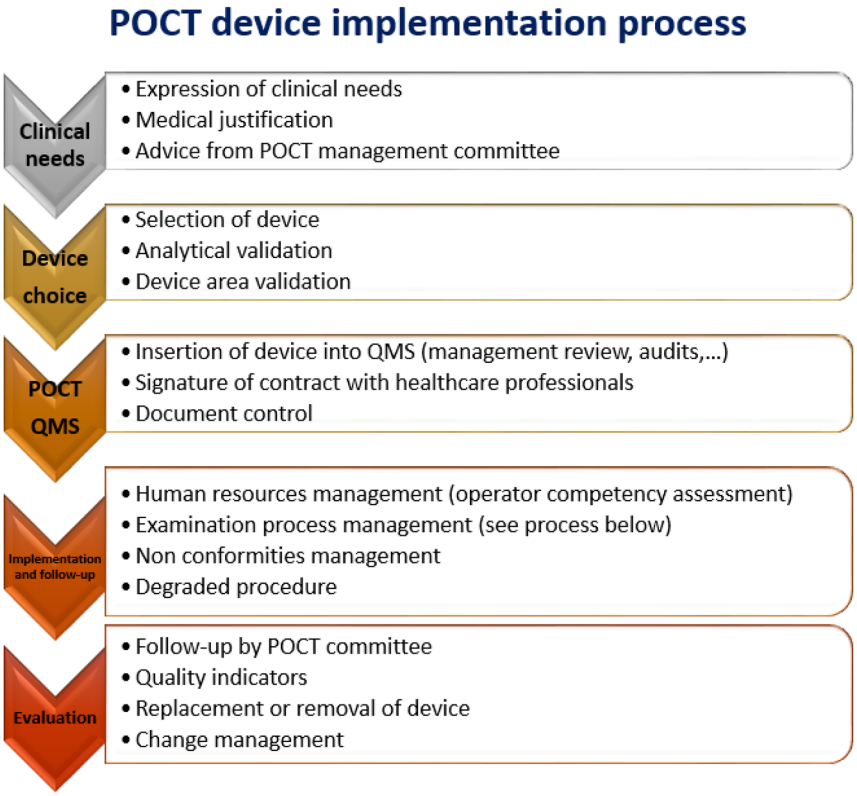

Figure 2: POCT inside or outside hospital under healthcare professionals' responsibility – POCT device implantation process.

[12]. The scoring system takes into account the following four main items: (1) the importance of the analyte in diagnosing and monitoring patients, (2) type of POC instrument, (3) user friendliness, and (4) the number of patient samples analyzed *per* week/month. The scoring system can easily be modified to different local environments. Quality control material target concentrations should be chosen so that one falls with [10] in the reference interval or close to decision limits of the assay and one in the abnormal range (high or low). For qualitative tests, one of the selected QC material should be negative and one positive.

4.2 Inter-instrument comparison

POCT operators and clinicians using these results for patient management should understand the comparability and possible discrepancies between results from different testing devices. For example, situations where the same analyte is measured by more than one type of POCT device and/or if both laboratory and POCT testing modalities are available for testing and results may be used interchangeably. Regular comparability studies between POCT devices and between POCT devices and laboratory methods, where applicable, using patient samples should be established and documented.

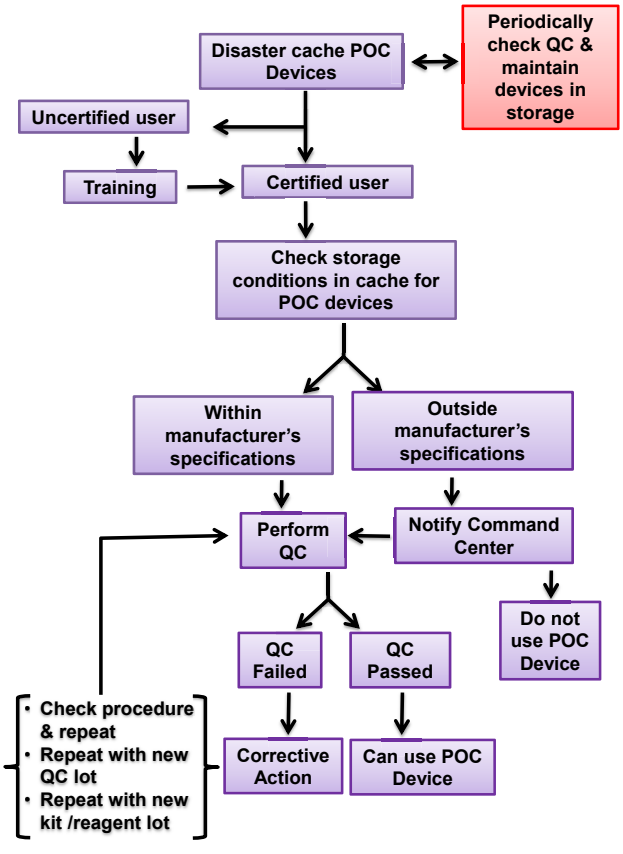

Figure 3: Showing effective use of quality control materials to ensure integrity of point-of-care testing instruments during periods of storage [8].

4.3 External quality assessment

Participation in external quality assessment (EQA) or proficiency testing (PT) can facilitate evaluation of the entire testing process, pre-analytical, analytical and post-analytical [6]. There are several not-for-profit and commercial EQA/PT providers for POCT and those performing POCT should subscribe to one, preferentially an EQA scheme using commutable material. Testing with control specimens should be performed by the operators who perform POCT to closely mimic the patient testing process as much as possible. EQA/PT results and reports should be reviewed by the POCT Director/Coordinator supervising the site and issues identified must be followed up on for quality improvement.

4.4 Biohazardous specimens

When dealing with bodily fluids, specimens must be considered infectious and therefore handled using appropriate personal protective equipment such as gloves. Depending on the type of test being performed, and the type of infectious material being handled, face shields, protective screen, overalls may also be used.

4.5 Documentation

All processes involved in POCT, as well as a defined document control system, should be documented. Examples of which include but should not be limited to:

(1) A personnel roster of all individuals trained to use POCT and their up-to-date certification status.
(2) Documentation of the process for method/instrument selection, instrument verification and acceptability criteria.
(3) Troubleshooting guidelines and interpretation of results, error indicators, clear instructions of how results are to be displayed, units of measurement, error signs, critical levels, identity of the operator and patient, date and time of testing.
(4) Documentation of safety procedures and chemical hygiene plan.

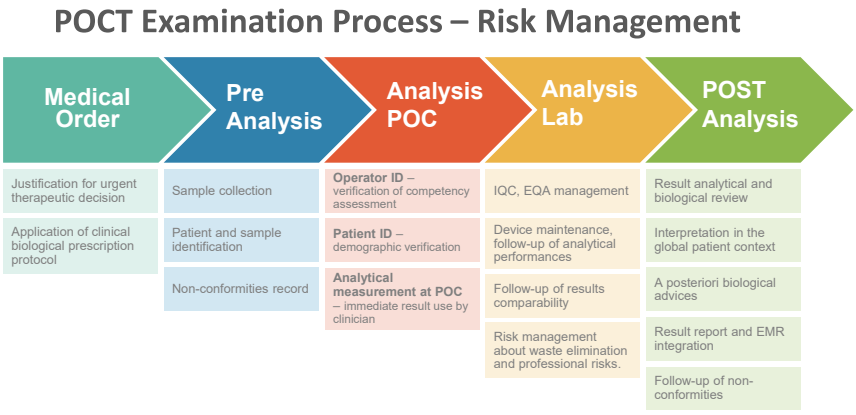

Figure 4: POCT inside or outside hospital under healthcare professionals' responsibility – risk management for POCT examination process.

(5) Instructions on management of consumables (e.g. storage temperature requirements and onboard reagent stability etc.).
(6) Device maintenance log.
(7) Record keeping of signed agreements with manufacturers.
(8) A log of changes to the document and dates.
(9) Records of all internal and external quality control data as well as reports on actions taken when results were outside acceptable limits.

4.6 Accountability

The entity responsible for the QMS oversight of the POCT program should be the POCT manager/director or team. Responsibilities and lines of accountability should be clearly defined. For example:

Who is accountable for training of POCT users?

Who is responsible for the running and interpretation of IQC and EQA results?

Who is responsible to view the POCT result?

Who is responsible to act on the POCT result?

Does the POCT user know who to contact for help with POC testing or POCT service issues?

4.7 Risk management

Risk assessments should be performed for POCT programs, with the aim of process improvement. There are several well established approaches for risk analysis, such as Ishikawa, Failure Modes and Effects Analysis – FMEA, which can be adapted for POCT risk assessment. Figure 4 illustrates a process map for POCT, which can be used as part of the risk assessment process. Published guidelines can be used to adapt this approach in each POCT situation [13, 14].

Risk assessments are key for identifying areas for quality monitoring and for operator training and re-training and are an important component of quality assurance to ensure patient safety. Ideally, risk assessments should be performed by the healthcare professionals performing POCT, with oversight from laboratory professionals (see summary Figure 4).

4.8 Auditing

Regular audits are mandatory for continuous improvement e.g. POC users have complete documentation of training and competency assessment, pass/fail rates in EQAs, compliance with performing IQC as recommended by manufacturer, repeat of critical results, and mislabeling of samples. Reporting, investigating and auditing patient related adverse incidents is integral to continuous quality improvement either internally or to an external body according to local regulations

4.9 Key performance indicators (KPI)

KPIs are performance measures that allow assessment of the POCT service to a target threshold defined by the POCT Director. They should be chosen by the POCT provider. Examples of KPIs should include but are not limited to: labelling errors (e.g. number of mislabeled POCT samples), handling errors (e.g. number of repeated tests due to improper material handling), POCT device utilization (the amount of time the POCT device was used in comparison with its total availability), throughput (number of POCT samples analyzed per time period) or

number of use complaints. Trends in KPIs should be analyzed in order to periodically assess the performance of the POCT service.

5 Operator training and competency assessment

Professionals performing POCT outside the hospital setting should be healthcare professionals, trained and deemed competent to perform testing. POCT should be considered part of the scope of practice by the college or regulatory body governing the particular healthcare professional in question.

Training and competency assessment should be developed and provided by the POCT team and/or supervising the POC organization or by an accredited clinical laboratory in collaboration with the supplier/manufacturer. A specific training program should be established for each POCT device intended for all healthcare professionals performing POCT. This training should include all the relevant issues regarding pre-analytical, analytical and post-analytical phases of the testing process.

Training should include a theoretical and practical component. Topics that should be covered in the theoretical section includes knowledge of, storage requirements for quality control, frequency of performing quality control, test method interferences and limitations, troubleshooting technical issues, including quality control failure. It should also have a practical component that includes assessment of correct operation of the device or kit, reagent handling and storage, sample collection, device maintenance, performance of IQC and EQA). It can also include basic knowledge/skills on aspects of the quality management system. A pass/fail criterion needs to be established and on successful completion, POC users are “certified” and will need to be recertified periodically depending on the local regulatory requirements. The training should be documented, and the operator given a specific code to use the respective POCT device if that capability exists.

The operator’s use of the instrument should be monitored using a data management system (middleware) if that tracking and connectivity is available. It should be noted that, depending on the country, some national regulatory requirements indicate a list of professionals authorized to do POC testing: in this case, only authorized personnel should be trained. The POCT team is responsible for the provision of continuous training and periodical competency evaluation for healthcare professionals performing POCT. This training could use e-learning tools combined with practical observations. The competency can be made paperless, for example, every staff member would receive an email with a link to the online course and when completed, becomes the competency on record in the data management system [5].

6 POCT results integration into patient electronic medical record

6.1 Device connectivity and electronic medical record (EMR)

The integration of POCT into the patient’s electronic medical record is an important component of their disease management. Connectivity of POC devices allows data to be transmitted from the device to a data repository (laboratory information system, hospital information system, electronic medical record, patient’s personal data repository). This aids documentation of results, supports continuity of care, and enables data review for quality assurance compliance. The Clinical and Laboratory Standards Institute (CLSI) has guidelines on the requirements that should be met when manufacturers are developing the connectivity features of the device [15–17].

6.2 Manual methods of documentation

Not all POC devices have the ability to be connected either through cable or wirelessly to the patient’s medical record. In these circumstances it is important that the result reporting contains the following elements:

(1) Two patient identifiers: it is usual to use the patient’s full name as one of the identifiers and for the second identifier the date of birth or an assigned medical identification number.
(2) The test result.
(3) Date and time the test was performed.
(4) Normal reference interval and the unit of measure, if applicable.
(5) Name of the person performing the test.

Conclusions

POCT plays an increasingly important role in disease management algorithms and in a variety of settings inside and outside the hospital. Individuals with very different educational backgrounds use POCT to manage or screen for

disease. This therefore underscores the importance of quality results at the Point of Care and further highlights the importance that effective and practical QMS is in place, together with oversight by laboratory professionals that can promote best laboratory practices. Following the guidelines given in this paper should help healthcare workers using POC testing achieve a program where results are reliable for effective patient management.

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