Compliance with Accreditation and Standardization of Point of Care Testing -from Vision to Action

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Abstract

Point of care testing is one of the most rapidly growing fields of laboratory medicine since the past few decades. As more and more laboratory tests are getting decentralised and performed by non-laboratory trained personnel it becomes very important that all procedures are reviewed and signed off by authorized individuals. Currently, accreditation programs such as CLIA, CAP, JCI, COLA are focusing strongly on the quality of POCT. They help the end users to abide with all aspects of POCT testing such as proficiency testing, training and competency, validation, quality assurance, documentation, audits etc. Standardization improves patient care and helps in reducing medical errors that could occur due to point of care. Using the same device and technology across multiple sites can reduce variation of result, improve staff efficiency and help in sharing the same policy and procedures across multiple POCT sites in an organization.

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Introduction

Point of care testing (POCT) are basically laboratory tests carried out by non-laboratory personnel on simple, portable, sophisticated instruments very often at the patient bedside. The principal tenacity of POCT is to generate results rapidly for early intervention, which is very important in an acute care setting [1]. POCT devices have found application in many clinical scenarios and is going to witness a tremendous growth in the coming years. This rapid growth in POCT has bought in a challenge of safety, quality, cost, and associated risks along its way [2, 3]. The evolution of POCT poses challenges to Laboratory Head, POC coordinators, and other professionals in appropriate instrument selection, validation, maintenance but also the need to ensure those performing testing are trained, follow quality control protocols, maintain appropriate documentation, and remain in compliance with clinical and regulatory standards[4] (Figure1).

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Although there are many challenges associated with POCT testing more focus on compliance with accreditation standards, Training and competency, quality assurance and safety consideration have been presented in this article.

Compliance with accreditation and regulatory standards

Accreditation is the manner in which providers of POC testing demonstrate that they comply with all applicable regulations, defined standards and best practices. They help the end users to abide with all aspects of POCT testing such as proficiency testing, training and competency, validation, quality assurance, documentation, audits etc. POCT standards and regulations are directed by the Clinical Laboratory Improvement Amendments (CLIA 88), the College of American Pathologists (CAP), Joint Commission International (JCI) and International Organization for Standardization (ISO) and COLA (Table 1).

CLIA was first passed in 1967, but at that time the regulations were passed only for the clinical laboratory, however in 1988 CLIA was expanded to POCT as well. CLIA categorizes tests based on their level of complexity as (i) waived, (ii) moderately complex, (iii) highly complex[5]. Waived test employ methodologies that are simple and accurate, and the chance of an error is negligible, or even if there is an error

the chances of harming the patients is very remote. If a site is performing waived testing, a CLIA certificate of waiver and adherence to manufacturer's instructions for quality control (QC) and maintenance is required. Under CLIA, Waived test are exempt from method evaluation, however, it is good laboratory practice to verify the performance criteria claimed by the manufacturer. Moderately and highly complex tests are defined by the US FDA using a complexity scoring based on seven criteria. They include (1) knowledge, (2) Training and experience, (3) Reagents and materials preparation, (4) Characteristics of operational steps, (5) Calibration, quality control, and proficiency testing materials, (6) Test system troubleshooting and equipment maintenance, (7) interpretation and judgment. Most of the POCT comes under moderately complex test and require verification for calibrations, analytic measurement ranges, lot-to-lot validations, instrument correlations, and methods evaluations.

CAP uses POCT checklist to check compliance with CAP standards and does not completely follow CLIA method of categorising test. CAP defines POCT as waived and non-waived test and are done only near the site where the patients are located [6]. CAP regulation allows POC accreditation of testing that is CLIA categorized as waived, moderately complex, or physician performed testing (PPT). Requirements for quality control, reagents, competency assessment and calibration are different for waived tests, as compared with moderately complex tests. Requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, testing personnel qualifications, and safety are the same for both waived and moderately complex tests.

ISO 15189 applies to clinical laboratory and ISO 22870 applies to POCT[7,8]. Both ISO can be used in conjugation for POCT in hospitals, clinics and health care organizations. Elements of these standards include establishment of procedures for external and internal QC, assessing testing personnel competence, appropriate specimen collection methods, test performance evaluation, equipment inventory maintenance and documentation of results into the medical record. ISO 15197 specifies requirements for the in vitro glucose monitoring systems that measures glucose concentration in capillary blood samples [9]. It is used to verify procedures and check validation performance and is intended for self-monitoring of glucose by lay personnel in their management of sugar levels.

With the continuous changes and updates in accreditation recommendations and requirements, it is imperative that POCT coordinators and staff stay up-to date on these recommendations to ensure smooth and successful operations.

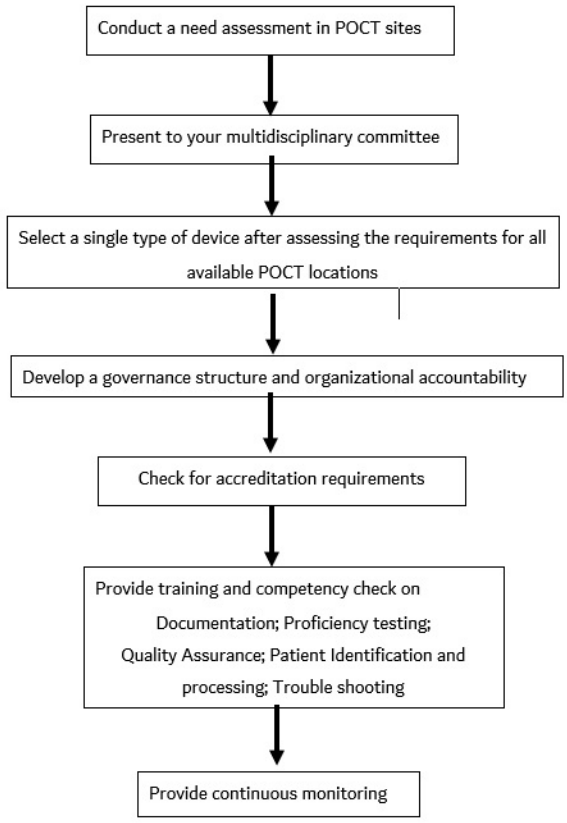

Figure 1. Standardization and harmonization of POCT İnstruments

Training and competency

POCT results helps in making quick clinical decisions, hence it is crucial for these results to be accurate. Currently, accreditation programs such as CLIA, CAP, JCI, JCAHO, COLA are focusing strongly on the quality of POCT. The first step would be to educate and train the trainer as he will be responsible to train the operators. Vendors support for training can be taken during initial implementation purpose.

The POCT operators must be adequately trained before certifying them to perform the test. They should be provided with proper hands-on training on the instrument, awareness of the test's principles, performing and reviewing the QC as

per manufacturer specifications, proper patient identification, interpretation of results, limitation of the test, and uploading the data, and critical result notification [10]. Standard operating procedures should be available at each site and should be easily accessible to the operators. The clinical staff should be trained to monitor for the concurrence of POCT results with clinical symptoms. Questionable results should be followed by repeat POCT and central laboratory testing to verify the nature of the discrepancy.

Once the initial training is done, a competency must be assessed six months later and annually thereafter to ensure satisfactory competence levels. Standard methods of providing operator performance are visual inspection, blind samples of known value, and auto verification of quality controls [11, 12]. Studies say that visual inspection or auditing is a much better way to recertify the end-users as auto-recertification does not necessarily confirm an operator's necessary competency skills [13,14]. Proficiency samples provided by accrediting bodies are also a way to monitor operators' performance and compliance with their institution's policies and procedures. Training done for operators should be documented and there should also be a retention policy for these records.

Quality control

The internal quality control (IQC) process plays a crucial role in assuring patient results. It is used to measure the performance and consistency of the POCT testing process, which includes the POCT system and the operator's performance in delivering results correctly [15]. Performing quality checks is a crucial step in POCT as it helps to identify and prevent systemic errors (calibration errors, pipette errors, reagent degradation) in the process but may not help in detecting random errors (haemolysis, lipemia, clots, drug interferences) [16]. IQC is usually performed before a patient test, when a patient result is queried, before a new lot of reagents or QC are put in place; after a morning maintenance procedure, when there is a suspicion of physical insult to the device such as dropping the device or exposure to high temperatures[17,18]. Manufactures instructions should be followed while performing the controls for waived testing and for moderately complexity testing a minimum of two levels must be performed, however if the workload is huge it is good to perform QC every 12 hours a day [19,20]. For blood gases one level of QC should be performed every 8 hrs a day. In instruments which have a inbuilt simulator an IQCP (Individualized Quality Control Plan) can be done after performing a proper risk analysis [18, 19,20].

The end-users should be adequately trained to perform and document the QC results, they should also be encouraged to document QC failures or any other failures witnessed during the testing process without the fear of getting slated. Problem solving skills should be developed so that required onsite corrective actions can be taken immediately thus reducing waiting time and dependency on the POCT coordinators who may be busy at other locations. In addition to running the IQC, POCT users should also be trained to monitor reagents for stability, storage, and expiry.

Handling of reagents and consumables

As per the CDC guidelines "Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired" [21]. Reagents such as strips for urine and glucose are stable if unopened until the manufacturer's expiration date if stored under appropriate temperature and environmental conditions. After opening, these reagents have an open stability date beyond which the reagent should be discarded. Once it is opened, POCT users need to mention the opening and expiration date on the reagent bottles. POCT users should always check the expiry prior to testing. It the bottles are opened but not labelled appropriately they should be discarded. As per FDA guidelines "Check the expiration date on the test strips. As a test strip ages, its chemical coating breaks down. If the strip is used after this time, it may give inaccurate results" [21].

Safety and Infection control

POC instruments can harbor many antibiotic-resistant microbes [22]. Hence these instruments should undergo routine maintenance and decontamination, thus taking care of patient and operator safety [23]. POCT devices are taken to the patients' bedside, and if these instruments are contaminated, they will add more risk to the patients. Staff needs to be made aware of the importance of keeping the instruments clean. As per FDA guidelines "POC blood testing devices, such as glucose meters and PT/INR anticoagulation meters, should be used only on one patient and not shared" • "If dedicating POC blood testing devices to a single patient is not

possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling". Regular hand washing can prevent the spread of infection. Hands should be washed before and after coming in contact with the patient and body fluids, irrespective of whether gloves are worn or not [23]. Training should be provided and competency assessed especially for use of personal protective equipment and discarding of sharps.

Care should be taken not to expose the instrument to either cold or hot conditions as both can affect the instrument. Reagents can deteriorate under extreme temperature and humidity; hence proper training should be given to closely monitor room temperature and humidity. Refrigerators should also be monitored for daily temperature. Cleaning and maintenance should be performed as per the manufacturer's instructions [24]. Damaged instruments with missing keys should not be used. Material safety data sheets should be are available to testing personnel and are placed in a place where it can be easily accessible. There should be a written policy to handle chemical hazards.

Standardization instrumentation and methods

With a lot of laboratory test getting decentralized and moving towards the patient bed side it is very important for health care organizations to focus more on standardization, consistency and harmonization of POCT results and instruments. Having multiple types of instruments can make interpretation difficult as the reference ranges, analytical measurement ranges may be different leading in wide variation in results. Different work flows, more pre-analytical errors, inventory issues, documentation issues can decrease the efficiency of operators. The operational cost could also increase due to increased interphasing cost, maintenance cost and low ordering values. Improving standardization can help in improving cost, quality and staff efficiency.

	CAP	JCI	ISO
Assessors	Volunteer peer inspectors who have undergone training and with a peer-based approach to inspection, currently working in medical laboratories.	Highly trained professional experts (doctors, nurses, hospital administrators, laboratory medical technologists and other health care professionals)	Full time assessors, with background in quality management and medical laboratory work
Frequency of Accreditation for waived and non-waived testing	Re-accreditation cycle takes place every two years. Laboratory is required to perform self-evaluation 12 months after initial accreditation.	Re-accreditation cycle takes place every three years.	Re-accreditation cycle takes place every three years. Surveillance assessments are scheduled in the first and second years and a re-accreditation onsite assessment in the third year.
Criteria used	Checks if POCT has met the requirements in the POCT checklist	Determine the organization's compliance with the standard(s) and IPSGs through various survey activities and methods such as direct observation, staff or patient interview, review of documents, review of medical record and/or personnel files, or the inspection of the physical facility	Focusing on quality system essentials. Current ISO certification combines standards 15189 and 22870
Training and competency	Waived test competency: once a year Non-Waived test competency: 6-month, 12-month, 1 year there after Assessing competence: Include, but not limited to a) patient identification, preparation & Collection b) Handling, processing & testing c) Monitoring documentation d) Interpretation, reporting of critical results e) Review of QC, PT, Maintenance records f) Problem solving skills.	Waived test competency: once a year Non-Waived test competency: 6-month, 12-month, 1 year there after •Direct observation of routine patient testing • Monitoring of test records and reports • Review of worksheets, QC, proficiency testing, and/or preventive maintenance records. • Direct observation of performance of preventive maintenance. • Duplicate or blind sample testing. • Assessment of problem-solving skills.	Waived test competency: once a year Non-Waived test competency: 6-month, 12-month, 1 year there after Same as JCI

Table 1. Comparison of accrediting bodies.

Conclusions

In the past few decades' POC has expanded exponentially and has become an important part of patient care. As POCT involves large number of operators, large number of instruments, large number of sites and a huge volume of test it is very important to properly plan and organize the POCT programme so that all the requirements of accreditation can be met. The main aim of all accrediting bodies is patient safety and quality there by providing patient centred high quality care and better patient outcomes. The greatest challenges of a successful POCT programme are implementation of a uniform quality policy in different locations across the hospital, training and competency of operators and meeting all the regulatory requirements. However, when it is properly implemented it can have a great impact on patient care.

Declaration of Interest

The authors report no conflict of interest.

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