The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine

eJIFCC

Best practices in the implementation of a point of care testing program: experience from a tertiary care hospital in a developing country

Aysha Habib Khan[1], Shahid Shakeel[1], Khairunnissa Hooda[2], Kashif Siddiqui[3], Lena Jafri[1]

[1] *Section of Chemical Pathology, Department of Pathology and Laboratory Medicine, Aga Khan University (AKU), Karachi, Pakistan*

[2] *Emergency Medicine, AKU, Karachi, Pakistan*

[3] *Software Development & Maintenance, AKU, Karachi, Pakistan*

ARTICLE INFO

Corresponding author:
Lena Jafri
Section of Chemical Pathology
Department of Pathology
and Laboratory Medicine
Aga Khan University (AKU)
Karachi
Pakistan
E-mail: lena.jafri@aku.edu

Key words:
point of care, laboratory, quality, safety, accuracy

ABSTRACT

Implementation of a structured Point of Care Test (POCT) program is challenging. Traditionally POCT was unregulated and the aim was to introduce a structured POCT program at our tertiary care hospital to ensure compliance with regulatory standards. The purpose of this article is to describe how a hospital in a developing country with limited resources has approached POCT program initiative. The benefits offered by such systems, including cost-effectiveness, robustness and the ability to generate reliable accurate POCT results in a short time, are appropriate to the clinical and social needs of the developing world.

BACKGROUND

Driven by quicker diagnostic paybacks, point of care testing (POCT), also known as bedside testing, near-patient testing, alternate-site testing, and ancillary testing, has modernized patient care (1). The College of American Pathologists (CAP) describes POCT as 'testing that does not require permanent dedicated space and it refers to those analytical patient-testing activities provided within the institution, but performed outside the physical facilities of the clinical laboratories' (2).

The POCT tests offer rapid results, allowing for timely initiation of appropriate management by reducing the turnaround time of the results through minimizing delays and errors in sample transport and processing (3, 4). Potential patient satisfaction comes from testing that is more convenient and less traumatic with minimal amount of blood draw. Furthermore improved turnaround time due to POCT results in prompt management reducing length of hospital stay (5, 6). Although the unit cost of POCT is higher than central laboratory, overall the testing is patient focused and cost-effective by reducing hospital stay and improving patients flow through busy critical care areas and emergency departments (7-9).

Despite the relative simplicity of POCT, regulations like Joint Commission International (JCI) and CAP dictate that all hospital based POCT must be supervised by the central laboratory. These regulatory bodies make certain that the laboratory director is responsible for standards of performance in all domains of POCT including pre-analytical, analytical and post analytical aspects. Delivery of medical diagnostic testing outside of the well-controlled environment of the clinical laboratory are affected by several organizational, environmental, operational, and technical challenges (10).

Managing preanalytical, analytical, and post-analytical processes compatible with centralized laboratory testing is a major challenge in POCT program implementation (11). Regular laboratory surveillance, inspection and prompt corrective action is essential for smooth operation of any POCT program. Additionally any POCT program requires continuous training of the operators, competency, method validation, and ongoing comparison with central laboratory results (12, 13). It is essential to maintain an appropriate record trail linking POCT operators' training and competency with POCT device validation, verification, maintenance and quality control. POCT execution and oversight poses a great challenge for laboratories as the testing being performed is actually out of their hands. Still the laboratory is responsible for ensuring that patient testing is performed in compliance with laboratory accreditation standards (14).

The POCT program at Aga Khan University Hospital (AKUH) was initiated in 2014 with the objectives of ensuring patient testing performed is in compliance to CLSI standards. Hereby we report our experience in establishment, organization and successive execution of POCT program at AKUH. The purpose of this review article is to highlight the importance of clinical needs assessment for development of POCT program, to discuss challenges in POCT implementation. We hereby provide a road map for POCT implementation and smooth execution.

NEEDS ASSESSMENT FOR POCT PROGRAM

Delineating program proposal

Like all laboratory testing, many regulatory guidelines have been put forth to address quality control, training and documentation to ensure patient safety. To start off with a thorough review of literature including International Organization for Standardization (ISO) guidelines, CLSI, Joint Commission International (JCI)

and CAP standards specific for POCT was completed by the Chemical Pathologists (15-17). A proposal delineating the scope of services was developed at the Section of Chemical Pathology, in the Department of Pathology and Laboratory Medicine, AKUH. It was decided that POCT would be performed in inpatient locations including wards, emergency department, operating rooms, special care units and intensive care units of the hospital. The POCT proposal highlighted the shortcomings of existing bedside testing identified in need assessment.

The core of the document was a regulatory proposal for the implementation of POCT including aspects related to personnel responsibilities, quality assurance, data management, and future tendencies. The goals of implementing the POCT program in the institute were clearly defined in the proposal.

The goals of POCT program were defined as follows:

- To ensure that POCT is high quality and cost-effective.
- To give guidance to all users and potential users of POCT.
- To provide consistency of test offering at all POCT sites.
- To simplify billing procedures on POCT sites.
- To provide faster turnaround times in test results with minimal inconvenience to the patient.
- To provide an organization-wide standardized policy for POCT application.

This document included following initial tasks as part of POCT program: outlining an organizational structure, defining roles and responsibilities of POCT teams and members and describing clinical needs of proposed POCT tests. The proposal was shared and approved by the senior management of the hospital and all stake holders.

Evidence based approach for POCT program development

Clinical needs assessment is a process by which information is gathered regarding the scope and potential impact of gaps or deficiencies in the current delivery and practice of health care (18). The POCT need assessment was done to gather information regarding current practices and clinical needs for developing a POCT program in our institute. Multiple surveys and site visits were conducted by the laboratory team at all the inpatient sites in the hospital prior to the development of the POCT program. The purpose of these surveys and site visits were to identify potential end users, optimize the use of the deployed equipment and identify the changes required to make the project efficient and effective by taking feedback from all concerned stakeholders. Table 1 outlines the domains which were covered in the surveys.

Cross sectional interview-based surveys and site visits were done at all the areas of the hospital where bedside testing was done. The survey included the infrastructure and connectivity requirements and current volumes of tests being performed near patients. The presence of deficiencies, gaps and challenges in POCT operation was documented (Table 2).

While most laboratory testing continued to be performed in the main clinical laboratory, arterial blood gases, electrolytes, glucose, urine analysis were performed in wards and critical care areas without central laboratory supervision, report generation, lack of training and lack of evidence of quality control. Manual record-keeping was inadequate for an audit trail for quality assurance. Compliance with requirements for documentation was difficult using handwritten records and going paperless was one of our goals. To address the challenges of POCT, to share experiences faced in previous clinical audits and to solicit opinions on executing POCT program

Table 1 Clinical needs assessment domains to identify and characterize existing gaps in current system

Personnel related	• Stakeholders assessment • User needs assessment • Acceptability assessment • Organization and responsibilities • Identification of POCT users
Policy and procedures	• POCT equipments and method validation requirement • Training and competency of users • Purchasing and inventory processes • Data management • Record keeping of POCT information • Quality control and proficiency testing • Security access
Facilities and safety	• Device location and POCT sites identification • Landscape analysis • Information technology connectivity check • Electrical points check

multiple focus group discussions with nursing managers were conducted and a strategic POCT roadmap was delineated.

POCT IMPLEMENTATION

Organizational structure

While the nursing staff and physicians may understand the day-to-day operation and provision of results, the overall responsibility of POCT program generally lies with the laboratory director. Responsibilities of the clinical laboratory include organization and implementation of the program, performing technical and general oversight and clinical consultancy and ensuring quality assurance. Laboratory director ensure compliance with all applicable regulations, rules and standards. To successfully achieve POCT implementation in an institute, a multidisciplinary organizational approach is a prerequisite. First and foremost, a clear organizational structure should be put in place for appropriate functioning and optimum utilization of each POCT site (19).

A multidisciplinary team comprising of all stakeholders with representatives from Pathology, Material and Management Division (MMD), IT, Biomedical Engineering (BE) and Nursing was formalized for execution of POCT program at AKUH. The team presented the POCT program at the Joint Staff meeting of the institute for approval. Concerns that arose with POCT implementation, like problems with ensuring quality, potential

Table 2 Deficiencies identified during clinical needs assessment

Categories	Gaps identified
Pre-analytical	• Lack of instructions for specimen collection and preservatives • Lack of evidence of training and competence assessment regarding pre-analytical factors that may influence the results • Lack of information regarding identification of POCT operator • POC test charging mechanism
Analytical	• Lack of evidence of training and competence assessment of POCT users • Lack of evidence of quality control processes • Absence of written quality assurance and quality control policies • No participation in proficiency testing program • Less than optimal information on policies, regulations, supplies & standard operating procedures • No identification or trail of site of testing • No records of equipment calibration and maintenance
Post analytical	• Absence of report generation • Manual recording of patient results • Previous POCT records of patients not accessible • Absence of records of POCT results interpretation • There is no connectivity of equipment/devices with Laboratory information system for prompt results reporting and to minimize errors

conflicts of interest, and an uncertainty of the responsibility, were all addressed with the stakeholders and the POCT end-users.

POCT policies and procedures

As per CLSI guidelines quality management system approach was followed for the development of standards and policies for POCT program. The organizational and regulatory requirements that should be considered when implementing POCT program in an institute should all be documented (Table 3). Laboratory director was made responsible for standards of performance in all areas, including quality control, quality assurance and test utilization in patient care. Each POCT site that performs POCT must have written policies and procedures available at the testing sites. Quality management plan, policies and testing procedures were written down and simultaneously POCT training program and curriculum were outlined by the pathologists and shared with POCT team members for approval and critique. Oversight and control of POCT program was hence provided by the laboratory

Table 3 Quality management system plan including policies and procedures needed for POCT program

POCT quality management system essentials	Quality management plan should include these policies/processes
Organization and integration	• POCT Committees • Roles and Responsibilities of teams • Responsibilities of POCT coordinator • Workflow • POCT program contact information
Quality assurance	• Internal quality control • Proficiency testing • Assessment and audits • Equipment procurement and method selection • Method validation • Standard operating procedures of each POCT • Result reporting and recording • Panic value reporting procedure • Unusual result reporting procedure • Equipment maintenance • Inventory and storage management • Safety and infection control • Occurrence management • Troubleshooting and backup plan • Customer satisfaction and complaint handling • Sample retention and storage process • Document control policy
Training and competence assessment	• Training curriculum • Training process • Competency assessment • Certification and access to POCT device

directorship along with all necessary assistance to run this program smoothly. The laboratory in writing agreed that under this program, a standard package of POCT services can be provided at any clinical facility in the institute, as long as the required training, proficiency testing, quality control and validation procedures were performed, verified and documented.

Coordination of central laboratory and POCT

The ultimate responsibility of POCT lies with the laboratory director. As soon as the POCT program approval was sought the central laboratory identified and selected a POCT coordinator from the clinical laboratory staff. The main role of POCT coordinator was to assist in oversight, management and synchronization of the entire POCT program. The responsibilities of POCT coordinator included all aspects of the POCT service, including overall supervision, management and oversight of POCT sites and devices (20). Additionally, he/ she would take input from and interface with the laboratory director regarding POCT activities and issues. The POCT coordinator supported the pathologists in developing policies and procedures, designing and interpreting method validations, and in communicating with clinicians. Periodically, the POCT coordinator inspected POCT sites to ensure that proper procedures are being followed and documentations for patient identification, patient preparation, specimen collection, specimen ID, specimen preservation and processing, and result reporting are in place. It was couple of months later that our POCT coordinator assistant was also hired and trained. Therefore depending on the size and nature of the POCT service, a POCT coordinator assistant may also be required.

Responsibilities of a POCT coordinator were clearly outlined in four domains of quality assurance, corrective action, training and education, and administration. To ensure quality assurance it was the responsibility of POCT coordinator to check if all POCT systems are in compliance with accreditation needs, to provide evaluation of the analytical performance and method validation of POCT devices, to monitor performance of internal QC and take corrective actions, to schedule proficiency testing surveys, to monitor performance of proficiency testing at each POCT site and take corrective actions, to monitor POCT quality indicators and share with quality improvement coordinators committee meetings and to conduct POCT site internal audits and take regular feedbacks from POCT site supervisors. All technical problems and complaints were to be handled by the POCT coordinator. He was also responsible to arrange for POCT user training, competence assessment and maintaining POCT users' records. He was the person responsible for coordinating POCT activities and connecting with other health care professionals. He acted as the liaison between nursing and laboratory personnel. Selection and installation of POCT instrument, maintaining the in house inventory of POCT tests, review and update of POCT standard operating procedures and policy manual were all his duties. He also ensured that updated POCT manual was available at all POCT sites and implemented safety rules and regulations at all POCT sites. Checking maintenance schedules and coordinating between Interdisciplinary and End user Committees were also done by him.

The Aga Khan University Hospital Clinical Laboratory has sections of clinical chemistry, clinical microbiology, haematology, histopathology, molecular pathology, blood bank and transfusion services. The POCT program came under the domain and responsibility of clinical chemistry. A middleware Cobas IT 1000 was installed to connect the Clinical Chemistry's laboratory information system (LIS) with hospital information system (HIS). POCT coordinator controlled all POCT activities via Cobas IT 1000.

This included review of POCT end users details and competence assessment, POCT patient results, QC transmission and validation. IT 1000 has the ability to communicate bi-directionally with HIS and POCT devices. In order to control POCT operation and the quality of patient care, and to ensure that results are integrated into and being networked with the LIS, the establishment of new relationships among the laboratory, clinicians and the Information Technology (IT) was needed. For establishing goals, addressing compliance matters and setting future directions of the program two committees were established; an interdisciplinary committee and end user committee. The interdisciplinary committee had representation from various departments and was headed by the laboratory director and pathologists while end user committee was headed by the POCT coordinator and had pathologists and nursing managers from various departments as members.

Responsibilities of interdisciplinary committee were as follows:

- To establish/allocate POCT system in defined areas.
- Any proposal to establish POCT must be referred to this Committee for approval via the POCT coordinator.
- To evaluate & select equipment for testing.
- To select appropriate methodology.
- To assign responsibility for test performance.
- To define policy/procedure for record keeping /documentation.
- To assess POCT impact or outcome.
- To assess whether POCT meets safety and quality standards.
- To ensure POCT meets the requirements in relation to protecting data, patient confidentiality and risk management.

Responsibilities of end user committee were as follows:

- To discuss ongoing issues and problems with POCT program.
- Recommendations for change should be forwarded to the interdisciplinary committee for consideration.
- To discuss various compliance reports.

Identifying POCT site supervisors

Nurse Directors or nursing managers qualify as POCT site supervisors. They are responsible for day to day supervision and oversight of POCT users performing and reporting test results in their respective areas or POCT sites. The responsibilities of POCT site supervisors were well defined in the POCT program manual before implementation at our institute. They were made responsible to set up and maintain a system of regular internal QC checks, maintain equipment in a manner appropriate to the proper collection, handling, preparation, testing and storage of specimens and operation of test results and patient's reports.

POCT site supervisors reviewed QC data on weekly basis to assure that testing and corrective action is taken and documented. They would contact laboratory and cooperate with troubleshooting and corrective measures if performance seemed unsatisfactory. They were the ones who would identify POCT user for competency assessment and ensure competency assessment of every POCT user. They documented certification and competency assessment of every POCT user in their respective sites. All requests for new POCT systems were made through them via the POCT committee in accordance with the selection and procurement criteria. POCT site supervisors also maintained in-house inventory, place orders for the required reagents and consumables from the hospital logistics and were responsible for

administration of the daily operation of POCT at their respective site.

Selection of POCT tests and analyzers

Comparison of the available equipment from different vendors according to the preset criteria and specific standards was done by the POCT team members from Pathology, Biomedical Engineering (BE), and Material and Management Division (MMD) (16-18). The test menu proposed included arterial blood gases, electrolytes, glucose and urine dipstick analysis. The team realized that the POCT instruments or devices must be user friendly, robust both in terms of storage and usage, capable of producing results consistent with the medical needs, less costly and safe.

The system performance of the proposed POCT devices was evaluated. Power and network requirements were considered and POCT site visits were conducted before making any decision.

Regulations mandate documentation of method selection, method validation before patient testing is performed for each POCT device placed. Validation of equipment, test method verification and instrument to instrument comparison was done by our POCT team according to CLSI guidelines at the Central Laboratory by POCT coordinator (19).

Protocol for POCT method validation according to CAP and CLIA standards included accuracy, precision, verification of reportable range and analytical measuring range, POCT inter-instrument comparison and comparison with bench top analyzers placed in the central laboratory. Reagent shipments and lot numbers were validated and tracked.

Management of consumables and reagents was and still is procured in a cost-effective manner to the clinical unit concerned. POCT costing was done which included the fixed capital cost (instrument, proficiency testing survey cost, service contract for vendor, ancillary infrastructure etc.) and variable cost (reagent consumption, internal controls, consumables etc.).

Data capture and connectivity

Improvements in testing technologies and the advancements in specialized informatics for POCT have greatly improved the ability of hospitals to manage their POCT program (15) (14, 20).

The benefits of POCT are enhanced when results and records are directly downloaded into a laboratory information system (14, 21). For accreditation and patient safety, trail must link each patient result to the operator to his/ her training records, the reagent lot used for testing and its validation, and the POCT device to its validation and maintenance. Managing the quality of large volumes of POCT data was a continuing challenge for our POCT team.

Confidentiality, security, legality, compatibility, interoperability, timeliness, and convenience of processes, records, communications, and software were reviewed by the IT support team of our institute. Connectivity of POCT equipment to a middleware POCT data management system (server) and then to integrated laboratory management system was established. The connectivity in place was bidirectional, from LIS to middle ware and then back to LIS. Through IT 1000 (middle ware) specific configuration were assigned to all POCT devices for internal quality control.

A QC lock provision was set up in all devices and at 8 AM all meters automatically are on QC lock. This does not allow patient testing until two level of quality control are passed. The middleware is also used to assign new lot configuration of reagents and control. The ‘client BG link’ connected with IT1000 gives facility to control all ABG analyzers remotely from the central laboratory.

All onsite POCT instruments and POCT users were connected via this server to the LIS. To reduce medical errors barcode was introduced for all POC tests. The POCT instruments, regardless of their site location, generated data related to sample analyses (POCT user and patient identification and test results), quality control and the instrument itself (calibration and maintenance). These voluminous data were managed through a middleware further linked to LIMS.

Table 4 Components of POCT training curriculum of POCT users

List of policies, processes and modules in the POCT training curriculum
Entry qualifications of POCT users.
Sample requirement, sample collection and handling including any special requirements.
Positive patient and operator identification before testing.
Stability of sample and reagents.
Device theory of operations and steps in analyte measurement.
Timely routing of results to the decision maker and the appropriate operator response to results that are outside predefined limits.
Clinical significance of results.
Actions to be taken in case of critical or unusual results.
Sources of common errors.
Maintenance, calibration and cleaning of instruments.
Performance of QC and review of POCT safety and security policies.
Information systems that support POCT, the rationale for using them, the benefits they provide, and the problems inherent in their implementation and use.
Safe disposal of the sample and sampling device.
POCT device error codes, their meanings and what to do if the device generates an error.
Documentation of all records and reports.
Maintenance tasks and consumable storage.
Who to call if there is a problem with the device or stock needs replenishing.

With the help of LIMS and hospital integrated management system a mechanism for record keeping, archiving, billing, and data entry into the electronic medical record was ensured.

Staff training and competency assessment

Unlike the modern central laboratory where the bulk of testing is conducted on few analyzers by a core group of skilled technologists, POCT is conducted by a variety of clinical staff on multiple devices in many locations (11, 22). Training and competency assessment of all POCT users was a logistical challenge. Like all other organization attrition was a constant challenge faced by the 'POCT Program implementation team'. (23). The POCT training plan and curriculum were developed in line with the CLIA'88 and CAP standards by the chemical pathologists and shared with Nursing Education Service (NES) for implementation as nursing staff are typically the largest percentage of POCT operators . CLIA'88 requirements for competency assessment involve "evaluating the competency of all testing personnel and assuring that staff maintains their competency to perform test procedures and report test results promptly, accurately and proficiently". CLIA'88 requires that laboratories have on-going mechanisms to monitor accurate patient test management. Competency assessment is one method used to ensure those POCT users that perform POCT are proficient in test procedure and reporting test result. The POCT training program at our institute ensured that testing personnel met regulatory requirements and provided regularly scheduled review of training and techniques. The POCT personnel training program chiefly consisted of three components: initial formal POCT training, POCT recertification and POCT competency assessment. Training of trainers (TOT) and assessing their competence to provide training to others was done. Training was performed of TOTs from NES followed by training of the end users. Fifty-eight trainers were trained from NES with the support from POCT Coordinator and manufacturer. The TOTs further conducted more than 100 sessions (3-4 lectures/ward) to train more than 1000 nursing staff. Training included classroom training, hands on training of POCT device correct operation and assessment. Training curriculum included all phases of the testing process (Table 4).

Competency assessment included observation of technique, written examination, analysis of quality control or specimens with known values, demonstration of maintenance, recording of test results, and evaluation of communication and problem-solving skills. Competency was documented through certifications that assured that individual POCT operators met training and experience standards. After POCT certification, the POCT users were issued barcoded access to use of the POCT devices. Recertification of this 'competency certificate' is done annually or sooner if need arises. Furthermore, all training and ongoing competency verification records were and are still maintained via the online connectivity server by the POCT coordinator. POCT training program ensures that testing personnel meet regulatory requirements and provides regularly scheduled review of training and techniques (24).

QUALITY ASSURANCE

In principle, no difference between POCT and conventional laboratory testing exists with respect to pre- and post-analytical errors (25). Therefore, the entire diagnostic process must be considered in quality assurance (26). Clinicians and nursing staff may fail to comprehend the importance of quality control and correct documentation when performing POCT (27). While ensuring the quality of POCT compliance with regulatory guidelines it is mandatory for institutions to maintain their accreditation status (28,

29). The analytical goals for POCT were equivalent to those used for our central laboratory and it was ensured that the use of POCT does not compromise standard of patient care and clinical decision making (28-30). Both internal quality control (IQC) and external proficiency testing (PT) programs were an essential component of QA for POCT program at AKUH (31).

Three main IQC requirements were addressed: procedure established for IQC at appropriate frequency, QC material procurement and correction of nonconformities. To assure that the POCT devices were working correctly all POCT users were trained for running and monitoring IQC along with remedial actions before patient testing. It should also be noted all the POCT devices had advanced levels of connectivity and the ability to electronically capture and transmit results to the middleware. The POCT management middleware offered features such as operator and patient ID lockout, QC lockout, remote configuration and management of consumables, improving efficiency and giving us strict control of our testing program. With the help of IQC the reproducibility or precision was monitored by the central laboratory on routine basis.

Policy for proficiency testing (PT) was outlined as part of POCT program. Before POCT execution all PT surveys were identified from CAP and acquired. Comparison of results and performance across different POCT sites was done by the central laboratory and communicated to all site supervisors routinely. Sub-optimal performance in PT and internal quality control was brought to the immediate attention of the POCT committees, which then determined corrective action. The POCT coordinator ensured that PT surveys generate accurate results, regardless of the location. Control of training and competence assessment, policies, procedures and IQC and PT are now under the guidance/oversight of clinical laboratory. The connectivity for our POCT program and the data management capabilities has given us the ability to monitor our whole program of >1500 operators and to produce accurate audit trail. Our POCT operators understand that the laboratory is overseeing every aspect of testing and monitoring it closely along with regular onsite inspections.

SERVICE EXECUTION

Pilot project and expansion

Finally, a POCT execution plan was laid down. A live demonstration on connectivity was performed in the laboratory before making it live at the patient testing sites. POCT reporting format was finalized and essential components were made part of POCT report (Table 5). Training refresher for all POCT users, review of instruments installation and inventory check was performed by POCT coordinator. A 24/7 hotline was in place to resolve POCT related query and complaints. A POCT contingency plan was put forward and the POCT team was open to suggestions or complaints based on the feedback from POCT users and physicians. The POCT team conscientiously monitored the whole process for one week at each site and implementation was signed off gradually one after another. Fifty-nine glucometers, five urine analysis devices and five arterial blood gas analyzer were installed at 22 sites (including emergency department, critical care units and wards). The initial week or the transition phase was the toughest time once POCT implementation was introduced at these various sites. The issues faced were frequent QC failures because of incorrect QC identification, frequent comparison of POCT results to central laboratory testing, decreased utilization of POCT by end users, frequent training refreshers and instrument breakdown because of mishandling. Laminated posters or flyers with simple step-by-step instructions on how to perform a test on a patient and how to conduct quality

Table 5 Elements of POCT report

Essential features to be specified in POCT reports
Patient identification and patient location
Demographics of patient
Time and date of test when performed
Patient results with units
Type of sample
Distinction that the test was done on POCT device and not in central laboratory.
Identification of POCT operator who performed the test
Reference interval of analyte
Treating physician's identification
The identification of the laboratory that issued the report

management (QC and PT) testing procedures into a practical, workable format was distributed at all POCT sites as a training refresher.

Clinical audit and ongoing POCT compliance

All POCT programs need to be observed and evaluated periodically in order to assure that the program is meeting the needs of patients, testing personnel and hospital (22). Once our POCT program was in place, a clinical audit was conducted by the institute's 'Quality Assurance Department'.

All POCT sites were audited and assessed for the policy, procedure and protocols, POCT users' knowledge, skills and practices. Most of the POCT users were aware about the procedures and policies, daily QC checks and reporting of the equipment related complaints. Daily QC checks were maintained and all POCT users were knowledgeable about the disinfection protocols. However audit revealed underutilization of few POCT instruments, manuals not easily accessible to end users and inadequate knowledge of some POCT users regarding result reporting and corrective action to be taken.

Based on audit findings and POCT team discussions some quality performance indicators were introduced in the practice to monitor POCT on a continuous basis. These include patient to QC testing ratio, moving average of blood glucose in the hospital and PT survey monitoring. The laboratory POCT team prepared for CAP inspection two years later and got accredited by CAP in 2016 and again in 2019.

The POCT program is now under strict oversight of CAP. Supervision of a POCT program requires continuous attention to POCT instruments and users management, competency management,

review of IQC and PT, presenting IQC and PT results in QA meeting of the institute, data monitoring, inventory management, monitoring all POCT devices and their remote access, processes of introducing new POCT in the institute and day to day issues (32).

CONCLUSION AND WAY FORWARD

The POCT allows rapid diagnostic and screening test results. Concerns over the quality of results and difficulties in managing the documentation have created challenges to the extensive adoption of POCT in hospitals in the developing world. A clearly defined organizational structure should be put in place for proper functioning and optimum utilization of each POCT unit. With our experience of implementing POCT program the key to success of establishment of POCT infrastructure was a dedicated project lead and team work. POCT implementation requires multidisciplinary, multimodal approach involving all stakeholders, giving respect to each other and with effective communication. In spite of major improvements in technology, assuring the quality of POCT remains challenging. This review may guide and assist other healthcare providers in implementing POCT effectively for improving patient safety and outcome.

REFERENCES

1. Shimetani N. [POCT (point of care testing) and rapid testing]. Nihon Naika Gakkai Zasshi. 2008;97(12):2913-9.

2. Howanitz PJ, Tetrault GA, Steindel SJ. Clinical laboratory quality control: a costly process now out of control. Clin Chim Acta. 1997;260(2):163-74.

3. Kendall J, Reeves B, Clancy M. Point of care testing: randomised controlled trial of clinical outcome. BMJ. 1998;316(7137):1052-7.

4. O'Leary D. College of American Pathologists Conference XXVIII on alternate site testing: keynote address. Global view of how alternate site testing fits in with medical care. Arch Pathol Lab Med. 1995;119(10):877-80.

5. Matsuo S. [Usefulness of POCT (point of care testing) in clinical practice]. Nihon Rinsho. 2004;62 Suppl 11:40-3.

6. DuBois JA. The role of POCT and rapid testing. Here is an overview of an evolving approach to direct patient care. MLO Med Lab Obs. 2013;45(9):18, 20, 2.

7. Simpson KN, LaVallee R, Halpern M, Palmer C. Is POCT cost effective for coronary bypass patients in ICUs? MLO Med Lab Obs. 1996;28(2):58-62.

8. Ward MJ, Self WH, Singer A, Lazar D, Pines JM. Cost-effectiveness analysis of early point-of-care lactate testing in the emergency department. J Crit Care. 2016;36:69-75.

9. Nichols JH, Christenson RH, Clarke W, Gronowski A, Hammett-Stabler CA, Jacobs E, et al. Executive summary. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: evidence-based practice for point-of-care testing. Clin Chim Acta. 2007;379(1-2):14-28; discussion 9-30.

10. Nichols JH. Point of care testing. Clin Lab Med. 2007;27(4):893-908, viii.

11. Gregory K, Tse JY, Wu R, Lewandrowski K. Implementation of an expanded point-of-care testing (POCT) site inspection checklist in a large academic medical center: implications for the management of a POCT program. Clin Chim Acta. 2012;414:27-33.

12. Mion MM, Bragato G, Casarotti A, Cosma C, Vigolo S, Vettore G et al. Clinical performance of cardiac Troponin I: A comparison between the POCT AQT90 FLEX and the Dimension Vista analyzer in an emergency setting. Clin Biochem. 2017 Sep;50(13-14):763-767.

13. Petersen JR, Graves DF, Tacker DH, Okorodudu AO, Mohammad AA, Cardenas VJ, Jr. Comparison of POCT and central laboratory blood glucose results using arterial, capillary, and venous samples from MICU patients on a tight glycemic protocol. Clin Chim Acta. 2008;396(1-2):10-3.

14. Shimetani N. [Current status of POCT and its future challenges]. Rinsho Byori. 2011;59(9):864-8.

15. Lewandrowski K, Gregory K, Macmillan D. Assuring quality in point-of-care testing: evolution of technologies, informatics, and program management. Arch Pathol Lab Med. 2011;135(11):1405-14.

16. Briedigkeit L, Muller-Plathe O, Schlebusch H, Ziems J. Recommendations of the German Working Group on medical laboratory testing (AML) on the introduction and quality assurance of procedures for Point-of-Care Testing (POCT) in hospitals. Clin Chem Lab Med. 1999;37(9):919-25.

17. Anderson M. POCT regulatory compliance: what is it and how does it impact you? Crit Care Nurs Q. 2001;24(1):1-6.

18. Weigl BH, Gaydos CA, Kost G, Beyette FR, Jr., Sabourin S, Rompalo A, et al. The Value of Clinical Needs

Assessments for Point-of-Care Diagnostics. Point Care. 2012;11(2):108-13.

19. Warade J. Organization of the POCT Unit. EJIFCC. 2015;26(2):125-32.

20. Yamada O. [Management of POCT Devices and Reagents]. Rinsho Byori. 2015;63(2):218-23.

21. Harris J, AbdelWareth LO, Lari S, Callaghan KO, Anderson P, Mirza I. Setting Up a Point-of-Care Testing Service in a Greenfield, Quaternary Hospital: An Implementation Review. Arch Pathol Lab Med. 2018;142(10):1223-1232.

22. Nichols JH. Quality in point-of-care testing. Expert Rev Mol Diagn. 2003;3(5):563-72. Review.

23. Lewandrowski K, Gregory K, Macmillan D. Assuring quality in point-of-care testing: evolution of technologies, informatics, and program management. Arch Pathol Lab Med. 2011;135(11):1405-14.

24. Briggs C, Guthrie D, Hyde K, Mackie I, Parker N, Popek M, Porter N, Stephens C; British Committee for Standards in Haematology General Haematology Task Force. Guidelines for point-of-care testing: haematology. Br J Haematol. 2008;142(6):904-15.

25. Hortas ML, Montiel N, Redondo M, Medina A, Contreras E, Cortés C, González C. Quality assurance of point-of-care testing in the Costa del Sol Healthcare Area (Marbella, Spain). Clin Chim Acta. 2001;307(1-2):113-8.

26. Wiencek J, Nichols J. Issues in the practical implementation of POCT: overcoming challenges. Expert Rev Mol Diagn. 2016;16(4):415-22.

27. Shaw JLV. Practical challenges related to point of care testing. Pract Lab Med. 2015 9;4:22-29.

28. Humbertson SK. Management of a point-of-care program. Organization, quality assurance, and data management. Clin Lab Med. 2001;21(2):255-68.

29. Wang P, Kricka LJ. Current and Emerging Trends in Point-of-Care Technology and Strategies for Clinical Validation and Implementation. Clin Chem. 2018;64(10):1439-1452.

30. Khanna S, Baron J, Gregory K, Lewandrowski K. Implementation of an expanded point-of-care site inspection checklist in an academic medical center: An eight year experience. Clin Chim Acta. 2018;476:173-177.

31. Crocker JB, Lee-Lewandrowski E, Lewandrowski N, Baron J, Gregory K, Lewandrowski K. Implementation of point-of-care testing in an ambulatory practice of an academic medical center. Am J Clin Pathol. 2014;142(5):640-6.

32. Nichols JH. Quality in point-of-care testing. Expert Rev Mol Diagn. 2003;3(5):563-72.