

POCT: Taking control in uncontrolled premises, part 2

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Point-of-care testing (POCT) covers a broad range of pathology and non-pathology testing. The volume of POCT is rapidly increasing with an annual growth rate of 12-15%.

By virtue of its compactness, portability, and the feasibility of operation by non-laboratory personnel, where fast and accurate testing methods and improving patient care are primary concerns [2], POCT has evolved as an important part of laboratory medicine.

The benefits of performing tests in this setting include convenience for clinicians, a faster turnaround time (TAT), and cost savings to the hospital administration. Rising concerns regarding POCT include problems with ensuring quality, potential conflicts of interest, and an uncertainty of responsibility [2].

In larger hospitals in India, testing may be performed at locations ranging from the

emergency room (ER), the operating room (OR), or intensive care units (ICUs) in the hospital to satellite outpatient clinics.

In my experience, most of these areas are outside the control of central laboratory, and the majority of clinical staff members involved in POCT are focused primarily on clinical care.

Training and ongoing competency maintenance for staff performing POCT can be overwhelming to manage and it is sometimes difficult to get this uncontrolled unsupervised area under control.

Considering the growing field of POCT, it is time for all stakeholders involved to manage the areas of POCT in a more systematic and professional way.

In the following, I will focus on phases 3-6 in the suggested systematic management approach to POCT facilities:

1. Planning
2. Building a structured POCT unit
3. Implementation
4. Introducing POCT devices/processes
5. Quality
6. Accreditations

To read about planning and building a structured POCT unit, please refer to the [first part of this article published in July 2015](#).

POCT implementation

Training

Staff members who have not been trained for the specific POCT device are not permitted to use it for performing tests, including simple dip-stick tests. This goes for hand-held POCT devices as well.

The training and certification of POCT users is overseen and monitored by the POCT Committee and the training courses are supervised by a qualified person provided by the supplier of the POCT device or appointed by the POCT Committee.

An appropriate and experienced trainer is certified by the respective POCT Committee which is appointed by the Hospital POCT Committee. Training includes: patient preparation, preanalytical aspects of the analysis and interpretation of results.

For some devices, follow-up training is necessary to maintain a high standard of performance. Records of training, follow-up training and competency are retained.

Standard Operating Procedure

Tests on the device in the designated area may only be carried out by those on the “authorized personnel for equipment” list. A SOP, written according to the standard required by auditors from accreditation agencies, must be available to, and followed by, all users of the device.

The SOP must include instructions on safe working practice, the interpretation of error messages, the recording of data and the relevant quality control procedures.

The POCT Committee must provide the standard format for SOPs and the POCT users must customize accordingly.

The SOP copies must be made available to the POCT Committee, and the POCT users are responsible for ensuring that the SOPs are available for accreditation agency auditors.

All devices must have a SOP covering:

- Sample suitability and stability
- Quality assurance procedures
- Performing analyses
- Method of recording results
- Actions required in case of suspected device failure or an unexpected result
- Interpretation of results
- Reference ranges
- Limitations and contraindications
- Health and safety issues.
- Health and safety

In both hospitals and clinics, managers in Clinical Services together with Pathology must jointly develop and enforce policies consistent with current legislation and guidance.

There will be close collaboration between Safety Officers of the testing site and the respective POCT Committees. POCT devices must be commissioned by the POCT Committee to the standard, e.g. FDA and CE requirements.

Risk management

Any POCT device has its merits and/or limitations. The POCT user should recognize this and maintain accountability for any undesirable consequences or outcomes of its use.

It is essential that the risks associated with the use and interpretations of results obtained are properly managed by training and support from the respective POCT Committee.

Recording and reporting of results

All patient results and IQC or EQA will be recorded. The record includes unequivocal patient identity, time of test, the result, relevant QC result and the identity of the user.

The results must be transferred as stated in the SOP and monitored by the authorized person. The format of the results form (i.e. electronic or paper) should be determined in discussion with the POCT Committee.

POCT Committee members have open access to IQC/EQA results. Results must be clearly legible and reported to persons authorized to receive and use medical information.

The result indicates if the qualities of the primary sample received was unsuitable for examination or could have compromised the result.

The POCT user maintains written policies and procedures regarding the recording and reporting of results. For results in critical intervals, a record of the actions taken must be kept. Records include:

- date
- time
- responsible POCT staff member
- person notified
- examination result

Any difficulty encountered in meeting this requirement is recorded and reviewed during audits.

In case a record is altered, the POCT user must document this. When altered, the record shows the time, date and name of the person responsible for the change, keeping the original entries.

Original electronic records retain any alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.

Results which have been available for clinical decision making and revised are retained in subsequent cumulative reports and are clearly identified as having been revised.

All patient results are treated as confidential and kept in a secure place. If patient results are stored in a computer system, local rules on access to the system, whether stand-alone or in a network, should be maintained.

Users should have access to the system by a regularly updated password. Results must be stored as described in the SOP and compatible with ISO requirements.

Log book

The POCT sites maintain a whole-life service history of all medical devices in accordance with MS ISO 22870:2008 and 15189:2007, for management of medical equipment, and its successors.

POCT users document all original evaluation records for the POCT Committee to evaluate in a timely manner.

POCT users ensure that all equipment is maintained either in-house or by service contract, in agreement with the budget holder, to a service schedule to ensure the safe, accurate and reliable operation of all equipment documented in the log book.

Each device has a device maintenance log book in either paper or electronic form where details are recorded concerning daily maintenance, IQC results, faults, corrective actions and individual repairs.

POCT Committee members have open access to these log books.

Technical support and withdrawal of services

There is a service-level agreement between the users and concession companies or suppliers defining the responsibilities for maintenance, troubleshooting and repairs.

Designated POCT users are responsible for the day-to-day care of the system as well as the maintenance of stocks of consumables and reagents within their shelf-life. If a device fails to perform to analytical specification, critical requirements are not met, safety becomes an issue or if devices are not used or cared for appropriately, the POCT Committee recommends that it is withdrawn from service.

The device is withdrawn immediately from service until full remedial action has been completed. The concession companies or suppliers are responsible for removing the device from service.

Users are informed immediately of any quality shortfalls by the POCT Committee. An inventory is maintained of all POCT equipment, including serial number and unique identification, manufacturer or supplier identification, date of purchase, service history, and the date(s) when the device was out-of-service.

In the event of a device failure, alternative sites for analysis should have been agreed, documented, and made known to the users.

Budgetary planning and monitoring

Prior to procurement, a budget proposal is created by Management (Hospital Director) and its users for the financial consequences of the purchase.

The Hospital POCT Committee will monitor the

cost implication and report to the Management (Hospital Director). POCT users are responsible for ordering and monitoring reagents, consumables, inventory, maintenance, servicing, training, support, quality control and quality assessment in POCT sites.

POCT users will budget and bear the direct costs of running, maintenance, consumables, quality control and service contract, including indirect costs for POCT Committee's involvement, support, training and QC/QA monitoring, as well as the inevitable cost of back-up.

Complaints

All complaints are directed to the Hospital POCT Committee in writing for further discussion. The relevant issues are addressed by the Management (Hospital Director) and, if required, corrective actions are taken.

Maintenance

It is mandatory that all POCT devices are regularly maintained. The POCT Coordinator is responsible for overseeing the maintenance of all such devices and the POCT Coordinator will be responsible for training designated operators as necessary.

Responsibility of the ward and laboratory carrying out maintenance procedures will be outlined in the SOP for each device. The manufacturers' engineers will perform service visits according to the individual companies' service schedules.

The POCT Coordinator determines responsibilities and procedures concerning communication with the manufacturer for all equipment problems and failures. Each device must have a "Device Record Book" or log book in paper or electronic form in which maintenance records, faults, corrective actions and repairs by individuals are documented.

These records are the responsibility of the

Section A: POCT Device/Process Details
1. Which new POCT process/device is proposed?
2. What is the proposed location for this device?
3. Is the design device static or portable?
4. Which individual is responsible for introducing the new POCT device?
5. Timing of use
6. Who will have the responsibility for the necessary training?
7. Where will records be held?
8. Who will actually perform the POCT?
9. Will system users be restricted to named (competent) staff? If not, please explain how you will maintain an audit trail.
10. What extra time is involved in performing the POCT device/process?
11. How will results be recorded, including access through EPR or LIS?
12. Who will be responsible for producing the standard operating procedure (SOP) for the POCT process/device?
13. What is the rationale and reason for using POCT rather than laboratory analysis?
14. Discussion with the relevant laboratory section regarding the particular technique.
15. Consult with the Pathology laboratory concerning units, reference ranges, sample types, correlation with laboratory results.

Pathology laboratory and must be accessible for inspection at all times.

Proposal: introducing point-of-care testing

Introducing of all POCT devices must be approved by POCT committee.

Quality assurance

Point of care testing – requirements for quality and competence, MS ISO 22870:2008 requires that departments participate in recognized External Quality Assessment schemes (EQA) relevant to their test repertoire.

A Quality Assurance Program (QAP) is an integral component of any POCT service and includes all measures taken to ensure the reliability and accuracy of patient results.

The Management (Hospital Director) ensures

that there is a clear link between the users of the device and the appointed POCT Committee. The Management (Hospital Director) also ensures that an adequate budget is provided for EQA schemes.

The Management (Hospital Director) Coordinator is informed of the legal implications involved if there is no supervision of devices through QA schemes. The appointed POCT Committee is involved in clinical governance issues and must carry out regular audits.

The appointed POCT Committee is responsible for ensuring that the performance of the device is checked by internal QC and external QA assessments as appropriate.

The Hospital POCT Committee is responsible for the design of QAP conforming to the quality standard of the POCT sites. The Hospital POCT Coordinator is responsible for the implementation and management of analytical quality assurance

for POCT sites and provides feedback to the State POCT Committee.

Internal quality control (IQC) is performed by the POCT users to determine that the POCT device is performing correctly. The IQC material must be stored and handled according to manufacturing instructions.

Calibration of the POCT analyzers is performed according to manufacturing instructions. The IQC of the POCT analyzers is performed according to the Hospital/District Health Office regulations.

The IQC performed is recorded and presented in a Levey-Jennings (LJ) chart. The POCT users are responsible for documenting and keeping the IQC data for monitoring and review by the State POCT Coordinator.

The POCT user is responsible for the enrolment with the EQA scheme in terms of planning, monitoring and financial support under the POCT Committee's regulations. The POCT Coordinator reviews the performance of EQA and discusses with the users the appropriate course of action in case of any shortfalls in quality standards.

The Pathology/District Health Office POCT Committee coordinates training for POCT users to be able to carry out the IQC and tests. Hospital Quality Management Review (Hospital Director Management) discusses quality performance of POCT.

In addition to IQC and EQA, audits are an important aspect of quality assurance. Internal audits examine local processes conducted by senior staff. Such reviews measure various parameters of performance, such as timeliness, accuracy and cost of reports, and identify weak points in the system where errors can occur.

External audits widen the input by involving others in the evaluation of analytical services. The users

of services are asked how they perceive the quality and relevance of the service provided.

Accreditation

Importance of accreditation

Accreditation by CPA for POCT is an important indicator of quality. CPA is regarded as the benchmark for quality, giving users confidence in the service they are procuring.

It also ensures the optimization of patient safety. It is essential for organizations to be accredited for POCT, as this helps to expand the POCT service into areas which previously had little or no governance, such as external sites.

Although CPA accreditation of POCT is not currently mandatory, it has the potential to become essential in the future. Hopefully, the cost of the accreditation process will be offset against new POCT contracts which are gained through having the CPA stamp of approval.

Scope of accreditation

- blood glucose testing, using both connected and non-connected meters
- urinalysis, including both automated/connected and visual/non-connected reading of results
- urine pregnancy testing
- blood gas testing
- hemoglobin testing
- HbA1C Analyzer
- cardiac markers
- other devices and respective procedures

The POCT team includes a combination of biomedical scientists, associate practitioners and assistant technical officers, and helps users achieve their care goals.

Accreditation is possible to achieve, providing

there is sufficient governance and control around the entire service. It is important for the POCT team to engage with all users and to provide adequate training both on and off site.

Accreditation process

The CPA process for POCT begins with a preassessment visit, which determines what work may still be necessary. The preassessment provides a gap analysis prior to the full assessment.

Without key elements, such as an effective quality management system, CPA will not recommend the full assessment. The gap analysis provides a framework, allowing us to concentrate on elements of the service that need tweaking or further development.

The team audits high- and low-usage areas to ensure that the same high quality of service is provided irrespective of demand.

Conclusion

The wider application of POCT is an inevitable part of today's healthcare system providing timely results in patient management in emergency and intensive care units. Without the proper organization of POCT facilities, it remains a challenge to control it.

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