

Thinking of Introducing PoCT – Things to Consider

Definition of PoCT

Point of Care Testing (PoCT) is defined as diagnostic testing at or near the site of patient care

PoCT is also known as:

- Bedside testing
- Near patient testing
- Ancillary testing
- Home testing
- Satellite testing
- Remote testing
- Physician's office laboratory testing
- Patient self-management

References

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

Organisation and Management

A broad spectrum of PoCT equipment is currently available covering most pathology specialties. To ensure reliable results are obtained when using PoCT, the patient must be prepared appropriately and the equipment used should be fit for the testing purpose. For the non-scientist, the number and diversity of PoCT instruments currently available is confusing and poor selection of instruments may compromise patient care. If used appropriately, PoCT can reduce the timeframe to therapeutic intervention potentially resulting in improved patient outcomes. Local selection of equipment should take into account local and international performance recommendations.

Before consideration of implementing any PoCT device, a clinical needs assessment should be performed. Clinical needs assessment defines unmet needs within healthcare and determines how to fill them. Limited need assessment studies have identified diagnostic testing gaps in hospital, emergency and disaster care.

Before implementing PoCT sites needs to carefully consider the following:

- Identify clinical needs
- Cost, benefits and disadvantages
- Literature search for evaluations of suitable instruments
- Is appropriate quality testing material available (QC, EQA)
- What support is available for training and on-going technical support
- Life of consumables – will expiry date allow usage before expiring?
- Do consumables require refrigeration and is there capacity to accommodate this?
- Do I have staff that can undertake tasks involved with implementing intended PoCT technology?

PoCT implementation requires a systematic approach which involves all stakeholders. Generally, one person from the organisation takes responsibility for the ongoing performance of the PoCT. This person should be identified before the process begins so that they can guide successful implementation.

The following requirements need to be planned as part of the PoCT implementation process:

- Identify suitable equipment that meets local guidelines and regulatory requirements
- All staff that will be performing tests will need to undergo appropriate training and be certified as competent
- Written policies and procedures should be prepared for all aspects of PoCT

- Manufacturer's instructions need to be incorporated into the site's procedures
- Routine monitoring of instrument performance to ensure it continues to perform optimally
- Storage of results should be considered. Electronic transfer and storage of patient results should be achieved whenever possible.

Selecting a suitable analyser

Selection of a suitable point of care device is an important process as it will ensure the device is the most appropriate for the patient care setting and the population served. For an inexperienced user, the diversity of different instruments available can lead to inappropriate selection which can result in wasted money and failure to achieve the anticipated improved patient outcomes.

Once the decision to perform PoCT has been made, sites should have answers to the following questions:

- What tests are required?
- What are the characteristics of the patient population – will their samples have unique characteristics that need to be considered?
- Will the PoCT application produce results that meet clinical needs?
- What is the expected frequency that testing will be performed?
- How many operators need to be trained and supported?
- Who will take the lead on introducing PoCT?
- Is treatment, counselling or follow-up required and can they be introduced (eg does a positive result require counselling)?
- Is there adequate medical, financial, workforce and IT capacity to support PoCT?

The choice of a PoCT device will be influenced by the expected number of tests to be put through the instrument. When assessing PoCT devices, seven criteria can be used to compare shortlisted devices:

1. Robustness and suitability of use in the field including:
 - Electricity required
 - Refrigeration required
 - Portable
 - Suitable for humid climates
 - Cope with dust and rugged enough for transport
 - Appropriate shelf life
2. Ease of Use:
 - Minimal maintenance
 - Minimal patient preparation
 - Sample type
 - Meets regulations
3. Education and Training:
 - What training and education is available and who will it be provided by?
 - Does the company assist with training of operators?
4. Accuracy:
 - Will it be safe to use for patient management?
5. Cost:
 - Running costs
 - Both fixed and variable costs need to be taken into consideration
 - Will cost of introducing device result in financial or administration costs or increase patient satisfaction
6. Connectivity:
 - Can the device be connected to a local database for electronic transfer of results?
 - Can software updates be performed electronically?

7. Are appropriate quality control (QC) and external quality assurance (EQA) materials available?

- Ensuring accuracy and precision of the device

When making assessments on purchasing and introducing PoCT, it is important to involve all stakeholders in the decision and planning process so that it is accepted by all as part of clinical practice once implemented. Final decisions should be made once all of the above questions have been considered. It is advisable to come up with important features of a device for the health unit and devise a table to record which shortlisted devices have the majority of the features considered important.

Staff training and Competency

The main aim of staff training for PoCT is to ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs. Fortunately, most PoCT devices have been designed to make their use easy to understand and training requirements are relatively easy to grasp by non-technical staff. However, the task soon becomes challenging when a large number of PoCT staff are envisaged. Good staff training is a cornerstone of a good quality management system and a well-documented training program will help to provide this foundation.

1. Start by writing a Training Plan

This document will get you thinking about all of the different aspects of training for your operators and should include:

- An assessment of the skills and competency needs for any staff that will be asked to perform PoCT activities, such as entry qualifications, skills and experience
- An assessment of the skills and competency needs for any staff that will be asked to train other operators

- A standard operating procedure for the PoCT training that will be required for new staff. Consider:
 - Health and safety for the operator and patient
Ensure that staff are aware of the current legislation and guidance, including the medical & legal implications of transmission of infection due to lack of safe specimen handling or spillage
 - Sample collection & handling including any special requirements
Ensure that staff are fully trained in sample collection techniques, including the selection of the appropriate sampling devices and avoidance of pre-analytical errors
 - Positive patient ID and operator ID
Provide guidance to staff on the importance of accurately recording the patient identity for the sample to avoid mix-ups and operator identity for process traceability
 - Sample presentation to the PoCT device and correct operation
 - Safe disposal of the sample and sampling device
 - Timely routing of results to the decision maker and the appropriate operator response to results that are outside pre-defined limits, including the preferred method of storing the result in the patient record
 - Highlight incorrect techniques and how to avoid mistakes
Ensure staff are made aware of typical mistakes and incorrect techniques and the likely adverse outcomes. Discuss PoCT device error codes, their meanings and what to do if the device generates an error. Staff should be instructed that all adverse incidents are recorded and reported.
 - Quality Control, maintenance tasks and consumable storage and handling for the PoCT device

- Who to call if there is a problem with the device or stock needs replenishing
- A determination of how best to provide the training - usually trainees will benefit from a combination of pre-reading and practical demonstration. The pre-reading should include the context and clinical utility of the PoCT results, theoretical aspects of the measurement system and best-practice guidelines for using and maintaining the device
- A definition of how the training will be documented
- A determination of the frequency for re-training and/or competency assessments. Periodic re-training is important even for highly experienced operators to avoid bad habits creeping in. Consider re-training and/or reassessment of all operators on an annual basis
- Finally, due consideration of how the effectiveness of the PoCT training will be determined, monitored and how corrective action would be taken if the required standard is not being achieved

2. Train the Trainer

- Determine who will conduct the training
- Ensure that this person(s) has the appropriate qualifications, experience and training to be able to train others and that these are documented in their training records
- Conduct the trainer training, and assess their competence to provide training to others
- Document the training and competency assessment

3. Train the Staff

- Schedule the training for the appropriate number of staff

- Ensure that these operators have the pre-requisite qualifications and experience and that these are documented in their training records
- Provide the pre-reading material ahead of the training
- Conduct the operator training and assess their competence
- Document the training and competency assessment

References

- *ISO 22870:2006. Point-of-care testing (POCT) – Requirements for quality and competence*
- *ISO 15189:2007 Medical laboratories — Particular requirements for quality and competence*

PoCT Coordinator

PoCT should be introduced in a systematic process which is inclusive of all stakeholders. Ad hoc approaches are potentially expensive and dangerous in terms of patient safety. To avoid this situation, a PoCT Coordinator should be employed.

The PoCT Coordinator should be an experienced medical technologist/scientist from a hospital, laboratory or specialist PoCT service provider background. The responsibilities of the PoCT Coordinator includes overall supervision and management of the PoCT activity, ensuring compliance with the policies and quality standards required by the program- particularly in relation to selection and evaluation of instruments, staff training and competency assessment, surveillance of the entire testing process, quality control and quality assurance procedures and resolving technical problems.

The PoCT Coordinator provides invaluable leadership in collaboration with nurses and physicians. Institutions should set up PoCT committees to oversee the PoCT service. The committee should be responsible for evaluating and prioritizing new tests and balancing use of limited resources. With numerous tests available for PoCT and each year, needs arising for more [e.g. avian flu, H1N9 (China), and MERS CoV—Middle East Respiratory Syndrome Coronavirus (Saudi Arabia)], the PoCT committee carefully determines clinical indications, test clusters, and valid applications before approving near-patient or bedside testing.

Traceability of measurement

The benefits of PoCT to a healthcare organisation have been well-documented, but the risks and complications arising from a poorly implemented PoCT activity should not be under-estimated. It follows that in order to reduce the risks to patients and the facility to an acceptable level, PoCT like laboratory testing, should be conducted in accordance with a robust Quality Management System (QMS).

The key to implementing a QMS is a well-considered and documented plan to ensure adherence to a set of policies, not least of which are management accountability and review.

1. Consider using ISO 22870 Point-of-care testing (PoCT) — Requirements for quality and competence as the basis for establishing a formal QMS
2. Consider gaining accreditation for your PoCT by a competent body that recognizes and takes into account the special requirements of PoCT

3. A frequent technique used by external auditors is to pick one or more test results at random and follow them back through the QMS. They are looking for compliance to the QMS at every step:
 - Can the test result be accurately traced to the patient?
 - Was the result assessed by a qualified person?
 - Were any error codes or out-of-limit conditions noted and acted upon?
 - Can the test result be accurately traced to the operator?
 - Was the operator competent to perform the test at the time?
 - Was the PoCT device appropriately maintained, calibrated, QC'd and operating within normal parameters at the time?
 - Were the consumables used for the test within their 'use by' date?
 - Had the consumables been stored according to the manufacturer's recommendations of temperature, humidity, ambient light etc?
 - Is there a Standard Operating Procedure on-hand that details how to achieve all of the above? Is it a current, controlled document?
4. Section 3 is not an exhaustive list and the answer to all of the questions needs to be YES. More importantly, you need to be able to support the YES claim with documented evidence. Consider the systems that you need to have in place to allow you to state YES with confidence.

References

- *ISO 22870:2006. Point-of-care testing (POCT) – Requirements for quality and competence*
- *ISO 15189:2007 Medical laboratories — Particular requirements for quality and competence*

Quality testing recommendations

In the laboratory setting, QC and EQA are used to assess analytical quality. These tools of quality assessment should also apply to the PoCT instruments and be performed on all PoCT devices by routine operators. Laboratory professionals are best able to set quality testing recommendations practicable in the field. They should tailor programs without excessive complexity adapted to be performed by non-laboratory operators in a non-laboratory environment. The degree of technological improvement of the PoCT devices, the level of connectivity and the volume of patient testing are major elements to be taken into account.

The goal of QC testing is to ensure that the PoCT system and the operator are performing correctly (testing reliability and routine work quality) and that results correspond to the expected values of the control material. The QC procedure includes control material testing, immediate results analysis and identification of errors to undertake remedial actions. If QC results fail, patient testing should not be performed until the problem is resolved.

EQA, also known as proficiency testing, is the testing of unknown samples from an external program in the same manner as patient specimens. Sets of samples are sent several times per year and results are graded by the program administrator in comparison to other participants' results.

Choices of programs, sample storage, procedure writing, operator training and review of results and remedial actions are major elements to master when introducing QC or EQA. Operators should document in records all corrective actions undertaken for failures of QC or EQA.

PoCT QC Programs

For laboratory-type instruments, the laboratory quality framework with daily testing of QC controls at different levels can be organized. However, many devices designed for PoCT do not really fit with traditional laboratory QC systems (strip-based devices or cartridge-based) and new-generation devices also have in-built quality controls that automatically check the device. For

these instruments, laboratory professionals should have an understanding of what type of instrument has to be checked and what parts of the instrument will be checked to set up the QC program (frequency and nature of control materials). Thus, there is no universal guideline and manufacturer's recommendations for QC will have to be adapted according to the PoCT device and site. In addition to the QC program, it is reasonable to undertake further testing when the device suffers a physical insult, when a critical maintenance was carried out, when a patient result was doubtful or when lot numbers of consumables/reagents changed. Quality control testing should be performed by all PoCT operators since the goal of the QC check is also to evaluate routine operator performance. Review of results should also be done by routine operators since immediate remedial action has to be taken. Laboratory professionals should periodically review QC failure documentation and verify that operators are adequately qualified for QC results, testing and interpretation.

PoCT EQA Program

Participation is recommended for each analyte being tested for every device and may be mandatory depending on local and national regulations. This is also a requirement of ISO 22870 standard. When no commercial program is available, a split of patient samples between different laboratories may replace EQA. However, parallel patient sample testing (correlations) between PoCT devices and a central laboratory is not an alternative of an EQA program. EQA testing should be performed by PoCT operators but review of results should be undertaken by laboratory professionals. Feedback should be provided to operators.

References

- Assuring quality in Point-Of-Care testing. Evolution of technologies, informatics, and program management. K Lewandrowski, K Gregory, D Macmillan. Arch Pathol Lab med. 2011;135:1405-1414

- The conduct of quality control and quality assurance testing for POCT outside the laboratory. J P Gill, M DS Shephard. Clin Biochem Rev 2010;31:85-88
- Quality Control issues in point of care testing. C L Martin. Clin Biochem Rev 2008;29 Suppl (i):S79-S82
- QC for the future: laboratory issues – POCT and POL concerns. V L Ng Labmedicine 2005;36:621-625
- International Organization for Standardization (ISO). Point-of-care testing (POCT). Requirements for quality and competence. Document ISO 22870:2006. Geneva

Pre-analytical Errors

The errors in the pre-analytical phase typically fall into two categories:

- Identification problems
- Sample problems

It is vital to keep pre-analytical errors under control in PoCT testing. There are more operators involved than in traditional testing, incurring a higher risk of errors.

Identification of samples

Incorrect or missing ID may be one of the most critical errors in PoCT testing. ID errors may lead to noncompliance with local and national regulatory requirements, misdiagnosis of a patient's condition, incorrect treatment of a patient, need for resampling and lost billing opportunities from tests that cannot be accounted for.

ID errors are typically caused by:

- Lack of patient identification and/or sample labeling
- Transcription errors due to manual data entry

- Lack of a dedicated procedure for identifying patients and samples

Possible means to avoid these types of errors include:

- Use at least two patient identifiers when collecting the samples, e.g. patient's name and date of birth or an accession number
- Use a pre-barcoded sampling device, if available
- Make sure the sample has a patient ID label attached to it before it leaves the patient
- Always enter a patient ID into the analyser before analysis
- Use barcode readers if available – both for bedside identification and at the analyzer – to avoid transcription errors

Sample problems

Examples of sample problems include:

- Incorrect sample type
- Haemolysed sample
- Clotted sample
- Incorrect fill level of sample
- Insufficient sample
- Insufficient mixing
- Contaminated sample
- Incorrect sample storage and/or transport

The means to avoid these types of errors are dependent on the type of analyte, sampling device and also the analyser used. It is thus pivotal that standard operating procedures are followed stringently. Vendors are often able to provide insight as to how to avoid pre-analytical errors.

Post-Analytical errors

Transcription errors are by far the most common post-analytical errors seen when using PoCT. These can be further sub-divided into single digit errors, incorrect rounding and accidental switching of digits. Sometimes the result is not written in the patient record or diary chart, either due to the need for urgent patient care or the judgement to disregard data that was not conducive

to making a clinical decision. Misinterpretation of the result, especially if it is a color change where it has to be matched to several different shades of the color, is also a common post-analytical error.

Sample collection

In PoCT, the quality of the specimen is known to have a significant effect on result validity. Therefore, training in capillary collection techniques such as finger prick or venous/arterial collections is essential. As with any other diagnostic testing, even though PoCT is being performed near to the patient and samples do not require transportation to the laboratory, the same quality requirements for specimen collection apply.

Cleansing the skin

The puncture site should be cleansed with alcohol wipes. Ensure the area has been dried thoroughly to minimise stinging of the puncture site and to reduce the risk of haemolysis. Alcohol swabs that contain glycerol additives should be avoided as these may interfere with results.

Capillary puncture

To increase arteriole flow to produce a satisfactory capillary specimen with the first lance, patients can wash hands under warm water, rub hands vigorously together or use a heat pack. The side of the middle or ring finger is usually the preferred site for capillary testing in an adult patient. The fifth finger is to be avoided due to insufficient tissue depth and the second finger avoided preventing callous formation. Excessive squeezing of the digit should be avoided, as this may result in haemolysis of the sample and/or tissue fluid in the specimen. Single use only lancing devices should be used in healthcare facilities.

Venepuncture

The tourniquet should be applied tight enough to occlude venous supply but not arterial. The median cubital, basilic and cephalic veins sites are generally used to draw blood and the choice of the site will also depend on several

factors. These include patient related factors such as age, medical history, general condition and previous venepunctures, condition of veins, expertise of the collector and the volume of blood required. Sufficient pressure must be applied to the area post-collection to control bleeding. When collecting an anticoagulated sample, the specimen should be adequately mixed by gentle inversion 8 – 10 times.

Arterial puncture

Arterial samples are obtained by percutaneous puncture of the radial, brachial or femoral artery. Arterial blood gas specimens are collected in plastic arterial blood gas syringes, which are heparinised to prevent clotting in the syringe. The syringe must not contain air bubbles and should be tilted back and forth to mix the heparin with the sample and then rolled between the fingers in a horizontal position until tested to prevent separation of the plasma. Firm pressure must be applied to the site post-collection for at least five minutes or 10-15 minutes for patients with delayed coagulation.

Infection control

Successful infection prevention and control involves implementing work practices that prevent the transmission of infectious agents through a two-tiered approach. This involves Standard Precautions, which includes the use of Personal Protective Equipment (PPE) such as gloves, eyewear, masks, aprons and safe use of sharps and Transmission Based Precautions (additional precautions).

Connectivity

In its simplest terms, PoCT connectivity essentially refers to a set-up where instruments have the ability to be connected to a dedicated computer that has specific software to manage data it receives from the instrument. This middleware is referred as the “data manager” and allows both device management and data management.

The term “device management” involves remote entry of information into the PoCT

device that previously needed to be manually entered directly into each instrument. This is achieved by typing items specific to the PoCT into the data manager or scanning bar codes and then uploading the information into the point of care device.

Such items include:

1. Quality control ranges
2. Critical reference ranges
3. Reagents / strip / control lot numbers
4. Expiration dates
5. Valid operator lists
6. Patient identifiers (e.g. medical record number, account number, date of birth, location)
7. Clearing data from device memory

However, “data management” refers to collecting, transferring and processing information from the PoCT device. Rules can be written into the data manager and then uploaded into the PoCT device. The data manager reviews results and accepts them if they are not violating any rules, otherwise the result would get transferred into an exception report. For example, a rule is written instructing that one of the patient identifiers is a 6 digit medical record number. If fewer or more numbers are entered then the result goes into the exception report and is held there until the result is reviewed by the user and manually moved into the result database. The data manager allows the tracking of operator certifications and can also generate graphs so that patient and quality control data can be monitored.

In both community hospitals and academic medical centers, data managers are increasingly being connected to the laboratory and hospital information systems so that patient results can be directly transferred into the patient’s medical record. This is further enforced by healthcare laws in the US, Europe and some other developed countries that stipulate a documentation trail connecting the patient’s result with their identification and that of the care giver that performed the test and their testing qualifications, with the instrument used and records of reagents and

controls used in the test.

There are a number of vendors that offer middleware for PoCT devices and data management. Their differences lie in the type of PoCT instruments they can connect to, equipment costs and license fees, user friendliness and technical support coverage. The latter two items are particularly important when choosing a data manager because user friendliness and an accessible technical support team ensures data can be retrieved quickly and manipulated to analyse trends and to troubleshoot instruments.

Safety and Waste Disposal

PoCT procedures should be performed in a way that does not compromise the operator or patient safety. Standard precautions should apply to the care and treatment of patients, regardless of their perceived infectious risk. They are required in the care of patients if there is any contact with blood, body fluids, non-intact skin and mucous membranes. Hand washing is generally considered the most important measure to prevent the spread of infection. Hands should be washed before patient contact, after patient contact and after contact with body fluids irrespective of whether gloves are worn or not.

For PoCT these include:

- Personal hygiene practices particularly hand hygiene
- Use of personal protective equipment
- Safe handling and disposal of sharps and other clinical waste. Only single use lancing devices should be used
- The PoCT instrument and surrounding work area should be cleaned daily. All blood and body fluid spills should be cleaned up immediately

All sample collecting lancets, cuvettes, strips and cartridges should be considered as hazardous “sharps” and disposed of in an approved sharps container. Other waste material including tissues or swabs contaminated with blood or body fluid should be disposed of in an infectious plastic bag and incinerated.

Useful resources

- www.acutecaretesting.org
- <http://labtestsonline.org>
- <http://www.pointofcare.net>
- <http://www.specimencare.com>
- www.appn.net.au
- <https://www.aacc.org/members/divisions/cpoc/pages/default.aspx>
- <http://www.cap.org/apps/cap.portal>
- Blood gas preanalytics App for iPhone, iPad, Android and Windows phone. (Scientific content, sponsored by Radiometer)