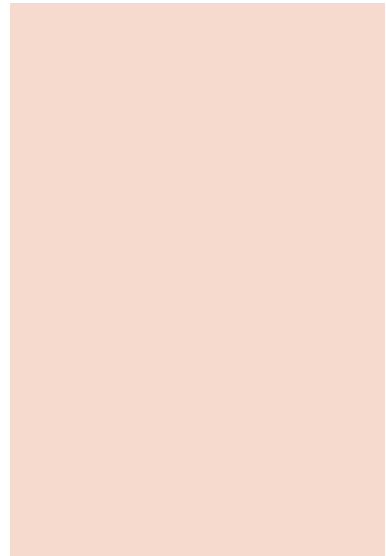
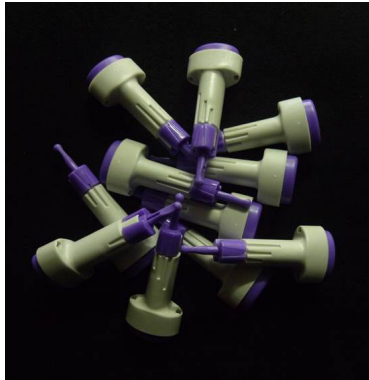




Point of Care Testing Implementation Guide



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Point of Care Testing Implementation Guide

Point of Care Testing Working Party

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CONTENTS

AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS (AACB).....	4
AACB POCT COMMITTEE.....	5
ABBREVIATIONS	6
SCOPE	7
BACKGROUND	8
POCT REQUIREMENTS	10
ORGANISATIONAL STRUCTURE	13
SELECTION OF ANALYSERS.....	15
STAFF TRAINING AND COMPETENCY	17
QUALITY CONTROL.....	20
EXTERNAL QUALITY ASSURANCE	22
SAFETY AND WASTE DISPOSAL	24
SOURCES OF ERRORS.....	27
INFORMATION TECHNOLOGY	29
LEGISLATIVE REQUIREMENTS.....	30
HELP/SUPPORT.....	32

AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS (AACB)

The Australasian Association of Clinical Biochemists (AACB) is the principal professional association dedicated to the advancement of Clinical Biochemistry in Australasia.

Our role is to provide education, training and other professional development opportunities for our members which include chemical pathologists, medical scientists and technicians working in pathology or related testing services in the Australasian region.

VISION STATEMENT

To be the lead Australasian organisation for clinical laboratory medicine, in advocacy, education, training and continual professional development. To promote better health outcomes by leading in the setting of standards for best practice. To promote and enhance effective communication within and between the pathology community and other healthcare professionals.

The AACB believes PoCT can make significant and positive medical, economic and social contributions to the health of the community when used appropriately. The AACB PoCT Committee has amongst its members individuals who can provide expertise in PoCT both within and outside the laboratory. The AACB is committed to supporting the safe and effective use of PoCT in Australasia.

AACB POCT COMMITTEE

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ABBREVIATIONS

AACB:	Australasian Association of Clinical Biochemists
APPN:	Australian Point of Care Practitioner's Network
PoCT:	Point of Care Testing
EQA:	External Quality Assurance
GP:	General Practitioner
INR:	International Normalised Ratio
IT:	Information Technology
NPAA CLIS:	National Pathology Accreditation Advisory Council
PoCT NPACC:	Point of Care Testing National Pathology Accreditation Advisory Council
QA PoCT:	Quality Assurance Point of Care Testing
QC:	Quality Control

SCOPE

Point of Care Testing (PoCT) is an alternative to laboratory based testing performed at or near the patient and is increasingly being used outside of the laboratory by non-laboratory health professionals. PoCT is performed in emergency rooms, operating rooms, by nurses in clinics or visiting patients at home in general practice, by patients at home and in pharmacies.

Technological advancements in PoCT have produced portable, easy to operate instruments that can deliver high quality test results rapidly. This has led to more and more PoCT being done outside of the laboratory.

The scope of this document is to give guidance to all potential users of PoCT with a particular emphasis on non-laboratory health professionals interested in implementing PoCT in their health centre.

BACKGROUND

It is accepted that where possible, PoCT should be conducted within a framework of quality standards to ensure that the quality of results is sufficient or exceeds that needed for clinical purposes. The quality framework for PoCT needs to take into account the safeguards that are now built into PoCT devices, that devices are being used by non-laboratory trained personnel and treating patients effectively and quickly is the priority. Thus the quality framework needs to be designed in a way that avoids unnecessary complexity and encourages its adoption rather than be ignored.

Self-testing, the fastest growing area in PoCT, presents its own unique issues. There are no regulations covering self-testing and yet the quality of results is no less important. The large PoCT vendors often provide technical support for self-testers via telephone support. The Australian Point of Care Practitioner's Network (APPN) is able to provide support to this group or direct them to appropriate resources. Self-testing is beyond the scope of this document and will not be discussed further.

The advantages of PoCT have been reported as:

- more rapidly available test results leading to more timely treatment
- simpler sample collection in some cases
- elimination of sample transport
- simplification of pre-analytical processes in the case of some unstable analytes, and
- greater convenience and satisfaction for the patient

However, these advantages should be weighed up against the following disadvantages and potential problems:

- introduction without proper examination of the clinical need
- increased workload
- errors due to lack of expertise
- insufficient quality control
- limited comparability of results due to use of different methods (laboratory versus non laboratory)
- increased costs due to additional instrumentation, expensive reagents, enrolment in external quality assurance programs
- inadequate documentation of results and outcomes

The advantages of PoCT are often at the forefront of conversations about its introduction without sufficient emphasis being placed on implications with respect to cost, errors, data collection etc. PoCT results from some devices are not comparable with the laboratory method due to differences in analytical method or other causes. Another concern is that some sites do not perform quality control or external quality assurance and understanding of result interpretation is poor.

Given the increased workload in an already over stretched workforce, why would a general practitioner or other healthcare provider consider introducing POCT? The primary reasons would be because a clinical need has been identified and introducing PoCT may lead to both improvements in patient outcomes and possible efficiencies within the practice or other healthcare location where it is being conducted.

In this document we discuss all aspects of PoCT commencing from how to choose a suitable device to where to find technical support when help is required.

POCT REQUIREMENTS

This section gives an overview of the steps that will be required for the introduction and implementation of PoCT in a healthcare centre. The APPN provides useful information including a flowchart (Fig 1) on how to implement PoCT, how to select an analyser and checklists to help determine clinical need for PoCT.

Prior to deciding to perform PoCT it is recommended that all of the stakeholders are part of the planning process including medical staff and those who will be performing the testing. The goal of this stakeholder group is to choose equipment which is fit for the testing purpose.

The steps to consider when introducing PoCT include:

- clinical need to be identified
- who in the healthcare centre will take the lead and manage the PoCT service
- what is the backup/alternative method if PoCT is not available?
- costs and benefits be analysed
- literature search for evaluations of appropriate instruments for clinical purpose
- eligibility for reimbursement be evaluated
- availability of technical support
- capability to electronically capture results (interfacing)
- testing equipment and consumables are procured
- a user manual be prepared or sourced from the vendor
- all PoCT users be trained
- all competent users be provided with certification
- quality control be monitored and the performance documented
- enrolment in an external quality assurance program or participation in split specimen testing where this is not practical
- any problems and corrective actions be documented
- continuing education and recertification be provided for device operators
- processes be audited and appropriate action taken

It should be recognised that PoCT will be carried out by a variety of healthcare personnel, many of whom do not have the expertise to assess the quality of results produced by the PoCT device. In particular, they may not have training in quality control and interpretation of results. As with

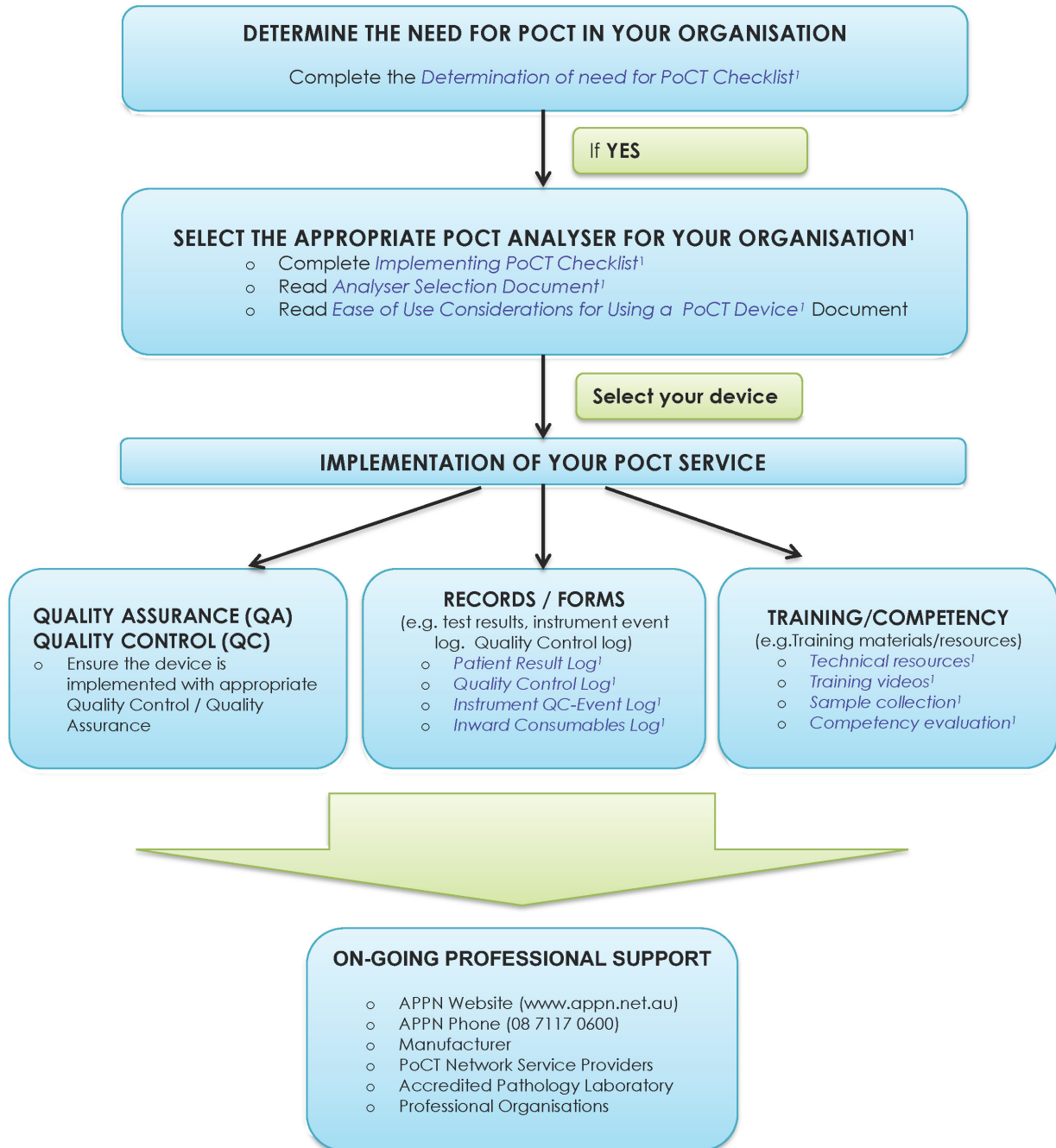
other medical procedures, formal training and competency assessment is an essential part of running a PoCT program.

Some organisations will only allow staff to run PoCT devices after they have received the appropriate certification. For PoCT to be carried out successfully, the personnel performing the testing need to have a support network that includes standard operating procedures, access to training and experts who are available for advice.

Any healthcare centre contemplating the introduction of PoCT should consider the cost implications prior to embarking on testing. The direct costs of PoCT are generally greater than laboratory testing but the savings gained downstream from the PoCT process, reduction in clinic visits, shorter lengths of stay in hospitals and the convenience for patients may offset the increased direct costs.

Implementing and Maintaining PoCT

IMPLEMENTING POINT OF CARE TESTING (PoCT) INTO YOUR ORGANISATION – FLOWCHART



¹APPN, Australian Point of Care Practitioners Network, 2010-2019, Designed by Syslinx
<<https://appn.net.au>>

Fig 1. Flowchart for how to implement PoCT

ORGANISATIONAL STRUCTURE

This section describes the organisation of a PoCT service within a framework of quality standards and are applicable to anywhere PoCT is being conducted.

Once PoCT has been introduced, there needs to be continuous coordination of the PoCT activities, from implementation of PoCT devices through to the ongoing performance of the systems. Ongoing tasks such as checking quality control, performing calibrations when necessary, coordination and review of external quality assurance programs, maintenance of devices, periodic comparisons with laboratory methods and being a resource for PoCT users are all essential functions. To be successful someone must take the lead in managing the PoCT.

PoCT should become an agenda item at the healthcare centre's regular meetings to ensure that all aspects of the PoCT service are discussed by all involved with delivering the service.

MINIMUM REQUIREMENTS FOR POCT

The following are suggested as minimum requirements for any PoCT service:

1. Selection of an appropriately qualified person who is the designated authority to be responsible for PoCT, is acceptable to all stakeholders, and who will ensure that the appropriate standards of quality are maintained.
2. Equipment selected should have an evaluation report available, preferably performed in Australia/New Zealand.
3. All tests to be performed at PoCT should meet with the intended clinical utility.
4. All individuals who perform PoCT should undergo appropriate training and be certified as competent.
5. Written policies should be in place for all aspects of PoCT. This will include organisational structure, personnel considerations, method/instrument selection, testing procedures, safety/waste disposal, quality control, external quality assurance, maintenance, reporting of results and patient education.
6. Users of PoCT equipment should follow manufacturers' recommended schedules and protocols.

7. Complete, accurate and timely records should be maintained for all aspects of PoCT.
8. Written procedures should be in place for each type of PoCT test performed.
9. There should be a process in place for routinely monitoring instrument performance, including quality.
10. Medical alert/critical/panic values for any appropriate tests must be defined and communicated immediately to the appropriate professional. Complete, accurate and timely records of patient results should be maintained. Wherever possible, electronic transfer of PoCT results should be implemented.
11. Backup and/or confirmatory testing procedures should be identified.

All PoCT devices should be managed through a quality system to ensure the quality of results and, if possible, should also be included in the accreditation process.

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SELECTION OF ANALYSERS

This section describes things to consider when selecting PoCT equipment for a healthcare centre.

There are a wide variety of PoCT devices from many different manufacturers, covering a large menu of tests from all areas of pathology. They range from the relatively simple glucose meter to highly sophisticated devices which resemble laboratory analysers. To the uninitiated this can be a potential minefield, with the sheer number and diversity of instruments creating confusion, incorrect decisions, and inappropriate applications. This can result in wasted money and lost opportunity for the end user.

To avoid this scenario, the following section offers some simple rules and advice to help with the selection of PoCT equipment.

POINTS TO CONSIDER WHEN SELECTING POCT EQUIPMENT

The following are desirable characteristics of PoCT equipment and should be considered when selecting a device:

- Is sufficient space available – the amount of space available for instruments, consumables and paperwork should be considered, including fridge/freezer space required for consumables
- Ease of use – will it be user-friendly for operators?
- Power/network requirements
- Maintenance requirements
- Sample volume
- Expiry date of consumables – will testing throughput ensure that consumables will be used before expiry?
- Testing throughput – will it be adequate to ensure ongoing operator competency?
- Results comparability with local laboratory - this is particularly important if a combination of laboratory and PoCT results are going to be used in patient management
- Connectivity – can results be transferred electronically to patient records?
- Precision and accuracy should be appropriate for the clinical need
- Portability - will you need to move PoCT equipment and if so, is it portable enough to meet your testing needs?
- Are appropriate quality control materials available?
- Are appropriate external quality assurance programs available?

- Capital cost – is it affordable?
- What warranty is offered for the equipment?
- Service contract – do you have access to ongoing service and support and what are the terms of the contract?
- Are the running costs (including maintenance contract, consumables, quality materials (internal QC and external QA) and connectivity costs) viable?
- Are training and/or training materials provided by the company?
- Is there a supplier Helpline?
- What is the reliability of reagent and consumable supply.
- Is there barcode capability for patients, operators and consumables

POCT STAKEHOLDERS PLANNING PROCESS

This section briefly outlines how a planning and selection process might be undertaken.

Prior to purchase of PoCT equipment, it is recommended that a “Planning Group” of stakeholders be formed. This group may include:

- Representatives of those performing PoCT or end users (to state their needs and wants)
- Information Technology staff (advice on software interfaces and functionality)
- Organisational Quality staff (registration, certification requirements)
- Purchasing / contracts officer (optional, depending on local practice)

The goal of this stakeholder group is to choose the best possible equipment for the testing purpose. A time frame should be set, in keeping with the scope of the project. Representation can be made to manufacturers to demonstrate and supply suitable evaluation instruments. Select a product and ask the manufacturer to demonstrate and possibly provide an instrument for evaluation purposes prior to purchase.

Selection should be made on the basis of the best instrument for the application, within cost and time restraints.

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STAFF TRAINING AND COMPETENCY

This section describes the general principles associated with how to set up and manage a PoCT training program.

PoCT should only be carried out by health professionals who have undergone appropriate initial training and competency certification, who have their competency levels regularly assessed and who participate in regular retraining and recertification sessions.

This is the overarching principle of conducting PoCT in any healthcare location .

The individual designated as PoCT lead should take responsibility of overall supervision and management of PoCT activities, and ensure compliance with policies and quality standards.

TRAINING MANUAL

A training manual, in hard copy and/or electronic form, should be provided to all PoCT operators attending training.

The content of the training manual will be determined by the nature of the PoCT service being implemented and the needs of the organisation undertaking PoCT. Most importantly it should be readily understood by non-laboratory trained health professionals.

Laminated posters with simple step-by-step instructions on how to perform a PoCT test on a patient and how to conduct quality management (QC and EQA) testing procedures, can also be used effectively as part of a training package.

TRAINING CURRICULUM

Training should cover both the theory and practice of conducting PoCT. Teaching the theory of PoCT should include the following aspects as a minimum requirement:

- explaining the clinical background of the test (disease process and pathophysiology),
- clinical utility and significance of the test,
- recommended frequency of performing the test,
- clinical decision limits or reference intervals,
- performance characteristics of the PoCT instrument and its technical limitations,
- patient preparation and sample collection requirements (including correct preservative or anticoagulant),

- reagent preparation and storage,
- how to perform the test on the device (including calibration),
- how to interpret, report and act on PoCT results (including those outside the measuring range of the device and outside the predefined clinical decision limits for the test),
- the principles and practice of quality control and external quality assurance,
- maintenance and common trouble shooting,
- occupational health and safety issues including infection control practices, waste management and
- compliance with accreditation requirements (if appropriate).

The practical side of training should include a complete demonstration by the PoCT Lead on how to use the device and perform a test, how to run QC and EQA samples and how to perform basic maintenance procedures, followed by a hands-on practical session for each person.

POCT COMPETENCY

At the completion of formal training, trainee competency should be determined by written and practical assessment.

Trainee competency should be assessed in a practical sense by both the successful conduct of a routine PoCT test (not just the analytical part but the entire testing procedure) in the presence of the PoCT Lead and by a written assessment through a series of short questions to ensure key theoretical concepts have been grasped.

Successful trainees should receive a competency certificate at the completion of initial training.

A certificate of competency should detail a certificate number, the name of the trainee, summarise the competency skills obtained for the PoCT test(s) and device(s), have a fixed expiry date (generally one or two years from the date of issue), and be signed and dated by the training organisation.

Once the PoCT operator has commenced routine patient testing, the operator's competency should be regularly reviewed through a number of means including:

- Monitoring of performance obtained for quality control and external quality assurance testing.
- Participation in educational activities such as meetings, reading of educational material and conference attendance
- Retraining - especially when there are instrument/software updates
- Ongoing assessments which may include written and/or visual auditing of the Operators' processes
- Frequency of performing tests

Records of competency participation must be kept for all operators and reviewed annually.

Attendance at retraining sessions should be viewed as mandatory. These sessions may be conducted on-site, at regional workshops, at annual workshops or by videoconference if the organisation is geographically isolated. If a PoCT operator fails a competency review (for example because their QC/EQA performance has been poor, their level of testing activity has fallen below minimum requirements, or they exhibit a high rate of analytical errors with their testing), then they should be retrained before being recertified.

A register of all persons receiving initial and renewed competency certificates should be prepared and maintained by the PoCT Lead.

The maintenance of a competency register may be required by government contract or accreditation agency.

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QUALITY CONTROL

This section describes the general principles associated with how to set up and manage a PoCT quality control program in a healthcare centre.

Regular monitoring or checking of the quality of a PoCT device's testing (or 'analytical') performance is a mandatory part of the quality framework for PoCT. The quality checks are 'internal quality control (QC) and external quality assurance (EQA) testing. (The latter is covered in the next section). Every pathology laboratory in Australia is required to conduct QC (and EQA) testing as an integral and mandatory part of their laboratory accreditation. It is important that equivalent standards of practice are adhered to when conducting PoCT outside the laboratory.

The basic principles behind performing QC and EQA tests are similar. QC samples should be treated just like a patient sample. In general, instead of testing a patient sample, the test is done on an artificial sample provided either by the manufacturer of the PoCT device in the case of internal QC or by a registered external provider of quality assurance programs for external QA. Quality samples generally have an assigned or 'target' value for each PoCT test being measured and 'set' limits for acceptable performance around that target. Where artificial samples are not available direct patient comparison with an accredited laboratory method may substitute. Set limits for acceptable performance should still be in place.

When it comes to testing, the quality control sample is treated exactly the same as a patient sample. For most types of quality control testing, the QC sample is transferred to a testing receptacle (e.g. strip, cartridge, cassette, tube or similar) containing the reagents required for measuring the test, which is then inserted into the PoCT device, and the result is displayed on the device once the test is completed.

The QC kit, produced by the manufacturer, generally contains either one, two or three levels of QC corresponding to different concentrations of the test being measured. Where the manufacturer provides two QCs for example, one generally has a value or concentration in the 'normal' range while the other generally has a level or concentration in the 'pathological' range.

The results of QC testing can be compared on-site to assigned values and limits for acceptable performance that are set by the PoCT Lead and/or the vendor for each QC. Most PoCT devices will store QC results electronically, but it is also a good idea to manually record QC results on a result sheet, which lists these assigned values and limits for each QC; your PoCT Coordinator can assist with the design of an appropriate result sheet.

It is important to record the date on which the QC testing is performed, the operator's name (or initials) and, as a minimum, a comment concerning the acceptability or otherwise of the QC result. If the QC test result is outside the limits of acceptability, then a protocol for actioning such results should be developed (by the PoCT Coordinator). There are common rules outlining these actions, and advice on these rules can be provided by organisations such as APPN and AACB, or your PoCT vendor.

Having completed a QC test, the PoCT operator will be able to compare the results with the assigned value and the set QC limits and thereby obtain an immediate internal assessment of the PoCT device's performance and whether to proceed with patient testing.

The key performance indicator for QC testing is imprecision. As the number of QC sample results accumulates, it is possible to calculate the imprecision (or degree of reproducibility) of your QC testing on the PoCT device.

Imprecision, expressed as a coefficient of variation [CV%], is calculated using the formula:
 $CV\% = (\text{standard deviation [SD]}/\text{mean}) \times 100\%$

As a general rule, the lower the imprecision, the better the performance of the device.

Your local laboratory or your specialist PoCT provider can help you assess whether the performance of your device meets acceptable analytical standards, according to a set of internationally accepted analytical goals that exist for most laboratory tests, including some common PoCT tests.

FREQUENCY OF QC TESTING

The AACB Position Statement on PoCT states:

- A quality control sample must be tested with every new delivery of reagents.
- One quality control sample per month must be tested as a minimum requirement. In this case, it is recommended that the sample tested has a value in the pathological range of test values.
- Electronic QC can also check part of the PoCT testing process.

While the procedure outlined above is common to most PoCT devices, there are other forms of QC that can check selected parts of the PoCT testing process. Electronic QC, as its name suggests, assesses the electronic measurement circuitry of a PoCT device. It uses a surrogate material (such as a reference cassette, coloured filter, coloured solution or bar code) to generate an electric signal that would normally be produced by a sensor responding to an analyte in a patient sample. Thus, electronic QC only tests the 'reader' steps in the total testing process. It does not test the analytical process.

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EXTERNAL QUALITY ASSURANCE

This section describes the general principles for conducting external quality assurance (EQA) for PoCT. EQA may also be called proficiency testing.

PRINCIPLES

EQA is an essential part of assuring the quality of the testing process. It is a system designed to objectively assess the quality of results obtained by comparing the performance of different methods and different testing sites mostly in comparison to peers.

All participating PoCT users analyse an identical unknown specimen on their PoCT equipment and send the results to the EQA provider. The EQA provider sends a report to the health centre detailing their performance.

EQA complements internal quality control to help assure the PoCT operator and the patient that the test results are valid.

EQA PROVIDERS

EQA should be provided by a third party to the PoCT vendor to ensure objectivity in results. The EQA provider should be accredited to ISO/IEC 17043.

Where participation in an EQA program isn't practical, the PoCT user should participate in a split specimen program, where the same sample is analysed by PoCT and also by the normal laboratory method. The results of the 2 methods are then compared against preset acceptance limits to evaluate performance.

HOW TO PERFORM

The healthcare centre enrolls in an EQA program for the tests being performed. The QAP will periodically send specimens to the PoCT operator for testing. These are tested according to a time schedule (due date) and the results returned to the EQA provider. Each returned result is then compared with other participants results. A "target value" for results is set by the EQA provider. The healthcare centre then receives a report outlining how they compare with the "Target Answer" and/or their peers.

REVIEWING EQA PERFORMANCE

The PoCT Lead reviews this report which shows whether the analytical performance of the PoCT instrument is clinically acceptable and comparable to other users of this instrument. This report also allows long term monitoring of analytical performance allowing early detection of problems.

If required, corrective action must be taken. This may include the PoCT analyser being taken out of service or the operator being retrained. All corrective action must be documented.

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SAFETY AND WASTE DISPOSAL

This section describes safety issues to be considered when implementing PoCT in a clinical setting.

It is essential that the same standard of safety and waste disposal is observed for PoCT as in any laboratory, hospital ward or GP office.

The following procedures are for guidance and are not intended to replace the standards already established in any certified accreditation you have received for your work area.

SAFETY

All PoCT procedures should be performed in such a manner that there is no compromise to the safety or well being of the patient or device operator:

- The devices should be operated following the manufacturer's instructions
- Any electrical components should be checked for safety before the instrument is first used
- The device should be cleaned as per the manufacturer's instructions at the prescribed time or immediately after there has been any excess blood or body fluid contamination, and on a regular basis as advised by the manufacturer or local regulations.

HYGIENE

It is important to prevent the spread of possible infection at the PoCT location and hand washing is generally considered the most important measure to achieve this.

Hands should be washed:

- Using either plain soap or alcohol-based hand rub
- Before patient contact
- After patient contact
- After contact with body fluids irrespective of whether gloves are worn or not
- After removal of gloves

Gloves should be used as an adjunct to hand hygiene when taking samples for PoCT as contamination of hands with blood or body fluid can be expected. Gloves should be changed and hands washed between each patient.

DECONTAMINATION

The instrument work area should be cleaned daily and all blood and body fluid spills cleaned up immediately.

The work area should be kept clean by scrubbing with hot soapy water. This will remove rather than kill micro-organisms therefore strong scrubbing of the complete area is important.

Decontamination of the work area is necessary in the case of contamination from blood or body fluids. A more rigorous procedure is necessary using chlorine generating bleach (household bleach).

- Use a solution of 1 part bleach to 10 parts water
- Wear gloves
- Remove the bulk of the contamination using absorbent towels and soapy water
- Apply bleach
- Leave for 10 minutes
- Rinse and dry

SHARPS AND CLINICAL WASTE

Sharps are classified as discarded objects or devices capable of cutting or penetrating the skin, e.g. syringe needles, broken glass or hard plastic items and auto lancets. All sharps have the potential to cause injury through cuts or puncture wounds. In addition, many sharps are contaminated with blood or body fluids, posing a risk of infection or illness if they penetrate the skin. It is therefore essential to follow safe procedures when using and disposing of sharps. There should be appropriately sized, yellow, puncture resistant (impervious) sharps containers which conform to Australian Standard AS4031 Non-reusable containers for the collection of sharp medical items used in health care areas, or to Australian/New Zealand Standard AS/NZS 4261. Disposal containers should be located close to where sharps are generated and in accordance with infection control guidelines. All sharps containers must be checked at least weekly and replaced when they have reached the marked fill line. All full sealed containers must be removed from the premises and disposed of by approved contaminated waste contractors.

WASTE DISPOSAL

It is the responsibility of everyone involved in PoCT to ensure the safe and correct disposal of all wastes produced in the course of their work. Improper and irresponsible disposal of wastes down drains, to the Local Authority refuse collection, or into the atmosphere is strictly forbidden by law. Storage and disposal of any dangerous materials should be undertaken in accordance with NHMRC guidelines for National Guidelines for Waste Management in the Health Care Industry. Sample collecting lancets and reagents (cuvettes/strips) should be considered as hazardous 'sharps' and disposed of in an approved sharps container. Each individual device operator is responsible for the 'sharps' they have used.

Other waste material such as tissues or swabs contaminated with blood or body fluid should be disposed of in an infectious material plastic bag (yellow) and incinerated.

Appropriate Personal Protective Equipment should be a consideration when handling waste, with reference to the relevant Material Safety Data Sheet (MSDS).

FURTHER READING

Garner J, Favero M (1985) 'Guidelines for Hand Washing and Environmental Control', CDC Guidelines for the Prevention and Control of Nosocomial Infections.

McGill Laboratory Biosafety Manual Second Edition, 1997.

www.hoslink.com/sterilisation.htm

NH&MRC Document 'National Guidelines for Waste Management in the Health Industry' endorsed March 1999. NHMRC Publications Department.

3rd Edition RACGP Sterilisation/disinfection Guidelines for General Practice www.nhmrc.health.gov.au

PoCT in General Practice Trial, Training Manual for Point of Care Devices. Australian Government Department of Health and Ageing, 2006

SOURCES OF ERRORS

This section describes potential sources of errors that could influence the quality of PoCT results.

PoCT errors may be device specific or due to preanalytical or postanalytical errors.

After selecting a PoCT device, the first step in ensuring high quality PoCT is to develop written procedures that are easy to follow by non-laboratory personnel. It is also important to note that the written procedure should reflect both the recommendations of the manufacturer and those of the individual PoCT site.

Sources of error include not following the manufacturer's instructions, using out of date reagents, inadequate recording of results, and no QC or EQA.

The likelihood of errors occurring will be reduced by:

- Properly identifying the patient and/or testing personnel
- Correct sample collection
- Checking that reagents have not exceeded use by dates
- Conduct the analysis according to the manufacturers' instructions
- Performing quality control (QC) and external QA at appropriate times
- Reviewing QC/EQA results
- Responding appropriately to out-of-control situations
- Documenting results in the patients' records
- Regularly evaluate operators' ongoing competency
- Observing all safety requirements

Many of these sources of errors can easily be avoided or eliminated by selecting test devices that incorporate appropriate safeguards.

SPECIMEN COLLECTION

The same precautions that apply for specimens being sent to the laboratory also apply for PoCT specimens. Furthermore the quality of capillary or fingerprick blood samples has a critical impact on results so training in such collection techniques is essential.

COLLECTION OF CAPILLARY SAMPLES

Potential sources of errors in sample collection include:

- Shallow skin puncture leading to a slow blood flow
- Not using the correct drop of blood, according to the manufacturer's instructions'
- Squeezing too hard
- Scooping blood along the skin as it dribbles from the puncture site
- "Milking" the heel or digit
- Puncturing in an awkward spot
- Collecting blood which has been smeared away from puncture site
- Incorrect or inadequate filling of the sample collection device e.g. allowing air in or underfilling
- Taking too long to apply the drop of blood'

COLLECTION OF ARTERIAL SAMPLES

The collection of arterial blood samples is technically difficult and is most sensitive to preanalytical errors. Improper collection or handling of arterial blood can lead to erroneous pH and blood gas results.

Potential sources of errors in arterial sample collection include:

- Presence of air bubbles in sample
- Room air contamination
- Failure to mix sample before analysis
- Haemolysis
- Failure to remove first drops of blood before analysis
- Use of the wrong type or amount of anticoagulant
- Analysis delay

INFORMATION TECHNOLOGY

Information Technology (IT) is becoming increasingly important in all areas of medicine and no less so than for PoCT.

DATA CAPTURE AND REPORTING RESULTS

Studies have shown that a high proportion of errors in laboratory medicine occur in the pre- and post- analytical phases of the testing process.

The results obtained from PoCT testing should at least be recorded but more appropriately, become part of the patient record. By its nature, PoCT should be used for tests where the result can be acted upon immediately however this often leads to the results being discarded and not retained in the patient file.

An international standard is available for connectivity and many organisations will only introduce PoCT devices that can be networked to the Clinical Software Package or Hospital Information System (HIS) or information systems in general.

ESSENTIAL IT CAPABILITY CHARACTERISTICS OF POCT EQUIPMENT

- Bidirectional data communication – communication from device to software and software to device
- Use existing infrastructure – an instrument that utilises existing communication infrastructure to capture/transfer results will save money on rewiring. It is highly desirable that all PoCT results be transferred electronically to an appropriate database. Wireless connectivity for PoCT devices could be added to an IT wish list which might include:
 - » Security of data and access is essential to ensure patient confidentiality. If results are to be transferred to outside users intranet encryption of results should be considered.
 - » Device should be plug and play – i.e. be able to connect to any database/LIS/HIS system.
 - » Device should use common docks, ports and wiring for communication.
 - » Allow scanning of patient barcode if available to enter patient information.
 - » Allow regular monitoring of QC data to evaluate system performance.

LEGISLATIVE REQUIREMENTS

This section describes current legislative requirements for pathology testing in Australia.

Pathology in Australia is administered under the Health Insurance Act (1973) and under this Act, laboratories must be accredited if their services are to be eligible to receive a Medicare benefit. The National Pathology Accreditation Advisory Council (NPAAC) is responsible for the development and maintenance of standards and guidelines under which pathology laboratories are accredited.

The role of NPAAC includes:

- Developing policy for accreditation of pathology laboratories;
- Introducing and maintaining uniform standards of practice in pathology laboratories throughout Australia;
- Adopting coordinated legislation and administrative action in providing pathology services;
- Initiating, promoting and coordinating educational programs in relation to pathology laboratory practice.

A list of NPAAC standards and guidelines is available at:

<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-index.htm>

Currently there are two sets of draft Australian standards or guidelines for PoCT being finalised.

The first set have been drafted by NPAAC and are available at:

[https://www1.health.gov.au/internet/main/publishing.nsf/Content/35DE5FC4786CBB33CA257EEB007C7BF2/\\$File/Guidelines%20PoCT%201st%20Ed%202015.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/35DE5FC4786CBB33CA257EEB007C7BF2/$File/Guidelines%20PoCT%201st%20Ed%202015.pdf)

These standards which have been available since 2015, are going through an extensive revision but are anticipated to be finalised by the end of 2019.

A second set of standards have been prepared by the Royal Australian College of General Practitioners (RACGP) and are available at: <https://www.racgp.org.au/running-a-practice/practice-standards/standards-for-other-health-care-settings/view-all-health-care-standards/point-of-care-testing>

Both sets of standards document the required quality processes that have been described in this Implementation Guide. They do not differ significantly and it is likely that they might eventually be unified into a single set of standards which should guide the conduct of all PoCT in Australia.

At the present time a considerable volume of PoCT is being conducted without accreditation in both the primary and secondary care sectors and, aside from concerns about the quality of some of this testing, none of it can be charged to the Medical Benefit Schedule.

A small number of GPs (<20) have set up what are called M class laboratories and been accredited through the usual laboratory based, NATA certified system and accordingly can charge such testing to the MBS.

HELP/SUPPORT

This section describes potential sources of help and support for healthcare centres performing PoCT.

The quality of PoCT results is tied to the ability to perform the test correctly. Many people consider PoCT products to be very easy to use and “idiot-proof”. There is no doubt that devices have become simpler to use such that they can be used by non-laboratory trained personnel but there is no such thing as an idiot-proof device. Thus managers of PoCT services need to ensure that the necessary help and support required to maintain a continuous quality service is provided to operators. Since the operators of PoCT devices are predominantly non-laboratory based or trained their needs are different and therefore PoCT support is critical. Support or help here is defined as the availability of information to the user during routine day to day operations and following introduction and implementation of the PoCT device

A partnership is required between the key stakeholders which may include the supplier, the pathology laboratory, other PoCT support network, and the end user to provide assistance as required and in a reasonably short timeframe. Australian and overseas regulatory authorities now require that PoCT manufacturers supply users with simple to follow instructions for use as well as appropriate specifications to ensure the system operates according to the intended use. Suppliers are encouraged to actively partner with the end users to achieve an uninterrupted service, and users are encouraged to liaise with APPN for further independent support.

In Australia, most PoCT suppliers have established Call Centres with the specific aim of answering any questions raised by PoCT users or laboratory staff acting on behalf of the end user. Such Call Centres are well equipped with knowledgeable staff that have been trained to respond to enquiries regarding issues concerning their specific products. In addition, most Australian PoCT suppliers are also prepared to provide support in areas such as additional training and formal documentation about their products. Many Australian PoCT suppliers have useful training material available in the form of CD, DVD or on dedicated websites covering many areas such as basic instrument usage, maintenance and basic troubleshooting.

Help/support may be required with the following:

- Routine operation of the POCT device
- Material management
- Quality control and quality assurance review
- Basic troubleshooting in obtaining a reliable result

- Identification of pre- and post-analytical effects that may have affected results
- Failure of the device to meet specifications
- Understanding analytical requirements and fitness for purpose

One of the greatest challenges in running an effective PoCT program is to ensure end users can easily distinguish problems resulting from lack of training, analytical and non-analytical issues. Support for this may be sought from several sources to provide external advice and guidance such as; local laboratory, APPN, RACGP PoCT Standards, AACB, and your PoCT supplier. This support can include:

- Maintaining contact with relevant POCT users (both those involved with the actual testing as well with those using the results for patient management) to ensure their needs are met
- Provide regular feedback on area-specific quality assurance performance as well as other communication items (e.g. changes to product specifications, material management, etc)
- Consider preparation of documentation of “Frequently Asked Questions”. Most PoCT manufacturers will also be happy to assist in the preparation of such material
- Regular visits to the PoCT sites in order to raise the profile and establish trust with the end users
- Provide appropriate contact details

It is important that healthcare centres take the time to establish a good working relationship with their local laboratories who can be a significant source of knowledge and support for healthcare centres performing PoCT and likewise laboratories should in turn become active in supporting healthcare centres performing PoCT.

Patients will be managed via a combination of PoCT and laboratory test results so PoCT users need to work with pathology laboratories to understand the potential differences that can arise from the two sources of results and patient care is not compromised when such results are compared.

PoCT users should make use of the resources of professional organisations such as the Australasian Association of Clinical Biochemists (AACB) who through its PoCT Working Party, is committed to developing educational materials and organising educational meetings for healthcare providers with an interest in PoCT, and the APPN which is set up to support users of PoCT.

RECOMMENDED REFERENCE MATERIALS

Clinical and Laboratory Standards Institute. Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline—Second Edition. Clinical and Laboratory Standards Institute document POCT4-A2 (ISBN 1-56238-618-2).

Price CP, St John A, Hicks JM. Point-of-Care Testing, 2nd edition, Washington DC: AACC Press, 2004

Price, Christopher P., St John, Andrew “Point-of-Care Testing for Managers and Policymakers: From Rapid Testing to Better Outcomes.” 2006 AACC Press ISBN: 1-59425-051-0

Shephard, Mark, A practical guide to Global Point-of-Care Testing. CSIRO Publishing (ISBN: 9781486305186)

