Australasian Association of Clinical Biochemists

Point of Care Testing

Implementation Guide

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AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS (AACB)

Founded in 1961, the Australasian Association of Clinical Biochemists Inc (AACB) is the professional society for practicing clinical biochemists in Australia and New Zealand and is a member of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and Asian and Pacific Federation of Clinical Biochemistry (APFCB).

The Association promotes professional excellence through an active educational program, continuing professional development opportunities and professional advocacy. It offers professional qualifications by examination (MAACB & FAACB) to encourage those engaged in this field to pursue advanced studies so as to more effectively render service to the public.

The AACB also has initiated the introduction of Lab Tests Online (www.labtestsonline.org.au) to Australia, an educational service designed for both medical referrers and the general public.

AACB activities are organised at both a local branch level and at a national level. Branch meetings provide a venue for a variety of presentations, which include original scientific work and educational material from both local and invited speakers. Activities coordinated at a national level include; the Annual Scientific Conference, Current Concepts Lectures, Roman Lectures, the annual education course organised in association with the Royal College of Pathologists of Australasia (RCPA), and various specialist meetings and advanced workshops. These may take the form of Scientific Education Seminars organised by the Scientific and Regulatory Affairs Committee (SRAC). This committee oversees a number of Working Parties including Point of Care Testing (PoCT).

Members of the AACB have expertise in PoCT and believe that this application of diagnostic pathology can make significant and positive medical, economic and social contributions to the health of the community when used appropriately. The AACB PoCT Working Party has amongst its members individuals who can provide expertise in PoCT both within and outside the laboratory. Through the Working Party, the AACB has become a valuable resource for both laboratory and non laboratory PoCT users. The AACB believes it has a responsibility to make this knowledge and expertise available to ensure such technology is used safely and effectively.
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ABBREVIATIONS

AACB
Australasian Association of Clinical Biochemists

PoCT
Point of Care Testing

EQA
External Quality Assurance

GP
General Practitioner

INR
International Normalised Ratio

IT
Information Technology

NPAAC
National Pathology Accreditation Advisory Council

LIS
Laboratory Information System

HIS
Hospital Information System

QA
Quality Assurance

QC
Quality Control
BACKGROUND

Point of Care Testing (PoCT) is now performed in a wide variety of locations outside of the laboratory including GP surgeries, nursing clinics, pharmacies and within the home. Given this diversity, for the purposes of this Implementation Guide we will use the generic term healthcare centre for the location of any PoCT practice.

Both the clinical demands for more rapid results and technological advancements leading to simpler, easy to use instruments have been the main driving forces behind more testing being performed outside of the laboratory and at the point of patient care.

The advantages of PoCT have been reported as:

• Simpler sample collection in some cases
• Simpler pre-analytical processes including reduced time between collection and analysis
• More rapidly available test results leading to more timely treatment
• Greater satisfaction for the patient

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

• Introduction without proper examination of clinical need
• Increased workload
• Errors due to lack of expertise and insufficient quality control
• Problems of comparability of results 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 output

It is probably fair to say that clinicians demanding quicker results and vendors of PoCT equipment will tend to focus on the advantages of PoCT and pay less attention to some of the disadvantages. To overcome these, requires significant resources, a scarce commodity in the current healthcare environment. Thus careful consideration should be given to the clinical need for PoCT before making a decision to embark on this type of testing. The fundamental question to ask is will the improvement in outcomes for the patient outweigh the costs of PoCT in terms of time and money?
In weighing up the advantages and disadvantages of this type of testing it is important to always remember that PoCT must be conducted within a framework of quality standards so as to ensure that the quality of results is as close as possible to those performed by a traditional pathology laboratory.

Much has been written about how to conduct PoCT, but the majority of this literature is intended for those trained in laboratory medicine. The purpose of this guide is to assist all potential users of PoCT but with a particular emphasis on those without a laboratory background who are interested in implementing PoCT in their healthcare centre. It will be relevant to a wide variety of locations except self-testing or testing by patients in their home. While this is one of the fastest growing areas of PoCT, it presents its own unique issues which will not be discussed in this document.
PoCT REQUIREMENTS

The organisational requirements that should be considered when introducing PoCT include:
• Identification of clinical needs
• Prepare a detailed specification
• Analysis of costs and benefits including eligibility for reimbursement
• Conduct a literature search for evaluations of appropriate instruments for clinical purpose
• Evaluate appropriate equipment and reagents
• Ensure if possible electronic capture of results
• Ensure availability of technical support
• Purchase all necessary testing equipment and consumables
• Produce a user manual
• Train and certify all PoCT users
• Document the performance of all quality control procedures
• Enrol in an external quality assurance program
• Document any problems and corrective actions
• Provide continuing education and recertification for device operators
• Regularly audit all processes and any actions taken

It should be recognised that PoCT will be carried out by a variety of healthcare personnel, many of whom do not have formal training in quality control and interpretation of results. Therefore they do not have the expertise to assess the quality of results produced by the PoCT device. Thus 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 doing the actual 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. The direct costs of PoCT are greater than usual laboratory testing but this may be offset by indirect savings from improved outcomes such as more rapid lifesaving treatment, reduced bed occupancies and avoidance of other expensive procedures such as triage to major hospitals.
ORGANISATIONAL STRUCTURE

There should be a systematic approach to the introduction of PoCT which includes all stakeholders. It is not uncommon for PoCT equipment suppliers to go directly to potential user, followed by an immediate decision to purchase and institute PoCT, without an appropriate needs analysis and evaluation of equipment. This ad hoc approach is potentially expensive and dangerous in terms of patient safety. To avoid this situation, any healthcare centre should identify one person who will be the PoCT Coordinator who will have the responsibility for the assessment of needs, implementation, conduct, quality and accreditation of PoCT.

Once PoCT has been introduced, the same PoCT Coordinator will also be responsible for the ongoing performance of the systems including checking quality control, performing calibrations when necessary, coordination and review of external quality assurance programs, periodic comparisons with the laboratory methods and providing assistance to all PoCT users. PoCT should become an agenda item at the healthcare centre’s regular meetings to ensure that all facets of the PoCT service are discussed by all those involved with delivering the service.

Minimum Requirements for PoCT

The following are suggested as minimum requirements for any PoCT service:
1. Appropriately qualified designated authority acceptable to all stakeholders 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. Type of PoCT selected should meet clinical requirements.
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.
There should be a process in place for routinely monitoring instrument performance, including quality.

Medical alert/critical/panic values must be defined and communicated immediately to the appropriate carer. Complete, accurate and timely records of patient results should be maintained. Wherever possible, electronic transfer of PoCT results should be implemented.

Backup and/or confirmatory testing procedures should be identified.

In summary, PoCT is part of the diagnostic assessment and management of a patient and should not be treated differently from normal laboratory testing. The devices should form part of a quality system to ensure the quality of results and, if possible, should also be part of an accreditation process.

Further Reading


**SELECTION OF ANALYSERS**

There is a wide variety of PoCT equipment available, measuring a range of tests or analytes from most of the pathology specialities. They range from very expensive highly sophisticated units, equally suitable for daily laboratory use, to the simple glucose meter. For the uninitiated, the sheer number and diversity of instruments can lead to confusion, incorrect decisions, and inappropriate applications. This can result in wasted money and a lost opportunity to improve patient care. The following section offers some simple rules and advice to help with the selection of PoCT equipment.

The following are desirable characteristics of PoCT equipment:
- Sufficient space availability – 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 type – whole blood is preferable for PoCT
- Sample volume – will you be testing paediatric patients?
- Expiry date of consumables – will you be performing sufficient tests to 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 will be used to assess the same patient
- Connectivity – can results be transferred electronically to patient records?
- Barcode capability for patients, operators and consumables
- Precision and accuracy should be appropriate for the clinical need
- Portability - will you need to move PoCT equipment and if you do, 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 control, quality assurance materials and connectivity costs) affordable?
- Are training and/or training materials provided by the supplier?
• Is there a supplier Helpline?
• Reliability of supply

PoCT Stakeholders Planning Process
Prior to purchase of PoCT equipment, it is recommended that all those with involvement in PoCT, namely the PoCT stakeholders, are part of the planning process. This group (in a hospital or clinic setting) might include, in addition to a PoCT specialist, or specialist in the area under consideration for testing, representatives from the following groups:
• End Users (to state their needs and wants)
• Biomedical engineering (information on analyser design issues)
• Information Technology staff (advice on software interfaces and functionality)
• Organisational Quality staff (registration, certification requirements)
• Purchasing / contracts officer (optional, depending on local practice)
• Representative from local pathology laboratory

It may be necessary to add a purchasing officer to ensure that supply contracts, particularly for multiple instruments, are properly negotiated.

The goal of this planning team is to choose the best possible equipment for the testing purpose. A time frame should be set that is in keeping with the scope of the project. Representation can be made to manufacturers to demonstrate and supply suitable evaluation instruments. When a product is selected 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.

Further Reading
Accuracy and Precision Wikipedia
http://en.wikipedia.org/wiki/Accuracy

**STAFF TRAINING AND COMPETENCY**

PoCT should only be carried out by healthcare staff that have undergone appropriate initial training and competency certification, who have their competency levels regularly assessed.

**PoCT Coordinator**

PoCT training should be organised by a PoCT Coordinator, who ideally should be an experienced medical scientist from a hospital, laboratory or specialist PoCT service provider background. The responsibilities of PoCT Coordinator includes overall supervision and management of the PoCT activity, and 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.

Training should be delivered by the PoCT Coordinator or his/her appointed representatives, who may include for example regional trainers, additional support staff from the pathology laboratory or specialist PoCT provider and/or the vendor of the PoCT device.

**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.

In a non-hospital setting, prospective PoCT operators are unlikely to have had access to any previous formal training in laboratory medicine (including quality control and external quality assurance) and therefore it is important for the PoCT Coordinator to translate scientific and analytical concepts into simple messages that can be readily understood by non-laboratory health professionals.

Laminated posters with simple step-by-step instructions to consolidate detailed information on how to perform a PoCT test on a patient and how to conduct quality management (QC and EQA) testing procedures into a practical, workable format can also be used effectively as part of a training package.
Training Curriculum
Training should cover both the theory and practice of conducting PoCT and include the following aspects as a minimum requirement:

• Setting the clinical scene (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
• Compliance with accreditation requirements (if appropriate)

The practical side of training should include a complete demonstration by the PoCT Coordinator (or primary trainer) of 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. The practical session should be conducted in small groups to enable each trainee to experience using the PoCT technology in a practical ‘hands-on’ sense and gain confidence prior to commencing patient testing.

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 (ideally the entire testing procedure not just analytical) in the presence of the PoCT Operator 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.

Post training surveillance of competency should be undertaken by regular review of quality control and quality assurance testing results.

Once the PoCT operator has commenced routine patient testing, the operator’s competency should be regularly reviewed by the monitoring of performance obtained for quality control and external quality assurance testing.

Competency should be formally and regularly reviewed through retraining and participation in education updates.

Attendance at retraining sessions should be viewed as mandatory. These sessions may be conducted on-site, at regional workshops, at annual workshops or possibly 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 Coordinator.

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

**Further Reading**


The conduct of quality control testing should be a mandatory component of a PoCT program. An essential part of conducting routine PoCT is the regular monitoring or ‘checking’ of the quality of a PoCT device’s testing (or ‘analytical’) performance. ‘Quality checks’ that should be mandatory components of all PoCT programs are ‘internal quality control (QC)’ and ‘external quality assurance (EQA)’ testing. (The latter will be 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.

QC samples should be treated just like a patient sample.

The basic principles behind performing QC and EQA tests are similar. 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 (internal QC) or by a registered external provider of quality assurance programs (external QA). This sample has 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 QC samples 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 for each QC. As stated, each QC has an ‘assigned value’ (set by the manufacturer) and what is called ‘limits for acceptable performance’ (set by the PoCT Coordinator and/or the vendor). 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 value 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).

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 the testing system’s suitability to continue.

The key performance indicator for QC testing is imprecision. As the number of QCs tested builds up, 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:

\[ CV\% = \left( \frac{\text{standard deviation [SD]}}{\text{mean}} \right) \times 100\% \]

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, as there are a set of internationally accepted analytical goals 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
- 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.

Further Reading

EXTERNAL QUALITY ASSURANCE

Principles
External Quality Assurance (EQA), sometimes referred to as Proficiency Testing, 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. This comparison between different testing sites is often referred to as peer comparison.

All participating health centres 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 programs are provided by suppliers known as quality assurance programs (QAP). For example: www.rcpaqap.com.au or www.bio-rad.com.

How to Perform
The health centre enrols in the QAP’s EQA program for the tests being performed. The QAP will periodically send multiple specimens to the PoCT operator. These are tested according to a time schedule and the results returned to the QAP. The QAP compares each health centre’s results with other participants and/or a “correct answer” and sends a report to the health centre which shows this comparison.

Who Performs the EQA
The EQA samples should be assayed in the same manner as a patient sample. Therefore the PoCT operator who performs the patient samples should run the EQA samples.

Reviewing EQA Performance
The PoCT Coordinator 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 should be taken. All corrective action should be documented.
**Further Reading**


AACB Point of Care Testing Position Statement
http://www.aacb.asn.au/web/Resources/
Standards for Point of Care Testing in General Practice Quality Management for Unit-Use Testing; Approved Guideline CLSI EP18A Vol22 No.28.

SAFETY AND WASTE DISPOSAL

It is essential that the same standard of safety and waste disposal is observed for the PoCT location as for any other laboratory, hospital ward or other healthcare centre. The following procedures are for guidance and are not intended to replace the standards already established in any certified accreditation that previously exits for the location where POCT is performed.

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 using the manufacturers instructions
• Any electrical components should be checked for safety before the instrument is first used
• The device should be cleaned as per the manufacturers instructions at the prescribed time or immediately after there as been any excess blood or body fluid contamination

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

**Waste Disposal**

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.

**Further Reading**


www.hoslink.com/sterilisation.htm


**Sources of Errors**

Errors in PoCT may occur before the analysis (preanalytical), during the analysis or device specific or after the analysis (postanalytical).

After selecting a PoCT device, the first step in ensuring high quality PoCT is to develop written procedures that are easy to follow by the users. 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.

The main sources of error include not following manufacturer’s instructions, using out of date reagents, inadequate recording of results, and no QC or EQA.

To avoid or reduce the likelihood of errors occurring:
- Follow manufacturers’ instructions
- Check outdated/expired reagents
- Ensure correct sample collection
- Properly identify the patient and/or testing personnel
- Perform quality control (QC)
- Perform external QA
- Review QC/EQA
- Respond to out-of-control situations
- Document the results in the patients’ record
- Evaluate operators’ ongoing competency
- Observe safety requirements

Many of these sources of errors can easily be avoided or eliminated by selecting test devices that incorporate appropriate safeguards. These vary between instruments but better designed ones are password protected from untrained operators, minimise operator interactions so that internal process checks, error checks and even quality control procedures proceed automatically and come with full electronic connectivity so that results can be recorded and transmitted to the desired location without manual transcription.

**Specimen Collection**

In PoCT, the quality of the specimen is known to have a significant effect on results, and training in collection techniques such as finger stick collection is essential. As with other diagnostic testing, even though PoCT is being performed near to the patient, there should be in place the same quality of specimen collection as exists for laboratory testing.
Collection of Capillary Samples

Proper collection of capillary puncture specimens is essential for accurate laboratory test results.

Potential sources of errors in sample collection include:
• Shallow skin puncture leading to a slow blood flow
• Failure to wipe away the first drop of blood
  Note: Some procedures such as INR require the use of the first drop of blood. Follow manufacturer’s instructions at all times.
• 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

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
• Failure to mix sample before analysis
• Haemolysis caused through excessive suction pressure during collection
• Failure to remove first drops of blood before analysis
• Use of the wrong type or amount of anticoagulant
• Delay in the analysis after collection
INFORMATION TECHNOLOGY

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 impact of Information Technology (IT) is predominantly on the post-analytical phase.

The results obtained from PoCT testing should at least be recorded but more appropriately, become part of the patient record. While PoCT should be used for tests where the result can be acted upon immediately, this does not mean that the results should be discarded; retention in the patient file remains essential.

An international standard is available for facilitating the connectivity of PoCT devices to information systems and many purchasing organisations will only introduce PoCT devices if that connectivity can be achieved.

IT is also integral to the PoCT device itself including software that requires operator identification, patient information scanning and quality control checks before the system can be operated.

Desirable IT Related Capabilities of PoCT Equipment
The following list includes features which are not possible on older legacy devices but are becoming more readily available on newer instruments.

• Bidirectional data communication to allow patient data to be downloaded to the device and results matched with patient data to be fed back to the information system
• Use existing infrastructure – an instrument that utilises existing communication infrastructure to capture/transfer results will avoid the costs of changing or upgrading the existing network. It is highly desirable that all PoCT results be transferred electronically to an appropriate database
• Wireless connectivity for PoCT devices is now available and allows more flexibility where devices are used
• Security of access and data is essential to ensure patient confidentiality. If results are to be transferred to outside users, intranet encryption of results should also be considered
• Devices should be “plug and play” in that they can be connected to any database/LIS/HIS system
• Device should use common docks, ports and wiring for communication
• Ability to scan patient barcodes to facilitate entry of patient information
• Allow regular monitoring of QC data to evaluate system performance
**LEGISLATIVE REQUIREMENTS**

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


Currently in Australia there are no mandatory standards or guidelines written specifically for PoCT and it is up to individual organisations to develop a framework under which PoCT is carried out. By its very nature, PoCT is generally carried out outside of the laboratory or organisation with which it is associated. One of the issues limiting the quality framework for PoCT is that under current legislation unless these “external” PoCT sites are located within the campus of the host laboratory, they must be accredited as stand alone facilities and not under the accreditation of the host laboratory. For many PoCT sites that only do a limited number of tests, this is not economically viable and consequently, the majority of PoCT sites are not accredited. The dilemma is that these sites would benefit most from being part of a quality system.
HELP/SUPPORT

The quality of PoCT results is directly related to the ability to perform the test correctly. Many people consider PoCT products to be very easy to use and “fool-proof” but there is no currently available device that meets this goal. 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 often not laboratory based or trained their needs are different and ongoing support is essential.

How such support is provided will depend upon the individual situation. Formation of a partnership between the supplier, the pathology laboratory and the end user can provide valuable assistance to PoCT users. 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.

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
• Management of consumables and reagents
• Review of quality control and quality assurance results
• Basic troubleshooting as part of obtaining a reliable result
• Identification of pre and post-analytical effects that may have affected results
• Determining causes of failure of the device to meet specifications

One of the greatest challenges in running an effective PoCT program is to ensure that end users can easily distinguish problems resulting from lack of training, analytical and non-analytical issues.
Support should be available from a coordinating or partnering laboratory by implementing or managing a number of programs including:

- Maintaining contacts 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 being 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 providing “Frequently Asked Questions”; most PoCT manufacturers will be happy to assist in the preparation of such material
- Regular visits to the PoCT sites in order to ensure involvement and establish trust with the end users
- Provide appropriate contact details

Local pathology laboratories are a huge source of knowledge and support for health centres performing PoCT. It is important that healthcare centres take the time to establish a good working relationship with their local laboratories. Pathology laboratories should in turn become active in supporting PoCT users. One major issue where collaboration between PoCT users and laboratories is essential is to resolve occasional but inevitable differences between PoCT and laboratory results on the same patient.

Health centres should make use of the resources of professional organisations such as the Australasian Association of Clinical Biochemists (AACB). The AACB recognises the importance of PoCT in Australasia through its PoCT Working Party which is committed to developing educational materials and organising educational meetings for healthcare providers with an interest in PoCT.

Improving patient care is the ultimate aim of all carers. PoCT performed in a framework of quality standards has the potential to improve both the management of chronic disease in primary care and acute care in remote sites.

The aim of all diagnostic testing is to produce information which can be used with confidence to manage patient care.
**RECOMMENDED REFERENCE MATERIALS**


