RACGP

Royal Australian College of General Practitioners

Standards for point-of-care testing

5th edition

racgp.org.au

Healthy Profession.
Healthy Australia.

Introduction

About the standards

About the standards

The Royal Australian College of General Practitioners (RACGP) has developed the *Standards for point-of-care testing* (updated 5th edition) (Standards for PoCT) to:

- improve the quality and safety of point-of-care testing (PoCT) performed by health services
- help services identify and address any gaps they have in their systems and processes.

The Standards for PoCT is a module of the RACGP *Standards for general practices* (https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed-1) (5th edition), and must be read in conjunction with those standards.

The Standards for PoCT is included as an appendix to the National Pathology Accreditation Advisory Council (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards/national-pathology-accreditation-advisory-council) (NPAAC) *Requirements for point of care testing (Second Edition 2021)*.

Definitions of terms used in this document.

Definition and benefits of PoCT

In this document, Point of Care Testing (PoCT) is defined as testing performed outside the laboratory environment, near to or at the side of the patient, which is not done under the supervision of a trained laboratory professional.[1] [1] (#_ftn1)

The potential benefits of PoCT include:

- healthcare practitioners' ability to make immediate and informed decisions about a patient's care, together with the patient, which may result in improved clinical management
- greater patient compliance with pathology requests, especially in at-risk patients
- greater convenience and satisfaction for patients because of the speed of diagnosis, management and treatment decisions
- more equitable access to pathology, regardless of where patients live
- more opportunities for patients to engage with the practice team.[2,3]

[1] (#_ftnref1) It is not necessary for a practice to be accredited against the Standards for PoCT to claim simple basic pathology tests (MBS Group P9) with the exception of MBS items 73812 or 73826.

Why do we need the Standards for PoCT?

Why do we need the Standards for PoCT?

The sophistication and reliability of the technology for PoCT systems and instruments have improved markedly in recent years, making PoCT more accessible for general practices.[4] Fit-for-purpose standards relating to the use of PoCT in general practices will ensure that PoCT contributes to the overall safety and quality of care provided in the practice.

Development of the Standards for PoCT

Development of the Standards for PoCT

These standards were developed and reviewed by the RACGP in consultation with general practitioners, practice managers, nurses, consumers, technical experts and other stakeholders. The RACGP gratefully acknowledges the generous contribution from members of the RACGP working group – Point-of-Care Testing:

- Dr Tim Senior (Chair)
- Dr Trina Gregory
- Dr Robert Menz
- Rosy Tirimacco (Technical expert)

Definition of a general practice that performs PoCT

Definition of a general practice that performs PoCT

In order for a practice or health service to seek accreditation:

- it must provide comprehensive, patient-centred, whole-person and continuous care; and
- its services must be predominantly* of a general practice nature.

* more than 50% of the practice's general practitioners' clinical time (ie collectively), and more than 50% of services for which Medicare benefits are claimed or could be claimed (from that practice) are in general practice.

The definition exists solely to identify services eligible to be assessed as a general practice against the RACGP *Standards for general practices* (the Standards) by an accreditation agency approved under the Australian Commission on Quality and Safety in Healthcare's National General Practice Accreditation Scheme. This definition is for the assessment of the environment and systems of quality and safety. There will be some services that are eligible to be accredited against the Standards but that may not be appropriate as training practice locations or eligible for entry into a training program.

The general practice, once acknowledged as meeting the definition, must still meet all mandatory indicators in the RACGP *Standards for general practices* (5th edition) to be accredited.

Accreditation of a general practice that performs PoCT

Accreditation of a general practice that performs PoCT

For a practice to be accredited against the Standards for PoCT:

- the practice must be accredited against the *Standards for general practices* (5th edition)
- the practice must be formally assessed against the Standards for PoCT by an accrediting agency approved under the National General Practice Accreditation Scheme (the Scheme), which commenced on 1 January 2017; a list of approved accrediting agencies can be found here (https://www.safetyandquality.gov.au/our-work/general-practice-accreditation/#Approved-accrediting-agencies)
- the PoCT accreditation visit can occur concurrently with or after the general practice accreditation visit.

In these Standards, a PoC Practitioner is any employee or contractor in the service who performs PoCT, including Practice Nurses

Surveyor teams

Surveyor teams

A surveyor team will conduct accreditation visits to assess the practice against the Standards for PoCT.

Each surveyor team comprises at least two surveyors:

- an appropriately qualified GP surveyor
- an appropriately qualified nurse, practice manager, allied health professional or Aboriginal and Torres Strait Islander health worker/health practitioner with relevant experience in general practice.

At least one member of the surveyor team must have practical expertise in PoCT and extensive knowledge of the Standards for PoCT in general practice.

The RACGP's Resource guide

The RACGP's *Resource guide*

The RACGP's *Standards, 5th edition: Resource guide* (https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/resource-guide) contains useful supplementary information that will help practices meet the Indicators in the Standards for PoCT.

PoCT and the Australian Register of Therapeutic Goods

In Australia, PoCT devices and systems are categorised as *in-vitro* diagnostic medical devices (IVDs) and are therefore regulated as a subset of medical devices by the *Therapeutic Goods Administration* (https://www.tga.gov.au/) .

The *Australian Register of Therapeutic Goods* (https://www.tga.gov.au/resources/artg) (ARTG) lists therapeutic goods that can be legally imported into Australia, or supplied for use in Australia, or exported from Australia.

Unless a specific exemption has been granted, it is a criminal offence under the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2017C00226) to import into, supply in or export from Australia a medical device that is not listed on the ARTG.

The Standards for PoCT assume that your practice's PoCT devices or systems, including but not limited to consumables, reagents, controls and software, are listed on the ARTG.

PoCT and the Australian Register of Therapeutic Goods

PoCT and the Australian Register of Therapeutic Goods

In Australia, PoCT devices and systems are categorised as *in-vitro* diagnostic medical devices (IVDs) and are therefore regulated as a subset of medical devices by the *Therapeutic Goods Administration* (https://www.tga.gov.au/) .

The *Australian Register of Therapeutic Goods* (https://www.tga.gov.au/resources/artg) (ARTG) lists therapeutic goods that can be legally imported into Australia, or supplied for use in Australia, or exported from Australia.

Unless a specific exemption has been granted, it is a criminal offence under the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2017C00226) to import into, supply in or export from Australia a medical device that is not listed on the ARTG.

The Standards for PoCT assume that your practice's PoCT devices or systems, including but not limited to consumables, reagents, controls and software, are listed on the ARTG.

PoCT Standard 1 - Clinical governance

Overview

PoCT Standard 1 | Clinical governance

Our practice uses clinical governance to establish and review clinical responsibility and accountability.

Effective clinical governance of PoCT ensures that:

- each practice team member takes ownership of PoCT processes, models good practice, and challenges poor practice
- each team member is jointly accountable for patient safety and quality care
- roles, responsibilities and accountabilities for achieving agreed outcomes are clearly allocated to and agreed to by team members, according to each person's scope of practice
- practice team members use what they have learnt to improve patient safety and quality of care.

Criterion PoCT1.1 – Clinical purpose

Criterion PoCT1.1 – Clinical purpose

Indicators

PoCT1.1 ▸ A Our practice team can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

PoCT1.1 ▸ B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

PoCT1.1 ▸ C Our practice team uses reference data that is based on best practice evidence to interpret test results.

PoCT1.1 ▸ D Our practice team applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

Why this is important

The purpose of PoCT is to help healthcare practitioners make immediate and informed decisions about a patient's care and management.[5]

How you intend to use PoCT

PoCT can improve the timeliness, efficiency and quality of care in some areas of clinical practice.[6] When deciding on the clinical and diagnostic purposes where PoCT may benefit your patients, consider current best practice evidence.

Because PoCT can be used to diagnose, monitor, manage or screen, your practice needs to define its analytical performance requirements, based on its intended clinical and diagnostic purposes. For example, using PoCT to monitor a patient's diabetes may have different analytical requirements than to diagnose infections with public health implications.[7]

Evaluation of PoCT systems

The quality of PoCT may be affected by many factors, including the storage of consumables, the knowledge and skills of PoCT practitioners, specimen quality and variability between instruments.[8]

Your practice needs to perform due diligence to ensure the PoCT device meets your needs. This may be through consulting literature or professional bodies. Evaluation of a PoCT system includes three aspects - Selection, Verification and quality procedures:

1. Selection - PoCT devices should be evaluated and selected based on intended clinical use. These PoCT devices need to be assessed against the manufacturer's claimed specifications.
2. Verification - the purpose of the verification process is to confirm (verify) that a particular PoCT system performs to and meets the manufacturer's stated specifications, and to validate the results against a known standard.
3. Calibration, quality control and quality assurance – it is important that the use of calibration, quality control and quality assurance is assessed prior to implementation of a PoCT, to independently confirm appropriate and accurate performance of a POCT system.

Interpreting test results

You can interpret test results by using reference data obtained from various sources, including PoCT suppliers, pathology providers, international bodies and professional societies.

It is important that your practice:

- agrees on which reference intervals and clinical decision limits you will use to interpret PoCT results
- only uses reference intervals and clinical decision limits that are based on current best practice evidence.

Quality use of PoCT

Having a consistent approach to PoCT, which includes having agreed reference intervals and clinical decision limits, may help GPs to interpret test results.

Each GP needs to exercise clinical judgement when:

- deciding whether to use PoCT
- deciding whether to use results of PoCT to make decisions about patient management.

Safe and effective PoCT is possible only if:

- staff have the required skills and receive appropriate training
- PoCT is undertaken often enough to maintain those skills
- the practice records, addresses and reviews non-conformance and adverse events.

Meeting this Criterion

Sources of information and evidence

PoCT suppliers, pathology providers, international bodies, professional societies and other sources can provide evidence about the clinical and diagnostic purposes, analytical performance and reference data for PoCT. Therefore, your practice does not have to generate its own evidence.

It is recommended that you:

- seek information from a validated source, relevant to the PoCT being carried out
- select information that is appropriate for your practice's clinical and diagnostic purposes and patient population.

Evaluating PoCT systems' analytical performance

It is important that your practice demonstrates how the analytical performance of a PoCT device has been verified to confirm that it performs to and meets the manufacturer's stated specifications:

- on commissioning
- following major repairs
- at other times as needed.

The Australian Point of Care Practitioner's Network (APPN) provides resources to help practices implement a PoCT program.

The APPN also has the resource *How to choose and evaluate a point-of-care testing instrument* (https://www.appn.net.au/Data/Sites/1/appn/05instrumentevaluations/01evaluationprotocol/how-to-choose-and-evaluate-a-poct-instrument-revised-130922.pdf) that you can refer to when evaluating a PoCT system's analytical performance.

Quality improvement and risk management

To improve quality of care and to minimise risks to patients:

- apply quality improvement and risk management processes to PoCT
- record and address adverse and non-conformance events in a timely manner
- notify the clinical team member with nominated responsibility for PoCT of adverse and non-conformance events. Adverse and non-conformance events could be included as an agenda item in team meetings.
- review adverse and non-conformance events, including how they are addressed
- report adverse events to the TGA.

The TGA has the following resources relating to reporting relevant adverse events related to the performance of PoCT devices: *Medical device Incident Reporting and Investigation Scheme (IRIS)* (https://www.tga.gov.au/resources/resource/guidance/medical-device-incident-reporting-and-investigation-

scheme-iris) , and information on *reporting an adverse event or problem* (https://www.tga.gov.au/report-adverse-event-or-problem-health-professionals#:~:text=adverse%20event%20reports.-,Medical%20device%20adverse%20events,-Complete%20the%20online) for health professionals.

Continuity of care

In the event of unplanned loss of PoCT, your practice needs to demonstrate how it will ensure continuity of care for patients.

Related Criteria

Criterion C6.4 – Information security (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=78)

Criterion QI1.1 – Quality improvement activities (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=96)

Criterion QI3.1 – Managing clinical risks (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=112)

Criterion GP2.1 – Continuous and comprehensive care (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=131)

Meeting each Indicator

PoCT1.1 ▸ A Our practice can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

You must:

- describe the clinical and diagnostic purposes for using PoCT
- ensure the clinical and diagnostic purposes of PoCT are evidence-based.

PoCT1.1 ▸ B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

You must:

- provide evidence that the analytical performance specifications of each test method are based on the clinical and diagnostic purposes for which they will be used
- demonstrate that the analytical performance of each test method has been evaluated upon commissioning and following major repairs.

PoCT1.1 ▸ C Our practice uses reference data that is based on best practice evidence to interpret test results.

You must:

- demonstrate that your practice uses reference intervals and/or clinical decision limits for interpreting PoCT results
- demonstrate reference intervals and/or clinical decision limits are evidence-based.

PoCT1.1 ▸ D Our practice applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

You must:

- record and address adverse and non-conformance events
- document how you are reviewing adverse and non-conformance events, and document the outcome of the review
- demonstrate that your practice can maintain continuity of care if PoCT is not available.

You could:

- report adverse events to the TGA

Criterion PoCT1.2 – Clinical responsibility

Criterion PoCT1.2 – Clinical responsibility

Indicators

PoCT1.2 ▸ A Our practice has at least one member of the clinical team who has primary responsibility and accountability for the quality of PoCT.

Why this is important

The successful implementation of PoCT requires skills, knowledge and time. To ensure results are of a uniformly high quality, your practice needs to properly manage relevant organisational and technical activities.

This can be best achieved if one member of the clinical team is responsible for, and oversees, PoCT activities.

Meeting this Criterion

A designated member of the clinical team must have ultimate responsibility for PoCT undertaken by the practice.

This person:

- must have an adequate understanding of PoCT, including
    - the diagnostic and technical applications and any limitations
    - these Standards for PoCT
    - your practice's PoCT policies and procedures
- must have competency in using PoCT. This may be through provision of evidence of appropriate PoCT training (eg external courses, in-house programs, 'on the job' training at the practice) that aligns with your practice's PoCT program or system
- can delegate their day-to-day PoCT responsibilities to an appropriately trained PoCT practitioner but must retain ultimate oversight of PoCT in the practice.

Meeting each Indicator

PoCT1.2 ▸ A Our practice has at least one member of the clinical team who has primary responsibility, authority and accountability for the quality of PoCT.

You must:

- have at least one clinical team member who has overall primary responsibility for the implementation, conduct, quality and accreditation of PoCT within the practice
- have at least one clinical team member on duty when PoCT is being used who accepts the responsibility of running PoCT within the practice
- demonstrate that the responsible team member is competent in using PoCT.

You could:

- maintain a clinical governance policy
- maintain a standing order for practice nurses to carry out a PoCT and to interpret the result according to their level of training and scope of practice.

PoCT Standard 2 - Education and training of PoCT practitioners

Overview

PoCT Standard 2 | Education and training of PoCT practitioners

Our practice team has the appropriate skills and knowledge to perform PoCT.

The quality of PoCT can be compromised by pre-analytical, analytical and post-analytical errors and issues, especially if performed by inadequately trained PoCT practitioners. This is why team members performing and managing PoCT require appropriate training and education and must be able to demonstrate competency when assessed.[9]

Criterion PoCT2.1 – Qualifications, education and training of PoCT practitioners

Criterion PoCT2.1 – Qualifications, education and training of PoCT practitioners

Indicator

PoCT2.1 ▸ A Members of our practice team who perform PoCT must:

- have successfully undertaken training
- participate in training and education updates.

Why this is important

Having PoCT practitioners who are trained reduces the risk of errors and safeguards the validity of results that inform clinical decision making, ensuring that your practice provides patients with safe, quality care.

The organisation responsible for providing the PoCT service must provide evidence that all PoCT practitioners:

- are suitably trained
- maintain the knowledge and skills that enable them to perform PoCT
- work within their scope of practice and competencies.

Meeting this Criterion

Your practice must maintain records that clearly show that the training of PoCT practitioners is appropriate for the PoCT they perform.

All PoCT practitioners must receive updated training if:

- significant changes to the PoCT method/s are introduced

- a new test and/or instrument is introduced

An individual PoCT practitioner must receive updated training if:

- a competency issue with that practitioner has been identified.

Training may cover areas such as the following:

General

- Your practice's policies
- Overview of clinical purposes

PoCT system

- Basic principles of analysis, calibration, bias, precision, range, sensitivity, specificity, interferences, method evaluation and method comparison
- Normal test performance according to the manufacturer's instructions
- Recognition of malfunctions and appropriate actions
- Error messages and actions
- Storage of consumables
- Care, maintenance and decontamination of your PoCT system

Patients and specimens

- Appropriate information for patients – including what the test is and why it is being done
- Patient preparation
- Specimen collection techniques
- Specimen identification and labelling
- Specimen handling and stability
- Recognition of unsuitable specimens
- Patient and staff safety

Results

- Recognition of abnormal, clinically urgent and erroneous results
- Documentation of the testing episode
- Data management

Quality

- Principles and procedures of PoCT quality control testing and external quality assurance programs
- Assessment of acceptable/unacceptable quality control testing and external quality assurance results, and appropriate actions

Assessment of PoCT practitioners

Practice team members must be assessed for competency in all aspects of their PoCT duties and responsibilities.

The Australian Point of Care Practitioner's Network

The APPN is an online platform that provides professional development programs for all PoCT practitioners. PoCT practitioners can also maintain an electronic record of their continuing professional development (CPD) on the APPN's portal.

Related Criteria

C8.1 – Education and training of non-clinical staff (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=91)

GP3.1 – Qualifications, education and training of healthcare practitioners (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=146)

Meeting each Indicator

PoCT2.1 ▸ A Members of our practice team who perform PoCT must:

- have undertaken training
- participate in training and education updates.

You must:

- provide evidence that PoCT practitioners can demonstrate competency in PoCT
- provide evidence that PoCT practitioners receive regular training and education updates
- provide evidence that all PoCT practitioners receive training updates when:
- significant changes to method(s) are introduced
- new tests and/or instruments are introduced
- provide evidence that individual PoCT practitioners receive training updates when a competency issue with that practitioner has been identified.

You could:

- record each employee's qualifications in your employment files
- keep a training calendar that lists PoCT professional development and training opportunities
- store documents that record training needs and training completed
- conduct annual performance reviews that identify learning and development goals
- keep training logs that record training that PoCT practitioners have completed.

PoCT Standard 3 - Implementation and performance

Overview

PoCT Standard 3 | Implementation and performance

Our practice ensures that the implementation and performance of PoCT is in accordance with manufacturers' recommendations and best practice.

The successful implementation and performance of a PoCT program includes:

- patient awareness of the need for and nature of the test
- conducting PoCT in a fit-for-purpose environment
- conducting PoCT in accordance with the manufacturers' instructions
- maintaining PoCT equipment in accordance with the manufacturers' instructions
- maintaining PoCT records.

Criterion PoCT3.1 – Facilities for testing

Criterion PoCT3.1 – Facilities for testing

Indicators

PoCT3.1 ▸ A Our practice conducts testing in a safe environment that ensures patient privacy.

PoCT3.1 ▸ B Our practice ensures that instruments and consumables are located and managed to optimise performance.

Why this is important

Optimising the operation and maintenance of PoCT instruments and consumables is important in delivering high-quality test results that clinicians can use when making clinical decisions.

Ensuring that PoCT is conducted in a safe environment is important in reducing the risk of infection for patients and the practice team. Additionally, it is important that the PoCT environment is considerate of patient privacy when conducting PoCT.

Meeting this Criterion

When conducting PoCT, ensure the area has adequate space for instruments, consumables, documentation and waste disposal and does not compromise patient privacy.

Provided that patient privacy is maintained, the area does not need to be solely dedicated to performing PoCT. For example, a consultation or nurse's room may be suitable.

The practice could have a procedure document or log that includes recording of consumables, lot numbers, expiry dates and monitoring. This may also include a risk matrix for documenting contingency plans in the event of unexpected events.

Related Criteria

Criterion GP4.1 – Infection prevention and control, including sterilisation (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=151)

Criterion GP5.1 – Practice facilities (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=159)

Criterion C3.3 – Emergency response plan (https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/core-standards/core-standard-3/criterion-c3-3-emergency-response-plan)

Meeting each Indicator

PoCT3.1 ▸ A Our practice conducts testing in a safe environment that ensures patient privacy.

You must:

- demonstrate that testing and result communication is performed in a safe area where patients' visual and auditory privacy is ensured.

PoCT3.1 ▸ B Our practice ensures that instruments and consumables are located and managed to optimise performance.

You must:

- have a testing area that has appropriate space, lighting, power, security and ambient temperature for sample/specimen handling, testing and documenting
- maintain a consumables inventory, including lot numbers and expiry dates
- store the required quantity of within-date consumables as per the manufacturers' instructions
- dispose of expired consumables in accordance with local, state and federal requirements
- where temperature-sensitive consumables are stored as per the manufacturers' instructions, use a minimum–maximum thermometer to monitor temperature, and keep records of that monitoring
- have a documented contingency plan for continued operations in the event of equipment and other failures.

Criterion PoCT3.2 – Performance of tests

Criterion PoCT3.2 – Performance of tests

Indicators

PoCT3.2 ▸ A Our practice follows the manufacturers' instructions for PoCT.

PoCT3.2 ▸ B Our practices records and communicates results appropriately.

PoCT3.2 ▸ C Our practice identifies and reviews errors and deviations.

PoCT3.2 ▸ D Our practice ensures that specimens remain positively identified with patients throughout the testing process.

PoCT3.2 ▸ E Our practice has documented its requirements for PoCT technical support services.

PoCT3.2 ▸ F Our practice commissions and maintains our PoCT equipment in accordance with each manufacturer's instructions.

Why this is important

The quality and safety of patient care depends on the result from PoCT being valid and reliable. To ensure that this is the case, the technology needs to be used in a standard way in accordance with the manufacturers' instructions, and errors need to be identified and acted upon.

Consistency is best achieved if your practice documents standard operating procedures and work instructions for all stages of testing and ensures that they are in accordance with the manufacturers' instructions.

To ensure continuity of PoCT, your practice could have an established arrangement with third-party suppliers of goods and services.

Suppliers of essential PoCT support services are also responsible for providing:

- consumables (directly or via authorised supplier channels)
- technical support
- maintenance (in addition to the routine maintenance your practice completes)
- education to team members who use their devices.

Meeting this Criterion

Standard operating procedures

Your practice must follow the instructions published by the PoCT manufacturer as they are approved by the Therapeutic Goods Administration (TGA). However, it is best practice to also create and maintain your own standard operating procedures or work instructions as the manufacturer's instructions may not include some critical steps such as patient interactions and result management. It is important to formally evaluate and approve any proposed changes to the standard operating procedures and work instructions before your practice uses them.

Communicating results

Your practice must ensure that all PoC test results are recorded, understood, and acted upon in a timely and appropriate manner.

Deviations and errors

Your practice must regularly review deviations and issues encountered during testing.

Avoiding transcription errors

Transcription errors are data entry errors that usually occur because of typographical mistakes when transferring data and results.

To avoid transcription errors, it is strongly preferred that results are transferred electronically.[10]

Your practice could demonstrate how they recognise and avoid potential transcription errors.

Specimens

Although there is no requirement to label specimens that are to be used completely in the testing process:

- it is important that specimens remain positively identified with the patient throughout the testing process
- if specimens are retained following testing, they must be clearly labelled and stored in accordance with relevant guidelines.

Technical services

When making arrangements with technical support services, consider the following:

- required response time for maintenance

- ownership or leasing arrangements of instruments
- required training of PoCT practitioners
- support for technical updates and troubleshooting.

If it is appropriate, you could have written agreements with third parties who provide technical support services.

Consumables

When making arrangements with suppliers of consumables, consider:

- required frequency and volume of consumables
- required response time for urgent consumables.

Manufacturers' instructions

Your practice must make records of preventative maintenance, service and calibration as per the manufacturers' instructions and keep these records as required by legislation. These requirements may vary from state to state, so consult with your medical defence organisation or check legislative requirements to identify specific requirements you must fulfil.

Suppliers of routine maintenance must provide your practice with a record of work and performance checks they undertake. If this is not possible, you must maintain your own records. This includes keeping a log of failures and investigations performed.

Related Criterion

GP5.2 – Practice equipment (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=163)

Meeting each Indicator

PoCT3.2▸ A Our practice follows the manufacturers' instructions for PoCT.

You must:

- demonstrate that your practice follows the manufacturer's instructions for each test method
- demonstrate that your practice checks the accuracy of transfers of data and transcription of results
- demonstrate that your practice records and investigates deviations appropriately.

You could:

- maintain standard operating procedures for each test method, ensuring only the latest versions are used
- keep a copy of the relevant procedures/work instructions with each test instrument.

PoCT3.2▸ B Our practice records and communicates results appropriately.

You must:

- demonstrate that your practice records and communicates results to the responsible clinician and the patient in a timely manner
- demonstrate that the results are acted upon appropriately

PoCT3.2▸ C Our practice identifies and reviews errors and deviations.

You must:

- demonstrate that your practice records and investigates deviations appropriately.

PoCT3.2▸ D Our practice ensures that specimens remain positively identified with patients throughout the testing process.

You must:

- demonstrate that specimens remain positively identified with patients throughout the testing process
- clearly identify patient specimens retained for any purpose.

PoCT3.2▸ E Our practice documents its requirements for PoCT technical support services.

You must:

- demonstrate that your practice has ongoing arrangements with providers of technical support services.

PoCT3.2▸ F Our practice commissions and maintains our PoCT equipment in accordance with each manufacturer's instructions.

You must:

- retain records of installation and commissioning
- ensure that maintenance is undertaken by appropriately trained operators
- retain records of maintenance in accordance with the manufacturers' instructions
- retain a log of failures and investigation performed

Criterion PoCT3.3 – Data management

Criterion PoCT3.3 – Data management

Indicator

PoCT3.3 ▸ A Our practice records results relating to PoCT in the patient's notes.

Why this is important

Maintaining appropriate records is a way of managing risks. It allows for recording of results in the context of a patient's history and examination, allowing for a record of clinical decision making that is essential for safe and quality care. Records of PoCT results and associated processes must be kept with the relevant patient's health information, in accordance with relevant legislation and guidelines.

Your practice needs to demonstrate that you can readily retrieve from your record systems all data related to a patient testing cycle.

Meeting this Criterion

If your practice needs to investigate the reliability of a test result, you may need to:

- identify the PoCT practitioner who conducted the test
- identify the kit or batch of reagents used
- identify whether quality control results were within the acceptable range
- review the transcription so that you can rule out errors and non-conformance events.

Therefore, this includes retaining records of the following:

- patient identifiers
- the PoCT practitioner
- who requested the test
- date and time of specimen collection
- test results
- relevant reference information
- relevant quality control results
- external quality assurance results.

Ensure the results are accessible for future consultations, trend determination and quality improvement activities by coding the information you need to record appropriately, rather than entering it as free text in the patient record.

Related Criteria

Criterion C6.2 – Patient health records systems (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=72)

Criterion C7.1 – Content of patient health records (https://www.racgp.org.au/FSDEDEV/media/documents/Running a practice/Practice standards/5th edition/Standards-for-general-practice-5th-edition.pdf#page=84)

Meeting each Indicator

PoCT3.3►A Our practice records results relating to PoCT in the patient's notes.

You must:

- keep PoCT records, including who performed the tests and the date.

You could:

- record results in a way that are readily accessible for future consultations, trend determination and quality improvement.

PoCT Standard 4 - Quality outcomes

Overview

PoCT Standard 4 | Quality outcomes

Our practice performs PoCT using an established quality system to ensure the safety and quality of our patient care.

This standard focuses on the systems that practices need to ensure PoCT supports patient safety and high-quality care.

Criterion PoCT4.1 – Quality control procedures

Criterion PoCT4.1 – Quality control procedures

Indicator

PoCT4.1▸ A Our practice uses quality control procedures to ensure the PoCT is functioning optimally.

Why this is important

Quality control (QC) testing helps your practice to:

- be confident that your PoCT is functioning properly
- detect and manage sub-optimal performance.

Meeting this Criterion

QC testing

QC testing is usually performed on artificial samples purchased from PoCT manufacturers or other commercial sources. The samples have different known levels of analytes to cover the range that practices might encounter clinically.

QC testing is conducted on the samples, QC results are recorded, then compared with the target range or acceptable window that the practice has been given.

Results falling within this range are considered acceptable. Results falling outside this range are unacceptable and may indicate a problem with the testing process.

The PoCT manufacturer can provide a simple quality control record sheet to enter, review and analyse QC results.

An acceptable window for QC results is usually determined when you first implement a PoCT device. It is recommended that QC results fall within the manufacturer's specified limits and that practices can demonstrate that they have a system for ensuring appropriately timed QC.

Standard decision-making rules are used to determine whether to accept or reject the QC results. QC test results must be recorded, and action must be taken should the QC result fall outside the acceptable range.[11]

Reviewing quality control results

It is important that the clinical team member responsible for PoCT:

- regularly reviews QC results
- investigates unacceptable results or performance
- records any remedial actions taken.

Meeting each Indicator

PoCT4.1 ▸ A Our practice uses quality control procedures to ensure the PoCT is functioning optimally.

You must:

- demonstrate that all quality control procedures comply with manufacturers' recommendations and applicable regulations
- have standard operating procedures or work instructions that include the acceptable limits for quality control testing results and record actions taken in the event of an unacceptable result
- regularly review quality control results.

You could:

- compare PoCT results with local laboratory results on the same specimen on the same patient and document the outcome.

Criterion PoCT4.2 – External quality assurance program

Criterion PoCT4.2 – External quality assurance program

Indicator

PoCT4.2 ▸ A Our practice participates in an external quality assurance program.

Why this is important

External quality assurance programs deliver peer review of your PoCT systems and monitor your PoCT performance, making it more likely that issues that might otherwise go unnoticed are detected early. [10]

Meeting this Criterion

External quality assurance programs provide identical samples to all program participants who then each test the sample using their routine test method. The program collates the results and provides each participant with:

- the range of results achieved
- an indication of whether their method is producing results significantly different to those produced by a different practice using the same method
- details of the accuracy and precision of their results.

If your practice has unacceptable results or performance, you must:

- investigate the reasons for these results or performance
- record any remedial actions taken.

Meeting each Indicator

PoCT4.2 ▶ A Our practice participates in an external quality assurance program.

You must:

- enrol all test methods in an approved external quality assurance program
- keep records of participation
- review reports from external quality assurance programs and keep records of action taken if reports indicate poor performance.

References

References used in this document

1. Australian Government. Therapeutic Good (Medical Devices) Regulations 2002 (updated 2024). Canberra, 2002. Accessed 22 March 2024 (https://www.legislation.gov.au/F2002B00237/latest/text) .
2. Department of Health and Ageing. Point-of-care testing in general practice trial: Final report. Canberra, DHA, 2009.
3. Spaeth BA, Shephard MD, Schatz S. Point-of-care testing for haemoglobin A1c in remote Australian Indigenous communities improves timeliness of diabetes care. Rural Remote Health 2014;14(4):2849.
4. Howick J, Cals JWL, Jones C, et al. Current and future use of point-of-care tests in primary care: An international survey in Australia, Belgium, The Netherlands, the UK and the USA. BMJ Open 2014;4:e005611. doi: 10.1136/ bmjopen-2014-005611.
5. Tirimacco R. Evolution of point-of-care testing in Australia. Clin Biochem Rev 2010;31(3):75–80.
6. Tideman P, Simpson P, Tirmacco R. Integrating PoCT into clinical care. Clin Biochem Rev 2010;31(3):99–104.
7. Shephard M, editor. A practical guide to global point-of-care testing. Clayton South, Vic: CSIRO Publishing, 2016.
8. Nichols, J. Quality in point-of-care testing. Expert Rev Mol Diagn 2003;3(5):563–72.
9. Shephard M, Mazzachi B, Watkinson L, et al. Evaluation of a training program for device operators in the Australian Government's Point of Care Testing in General Practice Trial: Issues and implications for rural and remote practices. Rural Remote Health 2009;9(3):1189.
10. Gill JP, Shephard MDS. The conduct of quality control and quality assurance testing for PoCT outside the laboratory. Clin Biochem Rev 2010;31(3):85–88.
11. National Pathology Accreditation Advisory Council. Requirements for Point of Care Testing (2nd edition). Canberra, 2021. Accessed 05 September 2023 (http://www1.health.gov.au/internet/main/publishing.nsf/Content/Requirements-for-Point-of-Care-Testing-(Second-Edition-2021)) .