



POINT OF CARE TESTING

ELEMENTS OF A QUALITY FRAMEWORK

PREPARED BY

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Preamble

This document is prepared as part of the Point-of-care testing Taskforce scoping project. It addresses elements of a quality framework primarily applicable to accredited pathology laboratories and integrated networks. However, smaller and/or remote services may adopt elements of the framework in a simplified manner suitable to the scope and scale of their practice and within jurisdictional requirements with patient safety as the prime objective.

1. Background

This report “POCT: Elements of a Quality Framework” is provided as part of the RCPA Point of Care Testing Scoping Project. The RCPA POCT task force is dedicated to the development of a quality framework for near patient testing whilst advancing awareness of the current value and future potential of POCT. The taskforce advocates excellence in the practice of POCT through research and a quality framework that ensures testing is performed with clinical governance, scientific rigor and an evidence base to produce accurate results and improved patient outcomes.

Innovation, simplicity and functionality of POCT devices provide many opportunities and challenges.^{1, 2} The main challenges encountered are related to the practitioner and environment of POCT i.e. non-pathology staff in a non-laboratory setting providing diagnostic pathology testing which is currently unregulated, with diverse stakeholders’ views on the role of POCT.³

Note: The RCPA POCT Quality Framework is recommended **in addition** to all current NPAAC standards pertaining to Laboratory Testing in Australia; Requirements for Quality Management in Medical Laboratories, and Requirements for Supervision of Medical Laboratories.

2. Definitions⁴⁻⁸

Accuracy (of measurement): a) Closeness of agreement between the result of a measurement and a true value of a measure and b) true or target value; freedom from error. The accuracy of results can be measured by comparing them to results accepted as correct by standard methods or by comparing them with those from a reference laboratory.

Analyte: Component represented in the name of a measurable quantity e.g. protein as mass or glucose as amount of substance represented as measure.

Analytical: the phase of the testing process that involves analysis (testing) of a sample.

Assay: a quantitative or qualitative analysis of contents. It may be used interchangeably with method.

Bias: The difference between test results and an accepted reference value. It is a quantitative measure of inaccuracy or a systematic departure from accuracy under specified conditions of analysis. Types of bias include: inter-instrument, inter-method, inter-laboratory or analytical bias of results when compared to results from a reference method or reference material.

Biohazard: A biological agent or condition that constitutes a hazard to humans or the environment.

Calibration: Set of operations that establish under specified conditions, the relationship between values of quantities indicated by a measuring system or measuring instrument or values represented by a material measure or a reference material and the corresponding values realised by standards.

Calibrator: A material or device with known qualitative/quantitative characteristics (concentration, activity, reactivity) used to calibrate, or adjust a measurement procedure.

Clinical Pathway: Clinical pathways are multidisciplinary plans (or blueprints for a plan of care) of best clinical practice for specified groups of patients with a particular diagnosis that aid in the coordination and delivery of high quality care (including POCT) e.g. a clinical pathway for the diagnosis and management of myocardial infarction.

Competency testing: Evaluating a person's ability to perform a test and to use a testing device. This includes aspects from: specimen collection to result reporting.

Control: To monitor the status of an analysis to maintain its performance within desired limits.

Connectivity: The ability to reliably transfer data between a POCT device and a computer system database e.g. between a POCT device and hospital computer system.

Control material: A solution or device intended for use in quality control process. Control materials are not used for calibration.

Correlation: The relationship between two or several, random variables within a distribution of two or more random variables or/and the comparison of results between the test (new) method and the reference (old) method. When two methods correlate they may be used interchangeably and the same reference interval can be used for both.

Diagnostic Sensitivity: The ability of a test to give a positive result for patients that have the disease or condition. It is measured as the ratio of positive tests to the total number of tests in those that have the disease and is expressed as a percentage. It is an important characteristic for screening for disease.

Diagnostic specificity: The ability of the test to give negative result for patients that do not have the disease condition. It is measured as the ratio of negative test to the total number of tests in those that do not have the disease or condition and is expressed as a percentage. It is an important characteristic for tests used for diagnosis of disease.

Disruptive Innovation: Rapid developments in medical electronics and analytical technology at the 'point of care' with faster delivery of results than current established practice i.e. disrupts the current market

External quality assessment scheme (EQA, proficiency testing): An external program in which samples are periodically sent to testing sites for analysis. Results are tabulated and compared with results from other sites that use a similar testing method. Samples may not be fresh, they have additives.

Interoperability: the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Medical alert values (critical values): Assay values that may require immediate medical attention due to clinical consequences of abnormal levels of a particular analyte e.g. high international normalised ratio (INR) and associated increase in bleeding risk.

Near patient testing: Another term used for point of care testing. May employ the use of non-instrumented, instrumented or portable testing in a separate location from the main laboratory

Performance characteristic: A property of a test that is used to describe quality. Examples are: accuracy, precision, analytical sensitivity/specificity, and reference range

Post-analytical: the phase of the testing process that follows analysis (testing) of a sample. It includes (not exclusively) connectivity, transcription of results, result interpretation, units and reference intervals, and clinical action taken based on the result.

Pre-analytical: the phase of the testing process that precedes analysis (testing) of a sample. It includes (not exclusively) patient preparation, sampling technique and sample type, patient and sample identification.

Precision (of measurement): The closeness of agreement between independent test results obtained under stipulated conditions. It is a measure of reproducibility.

Procedure manual: A handbook that contains the methods, materials, and other information needed to perform a test.

Quality assurance (QA): Part of quality management focused on providing confidence that quality requirements will be fulfilled. A comprehensive set of policies, procedures, and practices used to monitor a service's entire testing processes and ensure that the testing site's results are reliable. QA also includes monitoring of corrective actions.

Quality control (QC): Part of QA focused on fulfilling quality requirements. Set of procedures designed to monitor the test method and results to ensure test system performance by charting QC material and analysing them for errors and documenting remedial action.

Reagent: Part of the in-vitro diagnostic medical device that produces a signal via a chemical or electrochemical reaction, which allows the quantity to be detected and its value in the sample measured.

Reference interval: Interval between, and including, the lower reference limit to the upper reference limit of the reference population. The range of test values expected for a designated population (e.g.95% of persons presumed to be healthy or normal).

Sensitivity (Assay): Lowest analyte concentration reliably determined as non-zero.

Test system: A unit or a device used to measure or assess the presence or absence of a particular substance or to quantitate that substance in body fluid.

Validation: Confirmation through the provision of objective evidence, that requirements for a specific intended use or application have been fulfilled. The action (or process) of proving that a procedure, process, system, equipment or method used performs as expected and achieves the intended results.

Verification: Confirmation through the provision of objective evidence that specified requirements have been fulfilled.

3. Abbreviations and Acronyms

AACB - Australasian Association of Clinical Biochemists

ARTG - Australian Register of Therapeutic Goods

CAP - College of American Pathologists

CLIA -Clinical laboratory Improvement Amendments

EQA - External Quality Assessment

EHR - Electronic Health Record

FDA - Food and Drug Administration

HIS - Hospital Information System

IFCC - International Federation of Clinical Chemistry

IVD - In Vitro Diagnostic

LIS - Laboratory Information System

NPAAC - National Pathology Accreditation Advisory Committee

NATA - National Association of Testing Authority

POCT -Point of Care Testing

QA - Quality Assurance

QC - Quality Control

RCPA - The Royal College of Pathologists of Australasia

RCPA-QAP - Royal College of Pathologists of Australasia Quality Assurance Programs

TGA -Therapeutic Goods Administration

UKNEQAS - United Kingdom External Quality Assessment Schemes

4. Introduction

POCT is seen by some as a key enabler to delivering changes through disruptive innovation,⁹ radically changing the way healthcare is delivered. The development of new technologies in tandem with electronic patient records, device connectivity and decision support systems have made it possible to further refine tests at a near patient setting.^{10,11} There is evidence in particular environments that POCT has created unique opportunities to increase the operational efficiency of clinical processes improving patient outcomes and reaching remote populations.¹²⁻¹⁴

Within Australia POCT has a role in diagnostic service delivery. It has been effective in both acute and chronic disease settings and has facilitated rural and regional community health engagement especially in indigenous medical services, country hospitals and remote health centres.¹⁵

However, ensuring the quality of POCT has proved challenging in many institutions and settings. Most practitioners have little competency and training in quality laboratory practices.¹⁶ Clinicians, although experts in their fields, may not appreciate the importance of quality management systems, incident monitoring and proper documentation when performing POCT.¹⁷ Compliance with a quality framework and regulatory guidelines is mandatory for laboratory practitioners to maintain their accreditation status. Unfortunately, lack of a quality framework and defined legislative regulation or mandatory requirements for managing POCT in Australia leaves a gap which can potentially compromise patient safety and the quality of testing.

In the body of the document the term Leadership is used to signify a POCT committee and/or a group or individuals charged with responsibility and oversight. Furthermore the term customer/s is used to signify patients, users, consumers and health practitioners involved in POCT.

5. Elements of a POCT Quality Framework

The complex nature of POCT services necessitates a need for a systematic approach to provide efficient and accurate testing. A quality framework is presented here to support organisations intending to provide POCT.¹⁸ The framework also addresses accreditation requirements and provides a structured approach to creating and maintaining processes and procedures for implementation of a quality system in a POCT service.¹⁹⁻²¹ When this quality framework is implemented, it is expected that the following quality management outcomes are enhanced:

- Reduction in pre-analytical, analytical and post-analytical errors
- Meeting patient and clinician expectations
- Running of cost-effective and efficient operations
- Compliance with accreditation requirements and international standards such as those of the Clinical and Laboratory Standards Institute (CLSI)
- Development and maintenance of quality objectives
- Provision of a safe environment for staff and patients
- Competent POCT practitioners

- Accuracy and optimal performance of testing devices
- Accurate and reliable results

5.1 Organisation: Formation of a POCT committee focused on clinical governance, with pathologists' stewardship is ideal,^{22,23} where possible. However, in all cases there must be oversight with clear lines of accountability. Planning of POCT must be aligned and integrated with patient care pathways to be efficient, cost-effective, and successful.²⁴

Key recommendations:

- Leadership must consider the “unmet needs” of clinicians, patients and pathologists as well as clinical pathways and practice guidelines in planning a POCT service.^{25,26} Duplication of effective existing laboratory services is wasteful of resources and must be avoided.
- A defined scope (type and extent documented within a handbook or procedures manual) of the POCT service with details of tests and their requirements, reference intervals, interpretation, reporting, trouble-shooting/problem solving, contact numbers for assistance/support, and consultations should be provided.
- A standardised “business Case” model or cost effective analysis for POCT with value based measures as a basis for financial planning should be prepared.^{27,28} The business plan should ensure sufficient allocation of resources for facilities, staffing, devices, equipment and consumables
- An organisation chart is recommended.²⁹
- Audits, incident monitoring and criteria for defining and prioritising risk (i.e. risk management) should be implemented.
- A plan for how information is disseminated between staff, health care providers and referral services should be in place.
- A plan for how results are conveyed to patients – including any supplementary or support services patients may require - must be in place
- A plan for acting on results where the patient has absconded when results are critical or notifiable should be in place.

5.2 Customer Focus and Resolution of Complaints: Customer focus addresses the POCT service's identification of its customer base and their expectations, the need to design work to meet those expectations and methods to seek customer input to confirm that expectations are continually met.³⁰

Key recommendations:

- Identification of the expectations of patients and health care providers e.g. by conducting a user's survey.
- Review of the capability of the POCT service to meet the users' expectations.
- Measuring operational efficiency of POCT by undertaking user and staff satisfaction surveys and analysis of feedback.
- Documented policies and procedures to investigate and respond to complaints to improve the POCT service.

5.3 Facilities and Safety: The POCT service must maintain an adequate physical environment together with health and safety programs to prevent and control healthcare associated infections and injuries.³¹

Key recommendations:

- A POCT facility design which incorporates requirements for privacy, comfort, safety, emergency systems and efficient work flow should be implemented. A dedicated facility or area may be required.
- Access to the testing instruments must be restricted to authorised POCT practitioners.
- POCT facilities must be adequately maintained. A bio-safety exposure control program for management and monitoring of blood and air borne pathogens, including needle stick and sharps injuries prevention should be in place.
- Documented policies and procedures for spill containment and clean-up, hazardous waste management and chemical hygiene.
- Documented first aid procedures including investigation, recording, reporting, and management of all POCT related injuries and accidents.
- Plans, procedures and training for appropriate responses to fire and other emergencies should be in place.
- Documented communication systems for staff including arrangements in emergencies. Up to date staff contact lists should be maintained.
- A vaccination program for staff as per employee safety regulations must be in place.

5.4 Personnel: Recruitment, training and retention of an adequate number of qualified and competent practitioners is important.³²

Key recommendations:

- All POCT services must comply with the supervision requirements prescribed by either the organisation's Leadership, or if seeking accreditation, NPAAC supervision recommendations. There should be POCT position descriptions to specify the education, skills, training, experience, duties and responsibilities of a POCT practitioner.
- An approved orientation program for all new staff be in place and successful completion of this program must be signed-off by an appropriate supervisor prior to new staff commencing work in the POCT facility.
- Comprehensive and documented training must be provided to all staff on all aspects of POCT testing and related operations including sample collection, proper use of the POCT device as per manufacturer instructions, calibration, quality control of tests, results reporting and recommended maintenance and quality assurance.
- Assessment of competence must be undertaken following initial employment, then annually. Retraining and reassessment to be conducted if the practitioner fails a competency test.³³
- Continuing education and professional development opportunities should be provided to all practitioners and records of these activities should be maintained and be available for inspection if required.
- Personnel files must be maintained and include records of education, training, experience, qualifications, performance evaluations and competency testing.

5.5 Purchasing and Inventory: Formal plans and agreements that a POCT service has with suppliers will ensure consistent service provision.

Key recommendations:

- Requirements for supply of devices, equipment, consumables and services must be established.
- Formal agreements with suppliers should be made to ensure guaranteed uninterrupted availability of critical supplies to the POCT service. Such agreements must be free from external commercial/financial conflicts of interest and reviewed as required.
- Maintain an approved supplier list.
- There should be clearly defined and delegated purchasing mechanism/s for POCT supplies.
- Maintain inventory management, identification and tracking of POCT supplies.
- Inspection, evaluation and verification of received POCT supplies and materials should be undertaken and assessed against documented and approved acceptance criteria for compliance, prior to supplies being released for use on devices or patients within the facility.
- Storage and handling of POCT materials and supplies must be in an appropriate and safe designated area that complies with manufacturer recommendations e.g. temperature requirements and monitoring.

5.6 POCT Equipment: This section describes requirements for selection, installation, calibration, operation and maintenance of POCT devices and documentation of these processes to ensure that POCT equipment performs as expected.^{34,35}

Key recommendations:

- Selection of an appropriate POCT device must consider the defined scope of service, the service environment, population served, ease of use, connectivity, safety and lock out features and requirements for engineering and supplies.³⁶
- Installation and operation of the device must be performed as specified by the manufacturer and meet expected standards for the purpose of testing (i.e. installation qualification, IQ, and operational qualification, OQ).
- A maintenance program for each device must include scheduled routine maintenance activities, functional checks, preventative maintenance, calibrations and troubleshooting activities. Maintenance records must be kept.

Decontamination procedures must be documented and be readily available for use in the event of a spill. Records detailing the service life of all POCT devices should be kept. Records must include full details outlining device selection, maintenance, and decommissioning. There must be a policy clearly outlining actions to be taken in the event of POCT device or POCT consumable malfunction and/or performance defects

5.7 Testing method (assay): The choice of device is highly influenced by the assay/s it uses to measure required analytes, the range of tests, and the target population/environment in which it will be used.

Key recommendations

- The POCT device methods must be validated to prove they are analytically (in terms of reproducibility and accuracy) and clinically (in terms of the population served and clinical requirements) fit for purpose. If this is not feasible, proof of the

aforementioned performance characteristics can be adopted from **relevant** literature or studies.

- Calibration must be carried out as per manufacturer recommendations. Calibration ensures results obtained are accurate and traceable to defined standards.
- Suitability of the method/assay must be confirmed and documented for the required population e.g. a glucose meter used for neonates must have a suitable lower limit because neonates may have lower blood glucose levels than adults.
- Performance of the assay must be under continuous scrutiny by performing quality control procedures: internal quality control, external quality control and periodic patient sample exchange with an accredited laboratory when possible. Deviations and discrepancies must be documented, investigated and remedial action taken to ensure clinically reliable results.

5.8 Process Management: Managing the entire path of workflow pre-analytically,³⁷ analytically,³⁸ and post analytically³⁹ is critical to POCT quality.^{40,41}

Key recommendations:

- Systematically identify, design, and document processes and activities to meet the users' needs.
- Maintain process mapping/flow charting for all POCT activities undertaken including the pre-analytical, analytical and post-analytical phases.
- When there is a change in device or any element in the testing process that would influence results e.g. reagents or methodology, there must be thorough validation and/or verification of device and assay performance and interference studies. Reference intervals and decision cut-offs must also to be reviewed.
- Monitor processes for all service activities to identify potential weak and error prone activities for focused/targeted improvement e.g. a pre-analytical plan for patient identification, specimen collection, analytical standard operating procedures including a quality control plan (with rules and QC matrix) and a monitoring plan with a suite of quality indicators for pre and post-analytical processes.
- A plan for transitioning through change (change management) and its impact on other processes must be communicated and documented.

5.9 Documents and Records Management: A document control system must be developed and maintained.⁴²

Key recommendations:

- A system for document control to ensure that only approved current versions of documents are available for use must be in place.
- Documents must be registered with identifiers and tracked through revisions, with obsolete documents being removed and archived.
- There should be clear processes for creating, identifying, revising, and approving POCT documents. Changes made should be reviewed and approved by authorised staff before use.

- There must be periodic review of all POCT documents by authorised staff to ensure they are correct, complete and current.
- Where applicable, an electronic master index or document log system should list and track all POCT service-related documents, with their dates of effect, scheduled dates for review, and locations.
- NPAAC requirements for document retention must be adhered to.

5.10 Information Management: An information management system must be developed to manage information generated by, entered into and transmitted electronically from the POCT device. Devices capable of interfacing and transmitting results to EHR and LIS allow seamless communication between multi-vendor POCT devices and clinical information systems.^{43,44}

Key recommendations:

- There must be an assessment of how POCT results and reports will be created, stored and disseminated (manually and/or electronically) with consideration of accessibility, accuracy, timeliness, security and confidentiality, and protection against loss of data.
- Consideration of key elements of information to be managed must include patient demographics, patient and sample identifiers, reagent/consumable batch or lot number, standardised test requesting, test procedure data sheets, entry/recording of test results.
- Patient identification via scanning is ideal. However, if not practicable, there must be check mechanisms in place to minimise errors in patient or sample identification.
- Manual result entry is discouraged. However if necessary, there must be check mechanisms to minimise transcription errors.
- There should be consideration of requirements for electronic transmission of results to other LISs, HISs or/and EHRs. POCT connectivity compliant devices are recommended where feasible with features of computerised physician order entry, decision support, and interoperability.
- If devices use electronic transmission of results, there must be a documented protocol for the handling/processing of results for times when data transmission fails/is unavailable (e.g. network issues, receiving database downtime etc).
- Back up and retrieval mechanisms for data in the event of IT failure should be in place.
- Integrity of data and confidentiality must be maintained during electronic exchange of patient information.
- Access to POCT data must only to be given to authorised staff and mechanisms to audit this should be developed and in place in order to ensure security of information.

5.11 Non-Conforming Event (NCE) Management: A systematic process is required to detect and document non-conforming events and to classify, investigate and take corrective and preventative actions to ensure patient safety and to reduce systematic errors.⁴⁵

Key recommendations:

- POCT related NCE examples include: inaccurate results, report discrepancies, instrument performance deviations, device malfunctions, device consumable

malfunctions, operator errors, transcription errors, patient harm and remarkable EQA reports.⁴⁶

- A dedicated POCT NCE program with procedures to identify, record and report deviations, unusual occurrences and adverse outcomes for all episodes such as an adverse event management program is highly recommended.⁴⁷ This should include a system to track and report final patient outcomes where patients have received treatment based on incorrect POCT results.
- There should be a defined policy for reporting, investigating and taking remedial action for NCEs. This policy should include:
 1. Classification and analysis of any trends in NCEs
 2. Identification through root cause analysis of the underlying causes of errors⁴⁸
- Leadership must receive, review and take action to resolve NCEs and allocate resources for resolution. This may be through a process improvement project.

5.12 Audits and Assessments: Participation in external and internal quality assessment programs is important to verify and validate how well the POCT service processes are performing. Accreditation and EQA exemplify external assessments.⁴⁹ Audits and Quality Indicators represent internal assessments.⁵⁰ Assessments are integral to achieving quality in a diagnostic POCT service and ensure that near patient testing is aligned with principles of best practice.

Key recommendations:

- Participation in a recognised POCT accreditation program where/when possible
- Registration and subscription with an appropriate POCT EQA program for all POCT tests performed if such a program is available
- A core set of quality indicators must be developed by the POCT operations management or Leadership to monitor and improve performance of near patient testing processes. Examples of quality performance indicators which may be monitored include accuracy of patient identification, turnaround time, competency assessment of POCT practitioners, POCT test error message or result failure rate, POCT consumable wastage rate (and reasons/categories for wastage), adverse events monitoring, rate of QC failures, sample acceptability for testing, POCT device malfunctions, critical results reporting, needle stick injuries and accidents, proportion of all patient test results correctly downloaded/entered into patient's health record.
- A periodic quality report must be prepared to monitor quality objectives. The report should summarise core quality indicator reports, gaps in external and internal assessment performance data, patient feedback/complaints, user satisfaction reports and NCEs. The frequency will depend on the scope and scale of the service, but should be no less than quarterly.

5.13 Continual Improvement: The POCT practitioner's role in the entire health care setting in which they operate provides an opportunity for a collaborative strategy for continual improvement

Key recommendations:

- Feedback from patients, clinicians, EQA reports, accreditation recommendations, quality indicators, and non-conforming events should be used as opportunities for improvement.
- Effective mechanisms to eliminate root causes of problems and gaps identified by reviews, audits and complaints must be in place.
- Proactive preventative action should be taken to reduce the occurrence of non-conformances, for example responding to trends identified in quality indicator data.

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