Australian Commission on **Safety and Quality** in Health Care

Point of Care Testing Guide

Health and Aged Care Services
Draft

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The Australian Commission on Safety and Quality in Health Care pays respect to the Gadigal people as the Traditional Custodians of Country where the Commission's office is located. We extend that respect to all Aboriginal and Torres Strait Islander peoples, and their deep time connections to land, water and sky.

We recognise that knowledge about healthy Country, community and culture has been developed by Aboriginal and Torres Strait Islander peoples over tens of thousands of years and has been shared for generations. We are committed to partnering with and learning from Aboriginal and Torres Strait Islander peoples through the work that we do.

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Introduction

About the Commission

The Australian Commission on Safety and Quality in Health Care (the Commission) partners with the Australian Government, state and territory governments and the private sector to achieve a safe, high-quality, sustainable health system. It also works closely with patients, carers, clinicians, pathologists, medical scientists, technicians, managers, healthcare organisations and policymakers.

Key functions of the Commission include:

- developing National Safety and Quality Standards
- developing Clinical Care Standards to improve the implementation of evidence-based health care
- coordinating work in specific areas to improve outcomes for patients
- providing information, publications and resources about safety and quality.

What is Point of Care Testing?

Pathology Point of Care Testing

Pathology Point of Care Testing (PoCT) is defined as a test performed by a PoCT operator outside the precincts of a traditional laboratory. Testing occurs near to or at the side of the patient that produces a rapid result without the supervision of a trained pathology laboratory professional.

PoCT is increasingly being used across health and aged care services to support the delivery of timely and accessible care.

The benefits of PoCT include:

- informed and immediate decision-making about patient care
- improved patient compliance with testing
- greater patient convenience
- improved access, especially in rural and remote centres.

However, these benefits must be balanced against the safety and quality risks associated with PoCT. Appropriate governance, training, quality management and communication processes are important to support the safe and effective use of PoCT.

About this guide

Purpose and scope

The *Point of Care Testing Guide for Health and Aged Care Services* (the Guide) has been developed to support health and aged care services to deliver safe, high-quality PoCT outside pathology laboratory settings. The Guide outlines best-practice actions and provides implementation guidance to reduce associated safety and quality risks.

Applicable settings

The Guide is intended to be relevant across diverse care contexts, including:

- rural and remote settings where resources, workforce and infrastructure may be limited
- services delivered through a range of organisational structures and governance arrangements.

The guide applies to:

- Aboriginal Community Controlled Health Organisations (ACCHOs)
- acute care settings
- aged and domiciliary care settings
- ambulance services
- clinicians working in rural and remote areas
- clinics
- community settings
- detention settings
- medical imaging practices
- mobile health units
- pharmacies.

The Guide **does not**:

- apply to the accreditation requirements for Approved Pathology Laboratories (APLs) undertaking PoCT
- replace the RACGP *Standards for point-of-care testing*, which continue to apply in general practice settings.

In scope

This Guide applies to pathology PoCT performed on in vitro patient specimens where the analytical process is completed outside a pathology laboratory.

Examples include:

- infectious disease testing, including rapid antigen tests, HIV viral load assays and nucleic acid amplification tests

- haematology and biochemistry testing, such as blood glucose testing, INR testing and cardiac marker testing
- inflammatory and infectious marker testing, such as C-reactive protein testing
- blood gas and electrolyte analysis
- urinalysis and pregnancy testing.

Out of scope

This Guide does not apply to:

- self-testing undertaken by lay users without direct supervision by a PoCT operator
- samples collected at the point of care and sent to a pathology laboratory for analysis
- PoCT performed by pathology providers operating under the NPAAC Requirements
- PoCT performed in hospital services with onsite pathology laboratory oversight
- physiological monitoring such as blood pressure monitoring, pulse oximetry and electrocardiography
- imaging-based examinations such as ultrasound and radiography.

Appendix A provides detailed scope information, additional examples and explanatory notes relating to activities that are in scope and out of scope.

Applying this guide

The actions described in this Guide represent best practice for the safe use of PoCT. Service providers should apply these actions in a proportionate, risk-based way, taking into account the:

- complexity of the test
- risk of inaccurate results
- potential for harm if the results are incorrect.

The Commission recognises that implementation of the actions will vary depending on the service setting and available resources. Service providers should support PoCT operators to deliver safe, high-quality care appropriate to the clinical purpose of the test and its associated risks. Timely use of accredited pathology laboratories to confirm findings arising from PoCT, where appropriate, will promote safe and high-quality care.

PoCT governance may be delivered through different models depending on the setting. In some contexts, particularly for smaller or resource-limited services (for example, general practices, small hospitals or aged care services), governance functions may be supported through regional, network or partnership arrangements. These approaches can reduce the burden on individual sites by providing access to shared expertise, protocols and oversight from larger organisations or pathology providers.

The content and complexity of policies and processes will vary depending on the size and context of the service provider. For example, a sole provider may use a simplified approach, whereas a larger service may require more comprehensive documentation.

How to use this guide

The Guide is organised into four safety and quality sections. Each section contains **actions** that describe best-practice expectations for the safe and effective use of PoCT.

> Each action is preceded by a short overview that explains the importance of the topic and the intent of the action.

Actions may include multiple components identified by letters of the alphabet.

All actions are supported by **reflective questions** and **suggested strategies**. Additional information, resources and case studies have been included, where they support understanding or implementation of the action.

Throughout this Guide, you will see these colour-coded boxes where these supporting elements are used.

Additional information

Additional background and information on the section topic.

Reflective questions

A starting point for service providers to support critical thinking, assess how they meet the intent of the section, and identify opportunities for improvement.

Suggested strategies

Examples of actions and activities that may help a service provider meet the intent of the section. The approaches implemented may vary and should be appropriate to the service provider's context, including the services delivered and the populations accessing those services.

Resources

Guidance, tools, references and support materials to enhance PoCT. The inclusion of a resource in this Guide should not be taken as an endorsement by the Commission.

Case studies

Practical examples that demonstrate how the principles and actions described in this Guide may be applied in different health and aged care settings.

Terminology

The following terminology has been adopted for clarity of purpose within the Guide. A full list of glossary definitions can be found at the end of the Guide.

Patient

In this Guide, the term ‘patient’ refers to the person receiving PoCT.

Consumer

A person who has had or may have a PoCT service, or their representative or advocate.

PoCT operator

Assessed and deemed competent to perform point of care testing using PoCT in vitro diagnostic medical devices (PoCT IVD medical devices). This includes registered and non-registered practitioners, who provide direct clinical care to patients within a health or aged care service as an employee, a contractor or under other working arrangements.

They include nurses, enrolled nurses, personal care workers, assistants in nursing, midwives, medical practitioners, allied health professionals, pharmacists, paramedics, Aboriginal and Torres Strait Islander Health Practitioners and Health Workers, trained peer and non-peer community workers, other professionals who provide health services and students who provide health care under supervision.

Health service

The Guide uses the term health service to describe a separately constituted organisation that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care. Health services vary in size, structure and complexity, ranging from sole providers and small community-based services to large organisations with a governing body, management structure and supporting workforce.

Health services include hospitals, aged care and domiciliary care services, community settings, detention settings, clinicians' rooms, clinics, medical imaging practices, ACCHOs, ambulance services, mobile health services, remote clinicians and pharmacies.

Background

Development of the guide

The development of the Guide was informed by a rapid literature review and environmental scan that identified significant safety and quality gaps.

The literature review highlighted PoCT errors such as:

- patient identification errors
- documentation gaps
- errors in specimen handling and result interpretation
- inadequate staff training.

These errors pose a significant risk to overall quality of patient care.

To address these concerns, there needs to be:

- effective governance and quality management systems
- adequate workforce training and competency
- culturally safe PoCT delivery
- appropriate result interpretation and reporting.

This Guide supports health and aged care services to address these risks by outlining best-practice actions and implementation guidance for the safe, effective and consistent use of PoCT.

In the development of this Guide, the Commission consulted extensively with aged care organisations, clinicians, consumers, healthcare services, jurisdictions and government agencies, medical practitioners, pathologists, pathology practices, professional and peak bodies, scientists, and technicians.

Aboriginal and Torres Strait Islander Impact Statement

The Commission is committed to supporting healthcare services to deliver safe and high-quality care to the Australian community and recognises that culturally safe and responsive health care is critical to improving equitable access and outcomes for patients, families and communities.

This Guide aims to:

- improve health equity for Aboriginal and Torres Strait Islander people by supporting the delivery of timely PoCT, reducing reliance on distant laboratories, and addressing barriers to care in rural and remote communities
- align with the National Agreement on Closing the Gap by supporting community-led models, and culturally safe service delivery
- strengthen partnerships with ACCHOs and support shared decision making in testing delivery
- promote safe, high-quality and locally appropriate PoCT in Aboriginal and Torres Strait Islander communities.

Overview of the guide

The sections in this Guide include:

1. Clinical governance of PoCT

This section describes the governance arrangements that support the safe, reliable and high-quality use of PoCT. It outlines the systems and processes used to identify and manage risk, support workforce capability, monitor performance and drive continuous improvement.

2 Person-centred care

This section supports service providers to deliver PoCT that respects and responds to the needs, preferences, values and cultural backgrounds of patients, and supports informed participation in decisions about their care.

3. PoCT management

This section supports service providers to ensure PoCT devices are safe and appropriate for use in accordance with the manufacturer's instructions for use, with quality control and quality assurance processes that provide confidence in result accuracy and reliability.

4 Communication and reporting

This section supports service providers to communicate, escalate and report PoCT results accurately and in a timely manner to support clinical decision-making, continuity of care and patient safety.

1. Clinical governance of PoCT

Clinical governance supports the safe and effective use of PoCT by establishing the systems, processes and accountabilities needed to identify and manage risks, support workforce capability and continuously improve the quality of care.

This section supports service providers to implement governance arrangements that promote safe, reliable and high-quality PoCT appropriate to their service setting and level of risk.

Additional information

PoCT governance may be delivered through different models depending on the setting. In some contexts, particularly for smaller or resource-limited services (for example, general practices, small hospitals or aged care services), governance functions may be supported through regional, network or partnership arrangements. These approaches can reduce the burden on individual sites by providing access to shared expertise, protocols and oversight from larger organisations or pathology providers.

Key areas

- Risk management
- Incident management
- Quality management
- Policies and procedure documentation
- PoCT operator training and competency
- Safe environment
- Feedback and complaints

1.1 Risk management

Risk management supports the safe and effective use of PoCT by helping service providers identify, assess and address risks before they result in patient harm. A structured approach to risk management assists with prioritising improvement activities, allocating resources and maintaining safe testing practices.

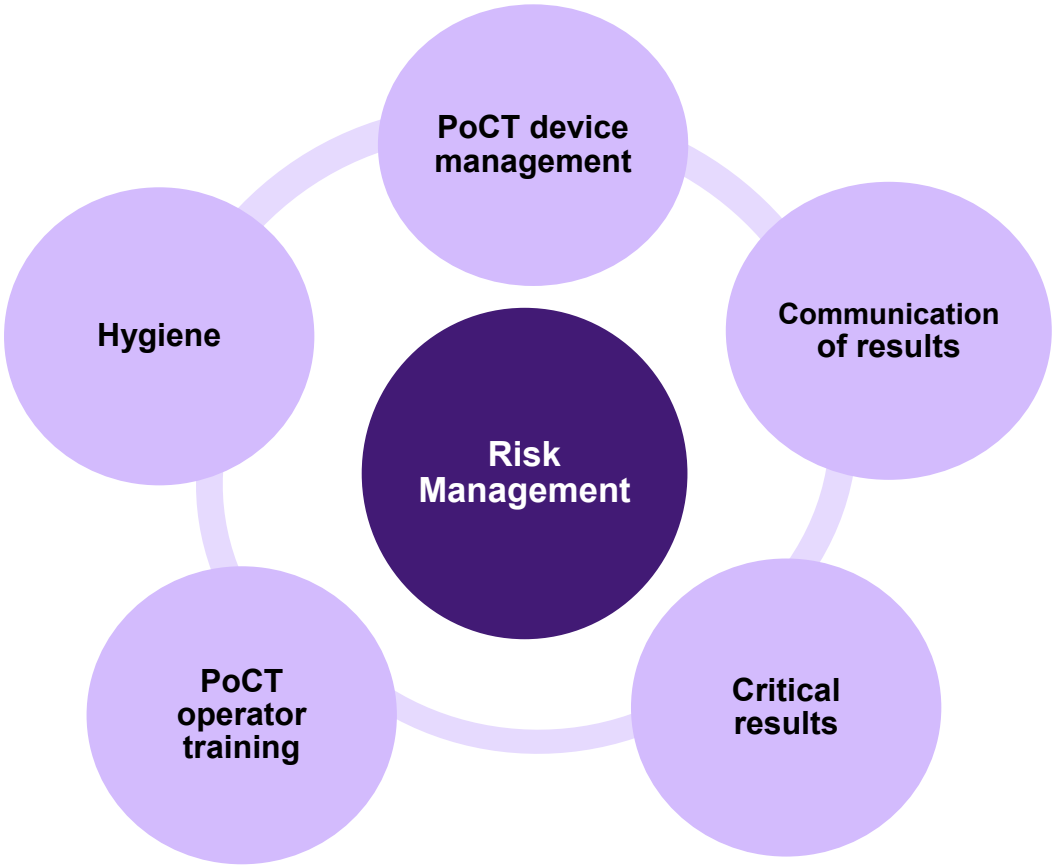
Action 1.1

The service provider has risk management policies that ensure risks are identified and assessed by:

a. maintaining organisational structures and reporting processes that support the early identification, escalation and management of risks
b. identifying and prioritising risks, undertaking risk assessments, acting to reduce risk and harm, and improving systems, patient outcomes and experience
c. using data to inform risk assessments, monitor trends and guide improvement activities
d. reporting risks and risk management activities to ensure transparency and shared accountability
e. regularly reviewing the effectiveness of the risk management system and its risk priorities to ensure they remain current, responsive, and effective

There are many different types of risks associated with PoCT. **Figure 1** provides examples of risk areas that service providers may consider when identifying and assessing PoCT-related risks. The risks relevant to a particular service will depend on the tests performed, the care setting and the local context.

Figure 1 PoCT risk management items



Reflective questions

- How are risks identified and documented? Where are they reported?
- How do PoCT operators identify, prioritise and report risks and how are they informed about key organisational risks?
- How is the risk management system used to improve safety and quality?
- How are risks to business continuity, disruptions, emergencies and disasters managed?

Suggested strategies

- Determine the PoCT risk rating by using a risk assessment rating outcome, in conjunction with a risk matrix (see Tables 1 and 2).
- Define the roles and responsibilities of those accountable for managing risk.
- Develop a risk management system including risk management processes, a risk register, and a systematic approach to identifying, assigning, assessing and addressing risks.

- Apply a risk management approach to the self-assessment of compliance.
- Allocate resources to support the risk management system.
- Provide PoCT operators with orientation and training on risk management.
- Inform PoCT operators of their roles, responsibilities and accountabilities for managing risk.
- Encourage PoCT operators, consumers, requesters, and other stakeholders to identify and report risks.
- Identify potential risks and develop plans to respond to emergencies and disasters.

A structured risk assessment process can support the identification, assessment and management of PoCT-related risks. **Table 1** provides an example of how a service provider may document and assess risks using a risk register. The examples shown are illustrative only and should be adapted to the service provider's context.

The example risk ratings in **Table 1** have been determined using the risk matrix shown in **Table 2**.

Table 1 PoCT risk assessment rating outcome (guide only)

Risk identification		Risk assessment				Risk management and Evaluation		
Risk Heading	**Risk Description**	**Potential causes**	**Likelihood**	**Consequence**	**Risk Rating**	**Mitigation strategy**	**Revised Risk Rating**	**Responsibility**
Positive patient identity	Patient identification mix-up in testing	- Sample not labelled accurately - Sample mix-up	Possible	Major	High	- Testing conducted at point of care with patient - Correct and accurate labelling of sample	Low	Service provider
Reporting critical results	Critical PoCT results are not escalated promptly	- Operator unfamiliar with critical result thresholds - No clear escalation pathway for remote settings - Critical values documented but not verbally communicated	Possible	Major	High	- Implement critical result protocol within a set timeframe - Improved PoCT operator training - Document critical result communications with mandatory verbal notification	Low	Service provider
PoCT operator training	Untrained staff perform PoCT incorrectly leading to inaccurate results	- High staff turnover or reliance on agency staff - Extended time gaps between training and testing - Infrequent testing	Likely	Major	High	- Maintain a competency register with expiry dates and refresher requirements - Provide simulation practice for low-volume tests - PoCT operators to complete PoCT training before	Low	Service provider

Risk identification		Risk assessment				Risk management and Evaluation		
						accessing the device		
Hygiene	Contamination during specimen collection leads to incorrect results	- Poor hand hygiene - Inadequate cleaning of PoCT device or sampling surface -	Possible	Moderate	Medium	- Adhere to relevant infection prevent control guidelines and conduct regular audits with feedback to staff - Perform device cleaning per manufacturer's instructions after each use	Low	Service provider
Communication of results	PoCT results are not communicated accurately leading to missing, inaccurate or misinterpreted results	- Results recorded in PoCT device but not entered into the patient record - Miscommunication between shifts - Cognitive impairment of the patient limits accurate symptom reporting	Possible	Major	High	- Implement real-time electronic result capture where possible - Establish handover protocol between shifts - Contact a substitute decision-maker when the patient has cognitive impairment - Communicate appropriately to patients with diverse care needs	Low	Service provider
Inaccurate sampling technique	Sample not taken in accordance with the manufacturer's	- Lack of training - Poor testing technique	Possible	Moderate	Medium	- Adhere to the manufacturer's instructions for use	Low	Service provider

Risk identification		Risk assessment				Risk management and Evaluation		
	instructions leading to inaccurate results					- Training and competency of PoCT operators		
Incorrect device storage	Inaccurate PoCT results due to degraded or expired consumables	- Materials used to perform PoCT are out of date, or have been exposed to heat/cold extremes	Possible	Moderate	Medium	- Adhere to the manufacturer's instructions for use - Maintain register of material expiry	Low	Service provider
Failure of quality control (QC)	Inaccurate PoCT results due to unsuccessful QC checks not being recognised or acted upon	- QC not conducted - QC result outside acceptable limits - Operators unaware of escalation process - Testing continues despite QC failure	Likely	Moderate	High	- Follow documented QC procedures - Train operators in recognising QC failures - Pause testing when QC is outside acceptable limits - Investigate and resolve issues before returning device to service	Low	Service provider
Failure of quality assurance (QA)	Inaccurate or unreliable PoCT results are not identified through ongoing monitoring and review activities	- QA activities not implemented - Audits not undertaken - Incident trends not reviewed - Corrective actions not monitored - Inadequate oversight of training, QC or documentation processes	Unlikely	Major	Medium	- Implement a QA program appropriate to the testing context - Conduct regular audits and reviews of PoCT processes - Review incident and QC data - Monitor corrective actions	Low	Service provider

Risk identification		Risk assessment				Risk management and Evaluation		
						- Participate in external QA programs where available -		

Table 2 Risk Matrix (guide only) [1]

Likelihood	Consequences				
	Insignificant	Minor	Major	Extreme	Catastrophic
Almost certain	Medium	High	High	Extreme	Extreme
Likely	Medium	Medium	High	High	Extreme
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Low	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Low risk	Manage by routine procedures.
Medium risk	Manage by specific monitoring or audit procedures.
High risk	This is serious and must be addressed immediately.
Extreme risk	The management of the consequences of an event, should it occur, and the likelihood of that event occurring, are assessed in the context of the effectiveness of existing strategies and controls.

[1] National Health and Medical Research Council (AU). Australian Guidelines for the Prevention and Control of Infection in Healthcare [Internet]. Canberra: Commonwealth of Australia, 2019. https://app.magicapp.org/#/guideline/Jn37kn (accessed 17 July 2026).

1.2 Incident management

Despite effective controls, incidents, near misses and adverse events may still occur. Incident management supports the timely identification, reporting, investigation and review of PoCT-related incidents, helping service providers reduce the likelihood of recurrence and improve the safety and quality of care.

Action 1.2

The service provider uses an incident management system that:

a. supports PoCT operators to recognise and report PoCT incidents
b. assesses and categorises incidents based on the level of patient harm
c. ensures appropriate management and mitigation of any patient harm arising from PoCT incidents
d. involves PoCT operators in the review of incidents
e. provides timely feedback on the analysis of incidents to the patients, PoCT operators and governing body
f. uses the information from the analysis of incidents to improve safety and quality
g. regularly reviews and acts to improve the effectiveness of the incident management and investigation systems
h. reports any adverse events related to a PoCT medical device to the governing body, the Therapeutic Goods Administration and Sponsor

Reflective questions

- Are PoCT operators supported to report near misses and incidents?
- How are near misses and incidents identified and managed?
- How are PoCT operators and consumers involved in reviewing incidents?
- How is the incident management system used to improve safety and quality?

Suggested strategies

- Encourage and support incident reporting.
- Develop processes that outline the incident management system elements, roles and responsibilities, reportable events and how to report, respond to, investigate and analyse incidents, near misses and adverse events.
- Adopt a process to classify and escalate serious incidents and incidents with major risks.
- Link the incident management system to the risk management and quality improvement systems.
- Support patients and carers to report incidents.

- Update patients and carers about the incident investigation and outcome.
- Inform PoCT operators about the incident management system, their responsibility to report incidents, and how to respond to patients and carers who raise concerns or report incidents.
- Ensure investigations are prompt and effective and all incidents are followed up.
- Involve PoCT operators in investigating incidents and implementing changes to reduce the risk of incidents recurring.
- Analyse incident data to identify trends and improvement opportunities.
- Report serious incidents, a summary of other incidents, system learnings and improvements to PoCT operators, the governing body and other parties as required under legislation.

Case study – Preventing patient identification errors

A PoCT operator is performing blood glucose testing for several residents in a residential aged care service during a morning medication round. Two residents with similar surnames are scheduled for testing.

Before beginning the test, the PoCT operator follows the service's patient identification procedure and confirms the resident's identity using approved identifiers. During this process, the operator realises that the resident they are preparing to test is not the resident listed on the testing record.

The operator pauses the testing process and confirms the identities of both residents before proceeding. No test is performed until the discrepancy is resolved. The operator confirms that no results have been attributed to the wrong resident and that no patient harm has occurred. The near miss is reported through the service's incident management system in accordance with local procedures.

The incident is assessed using the service's incident management process and categorised as a near miss because the error was identified before testing occurred and no patient harm resulted.

The incident review identifies that the two residents' records had been placed together during handover, increasing the risk of confusion. As a result, the service introduces additional safeguards, including revised handover processes, reinforcement of patient identification requirements and refresher training for PoCT operators.

This example demonstrates how patient identification procedures, staff awareness and incident reporting processes help prevent errors from reaching the patient and support continuous improvement in the safety and quality of PoCT.

1.3 Quality management

Quality management supports ongoing monitoring, evaluation and improvement of PoCT services. By collecting and reviewing information about performance, outcomes and areas for improvement, service providers can maintain confidence in the safety, reliability and effectiveness of PoCT over time.

Action 1.3

The service provider has a quality improvement system that:

a. collects and evaluates information about the safety, quality and performance of PoCT
b. identifies and implements quality improvement activities
c. monitors the effectiveness of quality improvement activities and responds to identified issues
d. supports timely reporting of safety, quality and performance information to the governing body and PoCT operators
e. involves PoCT operators in quality improvement and system review activities

Reflective questions

- How does the service provider collect and review information about the safety, quality and performance of PoCT?
- How are opportunities for improvement identified and prioritised?
- How does the service provider monitor whether quality improvement activities have been effective?
- How are findings from audits, incidents, feedback, quality control and quality assurance activities used to improve PoCT?
- How are PoCT operators involved in quality improvement activities and reviews of PoCT systems and processes?
- How are safety, quality and performance findings communicated to those responsible for governing, managing and delivering PoCT?

Suggested strategies

- Collect and review information from incidents, audits, feedback, quality control and quality assurance activities to identify improvement opportunities.
- Implement quality improvement activities and monitor their effectiveness over time.
- Involve PoCT operators in quality improvement initiatives and reviews of PoCT systems and processes.
- Regularly report safety, quality and performance information to the governing body and PoCT operators.

1.4 Policies and procedures documentation

Clear and accessible documentation supports consistent and safe PoCT practices. Documented processes help PoCT operators understand their responsibilities, perform testing correctly, communicate results appropriately and respond consistently to known risks and unexpected situations.

Action 1.4

The service provider has policies and procedures that describe:

a. the point of care tests they use, and their intended use
b. who can request tests when they are required
c. the processes for communicating results
d. the training or competency requirements for PoCT operators
e. how findings are verified in the instance of a positive PoCT result

Reflective questions

- How does the service provider ensure the essential PoCT documentation is current, accurate and accessible to PoCT operators?
- How does the service provider identify, assess and review risks associated with PoCT?
- How does the service provider ensure PoCT incidents are consistently reported, investigated and acted upon in a timely manner by PoCT operators?
- How does the service provider implement, monitor and report on quality improvement activities to the governing body and PoCT operators?

Suggested strategies

- Establish a scheduled documentation review cycle to update PoCT policies and procedures.
- Use a structured risk assessment tool to map risks across the entire PoCT process.
- Ensure PoCT incidents findings and improvements are communicated back to PoCT operators and governing body to support learning and prevent recurrence.
- Collect and analyse data related to PoCT performance to inform the development of quality improvement initiatives.

1.5 PoCT operator training and competency

PoCT should only be carried out by PoCT operators who have the appropriate training, knowledge and skills to perform the test in accordance with the manufacturer's instructions for use.

Action 1.5

The service provider ensures that PoCT operators receive training appropriate to the tests they perform, their role and the context in which testing occurs.

The service provider:

a. tailors training to their setting, including device complexity and the number and frequency of tests

b. ensures training programs cover testing procedures, specimen collection, quality control, infection prevention and control, and result interpretation

c. reviews training and educational resources to ensure they are appropriate for the PoCT being performed and the intended PoCT operators

d. regularly reviews training processes, including through regional or network supports where available, to support the accurate and safe performance of PoCT

e. assesses and reassesses competency at intervals appropriate to the risks associated with the PoCT, including consideration of test volume, testing frequency and test complexity

f. monitors and reviews training and competency processes, including through audits where appropriate, to identify gaps, support compliance and improve practice

Additional information

If the PoCT is not carried out according to the instructions for use, then it is considered as off-label use (see Appendix B).

Reflective questions

- How does the service provider ensure PoCT training is appropriate to the devices used and clinical environment?
- How does the service provider support access to training where on-site education or supervision is limited?
- How are changes to devices or methods reflected in competency requirements?
- How does the service provider ensure PoCT operators remain competent, particularly when testing is infrequent?
- How often is training occurring where there is an extended time period between training and testing?

Suggested strategies

- Establish a structured PoCT training program based on the complexity, risk and frequency of each test.
- Use varied training delivery methods to support different PoCT operators and geographic contexts (for example, online modules, videos, simulation or supervised practice).
- Establish a competency framework that defines initial assessment, reassessment and triggers for reassessment (for example, extended time since last testing, incidents, device or method changes).
- Maintain a competency register that records assessment and reassessment dates, refresher requirements and authorisation status.
- Confirm that PoCT operators have the training, knowledge and skills required to use PoCT devices and interpret results.
- Review the PoCT operator's scope of clinical practice when a significant change to the PoCT method is introduced or when a new device is introduced.
- Plan reassessment of ongoing competency as part of continuing professional development.
- Conduct competency reassessment at planned intervals appropriate to the PoCT being performed.
- Low-volume, infrequently performed or higher-complexity tests may require simulation-based refreshers, supervised practice or remote support.

Resources

Accredited courses

- **Training.gov.au** – *National training register* - provides information on nationally recognised training, including qualifications, units of competency, accredited courses and skill sets relevant to healthcare and PoCT-related practice

Certification

- **NSW Health Pathology** – *PoCT Operator Certification* - certification program requiring completion of e-learning, practical training and competency assessment before use of PoCT devices
- **Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS)** – PoCT Operator Training - *QAAMS Program Training* - training resources and competency assessment for participating Aboriginal and Torres Strait Islander health services undertaking PoCT
- **Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)** – *Hepatitis C, Hepatitis B, HIV Infections Training* - the key processes involved in point of care testing for hepatitis C, hepatitis B, and HIV infections using tests accessible in Australia

Training resources

- **NSW Health Pathology** – *PoCT Education and Training Resources (webpage and YouTube channel)* - training kits, device guides, case studies and recorded education webinars to support PoCT training and competency
- **PathWest Laboratory Medicine WA** – *PoCT Resources* - information, guidance and support resources relating to PoCT implementation and use
- **Flinders University International Centre for PoCT** – *PoCT Training* – i-STAT and WBC DIFF training
- **Abbott** – *i-STAT training*

1.6 Safe environment

PoCT occurs in diverse healthcare settings. A safe and fit-for-purpose environment is essential to reduce the risk of errors, contamination and device malfunction in PoCT.

Action 1.6

When PoCT is undertaken in traditional, clinical settings[2], the service provider ensures that:

a. there is adequate space for instruments, consumables, documentation and waste disposal
b. the operational environment and premises are fit for purpose and well maintained
c. PoCT is conducted in a manner that supports privacy, dignity, confidentiality and culturally safe communication
d. the environment supports infection prevention and control requirements
e. storage conditions for PoCT devices, reagents, consumables and specimen collection materials are managed in accordance with the manufacturer's instructions for use, including temperature, and other environmental requirements where applicable
f. processes are in place to identify, assess and respond when environmental or storage conditions fall outside the manufacturer's specified limits.

Reflective questions

- Is the environment fit-for-purpose, including lighting, ventilation, temperature control and electrical safety?
- Does the physical environment support equitable access for patients with diverse care needs?
- When PoCT occurs outside of the clinical setting, what strategies are implemented to mitigate risks?

Suggested strategies

- Establish policies to ensure safe handling and disposal of specimens, collection devices, and consumables, which comply with jurisdictional regulations relating to the disposal of biological material.
- Provide an environment that supports accurate result interpretation, including appropriate lighting, minimal distractions, and suitable equipment.
- Provide an environment that supports privacy, dignity and confidentiality during PoCT, including access to a private area for sensitive discussions where feasible.

[2] When PoCT is undertaken outside of clinical settings, health practitioners should do a risk assessment of the environment and implement strategies to ensure patients receive person-centred, high-quality care.

- For PoCT involving suspected or confirmed communicable diseases, implement appropriate measures to reduce transmission risk to other patients, residents, staff and visitors, consistent with local infection prevention and control requirements. This may include patient separation, use of personal protective equipment (PPE), environmental cleaning and disinfection, and management of waiting areas.

1.7 Feedback and complaints

Effective feedback and complaints processes allow service providers to identify risks, learn from lived experience and improve PoCT safety and quality.

Transparent and culturally safe responses support PoCT operators' learning, continuous quality improvement and person-centred care.

Action 1.7

The service provider ensures there is a process for the management of feedback and complaints by:

a. documenting feedback and complaints from patients, carers and PoCT users
b. reporting on feedback and complaints from patients and their carers, requesters, referrers and other service providers to the governing body
c. acting on feedback and addressing complaints in a timely manner, and informing patients and carers of the outcome
d. documenting the timeliness of responses, evaluation and improvements made because of the feedback and complaint
e. analysing feedback and complaints to improve the safety and quality of PoCT

Reflective questions

- Does the service have a clear and culturally safe process to capture feedback and complaints related to PoCT?
- Does the service analyse feedback and complaints to drive timely, meaningful, measurable improvements in PoCT processes?
- When and how is feedback collected from the patients and their carers, requesters, referrers and PoCT operators?
- How are complaints received, reviewed and resolved in a timely manner?
- How is feedback and complaints data used to improve safety and quality?
- How is the effectiveness of the feedback and complaints management system reviewed?

Suggested strategies

- Establish an accessible and culturally safe process for receiving feedback and complaints related to PoCT from patients, carers and PoCT operators.
- Clearly communicate, through publicly accessible information, how feedback and complaints can be submitted, how they will be managed, and how privacy and confidentiality will be protected.

- Establish a systematic approach to collecting, recording, assessing, responding to and analysing feedback and complaints, including assigning roles and responsibilities, protecting privacy, and identifying opportunities for quality improvement.
- Provide options for anonymous feedback or complaints where people are concerned about being identified.
- Train PoCT operators to receive, manage and respond appropriately to feedback and complaints.
- Ensure feedback and complaints are followed up promptly, responses are provided, and agreed improvements are implemented.
- Link feedback and complaints processes to risk management and quality improvement activities.
- Analyse and report feedback and complaints trends, learnings and improvement opportunities to PoCT operators and the governing body.

Resources

- **Australian Health Practitioners Regulation Agency (Ahpra), National Boards and the Commission** – *Checklist for practitioners handling feedback and complaints* - practical guidance for receiving, responding to and learning from feedback and complaints
- **Commission** – *Australian Hospital Patient Experience Question Set* -patient experience measures that may support collection and analysis of patient feedback
- **Ahpra** – *Concerns about practitioners* - information on how concerns about registered health practitioners can be raised and managed

2. Person-centred care

Service providers deliver person-centred PoCT that recognises the importance of working with patients in planning and delivering their health care and providing clear communication to minimise the risks of harm. It recognises and respects differences in individual needs, beliefs and cultures. Patients are partners in their own care, to the extent that they choose.

This section supports service providers to deliver person-centred PoCT by creating mutually beneficial outcomes through effective partnerships with patients, carers and consumers.

Key areas

Healthcare rights

Informed consent

Diverse care needs

Person-centred communication

2.1 Healthcare rights

Patients have the right to receive safe and high-quality health care. When providing PoCT, service providers should recognise and uphold healthcare rights by ensuring testing is clinically appropriate, performed safely, and supported by systems that promote transparency, accountability and respect for patients.

Action 2.1

The service provider must:

a. use a charter of rights consistent with the Australian Charter of Healthcare Rights

b. support PoCT operators to apply the principles of the Charter of Rights

Reflective questions

- How are patients informed about their healthcare rights when PoCT is provided?
- How does the service provider ensure the Charter of Healthcare Rights is accessible to patients and consumers?
- How are PoCT operators supported to apply the principles of the Charter of Healthcare Rights in their interactions with patients?

Suggested strategies

- Use a charter of rights that is consistent with the Australian Charter of Healthcare Rights.
- Make information about healthcare rights visible and accessible at the point of care, using formats appropriate to the patient population.
- Support PoCT operators to apply the principles of the Charter of Healthcare Rights when delivering PoCT.

Resources

- **Commission** – *Understanding your healthcare rights* - information and resources for consumers and health professionals on the Australian Charter of Healthcare Rights

2.2 Informed consent

Informed consent is fundamental to person-centred care, including PoCT, and supports patients to understand and participate in decisions about testing, how their information may be used and shared, and the implications for diagnosis, treatment and follow-up care. Certain results may also be subject to legislative or public health reporting requirements.

Action 2.2

The service provider has processes to:

a. ensure informed consent for the use of PoCT is suitable for the context and complies with legislation and guidelines

b. provide transparent financial consent when information of the test and cost are known, prior to the PoCT being conducted

c. support PoCT operators to actively involve patients who require shared decision making to make decisions and include substitute decision-makers to the degree a patient wants them involved

d. ensure informed ongoing consent to provide a report to the patient's other service providers, where required

e. ensure informed ongoing consent to collect, store and distribute identifiable or de-identified personal data and records for purposes other than patient direct care, quality control and training

f. explain any circumstances where personal information or test results may need to be disclosed to comply with legislative or public health reporting requirements

Additional information

Notifiable diseases

Some conditions identified through PoCT may be subject to mandatory notification requirements under Commonwealth, state or territory legislation. Service providers should ensure PoCT operators understand local reporting requirements and can explain to patients when personal information or test results may need to be disclosed to public health authorities.

The National Notifiable Diseases Surveillance System (NNDSS) collects and shares information on nationally notifiable diseases, including Hepatitis B and C, to support public health surveillance and response activities. Information collected may include age, sex, postcode, Indigenous status and disease-specific information. Collection of Indigenous status information is important for identifying health inequities, monitoring disease burden and supporting culturally safe public health responses for Aboriginal and Torres Strait Islander peoples. Indigenous status information should be collected with informed consent in a culturally appropriate way.

Reflective questions

- How does the service provider ensure patients understand the purpose, benefits, limitations and implications of PoCT before testing occurs?
- How are patients informed about how their information and test results may be used, shared or disclosed?
- How does the service provider support shared decision making, including involvement of carers or substitute decision-makers where required?
- How are financial costs communicated to patients before PoCT is undertaken, where relevant?
- How does the service provider ensure PoCT operators understand circumstances where public health reporting or other legislative disclosure requirements apply?

Suggested strategies

- Establish and document clear processes for obtaining and recording informed consent for PoCT.
- Provide information about the purpose, benefits, limitations, costs and follow-up implications of PoCT before testing occurs.
- Develop processes to support shared decision making, including involvement of carers or substitute decision-makers where appropriate.
- Explain how PoCT results and personal information may be used, shared or disclosed, including any legislative or public health reporting requirements.
- Regularly review consent processes and supporting information to ensure they remain current, accurate and person-centred.

Case study – Obtaining informed consent for PoCT

A 55-year-old person attends a community pharmacy to collect their regular medicines for diabetes and hypertension. During routine interaction, the patient mentions they have not had blood tests for some time.

The pharmacist offers a consultation in a private consultation room to support confidentiality and undertakes a brief review, including current medicines and relevant health history. Based on this discussion, the pharmacist explains that PoCT, such as a finger-prick blood test to check indicators like blood glucose or HbA1c, may support up-to-date monitoring.

The pharmacist obtains verbal informed consent, explaining:

- the purpose of the test and why it is being recommended
- how the test will be performed
- the limitations of PoCT and the role of confirmatory laboratory testing
- the cost of the test
- how results will be used and shared, and any follow-up required.

With consent, the pharmacist performs the PoCT in accordance with the manufacturer's instructions for use. Results are available during the consultation and are explained in plain language.

The patient is provided with a record of the results. The pharmacist provides lifestyle advice within their scope of practice and communicates relevant information to the patient's usual healthcare provider. Where appropriate and available, results may also be uploaded to My Health Record or otherwise shared with the patient's usual healthcare provider to support continuity of care.

This example demonstrates how informed consent processes, private consultation environments, clear communication, documentation and information-sharing arrangements support the safe and person-centred use of PoCT in community pharmacy settings.

2.3 Diverse care needs

The service provider ensures person-centred PoCT is delivered equitably and safely for people with diverse care needs by upholding patient privacy, dignity and security.

Service providers consider how PoCT systems and processes can support the needs of the whole population without disadvantaging or privileging any one patient group over another. Some patient groups may be more vulnerable and require additional support to access services and additional sensitivity when collecting, testing and reporting on specimens.

Action 2.3

The service provider creates a safe environment and delivers person-centred care including to people with diverse care needs by:

a. supporting equitable access to PoCT and reducing barriers to testing
b. ensuring PoCT is provided in a manner that respects individual preferences, communication needs and cultural backgrounds
c. ensuring PoCT is culturally safe for Aboriginal and Torres Strait Islander peoples and supports partnerships in care
d. providing additional support where required to facilitate informed decision-making and participation in care

Reflective questions

- How are patients informed of their rights in relation to PoCT, including dignity, respect and participation in decision-making?
- How does the service provider ensure patients understand the purpose, benefits, limitations and implications of PoCT before testing occurs?
- How does the service provider support shared decision making, including involvement of carers or substitute decision-makers where required?
- How does the service provider support people from culturally and linguistically diverse backgrounds to understand PoCT information, provide informed consent, receive results and participate in decisions about their care?
- How does the service provider ensure PoCT is culturally safe for Aboriginal and Torres Strait Islander peoples and supports partnerships in care?
- How are PoCT systems and environments designed to support equitable access and safe testing for all patient groups?

Suggested strategies

- Make information about patient rights visible and accessible at the point of care, using formats appropriate to the patient population.
- Use qualified interpreters, translated resources, plain language or alternative communication methods as required.

- Provide training on culturally safe and inclusive practices in PoCT contexts.

Resources

- **Commission** – *NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health* - guidance on culturally safe care and partnering with Aboriginal and Torres Strait Islander peoples
- **Commission** – *NSQHS Standards User Guide for Health Service Organisations Providing Care for Patients from Migrant and Refugee Backgrounds* - guidance on providing safe and responsive care for people from culturally and linguistically diverse backgrounds
- **TIS National** – *Free Interpreting Service* - interpreting services and resources to support communication with people who require language assistance

2.4 Person-centred communication

Person centred communication ensures patients are engaged in a respectful and culturally safe way that meets their individual needs. This includes clearly explaining PoCT, supporting understanding of results and providing guidance for follow up care, including sensitive discussions.

Action 2.4

The service provider:

a. communicates with patients and carers in a tailored way to meet their individual needs and preferred communication modalities

b. ensures all communication is confidential, culturally safe and free from racism

c. provides consumer focused PoCT pre-test information, including the benefits and limitations of the PoCT

d. provides advice on accessing follow-up care and provision of post-test counselling, including appropriate support when communicating sensitive results

e. ensures the patients and carers understand relevant infection prevention and control guidance

Reflective questions

- When, what and how is information about PoCT communicated to patients?
- How are PoCT operators supported to meet the individual information needs of patients?
- Are PoCT operators trained and supported to provide guidance for follow up?
- How are sensitive test results communicated to the patients?

Suggested strategies

- Develop processes for patient communication that support open and effective communication about PoCT.
- Establish a process for identifying and selecting appropriate consumer information materials and resources.
- Provide accessible, easy-to-understand patient information in formats that meet the needs of the consumers using the service.
- Provide PoCT operators with training on communicating PoCT results
- Seek patient feedback on communication processes and implement improvements where opportunities are identified.

Case study – Communicating sensitive test results

A 22-year-old person attends a community health service seeking sexually transmitted infection (STI) screening after a recent potential exposure.

The PoCT operator explains the purpose of the test, its benefits and limitations, potential results, confidentiality arrangements and available support services. The PoCT operator also explains that some positive STI results may be subject to public health notification requirements. The patient provides informed consent before testing.

The test returns a positive result for syphilis. In accordance with service procedures, the result is discussed in a private consultation room. The PoCT operator uses clear, non-judgemental language and checks the patient's understanding of the result and next steps.

The patient is advised about confirmatory laboratory testing where appropriate, referral pathways and treatment options. Information about partner notification services, public health notification requirements and support resources is also provided.

The result, discussion, referrals and follow-up arrangements are documented in the patient record.

This example demonstrates how documented consent processes, person-centred communication, access to private consultation spaces, and clear referral and follow-up pathways support the safe management of sensitive PoCT results.

3. PoCT management

PoCT management supports the safe and effective use of PoCT devices throughout their lifecycle. It involves selecting, using, maintaining and monitoring devices in accordance with the manufacturer's instructions for use, with quality control and quality assurance processes that support accurate and reliable results.

This section supports service providers to implement systems and processes for the safe management of PoCT devices and testing practices, helping to minimise risks to patients and support high-quality care.

Key areas

PoCT medical device selection

Safe use of PoCT medical devices

Safe management of PoCT medical devices

Specimen collection

Infection prevention and control

Quality control

Quality assurance

3.1 PoCT medical device selection

PoCT medical device selection is a critical step in ensuring testing is fit for purpose and clinically appropriate for the setting of its use. Service providers apply a structured, risk-based approach to device selection to ensure it meets the clinical need, PoCT operator capability, environmental conditions and governance requirements.

Action 3.1

The service provider:

a. uses a structured, risk-based approach to select PoCT medical devices appropriate for the intended clinical purpose, patient population and testing environment

b. ensures PoCT medical devices meet applicable regulatory requirements and organisational requirements

c. monitors the ongoing suitability, performance and fitness for purpose of PoCT medical devices throughout their lifecycle

d. seeks advice from pathology laboratories or other technical experts during device selection and review, where appropriate

Reflective questions

- What clinical need or service gap is the proposed PoCT device intended to address, and is the device the most appropriate solution for the context?
- How are PoCT operator capability, environmental conditions and infrastructure considered during device selection?
- How does the service provider ensure PoCT devices are implemented to produce accurate, reliable and clinically appropriate results?
- How does the service provider assess manufacturer information, including intended use, limitations and quality claims, when selecting devices?
- How does the service provider monitor the ongoing suitability, fitness for purpose and regulatory status of PoCT medical devices after implementation?

Suggested strategies

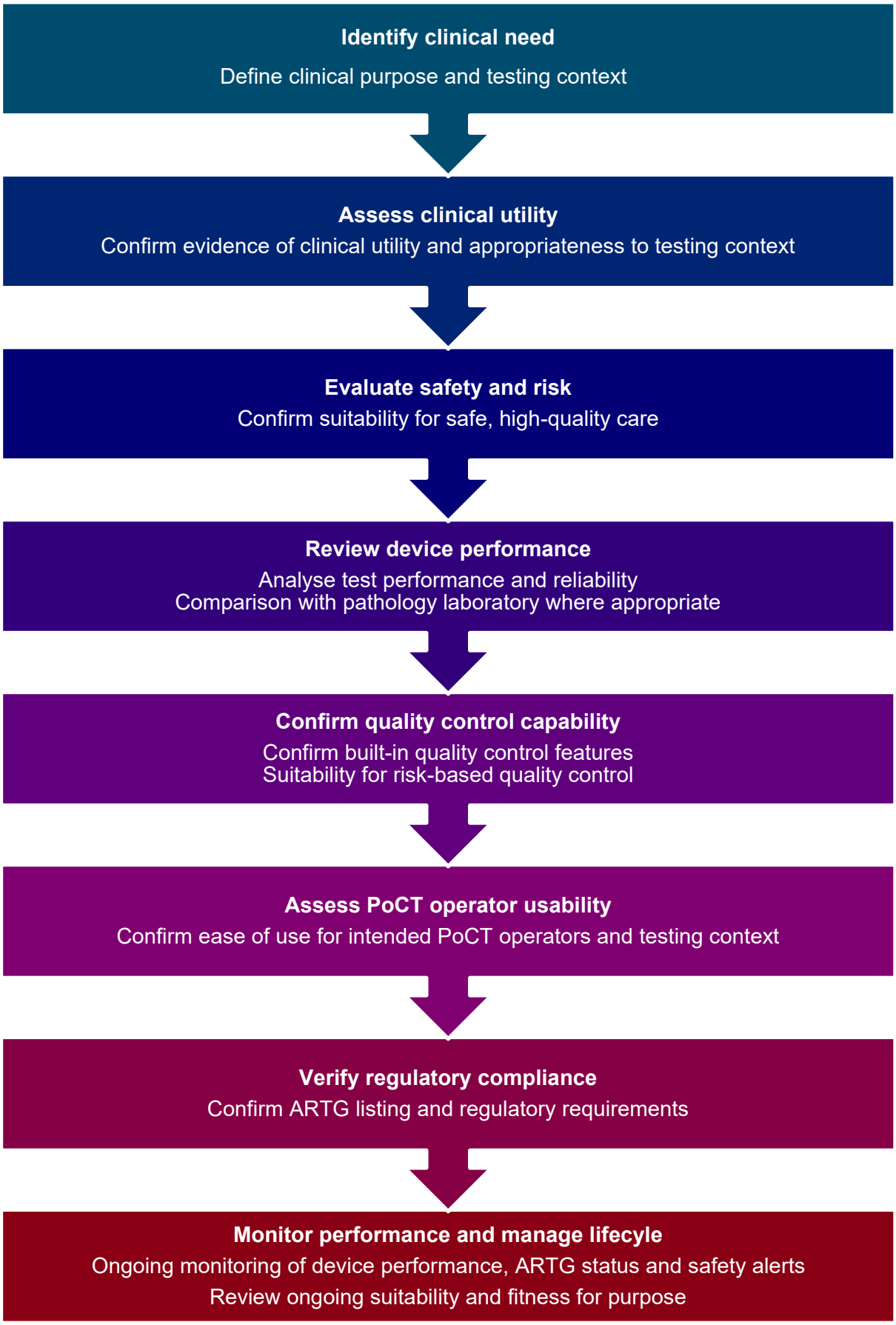
- Use a structured, documented device selection process, as outlined in **Figure 2**.
- Involve relevant stakeholders in device selection decisions where appropriate (for example, PoCT operators, clinicians, technical experts, governance advisors, pathology laboratories).
- Confirm the selected device aligns with PoCT operator skills and training capacity, particularly in settings with limited access to specialist support.
- Review device selection decisions periodically or when there are changes to clinical use, PoCT operator capacity, environment or manufacturer requirements.

- Periodically review whether the device remains fit for purpose for the clinical setting, intended use, testing volume and operator group.

Resources

- **SKUP (Scandinavian Evaluation of Laboratory Equipment for Point-of-Care Testing)** – *Evaluation reports* - independent evaluations of PoCT devices and performance reports
- **Peer reviewed literature** – Published evaluations and performance studies may provide additional information about the reliability and limitations of PoCT devices.

Figure 2 PoCT medical device selection process



3.2 Safe use of PoCT medical devices

To ensure standardised use of PoCT systems, service providers must comply with standard operating procedures and the manufacturer's instructions for use. The instructions for use identifies the critical aspects for all testing stages, so testing is performed consistently.

Action 3.2

The service provider:

a. ensures PoCT medical devices are used in accordance with the manufacturer's instructions for use

b. identifies and manages risks associated with off-label use of PoCT medical devices.

Additional information

Off-label use

For service providers using a PoCT medical device outside the scope of its instructions for use constitutes off-label use, which converts it into an in-house PoCT medical device. More information on off label use, refer to **Appendix B**.

Specimen testing errors

Not following the manufacturer's instructions for use can cause incorrect or misleading results and put patients at risk. This includes changes such as:

- using the test for a purpose it was not designed for
- using the wrong sample type
- having unapproved or untrained staff perform the test
- not following the required testing steps or limits
- changing how results perform, such as accuracy or reliability
- not following infection control practices or using contaminated supplies
- incorrect device settings, such as wrong units of measurement
- using expired quality control materials
- reading results at the wrong time, such as with urine dipsticks or rapid tests.

Reflective questions

- How does the service provider ensure PoCT operators have access to current versions of the manufacturer's instructions for use?
- How does the service provider ensure PoCT medical devices are used consistently and in accordance with the manufacturer's instructions for use?
- How are proposed changes to testing procedures reviewed before implementation?

- How does the service provider identify and manage off-label use of PoCT medical devices?
- How do PoCT operators know when a proposed use of a PoCT medical device differs from the manufacturer's intended use?

Suggested strategies

- Ensure current versions of the manufacturer's instructions for use are readily available to PoCT operators.
- Develop local procedures that are consistent with the manufacturer's instructions for use.
- Review proposed changes to testing procedures before implementation.
- Assess and manage risks associated with off-label use of PoCT medical devices.
- Seek expert advice where use of a PoCT medical device differs from the manufacturer's intended use.

3.3 Safe management of PoCT medical devices

PoCT medical devices should be managed throughout their lifecycle to ensure they remain safe for use, effective and fit for purpose. Appropriate selection, storage, maintenance, monitoring and decommissioning of devices helps reduce the risk of inaccurate results and supports safe patient care.

Action 3.3

The service provider:

a. has processes to manage PoCT medical devices throughout their lifecycle, including decommissioning when devices are no longer fit for purpose

b. ensures PoCT medical devices, reagents and consumables are managed, maintained, monitored and serviced in accordance with the manufacturer's instructions for use

c. maintains systems to support the management and oversight of PoCT medical devices, reagents and consumables

d. plans for service continuity when devices are unavailable or unable to be used

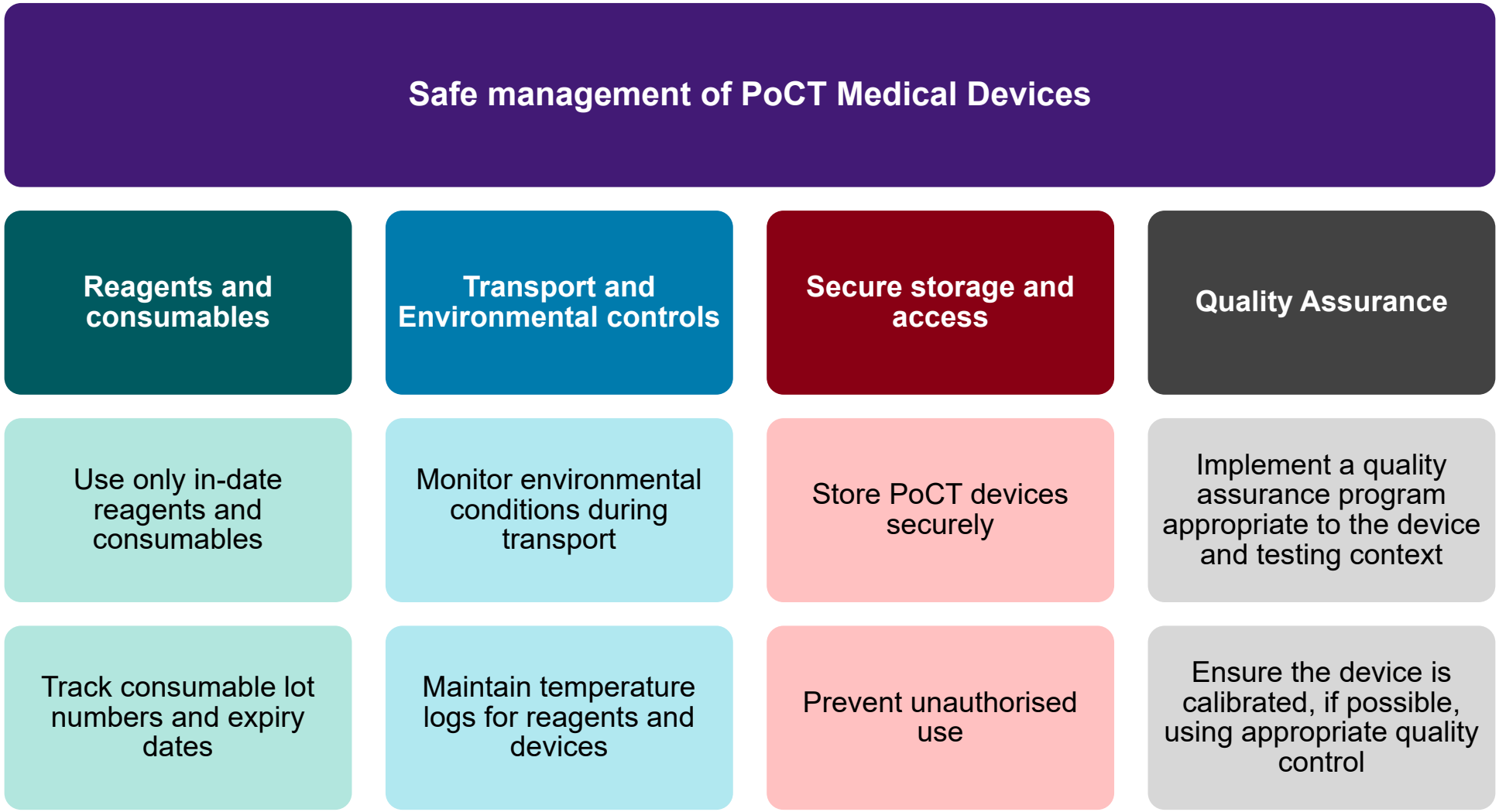
Reflective questions

- How does the service provider ensure PoCT medical devices are managed throughout their lifecycle?
- How does the service provider ensure devices, reagents and consumables are stored, maintained and managed in accordance with the manufacturer's instructions for use?
- How does the service provider maintain oversight of device performance, maintenance and consumable management?
- What arrangements are in place to support continuity of testing when a device is unavailable or unable to be used?

Suggested strategies

- Maintain an asset register or similar system for PoCT medical devices, including device identification, location, maintenance history, servicing requirements, software or firmware updates, and device status.
- Maintain a consumables log or similar system that records lot numbers, expiry dates and actions taken for expired or unsuitable consumables.
- Establish documented processes for device storage, transport, device calibration, cleaning, maintenance and servicing in accordance with the manufacturer's instructions for use. **Figure 3** provides examples of activities that may support the safe management of PoCT medical devices throughout their lifecycle.
- Monitor and document device maintenance, servicing and software or firmware updates where applicable.
- Establish contingency arrangements for patient testing when a PoCT device is unavailable due to maintenance, quality concerns or device failure.

Figure 3 Safe management of PoCT medical devices



Safe management of PoCT Medical Devices

Maintenance and repair	Post-maintenance verification	Service continuity	Device lifecycle management
Use qualified personnel for planned maintenance and repairs	Perform quality control testing after maintenance or repairs	Ensure continuity of diagnostic services during device downtime	Maintain an asset register for PoCT medical devices
Enable remote support where on-site access is limited	Confirm device performance before returning to service	Have contingency arrangements in place	Decommission devices beyond their intended lifespan or no longer fit for purpose

3.4 Specimen collection

Correct specimen collection and positive patient identification are essential to ensure PoCT results are accurate, reliable and attributed to the correct patient. Service providers should have processes in place to support safe specimen preparation, collection, handling and identification throughout the testing process.

Action 3.4

The service provider:

a. has processes to support safe and appropriate specimen collection, preparation and handling

b. ensures specimens are collected and managed in accordance with the manufacturer's instructions for use

c. supports positive patient identification throughout the specimen collection and testing process

Additional information

Supporting specimen quality

To support accurate and reliable PoCT results, service providers should ensure that:

- PoCT medical devices, specimen collection materials and consumables are available and within their expiry dates
- specimens are prepared and collected in a way that preserves their original characteristics
- specimen collection devices recommended by the manufacturer are used
- specimen sample volume quantity is adequate for testing.

Specimen collection errors

Most PoCT errors happen before the test is even run, usually because of patient identification errors (see **Figure 4**), poor patient preparation, or problems with how the sample is collected or handled. If these errors are not picked up early, test results can be wrong, and patient safety can be affected.

Common collection errors include:

- taking blood from the wrong tube
- doing a finger prick test on unwashed hands
- not using the correct drop of blood after a finger prick
- using the wrong type of sample
- air bubbles in the sample holder
- using collection devices not recommended by the manufacturer
- collecting too much or too little sample

- delays in testing or mishandling the sample.

Getting specimen collection right is essential to ensure accurate results and safe patient care.

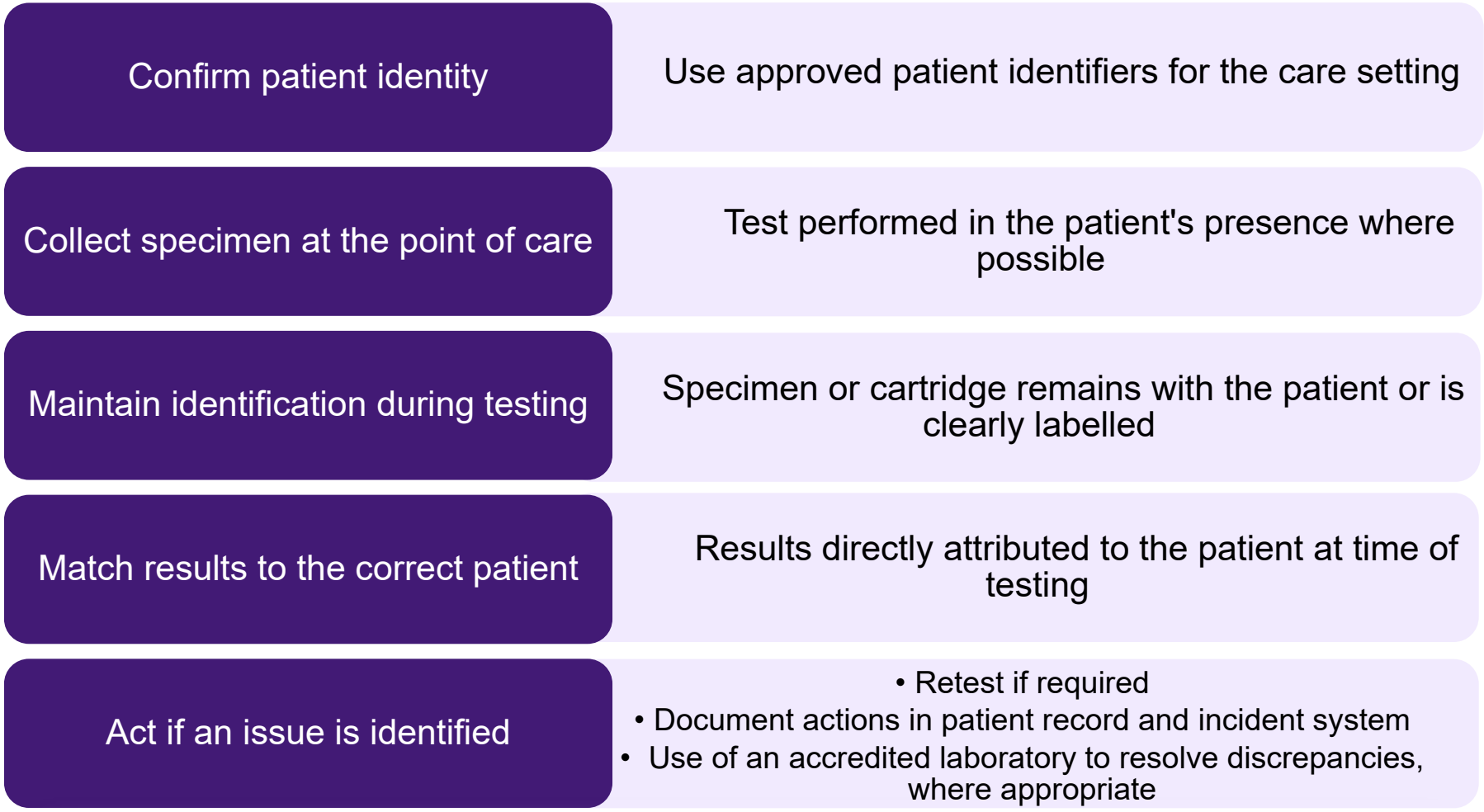
Reflective questions

- How does the service provider ensure specimens are collected, prepared and handled correctly before testing?
- How are PoCT operators supported to perform specimen collection in accordance with the manufacturer's instructions for use?
- How does the service provider support positive patient identification throughout specimen collection and testing?
- What processes are in place to identify and respond to specimen collection errors or specimen quality concerns?
- How does the service provider ensure specimen collection materials and consumables are suitable for use and within their expiry dates?

Suggested strategies

- Develop documented procedures for specimen collection, preparation, handling and identification for each PoCT performed.
- Ensure PoCT operators receive training and competency assessment in specimen collection techniques relevant to the tests they perform.
- Use specimen collection devices and materials recommended by the manufacturer.
- Use processes for positive patient identification appropriate to the care setting, consistent with the principles outlined in **Figure 4**.
- Where specimens are labelled, ensure labelling occurs in a manner that maintains the link between the patient, specimen and result throughout the testing process.
- Establish processes to identify, document and manage specimen collection errors, including patient identification errors and unsuitable specimens.

Figure 4 Positive patient identification across the PoCT process



For immediate PoCT where the specimen is tested at the point of collection, and there is no risk of sample mix-up, positive identification may be achieved without physical labelling, provided the result is correctly attributed to the patient.

3.5 Infection prevention and control

Infection prevention and control practices are essential to the safe delivery of PoCT. Appropriate measures during specimen collection, testing, cleaning and waste disposal help reduce the risk of infection transmission and protect patients, PoCT operators and others in the testing environment.

Action 3.5

The service provider:

a. has infection prevention and control processes that support the safe collection, handling and testing of specimens, including cleaning, disinfection and waste management processes, and minimise the risk of infection transmission associated with PoCT

b. ensures infection prevention and control activities are undertaken in accordance with the Australian Guidelines for the Prevention and Control of Infection in Healthcare and the manufacturer's instructions for use, where applicable

c. provides PoCT operators with access to infection prevention and control training appropriate to the testing being performed.

Reflective questions

- How does the service provider identify and manage infection risks associated with PoCT?
- How are cleaning, disinfection and waste management requirements determined for PoCT devices, equipment and testing environments?
- How frequently and with what disinfectants are the facilities cleaned, for example, clinical and patient waiting areas?
- How does the service provider ensure infection prevention and control activities are undertaken in accordance with the Australian Guidelines for the Prevention and Control of Infection in Healthcare and the manufacturer's instructions for use?
- How does the service provider ensure PoCT operators understand infection prevention and control requirements relevant to the tests being performed?

Suggested strategies

- Have processes to maintain a clean, safe, and hygienic environment.
- Define roles, responsibilities and accountabilities for environmental cleaning and disinfection.
- Use cleaning products listed on the Australian Register of Therapeutic Goods.
- Have contracts with external cleaning providers that outline the service provider’s cleaning and disinfection requirements.
- Provide PoCT operators with cleaning and disinfection training.

- For PoCT involving suspected or confirmed communicable diseases, implement measures to minimise transmission risks to patients, residents, staff and visitors, including the use of PPE, environmental cleaning and patient separation where required.
- Obtain feedback from patients and PoCT operators on the service provider's cleanliness and hygiene and take action to improve.
- Monitor compliance with infection prevention and control processes and address identified issues.

Resources

- **Commission** – *Australian Guidelines for the Prevention and Control of Infection in Healthcare* - national guidance on infection prevention and control practices in healthcare settings.
- **Australian Government Department of Health and Aged Care** – *Australian Immunisation Handbook* - guidance on vaccine-preventable diseases and workforce immunisation

Case study – Managing an infectious disease outbreak

Several residents in a residential aged care service develop fever, cough and other influenza-like symptoms over a short period.

In accordance with the service's documented infection prevention and control and outbreak management procedures, a trained PoCT operator performs influenza testing on all symptomatic residents. The PoCT operator has completed infection prevention and control training relevant to the testing being performed.

Before testing, the operator prepares the testing area, performs hand hygiene and dons the required PPE. Following specimen collection and testing, specimens and consumables are disposed of safely, and the testing environment and equipment are cleaned and disinfected in accordance with local procedures and the manufacturer's instructions for use.

Four residents return positive influenza results. As this meets the service's outbreak definition of two or more confirmed cases, an outbreak is declared and reported through the required notification pathways. The service implements its outbreak management plan, including enhanced infection prevention and control measures, increased resident monitoring, environmental cleaning and disinfection, use of PPE where required, and communication with residents, families and staff.

The rapid availability of PoCT results also enables timely clinical decisions regarding antiviral treatment for affected residents and antiviral prophylaxis for exposed residents, in accordance with local clinical pathways and public health guidance.

This example demonstrates how infection prevention and control training, safe specimen handling, use of PPE, cleaning and disinfection procedures, and adherence to the manufacturer's instructions for use support the safe use of PoCT and management of infectious disease outbreaks in aged care settings.

3.6 Quality control

Quality control (QC) helps ensure PoCT devices are performing as intended and producing reliable results at the time of testing. QC supports the early identification of issues that may affect result accuracy and provides confidence that patient testing can proceed safely. QC helps answer the question: “Is the test system performing correctly right now?”

Action 3.6

The service provider has documented QC processes that:

a. ensure the ongoing suitability of PoCT devices for patient testing
b. support the timely identification and management of issues that may affect the accuracy or reliability of results
c. are aligned with the manufacturer's instructions for use and the clinical context in which testing is performed
d. require appropriate documentation, review and follow-up of QC activities

Additional information

QC may include internal electronic checks built into a device (internal quality control - IQC), as well as external checks using control materials, usually provided by the manufacturer of the device, with known values (external quality control - EQC). These checks help confirm the device and test system are functioning as expected before or during patient testing.

What PoCT operators need to know about QC

PoCT operators should:

- recognise QC failures and know how to respond
- understand when QC is required for the device they are using (not at every use unless required)
- not report patient results when the device displays an error or QC failure
- know when a device should not be used
- escalate concerns in accordance with local procedures and escalation pathways.

Examples of situations when QC may be required

The frequency of QC should be based on the manufacturer's instructions for use, device characteristics and local risk assessment. Examples of circumstances where QC may be performed include:

- introduction of a new consumable or reagent lot
- concern about inaccurate, unreliable or discordant results
- when results are inconsistent with the patient's clinical presentation
- after device maintenance or repair
- following a device software or firmware update

- after a device has been relocated
- after a device has been dropped, physically impacted or exposed to adverse environmental conditions
- following a power interruption or unexpected device shutdown
- when there is a change in PoCT operator
- when otherwise required by the manufacturer's instructions for use or local procedures.

Reflective questions

- How does the service provider determine the type and frequency of QC required for each PoCT device?
- How are QC results reviewed and acted upon?
- What happens when QC results fall outside acceptable limits?
- How does the service provider ensure QC requirements are accessible and understood by PoCT operators?
- How does the service provider ensure that patient testing only proceeds when QC requirements have been met?

Suggested strategies

- Perform QC in accordance with the manufacturer's instructions for use.
- Use a risk-based approach to determine the type and frequency of QC required.
- Ensure PoCT operators have access to current QC procedures and requirements.
- Define acceptable QC limits and actions to be taken when results fall outside those limits.
- Pause patient testing when QC requirements are not met and escalate concerns in accordance with local procedures.
- Document QC activities, results, investigations and corrective actions.

Resources

- **SKUP:** Evaluation Reports - information on device limitations and quality-related issues identified through independent evaluation

Case study – Responding to a QC failure

Before commencing patient testing in the emergency department, a trained PoCT operator performs the required QC checks on a PoCT analyser, in accordance with local procedures and the manufacturer's instructions for use.

The QC result falls outside the acceptable range. In line with the service's documented process, the operator does not proceed with patient testing and repeats the QC check. When the repeat QC result also falls outside the acceptable range, the device is removed from service, and the issue is escalated to the designated support person.

An investigation is undertaken to determine the cause of the failure. The review identifies that a recently opened reagent lot had not been stored within the temperature range specified by the manufacturer. The affected reagents are removed from use and replaced. QC is repeated and satisfactory results are obtained before the device is returned to clinical service.

The event is documented through the service's incident management system. The investigation findings are reviewed, and additional controls are introduced to improve monitoring of reagent storage conditions and reduce the likelihood of a similar issue occurring in the future.

This example demonstrates how QC procedures, staff training, incident reporting, investigation and corrective action processes help ensure PoCT devices are performing as intended and support the delivery of safe and reliable patient care.

3.7 Quality assurance

Quality assurance (QA) is the planned, ongoing activities a service uses to monitor and demonstrate that PoCT results are reliable, accurate and safe to use over time. Unlike QC, which checks that a test system is performing as expected at a particular point in time, QA provides confidence that testing systems, processes and results remain reliable over time. QA helps answer the question: “Are our testing processes working well on an ongoing basis?”.

Action 3.7

The service provider should:

a. monitor the ongoing performance, reliability and suitability of PoCT services
b. identify opportunities to improve the quality and consistency of PoCT results
c. support investigation and follow-up of unexpected performance issues
d. use QA information to inform continuous improvement activities
e. ensure any identified problems are corrected prior to using the PoCT device clinically

Additional information

QA activities may be conducted within an organisation (internal quality assurance - IQA) or through external programs (external quality assurance - EQA), which may include comparison with other services or reference standards. These processes (for example, training, audits, external quality programs, maintenance, documentation, incident review) provide confidence that testing systems, staff practices and results remain consistent and meet expected standards over time.

The role of EQA is also to ensure that a patient receives the same result no matter on which device the sample is analysed. Comparison of EQA results across different sites identifies problems with different devices that will not be identified with IQC or QC. EQA is provided by an independent organisation from the device manufacturer.

Reflective questions

- How does the service provider ensure PoCT results remain reliable over time?
- What QA information is reviewed and how often?
- How are QA findings investigated and acted upon?
- How does the service provider identify trends, recurring issues or opportunities for improvement?
- What alternative approaches are used when a suitable external QA program is unavailable?

Suggested strategies

- Participate in EQA or proficiency testing programs where available and appropriate.

- Review EQA findings and investigate unexpected or unsatisfactory results.
- Monitor quality-related information such as QC results, incidents, complaints, audits and feedback.
- Implement corrective actions and monitor their effectiveness.
- Use QA findings to improve policies, procedures, training and testing practices.

Resources

- **Royal College of Pathologists of Australasia, Quality Assurance Programs (RCPAQAP)** – *Chemical Pathology Analytical Performance Specifications* - performance specifications supporting quality assurance activities
- **RCPAQAP** – *Haematology Analytical Performance Specifications* - performance specifications supporting quality assurance activities

QA plays an important role in maintaining confidence in the safety and reliability of PoCT. The following case studies illustrate two different ways that QA activities can identify issues and support investigation, corrective action and continuous improvement.

Case study – EQA identifies calibration drift

A primary health service uses a PoCT analyser for HbA1c testing. The device has consistently passed routine QC checks, and no operational issues have been identified by PoCT operators.

As part of the service's EQA program, a blinded proficiency testing sample is analysed and submitted for assessment. When the EQA report is received, the service learns that its reported result is significantly outside the acceptable performance limits when compared with peer services using the same testing method.

The result is escalated in accordance with the service's QA and incident management procedures. An investigation is commenced to determine the cause of the discrepancy.

The review confirms that recent QC results were within acceptable limits and that no obvious device faults had been identified. Further investigation identifies a calibration drift that was not detected through routine QC processes but became evident through comparison with the EQA results.

The service temporarily suspends patient testing on the device and seeks advice from the manufacturer and a pathologist. Affected devices are recalibrated if possible and additional verification testing is undertaken before the analyser is returned to clinical use.

The service reviews recent patient results to determine whether any were potentially affected and, where required, initiates clinical review and follow-up in accordance with local policies and procedures.

The incident, investigation findings and corrective actions are documented. The service updates its QA procedures and provides additional education to PoCT operators on recognising and responding to EQA performance concerns.

This example demonstrates how external QA programs can identify performance issues that may not be detected through routine QC activities, and how documented escalation, investigation and corrective action processes help maintain confidence in the safety and reliability of PoCT results.

Case study – Patient impacted by undetected device fault

A PoCT operator performs a haemoglobin test in an urgent care service. The result falls within the expected range and is documented in the patient's healthcare record. Later that day, routine quality assurance activities identify that the analyser had been producing inaccurate results due to an undetected device fault.

A review determines that the patient may have received an incorrectly low assessment of clinical risk. The patient is contacted and recalled for repeat testing. The repeat test identifies significant anaemia requiring further investigation.

The incident is reported through the incident management system and assessed using the organisation's incident severity assessment process. Because the patient required additional clinical review and there was potential for delayed diagnosis, the incident is categorised as a moderate-harm incident and escalated in accordance with local procedures.

A multidisciplinary review is undertaken to identify contributing factors, including why the device issue was not detected earlier. The findings are communicated to relevant PoCT operators and service leaders, and corrective actions are implemented. These include additional quality assurance checks, revised escalation guidance and refresher training for PoCT operators.

The service monitors the effectiveness of the corrective actions and reviews incident trends to determine whether further improvements are required.

This example demonstrates how incident severity assessment, harm categorisation and proportionate escalation pathways support the safe management of PoCT incidents and help ensure that incidents with a higher risk of patient harm receive timely review, investigation and follow-up.

4. Communication and reporting

Communication and reporting support the safe, timely and effective exchange of PoCT information between patients, PoCT operators and healthcare providers. Effective communication is critical at high-risk times, including transitions of care and when results require escalation, and helps ensure PoCT results are understood, acted on appropriately and incorporated into ongoing patient care.

This section supports service providers to communicate, document, escalate and report PoCT results accurately and in a timely manner, supporting clinical decision-making, continuity of care and patient safety.

Key areas

Reference intervals

Test results

Sensitive results

Result escalation

4.1 Reference intervals

Reference intervals and clinical decision limits support the interpretation of PoCT results and assist clinicians to make informed decisions about patient care. Service providers should ensure PoCT operators have access to the reference intervals and clinical decision limits specified in the manufacturer's instructions for use for the device and test being used, and understand when results require further review, escalation or follow-up.

Action 4.1

The service provider has processes to:

a. ensure reference intervals and clinical decision limits are consistent with the manufacturer's instructions for use for the specific PoCT device and test being used

b. make current reference intervals and clinical decision limits readily available to PoCT operators

c. support PoCT operators to understand and apply reference intervals within the clinical context

d. define when results require escalation, confirmatory laboratory testing or further clinical review

e. regularly review reference intervals and clinical decision limits following manufacturer updates or changes to PoCT devices and tests

Additional information

Reference intervals and clinical decision limits may vary between PoCT devices, tests and patient populations. Factors such as age, sex, pregnancy status and clinical context may influence the interpretation of results. Service providers should ensure PoCT operators use reference information that is specific to the device and test being performed.

Reflective questions

- Are there clear, documented reference intervals and clinical decision limits for each PoCT device and test used by the service?
- Does the service provider have processes to regularly review and update reference intervals?
- Do PoCT operators understand how reference intervals should be interpreted?
- How are PoCT operators supported to identify results requiring escalation or further investigation?

Suggested strategies

- Define device-specific and test-specific reference intervals and clinical decision limits where applicable.
- Use reference ranges from trusted and recognised sources, such as PoCT manufacturers, pathology services, international organisations or professional bodies.
- Ensure reference ranges are supported by strong clinical evidence and demonstrate reliable test performance.
- Regularly review and update reference ranges to align with current best-practice evidence.
- Clearly describe escalation processes, including when further testing or specialist review is required.

Resources

Sources of reference intervals include:

- **Manufacturers** – *instructions for use* - device-specific reference intervals and clinical decision limits
- **Pathology services** – Reference intervals and interpretive guidance relevant to local clinical practice
- **Professional colleges and societies** – Evidence-based guidance on result interpretation and clinical decision-making
-

4.2 Test results

Accurate and timely communication of PoCT results supports safe patient care and informed clinical decision-making. Service providers should ensure PoCT operators are competent in interpreting and communicating results, recognising when further advice is required, and escalating results appropriately to support safe and coordinated care.

Action 4.2

The service provider has processes to:

a. ensure PoCT operators are trained and competent in interpreting and communicating PoCT results relevant to their role and scope of practice

b. support interpretation of PoCT results using the reference intervals and clinical decision limits applicable to the specific device and test being used

c. define when advice should be sought from a clinician, pathology provider or other appropriate expert regarding unexpected, inconsistent or difficult-to-interpret results

d. ensure abnormal, unexpected or clinically significant results are escalated in accordance with local procedures and seek pathology advice where appropriate

e. support communication of results and follow-up actions to patients, carers and other healthcare providers, where appropriate

Reflective questions

- How does the service provider determine when PoCT results should be communicated to patients, what information should be provided, and how that information should be communicated?
- How are PoCT operators supported to meet the individual information needs of patients?
- How does the service provider ensure PoCT operators are competent in interpreting and communicating PoCT results?
- How do PoCT operators know when a result requires escalation, further review or confirmatory testing?
- How do PoCT operators access clinical or technical advice when results are unexpected or difficult to interpret?

Suggested strategies

- Ensure PoCT operators have the knowledge, skills and competency required to interpret and communicate PoCT results.
- Provide PoCT operators with access to current reference intervals and clinical decision limits for each PoCT device and test.
- Implement clear pathways for seeking advice from a clinician, pathologist, pathology provider or other appropriate expert, and for escalating abnormal, unexpected, inconsistent or clinically significant results.

- Support communication of PoCT results and any required follow-up, referral, confirmatory testing or ongoing care to patients and relevant healthcare providers.

Case study – Supporting safe transitions of care

A paramedic crew attends a 58-year-old patient with an altered conscious state. During the initial assessment, the paramedics perform a point-of-care blood glucose test in accordance with the ambulance service's clinical practice guidelines. The result confirms marked hypoglycaemia consistent with the patient's clinical presentation, and treatment is commenced.

Serial blood glucose testing demonstrates a further decline in the patient's glucose level, accompanied by a worsening conscious state despite initial treatment. The paramedics continue treatment, monitoring and reassessing while arranging urgent transport to hospital.

During transport, the crew provides a concise pre-arrival clinical notification to the receiving emergency department using the ambulance service's established communication process. The notification includes the patient's presenting condition, initial and repeat PoCT trends, relevant clinical observations, treatment provided, response to treatment and estimated time of arrival. This enables the receiving service to prepare for the patient's immediate assessment and ongoing management.

The initial and repeat PoCT results, relevant clinical observations, treatments administered, and the patient's response are documented in the ambulance service's patient care record.

On arrival at hospital, the paramedics provide a structured clinical handover to the receiving clinician. The handover includes the presenting complaint, clinical history where available, initial and repeat PoCT results, trends in the patient's condition, relevant observations, treatments provided and the patient's response. Responsibility for care is transferred in accordance with the ambulance service's clinical handover process.

The patient care record, or relevant information from the record, is made available to the receiving service in accordance with local procedures to support continuity of care and ongoing clinical management.

This example demonstrates how timely documentation, structured communication and effective clinical handover support the safe use of PoCT and continuity of patient care during transitions of care.

4.3 Sensitive results

Some PoCT results may be sensitive due to their personal, social, cultural, psychological or clinical implications. Service providers should identify tests that may produce sensitive results and ensure appropriate processes are in place to support their communication and management.

Sensitive results may include results relating to STIs, blood-borne viruses, pregnancy, substance use or other conditions that may have significant personal, social, cultural or psychological implications. The sensitivity of a result will depend on the individual patient's circumstances and the context in which testing is performed.

Action 4.3

The service provider:

a. identifies PoCTs that may produce sensitive results

b. has processes in place to support appropriate communication and management of sensitive results

Reflective questions

- Which PoCTs used by the service may produce sensitive results?
- How does the service determine whether additional communication or support is required?
- How are privacy, confidentiality and cultural considerations taken into account when discussing sensitive results?
- What support, referral or follow-up pathways are available when sensitive results are identified?
- How are PoCT operators supported to communicate sensitive results appropriately?

Suggested strategies

- Develop guidance for PoCT operators on communicating sensitive results.
- Ensure private and appropriate settings are available for discussions about sensitive results.
- Establish referral pathways to clinical, counselling, social support or other relevant services where required.
- Consider cultural, language, communication and accessibility needs when discussing sensitive results.
- Provide PoCT operators with training and support relevant to the sensitive tests used by the service.

4.4 Result escalation

Some PoCT results may require escalation because they are abnormal, unexpected, inconsistent with the patient's clinical presentation, or indicate an urgent risk to patient safety. Service providers should have documented processes that support timely review, communication and management of these results.

Some PoCT results may be critical and indicate a potentially life-threatening or otherwise urgent clinical situation. These results require immediate action to support patient safety and may require escalation outside normal communication or reporting pathways. Service providers should have processes in place to ensure critical results can be escalated, communicated and acted upon without delay, including outside normal operating hours where relevant. Escalation processes should be aligned with local policies and procedures and support the review, confirmation or supplementation of results through laboratory testing where appropriate.

Action 4.4

The service provider:

a. has documented processes for identifying and escalating abnormal, unexpected, inconsistent and critical PoCT results

b. ensures critical results are escalated in accordance with local policies, procedures and clinical pathways

c. defines when clinical review, specialist advice, confirmatory laboratory testing or urgent intervention is required

d. documents escalation actions, communication of results and follow-up activities

e. audits critical result processes regularly to support continuous improvement.

Reflective questions

- What types of PoCT results require escalation within the service?
- How do PoCT operators interpret and report critical results in accordance with defined critical limits?
- How do PoCT operators know when a result requires clinical review, further investigation or urgent intervention?
- How are critical results communicated to ensure timely action is taken?
- How do PoCT operators promptly escalate critical results when on-site clinical expertise is available and when escalation to off-site clinical expertise is required?
- How are critical result escalation, communication, de-escalation and follow-up actions documented to support continuity of care?
- How are after-hours escalation and clinical support arrangements managed?
- How does the service provider monitor, audit and assure compliance with critical result escalation and communication processes to identify and address gaps?

Suggested strategies

- Define abnormal, unexpected and critical results for each PoCT used by the service, where applicable.
- Establish documented escalation pathways that align with local policies, procedures and clinical requirements.
- Ensure PoCT operators understand when and how to seek advice from a clinician, pathologist or other appropriate expert, and when escalation is required.
- Establish processes for obtaining confirmatory laboratory testing where required.
- Consider after-hours arrangements to ensure urgent results can be reviewed and acted upon in a timely manner.
- Ensure critical result escalation, communication, de-escalation and follow-up actions are documented to support continuity of care.
- Record results in the patient's healthcare record and, where appropriate, communicate them to relevant healthcare providers.
- Provide PoCT operators with training on recognising, escalating and communicating critical results.

Case study – Escalating abnormal test results

A 60-year-old woman presents to a small rural facility with fever and respiratory symptoms. In accordance with the service's agreed indication list, a C-reactive protein (CRP) PoCT is undertaken to support clinical assessment. A nurse who is trained and authorised performs the test within their scope of practice and in line with site procedures, including completing the required QC checks before testing. The result is outside the normal range.

The service has documented processes that identify when PoCT results require clinical review and how PoCT operators can access this support. Recognising that the result requires further clinical assessment, the nurse follows the service's escalation pathway. As there is no clinician on-site, the nurse calls the clinician designated for this role through the service's established regional support arrangements.

The nurse communicates the PoCT result, the patient's symptoms, observations and relevant clinical information. The clinician interprets the result in the context of the patient's presentation, arranges confirmatory laboratory testing and initiates appropriate management.

The nurse documents the result, clinical advice received, actions taken and clinical decisions in the patient's healthcare record and uploads this information to My Health Record to support continuity of care across providers.

This example demonstrates how documented escalation pathways, access to remote clinical support, timely communication and clear documentation support the safe and consistent use of PoCT in rural health services.

Glossary

Term	Definition
Adverse event	An incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.
Audit	Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
Carer	A person who provides personal care, support and assistance to another individual who needs it because they have a disability, medical condition (including a terminal or chronic illness) or mental illness, or they are frail or aged. An individual is not a carer merely because they are a spouse, de facto partner, parent, child, other relative or guardian of an individual, or live with an individual who requires care. A person is not considered a carer if they are paid, a volunteer for an organisation, or caring as part of a training or education program. For Aboriginal and Torres Strait Islander people, there may be a collective approach to carer responsibilities. Confirming who is responsible for different aspects of care is important for ensuring that carer engagement is effective.
Clinical Governance	The combination of organisational culture, systems and structures that enables everyone in a service to deliver consistently high-quality PoCT services.
Clinician	A trained health professional, including registered and non-registered practitioners, who provides direct clinical care to patients. Clinicians

Term	Definition
	may provide care within a healthcare service as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include Aboriginal health practitioners, nurses, midwives, medical practitioners, allied health professionals, pharmacists, paramedics and other professionals who provide health care, and students who provide health care under supervision. For genetic testing, a health professional would also include a genetic counsellor.
Confidentiality	The state of keeping or being kept secret or private. *Protection of information from unauthorised access, use or disclosure.*
Consumer	A person who has had or may have a PoCT service, or their representative or advocate.
Critical results	Results outside defined limits which may indicate a life-threatening situation and require immediate notification of the referring doctor, nurse or physician's assistant.
Environment	The context or surroundings in which health care is delivered. The environment can include other patients, consumers, visitors and the workforce.
External quality assurance	A system for objectively checking a health service's performance using an agency external to the service. The external agency provides samples, and the testing results are evaluated externally and compared to peers or a reference laboratory who are undertaking the same test with the same methodology.
Governing body	The highest level of governance responsible for strategic and operational decisions of health services.
Health service	A health service is a separately constituted organisation that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. It includes hospitals, community settings, clinicians' rooms, clinics, medical imaging practices and pharmacies.
Healthcare vs. health care	Healthcare is used as an adjective; health care is used as a noun.
High-quality care	Health care services that are person-centred, safe, effective, accessible, integrated, equitable, efficient, and sustainable.
Informed consent	A process of communication between a patient and clinician or PoCT operator about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care, which may include not doing the test. The communication should ensure that the patient understands what will happen, the available

Term	Definition
	options and the expected outcomes, including success rates and side effects for each option.
Medical device	A medical device is defined in the legislation as: a. any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; (iv) control or support of conception; (v) in vitro examination of a specimen derived from the human body for a specific medical purpose; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or (aa) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection (2B); or b. an accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a), (aa) or (ab); or c. a system or procedure pack.
Medical practitioner	A person who has a medical degree and has current registration with AHPRA – Medical Board of Australia.
Pathologist	Specialist medical practitioner who studies the cause of disease and the ways in which diseases affect our bodies by examining changes in the tissues and in blood and other body fluids. Currently pathology has eight major areas of activity. These relate to either the methods used or the types of disease which they investigate and include: a. Anatomical pathology b. Chemical pathology c. Forensic pathology d. General pathology

Term	Definition
	e. Genetic pathology f. Haematology g. Immunopathology h. Microbiology.
Pathology laboratory	Premises where biological samples are examined to support diagnosis, monitoring, and treatment.
Pathology practice	An entity overseeing laboratories and collection centres with responsibility for services, governance, and administration.
Pathology service	A test performed on a patient specimen following a clinician's request.
Patient	A person receiving health care services.
Patient identifiers	Items of information used to unambiguously identify a patient, including family and given names, date of birth, birth sex, address, a healthcare record number and individual healthcare identifiers.
Policies	Documented principles and direction by the health service's governing body and senior leadership that guides the delivery of health care services. Policies include delegation of authority and supervision.
Procedure	The set of instructions specific to a health service that operationalises policies and processes.
Quality assurance	Relates to participation in relevant continuous improvement activities (or programs), performance reviews and corrective actions where performance is unsatisfactory.
Quality control	Internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released.
Quality improvement	The combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually.
Quality management system	Set of interrelated or interacting elements of an organisation to establish policies and objectives, and processes to achieve and improve quality.
Report(s)	The provision of results, interpretation and opinions.
Request	A written communication received that identifies the health care services required and the patients personal and clinical details.

Term	Definition
Risk	Combination of the probability of occurrence of harm and the severity of that harm.
Risk assessment	Overall process comprising risk analysis and evaluation.
Risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.
Sample	A portion of the specimen assumed to contain the target analytes in the same proportion to that found in the original specimen. Also includes non-patient derived material such as controls, blanks, and reference materials.
Scope of practice	The range of activities a worker is trained and competent to perform.
Specialist	As defined in subsection 3(1) of the *Health Insurance Act 1973*: In relation to a particular specialty (other than general practice), means a medical practitioner in relation to whom there is in force a determination under section 3DB or 3E that the medical practitioner is recognised for the purposes of this Act as a specialist in that specialty, or a medical practitioner who is taken to be so recognised under section 3D.
Specimen	Discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole.
Standard	The agreed attributes and processes to ensure that a product, service or method will perform consistently at a designated level.
Systems	Organised resources, policies, processes, and procedures used to achieve safety and quality goals.
Training	The development of the workforce's knowledge and skills.
Verification	Confirms that a standard test method or device performs as expected under specific laboratory conditions, ensuring accuracy and safety in patient diagnosis or product use.
Workforce	All individuals contributing to pathology services, including employees and contractors.

Appendix A: Detailed scope and examples

Defines what scenarios are in-scope of this guide, and what is out-of-scope.

In scope

All point of care testing described in this guidance is conducted on in vitro patient specimens, with the analytical process completed outside a pathology laboratory.

The guidance applies across a range of PoCT, from simple, routinely performed tests to more complex testing. Actions in this Guide should be applied proportionate to the level of risk, complexity and potential for patient harm. While commonly used tests such as blood glucose testing, urine dipsticks, pregnancy tests and rapid antigen tests are often lower risk, they still benefit from appropriate governance. The intent of this Guide is not to create barriers to access, but to support safe and appropriate use across all levels of complexity.

Examples of point of care testing include, but are not limited to:

- Infectious disease testing, including rapid antigen tests, HIV viral load assays and nucleic acid amplification tests
- haematology and biochemistry testing, such as blood coagulation typing, blood glucose testing, international normalised ratio and cardiac marker testing
- inflammatory and infectious marker testing e.g. C-reactive protein and streptococcal infection testing
- blood gas and electrolyte analysis
- urinalysis chemistry and pregnancy testing.

Out of scope

The PoCT guidance does not address:

- self-testing, where sample collection is performed by lay users without direct supervision from a PoCT operator.
- when a sample is collected at the point of care but sent to a pathology laboratory for analysis. Such testing remains laboratory-based testing.
- self-collection by lay users when the sample is sent to a pathology laboratory and results are sent directly to the tester / patient (lay user). This constitutes direct to consumer testing and falls outside self-test or point of care testing.
- PoCT performed in an accredited pathology practice who operate under the NPAAC Requirements, i.e. is supervised and managed by a pathology provider
- PoCT performed in a hospital service with onsite pathology laboratory oversight
- the regulation and evaluation of specific PoCT in vitro diagnostic medical devices (PoCT medical devices)
- Tests where samples are not collected in vitro. Examples of excluded tests include, but are not limited to:
    - respiratory testing such as spirometry and peak expiratory flow measurement
    - physiological monitoring such as non-invasive blood pressure monitoring, pulse oximetry, heart rate monitoring and electrocardiography
    - imaging-based examinations such as ultrasound or radiography
    - non-invasive screening or assessment tools that do not analyse patient specimens.

Appendix B: Off-label use

Use of a PoCT device outside the manufacturer's intended purpose or instructions for use (off-label use), and outside established quality management systems constitutes off-label use. This may compromise the validity and reliability of test results. Where such use has not been appropriately validated and verified, there is an increased risk of erroneous results or result misinterpretation, which may lead to inappropriate decisions relating to a patient's diagnosis, treatment, monitoring or ongoing care.

Off-label use converts a PoCT device into an in-house PoCT medical device. This requires the service provider to comply with additional TGA and accreditation obligations, including:

- Therapeutic Goods (Medical Devices) Regulations 2002 and the Essential Principles for safety, quality and performance
- notifying the TGA of Class 1–3 in-house in vitro diagnostic medical devices.
- applying for ARTG inclusion for Class 4 in-house in vitro diagnostic medical devices.

To ensure the continuity of PoCT, providers should establish relationships with suppliers of PoCT goods and services, who can provide consumables, technical support, maintenance and education. A consumables log should document lot numbers, expiry dates and disposal of expired items.

Each test performed is traceable to a patient, records of QC, PoCT operator ID and, where applicable, lot numbers of consumables.

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