Point of Care Testing guidance – providing a gold standard service

'Point-of-care testing, also known as near-patient testing, is the analysis of clinical specimens outside the traditional laboratory, near to or at the site of patient care. It may be performed by non-laboratory personnel including clinical staff whose primary training is not in medical laboratory science. It has an important role to play in the delivery of an efficient healthcare system because of its ability to provide a rapid result near the patient which can be acted upon immediately, and which may lead to a diagnosis or a possible change in patient care.'[1]

Background

Point of Care Testing (POCT) capability is becoming increasingly available in general practice. Within general practice, there are quality assurance requirements for enhancing patient safety, through safe use of medication and resources, and to provide staff and consumers' confidence in accessing timely results.

POCT has the potential for less accurate results than traditional laboratory testing. This can be attributed to variable personnel training and control over pre-analytical, analytical, and post-analytical variables, which can be better managed in a laboratory setting (Larkins et al, 2023). Internal quality control as recommended by the manufacturer are paramount if standards for best practice is to be maintained.

By providing primary care relevant standards adapted from the national best practice guidelines, and advice around how to meet those standards this document offers guidance to support your new POCT capability and reduce the risk of inaccurate results. Specific informed consent when offering POCT forms part of routine practice in the patient encounter and is not discussed in this document.

Guidelines for POCT

The New Zealand Best Practice Guidelines for Point-Of-Care Testing 2022 (updated November 2022) are laboratory developed guidelines for POCT. While laboratory-focused, key points related to risk, internal quality control, adverse event reporting and record keeping are vital in providing this new service.

In addition, NZMA have provided a one-page position statement on POCT indicating principles for testing[2]. These include:

- careful consideration of clinical need should be given before introducing point-of-care testing
- point-of-care testing should be seen as complementary to, and not as a replacement, for conventional laboratory testing
- an accredited laboratory should play a key role in the development and management of a point-of-care testing service
- as far as possible, results obtained from point-of-care testing should be incorporated into the patient's health record

[1] *New Zealand Best Practice Guidelines for Point-of-Care Testing 2022 (page 4)*

[2] *New Zealand Medical Journal Position Statement: Point-of-Care Testing (Approved April 2020)*

- funding and regulatory arrangements should ensure a level playing field for providers of point-of-care testing and should not exacerbate health inequities
- cost-effectiveness considerations should be taken into account when developing and deploying point-of-care testing.

Risk

Standard 1: *Testing is performed to support decision-making where there is clinical uncertainty or for monitoring of a known condition where this is an acceptable method, and having a timely result will make a difference to patient outcomes or management.*

Why this is important?

The major risks related to POCT[3] include:

- patient harm - erroneous and misleading results due to inadequate quality assurance and operator training, lack of supervision, poorly performing devices.
- risks to staff – infectious disease transmission; devices which are difficult to use or results which difficult to interpret may cause frustration and stress.
- risks to equipment – damage to expensive analysers due to incorrect operation; incorrect or unsuitable patient samples.
- financial risks – wastage of consumables and unnecessary or inappropriate testing, which may cause patient harm and increase morbidity and costs of care.
- risks to the organisation – patient or public loss of confidence; damage to reputation and
- litigation caused by POCT misadventure.

Suggested solutions

Practices should document the conditions and situations where POCT is used within their practice and the rationale for using POCT. Examples below.

- Random blood glucose - rationale - a timely diagnosis of low or elevated blood glucose is essential in management of acutely unwell patients.
- Screening for diabetes can be aided by RBG when there are barriers to the patient accessing formal HBA1C.
- Troponin - under the accelerated chest pain pathway troponin POCT is an acceptable way to assess people with past chest pain.

Internal quality control

Standard 2: *Each practice has at least one trained and certified super-user who is accountable for ensuring calibration and validation of equipment and consumables for POCT.*

Standard 3: *Calibration and monitoring along with any action taken must be documented.*

Why this is important?

Studies demonstrate the need for a well-designed quality control procedure in a point-of-care setting to minimise the risk associated with POCT devices. Internal quality control involves running quality control material, that contains analytes of known concentration, to monitor the precision of the analytical process over time. Quality control is performed to ensure the equipment meets the required standard and when new consumables arrive. ***POCT procedures in general practice have been shown to be less stable than those run within the laboratory***.

[3] *New Zealand Best Practice Guidelines for Point-of-Care Testing 2022 (page 8)*

At a minimum, for staff who have received training in quality assurance testing, performance of liquid quality control testing, and external sample testing (referred to as a 'super-user'), they will be trained and certified as competent in the full use of the POCT device and following manufacturers recommendations can ensure all items related to POCT meets the requirements for internal quality control.

Suggested solutions

A training log is kept of staff training and revalidation for training in using each POCT device."

"A calibration and monitoring process is documented for each POCT device" For simple devices such as glucometers this can be an internal process based on calibration tests provided by manufacturers, for more complex devices, this may include external calibration and monitoring by a formal laboratory. Currently in NZ (2024) decisions about which devices need external validation are based on manufacturers advice."

Adverse Event Reporting

Standard 4: *Each practice must have a robust process for adverse event reporting and escalation of issues specifically relating to POCT.*

Why this is important?

An adverse event may cause, or may potentially cause, an unexpected or deleterious effect. In a POCT environment an adverse event may impact on the health and safety of patients, service providers or other persons. For example, **an incorrect result may lead to a delay in treatment, inappropriate treatment, a life-threatening illness or injury, a serious deterioration in the state of health, or even death.**

Suggested solutions

Any adverse event involving a POCT device or test should be reported through the practice's significant event process and the outcome reported to your PHO Clinical Governance Committee. This will ensure safety issues are identified, addressed, and shared across all providers of POCT. At a minimum, you are asked to provide your details (person reporting), details of which POCT device, description of incident/event and any actions taken. This report should also be provided to the supplier of the device.

For Pinnacle practices and those practices who are part of the roll-out of POCT equipment to Pare Hauraki, please report here: (POCT Adverse Event Monitoring System[4]).

A record of all incidents and actions taken must also be kept at your site as per the requirements of Foundation standard 13.3. Adverse event reporting.

There is a documented process for reporting adverse events to the Centre for Adverse Reactions Monitoring (CARM) via Medsafe and information on the process of reporting may be found on the Medsafe website. https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicine-safety.asp

[4] POCT Adverse Event Monitoring System https://forms.office.com/r/AUQPBZAqcH

As per HQSC National Adverse Events Reporting Policy[5], the practice will have processes for monitoring and escalation where an event occurs.

Record keeping

Standard 5: *POCT results must be entered in an accurate and timely manner where they form part of the clinical record of care.*

Standard 6: *Documentation in the clinical record states POCT test, including rationale, results, and action taken.*

Standard 7: *Clinical records must be kept for a minimum of 10 years + 1 day[6], and equipment logs for a minimum of 4 years[7].*

Why this is important?

Documentation is a core requirement of Good Medical Practice[8] and essential to help patients and regulators understand the rationale behind decisions made. Nursing documentation is a legal record of patient/ client care. It is essential for good clinical communication and a core requirement of the Nursing Council of New Zealand (NCNZ)[9] [Domain two: Management of nursing care. Competency 2.3.

Suggested solutions

A variety of logs are available which include quality control logs, quality control action logs, expiration data and storage conditions logs, room temperature logs and electronic simulator logs. Processes for receipt and storage of stock must be robust to ensure cold chain remains intact. Storage conditions (fridge monitoring) are completed for vaccines and there is no reason to hold a separate log where this causes duplication of the same information.

Logging receipt of cartridges and consumables, calibration and validation tests and use of cartridges supports a gold standard process. Identifying how best to utilise these logs should be developed by the practice.

For the clinical record, identifying the point-of care test result (to distinguish it from laboratory test results) is important, including date and time of test, name of requester, rationale for test, e.g. clinical uncertainty with description, result and action taken.

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[5] HQSC National Adverse Events Reporting Policy 2023 https://www.hqsc.govt.nz/assets/Our-work/Leadership-and-capability/Building-leadership-and-capability/Publications-resources/DRAFT-Clinical-Governance-framework-collaborating-for-quality-for-feedback-1-November-2023.pdf. p19/20
[6] Clause 5 of Health (Retention of Health Information) Regulations 1996 https://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html
[7] NPAAC - Requirements for the retention of laboratory records and diagnostic material (safetyandquality.gov.au), p14
[8] Te Kaunihera Rata o Aotearoa/Medical Council of New Zealand. Good Medical Practice. (Nov 2021) https://www.mcnz.org.nz/assets/standards/b3ad8bfba4/Good-Medical-Practice.pdf
[9] Nursing Council of New Zealand. (2014). Competencies for Registered Nurses. Wellington

The College's Foundation Standards

The College supports general practices to provide safe, equitable and high-quality health care through the Foundation Standard ©, which provides assurance of the baseline quality standard expected of general practices and is a nationally recognised mark of quality. The criteria in the Foundation Standard which relate to POCT are 11.1 Equipment and medicines, and 11.2 Calibration and monitoring.

11.1 Equipment and medicines

All medical equipment and resources must be suitable for supporting comprehensive primary care, safe resuscitation and safe performance of any additional procedures offered in the practice.

https://www.rnzcgp.org.nz/running-a-practice/the-foundation-standard/taputapu-medical-equipment-and-resources/111-equipment-and-medicines/

11.2 Calibration and validation

Calibration of medical equipment refers to the process of adjusting the accuracy of equipment in line with regulatory standards.

https://www.rnzcgp.org.nz/running-a-practice/the-foundation-standard/taputapu-medical-equipment-and-resources/112-calibration-and-validation/

POCT guidelines: Standards in a nutshell

Standard 1: *Testing is performed to support decision-making where there is clinical uncertainty or for monitoring of a known condition where this is an acceptable method, and having a timely result will make a difference to patient outcomes or management.*
Standard 2: *Each practice has at least one trained and certified super-user who is accountable for ensuring calibration and validation of equipment and consumables for POCT.*
Standard 3: *Calibration and monitoring along with any action taken must be documented.*
Standard 4: *Each practice must have a robust process for adverse event reporting and escalation of issues specifically relating to POCT.*
Standard 5: *POCT results must be entered in an accurate and timely manner where they form part of the clinical record of care.*
Standard 6: *Documentation in the clinical record states POCT test, including rationale, results, and action taken.*
Standard 7: *Clinical records must be kept for a minimum of 10 years + 1 day, and equipment logs for a minimum of 4 years.*