

Clinical governance and point-of-care testing at health provider level

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ABSTRACT

Clinical governance provides a quality assurance and safety framework. A large proportion of point-of-care testing (POCT) activities in New Zealand are not subject to the same levels of regulation and accreditation that must be met by conventional medical laboratory testing. Providers who use POCT for diagnosis, monitoring and treatment need to develop programmes that are subject to effective clinical governance to ensure that POCT devices are suitable and safe for the clinical setting in which they are being used, and test results are consistently accurate and precise, ie reliable, at all times. POCT needs to be integrated with clinical management protocols and test results need to be accessible to healthcare personnel.

Effective clinical governance of POCT by providers requires recognition by top management that the scale and scope of testing within New Zealand is large and expanding, and that there are associated risks and costs. Systematic input from laboratory, clinical and managerial stakeholders, and compliance with guidelines and standards is required to ensure that POCT is safe, clinically justified and cost effective.

Introduction

Point-of-care testing (POCT) is defined as, “testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient and is performed in a variety of clinical settings.”^{1,2} POCT in hospitals is used to obtain test results more quickly than by conventional laboratory testing in order to improve clinical decision making.¹⁻⁶

POCT devices are classified as *in vitro* diagnostic devices (IVDD). In many situations, non-laboratory trained personnel carry out the actual testing. Examples include blood gas analysis and thromboelastography in operating theatres; pregnancy tests, urinalysis, and cardiac troponins in emergency departments, and HbA1c in outpatient diabetes clinics. Patients can self-monitor glucose levels at home and adjust medication accordingly. In general practice, infectious diseases can be screened for using POCT devices.

Point-of-care technologies can help to improve access to healthcare.^{3,5} For example,

the community pharmacist-led anticoagulant monitoring service (CPAMS) for patients on warfarin in New Zealand,⁷ which is consistent with the concept of ‘better, sooner, more convenient’ healthcare.⁸

Implementation of POCT in hospitals and clinics can also shorten the ‘therapeutic turn-around time’ when compared with conventional laboratory testing.⁹ However, POCT devices must be ‘fit for purpose’¹⁰ in the clinical setting in which they will be used and because many tests are carried out by staff who are not professionally trained in medical diagnostic testing, appropriate onsite certification and quality control is required to ensure ongoing clinical safety.

POCT can improve patient outcomes, but presents significant challenges. This type of testing needs to be governed and regulated at a national level,¹ but also needs to be supported by adequate clinical governance and quality management systems at provider level.^{2,11} Standards and guidelines are needed in the interests of patient safety because currently there are no requirements for POCT to be performed

Box 1: Challenges for POCT—Organisational Perspectives in New Zealand

- laboratory staff perspectives — perceived high cost, inferior results, erosion of work place, deskilling
- medical/nursing/midwifery/management perspectives
- attitudes to quality control testing: “it’s only glucose...”
- attitudes to certification: “where is your evidence?”
- attitudes to accreditation: “why do we need it?”
- prevalence of “silo mentality and budgeting”
- prevalence of high perceived cost of POCT by management
- lack of appreciation that modern medicine is impossible without POCT
- lack of appreciation in terms of improved patient outcomes
- lack of appreciation that POCT can improve both access to healthcare and the patient experience
- lack of appreciation of the need for pathologist and medical laboratory scientist advice and oversight

to any specific quality standards in New Zealand. This is in contrast to the US, where federal government regulations “imposes uniform requirements for all clinical laboratory testing regardless of where it is performed”.¹²

In view of the large number of settings in which POCT is used, combined with rapid expansion of this technology, quality and risk management of POCT is ‘likely to be difficult’ both in hospitals and the community.² POCT technology may appear to be simple to use, but if not used correctly it may pose risks^{2,10} to patients who have the right to be treated with respect, dignity and appropriate standards of care.¹³ This viewpoint article discusses governance for POCT programmes and the implications for executive teams and providers, with examples of successfully implemented programmes in New Zealand.

Clinical governance for POCT at healthcare provider level

Evidence-based laboratory medicine (EBLM) provides a platform for the selection of diagnostic technologies and is crucial for effective clinical governance of POCT. EBLM can help to assure that: (i) a particular test or technology is clinically appropriate for use at the point of care; (ii) the test or service meets the analytical and logistical requirements for the clinical setting; (iii) the POCT technology meets the established standard of care and assists with achieving best health outcomes.^{14,15} Therefore, from a governance perspective, the most important step is to define the clinical problem which needs to be solved by point-of-care testing which cannot be solved by conventional laboratory tests.¹¹

A POCT governance group representing the clinical specialties, pathology, nursing, finance, information services and logistics^{2,11} will have the clinical and management expertise to determine if a point-of-care test is appropriate in the

intended clinical setting, identify risks, and ensure that it is integrated with patient care pathways.^{3,16}

The New Zealand Point-of-Care Testing Advisory Group (NZPOCTAG) has developed a set of Best Practice Guidelines for POCT which reflect the current literature and experience from ISO 22870:2006¹⁸ accredited New Zealand medical testing laboratories. The guidelines provide a framework for establishing a sustainable POCT quality management system which encompasses the clinical and financial risks and the operational impact of the new POCT service in terms of clinical staff and laboratory scientists time, health and safety, infection control, location of equipment, services, data transmission, storage and dispatch of consumables, documentation, collection of samples, education and training of staff. Adverse event or incident reporting systems¹⁹ and clinical audits should be implemented to ensure ongoing quality, safety and corrective or preventive action taken as required. It is also important to determine how the POCT results correlate with those obtained by conventional laboratory instruments in terms of sensitivity, specificity, accuracy, bias and uncertainty of measurement.^{11,18}

The strategy outlined above should be supported by an organisational POCT policy and the appointment of a POCT Coordinator or Manager to manage the clinical and financial risks and operational impact associated with POCT.^{2,11,20} This approach attempts to address the constraining problem of ‘silo budgeting’, meets the challenges and mitigates the disadvantages of POCT and also rests on evidence for its potential to improve health outcomes.²¹ Some of the organisational perspectives and challenges associated with implementation of quality management systems for POCT are listed in Box 1. A governance group will have the authority and expertise to address these challenges.

Evaluation and validation of POCT devices

In the UK, the Medical Devices and Health Products Regulatory Agency (MHRA) has published evaluation information on POCT devices.²² In New Zealand, there are no minimum standards manufacturers must meet for quality and analytical performance (with the exception of glucose meters). Information on the performance of some POCT devices is limited, and it is strongly recommended that devices are validated before use.

At the time of writing, the NZPOCTAG is in the process of developing a national database of POCT devices, but a Reference Laboratory Device Evaluation Service is needed for independent evaluations of POCT devices.¹ This service would need to use internationally accepted evaluation protocols, such as those published by the Clinical Laboratory Standards Institute. This concept is similar to the Scandinavian Evaluation of Laboratory Equipment for Primary Health Care (SKUP) service.²³

So how do stakeholders decide which technology or device should be used for a POC test? In the absence of a centralised repository of information, reliance on literature, knowledge and evaluation expertise from pathologists and medical laboratory scientists is recommended by the NZPOCTAG, the Australasian Association of Clinical Biochemistry (AACB) and the Royal College of Pathologists of Australasia (RCPA). The lack of a central repository of information also means that devices must be evaluated and validated in the intended clinical setting by pathology and clinical staff locally. Validation tests may require ethical approval and is also time consuming and costly both for providers and suppliers.

Patient safety, quality and POCT

The principal reason for any clinical quality management system is to reduce error and improve patient outcomes. The main sources of error related to POCT are: operator incompetence or non-adherence to procedures; the use of uncontrolled reagents and/equipment; and technical issues at the time of performing POCT. The impact of these errors can be amplified by incoherent regulation and rapid result availability which in turn may lead to misinformed therapeutic intervention.²⁴

Basic information on sources of error is available from device manufacturers but pathologists and medical laboratory scientists from accredited laboratories can provide leadership and objective advice on the implementation of robust quality assurance systems to ensure the on-going quality of the test results.

Where possible, test results should be incorporated into the patient's electronic medical record, and technologies which are compatible with connectivity standard POCT1-A2²⁵ should be used. Connectivity-based systems improve compliance with test procedures and quality control to prevent analytical errors, ensure traceability of test results between operators and the patient's record, reduce test gaps, transcription errors, and the risk of patient harm. Connectivity helps to integrate the patient's POCT results with other health information.²⁶

Portable devices, such as glucose meters and lactate analysers, which are used between patients can be a source of healthcare acquired infections and therefore, appropriate infection prevention strategies and decontamination procedures should be implemented.

Standards and guidelines for POCT in New Zealand

International Accreditation New Zealand (IANZ) is responsible for accreditation of medical testing and POCT against the ISO 15189:2012¹⁷ and the ISO22870:2006¹⁸ standards. In addition to the two medical testing standards, and the connectivity standard POCT1-A2,²⁵ the AACB, the NZPOCTAG and RCPA have developed guidelines and position statements for the implementation of POCT systems.^{10, 11, 27-29}

Copies of the NZPOCTAG Best Practice Guidelines for POCT have been distributed to a wide range of New Zealand health agencies and are also available from the authors (the New Zealand Institute of Medical Laboratory Science (Inc)) website, www.nzimls.org.nz, and the Institute of Clinical Excellence website, www.nzice.co.nz.

Regulation and accreditation for POCT in New Zealand

The majority of POCT devices are not regulated in New Zealand. Pregnancy test kits are IVDD, which are not medicines but undergo the same the regulatory process as

medicines under the Medicines Act 1981. Medical devices are required to be listed on the Web Assisted Notification Database (WAND) but IVDDs are exempt from inclusion on this database and suppliers are not required to comply with pre-analytical standards. PHARMAC is due to assume responsibility for management of medical devices from 2015, and this may provide an opportunity for a formal approval process for POCT devices with information on their analytical performance and enhancement of the New Zealand database.

Assessment of POCT testing is not specified as part of hospital accreditation and certification, although hospital and community medical laboratories are accredited by IANZ to ISO 15189:2012. In addition, District Health Board (DHB) contracts for community-based medical laboratory testing require accreditation to ISO 15189:2012, but accreditation for POCT to ISO 22870:2006 in hospitals is not mandatory.

At the time of writing, in New Zealand there are 63 conventional medical testing laboratories, both in hospitals and in the community, which are accredited for medical testing to by IANZ to ISO15189:2012. Eighteen of these laboratories have accreditation to ISO 22870:2006 for POCT. The latter group which have POCT accreditation only include DHB-based public hospital laboratories. Examples of the scope and scale of POCT accreditation in New Zealand vary from one device in one location, up to 42 different devices across many locations and may involve certification of less than ten operators, to hundreds of operators. The IANZ website lists DHB medical laboratories and the scope of testing encompassed by accreditation for POCT in their respective hospital settings.³⁰

It is of note that while private surgical hospitals routinely perform point-of-care tests throughout New Zealand, eg blood gas analysis or capillary blood glucose, a minority are supported by a medical laboratory and none of these hospitals have accreditation to ISO 22870:2006 for POCT (S Turner, IANZ personal communication).

Accreditation by IANZ provides an independent assessment of the effectiveness of a POCT quality management

system and should be a key goal where practicable. In view of the large scale of POCT testing in New Zealand, it is recommended that organisations which do not have IANZ accreditation, or the support of a medical laboratory, ensure that POCT is carried out with the oversight of governance and a robust quality management system. Clinical and executive teams are encouraged to review their POCT services and implement the NZPOCTAG Best Practice Guidelines for Point-of-Care Testing¹¹ in the interests of patient safety.

Examples of successful implementation of non-DHB POCT services

Despite its challenges, POCT programmes have been successfully implemented in non-accredited settings. Rawene Hospital in the Hokianga, an area of high deprivation, does not have an on-site laboratory service. The use of POCT improved patient disposition and diagnostic certainty and resulted in fewer transfers to Whangarei Hospital. The total annualised treatment costs to Hokianga Health Enterprise Trust were \$90,222, but the net saving to the Northland DHB was \$362,360.^{5,6}

A review of the CPAMS initiative showed that the mean Time in Therapeutic Range (TTR) for the 671 patients whose results were evaluated was 78.6%, rising to 79.4% and 80.2% for patients who had been in the CPAMS for 16 weeks or 26 weeks respectively. All pharmacy sites achieved a mean TTR in excess of 70% (range 71.4% to 84.1%), well above the recommended target of 60%.⁷

These programmes are supported by quality management systems based on ISO 22870:2006 and the NZPOCTAG Best Practice Guidelines for Point-of-Care Testing.

Conclusion

Clinical governance and quality assurance systems among health providers who use POCT are not universal in New Zealand. POCT can improve access to healthcare but presents some unique organisational challenges. Providers need to ensure that if a POCT service is to be implemented, it needs to be clinically appropriate for the intended setting, that POCT is a suitable alternative to conventional laboratory based testing and that the clinical and financial risks are considered by a clinical governance group.

There is a diverse and rapidly expanding range of POCT technologies available which are used by large numbers of clinical staff who are not specifically trained in medical laboratory testing. Therefore, the selection of devices needs to be integrated with clinical pathways and their implementation needs careful management in the interests of patient safety. The authors recommend that a national reference laboratory service be established to evaluate and provide objective advice on POCT devices. Where possible, connectivity-based systems should be selected so that the results of POC tests

can be integrated with the patient's electronic medical record.

The New Zealand Point-of-Care Testing Advisory Group has developed Best Practice Guidelines for Point-of-Care Testing. Clinical and executive teams are encouraged to use this document to guide decision making and to seek advice from accredited medical testing laboratories with regard to device selection and the design of quality management systems for POCT. Accreditation for POCT should also be considered where practicable.

Competing interests:

Geoffery Herd reports other from Roche Diagnostics New Zealand, other from Radiometer Pacific New Zealand, other from Siemens Ltd New Zealand Healthcare Sector, outside the submitted work; he is a member of the New Zealand Point-of-Care Testing Advisory Group.

This group is comprised of medical laboratory scientists and pathologists from District Health Board and Community Pathology Laboratories who are actively involved in point-of-care testing in New Zealand. The group provides advice on point-of-care issues and best practice to a wide variety of health groups and agencies.

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