Point-of-care testing governance in New Zealand: a national framework

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Abstract

Point-of-care testing (POCT) devices are in-vitro diagnostic devices used near the patient and for the most part distant from the pathology laboratory. By definition they have a large scope of settings and user profiles. POCT optimises care pathways and overcomes geographical barriers but has a high potential for adverse incidents.

A successful POCT service needs good clinical governance and a comprehensive quality management system. In New Zealand, Medsafe regulates medical devices including POCT devices in accordance with the Medicines Act 1981. A number of regulations impact on the use of devices but none address analytical and clinical performance.

In 2015 PHARMAC will assume responsibility for management of medical devices. We propose a governance framework that optimises patient safety and maximises benefit from this indispensable technology. This is the first of two articles; the second will address point-of-care governance at healthcare provider level.

Clinical governance and the need for it

“First do no harm” is a cornerstone of medical practice, however clinical mistakes are inevitable. One of the challenges of modern-day medicine is to develop principles to minimise these mistakes. In 1997, in response to medical misadventure incidents including the Bristol Heart Scandal,1,2 the National Health Service (NHS) first introduced the concept of clinical governance.3

The NHS defined clinical governance as “a framework through which NHS organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”.3 It ensures up-to-date clinical practice, continuous education of health carers, cost-effective health care delivery, effective clinical management pathways, clinical audit and transparent feedback of performance and outcomes, continuous process improvement, risk management and information management culminating in a safe effective medical service.4

Clinical governance has since been adopted by several international healthcare communities as being a robust foundation for high quality healthcare delivery and patient safety. However, it needs to be applied judiciously to safeguard against an autocratic “top down” approach.

Governance of in-vitro diagnostic devices in New Zealand

In-vitro diagnostic devices (IVDs) comprise a spectrum of laboratory medical devices including POCT devices.
At the time of writing this article Medsafe (New Zealand Medicines and Medical Devices Safety Authority), a government regulatory body, is responsible for governance of medicines and medical devices in New Zealand (NZ) in accordance with the Medicines Act 1981. It defines medical devices as “... any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold, or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose...”. IVDs “have a therapeutic purpose of diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition and are considered as medical devices in the Medicines Act 1981......”.

POCT devices are IVDs that are used for testing outside of the laboratory and in the vicinity of the patient—e.g. urine pregnancy tests, glucose meters, International Normalised Ratio meters and urine dipstick kits. It is a requirement that information on all medical devices in NZ is entered into a dedicated database, the Web Assisted Notification of Devices (WAND). IVDs however are exempt from this requirement under schedule 1(i) of the Medicines Regulations 2003, notification being optional. Risk classification has been cancelled since 2011.

IVDs in NZ can be bought, used, and sold by any client or patient as long as they comply with the Medicines Act 1981 and its regulations. The regulations cover legal definitions and interpretation, powers of the Minister of Health (MoH), restrictions on sale and requirements for advertising and compliance with standards.

These regulations are enforced by Medsafe. Although other device regulations may impact on IVD supply in the NZ market, none of the above mandates any requirement for analytical quality specifications or validation of assays/methods in NZ. Suppliers of IVDs are advised to keep records for recall purposes but not required to comply with any pre-defined analytical quality standards.

Adverse incidents or “reportable events” are required to be reported to Medsafe within pre-defined time frames depending on the type of event. Reportable events include “incorrect or out of specification results”, “discovery of a serious public health threat”, “malfunction or deterioration in characteristics...” and “inaccuracy in labelling, instructions for use.....”. It can only be assumed that since there is no legislative requirement for independent validation the “specification” is defined based on manufacturers’ information.

Whereas this may not be a concern within medical laboratories or for POCT devices subject to a quality management system (QMS) where it is standard practice to independently validate devices and their tests to ensure fitness for purpose, it is however inadequate for POCT devices sold and used freely in the community where there is no immediate oversight.

The Integrated Healthcare Model proposed by the IT Health Board links general practitioners (GPs) and electronic prescribing within primary health care to national specialty systems and medicines reconciliation within secondary and tertiary care under a common theme of shared care. It fails, however, to establish a link between users of POCT at all levels with each other and with primary, secondary and tertiary care and hence omits a vital element of patient care.
Inadequate governance of POCT devices allows the utilisation of inappropriate instruments that are sometimes not fit for purpose, by poorly trained individuals, in unsuitable settings, with lack of accountability and potential for adverse patient outcomes. Whereas POCT is part of medical laboratory testing it poses different challenges.

A POCT device is used to perform tests near the patient, geographically distant from the main medical laboratory and intellectually remote from the trained laboratory scientist and pathologist. By definition it can be performed in numerous settings and by multiple users of varying expertise ranging from health professionals to lay people. The scope of tests and devices is varied and is still expanding. With its benefits come potential risks. There is sufficient evidence to demonstrate the risks and patient harm that POCT poses in case of lack of regulation and flawed QMSs.8-13

**Proposed changes to governance of POCT in New Zealand**

It is our view that the current regulatory environment in NZ does not provide an adequate framework that optimises the quality and safety of POCT devices that are used in the health system.

The pharmaceutical management agency (PHARMAC) is a Crown entity instituted in 1993 that has been responsible for prioritising funding of pharmaceuticals and commenced management of hospital pharmaceutical purchasing since 2002.14

In 2010 Cabinet announced that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices. A timeline for process building was released with clinical and stakeholder consultation until 28 March 2013 with management of devices planned to formally commence in 2015. PHARMAC partners with Health Benefits Limited in securing cost savings.14,15

A national framework for the governance of POCT in NZ, inclusive of all stakeholders is proposed in Figure 1.

Figure 1 depicts a POCT service overseen by a governing body, controlled by gateways, fluid and cyclical by nature with clear objectives. The governance group includes stakeholders with PHARMAC, accountable to the MoH, acting at a regulatory level (Gateway 1). Legislation and evidence based policies that PHARMAC adopts, determine the quality of POCT devices available to the NZ healthcare system. This will subsequently aid in prioritising funding for POCT devices.

PHARMAC will be informed by partnering with the scientific community, consumers and relevant stakeholders. Pathologists and medical laboratory scientists are experts in device and method validation to ensure “fitness-for-purpose”. Their expertise is vital to inform PHARMAC of which devices are accurate, precise, safe and cost-effective for the NZ population. Their recommendations to PHARMAC are informed by professional body guidelines, up-to-date literature, and tried and tested clinical pathways and laboratory protocols.
Figure 1. A national governance framework and expected outcomes

It is expected that IVD companies endeavour to provide devices of the highest calibre of quality. Manufacturers evaluate their instruments before marketing but often small numbers of samples are studied, in patient populations that are sometimes different from a NZ demographic.

Evaluation frequently takes place in controlled environments under resource constraints and the literature referenced may not be applicable for local needs. The information provided by manufacturers therefore cannot form a solid foundation for the unequivocal use of a device. There are professional international guidelines (independent of IVD industry) for the study, validation and choice of instruments that are adhered to by NZ medical laboratory health-carers. 16-22

The concept of a checkpoint or gateway (Gateway 1) to ascertain “fitness-for-purpose” is fundamental. The ideal set up would be to establish a system of formal device validation in NZ, enabled by legislation, and provided by pathologists and medical laboratory scientists. A National Reference Laboratory for validation of all POCT devices available in the NZ market can be a starting point.

Currently each laboratory service validates all POCT devices to be used in the laboratory and/or within the relevant hospital service to ensure good analytical and clinical performance. Pre-defined quality goals are assessed centred on local needs and professional scientific guidelines. This is time consuming for scientists and
A national laboratory would consolidate these efforts saving valuable time and potentially reduce cost. A catalogue of all validated devices, whatever the outcome of validation, would serve as a reference for POCT users and as a funding guide for a regulator such as PHARMAC. Certification of devices based on local validation would encourage compliance with regulations and allow users to make informed decisions.

Expert groups like the New Zealand Point-of-Care testing Advisory Group (NZPOCTAG) are key to the success of a governance scheme. The NZPOCTAG had been formed in 2009 under the chairmanship of the point-of-care coordinator at Whangarei Hospital, Northland District Health Board and coauthor of this article (GH).

Its core membership includes POCT coordinators, senior medical laboratory scientists, laboratory managers and pathologists from all around NZ. It includes representation from the Medical Sciences Council, the Royal College of Pathologists of Australasia (SM, coauthor) and International Accreditation New Zealand. The group possesses the scope of expertise and professional links to practically assess, advise and guide the choice of POCT devices, settings, application and cost effectiveness of POCT instruments and services. NZPOCTAG is therefore an obvious resource to include in POCT governance.

For simplicity, as shown in Figure 1, district health boards (DHBs), health organisations and pharmacies are classed as purchasers while patients and lay people as consumers. The second Gateway between the latter 2 groups serves to facilitate the rational and patient centred approach to the application of POCT. The roles of pathologists and medical laboratory scientists is to implement robust QMSs to ensure the reproducibility of accurate test results, continuous training and certification of users of POCT devices, application of internal and external quality controls (IQC and EQC) and risk management. 23

Clinicians have an essential role to incorporate POCT results within effective clinical pathways that maximise the benefit from a valid POCT analysis. 9 The net result is improved delivery of care.

A large proportion of POCT devices are sold in community pharmacies where pharmacists train lay people on the use of the devices. This makes pharmacists important players in the governance of POCT. Other stakeholders that should be involved in governance include community nurses and midwives, and the commercial sector with their duty to inform of any relevant variables that may affect the test performance.

The NZPOCTAG can act as an interface between the regulator (PHARMAC) and all other stakeholders (clinicians, health organisations, pharmacists and industry). Its membership can be expanded to involve representatives from respective interested parties.
Feedback enables the assessment of target attainment. This entails open lines of communication, transparency and efficient information technology (IT) systems in place. Forms of feedback include incident reporting, audit, monitoring, evaluation and evidence gathering. It will inform decision-makers and ensure continuity of quality improvement. Equally, processes in place should ensure timely response to consumer needs.

**Connectivity in integrated care**

Connectivity of POCT devices entails that all results of a POCT assay are available and displayed in the patient’s electronic health record. Though arguably essential, this is not the current state of affairs because not all POCT devices possess connectivity technology and possibly because it is not a mandatory requirement. The gap is demonstrated in the current Integrated Healthcare Model.\(^7\)

Connectivity is a feature that laboratory professionals seek in all POCT devices.\(^8,9,11\) It allows all professionals involved in the care of a patient to access all information needed for a comprehensive care plan. The unavailability of POCT results creates knowledge gaps leading to replication of testing, delays in diagnosis and management, frustration of both patient and health carer and increased expenditure. It is therefore prudent to foster connectivity if not legislate to implement it.

**What the proposed framework means**

Health leadership takes several forms and there is no place for observational leadership in POCT. Its scope of applications, settings, users and safety concerns dictates interventional leadership measures. This needs to be balanced by consumer leadership by means of challenging policies and regulations that impact negatively on the quality of healthcare delivery.

The collective goal is an effective, deliverable, safe and equitable health care system nationwide. The framework supports plans for improved primary healthcare such as the “Better, sooner, more convenient” initiative.\(^24\) It also advocates for a whole system approach recognising that decisions made at higher levels have a downstream effect and those made at ground level have an upstream effect. It makes a clear distinction between first- and second-order governance (2\(^{nd}\) and 1\(^{st}\) gateways respectively) clearly defining roles and systems. Furthermore, by ensuring adequate QMSs in place, it fosters proactive rather than reactive health service delivery.

The framework adheres to the principles of evidence based laboratory medicine (EBLM),\(^25\) the concepts of effective clinical governance and public health safety. It encompasses all layers of provision of a POCT service from manufacturers and importers to the use of a POCT device by a lay person. By ensuring involvement of all relevant stakeholders and continuous clinical outcome feedback it partners “bottom up” with “top down” hence creating a balanced approach.

The NZ market should be open to state of the art technology. Local validation and certification is not meant to restrict choices, stifle market availability nor curb competition. It aims to provide an evidence based and scientifically sound means to allow informed decisions. It will ultimately have fiscal implications but this is not a
disadvantage because this is needed for governing potentially costly services such as POCT within the constraints of a healthcare budget.

Commercial leadership should continue charting new technology frontiers and balance the pursuit of profit by responding to consumer expectations and local population and market needs.

Summary

In summary, POCT is an essential limb of mainstream pathology laboratory testing. There is no mature health care delivery service that can operate without POCT to various degrees.

Due to its varied nature, risks associated with POCT are higher than those associated with testing in the environmentally controlled pathology laboratory. It therefore necessitates robust regulatory measures at a political/governmental level, implementation of vigorous QMSs at an operational level and efficient patient care pathways at a clinical level.

We propose a framework that is all-inclusive in an attempt to maximise the benefit from an indispensable technology. We recommend reliance on local expertise such as the NZPOCTAG and not to alienate the commercial sector. We recommend balancing short-term costs with long-term gain in relevant health outcomes and uniting the “top down” with the “bottom up” approach.

Furthermore we recommend that PHARMAC and Medsafe actively engage with international bodies enabling NZ to be a global player in healthcare delivery and device regulation.

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Note: The views expressed in this article are those of the authors and do not represent views of any particular organisation.

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