Point-of-care testing governance in New Zealand through the lens of quality: an update on a national regulatory framework

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ABSTRACT

Point-of-care testing (POCT) devices are in vitro diagnostic devices used in hospitals, primary care and at home to provide rapid medical test results to support decision making. Most POCT devices are not regulated in New Zealand and there is no requirement for public or private hospital providers who use POCT devices to meet minimum accreditation standards for POCT. This article describes a regulatory framework for POCT devices, which is consistent with the principles of the draft Therapeutic Products Bill 2018. The proposed framework includes thorough evaluation, laboratory validation and approval processes for devices, improved traceability, accreditation for POCT and an adverse event management system; in the interests of patient safety.

Background

POCT devices are not subject to effective regulation in New Zealand. Urine pregnancy test kits are the only POCT devices that require mandatory registration in the Web Assisted Notification of Devices Database (WAND). This relatively ineffectual system contrasts with the regulatory framework in the UK by the Medicines and Healthcare Products Regulatory Agency. In New Zealand, POCT devices are not subject to thorough evaluation prior to distribution for use in the community. This is in contrast with the Scandinavian evaluation of laboratory equipment for point-of-care testing (SKUP) service in Scandinavia.

Patients are protected by the 10 rights of consumers and duties of providers, as stipulated in the New Zealand Health and Disability Code of Consumers Rights, established in 1996. Right 4 states that consumers are entitled to appropriate standards of care. Test results obtained from POCT devices are used to inform clinical decision making, therefore consumers have the right to expect that POCT devices and tests are fit for purpose irrespective of location and technology. In this context, “fit for purpose” implies regulation and clinical governance.

Right 6 states that “every consumer has the right to information that a reasonable consumer would expect to receive”, including limitations and side-effects of services. In the case of POCT devices, this clause relates to the performance of the device, the evaluation process and inherent limitations.
In 2013, the authors proposed a national regulatory and governance framework for POCT devices, as shown in Figure 1. This was the first schematic vision of a regulatory framework for POCT in New Zealand. It was born of concern over the existence of significant regulatory gaps with potential deleterious consequences. Since then Medsafe has updated its website to include a more diligent approach for the reporting of adverse events for POCT, encouraging reporting of potential adverse incidents or near misses as opposed to only definite events. The section “Information for Industry, Part 3: Regulatory requirements for medical devices” is currently under construction, implying that more changes are underway.

At the time of writing, December 2018, the Minister of Health had released a draft of the Therapeutic Products Bill 2018 and a Therapeutic Products Regulatory Scheme consultation paper. The Regulatory Scheme covers all therapeutics products used in public and private healthcare. The draft Bill defines four types of therapeutic products: medicines, active ingredients of medicines, medical devices (including in vitro tests and software) and type 4 products. The draft Bill provides for a unique device identifier to: improve identification and traceability of medical devices, the identification of adverse events, reduce error and support documentation and longitudinal capture of data in clinical registers. The draft Bill and the consultation document recognise the scale and complexity associated with the medical devices sector and that some devices are used for in vitro diagnostic medical tests in primary, secondary and home-based care. However, significant gaps remain to be addressed because, unlike devices such as joint prostheses and stents, POCT devices require validation of performance by accredited medical laboratories before funding approval. This article presents a revised, regulatory framework based on the first one proposed in 2013 as shown in Figure 1.

**Regulation of POCT: a revised and updated framework**

Three pillars underpin governance and regulation of POCT, namely:

1. **Selection**: only approved devices, validated by accredited laboratories should be available for use by the healthcare sector;
2. **Quality and Accreditation**: only certified providers should use POCT in public and private hospitals, supported by quality-controlled testing services accredited by International Accreditation New Zealand (IANZ);

**Figure 1**: A national governance framework and expected outcomes.
Figure 2: An updated framework for regulation and governance of point of care testing in New Zealand.

Industry, providers, & consumers

Step 1

Regulation and Clinical Governance at a National Level (Medsafe)

Evidence gathering by committee; a two phase process.

Phase 1 Scrutiny

Reject

Phase 2 Evaluation

Accept

No.

Funding Decision

Accept

Gateway 1

Final decision for funding (or not) made by PHARMAC

Local evaluation:
- Devices that are not fit for purpose. No further action.
- Devices deemed fit for purpose should be registered in the WAND database.

Gateway 2

Public & Private Hospitals, DHBs, & General Practice

Clinical governance at a Regional Level: e.g. Northern Region Alliance POCI

Group to be well resourced and supported by management and NRA and to include representation from all three disciplines of clinical pathology, scientists, Information Technology, and ACC (consumer).

When considering a new device for all or some of the providers:
1. Address clinical and operational needs relevant to the interested provider (e.g. DHB, laboratory, Hospital, GP practice)
2. Ensure and document clear lines of communication and accountability with relevant stakeholders and departments
3. Add the device to a regional register if when decision is made to use it
4. If the decision is not to use it – document the reason

Pharmacies/Private Hospitals
1. Register their procurement in a registry
2. Full training of pharmacists & providers by laboratorians and/or approved suppliers.

The Community

New Zealanders

Should be educated with regards to how to use their devices and to be aware of unsafe devices that are not supported by the New Zealand government or PCTI services.

Have the right to be able to provide feedback and to seek assistance in case of unexpected results or device malfunction.

Key: ACC: Accident Compensation Corporation; WAND: web assisted notification of devices; NRA: Northern Region Alliance.
3. Monitoring: including traceability of devices and the establishment of an accessible, adverse events management system (AEMS) designed to alert the regulatory agency, consumers and suppliers.

This article proposes an updated regulatory framework which is more descriptive than the 2013 framework and provides advice on how POCT devices should be approved, validated, regulated and managed in the interests of patient safety. This updated framework is summarised in Figure 2.

In the proposed regulatory framework industry and in vitro diagnostic (IVD) companies, providers—eg, clinicians, pathologists, medical scientists and consumers—must formally apply for introduction of an IVD device to the New Zealand market (Step 1) through Medsafe or an otherwise governmental regulator. (Note: Medsafe will be considered the regulator for the remainder of this article).

Medsafe would be the first of two gatekeepers and will initiate Step 2. In the initial phase of Step 2 an expert advisory committee in Medsafe would decide to support the use of a POCT device in New Zealand. Devices that have been evaluated and scrutinised and that meet predefined standards would then enter the second phase of Step 2 and be subject to local New Zealand evaluation by accredited laboratories. Any device that is approved for the local market should be registered in the WAND database which will act as a registry of all devices supported by Medsafe for use by the consumer. Decisions regarding funding can be made by PHARMAC or alternative funding body (Step 3).

Regions and district health boards (DHB) should have local clinical governance bodies to oversee local clinical needs; this would constitute the second gateway. For example, in the Northern Region this could be the Northern Region POCT (NRPOCT) Group; these groups will undertake Step 4.

Individuals or patients who use a POCT device at home should be fully trained and supported with advice on the limitations of the device and how to prevent common problems which may occur with these devices. Support may come from the supplier of the device, eg, pharmacist, or from delegated personnel/institution.

Discussion

Medsafe regulatory committee members with responsibility for POCT devices should include representatives from clinical pathology, medical laboratory scientists, healthcare practitioners, technical experts, and relevant allied healthcare providers. The New Zealand Best Practice Guidelines for Point-of-Care Testing should be the primary source of guidance for setting quality standards. In the first phase, a set of predefined criteria should be the basis of initial screening for acceptance or rejection of POCT devices. Primary considerations should be given to clinical safety of the test or device, including evidence of clinical and analytical performance and history of international recalls, local needs and cost-effectiveness. Reasons for a decision should be clearly documented and defensible. Devices that are approved at the first phase would proceed to be evaluated in the second phase, the local environment. This requires a national POCT laboratory service appointed by the regulator to evaluate point-of-care (POC) tests and devices.

Evaluation of devices must be carried out locally by an accredited laboratory service. It is not sufficient to completely rely on the results of overseas validation data even though such data can add to the evidence-base. In New Zealand, medical laboratories are accredited for medical laboratory services by International Accreditation New Zealand (IANZ) against the medical testing standard ISO (International Organisation for Standardisation) 15189:2012.

Eighteen medical laboratories are accredited against the POCT standard ISO 22870:2016. Until all laboratories that offer POCT in New Zealand are required to be accredited against ISO 22870:2016, the minimum requirement to perform evaluation of devices should be accreditation against ISO 15189:2012. The criteria for scale and scope of the evaluation for each device or test will depend on the clinical utility and complexity of the device or test and on the quality of overseas evaluations if applicable. These criteria would be defined by the national POCT laboratory evaluation service. This approach is consistent with section 95 of the draft Therapeutic
Products Bill 2018; which states the criteria for product approval and includes quality, safety and performance.\textsuperscript{7}

Traditional laboratory instruments are evaluated by experts in the medical laboratory; this is bread-and-butter of laboratory practice. Regulation is important for these instruments, and because of the detailed evaluations that they are subjected to within the laboratory, instruments that are not fit-for-purpose are not used. The same regulatory authority does not currently apply to POCT devices and tests, because they can be acquired by non-laboratory trained individuals, many of whom are not health professionals. As opposed to laboratory-based instruments, POC devices need tailor-made validation protocols that include field testing to accommodate all types of users and clinical settings.

A national evaluation laboratory service for POCT devices will prevent duplication of effort and resources between laboratories, ensure safe devices and tests are available to the New Zealand consumer, and ensure POC tests are fit for local purpose. This national evaluation laboratory service may be a standalone laboratory or a virtual laboratory made up of experts around the country who are contracted by Medsafe or the Ministry of Health. This national evaluation laboratory service is consistent with section 207 of the draft Therapeutic Products Bill 2018 which states that “the Regulator may rely on reports, assessments or decisions made by, or information received from, a recognised authority”.\textsuperscript{7}

An approved device would then be registered in the WAND database. Compulsory registration ensures traceability and effective management of recalls or adverse events. Approved devices will be available for the New Zealand consumer regardless of funding status but government funding supports equitable healthcare delivery.

When devices are approved and made available for use, the results of the evaluation or validation need to be accessible and publicly available. This aligns with the consumers’ right to be informed\textsuperscript{2} and provides a reference point on which to base decisions in case an adverse event occurs. Decisions could include repeat validation testing on a suspect device, batch or lot number of consumables, or a recall notice and substitution options. A national adverse events monitoring system (AEMS) for POCT was proposed in 2015,\textsuperscript{12} details of which are beyond the scope of this article.

The Pharmaceutical Management Agency PHARMAC decides which devices are to be publicly funded to get the best possible health outcomes.\textsuperscript{13} Each DHB in turn decides what devices to use in order to deliver local services; the choice would usually be from a national medical devices list that PHARMAC manages. It is prudent that PHARMAC have clear and functional timelines to prevent stalling of decision-making. This would avoid unnecessary delays in introducing a funded device that would benefit the New Zealand consumer. It would also allow for timely responsiveness to local needs and evolving technology. It is important to have open lines of communication between Medsafe, PHARMAC and clinical governance groups, and to avoid a silo mentality. Appointed coordinators for communication would ensure coherence of messages and a single point of contact for responses and decisions in addition to the website. Furthermore, in the unlikely event that a decision made by Medsafe or PHARMAC is deemed to disadvantage patients’ clinical needs, there should be an opportunity within a defined timeframe to appeal to the relevant body. Appointees to POCT device regulatory and governance teams need to be resourced appropriately with adequate time and travel sponsorship as required, to enable them to carry out evaluation, investigative and review functions efficiently and effectively.

**Accreditation for POCT**

The regulatory framework should also include provisions so that DHB contracts with contracted laboratory service providers require the provider to support and implement quality controlled, accredited POCT services where applicable within DHB hospitals.\textsuperscript{14} Many private hospitals use complex POCT devices, such as blood gas analysers, to manage patients intra-operatively and in critical care units. They may choose to maintain independent clinical governance but it is essential that the regulatory framework includes provisions for mandatory POCT accreditation against ISO 22870:2016 for these hospitals in the interests of patient safety.
Community settings should fall under the governance structure of their local DHB or regional POCT clinical governance groups. Pharmacists can be fully trained by laboratory personnel, eg, relevant DHB staff or approved suppliers; this will ensure standardised training and safe practices. An approved supplier is one that is deemed reliable and recommended by the local POCT governance group. As is the case in accredited laboratories there should be periodic recertification of pharmacists who sell POCT devices. This can be done electronically after initial face-to-face training.

Patients should be trained by the pharmacists and should have a mechanism for feedback, eg, a help-line. In the interest of traceability and patient-centred care, it may be prudent that patients or carers demonstrate their understanding of testing technique, limitations and who to contact for support. This contractual agreement co-signed by the trainer would facilitate a balance of shared responsibility.

Commercial arrangements

Commercial arrangements with suppliers need standard provisions for surety of supply and device performance. In addition, these supply agreements need to be flexible in the event that a device is found to be faulty and the decision is taken by the regulator or a provider to halt or cease the use of a device in New Zealand based on clinical evidence and risk assessment. While pre-evaluation (phase 2 of Step 2) will help avoid such a scenario, there should be safeguards for this rare, yet possible event since patient safety is the primary goal.

Education

It is the responsibility of the Ministry of Health, health providers and all healthcare personnel to educate the public regarding purchase of untested devices, eg, through the internet. While such practices cannot be stopped, our moral responsibility and duty of care cannot be disputed. This applies to patients and individuals in hospitals and in the community.

Adverse event monitoring system (AEMS)

POCT is ubiquitous and very large in scale and scope. In its own right POCT is a stand-alone virtual laboratory with a myriad of potential risky practices due to the variety of end-users who are for the most part not laboratory trained. This necessitates a dedicated national POCT AEMS, separate from traditional laboratory incident reporting. Such a system would consolidate evidence under one umbrella, will streamline event monitoring, allow timely dissemination of information among relevant parties, facilitate recalls and be an effective means for monitoring of (un) safe practices or devices. Medsafe has made progress towards reporting of incidents albeit not specific to POCT.

In the event of an adverse incident involving a device, consumers and providers will need to know that an investigation has been completed and that if the device is withdrawn, this is the advice of the regulator, the investigators and the AEMS committee. However, if the device is considered to be suitable for continued use then consumers and providers need to have confidence that the thorough validation checks have been completed and this data will again form part of the public record.

Challenges

Fiscal resources are a common limitation in all healthcare systems. Populations are expanding and aging, and patient expectations are rising while resources are not catching up. A long-term and ethical perspective would be to view people as entitled to the best healthcare possible and to invest in long-term safety; an investment that would secure the health of generations. This far-sightedness would inevitably guarantee considerable fiscal returns in terms of averting iatrogenic complications at an individual's level and increasing productivity at a population level.

Other challenges include political agendas, ineffective communication, lack of transparency, duplication of work and regulatory ‘speed bumps’. Not all of these potential challenges can be avoided but a focus on the patients’ wellbeing and providence is an important start.

Attitudes can also be a challenge. Some leading professionals express the lack of need for local regulation of POCT devices, stating “We are a small country. We are happy to rely on other countries’ or jurisdictions’ regulatory systems and transfer their framework to New Zealand” (personal communication). The authors acknowledge...
that re-inventing the wheel is inefficient but complete reliance on imported ideas discredits local expertise and fosters a culture of apathy. It also defies the norm of differences; nations have different cultures and population characteristics, and therefore regulatory systems should accommodate these differences.

**Conclusion**

The authors recognise that a regulatory framework for POCT devices will be subject to political, economic and practical constraints. However, given the increasing complexity and demands of the modern medical landscape, the public has genuine rights with regards to POCT in the healthcare system. These expectations include but are not limited to, that accredited health providers use validated POCT medical devices, approved by the appropriate regulatory and funding agencies and that approved validated devices are available for home use.

We have outlined a vision for an efficient and flexible governance framework for POCT in New Zealand. It addresses regulation at a governmental level and clinical governance at a regional level. The framework presents broad principles that when embedded in the structure of healthcare delivery in New Zealand enables a robust risk-averse approach to the practice of POCT. It is focused on delivering high-quality POCT services and is aligned with the New Zealand Health and Disability Consumers Code of Rights 1996 and the draft Therapeutic Products Bill 2018. Despite potential challenges, the framework as outlined is achievable in the interests of assuring patient safety.

**Competing interests:**

Mr Herd reports affiliation with Radiometer Pacific Ltd and Roche Diagnostics NZ Ltd outside the submitted work; he is a member of the New Zealand Point of Care Testing Advisory Group and the Northern Region District Health Board Point of Care Testing Group.

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