

Connectivity for point-of-care testing results: a call for change

A New Zealand national point-of-care testing advisory group (NZ POCT AG) position statement

Samarina MA Musaad, Vanessa Buchan, Geoff Herd, on behalf of the NZ POCT AG

ABSTRACT

This article hopes to minimise challenges such as result transcription errors, undocumented tests and results, delays in management and over-testing, by making seven recommendations in support of implementing nation-wide connectivity for point-of-care testing. The ultimate goal is to facilitate safer and equitable point-of-care medical laboratory testing throughout the patient journey and in all geographical locations of New Zealand. The recommendations have been endorsed by the New Zealand Society for Pathologists and The New Zealand Institute of Medical Laboratory Science.

Connectivity for point-of-care testing (POCT) results helps ensure that clinicians have access to complete and accurate diagnostic information for decision making. It is the capability of a POCT device to link electronically with the laboratory, hospital information systems and patients' permanent electronic medical record or general practice patient management systems. Connectivity facilitates continuity of patient care and quality assurance of POCT practices.

Electronic transfer of results for laboratory-based testing is a given, and yet, the state of connectivity for POCT is highly inconsistent across New Zealand, depending on individual organisations and their progress in this space. There are regional, bureaucratic, operational and fiscal barriers to implementation at the expense of an increased and avoidable clinical risk to patients. Variations in these barriers would lead to inequitable care. This article highlights the need for connectivity of POCT devices in New Zealand wherever POCT is conducted by discussing its benefits, the risks directly associated with lack of connectivity and barriers to implementation. It seeks to draw the attention of funders and policy makers to the current state of connectivity in the country and to canvass clinical and political will for improvement.

Background and context

A glucose result on a neonate was transcribed

into the notes as 4.1 mmol/L. The correct glucose result transmitted from the connected glucose meter to the patient's electronic medical record was 1.4 mmol/L. The clinical range for neonatal glucose is 2.6 to 8.0 mmol/L. This was a true near miss. See Appendix 1 for more real-life examples of near misses and incidences contributed to by using unconnected POCT devices.

POCT is medical laboratory testing carried out at the "point of care". It is also known as "bedside testing" or "near patient testing" and is carried out in a variety of settings including hospital wards, emergency departments, intensive care units, operating theatres, outpatient clinics, pharmacies, community general practice, marae and in patient homes.

Connectivity is the capability of a POCT device to link electronically with laboratory and hospital information systems and patients' electronic medical records (EMR) in hospitals and primary care. Connectivity is a standard of care for POCT. It is a requirement of the New Zealand Best Practice Guidelines for Point-of-Care Testing¹ where possible, and of the Australasian Association of Clinical Biochemists (AACB) Point-of-Care Testing Implementation Guide.²

Electronic transfer of results for laboratory-based testing is an expected given, yet currently, connectivity for POCT is highly inconsistent across New Zealand, depending on individual organisations' infrastructure and set-up. For example, most of the large metropolitan hospitals use a wide range

of POCT devices and have extensive connectivity systems for monitoring devices, quality assurance and integration of test results in the patient EMR. In contrast, medium sized hospitals have incomplete connectivity systems for POCT. Small rural hospitals without on-site laboratory support rely on POCT for decision making. However, these hospitals often have very limited connectivity and consequently, the test results from the point-of-care (POC) devices used at these hospitals may not be included in the EMR. In addition, these test results are not available for review by clinicians at the referral hospitals within the region.

A main challenge is that the scope and scale of POCT in New Zealand is extensive and includes a large number of devices used in many clinical settings. These devices range from simple dipstick tests (many of which have no connectivity capability) and polymerase chain reaction tests used to screen for and detect SARS-CoV-2 or Influenza A and B, to expensive and complex blood analysers with connectivity capability. All these tests are performed by a large number of staff who are non-laboratory trained, e.g., nurses, pharmacists, midwives or clinicians. In addition, some devices are used by patients and whānau. Where a device does not have inherent connectivity capability, alternative technologies can be leveraged, e.g., the rapid antigen test (RAT) catcher technology used for SARS-CoV-2 POCT (RAT test) screening. Unlike straightforward connectivity, such technology involves human input. When available, connectable RAT tests should replace current RAT tests.

Te Whatu Ora – Health New Zealand advocates for regional and national plans to bring healthcare closer to home, supporting primary care and ensuring safe and equitable healthcare delivery. Patient care is a continuum: home → primary care → secondary care → tertiary care; POCT connectivity is an important aspect of such a continuum and of the new health delivery paradigm to deliver equitable standardised services across New Zealand.

For connectivity to be implemented, there needs to be political and logistic integration across the health system framework of funding, delivery and education/governance and, indeed, end users and beneficiaries. Connectivity for POCT requires buy-in from a wide range of agencies, including: Manatū Hauora – Ministry of Health, Te Whatu Ora – Health New Zealand, Te Aka Whai Ora – Māori Health Authority, Health Information Technology groups, Pharmaceutical

Management Agency (Pharmac), New Zealand Medicines and Medical Devices Safety Authority (Medsafe), Royal New Zealand College of General Practitioners, Hauora Taiwhenua – Rural Health Network, Pasifika Medical Association Group, Royal New Zealand College of Urgent Care, College of Nurses Aotearoa (NZ), New Zealand College of Midwives, Pharmaceutical Society of New Zealand, private hospitals, Ara Poutama Aotearoa – Department of Corrections, New Zealand Defence Force, St John Ambulance, community health providers, marae, patients, and all other providers and users of POCT in New Zealand. In addition, the manufacturers and local suppliers of POCT devices are essential for the successful implementation and ongoing support of connectivity systems.

All the above create bureaucratic, operational and fiscal challenges to providing a standardised fit-for-purpose model, at the expense of an increased and avoidable clinical risk to patients.

Repercussions of lack of connectivity for POCT results include, but are not limited to: 1) management without knowledge of all tests previously conducted, giving rise to avoidable medical intervention and under or over-prescribing, 2) incomplete or inaccurate clinical records due to typographical errors arising from manual transcription necessary in the absence of electronic connectivity, and 3) delays in disposition or treatment while waiting for repeat testing, all of which potentially carry significant clinical and medico-legal risk at provider and organisational levels. Repeat testing and investigating clinical incidences have financial and resource implications. Furthermore, lack of connectivity compromises quality assurance practices, because connectivity is a key component for device management such as customisation (e.g., gender and age adjusted reference ranges), software upgrades, quality control (an essential frequent check to ensure the device is functioning as expected) and operator lock out for untrained operators. Connected devices can alert POCT coordinators to device malfunction. Newer POCT devices, such as glucose meters with connectivity, assist operators to perform tests correctly. For example, the device will not perform the test measurement if the patient specimen is clotted or there is insufficient specimen applied to the test strip. Therefore, consumers and patients who use unconnected POCT devices receive substandard care.

Benefits of connectivity include, but are not limited to:

1. Helping ensure test results are accurate and clinically reliable.
2. Ensuring continuity of care by allowing test results undertaken by the patient/user to be accessible to all clinicians providing care, e.g., a tertiary clinician knowing a result of a test performed by the patient/primary provider and *vice versa*.
3. Mitigating risk due to human transcription errors.
4. Reducing clinical risk and supporting safer patient care.
5. Health cost saving through reduction of repeat testing.
6. Supporting public health measures and epidemiological data gathering and data mining when needed.
7. Ensuring all devices/tests are connected, supporting equity of care across New Zealand, with quality-integrated testing in patients' localities throughout the country.
8. Connectivity across New Zealand, helping assist with capturing and reporting of clinical adverse events associated with POCT devices and tests.³
9. Improving quality assurance practices.
10. Providing support for medico-legal accountability for health carers and their organisations.
11. Traceability facilitating post-market surveillance.

Barriers to implementation

1. Connectivity solutions are expensive. Each organisation is required to capitally fund the project start-up and ongoing operational cost. A national approach would be highly advantageous and create efficiencies across the health system.
2. Concerns about patient confidentiality. Some patients may not desire connectivity for their test results for personal reasons. Patient consent should always be sought.
3. Information technology security concerns can be minimised by working with health information technology structures that already exist in our health system.
4. A conceptual barrier exists, in that a carefully thought-out national quality assurance framework for POCT needs

to be implemented. This may need to be individualised and adapted to various geographies, but the underpinnings should be uniformity of access to standardised quality POCT.

Summary and recommendations

The current state of connectivity for POCT is highly variable across New Zealand, creating avoidable clinical risk and inequity in service delivery which a national solution could address. Connectivity is achievable where there is clinical and political will. For these reasons, the NZ POCT AG makes the following recommendations, endorsed by the New Zealand Society for Pathologists (NZSP) and The New Zealand Institute of Medical Laboratory Science (NZIMLS):

1. *Recommendation:* real time and historical results (with patient consent) from POCT devices in any geographical location in New Zealand should be universally accessible to health carers involved in the patient's care. *Rationale:* POC diagnostic information and test results are not universally integrated within the patient's EMR.
2. *Recommendation:* a secure means of actioning recommendation 1 should be implemented using alternative technologies until connectable POCT devices are in the market. *Rationale:* a number of devices in New Zealand do not have connectivity capability.
3. *Recommendation:* patients should be allowed to share their results with their health providers. *Rationale:* many POC tests are performed by patients on themselves (or use wearable devices) or by caregivers. Patients and whānau should be informed and have access to devices with connectivity capability.
4. *Recommendation:* implementation of a nation-wide connectivity framework for POCT tests, leveraging existing successful connectivity platforms and championed by Manatū Hauora – Ministry of Health, Te Whatu Ora – Health New Zealand and Te Aka Whai Ora – Māori Health Authority, is needed to help integrate patients' POCT results within their EMR in all settings. *Rationale:* a nation-wide connectivity framework for POCT tests does not exist.
5. *Recommendation:* a process is required to conduct an immediate, and periodic,

gaps and needs assessment of the state of connectivity solutions across the health continuum to inform a sustainable work plan.

Rationale: the scope and scale of POCT is evolving and expanding rapidly.

6. *Recommendation:* the existing funding and regulatory agencies, Pharmac and Medsafe, respectively, and any future purchasing and regulatory bodies, should incorporate connectivity as an essential component for funding decisions and regulation of POCT devices. These decisions must be made in accordance with the NZ POCT AG recommendations submitted to the select

committee on the Therapeutics Products Bill currently before Parliament.⁴

Rationale: consideration and financial support of connectivity for POCT devices is not currently a priority.

7. *Recommendation:* an Adverse Events Management System (AEMS) should be implemented in the interest of patient safety,³ and was also recommended in the NZ POCT AG submission on the Therapeutics Products Bill.⁴ The success of such a system would depend on successful connectivity for POCT devices.

Rationale: New Zealand does not have an integrated national AEMS for POCT devices.

COMPETING INTERESTS

Nil.

AUTHOR INFORMATION

Samarina MA Musaad: Consultant Chemical Pathologist, Chemical Pathology Department, Te Whatu Ora – Waitematā, LabPlus Te Toka Tumai, and Te Tai Tokerau; Clinical Lead Northern Region POCT Network.

Vanessa Buchan: Service Manager, Pathology, Te Whatu Ora – Waitaha Canterbury.

Geoff Herd: Point of Care Testing Coordinator, Pathology Services, Whangārei Hospital, Te Tai Tokerau Northland; Lead Scientist Northern Region POCT Network.

CORRESPONDING AUTHOR

Samarina MA Musaad: Chemical Pathology Department, Te Whatu Ora – Waitematā, 124 Shakespeare Road, Takapuna 0620, Auckland.
E: Samarina.musaad@waitematadhb.govt.nz

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Appendix 1: Scenarios.

Examples of more real-life clinical risks associated with lack of connectivity:

1. An operator/health carer missed recording a positive urine pregnancy test. The patient was exposed to a radiological investigation with the risk of harm to the unborn foetus.
2. Surgically operating on a patient without knowing their COVID-19 rapid antigen test result because of delays in implementing connectivity.
3. An International Normalised Ratio (INR) result for warfarin monitoring, requiring medical intervention may not be viewable by the treating clinician; this can result in mismanagement, bleeding, or thrombosis.
4. Patient C says they had two POCT Hepatitis C screening tests. Dr F cannot find a record of the tests and results. The test is repeated.