Point-of-care testing comes of age in Australia

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Summary

A wide range of point-of-care tests is available and being used in both hospital and community settings for acute and chronic illnesses. There have been significant improvements in device technology as well as advances in training methods, procedures to monitor analytical quality, and the electronic capture and management of test results from a central location. Various point-of-care tests have been found to be non-inferior to laboratory testing for managing chronic conditions in general practice and Aboriginal medical services. Maintaining the analytical quality of devices and ensuring that staff are properly trained are critical elements in sustaining a high quality point-of-care testing service.

Key words: clinical tests, general practice.

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Introduction

Point-of-care testing can be defined as pathology testing performed on-site during the patient consultation. It allows a rapid test result to be generated and used to make an immediate, informed clinical decision.

There have been significant technological and analytical advances in point-of-care testing devices and reagent manufacture. An increasing range of tests can now be performed on very small sample volumes in less than 10 minutes. These include tests for glucose, glycated haemoglobin (HbA1c), lipids, electrolytes, urea and creatinine, blood gases and coagulation and cardiac markers. The analytical performance of many point-of-care testing devices is equivalent to that of a laboratory and meets profession-derived analytical goals.[1,2]

Clinical applications

Point-of-care tests (both singly and in profile) are now available for acute and chronic situations and can be used for example in managing diabetes, warfarin requirements, electrolyte and acid–base disturbances and risk stratification of patients with suspected acute coronary syndrome. Table 1 lists examples of the more common biochemistry and haematological tests. Some tests such as haemoglobin and INR have both chronic and acute applications.

Table 1

Point-of-care tests for chronic and acute care

Parameters	Test
Chronic care	
Carbohydrate metabolism	Glucose
	Glycated haemoglobin
Lipids	Triglyceride
	Total cholesterol
	High-density lipoprotein cholesterol
	Low-density lipoprotein cholesterol (calculated)
Renal function	Urea
	Creatinine (estimated glomerular filtration rate)
	Urine albumin
	Urine albumin–creatinine ratio
Haematological/ coagulation	Haemoglobin
	INR
Liver function	Total protein
	Albumin
	Alanine aminotransferase
	Aspartate aminotransferase
	Gamma-glutamyltranspeptidase
	Alkaline phosphatase
	Bilirubin
Acute care	
Electrolytes	Sodium
	Potassium
	Chloride
	Total CO_2
	Anion gap
Arterial blood gas	pH
	Partial pressure CO_2
	Partial pressure O_2
	Saturated O_2
	Base excess
Cardiac function	Troponin I
	Troponin T
	Creatine kinase myocardial band
	Myoglobin
	N-terminal pro b-type natriuretic peptide
	Brain natriuretic peptide
Miscellaneous	
	C-reactive protein
	Ionised calcium

Glycaemic control

HbA1c remains the gold standard pathology test for long-term monitoring of glycaemic control in patients with diabetes. Devices measure HbA1c using either immunoassay or boronate affinity chromatography methods.

There are numerous strip-based testing devices for glucose monitoring. These generally measure whole blood glucose rather than plasma glucose, although newer devices can report a plasma-equivalent glucose concentration.

Blood lipids

Measuring blood lipids is useful for cardiovascular disease risk assessment and for managing patients on lipid lowering therapy. Testing devices measure a full lipid profile on capillary or venous blood. However, they calculate the low density lipoprotein (LDL) cholesterol using the Friedewald formula and cannot, as yet, determine LDL cholesterol directly as laboratories can now do.

Assessing renal function

Quantitative measurement of urine albumin or urine albumin–creatinine ratio is a key component in the review of patients with diabetes. Plasma creatinine measurement is currently the subject of an international standardisation, in which both laboratory and point-of-care testing methods are being aligned to an isotope dilution mass spectrometry reference method.

Warfarin monitoring

Point-of-care INR testing is becoming increasingly popular in general practice for monitoring patients on warfarin therapy.[3] Results can be linked with computer decision support software that automatically recommends the patient's next dose of warfarin.

Acute care

In an acute situation, electrolytes (including anion gap), blood gases and cardiac markers, notably troponin I or T, can be assessed. Some devices can measure these cardiac troponins down to the nanogram per mL range. Newer markers including brain natriuretic peptide (BNP) and N-terminal pro b-type natriuretic peptide (NT-proBNP) remain expensive and their clinical utility continues to be debated.

Point-of-care testing models

In Australia, point-of-care testing is being used in the community as well as in hospitals particularly in rural and remote areas where access to laboratory services may be poor. There are now a number of working examples of innovative community-based point-of-care testing models that have improved clinical outcomes in both chronic and acute situations and are analytically sound (see box).

Managing point-of-care testing

A systematic approach is needed to organise and manage a sustainable and clinically effective point-of-care testing service.[4]

Models of community-based point-of-care testing

The national Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program (www.qaams.org.au) provides glycated haemoglobin (HbA1c) and urine albumin–creatinine ratio testing for diabetes management in over 100 indigenous medical services across Australia.[2,5]

Queensland Health's statewide i-STAT network provides portable analysers throughout Queensland. These measure blood gases, electrolytes, coagulation, haematological and cardiac markers in critical care situations.[6]

The Integrated Cardiovascular Clinical Network SA (iCCnet SA) operates in rural South Australia (www.iccnetsa.org.au).

Physical requirements

Only a small area of dedicated bench space is required to conduct most point-of-care testing, as most devices are 'desktop' in size or smaller. Most devices require an AC power source although an increasing number of newer devices can work off battery power as well. Storage of reagents and consumables is generally at room temperature or 4º C, depending on the individual test.

Staff training

Training programs for staff who perform the tests (such as doctors, nurses and Aboriginal health workers) are required. The type and duration of training needed depends on the complexity of the device and the range of tests available, as well as the number of people being trained. For example, a training session for a simple device such as a glucose meter for a small number of trainees may take less than half a day, while regional training workshops for the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program, the largest national point-of-care testing program for diabetes management, take two full days for 20–30 trainees. Initial and ongoing training with competency assessment and updates are crucial for a sustainable high quality point-of-care testing service. Web-based training is now available for some Australian models.[2,5]

Analytical quality

A management system incorporating quality control and quality assurance processes adapted for non-laboratory settings is needed to continually ensure that the analytical quality of point-of-care testing results is appropriate for patient care.

The frequency of these checks depends on a number of factors including device complexity, size of the point-of-care network and the volume of patient testing at each site. For example, in the QAAMS program for diabetes management, quality control and quality assurance testing is performed monthly.[2] Should an abnormal result be obtained that does not fit the patient's clinical picture, the treating practitioner should repeat the point-of-care test and send the sample to the laboratory for confirmation of the result.

To sustain a point-of-care testing service, it is important to have ongoing technical support from the manufacturer of the device.

Test results

A further recent technological advance has been the capacity to send results electronically from multiple point-of-care testing devices to a central management point and from there to a clinical or hospital information system. This improved connectivity has enhanced the ability to develop large-scale point-of-care testing networks and streamline the delivery of testing services. Many Australian diagnostic companies provide connectivity software for their testing devices.

Is point-of-care testing effective?

There is a growing evidence base for the clinical, operational and economic effectiveness of point-of-care testing in hospitals and in the community.

Chronic care

For chronic care, there are published examples of how point-of-care testing can be an effective tool for improving control of chronic conditions either by reductions in HbA1c (for diabetes management)[7] or increased time in therapeutic or target ranges (coagulation studies).[3]

Acute care

The ability to perform tests such as potassium and blood gases by point-of-care testing in under five minutes on an acutely ill patient can inform initial management. For example, being able to measure potassium levels in a patient presenting with severe vomiting or diabetic ketoacidosis in a remote health centre is particularly useful. Similarly, the ability to rapidly stratify risk in patients with suspected acute coronary syndrome using supportive cardiac marker point-of-care testing can have benefits. These relate to reduced length of stay in emergency departments or reduced mortality through more rapid and effective risk stratification and treatment.[8,9]

General practice

A large randomised controlled trial of point-of-care testing in Australian general practice was commissioned by the Department of Health and Ageing.[10] As part of the trial, the effectiveness of point-of-care testing versus laboratory testing was assessed for managing chronic conditions in general practice. Data from 53 practices located in urban, rural and remote locations in Australia were analysed. Based on the primary outcome of percentage of patients with test results in the target range, point-of-care tests for HbA1c, urine albumin, albumin–creatinine ratio, total cholesterol and triglycerides were non-inferior to laboratory testing, but not for INR and HDL cholesterol.[11,12]

Limitations of point-of-care testing

While point-of-care testing may appear simple and easy to adopt, it is critical that health professionals seek the support of their local laboratory or specialist point-of-care testing service provider to support and maintain their service. These services may be helpful when selecting a device and with training and quality surveillance. The capacity to sustain a point-of-care testing service in a remote health service setting is often limited by high rates of staff (device operator) turnover.[13]

At present there is no Medicare rebate for point-of-care tests in general practice (other than a small group of mainly qualitative tests such as a pregnancy test). This limits the potential uptake of point-of-care technology and means a thorough cost–benefit analysis is needed before making the decision to implement point-of-care testing.

Conclusion

General practice and particularly rural and remote medical services are increasingly using point-of-care testing. Technological advances in device and reagent manufacture have now ensured that this type of pathology testing can be performed safely and effectively. It is convenient and accessible for the patient and allows immediate decision making for the doctor. Nonetheless, in implementing point-of-care testing, a significant commitment to operator training (particularly in the face of high staff turnover rates in remote areas) and surveillance of analytical quality are paramount.

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Further reading

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Adverse reactions and *Australian Prescriber*: back to the future

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The Australian Adverse Drug Reactions Bulletin was first published in 1974.[1] This monthly publication became colloquially known as the ADRAC Bulletin as its content was determined by the Adverse Drug Reactions Advisory Committee.

In 1975 *Australian Prescriber* was launched and the ADRAC Bulletin was incorporated into it. There was some initial disquiet about the merger as the rate of reporting of adverse drug reactions reduced. This fall may have reflected the change from monthly to quarterly publication of the Bulletin.[2]

The Adverse Drug Reactions section was a regular feature of *Australian Prescriber* until 1982, when the publication of the journal was temporarily suspended.[3] The Bulletin then resumed its existence as a separate publication. It remained separate when the publication of *Australian Prescriber* restarted in 1983.

Both publications were distributed using a government mailing list, but an *Australian Prescriber* survey in 1989 found that more than 25% of respondents were not receiving the publications.[4] This problem was mentioned in the Baume review of drug evaluation in 1991. The review recommended that the mailing list should contain at least all medical practitioners, pharmacists and dentists. This was because the Bulletin was recognised as the major means of informing health professionals about the analysis of adverse drug reaction reports.[5]

Shortly after the Baume review a decision was made to distribute the Bulletin in the same package as *Australian Prescriber*. Although there were concerns that this could affect the rate of reporting of adverse reactions, the joint mailing went ahead. This arrangement has continued until now, despite *Australian Prescriber* moving publishers.[3] In 1999 *Australian Prescriber* increased publication to six issues per year and the Bulletin followed in 2003.

From 2010, information about adverse reactions will once again be included in a special section of *Australian Prescriber*. Medicines Safety Update will be prepared by the production team of the former ADRAC Bulletin under the guidance of the new Office of Medicines Safety Monitoring (OMSM). As the electronic version of *Australian Prescriber* has many overseas readers, the new arrangements will deliver important information about adverse reactions to a wider audience.

Australian Prescriber is pleased to be part of the new direction for informing health professionals about adverse reactions to medicines.

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