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Point of Care Testing in Australia – Where are we up to and why do we need it?

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Point of Care Testing in Australia – Where are we up to and why do we need it?

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Background

Pathology in Australia is administered under the Health Insurance Act (1973). The Act states that if a laboratory is to be eligible to receive Medicare Benefits it must be accredited under set standards and guidelines developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC).[1]

Point of Care Testing (PoCT) is diagnostic testing performed at or near the site of patient care.[2] As this definition implies, it is generally performed outside the routine laboratory and as such would not fall under a laboratory's accreditation.

A key objective of PoCT is to generate a result quickly so that appropriate treatment can be implemented leading to an improved clinical or economic outcome. For PoCT to be able to improve health outcomes it needs to be performed within a quality framework.

Although PoCT has been used for several decades in Australia the debate about its use continues. The advantages and disadvantages of PoCT (Table 1) feature heavily in this debate. PoCT has the potential to impact many facets of the healthcare system including the workforce. Consequently the debate on PoCT standards, accreditation and rebates involves many stakeholders and is an important one. This paper will discuss different aspects of the debate. Most importantly whatever is decided must ensure that there are no barriers to its use when clinically indicated and that it is always used within a safe quality framework.

Current Status

Currently there are no mandatory standards or guidelines written specifically for PoCT in Australia. Responsibility lies with individual organisations running PoCT to develop their own quality framework. Most PoCT tests are not eligible for Medicare rebates because they are performed at sites which are not accredited.

Sites wishing to perform other PoCT tests and receive a Medicare rebate must essentially follow accreditation procedures designed for laboratories. Steps include:

- Application to become an Approved Pathology Practitioner (current cost $500/doctor).
- Registration as an Accredited Pathology Laboratory ($750, Category M). The area where PoCT is performed is normally referred to as a laboratory. Accreditation is administered by National Association of Testing Authorities (NATA) to Australian Standard 4633 (ISO 15189) (with costs including administration, a site visit and travel[3]). Medical practices would generally be accredited as category M laboratories.
- Application to become an Approved Pathology Authority ($1500). The proprietor of the laboratory (in this case surgery) has to be approved.

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- Adherence to ISO 15189 standard dictating that tests be enrolled in an external quality assurance program.

The cost of following the laboratory accreditation process makes accreditation of PoCT uneconomic for most sites. Consequently most PoCT sites within Australia are not accredited and potentially the PoCT tests are not performed within a quality framework.

Currently if PoCT is to be performed in a hospital, general practice or a healthcare clinic wishing to be accredited, the PoCT standard, International Organisation for Standardization (ISO) 22870, can be used in conjunction with ISO 15189 to accredit the site. While this standard provides an excellent quality framework for PoCT, it is 'laboratory centric' and more suited to PoCT run by laboratories rather than by services operating outside the laboratory.

What do we require moving forward?

The danger in having a quality framework that potentially "overstates" what should be done is that it isn't adopted. This is detrimental to having a quality point of care service particularly in rural and remote areas who don't have access to on-site laboratories. Scientists have, in my opinion, a duty of care to guide implementation and support of PoCT so it is used in an appropriate manner. To ensure precision testing, important issues to be addressed include:

1. Ensuring equipment chosen is suitable for clinical use it is intended for
2. Appropriate education, training and certification program is available
3. On-going technical support
4. Access to control samples for quality testing as part of a quality framework
5. Appropriate regulations that ensure PoCT when performed is within a quality framework
6. Regulations that enables rebates for POCT equipment that meet minimum precision requirements. This will make sure unsuitable equipment which doesn't meet analytical requirements for that test aren't used.

Department of Health and Ageing Reviews and Research on PoCT

The Australian government has been under increasing pressure to simplify regulatory requirements for PoCT so that rebates for these tests can be more easily claimed by general practitioners or other healthcare workers outside the laboratory.

In 2001 a report on "Review of the Role and Value of Near Patient Testing (NPT) In General Practice" was published.[4] The aim of this review was to provide a series of recommendations to the Commonwealth Department of Health and Aged Care's expert pathology committee on ways it might progress the NPT (now referred to as PoCT) agenda. The review included a number of recommendations to government and the medical profession on how to introduce efficient cost-effective PoCT in general practice.

It also recommended that:

- diagnostic accuracy, efficacy, clinical effectiveness and cost effectiveness need to be evaluated
- national guidelines on the use of PoCT are essential

- a system that promotes collaboration between pathologists and general practitioners is desirable
- a PoCT accreditation process is essential

In 2005-06, the Department of Health and Ageing (DoHA) on behalf of the Australian Health Ministers' Advisory Council (AHMAC) commissioned a review by Phillips Fox (a large legal practice) to assess the extent of public health risk associated with non-Medicare pathology services including PoCT.[5]

The Review Team acknowledged that there are risks associated with all types of healthcare but noted that the available evidence did not support perceived unacceptable levels of risk associated with non-Medicare pathology services. They concluded that adoption of mandatory accreditation requirements for PoCT would impose a substantial cost and administrative burden on specialised or small-scale providers of pathology not justified by the level of risk. This in turn could prevent the use of PoCT in rural and remote communities where it had the greatest potential to benefit clinical care.

A key recommendation of the review team was that AHMAC should convene a working party led by DoHA and comprising nominees of NATA, Royal College of Pathologists of Australasia (RCPA), consumers, Royal Australian College of General Practitioners (RACGP), Pharmacy Guild, Pathology Associations Committee and other relevant stakeholders to develop non-statutory guidelines for the conduct of pathology services in non-accredited settings including PoCT.

The Second National Workshop on Safety and Quality in Pathology was held in Canberra in 2008 to discuss issues raised in the Phillips Fox Report.[6]

In 2015 the National Pathology Accreditation Advisory Council released Guidelines for Point of Care Testing (First Edition). The document sets out POCT best practice guidelines for governance, quality systems, staff training, safety, environmental issues, specimens and result integrity.[7] This document was put together by a a broad range of stakeholders including pathologists, scientists and general practitioners and provides a solid framework which could be used to develop an appropriate accreditation guideline. Rural and remote areas of Australia have without a doubt the biggest need for PoCT and currently Medicare rebates are a barrier for them to use this technology to provide safer patient care and in many cases care closer to home. In order for PoCT to be safe and cost effective in this setting any accreditation model needs to be integrated into existing practise accreditation rather than layered on top with addition of bureaucracy and cost. Pharmacy is another area adopting PoCT for potentially good reasons but who is monitoring the quality of this testing? If patients are paying for tests they should be guaranteed safe quality results. Similar to general practice, pharmacy needs an appropriate accreditation model that they can undertake and have access to Medicare rebates to enable testing when required to improve patient care.

Why does Australia need to consider a National Rollout of PoCT?

General practice continues to be the cornerstone of Australia's health services with 85% of Australia's population visiting a GP at least once a year costing Medicare in 2006/7 about $4 billion.[8]

Chronic disease management is a major challenge confronting the Australian health system, with 77% of Australians reporting one or more long-term health problems and more than half of those aged 65 years and older having five or more chronic conditions.[9] Seven out of ten visits to general practice are due to chronic disease.[10] General practitioners are usually the first point of contact in the health system thereby having key role to play in the primary intervention, prevention, diagnosis and management of chronic disease within the community. Australia is currently experiencing a shortage of general practitioners which increases the challenge of managing chronic disease patients.[11]

Pathology tests are used widely in the diagnostic work-up and monitoring of patients. Identification of disease in its infant stages potentially decreases the patient's likelihood of developing a more severe form of the disease requiring more intensive and costly care. The RCPA has stated that shortages of pathologists and senior scientists are a threat to service quality, timeliness and effective treatment leading to delayed discharges, increased hospital lengths of stay and increased health costs.[12]

The Australian Pathology Workforce Crisis report identified that PoCT should be considered as part of the strategy to improve pathology productivity by expanding its use by clinicians and by promoting further development and adoption.[13] Advantages of PoCT include faster pathology results, potentially resulting in faster patient treatment without the need for an additional patient appointment. PoCT could assist with the frontline management of chronic disease potentially relieving stress on general practice while at the same time expanding the reach of pathology services.

There is no question that PoCT has the potential to do harm if not implemented appropriately. To ensure that clinical care is not compromised and that risk to the public is minimal, PoCT must be implemented within a quality framework that is tailored to recognise the resources of non-laboratory environments while at the same time producing pathology results that meets the clinical intent.

Point Of Care in General Practice Trial

The Australian Government funded the PoCT in General Practice Trial in 2005. This was a multi-centre, clustered, randomised controlled trial to determine the safety, clinical effectiveness, cost-effectiveness and satisfaction of PoCT in general practice. In addition, the trial sought to determine the following:

I. Were performance measures different between urban, rural and remote geographical regions?
II. If PoCT was to be rolled out, did the regulatory environment used for the trial meet stakeholders' needs?
III. What would be an appropriate Medical Benefits Schedule fee for the tests selected in the trial?

Fifty-eight practices over a large geographical area (urban, rural and remote areas in South Australia, New South Wales and Victoria) were involved in the trial. Twenty practices were randomised in the control group and 32 practices in the intervention group. These practices involving 247 GPs recruited 5,234 patients, 2034 in the control group and 3200 in the

intervention group. The trial commenced in 2005, continued over an 18-month period and evaluated PoCT intervention on the management of patients with diabetes, hyperlipidaemia and those on long-term anticoagulant therapy.[16]

The PoCT standards discussed earlier provided the framework for developing a comprehensive accreditation program for practices in the intervention group.
The aim of the accreditation program was to ensure that the minimum standard for PoCT in the practice was met, and that all quality and safety aspects were adhered to. Practices were reviewed on site twice in the period of the trial. The surveyors included a scientist, a GP/practice manager and a member of the trial management team.

An overall conclusion of the trial was that PoCT has a role in enabling GPs to make more timely clinical decisions while facilitating discussion of self-management with patients. It was also concluded that the trial model worked within the current regulatory environment and appeared to be broadly acceptable to all stakeholders.[17] While the trial showed that PoCT could be performed safely in general practice, the negative issues of cost and administrative burden highlighted by Phillips Fox [5] were not addressed.

In particular, the costs of PoCT in the trial were calculated to be much higher than the same tests performed in the laboratory, a cause for concern among stakeholders. Factors that contributed to the high costs associated with PoCT tests run in the trial included:

- It was a “Rolls Royce” approach to running PoCT. Operators took part in a comprehensive training program and were supported by a team who monitored QC/QA results to ensure patient safety
- It was designed so that close monitoring of intervention practices took place to ensure patient safety
- The accreditation process for the trial itself had to be stand-alone and could not be integrated into practice accreditation
- QC/QA costs were greater for smaller practices with low test numbers.
  This scenario is similar to specialised laboratory tests with low patient numbers but multiple QC specimens and calibrators

For PoCT to be rolled out nationally, the trial model provides regulatory authorities with a framework for implementation although some modifications would need to be made. Each of these factors needs to be considered when determining potential MBS fees.

Australian Point of Care Practitioners Network

To address the challenge of costs associated with establishment and ongoing processes that are necessary to assure testing is carried out within a quality framework resulted in the development and implementation of the Australian Point of Care Practitioner’s Network (APPN). The APPN was initially funded by Department of Health and Ageing Quality Use of Pathology grant. It provides all the information required to perform POCT including identification of clinical needs, selection of instruments, test-specific clinical information, installation process, operator training, quality control, and quality assurance procedures and certification. The APPN also has a module to manage quality control testing with suggestions of why a result may be out of range to assist in the running PoCT within a quality framework.

The APPN could be used as a cost effective way of establishing a POCT quality framework in partnership with GP accreditation bodies.

Conclusion

All stakeholders agree that PoCT has clinical benefits in the management of chronic diseases and that it should only be implemented within a quality framework. An appropriate POCT quality framework should be implemented in Australia to ensure testing meets clinical needs.

Taking into consideration the size of Australia and how dispersed the population is, it would be hard to argue against PoCT having a place in clinical care. Should it be the same quality framework as used in the laboratory? Probably not, but whatever the framework adopted, it has to achieve the same outcome as the laboratory framework in producing high quality results that enhance clinical care.

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Advantages	**Disadvantages**
Simpler sample collection	Increased workload
Reduced pre-analytical errors	Potential errors due to poor analytical performance
Faster test results available leading to more timely treatment	Potentially incompatible to local laboratory method
Removes pathology access barriers in rural and remote areas	Increased costs
Increased patient satisfaction	Inadequate storage of results
Improved medical outcomes	Inadequate QC, QA and documentation

Table 1: Possible advantages and disadvantages of PoCT

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