

Quality of pathology services

Maintaining the quality and safety of pathology services is crucial to the efficient delivery of health care. Australia has a long history of focusing on quality assurance and continuous improvement in pathology services, and it is imperative that this is maintained.

The Specialty of Pathology

Pathology testing is used to predict, pre-empt, diagnose and monitor disease, and to determine and monitor appropriate therapies. It has been estimated that pathology investigations feature in up to 70% of diagnoses¹, making this a foundation stone of modern health care. This dependence on pathology testing will increase in the genomic medicine era (Appendix A) and genetic testing will change the patterns of disease in our society.

However pathology is perhaps the least understood of the medical specialties. In particular, the scope of pathology and the integral role it plays in all areas of medicine are not well recognised even by some of those working in health care environments. The 'hidden' nature of pathology, being undertaken largely in laboratories that other health workers never see, means that it has frequently been omitted from health system planning processes, or worse still targeted for funding cuts. Yet it is axiomatic that compromising foundations leads to disintegration later on.

Delivering High Quality Pathology Services

Fortunately for Australians, the concept of quality has been well established in laboratory medicine here for over fifty years. RCPA Fellows have driven the implementation of a quality framework that is unparalleled internationally², including:

- National Pathology Accreditation Advisory Council (NPAAC) created in 1979.
- A laboratory accreditation system established in 1984 by NATA in conjunction with the RCPA to promote a uniform approach to assessing and fostering high quality pathology services. A consistent high standard sets Australia apart from countries such as the USA and UK where quality is significantly more variable.³
- RCPA Quality Assurance Programs Pty Ltd, set up by the RCPA in 1989 to provide external QA systems for laboratories across Australia initially and now in many other countries. New programs include a Key Incident Monitoring and Management System designed to identify and prevent errors occurring in the pre- and post-analytical phases of pathology testing.
- Compulsory Continuing Professional Development for RCPA Fellows since 2006.
- Institution of the Quality Use of Pathology Program as part of the second MoU between the profession and the Australian Government.

RCPA work on quality initiatives is ongoing, with advisory committees considering issues such as critical values / standardised reference ranges; collaboration with the TGA regarding safety requirements for In Vitro Diagnostics; and oversight and implementation of a range of quality projects funded by the Quality Use of Pathology Program.

The quality framework in Australian pathology is more mature than in most other medical disciplines and this has been attributed to the "strong and constructive" culture amongst pathologists and scientists and "considerable volunteer effort"³.

¹ Department of Health Pathology Modernisation Team. Modernising pathology. Accessed via http://www.dh.gov.au/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4073106

² NPAAC Strategic Plan 2007

³ The Evaluation of Australian Pathology Laboratory Accreditation Arrangements for Commonwealth Department of Health and Ageing 2002 (Corrs Chambers Westgarth Lawyers)

Australian laboratories have a history of innovation and have implemented quality systems beyond regulatory requirements (e.g. ISO accreditation, Lean engineering) to a greater extent than in the USA. Other forces contributing to quality improvement over the last decade include automation, centralisation of services to large laboratories in both public and private sectors, and enhanced laboratory information systems.

Risks in Pathology Service Delivery

Risks to patients during health care episodes are well documented. The Quality in Australian Health Care Study (1995)⁴ reported that 16.6% of hospital admissions were associated with an adverse event, and the 1999 Institute of Medicine report *“To Err is Human: Building a Safer Health System”*⁵ revealed that error in healthcare is the fifth most common cause of death in the USA.

As pathology is pivotal to health care, it is no surprise that deterioration in the quality of pathology services can compromise patient care and lead to adverse health events. This has been demonstrated recently in Canada, where wide-ranging investigations are underway into adverse patient outcomes that stem directly from an inadequately resourced and manned pathology system with a very poor quality framework⁶.

The Institute of Medicine identified six core aims for health care services – that they be safe, effective, patient-centered, timely, efficient, and equitable⁷ – and similar attributes feature as key elements in quality frameworks in Australia⁸. Australian pathology services perform creditably against these standards. In particular, pathology testing is effective and efficient, with timely turnaround for obtaining results. Bulk-billing rates of over 85% make access to tests listed on the Medicare schedule highly equitable.

There is mounting concern within the profession, however, that these high standards may not be sustainable.⁹ The workforce crisis amongst pathologists and senior scientists, identified as the leading threat to the quality of Australian pathology services, presents a growing challenge particularly for timeliness and access. For example:

- Delays in the diagnosis and staging of diseases which increases angst for patients as they wait for test results, and may delay treatment, which in turn could affect prognosis.
- Delays in screening for disorders such as diabetes, which could result in early deaths or serious complications such as kidney failure and blindness.
- Delays in discharging patients causing hospital bed blockages, particularly in emergency departments.
- Delays in autopsies, causing unnecessary distress for grieving families

Rural communities are hit hardest and in some cases timeliness and equitable access are already seriously compromised. In Albury Wodonga, for instance, retirements and resignations of pathologists have seen a reduction from three full time pathologists to one visiting but no permanent pathologists in the last year. Pathology tests must now be sent away and some patients have to travel elsewhere for investigation and treatment.

⁴ Accessed through <http://www.mja.com.au/public/issues/misc/wilson.pdf>

⁵ Accessed through <http://www.iom.edu/?id=12735>

⁶ <http://www.cmaj.ca/cgi/content/full/178/12/1523#R12-3>

⁷ From *“Crossing the Quality Chasm: a New Health System for the 21st Century”* (Institute of Medicine, USA, 2001 accessed through <http://www.iom.edu/?id=12736>)

⁸ Australian Commission for Safety and Quality in Health Care submission to the National Health and Hospitals Reform Commission accessed via [http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/703C98BF37524DFDCA25729600128BD2/\\$File/NHRC-Submission.pdf](http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/703C98BF37524DFDCA25729600128BD2/$File/NHRC-Submission.pdf) and NHHRC’s *‘Beyond the Blame Game’* Report accessed via

www.nhhrc.org.au/internet/nhhrc/publishing.nsf/Content/commission-1lp

⁹ National Workshop on Safety and Quality in Pathology 2007 Aust Dept Health and Ageing

The manpower crisis affects laboratory supervision and puts accreditation at risk. Small pathologist owned laboratories and all laboratories in rural and regional Australia are at risk of closure, which will further compromise timeliness and accessibility. There is also concern that new technologies (patient identification, smart ordering, smart reporting - "the right test at the right time with the right result.") which have the potential to reduce error, are not being developed in Australia¹⁰.

Funding cuts pose a real risk to quality, and this may have serious consequences for patients, as evidenced in Canada. Economies to be gained in pathology from automation and task delegation have been largely realised already; there is no capacity to continue absorbing reductions in funding without reducing the quality of the service provided.

Finally, there is little recognition of the role high quality pathology services play in making patient care safe and effective. For example, the greatest risk to hospitalised patients is healthcare associated infection, which causes significant morbidity and mortality and impacts on costs through the need for interventions and delayed discharge. Monitoring by laboratories and development of infection control strategies has been highly effective in reducing these adverse impacts. Similarly, rapid turnaround pathology testing is a high priority in critical care settings because of the benefit for patient outcomes and healthcare costs. Conversely, failure to comply with evidence based guidelines for monitoring diabetes has resulted in an estimated 7400-15000 avoidable diabetes deaths and \$1.35 -\$1.62 billion in avoidable hospital costs in the United States in 2005¹⁰.

This lack of recognition of the contribution pathology testing makes to curbing healthcare costs renders it vulnerable to ill conceived strategies for cost containment.

Aligning Expectations

It is understandable that the Government wants to manage growth in expenditure on pathology services, with efforts to avoid waste and increase the focus on preventive care. There are obvious benefits in maintaining high levels of bulkbilling as this fosters equity of access for the community.

The community is more aware than ever of advances in health care, and many use the internet to gather information about possible investigations and treatments¹¹. Australians expect that they will be able to access pathology testing with a range and quality that matches international standards. One area that currently fails to meet those standards is genetic testing, most of which is state funded and delivered in an ad hoc fashion that leaves some patients without access or with significant out of pocket expenses.

Referring practitioners, most of whom are GPs, want the clinical autonomy to decide what pathology investigations they will request and to which provider they will refer¹². They expect the pathology services they use to be reliable and effective, with timely return of results on which they can base subsequent patient management decisions. They want to see new tests added to keep pace with medical advances.

For pathologists, the growing workforce crisis has already driven significant measures to improve efficiency, with strenuous efforts to ensure quality is not compromised. They want to continue providing an excellent service, being able to add new tests when appropriate and introduce new initiatives aimed at continuing quality improvement.

¹⁰ "Laboratory Medicine: A National Status Report" prepared for Centers for Disease Control and Prevention (USA) by The Lewin Group, May 2008

¹¹ "The internet and the changing roles of doctors, patients and families", Pemberton PJ and Goldblatt J accessed via <http://www.mja.com.au/public/issues/xmas98/pemberton/pemberton.html>

¹² Royal Australian College of General Practitioners Standards <http://www.racgp.org.au/standards/142>

The future

The future of pathology services provided in Australia must reflect shared expectations as to the nature of testing that can and will be provided. Policy makers must be aware of the international context in which the focus for funding of pathology services has moved from cost containment to managing usage to ensure better patient care¹³.

Optimising use of pathology to both prevent and manage disease requires:

1. Incorporation of pathology testing into guidelines in key prevention strategies and National Health Priority Areas, and quality measures for the use of pathology e.g.:

- Arthritis and Musculoskeletal conditions –
 - diagnosis and monitoring of Rheumatoid arthritis (immunopathology)
 - diagnosis and monitoring of osteoporosis (chemical pathology)
- Asthma –
 - testing for allergens and irritants where required (immunopathology)
 - testing for infectious triggers (microbiology)
- Cancer control –
 - analysis of biopsies and resected tumours (anatomical pathology)
 - management of leukaemias and lymphomas (haematology)
 - testing of tumour tissue for drug susceptibility (genetics)
 - testing of relatives to determine risk of developing cancer (genetics)
- Cardiovascular Health –
 - Investigation and monitoring of various cardiovascular conditions (chemical pathology, haematology)
- Diabetes Mellitus –
 - diagnosis and monitoring (chemical pathology)
- Mental Health –
 - potential for pharmacogenetics in drug selection and monitoring

2. Development of guideline based electronic ordering which has been shown to reduce redundant ordering¹³.

3. A greater emphasis on teaching medical students and doctors in training about the appropriate use of pathology.

4. Development of a coherent and efficient national framework for genetic services. Currently, the provision of genetic testing exists outside the pathology quality framework with barriers to access. It is erratic and will not cope with rapid evolution and the need for health care to be efficient and equitable. If we are to improve health care and reduce spending on chronic disease, a national framework must be developed urgently, with:

- appropriate investment in infrastructure
- funding to train pathologists and scientists to perform the testing
- one national catalogue of tests building on the existing Medicare Schedule list to include tests only done currently through state public hospitals
- prompt and apposite assessment of new genetic technologies and
- education for patients and referring clinicians about the role of genetics.

Conclusion

Pathology testing influences the majority of patient care decisions and plays a vital role in patient safety. It is crucial that the high quality of pathology services in Australia is maintained and enhanced in line with international standards, and pathology testing is used to optimal advantage for disease management.

¹³ "Laboratory Medicine: A National Status Report" prepared for Centers for Disease Control and Prevention (USA) by The Lewin Group, May 2008