

## Pathology in Australia

### Pathology: the Profession

Pathology is literally "the study of disease" and is the science upon which medicine is based. Pathologists are medical specialists who must undergo a minimum of 11 years medical training to qualify. There are six areas of specialty within pathology, viz Anatomical Pathology, Haematology, Chemical Pathology, Microbiology, Immunopathology, and Genetics; this diversity in expertise throughout private and public sectors in all states is essential to ensure that all Australians have access to the highest quality specialist pathology care.

Pathology and pathologists are responsible for 70% of all medical diagnoses<sup>1,2</sup> and 100% of all cancer diagnosis and make a significant contribution to the management of disease.

Pathologists and pathology play an essential role in the majority of preventive health programs and are crucial for the diagnosis and management of many chronic diseases such as cancer, diabetes, arthritis, hepatitis, and HIV.

### Australian Pathology: world's best practice

Australian pathology is considered world's best practice and all Australians enjoy the highest quality pathology care, regardless of their socio-economic status or geographical location.

*"Australia has a long history of focusing on quality assurance and continuous improvement in pathology services.... RCPA (Royal College of Pathologists of Australasia) has driven the implementation of a quality framework that is unparalleled internationally."<sup>3</sup>*

Pathology is the most highly regulated of all medical specialties with stringent regulations and legislation that underpin the provision of high quality safe pathology services. RCPA's paper entitled "Quality of pathology services" is attached at Appendix A to illustrate and expand on this point.

Also attached at Appendix B is a short overview and history of the regulations and quality measures that govern the collection of pathology specimens in the community.

### Pathology: a leader in e-health

Of all the disciplines in health, pathology has led in the use of information technology for the transmission of its records. In fact, for more than a decade pathology laboratories have been delivering electronic information to customers. With around 40 million reports delivered electronically in 2007, pathology remains the leader in this important area of e-health.

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<sup>1</sup> Department of Health Pathology Modernisation Team. Modernising pathology

<sup>2</sup> RCPA "Quality of pathology services " July 2008

<sup>3</sup> RCPA "Quality of pathology services " July 2008

## **Pathology: efficient billing practices**

As with other Australian medical services, each pathology episode is charged on a “fee-for-service” basis. Fee for service billing is a simple and efficient billing method ensuring only tests undertaken are billed, so that the services performed are described for each episode. Fee for service also results in a very comprehensive data base enabling sophisticated and continuous analysis and monitoring of the incidence and cost of pathology services.

## **Pathology: the process**

Pathology services are also governed by internal administrative pathology processes. This process is illustrated at Appendix C.

## **Pathology: ensuring equity and access for all**

The pathology sector has worked hard to ensure that all Australians have equal access to pathology services, regardless of their social, economic or ethnic background. In contrast to many other areas of health and medical care (for example as described in the “Australia the Healthiest Country by 2020” discussion paper), there are no disparities of access to pathology services between Aboriginal and non-Aboriginal Australians in metropolitan, regional or remote Australia.

Medicare Australia data<sup>4</sup> provide robust evidence for the high level of access provided by the pathology sector in Australia:

- In the fiscal year 2007/08 there were 29,777,903 Medicare items claimed for referred pathology services (PEIs);
- 14,305,832 of these were collected in Approved Pathology Collection Centres (APCCs) located throughout Australia. Approximately 38% of APCCs are in regional, rural and remote locations; and
- There were 851,183 specimens collected from patients' homes and 418,076 collected from nursing homes during that period.

Pathology specimens are transported (over 1400 vehicles are owned and operated by private pathology) to one of the 376 laboratories<sup>5</sup> (includes category B, GX or GY but excludes Category S, M<sup>6</sup>) located throughout metropolitan, regional and remote Australia for testing. Laboratories provide 24 hour and/or on call services<sup>7</sup> to GPs, specialists and hospitals, at their own expense with no additional costs accruing to patients or Medicare.

For the convenience of the Australian public and requesting practitioners, private pathology performs over 600,000 non-pathology tests within its laboratories. These include Warfarin dosing, ECGs, Holter Monitors, 24 hour blood pressure monitor, spirometry, peer reviews, case reviews with various specialist groups, vaccine delivery, infection control within hospitals, intravenous cannulation for private hospital and blood transfusion services, pre-employment testing and occupational health/environmental testing e.g. water quality testing. Without the provision of these services by private pathology providers many Australians would not have convenient access to these essential medical services.

Pathology laboratories also maintain regular contact with public hospitals to manage histopathology services and provide hospital and forensic autopsies. They provide, without charge, notifications to the

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<sup>4</sup> Medicare Australia Statistical Item reports June 2007 -08 accessed via [www.medicareaustralia.com.au](http://www.medicareaustralia.com.au)

<sup>5</sup> NATA list of 423 Laboratories accessed via the website [www.nata.asn.au](http://www.nata.asn.au)

<sup>6</sup> All Australian pathology laboratories are categorised under Australian Government regulations governing pathology services

<sup>7</sup> AAPP survey September 2008

various health/cancer/infectious disease registers, for example the Pap Smear Register, and conduct clinical research in a range of areas. Many laboratories also contribute to local drug and alcohol monitoring programs. These contributions provide significant benefits for the current and future health and welfare of the Australian community.

Private pathology providers also play a major role in medical and public education and training including:

- Conducting education/training sessions for GPs/Divisions of General Practice, medical specialists, scientists, collection staff, medical registrars and non-medical staff;
- Producing and distributing public educational flyers and brochures; and
- Giving lectures at universities on a range of relevant health and medical topics.

It is estimated that there are 36,000 people directly employed in providing private pathology services within Australia. Pathology laboratories contribute to their local communities by employing staff from the area and supporting local businesses, either by engaging their services or sponsorships. Representatives from local laboratories participate on many hospital/academic committees in the areas of patient management, infection control and clinical auditing.

## **Pathology: the Business**

Pathology in 2008 operates a very different business model<sup>8</sup> from that of 20 years ago. Major changes and operational efficiencies within the sector have resulted from the rising cost<sup>9</sup> of running pathology services whilst, concurrent with cost increases, pathology rebates have remained stagnant or have been cut. Some of the major factors affecting the business environment in which the pathology sector operates are as follows:

- AWE and CPI have increased by approximately 200%<sup>10</sup> since 1988 (pathology employs over 36,000 people nationwide)<sup>11</sup>;
- Medicare rebates are today lower than they were in 1985. This long term fee attrition has been offset by increased automation, practice aggregation (economies of scale) and sophisticated management practices. Pathology providers can no longer significantly expand on their use of these mechanisms to offset continuing fee attrition. Since 2000, these combined measures have saved the Australian taxpayer over \$3 billion;
- If a GP orders four or more tests on a patient at any one time the pathologist will only get paid for three tests (“coning”). This unpaid work currently adds up to \$200 million per year;
- Medicare Services data suggest that 34.3% of all Medicare activity relates to pathology (and this is rising), and pathology attracts 14.5%<sup>12</sup> of rebates (and this is falling); and
- Private pathology currently bulk bills approximately 90% of all patients. This is higher than any other medical specialty, including general practice.

The pathology sector has responded to the above factors by implementing business model changes to increase efficiency within the sector. However, there are now no more significant cost efficiencies to be

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<sup>8</sup> Profitability and returns in the non- government sector” Price Waterhouse Coopers August 2008

<sup>9</sup> Review of cost and cost drivers for the non government pathology sector Oct. 2008

<sup>10</sup> AAPP Review fact sheet

<sup>11</sup> DOHA “Pathology Workforce in Australia” 2008 and AAPP survey

<sup>12</sup> Pathology a declining proportion of Medicare outlays , EW consulting July 2008

gained<sup>13</sup>. Despite this the profession continues to be placed under financial pressure, including from the following:

- Ever increasing demand for pathology services/utilization inside a capped funding environment where GP/specialist ordering is not within the control of the pathology profession<sup>14</sup>;
- Government initiatives and policies, and advances in best practice medicine principles<sup>15, 16</sup>;
- More than 10% of revenue being lost to pathology practices through “coning”<sup>17</sup>;
- Pathology laboratories requiring high volumes of tests to sustain financial viability<sup>18</sup> but without the option of further amalgamations, giving higher volumes, due to restrictions of the Trade Practices Act;
- Reaching the limit in revolutionary technological advances, restricting significant further automation savings.

The Medicare funding reduction of pathology testing, in real terms, over the past 20 years, has resulted in a large reduction in the number of small to medium sized laboratories, reflecting their difficulty in achieving cost containment (see Appendix D - *The Role of Small-medium Private Pathology Practices in Australia*).

If these issues are not addressed, private pathology will find it difficult to continue to provide into the future the same high level of service to the Australian community (including access and affordability), particularly in areas which are currently unfunded or under-funded by governments.

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<sup>13</sup> “Profitability and returns in the non- government sector” Price Waterhouse Coopers August 2008

<sup>14</sup> “An Analysis of Pathology Test Use in Australia “ a collaborative study BEACH, Uni of Sydney and AAPP July 2008

<sup>15</sup> “An Analysis of Pathology Test Use in Australia “ a collaborative study BEACH, Uni of Sydney and AAPP July 2008

<sup>16</sup> “Profitability and returns in the non- government sector” Price Waterhouse Coopers August 2008

<sup>17</sup> AAPP 2007/08 Review Fact sheet

<sup>18</sup> Profitability and returns in the non- government sector” Price Waterhouse Coopers August 2008

## **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 diagnoses<sup>1</sup>, 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 internationally<sup>2</sup>, 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.<sup>3</sup>
- 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"<sup>3</sup>.

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<sup>1</sup> Department of Health Pathology Modernisation Team. Modernising pathology. Accessed via [http://www.dh.gov.au/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4073106](http://www.dh.gov.au/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4073106)

<sup>2</sup> NPAAC Strategic Plan 2007

<sup>3</sup> 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)<sup>4</sup> 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”*<sup>5</sup> 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 framework<sup>6</sup>.

The Institute of Medicine identified six core aims for health care services – that they be safe, effective, patient-centered, timely, efficient, and equitable<sup>7</sup> – and similar attributes feature as key elements in quality frameworks in Australia<sup>8</sup>. 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.<sup>9</sup> 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.

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

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

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

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

<sup>8</sup> 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](http://www.nhhrc.org.au/internet/nhhrc/publishing.nsf/Content/commission-1lp)

<sup>9</sup> 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 Australia<sup>10</sup>.

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 2005<sup>10</sup>.

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 treatments<sup>11</sup>. 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 refer<sup>12</sup>. 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.

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

<sup>11</sup> "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>

<sup>12</sup> 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 care<sup>13</sup>.

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 ordering<sup>13</sup>.

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.

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



## Appendix D

### The Role of Small-Medium Private Pathology Practices in Australia

Following 20 years of consolidation of pathology laboratories, approximately 75-77% of Medicare outlays for pathology are for services provided from the private sector by three large, publicly listed companies:

1. Sonic Healthcare;
2. Primary Health Care-Symbion Health; and
3. Healthscope-Gribbles.

Approximately 10% of Medicare outlays for pathology are for services provided by the government sector through state-owned pathology providers mainly attached to public hospitals. These pathology services are now commonly organised on an area, region or whole-state basis.

**The remaining 13-15% of Medicare outlays for pathology services are provided by:**

- A) The “Not-for-Profit” sector: pathology services are commonly established in hospitals associated with various religious orders. These pathology services often extend to providing pathology services in the community outside the hospital environment;
- B) Small to medium private pathology companies providing a wide range of pathology services across all pathology disciplines; and
- C) Small niche (“boutique”) private pathology companies providing pathology services in only one or two pathology disciplines such as histopathology, cytopathology, microbiology or IVF specialised testing. Some of these more specialised services may be involved in the development of new and emerging tests not funded under Medicare.

**Small pathology laboratories as described in categories A) to C) provide a number of benefits to patients and the community under the current Medicare arrangements, including providing alternative ownership models to the larger corporatised pathology structures in the private and government sectors.** These different models of ownership allow small laboratories to:

- a. Allow specialist pathologists to own and manage their own pathology service provided;
- b. Develop niche areas of specialist expertise, including in some fields of low volume testing;
- c. Allow some stand alone private hospitals, including in the “Not for Profit” sector, to provide internal pathology services; and
- d. Enhance competition. Competition has been an important element in maintaining affordability of testing for patients (as evidenced by pathology’s high rate of bulk billing), in maximising patient access to pathology services through the geographical spread of collection and testing within Australia, and in ensuring the currently high quality of pathology testing in Australia. Competition policy demands that a level playing field should exist for both incumbent and new players in the pathology market.

The Medicare funding reduction of pathology testing, in real terms, over the past 20 years, has resulted in a large reduction in the number of small to medium sized laboratories, reflecting their difficulty in achieving cost containment (see separate Australian Association of Pathology Practices (AAPP) papers). However, small laboratories will continue to be strong competitors in price, access and quality of service.

The AAPP continues to support the benefits delivered to the Australian community by our small and medium sized laboratories.