



FINAL REPORT

The economic value of pathology: achieving better health, and a better use of health resources



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Pathology Awareness Australia
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Summary

Pathology is at the heart of Australia's healthcare system.

It provides accurate and timely information that directly affects population health by providing clinicians with the insights to manage patients appropriately.

By identifying those at risk of disease, guiding treatment and monitoring progress, pathology provides the assurance that we are achieving our best possible health outcomes.

Pathology directly reduces the cost of healthcare. It provides the certainty needed to achieve minimum hospital length of stay, and avoid treatments and hospital admissions that are unnecessary or avoidable.

The benefits to individuals and society are clear. Quality of life is improved, people are more productive, and the economy and community are strengthened.

Pathology is the medical specialty concerned with the study of the nature and causes of diseases. It underpins every aspect of medicine, from diagnostic testing and monitoring of chronic diseases to cutting-edge genetic research and blood transfusion technologies. Pathology plays a vital role across all facets of medicine throughout our lives, from pre-conception to post mortem.

Pathology is used in every phase of health

Pathology is used to:

- **predict** susceptibility to disease
- **prevent disease** by identifying risk factors in patients that can be modified
- **diagnose** many diseases. For cancer, every case is diagnosed by pathology
- determine patient **prognosis**
- **show the presence or absence of infection**
- **monitor** disease, identifying whether treatments work or should be adjusted or avoided, and
- **personalise treatment** to get the best results.



General Practitioner (GP) referral for **pathology testing is an essential element of primary healthcare:**

- one in every two GP visits involve a pathology referral
- one in every three problems presented to a GP involve a pathology referral, most commonly for the management of diabetes, general health checks, hypertension, and lethargy, and
- sixty per cent of GP referrals for pathology relate to preventative health and chronic illness, which are essential to population health.

In hospitals, pathology is used to diagnose and treat patients with the most complex and life-threatening conditions such as cancer and cardiovascular disease, ensuring hospital length of stay is minimised and health outcomes are maximised.

Access to pathology services is widespread, with close to 40 per cent of collection centres located in regional, rural and remote areas, demonstrating the commitment to promoting access to pathology across Australia.

Services provided in the community are funded through Medicare, with pathology having the highest bulk billing rate of any medical service, at 87.8 per cent in 2014-15 and schedule fee observance at 93 per cent (99 per cent for out-of-hospital only). Over the last 15 years, the number of tests funded under Medicare has grown from 40 million in 2000 to almost 90 million in 2015. This has been achieved with relatively little growth in pathology funding. When this figure is combined with tests not funded by Medicare or performed on patients in public hospitals, **there are around 500 million laboratory based tests provided to Australians each year.**

The cost of most pathology tests is relatively small compared to many other healthcare services. One of the most widely used pathology tests is the full blood count, which provides information on all the cells in a person's blood, and is used extensively in decisions about medical care. In 2014-15 there were 11.4 million full blood count examinations recorded by the MBS, for a scheduled fee of \$14.45. The total cost of delivering 500 million pathology tests per year across the community and in hospitals is estimated to be just 3 per cent of total health spending, or 0.2 per cent of GDP.

The use of pathology services is higher for older age groups, with those aged 55 years and over accounting for over 50 per cent of Medicare funded services. Older Australians will increasingly account for more testing activity over time. Much of this activity is directed towards managing chronic disease including cancer, diabetes, and cardiovascular disease, which are part of the National Health Priority Areas for the Australian Government.

An estimated 35 000 people are employed in pathology in Australia. Pathology practices generate significant economic activity through their investments in plant and equipment and associated transactions with many businesses and organisations.

The economic benefits of pathology are considerable

As well as improving quality of life, pathology helps to improve the productivity of the economy, and the value of expenditure across the health system. Three case studies show how pathology helps to improve health outcomes and minimise health costs.

1 Minimising complications with diabetes

There are currently 1.5 million Australians living with diabetes, which is forecast to rise to 3.5 million by 2033. Already, the annual cost of diabetes is \$4–\$6 billion. Diabetes complications account for 14 per cent of potentially preventable hospitalisations for chronic conditions, one of the highest of any chronic disease condition.

However, average treatment costs can fall by more than half if complications can be avoided with the use of pathology. Diabetes accounts for over 10 per cent of the growth in Medicare funded pathology tests, and accounts for 6 per cent of all GP requested pathology as it is used to help people manage their condition and avoid the serious effects of poorly managed diabetes. For instance, monitoring diabetic patients via a pathology test that includes measurement of glycated haemoglobin (HbA1c) helps reduce the risk of complications associated with diabetes. Just a 1 per cent reduction in HbA1c has been shown to reduce the cumulative incidence over 5 years of:

- end stage kidney disease by 40 per cent
- amputation by 21 per cent
- advanced eye disease (proliferative retinopathy) by 43 per cent, and
- myocardial infarction by 16 per cent.

The economic gains from this are substantial. Diabetes prevention programs in Australia have been found to be cost-saving or extremely cost effective, delivering benefits of \$2600 to \$5300 per person for every year they are able to avoid complications or better manage the condition.

2 Improving the management of patients with a suspected heart attack

Patients presenting to the Emergency Department with a suspected heart attack are tested for their troponin levels in pathology laboratories. This helps doctors escalate the right patients for admission and enables patients without confirmed cardiac disease to be safely discharged, without a prolonged or unnecessary hospital stay. Troponin testing has been shown to enable around 40 per cent of cases to be discharged early, which can help to reduce ED costs by up to \$167 million annually, as well as save on the costs of hospital admissions for patients that can be safely managed in the community.

3 Making a difference to cancer care

Personalised medicine has revolutionised cancer care, and is only possible because of pathology. In the case of colorectal cancer, the second most commonly diagnosed cancer in Australia, pathology now tests the genetic characteristics of the cancer to determine whether treatments will work. KRAS and RAS mutation tests have been found to provide net cost savings to the Australian Government for anti-EGFR antibody treatments by ruling out treatment for those that won't respond well, thus reducing harm and improving outcomes for patients that will. This has underpinned dramatic improvements in survival and reductions in deaths from colorectal cancer over the past decade, with the 5-year survival rate for metastatic colorectal cancer having risen dramatically up to 67 per cent.

1 Pathology activity in Australia

Pathologists, medical scientists and the wider laboratory network team are an essential resource for doctors and medical specialists, providing the interpretation and oversight needed to help people achieve their best health outcome possible.

Pathology services are widespread, provided by public and private sector practices in both hospital and community settings all around Australia to ensure that location is not a barrier to access.

Close to 40 per cent of collection centres are located in regional, rural or remote areas, highlighting the importance of pathology to delivering regional, rural and remote healthcare.

Services provided in the community are funded through Medicare, with pathology having the highest bulk-billing rate of any medical service, at 87.8 per cent in 2014-15 and schedule fee observance at 93 per cent. Close to one in every two GP visits and one in every three health concerns presented to a GP, involve a pathology test or panel of tests. Every Australian receives an average of 7 Medicare funded pathology tests per year (excluding patient episode initiation), referred by GPs or other medical specialists to assess their health status and manage any health concerns.

Hospital inpatient pathology services are provided to diagnose and treat patients with the most complex and life-threatening conditions.

What is pathology?

Pathology is the medical specialty concerned with the study of the nature and causes of diseases. It underpins every aspect of medicine, from diagnostic testing and monitoring of chronic diseases to cutting-edge genetic research and blood transfusion technologies. Pathology plays a vital role across all facets of medicine throughout our lives, from pre-conception to post mortem.

Pathology is used to diagnose almost all diseases and is used to diagnose every case of cancer. It uses a range of samples (cells, organs, tissue, and body fluids) and methods to diagnose disease, and covers a number of scientific disciplines (box 1.1).

As medical specialists, pathologists are a valuable resource to GPs and other specialists, providing advice on appropriate tests to request, interpretation of results, best treatments to use, future testing, and advances in pathology testing technologies.

Often described as ‘the doctors’ doctor’, pathologists provide interpretation and oversight to inform clinical decisions and assist in the development of a patient’s treatment plan.

1.1 Disciplines of pathology

- **Anatomical Pathology**, including:
 - Histopathology; that is, diagnosing disease by analysing solid tissue samples
 - Cytopathology; that is, examining separated cells (rather than solid tissue) including fluids and tissue smears to diagnose disease and determine disease post-mortem.
- **Chemical Pathology**: examining chemical changes in blood and body fluids to detect disease and/or check the functional status of organs and tissue to detect conditions like diabetes, high cholesterol and nutritional disorders.
- **Forensic Pathology**: examining human tissue after death, focusing mainly on determining cause of death in legal investigations or in sudden or unexpected death.
- **Genetic Pathology**: diagnosing genetic conditions or determining predisposition to future disease using tissue, blood and body fluid samples, including:
 - Clinical cytogenetics; that is, microscopic analysis of chromosomal abnormalities (for example to detect Down Syndrome)
 - Molecular genetics; that is, using the tools of DNA technology to identify mutations (changes) in genes.
- **Haematology**: the study of blood and bone marrow to identify abnormalities, including to diagnose and treat blood cancers (for example leukaemia), bleeding disorders and management of blood transfusions.
- **Immunopathology**: involving the design, performance and supervision of tests of the immune system. For example, tests for 'allergy antibodies' to various substances or measurement of different classes of antibody proteins to determine the state of the immune system's defence mechanisms.
- **Microbiology**: diagnosing disease caused by infectious agents such as bacteria, viruses, fungi and parasites (for example, AIDS, Golden Staph, Legionnaires' disease, tuberculosis, malaria, and whooping cough).

Source: Pathology Australia, <http://www.pathologyaustralia.com.au/about-pathology/different-types-of-pathology>, <https://www.rcpa.edu.au/Prospective-Trainees/What-is-Pathology/#item1>

More than a test — the end to end process of pathology

Delivering pathology services involves a combination of activities requiring staff with varied qualifications and training, unique equipment, and specialist reporting systems.

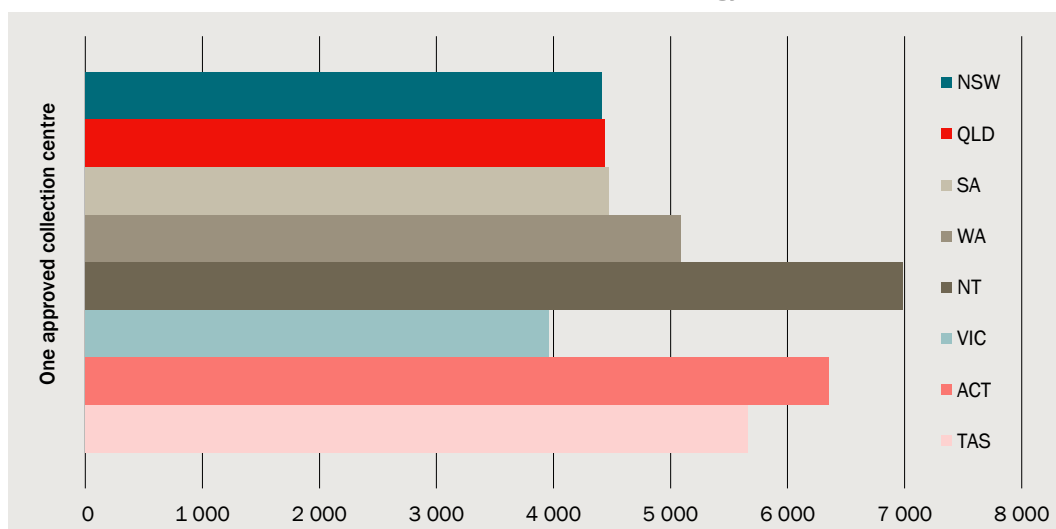
Pathologists are medical specialists with many years of post-graduate education and training. Practices are supported by teams of scientists, laboratory assistants, phlebotomists (pathology collectors), couriers, clerical staff, management and support services to ensure the correct specimens are collected, preserved, analysed and reported in a timely way.

The pathology process commences at the point of referral by a doctor or specialist for the appropriate test/panel of tests, sometimes with the support of a pathologist. There are

459 pathology services listed on the Medicare Benefits Schedule (MBS)¹ and most practices offer additional services that are not covered by Medicare.

Specimen collection is conducted within hospitals, at collection centres, or through home visits and aged care facilities. Many GPs also have collection centre rooms within their practice. Across Australia, there are currently 5344 community based collection centres. Around a third of centres are in regional, rural or remote areas², **demonstrating the commitment to promoting access to pathology in all areas of Australia** (chart 1.2).

1.2 Ratio of resident population to an approved pathology collection centre



Data source: ABS population data category 3101.0 Dec 2014; NATA APCC; The CIE..

For private (non-hospital based) pathology practices, laboratories are generally located away from the collection centre, requiring a network of couriers to deliver samples in a timely manner, using proper handling techniques. The private sector has over 1400 courier vehicles for this purpose.³

In the laboratory, a team of pathologists, scientists and laboratory technicians analyse and interpret results. Specialist instrumentation, reagents, and other testing equipment are used to assist and in disciplines like Anatomical Pathology, the pathologist is directly involved in the reporting of every specimen.⁴

¹ NATA accreditation is required to be eligible for MBS payments. Some practices provide both community and public pathology services.

² <http://www.health.gov.au/internet/publications/publishing.nsf/Content/qupp-benefits-and-risks-for-consumers-of-pathology-testing~qupp-where>.

³ Pathology Australia *Pathology in Australia* http://www.pathologyaustralia.com.au/wp-content/uploads/2015/09/141105_ref_Pathology-in-Australia.pdf Accessed 25 September 2015

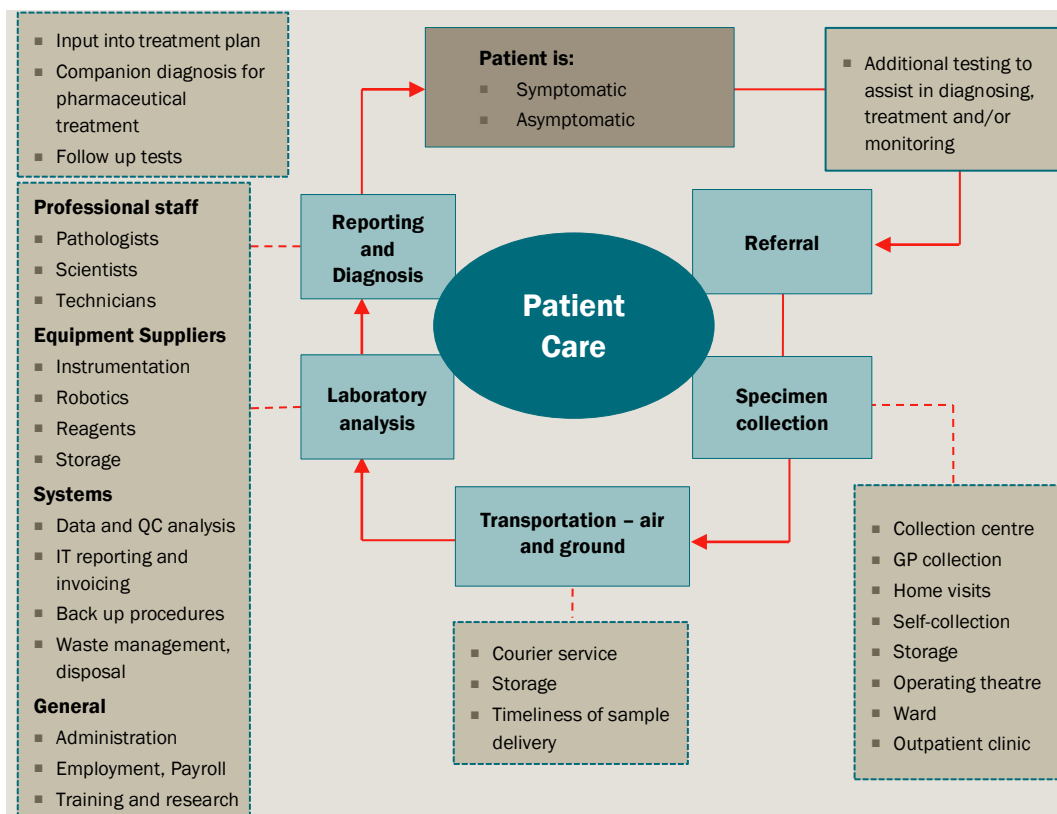
⁴ The Royal College of Pathologists of Australasia (2014) *The Pathology Request-Test-Report Cycle* <https://www.rcpa.edu.au/getattachment/cb14bc34-0a01-4c09-839c-614e098c84b6/Pathology-Request-Test-Report-Cycle-Guidelines.aspx> page 10

Pathologists may also initiate additional tests in consultation with the requesting physician in the interests of patient care.⁵

IT systems identify specimen information, results and provide invoicing capabilities that are interoperable with the MBS system. Across Australia there are 732 laboratories including 615 NATA accredited pathology laboratories.⁶ Accredited pathology laboratories provide services in both the public and private sectors and in either community or hospital settings. In order to be able to charge Medicare for services, laboratories must be NATA (National Association of Testing Authorities)/RCPA (Royal College of Pathologists of Australasia) accredited.

Pathology results are **reported** to the requesting doctor to assist in the final diagnoses and to contribute to the development of a patient's treatment plan. Reports typically contain commentary to help doctors interpret results, providing guidance and reassurance around treatment options and decisions. Beyond the report itself, there is ongoing interaction between pathologists and other medical specialists to assess a patient's responsiveness to treatment, or identify any related health issue.

1.3 The process of pathology



Source: The CIE, NATA, Pathology Australia.

⁵ The Royal College of Pathologists of Australasia (2014) *The Pathology Request-Test-Report Cycle* <https://www.rcpa.edu.au/getattachment/cb14bc34-0a01-4c09-839c-614e098c84b6/Pathology-Request-Test-Report-Cycle-Guidelines.aspx> page 10

⁶ NATA (2015) *Facilities and Labs* <http://www.nata.com.au/nata/orgs-and-facilities/export-lab-detail> Accessed 25 September 2015.

Over the last 15 years, the number of pathology tests reported through the MBS (excluding PEI⁷ and specimen referrals) has more than doubled – from approximately 40 million in 1999–2000 to 89.4 million 2014–15.⁸ This increase is linked to the introduction of enhanced diagnostic technologies that offer superior patient insights and create new clinical demands as pathology becomes increasingly integrated into the Australian health system.⁹ The ageing population and increasing focus on prevention have also spurred strong growth, with men over 75 in particular, now accessing more testing for chronic disease management and preventative health strategies, accounting for much of the recent growth.¹⁰ It is estimated that 32 per cent of the increase in pathology requests by medical practitioners is due to preventative health treatments.¹¹

Annual growth in pathology tests of 5.4 per cent over 15 years has been achieved with only 5.8 per cent annual growth in outlays, with the pathology industry absorbing the impact of inflation and other cost increases. Australia has benefited from two decades of industry amalgamation, vertical integration, and investment in automation, which have contained costs and substantially improved the value for money of pathology in Australia.

Close to one in every two GP visits and one in every three issues, or problems, presented to a GP involve a pathology test or panel of tests.

In 2014–15, **47 out of every 100** ‘average’ GP encounters (interaction between the patient and the GP) involved a pathology referral, up from 36.7 in every 100 encounters in 2004–05. The number of health issues managed by GPs that involve a pathology test/panel of tests is 30 per 100 problems managed, up from 25.2 in 2004–05.¹²

The total level of pathology testing in Australia is difficult to measure due to the complex funding arrangements across the community and hospital sectors. The most comprehensive data source available (Medicare) understates the amount of pathology services provided to Australians every year because not all activity is funded in this way.

In 2014–15, the Commonwealth Government provided \$2.55 billion in MBS funding for 128.8 million pathology services (89.4 million actual tests plus the patient episode initiation and bulk billing incentive). The bulk-billing rate for pathology remains

⁷ The Patient Episode Initiation (PEI) fee is designed to compensate for collection overheads.

⁸ This includes all services in and out of hospital across categories P1-P11 of the Medicare Benefits Schedule. 88.72 per cent of services were conducted out of hospital. Department of Human Services (2015) Medicare Australia Statistics, Group Report http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp Accessed 12 September 2015.

⁹ Growth in total MBS funded services (including PEI and specimen referred) rose from 58.7 million in 2004-05 to 128.8 million in 2014-15.

¹⁰ Parliamentary Budget Office 2015, Medicare Benefits Schedule: Spending trends and projections, Report no. 04/2015, Parliament of Australia, Canberra.

¹¹ Australian Association of Pathology Practices 2008, An analysis of pathology test use in Australia, September 2008, p. 13.

¹² The University of Sydney (2015) *A decade of General Practice Activity 2005-06 to 2014-15*, General Practice Series number 38, and *A decade of General Practice Activity 2004-05 to 2013-14*, General Practice Series number 37.

exceptionally high at 87.8 per cent, and the schedule fee observance is 93 per cent (99 per cent for out-of-hospital tests only).¹³

This does not include public sector testing on public patients in hospitals, and tests that are not reimbursed under Medicare due to coning rules.¹⁴ Industry estimates that up to 500 million individual tests per annum are performed annually across all of pathology in Australia.

The most common test requests are chemistry and haematology. These provide essential information about people's vital organs, identifying signs of ill health, and showing how patients are responding to treatments.

Chemistry and haematology tests account for 53 per cent of MBS claimed tests. (excluding patient episode initiation and specimen referrals). These include tests for haemoglobin, lipids, biochemical profiles, and thyroid function.¹⁵ Common health problems like diabetes, high cholesterol, hormone abnormalities and vitamin deficiencies are diagnosed with the aid of these commonly requested chemistry and haematology profiles. Importantly, they can confirm that certain parts of the body are functioning correctly, allowing GPs and medical specialists to move on to explore other potential causes of symptoms or ill-health.

One of the most widely used pathology profiles is the full blood examination (FBE), which provides information on all the cells in a person's blood. In 2014–15 there were 11.4 million full blood count examinations recorded by the MBS,¹⁶ for a MBS scheduled fee of \$14.45. The actual number is estimated by industry to be 28 million, which takes into account the large number of full blood examinations excluded due to coning or because they are performed on public patients in public hospitals.¹⁷

¹³ Department of Health (2015) *Annual Medicare Statistics – Financial year 200708 to 2014-15*
<http://www.health.gov.au/internet/main/publishing.nsf/Content/Annual-Medicare-Statistics>

¹⁴ Coning places an upper limit on the number of claimable services under the MBS. Where GPs order four or more tests, costs are generally absorbed by the pathology practice. The AAPP estimates \$200 million in test costs is absorbed by practices each year (see Pathology Australia *Pathology in Australia*) and industry revenue is reduced by 19 per cent as up to half of all pathology tests in the community are provided as a free service (no cost to the patient nor rebated through the MBS) (see AAPP, Submission to Strategic Review of Future Arrangements for Pathology and Diagnostic Imaging Services, May 2010).

¹⁵ Department of Human Services (2015) Medicare Australia Statistics, Group Report
http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp Accessed 12 September 2015

¹⁶ Includes erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument generated differential count - not being a service where haemoglobin only is requested - one or more instrument generated set of results from a single sample; and (if performed) a morphological assessment of a blood film or any service in MBS item 65060 or 65072.

¹⁷ Consultations with Sonic suggest over half of its item 65060 full blood count tests are not reimbursed due to coning, with these tests paid for by the practice from other source revenue.

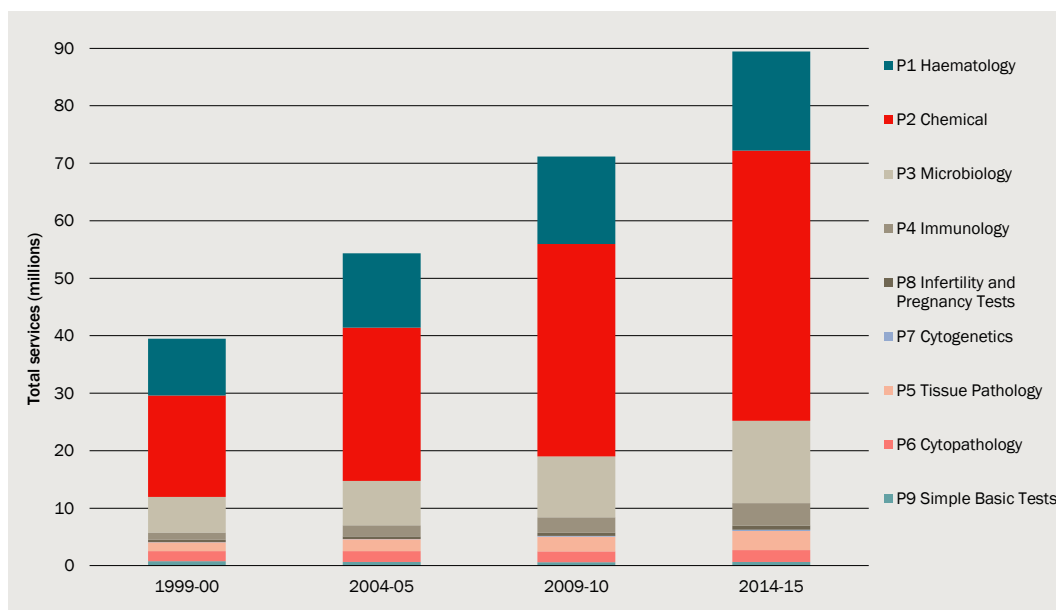
Even using this ‘lower bound’ activity measure, in 2014–15, this test alone accounted for 8.8 per cent of total pathology tests funded under the MBS.¹⁸ Information from a full blood count is used extensively in decisions about medical care:

- to identify risk factors in patients that require early intervention to **prevent** disease
- to **diagnose** disease, by providing information on the size and volume of cells and demonstrating the presence or absence of infection — leukaemia for instance *cannot* be diagnosed without it
- to **monitor** disease by identifying if treatment has worked or requires adjustment, and
- to tailor **treatment** to get best results, helping to pinpoint the molecular profile of a disease that can in turn match it with a health intervention that is likely to be effective.

The fastest area of growth in tests funded under the MBS has been cytogenetics, increasing at an average annual rate of 14.3 per cent since 2000, although still only accounting for 0.3 per cent of total MBS tests provided in 2014–15.¹⁹

MBS funded pathology tests *per patient* have also increased — from 5.8 per patient in 2004-05 to 7 per patient in 2014–15.²⁰ The use of pathology services is higher for older age groups. Those aged 55 years+ account for 53 per cent of MBS services in 2014–15, and older Australians account for more testing activity over time.

1.4 Chemistry and haematology profiles are the most common MBS funded tests



Note: Excludes Patient Episode Initiation and Specimen Referred.

Data source: Department of Human Services (2015) Medicare Australia Statistics, Group Report http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp Accessed 12 September 2015

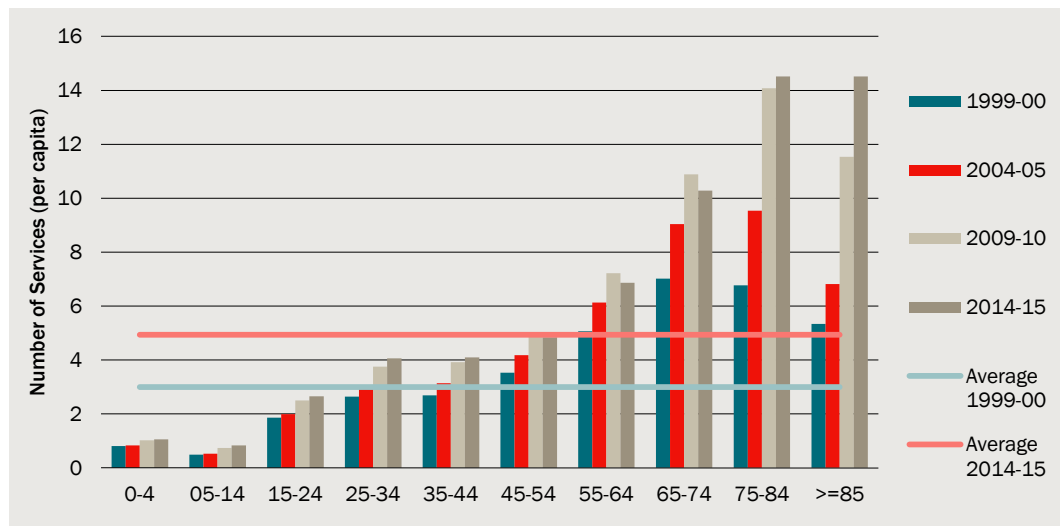
¹⁸ Department of Human Services (2015) Medicare Australia Statistics, Group Report http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp

¹⁹ Department of Human Services (2015) Medicare Australia Statistics, Group Report http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp

²⁰ Excludes Patient Episode Initiation. Department of Health (2015) *Annual Medicare Statistics* <http://www.health.gov.au/internet/main/publishing.nsf/Content/Annual-Medicare-Statistics>

In 2000, those aged 65-74 had the highest number of services per capita. In 2005, those aged 75-84 had the most per capita, and since 2005, the highest numbers per capita have been for those aged 85+ (chart 1.5). Most services for those 85 and over are for haematology and chemical tests, which are typically the least expensive tests.

1.5 Per capita service consumption by age, 1999-00 to 2014-15



Data source: Department of Human Services (2015) Medicare Australia Statistics, Group Report
http://medicarestatistics.humanservices.gov.au/statistics/mbs_group.jsp Accessed 12 September 2015

GP referral for pathology testing is an essential element of primary care. The most common number of tests ordered by a GP is one, although the instances of orders of five tests has increased from 11.5 per cent in 2000–02 to 19 per cent in 2006–08 (table 1.6).²¹ Of the tests requested in 2013–14, almost 40 per cent were for 10 problems. The most common was diabetes, followed by general health checks, hypertension and weakness/tiredness.²² Research conducted into GP test ordering found that GPs demonstrate appropriate use of requesting, with 60 per cent of requests related to preventative health and chronic illness.²³

1.6 Percentage of tested encounters

	1 test	2 tests	3 tests	4 tests	5 tests
2000-02	48.7	17.0	13.5	9.3	11.5
2006-08	43.1	14.5	13.0	10.5	19.0
2000-08	45.6	15.9	13.5	10.0	15.1

Note: 95 per cent confidence level

Source: Bayram, C. (2013) *Evaluation of pathology ordering by general practitioners in Australia*

²¹ This could be one groups of tests, funded under one MBS item.

²² The University of Sydney (2014) *General Practice Activity in Australia 2013-14* General practice series number 36, page xvi

²³ Britt, H. (2008) *An Analysis of Pathology Test Use in Australia*, p. 4, Bayram, C. (2013) *Evaluation of pathology ordering by general practitioners in Australia*, p. 50.

Public and private providers of pathology services

Pathology services are provided by private and public sector laboratories.

Private practices principally service the community whereas public sector practices generally service public hospitals, although there is some sharing with public laboratories providing community services and private practices providing hospital based and specialist work. Following decades of industry restructuring and consolidation to achieve economies of scale, the largest four private pathology practices account for over 85 per cent of MBS revenue.²⁴ Capital costs, including equipment and consumables accounts for up to 30 per cent of total private pathology expenditure.²⁵

1.7 Industry data for the largest private pathology practices, 2015

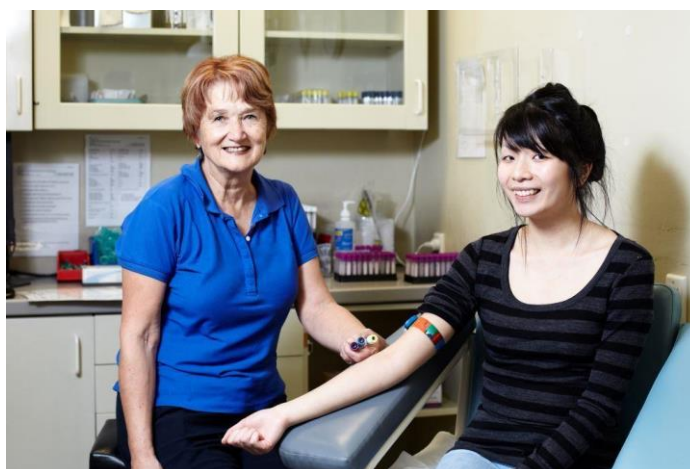
	Sonic Healthcare	Primary Health Care	Crescent Capital Partners/Healthscope	St John of God
Market share	42.5%	35.6%	10.0%	4.7%
Laboratories	59	98	31	18
Collection Centres	1404	1992	550	153
Revenue from pathology	\$1 175.0m	\$985.0m	\$277.0m	\$130.0m

Note: Revenue figures relate to the Australian private pathology component only. Estimates for 2015-16.

Source: IBISWorld (2015), Industry Report Q8521: Pathology Services in Australia, and CIE calculations based on NATA list of approved pathology collection centres and company websites.

Public pathology provides 24/7 services in teaching hospitals and major centres as well as services in regional and remote settings. They contribute significant expertise in diagnosing patients with the most complex and life-threatening conditions, such as those encountered in emergency departments, intensive care and oncology units. They provide direct care to patients on wards or in outpatient clinics. Pathologists and medical scientists are also involved in the development of health policies, and undertake management responsibilities in the health system.

Public pathology services are funded through the National Healthcare Agreements between the Australian, State and Territory Governments, which provide public hospital services (including pathology) to admitted and non-admitted public patients. To a lesser extent public pathology is funded through the MBS when



²⁴ Richardson, A., IBISWorld (2014) *Pathology Services in Australia*, page 23.

²⁵ PwC (2010) prepared for DoHA *Capital Expenditure in the Pathology Sector*, page 7

testing services are provided to GPs and specialists in private practice. In some jurisdictions, public pathology is a significant provider of testing services to patients outside of public hospitals.²⁶

In some public hospitals, public pathology services are the sole provider of tests in a defined health district.²⁷

Public pathology is estimated to employ 40 per cent of the Australian pathology workforce,²⁸ highlighting the importance of public pathology to the overall pathology sector. Pathology remains a skills based discipline and labour costs comprise up to 70 per cent of practice expenditure.

Pathology is a significant skills based employment industry. Current industry estimates are that **approximately 35 000 people are employed in pathology in Australia**, including pathologists, scientists, phlebotomists, couriers, management and clerical staff. This is based on publicly available information on selected private practices and websites for public pathology, extrapolated to the whole sector based on testing volume for various providers.

For instance, Sonic Healthcare employs 10 000 people in Australia, Primary Healthcare employs 7831 staff in pathology, and St John of God Pathology employs 1278 staff in WA.²⁹ In the public sector, NSW Health Pathology employs 4653 people in its pathology workforce, and Pathology Queensland employs 1500 staff.³⁰

This is midway between estimates in previous published reports that have tried to quantify industry size.

One 2011 study estimated that around 24 000 people were employed in the pathology sector, based on a survey of 20 per cent of pathology practices, and omitting one large practice with over 1500 employees that did not participate (table 1.8). Another 2005 report on the pathology workforce suggested there were 30 000–50 000 people employed in pathology in Australia, which was equivalent to 5 per cent of the health workforce.³¹

²⁶ http://www.ncopp.org.au/site/Funding_.php

²⁷ Paxton Partners (2011), *MBS Use by Public Hospitals*, June 2011, Canberra.

²⁸ Legg, M., 2008, *The Australian Pathology Workforce Crisis*, prepared for the Department of Health and Ageing, Medical Benefits Division.

²⁹ Based on latest available published annual reports for each pathology practice. Excludes Healthscope, which is one of the largest providers but does not itemise employment in pathology in Australia only.

³⁰ NSW Health Pathology Workforce Strategy, <http://www.pathology.health.nsw.gov.au/about-us/plans-priorities>; <http://www.breastscreen.qld.gov.au/qhcss/qhps/about.asp>.

³¹ Legg, M., 2008, *The Australian Pathology Workforce Crisis*, prepared for the Department of Health and Ageing, Medical Benefits Division.

1.8 Employment in pathology

Size	Services	Employees	Approved Pathology Authorities		Estimated employees
	Per annum	Range	Public Practices	Private Practices	Total
Very large	>5 000 000	>1 500	0	3	6 434
Large	500 000 – 4 999 999	501 – 1 500	8	4	11 360
Medium	100 000 – 499 999	81 – 500	11	12	5 253
Small	20 000 – 99 999	15 – 80	4	12	628
Very Small	<20 000	<15	5	64	483
Total					24 157

Source: URBIS for the Department of Health and Ageing (2011) *Survey of the Pathology Workforce*.
<https://www.aims.org.au/documents/item/197> p. 11.

Innovation in pathology

The Australian pathology sector is highly innovative and dynamic, being early adopters of new technologies to improve tests and services.

Pathology laboratories commit significant resources to research and development.

Strong public–private research and development collaborations in pathology have led to significant international advances in medicine, demonstrating the sectors commitment to innovative research and implementation.

For instance, Australian pathologists won the Nobel Prize for proving that the bacterium *Helicobacter pylori* is the cause of most peptic ulcers, a discovery which revolutionised the diagnosis and treatment of peptic ulcer disease and reduced the prevalence of gastric cancer in Australia and around the world.

Test procedures are also continually being improved and adopted throughout the sector, and these innovations are often adopted in other parts of the world.

Diagnostic suppliers supporting the innovative R&D of pathology

Diagnostic suppliers market and sell medical devices that are used to perform pathology tests. These are sometimes referred to as In Vitro Devices (IVD's).

IVD companies are an integral component of the pathology value chain in Australia.

IVDs include the components that make up a testing device; e.g. reagents, software, instruments, quality control material, calibrators and consumables.³² Diagnostic devices also include items that can be purchased 'over the counter' by consumers, such as pregnancy test kits and blood glucose meters for diabetes monitoring.

³² Therapeutic Goods Administration *Overview of the regulatory framework for in-vitro diagnostic medical devices* <https://www.tga.gov.au/overview-regulatory-framework-vitro-diagnostic-medical-devices>

Advances in IVD technologies are fundamental to the way that pathology is used in modern day healthcare. There is an increasing range of pharmacogenomic tests (genetic testing to assist in tailoring medication dosing to an individual) and point of care testing (PoCT) products for near patient testing, including tests for carbohydrate metabolism, lipids, HbA1c, renal function, liver function, and haematology/coagulation.³³

The IVD market is a global growth industry. The Australian IVD industry supplies products valued at over \$1.2 billion annually and employs over 3 000 staff.³⁴ By 2018, the IVD industry is expected to be the world's largest medical technology segment.³⁵



Australia's high performing health system

With its current program of health spending, compared to spending in other developed countries, Australia has one of the highest performing health systems in the world.

Life expectancy is high (82.1 years compared to an OECD average of 80.2 years), and health expenditure as a proportion of GDP is relatively low (9.1 per cent compared to the OECD average of 9.3 per cent).³⁶

Like other critical components of the health system, pathology expenditure in Australia is essential to achieve both of these quality indicators of a first class health system.

³³ Shephard, M (2010) *Point of care testing comes of age in Australia* Australian Prescriber. Volume 33, Number 1, February 2010, page 8

³⁴ IVD Australia 2016, unpublished.

³⁵ Medical Technology Association of Australia (2014) *Medical Technology in Australia: Key facts and figures 2014* http://www.mtaa.org.au/docs/key-documents/facts-figures_final-website-version.pdf?sfvrsn=2 page 20

³⁶ OECD Health Statistics 2014, 'How Does Australia Compare,' <http://www.oecd.org/els/health-systems/Briefing-Note-AUSTRALIA-2014.pdf>.

2 *The impact pathway of pathology on health outcomes*

Pathology generates a range of direct and indirect benefits to patients, carers, the health system, and the broader community. By providing unique information about the health status of individuals, it influences decisions about healthcare that lead to valuable health, safety, economic, and societal outcomes. Pathology's value continues to grow as the science of pathology evolves and the sector becomes even more efficient, further enhancing its productivity potential for the Australian economy.

The diffusion of pathology throughout the economy

The economic value of pathology extends beyond the laboratories and collection centres of a pathology practice. Pathology also affects the economy by improving the productivity of the health system and supporting a healthy workforce and community. All these elements comprise the real 'impact pathway' of pathology, where vital medical information and the stewardship provided by pathology leads to change in choices and behaviours that result in improved health, economic, and societal outcomes. The ways in which pathology impacts on the economy and society are illustrated in chart 2.1.

Patient health: disease prevention and better treatment and wellness

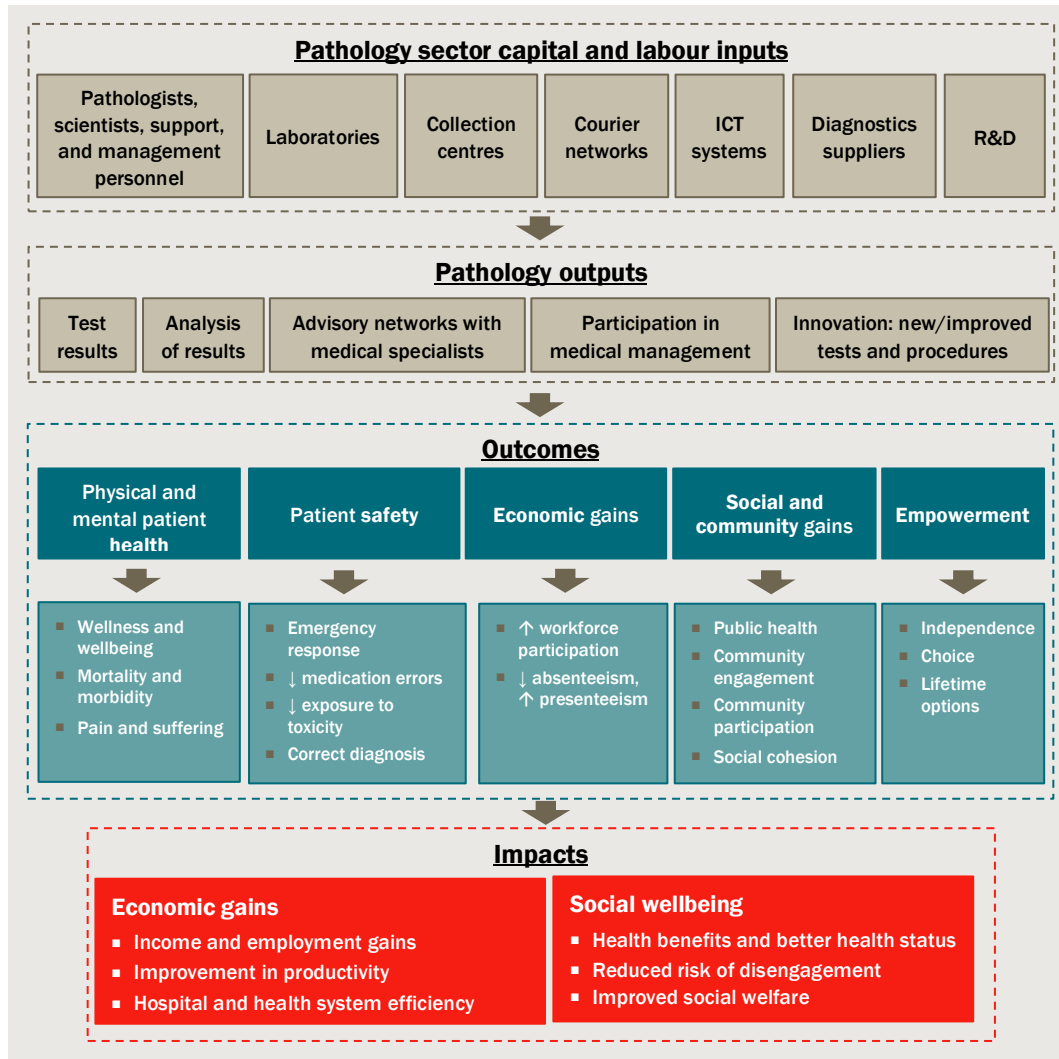
Because of pathology, Australians are better able to live healthier lives.

- Evidence shows that **early detection** made possible through pathology means earlier stage diagnosis of disease, where the odds of successful treatment and recovery are at their best. For instance, 40 per cent of colorectal cancer diagnosis via screening programs are Stage 1 cancers, and only 3 per cent are metastatic, compared to just 14 per cent of Stage 1 cases diagnosed through symptomatic presentations and a much higher 15 per cent symptomatic diagnoses that are Stage IV cancers.³⁷
- Through confirmation or exclusion of a disease or condition, pathology, enables patients to receive appropriate treatment. For instance, access to subsidised cancer medicines such as Herceptin[®] for breast cancer patients is contingent on confirmed pathology diagnostics through HER2 testing to ensure only patients who are likely to respond are treated and to avoid toxic side effects in those who won't. More recently the Australian Government extended MBS listing of in situ hybridisation (ISH) testing

³⁷ Ananda, McLaughlin, Chen, Hayes, Hunter, Skinner, Steel, Jones, Hastie, Rieger, Shedd, Compston, and Gibbs (2009), Initial impact of Australia's National Bowel Cancer Screening Program, *Med J Aust* 2009; 191 (7): 378-381.

of tumour tissue from patients with breast cancer to include its use to support the extended PBS listing of trastuzumab in the neoadjuvant setting.³⁸

2.1 Impact pathway of pathology on outcomes



Data source: The CIE.

- Ongoing testing helps to ensure the **continuity of medical management**, particularly for those with chronic disease requiring frequent updates to health status and a responsive, dynamic approach to medical intervention.
- By providing accurate information that is specific to each patient, pathology is often the best evidence based guide to **the best treatment plan**. When treatment is most appropriate, and diseases avoided, delayed, or made less severe, quality of life is improved. For instance, disability weights (measuring the loss of quality of life) for diabetes patients worsen if they go on to develop complications associated with cardiovascular disease, a diabetic foot, neuropathy, nephropathy, retinopathy, or

³⁸ <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1230-public>.

amputation,³⁹ all of which are better avoided or managed with the assistance of pathology.

Through ongoing investments in research and development, pathology becomes more sophisticated, accurate, and timely and its impact on healthcare is enhanced and expanded.

Economic value: channelling health resources to best effect

When health outcomes improve, value accrues to:

- individuals, in terms of the **duration** and **quality of life**. Avoiding death due to disease is valuable to individuals and the economy. A person's life not shortened by avoidable death is worth between \$1.26 million and \$1.4 million, including the loss of workplace labour, loss of home and community labour, and loss of quality of life⁴⁰
- the health system, through **reducing the burden of disease** and ensuring **value for money in health spending**, and
- the wider economy, through **workforce participation and productivity effects**, improving the quality of the labour force:
 - people with three or more chronic diseases are half as likely to be in the paid workforce compared to people that have no chronic diseases (based on age standardised data and adjusted for increasing rates of chronic disease as people get older). This creates a loss to the labour force because people are not working, or are working less because of having to care for someone with a chronic disease. The **productivity losses** have been estimated at 10 per cent, compared to labour participation not being reduced by chronic disease,⁴¹ and
 - being ill at work or having a medical condition that affects a persons' ability to work well also has significant negative productivity effects. 'Presenteeism' (the act of attending work while sick) costs the Australian economy approximately \$34.1 billion per annum, and is equivalent to a productivity loss of 2.6 per cent and a gross domestic product loss of 2.7 per cent.⁴²

Spending on pathology also makes health spending more efficient. Australia now spends \$155 billion on healthcare, or 9.8 per cent of GDP. On average, Australia spends \$6639 per person annually on managing peoples' health.⁴³

Australian Government health expenditure alone is forecast to rise from 4.2 per cent of GDP in 2014-15 to 5.7 per cent of GDP by 2054-55 (\$260 billion in today's dollar terms).

³⁹ http://www.who.int/healthinfo/global_burden_disease/GBD2004_DisabilityWeights.pdf.

⁴⁰ http://www.applieconomics.com.au/pubs/papers/pa03_health.htm

⁴¹ Business Council of Australia 2011, *Selected facts and statistics on Australia's healthcare sector*.

⁴² KPMG 2011, *Sick at work: the cost of presenteeism to your business and the Australian economy*, Medibank Research Series 2011.

⁴³ AIHW 2015, *Health Expenditure Australia 2013-14*, Cat. No. HWE 63, AIHW Canberra. Includes expenditure by all levels of Government.

By 2027–28, Medicare spending is forecast to rise from \$855 to \$1071 per person annually in today's dollar terms (an increase of over 25 per cent in real dollar terms), pharmaceutical spending is forecast to rise from \$420 to \$474 per person in 2027-28 in today's dollar terms, and public hospital spending is expected to rise from \$647 to \$680 per person by 2017-18 in real terms and then remain constant.⁴⁴

Spending on pathology through the MBS alone is \$2.5 billion (1.6 per cent of health spending).⁴⁵ Combined with estimated pathology spending in public hospitals it is estimated that total spending on pathology in Australia is 3 per cent of health spending, or 0.2 per cent of GDP. This equates to less than \$200 per person per annum.

This is a small investment relative to the benefits of pathology in ensuring patient health is maximised, and health spending is targeted to where it matters most.

⁴⁴ Commonwealth Treasury Projections, Intergenerational Report 2015.

http://www.treasury.gov.au/~media/Treasury/Publications%20and%20Media/Publications/2015/2015%20Intergenerational%20Report/Downloads/PDF/05_Chapter_2.ashx.

⁴⁵ AIHW 2015, Health Expenditure Australia 2013-14, Cat. No. HWE 63, AIHW Canberra, Department of Health 2015, MBS Review Taskforce Consultation Paper.

3 *The economics of how pathology works*

Three case studies — diabetes management, emergency medicine relating to heart attacks, and cancer treatment — show the various ways in which pathology impacts on health outcomes and health costs, providing economic value to individuals and the broader community. Across these examples, pathology generates the data, and provides the clinical knowledge through consultation, interpretation, decision support, and improvements in quality management, to support better health outcomes.

Minimising complications with diabetes

Health costs are reducible if disease and associated complications can be avoided, delayed, or their effects minimised. The cost of diabetes is \$4-\$6 billion annually but average treatment costs can fall by half or more if complications are avoided, and with the use of pathology, they can be. Diabetes complications accounted for 14 per cent of potentially preventable hospitalisations for chronic conditions in 2013-14, one of the highest of any chronic disease condition. Reducing HbA1c levels has a direct impact on risks of complications associated with diabetes, demonstrating the tangible impact of pathology test knowledge on managing care.

Better managing patients with acute chest pain in Emergency Departments

Pathology is playing a vital role in distinguishing between more serious and benign chest pain presentations in EDs, enabling more urgent cases to get the attention they require and allowing other patients to be safely discharged and given outpatient or accelerated in-patient follow up care. Based on current ED presentations relating to chest pain, pathology directly manages down costs of \$166.5 million a year being incurred in EDs for patients that need not stay within ED or be admitted.

Improving cancer care

The Australian Government spends around \$611 million on cancer medicines annually, which is money best spent on patients for whom treatments should work. It is the pathologist who diagnoses cancer, identifies the cancer type, confirms whether a particular treatment will work for a particular patient, and monitors the response to treatment with hopefully a positive outcome and a return to good health. In the case of colorectal cancer (CRC), which is the second most common cause of cancer-related mortality in Australia, pathology continues to drive better treatment choice, better clinical knowledge, and better chances of survival for patients. As pathology knowledge and data accumulates and is integrated into all stages of patient diagnosis and care, the five-year survival rate for Australians with CRC has increased to 67 per cent in 2007-2011 up from 47 per cent in 1982-86.

Improving the prospects for diabetes prevention and management

There are currently 1.7 million Australians living with diabetes, which is forecast to rise to 3.5 million by 2033. Two hundred and seventy-five (275) Australians get diagnosed with Type 2 diabetes every day, and by 2023, Type 2 diabetes is expected to be the leading cause of disease burden for men, and the second leading cause of disease burden for women.⁴⁶

Adults with diabetes are at risk of microvascular disease (retinopathy, neuropathy, and nephropathy), macrovascular disease and cardiovascular disease. Sixty-eight per cent of adults with diabetes will die of heart disease or stroke, and the risk for stroke is 2 to 4 times higher. Sixty-seven per cent have high blood pressure.⁴⁷

Managing diabetes well is essential for good health and reducing the costs of diabetes to the health system. Diabetes accounts for 10.5 per cent of the growth in pathology tests associated with problems managed in general practice and accounts for 6 per cent of all GP pathology.⁴⁸

Type 2 diabetes is estimated to cost Australia \$6 billion annually in healthcare costs, carer costs, and Commonwealth Government subsidies, with Type 1 diabetes costing another \$570 million annually.⁴⁹ Different studies that have estimated costs per person consistently show that costs increase dramatically for people with complications. A 2012 study funded by Diabetes Australia estimated that average comparative treatment costs are \$9 645 and \$4 025 comparing those with and without micro and macrovascular complications for type 2 diabetes, and \$16 698 and \$3 468 for type 1 diabetes for those with and without micro and macrovascular complications (table 3.1).

3.1 Average annual healthcare cost of diabetes per person

	Type 1 diabetes	Type 2 diabetes
	\$	\$
No complications of diabetes	3 468	4 025
Microvascular complications only	8 122	7 025
Macrovascular complications only	12 105	9 055
Micro and macrovascular complications	16 698	9 645

Source: Colagiuri, S., Colagiuri, R., Conway, B., Grainger, D., 2003, DiabCost Australia: assessing the burden of Type 2 diabetes in Australia, Canberra, Diabetes Australia, and Colagiuri, S., Brnabic, A., Gomez, M., Fitzgerald, B., Buckley, A., Colagiuri R. 2009, DiabCost Australia: assessing the burden of Type 1 diabetes in Australia, Canberra, Diabetes Australia.

⁴⁶ Diabetes Australia, National Election Agenda 2013-15, <http://www.flinders.edu.au/medicine/fms/sites/helpp/documents/National%20Diabetes%20Election%20Agenda%202013-2015.pdf>.

⁴⁷ National Diabetes Fact Sheet, Centres for Disease Control and Prevention (CDC), 2011.

⁴⁸ Sikaris, K. 2014, Impact of the diabetes epidemic and changing guidelines on laboratory workload, presented to the National Pathology Forum 2014.

⁴⁹ Baker IDI Heart and Diabetes Institute (2012), Diabetes, the silent pandemic and its impact on Australia, Melbourne, see <http://www.diabetesaustralia.com.au/Documents/DA/What's%20New/12.03.14%20Diabete%20management%20booklet%20FINAL.pdf>.

More recently, estimates published by the Department of Health in 2014 dollars suggest the annual direct healthcare costs for a person with diabetes ranges between \$3 800 and \$6 100 in 2014 dollars (without complications) which, given current prevalence, equates to \$4-\$6 billion per year.⁵⁰

Consistent evidence from the literature is that the potential gains of improving information about diabetes risks, and adopting a treatment program delivers large economic gains.

Managing complication risks and reducing health costs

Pathology plays a vital role in helping people with diabetes manage their condition and avoid the more serious presentations associated with poorly managed diabetes, through the following tests:

- glucose testing is used to help monitor Type 1 diabetes, Type 2 diabetes, and gestational diabetes
- fasting plasma glucose testing provides immediate information on glycaemic status and is used to diagnose possible diabetes and prediabetes
- oral glucose tolerance testing measures how well the body is able to break down glucose, or sugar, and is also used to diagnose the presence of gestational diabetes and Type 2 diabetes
- Haemoglobin A1c (HbA1c) testing is done to measure the percentage of glucose that has bound to haemoglobin over time. High levels are diagnostic for diabetes and are used to screen for and predict the risk of developing complications, and
- genetic testing is used to check for hereditary hemochromatosis, a disorder that causes the body to absorb too much iron, leading to an accumulation of iron in the blood, liver, heart, pancreas, joints, skin, and other organs, that can be associated with the onset of diabetes.

Achieving better health outcomes and promoting health system savings

Information from pathology can reap large financial savings by improving diabetes management. Diabetes complications accounted for 14 per cent of **potentially preventable hospitalisations** for chronic conditions in 2013-14, one of the highest of any chronic disease condition.⁵¹ Testing for diabetes and monitoring diabetes markers:

- enables diagnosis prior to symptom development, so as to enable control of blood glucose levels to prevent the occurrence of complications
- identifies pre-diabetic patients requiring re-testing for diabetes

⁵⁰ Commonwealth Government of Health (2014), Evaluation Report of the Diabetes Care Project, Canberra, p. 7.

⁵¹ AIHW 2015, Admitted Patient Care 2013–14 Australian Hospital Statistics, AIHW Canberra, p. 93.

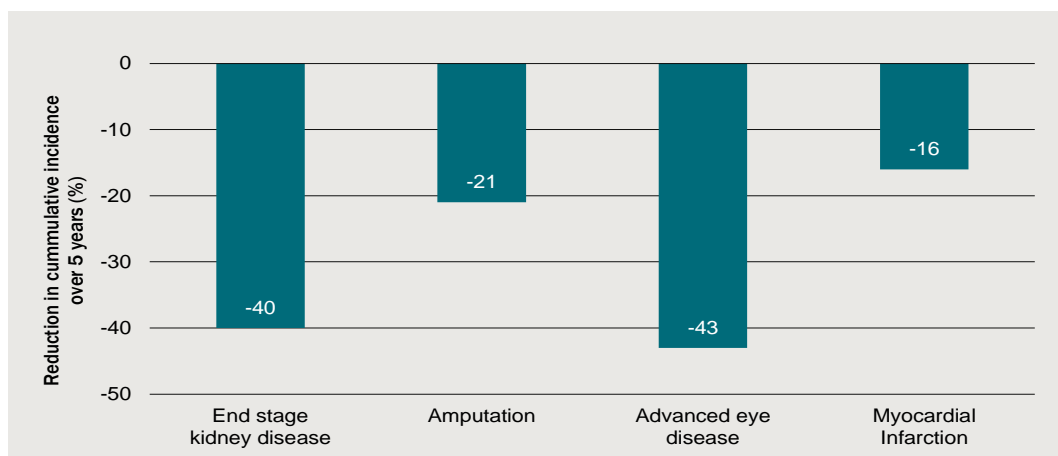
- confirms whether interventions work well by monitoring glucose levels before, during and after various interventions e.g. surgical, pharmacological, psychological, physiological and dietary
- identifies disease risk and triggers for risk events such as heart attacks and signs of premature mortality, and identifies the relative change in risk events due to different types of interventions, to help delay onset or reduce the severity of the disease.

For instance, economic analysis of HbA1c testing found that the incremental cost effectiveness ratio of testing lies between \$6 133 and \$16 762 per quality adjusted life year.⁵² By monitoring, responding to information, and then reducing HbA1c levels, the risk of complications associated with diabetes can be reduced. Just a one per cent sustained reduction in HbA1c has been shown to **reduce the cumulative incidence** over 5 years of:

- end stage kidney disease by 40 per cent
- amputation by 21 per cent
- advanced eye disease (proliferative retinopathy) by 43 per cent, and
- myocardial infarction by 16 per cent (chart 4.3).

When pathology is used to prevent diabetes, the economics gains are substantial. Studies that have compared the costs of prevention programs to costs of type 2 diabetes have found them to be cost-saving or extremely cost effective, with Australian estimates ranging from \$2 600 to \$5 300 per life year.⁵³

3.2 Impact on diabetes complications of reducing HbA1c by 1 per cent



Data source: PALMER, A. J., ROZE, S., VALENTINE, W. J., MINSHALL, M. E., FOOS, V., LURATI, F. M., LAMMERT, M. & SPINAS, G. A. 2004a. Validation of the CORE Diabetes Model against epidemiological and clinical studies. *Curr Med Res Opin*, 20 Suppl 1, S27-40.

⁵² The incremental cost effectiveness ratio is the difference in cost between two possible interventions, divided by the difference in their effect. Quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.

⁵³ Segal L, Dalton AC, Richardson J. Cost-effectiveness of the primary prevention of non-insulin dependent diabetes mellitus. *Health Promotion Int*. 1998;13:197–209, and Palmer AJ, Roze S, Valentine WJ, Spinas GA, Shaw JE, Zimmet PZ. Intensive lifestyle changes or metformin in patients with impaired glucose tolerance: modelling the long-term health economic implications of the diabetes prevention program in Australia, France, Germany, Switzerland, and the United Kingdom. *Clin Ther*. 2004;26:304–32.

This excludes the positive impacts that would also accrue in terms of enhanced productivity and workforce participation when better health is achieved.

Identifying heart attacks in emergency departments

Patients presenting with chest pain in the Emergency Departments (ED) of hospitals around Australia is commonplace, accounting for approximately 10 per cent of ED presentations, and 25 per cent of hospital admissions.⁵⁴

In some cases, the condition is life threatening and requires immediate and extensive attention; e.g. when patients present with acute coronary syndrome (ACS) which can include acute myocardial infarction and unstable angina pectoris. In other cases, symptoms may be caused by less serious gastro-oesophageal reflux, and will simply subside with time.

Telling the difference can be difficult, with substantial consequences for patients and the cost of healthcare. Pathology testing for troponin is one of the vital, and more immediate, ways of:

- escalating urgent patients for admission to ensure they get the medical attention they require
- enabling non-ACS patients to be early and safely discharged without a prolonged or unnecessary hospital stay, and
- minimising the risk of missed diagnosis of ACS, which can otherwise lead to further ischemic events and potentially preventable death or disability.

There are approximately 80 000 hospitalisations associated with ACS in Australia annually. The health care system costs associated with ACS are considerable, estimated to be \$1.8 billion per annum, with a cost per separation of \$22 000 for direct costs only.⁵⁵

Approximately 80 per cent of patients presenting to the ED with chest pain *will not* end up with a diagnosis of ACS, and troponin is a vital 'rule out' test, which is able to identify patients that can be safely discharged. Identifying these patients *early* has a substantial impact on the health system costs of ACS, and the efficient allocation of time and resources in hospitals.

International guidelines for the investigation of ACS recommend serial measurement of cardiac troponin at the onset of symptoms.⁵⁶ Studies show that:

⁵⁴ Than, M., Cullen, L., Aldous, S. et al 2012, '2 hour accelerated diagnostic protocol to assess patients with chest pain symptoms using contemporary troponins as the only biomarker', *Journal of the American College of Cardiology*, Volume 59, No. 23, 2012.

⁵⁵ Access Economics 2009, *The Economic Costs of Heart Attack and Chest Pain (ACS)*, [http://www.bakeridi.edu.au/Assets/Files/FullReport%20-%20the%20economic%20costs%20of%20heart%20attack%20and%20chest%20pain%20\(emilable.pdf](http://www.bakeridi.edu.au/Assets/Files/FullReport%20-%20the%20economic%20costs%20of%20heart%20attack%20and%20chest%20pain%20(emilable.pdf)

⁵⁶ Pathology testing is part of the ADAPT (Accelerated Diagnostic Protocol to Assess Patients with Chest Pain Symptoms Using Contemporary Troponin as the Only Biomarker) accelerated

- high sensitivity troponin testing is associated with more rapid diagnosis and less time spent in the Emergency Department⁵⁷
- using testing of troponins as the only biomarker, an early discharge strategy can be safely pursued for approximately 40 per cent of patients with suspected ACS⁵⁸
- the availability of troponin assays has led to more patients who are at increased risk of recurrent cardiac events being identified, such as improvements in selecting patients who might benefit from early invasive management and revascularisation with potent antithrombotic therapy.⁵⁹

While evidence is still emerging, it is becoming increasingly clear that high sensitivity troponin assays have better predictive power and are more valuable as a guide to separating high-risk patients in need of the most care from those that can be managed in more cost effective ways.⁶⁰ The potential savings to the health system can be substantial. In 2013–14, there were 7.2 million presentations to public hospital EDs in Australia.⁶¹ With 10 per cent of ED presentations relating to chest pain symptoms and an average cost for an emergency presentation of \$578,⁶² this suggests that \$416.2 million is being spent on *potential* ACS patients each year in the ED alone. If troponin testing can safely discharge 40 per cent of cases early, this directly manages down costs of \$166.5 million being incurred in ED's for patients who need not stay within the ED, or be admitted.

Making a difference to cancer care

One of the areas in which pathology is making a vital difference to patient and health system outcomes is personalised medicine, particularly in the area of cancer care.

Personalised medicine uses genetic information in preventative, diagnostic and therapeutic strategies to allow better therapies to be selected for patients in terms of efficacy, safety and treatment length, and contributes to reduced treatment costs.

diagnostic protocol, along with ECG examinations, familial history checks, and identification of recent health events and treatments.

⁵⁷ Yip, T., Pascoe, H., and Lane, S. 2014, Impact of high-sensitivity cardiac troponin I assays on patients presenting to an emergency department with suspected acute coronary syndrome, *Med J Aust* 2014; 201 (3): 158-161.

⁵⁸ See, for instance, Cullen, L., Mueller, C., Parsonage, W. et al 2013, 'Validation of High-Sensitivity Troponin I in a 2-Hour Diagnostic Strategy to Assess 30-Day Outcomes in Emergency Department Patients with Possible Acute Coronary Syndrome', *Journal of the American College of Cardiology*, Vol. 62, No. 14, 2013.

⁵⁹ Chew, D., and Cullen, L. 2014, The promise of high-sensitivity troponin testing, *Med J Aust* 2014; 201 (3): 125-126.

⁶⁰ Health Policy Advisory Committee on Technology 2013, Technology Brief Update: High-sensitivity troponin assays for the diagnosis of myocardial infarction.

⁶¹ AIHW 2014. Australian hospital statistics 2013–14: emergency department care. Health services series no. 58. Cat. no. HSE 153. Canberra: AIHW.

⁶² National Hospital Cost Data Collection Australian Public Hospitals Cost Report 2012-2013, Round 17, p. 93.

Personalised medicine is only possible because of pathology.

The value of pathology in unlocking opportunities from personalised medicine can be seen in the case of colorectal cancer, where transformations in medical science and genetic pathology improve the effectiveness of treatments over time, support screening programs that enable early cancer detection, and direct healthcare spending to its most valuable uses.

Improving decision making at every stage of colorectal cancer care

Colorectal cancer (CRC) is the second most commonly diagnosed cancer in Australia, and incidence generally increases with age. In 2011 there were 15 151 new cases diagnosed in Australia, and in 2015 it is estimated that there will be 17 070 new cases diagnosed, accounting for 13.5 per cent of all new cancers.⁶³ Today, colorectal cancer prevention, diagnosis, monitoring and treatment are reliant on pathology to get the **best outcomes for patients**, and the **best use of health resources**:

- early detection tests are supported by large scale national programs, such as the National Bowel Cancer Screening Program, providing free bowel cancer screening kits to people over 50 to test at home, which are sent off to pathology to identify cancer early
- early identification and prevention is facilitated for people at an elevated risk of colorectal cancer due to Lynch Syndrome (or hereditary non-polyposis colon cancer, HNPCC),⁶⁴ detected using pathology and monitored through regular check-ups after the age of 25
- tests can be undertaken to determine if cancer has penetrated deeper tissues in the bowel or spread to lymph nodes and beyond. This helps determine the best treatment and also predicts prognosis
- genetic tests can be done to see if KRAS or NRAS genes have mutated, which determines whether expensive anti-EGFR treatment is worthwhile, and whether it will be made available and funded by the Australian Government,⁶⁵ and
- spending on healthcare is improved as access to funded treatments is contingent on pathology confirmation that treatments will work.⁶⁶

⁶³ AIHW 2015, Bowel Cancer in Australia, <http://www.aihw.gov.au/cancer/bowel>.

⁶⁴ Lynch Syndrome is characterised by the development of colorectal cancer, endometrial cancer and various other cancers, and is caused by a mutation in one of the mismatch repair genes: MLH1, MSH2, MSH6 or PMS2, see <http://www.ncbi.nlm.nih.gov/pubmed/17327285>.

⁶⁵ Epidermal growth factor receptors (EGFR) are overexpressed in colorectal cancer, which can be targeted by EGFR inhibitors depending on the status of the KRAS gene. Research has found that the impact of EGFR inhibitors on progression free survival (PFS) in the wild-type KRAS group was significantly greater than in the mutant group. Wild-type KRAS patients had longer overall survival, see Amado RG, Wolf M, Peeters M, Van Cutsem E, Siena S, Freeman DJ, Juan T, Sikorski R, Suggs S, Radinsky R, Patterson SD, Chang DD *J Clin Oncol*. 2008 Apr 1; 26(10):1626-34. Subsequent clinical trials have confirmed these results.

⁶⁶ The Australian Government has funded access to personalised EGFR inhibiting drugs such as Erbitux® since September 1 2011 and Vectibix® since May 1 2014. In May 2012, the MBS

Economic analysis on the impact of pathology tests for colorectal cancer has found that:

- expanding testing from KRAS to RAS provides net cost savings to the Australian Government by decreasing anti-EGFR antibody treatment costs through ruling out treatment for those that won't respond well,⁶⁷ and
- expanding testing to include all RAS mutations and limiting subsidy of cetuximab to those patients demonstrated to have no RAS mutations both reduces harms and improves health outcomes, and the cost of RAS mutation testing is negligible compared to the cost of therapy for patients with metastatic colorectal cancer.⁶⁸

With continuous improvements in quality and standards⁶⁹ and the deeper integration of pathology knowledge into patient care including through multi-disciplinary clinical meetings,⁷⁰ high quality pathology is routine and ubiquitous in colorectal cancer care:

- standards and practices for specimen collection are now achieving more uniform slicing of surface and subsurface tissue, and the number of lymph nodes being collected for analysis has increased — providing more accurate information about prognosis and treatment options, and
- analysis of genetic characteristics is now routine so that patients presenting with colorectal cancer are tested to determine suitability for EGFR inhibitor treatments, directing patient care and health system resources in ways that should work well, and away from treatments that will not.

As diagnoses become more specific and accurate, patient prospects continue to improve and the value of pathology is enhanced. Between 1982 and 1986, 5-year survival for CRC was 47 per cent. Between 2007 and 2011, this increased to 67 per cent, meaning patients have a 67 per cent chance of surviving for 5 years.⁷¹

With improvements in survival, the age standardised mortality rate is trending downwards, as is the number of deaths from colorectal cancer (chart 3.3). Pathology has been vital to this trend, guiding medical research, medical practice, treatment choice, patient monitoring, and care.

began to subsidise KRAS tests for patients with mCRC to determine their eligibility for PBS-subsidised Erbitux, and PBS funding for Erbitux® and Vectibix® is now available for patients identified as having RAS wild-type status, which requires an even finer level of genetic testing (reference does not include a commentary)

⁶⁷ Medical Services Advisory Committee, Public Summary Document: Application No. 1363 — RAS (KRAS and NRAS) mutation testing for eligibility to access panitumumab, October 2014.

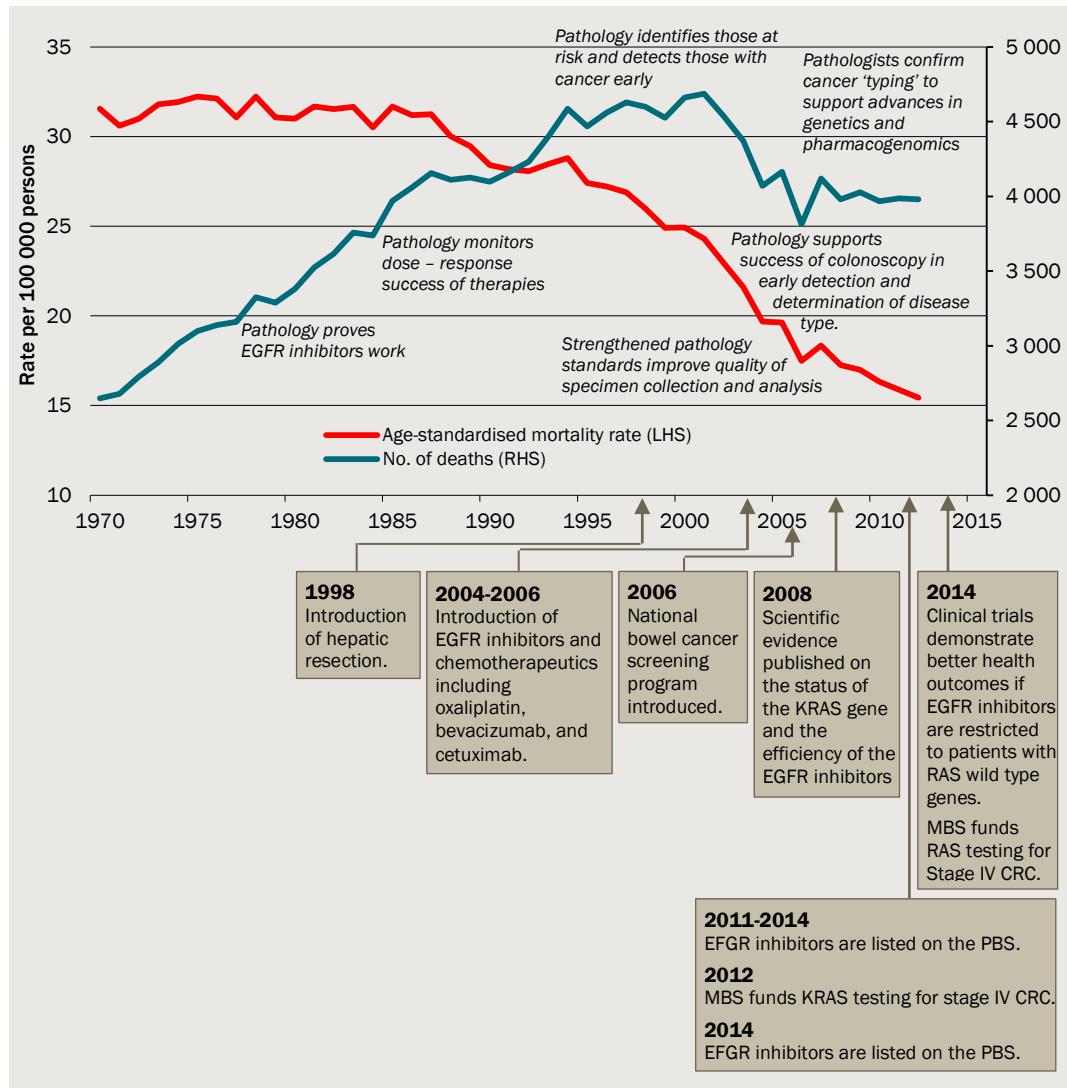
⁶⁸ Medical Services Advisory Committee, Public Summary Document: Application No. 1362.1 — Cetuximab and KRAS mutation testing under MBS 73330, October 2014.

⁶⁹ For instance, see the Quality Use of Pathology Program <http://www.health.gov.au/qupp>.

⁷⁰ For instance, see <http://canceraustralia.gov.au/clinical-best-practice/multidisciplinary-care>.

⁷¹ AIHW 2015, Bowel Cancer in Australia, <http://www.aihw.gov.au/cancer/bowel>.

3.3 Pathology contributes to improved treatment and survival for CRC patients



Data source: AIHW 2015 Australian Cancer Incidence and Mortality book for colorectal cancer.

Future focus for the sector

Pathology is at the heart of the healthcare system. It transforms individual lives, their contribution to the economy, as well as ensuring that health spending is well targeted and worthwhile.

In proportional terms, it comprises a small fraction of healthcare costs at just 3 per cent of spending, although it drives decision making on prevention, diagnosis, monitoring, and treatment for virtually every health condition.

However, more can be done to ensure that Australia gets the most out of its investment in pathology.

- **The value of pathology needs to be better demonstrated to influence funding decisions about pathology** and improve the level and direction of pathology

investment in Australia. Three case studies have been presented in this report that show the substantial economic impact of pathology in significant areas of disease burden in Australia, namely diabetes, cardiovascular disease, and cancer. Without pathology, detection would be almost impossible until symptoms became more pronounced, more costly to address, and more life threatening to patients. However, even in these cases, there is a paucity of economic analysis on how total health spending is made more efficient. Economic analysis at the test level is needed to demonstrate how patients benefit and how health resources are conserved as a direct outcome of a pathology test. This should also be used to direct health spending away from tests that have become superseded or out-dated.

- **The contribution of pathology across the full spectrum of tests needs to be better recognised**, from the simple tests that assess whether health states are ‘normal’, to sophisticated companion tests that determine whether patients can access expensive treatments and enjoy positive health outcomes from treatment. Pathology guides medical decision making on patient care on a daily basis, when things are normal as well as when things are not.
- **The policy and funding environment for pathology should focus on how to ensure pathology maximises value, rather than minimises costs**. An increase in testing activity should typically be value creating, providing the evidence for informed prevention, treatment, and monitoring plans. Pathology comprises a very small proportion of healthcare costs and directs use of health resources in cost effective ways. Like any government-funded service, the funding framework must ensure that the business of pathology remains responsive, innovative, and cost conscious. It must also ensure that enough investment is made to provide the information needed by doctors and specialists to help them achieve the best for patients and the broader health system.

Conclusion

This report clearly demonstrates the vital role that our world-class pathology service plays in Australian healthcare.

If pathology is undervalued and underfunded, prevention and diagnosis opportunities will be missed, leading to expensive end stage treatments and the high personal costs of poor health.

This makes investment in pathology critical to containing future health care costs, achieving the best quality of life for Australians, and ensuring that Australia gets the most out of its total investment in health.



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