



Australian Government
Department of Health and Ageing

Strategic Review of Health and Medical Research

Summary Report | February 2013

Better Health Through Research



Cover Art. The images on the front cover reflect the connection between health and medical research, improved healthcare and economic and social outcomes:

1. Clinician researchers are often the starting point for health and medical research hypotheses.
2. Biomedical research, such as research into brain neurons, provides the foundation knowledge that leads to new discoveries and clinical interventions.
3. CSL Limited is a global leader in blood products, and uses research discoveries to create national wealth and deliver improved healthcare (Image courtesy of CSL Limited).
4. Health professionals deliver improved services to consumers into evidence-based healthcare.
5. The Australian community benefits from increased longevity and good health.
6. Health and medical research drives benefits for all Australians in terms of better health and increased prosperity.

Strategic Review of Health and Medical Research in Australia – Better Health Through Research

ISBN: 978-0-9872039-5-3

© Commonwealth of Australia 2013

This work is copyright. You may download, display, print and reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the Copyright Act 1968 or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given the specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the Online, Services and External Relations Branch, Department of Health and Ageing, GPO Box 9848, Canberra ACT 2601, or via e-mail to copyright@health.gov.au.

Report design by Chromeworks
www.chromeworks.com.au

TABLE OF CONTENTS

Review Panel	ii
Acknowledgements	iii
Foreword	iv
Executive Summary	1
1. Vision for 'Better Health Through Research'	6
1.1 Vision	6
1.2 A Healthy and Wealthy Australia	7
1.3 The World's Best Health System	9
1.4 A World-Class HMR Sector	12
1.5 Strategy	14
2. Embed Research in the Health System	16
2.1 Introduction	16
2.2 Drive Research Activity in the Health System	17
2.3 Establish Sector Leadership and Governance	19
2.4 Establish Integrated Health Research Centres	22
2.5 Build Health Professional Research Capacity	23
2.6 Accelerate Clinical Trial Reforms	24
3. Support Priority-Driven Research	26
3.1 Introduction	26
3.2 Align Priority-Setting Process	27
3.3 Support a Range of Strategic Topics	27
4. Maintain Research Excellence	30
4.1 Introduction	30
4.2 Train, Support and Retain the Workforce	30
4.3 Streamline Competitive Grant Processes	32
4.4 Rationalise Indirect Cost Funding for Competitive Grants	33
4.5 Build Enabling Infrastructure and Capabilities	34
5. Enhance Non-Commercial Pathway to Impact	36
5.1 Introduction	36
5.2 Enhance Public Health Research	37
5.3 Enhance Health Services Research	38
5.4 Accelerate Health System Innovation	38
5.5 Inform Policy with Evidence	39
6. Enhance Commercial Pathway to Impact	41
6.1 Introduction	41
6.2 Support Research Commercialisation	41
6.3 Enhance Commercialisation Environment	43
7. Attract Philanthropy and New Funding Sources	45
7.1 Introduction	45
7.2 Attract Philanthropy	45
7.3 Identify New Funding Sources	47
8. Invest and Implement	48
8.1 Introduction	48
8.2 Invest for the Future	48
8.3 Action Report Recommendations	53
9. Abbreviations	55

REVIEW PANEL



**Mr Simon McKeon AO
(Chair)**

Mr McKeon is Chairman of the Board of CSIRO and also holds the positions of Executive Chairman

of Macquarie Group's Melbourne Office and Chairman of Business for Millennium Development. Mr McKeon is a Fellow of the Australian Institute of Company Directors. Previous Board appointments include Chairman of the Board of Multiple Sclerosis Research Australia and Director of Bio 21 Australia. Mr McKeon was Australian of the Year in 2011.



Ms Elizabeth Alexander AM

Ms Alexander is Chancellor of the University of Melbourne, immediate past Chairman of CSL Limited, non-Executive Director of

Dexus Property Group and Medibank, and Advisor to Ashurst. Ms Alexander is also a Fellow of the Institute of Directors in Australia and a former national president of both CPA Australia and the Institute of Directors.



Professor Henry Brodaty AO

Professor Brodaty is Scientia Professor of Ageing and Mental Health, Montefiore Chair of Healthy Brain Ageing, Director of the

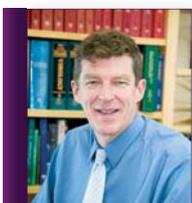
Dementia Collaborative Research Centre and Co-Director of Centre for Healthy Brain Ageing at UNSW. He is a senior psychogeriatrician and Head of the Memory Disorders Clinic at Prince of Wales Hospital in Sydney, President-Elect of the International Psychogeriatric Association and a member of key national and state committees for dementia and mental health of older people.



Mr Bill Ferris AC

Mr Ferris has been Executive Chairman of CHAMP Private Equity since its formation in 2000. He is Chairman of the Garvan

Institute of Medical Research, Director of the Garvan Research Foundation, and immediate past Chairman of the Health and Hospitals Fund Advisory Board as part of the Federal Government's Nation-Building Funds initiative. Mr Ferris was made an Officer of the Order of Australia in 1990 and in 2008 was appointed a Companion of the Order of Australia for service to the community.



Professor Ian Frazer AC

Professor Frazer is CEO and Research Director of the Translational Research Institute in Brisbane. He is a fellow of the Royal

Society of London, and is a board member of two Australian Biotech companies. Along with fellow researcher the late Dr Jian Zhou, Professor Frazer developed the vaccine technology for the human papillomavirus. Professor Frazer was Australian of the Year in 2006 and appointed a Companion of the Order of Australia in 2012 for 'eminent service to medical research'.



Professor Melissa Little

Professor Little is a National Health and Medical Research Council (NHMRC) Senior Principal Research Fellow at The

University of Queensland's Institute for Molecular Bioscience where she leads the Renal Development and Disease research laboratory. Professor Little was a member of the 1998 Health and Medical Research Strategic Review (the Wills Review). She is a recipient of the GlaxoSmithKline Award for Research Excellence, a Gottschalk Medallist, and was an Eisenhower Fellow.

ACKNOWLEDGEMENTS

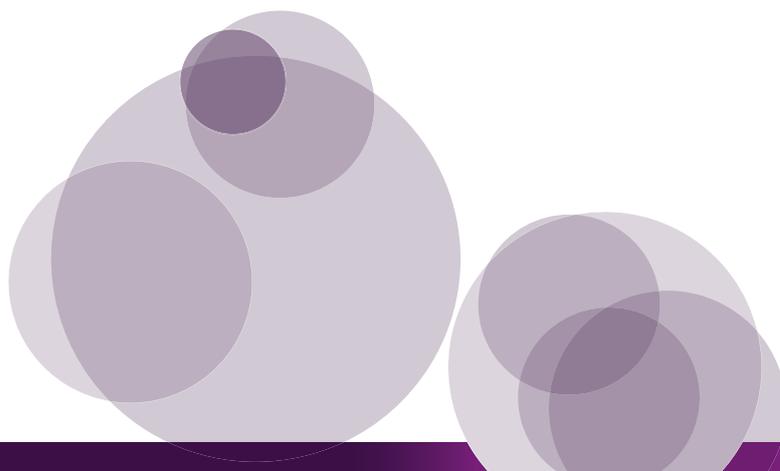
The final report of Strategic Review of Health and Medical Research (HMR) in Australia represents the combined insights of thousands of individuals who contributed their ideas and time to the review in different ways. The Panel's task of distilling these insights into a coherent 10-year strategy simply would not have been possible without the passion and commitment of these contributors. The Panel would like to thank:

- individuals who attended the public consultations that were held across all states and territories;
- over 300 individuals from universities, MRIs, governments, hospitals, businesses and not-for-profit organisations who met with the Panel to discuss specific topics;
- around 400 organisations and individuals who provided written submissions;
- subject-matter experts who reviewed and improved the case studies, or added detail and clarity to specific recommendations; and
- the titans who have contributed so much to the sector and Australia, for their wise counsel and advice.

The Panel would particularly like to thank the members of its Secretariat, who formed an incredible team that maintained a professional process, while developing a high-quality strategy and clear communications:

- Department of Health and Ageing – Kathy Dennis and Matthew Murphy;
- Secretariat Australia – Dr Pippa Carron, Charles Willoughby, Celia Tancred, Roz Mackenzie and Sarah Lording; and
- [Pacific Strategy Partners](#) – Kiril Alampieski, Ian Clarke, Roshan Mendis, Veronica Mullins and Andrew Wilson.

The Panel travelled extensively across Australia to complete this review, and also spent many hours debating the issues by phone, text and email, writing and editing. This effort, combined with our normal busy lives, would not have been possible without the extraordinary support from our families and friends, to whom we express our gratitude. You know who you are and how much you mean to us, and we thank all of you for allowing us to make our contribution to the future health of Australia.



FOREWORD

For many years Australia has produced some of the best scientific and medical researchers in the world. The success of our health and medical research (HMR) has resulted in healthier Australians and led to innovations that have boosted our national wealth. As a nation, Australia has undeniably generated substantial benefits from research.

Australia has one of the world's best performing health systems. Yet there is tremendous potential for improvement in healthcare delivery, and it is in this very area that research can be better leveraged and take on a more active role. Australians have clearly indicated that they want better hospitals and healthcare services to deliver better health, and we are well placed to deliver this by aspiring to become the world's best health system over the next 10 years.

To achieve this aspiration, we need to create a strong culture of continuous improvement that delivers the best and most efficient evidence-based healthcare for Australians. We must strive to develop new interventions and procedures that alleviate sickness and enhance wellbeing as well as reducing the costs of delivering healthcare. HMR, as the R&D arm of this major sector of the economy, must be at the heart of the efforts to achieve this aspiration.

Indeed, an overarching message that emerged during this review was the lack of a sufficiently strong connection between HMR and the delivery of healthcare services. There is no better means to do this than by fundamentally embedding research within healthcare delivery. That is to say, research must be routinely performed as a part of healthcare delivery and there must be greater linkage between healthcare providers and

research organisations. We live in exciting but challenging times of rapidly changing societal, economic and technological circumstances—including an ageing population, a shifting burden of disease profile, climate change, and the development of frontier technologies such as genomics. The Australian Government is determined to ensure that its research investment is used wisely and equitably so that all Australians benefit through better health outcomes, and so that it delivers the greatest economic value for the nation. As we face a trajectory of unsustainably increasing healthcare costs, we must use research to improve the efficiency and effectiveness of the health system.

Australia needs a comprehensive strategic plan to ensure it optimises government investment in HMR. In establishing this review, the Australian Government has taken a vital step in support of this need. Now that we have developed a blueprint for the future, efforts should be focused on implementing these reforms that will ensure Australians receive the very best in healthcare and benefit from the wealth creation that comes from HMR innovation.

The overarching vision for health and medical research is one where research is fully embedded in all aspects of healthcare to deliver 'Better Health Through Research' and achieve the aspiration for Australia to build and maintain the world's best and most efficient health system. To achieve this vision, I call on researchers, healthcare professionals, governments and the community to work together with strengthened partnerships.

Simon McKeon AO

Chair, Strategic Review of Health and Medical Research in Australia

I. Vision for 'Better Health Through Research'

The purpose of health and medical research (HMR) is to achieve better health for all Australians. Better health encompasses increased life expectancy, as well as social goals such as equity, affordability and quality of life. HMR investment supports innovation in Australia's \$135bn p.a. health sector and is vital for delivering health outcomes, creating national wealth and ensuring the efficiency and sustainability of the health system. Implementing the following recommendations to embed HMR in the health system over the next 10 years will help deliver a wealthy and prosperous Australia that boasts the world's best and most efficient health system.

II. Embed Research in the Health System

1. **Drive Research Activity in the Health System.** Optimise current HMR investment and over the longer term, monitor and manage 3%–4% of total Australian Government and state and territory government health expenditure on HMR.
 - a. Manage and refocus current state and territory government Local Hospital Network (LHN) HMR investment, using the National Health Reform Agreement to strengthen and build upon the approximately \$1.0–\$1.5bn p.a. estimated HMR investment in the health system, and set research key performance indicators for LHN (or groups of LHNs) and hospital CEOs.
 - b. Add competitive programs (outlined in other recommendations) to provide an additional \$1.5bn p.a. for research in the health system within 10 years.
 - c. Establish a national health system R&D investment target of 3%–4% of government health expenditure (including HMR in LHNs, the National Health and Medical Research Council Medical Research Endowment Account, and new competitive programs) and, over the longer term, progress towards this benchmark.
2. **Establish Sector Leadership and Governance.** Establish and resource a leadership body to work with key organisations charged with delivering better health services.
 - a. Provide direction, focus, oversight and leadership for the HMR sector.
 - b. Facilitate translation of research into evidence-based healthcare and policy.
 - c. Provide policy advice and drive sector reforms.
 - d. Track and monitor HMR investment and outcomes.
3. **Establish Integrated Health Research Centres.** Establish and fund Integrated Health Research Centres (IHRCs) that combine hospital and community-care networks, universities, and research organisations such as medical research institutes (MRIs).
 - a. Establish a clear set of criteria around integration, excellence, translation, strategy, leadership and governance.
 - b. Initially select 4–8 IHRCs and provide funding of up to \$10m p.a. each for five years, and add 1–2 IHRCs every 1–2 years, building to a total of 10–20 over a 10-year period.
 - c. Monitor and evaluate the performance of the IHRCs to determine whether funding should be renewed at the end of the five-year funding period.

4. **Build Health Professional Research Capacity.** Build and support health professional researcher capacity and capability.
 - a. Support 100 research-focused health professionals with practitioner fellowships and competitive grants and, if successful, increase up to 1,000 over the next 10 years.
 - b. Embed research into health professional training and accreditation, and support dual research-practitioner education pathways.
 - c. Streamline medical practitioner accreditation processes for leading overseas research professionals.
5. **Accelerate Clinical Trial Reforms.** Build on the Clinical Trials Action Group report recommendations and drive a national implementation approach to clinical trial reforms.
 - a. Develop an online approval workflow system and enhance the existing consumer recruitment portal.
 - b. Establish 8–10 national ethics committees to replace the proliferation of local committees.
 - c. Implement a national clinical trials liability insurance scheme.
 - d. Create a national clinical trials office within the HMR leadership body to drive reforms.

III. Support Priority-Driven Research

6. **Align Priority-Setting Process.** Establish, fund and create a structure around a set of national HMR priorities.
 - a. Set national HMR priority areas through the leadership body and the Council of Australian Governments Standing Council on Health on a triennial basis.
 - b. Allocate a defined portion of the NHMRC Medical Research Endowment Account budget (10%–15%) to priority areas for 'top-down strategic research'.
 - c. Create a panel of experts for each priority area to set the research agenda, leverage funding and evaluate outcomes.
7. **Support a Range of Strategic Topics.** Provide targeted investment in four strategic topics and possibly include as national priorities.
 - a. Build Indigenous research capacity through a virtual Integrated Health Research Centre (IHRC), refocus NHMRC People Support Schemes on capacity-building, and expand long-term NHMRC programs.
 - b. Establish a virtual rural and remote IHRC which has links to other IHRCs and leverages national data platforms for research, streamlined clinical trials processes and patient record management.
 - c. Support global health research through partnerships and collaboration.
 - d. Develop capacity and capability in genomics through a national HMR network, ongoing training, NHMRC People Support Schemes and data infrastructure investment.

IV. Maintain Research Excellence

8. **Train, Support and Retain the Workforce.** Manage, train, build capacity for and retain a high-quality research workforce.
 - a. Actively monitor the shape and dynamics of the HMR workforce and NHMRC People Support Schemes.
 - b. Support career entry with higher Australian Postgraduate Award stipends and 'early investigator' grants, with a focus on 'few total research years' rather than 'new to NHMRC'.
 - c. Retain more researchers in the system with flexibility for career breaks or part-time work, remove barriers to retention, and fund capacity for mentoring.
 - d. Provide increased flexibility of track record definitions in grant applications to encompass a broader range of research activities and contributions.
 - e. Build capacity in key enabling areas (e.g. genomics) and disciplines that will deliver health system impact (e.g. health economics) with NHMRC People Support Schemes.
9. **Streamline Competitive Grant Processes.** Re-engineer the NHMRC grant application and assessment processes to include, but not be limited to, the following initiatives.
 - a. Streamline NHMRC grant application processes and systems, and align with other major granting agencies.
 - b. Simplify grant assessment processes to reduce reviewer burden and support a limited but significant quantity of high-risk/potential high-return research.
 - c. Stabilise the workforce by moving towards a standard Project Grant duration of five years and adopt quanta funding.
10. **Rationalise Indirect Cost Funding for Competitive Grants.** Ensure that all qualified HMR institutions, including healthcare service providers, MRIs and universities, receive at least 60% indirect cost loading for national competitive grants.
11. **Build Enabling Infrastructure and Capabilities.** Provide significant funding for large infrastructure, including patient databases, registries, a biobank hub and enabling technologies.
 - a. Create a research infrastructure funding vehicle of \$150–\$200m p.a. to fund major infrastructure and key enabling technologies, and ensure access for the HMR sector.
 - b. Accelerate development of national patient databases and clinical registry infrastructure and management.
 - c. Develop a national biobank hub linking existing and future specimen biobanks.
 - d. Increase new enabling technologies and supporting analytical services.

V. Enhance Non-Commercial Pathway to Impact

- 12. Enhance Public Health Research.** Focus efforts on capacity-building and new schemes for public health research.
 - a. Build capacity in public health research and expand partnership schemes.
 - b. Refine NHMRC Project Grant schemes and leverage for Australian National Preventive Health Agency research.
 - c. Consider new approaches to funding clinical trials for long-term public health.
- 13. Enhance Health Services Research.** Focus efforts on capacity-building and new schemes in health services research and health economics.
 - a. Build capacity in health services research and health economics to understand, assist and evaluate translation.
 - b. Refine NHMRC selection criteria to encourage health services research.
 - c. Establish an influential institute of health services research.
- 14. Accelerate Health System Innovation.** Accelerate research translation and health system innovation.
 - a. Provide incentives to generate clinically-relevant research.
 - b. Ensure guidelines have an implementation plan and encourage wider communication.
 - c. Provide funding for non-commercial clinical trials based on potential to deliver impact.
- 15. Inform Policy with Evidence.** Inform health policy and practice with research evidence.
 - a. Enhance the capability of NHMRC and researchers to support policy makers.
 - b. Encourage the embedding of researchers within government policy departments.
 - c. Conduct research on gaps between health policy and practice, and the evidence base.

VI. Enhance Commercial Pathway to Impact

- 16. Support Research Commercialisation.** Provide funding to address the twin 'valleys of death' in commercialising research.
 - a. Institute a Matching Development Grants scheme to provide \$0.5m p.a. to each of the 20 consistently most successful NHMRC peer-reviewed grant recipient organisations, contingent on matching commitments and access to business development capabilities.
 - b. Maintain HMR access to the Australian Research Council Linkage Projects scheme.
 - c. Establish a Translational Biotech Fund for early-stage development of around \$250m, funded by the Australian Government and the private sector on a one-to-one matching basis.
 - d. Continue to support the Innovation Investment Fund program.

- 17. Enhance Commercialisation Environment.** Improve commercialisation capability, culture and practices.
- Foster a culture of commercialisation through freer interchange between researchers and industry, and recognise commercialisation achievements through institutional rankings and industry awards.
 - Encourage research organisations with sub-scale or no business development offices to engage larger institutions/precincts for commercialisation requirements.
 - Protect valuable intellectual property (IP) by strengthening Australia's IP system and encouraging researchers to seek sound advice on the commercial value of their IP before filing patent applications.
 - Implement clinical trial reforms as an urgent national priority (see Recommendation 5).

VII. Attract Philanthropy and New Funding Sources

- 18. Attract Philanthropy.** Attract and optimise philanthropic investment.
- Attract large global philanthropy through strategic alliances.
 - Allocate funding (up to \$50m p.a.) to match new large philanthropic donations based on leverage and alignment to HMR priorities.
 - Track philanthropic investment, and encourage collaboration, scale and innovation.
- 19. Identify New Funding Sources.** Identify other possible funding sources such as alternative debt finance, R&D tax incentives and levies, and schemes such as research prizes.

VIII. Invest and Implement

- 20. Invest for the Future.** Enhance and align HMR investment programs, with extended oversight by the new HMR leadership body.
- Focus initially on investing in high-priority initiatives that deliver the most impact, while realigning and better managing existing investment.
 - Review and evaluate the first four years of the investment program in 2018–19 and determine whether to accelerate investment, maintain trajectory or withdraw investment, as well as identify any improvements required for each program.
 - Index competitive research grant budgets (particularly the NHMRC Medical Research Endowment Account) to increases in health expenditure.
- 21. Action Report Recommendations.** Set out a robust implementation plan and process to deliver the recommendations.
- Establish an implementation committee and a robust implementation process with a clear plan.
 - Use appropriate incentives to ensure outcomes are delivered.
 - Conduct a medium-term follow-up review to evaluate initial outcomes of investment program.
 - Refine the plan and invest in success.

1. VISION FOR 'BETTER HEALTH THROUGH RESEARCH'

1.1 Vision

The purpose of health and medical research (HMR) is to deliver better health outcomes for all Australians. It is an essential element of the \$135bn p.a. health sector, which includes health professionals, consumers, businesses, not-for-profit organisations and governments. In the context of an uncertain economic environment and expected continuing inflation of healthcare costs, HMR has a vital role to play in improving health outcomes for Australians, delivering a more efficient and effective health system and contributing to the national economy. The vision is therefore for 'Better Health Through Research', where 'better health' is defined by population health outcomes, such as increased life expectancy, together with social goals such as equity, quality of life and affordability.

Exhibit 1

HMR is vital to build and maintain a healthy and wealthy Australia with the world's best health system

HMR Vision



HMR Outcomes

- Leverage and extend reforms
- Maintain world-class research
- Focus on translation and impact
- Monitor investment and outcomes
- Build and maintain the world's best health system
 - HMR augments healthcare reforms
 - HMR is key to health system efficiency
 - Health is the highest priority for Australians
- Deliver evidence-based healthcare and policy
- Increase longevity and quality of life
- Boost national wealth
 - Health system sustainability
 - Workforce productivity
 - Medical innovation and industry
- Drive shift to knowledge-based jobs
- Enhance international standing and engagement, particularly with Asia

Over the next 10 years, a HMR sector deeply embedded in the health system will help to deliver significant social and economic outcomes.

- For all Australians:
 - Australia's health system (the most important national issue for most Australians) to be world leading, with better care, greater efficiency and cost inflation at or below the Consumer Price Index;
 - increased average life expectancy to above 85 years; and
 - improved quality of life for all, including a significant reduction in the Indigenous health gap and a robust measure to quantify and monitor changes in quality of life.

- For the nation and the economy:
 - a healthier and more productive workforce, with a 5% increase in productivity due to less illness and better chronic disease management;
 - a listed biotechnology sector generating wealth worth over \$60bn, and high-paying jobs;
 - a biotechnology and pharmaceutical manufacturing export sector, already Australia's largest at \$4bn p.a., that is at least twice its current size;
 - over 80,000 jobs in the knowledge-based biotechnology industry; and
 - increased international engagement, particularly with Asia, to increase research collaboration and share best-practice healthcare.

1.2 A Healthy and Wealthy Australia

1.2.1 Increase Longevity and Quality of Life

Since the advent of the modern scientific research method, Australians have enjoyed significant increases in life expectancy from around 50 years in the late 19th century to 82 years today. The average years lived without disability has also increased to 63 in 2009.¹ Australians rightly place a significant value on each additional year of life, estimated by some studies at \$432,000² and implicitly by the Australian Government at around \$42,000³ per quality-adjusted life year (QALY).

1.2.2 Boost National Wealth

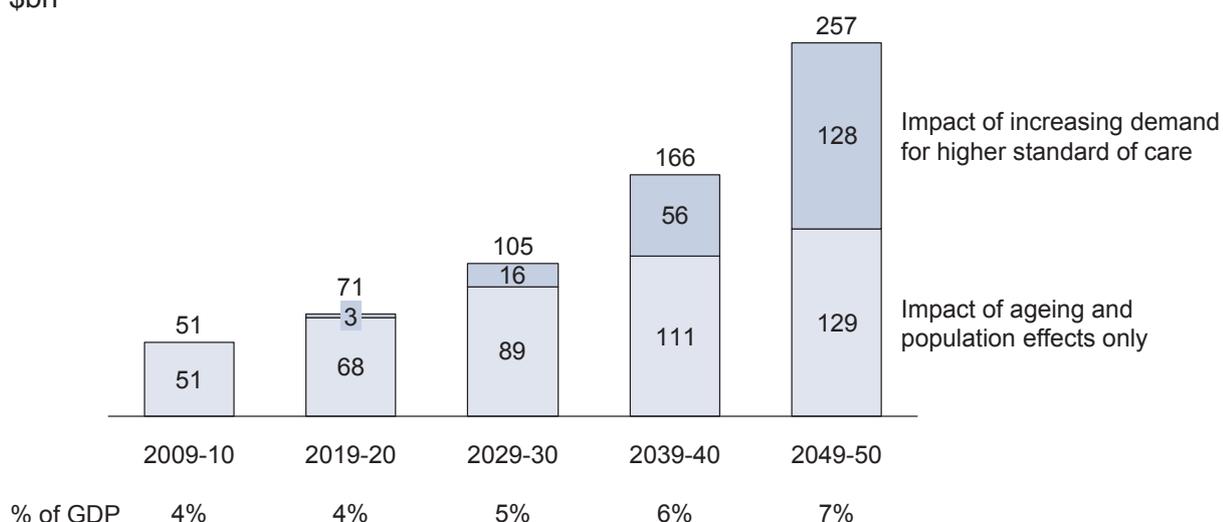
A dollar invested in Australian HMR is estimated to deliver a return in health benefits of \$2.17.⁴ HMR is vital to ensure the health system is sustainable and efficient, increase the productivity of Australia's workforce and deliver medical innovation. Healthcare costs are projected to grow at an unsustainable rate. Treasury forecasts show that Australian Government expenditure alone will increase from 4% of GDP in 2009–10 to 7% of GDP in 2049–50. Health services research is important to increase the efficiency of health services and ensure health system sustainability.

Exhibit 2

Projected Australian Government health expenditure is unsustainable

Treasury Projections of Australian Government Health Expenditure¹

\$bn



Notes: 1. Excludes state and territory government health expenditure
 Source: Australian Government, *Intergenerational Report 2010*, Canberra, 2010

1 Australian Institute of Health and Welfare, Australian Bureau of Statistics.
 2 S Mak, *Evaluation of Health Programs: Application of Social Cost Benefit Analysis in the Pharmaceutical Benefits Scheme Listing of Australia*, Dissertation, 2005.
 3 J Raftrey, 'Paying for Costly Pharmaceuticals: Regulation of New Drugs in Australia, England and New Zealand', *Med J Aust*, 188 (1), 2008, pp.26-28.
 4 Australian Society for Medical Research (ASMR), *Exceptional Returns: The Value of Investing in Health R&D in Australia II*, prepared for ASMR by Access Economics Pty Ltd, Canberra, 2008.

Gains in health and well-being through research can provide significant economic benefits and lift workforce participation and productivity. Chronic disease alone affects about 3.4 million Australians, or a third of the working-age population. Addressing this with research would reduce annual costs of around \$30bn in direct costs and lost productivity annually.⁵

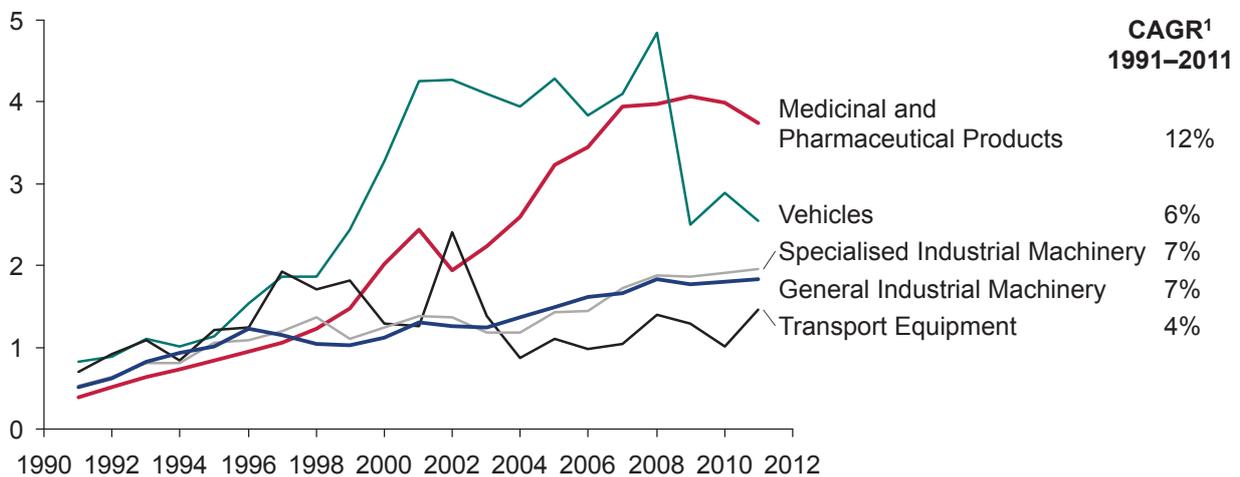
HMR also delivers significant economic benefits through commercialisation of research. The biotechnology industry in Australia now includes over 1,000 companies. A small subset of these companies is listed on the Australian Stock Exchange and comprises a total market capitalisation of \$32.6bn as at 31 December 2012.⁶ HMR has also underpinned growth in medical exports, which has become Australia's largest manufacturing export category, overtaking the motor vehicle industry in 2009.

Exhibit 3

Medicinal and pharmaceutical products have grown at 12% p.a. over the last 20 years and is now Australia's largest manufacturing export sector

Australian Manufactured Exports – Top Five Sectors

\$bn



Notes: 1. CAGR – compound annual growth rate
 Source: Australian Bureau of Statistics

1.2.3 Drive Shift to Knowledge-Based Jobs

The last 30 years have seen jobs in manufacturing and agriculture replaced by those in knowledge and knowledge-based industries, such as healthcare services. HMR is the key driver of productivity in the healthcare sector, in the same way that mining R&D increases mining productivity. The Australian HMR sector comprises over 23,000 research professionals⁷ who support a broader medicines industry of over 40,000 employees⁸ and a health sector of over one million workers.⁹ The HMR sector, therefore, plays a vital role in supporting high-value jobs which help to retain skilled professionals in Australia and attract outstanding talent from overseas.

1.2.4 Enhance International Standing and Engagement, Particularly with Asia

Australia should maintain its role as a global leader in HMR to foster international collaboration and innovation. As noted in the Australian Government's *Australia in the Asian Century White Paper*, Asia is the world's fastest growing science innovation zone and Australia will collaborate more with Asian countries in the future. In particular, Australia can leverage its research capability to solve healthcare challenges specific to the region and augment its influence.

5 R Mead, 'Health reform hasn't started', *The Australian*, 14 February 2011.
 6 Bloomberg 2013 Customised data extract.
 7 ASMR, *Planning the Health and Medical Research Workforce 2010-2019*, prepared for ASMR by Dr Deborah Schofield, 2009.
 8 Submission 108, Medicines Australia.
 9 IBIS World data request.

1.3 The World's Best Health System

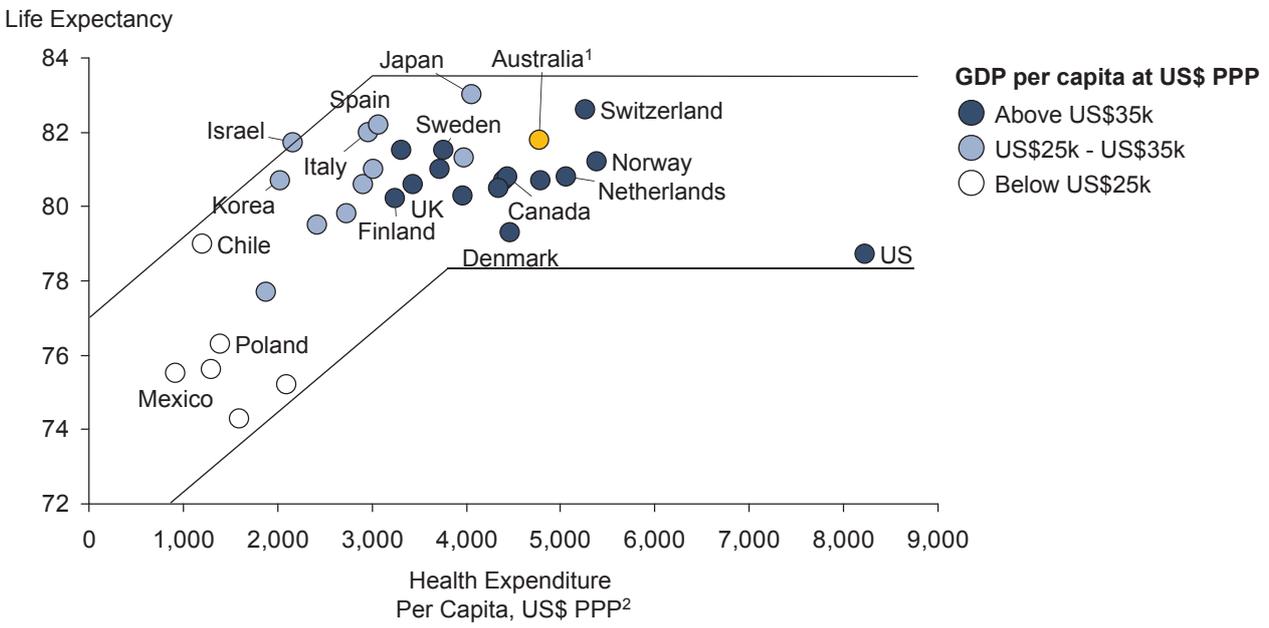
1.3.1 Build and Maintain the World's Best Health System

The Australian health system costs about \$135bn p.a. and delivers a life expectancy of around 82 years and a high quality of life. Australia has created a good health system at a reasonable cost, with only Japan, Italy and Spain achieving higher life expectancy at lower per capita cost. These international comparisons show that simply increasing healthcare expenditure will not necessarily lead to improved health outcomes.

Exhibit 4

Australia's health system delivers good outcomes for a reasonable cost

Life Expectancy Versus Health Expenditure 2010



Notes: 1. Australia's per capita GDP is above US\$35k
 2. PPP – purchasing power parity
 Source: OECD, Pacific Strategy Partners analysis

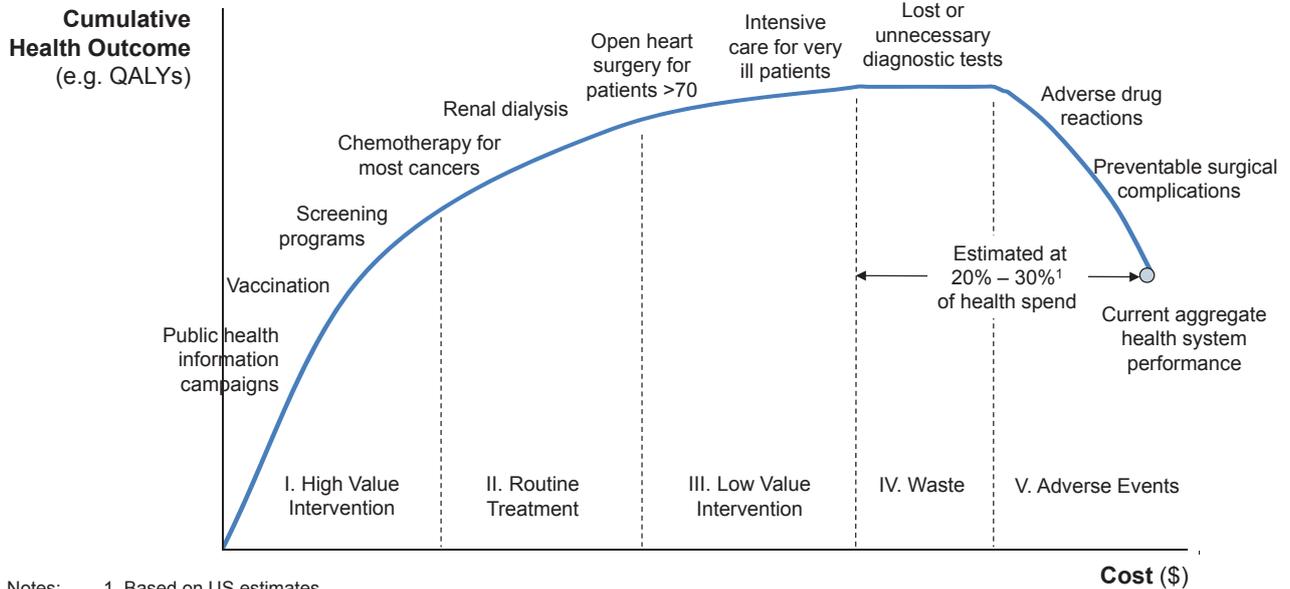
A more strategic investment approach can improve outcomes and control costs. The health system comprises millions of separate clinical interventions, each with different levels of productivity and cost-effectiveness. Some of these interventions are based on sound evidence of effectiveness, but since many are not, Exhibit 5 is indicative of the economics of the health system as a whole.

A more strategic approach would place greater emphasis on high-value interventions, such as vaccine development, and reducing adverse events that consume resources and reduce life expectancy. Health services research on the Australian health system must be a priority for identifying opportunities such as full compliance with hand-washing protocols (Case Study 1) that, by itself, could save up to \$2bn p.a. Research is an essential component of the Australian Government's health reforms that should be focused on healthcare productivity and effectiveness.

Exhibit 5

Health outcomes are driven by productivity and cost-effectiveness of interventions

Health System Performance



Notes: 1. Based on US estimates
 Source: Pacific Strategy Partners analysis; TO Tengs, et al, 'Five-hundred life saving interventions and their cost effectiveness', *Risk Analysis*, 1995, 15(3):369- 484; Institute of Medicine of the National Academies, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*, 2012; DM Berwick & AD Hackbarth, 'Eliminating Waste in US Health Care', *Journal of the American Medical Association*, 2012, 307(14):1513-1516; Pricewaterhouse Coopers (PWC) Health Research Institute, *The Price of Excess: Identifying Waste in Healthcare Spending*, 2008

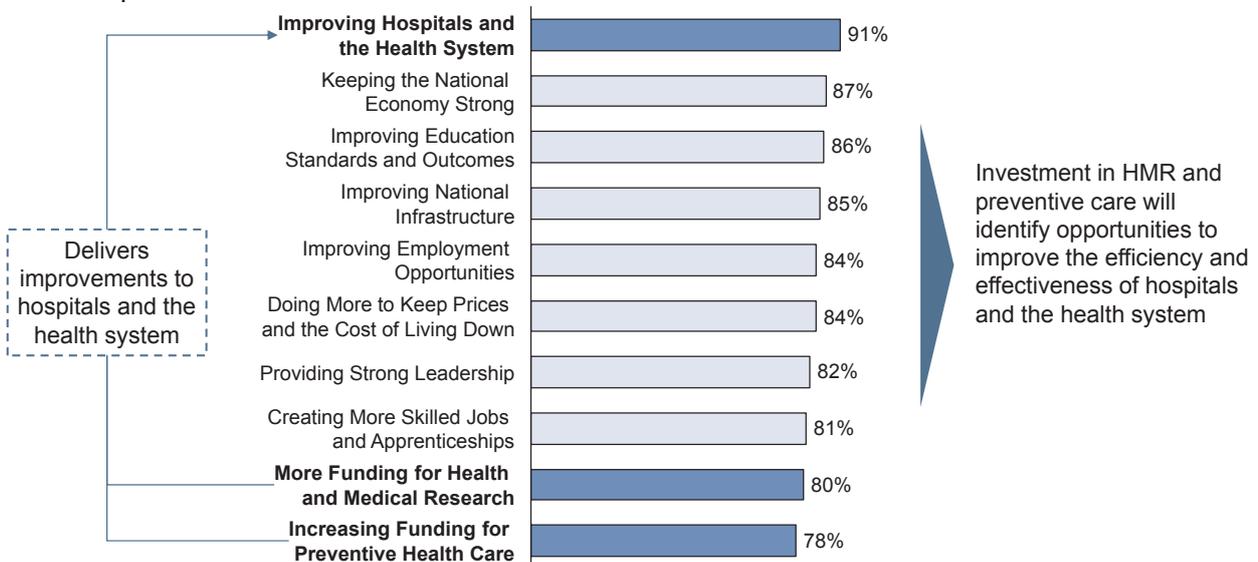
A recent survey conducted by Research Australia found that 91% of Australians considered that 'improving hospitals and the health system' should be the highest priority for the Australian Government.¹⁰ The related topics of more funding for HMR and increasing funding for preventive healthcare were the 9th and 10th priorities.

Exhibit 6

Australians believe that improving hospitals and the health system is the highest priority for the Australian Government

Consumer Survey Results – Top Ten Ranking of Priorities

% of Respondents¹



Notes: 1. Percentage of survey respondents who rated the importance of the issue as seven out of ten or greater
 Source: Research Australia, *What do Australians think about health and medical research? 2012 opinion poll – views of over 1,000 Australians*, 2012

10 Research Australia, *What do Australians think about health and medical research? 2012 opinion poll – views of over 1,000 Australians*, 2012.

CASE STUDY 1

Addressing healthcare-associated infections could save up to \$1–2bn p.a. in healthcare costs in Australia

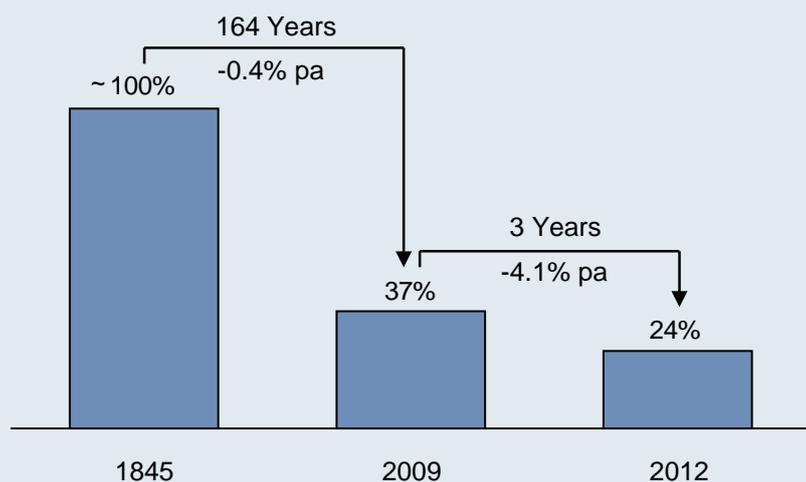
Background. Healthcare-associated infections (HAIs) are the most common complication during hospital stays and occur in 5%–15% of all admissions. HAIs occur as a result of poor hygienic practices, such as non-compliance with hand-washing guidelines and lack of adequate sterilisation during surgical procedures. HAIs not only inflict pain and suffering on patients, but impose significant but avoidable costs on the healthcare system.

International cost/benefit studies have highlighted significant benefits of hand-hygiene programs:

- Chen (2011) found a hand-hygiene program conducted at a 2,200-bed teaching hospital in Taiwan led to increased compliance rates from 43% to 96% over four years, preventing over 1,500 HAIs—a total saving of almost US\$8m.
- MacDonald (2004) found that the implementation of a hand-hygiene program in the plastic surgery unit of a district general hospital in the UK resulted in a 53% reduction of *Methicillin-resistant Staphylococcus aureus*. This yielded over £9 in savings for every £1 invested in addressing HAIs. Expanding the program to the medical, surgery and orthopaedic units increased the return to £20 for every £1 invested.

Australian Hand-washing Non-Compliance – Public Hospitals

% Non-Compliance Rate



Key Lessons:

1. **Health services research can identify opportunities to reduce healthcare costs.** Health services researchers have identified that there are more than 200,000 incidents of HAIs that occur annually, at a total cost of \$1–2bn p.a. to the healthcare system.
2. **Focused implementation programs accelerate research translation in the health system.** The Australian Commission on Safety and Quality in Health Care launched the National Hand Hygiene Initiative in 2009 to improve hand hygiene, with non-compliance rates in hospitals decreasing from 37% in 2009 to 24% in 2012.

Source: M Best & D Neuhauser, 'Ignaz Semmelweis and the birth of infection control', *The International Journal of Healthcare Improvement*, vol.13, 2004; National Health and Hospitals Reform Commission, *The Australian Health Care System: The Potential for Efficiency Gains (A Review of the Literature)*, NHHRC, 2009; NHMRC, *Australian Guidelines for the Prevention and Control of Infection in Healthcare*, 2010; N Graves, K Halton, D Paterson & M Whitby, *Economic Rationale for Infection Control in Australian Hospitals*, Queensland University of Technology, 2009; YC Chen, WH Sheng, JT Wang, SC Chang & HC Lin, *Effectiveness and Limitations of Hand Hygiene Promotion on Decreasing Healthcare-Associated Infections*, PLoS ONE, undated; A MacDonald, 'Performance feedback of hand hygiene, using alcohol gel as the skin decontaminant, reduces the number of inpatients newly affected by MRSA and antibiotic costs', *Journal of Hospital Infection*, vol.56, 2004

1.3.2 Deliver Evidence-Based Healthcare and Policy

Since HMR is the R&D arm of Australia's \$135bn p.a. health sector, research across the spectrum from biomedical to health services research has significant potential to improve health system outcomes and cost-effectiveness via three main levers:

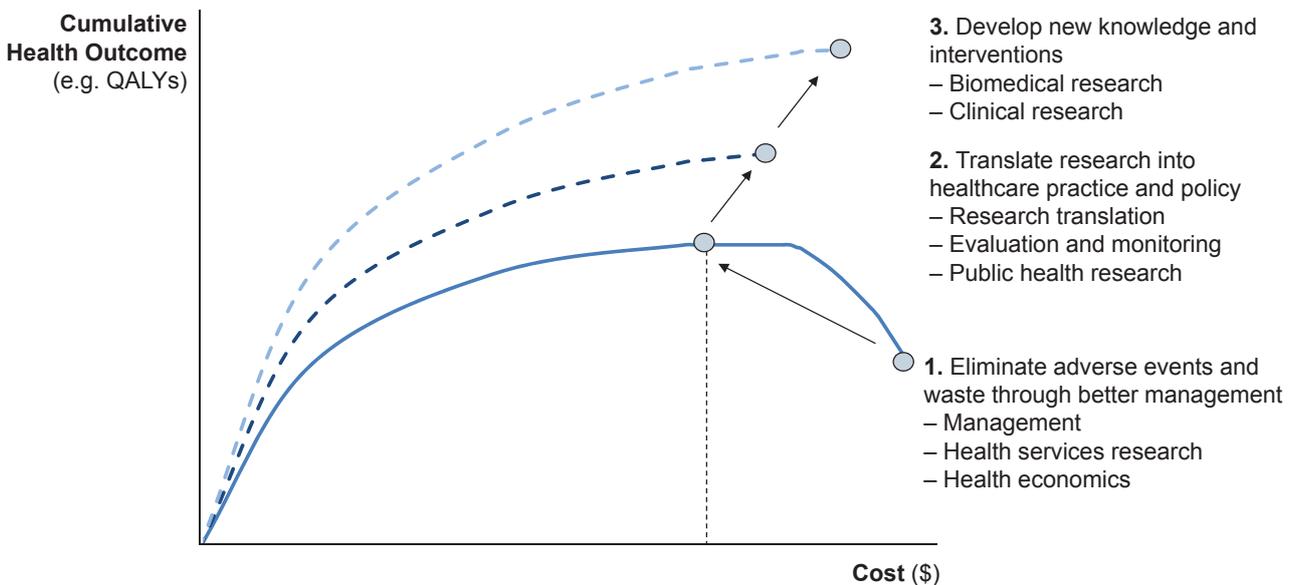
1. health services research to identify ways to minimise adverse events and waste
2. more effective research translation to improve healthcare delivery
3. new knowledge to create new clinical interventions.

Optimising each lever requires a holistic approach to embed research into the health system where clinical practice is based on evidence and research evidence is routinely translated into clinical practice.

Exhibit 7

Health outcomes can be improved by better management, increased research translation and new knowledge

Levers to Improve Health System Performance



Source: Pacific Strategy Partners analysis

1.4 A World-Class HMR Sector

1.4.1 Leverage and Extend Reforms

The vision for HMR leverages and extends on the reforms following the 1998 Wills Health and Medical Research Strategic Review that created a fundamental shift towards competitive grants and increased the quality of research across the sector. The next phase of reform will be defined by a continued focus on high-quality research, with an increased emphasis on translational impact and a more strategic approach to target Australia's highest priority HMR issues. It is important that Australia maintains capabilities across the full spectrum of research, from biomedical and clinical research to public health and health services research.

The 10-year strategy also strongly ties into the overarching objectives of the Australian Government's 2012 National Research Investment Plan, to translate research outcomes into public and private benefits through increasing the stock of knowledge, developing new applications and innovating through implementation of new products and processes.

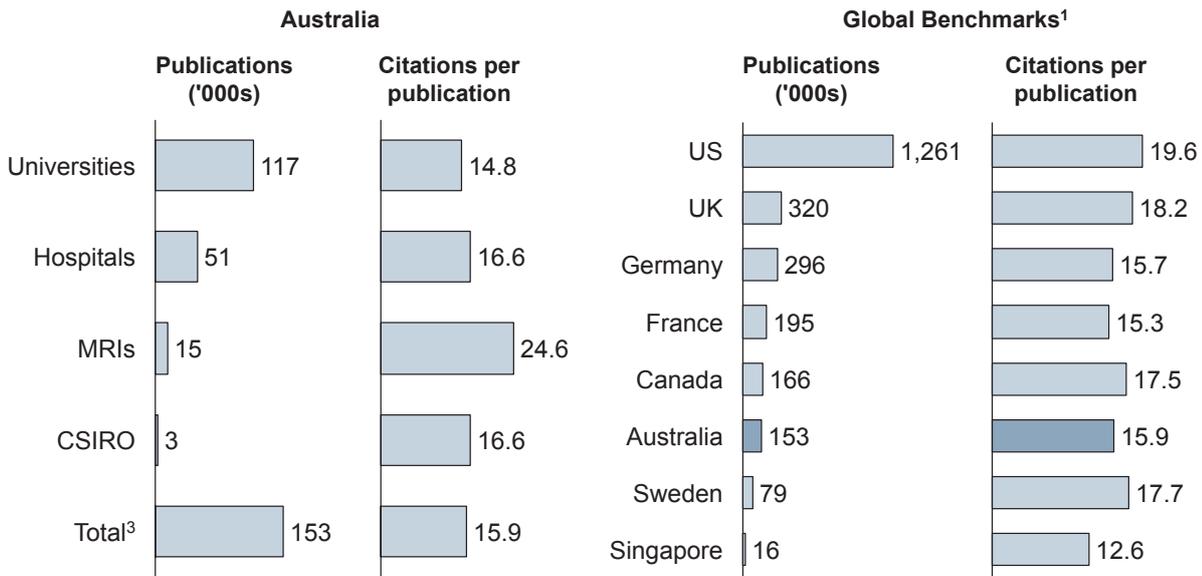
1.4.2 Maintain World-Class Research

Australia ranks highly against a range of international benchmarks for HMR, 'punching above its weight' in publication output, with relatively high citation rates. This performance is due to long-term investment in HMR and active reform to improve its effectiveness—particularly over the last decade.

Exhibit 8

Australia's health and medical research output is highly cited, particularly from MRIs

Health and Medical Research Bibliometrics Overview 2001–10 Total



Notes: 1. Covers journals in HMR-related fields (Biology & Biochemistry, Clinical Medicine, Immunology, Molecular Biology & Genetics, Neuroscience & Behaviour, Pharmacology & Toxicology)
 2. Australian figures in international dataset aligned to domestic (CPP difference of 15.9 vs. 15.4 and number of publications of 153k vs. 107k)
 3. Sum of segments do not add to total due to double counting
 Source: Thomson Reuters

1.4.3 Focus on Translation and Impact

Australians value investment in HMR because it delivers impact in the form of better health outcomes. Accordingly, there is need for greater translational research, including health services research that identifies opportunities and strategies to increase health system efficiency and research into evidence-based healthcare and policy. Australia should also build capability in driving top-down strategic research to focus the best researchers on the most important issues.

1.4.4 Monitor Investment and Outcomes

To deliver optimal returns on HMR investment, it is critical to track and monitor both investment and outcomes. While total investment in HMR is not known, it is estimated to be over \$6bn in 2012. Apart from the NHMRC competitive schemes, the rest of the total investment of \$6bn is not adequately tracked and its outcomes are unclear. In particular, understanding the HMR investment in Local Hospital Networks (LHNs), estimated to be \$1.0–1.5bn p.a., should be a priority, given it is critical to helping to establish a culture of continuous improvement that will deliver evidence-based healthcare.

Currently, there are no formal processes to evaluate the research performance of LHNs. Evaluating and tracking research outcomes will assist in driving the required cultural change towards an impact-oriented mindset, while also increasing the accountability of health professional researchers.

1.5 Strategy

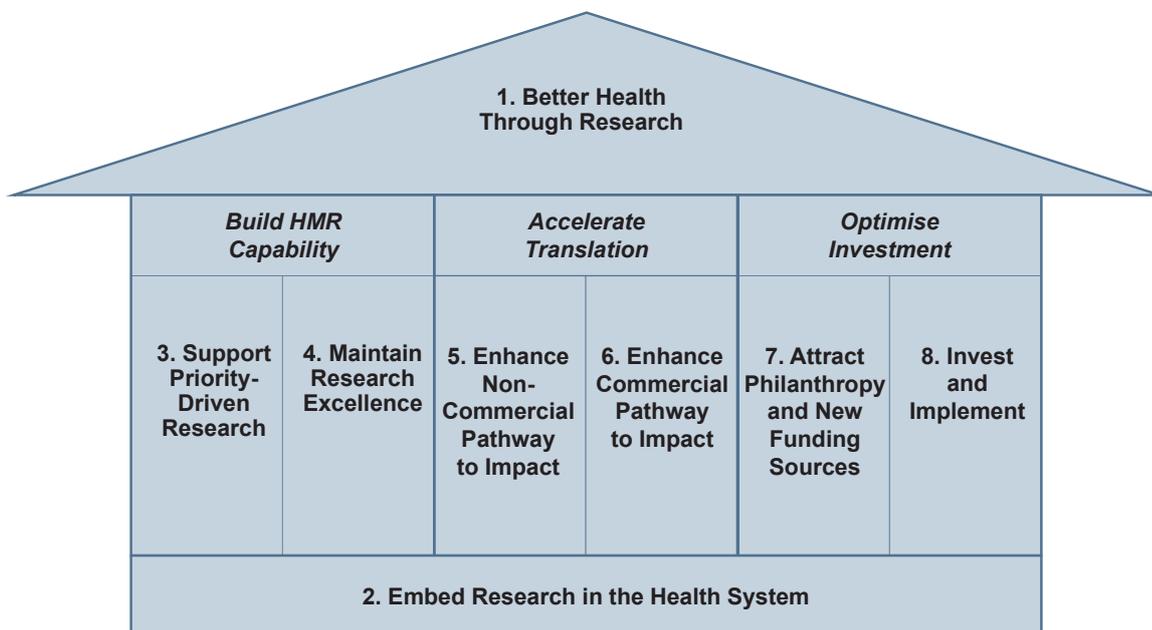
1.5.1 A New Strategy

Implementing a new strategy to embed research in the health system over the next 10 years will deliver the vision to build and maintain a healthy and wealthy Australia that has the world's best and most efficient health system. The 10-year strategy is built upon a number of themes that focus on building HMR capability, accelerating translation and optimising investment. Embedding research in the health system will provide the necessary foundation to support these themes and deliver impact.

Exhibit 9

To achieve the vision of 'Better Health Through Research', the 10-year strategy builds upon a number of themes

HMR Strategy

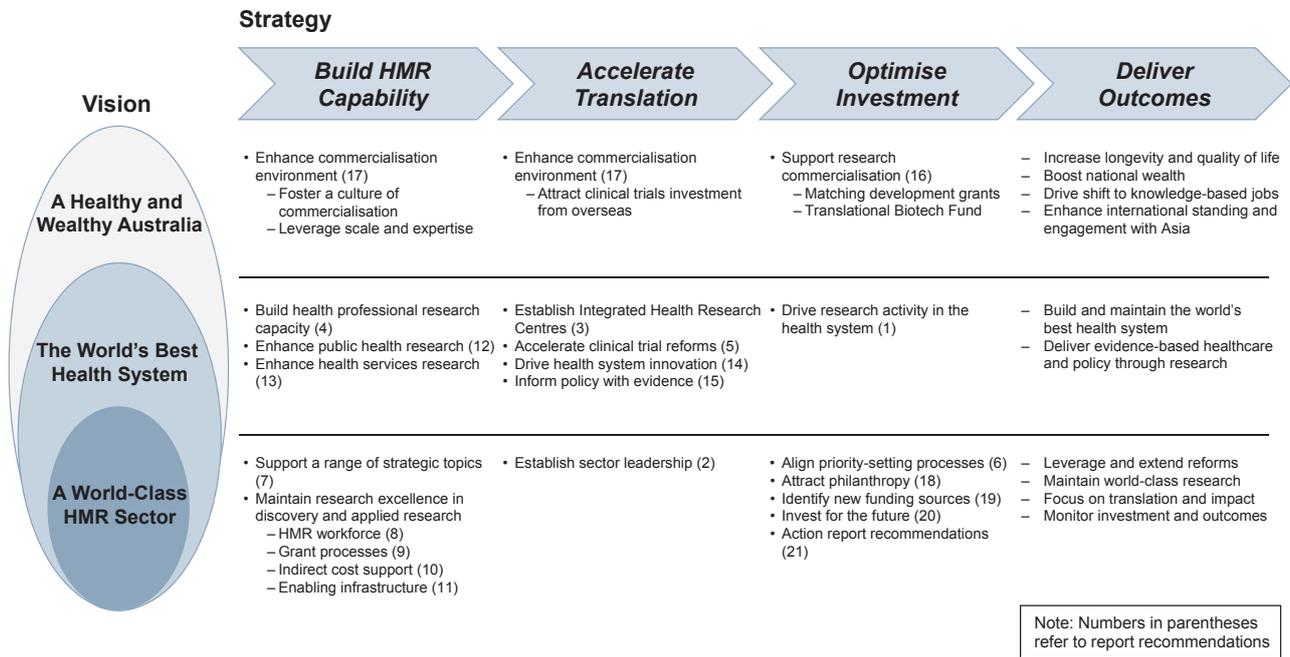


The strategy will deliver the vision to build and maintain a healthy and wealthy Australia with the world's best health system, and achieve the aspirational outcomes discussed in Section 1.1. Maintaining the current course of direction or reducing investment would carry a number of risks which are detailed in Section 8.2.3. The themes and initiatives that form the strategy are covered in detail in the following sections.

Exhibit 10

The 10-year strategy will deliver the vision's aspirational outcomes

Strategic Initiatives



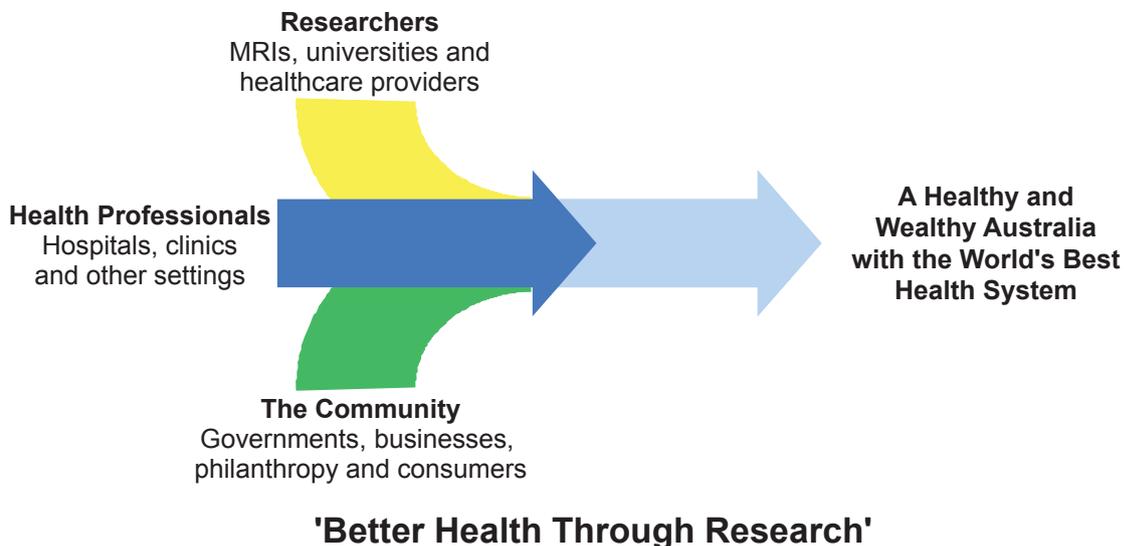
1.5.2 Delivery Through Partnerships

The vision calls for strengthened partnerships at many levels—health professionals across various settings, the Australian Government, state and territory governments, businesses, philanthropy, consumers and, of course, researchers themselves—so that all stakeholders can work together to embed research in the health system and deliver the vision of 'Better Health Through Research'.

Exhibit 11

The vision calls for strengthened partnerships between researchers, health professionals and the community

Delivery Through Partnerships



2. EMBED RESEARCH IN THE HEALTH SYSTEM

2.1 Introduction

While Australia performs groundbreaking HMR within its universities, research institutions and companies, increasing pressure to deliver healthcare services has restricted research activity in the health system. This pressure has also created barriers for research translation into better care through evidence-based clinical and health interventions. The aim of embedding research into healthcare delivery is to involve the health delivery workforce in research, with the result that it will be a routine and universally-accepted component of healthcare and create a Kaizen¹¹ or continuous improvement mindset in the health system. Ultimately, this will lead to better health for consumers, which encompasses greater wellness and reduced illness, and a more efficient and sustainable health system that delivers this.

Exhibit 12

Health and medical research should be fundamentally embedded in the health system with major changes to five key areas

Role of HMR in the Health System



11 A Japanese business philosophy advocating the need for continuous improvement.

2.2 Drive Research Activity in the Health System

2.2.1 Introduction

In August 2011, the Australian Government entered into the National Health Reform Agreement (NHRA) with state and territory governments under which it agreed to increase its contribution to efficient growth funding for public hospital services to 45% from 1 July 2014 and to 50% from 1 July 2017. The primary mechanism to deliver this funding increase is through an Activity Based Funding (ABF) system, with efficient prices for the delivery of hospital services set by the Independent Hospital Pricing Authority (IHPA). Teaching, training and research (TTR) will also be provided as a component of NHRA funding. The current allocation for TTR block funding is 3.68% of Australian Government hospital funding. The mechanism for funding TTR activities under NHRA has yet to be determined and IHPA is expected to provide advice on this by no later than 30 June 2018.

2.2.2 Manage and Refocus Research in Local Hospital Networks

In initiating its recent health reforms, the Australian Government acknowledged that 'funding pressures in public hospitals have often resulted in limited funding for non-consumer services such as research and training, which are essential to building the specialist workforce for the future and retaining expertise within the public hospital system'.¹² Funding originally designated for research is often reallocated by hospital managers to other areas of healthcare delivery, particularly where pressure exists to reduce waiting times for publicly-funded health services.

With the new reform agreement, there is a major risk that tighter management of clinical services via ABF will further squeeze research activity, as it will be one of the few remaining sources of discretionary funding. Conversely, a well-managed research program has the potential to address significant opportunities to increase clinical efficiency and effectiveness. There is a clear need for increased focus on protecting, embedding and monitoring research in Australia's major healthcare institutions and other clinical settings.

2.2.3 Add Competitive Programs

The Panel proposes that a suite of competitive programs be added that would be aimed at a much broader range of researchers than under current programs. National competitive programs are the best mechanism to ensure resources flow to the most productive researchers and the most promising research ideas within the health system. There are a number of competitive programs proposed:

- establish Integrated Health Research Centres (IHRCs) (Section 2.4)
- build health professional research capacity (Section 2.5)
- enhance public health research (Section 5.2)
- enhance health services research (Section 5.3)
- support non-commercial clinical trials (Section 5.4.2)
- inform policy with evidence (Section 5.5).

2.2.4 Establish a National HMR Investment Target

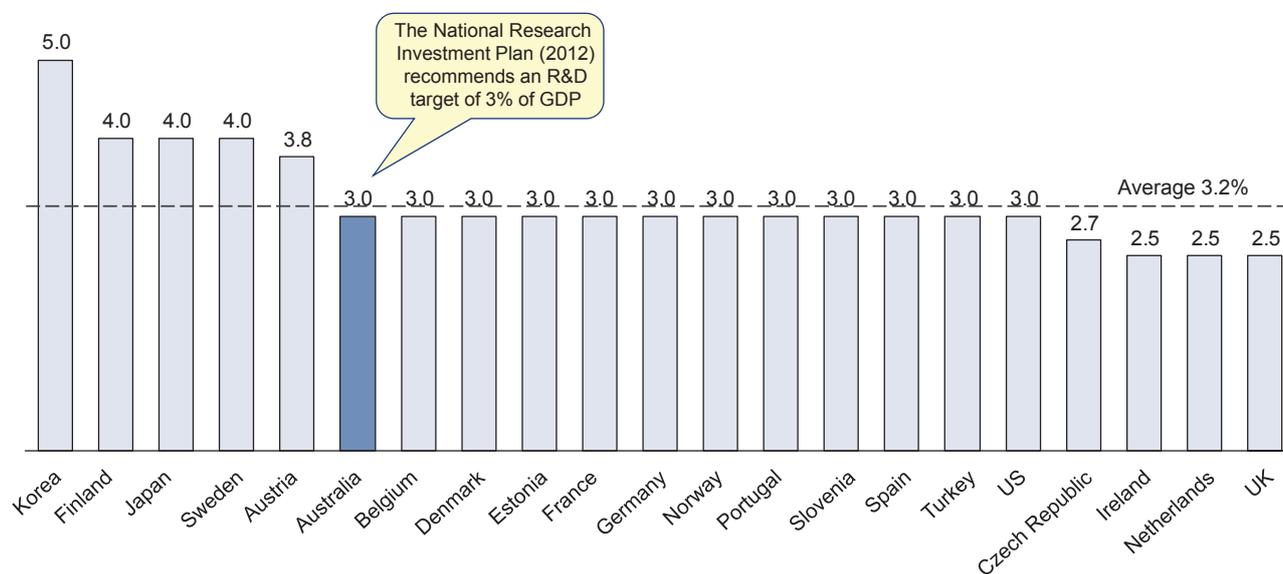
As discussed in Chapter 1, HMR is the R&D arm of the health sector and is responsible for delivering system and service improvements. Defined and well-managed HMR activity should be a key performance indicator for the health system, with cascading targets for state and territory governments, and LHNS.

12 National Health and Hospitals Network, *A National Health and Hospitals Network for Australia's Future*, 2010.

Exhibit 13

Leading OECD countries have adopted R&D targets of at least 3% of GDP

Target R&D Benchmarks for Top 20 OECD Nations – Country Targets (Not Actual) % GERD of GDP



Notes: 1. GERD – Gross expenditure in research and development
Source: Australian Government, *National Research Investment Plan*, 2012; OECD; UNESCO

The Panel recommends the Australian Government adopt a minimum R&D target of 3%–4% of total Australian and state and territory government health expenditure on defined and well-managed HMR. The majority of OECD countries have set overall R&D targets of 3%, and across sectors for R&D investment, it would be reasonable to expect that healthcare warrants a higher level of investment as a key knowledge-based industry. The R&D goal will provide a mechanism to ensure that the level of research funding remains linked to the health needs of the community.

The benchmark should be defined to encompass the following three areas of HMR expenditure.

- 1. Research in LHNs.** HMR undertaken in acute health delivery settings is likely to create a culture of continuous learning and improvement that encourages evidence-based practice.
- 2. Existing NHMRC Medical Research Endowment Account (MREA).** The NHMRC MREA delivers high-quality research and includes a range of research that can have short-term and long-term impacts on the health system.
- 3. Health system competitive programs.** New HMR competitive schemes aimed at driving impact in the health system are likely to significantly improve health outcomes for Australians and increase the cost-efficiency of health services.

The current R&D benchmark level (as defined above) is around 2.0% of health expenditure, based on an estimate of \$1.1bn of research in LHNs and \$0.8bn of the existing NHMRC MREA. Investment should be increased to 3%–4% of health expenditure over the longer term through the introduction of new competitive programs, provided the initial programs deliver good results.

Recommendation 1: Drive Research Activity in the Health System. Optimise current HMR investment and over the longer term, monitor and manage 3%–4% of total Australian Government and state and territory government health expenditure on HMR.

- a. Manage and refocus current state and territory government Local Hospital Network (LHN) HMR investment, using the National Health Reform Agreement to strengthen and build upon the approximately \$1.0–\$1.5bn p.a. estimated HMR investment in the health system, and set research key performance indicators for LHN (or groups of LHNs) and hospital CEOs.
- b. Add competitive programs (outlined in other recommendations) to provide an additional \$1.5bn p.a. for research in the health system within 10 years.
- c. Establish a national health system R&D investment target of 3%–4% of government health expenditure (including HMR in LHNs, the National Health and Medical Research Council Medical Research Endowment Account, and new competitive programs) and, over the longer term, progress towards this benchmark.

2.3 Establish Sector Leadership and Governance

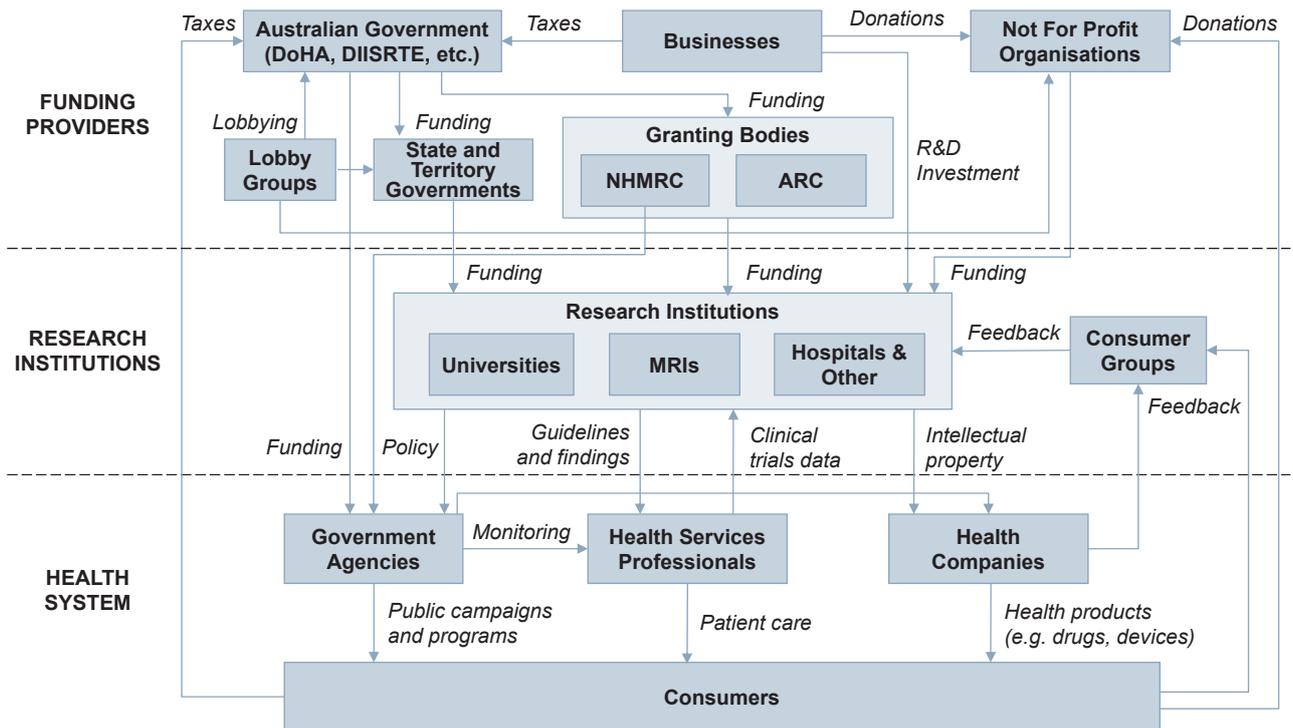
2.3.1 Introduction

While the HMR sector is complex and comprises various stakeholders and types of activities, there is no true leader for the sector. A single entity should assume the role of champion for HMR, drive key reforms across the sector and unite major stakeholders. The lack of accurate statistics on HMR, particularly research conducted in the health system, is one of the consequences of the current lack of national leadership.

Exhibit 14

The health and medical research sector is complex and comprises various stakeholders and types of activities

HMR Funding and Activity Flows



2.3.2 Establish Sector Leadership

There are two main options to establish the leadership needed to deliver the vision and aspirational outcomes, and coordinate activities to drive the efficiency and effectiveness of the sector:

1. Task the NHMRC with complete oversight and leadership of HMR (in addition to its current role) and resource it appropriately.
2. Establish a new 'Office of Medical Research' that sits separately from the NHMRC and leads and champions the sector (while NHMRC retains its current role).

While consideration has been given to the possibility of establishing a new body to drive leadership, the Panel is inclined towards the approach of re-tasking a revamped and expanded NHMRC with a leadership role. The NHMRC does not, however, currently have the capacity and capability to drive leadership across the sector, and changes would be required to NHMRC's mandate, governance and resources to enable it to assume the role of a true sector leader. In addition, there is a need for increased NHMRC independence and representation from state and territory governments that are responsible for health services delivery. To address this, the current NHMRC governance structure of an advisory council should be modified to that of the more common board structure that is accountable for management and operations.

The HMR leadership body, regardless of the option selected, should have a board and include members at an equivalent responsibility level to departmental secretaries sitting on the Australian Health Ministers' Advisory Council (AHMAC). Ideally the HMR leadership body should also play a greater role in the Council of Australian Governments (COAG) Standing Council on Health (SCoH) and AHMAC health system.

Exhibit 15

There are various responsibilities that could be assumed by the new HMR leadership body

Key Leadership Responsibilities

Responsibilities	Description	Potential Body
1. Overall Sector Leadership	Assume role of champion, drive sector reform, provide governance, increase public engagement	NHMRC, New Office of Medical Research
2. National HMR Priorities	Set the national HMR agenda and coordinate activity, particularly for urgent health issues	NHMRC, COAG SCoH, New Office of Medical Research
3. Policy Advice	Advise Australian and state and territory governments on health and medical policy	NHMRC, possibly a new Academy of Health Science
4. Research Translation	Drive research translation in the health system	NHMRC, COAG SCoH, New Office of Medical Research
5. IHRC Selection	Determine criteria and select centres	NHMRC, COAG SCoH, New Office of Medical Research
6. Monitoring and Evaluation	Track HMR investment across sector and evaluate performance outcomes/impact	NHMRC, AIHW or ABS
7. Clinical Trials Reforms	Implement clinical trials reforms	NHMRC, CTAG Coordination Group, AHMAC
8. Review Implementation	Implement recommendations of this Review over the next 10 years and beyond	NHMRC, New Office of Medical Research
9. Consumer Engagement	Engage consumers and involve in priority-setting, clinical trials and patient database participation	NHMRC, AIHW

2.3.3 Track Investment and Evaluate Outcomes

While understanding the growth and composition of HMR investment is critical to driving any improvement efforts across the sector, this area remains poorly understood.

- Australian Government – HMR spend is well tracked for competitive grants, data on Department of Health and Ageing (DoHA) expenditure is reported in aggregate.
- State and territory governments – direct support is well understood, but indirect support via the health system is generally not measured, and unlikely to be well managed.
- Business investment – reasonably well managed as it is deployed largely in the commercial sector and tracked by the Australian Bureau of Statistics (ABS) via annual surveys.
- Philanthropy – currently only partially tracked via a survey conducted by Research Australia every few years, and could be spent more effectively through increased scale and collaboration, and better tracking of investment and outcomes.

Systematic tracking of investment and expenditure in the HMR sector should be overseen by the new HMR leadership body and possibly carried out by a lead Australian Government agency, such as the Australian Institute of Health and Welfare (AIHW) or ABS.

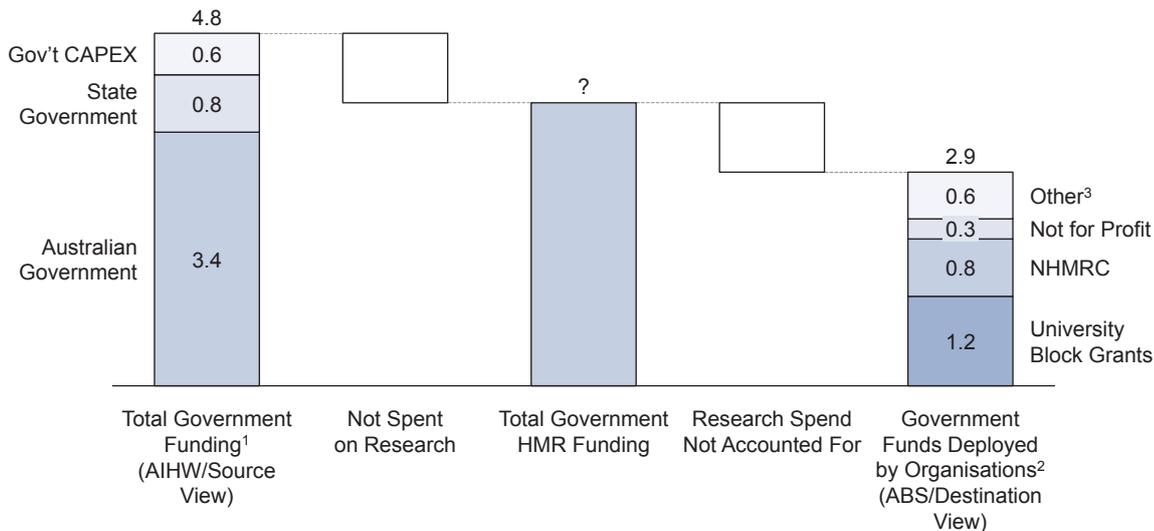
Exhibit 16

Total government investment in HMR is likely to be between ~\$3 to \$5bn

Total Government HMR Expenditure – Reconciliation¹

\$bn

2011–12e



Notes: 1. Based on AIHW health expenditure figures. Gov't CAPEX (capital expenditure) is an estimate based on ABS data across all research areas
 2. Based on ABS R&D expenditure estimates by sector and source of funds and other sources
 3. Other includes CSIRO, MRI infrastructure, DoHA, ARC Discovery Projects, ARC SRIs, RIBG to universities, CRCs
 Source: AIHW Health Expenditure; ABS Research and Experimental Development 2008–09; research organisations

Recommendation 2: Establish Sector Leadership and Governance. Establish and resource a leadership body to work with key organisations charged with delivering better health services.

- Provide direction, focus, oversight and leadership of the HMR sector.
- Facilitate translation of research into evidence-based healthcare and policy.
- Provide policy advice and drive sector reforms.
- Track and monitor HMR investment and outcomes.

2.4 Establish Integrated Health Research Centres

2.4.1 Introduction

Clusters dominate global creative output in many industries (e.g. Hollywood and Silicon Valley). HMR clusters are typically characterised by co-location and collaboration of researchers in universities, MRIs, hospitals and other health service providers, and are found in all leading healthcare countries, such as the US, UK and Canada. One of the leading examples is Johns Hopkins Medicine, which for many decades has fully integrated healthcare, research and education.

2.4.2 NHMRC Model of Advanced Health Research Centres

In December 2010, NHMRC released a discussion paper promoting 'Advanced Health Research Centres', and is proposing to invite consortia of universities, hospitals and MRIs to apply for recognition of excellence. While this is an excellent initiative, no funding was provided and it is not clear whether recognition alone would be a sufficient incentive for genuine clusters to emerge and thrive.

2.4.3 Proposed Integrated Health Research Centres

Research clusters are one of the key drivers for the vision of embedding research in the health system. The Panel's proposal is for funded IHRCs to integrate research excellence with healthcare services delivery and facilitate best-practice translation of research into healthcare practice. Supported by a strong governance model that facilitates collaborative partnerships, IHRCs would bring together researchers within universities, MRIs and health services (e.g. acute care, primary care, aged and community care), and ensure cooperative access to skilled professionals, infrastructure, patient data and a capacity to implement change. In certain circumstances (e.g. Indigenous and rural and remote research), these may operate as a virtual IHRC.

The Panel recommends establishing a rigorous, national, competitive IHRC selection process around five key criteria.

1. **Integrated and clustered** – represents collaboration across key stakeholder types, with infrastructure shared and preferably geographically co-located.
2. **World-class** – demonstrates research excellence and global relevance.
3. **Translation-focused** – at the forefront of translation and evidence-based healthcare.
4. **Shared vision and strategy** – a common vision and shared strategy to deliver impact.
5. **Strong leadership and governance** – a strong leadership team and governance model.

Recommendation 3: Establish Integrated Health Research Centres. Establish and fund Integrated Health Research Centres (IHRCs) that combine hospital and community-care networks, universities, and research organisations such as medical research institutes (MRIs).

- a. Establish a clear set of criteria around integration, excellence, translation, strategy, leadership and governance.
- b. Initially select 4–8 IHRCs and provide funding of up to \$10m p.a. each for five years, and add 1–2 IHRCs every 1–2 years, building to a total of 10–20 over a 10-year period.
- c. Monitor and evaluate the performance of the IHRCs to determine whether funding should be renewed at the end of the five-year funding period.

2.5 Build Health Professional Research Capacity

2.5.1 Introduction

Research capacity within the health professional workforce is critical for both conducting research and driving the translation of research into evidence-based healthcare. Health professionals are closest to consumers and therefore have a key role in identifying important research questions and gaps in healthcare practice and the evidence base. Similarly, health professionals are in many cases the conduit through which research needs to be implemented and hence have a key role to play in facilitating the translation of research into evidence-based healthcare.

2.5.2 Promote Research Participation by Health Professionals

The current system does not adequately facilitate, incentivise or support research by the clinical workforce. Research is rarely financially rewarding for health professionals, who face increasing pressure to deliver clinical services rather than research. Protected research time through practitioner fellowships is required to ensure the best health professional researchers remain active in research. Health professionals with a track record in research would be the primary target, and the program could be extended to junior health professionals in training under the guidance of senior researchers. There is also a pressing need for health professionals to spearhead the efforts of translating research into evidence-based healthcare practice. As part of establishing a culture of continuous improvement, practitioners should be encouraged to disseminate knowledge of research findings and best-practice healthcare through the establishment of health professional research networks.

2.5.3 Train Health Professionals in Research

There is also a lack of research capability within the broader health workforce. Research training should be further enhanced with the establishment of dual accreditation programs to facilitate and encourage research-practitioner career pathways. Examples of successful models overseas include prestigious MD–PhD programs supported by the US National Institutes of Health (NIH) and run by most top medical schools in the US.

2.5.4 Facilitate Entry of Overseas Professionals

Participation in research by leading overseas health research professionals is constrained by restrictions on obtaining visas and issues with accreditation of international medical graduates. The use of workplace-based assessment for peer review of international medical graduates would assist in addressing these issues, as was recommended by a House of Representatives committee report in March 2012.¹³

Recommendation 4: Build Health Professional Research Capacity. Build and support health professional researcher capacity and capability.

- a. Support 100 research-focused health professionals with practitioner fellowships and competitive grants and, if successful, increase up to 1,000 over the next 10 years.
- b. Embed research into health professional training and accreditation, and support dual research-practitioner education pathways.
- c. Streamline medical practitioner accreditation processes for leading overseas research professionals.

¹³ On 19 March 2012, the House of Representatives Standing Committee on Health and Ageing tabled its report on the inquiry into Registration Processes and Support for Overseas Trained Doctors entitled *Lost in the Labyrinth: Report on the inquiry into registration process and support for overseas trained doctors*. URL: http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=haa/overseasdoctors/report.htm.

2.6 Accelerate Clinical Trial Reforms

2.6.1 Introduction

The process of conducting clinical trials is an important research methodology that tests the safety and efficacy of health interventions, generally in a clinical setting. Australia has become one of the most expensive locations for clinical trials in the world and is inefficient in ethics approvals and governance processes. For Australia to remain globally competitive, it is imperative that clinical trial processes are reformed to address major constraints of clinical trial approvals, perceived governance risks, inadequate infrastructure and access to patient data.

2.6.2 Build on CTAG Report Recommendations

The 2011 Clinical Trials Action Group (CTAG) report, *Clinically Competitive: Boosting the Business of Clinical Trials in Australia*, set out recommendations covering ethics review and research governance, the cost recovery of efficient clinical trials, linkage with e-health system and patient recruitment and clinical trials coordination. The Panel supports the CTAG recommendations and notes additional areas that should be addressed.

- Clinical trial processes are manual, inefficient, and inconsistent. Online workflow solutions can standardise and manage processes and enable virtual ethics review.
- Ethics approval processes are inconsistent and often take longer than the target 60-day benchmark. Best-practice examples are the Western Institutional Review Board in the US and Bellberry Limited in Australia, with average turnaround times of eight and 20 days respectively. Rationalisation to 8–10 national professionalised ethics review panels using a similar model to these companies is needed.
- Indemnity risks may encourage continued use of local ethics committees. To mitigate risks and reduce costs, a national insurance scheme should be established to cover damages.
- The current clinical trial consumer recruitment portal lacks functionality, has low uptake and should be improved.

2.6.3 Drive a National Implementation Approach

There are currently two approaches to streamlining clinical trials.

1. **CTAG Coordination Group.** A CTAG Coordination Group, comprising Australian Government and state and territory government agencies, as well as industry stakeholders, consumer representatives and researchers, was formed in May 2011 to assist in implementing CTAG's recommendations.
2. **State-based systems and Eastern Seaboard Memorandum of Understanding (MOU).** The health departments of Queensland, New South Wales and Victoria have signed an MOU that builds on each state's existing ethical review processes and recognises multicentre ethics review in public hospitals. This MOU agreement will soon be extended to South Australia.

While the CTAG and state-based approaches have resulted in some progress, neither approach has tackled end-to-end streamlining of ethics approvals and governance, or resulted in a nationally consistent set of standards and processes. A national, centralised approach is required, and the Panel recommends establishing a national Office of Clinical Trials that forms part of the HMR leadership body and reports directly to the CEO to drive implementation.

Recommendation 5: Accelerate Clinical Trial Reforms. Build on the Clinical Trials Action Group report recommendations and drive a national implementation approach to clinical trial reforms.

- a. Develop an online approval workflow system and enhance the existing consumer recruitment portal.
- b. Establish 8–10 national ethics committees to replace the proliferation of local committees.
- c. Implement a national clinical trials liability insurance scheme.
- d. Create a national clinical trials office within the HMR leadership body to drive reforms.

3. SUPPORT PRIORITY-DRIVEN RESEARCH

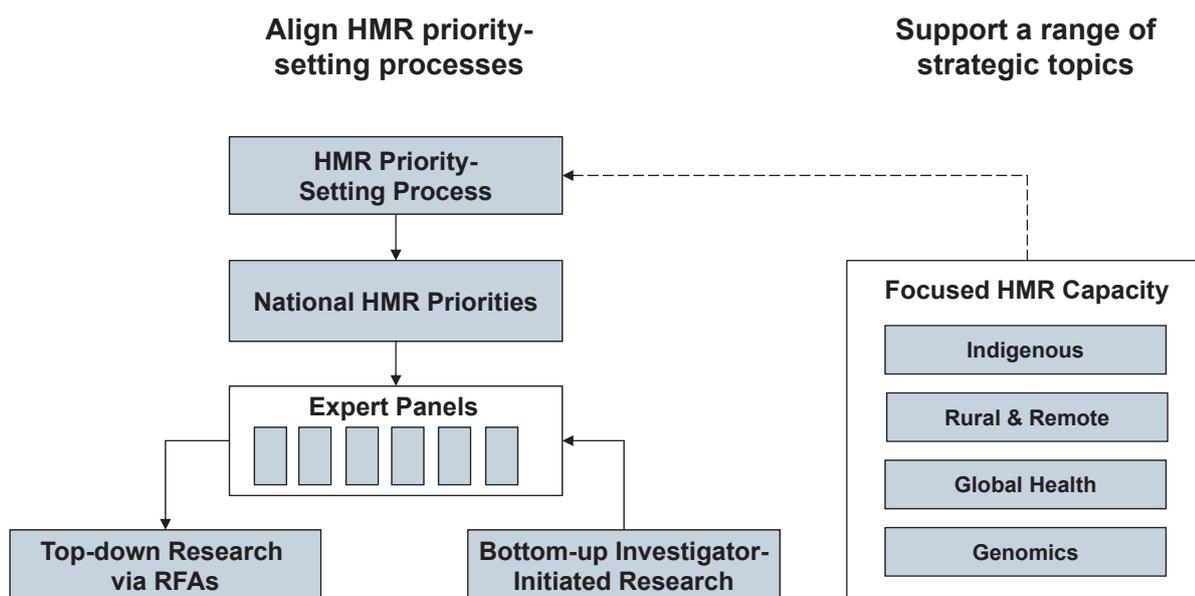
3.1 Introduction

While Australia has various priority frameworks, none has been effectively leveraged to drive top-down strategic research. Strategic focus through request for applications (RFAs) can ensure that the highest priority research questions are identified and addressed with the best possible research. The Juvenile Diabetes Research Foundation demonstrates the benefits of adopting a strategic priority-driven research agenda which, as a result, significantly accelerated the development of a cure (Case Study 2). Strategic priority-driven research should leverage a mix of top-down research via RFAs and bottom-up investigator-driven research. In addition, focused capacity-building efforts should be undertaken in a select number of strategic topics that require urgent attention.

Exhibit 17

Priority-setting will leverage a mix of top-down and bottom-up HMR, while strategic topics will ensure capacity-building in key areas of need

Priority-Driven Research



There are a number of overseas examples, such as in the US and Canada, where the primary research funding body is organised around institutes (physical or virtual) that focus on broad priority themes. These institutes are given responsibility to identify priority areas, deploy funding and leverage external sources of funding. The model of devolving part of the responsibilities for funding to a set of priority-focused virtual institutes would be well suited for adoption in Australia.

3.2 Align Priority-Setting Process

The purpose of HMR is to improve health outcomes and, as such, strategic decisions should influence research directions. This should augment the investigator-initiated approach to focus resources on the most promising research directions, with a broad engagement process. An overarching set of national health research priorities should be established and reviewed on a triennial basis by the HMR leadership body in conjunction with COAG SCoH.

To address the lack of strategic priority-driven research, a portion of the NHMRC MREA, possibly 10%–15%, should be allocated to fund top-down, strategic, priority-driven research through RFAs. In addition, a panel of experts should be established for each priority area to assume primary funding responsibilities in that area and drive the research and translation agenda.

Recommendation 6: Align Priority-Setting Process. Establish, fund and create a structure around a set of national HMR priorities.

- a. Set national HMR priority areas through the leadership body and the Council of Australian Governments Standing Council on Health on a triennial basis.
- b. Allocate a defined portion of the NHMRC Medical Research Endowment Account budget (10%–15%) to priority areas for 'top-down strategic research'.
- c. Create a panel of experts for each priority area to set the research agenda, leverage funding and evaluate outcomes.

3.3 Support a Range of Strategic Topics

3.3.1 Introduction

Submissions to the Review identified a range of specific topics for research attention. Those most frequently cited included the social determinants of health, primary care research, medicines clinical research,¹⁴ health impact of climate change, and preventive medicine. The Panel suggests that these topics, and others, would be candidates for consideration as national priority areas. While the Panel was not tasked with identifying national health research priority areas, in the course of its Review it became obvious that there were four areas that the Panel recognised as potentially representing national health research priorities. These are described in the following sections.

3.3.2 Support Indigenous Health Research

Indigenous health has clearly been recognised as an area for priority funding and action in HMR over the last decade. Indigenous HMR is difficult to fund due to the longer-term timeframes involved, the need for researchers to visit and develop close relationships with the community, and the need to understand the delivery of health services. A national integrated network or virtual IHRC for performing Indigenous health research is needed in conjunction with targeted researcher training and capacity-building.

3.3.3 Support Rural and Remote Health Research

Almost one third of Australia's population lives in non-metropolitan settings, and rural and remote communities experience significantly worse health outcomes than metropolitan populations. Research capacity should be built up and better organised to focus on understanding and addressing this gap, with a national integrated network or virtual IHRC to lead these efforts.

¹⁴ For example, there are substantial gains to be made in using current medicines more effectively while, in contrast to drug discovery, research into older medicines is not generally funded by industry.

3.3.4 Support Global Health Research

Australia has an important role to play in global health research in the Asia-Pacific region and internationally, and can leverage its strengths in areas such as tropical medicine and immunology. The Australian Agency for International Development has proposed increased collaboration with NHMRC to access research capability through the competitive granting processes to drive research that will deliver an impact in the region and globally.

3.3.5 Support Advances in Genomics

The analysis of individual genomes for the purposes of diagnosis and personalised treatment represents an area of research that is most likely to directly influence the future delivery of health and has significant potential to improve health outcomes. While the technology for genomic sequencing is advancing quickly, the rate at which we are tapping into its potential and linking the information to healthcare delivery lags considerably. To take advantage of the benefits genomics offers in delivering better healthcare, there is a need to rapidly integrate and embed genome sequencing within clinical healthcare delivery. Increased research capacity and capability are also needed, particularly in supporting the application of genomics to clinical practice.

Recommendation 7: Support a Range of Strategic Topics. Provide targeted investment in four strategic topics and possibly include as national priorities.

- a. Build Indigenous research capacity through a virtual Integrated Health Research Centre (IHRC), refocus NHMRC People Support Schemes on capacity-building, and expand long-term NHMRC programs.
- b. Establish a virtual rural and remote IHRC which has links to other IHRCs and leverages national data platforms for research, streamlined clinical trials processes, and patient record management.
- c. Support global health research through partnerships and collaboration.
- d. Develop capacity and capability in genomics through a national HMR network, ongoing training, NHMRC People Support Schemes and data infrastructure investment.

CASE STUDY 2

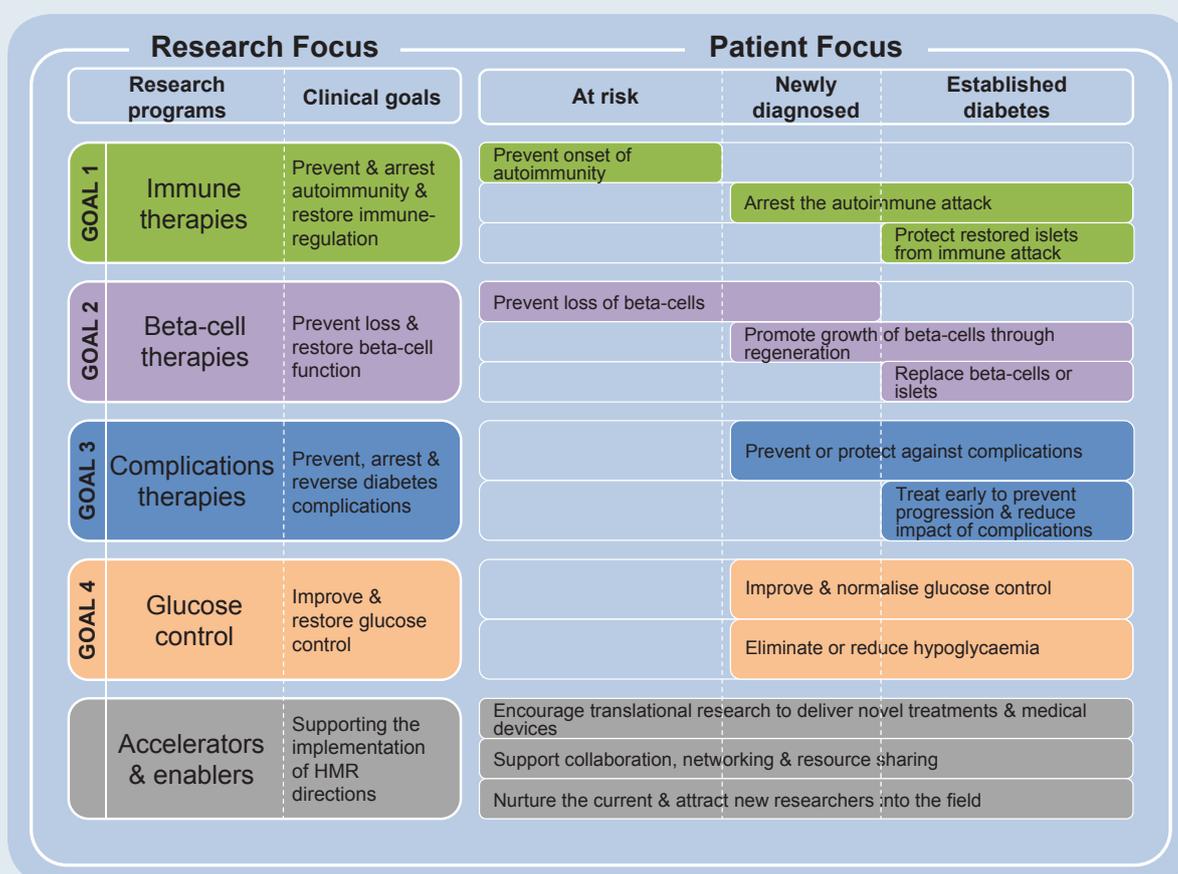
Strategic priority-driven research has significantly accelerated the development of treatments for Type 1 diabetes

Background. Type 1 diabetes accounts for 13% of all diabetes and more than 90% of diabetes in people under 15 years old. The Juvenile Diabetes Research Foundation (JDRF) is a global affiliation of national charities which has invested over \$1.6bn globally (\$120m in Australia) on Type 1 diabetes. JDRF has adopted a strategic priority-driven approach to its research efforts and leveraged Australian research strengths to deliver against broader global research priorities.

Through this strategic approach, numerous promising research programs have been identified which have an emphasis on prompter translation of research into treatment. The approach has also avoided resources being wasted on less promising research programs.

JDRF's *Australian Type 1 Diabetes Research Agenda* is centred on four research programs which aim to prevent, treat and cure juvenile diabetes, across the spectrum of patient needs.

Type 1 Diabetes Research Agenda



Key Lessons:

- 1. A strategic priority-driven approach optimises the allocation of investment.** The Foundation revises its research focus every 3-5 years to identify the main goals that need to be addressed to improve treatment and ultimately to cure Type 1 diabetes. This allows for a reallocation of funding and research efforts to the most promising areas of research to address the needs of patients who are at risk, newly diagnosed and established diabetes sufferers.
- 2. A strategic targeted approach leads to accelerated translation and improved healthcare outcomes.** In 2006, the Foundation launched the Artificial Pancreas Program to accelerate the development of a commercially viable artificial pancreas. In just over six years, a series of strategically-designed global clinical trials were conducted with a new treatment now proving successful in healthcare practice.

4. MAINTAIN RESEARCH EXCELLENCE

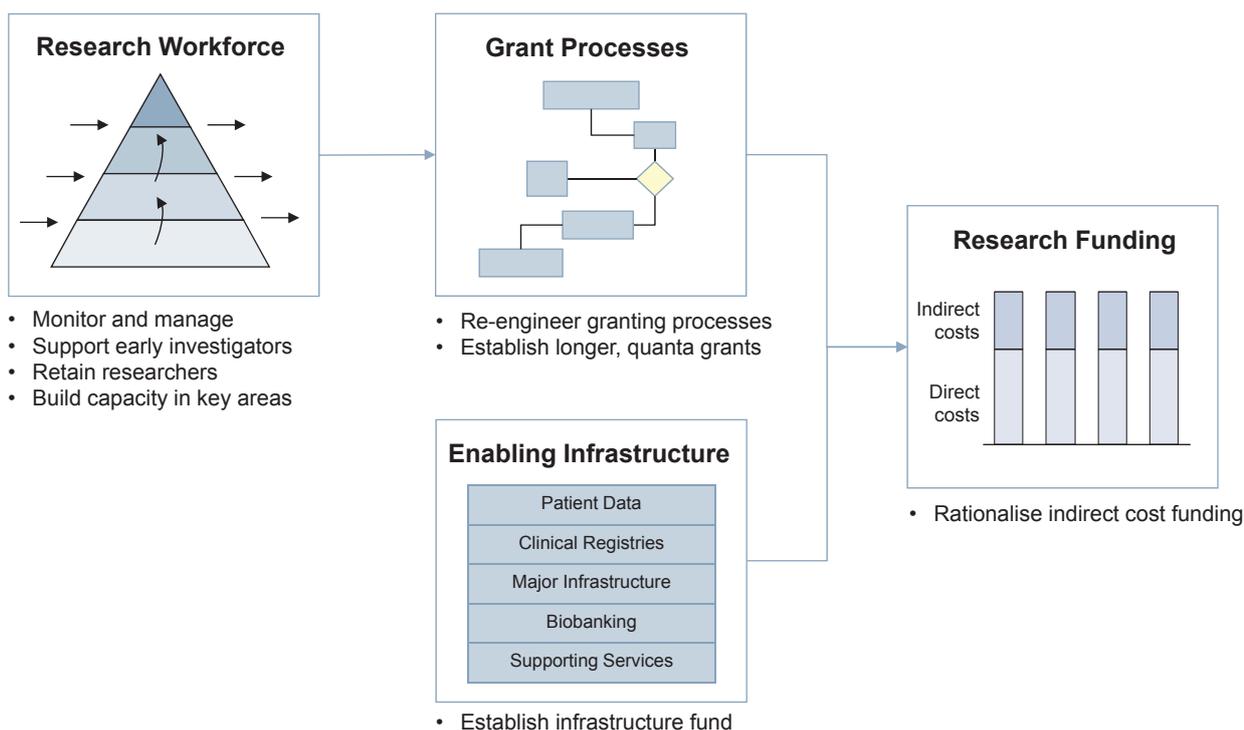
4.1 Introduction

While Australia's performance in HMR is world class, continued support across the spectrum of research areas (e.g. biomedical, clinical, public health and health system) is required to maintain our international standing. Competitive research funding has played a vital role in driving high-quality research, but has resulted in workforce instability and disproportionate time and effort being spent on grant applications and assessment. Reforms to granting systems are therefore required to retain the benefits of competition and mitigate its unintended consequences. Supporting this is a research delivery system which is comprised of four interrelated components, each of which has a number of important issues that should be addressed to ensure Australian HMR can maintain excellence.

Exhibit 18

Improvements are required across the four main components of the research delivery system

Research Delivery System



4.2 Train, Support and Retain the Workforce

4.2.1 Introduction

The workforce contributing to HMR in Australia is diverse and can broadly be divided into those with a background and primary training in medicine and allied healthcare practices, those with a primary training in science, and those in supporting disciplines such as biostatistics and bioinformatics. The challenges for each of these groups are markedly different, with researchers, in particular, experiencing fundamental career challenges relating particularly to career progression and alternative pathways, job security and remuneration.

4.2.2 Manage and Monitor the Workforce

The overall HMR workforce is not actively monitored or managed and there is very poor visibility of its dynamics. One survey estimated the research workforce at approximately 23,000.¹⁵ It is estimated that about 25% of these researchers are supported by NHMRC competitive grant schemes. The new HMR leadership body should be tasked with HMR workforce planning, from analysis through to management, monitoring and providing policy advice.

Exhibit 19

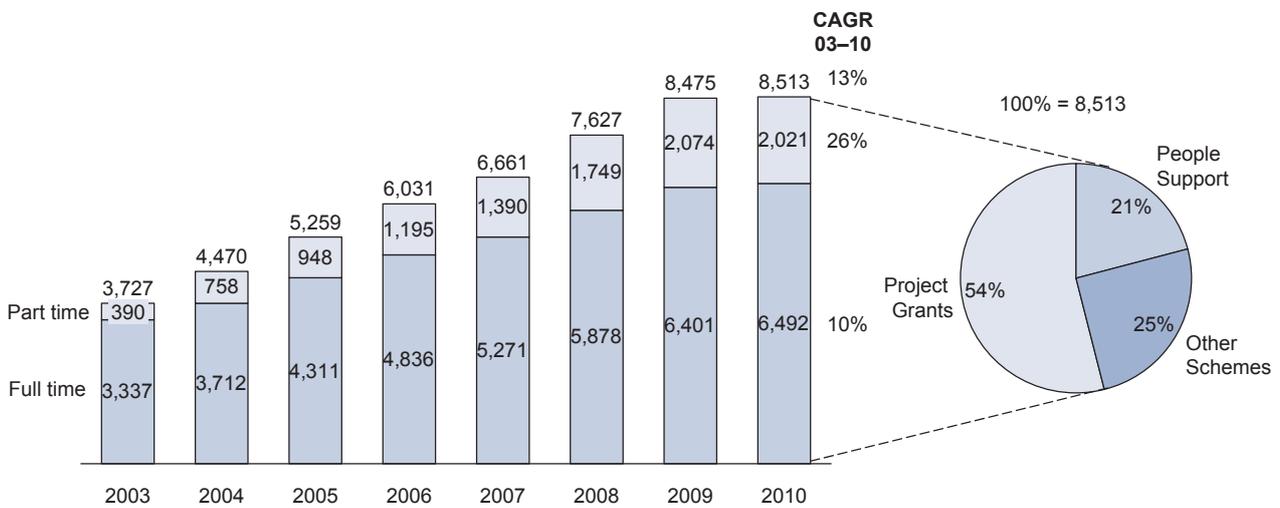
The number of researchers supported by NHMRC funding has grown at 13% p.a. over the last seven years

Researchers Supported by NHMRC Schemes

Researchers

By Scheme

Researchers
2011



Source: NHMRC Funding Facts Book 2011, 2012

4.2.3 Support Early Investigators

It is vital that Australia continues to invest and support its young researchers—particularly to raise the profile of HMR as a rewarding career path. Early investigator support is not well targeted, Australian Postgraduate Award stipends are too low, and any expansion of the PhD cohort requires career path options, including training for subsequent non-research roles, to be attractive.

4.2.4 Retain Researchers within the System

There are a number of career progression barriers, such as career interruptions, that detrimentally affect a researcher's track record and make it difficult to re-enter the workforce. There also appears to be a lack of capacity to mentor young researchers. Reforms to the granting processes are needed to ensure career breaks and inequality issues do not adversely affect career paths, and allow greater time for training and mentoring.

15 ASMR, *Planning the Health and Medical Research Workforce 2010–2019*, prepared for ASMR by Dr Deborah Schofield, 2009, p.4.

4.2.5 Increase Track Record Flexibility

Track record is a major selection criterion for grants within research support or People Support Schemes for competitive granting agencies, such as NHMRC and the Australian Research Council (ARC), and is used as a major determinant of excellence and potential. Non-clinical research areas, knowledge translation and non-publication work are not sufficiently valued for research track records, while mid-career researchers have trouble demonstrating their track record. Track record definitions should be made more flexible and research staff who are not chief investigators should also appear on grants to assist their career progression.

4.2.6 Build Workforce Capacity

NHMRC currently supports 492 research fellowships, which are renewable every five years. While NHMRC should continue to focus funding the best and brightest researchers (many of whom are and will continue to be funded by hospitals, universities, and research institutes), there is a need to build capacity in newly emerging disciplines, such as genomics, bioinformatics, biostatistics, and key areas that will deliver health system impact, such as public health research, health services research and health economics.

Recommendation 8: Train, Support and Retain the Research Workforce. Manage, train, build capacity for and retain a high-quality research workforce.

- a. Actively monitor the shape and dynamics of the HMR workforce and NHMRC People Support Schemes.
- b. Support career entry with higher Australian Postgraduate Award stipends and 'early investigator' grants with a focus on 'few total research years' rather than 'new to NHMRC'.
- c. Retain more researchers in the system with flexibility for career breaks or part-time work, remove barriers to retention, and fund capacity for mentoring.
- d. Provide increased flexibility of track record definitions in grant applications to encompass a broader range of research activities and contributions.
- e. Build capacity in key enabling areas (e.g. genomics) and disciplines that will deliver health system impact (e.g. health economics) with NHMRC People Support Schemes.

4.3 Streamline Competitive Grant Processes

4.3.1 Introduction

While NHMRC funds a number of competitive grant schemes across various research areas, there are issues with administrative processes and systems.

4.3.2 Streamline NHMRC Grant Application Processes

NHMRC grant applications are complex and time consuming for researchers, generally due to onerous data requirements. There is potential for considerable improvement in the NHMRC's online Research Grant Management System, and merit in standardisation of submission process elements with other major competitive granting agencies such as ARC, including the adoption of a standardised CV template.

4.3.3 Simplify NHMRC Grant Assessment Processes

There has been a steady increase in the number of applicants to almost all NHMRC schemes over the last decade that has not been accompanied by a commensurate increase in funds available. A process of early triage for those applications unlikely to be successful is critical to reducing the load on the reviewing process.

4.3.4 Move to Longer Quanta Grants

Research is becoming increasingly complex to perform. The current typical three-year project grant cycle results in career insecurity, reduced quality and impact of the research being generated and an administrative burden. Grant request standardisation should be changed to predominantly five-year terms with fixed budget quanta to simplify budget preparation and assessment and improve job security and quality of outcomes delivered.

Recommendation 9: Streamline Competitive Grant Processes. Re-engineer the NHMRC grant application and assessment processes to include, but not be limited to, the following initiatives.

- a. Streamline NHMRC grant application processes and systems, and align with other major granting agencies.
- b. Simplify grant assessment processes to reduce reviewer burden and support a limited but significant quantity of high-risk/potential high-return research.
- c. Stabilise the workforce by moving towards a standard Project Grant duration of five years and adopt quanta funding.

4.4 Rationalise Indirect Cost Funding for Competitive Grants

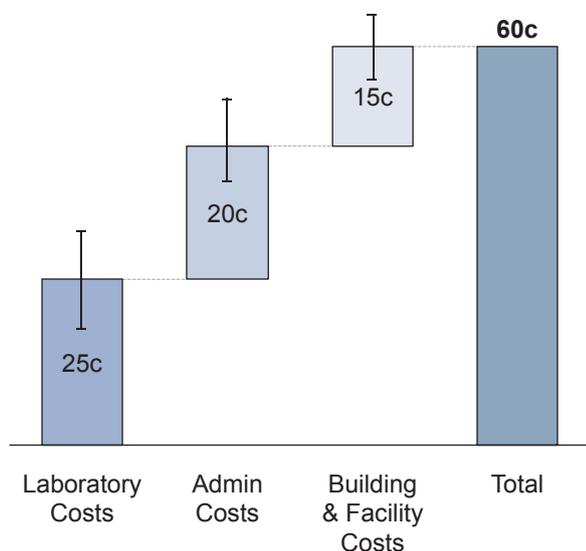
Indirect cost funding for research activities is inadequate, and the level of funding partially depends on the type of institution and state or territory in which the research is undertaken. Indirect research costs are, on average, around 60c per direct research dollar and comprise laboratory costs (25c), administrative costs (20c) and building and facility costs (15c). The current system is inequitable with universities given 30c per direct research dollar through one set of schemes and MRIs given 20c per direct research dollar through another scheme, while hospitals do not have access to any support schemes. As noted by previous reviews, a rational approach to indirect cost funding is urgently needed where indirect costs are stapled to national competitive grants.

Exhibit 20

Indirect costs are on average 60c per dollar of research, leaving current research organisations underfunded

Average MRI Indirect Research Costs

Cents per research dollar
2008



- Currently research organisations receive varying levels support but all are below 60c
 - Universities receive 30c via SRE and RIBG¹
 - MRIs receive 20c via IIRISS²
 - Hospitals receive no indirect cost support
- Top-up funding to the actual costs of research of 60c should be provided, stapled to NHMRC competitive grants

Notes: 1. SRE – Sustainable Research Excellence Program; RIBG – Research Infrastructure Block Grant
2. IIRISS – Independent Research Institutes Infrastructure Support Scheme
Source: AAMRI, *Australian MRI Indirect Cost Funding*, 2010

Recommendation 10: Rationalise Indirect Cost Funding for Competitive Grants. Ensure that all qualified HMR institutions, including healthcare service providers, MRIs and universities, receive at least 60% indirect cost loading for national competitive grants.

4.5 Build Enabling Infrastructure and Capabilities

4.5.1 Introduction

Modern HMR is a complex activity that requires both infrastructure support and, increasingly, support from a broad range of other enabling technologies. Providing infrastructure support on a secure, ongoing basis and building skilled research capability in enabling areas are both vital to ensure the long-term effectiveness of HMR. Strategic funding and coordination is required to ensure access across the full range of HMR organisations.

4.5.2 Secure Long-Term Funding for Major Infrastructure and Enabling Technologies

In *Powering Ideas*, the Australian Government's 10-year research reform agenda released in the May 2009 Budget, the Government made a commitment to continue to invest in research infrastructure. However, funding under the National Collaborative Research Infrastructure Strategy concluded on 30 June 2011 and funding from the Super Science Initiative will conclude on 30 June 2013. To date, there have been no announcements of additional funding for national infrastructure programs. The Panel is concerned that investment in major infrastructure in Australia has now slipped into a hiatus which should be addressed as a matter of priority.

HMR requires access to a suite of supporting technologies, including biobanked material, medical imaging, simulation technologies, micro and nanobiotechnologies, proteomics, metabolomics and genomics. Short-term research project timeframes have led to a limited supply of longer term funding for major equipment and enabling technologies. HMR should be given access to the proposed infrastructure fund as outlined in the 2012 National Research Investment Plan, or alternative funding should be provided to support research.

4.5.3 Accelerate Efforts to Build and Support National Patient Databases

The ease with which data can be collected, analysed and disseminated is a critical factor in the advancement of medical research and its translation to better healthcare. While the National E-Health Transition Authority is developing data protocols, there is a gap in long-term data storage and discovery infrastructure.

4.5.4 Establish Clinical Registries

Clinical registries which systematically collect information on treatments and their outcomes from hospitals are one of the most effective means of monitoring and encouraging the uptake of guidelines. There are numerous overseas examples where the establishment of clinical registries has improved the uptake of evidence-based treatment guidelines. For example, there are over 70 clinical registries in Sweden, with over 20 having greater than 85% patient coverage. While there are 28 identified clinical registries in Australia across various healthcare sites, only five have national coverage.¹⁶

4.5.5 Develop a National Biobank Strategy and Platform

Australia has developed a wide, fragmented array of biobanks,¹⁷ ranging from small to large, and from individual collections to networked, 'hub and spoke' or 'multiple distributed node' facilities. The current fragmented and *ad hoc* approach is costly and difficult for researchers to access efficiently. A national biobank strategy underpinned by a national platform that provides linked access to datasets is needed to ensure efficient access for researchers.

4.5.6 Increase Support Services Capacity

Support services capacity is necessary to high-quality research, but there is a significant skills shortage in enabling technologies and analytic services in Australia, with a strong need to build capacity in key enabling technologies and supporting services (e.g. bioinformatics). Researchers lack access to a general research support service and a research design service should be provided to assist in improving the quality of research.

Recommendation 11: Build Enabling Infrastructure and Capabilities. Provide significant funding for large infrastructure, including patient databases, registries, a biobank hub and enabling technologies.

- a. Create a research infrastructure funding vehicle of \$150–\$200m p.a. to fund major infrastructure and key enabling technologies, and ensure access for the HMR sector.
- b. Accelerate development of national patient databases and clinical registry infrastructure and management.
- c. Develop a national biobank hub linking existing and future specimen biobanks.
- d. Increase new enabling technologies and supporting analytical services.

16 SM Evans, M Bohensky, PA Cameron & J McNeil, 'A survey of Australian clinical registries: can quality of care be measured?' *Internal Medicine Journal*, Vol. 41, Issue 1a, 2011, pp.42–48.

17 Defined as a generally large collection of human biological materials (biospecimens) linked to relevant personal and health information and held specifically for use in health and medical research in the NHMRC 2010 Biobank Information Paper. URL: http://www.nhmrc.gov.au/_files_nhmrc/file/your_health/egenetics/practioners/biobanks_information_paper.pdf.

5. ENHANCE NON-COMMERCIAL PATHWAY TO IMPACT

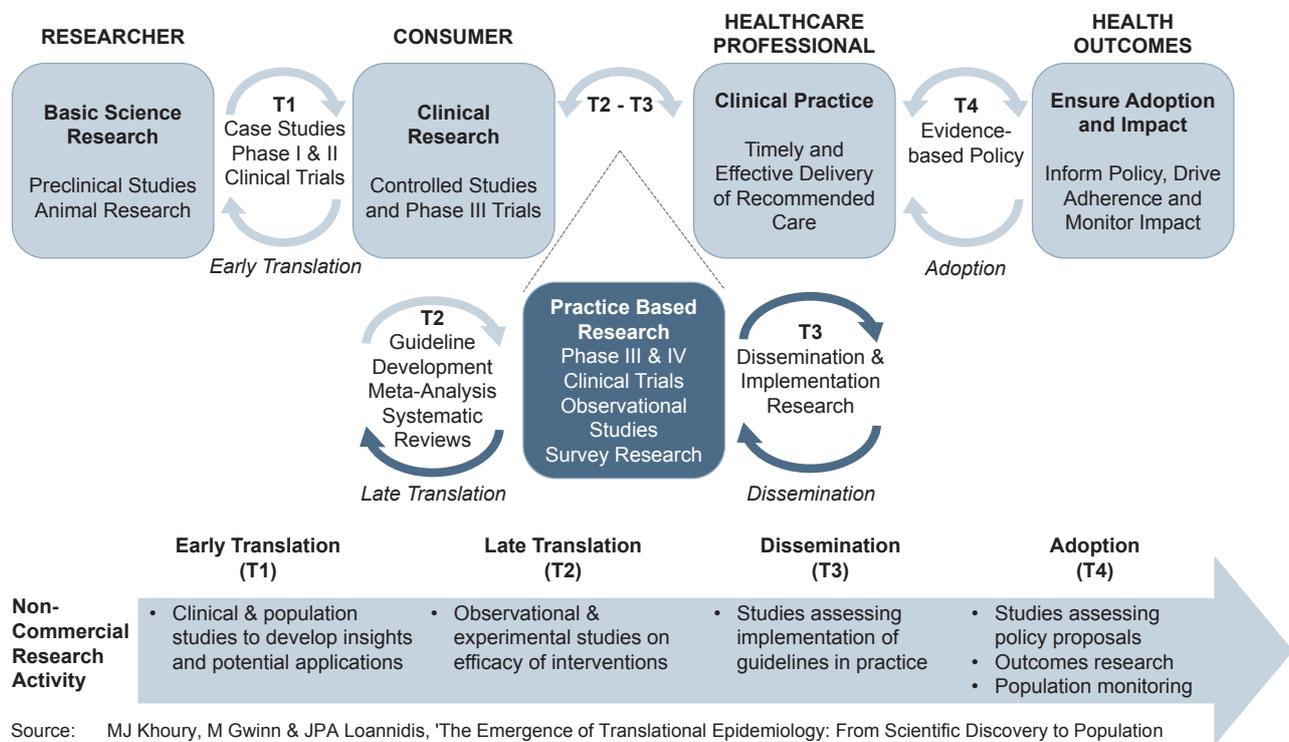
5.1 Introduction

Research translation is the key to delivering improved health outcomes. There are different translation pathways for different research types and they are summarised below in a T1 – T4 framework used by NIH. While commercial translation usually has a corporate sponsor driving progress through clinical trials that results in a marketable product, non-commercial translation that creates public-good innovations may have no natural champion to drive research and subsequent uptake.

Exhibit 21

The NIH Research Translation Framework can be applied to non-commercial translation

NIH Research Translation Framework



Source: MJ Khoury, M Gwinn & JPA Loannidis, 'The Emergence of Translational Epidemiology: From Scientific Discovery to Population Health Impact', *American Journal of Epidemiology*, 2010, 172:5, p.518

Non-commercial HMR can be classed into four areas (public health research, health services research, health system innovation and evidence-based policy) and by level of focus on impact.

Exhibit 22

There are various types of non-commercial research and translation with different areas of focus

Types of Non-commercial Research and Translation

Focus on Impact	Type of Research	Evidence Creation		Evidence Translation	
		Public Health Research	Health Services Research	Health System Innovation	Evidence-based Policy
	1. Descriptive Studies ('Describe Y')	• Epidemiology and population studies	• Health system studies	• N/A	• N/A
	2. Evaluation ('Does Intervention X work?')	• Assessment of preventive measures	• Comparative effectiveness • Health economics	• Assessment & audit of evidence-based practice	• Policy evaluation
	3. Translation ('How best to implement X?')	• Public health improvement	• Implementation evaluation	• Clinical guidelines • Implementation research	• Social and behavioural studies • Policy proposals
	4. Implementation ('Do X')	• Preventive programs	• Change Management	• Adoption of guidelines • Regulation	• Evidence-based policy

5.2 Enhance Public Health Research

Public health programs, such as vaccination, smoking reduction and safe sex, are driven by research evidence and have delivered significant cost-effective improvements in health outcomes. Ongoing public health research, for example, on the impact of different Medicare Locals and LHN strategies, or Australian National Health Preventive Health Agency (ANPHA) preventive health programs on population health, are likely to make a significant contribution to Australia's HMR priorities. Despite considerable growth in public health research over the last decade, it requires more focused capacity-building and a dedicated competitive grant program. Duplication of research proposal assessments by ANPHA and NHMRC should be minimised by leveraging NHMRC competitive assessment processes for ANPHA project funding.

Recommendation 12: Enhance Public Health Research. Focus efforts on capacity-building and new schemes for public health research.

- Build capacity in public health research and expand partnership schemes.
- Refine NHMRC Project Grant schemes and leverage for Australian National Preventive Health Agency research.
- Consider new approaches to funding clinical trials for long-term public health.

5.3 Enhance Health Services Research

Compared to other areas of research, there are relatively fewer researchers in health system research (which comprises health services research and health economics) despite such research being essential to efficient health care. Given the substantial health reforms underway, increased capacity is vital to ensure research is performed to evaluate the impact of these reforms and identify opportunities for improvement.

The NHMRC Project Grant process is not optimised for health services research and should be reweighted to focus more on an assessment of outcomes and relevance. Introducing criteria around health system impact will encourage health services and health economics research activity in LHNs. Health services research often requires initial short-term and small-scale pilot studies which are potentially better assessed and funded locally as part of research in LHNs rather than via a national competitive assessment process. A health services research institute should be established to gather and analyse health services data, and support performance monitoring of key aspects of health services.

Recommendation 13: Enhance Health Services Research. Focus efforts on capacity-building and new schemes in health services research and health economics.

- a. Build capacity in health services research and health economics to understand, assist and evaluate translation.
- b. Refine NHMRC selection criteria to encourage health services research.
- c. Establish an influential institute of health services research.

5.4 Accelerate Health System Innovation

5.4.1 Deliver Evidence-Based Healthcare

Translating research into evidence-based healthcare is a vital step of the research process that is responsible for impact. Implementation of research guidelines is slow and inconsistent, and in some areas they are non-existent or inapplicable. Ongoing health system innovation requires better incentives to generate clinically-relevant research evidence, adopt proven guidelines and seek better practice in all settings. An additional barrier to increased translation is that research guidelines are typically not in the optimal format for the needs of its various end-users, so researchers should be encouraged to write up guidelines for wide dissemination and in a variety of formats for different end-users.

5.4.2 Support Non-Commercial Clinical Trials

Non-commercial clinical trials are an important part of efforts to improve health outcomes and reduce healthcare costs. Given their nature, non-commercial trials require government funding, as well as access to resources in hospitals and from health services providers. The Australian Government should fund non-commercial clinical trials with an additional \$50–\$100m p.a. and monitor this investment to ensure it delivers health system impact.

Recommendation 14: Accelerate Health System Innovation. Accelerate research translation and health system innovation.

- a. Provide incentives to generate clinically-relevant research.
- b. Ensure guidelines have an implementation plan and encourage wider communication.
- c. Provide funding for non-commercial clinical trials based on potential to deliver impact.

5.5 Inform Policy with Evidence

The information needs of policy makers are generally not aligned with the current form of research output. Concerted efforts are needed to identify the most significant gaps in policy and evidence base and to build research capacity and capability to inform policy. In particular, more frequent engagement and fast-turnaround advice are required by policy makers. A structured process should be established by the leadership body to facilitate closer interaction between researchers and policy makers and embed researchers within government policy departments, to leverage capability from existing institutes that have successfully delivered outcomes. The strategic, responsive measures taken by the Australian Government in dealing with the Hendra virus are illustrative of the strong linkage required between government policy and research (Case Study 3).

Recommendation 15: Inform Policy with Evidence. Inform health policy and practice with research evidence.

- a. Enhance the capability of NHMRC and researchers to support policy makers.
- b. Encourage the embedding of researchers within government policy departments.
- c. Conduct research on gaps between health policy and practice, and the evidence base.

CASE STUDY 3

Strategic research into the Hendra virus quickly led to an understanding of its causes and a subsequent vaccine

Background. In September 1994, a Queensland horse trainer and 14 of his horses caught an unidentified illness and were dead within days. The Queensland Department of Primary Industries collected samples from the affected horses and submitted them to the Commonwealth Scientific and Industrial Research Organisation (CSIRO) for testing at the Australian Animal Health Laboratory (AAHL). Collaboration between public health departments and researchers led to the identification of the Hendra virus—just two weeks after it was first observed in humans.

Since the outbreak and identification of the Hendra virus, AAHL has been involved with every Hendra incident, with no recorded cases outside Australia. Scientists believe bats are the natural host of the virus, which can affect more than one species. The infection pathway to date has been from bats to horses, then from horses to humans.

In May 2011, CSIRO developed a Hendra vaccine for horses (Equivac HeV). The development was the result of close collaboration with US partners and Pfizer Animal Health, and is critical to reducing the risk of spread of the virus to people. CSIRO is currently researching post-infection treatments for humans.

Key Lessons:

- 1. Strategic research can rapidly address urgent disease outbreaks.** Research conducted by CSIRO isolated and identified the virus within two weeks of its first appearance and further studies confirmed bats as the primary hosts of the Hendra virus, although it has affected horses, humans and dogs. CSIRO, in conjunction with agricultural and veterinary agencies and the Department of Health and Ageing, also issued information regarding the nature of the Hendra virus and guidelines on prevention.
- 2. Collaborative research efforts are important to deliver timely, high-quality interventions.** Australian Institute for Bioengineering and Nanotechnology, Queensland Health, Princess Alexandra Hospital and US researchers produced antibodies for emergency treatment of humans exposed to the virus.
- 3. Investment in world-class research consolidates Australia's global role in health and medical research.** AAHL is a world-renowned centre for research into new and emerging animal diseases. International researchers are able to access AAHL's high-containment laboratories and specialist services for studies on infectious diseases that affect the health of animals and humans.



Note: Image showing first horse to receive the Equivac HeV vaccine, administered by Dr Nathan Anthony. Image courtesy of Pfizer Animal Health
Source: CSIRO Website; Australian Veterinary Association Website; DoHA, *Hendra Virus CDNA National Guidelines for Public Health Units*, 2012

6. ENHANCE COMMERCIAL PATHWAY TO IMPACT

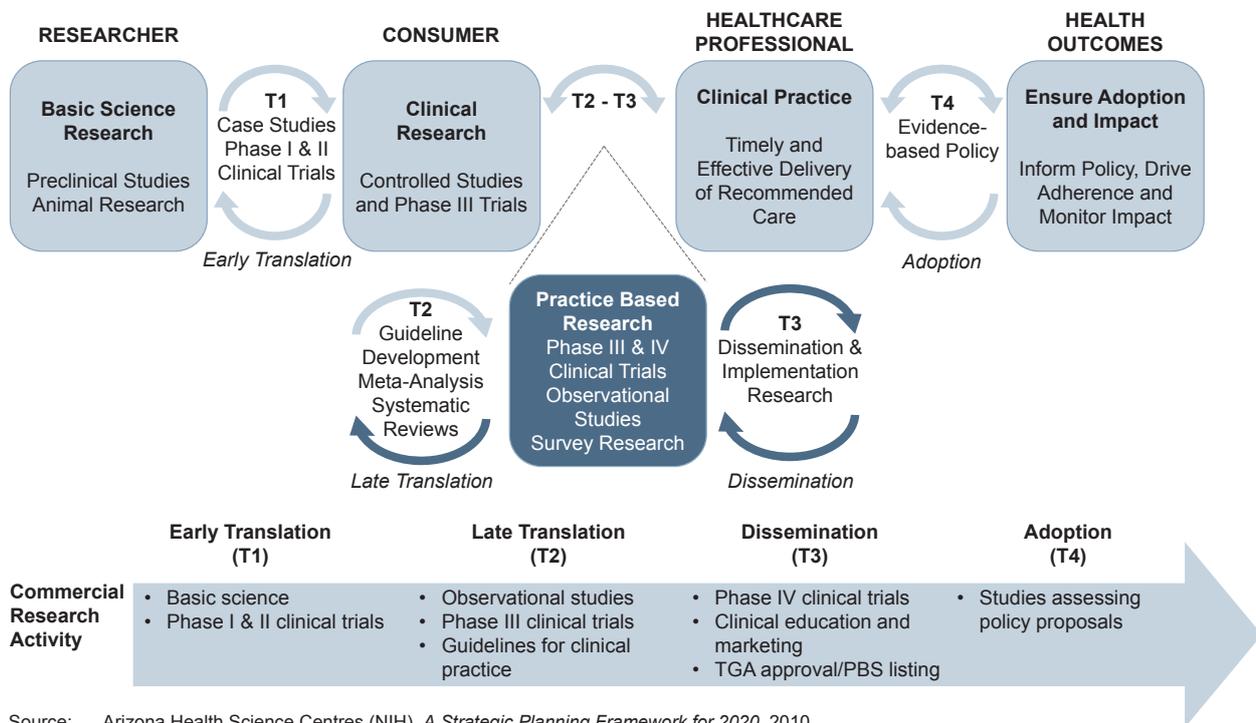
6.1 Introduction

Commercialisation is a necessary step to deliver research benefits to the community, and has the potential to create economic benefits including high-value jobs. It also requires risk capital and Australia is failing to extract the full benefits from its research output due to lack of funding for early clinical projects and a relatively immature commercialisation environment and culture.

Exhibit 23

The NIH Research Translation Framework can be applied to commercial translation

NIH Research Translation Framework



Source: Arizona Health Science Centres (NIH), *A Strategic Planning Framework for 2020*, 2010

While Australia has clearly produced some great commercialisation successes, such as CSL Limited, Resmed and Cochlear, these have been too few and value creation is predominantly concentrated among these few large companies.

6.2 Support Research Commercialisation

6.2.1 Introduction

In the HMR sector, the portion of 'D' (development) in the R&D mix is too small and inhibits innovation. There are three main funding stages: preclinical, early clinical and late clinical. The first two are colloquially known as 'valleys of death' due to a significant shortfall in funding at these points. While Australia has built up modest capacity in venture capital and private equity, and can fund a small number of projects that emerge from these 'valleys of death', additional support is required to generate an increased flow of investable projects. Commercialisation Australia is playing a valuable role in this area but much more support is required.

Exhibit 24

Commercialisation requires funding across three stages and must navigate across the twin 'valleys of death'

Commercialisation Funding Stages

	'Valley of Death #1'	'Valley of Death #2'	
	Preclinical	Early Clinical	Late Clinical
Example	<ul style="list-style-type: none"> Research has identified potential new diagnostic/assay/drug via lab research, initial animal models, etc. 	<ul style="list-style-type: none"> Research has discovered a molecule as drug candidate, evidenced by animal studies 	<ul style="list-style-type: none"> 'In man' clinical trials already through phases I and II (pilot), and addressable market scoped as commercially significant
Funding Required	<ul style="list-style-type: none"> No funding for further lab or animal trials available from grants, but too early for biotech, venture capital or industry investment Requires ~\$200k–\$1m per project over 2 to 3 years 	<ul style="list-style-type: none"> Funding for phases I and II (pilot) clinical trials to collect data that can support proposals to venture capital, biotechs and industry Requires up to ~\$10m per project over 5 years 	<ul style="list-style-type: none"> Funding through phases II (well controlled) and III global clinical trials Requires ~\$15–\$500m over 5+ years
Current Funding Sources	<p>Grant Schemes:</p> <ul style="list-style-type: none"> NHMRC Development Grants Commercialisation Australia ARC Linkage Projects scheme <p>Commercial Investment:</p> <ul style="list-style-type: none"> Discretionary MRI and university reserves (~\$2–\$10m p.a.) MRCF (~\$1–\$2m p.a.) Biopharma/other (~\$2–\$3m p.a.) 	<ul style="list-style-type: none"> Innovation Investment Fund (~\$10m p.a.) MRCF (~\$10m p.a.) Other private sector biotech fund managers (~\$5–\$10m p.a.) Small cap public biotechs (~\$0–\$20m p.a.) 	<ul style="list-style-type: none"> Innovation Investment Fund MRCF and other private sector biotech fund managers Small cap public biotechs CSL and other large pharma (Note: All above source actively, but MRCF and other private sector biotechs underfunded)
Recommended New Funding	<ul style="list-style-type: none"> \$25m p.a. 	<ul style="list-style-type: none"> At least \$50m p.a. 	<ul style="list-style-type: none"> Case for government investment not clear given scale; may be better suited to large biopharma investment

Notes: Includes drugs and devices
Source: Panel interviews

6.2.2 Bridge 'Valley of Death #1' – Preclinical Stage

Developing ideas from preclinical (discovery to proof-of-concept) stage research lack funding as they are at too early a stage to attract biotech, venture capital or industry investment. The NHMRC Development Grants scheme is one approach to fund research commercialisation, and this scheme should be further leveraged and enhanced. Several submissions to the Panel suggested that the commercial criteria required by applicants to this scheme are too onerous and unrealistic for such early-stage developments.

An option to address the preclinical 'valley of death' is to leverage the NHMRC program by instituting a Matching Development Grants scheme to significantly increase funding for this stage and devolve the selection criteria burden to recipient organisations, while increasing the likelihood for success with a requirement for co-investment. The proposed scheme would provide \$0.5m p.a. to each of the 20 consistently most successful NHMRC peer-reviewed grant recipient organisations.

ARC recently introduced significant restrictions to health and medical researchers with respect to their eligibility to apply for Linkage Projects scheme grants, which has impacted a large section of early commercial translation. HMR access to ARC's Linkage Projects scheme should be restored, given the importance of funding in this area and endorsement for this scheme received from a number of submissions.

6.2.3 Bridge 'Valley of Death #2' – Early Clinical Stage

The second 'valley of death' requires funding for phase 1 and 2 clinical trials and testing of devices to collect data to support investment proposals targeting venture capital, biotech companies and the industry. Funding at this stage is also considered insufficient and there is a need for the Australian Government to provide a mechanism to stimulate institutional investment. The Panel proposes establishing a \$250m Translational Biotech Fund styled along Innovation Investment Fund lines, with the fund managed by a well-qualified external manager and, in the long-term, designed to be a revolving, self-sustaining program. The Australian Government would provide half of the funds with the other half provided by institutional investors on terms designed to compensate for the high risks involved with early stage investing.

Recommendation 16: Support Research Commercialisation. Provide funding to address the twin 'valleys of death' in commercialising research.

- a. Institute a Matching Development Grants scheme to provide \$0.5m p.a. to each of the 20 consistently most successful NHMRC peer-reviewed grant recipient organisations, contingent on matching commitments and access to business development capabilities.
- b. Maintain HMR access to the Australian Research Council Linkage Projects scheme.
- c. Establish a Translational Biotech Fund for early-stage development of around \$250m, funded by the Australian Government and the private sector on a one-to-one matching basis.
- d. Continue to support the Innovation Investment Fund program.

6.3 Enhance Commercialisation Environment

6.3.1 Introduction

Australia suffers from a lack of critical mass in its innovation culture in commercialisation of research compared to other countries. While this is a broader issue, there are some actions that the HMR sector can take to help improve the flow of investable ideas. Successful models are typically focused around 'product' (partnering with industry and licensing) or 'platform technology' (setting up a spin-out company to develop).

6.3.2 Foster a Culture of Commercialisation

Many researchers do not have an appreciation of the work required to commercialise a good research idea. An internship program should be established to enable freer interchange between researchers and the biotech, pharma and investment industries to help embed a greater commercialisation culture in research. Increased visibility should be encouraged through inclusion of commercialisation as one of the measures for research evaluation, institutional rankings, and for industry awards.

6.3.3 Leverage Scale and Expertise

With a few exceptions, university and MRI commercialisation offices are sub-scale and do not have the required level of expertise in their own domain areas to assess opportunities adequately for their international relevance and competitiveness. The difference between the best and second-best resources and advice can be decisive. Given the scarcity of commercialisation skills, there is a need to encourage scale and leveraging of larger commercialisation resources with the breadth and depth of expertise required, rather than have each small institution attempting to build an end-to-end commercialisation capability.

6.3.4 Protect Valuable Intellectual Property

Australia's IP system is weak and not harmonised with international best-practice. There is a need for the Australian Government to ensure the strength and stability of Australia's IP system. In addition, while researchers file a significant number of patents, many of them are not commercially valuable ideas. Researchers should be encouraged to consult business development offices and ensure IP is adequately assessed for its potential commerciality prior to filing patents.

6.3.5 Attract Clinical Trials

Australia is at risk of losing its competitive position for global clinical trials, and is now one of the most costly countries for clinical trials. Competitive and efficient clinical trials capacity is of fundamental importance to developing an internationally competitive biotech infrastructure in Australia. Furthermore, it is vital for our ability to translate research results that improve health outcomes for Australians and to maximise the value of IP developed locally that builds national wealth and creates new jobs. It is, therefore, imperative that clinical trial processes are reformed as a matter of urgency.

Recommendation 17: Enhance Commercialisation Environment. Improve commercialisation capability, culture and practices.

- a. Foster a culture of commercialisation through freer interchange between researchers and industry, and recognise commercialisation achievements through institutional rankings and industry awards.
- b. Encourage research organisations with sub-scale or no business development offices to engage larger institutions/precincts for commercialisation requirements.
- c. Protect valuable intellectual property (IP) by strengthening Australia's IP system and encouraging researchers to seek sound advice on the commercial value of their IP before filing patent applications.
- d. Implement clinical trial reforms as an urgent national priority (see Recommendation 5).

7. ATTRACT PHILANTHROPY AND NEW FUNDING SOURCES

7.1 Introduction

Additional investment sources have an important part to play in supporting HMR. Traditional philanthropy has always been a substantial contributor to health and medical research, as a tangible expression of the public's desire for greater investment in this sector. Recently, more innovative funding mechanisms have been explored and implemented, including social bonds, lotteries, matching schemes and prizes. There are various alternative approaches that can be drawn upon to attract more investment into the sector.

Exhibit 25

There are different ways to leverage additional sources of funding

Additional HMR Funding Sources – Leverage

Category	Segment	Opportunity	Approach to Best Leverage
Attract Philanthropy	Large Global Philanthropy	<ul style="list-style-type: none"> Attract investment to tackle global and developing-world issues 	<ul style="list-style-type: none"> Make Australia more attractive destination for global philanthropy
	Government Matched Funds	<ul style="list-style-type: none"> Reduce gap in donations among high-net-worth individuals 	<ul style="list-style-type: none"> Incentivise large philanthropy with government matched funds
	Collaboration, Scale and Innovation	<ul style="list-style-type: none"> Encourage sector collaboration and scale to increase efficiency and effectiveness 	<ul style="list-style-type: none"> Facilitate collaboration and coordination within sector to increase efficiency
Identify New Funding Sources	Alternative Debt Financing	<ul style="list-style-type: none"> Health bond/social bond schemes to match benefit timing or align outcomes 	<ul style="list-style-type: none"> Explore Treasury appetite for bond-type schemes and models
	Tax Rebates and Levies	<ul style="list-style-type: none"> Focused funding on HMR aligned with public appetite 	<ul style="list-style-type: none"> Review potential opportunity based on fiscal environment
	Other Schemes (Prizes, Lotteries)	<ul style="list-style-type: none"> Prizes for measurable developments to encourage new research efforts and funding 	<ul style="list-style-type: none"> Explore/test prizes for key, measurable developments

7.2 Attract Philanthropy

7.2.1 Attract Large Global Philanthropy

Leveraging Australia's world-class HMR capability and track record of existing investment from large philanthropic organisations will provide additional sources of investment for Australian HMR. Some of the largest and best-known global foundations focused on improving health include the Bill and Melinda Gates Foundation, the Wellcome Trust and Atlantic Philanthropies. Australian researchers have successfully secured investment from each of these organisations and greater focus from the Australian Government, and state and territory governments, coordinated by the NHMRC, could lead to greater success.

7.2.2 Leverage Philanthropy with Government Matching

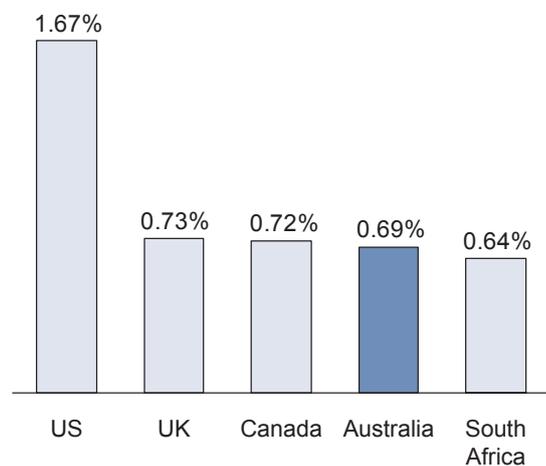
Overall, Australian high-end philanthropy is weak and relatively underdeveloped, especially compared with the culture of driving large philanthropy among high-net-worth individuals in other countries such as the US.

Exhibit 26

The US is a leader in philanthropy, while Australia significantly lags the US and Canada in high-net-worth contributions

National Giving Levels

% donations of GDP
2004



High-Net-Worth Contribution Rate

% donations of pre-tax income
2004



Source: Philanthropy Australia, *Strategies for Increasing High Net Worth and Ultra High Net Worth Giving*, 2011

Matched funding provides an effective mechanism for stimulating philanthropic and private sector investment in research. In the UK, the recently launched Research Partnership Investment Fund promotes partnerships between higher education institutions and the private sector through its one-for-two matching arrangement and has contributed £300m to support over £600m in private funding for projects to date.

The Panel proposes a government-matched funding program in the order of \$50m p.a. to stimulate philanthropic contributions from the high-net-worth segment. It is envisaged such a program would be coordinated by the new HMR leadership body, with weighting towards applications offering a stronger ratio of private to public funding and projects within nationally-agreed HMR priority areas.

7.2.3 Encourage Philanthropy Through Collaboration, Scale and Innovation

There is a lack of good data on charitable organisations that are HMR focused or provide HMR funding. Regular tracking of the amounts and types of donations to HMR in Australia is required to better understand Australia's philanthropy milieu and to assess Australia's giving environment relative to benchmark countries such as the US, UK and those in Europe. This work should also help assure charitable organisations are investing in research effectively.

Many small medical research charities do not have sufficient economies of scale in fundraising and overheads. Increased collaboration and coalescence between charities in funding health research will assist in leveraging funding to deliver greater impact. Australia's lack of philanthropic culture at the high-net-worth end is also partly due to the lack of innovation in fundraising, particularly compared to the US, which regularly uses measures such as naming rights, endowing chairs and board philanthropy. Such innovation should be encouraged and further developed.

Recommendation 18: Attract Philanthropy. Attract and optimise philanthropic investment.

- a. Attract large global philanthropy through strategic alliances.
- b. Allocate funding (up to \$50m p.a.) to match new large philanthropic donations based on leverage and alignment to HMR priorities.
- c. Track philanthropic investment, and encourage collaboration, scale and innovation.

7.3 Identify New Funding Sources

7.3.1 Consider Alternative Debt Financing

Social bonds are a performance-based financial instrument with governments, promoters and non-government organisations seeking investors to provide funding for initiatives that generate specific social outcomes and typically long-term cost savings. Social bonds have been used in the UK for initiatives such as supporting families and reducing recidivism, and have recently been trialled by the NSW Government. Potential risks in using social bonds include the difficulty of accurately measuring social outcomes, shifting accountability away from governments and increased influence of investors. The outcomes that investors may be able to measure and the outcomes governments may want to achieve may differ, requiring a balance in order to achieve long-term social benefit while attracting funding.

To encourage incremental funding of HMR from private lenders, the Australian Government may wish to consider a special-purpose bond issuance program (e.g. the Future Health Institute Health Bond). The purpose of the bond would be to provide funding for health and medical translational research directed to reducing the cost and health burden caused by major chronic diseases such as cardiovascular disease, diabetes and asthma. Were governments attracted to the use of guarantees in such a funding program, the Panel would recommend a rigorous benefits analysis.

7.3.2 Support R&D Tax Incentives and Consider Levies

R&D tax incentives are currently provided by the Australian Government and on 1 July 2011 R&D tax incentives were increased to 45% refundable¹⁸ R&D tax offset for small and medium enterprises, and 40% non-refundable tax offset for all other R&D entities. The R&D Tax Incentive program should continue to be supported by the Australian Government and reviewed periodically to identify opportunities for further enhancement. Another public funding mechanism type is the use of levies—for example, a \$1 levy on all pharmaceuticals bought in Australia could be introduced with the revenue directed to HMR. Given levies are simply a form of additional taxation, and the need for HMR to deliver benefits to the whole population through long-term investment, levies probably do not present a suitable mechanism for funding HMR.

7.3.3 Explore Other Schemes

Prizes have been used successfully to stimulate interest and investment in solving challenging and complex problems. For example, in 2004 the US Defense Advanced Research Projects Agency launched its first Grand Challenge to develop a fully-automated vehicle. Similarly, research prizes could be designed to stimulate interest and investment to solve key HMR challenges.

Recommendation 19: Identify New Funding Sources. Identify other possible funding sources such as alternative debt finance, R&D tax incentives and levies, and schemes such as research prizes.

¹⁸ 'Refundable' means that an eligible small to medium enterprises can access cash refunds if the business is in tax loss.

8. INVEST AND IMPLEMENT

8.1 Introduction

As previously outlined, HMR is the R&D arm of Australia's \$135bn p.a. health system and is therefore a critical component of the current health reform process. There is a strong case for HMR investment given the high social and economic returns. To achieve the vision for the future and fully realise the potential for HMR to improve the health system, a robust implementation process should be established to ensure the recommendations and implementation tasks agreed by the Australian Government are implemented as intended.

8.2 Invest for the Future

8.2.1 The Case for Increased Government HMR Investment

Australia has a strong national balance sheet, with financial, infrastructure, corporate and resource assets greatly exceeding public debt. Investment in HMR is affordable and should be a priority for Australian governments, given the size and nature of the returns available. As highlighted in the 2012 National Research Investment Plan, in the absence of government investment, neither the business nor not-for-profit sector is likely to conduct the level of research and innovation that Australia needs to increase well-being.

The HMR sector has undertaken reform since the 1998 Wills Review to increase the quality, quantity and relevance of research output. The nature of the health system has meant that translation has, however, been less balanced, being overweight on new drugs and devices that save lives but generally require increased funding, and underweight on service innovation that improves productivity and effectiveness, saving lives and reducing costs.

The health system employs over one million people when including healthcare professionals and support staff, and this large workforce needs HMR to identify opportunities and develop strategies to improve its productivity and effectiveness. HMR can hence grow the economy in four ways:

- increase the population, and hence consumption, by extending lifespan
- increase workforce participation by delaying retirement and reducing chronic disease
- add high-value jobs and increase exports in HMR-related sectors such as biotechnology
- improve the productivity and effectiveness of the one million health workforce.

8.2.2 Investment Strategy

Future HMR investment can be better focused and deliver the best possible returns by rebalancing the investment mix towards translation, particularly targeting health system productivity and effectiveness. The existing \$0.8bn p.a. NHMRC MREA investment can be optimised through increased strategic priority-driven research and re-engineering the granting processes. The \$1.0–\$1.5bn p.a. research investment in the state and territory government health system can be optimised to provide greater control, transparency and accountability.

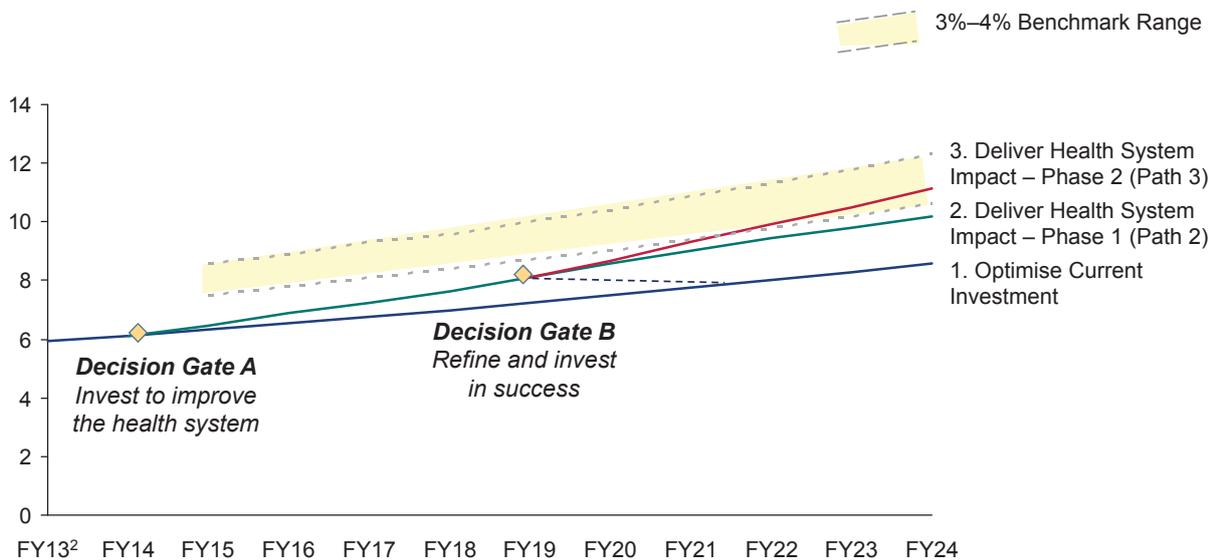
Under normal circumstances, the Panel would recommend implementing all initiatives in full immediately, since the return on investment will greatly exceed the bond yield and therefore create value for the Australian economy. The Panel is cognisant of the current fiscal environment, however, and has therefore identified three investment paths that progressively build up over the 10-year period. The new investment programs proposed, if successfully implemented in full, will help build a healthy and wealthy Australia.

1. **Optimise Current Investment** – No new investment would be made in real terms, and the focus would be on re-allocation of existing NHMRC expenditure which includes reallocation to priority-driven research, and supporting early investigators. Research in state and territory hospitals would be partly funded by the Australian Government as per the NHRA formula. This is the status quo and the Panel strongly recommends moving to the second path before 2014-15 and investing to improve the health system.
2. **Deliver Health System Impact Phase 1** – Key recommendations would be implemented in a phased approach, such as building to 10–12 IHRCs by 2018-19, funding 200 health professional researchers by 2018-19, indirect cost support phased in, starting at 40c per dollar in 2014-15 and increasing to 60c of top-up funding by 2018-19, and other initiatives implemented at pilot scale.
3. **Deliver Health System Impact Phase 2** – Recommendations would be implemented in full including extending to 15–20 IHRCs, 1,000 health professional researchers by 2023–24 and full indirect cost support of 60c per dollar top-up funding. Investment in this scenario would achieve the goal of 3%–4% of total health system expenditure invested in health system R&D.

Exhibit 27

New investment would be progressively built up over a 10-year period based on decision gates in 2013–14 and 2018–19

Investment Summary \$bn¹



Notes: 1. Nominal dollars inflation adjusted at 3%
2. FY – Financial year (e.g. FY13 is 2012–13)
Source: ABS; AIHW; NHMRC; DoHA; Pacific Strategy Partners analysis

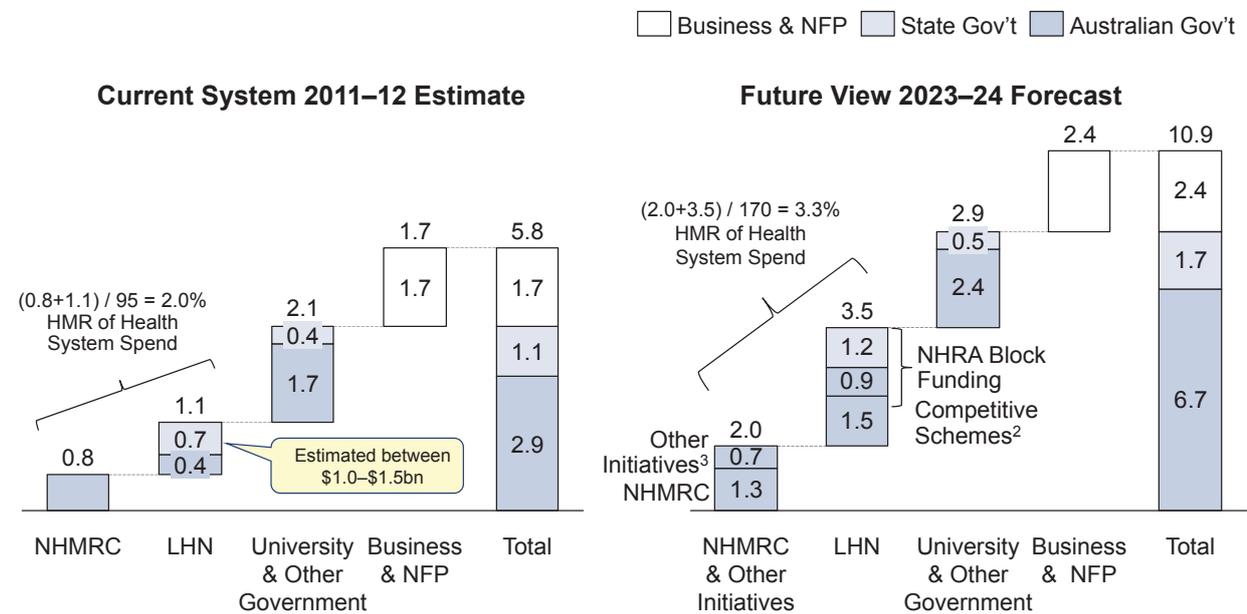
The proposed total government, business and not-for-profit HMR investment will increase from \$6bn in 2011–12 to \$11bn in 2023–24, and can be divided into four areas.

- NHMRC and other initiatives** – Comprises existing NHMRC MREA funds, which should be indexed to health expenditure and hence will grow from \$0.8bn in 2011–12 to \$1.3bn by 2023–24, and new investments, possibly funded outside the MREA but with oversight from the HMR leadership body, for example, to attract new commercial and philanthropic funding.
- Local Hospital Network funding** – Currently research in LHNs is block funded and not well monitored—the allocation for research should be determined and ring-fenced for use on defined research activity as an urgent national priority. In addition, a set of competitive schemes will drive an increased focus on research quality in the broader health system.
- University block grants and other government funding** – Research conducted in the university sector and other government institutions such as the Commonwealth Scientific and Industrial Research Organisation should continue to be supported. Ideally, research direction should be guided by the national HMR priority-setting process and aligned with developments such as IHRCs and LHN competitive HMR programs.
- Business and not-for-profit funding** – To maintain growth in commercial and philanthropic investment, it is imperative that the investment environment is strengthened and specific initiatives aimed at attracting these funding supports are deployed and sustained.

Exhibit 28

The impact of the new initiatives and growth in existing funding will increase total HMR investment from ~\$6bn to ~\$11bn by 2023–24

Total HMR Investment¹
\$bn



Notes: 1. Nominal dollars (assumes 5% forecast growth 2011–12 to 2023–24 for existing HMR funding and new initiatives inflation adjusted at 3%)
 2. Competitive schemes include funding for IHRCs, clinician researchers, non-commercial clinical trials, enhancing public health and health services HMR, accelerating health system innovation and creating evidence-based health policy guidelines
 3. Other initiatives largely overseen by NHMRC and include funding for expanding NHMRC, streamlining clinical trial processes, career support, indirect costs, enabling infrastructure, commercialisation fund, matched philanthropic donations and implementation
 Source: Treasury; DoHA; NHMRC; ABS; AIHW; Pacific Strategy Partners analysis

Each recommendation will deliver important benefits for the health and wealth of the nation, the health system and the HMR sector. Exhibit 29 outlines the incremental investment required to implement each recommendation, over and above the re-allocation of existing funds. New investment of about \$1–3bn p.a. is needed to achieve the vision, and this investment should be built up over the next 10 years.

8.2.3 Risks of Non-Investment

The current round of health reform has focused on reforming the funding arrangements between the Australian and state and territory governments. In the Panel's view, this is a necessary step in increasing transparency within acute-care settings, but it does not have the potential to 'shift the curve' in the same way that research can. Not changing the current system of HMR risks either missing the potential benefits available to the nation, or losing some of the benefits that are currently being delivered.

The most important concern is that not embedding research in the health system runs the risk that translational research activity for benefits tomorrow will be 'squeezed out' by a biased focus on clinical services today. This will exacerbate the already slow process of research translation and lock the healthcare system into a high-cost inflation pathway, with only high-cost commercial innovation overcoming the barriers to translation. Lack of reform of the HMR sector itself risks undermining the progress made over the last decade, and reducing the returns on investment HMR delivers for the community.

Each strategic theme addresses an important element of the HMR system, and there are specific risks in not committing the appropriate levels of targeted investment across these themes.

1. **Embed Research in the Health System** – Failure to embed research into healthcare delivery will maintain the status quo where research activity continues to be 'squeezed out' and separated from clinical care and health services delivery. This separation hinders the development of an environment and culture that facilitates the translation of research to deliver better health and reduce healthcare costs.
2. **Support Priority-Driven Research** – Maintaining the status quo of purely investigator-driven research means that key challenges and areas with the greatest potential for impact are unlikely to be given adequate strategic focus and consideration.
3. **Maintain Research Excellence** – Australia risks losing its world-class research standing without indirect cost support and enabling grant infrastructure. Current competitive grant processes are inefficient and, if not addressed, will constrain sector productivity and eventually impact on the quality of research.
4. **Enhance Non-Commercial Pathway to Impact** – Lack of support for non-commercial research and translation will result in continued healthcare cost inflation and inhibit any ability to identify opportunities to deliver more appropriate and cost-effective health services.
5. **Enhance Commercial Pathway to Impact** – Inadequate measures to stimulate institutional and industry investment sources will hold Australia back from delivering commercial innovation and creating jobs and national wealth.
6. **Attract Philanthropy and New Funding Sources** – Australia's philanthropy sector is underdeveloped, particularly within the high-net-worth segment. In the absence of adequate financial incentives and a more coordinated approach, the potential to build this sector will remain untapped.

Exhibit 29

New investment will embed research in the health system, build HMR capability, accelerate translation and optimise investment

Investment Summary (Deliver Health System Impact – Phase 2)

New Investment¹ (\$m)

#	Recommendation	FY19 ²	FY24	FY15-24	Investment Benefits
1	Drive Research Activity in the Health System	N/A	N/A	N/A	Refocus and better manage LHN HMR (reallocation of existing funds)
2	Establish Sector Leadership and Governance	6	10	72	Drive sector activity and reforms
3	Establish Integrated Health Research Centres	99	208	1,091	Lead research translation efforts to deliver impact
4	Build Health Professional Research Capacity	94	682	2,254	Ensure research is relevant and facilitate translation
5	Accelerate Clinical Trial Reforms	6	7	61	Reduce start up times and costs, and facilitate translation
6	Align Priority-Setting Process	0	0	0	Drive strategic research (reallocation of existing funds)
7	Support a Range of Strategic Topics	0	14	65	Build capacity in key areas
8	Support Early Investigators and Review Schemes	N/A	N/A	N/A	Train younger researchers and optimise funding (reallocation of existing funds)
	Increase APA Stipends	23	49	269	Retain young research talent
9	Streamline Competitive Grant Processes	N/A	N/A	N/A	Increase efficiency for applicants and assessors (use existing funding)
10	Rationalise Indirect Cost Funding	272	402	2,498	Support full costs of high-quality research
11	Build Enabling Infrastructure and Capabilities	75	266	1,240	Build infrastructure to support quality research
12	Enhance Public Health Research	38	223	899	Increase focus on preventive health and lower treatment costs
13	Enhance Health Services Research	38	223	899	Identify and evaluate opportunities to reduce healthcare costs
14	Accelerate Health System Innovation	54	145	657	Deliver better health outcomes and lower costs
15	Inform Policy with Evidence	6	21	96	Align policy with evidence and deliver better population health outcomes
16	Institute Matching Development Grants Scheme	12	14	111	Stimulate investment and devolve selection burden
	Establish Translational Biotech Fund	30	0	154	Stimulate industry investment and build national wealth
17	Enhance Commercialisation Environment	N/A	N/A	N/A	Increase commercialisation effectiveness (use existing funding)
18	Attract Philanthropy	36	69	453	Stimulate philanthropic investment
19	Identify New Funding Sources	2	3	24	Stimulate investment through prizes
20	Index NHMRC MREA to Increases in Health Expenditure	218	495	2,525	Ensure sufficient R&D investment in health system
21	Action Report Recommendations	2	3	7	Ensure recommendations are implemented
Total Investment		1,010	2,834	13,377	

Note: 1. New incremental investment required (i.e. over and above the reallocation of existing funds)
2. Financial year (e.g. FY19 is 2018–19)

Recommendation 20: Invest for the Future. Enhance and align HMR investment programs, with extended oversight by the new HMR leadership body.

- a. Focus initially on investing in high-priority initiatives that deliver the most impact, while realigning and better managing existing investment.
- b. Review and evaluate the first four years of the investment program in 2018–19 and determine whether to accelerate investment, maintain trajectory or withdraw investment, as well as identify any improvements required for each program.
- c. Index competitive research grant budgets (particularly the NHMRC Medical Research Endowment Account) to increases in health expenditure.

8.3 Action Report Recommendations

The majority of the 1998 Wills Review recommendations were successfully implemented, delivering a substantial positive impact on the sector. The recommendations that were not implemented successfully were generally those that cut across multiple parts of government. Therefore a robust implementation process that effectively engages key stakeholders and drives reforms is critical. The process proposed in this Review draws on quality management techniques to ensure the recommendations deliver, as intended, better health outcomes and increased national wealth.

8.3.1 Plan

Once the Australian Government has considered and accepted all or some of the Review recommendations and implementation tasks, an implementation committee should be immediately established to plan implementation and drive the process. Since Australian Government leadership is required to align different stakeholders, this committee should report to both the Minister for Health and the Minister for Industry, Innovation, Science, Research and Tertiary Education, with an independent chair to ensure the interests of all stakeholders are considered, and accountability for actions are agreed across the sector. The committee should be inclusive, and comprise Director General and CEO level representatives of states and territories, hospitals, universities, companies, NFPs, and members of the Panel.

The role of the committee should be to create a detailed implementation plan, and ensure the actions agreed by governments have clear responsibility for implementation. At an appropriate time, the committee should hand its role on to the leadership body recommended to oversee the sector.

8.3.2 Deliver

Each implementation task will need to be appropriately resourced, with a project plan that sets realistic timeframes for delivery. For many of the proposed recommendations, there are natural incentives to deliver on time through access to block funding or competitive schemes. Others may require incentives to ensure that the accountable parties implement actions as intended. Responsibility for the overall implementation could be transitioned from the implementation committee to the HMR leadership body once established and fully operational.

8.3.3 Check

Where incentives are identified, a body should be tasked with checking that the actions were implemented, and are delivering the results intended. Given the wide ranging actions proposed, an independent panel would be able to provide this check point most effectively.

8.3.4 Refine

Based on the experience of this Panel, it is likely that there will need to be some refinement of the implementation approach or programs to ensure the recommendations are delivered as intended. This work would be best completed by a subsequent independent review.

Recommendation 21: Action Report Recommendations. Set out a robust implementation plan and process to deliver the recommendations.

- a. Establish an implementation committee and a robust implementation process with a clear plan.
- b. Use appropriate incentives to ensure outcomes are delivered.
- c. Conduct a medium-term follow-up review to evaluate initial outcomes of investment program.
- d. Refine the plan and invest in success.

9. ABBREVIATIONS

AAHL	Australian Animal Health Laboratory
ABF	Activity Based Funding
ABS	Australian Bureau of Statistics
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
ANPHA	Australian National Preventive Health Agency
ARC	Australian Research Council
ASMR	Australian Society for Medical Research
bn	billion
CEO(s)	chief executive officer(s)
COAG	Council of Australian Governments
CPI	Consumer Price Index
CPP	citations per publication
CRC(s)	Cooperative Research Centre(s)
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CTAG	Clinical Trials Action Group
CV	curriculum vitae
DIIRTE	Department of Industry, Innovation, Science, Research and Tertiary Education
DoHA	Department of Health and Ageing
FY	financial year
GDP	gross domestic product
HAIs	healthcare-associated infections
HMR	health and medical research
IHPA	Independent Hospital Pricing Authority
IHRCs	Integrated Health Research Centres (proposed)
IP	intellectual property
IRIIS	Independent Research Institutes Infrastructure Support Scheme
LHN(s)	Local Hospital Network(s)
m	million
MOU	Memorandum of Understanding
MRCF	Medical Research Commercialisation Fund
MREA	Medical Research Endowment Account (NHMRC)
MRIs	medical research institutes
N/A	not applicable
NFP	not for profit
NHMRC	National Health and Medical Research Council
NHRA	National Health Reform Agreement
NHS	National Health Service (UK)
NIH	National Institutes of Health (US)
OECD	Organisation for Economic Cooperation and Development

p.a.	per annum
PBAC	Pharmaceutical Benefits Advisory Committee
PPP	purchasing power parity (OECD)
R&D	research and development
RFAs	request for applications
SCoH	Standing Council on Health (of COAG)
TGA	Therapeutic Goods Administration
TTR	teaching, training and research
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States (of America)

