Strategic Review of Health and Medical Research

Final Report | February 2013
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

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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.

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’.

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 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.
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

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.
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
EXECUTIVE SUMMARY

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.

   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.

   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.
   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).

VII. **Attract Philanthropy and New Funding Sources**

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.

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.
   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.

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.
1. Vision for 'Better Health Through Research'
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 broader health sector, which includes health professionals, consumers, businesses, not-for-profit organisations and governments. In the context of an uncertain economic environment and expected inflation of healthcare costs, HMR has a vital role to play in improving health outcomes for all Australians, delivering a better health system and contributing to the national economy. Over the next 10 years, a world-class HMR sector, fully embedded in the health system, will help build a healthy and wealthy Australia with the world’s best health system.

Exhibit 1.1

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

HMR Vision

'Better Health Through Research'

Embedded HMR Investment  A World-Class HMR Sector  The World’s Best Health System  A Healthy and Wealthy Australia

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

A healthy and prosperous nation means increased longevity and quality of life for individuals and gains in wealth for the economy. To deliver this, Australia should aspire to build the world’s best health system which can more efficiently ensure a healthy population and can leverage medical innovation and industry to create wealth, high-value jobs and increase economic productivity. In doing so, Australia will also enhance its standing as a leader in healthcare and research globally, and be well positioned to engage with its partners in the region. A focused HMR program, embedded in health service delivery, will play a vital role in delivering these aspirational outcomes and can help Australia achieve significant 10-year health, social and economic outcomes (Exhibit 1.2).
• 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.

Exhibit 1.2

A focused HMR program embedded in health service delivery can achieve significant 10-year health, social and economic outcomes

Delivering Aspirational Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>10-Year Aspiration</th>
<th>Role of Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longevity and quality of life</td>
<td>• Average life expectancy above 85 years</td>
<td>• Identify effective strategies to better prevent and manage chronic disease</td>
</tr>
<tr>
<td></td>
<td>• Improved and robust measure of quality of life</td>
<td>• Identify ways to quantify quality of life</td>
</tr>
<tr>
<td></td>
<td>• Reduced Indigenous health gap</td>
<td></td>
</tr>
<tr>
<td>Health system sustainability</td>
<td>• The world’s best health system delivering the best wellness and care, most efficiently</td>
<td>• Use research to identify savings from better healthcare management and practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Deliver evidence-based healthcare &amp; policy</td>
</tr>
<tr>
<td>Workforce productivity</td>
<td>• 5% increase in workforce participation due to better health</td>
<td>• Focus health systems research on delivering proven preventive healthcare to the working population</td>
</tr>
<tr>
<td>Medical innovation and industry</td>
<td>• A listed biotechnology sector valued at over $60bn</td>
<td>• Support ongoing local innovation and ‘blue sky’ HMR to create new intellectual property</td>
</tr>
<tr>
<td></td>
<td>• Double medical manufacturing exports to over $8bn</td>
<td></td>
</tr>
<tr>
<td>Knowledge-based jobs</td>
<td>• A thriving HMR sector with over 80,000 jobs in the biotech and pharmaceutical sectors</td>
<td>• Develop clusters of innovation based on health professionals trained in research, universities, MRIs and industry</td>
</tr>
<tr>
<td>International standing and engagement, particularly with Asia</td>
<td>• Continued world-class standing in HMR</td>
<td>• Increase engagement through research collaboration, while ensuring Australia stays on the leading edge of HMR</td>
</tr>
<tr>
<td></td>
<td>• Significant growth in international research links, especially with Asia</td>
<td></td>
</tr>
</tbody>
</table>
1.2 A Healthy and Wealthy Australia

1.2.1 Increase Longevity and Quality of Life

Since the advent of the modern scientific method, Australians have enjoyed the fruits of research that have led to significant increases in life expectancy from around 50 years in the late 19th century to 82 years today which represents on average about 0.27 years annually (Exhibit 1.3). This includes HMR discoveries such as the influenza vaccine in the first half of the 20th century, heart and kidney transplants in the mid to late 20th century and the mapping of the human genome at the turn of the millennium. Advances in healthcare have also led to significant increases in years lived disability free, which has increased from 60 in 1999 to 63 in 2009. It has been estimated that roughly two-thirds of the increase in life expectancy from 1995 to 2003 was due to health and medical research.

Exhibit 1.3

Australians' life expectancy has increased by 25 years over the last century

Average Australian Life Expectancy at Birth

Note: Life expectancy calculated as a weighted average of male and female life expectancy and interpolated between census dates
Source: Australian Bureau of Statistics

“Australians now live longer and healthier lives, thanks to major, and often revolutionary, changes in disease prevention and clinical care introduced as a result of discoveries in health and medical research over the last 100 years.”

Australian Academy of Science

Australians rightly place a significant value on each additional year of life, estimated by some studies at $432,000 (Exhibit 1.4), compared to the Australian Government's implicit valuation of approximately $42,000 per quality-adjusted life year (QALY). The increase in life expectancy equates to an aggregate value of approximately $2,700bn each year by Australians—almost double Australia's GDP. While such spending is obviously unaffordable, these studies highlight why Australians value high-quality health services and advances in HMR.

**Exhibit 1.4**

The value of a quality-adjusted life year is estimated at ~$432,000

**Value of a Quality-Adjusted Life Year**

<table>
<thead>
<tr>
<th>$000s</th>
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<tbody>
<tr>
<td>432</td>
</tr>
<tr>
<td>332</td>
</tr>
<tr>
<td>192</td>
</tr>
<tr>
<td>51</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Capital</th>
<th>Revealed Preference (Safety)</th>
<th>Willingness to Pay</th>
<th>Revealed Preference (Job Risk)</th>
<th>All Study Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>432</td>
<td>881</td>
<td>332</td>
<td>192</td>
<td>51</td>
</tr>
</tbody>
</table>

- There are four main methodologies to measure the value of a QALY:
  - **Human capital** – reflects ability to generate earnings, but does not capture value to individual
  - **Revealed preference (safety)** – based on value of life in relation to non-occupational safety risks
  - **Willingness to pay** – value individuals place on their life contingent upon their ability to pay
  - **Revealed preference (job risk)** – reflects wage premium required to attract the most risk-averse worker to accept a risky job

The median value across all studies is $432,000

Notes: 1. Median values from a literature review encompassing 42 studies that were deemed appropriate. Values originally based on 1997 US$ converted to A$ assuming an exchange rate of US$1 = A$0.74 and inflation adjusted to 2012 values


1.2.2 Boost National Wealth

**Return on investment.** HMR is estimated to deliver a return on investment of around 117%, which means that a dollar invested in Australian health research and development (R&D) is estimated to return an average health benefit of $2.17.5

**Health system sustainability.** After fluctuating throughout the 1970s and 1980s, spending on healthcare has been on a steadily rising path since the early 1990s. Australia’s national expenditure on health is estimated at over $135bn in 2011–12, or around 10% of gross domestic product (GDP). Of this, the Australian Government provides about $50bn (4% of GDP). Over the decade from 1999–2000 to 2009–10, Australia's expenditure on health grew in real terms at an average of 5.3% per year, compared with average real growth in GDP of 3.1% per year. A large part of the growth over this period was driven by non-demographic factors, including increasing use of clinicians, diagnostics and pharmaceuticals, and decisions to subsidise the introduction of new technologies or list new drugs on the Pharmaceutical Benefits Scheme (PBS).

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5 The 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.
While Australia’s health system compares well to other countries, delivering life expectancy for a relatively low share of GDP, 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 (Exhibit 1.5). This does not include state and territory government and private sector health expenditure. Health services research has an important role to play in identifying opportunities and strategies to increase efficiency of health services and ensure sustainability of the overall health system.

**Exhibit 1.5**

**Projected Australian Government health expenditure is unsustainable**

<table>
<thead>
<tr>
<th>Year</th>
<th>% of GDP</th>
<th>Impact of increasing demand for higher standard of care</th>
<th>Impact of ageing and population effects only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-10</td>
<td>4%</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>2019-20</td>
<td>4%</td>
<td>71</td>
<td>68</td>
</tr>
<tr>
<td>2029-30</td>
<td>5%</td>
<td>105</td>
<td>89</td>
</tr>
<tr>
<td>2039-40</td>
<td>6%</td>
<td>166</td>
<td>111</td>
</tr>
<tr>
<td>2049-50</td>
<td>7%</td>
<td>257</td>
<td>129</td>
</tr>
</tbody>
</table>

Notes: 1. Excludes state and territory government health expenditure

“A critical factor facing health systems today is the increasing costs of care. Health services/systems research can assist in identifying the most effective ways to organise, finance, manage and deliver high-quality health care.”

*South Australia Health*

**Workforce productivity.** An increase in wellbeing provides benefits to the economy and society through productivity gains from the avoidance of premature mortality and morbidity, avoided carer costs, and avoided associated indirect costs such as deadweight losses from taxation revenue forgone and welfare and disability payments. Chronic disease affects about 3.4 million Australians or a third of the working-age population, and has a substantial impact on productivity (Exhibit 1.6). Chronic disease sufferers who do not participate in the workforce comprise 10% of the total working-age population. Rates of non-participation in the workforce among chronic disease sufferers are twice as high (32%) as people without a chronic disease (16%).

“Investments in health and medical research are investments in improving the nation’s overall productivity. Improvements in health are particularly important in increasing the labour participation rates of older working Australians. The most common reason given by Australian retirees for why they retired was their health. Improving Australians’ health can therefore defer the decision to retire.”

*Research Australia*

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The loss to the labour force from people suffering from chronic disease and their carers, was estimated in 2009 to be 537,000 full-time person years and 47,000 part-time person years. The Australian Institute of Health and Welfare (AIHW) estimates the cost of chronic disease to be approximately $30bn in direct costs and lost productivity annually. Sickness and absenteeism are also major costs to the economy, estimated at $2,700 per employee each year, and in total this represents a cost of about $30bn p.a. Depression is known to be one of the leading causes of workplace sickness and undiagnosed depression in the workplace costs $4.3bn p.a in lost productivity. Indeed, while absenteeism is estimated to cost $7bn annually, presenteeism, whereby individuals go to work but are not able to fully function due to medical conditions, is estimated to be $26bn annually.

Greater investment in HMR can significantly improve workforce productivity by reducing the burden of chronic disease and improving workforce wellbeing. Eliminating chronic disease would improve productivity by an estimated 10%, and hence a reduction of chronic disease by 25% would lead to a significant 2.5% increase in productivity. Research evaluating the effectiveness of health and wellbeing programs in the workplace can assist in improving their delivery and ensure they are aligned to evidence-based practice. Initial studies have demonstrated that companies undertaking health and wellbeing programs on average can reap $5 for every $1 invested.

**Exhibit 1.6**

**Chronic disease affects 3.4m working-age Australians, 32% of whom are not in the workforce**

**Australian Working-Age Population Profile**

<table>
<thead>
<tr>
<th>Chronic Disease</th>
<th>Employed Full Time</th>
<th>Employed Part Time</th>
<th>Not in Workforce</th>
<th>Unemployed</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4 (62%)</td>
<td>0.7 (21%)</td>
<td>1.4 (20%)</td>
<td>1.1 (32%)</td>
<td>1.1 (3%)</td>
</tr>
<tr>
<td>3.4</td>
<td>1.5 (44%)</td>
<td>0.7 (21%)</td>
<td>1.1 (32%)</td>
<td>1.1 (3%)</td>
</tr>
<tr>
<td>7.1</td>
<td>1.5 (44%)</td>
<td>0.7 (21%)</td>
<td>1.1 (32%)</td>
<td>1.1 (3%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proportion of Total Working-Age Population</th>
<th>No Chronic Disease</th>
<th>Chronic Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/3</td>
<td>1/3</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
1. Based on working-age population (classified as individuals between 25-64 years and excludes full-time students)
2. Between 25-64 years with one or more chronic disease


---

7 Ibid.
Medical innovation and industry. HMR has underpinned growth in medicinal and pharmaceutical exports, which has become Australia’s largest manufacturing export category, overtaking the motor vehicles industry in 2009 (Exhibit 1.7). Major markets for Australian medicinal exports include Asia (40%), southern Africa (20%) and Europe (16%).

Exhibit 1.7

Medicinal and pharmaceutical products has 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

HMR has led to significant value creation for the economy over the last decade. The biotechnology industry in Australia now includes over 1,000 companies, with over 100 listed on the Australian Stock Exchange, and has grown at 17% p.a. to a market capitalisation of $32.6bn as at 31 December 2012 (Exhibit 1.8).

13 Department of Foreign Affairs and Trade, STARS Database, ABS Cat No. 5368.0, 2011.

Exhibit 1.8

**ASX200 HMR-related companies have outperformed benchmark indices, with growth of 17% p.a. over the last decade**

**Performance of HMR-Related Sectors**

<table>
<thead>
<tr>
<th>Market Capitalisation ($bn)</th>
<th>CAGR 00–13</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASX 200 Pharma, Biotech and Life Sciences Index</td>
<td>17%</td>
</tr>
<tr>
<td>ASX All Ords</td>
<td>7%</td>
</tr>
<tr>
<td>NASDAQ Biotech</td>
<td>2%</td>
</tr>
<tr>
<td>NASDAQ Composite</td>
<td>-3%</td>
</tr>
</tbody>
</table>

Notes: 1. ASX200 All Ords, NASDAQ Biotech and NASDAQ Composite indices rebased to market capitalisation of S&P ASX 200 Pharmaceutical, Biotechnology and Life Sciences Index

Source: Bloomberg 2013

The health and medical tourism industry has also benefited from a strong HMR sector, estimated at $50m p.a. in total value and growing at 14% p.a. between 2005–10, compared to 2% for the broader tourism sector. The average medical tourist stays 14 nights in Australia and spends approximately $4,000 on travel and treatment, compared to the overall average tourist who stays approximately 34 nights and spends $3,300 on travel, accommodation and other activities.

Australia attracts less than 1% of total medical tourists globally, despite accounting for 4% of total Organisation for Economic Cooperation and Development (OECD) healthcare expenditure, out of a global market estimated at US$60bn and growing at 20% p.a. Australia’s primary advantage in health tourism is its reputation for safety and quality in health services. It is likely to attract growing demand from Asia due to its geographical proximity and, potentially, affordability relative to the United States (US) and Europe. Increased health and medical innovation and improved healthcare services will improve Australia’s competitiveness and increase its share of this large, global market.

1.2.3 Drive Shift to Knowledge-Based Jobs

The last 30 years have seen a shift away from traditional industries such as manufacturing and agriculture and the rise of knowledge-based industries such as healthcare services. The biotechnology sector grew at 4% p.a. between 2001 and (Exhibit 1.9), and HMR is the key driver of productivity in the healthcare sector, in the same way as mining R&D increases mining productivity. The Australian HMR sector consists of over 23,000 research professionals who support a broader medicines industry of over 40,000 employees and a health sector of over one million workers. 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.

15 OECD health expenditure data.
16 Department of Resources, Energy and Tourism, op cit.
18 Submission 108, Medicines Australia.
19 IBIS World data request.

Exhibit 1.9

There is a shift away from manufacturing and agriculture to services and knowledge-based industries such as biotechnology and research

Employment by Industry

<table>
<thead>
<tr>
<th>Industry</th>
<th>'000 Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail</td>
<td>2%</td>
</tr>
<tr>
<td>Healthcare</td>
<td>3%</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>0%</td>
</tr>
<tr>
<td>Knowledge-based</td>
<td>5%</td>
</tr>
<tr>
<td>Agriculture and Fishing</td>
<td>-1%</td>
</tr>
<tr>
<td>Social Assistance</td>
<td>3%</td>
</tr>
<tr>
<td>Mining</td>
<td>4%</td>
</tr>
</tbody>
</table>

Notes:
1. Comprises professional, technical and scientific services
2. Growth of HMR workforce not tracked—industry groups are derived using 2011 split of services

Source: Australian Bureau of Statistics, IBISWorld

1.2.4 Enhance International Standing and Engagement, Particularly with Asia

Continued investment in quality research is essential to ensure Australia maintains its position as a global leader in HMR. Strengthening Australia’s international standing generates intangible benefits for the nation and also attracts overseas research grant funding into the country. Over the last five years, National Health and Medical Research Council (NHMRC) project grants and programs leveraged over $800m of international funding, largely due to the increased quality of research being delivered through competitive granting schemes.

Australia should look to leverage its strong ties with Asia to increase collaboration with the world’s fastest growing science innovation region. Asia accounts for a growing share of global science and innovation activity, driven by China, India, South Korea and Japan. As noted in the Australian Government’s Australia in the Asian Century White Paper (2012), Australia’s collaborative links with Asia have strengthened over the last decade (Exhibit 1.10), augmenting strong economic and political ties. As international focus is increasingly shifted to Asia, Australia will face more competition to collaborate with the region’s leading researchers. Investment in HMR will ensure that Australia continues to be an attractive partner in HMR.

International collaboration is important to Australia because our size prevents us from undertaking research in every possible field in health and medical research. International collaboration enables local expertise in particular areas to combine with other, complementary areas of expertise that exist internationally to undertake research that cannot be undertaken solely in Australia. Furthermore, promoting collaboration between institutions both nationally and internationally is an important means of raising the quality of Australian health and medical research.
Exhibit 1.10

Australia’s links with Asia have increased over the last decade

Scientific Links Between Australia and Asian Nations

Australia should also look to leverage ties with global leaders in HMR to build on research advances and foster cross-border communication of ideas and innovation. Increased collaboration with researchers producing innovative research will not only bring Australia to the forefront of global HMR, it will also enhance the skill-set of Australian researchers. Collaborating with Asian countries to solve common healthcare challenges and issues specific to the region will create a source of soft power and augment Australia’s influence in the region.

“As the countries of Eastern Asia develop their research efforts, Australia has unique opportunities to join this part of the world, as it becomes the third region of health and other scientific research energy and drive. Support of collaboration can ensure that Australia gains from and adds to this growth. Already, most Australian Universities have campuses and research links throughout East Asia and India, a strong platform upon which to build for the future.”

National Health and Medical Research Council
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 life expectancy of around 82 years. Since health consumers have been shown to value an additional life year at about $432,000 based on their willingness to pay, this is an extraordinarily good deal. By world standards, Australia has created a good health system for reasonable per capita health expenditure. Only Japan, Spain and Italy achieve a higher life expectancy at lower per capita cost (Exhibit 1.11).

Exhibit 1.11
Australia’s health system delivers good outcomes for a reasonable cost

Life Expectancy Versus Health Expenditure
2010

HMR augments healthcare reforms. For the health system to improve health outcomes, such as increased life expectancy, decreased burden of disease and improved consumer attitudes, behaviour and satisfaction, it must change one or more of four inputs (Exhibit 1.12):

- resources (money spent by consumers, either directly or indirectly through health funds or taxation)
- unit people costs (direct employee and embedded capital costs)
- productivity (clinical services per person)
- effectiveness (health outcome per clinical service).

In Australia, the debate on improving health outcomes has relied too much on arguments about increasing resources, and not enough on improving productivity and effectiveness through micro-economic reform and translation of innovations from research. The total resources available and people costs are largely determined by government budget allocations. Productivity and effectiveness, on the other hand, are driven by choices on interventions that have varying costs and impacts on health outcomes. Decisions on some of these interventions, such as vaccination, are made at a population level as public health policy, while others are choices made by health professionals within hospitals and other settings.
Exhibit 1.12
There are four drivers of health outcomes

Drivers of Health Outcomes

<table>
<thead>
<tr>
<th>Health Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Life expectancy</td>
</tr>
<tr>
<td>• Quality-adjusted life years</td>
</tr>
<tr>
<td>• Burden of disease</td>
</tr>
<tr>
<td>• Consumer satisfaction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resources ($ p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consumer (~20%)</td>
</tr>
<tr>
<td>• Consumer via health funds (~10%)</td>
</tr>
<tr>
<td>• Consumer via taxation (~70%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unit People Costs ($ p.a./FTE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Direct employee costs</td>
</tr>
<tr>
<td>• Embedded capital costs</td>
</tr>
<tr>
<td>• Other costs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Productivity (Clinical Services p.a./FTE) e.g.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Vaccinations per GP</td>
</tr>
<tr>
<td>• Births per obstetrician</td>
</tr>
<tr>
<td>• Diagnostic tests per pathologist</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effectiveness (Health Outcome/Clinical Service) e.g.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• QALY saved per diagnosis</td>
</tr>
<tr>
<td>• QALY saved from prevention or high-value intervention</td>
</tr>
<tr>
<td>• Healthy babies per birth</td>
</tr>
</tbody>
</table>

HMR is key to health system efficiency. The health system comprises millions of separate interventions, with different levels of productivity and cost-effectiveness (Exhibit 1.13). Some of these interventions have been assessed for their effectiveness, but many interventions, and especially clinical interventions, have no evidence base to show how effective they are. Exhibit 1.13 is therefore indicative of the economics of the health system, but the exact shape of this curve is not known.

“The implementation of optimally efficient health reform will depend upon the engagement and effective interactions of basic science researchers, physician researchers, clinicians, allied health workers, carers and patients. The great divides which isolate these groups from each other can and must be overcome.”

The Australian Society for Medical Research

Exhibit 1.13

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

Health System Performance

<table>
<thead>
<tr>
<th>Cumulative Health Outcome (e.g. QALYs)</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination</td>
<td></td>
</tr>
<tr>
<td>Public health information campaigns</td>
<td></td>
</tr>
<tr>
<td>Screening programs</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy for most cancers</td>
<td></td>
</tr>
<tr>
<td>Open heart surgery for patients &gt;70</td>
<td></td>
</tr>
<tr>
<td>Intensive care for very ill patients</td>
<td></td>
</tr>
<tr>
<td>Lost or unnecessary diagnostic tests</td>
<td></td>
</tr>
<tr>
<td>Adverse drug reactions</td>
<td></td>
</tr>
<tr>
<td>Preventable surgical complications</td>
<td></td>
</tr>
<tr>
<td>Estimated at 20% – 30%1 of health spend</td>
<td></td>
</tr>
<tr>
<td>Current aggregate health system performance</td>
<td></td>
</tr>
</tbody>
</table>

Notes: 1. Based on US estimates

Broadly, however, health interventions can be classified as one of five types.

1. **High-Value Interventions.** High-value interventions are generally public health or primary care preventive programs applied at a population level. Examples are Australia’s well organised childhood vaccination program, the 1980s AIDS campaign, and addition of fluoride to drinking water. Since these programs are preventive in nature, they can generate a net economic benefit by improving workforce participation and/or reducing future healthcare costs. For example, a childhood immunisation program has a net benefit per QALY, while an influenza vaccination costs about $300 per QALY. Clearly identification, design and implementation of such programs should be a key priority for the HMR sector, and often requires collaboration between different types of researchers.

2. **Routine Treatment.** Routine treatment encompasses interventions by clinicians in primary care and acute settings. These can vary from highly effective, cheap interventions such as prescribing antibiotics for early treatment of infections, to expensive but nevertheless potentially life-saving treatments such as chemotherapy for cancer patients. In general, routine treatment in primary care settings or day surgery is much cheaper than in-patient treatment requiring hospitalisation. Research that can identify ways to substitute a more effective or cheaper treatment is therefore of particular benefit to the system as a whole.

3. **Low-Value Interventions.** Low-value interventions are problematic for the health system and are dealt with in a number of ways. Some of these, such as prescribing drugs listed on PBS, are quite rational and use solid evidence and health economics when a decision is made whether a drug is cost-effective. In many cases, however, decisions on whether to proceed with a given intervention are left to clinicians, hospital managers and consumers. Often it is not known in advance whether a proposed treatment will actually be effective. Research into both health economics and health services can help inform decision-making.
4. **Waste.** Many reviews have found that there is substantial waste in the health system, and spending that delivers no health benefit. For example, it is estimated that in the US 'up to one-third of the over $2,000bn spent annually on healthcare is lost on unnecessary hospitalizations, unneeded and often redundant tests, unproven treatments, over-priced, more expensive drugs, procedures and devices with no evidence of improved efficacy, and end-of-life care that brings neither comfort, care nor cure'. While the equivalent estimate has not been calculated for Australia, if it represents only 10% of health expenditure, savings of $13bn p.a. would accrue to the community, including $9bn to the Australian and state and territory governments.

5. **Adverse Events.** Adverse events are interventions that harm the patient while using health system resources. A basic example is post-operative infections, caused by inadequate hand washing, which are estimated to cost $1-2bn p.a. (Case Study 1.1). Others include surgical mistakes, or drug side effects or interactions. Many adverse events can be avoided by implementing safety techniques (e.g. checklists) that have long been common in other high-stakes settings such as aviation.

Research to inform the efficient allocation of health resources is a key priority for Australia. Both the Productivity Commission and the National Health and Hospital Reform Commission note that Australia often fails to use evidence from research to inform investment decisions, to improve services or to discontinue them. Relevant research includes observational studies of variation in the provision of health services, their costs and their outcomes, and comparative effectiveness research.

*The Sax Institute*

**Health is the highest priority for Australians.** A recent survey conducted by Research Australia found that Australians regard improvements in hospitals and the health system as the highest priority for the Australian Government with 91% of respondents giving 'improving hospitals and the health system' a rating of seven or greater out of 10. Increased funding for health and medical research and preventive care were the 9th and 10th priorities, and both are essential to delivering better healthcare (Exhibit 1.14).

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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

<table>
<thead>
<tr>
<th>Year</th>
<th>% Non-Compliance Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>~100%</td>
</tr>
<tr>
<td>2009</td>
<td>37%</td>
</tr>
<tr>
<td>2012</td>
<td>24%</td>
</tr>
</tbody>
</table>

**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.


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

**Exhibit 1.14**

*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 Respondents

<table>
<thead>
<tr>
<th>Priority</th>
<th>% of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving Hospitals and the Health System</td>
<td>91%</td>
</tr>
<tr>
<td>Keeping the National Economy Strong</td>
<td>87%</td>
</tr>
<tr>
<td>Improving Education Standards and Outcomes</td>
<td>86%</td>
</tr>
<tr>
<td>Improving National Infrastructure</td>
<td>85%</td>
</tr>
<tr>
<td>Improving Employment Opportunities</td>
<td>84%</td>
</tr>
<tr>
<td>Doing More to Keep Prices and the Cost of Living Down</td>
<td>84%</td>
</tr>
<tr>
<td>Providing Strong Leadership</td>
<td>82%</td>
</tr>
<tr>
<td>Creating More Skilled Jobs and Apprenticeships</td>
<td>81%</td>
</tr>
<tr>
<td>More Funding for Health and Medical Research</td>
<td>80%</td>
</tr>
<tr>
<td>Increasing Funding for Preventive Health Care</td>
<td>78%</td>
</tr>
</tbody>
</table>

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

A more strategic focus on research that will deliver greater impact in the health system would naturally place greater emphasis on high-value interventions, such as vaccine development and other preventive measures, and on reducing waste and adverse events. Research, therefore, has a vital role to play to deliver a more efficient and effective health system.

**1.3.2 Deliver Evidence-Based Healthcare and Policy**

In every sector of the economy, R&D facilitates innovation which drives the creation of economic value via improvements in quality, productivity, price or profitability. The inherent relationship between research and better outcomes can be seen in the agricultural sector, where continuous advances in seed technology, and in growing and harvesting crops, for example, continue to drive greater efficiencies and improved financial outcomes.

Similarly, HMR is essential to facilitating continuous improvements in our health system. This sector is, however, somewhat different to others in the economy in that there is a major disconnect between those areas which predominantly carry out the research, those areas where the services are delivered, and the sources of investment and consumption.

This disconnect has impeded the translation of research findings into better healthcare practice and products. Indeed, the consequence of lack of integration of research into healthcare practice is the fact that health services and medical treatments are still not, overall, sufficiently well underpinned by evidence-based practice. Many healthcare practices appear to show evidence of harmful impacts, have been proven to be beneficial but have not been implemented, have evidence of no impact, or have no evidence base at all. A recent healthcare audit found that up to 43% of Australians do not receive appropriate, evidence-based healthcare (Case Study 1.2). This is likely to be a key driver of waste in the healthcare system and, more importantly for consumers, can lead to adverse events that cause morbidity and mortality.

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Ten years from now, Australia can aspire to a health system that is firmly based on evidence gained from health and medical research … In this system, patients will receive care that research has shown to be effective, new science based therapies can overcome the ill-health burdens of today, public health can be improved by policies based on evidence of what works, health costs can be contained by using public funds only for evidence based interventions and therapies, our health system can be infused with practitioners and policy makers who make their decisions based on evidence.

National Health and Medical Research Council

There appears to be much to be gained by strengthening the connection between researchers and healthcare practitioners—starting with translation of existing research evidence into clinical practice. Australia must move to a health system in which healthcare practice and policy are consistently based on evidence and research evidence is routinely translated into practice and policy.

There are three levers to improve the health system in which research can be used to identify improvement opportunities and evaluate implementation (Exhibit 1.15).

Exhibit 1.15

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

Levers to Improve Health System Performance

1. Eliminate adverse events and waste through better management
   - Management
   - Health services research
   - Health economics

2. Translate research into healthcare practice and policy
   - Research translation
   - Evaluation and monitoring
   - Public health research

3. Develop new knowledge and interventions
   - Biomedical research
   - Clinical research

Source: Pacific Strategy Partners analysis
1. **Eliminate Adverse Events and Waste.** The potential benefits available to the community from addressing waste and adverse events were noted by the National Health and Hospitals Reform Commission (NHHRC):

- 'We know that far too many diagnostic tests, medicine and procedures that are performed are unnecessary, inappropriate, and even sometimes harmful'.
- 'Growing concerns about quality and safety … there is an accumulation of evidence that simple mistakes—such as failure to wash hands between patients— … are too frequent and could be reduced'.

A much greater investment in health services research is therefore warranted to identify and implement ways to avoid waste and adverse events. Such an investment has the potential to both improve health outcomes and reduce costs (allowing political decisions to increase spending on more effective health interventions, fund other government programs or reduce taxes). To be effective, this effort must be matched by corresponding changes within the health system to be able to effectively utilise research findings. Collaboration between clinicians and researchers working in close proximity is a proven method to ensure that research has real impact.

2. **Translate Research into Healthcare Practice and Policy.** There is potential for significant gains in the health and wellbeing of Australians by simply translating existing knowledge. Increased alignment of Australia’s health services delivery with evidence-based healthcare and policy will improve quality and cost-effectiveness. Research needs to be done in this field to evaluate evidence-based healthcare and policy and develop strategies to improve alignment.

3. **Develop New Knowledge and Interventions.** Biomedical and clinical research to develop breakthrough discoveries delivers significant advances in health outcomes over time, and generally at a reasonably efficient cost. A major objective of HMR should be to improve the efficiency and cost-effectiveness of health services. This aspect of R&D may be overlooked as a driver of efficiency and effectiveness of the broader health system due in part to the relatively large public sector involvement, where the ‘invisible hand’ of the market is consequently absent. For example, a novel but unnecessary diagnostic test may have no health benefit and divert resources from more beneficial uses, but represents revenue for a pathologist and a diagnostics company. Consequently, research must be firmly embedded into the health system and appropriate measures set to ensure that research translation occurs at the ‘moments of truth’—healthcare practice and policy. Failure to do so will prevent further investment from delivering optimal health outcomes. Research in its different forms, therefore, has significant untapped potential to improve health outcomes and cost effectiveness of the health system.

> The concept of research-driven clinical care is essential for a health system. It produces an enquiring and questioning form of health care, which produces best clinical outcomes for patients and cost-efficient delivery as ineffective treatments are evaluated and discarded.

*Victorian Government*

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CASE STUDY 1.2

43% of Australians do not receive appropriate, evidence-based healthcare

Background. A recent study on healthcare delivery found that about 43% of people do not receive healthcare that is considered appropriate and based on evidence. The CareTrack Australia study, which is part of an NHMRC program grant to examine the appropriateness of care provided in Australia, undertook the assessment of healthcare received by over 1,000 Australians in over 35,000 healthcare encounters, and across 22 conditions ranging from coronary heart disease and low back pain, through to depression.

Levels of appropriate, evidence-based care varied significantly. Alcohol dependence (13%), antibiotics (19%) and obesity (24%) fared the poorest, while coronary artery disease (90%) and chronic heart failure (76%) were among the highest scoring conditions delivering appropriate care. Other major findings included:

- Nearly 90% of patients with sinusitis were prescribed antibiotics, when this is known to be ineffective.
- Only 18% of patients with asthma had a documented action plan for when they had an attack.
- Less than 30% of patients over 50 had a documented bowel cancer screening test.
- Only 73% of 50–69 year-old women had a mammogram every two years.

Level of Appropriate Care
% Appropriate Care Received (For Conditions Scoring Below 50%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Dependence</td>
<td>13%</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>19%</td>
</tr>
<tr>
<td>Obesity</td>
<td>24%</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>35%</td>
</tr>
<tr>
<td>Asthma</td>
<td>37%</td>
</tr>
<tr>
<td>Surgical Site Infection</td>
<td>38%</td>
</tr>
<tr>
<td>Preventive Care</td>
<td>44%</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>45%</td>
</tr>
</tbody>
</table>

Key Lessons:

1. **Auditing healthcare delivery identifies opportunities for improvement.** The CareTrack study evaluated the healthcare outcomes of 1,154 individuals and highlighted that there is a high incidence of healthcare that is not appropriate or based on evidence.

2. **Evidence-based care delivers better health for Australians.** Implementing measures of appropriateness of healthcare can drive continuous improvement and deliver improved health outcomes for consumers.


1.4 A World-Class HMR Sector

1.4.1 Leverage and Extend Reforms

**Wills Review Reforms.** In 1998 the Health and Medical Research Strategic Review committee, chaired by Mr Peter Wills AC, presented a report to the Australian Government (*The Virtuous Cycle*) which led to both a significant increase in funding for the sector, and a range of other beneficial reforms. The HMR sector now needs to leverage and extend the reforms from the Wills Review that have reshaped the sector over the last decade, to embed research in the health system with greater integration and collaboration between researchers, health professionals and the community (Exhibit 1.16). The Wills Review reforms created a fundamental shift towards competitive grants and increased the quality of research across the sector. The next phase should be defined by a relentless focus on the highest quality of research via continued support of competitive schemes, and an increased focus on translational and impact-oriented research that delivers health system impact and priority-driven, strategic research that targets Australia’s highest priority issues.

**Exhibit 1.16**

The Australian HMR sector needs to build on previous sector reforms to become an embedded component of the health system

Eras of Australian HMR

**Pre-Wills Era**
- Ring-fenced NHMRC research from ARC
- Narrowed focus on medical research
- Established MRIs

**Wills to Present Day**
- Moved from block funding to competitive grants
- Identified importance of priority-driven and strategic research
- Revised NHMRC governance
- Reiterated focus on policy and practice-focused research
- Increased funding significantly

The Wills Review also identified the different types of research which should continue to be embraced across the full spectrum. Research can be classified into four primary categories.

- **Biomedical research.** Research undertaken to address fundamental questions about the biological, behavioural and social mechanisms which underlie wellness and disease.

- **Clinical research.** Research involving clinical patients or tissue samples from patients, undertaken to find better ways of identifying and caring for people in ill health.

- **Public health research.** Research involving communities or populations, undertaken to identify the factors which contribute to ill-health in populations and ways of influencing those factors to prevent disease.

- **Health services research.** Research into health services to examine ways of improving delivery of health services, e.g. cost benefit studies of health programs.

Research Embedded in the Health System

**The Future**
- Embed research in the health system
- Support priority-driven research
- Maintain research excellence
- Enhance non-commercial and commercial pathway to impact
- Attract philanthropy and new funding sources
**National Research Investment Plan.** The Australian Government's National Research Investment Plan (NRIP) states 'Australia's national wellbeing, as reflected in the health and lifestyle of the population and the security and sustainability of the environment in which Australians live, is dependent on research and innovation'. The plan highlights the need for capacity 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 (Exhibit 1.17).

**Exhibit 1.17**

**Australia’s national wellbeing is dependent on research, development and innovation**

**How Australia Benefits from Research**

<table>
<thead>
<tr>
<th>Increased National Wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved living standards</td>
</tr>
<tr>
<td>Increased participation</td>
</tr>
<tr>
<td>Improved health and environment</td>
</tr>
<tr>
<td>More sustainable and resilient communities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Productivity Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>For example:</td>
</tr>
<tr>
<td>More efficient businesses</td>
</tr>
<tr>
<td>Better service delivery by government</td>
</tr>
<tr>
<td>Increased competitiveness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Solving National and Global Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>For example:</td>
</tr>
<tr>
<td>Improved treatment of disease</td>
</tr>
<tr>
<td>Increased food production</td>
</tr>
<tr>
<td>Protection of the environment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing the stock of knowledge</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devising new applications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing new products and services</td>
</tr>
</tbody>
</table>

Source: Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE), National Research Investment Plan, 2012

NRIP puts forward the need for a national research 'fabric', so Australian researchers can draw on high-quality, focused and nationally coordinated support for their research. There are five subject domains, and HMR is considered to be within the human domain. Across these domains, research is underpinned by the fundamental elements of the research system, comprising public research investment, workforce, infrastructure, collaboration and business research investment. HMR represents 14% of total Australian Government funding for the science, research and innovation portfolio.24

Also highlighted in NRIP is the need to move from traditional 'silo-based' delivery of research to a more interlinked and interdependent system of collaboration and multi-disciplinarity that strengthens the current research fabric and contributes to improved national wellbeing. This is supported in the Panel's 10-year vision for HMR, recognising the need for a multi-disciplinary approach and increased collaboration across research areas and geographies.

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NRIP also notes the need for maintaining a strong basic (e.g. biomedical) research capability in Australia to:

• provide early access to research findings that it needs to become an 'anticipator' of new trends and directions;
• avoid having to be a 'follower' which is forced into the position of a 'price taker', having to buy in new technology from overseas once it has been fully developed;
• ensure depth of knowledge, and strength of research industry relationships, needed to make effective use of new technologies and processes;
• capture spill-over benefits such as the availability of trained researchers and the development of new instrumentation and methodologies; and
• retain capacity to address unique Australian challenges.

**Likely Future Developments.** Trends in HMR are likely to be driven by broader changes in the healthcare and research sectors (Exhibit 1.18). Major healthcare trends such as the increasing prominence of personalised medicine and rising healthcare costs will provide significant opportunities for HMR to contribute. The way research is being undertaken and disseminated will also drive changes in the delivery and translation of HMR. With increasing global collaboration, there is a need for greater integration between researchers and health service professionals.

**Exhibit 1.18**

Future developments in HMR are likely to be driven by changes in healthcare delivery and research

**Likely Future Developments in HMR**

**Healthcare Trends**
- Demand
  - Personalised medicine (e.g. genomics)
  - Ageing population
  - Environmental challenges
  - Medical tourism
- Supply
  - Rising costs of healthcare
  - Preventive health
  - Evidence-based practice
  - New delivery modes (e.g. home care)

**Research Trends**
- People
  - Globalised research teams
  - Emergence of developing economies (e.g. India, China)
  - Advances in technology and sharing of infrastructure
- Technology
  - Electronic dissemination
- Funding
  - Rapid grant application processes
  - Innovative sources of funding

**HMR Trends**
- Integration of health services delivery and research
  - Top-down strategic research
  - Streamlining grant processes
  - Preventive health research
  - Increased use of evidence in healthcare practice and policy
  - Increased use of philanthropy and new funding sources (e.g. social bonds)

1.4.2 Maintain World-Class Research

A world-class research sector is essential to avoid having to procure intellectual property (IP) from overseas and to building capability and expertise to translate research locally. Australia ranks highly against a range of international benchmarks for HMR, ‘punching above its weight’ in publication output with relatively high citation rates. According to a recent benchmarking analysis undertaken by the Office of the Chief Scientist, HMR is one of Australia’s strongest fields of research, with citation rates above the average of comparable European country benchmarks. This performance is the fruit of long-term investment and ongoing sector reform to improve the quality and effectiveness of HMR, particularly over the last decade.

As measured by research outputs (journal publications and citations) over the decade from 2001 to 2010, Australia ranked sixth internationally in terms of citations per publication (Exhibit 1.19). Of the four main research sectors, MRIs have a particularly high rate at 24.6 citations per publication. While there are more sophisticated methods of assessing HMR performance, such as using the Relative Citation Index methodology that adjusts for research field, citations per publication provides a relatively robust measure that is broadly in alignment and is useful as a comparative international benchmark. This level of excellence is the result of consistent investment and reform in HMR over the last decade.

Exhibit 1.19

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

HMR Bibliometrics Overview
2001–10 Total

<table>
<thead>
<tr>
<th></th>
<th>Australia</th>
<th>Global Benchmarks¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Publications ('000s)</td>
<td>Citations per publication</td>
</tr>
<tr>
<td>Universities</td>
<td>117</td>
<td>14.8</td>
</tr>
<tr>
<td>Hospitals</td>
<td>51</td>
<td>16.6</td>
</tr>
<tr>
<td>MRIs</td>
<td>15</td>
<td>24.6</td>
</tr>
<tr>
<td>CSIRO</td>
<td>3</td>
<td>16.6</td>
</tr>
<tr>
<td>Total²</td>
<td>153</td>
<td>15.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Australia produces a high relative proportion of publications in key international fundamental science and clinical journals (Exhibit 1.20), and performs well above world standard in terms of publication output and citation impact in seven specific medical disciplines: Cardiovascular Medicine and Haematology, Oncology and Carcinogenesis, Immunology, Medical Physiology, Human Movement and Sports Science, Clinical Sciences, and Pharmacology and Pharmaceutical Sciences.25

**Exhibit 1.20**

Australia has a high share of publications in major global journals relative to its contribution in investment

<table>
<thead>
<tr>
<th>% Share of Total Publications</th>
<th>Three Fundamental Science Journals: Science, Cell and Nature</th>
<th>Two Key Clinical &amp; Public Health Oriented Journals: The Lancet &amp; NEJM²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell</td>
<td>2.1% 2.4% 2.7% 2.8% 2.5% 2.5% 3.0%</td>
<td>3.4% 3.7% 4.3% 5.4% 4.8% 4.1% 4.6%</td>
</tr>
<tr>
<td>Science</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>108</td>
<td>108</td>
</tr>
<tr>
<td>2005</td>
<td>131</td>
<td>126</td>
</tr>
<tr>
<td>2006</td>
<td>151</td>
<td>124</td>
</tr>
<tr>
<td>2007</td>
<td>146</td>
<td>144</td>
</tr>
<tr>
<td>2008</td>
<td>131</td>
<td>180</td>
</tr>
<tr>
<td>2009</td>
<td>129</td>
<td>153</td>
</tr>
<tr>
<td>2010</td>
<td>153</td>
<td>131</td>
</tr>
</tbody>
</table>

Notes: 1. Australia is estimated to account for ~1.1% of health R&D and ~1.8% of global GDP, but ~3.6% of the above health and medical publications
2. New England Journal of Medicine


NHMRC-supported research has a particularly high standing and, with publication citation rates above the Australian average in all fields and sub-fields, accounts for a significant number of the country’s most highly-cited publications. For all schemes, NHMRC publications achieve citations at a rate close to 50% or higher above the world benchmark.26 Over all disciplines, Australia has produced 15 Nobel Laureates, which is the highest number per head of population of any country in the world. Of these 15, seven have been in ‘Physiology or Medicine’.27

1.4.3 Focus on Translation and Impact

An increased focus on translational research and research that directly improves the health system is essential to the vision of building the world's best health system. Australians value investment in HMR because it delivers impact in the form of better health outcomes. Accordingly, research undertaken should ensure efforts are focused with this objective in mind. One example of research that is focused on translation and direct health system impact is research which identifies opportunities to eliminate adverse events and waste.

A greater focus on research that can be readily applied to evidence-based practice is critical, and greater collaboration between health professionals and researchers should be fostered to deliver research with greater impact. An example of translation-focused research is the Hendra virus (Case Study 5.11), where within two weeks of the first incidence of this new virus, scientists had isolated the source of the virus to be in bats. Instead of focusing their efforts on the bat population, which would have been more affordable and easier to apply for grant funding, researchers collaborated with veterinary health practitioners and focused their efforts on preventing and treating the virus in horses, dogs and humans to prevent an outbreak. Focusing on the end outcome enabled the issue to be resolved much more quickly than it would have otherwise been.

There are also significant benefits of increased strategic research, as highlighted in the 2011 Focusing Australia's Publicly Funded Research Review, which led to the establishment of the Australian Research Committee. One of the key findings of that review was that ‘it is critical for Australia to have a national and a strategic approach and better coordination of effort and investment in research’.28

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. Currently the value of investment in the HMR sector is not well known, with estimates varying based on the source of data used. Taking into account all available data sources and including estimates where data are not available, the total Australian HMR sector investment is estimated to be around $6bn in 2011–12 (Exhibit 1.21). Apart from the NHMRC competitive schemes which are well documented, the rest of total $6bn in investment is not adequately tracked and its outcomes are unclear. In particular, the investment in research in Local Hospital Networks (LHNs), estimated to be $1–$1.5m or 1.6% of total government health expenditure ($95bn in 2011–12), should be determined as an immediate national priority. Investment in research in LHNs is critical to lay the groundwork and help to establish a culture of continuous improvement that delivers evidence-based healthcare.

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**CASE STUDY 1.3**

Collaborative efforts have led to the discovery and development of a vaccine technology that prevents cervical and other cancers

**Background.** The human papillomavirus (HPV) vaccine was the first designed to prevent cervical cancer. HPVs are responsible for 100% of genital warts, almost 100% of cervical cancers, 40% of vulvar cancers, 85% of anal cancers and 50% of penile cancers. In 2002, over half a million new cancer cases globally were attributable to persisting HPV infections.

Researchers at The University of Queensland (UQ) discovered a way to create a virus-like particle (VLP) to mimic HPV and provide protective immunity against HPV infection. This technology was licensed through UniQuest to CSL Limited, who on-licenced to Merck and GSK, to develop and commercialise two vaccines which were released to the market as Gardasil and Cervarix.

The rollout of Gardasil through the Australian National HPV Vaccination Program has resulted in improved health outcomes for females, with a reduction in the incidence of HPV-associated genital wart disease by ~75% and an expected corresponding reduction in cervical cancer incidence over the next 30 years. Vaccination for males aged 12-13 will commence in 2013.

**HPV Vaccine Technology – From Basic Research to Health System Impact**

<table>
<thead>
<tr>
<th>Basic Research</th>
<th>Development</th>
<th>Immunisation Program</th>
<th>Health System Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980-1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1989-1991 Synthesis of particles to mimic HPV at UQ leads to the creation of a VLP in Australia.</td>
<td>1995-2006 CSL sub-licenses to Merck and GSK, who scale up technology and pursue vaccine clinical trials.</td>
<td>2013 Gardasil added to the National Immunisation Program for 12-13 year old boys.</td>
<td></td>
</tr>
</tbody>
</table>

**Key Lessons:**

1. **Collaborative research can deliver breakthrough discoveries of interventions to prevent major illnesses.** Basic and clinical research identified the link between HPV and cancer. This promoted research leading to the development of VLPs that mimics HPV and designed to induce immunity to the strains of HPV responsible for the majority of cervical cancers and genital warts. HPV vaccines have been approved in more than 120 countries and over 70 million doses have been distributed worldwide.

2. **Commercialisation expertise is key to ensure translation of breakthrough discoveries.** HPV vaccine development was supported by UniQuest, CSL, Merck and GSK in patenting, technology development, undertaking clinical trials, and bringing the vaccine to market.

3. **Evidence-based policy leads to significantly improved healthcare outcomes for the broader population.** The addition of Gardasil to the National Immunisation Program has already reduced, and will continue to reduce, HPV-related diseases including cancers in Australia.

**Source:** S Tabrizi et al, ‘Fall in human papillomavirus prevalence following a national vaccination program’, *Journal of Infectious Diseases*, 19 October 2012, pp.1-7; National Immunisation Program, *Fact Sheet: HPV Vaccination for Boys*, 2013
Exhibit 1.21

Total HMR investment is estimated at ~$6bn in 2011–12

Total HMR Investment\(^1\)

\(\text{$bn} \)

\(2011–12\text{e} \)

\[ \begin{array}{c|c|c|c|c}
\text{NHMRC} & \text{LHN} & \text{University} & \text{Business} & \text{Total} \\
& & & \text{& Other} & \text{& NFP} \\
0.8 & 0.4 & 1.1 & 2.1 & 5.8 \\
\hline
\end{array} \]

\( \text{HMR of Health System Spend} \)

\((0.8 + 1.1) / 95 = 2.0\% \)

Source: Treasury; DoHA; NHMRC; ABS; AIHW; Pacific Strategy Partners analysis

International HMR benchmarks published by the OECD do not provide a comparable set of metrics for looking at government HMR investment in the context of research performed across the sector due to the different definitions used. Nevertheless, they still provide some insights into relative positioning across countries. Australian investment in both health and HMR is generally comparable with that of other OECD countries (Exhibit 1.22).

Exhibit 1.22

Australia’s investment in health and R&D as a proportion of GDP is slightly below the OECD average

<table>
<thead>
<tr>
<th>Public and Private Health Expenditure</th>
<th>Government Health R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>as % of GDP</td>
<td>as % of GDP</td>
</tr>
<tr>
<td>2009</td>
<td>2009</td>
</tr>
<tr>
<td>Private</td>
<td>Public</td>
</tr>
<tr>
<td>17.4</td>
<td>8.3</td>
</tr>
<tr>
<td>11.8</td>
<td>9.2</td>
</tr>
<tr>
<td>11.6</td>
<td>8.9</td>
</tr>
<tr>
<td>11.5</td>
<td>9.8</td>
</tr>
<tr>
<td>11.4</td>
<td>8.1</td>
</tr>
<tr>
<td>11.4(^1)</td>
<td>8.8</td>
</tr>
<tr>
<td>10.0</td>
<td>8.2</td>
</tr>
<tr>
<td>9.8</td>
<td>8.2</td>
</tr>
<tr>
<td>9.6</td>
<td>6.9</td>
</tr>
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<td>9.5</td>
<td>7.0</td>
</tr>
<tr>
<td>9.5</td>
<td>7.4</td>
</tr>
<tr>
<td>8.7</td>
<td>6.5</td>
</tr>
<tr>
<td>8.5(^2)</td>
<td>6.9</td>
</tr>
<tr>
<td>7.8</td>
<td>4.6</td>
</tr>
<tr>
<td>US</td>
<td>0.31</td>
</tr>
<tr>
<td>France</td>
<td>0.05(^1)</td>
</tr>
<tr>
<td>Germany</td>
<td>0.04</td>
</tr>
<tr>
<td>Denmark</td>
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</tr>
<tr>
<td>Canada</td>
<td>0.10</td>
</tr>
<tr>
<td>Switzerland</td>
<td>0.00(^2)</td>
</tr>
<tr>
<td>Sweden</td>
<td>0.01</td>
</tr>
<tr>
<td>UK</td>
<td>0.11(^1)</td>
</tr>
<tr>
<td>OECD Average</td>
<td>0.11(^1)</td>
</tr>
<tr>
<td>Spain</td>
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</tr>
<tr>
<td>Italy</td>
<td>0.05(^2)</td>
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<tr>
<td>Australia</td>
<td>0.09(^2)</td>
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<tr>
<td>Japan</td>
<td>0.03(^2)</td>
</tr>
<tr>
<td>Israel</td>
<td>0.01(^2)</td>
</tr>
</tbody>
</table>

Notes:
1. Based on expenditure in 2008
2. Based on expenditure in 2010
Source: OECD, Research and Development Database, 2011
CASE STUDY 1.4

A targeted approach to cerebral palsy has led to improved clinical practices, delivering better health and reducing healthcare costs

**Background.** The Cerebral Palsy Alliance is an established Australian charity that launched a Research Foundation in 2005 dedicated to preventing and curing cerebral palsy. Despite being the most common physical disability in childhood with a high economic and social impact, there was relatively little research into the prevention and cure of cerebral palsy. This was partly due to conventional wisdom that cerebral palsy was caused by oxygen deprivation at birth.

In 2007, the Cerebral Palsy Alliance established a strategic review process which identified 33 areas of research that could help reduce the incidence and impact of cerebral palsy. This targeted approach shed new light on what research should be prioritised, with research evidence consistently showing that cerebral palsy is largely unrelated to clinical procedures around the time of birth.

As a result, researchers now focus on preventive treatments during gestation and labour, as well as cures that repair the brain after injury. Two research findings have been translated into clinical practice as a consequence:

- Brain cooling can reduce incidence by 15% in babies sick at birth.
- Magnesium sulphate can reduce incidence by 30% in extremely premature infants.

**Key Lessons:**

1. **A targeted approach to health and medical research can provide significant benefits.** Undertaking a targeted strategic review focused research efforts on key priority areas and disproved erroneous beliefs regarding the cause of cerebral palsy. New preventive treatments have since been developed as a result.

2. **Translating research into clinical practice delivers better health and reduces healthcare costs.** Increased prevention of cerebral palsy leads to significant gains in the quality of life and reduced healthcare costs. It is calculated that for every case of cerebral palsy prevented, $2m is saved over the child’s first 18 years of life which is a high return on investment for a cost of prevention of less than $190k per case.

**Notes:** Image courtesy of the Cerebral Palsy Alliance  
Source: S Schofield, *How do I know if my intervention was cost effective?*, Cerebral Palsy Alliance Research Foundation, undated
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—the embedding of research in the health system will provide the necessary foundation for the supporting themes to deliver impact (Exhibit 1.23).

Exhibit 1.23

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

HMR Strategy

This 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 (Exhibit 1.24). Maintaining the current 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 more detail in the following sections of the report.
Exhibit 1.24
The 10-year strategy will deliver the vision’s aspirational outcomes

Strategic Initiatives

Strategy

Build HMR Capability
- Enhance commercialisation environment (17)
  - Foster a culture of commercialisation
  - Leverage scale and expertise

Accelerate Translation
- Enhance commercialisation environment (17)
  - Attract clinical trials investment from overseas

Optimise Investment
- Support research commercialisation (16)
  - Matching development grants
  - Translational Biotech Fund

Deliver Outcomes
- Increase longevity and quality of life
- Boost national wealth
- Drive shift to knowledge-based jobs
- Enhance international standing and engagement with Asia

• Build health professional research capacity (4)
• Enhance public health research (12)
• Enhance health services research (13)
• Establish Integrated Health Research Centres (3)
• Accelerate clinical trial reforms (5)
• Drive health system innovation (14)
• Inform policy with evidence (15)

• Support a range of strategic topics (7)
• Maintain research excellence in discovery and applied research
  - HMR workforce (8)
  - Grant processes (9)
  - Indirect cost support (10)
  - Enabling infrastructure (11)
• Establish sector leadership (2)

• Drive research activity in the health system (1)
• Align priority-setting processes (6)
  - Attract philanthropy (16)
  - Identify new funding sources (19)
  - Invest for the future (20)
  - Action report recommendations (21)

Note: Numbers in parentheses refer to report recommendations

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, the researchers themselves—so that all stakeholders can work together to embed research in the health system and deliver the vision. (Exhibit 1.25).

Exhibit 1.25
The vision calls for strengthened partnerships between researchers, health professionals and the community

Delivery Through Partnerships

Researchers
MRRs, universities and healthcare providers

Health Professionals
Hospitals, clinics and other settings

The Community
Governments, businesses, philanthropy and consumers

A Healthy and Wealthy Australia with the World’s Best Health System

‘Better Health Through Research’
2. Embed Research in the Health System
2. EMBED RESEARCH IN THE HEALTH SYSTEM

2.1 Introduction

Scientific research underpins the modern health system. It is also essential to improving the Australian health system in the future, and making it more efficient financially. While Australia performs ground-breaking HMR within its research institutions, universities, hospitals and companies, increasing pressure to deliver healthcare services has actually restricted research activity within the health system itself. This pressure has also created barriers for research translation into better care through evidence-based clinical and health interventions. Additionally, the distributed business model of healthcare delivery, in which multiple independent individuals and organisations are responsible for service delivery, hinders a national, integrated approach to research and healthcare delivery.

The aim of embedding research in healthcare delivery is to facilitate overt involvement of the health-delivery workforce in research, with the result that it would be a routine and universally-accepted component of healthcare. Research would be carried out across every facet of healthcare delivery, not necessarily by each and every healthcare practitioner, but by all categories of healthcare practitioners. This would drive a Kaizen or continuous improvement mindset in the health system (Case Study 2.1) where:

- research is carried out in a purposeful manner, valued and rewarded;
- outcomes and impacts—beneficial or detrimental—are tracked and evaluated; and
- a feedback system is in place to direct future research to areas of strategic need.

Exhibit 2.1

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
Embedding HMR across the breadth of Australia’s healthcare system will require major changes to five key areas (Exhibit 2.1):

- investment – to drive research activity in the health system
- leadership – to establish sector leadership and governance
- excellence – to fund world-class 'Integrated Health Research Centres'
- capability – to build health professional research capacity
- processes – to accelerate clinical trial reforms and facilitate translation.

“... there needs to be an active embedding of a research culture throughout the health system, so that health care providers and administrators contribute to, foster and draw from the expanding body of knowledge, and provide high-quality training for the next generation of health professionals. Key Result Indicators need to include research indicators of excellence, across the health system.

The Group of Eight Limited

Numerous benefits would be derived from more deeply embedding research into the healthcare system in Australia, including:

- better feedback from consumers to researchers, and a much closer connection between consumers and the research that is conducted for their benefit—this is a process clearly requested by consumer groups and is demonstrably beneficial when performed well;
- increased innovation and faster, more comprehensive translation of research outcomes into evidenced-based practice in healthcare settings;
- health system improvements supported by research evidence, resulting in both better consumer outcomes and improved productivity and effectiveness; and
- overall, a more affordable and cost-effective healthcare system.

The current backdrop of national health reforms provides an opportune environment to embed research in the health system.

“... research should be embedded into every level of the health system from prevention to primary care, and tertiary services. The new national health reform agenda provides the ideal opportunity to reassert health and medical research as a core activity within our public health systems … The flow on effects of such a paradigm shift would be significant.

Baker IDI Heart and Diabetes Institute

“The National Health and Hospital Reform provides an opportunity to clarify funding for research for LHDs to support improvements in the strategic direction and management of this research. This could be achieved through an expectation that LHDs develop a strong research culture (e.g. through research strategic leadership, governance, support for clinician-researchers and by ensuring LHD infrastructure support research activities) and ensuring that this work is appropriately funded.

NSW Ministry of Health
CASE STUDY 2.1

Continuous improvement programs deliver better patient care and reduced costs

Background. In 2002, Virginia Mason Medical Centre embarked on a system-wide program to change the way it delivered healthcare to improve safety and quality of patient care. It adopted the basic tenets of the Toyota production system as the basis for its continuous improvement program.

Delivery of the improvement program involved research activities throughout the organisation, with opportunities for improvement identified and strategies implemented. Examples of initiatives include:

- **Reducing unnecessary tests.** Introduced software to reject unnecessary magnetic resonance imaging scans, resulting in a 31% reduction.
- **Adding valuable nursing time at bedside.** A study of nurses' time and opportunities for efficiency gains (e.g. reducing time to collect supplies) led to increased time spent with patients from 35% to 90%.
- **Reducing adverse events.** Initiatives such as preventive screenings for patients prior to appointments and level loading to manage staff workload and skill level have minimised the potential for adverse events and led to a significant increase in quality of care.

As a result of the continuous improvement program, Virginia Mason Medical Centre increased the efficiency of its workforce, created more capacity in existing healthcare programs and practice, and reduced capital and operating costs. Patient and staff satisfaction also increased significantly.

### Results of Continuous Improvement Program

<table>
<thead>
<tr>
<th>Category</th>
<th>2004 Results</th>
<th>Metric</th>
<th>Change from 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory</td>
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<tr>
<td>Productivity</td>
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<td>FTEs</td>
<td>36% redeployed to other positions</td>
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<td>Down 41%</td>
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<td>Hours</td>
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<td>Product Distance</td>
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<tr>
<td>Setup Time</td>
<td>7,744</td>
<td>Hours</td>
<td>Down 82%</td>
</tr>
</tbody>
</table>

### Key Lessons:

1. **Research can help identify opportunities to drive improvement in healthcare and deliver better patient outcomes and reduced costs.** Virginia Mason Medical Centre identified and implemented initiatives to improve the effectiveness and efficiency of its healthcare services, which resulted in better patient outcomes, staff satisfaction and reduced costs. Since embarking on its continuous improvement journey, Virginia Mason Medical Centre has been the recipient of numerous quality awards.

2. **Leadership and a culture of continuous improvement are key to driving change within healthcare organisations.** The implementation of the continuous improvement program was driven by senior management, and led to a significant cultural shift within the organisation.

2.2 Drive Research Activity in the Health System

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 estimated $1.0–$1.5bn p.a. 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.

2.2.1 Introduction

Implementation of the National Health Reform Agreement (NHRA). In August 2011, the Australian Government entered into the NHRA with the states and territories 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 Government will also increase its commitment to additional funding for public hospital services to at least $16.4bn between 2014–15 and 2019–20 (in addition to the contribution it would otherwise have made to base funding).

The primary mechanism to deliver this funding increase is by adding an Activity Based Funding (ABF) system, with efficient prices for the delivery of hospital services set by the Independent Hospital Pricing Authority (IHPA). This system will ensure that hospitals are paid according to the number and types of services they actually deliver, though some rural and remote hospitals will still receive block funding. The National Health Performance Authority (NHPA) will report on the services provided by public hospitals. Health services have also been reorganised into LHNs and Medicare Locals for primary care.

Allocation for teaching, training and research (TTR). Funding for TTR will also be provided as a component of NHRA funding. The current TTR allocation is 3.68% of Australian Government funding, although it varies between states and territories from 2% to 6%. The mechanism for funding TTR activities under NHRA has yet to be determined. Under NHRA, it has been agreed that IHPA will provide advice to the Council of Australian Governments Standing Council on Health (COAG SCoH) on the feasibility of transitioning funding for TTR to ABF (or other appropriate arrangements reflecting the volumes of activities carried out under these functions) by no later than 30 June 2018.

For NHRA to achieve its targeted impact on the Australian population, the Panel strongly believes that research must become integral to, and embedded in, the $135bn p.a. health system. This system includes primary care (Medicare Locals), the Pharmaceutical Benefits Scheme (PBS) and acute care through LHNs. It is different from other sectors in the national economy in that almost 70% of the total cost of health services ($95bn p.a.) is provided by government (either the Australian Government, or state and territory governments). For research to be fully embedded within the health system there is a need for coordination across the Australian Government and between the Australian Government and the state and territory governments in a unified approach, from COAG down.

National health reform, and its renewed focus on primary health care, will change the way in which many health services are accessed and delivered across the country. The shifting focus from acute care to primary health care will impact the way in which health services operate; affecting both the health professions as well as the way in which individuals negotiate their own involvement with the health care system. Research must accompany the reforms to ensure evidence-based decision-making.

Royal College of Nursing, Australia

The Panel's proposed mechanism to embed HMR in the health system requires initiatives across three areas:

1. **Manage and Refocus Research in Local Hospital Networks** – Maintain and focus block funding using the NHRA formula already agreed with the states and territories, or by simply matching LHN expenditure (Section 2.2.2).

2. **Add Competitive Programs** – Add national competitive programs that would fund individuals and infrastructure to conduct research within the health system, including practitioner fellowships, Integrated Health Research Centres (IHRCs), clinical trials and other policy initiatives. The focus of the competitive programs should be broader than LHNs and include primary, community and residential care, and other health professionals (Section 2.2.3).

3. **Establish a National HMR Investment Target** – Evaluate effectiveness of competitive programs, and increase investment towards a national health system R&D investment target (Section 2.2.4).

### 2.2.2 Manage and Refocus Research in Local Hospital Networks

**Issue:** Research is generally undervalued and poorly managed in the hospital system. 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’. The current level and quality of research output from health professionals is a testament to their energy and commitment, as much of this work is carried out after normal work hours or during weekends. However, there are considerable barriers and disincentives in place which impede research within the sector itself.

Resources provided to hospitals predominantly focus on immediate consumer needs. Even in large public hospitals, research can be seen as an 'added cost' which is subtly, or sometimes overtly, discouraged. Funding originally designated for research may not be clearly defined as being for this purpose and can be reallocated by hospital managers to other ‘more urgent’ areas of healthcare delivery, especially where pressure exists to reduce waiting times for publicly-funded health services.

Funding of research within hospitals is recognised as part of existing health budgets, but this funding is often lost because it is not separated out from the cost of clinical care (and can be used to fund clinical care). Funding for research is also not appropriately coordinated across areas of need when it is allocated at hospital level. To avoid these problems, the Government must:

- explicitly identify the research component within the cost of health care; and
- establish a health system-wide process for distributing that funding so that it has maximum impact.

*Australian Medical Association*

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These problems are compounded by inadequate management controls. Resources that are nominally allocated for research in hospitals are not adequately tracked, nor are the outputs usually audited. The Panel found it nearly impossible to determine how much investment in HMR is undertaken in hospitals and other health services settings. What did emerge from the public consultations was that funding originally earmarked for research in hospitals was typically used instead to cross-subsidise other services, and there was little or no auditing of research time expended, outputs or outcomes by professional staff in hospitals.

“… even research active Local Health Districts can lack a clear picture of the research undertaken, its purpose and outcome.”

**NSW Ministry of Health**

There is a major risk that tighter management of clinical services via ABF will further squeeze research activity, as funding earmarked for research will be one of the few remaining sources of discretionary funding. Conversely, a well-managed research program has the potential to address high-value problems that could increase clinical effectiveness and to free up resources by increasing productivity. This clearly indicates a need for increased focus on protecting, embedding and monitoring research in Australia's major healthcare institutions and other settings.

**Option: Manage and Refocus LHN research, implement key performance indicators (KPIs) and monitor performance.** The immediate imperative is to improve management of funds allocated for research in the health system. IHPA is rightly currently focusing on determining prices for defined clinical services. Research is not so easy to define, as insights can arise as easily in the bathtub as in the office or laboratory, and the most valuable research outputs may not be published papers. The best way to measure research may be to count inputs (time and infrastructure) expended in the pursuit of agreed outputs (papers, guidelines or change in clinical practice). This is effectively the way research is managed in universities and MRIs.

Accreditation and funding of hospitals and LHN research should be determined in part on an acceptable level of participation in clinical research, as an integral part of high-quality healthcare delivery. This should require hospitals and LHNs to report on a range of research KPIs in annual reports, including research budget and actual spending, number of staff active in research, number of clinical trials undertaken, number of consumers recruited to trials and outputs from clinical research, including outcomes for patient care.

“*It is important to remove financial and other barriers impeding research in hospitals. A first step would be to ensure that carrying out, or facilitating, research is included as a KPI in the assessment of every senior health care professional, clinician and manager in the public health and hospital system.*”

**Australian Academy of Science**

Research activity undertaken by health professionals should be facilitated through existing employment arrangements that provide time for research alongside health services duties, as well as through the introduction of a set of competitive practitioner fellowships that provide protected time (50% of work time) for the most promising health professional researchers (discussed in Section 2.5). Health professionals across all lines of delivery should be given the opportunity to be trained in and participate in research should they wish to.
The allocation of Australian Government funding could be determined through:

- the agreed NHRA formula, with efficiency defined as a similar ratio of inputs to outputs to that achieved by NHMRC grants; or
- simple matching of actual spending.

Although simple matching is more elegant, and provides an immediate incentive to better understand, maintain and increase state and territory government investment, the Panel believes that using the NHRA formula administered by IHPA is more likely to be acceptable to government stakeholders.

"In our experience, hospital boards and executive leadership in the USA support research in a manner that is rarely seen in Australia. Research is included and evaluated as a Key Performance Indicator. Until this is more widespread in the Australian hospital and health care management culture, research will take a lower priority in the health services delivery system."

The Group of Eight Limited
<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
</table>
| 1a.1 Maintain and refocus current state and territory government funding for research in LHNs, or groups of LHNs, of around $1.0bn–$1.5bn p.a., using the agreed NHRA formula.  
• Appoint a Research Sub-Committee of each LHN board that is both accountable for and able to influence an agreed research budget.  
• Define a set of valid research activities that can be funded from this budget.  
• Agree on the desired outputs and outcomes for funding from the research budget.  
• Audit the actual research expenditure (as a component of normal financial reporting).  
• Report and monitor research expenditure, outputs and outcomes. | LHNs, COAG SCoH, DoHA                  | 2014–15   |
| 1a.2 Determine the amount of LHN funding for research (block grant based) using LHN inputs and outputs.  
• Initially base funding on research inputs (e.g. time spent), provided LHNs have minimum level of reporting on research outputs and activity.  
• In the longer term, consider adjusting funding model to account for quantity and quality of research outputs. | IHPA                                   | 2014–15   |
| 1a.3 Define agreed outputs and outcomes, and report against this to state and territory government health departments and then up to the HMR leadership body. | LHNs (Research Sub-Committees)         | 2014–15   |
| 1a.4 Include research as a KPI for LHNs (or groups of LHNs), report and monitor research outputs, and develop an accounting-based system of separate reporting of TTR by LHNs for the purposes of the NHRA in collaboration between the Australian Government and state and territory governments. | NHPA, COAG SCoH                       | 2014–15   |
| 1a.5 Include research KPIs as part of performance indicators and appraisal for LHN Boards (or groups of LHNs) and hospital CEOs. | State and territory government health departments, LHNs | 2014–15   |
| 1a.6 Report on research expenditure, outputs and outcomes in clinical practice to state and territory government health departments and then up to the national HMR leadership body. Provide data to relevant government agencies (e.g. IHPA, NHPA, NHMRC, AIHW, etc). | LHNs                                   | 2014–15   |
| 1a.7 Monitor and evaluate HMR activity and outcomes appropriately at a national level. | Leadership body                        | 2014–15   |
2.2.3 Add Competitive Programs

Issue: Lack of competitively-funded research in the health system. While research in public hospitals is important to improving efficiency and treatment effectiveness for acute care services, research into preventive health programs, public health, primary care, aged care and mental health care is equally important. If the whole health system is to be improved, and research fully embedded, these activities must be supported throughout all parts of the system.

"RACGP recognises that the peer review processes developed by the NHMRC offer opportunities to facilitate high-quality research in Australia. As the primary care research sector is less developed compared with other areas of medical research, the peer review process of funding applications pertaining to primary care, public health and health services research should be reviewed by experts within the sector. This means a major effort should be made to ensure the input of primary care researchers into peer review of applications across the spectrum of clinical, public and health service topic areas relevant to the breadth of primary health care, as well as to the peer review of applications from primary care researchers."

The Royal Australian College of General Practitioners

The current Australian Government reimbursement model for private healthcare through general practice and private specialist practice makes no provision for and provides no incentive to conduct research. In contrast, in private hospitals there is an obvious commercial driver for research into productivity and effectiveness. Consequently, a distinct and significant component of healthcare delivery is not currently amenable to research activity. The exception is in fully private niches with high consumer demand, such as in vitro fertilisation (IVF), where there has been significant innovation in effectiveness, cost and business models (Case Study 5.7).

For primary care, research needs to be undertaken within its own setting, and primary care research infrastructure needs to be funded adequately through measures such as supporting national practice-based research networks. General practice faces significant barriers to research participation, particularly due to a lack of time and training in research methods. The model of funding practitioner time based on units of services is a major disincentive to involvement in research, as it is for teaching. Primary care, however, plays a vital role in prevention and early intervention and hence impacts on the overall efficiency of the health system.

"General practitioners are well placed to lead primary healthcare research and service innovation. Despite this, general practice faces significant barriers to research participation due to a lack of time, training in research methods, clinical research career pathways, underdeveloped infrastructure, and inadequate project funding."

The Royal Australian College of General Practitioners

"The Australian Government’s National Health Reform ‘aims to shift health services from hospital to primary care’, particularly ‘to meet the demands of an ageing population, increasing rates of chronic diseases and to take advantage of improvements in technology’... A viable and internationally competitive primary care research sector in Australia will ensure that research is relevant to and reflective of the major health issues facing our community. Primary care research is also of great relevance to rural and remote communities."

University of Sydney, Discipline of General Practice
Increasingly, as the population ages and health costs increase, more and more care will be provided in community and residential care. The residential aged-care system alone costs $9b annually and this is projected to triple in the next 40 years, yet there is little research capacity or activity in these settings. Competitive research programs to embed research capacity in community and aged-care delivery are needed.

**Option: Add competitive programs to build capacity, drive quality and deliver impact.** The Panel proposes that a suite of competitive programs be introduced that can be accessed by a much broader range of researchers than under current programs. National competitive programs are the best mechanism to ensure resources flow to qualified researchers and the most promising research ideas within areas which will impact favourably on health outcomes. These new programs must be competitive to ensure that the investment is focused on the most important research questions and attract the best research teams. The competitive programs proposed are:

- 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).

The rationale for each of these programs and suggested implementation tasks are detailed in the following chapters. A leadership body (probably NHMRC, see Section 2.3) should manage these programs to ensure that resources flow to where they can be used most effectively across the nation. A national approach should also ensure that innovations from one jurisdiction are communicated to and translated to others. These programs will ultimately give the Australian Government a leading role in driving research that will ensure that health funding improves health outcomes for all Australians through a more effective and efficient health system.

 “… build health research infrastructure and increase program and project grant funding to improve the evidence base for health care and to ensure that high-quality evidence is implemented as an integrated component of routine clinical care. This is essential to the evaluation of health reforms and will provide evidence to drive excellence and continuous improvement in the health system.

*Australian Medical Association*

The 1993 National Competition Policy Review (the Hilmer Review) highlighted the importance of efficient competition. Competition increases efficiency by allocating scarce resources to their most productive uses, spurring innovation and invention, and resulting in the creation of new industries and new jobs. This policy has been a major contributor to the productivity surge that has supported years of continuous innovation and economic growth. Establishing competitive programs for funding research in the health system will drive increased research excellence across the sector and deliver better health outcomes and greater economic benefit.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1b.1 Establish a set of national HMR competitive programs with a focus on delivering health system impact.</td>
<td>NHMRC</td>
<td>2014–15</td>
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2.2.4 Establish a National HMR Investment Target

**Issue: Lack of a national HMR investment target.** HMR is the R&D arm of the health sector, delivering system and service improvements. As such, the Panel recommends that defined and well-managed HMR activity should be a KPI for the health system as a whole, with cascading KPI targets for state and territory government health departments and LHNs. The R&D goal should be to ensure that clinical services are based on research evidence, and that research is routinely translated into clinical practice, with an initial focus on raising productivity by minimising adverse events. KPIs for hospitals should include benchmarks relating to research translation, as well as outputs. Short-term KPIs should be focused on easily defined inputs and outputs, rather than broad outcomes such as return on investment which is difficult to measure and achieve in a reasonable timeframe.

**Option: Adopt an R&D target of 3%–4% of health system expenditure (including the NHMRC MREA).** The Panel recommends, firstly and as a matter of priority, that the current level of expenditure on TTR be understood and tracked in terms of an accounting-based system of separate reporting of each TTR item (i.e. teaching, training and research) so that the research component can be clearly identified and benchmarked against healthcare outcomes in individual LHNs. Accompanying this, the Panel recommends a 10-year goal of 3%–4% of government expenditure on health R&D be adopted, given that:

- leading OECD countries have adopted overall R&D targets of at least 3%;
- healthcare is a knowledge-based industry that is a large part of the economy, employs over one million people and is primarily managed by the public sector; and
- R&D investment by leading health and medical companies is, on average, 13%.

Leading OECD countries recognise the need for increased R&D investment to maintain competitiveness and have set investment targets of at least 3% of total GDP (Exhibit 2.2). Given this benchmark is set across all research areas, and the importance of healthcare to the wellbeing of the nation, it would reasonable to expect that the target HMR investment should be above this.

**Exhibit 2.2**

**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)**

<table>
<thead>
<tr>
<th>% GERD of GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korea</td>
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<td>Belgium</td>
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<tr>
<td>Denmark</td>
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<tr>
<td>Estonia</td>
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<tr>
<td>France</td>
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<td>Germany</td>
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<td>Norway</td>
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<td>Portugal</td>
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<td>Slovenia</td>
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<td>Spain</td>
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<tr>
<td>Turkey</td>
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<tr>
<td>US</td>
</tr>
<tr>
<td>Czech Republic</td>
</tr>
<tr>
<td>Ireland</td>
</tr>
<tr>
<td>Netherlands</td>
</tr>
<tr>
<td>UK</td>
</tr>
</tbody>
</table>

Average 3.2%

Notes: 1. GERD – Gross expenditure in research and development
Source: Australian Government, National Research Investment Plan, 2012; OECD; UNESCO
Successful global and Australian biotech and pharmaceutical companies go further and invest at higher levels of R&D as a percentage of their revenue, approximately 13% on average, to drive the innovation they need to remain globally competitive (Exhibit 2.3).

**Exhibit 2.3**

Successful biotech and pharmaceutical companies have high levels of R&D investment

**Biotech and Pharmaceutical Company R&D Benchmarks**

<table>
<thead>
<tr>
<th>Company</th>
<th>% R&amp;D of Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck</td>
<td>18%</td>
</tr>
<tr>
<td>Cochlear</td>
<td>15%</td>
</tr>
<tr>
<td>GSK</td>
<td>14%</td>
</tr>
<tr>
<td>Pfizer</td>
<td>14%</td>
</tr>
<tr>
<td>CSL</td>
<td>8%</td>
</tr>
<tr>
<td>Res Med</td>
<td>7%</td>
</tr>
</tbody>
</table>

As at Revenue (A$m)

<table>
<thead>
<tr>
<th></th>
<th>2010–11</th>
<th>2011–12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck</td>
<td>47,214</td>
<td>779</td>
</tr>
<tr>
<td>Cochlear</td>
<td>41,587</td>
<td>66,256</td>
</tr>
<tr>
<td>GSK</td>
<td>2010–11</td>
<td>2011–12</td>
</tr>
<tr>
<td>Pfizer</td>
<td>4,433</td>
<td>1,173</td>
</tr>
</tbody>
</table>

Source: Company financials

While numerical targets can sometimes create complexity and unintended consequences, indicators such as the Consumer Price Index and GDP growth are now accepted as important to managing the economy. Similarly, the ratio of research to current spending is an important indicator of the effort to improve the health system, an issue that is of prime importance to many Australians.

The Panel believes that the appropriate R&D target benchmark should 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 around evidence-based practice, ultimately leading to better health services and outcomes.

2. **Existing NHMRC MREA** – The NHMRC MREA includes a range of research that can have both short and long-term impacts on the health system. The Panel also notes that the increases in NHMRC grant expenditure and processes over the last decade have resulted in increased research quality and delivered significant outcomes, and believes this funding should continue to be supported and increased in line with growth in healthcare expenditure.

3. **New health system competitive programs** – New national HMR competitive schemes aimed at driving impacts in the health system can provide strategic focus to research activities, and are likely to produce a very significant and direct impact on health services delivery and outcomes.
CASE STUDY 2.2

Clinician participation in research advances health and medical practice and was pivotal to the discovery of disinfection

Background. Ignaz Semmelweis, a Hungarian physician, was an early pioneer of disinfection through hand washing. In 1847 during his time as Chief Resident at Vienna General Hospital, he discovered that infections were caused by lack of hand hygiene.

Semmelweis observed that the doctors’ clinic had three times the mortality of the midwives’ clinic, and observed that clinicians and medical students had not been washing their hands between inspections of corpses and attending to births. Since midwives did not undertake cadaverous inspection, he concluded that 'cadaverous material' was being transmitted to the clinical ward due to a lack of hand hygiene practices.

In response to this hypothesis, a policy of hand washing with chlorinated lime between attending to corpses and patients was instituted. As a result, the mortality rate in the clinical ward dropped by 90%. Due to his inability to scientifically demonstrate findings, however, his observations on the rate of infection and the absence of hand hygiene practices were disregarded by the medical community. The findings were not heeded until the 1860s when Louis Pasteur and Joseph Lister, among others, formally developed the germ theory of disease.

Monthly Mortality Rates for Births – Vienna General Hospital

% of Mortalities

<table>
<thead>
<tr>
<th>Year</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1845</td>
<td>10%</td>
</tr>
<tr>
<td>1846</td>
<td>15%</td>
</tr>
<tr>
<td>1847</td>
<td>20%</td>
</tr>
<tr>
<td>1848</td>
<td>5%</td>
</tr>
<tr>
<td>1849</td>
<td>0%</td>
</tr>
</tbody>
</table>

Key Lessons:

1. Clinician participation in research is critical to advance in health and medical practices. Semmelweis identified hand washing empirically as a way to reduce mortality from infection in 1847. This finding was rejected by the medical community until a scientist, Louis Pasteur, developed germ theory in the 1860s.

Total HMR expenditure should be benchmarked by the Australian Government and all state and territory governments to expenditure on health and illness, including primary care, hospital care, the cost of the PBS, and community care. This would then provide a mechanism which ensures that the level of research funding remains linked to the health needs of the community. The current R&D benchmark level (as defined above) is around 2% of health expenditure (Exhibit 1.21), based on an estimated $1.1bn research funded by LHNs and $0.8bn of the existing NHMRC MREA. Investment should be increased to 3%–4% of health expenditure through the introduction of new competitive programs that will deliver health system impact.

“As an evidence-based response for mitigating escalating health costs … we urge the Government to consider good business practice and ASMR’s data, for investing 3% of the health spend on R&D in this sector.

The Australian Society for Medical Research

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1c.1 Establish an R&amp;D investment target of 3%–4% of Australian and state and territory government health system expenditure. Define target to include research in LHNs, existing NHMRC MREA and new health system competitive programs. Track and monitor going forward.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>1c.2 Review impact of LHN HMR and national HMR competitive schemes and progress towards the 3%–4% R&amp;D investment target.</td>
<td>Leadership body</td>
<td>2018–19</td>
</tr>
</tbody>
</table>

2.3 Establish Sector Leadership and Governance

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 for 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.

2.3.1 Introduction

The HMR sector in Australia is complex, involving many stakeholders and types of activities (Exhibit 2.4). While NHMRC effectively manages some vital roles, its legislatively-defined responsibilities, governance structure and association with a particular government department prevent it from assuming the role of an independent and overarching leader of the HMR sector.

In addition to NHMRC, there are other national agencies with important roles in research related to health and medical sciences, including the Australian Research Council (ARC), Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australian Nuclear Science and Technology Organisation (ANSTO) and some of the Cooperative Research Centres (CRCs), or roles in health policy, advice, delivery and monitoring, including the Australian National Preventive Health Agency (ANPHA) and the Australian Institute of Health and Welfare (AIHW). The overlap in funding responsibilities for health-related research between NHMRC and ARC, in particular, creates problems, not least with funding demarcation, but also with leadership functions. The overlap in policy and healthcare advice between NHMRC and other government entities also creates confusion, lack of coordination or integration, and potential redundancy of effort. Overall,
no body exists as a natural champion to coordinate and oversee the HMR sector by driving performance and implementing reforms. Australia needs an HMR leader that can move the sector forward in a holistic and strategic manner and unite all other stakeholders in a common purpose of delivering better healthcare for all Australians.

“Health and medical research in Australia currently operates without an appropriate structure to set priorities and coordinate Commonwealth, State and Territory and other support.”

Victorian Government

An example of the lack of high-level leadership in the sector is the debilitating absence of accurate aggregate statistics for HMR expenditure, with no single dataset able to provide a clear picture of what is spent and what the sector is achieving. Without such information, it is difficult to assess long-term costs and benefits. A clearly articulated set of nationally-agreed research objectives, tied to strategic national health goals, is also absent. With the current system, there is a significant risk of duplication of research funding and activities due to lack of centralised information and direction.

Exhibit 2.4

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

HMR Funding and Activity Flows

Diagram showing funding flows between various stakeholders and activities in the health and medical research sector in Australia.
Consumer engagement is also an important area which requires leadership. Consumers can and should play a prominent role in the HMR sector, particularly in setting priorities for research agendas and participating in clinical trials. By involving consumers in the initial stages of research, they are able to identify and shape research topics that are relevant to their needs and therefore contribute in a meaningful way to improving health outcomes. Additionally, this generates a greater awareness among policy makers and researchers of pressing consumer issues and provides another avenue to continuously improve the quality of research through consumer feedback. By participating in clinical trials, consumers become engaged in the research and develop greater awareness and understanding of treatments and the role of research in improving health. They are also more likely to inform others of results, hence playing an important role in research translation. Consumer engagement for personal electronic health records is also required to ensure consumers understand the importance of their data, particularly for research.

2.3.2 Establish Sector Leadership

Issue: Leadership is needed to direct, focus and coordinate activity and drive the strategic vision. The Panel firmly believes that a high-level leadership body able to respond and influence at all levels is required to direct, monitor, champion and coordinate the HMR sector, drive key reforms and unite major stakeholders. The Canadian Institutes of Health Research (CIHR) has demonstrated leadership in many of these areas (Case Study 2.3). A single leadership body would be the most efficient and effective way to drive alignment and coordination across the many stakeholders in the sector and is essential to fully embedding HMR in the health system. As the nation’s leader in HMR, its responsibilities would include: overall sector leadership; setting HMR priorities; providing policy advice; driving research translation; managing IHRC selection; tracking HMR investment; streamlining clinical trials processes; and implementing the recommendations of this review (Exhibit 2.5).

Two main options exist for establishment of such a body:

- Option A – Task NHMRC with complete oversight and leadership of HMR (in addition to its current role) and resource it appropriately
- Option B – Establish a new ‘Office of Medical Research’ that sits separately from NHMRC and leads and champions the sector (while NHMRC retains its current role).

Option A: Task NHMRC with sector leadership duties. NHMRC was first constituted in September 1936 and has had many changes to its legislative basis. The last decade, in particular, has seen significant strengthening of NHMRC as a result of the Wills33 and subsequent Grant34 reviews and, more specifically, the Zerhouni and Bernstein reviews.35 The NHMRC’s charter of responsibility relates to four main functions that it carries out on behalf of the Australian Government:

1. Raise the standard of individual and public health throughout Australia;
2. Foster the development of consistent health standards between the various States and Territories;
3. Foster medical research and training and public health research and training throughout Australia; and
4. Foster consideration of ethical issues relating to health.36

35 NHMRC, NHMRC response to the independent review of NHMRC’s funding processes incorporating: International Perspective on the NHMRC Research Strategy (The Zerhouni Review) and The Independent Review of the NHMRC Research Funding Process (The Bernstein Review), Canberra, 2009.
### Exhibit 2.5

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

**Key Leadership Responsibilities**

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

While NHMRC is an influential and valued body in running competitive grant schemes and in providing guidelines and advice to the sector nationally, the current NHMRC structure, governance and resources do not allow it to take a broader role of overseeing and coordinating the entire gamut of HMR activity across Australia. Further, while NHMRC has responsibility for a range of research-related activities, it does not fully take up all of those responsibilities. For example, the NHMRC legislation was amended in 2006 to specifically include a mandate in relation to policy and research translation, but this activity is not particularly strongly pursued by NHMRC due to limited resources, despite the pressing need for greater promotion of evidence-based practice and policy. In addition, the governance relationship of NHMRC with the Department of Health and Ageing (DoHA), without a clear link to COAG SCoH, disconnects its recommendations from implementation on a national stage.

> NHMRC and other similar bodies around the world therefore have a leadership role upon which all others depend. Splitting the governmental health research as occurs in some other countries (e.g. France) is therefore contrary to such leadership. In contrast, NHMRC has been charged with all research relevant to health, regardless of discipline or methodological approach, since its inception.

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National Health and Medical Research Council

If NHMRC’s role was elevated to take on much stronger sectoral leadership responsibilities, a substantial overhaul and revamp of its governance, organisational structure, effectiveness and association with DoHA would be necessary. It would need to be guided by, and to source its mandate from, an appropriate board of stakeholders which should include federal agency representatives, health jurisdictions, health professionals, industry and consumers. It would also need to maintain regular, structured interactions with other key national research-related agencies (such as ARC, CSIRO and CRCs), other national health-related agencies (such as the Australian Commission on Safety and Quality in Health Care (ACSQHC), ANPHA and AIHW), and state and territory health ministries.
Option A has the advantage that NHMRC is the natural body to take on this role—its Act enables a leadership role, but current NHMRC practice, resourcing and capability, for historical reasons, is restricted to a narrower scope. With an expanded remit and working with key organisations charged with delivering better health services, particularly those newly established under NHRA, NHMRC could significantly leverage capability with other institutions and provide a powerful force to place research in a central position within the broader health sector. If fully enacted, this proposal could contribute considerably to improvements in the sector’s efficiency and effectiveness.

"The NHMRC is still the best positioned organisation to lead the major federal funding and investment in HMR in Australia … The Australian HMR sector needs strategic leadership at the national level.

Royal Perth Hospital

The main disadvantage is that NHMRC does not currently have involvement of the jurisdictions at senior level. In addition, concerns were expressed to the Panel about NHMRC’s capability and suitability for an expanded role, particularly to assume sector leadership in areas such as public health and health services research. NHMRC is currently not well positioned to cover areas of translational policy or areas impacting health beyond the healthcare system itself. This includes interactions with policy makers, addressing efficacy, quality and safety issues, and disparities in healthcare outcomes. The mixed role of a granting body (a sector participant) and overall sector leadership may result in a conflict of interest in some cases, although this is also the case with CIHR which does appear to have managed this balance. Furthermore, at this point, NHMRC needs to focus on a range of internal improvements, and the option could only be explored if there was a higher level of confidence that its current core services were being delivered in an efficient and transparent way. Adding further tasks and responsibilities, without additional resourcing, is likely to be highly counterproductive. These concerns notwithstanding, key stakeholders and major research organisations were broadly very supportive of an enhanced NHMRC.

If the new leadership body is not to be NHMRC, then another body would need to be established. An appropriate body does not exist and the role does not fit naturally within any of the new bodies established under the recent NHRA.

Option B: Establish a new leadership body. Establishing a completely new body has the advantage that it could be set up with the desired remit and relevant high-level stakeholders, and could avoid concerns about conflict of interest. It would then leave NHMRC to focus on its current core areas of competency—supporting Australian Government HMR funding programs, producing guidelines and overseeing research ethics. The major disadvantage of establishing a completely new agency is exactly that—there are already many government administrative agencies at a national level and the Panel is therefore hesitant about the establishment of yet another entity. There appears to be no overseas example of a completely independent HMR leadership agency (i.e. one that leads the sector but does not also administer funding) across the leading HMR countries, although many countries commission independent reviews of their primary HMR agencies from time to time.

The Panel notes recent discussions about the concept of an Australian Academy of Health Sciences. Such a body could potentially serve a different leadership role in providing objective policy advice to Government on areas such as national priority setting. Such an Academy could also play a role of lobbying for the national interests of the HMR sector. International examples of health and medical academies include the UK Academy of Medical Sciences, an independent body founded in 1998, which promotes advances in medical science and campaigns to ensure they are translated into healthcare benefits for society, and the Canadian Academy of Health Sciences which was mandated by the Canadian Government in 2004 and aims to provide timely, informed and unbiased assessments to government of urgent issues affecting the health of Canadians based on evidence reviews and leading expert opinion.
Although independent, the difficulty with using an academy of health sciences as a leadership body is that it could only act in an advisory role, with no legislative foundation or mandated source of funding. This limits the leadership that it could provide, and effectively excludes its involvement in translation of HMR into clinical practice, which is a critical aspect of integrating HMR with health services delivery. An academy would also have limited ability to influence government and stakeholders across the HMR sector. Hence, this alone is not a solution to the need for a new leadership body, although creation of an academy, which would need to be driven by its members, could provide a useful external source of advice to the chosen leadership body, as well as critical independent appraisal of HMR performance across the sector.

Preferred Option. On balance, the Panel prefers Option A—tasking NHMRC with a broader leadership mandate, facilitating this legislatively and resourcing it appropriately to fully deliver on its existing stated functions (listed above). Notably, this will require the following responsibilities:

- interact with the Australian Health Ministers’ Advisory Council (AHMAC), COAG SCoH and key national research-related agencies to facilitate national implementation of research outcomes and prioritisation of research activities
- develop on a regular basis and via wide sectoral input, national priorities for HMR for the nation
- monitor research outcomes at the national (including in association with state health departments) and international level and ensure that Australia remains fully able to address any emerging health threat or embrace any new technology
- monitor the size and scope of the HMR workforce and the investment into HMR at a national level (see Section 2.3.3)
- monitor and report the outcomes and assess the effectiveness of HMR investment by universities, MRIs, IHRCs and LHNs
- continue to provide policy guidelines on standards for the delivery of healthcare across the nation
- oversee research integrity by requiring administering institutions receiving funding from NHMRC to agree to independent audit and investigation of failure to fulfil conditions
- report on refined KPIs to ensure accountability.

Such changes should also improve the capacity of NHMRC to deliver on its existing mandate to foster the development of consistent health standards between the various states and territories. Consideration should also be given to identifying activities that currently exist outside NHMRC which could be subsumed by NHMRC, such as ACSQHC, oversight of the national human ethics committees, and the research budget of ANPHA. Changing NHMRC’s name to place greater emphasis on its newly expanded role could also be considered by the Government but would not necessarily be required.

Issue: Need for increased independence of NHMRC and representation from states and territories. NHMRC directly reports to the Australian Government Minister for Health and is overseen by and works closely with DoHA. While state and territory governments are represented on the NHMRC Council, this is only in an advisory capacity and representation is not at a senior level. Furthermore, state and territory members of the NHMRC Council are typically not part of AHMAC, leaving a wider gap between NHMRC and the state and territory governments.
CASE STUDY 2.3

The Canadian Institutes of Health Research brings together key stakeholders to drive research and translation efforts

Background. The Canadian Institutes of Health Research (CIHR) aspires to be a world leader in the creation and use of knowledge through health research. Structured around 13 virtual institutes or networks of researchers brought together to focus on important HMR issues, CIHR encourages partnerships and collaboration across sectors, disciplines and regions.

CIHR funded over C$800m in research grants in 2009–10, with an allocation of 33% to strategic priority-driven research. Priority areas are determined in consultation with institutes, researchers, health professionals and policy makers. CIHR supports effective knowledge translation by facilitating collaborative efforts and ensuring pertinent research is prioritised, conducted and ultimately disseminated.

The collaborative approach between multiple CIHR institutes as well as partnerships with federal and territorial agencies, funding organisations, health charities, non-governmental organisations and industry results in research that is more likely to deliver impact and facilitates mutual learnings, cross pollination of knowledge and ultimately, improved translation outcomes.

Key Lessons:

1. Leadership transcends jurisdictions, disciplines and sectors and unites major stakeholders. The CIHR virtual institutes drive collaboration and innovation across dedicated priority areas. Each institute has responsibility for driving its own research agenda and leveraging other funding sources.

2. Leadership sets clear priorities and focuses research efforts. CIHR strategic priority-driven research ensures key research and health system priorities are addressed.

3. Leadership can accelerate translation. CIHR follows a Knowledge Translation and Knowledge to Action framework to promote translation in the health system. The Strategic Training Initiative in Health Research and clinical investigator programs encourage clinician training in research and facilitate research translation into healthcare practice.

Notes: 1. Aboriginal Peoples’ Health; Aging; Cancer Research; Circulatory and Respiratory Health; Gender and Health; Genetics; Health Services and Policy Research; Human Development, Child and Youth Health; Infection and Immunity; Musculoskeletal Health and Arthritis; Neurosciences, Mental Health and Addiction; Nutrition, Metabolism and Diabetes; and Population and Public Health; 2. Current Strategic Initiatives include the Canadian Longitudinal Study on Aging, CIHR and Global Health Research, Drug Safety and Effectiveness Network, HIV/AIDS Research Program, Regenerative Medicine and Nanomedicine Initiative, Strategy for Patient-Oriented Research and Strategic Training Initiative in Health Research

Source: Canadian Institutes of Health Research: www.cihr-irsc.gc.ca/e
Option: Change governance structure of NHMRC to report to a board. NHMRC’s governance structure and state and territory representation should be strengthened with oversight by a board. Board members should be at an equivalent level to department secretaries or their senior delegates from COAG SCoH. There should also be greater interaction with COAG SCoH and AHMAC in order to increase alignment and more tightly embed NHMRC into the COAG health system. Alternatively, the current NHMRC Council membership and role could be adjusted to deliver the desired oversight role rather than its current advisory role.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a.1 Establish HMR sector leadership (either within NHMRC or through a new body), covering the full spectrum of research.</td>
<td>Minister for Health, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.2 Amend the NHMRC Act and the governance of NHMRC to increase representation from the state and territory governments and AHMAC, and increase independence from DoHA.</td>
<td>Minister for Health, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.3 Define a role for the leadership body to monitor and report on the effectiveness of investment in HMR across the sector, including universities, medical research institutes, LHNs and the proposed IHRCs.</td>
<td>Minister for Health, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.4 Reinforce oversight role in ensuring research integrity by requiring administering institutions receiving funding from NHMRC to agree to independent audit, and investigating any apparent failure to fulfil conditions.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.5 Appropriately increase the administrative budget of NHMRC to deliver these enlarged responsibilities.</td>
<td>Minister for Health, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.6 Refine NHMRC key performance indicators to ensure accountability.</td>
<td>Minister for Health, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>2a.7 Develop and implement workforce planning processes to more effectively manage and monitor the HMR workforce.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>2b.1 Drive research translation efforts to deliver evidence-based healthcare and policy by facilitating strengthened partnerships between healthcare delivery sector, policy makers and researchers.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>2c.1 Provide policy advice to the Australian and state and territory governments to drive improvements to the delivery of health services and public health.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

2.3.3 Track Investment and Evaluate Outcomes

Different Measures of HMR Investment. HMR investment in Australia involves a complex matrix of funding by first-party agencies (e.g. NHMRC and ARC), expenditure of funds on research by second-party agencies (e.g. universities and MRIs) and, in some cases, third-party administrators of research funds (usually universities that administer funds on behalf of MRIs).

Data published by AIHW and the Australian Bureau of Statistics (ABS) on the total investment in HMR provide two different views. This is due to the way the data are collected, with AIHW data focusing on the sources of health research funding, and ABS data focusing on the destinations of the funding.
Data published by AIHW (Exhibit 2.6) show that, in 2011–12, estimated expenditure on health research was $4.8bn (including $0.8bn in capital expenditure). Over 80% of the expenditure on HMR in 2011–12 was funded by the Australian Government ($3.4bn), with the remainder funded by state and territory governments ($0.8bn). Of the $3.2bn allocated by the Australian Government to HMR in 2009–10, about $800m was administered by NHMRC. The remaining proportion was expenditure by other Australian Government-funded or funding agencies, such as the ARC, CSIRO, CRCs, universities and, to a much lesser extent, other portfolios and agencies.

**Exhibit 2.6**

**AIHW provides a source view of government HMR investment, estimated at ~$4.8bn in 2011–12**

**Government HMR Expenditure by Source of Funds (Excludes Business and NFP)**

<table>
<thead>
<tr>
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<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Government</td>
<td>1.8</td>
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<td>2.5</td>
<td>3.1</td>
<td>4.5</td>
<td>4.8</td>
</tr>
<tr>
<td>State and Territory Governments</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.4</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Total</td>
<td>2.1</td>
<td>2.3</td>
<td>2.8</td>
<td>3.5</td>
<td>5.2</td>
<td>5.6</td>
</tr>
</tbody>
</table>

**Notes:**
1. CAPEX (capital expenditure) reflects annual depreciation of land, buildings and equipment, and is estimated based on CAPEX proportion of total research expenditure across all research sectors (ABS)
2. 2011–12 forecast assumes 5% growth

Source: AIHW, Health Expenditure 2009-10

Data published by ABS present a view of total HMR expenditure by destination sector (Exhibit 2.7). Of the total $4.7bn, ~$2.9bn is estimated to be sourced from Australian, state and territory government funds.

37 Note that health research funded by ‘for-profit’ corporations is not included here, as it is considered to be an intermediate good, the cost of which has already been included in the cost of the associated final output.
Exhibit 2.7

ABS provides a destination view of total HMR expenditure, estimated at ~$4.7bn in 2011–12 of which ~$2.9bn is government-sourced.

**Overall HMR Expenditure by Destination Sector (Includes Business and NFP)**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher Education</td>
<td>2.5</td>
<td>0.9</td>
<td>0.5</td>
<td>1.3</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>Business</td>
<td>1.0</td>
<td>0.6</td>
<td>0.9</td>
<td>2.2</td>
<td>2.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Private Not For Profit</td>
<td>0.6</td>
<td>0.4</td>
<td>0.3</td>
<td>1.8</td>
<td>2.9</td>
<td>1.0</td>
</tr>
<tr>
<td>State &amp; Territory Gov’t</td>
<td>0.9</td>
<td>0.5</td>
<td>0.7</td>
<td>0.9</td>
<td>1.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Australian Gov’t</td>
<td>2.2</td>
<td>1.0</td>
<td>1.8</td>
<td>2.7</td>
<td>3.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Total Australian Gov’t</td>
<td>4.7</td>
<td>2.5</td>
<td>3.6</td>
<td>4.2</td>
<td>5.3</td>
<td>4.7</td>
</tr>
</tbody>
</table>

**CAGR 02–12e**

- Australian Gov’t: 12%
- State & Territory Gov’t: 10%
- Private Not For Profit: 16%
- Business: 12%
- Higher Education: 12%
- Total: 2%

**By Source of Funds**

- Government: 62%
- Non-government: 38%

The difference in definition between funds provided by government and funds deployed by organisations highlights the uncertainty about total government HMR investment, which shows expenditure is somewhere between $3bn and $5bn (Exhibit 2.8).

Exhibit 2.8

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

**Total Government HMR Expenditure – Reconciliation**

<table>
<thead>
<tr>
<th>Source View</th>
<th>2011–12e</th>
<th>2009–10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Government</td>
<td>3.4</td>
<td>2.5</td>
</tr>
<tr>
<td>Gov’t CAPEX</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>State Government</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Total Government Funding (AHW/Source View)</td>
<td>4.8</td>
<td>3.4</td>
</tr>
<tr>
<td>Not Spent on Research</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Total Government HMR Funding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Spend Not Accounted For</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Funds Deployed by Organisations (ABS/Destination View)</td>
<td>2.9</td>
<td>1.8</td>
</tr>
<tr>
<td>Other</td>
<td>0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>NHMRC</td>
<td>0.8</td>
<td>1.2</td>
</tr>
<tr>
<td>University Block Grants</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.
**Issue: Lack of data on HMR investment.** While the flow of investment and location of expenditure in research is understood in terms of direction and key stakeholders, detailed information about exactly how much is spent, and where it is spent, is lacking for the HMR subsectors. Current collections of research funding and expenditure data vary considerably in definitions and methodology, and generally do not provide sufficient level of detail to fully understand funding sources (e.g. government, business, private), destination sectors of expenditure (e.g. GOVERD, HERD, BERD and PNPERD\(^{38}\)), and types of funding (e.g. infrastructure, salary, indirect costs).

For the Australian Government, the amount of money spent on competitive and strategically targeted grants (NHMRC and ARC) is clearly documented, and data on expenditure in the wider DoHA portfolio are reasonable (at least in terms of those programs with research components clearly identified). Less clear is some of the expenditure that comes through the Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE). Portfolio expenditure on health-related research for items such as the CRC program, CSIRO and ANSTO can be tracked, but for items of a more general nature, such as broad industry assistance programs, it is much harder to determine the amount spent on health-related research. Similarly, while HMR conducted in universities is frequently carried out with NHMRC or ARC grant assistance, there is an indirect cost component to that research which is paid for by the universities through the DIISRTE portfolio, the total of which is not audited in any way that can be apportioned to the HMR sector.

For state and territory governments, the direct-support component is well understood, but the indirect-support component via the health system is much less well quantified, particularly for hospitals. The Review undertook a survey of the amount of money spent by hospitals on research, and the results showed a wide range of reported expenditure, and ability to report. There was little consistency in definitions and, in general, a weak ability to identify specific research investment amounts.

Thus the uncertainty in total government HMR investment is largely due a lack of monitoring of research performed in state and territory hospitals and associated networks. Research in hospitals can be estimated by inputs (e.g. time spent) or outputs (e.g. publications produced), and is estimated at about $1.5bn p.a. based on output (Exhibit 2.9).

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38 GOVERD – Government Expenditure on R&D; HERD – Higher Education Expenditure on R&D; BERD – Business Expenditure on R&D; and PNPERD – Private Non-Profit Expenditure on R&D.
Exhibit 2.9

HMR investment in hospitals is estimated to be ~$1.5bn based on publication output produced

State Local Hospital Network HMR Investment – Estimate
$bn
2011–12e

**Input based**
- ~42,000 clinicians\(^1\)
  - 5%/15% research time (low/high)
  - $320k salary and indirect costs
- ~3,600 researchers\(^2\)
  - 100% research time
  - $160k salary and indirect costs

**Output based**
- ~6,700 publications p.a.
- $230k cost per publication\(^3\)

**Selected Methodology**

**Input -**
- Low (5%)
  - 1.3
- High (15%)
  - 2.7

**Output -**
- 1.5

**Estimate Used**
- Input-based estimates range widely and may include unfunded research (i.e. in clinician’s time)
- Output-based estimates are more likely to represent funded research

**Notes:**
1. From AIHW Medical Workforce Survey and includes specialists, hospital non-specialists, specialists-in-training and other clinicians
2. Non-clinician and nurses researchers from AIHW Medical Workforce Survey and Nursing and Midwifery Labourforce Survey
3. Garvan Institute used as benchmark (204 publications produced with total operating costs of $47m in 2010)

Source: AIHW, Medical Workforce 2009; Thomson Reuters 2011 Customised data request; Garvan Institute, Annual Report 2010; Pacific Strategy Partners analysis

Accounting for funding from other sectors, such as NHMRC, universities, business and not-for-profit (NFP) organisations, about $1.1bn of $1.5bn is estimated to be funded through LHNs (Exhibit 2.10). This is a rough estimate only, and the actual number should be determined as a priority. While it is understood that the National Hospital Cost Data Collection is attempting to determine the amount spent on research as part of standard reporting, it is unclear whether this will provide the level of detail needed to manage and monitor investment in future.

Exhibit 2.10

Of the ~$1.5bn total LHN HMR, it is estimated that ~$0.4bn is funded by other sectors and the remaining ~$1.1bn is funded through LHNs

Local Hospital Network HMR Investment – Estimate
$bn
2011–12e

**NOTES:**
1. Based on proportion of NHMRC grant funding performed in hospitals, and assumed to be the same for other sectors

Source: NHMRC, ABS; Panel interviews
Expenditure on HMR in the business sector is reasonably well understood at the aggregate level, though often not separately reported. The charitable and philanthropic sector is characterised by a small number of relatively large private philanthropic foundations (e.g. the Ian Potter Foundation, Myer Foundation and Sidney Myer Fund, Pratt Foundation, and CASS Foundation Ltd), a small number of medium-sized charitable trusts (e.g. Cancer Council, Diabetes Australia and the Australian Lung Foundation) and a very large number of small charitable trusts. Aggregate figures for the NFP component of HMR investment are tracked by ABS and published by AIHW. For 2009–10, AIHW data show that about $252m was spent on HMR by non-government, non-business sources. Research Australia also tracks HMR expenditure in the private sector every few years, although by survey rather than audit.

The fact that there are no comprehensive data sets describing the magnitude and nature of research in the health and medical sector is of considerable concern for several reasons. First, for such an important sector, and one which lies at the base of a significant portion of GDP expenditure, comprehensive data simply should be available for policy and strategic planning purposes. Second, for some parts of the HMR sector (e.g. the hospital subsector), the lack of data brings into question whether the money allocated is indeed being spent on research, or whether it is being sequestered for some other activity deemed by administrators as being more important or urgent. Third, without clear data on exactly where research funds are being spent, there is no way to audit to ensure the appropriate and efficient use of funds, nor is there a way to monitor research outputs and, more importantly, research outcomes. While some research programs with good auditing can claim ‘exceptional returns’, there are many which cannot, simply because expenditure data cannot be traced.

Option: Systematically track HMR investment and expenditure. Systematic tracking of expenditure in the HMR sector should be carried out by a lead Australian Government agency, such as AIHW, and monitored by the leadership body. As Australia’s leading national information and statistical body for health and welfare, AIHW is well positioned to collate HMR data and provide them to the leadership body for sector-wide monitoring. The existing ABS and AIHW data collection surveys could be leveraged, further expanded and aligned to build a more comprehensive and clearer view of money actually spent on HMR.

In addition, agencies which conduct HMR using Australian Government funds should be required to report to AIHW on research activities in a much more comprehensive manner. Ideally, state and territory government agencies would also require more rigorous reporting of research activities and provide statistics to their own lead agencies which in turn would provide data to AIHW.

With the introduction of NHRA arrangements with the states and territories, the Australian Government has the opportunity to tie all funds dispersed from the National Health Funding Pool (NHFP) to a reporting requirement that includes inputs, outputs and outcomes relating to HMR, as well as workforce statistics. LHNs, in particular, should be required to produce annual statistics on all research activity. Both funding to the states and territories through the NHFP and all other Australia Government HMR funding should have rigorous reporting requirements, perhaps similar to those used by the DIISRTE Sustainable Research Excellence in Universities program. NHMRC should work with AHMAC to define ‘research’ under the NHRA/ABF model.

Issue: Lack of evaluation of research performance and outcomes across sector. Currently, there is a lack of formal systems to evaluate the performance of research activity within research institutions and LHNs. Without adoption of an adequate evaluation process, there is no certainty that investment is being optimally deployed to deliver improved health outcomes and increased health system efficiency.

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39 AIHW, Health expenditure Australia 2009-10, Health and welfare expenditure series no. 46. Cat. no. HWE 55, Canberra, 2011.
40 For example, see: http://researchaustraliaphilanthropy.org/publications/special-reports.html.
Option: Establish and encourage research organisations to evaluate performance and research outcomes of investment. Sector-wide performance evaluation criteria will ensure outcomes of HMR investment are measured and monitored, and will increase the accountability of research organisations to deliver impactful research. Traditional measures of output, pioneered by universities, have focused on publication activity in peer-reviewed publications; however, as embedded research centres are encouraged to undertake research that also translates to better healthcare outcomes, more robust and comprehensive measures are needed. By evaluating performance across a mix of knowledge-based outputs, research inputs, and commercial, clinical and public health outcomes, research that not only advances scientific insight but is also high quality and delivers impact will be encouraged and strengthened.

Performance evaluation across knowledge creation (such as publication output), research inputs (such as competitive funding received) and commercial, clinical and public health outcomes provides a standardised measure of the effect of research and allows for the comparison of a range of research areas (Exhibit 2.11).

Exhibit 2.11
Research organisations should adopt and formalise performance evaluation processes

Example Performance Evaluation Scorecard

<table>
<thead>
<tr>
<th>Performance</th>
<th>Measure</th>
<th>Score</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge Creation</td>
<td>Peer-Reviewed Publications</td>
<td>25%</td>
<td>Publication activity – number of peer-reviewed articles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10%</td>
<td>Publication impact – highly cited papers from the preceding five-year period</td>
</tr>
<tr>
<td></td>
<td>Research Synthesis</td>
<td>5%</td>
<td>Technical papers that assist the translation of research practice (e.g. policy, guidelines, books)</td>
</tr>
<tr>
<td>Research Inputs</td>
<td>Peer-Reviewed Grants</td>
<td>30%</td>
<td>Competitive peer-reviewed funding weighted by associated infrastructure received</td>
</tr>
<tr>
<td></td>
<td>Students</td>
<td>5%</td>
<td>Research students trained</td>
</tr>
<tr>
<td>Public Health, Clinical and Commercial Outcomes</td>
<td>Research Outcomes</td>
<td>20%</td>
<td>Research outcomes, adoption, implementation and evaluation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3%</td>
<td>Commercialisation activity – contract funding gained through contracted research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2%</td>
<td>Commercialisation activity – patents filed for</td>
</tr>
</tbody>
</table>

Similar performance evaluation models have been implemented at the Royal Children's Hospital Campus, where it evaluates performance across its main research themes, and then uses this to allocate funding and assess its progress in achieving its strategic mission—to be a major national and international contributor of knowledge leading to improved child health.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>2d.1 Coordinate data collection and analysis activities between ABS and AIHW to produce a more comprehensive, but clear set of data about HMR expenditure.</td>
<td>Leadership body, AIHW, ABS</td>
<td>2014–15</td>
</tr>
<tr>
<td>2d.2 Track and monitor HMR expenditure, the HMR workforce, research outputs and outcomes and report to leadership body for sector-wide monitoring.</td>
<td>Leadership body, AIHW</td>
<td>2014–15</td>
</tr>
<tr>
<td>2d.3 Tie reporting requirements on expenditure and outcomes to all national competitive grant funding.</td>
<td>NHMRC, ARC</td>
<td>2014–15</td>
</tr>
<tr>
<td>2d.4 Ensure LHNs audit and report on all research activity using agreed national standards.</td>
<td>NHPA</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

2.4 Establish Integrated Health Research Centres

**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.

2.4.1 Introduction

The last decade has seen a major shift towards increasingly collaborative research activity, encouraged by findings of major reviews such as the 1999 Wills Review, the 2009 Zerhouni Review of NHMRC, the broader 2008 Cutler Review of the nation’s innovation system, and the Australian Government’s 2009 Innovation Agenda, *Powering Ideas*. Much of this collaboration has occurred on a virtual basis, bringing together researchers with similar interests from a range of national and, increasingly, international institutions.

The value of real, knowledge-based geographic clusters (also variously known as hubs or precincts) has recently been promoted as a more effective way to achieve significant outcomes than virtual clusters. Innovation is more likely to occur in a geographic cluster, especially where the concentration of a network of complementary and competitive participants drives a faster flow of ideas. Global examples show that clusters dominate creative output in many industries (for example, Hollywood and Silicon Valley).

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CASE STUDY 2.4

Johns Hopkins integrates patient care, research and education to deliver breakthrough discoveries and quality care

**Background.** Collaboration between clinicians and researchers at Johns Hopkins has led to numerous breakthroughs in health and medical research and delivered improved health outcomes. The Johns Hopkins University was established in 1876 as a private research university, with the Johns Hopkins Hospital opening in 1889, followed by the Johns Hopkins University School of Medicine soon after in 1893.

The success of Johns Hopkins has been underpinned by the integration of patient care, research and teaching. It has ranked as the best hospital in the United States consecutively from 1992 to 2011, and has a research program which receives more than US$450m in competitive grants annually—significantly more than any of its peers.

This emphasis on collaboration between clinicians and researchers has helped produce 20 Nobel Prize laureates and reinforced Johns Hopkins leading position in delivering quality healthcare and being at the forefront of important medical discoveries including:

- 1889 – Pioneered surgery for breast cancer
- 1893 – First major medical school in the US to admit women
- 1912 – First to develop renal analysis
- 1944 – First direct heart surgery
- 1958 – Developed cardiopulmonary resuscitation
- 1972 – First implantable rechargeable pacemaker
- 1987 – Pioneered surgery for separating twins joined at the head
- 1998 – Among the first to isolate and cultivate human embryonic stem cells
- 2002 – First biological pacemaker for the heart

**Key Lessons:**

1. **Integration of healthcare and research leads to better research and health outcomes.** Between 1999 and 2009, Johns Hopkins was the third most cited institution in the world, with over 1.2m citations and 54,000 papers.¹ This collaborative approach to research has led to more than US$450m annually in competitive grants, leadership in a number of medical breakthroughs and more than 20 Nobel Prize laureates and 34 Lasker Award winners. The integrated research and healthcare approach at Johns Hopkins has resulted in it being ranked as the leading hospital in the US every year for the last 20 years.

Note: ¹ Australian HMRs were cited 2.4m times in 153,000 papers in the 2001–10 period
Source: Johns Hopkins Medicine: www.hopkinsmedicine.org; Thomson Reuters: www.reuters.com
International examples of HMR-focused geographic clusters, sometimes known as Academic Health Science Centres (AHSCs), can be found in all leading healthcare jurisdictions, including the US, Canada, UK, in Europe and in Asia. In the US, the 16 highest-ranked hospitals are all AHSCs, while five of the top 15 hospitals for cancer care are specialist cancer AHSCs. One of the leading global examples is Johns Hopkins Medicine in Baltimore, Maryland, which for many decades has fully integrated consumer care, research and education (Case Study 2.4).

The UK has recently established five AHSCs, following a 2007 review of healthcare in London, which recommended the establishment of five to 10 AHSCs, with a concentration of expertise and excellence to compete internationally with established research leaders such as the US and Canada. The Global Medical Excellence Cluster is a NFP company that provides a framework within which universities, companies and National Health Service (NHS) Trusts collaborate. It was founded by five of the world’s top universities, Cambridge University, Imperial College London, King’s College London, Oxford University and University College London and operates in partnership with GlaxoSmithKline, GE Healthcare, Pfizer UK, the Royal Marsden NHS Trust and the South London and Maudsley NHS Trust.

In other parts of the world, Canada has 17 AHSCs, which focus on providing specialised healthcare services, advancing leading-edge innovative practices through health research, and educating the next generation of healthcare professionals, the Netherlands has eight AHSCs currently in operation, and in Asia AHSCs have been established in Singapore and Japan. Singapore’s biomedical sciences cluster has emerged as one of the leaders in its field, largely driven by active government support and investment since its establishment in 2000.44

In Australia, clusters have emerged through early serendipitous and more recent deliberate co-location. They are characterised by the integration of research excellence with clinical activity and subsequent translation of that research into service delivery. Examples include:

- Royal Children’s Hospital Campus which includes the Royal Children’s Hospital, the Murdoch Children’s Research Institute and the University of Melbourne Department of Paediatrics
- Parkville Precinct Bio21 Cluster in Melbourne which includes the Royal Melbourne Hospital, the University of Melbourne, Walter and Eliza Hall Institute and a number of other members
- Translational Research Institute in Brisbane which includes the Princess Alexandra Hospital, Diamantina Institute, Mater Medical Research Institute and The University of Queensland
- Westmead Millennium Institute in Sydney which includes Westmead Hospital, Westmead Children’s Hospital, University of Sydney and MRI facilities.

In Australia, support for a closer alignment of research, teaching, training and clinical services through partnerships between research institutes, universities and health services is widespread. A wide range of stakeholders support the AHSCs model, or some variation of it. NHMRC has recently promoted the concept as Advanced Health Research Centres (see Section 2.4.2 below).

Co-locating high-quality laboratory-based and hospital based clinical research ‘makes good sense’. It ensures that each discipline benefits from the expertise of the other, a synergy which would undoubtedly fast-track novel approaches to addressing many unresolved clinical issues.

Peter MacCallum Cancer Centre

Research clusters support multidisciplinary team building, attract high-calibre researchers and health professionals, and facilitate rapid multilateral exchange of information. They also provide a mechanism for incorporating private providers of healthcare services (general practitioners, specialists, allied health professionals) into the process of medical research. The major barriers to effective research clusters are governance and management structures that work against genuine collaboration and integration. As with any collaboration with diverse funding inputs, AHSCs need robust governance structures, KPIs and monitoring and reporting arrangements.

2.4.2 NHMRC Model of Advanced Health Research Centres

In supporting increased collaboration between universities, MRIs and hospitals to enhance research and research translation, NHMRC released a public discussion paper in December 2010 on Developing Advanced Health Research Centres in Australia.45 In doing so, NHMRC actively promoted a philosophy of 'bench to bedside and back' which 'would be achieved with the creation of knowledge through research that flows quickly into consumer benefits, strengthened support of clinical and research training in all health professional domains and enhanced collaboration and integration of universities, MRIs and hospitals'.46

In NHMRC’s vision, Advanced Health Research Centre (AHRC) collaborations would include:
• sharing advanced technical equipment and databases essential for 21st century health research;
• sharing research laboratories and other facilities and providing access to facilities and labs to clinicians on the campus;
• making stronger links between research and consumer care (to boost 'bench to bedside' translation);
• making better research use of data and information within the hospital to improve knowledge and consumer care;
• providing university medical, nursing and allied health students with enhanced access to research and translational activities and a wider educational experience;
• providing nodes of excellence across the nation in evidence-based clinical care; and
• providing national leadership in research translation and evidence-based clinical care through example.47

In its paper, NHMRC proposed inviting consortia of universities, hospitals and MRIs to apply for recognition of excellence in research and research translation, and to recognise the most outstanding campuses with designation as an 'NHMRC Advanced Health Research Centre'. The submission by NHMRC to the Review stated that 'we expect to introduce Phase 1 of the AHRC initiative within the next few months'.48 While this initiative has significant merit, to date no funding has been provided and it is not clear whether recognition of such a centre will be sufficient incentive for genuine clusters to form and deliver impact without specific funding related to performance.

48 Submission 222, NHMRC, p.28.
2.4.3 Proposed Integrated Health Research Centres

Issue: Greater integration and embedding of research in the health system is required. The Australian healthcare system, and the research subcomponent, is characterised by a very large number of stakeholders and very few collaborations which embrace the full spectrum of major entities—hospitals and other public and private health services (such as aged-care facilities), universities, MRIs, community care agencies, and non-government consumer organisations (for example, the various disease-based peak bodies). Some partnerships between research institutions, universities and health services already exist and have demonstrated excellence in this area. But for the most part, a concerted effort is required to bring together these key stakeholders to provide a mechanism for research to be more fully embedded in the health system.

Option: Establish clusters to drive research excellence and translation. The Panel strongly believes that research clusters will be a key driver in embedding research in Australia’s health system. In line with this new paradigm of embedded research, the Panel’s proposal is for funded Integrated Health Research Centres (IHRCs) to integrate research excellence with healthcare service delivery and facilitate best-practice translation of research directly into healthcare delivery.

The Panel believes that the structure best suited to Australia is a 'hub and spoke' model which would facilitate the very necessary inclusion of stakeholders in community care settings and even in regional and rural areas, where appropriate. IHRCs would bring together researchers and educators within universities, MRIs and health services (e.g. LHNs, Medicare Locals, other public and private deliverers of health services and aged-care facilities), and ensure cooperative access to skilled professionals, infrastructure, patients and data and a capacity to implement change. In certain circumstances (e.g. rural and regional) these may need to operate as a virtual IHRC. Since the main purpose of IHRCs is behavioural change, a competitive and rigorous selection and accreditation process would be required to ensure candidate centres demonstrate excellence, effective collaboration and a strategy to deliver health system impact.

The Australian Government’s recent establishment of LHNs and Medicare Locals offers an opportunity to strongly engage primary care and other elements of prevention and treatment activities within IHRCs—integration must include the broader realm of health services (e.g. primary health care, community care and public health networks) as a close interface between primary-care and hospital-care research is important for translation, particularly at the preventive health end of the spectrum. The spokes of IHRCs should be able to cross state boundaries, with some IHRCs being truly national in that they involve researchers from most or all states and territories, though maintaining a strong geographic hub.

The Panel’s vision for IHRCs is that they would attract the best institutions capable of forming clusters and collaborative leveraging. Initially 4–8 would be funded (including those already in existence), with a target of expanding to 10–20 over a 10-year period based on assessment of the impact of the initial IHRCs. Funding of up to $10m p.a. for five years for each IHRC would be necessary to provide incentives, cover establishment costs, deliver anticipated benefits, support shared infrastructure and staffing, and make the IHRC relevant to its collaborating institutions. The performance of each individual IHRC should be evaluated after three years to determine whether funding should be renewed for a further five-year term, and thereafter every five years (i.e. two years in advance of funding renewal).
Issue: Need for a clear set of criteria to select potential IHRCs. A rigorous selection and accreditation process would be needed whereby potential clusters would need to demonstrate robust governance, existing research excellence, skilled health workers, appropriate research infrastructure, data access and sharing, ability to attract funding from state and territory governments and private organisations, access to consumers, collaboration across the relevant healthcare sector, a strategy to deliver health system impact, and demonstrated integration of research and service delivery across the various health professional groups. They would also need to describe their research capability and the way in which becoming a cluster would leverage scale in their niche (i.e. a business plan that demonstrates how the strategic vision for world-class integrated healthcare will be achieved) as well as establishing KPIs against which their success can be measured.

Option: Establish a set of national competitive selection criteria. The Panel recommends five criteria as the basis for national competitive IHRC selection.

1. Integrated and clustered – represents partnerships across key stakeholder types and preferably co-located. For example:
   - a healthcare delivery component (likely, but not exclusively, a hospital)
   - research capability that includes a university that is responsible for and actively involved in training healthcare professionals and medical students, and an MRI
   - competitive commercialisation capacity, with established linkages to industry
   - a research facility located next to healthcare delivery and nearby other organisations with key infrastructure shared, but may be a virtual network where appropriate (e.g. Indigenous, rural and remote) with good communication mechanisms.

2. World-class – demonstrates research excellence and global relevance. For example:
   - recognised leadership in a research field or function with demonstrated research across the spectrum (biomedical, clinical, public health and health services)
   - at the forefront of e-health adoption and clinical registries for research use.

3. Translation-focused – at the forefront of research translation and evidence-based healthcare. For example:
   - demonstrated track record of research translation and healthcare innovation
   - culture of research and continuous improvement in healthcare services
   - capacity to run clinical trials, leading adoption of streamlined processes (see Section 2.6) and offering clinical trial participation to all eligible patients.

4. Shared vision and strategy – a common vision among entities and shared strategy to deliver impact. For example:
   - clarity on areas of focus and how to achieve common IHRC goals
   - leverage to attract additional funding from business or philanthropy.

5. Strong leadership and governance – a strong leadership team with authority and accountability for performance and robust governance model. For example:
   - leadership and accountability from a steering committee or board (different models may be successful)
   - sound business plan of expected outcomes and regular monitoring and evaluation
   - joint appointments that ensure appropriate controls over research integrity and use of Australian Government funds.
The model preferred by the Panel is one where IHRCs would be accredited by the national HMR leadership body as the administering agency and provided with both block funding and unrestricted eligibility to access competitive grants. The leadership body would need to have strategies in place to regularly monitor and evaluate each cluster through annual reports and have clear benchmarks for success which, if not achieved, would be triggers for review and possible cessation of funding. IHRCs would be encouraged to adopt a culture of innovation, with commercial business links, and office space and facilities should be provided to support these types of activities.

There would need to be clear policy mechanisms and a commitment to ensure, through strong engagement with DoHA, and government more broadly, that the HMR outcomes from IHRCs were both translated into practice and used to inform national policies. IHRC governance should facilitate integration of effort and accelerated translation outcomes, and governance guidelines should not otherwise be too prescriptive, allowing IHRCs to emerge and evolve so as to best suit their particular goals. While co-location is desirable, virtual models may also be feasible and necessary for some health areas (e.g. Indigenous and rural and remote), forced co-location (i.e. amalgamation and consolidation of existing resources) is likely to be costly and undesirable. On the other hand, opportunities to co-locate should be supported.

**Issue: Need for strong leadership and robust governance in IHRCs.** Strong leadership is vital and each IHRC should be led by a high-performing, recognised leader in the field with a demonstrated track record in delivering outcomes. Many stakeholders have expressed concerns about overly prescriptive governance arrangements for IHRCs. Experience also shows that shared endeavours require clear governance to cope with success, lack of success and unexpected events, particularly given the likely diversity of employment arrangements for employees of different IHRC partners. While the Panel recognises that the likely participants in IHRCs will themselves have diverse governance arrangements, a clear and strong governance model is required to ensure IHRC investment is deployed effectively and with clear accountability.

**Option: Specify a clear set of governance principles and requirements.** The governance guidelines below (Exhibit 2.12) are based on Australian Securities Exchange principles and provide a clear set of criteria for the type of governance arrangements that are likely to successfully deliver the desired outcomes. Incorporation of the IHRC, with a steering committee regulated by the Corporations Act, CEO, constitution and charter, is one way to achieve appropriate governance, but there may be others.
CASE STUDY 2.5

The Royal Children's Hospital Campus has shown that the integration of research and healthcare delivers better health outcomes

Background. The Royal Children's Hospital Campus is a collaborative effort between the Royal Children's Hospital, the Royal Children's Hospital Foundation, the Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics. The Campus facilitates collaborative efforts between healthcare delivery, medical research institutes and university researchers to conduct and translate research to deliver impact.

The four participating entities retain their own independent structure but come together under the Campus Council to set strategic goals and initiatives. Each entity is an equal partner in the Council, represented by their CEO and Chair, while an independent Chair oversees the collaborative effort. The Campus uses a set of research performance evaluation criteria (which includes translation and commercialisation) to influence funding allocation and decisions.

The integrated, collaborative approach to research has ensured the Royal Children's Hospital Campus remains at the forefront of research and translation in this field. Three examples are described below.

• **Ventilation practices.** Ventilation practices at the Paediatric Emergency Department at the Royal Children's Hospital has resulted in the creation of a new algorithm for ventilators to reduce the risk of respiratory complications.

• **Rotavirus vaccine.** Since the discovery of the link between rotavirus and severe gastroenteritis, researchers at the Campus have been developing a low-cost vaccine which is currently in Phase II clinical trials. It is expected to significantly reduce the incidence of rotavirus which causes more than 600,000 deaths each year in children under five worldwide.

• **Diagnosing mitochondrial disorders.** Researchers have defined the biochemical and genetic spectrum of Leigh disease. Clinical and biomedical teams have applied new genomic techniques to further improve diagnosis of mitochondrial disorders, as well as heart disease, epilepsy, deafness, and development delay.

Key Lessons:

1. **Collaborative research focused on better healthcare delivery improves health outcomes.** Research into areas of clinical care that lack an evidence-base, such as the ventilation practices in the Paediatric Emergency Department of the Royal Children's Hospital, has delivered improved health outcomes upon translation.

2. **Evaluation and monitoring of research outcomes leads to more effective translation.** The Campus evaluates research outcomes across its various departments, and performs follow-up audits for verification. The results are used to influence funding decisions and optimise investment. As a result, members are incentivised to conduct research that delivers impact and ensure findings are translated into evidence-based healthcare.

Note: Image courtesy of Murdoch Children's Research Institute
Source: Royal Children's Hospital: www.rch.org.au; Murdoch Children's Research Institute: www.mcri.edu.au
Exhibit 2.12

Governance structures for IHRCs should ensure that a number of key principles are met

**IHRC Governance Principles**

<table>
<thead>
<tr>
<th>Principle</th>
<th>Requirements</th>
<th>Possible Approaches</th>
</tr>
</thead>
</table>
| Management and oversight         | • Enable the steering committee to provide strategic guidance and oversight of management  
• Clarify roles of steering committee and senior management to facilitate communication and accountability | • Codify formal responsibilities and role of steering committee and senior management  
• Formally disclose senior management evaluation process and regularly review performance |
| Independent and accountable steering committee | • Ensure steering committee has adequate understanding and competence  
• Promote independent thinking and judgement | • Ensure the majority of the steering committee is independent of senior management, including the chairperson  
• Establish a transparent appointment and review process |
| Ensure integrity in financial reporting | • Establish an independent audit committee  
• Ensure independence of external auditors | • Independent audit committee should consist of independent directors and operate with a charter |
| Promote regular disclosure       | • Promote reporting of activities and financial position to stakeholders | • Establish reporting policy to regularly report to stakeholders  
• Establish KPIs to monitor inputs and outcomes of research and funding allocation |
| Promote ethical and responsible decision making | • Clarify ethical standards expected of the steering committee and senior management  
• Comply with legal obligations and expectations of stakeholders | • Establish a code of conduct to maintain stakeholder confidence  
• Inform steering committee and senior management of responsibility for reporting unethical behaviour |

Source: ASX corporate governance principles

Strong leadership that effectively manages the needs of the various IHRC partners and drives the research agenda is needed. Johns Hopkins Medicine and the Bio21 Cluster provide examples of robust governance structures (Exhibit 2.13).

Johns Hopkins Medicine is governed by a Board of Trustees, which oversees the Johns Hopkins School of Medicine and the Johns Hopkins Health System, and comprises six academic and community hospitals, four suburban healthcare and surgery centres, over 30 outpatient sites and programs for national and international patient activities. The Board of Trustees has over 50 members from the University and the Health System, and is advised by the Board of Advisors, comprised of leaders from Johns Hopkins Medicine, as well as prominent researchers, clinicians, corporate and community leaders. The Board of Trustees directs the research, teaching and patient care efforts of Johns Hopkins Medicine, which is executed through the leadership bodies in Johns Hopkins School of Medicine and Johns Hopkins Health System, with joint research efforts.
The Bio21 Cluster in Parkville Precinct, Victoria, operates in a similar manner. The cluster, comprising 21 Founding and General Member organisations, is governed by a Board that represents the interests of the member organisations. The Founding organisations are each directly represented on the Board, with select General Member organisations also represented. The Board has a number of committees, councils and forums which are tasked as working groups to drive the agenda set by the Board and are open to all member organisations. In addition to an audit committee, there is a Scientific Advisory Council, which meets monthly to share information, determine priorities and advance key shared initiatives, as well as a Hospital Research Directors Forum, which addresses issues such as research governance, translation and funding. These committees form the collaborative effort of the Bio21 Cluster and drive the research agenda of its member organisations. The CEO reports to the Board and manages the projects conducted through the cluster, as well as the cluster's technological infrastructure. This governance structure allows the cluster to set research agendas, drive translation and act in the best interests of its member organisations.

Exhibit 2.13

The IHRC governance structure should ensure appropriate oversight of management actions and alignment with stakeholder interests

Example Governance Structures

**Johns Hopkins (JH)**

- **Board of Advisors**
  - Leaders from JH Medicine, prominent researchers, clinicians and corporate leaders

- **Board of Trustees (JH Medicine)**
  - Over 50 members

- **JH School of Medicine Dean**
- **JH Health System CEO**
- **Researchers**

**Bio21 Cluster**

- **Board**
  - Founding Members and selected General Members appointed

- **CEO**

- **Councils/Committees**
  - Working groups and governance committees
  - Consist of Bio21 Cluster members

- **Projects Manager**
- **Platform Technology Network**
- **Researchers**

Source: Johns Hopkins Medicine Website; Bio21 Cluster 2011-12 Annual Report

In Australia, a corporate structure (e.g. a company limited by guarantee) has advantages over alternative models as many governance basics are stipulated by the Corporations Act, and pre-existing templates exist for constitutions and shareholder agreements. These can ensure the most important issues are agreed in advance without the complexity and expense of a bespoke governance model.
2. Embed Research in the Health System

Implementation Tasks | Responsibility | Timeframe
--- | --- | ---
3a.1 | Develop appropriate criteria for selecting IHRCs and evaluating performance. This should include integration, world-class quality, translation focus, shared vision and strategy, and strong leadership and governance. | Leadership body | 2014–15

3a.2 | Approve criteria and IHRC selection process through COAG SCoH to ensure buy-in from states and territory governments. | Leadership body, COAG SCoH | 2014–15

3b.1 | Initially award between 4–8 IHRC competitive grants, based on the defined criteria, with up to $10m p.a. of block funding each for a five-year period to support critical elements of governance, clinical research infrastructure and research support staff. | Leadership body | 2014–15

3b.2 | Award an additional 1–2 IHRC grants every 1–2 years, building to 10–20 over a 10-year period. | Leadership body | 2014–15 to 2023–24

3c.1 | Monitor performance of IHRCs including strategic plans, outputs and outcomes through annual reporting to the leadership body. | Leadership body | Ongoing

3c.2 | Evaluate the performance of each IHRC across a number of KPIs (e.g. output, impact) after three years to determine whether funding should be renewed at the end of the five-year term for a further five years, and repeat process thereafter on a five-year basis (i.e. two years in advance of funding renewal). | Leadership body | Ongoing

2.5 Build Health Professional Research Capacity

**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.

2.5.1 Introduction

In addition to increasing research within the health system through top-down measures, the Panel also believes that there is a need to promote research activities from the bottom up. All health professionals who have the desire, training and ability to be involved in research should be able to do so, no matter what their role in the health sector. Research capacity among health professionals is critical for conducting research, promoting research translation and improving the health system. The importance of research in driving innovation in clinical practice was noted by the NHHRC:
Valuing clinical leadership and embedding a culture which frees health professionals to invest time in quality improvement may be as important as structural change in achieving health reform ... Providing health professionals with opportunities to combine teaching and research with their service responsibilities builds a culture of quality and is demonstrated to lead to better uptake of new knowledge and better outcomes.49

Although the NHHRC noted the importance of research in driving innovation in clinical practice, the translation of research into clinical practice in Australia's healthcare system is inherently problematic, with a huge cultural gulf between knowledge generated by researchers and that which is used in clinical practice. This is driven by the different goals of each party.

• The goal of many researchers is to produce high-quality research with citation by others as a key measure of its significance.
• The goal of clinicians and other health workers is to treat consumers and deliver services likely to result in the best possible health outcomes for them.

Also important for the translation of health outcomes is the two-way dialogue between the biomedical scientist and clinician researcher. For this very important collaboration to be effective, we need to improve clinician researcher career paths, promote alliances between institutions, integrate academic/research/clinical centres and introduce more effective science research education to clinicians, and clinical education to scientists.

Health professional researchers must trade off these distinct and non-aligned goals, ultimately requiring an increased workload, calling for a high degree of focus, self-discipline and time management skills, for limited direct reward. It is not known how many of the 70,000 clinicians or over 600,000 other nursing, allied and other health practitioners registered in Australia are currently engaged in research in healthcare facilities.50 Some hospital-based researchers are recipients of NHMRC grants, although with hospitals administering only 0.6% of NHMRC funds in 2010–11 this is extremely small compared to universities (75%) and MRIs (24%).51 NHMRC supports approximately 75 Practitioner Fellows (Exhibit 4.2) to be research active (ranging from 0.3 to 1.0 FTE Fellowships). Crucially, this is likely to represent <0.1% of the trained clinicians practising in Australia.

Research by other health professionals is facilitated through various state and territory government schemes, although this varies between jurisdictions, and the total extent of involvement is unknown, particularly as hospital-based researchers may channel their NHRMC grants through attached universities to take advantage of Research Infrastructure Block Grants (RIBG) scheme infrastructure payments.

There are four main ways to actively build health professional research capacity in the health services delivery sector:

• build research capability among clinicians and allied health professionals
• support dedicated research time and increase the number of practitioner fellowships
• fully reimburse the overhead costs of peer-reviewed and competitively-funded research in healthcare facilities
• facilitate faster entry into Australia and into clinical practice of leading qualified overseas HMR professionals.

CASE STUDY 2.6

Clinician research and translation is critical to advance health and medical research and deliver improved patient outcomes

**Background.** Mood or affective disorders such as depression and mania are very common, with one in four Australians experiencing a significant mood disorder during their lifetime. For 40-70% of those affected, mood disorders can cause severe disruptions to their lives and represents a major cost to the community. About 5% of people will experience a bipolar affective disorder.

In 1949, Melbourne psychiatrist John Cade published his observations that lithium salts resolved psychotic excitement in 10 manic patients, but had no effect on patients with schizophrenia. His findings were confirmed, with subsequent research over the next 30 years establishing lithium carbonate as a mainstay treatment for mania, a mood stabiliser which prevented the recurrence of bipolar disorder, and an important adjunctive treatment for depression.

The discovery of lithium's benefits has changed the face of psychiatry. Patients who were previously institutionalised can now enjoy a more normal, productive and less distressed life. A 1994 study quantified savings to the US economy alone to be a staggering $145 billion.

**Key Lessons:**

1. **Clinician researchers are critical in advancing health and medical knowledge.** Protected time for clinicians to engage in research and follow-up on their clinical observations is critical.

2. **Research translation from bedside to bench delivers improved patient health outcomes.** Observations made at the bedside led to major laboratory investigations about lithium and to the pharmaceutical industry investing heavily in medications to assist people with serious psychiatric disorders.

Note: Image courtesy of Richard Cade
2.5.2 Promote Research Participation by Health Professionals

Issue: Research activity among health professionals is in decline. In the past, clinician researchers dominated the HMR field, but in the last decade there has been a steady shift to non-clinician researchers. The clinician and broader health professional research workforce is reputed to be ageing, with insufficient younger researchers emerging, although the lack of data makes this impossible to verify. If the number of health professional researchers is in decline, so is the number of mentors available to train and encourage younger researchers.

... there is increasing concern worldwide about the future of clinical (i.e. patient based) research and clinician researchers. A range of factors are impacting on the ability of the health system to attract and retain the best minds in clinical research roles. These include inconsistent and fragmented funding models, significantly reduced levels of funding and extended training pathways, the combined outcome of which is a critical reduction in the number of people with advanced academic skills and qualifications seeking clinical research roles.

Bio21 Cluster

The decline in popularity of research-focused careers within clinical services may be due to healthcare professional students being neither adequately exposed to research methodologies in their professional training nor encouraged to engage in clinical research after completing their tertiary studies. Further, when healthcare professionals enter the workforce, they usually have a tuition debt to repay, and further research training through pursuit of a higher degree entails further debt and a period without substantial income. A research-focused (academic) career is also generally associated with a significantly lower income than would be achieved by a healthcare professional in specialist private or public practice. Health professionals who decide to train in research at some later stage in their career have an even greater financial disincentive, as many have family responsibilities and a mortgage. The pathway for newly-graduated healthcare professionals into clinical research is neither well defined nor financially attractive. In short, there is no clear career path for those who want to do more than just contribute patients or clinical samples from time to time to research projects conceived and driven by others.

The unattractiveness of a research-focused career, particularly for those undergoing the prolonged process of advanced training, is exacerbated by the inherent uncertainty of research funding, in contrast to the flexibility and relative certainty of employment in private or public clinical practice. In addition, hospitals do not usually offer financial support for indirect research costs, and the lack of appropriate infrastructure and protected time for research are significant disincentives. This is particularly the case in primary healthcare.

Anecdotal evidence suggests that only a small percentage of general practitioners are willing to participate in research. There is no secure career structure for budding researchers and limited incentives. The current capacity of primary care providers to undertake research necessary to establish and maintain a firm evidence base is limited.

Royal Australian College of General Practitioners
A further disincentive is that those clinicians with substantial service and teaching loads, who wish to pursue research, compete for funding from the same pool as research-focused full-time researchers, and are less likely to be competitive if research output is judged predominantly on academic publications. Hence, a separate system for evaluating support schemes designed for health professionals is required, together with a stronger emphasis on the provision of support to teams that include health professionals. In addition, there is a lack of health professional researcher appointments and of specific schemes to foster health professional researchers. This reinforces the dominant paradigm whereby research across the entire spectrum of translation is not valued in healthcare delivery.

In 2011, the VCRN conducted an online multisite survey of health care professionals in 15 hospitals across Victoria. The survey elicited 1027 responses from doctors, nurses and allied health workers and, despite a majority who indicated that they were either currently involved in research or were interested to become involved in future, a number of barriers to translating research to beneficial patient outcomes emerged, including: lack of time due to clinical commitments; lack of funding for research; absence of protected research time; lack of management and institutional support; no seed funding to support pilot research projects; absence of mentoring; and competing commitments to family life.

Bio21 Cluster

One consequence of an environment which discourages research activity among health professionals is a disproportionate amount of disease-focused research being conducted by scientists who may not have a good understanding of clinical need. There is a great need to focus disease-orientated research towards solving significant clinical problems, which is best achieved by increasing involvement of clinicians in the research, both in the study team and in grant review. While engaging health professionals in HMR may exacerbate the chronic problem of limited healthcare practitioner availability, the efficiencies gained through targeted research involving practitioners could be expected, overall, to counter this impact in the long term.

**Option: Provide protected time with practitioner fellowships and project grant funding.** The aspiration is to support 1,000 new practitioner research fellowships for health professionals over the next 10 years to build capacity and capability for research in the health system. The financial disincentives to a research-focused clinical career will need to be addressed. These fellowships should fully cover the cost of at least 50% of work time for three to five years, at a salary level commensurate with their qualifications and experience, and should provide a component for indirect research costs. Funding should be allocated to the researcher’s employer, and time spent on research should be identifiable for audit purposes. Involvement of health professionals in all areas of research should be supported and this should cover a range of settings and roles (hospitals, GPs/primary care, nurses, community care, aged care, etc), preferably with access to quality research infrastructure and productive public health and health services research groups.

Additional funding should be specifically provided via the national competitive grant funding schemes to support research proposals from health professionals. Such investment should cover the involvement of health professionals across the whole spectrum of research. Additional support for both the research (Project, Program and Partnership funding) and the researchers (Fellowships and Scholarships) will be required. A number of existing schemes could also be enlarged or modified to accommodate this. For example, this may involve building upon the current NHMRC Translating Research Into Practice (TRIP) Fellowships program, which provides support for future leaders in translating important research findings into clinical practice, and allows for protected time for health professionals in researching approaches to applying evidence to improve care, and developing the range of skills needed for leadership in research translation.
While health professionals with a track record in research would be the primary target, the program could be extended to younger health professionals in training under the oversight of more experienced researchers. This should, at the same time, enrich the medical significance of the research being conducted in healthcare facilities. This may best be achieved via practitioner fellowships providing clinicians in training with time during their professional development to pursue mentored patient-focused research. It would be expected that these fellowships would be particularly appropriate for an IHRC-type environment which is conducive to high-quality research, and at the forefront of research translation and delivery of evidence-based healthcare.

To meet these requirements, healthcare institutions will need to change their culture to fully embrace research as a valued activity, providing not only time, but space and infrastructure either within the hospital or in collaboration with partner organisations, such as MRIs or universities. While only some health professionals will be regularly active as researchers, all should be knowledgeable and aware of the process and implications of research and ways it can be incorporated into day-to-day practice. Research training should be a component of continuing professional development for health professionals across the spectrum of clinical and allied health services, and evaluation of research participation a component of performance appraisal. To ensure that practitioners are research-enabled, and encouraged to participate in research, time spent by clinicians in specialist training in research, including higher degrees, must count towards and should be required for ongoing accreditation by the professional colleges or other specialist accreditation bodies. For general practitioners, incentives might need to be provided (e.g. a practice incentive payment) to enable them to facilitate research within their practice.

**Issue: Need for health professionals to drive translation.** One of the underlying aims of the existing NHMRC Practitioner Fellowships program is to drive translation of research in the health system to deliver better health outcomes for consumers. All too often, research efforts stop at the stage of writing up and publishing a guideline. There is a pressing need for health professionals to take a more active role in facilitating knowledge translation and sharing learnings from research and best-practice healthcare.

> Over the past 5 years WA Health has gained evidence that suggests that the direct participation of clinicians/health practitioners in research that is based in their areas of work, and the subsequent translation of successful research outcomes into practice, can make a significant contribution to improving the quality, efficiency and cost effectiveness of healthcare delivery. An additional benefit of this is improving the engagement and morale of the health workforce.

*Department of Health Western Australia*

**Option: Encourage creation of health professional research networks.** To increase the impact of health professional research, the Panel encourages health professionals to form research networks based on areas of research or lines of healthcare delivery to facilitate increased research collaboration and provide a means of sharing research findings. One such model to consider is the Australian Primary Health Care Research Institute, which has been responsible, as part of the Australian Government’s Primary Health Care Research, Evaluation and Development Strategy, for building research capacity in primary care since it was established in 2002. The Institute distributes research funding in a competitive process for primary healthcare services research, and has built up a network of primary healthcare researchers across Australia. Currently, the Institute funds eight Centres of Research Excellence in primary health care, including projects in Indigenous Health, Chronic Disease Prevention, Primary Health Care Microsystems, Finance and Economics of Primary Health Care, and Access and Equitable Use of Services in Rural and Remote Communities—all with clear links to current policy, and with a remit to ensure that research findings are effectively translated. These could be potential candidates for fellowships, as described below.

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52 Allied health professionals make up 20% of Australia’s healthcare workforce and include audiologists, chiropractors, dieticians, exercise physiologists, occupational therapists, orthoptists, orthotists and prosthetists, osteopaths, hospital pharmacists, podiatrists, psychologists, sonographers and speech pathologists, according to Allied Health Professionals Australia Source: http://www.ahpa.com.au/.
CASE STUDY 2.7

Australian Nobel Laureates, Robin Warren and Barry Marshall, made a remarkable and unexpected discovery of the bacterium Helicobacter pylori

**Background.** Dr Robin Warren was a pathologist at the Royal Perth Hospital (RPH) when he discovered the bacterium *Helicobacter pylori* and commenced his research in 1979. In 1981, he involved Dr Barry Marshall, who was a gastroenterology clinical fellow at the time. They conducted biopsies on patients and used technologies such as fibre endoscopy, silver staining of histological sections and culture techniques for microaerophilic bacteria.

Their findings concluded that:

- Peptic ulcers are an infectious disease – *H. pylori* causes over 90% of duodenal ulcers and up to 80% of gastric ulcers.
- *H. pylori* causes long-life infection, being typically contracted in early childhood, often by transmission from mother to child. The bacteria may remain in the stomach for the term of life.
- In most individuals *H. pylori* infection is asymptomatic (shows no sign of symptoms). About 10–15% of infected individuals will at some time experience peptic ulcer disease.
- *H. pylori infection* can also lead to stomach cancer.

In 2005, Barry J Marshall and J Robin Warren won the Nobel Prize in Physiology or Medicine for their 1982 discovery of the bacterium *Helicobacter pylori* and its role in gastritis and peptic ulcer disease, which was previously believed to be caused by stress and lifestyle factors.

As a result of Marshall and Warren’s breakthrough discovery, peptic ulcer disease is no longer a chronic condition, but a disease that can be cured by a short regimen of antibiotics and acid secretion inhibitors.

**Key Lessons:**

1. **Participation of health professionals in research can lead to breakthrough discoveries for treatment of chronic diseases.** Robin Warren and Barry Marshall conducted biopsies on tissue from consenting patients (one for culture, the other for histological examination). Their discovery has stimulated the search for microbes as possible causes of other chronic inflammatory conditions such as Crohn’s disease, ulcerative colitis, rheumatoid arthritis and atherosclerosis.

2. Embed Research in the Health System

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>4a.1 Fund healthcare practitioner fellowships, starting with 100 in the first year and building up to 1,000 over 10 years. Fellowships to protect 50% of health professional time for research for three to five years, and to include an allowance for indirect research costs. Funding should be allocated to the researcher's employer, and time spent on research should be identifiable for audit purposes.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>4a.2 Provide nationally-competitive research project grants across the spectrum of HMR, to an estimated total of $200m p.a. (or ~1,000 grants) at the end of the 10-year period, to support the increase in research-active health professionals that will follow from increased capacity-building.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>4a.3 Include research activity in clinical professional development and its evaluation.</td>
<td>DoHA</td>
<td>2014–15</td>
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<tr>
<td>4a.4 Encourage the formation of health professional networks to collaborate and then share findings that are disease or issue-oriented.</td>
<td>Leadership body</td>
<td>2014–15</td>
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2.5.3 Train Health Professionals in Research

**Issue:** Research is not promoted as a viable career by medical schools. The process of educating a healthcare professional is lengthy and labour intensive, with many undergoing up to 15 years training to become a medical specialist. Yet when doctors become accredited as either GPs or specialists, they have usually spent relatively little time learning how to conduct research because medical schools and specialist colleges have traditionally provided limited or optional training in conducting laboratory and patient-focused research. While there is a trend towards increased exposure of healthcare professionals to research training, most current health professionals have never been actively exposed to current research methodologies.

“The critical difference between health and medical research and other sectors is the amount of training required by its workforce. In many areas of the economy, when a skills shortage is identified, this can be addressed relatively rapidly. With health and medical research, it takes a generation to train its workforce appropriately. Therefore, it takes great vision to foresee the enormous challenges faced in the next forty years and say, ‘we need to address this now’. A skills shortage in health and medical research does not mean economic stagnation, it means serious economic decline. If the cost of disease burden gets out of control, it cannot be fixed overnight. We must plan well in advance.”

*University of Western Australia Researchers’ Association*

**Option:** Enhance research training and establish dual accreditation programs. The Panel believes that to promote participation in research by health professionals, there is a need to actively build health-scientist capacity through further research training in medical schools and specialist colleges. Training in research methodology should be integral, rather than optional, in the training given to health professionals, both at tertiary level and as part of continuous professional development. Indeed, accreditation by the professional colleges should encompass some evaluation of research capability. Ideally, research training should be built into training without further extending the time required to qualify, as otherwise this would be a continuing barrier to maintaining an adequate workforce.
… it is essential that there are academics who train and enthuse undergraduate students, doctors, nurses and allied health professionals who deliver health care in clinics and hospitals or who work in health policy development. Training of future doctors and other health professionals, at university and in the clinic, will be poorer if it is not undertaken in part by practitioners who also conduct research, are enthused by the gaining of new knowledge, and who in turn enthuse practitioners on the need for evidence based practice themselves.

National Health and Medical Research Council

There also is a need to reduce the financial and practical disincentives for health professionals to gain dual clinical and research qualifications (e.g. MD–PhD). The prestigious MD–PhD programs supported by the US National Institutes of Health (NIH) and offered by most top medical schools in the US may be a good example to follow.

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<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tr>
<td>4b.1 Enhance research training for healthcare professionals in universities, medical</td>
<td>DoHA, universities, medical</td>
<td>2014–15</td>
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<tr>
<td>schools and professional colleges, by provision of research training options, as</td>
<td>colleges</td>
<td></td>
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<td>a pathway towards eligibility for health professional training fellowships.</td>
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<tr>
<td>4b.2 Embed research training and experience into continuing professional development</td>
<td>Medical colleges, state and</td>
<td>2014–15</td>
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<td>of clinicians, nurses and allied health professionals and assess through</td>
<td>territory health departments</td>
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<td>performance evaluation.</td>
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<tr>
<td>4b.3 Accept and possibly mandate one year of research training towards the</td>
<td>Medical colleges</td>
<td>2014–15</td>
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<tr>
<td>requirements for specialist clinical professional accreditation.</td>
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</table>

2.5.4 Facilitate Entry of Overseas Professionals

Fully embedding HMR into the health sector will require research leadership that is currently in short supply within this country compared with the US, UK and many European countries. One relatively rapid solution to this problem would be to attract high-calibre, research-active health professionals to Australia. While it is a highly attractive destination for many overseas professionals, Australia’s professional accreditation barriers act as a strong disincentive to the recruitment of overseas clinically-trained research leaders. Australia needs to facilitate the process of bringing in high-quality health professional researchers from overseas to work either for a short period of time as guest researchers or as long-term migrants. With recent Government initiatives arising from the June 2011 House of Representatives committee report, *Australia’s International Research Collaboration* difficulties with visas for short visits by researchers should no longer be an issue. The problem is more with professional accreditation of high-calibre overseas medical professionals, to enable them to practise clinically as team leaders in Australia, facilitating clinically-focused medical research, and training of upcoming clinical researchers.

**Issue: Accreditation of leading health professional researchers is inefficient.** There are a number of leading clinician scientists and research-active health professionals who have experienced difficulty in getting accreditation to practise and do research in Australia. A recent House of Representatives committee report highlighted the excessive ‘red tape, duplication and administrative hurdles’ faced by international medical graduates (IMGs) when attempting to gain accreditation to practise in Australia. The report concluded that there should be a significant reduction in the hurdles faced by IMGs while still ensuring that the Australian

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standards continued to be rigorously applied. While the Panel strongly agrees that the Australian standard of accreditation should continue to be rigorously applied, it highlights the criticism of the administration of the accreditation system by pointing out that many well-qualified IMGs are prevented from taking up prominent roles in the clinical research workforce in Australia because they cannot have their professional accreditation recognised in a timely manner.

**Option: Use workplace-based assessment for IMG peer review.** The 2012 House of Representatives Standing Committee on Health and Ageing report recommended: ‘that specialist medical colleges adopt the practice of using workplace-based assessment during the period of peer review to assess the clinical competence of specialist IMGs in cases where applicants can demonstrate that they have accumulated substantial prior specialist experience overseas’. The Panel agrees with this recommendation as a mechanism to facilitate faster entry of overseas medical professionals so that they can join Australia’s HMR workforce in a timelier manner. Further, prospective migrant health professional researchers should be eligible to apply as principal investigators on grant applications submitted to NHMRC, provided that they are resident by the commencement of grant funding.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>4c.1 Streamline permanent migration assessment and specialist professional accreditation for leading overseas health professional researchers, either through the colleges or an alternative accreditation body, and streamline their eligibility to be principal investigators in grant applications to NHMRC.</td>
<td>Leadership body, NHMRC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

### 2.6 Accelerate Clinical Trial Reforms

**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.

### 2.6.1 Introduction

**Role of Clinical Trials.** The process of conducting clinical trials is a key research methodology performed within clinical settings. They include both clinical trials sponsored by pharmaceutical companies developing new treatments and non-commercially-sponsored clinical trials comparing relative effectiveness of different treatment regimes. Clinical trials can test whether innovations in patient and disease management are effective and safe. They do not, however, necessarily prove that an innovation is cost effective or clinically superior to an existing clinical process.

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Australia’s medical community needs to conduct relevant research to ensure that the nation is in a position to expertly assess and promptly translate research into the Australian context. Through involvement in clinical trials, Australian researchers ensure the earliest access for Australians to advances in therapeutics and medical devices, as well as facilitating knowledge transfer and training around the use and deployment of these innovations. Ultimately, this level of engagement in research can contribute to improved health outcomes here in Australia.

The Royal Australasian College of Physicians

While clinical trials conducted overseas can answer these questions, local conduct of clinical trials can be of significant benefit because they ensure rigour and build expertise in current best-practice disease management, allow consumers early access to novel therapies, and can fund a portion of consumer healthcare costs. Clinical trials also expose healthcare professionals to novel research methodologies and lead to a higher uptake of clinical innovations. Hospitals that participate in clinical trials are proven to deliver better patient outcomes (Case Study 2.8). They also represent a source of income for the hospitals involved, although they require appropriate infrastructure, and they may involve ethical and legal risks. Furthermore, clinical trials provide economic benefit as a source of export income.

Clinical trials are important not only for the massive investment they bring to Australia, but also for the role they play in improving Australia’s healthcare system. Among other things, clinical trials provide early and often free access to new healthcare technologies, which, according to the Government’s own estimates, saves Australian taxpayers around $100 million each year in hospital and PBS costs.

Medicines Australia

Overview of Activity. There are broadly four phases of clinical trials, with varying levels of participant numbers and costs.

• Phase I trials – first in-humans studies, screening for safety (for drugs, at a range of possible doses) and to achieve some surrogate assessment of expected clinical outcome, either in healthy volunteers or patients (typically 20–100 participants).
• Phase II trials – establishment of efficacy, surrogate markers of efficacy, and further safety parameters, in a selected patient group, for drugs at the expected range of clinically useful doses (typically 100–500 participants).
• Phase III trials – pivotal trials, in otherwise unselected patients from the target group, either demonstrating efficacy or comparing the treatment with already proven alternatives for non-inferiority, and further evaluating adverse effects (typically over 1000 participants).
• Phase IV trials – undertaken after the medicine has been approved for purposes such as safety surveillance, comparison with a wider range of existing medicines and therapies and providing ongoing technical support for treatments.

The value of the clinical trials sector in Australia is estimated at around $1bn p.a., with approximately 600 new trials reported by the Therapeutic Goods Administration (TGA) in 2011, the majority of which were Phase II and Phase III. The total number of new clinical trials has been stagnant to declining over the last five years, driven by increasing competitive pressures from lower-cost countries (Exhibit 2.14).
CASE STUDY 2.8

Hospitals actively involved in clinical trials deliver a higher quality of patient care

**Background.** There is compelling evidence of a positive relationship between hospitals that conduct research and a higher quality of patient care in those hospitals.

Outcomes were gathered from over 170,000 patients across 494 participating hospitals in the United States who experienced acute coronary syndromes.¹ Hospitals were assessed by their level of clinical trial participation and mortality and guideline adherence. Results showed that hospitals with higher levels of clinical trials led to lower mortality rates and lower rates of non-compliance with clinical guidelines.

**Patient Outcomes by Level of Clinical Trial Participation**

<table>
<thead>
<tr>
<th>% Guideline Non-Compliance and Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (23.1%)</td>
</tr>
<tr>
<td>Low (21.7%)</td>
</tr>
<tr>
<td>None (18.9%)</td>
</tr>
</tbody>
</table>

**Key Lessons:**

1. **Involvement of health services providers in clinical trials delivers better quality care for patients.** Hospitals that have a high level of participation in clinical trials were found to have a 4% lower level of non-compliance with clinical guidelines and a 2.5% lower mortality rate than hospitals that did not undertake any clinical trials.

Note: ¹ Acute coronary syndromes considered in this study were high-risk non-ST-segment elevation acute coronary syndrome with unstable angina and non-ST-segment elevation myocardial infarction
### Exhibit 2.14

**Clinical trial activity in Australia has been largely stagnant to declining, particularly over the last five years**

<table>
<thead>
<tr>
<th>Number of New Clinical Trials</th>
<th>New Clinical Trials by Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td># TGA Trials</td>
<td>% Trials</td>
</tr>
<tr>
<td>1999–2011</td>
<td>2011</td>
</tr>
<tr>
<td>539</td>
<td>100% = 635</td>
</tr>
<tr>
<td>559</td>
<td>Phase IV</td>
</tr>
<tr>
<td>603</td>
<td>10%</td>
</tr>
<tr>
<td>676</td>
<td>Phase III</td>
</tr>
<tr>
<td>865</td>
<td>22%</td>
</tr>
<tr>
<td>673</td>
<td>Phase II</td>
</tr>
<tr>
<td>635</td>
<td>25%</td>
</tr>
<tr>
<td>1999</td>
<td>Not Specified</td>
</tr>
<tr>
<td>2001</td>
<td>38%</td>
</tr>
<tr>
<td>2003</td>
<td>Phase I</td>
</tr>
<tr>
<td>2005</td>
<td>10%</td>
</tr>
<tr>
<td>2007</td>
<td>5%</td>
</tr>
<tr>
<td>2009</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td></td>
</tr>
</tbody>
</table>

Source: Therapeutic Goods Administration, customised data request, 2012

**Decline in International Competitiveness.** Australia is now the second most expensive country in the world for clinical trials after Japan, and is at risk of losing its competitive position for global clinical trials. This is reflected in a recent survey of global companies which indicated that Australia’s competitiveness would remain stagnant or may even decline (Exhibit 2.15). There are various reasons for this, including:

- increasing costs due to the rising relative value of the Australian dollar;56
- rapid increase in capacity of low-cost countries (e.g. China, India and in Eastern Europe) to conduct quality clinical trials;
- complex, time consuming and costly approvals processes for ethics and governance review, still despite recent initiatives (e.g. Harmonisation of Multi-centre Ethical Review—HoMER), particularly for multi-site trials;
- lack of standardised costs for clinical trial activities across Australia;
- lack of access to appropriate clinical trial support infrastructure; and
- difficulty in recruiting participants driven by limited access to patients by healthcare providers and lack of national patient data infrastructure to identify participants.

To remain competitive, Australia must reform its clinical trials process to address major constraints of approval times, infrastructure, lack of uniform costing, funding and patient access.

56 Over the last 10 years the Australian dollar has roughly doubled in value against the American dollar, from about 50 cents to $1.00.
Exhibit 2.15

Australia’s future competitiveness is currently perceived by the global industry as stagnant to declining

Company Perceptions of Australia’s Future Competitiveness
% Respondents

<table>
<thead>
<tr>
<th>Region</th>
<th>Improve</th>
<th>Remain the same</th>
<th>Decline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Europe</td>
<td>31%</td>
<td>44%</td>
<td>25%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>25%</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td>Canada</td>
<td>19%</td>
<td>50%</td>
<td>31%</td>
</tr>
<tr>
<td>United States</td>
<td>20%</td>
<td>47%</td>
<td>33%</td>
</tr>
<tr>
<td>Asia Pacific</td>
<td>11%</td>
<td>41%</td>
<td>47%</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>6%</td>
<td>31%</td>
<td>62%</td>
</tr>
<tr>
<td>South America</td>
<td>13%</td>
<td>88%</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>13%</td>
<td>41%</td>
<td>46%</td>
</tr>
</tbody>
</table>

Notes: 1. Survey question asked was ‘over the next 5-10 years, Australia’s competitiveness versus other countries will …’

2.6.2 Build on CTAG Report Recommendations

The Clinical Trials Action Group (CTAG) was established in October 2009 as a subgroup of the Pharmaceuticals Industry Working Group to identify and progress reforms aimed at increasing Australia’s competitiveness in the clinical trials sector. Co-chaired by the Parliamentary Secretary for Innovation and Industry, the Hon Richard Marles MP, and the Parliamentary Secretary for Health, the Hon Mark Butler MP, the review was initiated partly in response to issues raised in the final report of the Pharmaceuticals Industry Strategy Group of 30 January 2009.57

The 2011 CTAG report, Clinically Competitive: Boosting the Business of Clinical Trials in Australia, set out recommendations covering four major areas:

- ethics review and governance
- cost recovery of efficient clinical trials
- linkage with e-health system
- consumer recruitment and coordination.

1. **Ethics review and governance** – Ethics reviews and governance approvals are highly complex and present a significant bottleneck for clinical trials. Statutory and legislative requirements vary considerably between state and territory jurisdictions, and the nature of multi-centre ethical reviews results in significant duplication of activity. In response to the CTAG report, NHMRC established the Harmonisation of Multi-Centre Ethical Review (HoMER) initiative. The first phase of HoMER was the development of a range of tools to support a national approach, including a national certification scheme, standardised participant information and consent forms, human research ethics committee (HREC) template letters and information on the roles and responsibilities of key stakeholders within single ethical review. The second phase involves the implementation and maintenance of the national approach to single ethical review.

Research-active clinical facilities are also concerned about insurance and indemnity in the case of misadventure following ethical review elsewhere, which has led to resistance and slow progress towards adopting a national system of ethics review. Research governance includes matters relating to delineation of project management responsibilities, delegations, research agreements, contracts, legal issues, indemnity insurance, risk management, adverse events, monitoring, reporting and acquittals.

2. **Cost recovery of efficient clinical trials** – Current clinical trial pricing and service charges vary significantly across healthcare providers. CTAG recommended that a table of standard costs associated with conducting clinical trials be developed for all trial sponsors in alignment with Australian Government health reform initiatives as they are introduced. A formal Legislative Instrument directing IHPA to cost the standard items and report to SCoH ministers by July 2013 has been signed by the Minister for Health.

3. **Linkage with e-health system** – Researchers undertaking clinical trials would derive significant benefit from linked datasets based on patient data. Healthcare practitioners do not, however, routinely request patient permissions during clinical trial processes for the inclusion of personal information in a de-identified form to be accessed later for research purposes. This means that a very large amount of potentially useful data is lost to research. The CTAG report identifies access to e-health systems through the National E-Health Transition Authority (NEHTA) as one of its recommendations. This is covered in Section 4.5.3.

4. **Consumer recruitment and coordination** – Clinical trial registries can be used to increase patient self-referral. The need for a consumer portal was identified by CTAG. This was built by NHMRC and launched on 11 October 2012. The website provides consumer information and links to resources, such as networks and clinical trial registries, to foster awareness, provide access to trials and improve patient recruitment rates. In addition to the consumer portal, the need for coordination across clinical trial networks and ongoing evaluation was also identified as a means of enhancing the conduct of clinical trials and levels of participation.

The Panel supports the CTAG recommendations and has proposed a number of additional initiatives that will lead to significant improvements in clinical trial activity in Australia, outlined below.

"**Effective and timely implementation of the CTAG Report recommendations will position Australia to remain a preferred destination for international clinical trials activity, delivering health and economic benefits. It will also provide an improved base for local, investigator-initiated trials and for clinical research more broadly, which are essential to support better clinical translation of Australian health and medical research.**

*Victorian Government*

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58 AustralianClinicalTrials.gov.au.
Issue: Clinical trial processes are inefficient, inconsistent and manual. While clinical trial application processes are often largely manual and paper-based, the CTAG report did not cover the need for a streamlined system to drive efficiency. The current National Ethics Application Form (NEAF) is not user-friendly, being difficult to understand and onerously long. While NHMRC has developed a Human Research Ethics Portal (http://hrep.nhmrc.gov.au/) to enable online submission of NEAF, the portal lacks integration with ethics review committee systems to provide end-to-end automation and online process workflow. It is, unsurprisingly, underutilised. As stated by the Kolling Institute of Medical Research: ‘NEAF is perceived as an obstacle by researchers and ethics committees and should be abandoned’. Attempting to optimise the current system risks ‘perfecting the steam engine’ instead of moving to a modern platform for process management.

Option: Develop an online-based workflow system to standardise and manage processes. The Panel recommends moving from the current manual process to a re-engineered, standardised set of processes supported by an online workflow system. A national end-to-end system which manages the processes from initial application through to review and approval will deliver significant efficiency gains and provide increased ease of access. There are many commercial organisations that have successfully implemented such systems for complex processes such as insurance claims management.

Issue: Consumer recruitment portal lacks functionality and has low uptake. While NHMRC implemented a consumer web portal that includes information on all current clinical trials in Australia, the Panel’s discussions with stakeholders suggest there is opportunity for further enhancement to increase user-friendly functionality. Furthermore, awareness of the portal among consumers remains relatively low. More assistance in recruitment could be provided by healthcare providers by identifying and offering eligible patients the opportunity to participate in clinical trials.

Option: Accelerate development of consumer recruitment portal and promote awareness. The Panel emphasises the need to facilitate consumer recruitment and recommends that NHMRC continues to develop the AustralianClinicalTrials.gov.au website. NHMRC should enlist the support of healthcare consumers who would be able to assist in dissemination of information, education of potential research participants, and provide advice (for example, about content and language used in participant information statements and consent forms), all of which have a direct influence on increasing rates of consumer recruitment and participation. Healthcare providers should be encouraged to identify and offer clinical trial participation to all eligible patients, and routinely seek patient or guardian consent for inclusion of patients in the clinical trial recruitment registry.

Issue: Ethics approval processes are inconsistent and take too long. The CTAG report did not address the need for centralisation and consolidation of ethics review. However, it did note a number of factors hindering national adoption of HoMER including a range of structural issues.

- There are a variety of IT systems in use in different jurisdictions and institutions.
- Differences between the various state and territory legal requirements exist for ethical approval.
- There is a need for a central advisory and dispute resolution system.
- Some forms and templates have been introduced, but have not been implemented Australia-wide.
- Ethics committee rulings are still not recognised from parallel committees assessing the same trial (e.g. public hospital, private hospital and university) or across jurisdictional boundaries (e.g. the eastern seaboard, Victoria, South Australia and Western Australia all have different systems and MOU).
Although the NHMRC, through HoMER, has established guidance on this subject, and some jurisdictions, including NSW, have established research governance frameworks for public health organisations, some institutions continue to struggle to adequately support and monitor the responsible conduct of quality research.

NSW Ministry of Health

There are currently over 250 HRECs in Australia, in public and private organisations, hospitals, MRIs and universities. This compares to England with 87 ethics review committees and France with 48 ethics review committees. The UK recently established the National Research Ethics Service as a central coordination body for clinical trial ethics approvals to reduce duplication of ethics review approvals.

Generally, Australia’s ethics committees are inadequately resourced and have to contend with tight institutional budgets, time constraints on members and burgeoning clinical trial activities brought about by an increasing number of multi-site trials. Almost all HREC members are voluntary (i.e. they are unpaid) and while the composition of a HREC committee is mandatory, it is often difficult to attract and retain appropriate personnel. HREC costs also vary considerably and typically range from $3000 to $5000 per application. While ethics approval times have improved on the whole, feedback from stakeholder meetings reinforced the research community’s discontent with the current system and desire for a better solution.

In noting that the ethics approval process is lengthy (with some taking over 10 months), CTAG set an industry benchmark approval time of 60 days which has been adopted in some jurisdictions. This is still slow compared to specialist providers such as Bellberry Ltd in Australia and the Western Institutional Review Board (WIRB) in the US. Bellberry takes an average of 20 days to process 300 reviews per year. WIRB delivers an average turnaround time of eight days for ethics approval and demonstrates the benefits of specialisation and scale apply to clinical trials (Case Study 2.9).

Option: Move to 8–10 national, professionalised ethics review panels. The Panel believes that Australia should move to a system of some five to 10 national ethics committees. Each major state would have at least one committee (i.e. Queensland, Victoria, NSW, South Australia and Western Australia) with Tasmania and the two territories either having their own, or accessing one in a nearby state.

Each panel would work in a very different way to the current committees. Currently, a committee is a group of part-time volunteers assembling around a table to debate issues while reading paper files. In the proposed system, national panels would have access to a range of full-time or part-time professional ethics reviewers, possibly specialised in certain application types. Expertise from specialist providers such as Bellberry could also be leveraged and potentially used as an outsourcing partner to manage workload. Most work could be performed in parallel, and possibly remotely using a workflow system to debate, critique and approve each proposal. In the private sector, such process specialisation is routine in back-office process such as mortgage processing. Similarly, by aggregating the work, greater specialisation would allow further efficiencies, perhaps by sorting applications into different risk categories, with a more thorough review for higher-risk applications. A fully streamlined system may require legislative change, but it is likely significant improvement could be made under current legislation.

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61 PRIVIREAL website France – RECs and Medical Research; URL http://www.privireal.org/content/rec/france.php.
CASE STUDY 2.9

The Western Institutional Review Board uses specialisation, scale and technology to deliver highly efficient ethics reviews

**Background.** The Western Institutional Review Board (WIRB) is a member of the WIRB-Copernicus Group (WCG) family of companies. WCG is the world's largest provider of regulatory and ethical review services for human research, and includes some of the world's largest and most well-recognised sponsors and contract research organisations, as well as the foremost research institutions in the US, among its clients.

WIRB's sister company, Copernicus Group Independent Review Board (CGIRB), is recognised for the efficiency of its review process, as well as the ease and innovation of its technology. As an important point of distinction, CGIRB is the only institutional review board to receive the International Standards Organization certification (ISO 9001:2008), in recognition of the high-quality processes employed in its operations.

Together, WIRB and CGIRB perform over 2,500 independent reviews of new clinical trials annually, and deliver rapid turnaround times for ethics approvals, with an average turnaround time of eight days, which is significantly lower than the US average (estimated to be 35 days) and Australia's industry benchmark approval time of 60 days.

Several factors have underpinned the success of WIRB and CGIRB.

- Back-office processes are fully integrated with electronic management systems.
- Development of processes are based on maximisation of regulatory flexibilities.
- Quality control and quality improvement programs are deployed to mine for and remove bottlenecks in the review process.
- Technology is utilised for real-time status updates and communication with sponsors and investigators.

**Key Lessons:**

1. **Specialisation and scale in ethics review drives efficient turnaround times.** WIRB has over 100 experienced board members operating across seven individual review panels, and 45 years of experience in protocol and study-related review, to ensure the highest standard of quality and service, and ensuring the most efficient and timely review. It also has specialist legal and medical departments to ensure timely input into and consultation on applications as required.

2. **Integrated electronic review management systems are critical to streamline processes.** Based on a fully-integrated, custom-built review management system, WIRB has developed streamlined workflow processes to deliver end-to-end management of review applications from online submission through to follow-up questions and approval.

Note: Image courtesy of Western Institutional Review Board
Source: Western Institutional Review Board: www.wirb.com
2. Embed Research in the Health System

Issue: Indemnity risks have led hospitals to set up and use local ethics committees. One of the reasons why research bodies are reluctant to adopt a national system of ethics review, such as HoMER, is concern over questions relating to insurance and indemnity in the case of misadventure following ethical review elsewhere. The issues of ethics and risk are often mistakenly linked, and it is the risk evaluation that is driving the behaviour of public hospitals as they see a risk in accepting the ethical approval of another site. The question of whether a protocol is ethical needs to be clearly separated from the issue of clinical trial risk and governance, but this is not being done. Each hospital now has its own ethics committee because they have been told they are responsible for risk assessment. This has resulted in a far higher number of ethics committees than is required.

Option: Establish a national insurance scheme. A national system of ethics review would be greatly facilitated by a national (i.e. joint Australian, state and territory government) no-fault clinical trial insurance scheme to cover damages from clinical trials. This could be established either as a national service provided by the Australian Government or by each state and territory with legislation harmonised through COAG consultation. The number of insurance payouts following an adverse clinical trial event in Australia is unknown, but is understood to be minimal. Self-insurance by government would therefore appear to be the most cost effective way of providing this service. The Panel’s preference is for a national scheme which would ultimately be simpler and more economical to administer. A national insurance policy should deliver significant cost savings through its scale. The Clinical Oncological Society of Australia previously administered a cooperative clinical trials group insurance policy for about $100,000 p.a. for 20 members and saved in total around $300,000 p.a.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a.1 Develop an online workflow system to standardise and manage clinical trial processes.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>5a.2 Accelerate development of the clinical trials consumer recruitment portal and promote awareness more broadly.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>5a.3 Encourage healthcare providers to identify and offer clinical trial participation to all eligible patients, and routinely seek patient or guardian consent for inclusion of patients in the clinical trial consumer recruitment registry.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>5b.1 Rationalise ethics committees down to 8–10 national ethics review panels.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>5b.2 Professionalise ethics review and consider leveraging expertise of specialist ethics review providers.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>5c.1 Introduce a national no-fault insurance scheme to cover approved clinical trial activities.</td>
<td>Leadership body, COAG SCoH</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

2.6.3 Drive a National Implementation Approach

There are currently two approaches to streamlining clinical trials operating in parallel.

1. **CTAG Coordination Group** – A CTAG Coordination Group, comprising Australian and state and territory government agencies, as well as industry stakeholders, consumer representatives and researchers, was formed in May 2011 to assist in implementing the recommendations. The group has held 10 meetings, the last of which was held on 26 September 2012.

2. **State-based systems and Eastern Seaboard Memorandum of Understanding (MOU)** – Several states have instituted their own single ethical review systems for multi-site trials in public research institutions (notably NSW, Victoria, Tasmania and Queensland), with some private research agencies adopting their state’s system. The health departments of Queensland, NSW 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 agreement is soon to be extended to South Australia.

62 Single ethics review processes were established by NSW in July 2007 for HMR, by Victoria in November 2009 for clinical trials only, and in Queensland in July 2010 for HMR.
A CTAG working group was convened from December 2011 to May 2012, chaired by Professor Chris Brook of Vic Health, and then referred implementation to a jurisdictional working group to be supported by a NSW Secretariat, with the existing tri-state MOU on mutual acceptance of ethics review to be used as the basis for a National Mutual Acceptance agreement. However, by August 2012 the CTAG working group had not been convened and membership had not been finalised. SCoH subsequently agreed to aim to implement a national approach to single ethical review by 1 January 2013, with a final date for implementation by 30 June 2013.63

**Issue:** While the CTAG and state-based approaches have resulted in some progress, there is scope for significant improvement. The need for radical change in the ways that ethics approvals and governance processes for clinical trials are managed is manifestly evident, well documented and widely supported. Progress with both implementation of HoMER and the CTAG recommendations has been slow for a number of reasons including the need for inter-jurisdictional agreements, limited resources64 and, in the Panel’s view, because the implementation committee does not have the level of authority and responsibility required to drive full implementation. This view is reinforced by Medicines Australia which points out that ‘the responsibility of regulating and overseeing clinical trials in Australia is given to a wide variety of state and federal government agencies. Because of this diffusion of responsibility, no single agency is ultimately responsible for making sure that Australia remains a competitive location for clinical trials investment’.65

Overall, it is clear that there has been insufficient focus on implementing CTAG recommendations expeditiously, leaving the sector uncertain as to the extent to which its needs will be met. The state-based system also carries with it a suite of difficulties, such as the fact that it only covers the public hospital system, does not cover governance, is still largely paper-based, and relies on voluntary review committees. This approach does not represent a fundamental reform process as envisaged by CTAG.

**Option:** Drive a national approach to implementation through the national HMR leadership body. A new approach is required to implement the CTAG recommendations and additional reforms proposed here. The Panel recommends that the leadership body be given responsibility for ensuring implementation and management of the CTAG recommendations and additional tasks identified in Section 2.6.2. The Panel believes that the establishment of a specific clinical trials office within the leadership body, reporting directly to the CEO would be the best way to ensure that clinical trials are elevated to a sufficient level of importance to ensure that the CTAG recommendations are implemented expeditiously.

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63 CTAG Coordination Group Meeting 9, 1 August 2012; URL: http://www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Pages/CTAGCoordinationGroupMeeting9.aspx
65 Stakeholder feedback on SRHMRA Consultation Paper, Medicines Australia.
… a national clinical trials office will provide structure and clear national leadership aimed at continually improving Australia’s global competitiveness in clinical trials across a complex regulatory and health environment. It would also play a key role in promoting Australia internationally as a destination for investment in clinical trials. Currently, the responsibility of regulating and overseeing clinical trials is given to a wide variety of state and federal government agencies. Because of this diffusion of responsibility, no single agency is ultimately responsible for making sure that Australia remains a competitive location for clinical trials investment.

Medicines Australia

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
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<tbody>
<tr>
<td>5d.1 Retask responsibility for implementing clinical trial reforms to the leadership body, with a mandate to drive a national approach and implement all recommendations in Section 2.6.2 as an urgent national priority. Set up an ‘Office of Clinical Trials’ that reports directly to the leadership body CEO.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
3. Support Priority-Driven Research
3. SUPPORT PRIORITY-DRIVEN RESEARCH

3.1 Introduction

An overarching theme of the 10-year strategy is greater integration between the research sector and the health system itself. This ensures that the most useful research is being performed and that the outcomes of that research is translated into healthcare practice and policy to deliver better health and reduce costs. This requires a level of strategic planning in order to maximise the outcome of the investment made. The process of priority-setting, at both the initial stage of identification of priority areas, as well as the decision-making around what research is most appropriate to advance any given priority area, also represents an as yet unfulfilled opportunity to engage with, and leverage funding from the private sector (including both the general public and the business sector).

Exhibit 3.1

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

Once priorities are set, priority-driven research can then take the form of top-down initiated research, typically commissioned research via requests for proposals or requests for applications (RFAs), or bottom-up investigator-initiated research where scientists more directly determine the area of research and outcomes, often within the confines of a specific application in mind. Top-down priority-driven research provides greater strategic and focused capability to directly address the most significant issues with the greatest potential for impact and hence, if pursued effectively, will deliver significant returns to the health system.

“Although there are national research priorities and national health priorities, how these priorities inform government research funding could be made more explicit.”

NSW Ministry of Health
A priority-driven research agenda for tobacco control is being developed by ANPHA to inform tobacco-control policy

**Background.** The Australian National Preventive Health Agency (ANPHA) has been developing a priority-driven research agenda for tobacco control to inform future tobacco-related health policy with evidence. The World Health Organization’s Framework Convention on Tobacco Control has been used to identify and organise research questions suitable for informing new health policies and evaluating existing ones. Population groups that have high prevalence of smoking (e.g. low socioeconomic, Indigenous Australians) have been targeted in the strategic research process.

**Common Adverse Effects of Smoking**

- Larynx cancer
- Oral cavity cancer
- Esophagus cancer
- Lung cancer
- Chronic bronchitis
- Emphysema
- Myocardial infarction
- Systemic atherosclerosis
- Peptic ulcer
- Bladder cancer
- Pancreas cancer

The priority-driven research agenda has been developed ‘top-down’ and in close consultation with a ‘delphi’ expert panel. The approach has consisted of a three-stage consensus process:

1. Key Australian and international tobacco control researchers and experts short-listed potential strategic research priorities.
2. Research questions were ranked by the expert panel in terms of their relevance and importance to the development of tobacco control policies.
3. Consultation with tobacco control representatives from the Australian, state and territory governments and not-for-profit organisations to review and further refine the questions.

While significant progress has been made in reducing smoking rates over the last half-century through initiatives such as increased taxation, public awareness programs and the banning of tobacco sponsorship of sporting events, smoking is estimated to incur social costs of over $30bn p.a. and over 15,000 smoking-related deaths in Australia. The research agenda is expected to focus tobacco control research efforts and inform future health policy.

**Key Lessons:**

1. **‘Top-down’ research questions using ‘delphi’ expert panels ensures research efforts are focused on high impact areas.** Development of the tobacco control research agenda in close consultation with a ‘delphi’ expert panel has efficiently leveraged relevant sources of expertise and devised a set of ‘top-down’ priority research questions that will deliver impact.

2. **Consultation with key stakeholders is critical to ensure research translation into policy and practice.** Consultation with Australian, state and territory governments and not-for-profit organisations on the research ensures focus on the most relevant research questions and has paved the way to ensure implementation of evidence-based tobacco control policy for Australia.

Source: ANPHA: www.anpha.gov.au; Submission 285, ANPHA, pp.2-7; Australian Cancer Council: www.cancer.org.au
Existing Priority Frameworks. In Australia, HMR is largely investigator-initiated. While the Panel supports this approach, with research across the spectrum, it also believes that a portion of investment should be strategically focused on ensuring key national health priorities are addressed. It also allows for investments of a different scale, breadth or focus from those under existing schemes. The setting of strategic HMR priorities, with the allocation of budgets to those priorities, accompanied by a national strategic planning process, will allow the identification of priority-specific grand challenges designed to deliver targeted change. The major challenge will be in identifying such health research priorities.

While Australia has multiple existing priority frameworks that impact on HMR, there is an uncertain relationship between them, and a lack of clarity on how they relate to research decision-making processes. There are at least four existing national priority frameworks, but only one addresses HMR priorities. This indicates that efforts to set national priorities are likely to have had little influence on previous HMR outputs. The four priority frameworks are described below.

A. National Health Priority Areas. Australia has a set of health priority areas that was established by the state and territory government health ministers. Initially, four NHPAs were defined in terms of burden of disease, with five later additions (as indicated):

- cardiovascular health
- cancer control
- injury prevention and control
- mental health
- diabetes mellitus (1997)
- asthma (1999)
- arthritis and musculoskeletal conditions (2002)
- obesity (2008)
- dementia (2012).66

B. National Chronic Disease Strategy. The strategy was established by the National Health Priority Action Council in 2005 as a nationally-agreed agenda in response to the growing impact of chronic disease on the health of Australians and the healthcare system.67 Five National Service Improvement Frameworks outline opportunities for improving prevention in relation to the following national health areas:

- asthma
- cancer
- diabetes
- heart disease
- stroke and vascular disease
- osteoarthritis
- rheumatoid arthritis
- osteoporosis.

C. National Research Priorities. Across the research sector as a whole, Australia established a set of national research priorities in 2002 through a consultative panel chaired by the Chief Scientist. These priorities include ‘promoting and maintaining good health’ with four subsidiary goals: ‘a healthy start to life; ageing well, ageing productively; preventive healthcare; and strengthening Australia’s social and economic fabric’.68 In 2012, DIISRTE reviewed the National Research Priorities and concluded that, while they provided a convenient summary of the scope of Australia’s research endeavour, they were not an effective mechanism for targeting government research investment. The ensuing National Research Investment Plan recommended that the Australian Research Committee prepare a statement of more specific, strategic research priorities that reflected government needs for research and innovation to replace the NRPs. Once developed, the priorities will be updated every three years or as required, and seek to outline specific priorities that will provide a basis for targeted government investment in research. This will include five ‘grand challenges’ including population health and community wellbeing.69 Such research priorities, however, are likely to be very high level and not address specific health and HMR issues.

D. NHMRC Priorities. NHMRC is the only government agency that sets health and medical research priorities at a national level, as opposed to setting exclusively health priorities or broader research priorities. The 10 HMR priority areas within the 2010–2012 NHMRC Strategic Plan were:

- building a self-improving health system
- indigenous health and wellbeing
- ageing and health
- chronic disease
- mental health
- genomic medicine and frontier technologies
- planning for emerging infectious disease threats
- examining alternative therapy claims
- global health
- health consequences of climate change.

The recently released 2013–2015 NHMRC Strategic Plan70 lists nine areas of specific focus:

- the National Health Priority Areas71
- improving the health of Aboriginal peoples and Torres Strait Islanders through the support of health research and its translation
- preparing Australia for the ‘omics’ revolution in health care
- primary health care; helping practitioners and patients to gain value from research evidence, especially in areas of health inequalities
- improving care of patients with multiple and complex chronic disease
- healthy start for a healthy life
- claiming benefits for human health not based on evidence
- new and emerging health threats – infectious diseases, environmental hazards, changes in the human environment
- health and research in our region.72


71 Arthritis and Musculoskeletal Conditions; Asthma; Cancer Control; Cardiovascular Health and Stroke; Dementia Diabetes Mellitus; Injury Prevention and Control; Mental Health (with a focus on depression); and Obesity.

72 NHMRC op cit.
Thus NHMRC endeavours to align funding with both the national health priority areas and its own strategic priority areas (Exhibit 3.2). This approach, however, is largely investigator-initiated rather than adopting a top-down priority-driven research approach. NHMRC previously requested grant applicants to indicate if their research pertained to a specific set of priority areas. Applicants in this year’s Project Grant round (and presumably all other NHMRC schemes) are asked to indicate the degree to which their application is pertinent to National Health Priorities, but no longer asked whether their proposal maps to strategic plan initiatives.

An RFA process, as used by NIH in the US and CIHR in Canada, has recently been initiated by NHMRC to seek applications in identified areas of priority, but the way in which such areas are selected or the process of consultation involved is unclear. NHMRC also occasionally calls for submissions to address urgent health needs, such as the recent funding of $3m in a targeted call for research into the Hendra virus. Overall, the scale of NHMRC’s commitment to using these mechanisms for strategic funding of priority areas remains unclear.

Exhibit 3.2

NHMRC investigator-initiated funding maps to a range of national health and strategic HMR priority areas

NHMRC Investment by Priority Areas

<table>
<thead>
<tr>
<th>National Health Priority Areas</th>
<th>$m Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>175</td>
</tr>
<tr>
<td>CVD</td>
<td>107</td>
</tr>
<tr>
<td>Diabetes</td>
<td>72</td>
</tr>
<tr>
<td>Mental health</td>
<td>60</td>
</tr>
<tr>
<td>Injury</td>
<td>36</td>
</tr>
<tr>
<td>Obesity</td>
<td>35</td>
</tr>
<tr>
<td>Arthritis</td>
<td>30</td>
</tr>
<tr>
<td>Asthma</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>533</td>
</tr>
</tbody>
</table>

NHMRC Strategic HMR Priority Areas

<table>
<thead>
<tr>
<th>Priority Areas</th>
<th>$m Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Disease</td>
<td>107</td>
</tr>
<tr>
<td>Ageing and Health</td>
<td>87</td>
</tr>
<tr>
<td>Global Health</td>
<td>38</td>
</tr>
<tr>
<td>Mental Health</td>
<td>32</td>
</tr>
<tr>
<td>Indigenous Health</td>
<td>30</td>
</tr>
<tr>
<td>Infectious Disease Threats</td>
<td>25</td>
</tr>
<tr>
<td>Self-improving Health System</td>
<td>21</td>
</tr>
<tr>
<td>Genomics &amp; Frontier Technologies</td>
<td>11</td>
</tr>
<tr>
<td>Climate Change Health Impact</td>
<td>4</td>
</tr>
<tr>
<td>Alternative Therapy Claims</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>359</td>
</tr>
</tbody>
</table>

Notes:
1. Excludes Dementia as only added in 2012
2. Top 10 priority areas outlined in the NHMRC 2010–2012 Strategic Plan. Includes some double counting

Source: NHMRC data, 2012
The distribution of investment across the health portfolio (for example, $107m on chronic diseases and $87m on ageing and health) represents a retrospective approach to research in priority areas (Exhibit 3.2), rather than focused research activity driven by targeted top-down research questions. Only one of the identified HMR priorities has received a defined financial commitment from NHMRC, with Indigenous health to receive at least 5% of the research budget. This has been achieved since 2008, though remains largely investigator-initiated and, in some cases, targets are met by funding research below the normal funding cut-off margin determined from ranking all competitive applications. In other countries, HMR priority setting is approached in various ways.

**US Institute Model.** Within the NIH, funding is distributed to 21 institutes that perform intramural research and are responsible for provision of extramural funding in their area of interest as well as the identification of areas of priority. Funding can be via investigator-initiated applications or via RFAs in specific priority-area funding. Most of the funding dispersed by the institutes is awarded via R01 grants, which are the equivalent of investigator-initiated Project Grants within NHMRC. The system is not substantially different from that of NHMRC with respect to focus on investigator-driven research, with the exception of the well-established RFA process. The key difference here is the clear devolution of budget to institutes for dissemination.

**UK Separation of Basic and Applied Research.** The approach taken in the UK has been to create the National Institute for Health Research (NIHR) as a separate entity from the Medical Research Council (MRC), with different types of funding supported by each organisation:

- NIHR focuses more on clinical and public health-related research as well as supporting enabling entities such as centres for research dissemination and clinical trials networks.
- MRC covers health-related basic research and early-stage development, and efficacy evaluation across all health priorities.

**Canadian Institute Model.** While the majority of the CIHR budget is allocated to investigator-driven projects, CIHR has created 13 institutes to represent key areas of health research priority pertinent to Canada. In this model, CIHR disperses a modest annual budget to each institute for identified areas of priority. Each institute director is charged with identifying the current areas of priority in that field and administering whatever scheme they might choose to support within that priority. In each year, they are also required to co-fund an initiative with at least one other institute director. Canada spends about 30% of the CIHR budget (C$1bn) on strategic research—part of this is directly devolved to the institutes and a portion is used to fund programs which involve cross-institutional collaboration. In all cases, funding within areas of priority covers the breadth of research from fundamental biomedical discovery to public health research.

It should be noted both within the NHMRC Strategic Plan priority areas and the institutes within the NIH and the CIHR, that research priority areas are not always a specific disease state but also include areas of technology (e.g. the National Human Genome Research Institute), regional priorities (e.g. global health) or demographic priorities (e.g. Indigenous health). In such instances, there is an opportunity to cover many conditions within a given institute and the focus may be more on capacity-building, training or removing barriers to equity than on curing a specific condition. This is where the dichotomy between national health priorities and national research priorities must be acknowledged and accepted.

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73 Institutes include the National Cancer Institute; National Institute of Allergy and Infectious Diseases; National Institute of Dental and Craniofacial Research; National Institute of Diabetes and Digestive and Kidney Diseases; National Heart, Lung, and Blood Institute; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; National Library of Medicine; National Institute of Child Health and Human Development; National Institute of General Medical Sciences; National Eye Institute; National Institute of Environmental Health Sciences; National Institute on Alcohol Abuse and Alcoholism; National Institute on Drug Abuse; National Institute on Aging; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Nursing Research; National Institute on Deafness and Other Communication Disorders; National Human Genome Research Institute; National Institute of Biomedical Imaging and Bioengineering; National Institute on Minority Health and Health Disparities.

74 Note: this is similar to what DoHA used to fund directly through the Research and Developments Grants Advisory Committee (RADGAC).

75 Aboriginal Peoples’ Health; Aging; Cancer Research; Circulatory and Respiratory Health; Gender and Health; Genetics; Health Services and Policy Research; Human Development, Child and Youth Health; Infection and Immunity; Musculoskeletal Health and Arthritis; Neurosciences, Mental Health and Addiction; Nutrition, Metabolism and Diabetes; and Population and Public Health.
Australia could consider elements of each of these systems to establish:

- priority areas like CIHR and formally assign a specific expenditure to a restricted number of priority areas;
- separate funding pools for biomedical/clinical versus health services/public health research like the MRC and NIHR; and
- institutes with a specific focus, such as Indigenous health like the CIHR Aboriginal Peoples’ Health Institute.

The separation of biomedical/clinical from public health/health services would undo efforts of more than a decade to build public health/health service research alongside other types of HMR. The creation of a new organisation to handle only one part of HMR would appear not to be cost effective and such a separation may reduce the chance of building integrated teams that extend from discovery to impact. Taking the NIH approach of creating silos and providing each a budget would represent a significant increase in administrative costs which is not feasible or desirable in a country the size of Australia. The CIHR option is the simplest to implement, with the major challenge lying in how the priority areas are set and how frequently these should be revised.

> Research investment should be guided by a clear understanding of the important questions for clinicians, policy makers, program designers and consumers.

*Cochrane Collaboration in Australia*

### 3.2 Align Priority-Setting Process

**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.

**Issue:** Australian HMR is not sufficiently driven by a nationally coordinated set of priorities and there is currently no nationally agreed mechanism for facilitating this. Given HMR aims to improve health outcomes and there are research funding and capacity constraints, a strategic approach to allocation of research funding is needed. In particular, there is a need for increased linkages between aspirational national health priorities and HMR priorities.

With the investigator-initiated approach being the dominant paradigm for funding decisions and research innovation in Australia, there is considerable risk that issues of critical importance may remain unresearched and that research efforts may be expended on areas with low potential for health benefit. A genuinely strategic approach would see priorities drive the design of research questions. Such an approach has been effectively used by various non-government organisations (NGOs) to good effect, such as the Juvenile Diabetes Research Foundation (Case Study 3.2).
3. Support Priority-Driven Research

“... Australia's investments in health and medical research are not always aligned to health priorities. This is attributable to a lack of specificity at the national level in current health priorities, a lack of distinct mechanisms to direct funding toward specific health priorities and a lack of a coordinated national focus on known health problems or desired outcomes. Victoria believes that new mechanisms, involving collaboration between the Commonwealth and State/Territory Governments, are needed to ensure that investment decisions are aligned with carefully selected health priorities. Further, Victoria believes that stronger use of research funding to solve known medical problems or reach desired health outcomes should be pursued, as well as a renewed emphasis on health service and health system research.

Victorian Government

While priorities for HMR should reflect the broader priorities of the health system and ensure that the overall mix broadly aligns, research priorities also need to take into account the global research environment, as well as the ‘ability to make a difference’ from research.

Fixing a set of priority areas for too long removes the capacity to be flexible and responsive to new challenges, while resetting priorities too frequently does not allow for the long lead time from discovery to impact. Choosing priority areas will require reflection, on the Australian burden of disease and disability,\(^76\) and the capacity for research to deliver better health outcomes.

There is also an increasing demand for engagement from the wider healthcare community (e.g. NGOs, consumer advocacy, community groups, industry and health experts), to which the research community must respond. Priority setting in HMR should involve broad engagement. This should not only involve identifying and ranking priorities but also proposing the most effective research strategies, whether they are capacity-building in the workforce, specific types of research technologies, or funding for a particular aspect of a disease area. Broad engagement would ensure a transparent process that also has the potential to leverage funds from interested groups for a particular priority area. This will help ensure that agreements made by government will actually make a difference to the research agenda by aligning funding flows and other incentives.

Option: NHMRC and COAG SCoH to establish overarching national HMR priorities on a triennial basis. In order to achieve truly national HMR priorities, the Panel recommends that NHMRC and governments work together to establish a set of principles through which national HMR priority areas can be assessed and ranked, based on a robust set of criteria that takes into account, inter alia, areas of greatest unmet need (e.g. burden of disease to the Australian health system, potential to deliver the greatest impact based on a cost/benefit analysis, emphasis on preventive health), contributions to a sustainable healthcare system, potential for translation, and healthcare expenditure. These national research priorities in health should ideally be determined in conjunction with priority-setting for health service delivery and health policy on a triennial basis.

Initially, analysis of research priority areas should be carried out by the NHMRC Research Committee in consultation with other government committees, experts within the HMR sector, consumer groups and the broader community. National HMR priorities should be aligned to burden of disease with consideration of both social impact, as measured through Disability Adjusted Life Years (opposite of QALYs), and economic impact, as measured through healthcare costs.

\(^{76}\) Often burden of disease is presented as quality-adjusted life year or years of life lost due to disability.
The priority areas should inform both short-term and strategic investment decisions. A key component in the process will be the establishment of a management strategy and benchmarks to evaluate success in strategic priority areas with regular reporting to NHMRC and COAG SCoH. The expert advisory arrangements should be part of existing governance structures. The Panel believes that NHMRC, with its strengthened leadership role, should lead this process, working closely with the health ministers and state and territory government agencies.

"The national research priorities and goals are necessarily broad. However, more specific priorities for health and medical research need to be determined. These should be identified by the application of transparent priority setting process that involves all stakeholders and uses robust criteria. As well as considering specific diseases, this should also include a consideration of population groups (e.g. Aboriginal health), types of research (e.g. fundamental research, intervention research, health systems research) and ensure there is flexibility to conduct research on emerging and urgent health issues."

**NSW Ministry of Health**

**Issue:** Despite a plethora of Australian Government priority frameworks and strategies, there is a lack of strategic priority-driven research. While NHMRC expenditure largely fell into its 17 priority areas in 2011, this funding was primarily for investigator-initiated research. Similarly, while NHMRC has identified Indigenous health as a ‘targeted area’ and allocates at least 5% of its research budget to this area, the research remains largely investigator-initiated.

**Option:** Allocate a defined portion of the NHMRC MREA to fund strategic priority-driven research. Once national HMR priority areas are set, the Panel recommends 10%–15% of the MREA budget be allocated to top-down strategic research within these areas, with the appropriate allocation of this funding to be defined by a multidisciplinary expert committee for each priority area. The Panel notes that this is less than overseas jurisdictions such as Canada, which allocates roughly 30% of the total CIHR budget (Case Study 2.3), and suggests that the 10–15% be increased over time once the capacity to perform top-down strategic research and deliver outcomes has been demonstrated.

It is envisaged that each expert committee would engage with the broader sector not only to seek advice in identifying the most effective use of this budget, but also to create an opportunity for leverage of additional funding on a case-by-case basis. While priority areas would ideally be set on a triennial basis, with the NHMRC Strategic Plan aligned accordingly, some flexibility in the system would be necessary to enable a shift of emphasis towards an emerging trend, or to increase the proportion of MREA set aside for national HMR priority areas. The annual budget for each priority area might be allocated to any of the various competitive NHMRC funding programs, including research or people support, as appropriately determined by the panel of experts. The panel may also identify a new approach to funding key research activities either alone or in collaboration with other priority areas and partners. This will allow the natural generation of ‘grand challenges’. NHMRC should still maintain the capacity to be able to respond to emergencies either from within priority areas or from the MREA more broadly.

**Issue:** Strategic priority areas do not have focused leadership and strategies to deploy and leverage funding. Priority areas do not have dedicated leadership and focused teams to drive deployment of funding as needed for the area and develop strategies to increase funding from other sources, particularly through partnerships and collaboration.
3. Support Priority-Driven Research

Option: Leadership body to create a panel of experts and strategy around priority areas.

Each strategic priority area should have its own panel of experts to make specific funding decisions on research and translation activities in that area. The multidisciplinary expert committee for each priority area should determine and leverage both top-down funding within each priority area, and select high-quality bottom-up investigator-initiated proposals that will deliver impact. The panel of experts should identify appropriate charitable groups, government, LHNs, industry partners and consumer and community groups to both refine advisable activities in each priority area and to investigate leveraging funding for that area. Leadership responsibilities and governance for the expert panels are recommended to ensure accountability of funding received and impact is delivered through the setting and monitoring of appropriate KPIs.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>6a.1 Establish a set of principles through which national HMR priority areas can be assessed and selected.</td>
<td>Leadership body, COAG SCoH</td>
<td>2014–15</td>
</tr>
<tr>
<td>6a.2 Set appropriate national research priorities in health, health service delivery and health policy on a triennial basis in consultation with other committees, relevant HMR experts, consumer groups and the broader community.</td>
<td>Leadership body, COAG SCoH</td>
<td>2014–15, 2017–18, 2020–21, 2023–24</td>
</tr>
<tr>
<td>6a.3 Establish a robust management strategy and benchmarks to evaluate success in strategic priority areas, with regular reporting to COAG SCoH against key performance indicators.</td>
<td>Leadership body, COAG SCoH</td>
<td>2014–15</td>
</tr>
<tr>
<td>6b.1 Assign a defined portion of the NHMRC Medical Research Endowment Account to fund 'top-down' strategic research across the national HMR priorities. The Panel recommends 10%–15% as a starting point, with an aspiration to significantly grow this over time.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>6c.1 Create a panel of experts for each priority area to establish and implement the top-down research agenda, fund high-quality investigator-initiated proposals that will deliver impact, make funding recommendations such as the mix of NHMRC competitive schemes and research areas, leverage funding from external sources and set key performance indicators and evaluate outcomes.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>6c.2 Establish a research strategy, translation plan and set benchmarks to evaluate success in strategic priority areas, with regular reporting against performance indicators.</td>
<td>Leadership body (expert panels)</td>
<td>2014–15</td>
</tr>
<tr>
<td>6c.3 Identify relevant stakeholders to engage, collaborate with and leverage funding from (e.g. charitable groups, government, Local Hospital Networks, commercial partners, consumer groups).</td>
<td>Leadership body (expert panels)</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
CASE STUDY 3.2

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 or 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.

Source: JDRF: www.jdrf.org.au; Juvenile Diabetes Research Foundation, Australian Type 1 Diabetes Research Agenda, 2010
3.3 Support a Range of Strategic Topics

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 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.

3.3.1 Introduction

In the previous section, the Panel recommended the identification of national HMR priorities on a triennial basis, by the leadership body and COAG SCoH, together with broader sector and community engagement to develop the most strategic research approach possible to drive improvements in health and economic outcomes. The approaches taken in any given national HMR priority may span research types (biomedical, clinical, public health, health service) as well as research mechanisms (project, program, partnership, capacity-building) to elicit change effectively.

Representations to the Panel through its initial submission process and in response to its Consultation Paper have identified a broad range of specific topics for research attention. Those most frequently cited included: the social determinants of health; primary care research; medicines clinical research; the potential health effects of climate change; nursing and midwifery; and preventive medicine. The Panel suggests that these topics, and others, would be candidates for consideration by the mechanisms described in Section 3.2. Non-commercial translation should also be considered in the priority-setting process, particularly for public health and health services research. These areas are described in more detail in Sections 5.2 and 5.3.

While the Panel was not tasked with identifying national HMR priority areas, in the course of its Review, it became obvious that there were a number of cross-cutting ‘at risk’ populations, global opportunities and enabling technologies that the Panel recognised as potentially representing national HMR priorities. These areas are: Indigenous health; rural and remote health; HMR in developing countries (global health); and advances in genomics. Indeed, three of the four identified here are already identified in some way within the NHMRC 2013–15 Strategic Plan as research priority areas. The Panel regards these as being areas of particular need and, in the following section, the unique opportunities, challenges or requirements of these particular priority areas are highlighted.

3.3.2 Support Indigenous Health Research

Increased focus on Indigenous health research over the last decade. Indigenous health has increasingly been recognised as an area for priority funding and action in HMR over the last decade. As noted above, NHMRC adopted Indigenous health research as a strategic priority in 2002 and since 2008 has allocated at least 5% of the MREA budget to this key priority area. Training scholarships for Indigenous health research were introduced by NHMRC in 1997 and in 2008–09 NHMRC established specific requirements and processes for all grant applications that 77 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.
involve Indigenous health research. In this process, all applications identified by applicants as having an Indigenous health research component are referred to the Indigenous Health Research Panel. In 2010, NHMRC introduced the Indigenous Grant Review Panels (GRPs). An Aboriginal and Torres Strait Islander Health Forum, which comprised the Indigenous members of Council and the Principal Committees, was formed in 2003 and in 2007 it was merged with the Aboriginal and Torres Strait Islander Health Research Working Committee to form a single Aboriginal and Torres Strait Islander Health and Research Advisory Committee.

In May 2010, NHMRC released *Road Map II – Strategic framework for improving Indigenous health*. This report had been prepared by the NHMRC’s Aboriginal and Torres Strait Islander Health and Research Advisory Committee with support from the NHMRC Co-ordination and Research Unit. With seven priority action areas for research, *Road Map II* is intended to be used by the NHMRC Research Committee to identify Indigenous health research topics requiring priority funding. While a number of submissions to this Review identified challenges in the implementation of recommendations from *Road Map II*, it is intended that *Road Map II* be used to guide researchers to develop research proposals around future NHMRC Targeted Calls for Research in Indigenous health, or in any biomedical, clinical, public or health services research field which includes Indigenous population-level health research.

The Australian Government has also supported the Cooperative Research Centre (CRC) for Aboriginal Health (2003–2009) and now the CRC for Aboriginal and Torres Strait Islander Health (2010–14; currently hosted by the Lowitja Institute). These CRCs have allowed the initiation of long-term projects that have facilitated engagement from the point of priority setting through evaluation and implementation. The current CRC is a virtual organisation that acts as a research broker with a focus ‘to ensure that research conducted into Aboriginal health is controlled by and benefits Aboriginal people’.78

More broadly, over the last five years the Australian Government has strongly supported Closing the Gap activities, specifically targeted at improving the health outcomes of Indigenous people, particularly through COAG and actions such as establishment of the National Indigenous Health Equality Council. AIHW operates the *Closing the Gap* clearinghouse which provides access to a collection of information on what works to overcome the challenges in improving Indigenous health outcomes. The clearinghouse identifies a number of problems in this area including:79

- ‘one size fits all’ approaches
- lack of collaboration and poor access to services
- external authorities imposing change and reporting requirements
- interventions without local Indigenous community control and culturally appropriate adaptation
- short-term, one-off funding, piecemeal interventions, provision of services in isolation and failure to develop Indigenous capacity to provide services.

**Issue: There are still many barriers to Indigenous HMR.** Notwithstanding NHMRC’s efforts over the last decade, the majority of the 5% MREA expenditure relating to Indigenous health research (54%) is on short-term research funding (Project Grants), with about half of the grants awarded not involving any Indigenous people in the research team. Most of the funding for Indigenous health research is focused on public health (82%), leaving a disproportionate lack of focus on biomedical and clinical research for this population. The short-term nature of project grants has resulted in transience, opportunism and lack of continuity.

Throughout the world, the health of Indigenous peoples in First World countries is significantly worse than that of the mainstream populations of those countries. However, while comparable countries such as New Zealand, the United States and Canada have seen an appreciable narrowing of the gap between Indigenous and mainstream populations over recent decades (measured by life expectancy figures), progress in Australia has been less significant.

The Lowitja Institute

While Indigenous health is a highly complex area, the little real progress over the last few decades is not entirely attributable to the lack of funding support. The Indigenous population is not confined to rural and remote areas but includes urban communities. Although there are common health issues for all Indigenous peoples, some are more distinct to either urban or rural communities, with the two areas requiring related, though separate, research efforts. Research into the life expectancy gap between Indigenous and non-Indigenous Australians has identified the need for improved evidence-based healthcare and prevention strategies (see for example, Case Study 3.3).

These issues point to an urgent need for the national identification of Indigenous health as a strategic research priority, in a similar fashion to the Aboriginal Peoples’ Health Institute within CIHR, with action in three main areas:

- establish a national integrated network or virtual IHRC for performing Indigenous health research
- refocus of NHMRC People Support Schemes on researcher training and capacity-building among Indigenous peoples themselves
- increase in NHMRC funding of long-term Program Grants for Indigenous research to build excellence (rather than an exclusive focus on more Project Grants).

**Option: Establish a national integrated network or virtual IHRC for performing Indigenous research.** The Panel believes that the creation of a national network of research excellence in Indigenous health is pivotal to improved Indigenous health research capability in Australia. While there are several options for the network structure, the Panel suggests that the best model would be a central node with disseminated centres of excellence similar to the national network in Canada through the Aboriginal Capacity and Developmental Research Environments program (an outcome of the Institute of Aboriginal People’s Health of CIHR).80 A similar model is seen in primary healthcare in this country with national funding of the Australian Primary Health Care Research Institute.81 In this model, strategic planning performed centrally results in distribution of research funds from the central node to the hubs based upon merit, strategic intent and significance.

Such a network should be encouraged to incorporate existing centres of research excellence as well as grow new nodes of activity in all areas of Indigenous health and should be provided with funding of sufficient duration (five years in the first instance) to build strategic research directions. Research within the network could span the spectrum of research types as they apply specifically to issues of particular importance to the Indigenous community. It should engage with all participants in Indigenous health research, including the community, researchers, the health system (including clinical, primary care and allied health) and government at all levels.

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80 IAPH; http://www.cihr-irsc.gc.ca/e/8668.html.
CASE STUDY 3.3

Research into the Indigenous life expectancy gap has identified a need for improved healthcare delivery and increased prevention

**Background.** The Kanyini Vascular Collaboration was established in 2005 to improve Indigenous health and address the burden of chronic diseases. There is an 18-year life expectancy difference between Indigenous and non-Indigenous Australians, with research identifying that chronic diseases, such as cardiovascular disease, kidney disease and diabetes are responsible for ~80% of this gap.

After receiving an NHMRC grant in 2006, the Collaboration conducted a series of projects focused on understanding health service barriers, developing, evaluating and implementing appropriate models of care and incorporating policy development through engagement with healthcare providers.

Key findings included identifying that over 70% of the remote Indigenous community experiences a high rate of major adverse cardiac events within four years of discharge from hospital, and that cardiac services exhibit highly variable levels of evidence-based care, particularly in rural and remote settings.

**Key Lessons:**

1. **Indigenous health research provides insights into the cause of the life expectancy gap between Indigenous and non-Indigenous Australians.** Chronic diseases are a major driver of Indigenous mortality, accounting for ~80% of the life expectancy gap and constituting at least a third of the Indigenous disease burden. The majority of this disease burden has been attributed to factors which can be prevented including tobacco, high body mass index, high cholesterol levels, physical inactivity, high blood pressure and low fruit and vegetable intake.

2. **Research on the delivery of healthcare to Indigenous communities can identify opportunities for improvement.** Comparisons of evidence-based therapies in Indigenous and non-Indigenous communities have identified parallels in the health outcomes for Indigenous and non-Indigenous communities, suggesting deficiencies across the whole system.

3. **Research can develop preventive health strategies to increase life expectancy and quality of life.** Vascular disease prevention strategies based on an individual's cardiovascular risk provides significant benefits. Improved identification and management of high-risk individuals could provide a major opportunity to reduce the burden of cardiovascular disease in Indigenous communities.

Note: Image courtesy of Kanyini Vascular Collaboration
Involving the users of research – Aboriginal and Torres Strait Islander organisations and individuals, service providers, and policy makers – from the beginning of the research process (including in determining research priorities ...) greatly increases the chance that research findings will be used by the Aboriginal and Torres Strait Islander health sector and beyond.

The Lowitja Institute

The network would not be simply an expanded CRC, but an altogether different entity which comprised a much broader and more representative association of Indigenous HMR organisations, agencies and individuals, with strong consumer and community input. The Indigenous strategic national network should adopt a holistic view of Indigenous health needs, and a broad spread across the spectrum from biomedical and clinical, to public health and health services research.

Issue: Lack of Indigenous health research capacity. There are not enough Indigenous researchers working in HMR. NHMRC expenditure on training and capacity-building is currently only a minor portion of total funding for Indigenous health research, and it should be expanded and refocused to build capacity in this priority area.

Option: Refocus NHMRC People Support Schemes on research training and capacity-building in Indigenous health. The initial need is to build capacity in Indigenous health research through training and expanded People Support Schemes. The balance of allocation of NHMRC funding should initially shift towards capacity-building in Indigenous health research with a specific focus on attracting and supporting Indigenous people to train in and perform research. In addition, in order to evaluate progress in this critical area, detailed information about the number of Indigenous health researchers supported by NHMRC should be reported in terms of not just the number of Project Grants but in terms of the proportion of the Indigenous Project Grants funded that have Indigenous chief investigators, plus data on capacity-building outcomes.

Strengthened people support could be provided through NHMRC scholarships and fellowships specifically for Indigenous applicants or via the promotion of Indigenous MD training schemes.

Often Indigenous health researchers enter a career in HMR later in life, making the PhD stipend quite unattractive; an increase in stipend (see Recommendation 8) will be particularly critical for this sector. At present, there are 153 Indigenous doctors registered in Australia and a further 218 Indigenous medical students across the nation.82

NHMRC assesses Project Grant applications in Indigenous health, as self-identified by the applicant, using an Indigenous Grant Review Panel (IGRP). Applications reviewed by this panel are assessed against two different sets of criteria, one relating to Indigenous significance and the other aligned with standard criteria. Feedback from stakeholder consultations suggested the assignment of Project Grants to this panel and the criteria for assessment may need to be reviewed to deliver capacity-building and specific relevance to Indigenous health.

Biomedical, laboratory-based research, as well as public health and clinical research, is needed to improve Indigenous health issues. A considerable number of researchers undertake biomedical research with projects addressing a research question directly and highly relevant to Indigenous health. However, biomedical research projects often do not fit with the criteria currently set up for Indigenous health funding. In addition, the IGRP may lack the biomedical expertise required to evaluate biomedical research. It is important to ensure that biomedical research into diseases of importance to this population is supported and seen as a component of Indigenous health priority setting.

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Access to Clinical Research Fellowships for Indigenous clinicians and researchers, as advocated in Recommendation 3, will also be critical. As with other emerging sectors, including health services research and bioinformatics, leadership and mentorship will also be crucial to capacity-building in Indigenous health research. While the Indigenous peoples of this country have specific health issues, aspects are shared with other Indigenous populations around the globe. Strengthening ties with international Indigenous health research efforts, particularly in New Zealand, Papua New Guinea, US and Canada, will be critical for leadership within this country. Consequently, this is an important aspect of our international HMR efforts.

**Issue: Project Grants are too transient and not sufficient for Indigenous HMR.** For Indigenous populations in remote areas, the delivery of health and record keeping of healthcare are major problems that are exacerbated by frequent consumer relocation, often across state boundaries and between health districts. The performance of Indigenous HMR, particularly where this involves data collection directly from rural and remote Indigenous participants, has a number of significant barriers and unique requirements for success:

- researchers must visit the site frequently
- researchers must develop a strong positive long-term relationship with the target community
- research must be performed and evaluated in the context of the delivery of better health and improved health services.

For these reasons, Indigenous HMR is not optimally funded via short-term grants. In addition, as most Indigenous HMR is performed by non-Indigenous researchers, it remains something that is predominantly 'done to' the Indigenous community, rather than jointly involving and closely working with the community. This may result in distrust and fatigue from research studies.

> Standard competitive grants processes are non-strategic in that they rely on high-quality research proposals to determine where funds are directed.

*The Lowitja Institute*

**Option: Increase NHMRC funding of long-term programs for Indigenous research to build excellence.** Grant funding by NHMRC needs to progressively shift from short-term project funding to long-term program funding. This could be done through NHMRC support of the proposed Indigenous IHRC based on the applications submitted. In addition, there is a need to reassess the identification and allocation of investigator-driven applications to Indigenous panels within NHMRC to reduce applications not primarily focused on or providing clear significance to Indigenous health issues.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>7a.1 Create a national integrated network or virtual Integrated Health Research Centre (IHRC) for Indigenous HMR that incorporates nodes of excellence in all aspects of Indigenous health across the nation.</td>
<td>Leadership body, prospective IHRC participants</td>
<td>2014–15</td>
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<tr>
<td>7a.2 Prioritise NHMRC funding of Indigenous HMR on capacity-building and longer term program and partnership funding.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<tr>
<td>7a.3 Facilitate international partnerships with Indigenous health researchers across the globe.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<tr>
<td>7a.4 Focus on training and capacity-building to increase number of researchers of Indigenous heritage.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<tr>
<td>7a.5 Review the appropriateness of selection criteria within the Indigenous Grant Review Panel process.</td>
<td>NHMRC</td>
<td>2014–15</td>
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Health services research can play a key role in identifying strategies to improve Indigenous health

**Background.** Indigenous Australians experience high morbidity and mortality due to greater prevalence of chronic illnesses. For example, the prevalence of diabetes among Indigenous adults is two to four times higher than that of non-Indigenous Australians and the incidence rate for final stage renal disease is nine times higher. Health centres located in Indigenous communities that focus on delivering primary healthcare are often overwhelmed by patient care needs due to chronic illness.

The Menzies School of Health Research, the National Research Partnership and the Lowitja Institute undertook a quality improvement study from 2002–2006, called the Audit and Best-practice for Chronic Disease (ABCD) project. It was conducted in Indigenous community health centres in the Northern Territory and aimed at better supporting health professionals to improve primary care systems for chronic illness and preventive care.

The research led to the implementation of the Primary Health Care Access Program, aiming at pooling primary healthcare funding across the Australian and state and territory governments in designated local areas, and at redressing the gap in Commonwealth-funded Medicare expenditure. Financial incentives were also introduced through the Enhanced Primary Care Program (now chronic disease management items under the Medicare Benefits Schedule) and Practice Incentive Programs.

**Participating Health Centres – Observations**

<table>
<thead>
<tr>
<th>System Component</th>
<th>Opportunities for Improvement</th>
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<tbody>
<tr>
<td>Organisational influence</td>
<td>• Lack of training in disease prevention and health promotion</td>
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<td></td>
<td>• Limited access to Medicare funding</td>
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<tr>
<td>Community linkages</td>
<td>• Staff shortage (esp. Aboriginal health workers working in the community)</td>
</tr>
<tr>
<td>Self management</td>
<td>• Limited focus on family and community-based activities</td>
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<tr>
<td>Decision support</td>
<td>• Inadequate access to and support from specialists</td>
</tr>
<tr>
<td>Delivery system design</td>
<td>• Staff shortage (especially doctors and Aboriginal health workers)</td>
</tr>
<tr>
<td></td>
<td>• High staff turnover</td>
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<tr>
<td>Clinical information systems</td>
<td>• Systems complexity</td>
</tr>
<tr>
<td></td>
<td>• Lack of IT maintenance and upgrade support</td>
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</tbody>
</table>

**Key Lessons:**

1. **Health services research in partnership with government policy and programs can deliver better health for Indigenous Australians.** The ABCD project resulted in new funding to improve Indigenous primary healthcare delivery, which would not have otherwise been provided. Financial incentives have also been introduced to encourage comprehensive and quality care.

2. **Auditing and benchmarking health services provides valuable insight to drive improvement in healthcare delivery.** Similar studies to the ABCD project can play a key role in improving the capability to adopt systems thinking within a healthcare delivery context.

3.3.3 Support Rural and Remote Health Research

**Poorer rural and remote health outcomes.** Almost one third of Australia’s population lives in non-metropolitan settings, and rural and remote communities have significantly worse health outcomes than metropolitan residents, with a quite different profile of morbidity and mortality (for example, higher rates of accident, injury and self-harm, greater levels of certain diseases, especially preventable lifestyle diseases, and greater rates of vaccine-preventable disease). People living outside major cities are more likely to be admitted to hospital for conditions that could have potentially been prevented through the provision of non-hospital services and care.

**Issue: Geographic isolation and lack of access to services.** Poorer health outcomes are in part due to geographic isolation and difficulties of access to appropriate medical facilities and services (let alone state-of-the-art medical facilities and diagnostic services), and in part due to the phenomenon of social determinants of health whereby patterns of disease are related to socioeconomic status. For example, remote areas have 58 generalist medical practitioners per 100,000 population (compared to 196 per 100,000 in capital cities. As a result, people living in outer regional and remote areas are four-and-a-half times as likely as those living in major cities to travel over one hour to see a GP. The excessive demand placed on primary healthcare (in the absence of accessible specialists) presents its own problems. The recent increase in workforce mobility, with workers perpetually moving in and out of rural and remote areas (e.g. the fly-in-fly-out mining workforce) has also placed considerable, though different, pressures on rural and remote health services.

As a subset of rural and remote health, Northern Australian health also needs prioritised focus. Northern Australian health combines elements of tropical health and health in the desert, and Australia’s northern population is susceptible to many of the same tropical infectious diseases that are prevalent in nearby tropical countries. Research in these areas has largely lacked coordinated support and efforts to bring about collaborative approaches to research across Australia’s north have been fragmented and largely ineffective (though there are some outstanding individual achievements).

**Option: Improve rural and remote health services delivery.** Poorer health outcomes in rural and remote areas—for both Indigenous and non-Indigenous populations—suggest a need for a different model of healthcare practice and policy. One example is the new technology-based approach to healthcare delivery, developed and implemented by The University of Queensland (Case Study 3.5). Importantly, these methodologies and services need to be applied through an evidence-based system—that is, one based on research.

**Issue: Rural and remote health services lack research capacity.** Rural and remote health services, which often suffer from capacity constraints due to the difficulty of attracting trained health workers, have a very limited role in research which has led to an overall lack of research capacity in this area. In addition, there are insufficient researchers active in these areas, and those who are face major difficulties in the recruitment and retention of skilled staff, which necessitates ongoing investment in the rural and remote HMR workforce. There is a need for greater effort in building relationships between researchers, service providers, clinicians, communities, and policy makers to facilitate the development of evidence-based policies and programs, and for recognition of the concomitantly greater costs of collaboration. As a result, rural and remote populations are under-represented in research studies.

“Research to address rural health needs to be conducted by researchers who are resident in rural [sic] who understand the contextual factors which determine appropriateness, acceptability, effectiveness and sustainability of rural health interventions. Considerable investment has been made in rural research capacity ...”

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83 Submission 119, James Cook University, p.4.
CASE STUDY 3.5

Research and development into telemedicine delivery has provided improved access to health services for rural and remote populations

**Background.** Rural and remote communities often experience inequity of access to specialist services due to their remote locations. In Queensland, about 650,000 out of the 4.2 million population are dispersed in remote locations. While specialists sometimes travel to regional centres for outreach clinics, these visits are usually short in duration yet require lengthy travel that consumes valuable clinician time. Alternatively, patients from rural and remote areas must undertake costly and inconvenient travel. Where distance is an issue, health services providers may assume patient travel costs, supported by the Queensland Government’s Patient Travel Subsidy Scheme which provides approximately $30m p.a. in funding.

Over the last 10 years, The University of Queensland’s Centre for Online Health has been collaborating with the Royal Children’s Hospital (RCH) in Brisbane to develop, test and implement a telepaediatric model. In 2004 the team designed and built its first mobile system in the shape of a child-friendly robot, which was used to conduct daily ward rounds with paediatricians based at the RCH. Once feasibility was proven, through funding from mining company Xstrata, four robot systems were built and delivered to hospitals in Queensland. For some hospitals, the system has mainly been used for consultations with paediatric specialists in Brisbane or for hospitals with a paediatric wards but no full-time paediatrician.

The centre currently delivers telepaediatric services to 82 regional hospitals in Queensland and several health centres in Northern NSW. It covers 37 different subspecialist areas, involves over 240 medical, nursing and allied health staff and has enabled over 7,000 consultations for thousands of children. A range of communication methods is used including email, telephone and videoconferencing. The service has greatly improved access to specialist healthcare services for rural and remote communities and resulted in significant cost savings to Queensland Health.

**Key Lessons:**

1. **Research and development can improve access to health services in rural and remote areas.** After the success of the telepaediatric services supported by a $1m NHMRC research grant, the Centre for Online Health and the Centre for Research in Geriatric Medicine will implement a randomised control trial of telehealth in residential aged-care facilities. If this study demonstrates either improvement in care or reduction in costs, it will have important implications for rural and remote health.

Note: Image courtesy of the Centre for Online Health, The University of Queensland
Option: Increase rural and remote health research capacity by establishing an IHRC. A hub-and-spoke IHRC is required that engages and supports health professionals who already work in rural areas to become involved in research, particularly as they have direct experience and understanding of the contextual factors which determine the appropriateness, acceptability, effectiveness and sustainability of rural health interventions. This research should also focus more on population health and health services research, which are likely to drive the greatest impact on rural and remote health outcomes.

"The close personal and environmental relationship between research problem and researcher improves the effectiveness of the research. The lived rural experiences can contribute to rural research in situ. Industries and institutions that are ‘rural’ are more committed to support the search for applied results."

National Rural Health Alliance

Considerable investment has already been made in rural research capacity through the Australian Government-sponsored University Departments of Rural Health program,85 rural clinical schools and among the regional universities. The Panel believes that it is important to build on this capacity, especially with an increased spread of collaboration and with longer term funding which would assist in the retention of skilled research staff. NHMRC People Support Schemes could be better targeted to support rural and remote health researchers. In line with the Panel’s recommendation to establish IHRCs, it recommends that a virtual rural and remote IHRC should be established as a matter of priority, with linkage of rural and remote doctors into other IHRCs and access to national data platforms around research, trials and patients.

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<tr>
<th>Implementation Tasks</th>
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<th>Timeframe</th>
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<tbody>
<tr>
<td>7b.1 Establish a focused virtual rural and remote Integrated Health Research Centre (IHRC), which has links to other IHRCs and leverages national data platforms for research, reformed clinical trials processes and patient record management.</td>
<td>Leadership body</td>
<td>2014–15</td>
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3.3.4 Support Global Health Research

**Australian HMR delivering global impact.** Australia provides a range of international aid assistance, primarily through the Australian Agency for International Development (AusAID). There are various, well-supported reasons for providing international aid to developing countries (e.g. alleviation of poverty and regional security), and it is equally appropriate for the Australian Government to provide international aid in the form of HMR. There are already many examples where Australia’s HMR has resulted in improved health outcomes in developing countries, including malaria treatment, rheumatic heart disease, parasite control and HIV (Case Study 3.6). HMR can have a strong flow-on effect to support other aspects of international aid assistance.

"It can be argued that we have a special responsibility to the nations in our region of Southeast Asia and the Pacific. Some of these countries in our neighbourhood have fewer resources and more pressing health problems than we do. Furthermore, such assistance in research represents an excellent example of good global citizenship, especially Australian assistance that both improves health and helps build intellectual infrastructure in the neighbouring countries. Few can doubt the goodwill and beneficial relationships that are being built between Australian [sic] and Asia through research."

National Health and Medical Research Council

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The Burnet Institute has developed a point-of-care disposable HIV test aimed at potential HIV-infected patients around the world

**Background.** Among the estimated 34 million individuals infected with HIV worldwide, approximately 15 million need Antiretroviral Treatment (ART) but only 7 million receive this. Furthermore, 43% of HIV-infected pregnant women do not receive effective interventions to prevent mother-to-child transmission. Current HIV monitoring tests such as CD4 are expensive and require highly trained laboratory technicians to perform the tests on equipment requiring power, clean water and regular maintenance. Rapid assessment at the point-of-care in pregnancy could markedly increase uptake of timely antiretroviral interventions, particularly in settings where women often come only once and often late to antenatal clinics, or where there is limited access to laboratory evaluation.

After six years of R&D, the Burnet Institute has developed the VISITECT® CD4, a disposable test for quickly testing HIV-positive patients globally. The CD4 is an inexpensive (US$5) test which does not require additional instruments or equipment, expensive reagents or highly trained personnel. Its format is similar to a pregnancy test and only requires a finger prick blood sample.

A project to bring VISITECT® CD4 to sub-Saharan Africa is now supported by a USD$250k grant from the Grand Challenges Saving Lives at Birth Initiative, jointly funded by USAID, the Government of Norway, the Bill and Melinda Gates Foundation, Grand Challenges Canada and the UK Department for International Development.

**Key Lessons:**

1. **Australia's HMR capability can be leveraged to combat some of the major barriers to improved health globally and attract new sources of funding.** The VISITECT® CD4 test won the inaugural Australian Life Sciences Innovations Award in 2012 and has been one of 15 projects nominated for the international 'Saving Lives at Birth' award (out of over 500 application received) and it has attracted funding from a number of international agencies.

2. **Collaboration between the research, healthcare and industry sectors are pivotal for the development of treatments.** The Burnet Institute coordinated the development in its laboratory, the validation with Alfred Hospital and the manufacturing and commercialisation with Omega Diagnostics Group. This relay race has led to the launch of a revolutionary, award-winning product and is expected to allow for rapid initiation of antiretroviral interventions and save the lives of thousands of HIV-infected men and women and prevent infection in newborn infants.

3. **Research across the spectrum from biomedical to public health are required to deliver global health impact.** The Burnet Institute's Centre for Virology and Centre for International Health, together with other public health specialists, are now conducting further testing of VISITECT® CD4 in sub-Saharan Africa.

**Note:** Image courtesy of the Burnet Institute

**Source:** Burnet Institute: www.burnet.edu.au; Omega Diagnostics: www.omegadiagnostics.com; Building Better Healthcare: www.buildingbetterhealthcare.co.uk
As a country with acknowledged research excellence, especially in key areas such as tropical medicine and immunology, Australia is ideally placed to have an impact on global health outcomes, particularly in the Asia-Pacific region. There are major opportunities for Australian researchers to improve the translation of research outcomes through international collaborations and by targeting research at neglected health and medical problems, for example snakebites (Case Study 3.7), many of which present major barriers to improved health in the developing world.

Australia can also provide support by assisting other countries to build research capacity and develop their own research programs. In addition, it is important for Australia to be involved in the promotion of international best-practice standards for HMR in countries with developing medical research programs, particularly in tropical medicine. Australia has an existing capability in this area, and with a large part of the country in the tropics, has similar issues as our northern neighbours and, consequently, the risk of pandemic disease in the region. Australia can benefit in this area in a range of ways by enhancing its workforce capability, joining international collaborations, and obtaining research outcomes on common health issues. Robust involvement in and contribution to global health also represents a key component of national security, particularly with respect to infectious diseases in our immediate geographical region.

Health and medical research has an important role to play in addressing the growing threats posed by tropical infectious disease. Australia is susceptible to many of the same tropical infectious diseases that are highly prevalent in other tropical countries (including our close tropical neighbours), and the reality of the increasing disease threat has been demonstrated by several recent zoonotic outbreaks that have had a substantial impact on health security in Queensland … It is far easier and more cost-effective to deal with infectious disease threats before they become epidemics.

James Cook University

Recently, AusAID has shifted Australia’s approach to global medical aid through research from an ad hoc and somewhat under-supported position (with neither NHMRC nor AusAID taking full responsibility) to a potentially more strategic approach. Following the April 2011 report of the Independent Review of Aid Effectiveness (the Hollway Review), AusAID released a draft medical research strategy for public comment that outlined a plan to invest in medical technology and innovations to help improve health outcomes and save lives in the Asia-Pacific region.⁸⁶ As described in that document, AusAID will invest in research into diseases and health issues which require new and improved medical interventions for use in poor communities and which are not being supported by the market. It will do this by supporting HMR in key areas that have the greatest potential to alleviate poverty, and best align with Australia’s national interests.

**Issue: Focus is needed to optimise the increased global health research budget.** AusAID’s research funding in 2010–11 amounted to $106m representing 2.4% of total overseas development assistance. There are plans for expansion of the overall aid budget from 0.35% of gross national income to 0.5% in 2016–17. The Independent Review recommended that ‘there should be more aid funding for research by Australian and international institutions, particularly in agriculture and medicine’ given they are ‘Australian strengths’.⁸⁷ These recommendations have been endorsed by AusAID and hence there are likely to be significant increases in funding for global health HMR projects. This further suggests AusAID will need guidance on ways to optimise its investment in HMR, particularly in the development of a suitable funding mechanism through which AusAID-sponsored international HMR programs can be managed to meet the strategic objectives of the Government’s international aid program. It will also need assistance with oversight of peer and ethical review in grant application processes. This shift in emphasis towards HMR is therefore likely to present AusAID with a number of strategic, organisational, governance and administrative challenges, given HMR is not one of its core areas of expertise or experience.

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Option: AusAID to contract NHMRC to manage its international HMR program and provide other strategic advice. The Independent Review also highlighted that ‘new modalities would need to be developed for medical research, possibly in collaboration with the NHMRC’. The Panel fully endorses the recent move by AusAID to increase Australia’s contribution to global HMR and notes that AusAID’s proposal to work in collaboration with NHMRC. The Panel also notes that AusAID is also seeking to increase the level of competitively-funded research from current levels of 14% to 30% by 2015–16 in order to align with the Government’s aid policy, and suggests that AusAID leverage NHMRC’s competitive grant funding processes and strategic research capability to ensure optimal deployment of AusAID’s global health research investment.

“... AusAID has limited capacity to provide the appropriate oversight and administrative mechanisms to conduct research, particularly in the areas of peer review and ethical review of research projects. There are tremendous opportunities for collaboration across agencies (AusAID and the NHMRC in particular) that will achieve much greater global health research output without additional research dollars above and beyond that already agreed to.

The Macfarlane Burnet Institute for Medical Research and Public Health

Issue: Global health research partners are ineligible for NHMRC funding. NHMRC strongly encourages international research collaboration by Australian researchers. However, its project grants do not appear to be directly accessible for funding the salary and infrastructure support needs of global health research partners. Anecdotally, there appears to be resistance among GRPs to directly provide funding to offshore work in developing countries. There is significant value in Australian researchers working with researchers in developing countries in areas of mutual interest. For this to be successful, NHMRC will need to work with AusAID and other Australian Government departments to jointly support research and research training in neighbouring countries. It is critical that NHMRC (as with other funding agencies) develops additional funding mechanisms aimed at supporting Australian-based researchers and health professional engagement with international collaborators.

Option: NHMRC to more fully embrace grant assistance for global health. Given the multiple benefits of HMR in developing countries, especially those in Australia’s immediate geographic region, the Panel believes that there is a need for NHMRC to make a clear statement in support of international research collaborations with developing countries in the region. NHMRC should encourage international researchers to apply directly to AusAid, or partner with an Australian researcher or academic institution to apply for NHMRC grants. Such an approach has been used successfully by the UK MRC and Wellcome Trust, and the US NIH International Centers for Infectious Diseases Research. Further, the recent move by AusAID to more strongly support HMR in developing countries provides the opportunity for NHMRC to facilitate the establishment of co-funded collaborative grants schemes for international research with large global philanthropic organisations such as the Bill and Melinda Gates Foundation and the Wellcome Trust.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>7c.1 Leverage competitive grant processes for the Australian Agency for International Development (AusAID) and other global health research programs to ensure funding is being deployed on high-quality research.</td>
<td>NHMRC, AusAID</td>
<td>2014–15</td>
</tr>
<tr>
<td>7c.2 Facilitate the establishment of co-funded collaborative grants schemes for international research with large global philanthropic organisations such as the Bill and Melinda Gates Foundation and the Wellcome Trust.</td>
<td>NHMRC, AusAID</td>
<td>2014–15</td>
</tr>
<tr>
<td>7c.3 Encourage international researchers to apply directly to AusAid or partner with an Australian researcher to apply for NHMRC grants.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
CASE STUDY 3.7

Australian researchers have collaborated with scientists in PNG and Costa Rica to develop a low-cost treatment for snakebites

Background. Snakebite envenomation is a neglected global health challenge with approximately 5.5 million people bitten by snakes globally each year leading to 400,000 amputations and up to 125,000 deaths—particularly impacting sub-Saharan Africa, Asia, Latin America and Papua New Guinea (PNG). As a result of short supply and high manufacturing costs, polyvalent and taipan\(^1\) anti-venoms, which are manufactured by CSL Limited, have a high cost per ampoule between $1,100 and $1,800.

Researchers at the University of Melbourne’s Australian Venom Research Unit and the Nossal Institute for Global Health collaborated with the University of Costa Rica (which manufactured the anti-venom) and University of PNG (which provided the researchers with infrastructure resources and support).

Together they developed a new low-cost Papuan taipan anti-venom that not only offers a sustainable solution, but potentially provides PNG with the opportunity to produce its own anti-venoms. Produced for less than $100 per dose, this new anti-venom has been proven to effectively neutralise the lethal effects of taipan venom in laboratory tests and is now suitable for human trials.

Key Lessons:

1. **Australia can leverage its strengths in HMR to help solve global health challenges.** The work of this international team has been published in a prestigious medical journal. They were able to involve the World Health Organization which recommended preclinical assessment tests. Funding has also been obtained for human studies that will take place soon.

2. **Focused research implementation programs can deliver improved health services in developing countries.** The Global Snakebite Initiative also includes snakebite management training courses for doctors and health workers to improve their capabilities and protocols. The course receives funding from the Australian Government and is now operated through various schools of medicine and health sciences throughout PNG.

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3.3.5 Support Advances in Genomics

Leading the revolution in personalised healthcare. Since the first human genome sequence was released in 2001, genomics has moved steadily towards medical applications and is on the brink of transforming health and medical science, and clinical practice, especially in areas such as cancer diagnosis (Case Studies 3.8 and 3.9). As medical genomics matures, it will deliver major benefits to patients, clinical practice, epidemiology and ultimately to health economics. Many of the advances in new therapies will come from applying new knowledge of the molecular basis of disease and matching this to the genotype and phenotype of patients to improve health outcomes.

The genomics era continues to rapidly advance with new technologies in nucleic acid analyses, which has led to the development and implementation of personalised medicine. In particular, Australia's contribution to the International Cancer Genome Consortium is paving the way for understanding and treating patients with pancreatic and ovarian cancer. However, advancements in the genomics field have been limited by the huge data sets generated, coupled with the limited capacity to store and analyse this information to its full potential. Accordingly, the potential of genomics and personalised medicine is reliant on the development of cross-platform training in the fields of bioinformatics and information technology.

The Australian Society for Medical Research

The genomics 'revolution' is driven by two factors:
- an exponential reduction in the cost of gene sequencing, making widespread, routine creation of a personal genome possible within 10 years
- a related exponential increase in our biological understanding of the link between gene sequence and disease, and hence diagnosis and potential treatment.

Genomics offers new tools to both improve diagnostic accuracy and make disease prevention or treatment more efficient. The current predominant paradigm in healthcare intervention is application at a disease level (e.g. pharmaceuticals) or population level (e.g. vaccines) aimed at a disease 'average', whereas genomics has the potential for application at the individual level, with highly increased specificity of intervention. The mapping of the human genome has opened up numerous avenues of research with the potential to identify health risk factors and personalise treatment depending upon an individual's genetic makeup and integration of this information with environmental factors (Exhibit 3.3). Personalised medicine offers the capacity to predict disease development and influence decisions about lifestyle choices and to tailor medical practice to individual needs, and holds enormous possibilities for streamlining treatments and associated reductions in inefficiencies and adverse outcomes.

Genomics can fundamentally change the way that medicine is practised, provided HMR capacity is built in the form of skilled researchers, coordination with clinical geneticists and clinicians, patient data/material access and key technical infrastructure. Australia is well positioned to take advantage of this opportunity, but only if links between research, the health system and data are forged. The key requirement is for an interface between genomic research, health consumers and clinicians that enables free flows of information, so a genomic expert becomes part of diagnosis in the same way that a pathology test is currently used. This will ultimately require the development of well-curated, evidence-based databases that medical professionals (especially clinicians), and the health system can refer to and draw upon. There is an opportunity to take a coordinated national approach to the development and provision of this information which has potential to deliver significant improvements in healthcare and also generate commercial benefits. It is therefore imperative that the HMR sector embraces genomic technologies and genome informatics at both discovery and translational levels.
Exhibit 3.3

Beyond today’s challenges, healthcare organisations must address the evolution of ‘personalised healthcare’

Evolution of Personalised Healthcare

Issue: Australia lacks capacity and capability in genomics research. Many countries, including US, UK, France and Korea, where thousands of patients are being coded, have been investing heavily in genomics research. Australia is involved in the International Cancer Genome Consortium which is using the sequencing of genomes from cancer patients to discover new subtypes, new mechanisms of action and patient-tailored approaches to treatment. While the Australian Genome Research Facility provides genomic sequencing to the research sector, this is largely in a technical capacity. A nationally coordinated strategy and approach are required.

There are numerous benefits to Australia from being involved in early research, especially in enhancing the speed of uptake of new genomic technologies. The current funding structures for genomics research are geared towards biologists in basic science discovering new genes. This leaves deficiencies in three main areas:

- skilled bioinformaticists for the analysis of genomic data
- translational research support by clinicians who have basic science training
- a formal national approach to driving the delivery of genomics into health.

Option: Develop a national approach to build genomics research capacity and capability.

For Australia to take advantage of the results of genomics research, it must ensure it has a strategic national investment approach, particularly in integrating genomics into health delivery. Australia must also ensure that it has sufficient people skilled in genomics application, which is addressed in Recommendation 8e. Genomics research will produce a huge amount of data and so requires upgraded capability in collection, storage and analysis to synthesise data into meaningful, clinically-useful information. At a more general level, affirmative action needs to be taken to encourage researchers to incorporate genomics technologies and approaches into their research agenda.
Issue: Need for integration between the sequencing of individual human genomes and clinical diagnosis practices. The speed of genomic sequencing continues to accelerate, and there will be larger amounts of genomic data made available over the next few years. The country that can best and most quickly integrate genomics into its healthcare system is likely to see dramatic improvements at all levels of society. However, there are two key barriers to the practical delivery of genome-based medicine:

- an understanding of the association between sequence and biology
- a capacity to integrate this understanding with the delivery of health services.

These are inextricably linked and need to be tackled in unison. The technical process of sequencing a patient’s genome is now feasible and relatively inexpensive. However, the link between sequence and predisposition to disease or patient prognosis has not been made for the majority of conditions. In many instances this is because insufficient examples are available to make that correlation or the condition is complex and involves many interacting genes. The greatest advances have been made in cancer where the sequence of the cancer and the sequence of the patient differ and so the analysis focuses on the difference between the two. For multigene disorders of unknown biology resulting from a combination of changes in the patient as a whole, less progress has been made. The stream of research focused on making these associations—bioinformatics—involves both biology and mathematical science and represents an area of research with a shortage of skilled professionals. At the clinical end of the equation, access by researchers to patient material is a major obstacle as, in most instances, acquiring a patient genome may provide no immediate patient benefit and hence is not generally provided for within normal health delivery.

The research and analysis needed to uncover the data on which personalised medicine will depend relies on analysis of large and multiple datasets (often via international collaboration), the ability to analyse and correlate data from multiple sources using e-Research tools, and a close, mutually supportive collaboration between clinicians in health care settings, laboratory based scientists and specialists skilled in analysing large datasets.

Neuroscience Society of Australia and New Zealand

Human research ethics approvals also represent a barrier, in that current approvals require a forward prediction of the purpose of the study whereas acquiring a human genome may inadvertently identify risks for conditions not predicted on an initial ethical application. Progress requires continued access to patient material for research, together with consent to pass back to clinicians any anomalies that may be identified as a result of examining that material. For the patient and the clinician, there must be assurances of confidentiality, data security and accreditation of the provider of both the sequence and the analysis. Most research facilities are not accredited for the provision of such information as a pathology provider would be. A key intervening step, therefore, involves the clinical geneticists and pathologists.

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88 R Taft, Genomics Policy Paper: An opportunity for Australia to be a global health leader, Institute for Molecular Bioscience, University of Queensland, Brisbane, 2012.
CASE STUDY 3.8

Australian-led international research collaboration on pancreatic cancer genomes has generated new insights into its causes and treatment

**Background.** Pancreatic cancer is the sixth highest cause of cancer-related mortality in Australia, with over 2,200 deaths in 2007 and a stagnant five-year survival rate that has remained below 5% for 50 years. In light of this, the NSW Cancer Council identified pancreatic cancer as a priority area and provided funding to researchers from the Garvan Institute under its Strategic Research Partnership grants program.

This initial investment has since led to the formation of the NSW Pancreatic Cancer Network, which subsequently became the Australian Pancreatic Cancer Genome Initiative (APGI) and makes up part of Australia’s International Cancer Genome Consortium (ICGC). This initiative brings together the world's leading scientists, through 11 funding organisations in eight countries, and is cataloguing the genetic changes of the 50 most common cancer types. The APGI comprises a network of over 20 hospitals and MRIs and is led by researchers at The University of Queensland and the Garvan Institute. Research is funded by a $27.5m NHMRC grant and includes collaboration with the US, UK, Canada and Italy.

Researchers have identified more than 2,000 gene mutations present in over 100 patients with pancreatic cancer, creating opportunities for future diagnosis and treatment. This research has identified that pancreatic cancer is not one disease, but many. This suggests that a more personalised treatment plan is necessary to improve survival rates. The study also identified that the axon guidance pathway, a set of genes, is frequently damaged in patients with pancreatic cancer. Researchers expect to use this set of genes to direct future research into more effective treatments.

**Key Lessons:**

1. **Strategic research focuses investment and effort on key issues that have impact.** The Cancer Council NSW defined pancreatic cancer as a strategic research priority through a consensus development process and provided early funding through its Strategic Research Partnership grants program. The Queensland Government has provided $5m to support large-scale cancer genomics infrastructure and the NHMRC has provided ICGC with funding through its largest ever single grant to support further genomics research into pancreatic cancer.

2. **Genetic research leads to insights on the causes of diseases and possibilities for treatment.** Understanding the genetic mutations that are responsible for cancer has the potential to increase our understanding of the causes of cancer and treat cancer based on the genetic mutation present instead of its location. Early research into pancreatic cancer genomes has the potential to improve the five-year survival rate through the identification of genetic mutations that can be treated using existing drugs.

Option: Integrate and embed genomic analysis in clinical health delivery. There must be integration between the sequencing of individual human genomes and the decision about appropriate treatment. This will require integrated relationships between patients, clinicians and genomics researchers, and a paradigm shift in the way healthcare is delivered, particularly in areas such as clinical genetics and pathology. For example, samples taken from cancer patients that are collected for pathology would be sequenced and the results of the detected genomic changes would assist in informing diagnosis and treatment. Given the potential scale of changes required, a genomic medicine task force should be established to facilitate top-down nationwide implementation of genomics, and to encourage private industry development to support it.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>7d.1 Build focused capacity in genomics with emphasis on translation into clinical practice and integration between research organisations and healthcare providers (including pathology companies).</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>7d.2 Resource a national consortium of networked bioinformatics research clusters linked to clinicians with access to patient material to drive forward understanding of the genome and its application to clinical care.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>7d.3 Establish a personalised medicine taskforce to facilitate top-down nationwide implementation of genomics applications, and encourage private industry support.</td>
<td>DoHA, COAG SCoH</td>
<td>2014–15</td>
</tr>
<tr>
<td>7d.4 Provide ongoing education within the health community in person-specific profiling technologies (such as genomics, proteomics, transcriptomics and metabolomics) and ensure linkages to clinical patient databases together with routine profiling.</td>
<td>College of Pathologists, clinical genetics services</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
CASE STUDY 3.9

Australian researchers have used genetic sequencing to advance the diagnosis and treatment of rare diseases

**Background.** Rare diseases are difficult to treat, diagnose and study. Despite the fact that 80% of rare diseases are genetic in origin, these illnesses tend to be refractory to traditional genome-wide association studies as it is often impossible to gather large cohorts of patients. This has severely limited the advance of research and the development of new therapies. About 30% of children with a rare disease die before their 5th birthday and rare diseases are responsible for 35% of deaths in the first year of life. The potential for genomics to revolutionise rare disease research and facilitate a healthy start to life is significant.

Researchers from The University of Queensland have led an international effort to use genome sequencing to reveal the genetic underpinnings of a group of rare and devastating inherited central nervous system disorders, called leukoencephalopathies. Like rare diseases generally, 50% of patients presenting with these disorders will remain without an ultimate diagnosis. By partnering with clinician scientists at the Murdoch Children's Research Institute (Australia), Children's National Medical Center (US) and the VU University (Netherlands), researchers have successfully used familial genome sequencing (which involves sequencing the affected child, parents and any siblings) to:

- identify the rare genetic variants responsible for a Melbourne boy's leukoencephalopathy, which subsequently led to the identification of 10 additional patients with same affliction and the characterisation of a new disease;
- in less than four months, identify the mutation responsible for a leukoencephalopathy subtype; and
- identify a new mutation in a potassium transporter gene in a child with an unclassifiable leukencephalopathy and severe epilepsy, which led to treatment with channel-specific therapies.

This network of scientists will soon embark on the first rare disease familial genome cohort study to dramatically reduce the number of undiagnosed leukoencephalopathy patients.

**Key Lessons:**

1. **Concerted research efforts in genomics can lead to rapid advances in disease gene discovery and associated molecular diagnostics.** The use of familial genome sequencing reduces the number of false positives, and enables the rapid detection of genetic changes that cause disease. This approach is laying the groundwork for the development of novel and targeted rare disease therapies, and for making genome sequencing an established component of the clinical diagnostic pipeline.

2. **Genome sequencing can deliver immediate impact on patient care.** In an increasing number of cases, genome-sequencing technologies are capable of identifying genetic changes that are immediately treatable with available interventions. In many instances, these therapies would not have otherwise been considered.

3. **Australia is well positioned to take advantage of international efforts in genetic applications in rare diseases.** Australia has a growing and internationally acknowledged expertise in genomics and bioinformatics, and is well positioned to be a leader in this area.

**Notes:** Image courtesy of Dr Ryan Taft, Institute of Molecular Bioscience, The University of Queensland

**Source:** Rare Diseases: Understanding this Public Health Priority, EURODIS, 2005
4. Maintain Research Excellence
4. MAINTAIN RESEARCH EXCELLENCE

4.1 Introduction

While Australia’s performance in HMR is globally recognised, continued support across the spectrum of research areas (e.g. biomedical, clinical, public health and health system) is required to maintain and improve its international standing. Increased government research investment over recent decades, particularly in response to the Wills Review recommendations, has raised research quantity and quality, encouraged business, private and philanthropic investment, and built some world-class research institutions. This has been underpinned by competitive schemes which have increased the quality of research and provided significant capacity-building across the spectrum. Supporting this is a research delivery system which is comprised of four interrelated components (Exhibit 4.1). Each of these components has its own set of issues which need to be resolved for Australia’s HMR excellence to continue.

Exhibit 4.1

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

Research Delivery System

Reform to the research delivery system is required to retain the benefits of competition, while mitigating its undesirable consequences. There are a number of major elements required to maintain and further enhance research excellence in Australia:

- train, support and retain the workforce
- streamline competitive grant processes
- rationalise indirect cost funding for competitive grants
- build enabling infrastructure and capabilities.
**4. Train, Support and Retain the Workforce**

**Recommendation 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 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.

**4.2.1 Introduction**

The workforce contributing to HMR in Australia is diverse and can be broadly divided into those with a background and primary training in medicine, nursing or allied healthcare practices, those with primary training in science, and those in supporting disciplines such as biostatistics and bioinformatics who provide enabling research capability. The challenges for each of these groups for training, career progression and job security are markedly different.

- Clinical and other health professionals focused on the delivery of healthcare, who despite being ideally placed to assess the relevance of research outcomes, face significant barriers to actively participating in research.
- PhD students and science graduates dedicated to conducting research who experience significant challenges with professional progression, alternative career paths, job security and remuneration.
- Professionals from supporting disciplines such as biostatisticians and bioinformaticists, who aside from being in significant shortage, are confronted with challenges around career stability and development opportunities.

While this section primarily focuses on scientists who make up the majority of the current HMR workforce, health professionals and those from supporting disciplines are also important.

“There needs to be specific attention paid to the developing of the future broader health and medical research work force. This need covers biomedical scientists across a wide range of sub-disciplines. It covers specialist qualified clinical academics in medicine and the allied health sciences. It covers epidemiologists, mathematicians, statisticians, health economists and econometricians, ethicists, and experts in technology transfer and in emerging sciences like nanotechnology and systems biology.”

*The Group of Eight Limited*
4.2.2 Manage and Monitor the Workforce

The Australian Society for Medical Research (ASMR) published a report in 2009 on the HMR workforce, identifying over 39,000 staff in universities and MRIs. Of these, 23,000 were research staff, with 15,000 (65%) holding PhDs. A portion of these researchers attract competitive research grant funding, typically from NHMRC. This may include personal salaries (generally for those at an earlier stage of their career or a lower professional level), or personal fellowships which range from early Early Postdoctoral to Senior Research Fellowships. NHMRC estimates that its granting schemes directly supported the salaries of approximately 8,500 researchers in total in 2010 (Exhibit 4.2).

Exhibit 4.2

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

<table>
<thead>
<tr>
<th>Researchers Supported by NHMRC Schemes</th>
<th>By Scheme</th>
<th># Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td># Researchers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td></td>
<td>3,337</td>
</tr>
<tr>
<td>Full time</td>
<td></td>
<td>3,337</td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td>3,337</td>
</tr>
<tr>
<td>2004</td>
<td></td>
<td>3,712</td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td>4,111</td>
</tr>
<tr>
<td>2006</td>
<td></td>
<td>4,311</td>
</tr>
<tr>
<td>2007</td>
<td></td>
<td>4,836</td>
</tr>
<tr>
<td>2008</td>
<td></td>
<td>5,271</td>
</tr>
<tr>
<td>2009</td>
<td></td>
<td>5,878</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td>6,401</td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td>6,492</td>
</tr>
<tr>
<td>2011 CAGR 03–10</td>
<td></td>
<td>13%</td>
</tr>
<tr>
<td>Other Schemes</td>
<td></td>
<td>25%</td>
</tr>
<tr>
<td>Project Grants</td>
<td></td>
<td>21%</td>
</tr>
<tr>
<td>People Support</td>
<td></td>
<td>10%</td>
</tr>
<tr>
<td>100% = 8,513</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: NHMRC Funding Facts Book 2011, 2012

People Support Schemes support 1,761 researchers, representing 21% of all researchers supported by NHMRC funding. The schemes span a number of researcher levels and align, to some extent, with the typical pyramid structure that characterises most professions (Exhibit 4.3).
The number of researchers supported by People Support Schemes saw solid growth of 11% p.a. from 884 researchers in 2002, to a peak of 1,783 in 2009 (Exhibit 4.4). This growth included support for PhD scholars (6% p.a.), through to Postdoctoral Fellowships (13% p.a.), Career Development Fellowships (27% p.a.) and Senior Fellowships (6% p.a.). Growth over the last couple of years, however, has been flat to in decline.
Exhibit 4.4

NHMRC People Support Schemes experienced strong growth up until 2009 and have since stabilised

### NHMRC People Support Schemes

<table>
<thead>
<tr>
<th># Researchers</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
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<tbody>
<tr>
<td>Total</td>
<td>884</td>
<td>249</td>
<td>115</td>
<td>142</td>
<td>361</td>
<td>421</td>
<td>434</td>
<td>539</td>
<td>549</td>
<td>536</td>
</tr>
<tr>
<td>PhD Scholarships</td>
<td>484</td>
<td>1,043</td>
<td>280</td>
<td>289</td>
<td>298</td>
<td>323</td>
<td>356</td>
<td>373</td>
<td>386</td>
<td>380</td>
</tr>
<tr>
<td>Senior Fellowships</td>
<td>228</td>
<td>1,215</td>
<td>1,373</td>
<td>1,491</td>
<td>1,543</td>
<td>1,734</td>
<td>1,783</td>
<td>1,764</td>
<td>1,761</td>
<td>1,764</td>
</tr>
<tr>
<td>Career Development Fellowships</td>
<td>13</td>
<td>2007</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
</tr>
<tr>
<td>Postdoctoral Fellowships</td>
<td>12</td>
<td>2007</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
</tr>
<tr>
<td>Other Fellowships</td>
<td>12</td>
<td>2007</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
<td>1,543</td>
</tr>
<tr>
<td>CAGR 02–09</td>
<td>11%</td>
<td>0%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>CAGR 09–11</td>
<td>6%</td>
<td>0%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Source: NHMRC data, 2012

**Issue:** The size and dynamics of the HMR workforce are not well understood. Despite the existence of some data sources—particularly from NHMRC and occasional surveys from ASMR—there are limited data and consequently limited understanding of the HMR workforce. The overall workforce is not actively or regularly monitored, with poor visibility of its size and dynamics. There is no central body responsible for the overall workforce that monitors its health, dynamics and sustainability. Workforce development happens in a somewhat ad hoc way, with changes happening in response to various funding schemes and initiatives rather than through any strategic planning mechanism.

**Option:** Task the leadership body with describing, monitoring and providing policy advice on planning the HMR workforce. The Panel strongly believes that there is a need for the new national HMR leadership body to develop a clear understanding of the magnitude and dynamics of the entire HMR workforce. This includes understanding the dynamics of NHMRC People Support Schemes and the way in which those schemes impact on the HMR workforce, on an ongoing and strategic basis.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a.1 Develop a clear view of HMR workforce planning, including the shape of the entire workforce as well as the dynamics of NHMRC People Support Schemes.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
4.2.3 Support Early Investigators

It is vital that Australia continues to invest in its young researchers and be recognised as a nation which strongly supports those with talent. This facilitates the perception and profile of HMR as a rewarding career path. Young researchers are particularly adept at new technologies and ways of experimenting. While enrolments in science increased by 30% between 2002 and 2010, this is the fourth slowest increase in enrolments of any discipline.\textsuperscript{90} Given science appears to have diminished in its appeal as a prospective career among young people over the last decade, there is a need to remove obstacles to those who do want to pursue a career in HMR. This can be done by providing increased certainty of career progression, appropriate training and mentoring for those with talent and enthusiasm.

\textbf{Issue: Limited career path options and support for PhDs.} PhD and postgraduate students lack appropriate financial support and broader training opportunities. The last decade has seen a 250\% increase in the number of students undertaking PhDs and, to a much lesser extent, Masters, with doctorate-by-research commencements at Australian universities increasing from 3,915 in 2000 to 10,415 in 2010. However, over this period, there has not been a commensurate increase in opportunities for postdoctoral researchers to access sustainable sources of funding to establish their research career with an adequate level of career security. Full-time PhD students receiving Australian Postgraduate Awards (APAs) currently receive about $24,000 annually, compared to the minimum wage which is estimated at $31,500.

"Students need more hands-on experience to gain practical skills, determine if they enjoy research and for prospective employers to gain the chance of attracting and retaining bright and passionate students ... PhD training needs to provide a broader skill set, including management, economics, teaching and good communication skills, to enable students to pursue alternative careers."

\textit{University of Melbourne and the Murdoch Children’s Research Institute\textsuperscript{91}}

\textbf{Option: Improve career options, training and financial support for PhDs.} PhD and postgraduate students should receive better support and training. The breadth of the PhD experience should be improved to ensure the delivery of graduates equipped for career moves into industry or government (e.g. communications skills and teamwork). This view is supported by Medicines Australia, who highlights that ‘growth in the Australian Medicines Industry is being hampered by the persistent shortage of skilled workers and with respect to clinical research especially, Australian bio-pharmaceutical companies have had to import labour to meet skills shortages’.\textsuperscript{92} In addition, higher stipends are required for APA students, although this should not be at the expense of the total number of APA stipends made available.

\textbf{Issue: Early-investigator support is not well targeted.} Within the current NHMRC Project Grants scheme, 10\% of grants are submitted by applicants meeting the criteria of New Investigator, while only 9\% of all Project Grants are awarded to such applicants. An arbitrary score of 0.5 is added to New Investigator grant application scores, resulting in funding for 86\% of New Investigator grants ranked at 5 or higher (compared with only 42\% of non-New Investigator grants). Most critically, the definition of New Investigator is ‘new to the NHMRC’ and hence includes applicants that are senior researchers and have recently come to Australia.

\begin{flushleft}\textsuperscript{90} Chief Scientist, \textit{Health of Australian Science}, Canberra, 2012. \\
\textsuperscript{91} Stakeholder feedback on SRHMRA Consultation Paper, Postgraduate Student Association, Department of Paediatrics, University of Melbourne, and the Murdoch Children’s Research Institute. \\
\textsuperscript{92} Stakeholder feedback on SRHMRA Consultation Paper, Medicines Australia.\end{flushleft}
**Option: Target NHMRC early-investigator support more effectively.** Early-investigator categories should be better implemented within the Project Grant system. Rather than adding an arbitrary score, NHMRC should redefine early-investigator to encompass researchers within 10 years of PhD completion, earmark a target range of 10–12% of the current NHMRC Project Grant budget for early investigators, and adjust weighting for key selection criteria during the grant assessment process.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>8b.1 Increase stipends for Australian Postgraduate Award students to at least be in line with minimum wage levels.</td>
<td>Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE)</td>
<td>2014–15</td>
</tr>
<tr>
<td>8b.2 Improve the breadth of the PhD student experience to ensure graduates are equipped for lateral career moves into industry or government. Include knowledge and skills in areas such as such as communication, commercialisation, IP protection, business and project management.</td>
<td>DIISRTE, universities</td>
<td>2014–15</td>
</tr>
<tr>
<td>8b.3 Improve early researcher opportunities for career progression by quarantining a portion of research funding for investigator-driven, early-investigator funding with different criteria:</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>• Change criteria of ‘new investigator’ (new to the NHMRC system) to ‘early investigator’ (within 10 years of PhD completion).</td>
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<tr>
<td>• Set a target range of 10–12% for Project Grants to be provided to early investigators.</td>
<td></td>
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<tr>
<td>• Evaluate these applications via the existing Grant Review Panels but using a different weighting for the key selection criteria.</td>
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</table>

### 4.2.4 Retain Researchers within the System

Universities, hospitals, MRIs and state and territory government health departments are the primary employers of HMR researchers. In addition, the national competitive schemes available through NHMRC and the Australian Research Council (ARC) provide specific additional support to the Australian HMR workforce across various levels.

Increasing funding for young investigators, including increasing the PhD stipend (as recommended in Section 4.2.3) will assist in securing researcher careers, as will having a more flexible assessment criteria for NHMRC track record (as described in this section) and building capacity in critical areas needed for improved translation (Section 4.2.5).

Another key career phase that requires attention is early-mid career researchers (EMCRs). These are people who are within 15 years post-completion of their research higher degree (usually a PhD). In the last 30 years, the average postdoctoral career phase has extended significantly, from 1–2 years in 1980 to in excess of 10 years in 2010. At the same time, this period has become characterised by insecurity in tenure for researchers.

EMCRs are not yet sufficiently well ranked or independent to gain larger Program Grants. They are drip-fed by short-term Projects Grants and People Support Schemes, and have much less certainty in their funding duration than the PhD students below them. Many of them are supported by one-year contracts, and spend the second six months of each year waiting anxiously for news of continuation of their job, looking for another job, or both.
A consequence of widespread insecurity in the mid-career period for health and medical researchers is the impact that it has on the type of research for which funding is sought. Conservative, short-term projects are favoured, rather than research which may have a higher level of risk, but might also carry a greater chance of producing innovative outcomes. Consequently, the post-doctorates who are seeking to make the transition to independence find it difficult to get support for higher-risk and longer-term projects. There is a need to acknowledge and find solutions for this widening gap in people support for researchers moving from Early Career Fellowships to Career Development Awards.

There are five key areas to address:

- career progression and salary barriers
- career break impact on re-entry into workforce
- gender inequities for both male and female researchers
- lack of capacity to mentor young researchers
- absence of viable career structure.

The issue of creating a more stable environment for the workforce as a whole, but most particularly those receiving salary from grants, is addressed also in Section 4.3.4.

“In 2008, a survey of the Australian HMR workforce (379 individuals) revealed that most researchers (73%) had considered leaving active research, as a result of shortage of funding (91%), lack of career development opportunities (78%) and poor financial rewards (72%).

ACT Health Directorate Research Office

**Issue: Career progression and salary barriers.** Over 5% of the NHMRC budget is spent on Early Career Researcher Fellowships, but this reduces to about 3% for mid-career Career Development Fellowships and increases again to about 7% for Senior Fellowships. This creates a powerful squeeze in the middle for EMCRs as they move beyond the three-years post-doctorate (postdoc) period, while the NHMRC salary quota does not cover their full salary cost. Consequently, younger, lower-level postdocs are preferentially engaged. Postdocs do not usually receive credit for supervising honours and PhD students, as co-supervision is not often recognised or permitted at academic level A.

While the salaries paid by an employer are the subject of local enterprise bargaining, NHMRC sets specific salary levels for named staff budgeted for on a grant. At present, these are regarded as well below the national average for researchers with equivalent skill sets and experience. NHMRC needs to either increase the salary levels or use institutional salary scales similar to those of ARC.

“There is a large and growing gap between NHMRC grant funds for salaries, and the actual salary levels which have to be paid to attract and retain good researchers. One Go8 university has estimated the gap in the current year as approximately 12%. Another university estimates a shortfall of the order of 25-30%, noting that this excludes some essential infrastructure costs … If this situation is not rectified, the best researchers are likely to be attracted to overseas positions, and/or research institutions will have to divert funds from other sources. Whatever occurs, the quality of Australian health and medical research is likely to suffer.

The Group of Eight Limited
Option: NHMRC to review salary levels. NHMRC should review its Support Package levels within its Research and People Support Schemes to bring these more in line with current national institutional salary-scale averages. Within the Research Support schemes, NHMRC must facilitate funding at an appropriate level of named experienced staff pertinent to the application. NHMRC should also consider adopting quantum approaches to grant budgets (see Implementation Task 9c.2).

Issue: Impact of career interruptions. When determining eligibility, some competitive fellowship schemes count years back since PhD. This means that when the number of years includes a substantial career interruption, the gap in productive years impacts heavily on the researcher’s track record, and they are less competitive than a peer who spent the same time without any career interruptions. Indeed, some fellowships from charitable trusts actually count the time out of the workforce when calculating years since PhD for eligibility.

“Currently there is little incentive for exchange across the HMR sector, nor is there any mechanism for researchers to take planned absences from the workforce for family or other reasons, due, at least in part, to the prohibitive Australian ‘publish or perish’ system that requires publicly-funded researchers to constantly demonstrate their worthiness for funding based on the number of peer-reviewed publications [and] presentations.

Bio21 Cluster

Child-bearing years coincide with the early-mid career stage. Parents, and particularly women, who have children and look after those children for their early years often find it very difficult to return to a research position afterwards. Similarly, there is a very real disadvantage for researchers who move from the research sector to industry or to the government sector to work on health and medical policy. There are three consequences of this.

• The structure of the research workforce features a predominance of women at PhD and postdoc level, but a lack of women at senior levels, with gender imbalance generally increasing with seniority.
• Many women, and a few men, take time out of work to be full-time carers which can impact on their research career.
• Researchers may find it difficult to return to the research workforce when they have been absent for a period, particularly:
  – women or men attempting to re-establish their careers after children
  – spouses who have accompanied their partners overseas for work
  – people who have been absent from work for health or carer responsibility reasons.

Option: Provide better assistance to researchers who have had career interruptions. There are several mechanisms which could assist people who have had significant career interruptions to re-enter the workforce, or re-establish their career at the level they were at when they left. These include the following options.

• As is now the case within NHMRC, competitive funding schemes should extend their assessment of productivity proportional to the period of time affected by a departure from the workforce (e.g. assess productivity over 10 years instead of five if they worked at a half-time rate or were out of the workforce for five years).
• Increase the flexibility of Project Grant duration and deadlines, full-time and part-time requirements, and the way fellowship support is used to make provision in their grant duration for periods when researchers are away from the workforce.
• Ensure that ways of measuring high-quality inputs to the sector, other than publications, are included in track record so people who choose to work in other industry sectors (such as industry or government) can have the achievements from that work included in funding assessments.
4. Maintain Research Excellence

Issue: Gender inequities affect both male and female researchers. Despite gender-equity action over the last three decades, women with career interruptions due to childbirth and childrearing need particular additional and flexible forms of support. In most instances, these need to be provided by employers within enterprise bargaining. In addition, although official policies may offer the same flexibility to men and women, in reality men are not utilising this flexibility the same way as women are, possibly because of a perception that it will harm their careers. Women are disadvantaged because they are perceived as being less competitive than men who are still working full time, and men are disadvantaged because they are not taking the flexible working arrangements to spend time with family or pursue other interests. This situation is reflected in the strong gender imbalance among senior researchers, with many more men than women reaching and remaining at chief investigator (CI) level and above.

Option: Implement gender-equity actions. Possible actions to promote greater equality across the HMR workforce include:

- establishing standard requirements for universities and other institutions to provide increased support for women and gender-equity policies (such as has been developed at the Walter and Eliza Hall Institute of Medical Research);
- introducing new programs specifically for women with career interruptions due to parenting such as ‘re-entry’ or ‘retention’ fellowships, or mentorship and support for senior women researchers; and
- providing funding for female researchers with children who are travelling to conferences and overseas institutes to either take their children with them or have them cared for at home.

The adoption of such proactive support processes should act as an incentive for recruitment of women by research organisations. In addition, research organisations should develop policies on gender equity, to support men wishing to have flexible working hours to spend more time with their families, and to enable more women to achieve promotion to senior researcher levels. This should apply to nursing and allied health professionals and other researchers in the health setting, particularly primary and community care, and not just biomedical researchers.

Issue: Lack of capacity to mentor young researchers. For a range of reasons—including the need to repeatedly apply for funding grants and the need to publish as frequently as possible—the pressure on senior researchers has increased to a point where many simply do not consider that they have the time to teach research skills to younger researchers. With this decline has also come a decrease in the practice of mentoring.

Option: Allocate time for mentoring. As senior-level researchers exit the system over the next 10 years, there will be an increasingly urgent need for mentorship by senior researchers of younger researchers. This will need to be supported by employers of both the senior and more junior researchers and could be incentivised by having mentorship as a reportable professional contribution that counts towards track record. In addition, retiring researchers could be formally encouraged and supported to maintain a link with their institution and provide a mentoring role to younger researchers.

Issue: Absence of viable career structure. Senior Fellowships funded by NHMRC as part of its People Support Schemes specifically aim to support and retain those researchers of the highest quality, enabling them to devote their careers to research. Within its Senior Fellowships scheme NHMRC currently supports 492 research fellows with tenure running for five years. Application for promotion or renewal is permitted in open competition with all other applicants. The scheme aims to support the 'best and brightest' but has not grown in size since 2009. In contrast, growth in mid-career fellowships (31% CAGR between 2002 and 2008) has created an increased pool of candidates.
In 2009, ARC initiated the Future Fellowships scheme that was open to all areas of science and is now supporting some 1,000 mid-career scientists across all research sectors including HMR for a single round of four years.\(^{93}\) In the 2011 Future Fellowships round, some 28\% of the Fellowships were awarded in the Promoting and Maintaining Good Health research priority area (a total of 56 Fellowships). The Future Fellowships scheme is scheduled to end with its 2013 round, after which there will be a significant gap in the number of mid-career fellowships available to health and medical researchers.

Both NHMRC and ARC have run other prestigious schemes for the very top of the profession: the NHMRC Australia Fellowship scheme (now discontinued) and the ARC Federation Fellowships (new funding for which ceased in 2008) were each a single five-year grant of substantial funding for the fellow and their research team. Overall, the one-off nature of these programs has further exacerbated the issues around retaining the HMR workforce and providing opportunities for recognition and career progression.

Any career scheme is sustainable only if there is exit as well as entry. Reliance on a capped scheme of limited size for the success of all senior scientists is not nationally feasible. However, to ensure that progression of our brightest and best into and through the NHMRC scheme was possible, NHMRC revised the scheme in 2006 so that incumbent fellows reaching the point of application for reappointment or promotion are considered in exactly the same way as all other applicants in that round. There has been no capping or specific modelling around the number of fellows at each level of the Senior Fellowships scheme, the rate of exit or the success of flow through this scheme. With a large increase in the number of fellowships at the mid-career level, there will be an inevitable and increasing constriction around entry into this scheme. It will be critical for NHMRC to consider the feasibility of establishing such a large cohort of mid-career fellowships if there is not a realistic degree of flow from career development fellowships to senior research fellow.

**Option: Map and manage the dynamics of existing fellowship schemes.** While acknowledging that NHMRC will continue to fund only the best and brightest career-level biomedical research staff via its People Support Schemes, and that the majority are and will continue to be funded by hospitals, universities, and research institutes, there is a need for NHMRC to consider the dynamics and optimum spread of fellowships within its People Support Schemes. They should effectively reward the best and brightest whilst allowing upwards promotion of up-and-coming researchers and retaining researchers across the spectrum of HMR including both science graduates and health professionals. This could include introducing caps on the number of years at a given level or not allowing re-entry at a lower level. NHMRC could also consider whether a portion of such People Support funding should be provided in part with contributions from employing organisations.

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<tr>
<th>Implementation Tasks</th>
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<th>Timeframe</th>
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<tbody>
<tr>
<td>8c.1 Review researcher remuneration levels and:</td>
<td>NHMRC</td>
<td>2014–15</td>
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</tbody>
</table>
| • recalibrate the average value of its fellowships and People Support packages within grants closer to the national mean within the university/MRI sector; and/or
• move to standard grants of a set quanta (see Implementation Task 9c.2 in Section 4.3.4). |                |           |
| 8c.2 Ensure national competitive granting schemes provide flexibility with respect to researchers returning from career breaks and part-time researchers. | NHMRC, ARC     | 2014–15   |
| 8c.3 Re-examine all barriers to the retention and promotion of researchers who have had to leave the workforce that may be embedded within the granting processes or within employee arrangements, and introduce more flexibility around Project Grants with regard to extended break periods from the workforce. | NHMRC, ARC, universities, MRIs | 2014–15 |
| 8c.4 Develop policies on gender equity, to support men wishing to have more flexible working conditions, and to enable more women to achieve promotion to senior researcher levels. | NHMRC, ARC, universities, MRIs | 2014–15 |
| 8c.5 Ensure that all HMR employers allocate time and training to allow senior researchers to mentor junior researchers and to embed mentorship activities in academic appraisals and track records. | Leadership body | 2014–15   |
| 8c.6 Map the dynamics of promotion through the existing NHMRC Senior Fellowship scheme and plan the best approach to manage the scale of the scheme by considering co-funding with employing institutions. | NHMRC          | 2014–15   |

### 4.2.5 Increase Track Record Flexibility

Track record is a major selection criterion for grants within research support or People Support Schemes from competitive granting agencies (e.g. NHMRC and ARC) and is evaluated within the university and MRI sectors as a major determinant of individual excellence and potential. Research track record assessment usually includes academic record (particularly record of publications in high-impact academic journals). Other professional contributions and activities (including mentorship, policy writing and translational and commercialisation activities) are variably included and potentially not sufficiently valued in track record evaluations. More critically, strong emphasis on track record assessment can end up discouraging researchers from engaging in research translation, given their performance is primarily judged on academic outputs. As a result, researchers are encouraged to move from project to project, resulting in a disconnect between evidence creation and translation of evidence into improved health outcomes. There are also specific groups that are disadvantaged by existing track record evaluation practices, such as mid-career researchers who often have trouble demonstrating growing independence from their supervisors. Career breaks for professional or personal reasons can also adversely affect track record.

Assessment criteria for research grant and fellowship funding should place a greater value on an academic researcher's success in engaging with communities, building research partnerships, and conducting research relevant to policy and practice in Australian settings. The focus on track record must encompass not only measurement of research outputs, but should place increased weight on other important contributions, particularly potential health outcomes.
**Issue: Professional contributions other than academic publications are not sufficiently valued for track record.** While NHMRC processes have made significant changes to the recording of such information, assessing non-academic features of a track record remains problematic. The relative effect of a career disruption, such as secondment to industry or parental leave, is also difficult to account for. While processes are being put in place to formally address assessment of track record relative to an episode of career disruption, there are also specific skill sets and productivity criteria that are not always considered. For example, for some disciplines, outcomes include patents or health policy guidelines rather than publications in journals. Specialists in biostatistics, bioinformatics or other types of data analysis may play a key role in many projects but not ever be the senior author on any publications. Researchers in these areas perceive a bias in ranking of track record towards researchers with traditional, academically-competitive NHMRC track records. The current model appears to define elite researchers as those leading investigator-driven research projects that target academic output rather than, say, providing solutions for health problems or demonstrating a clear potential to improve health outcomes.

Research excellence in four specific translational areas cannot be adequately represented and easily used by applicants to gain credit for their cumulative track record as assessed by NHMRC. This acts as a disincentive to work in areas of translation-oriented research, particularly in public health and health services research, and is therefore misaligned with the vision of embedding research in the health system.

1. **Policy and practice** – Influence on policy and practice is not necessarily measured solely by peer-reviewed publications.

2. **Longitudinal patient cohort studies and long-term service evaluation and intervention studies** – These projects progress more slowly because of the need to recruit sufficiently large cohorts of participants, so researchers have a much slower rate of publication output than those in laboratory and preclinical research, but are important clinically and practically.

3. **Lifestyle diseases** – These major health challenges transcend the boundaries between the social and health sciences and research programs are frequently composed of multidisciplinary teams that may not have an elite-level academic research background and who thus receive a poorer grading on track record.

4. **Commercialisation** – Researchers who attempt commercialisation of their research findings, or who focus on developing intellectual property, drugs and devices, may find it difficult to become re-established in conventional research funding programs.

**Option: Make track record assessment more flexible.** As well as further incorporating measures of a broader range of key research activities that lead to better health outcomes (e.g. research translation activities), NHMRC should provide greater clarity and guidance on the assessment of these elements of track record in grant applications to those people participating in grant application and review processes.

**Issue: Mid-career researchers have trouble demonstrating their track record.** There is also a specific challenge in presenting a superior track record for mid-career researchers, many of whom are employed within a research program and lead and perform a significant part of the research, but are not the program leader. They therefore may not appear to have a track record of independent research sufficient to appear as an applicant on a grant application to support their own work. This has provided some perverse drivers away from the inclusion of younger or specialised team members as CIs in research programs, to the detriment of the program of research and careers of those scientists.
Option: Allow non-CIs to appear on grant applications. One way to address the difficulty in having early investigators establish track record is to enable them to be specifically named on grant applications without having their individual track records weighted at all or as heavily as CIs. This may require the creation of a second tier of participants or a review of how the team as a whole is assessed for track record. Success as a participant on such a grant could then be explicitly recorded in their individual track records, which will assist them with their career progression.

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<th>Timeframe</th>
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<tbody>
<tr>
<td>8d.1 Develop explicit guidelines on the assessment of track record in grant applications to incorporate a broader range of key research activities that lead to better health outcomes.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>8d.2 Consider ways in which NHMRC can include mid-career researchers as formal applicants on grant applications as a team member without penalising their overall track record.</td>
<td>NHMRC</td>
<td>2014–15</td>
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4.2.6 Build Workforce Capacity

Our understanding of the biological, social or environmental basis of health and disease is ever changing as are the research approaches used to investigate these associations. Emerging scientific technologies may revolutionalise our delivery of healthcare, but Australia as a nation will not optimally benefit without skilled practitioners of these tools. At this point in time, changes in our understanding of genomics, for example, and our ability to interpret the genome of an individual or even a pathogen represent the technological advances most likely to change the face of healthcare (Section 3.3.5). As well as ‘tooling up’ with respect to infrastructure, we must build capacity to ensure our workforce can fully take advantage of these advances.

Issue: Lack of capacity in key enabling areas such as genomics and bioinformatics. There is an urgent need to build capacity in a range of disciplines, including some newly emerging disciplines, in which Australia lacks strength, particularly in genomics, bioinformatics, biostatistics, health services research and health economics. Such capacity-building must extend from initial training at an undergraduate level right through to scholarship and fellowship levels.

“… independent and well trained statisticians, bioinformaticians and systems biologists are absolutely vital for Australia to remain competitive and functional in all areas of health and medical research. Yet these positions are usually the least well supported and are generally based on short term contacts. These individuals are key to the success of any major research project and as such are usually put under a high degree of pressure, which is only exacerbated by the tenuous nature of their employment. As such, Australia continues to lose many skilled statisticians and bioinformaticians to overseas employment opportunities, and many Australian research groups are forced to outsource some of their analyses, rely on untrained PhD students or place increasing amounts of workload/pressure on the few skilled individuals who choose to remain.

The Australasian Genomic Technologies Association
Option: Encourage collaboration among research organisations to build capacity in key enabling areas. The development of new courses for emerging areas can be slow. One possible model that could be considered is the collaborative approach employed by Biostatistics Collaboration of Australia (BCA). BCA is based on collaborative arrangements that enable the pooling of teaching expertise to provide for a Masters of Biostatistics degree offered by universities participating in the BCA. The model was developed specifically to address the shortage of well-trained graduates in this field, and provides essential prerequisite knowledge for doctoral and postdoctoral training in biostatistics. This could be employed for similar specialist disciplines for which rigorous postgraduate coursework is an essential component, such as genomics, bioinformatics, health economics and health services research.

Another means of building capacity in key enabling areas is to target fellowship and grant funding schemes at these specific skill sets. The creation of targeted TRIP Fellowships and Practitioner Fellowships by NHMRC in recent years has been an important and effective capacity-building exercise that is well aligned to the overarching vision for embedding research into the health system to deliver better health outcomes. The benefit of targeting people support funding for specific capacity-building must be considered in the re-evaluation of the people support/fellowship schemes within NHMRC and ARC.

Issue: Increasing funding gap for projects at the interface between ARC and NHMRC. The Panel has highlighted several areas of emerging need with a requirement for capacity-building. These also embrace mathematical science, computer science and economics, for which training is not always targeted to the HMR workforce. Many undergraduates who may be attracted into these aspects of HMR do not represent the classical HMR workforce and many will propose research projects for scholarships and fellowships that fall into areas usually regarded as the remit of the ARC. There is an ongoing problem with projects at the interface between ARC and NHMRC, as noted by Griffith University: “Projects in a range of disciplinary areas including psychology, public health and other more applied areas, as well as some projects in basic medical science with potential long-term health or medical application, may fail to be considered eligible by either funding agency”.94

Option: NHMRC and ARC to review funding criteria for their discipline areas to ensure overlaps rather than gaps. Given the importance of HMR, the sector should benefit from overlaps in funding from agencies in discipline areas rather than contend with funding gaps. Specific discussions around mathematics, computer science and economics as they may apply to HMR are required between these agencies. The specific barriers to application eligibility should also be revised to ensure synergy rather than competition.

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<th>Implementation Tasks</th>
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<th>Timeframe</th>
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<tbody>
<tr>
<td>8e.1 Evaluate the optimum spread of training awards and fellowships within NHMRC People Support Schemes to address the need for capacity-building.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>8e.2 Support capacity-building in key enabling areas such as genomics, bioinformatics, biostatistics, health economics, health services research, and Indigenous health research, led by universities and supported by key research granting agencies (e.g. NHMRC and ARC).</td>
<td>Universities, NHMRC, ARC</td>
<td>2014–15</td>
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<tr>
<td>8e.3 Review NHMRC and ARC funding for respective discipline areas and ensure there are overlaps, not gaps.</td>
<td>NHMRC, ARC</td>
<td>2014–15</td>
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</tbody>
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94 Stakeholder feedback on SRHMRA Consultation Paper, Griffith University.
4.3 Streamline Competitive Grant Processes

**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.

### 4.3.1 Introduction

NHMRC funding is deployed across various schemes and research areas, and is largely administered through universities and MRIs (Exhibit 4.5). The suite of grants offered by NHMRC currently comprises six different People Support awards,95 and three research support schemes (Project Grants, Program Grants and Development Grants), plus a range of other schemes—an infrastructure support scheme (the National Health Research Enabling Capabilities scheme), the Centres of Research Excellence scheme, a suite of Strategic Awards (currently six), and the NHMRC Partnerships for Better Health program.

**Exhibit 4.5**

**NHMRC funding is deployed across various schemes and research areas, and is largely administered through universities and MRIs**

**NHMRC Expenditure**

$\text{m}$ and $\%$ Mix of Total Expenditure

<table>
<thead>
<tr>
<th>Year</th>
<th>Infrastructure</th>
<th>Other Research Programs</th>
<th>People Support Schemes</th>
<th>Project Grants</th>
<th>Health Services</th>
<th>Public Health</th>
<th>Clinical</th>
<th>Biomedical</th>
<th>University</th>
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<tbody>
<tr>
<td>2011</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>45%</td>
<td>32%</td>
<td>13%</td>
<td>27%</td>
<td>72%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Notes: 1. Mostly equipment and infrastructure grants not allocated to a field of research

Source: NHMRC data, 2012

---

95 Research Fellowships, Practitioner Fellowships, Career Development Fellowships, Translating Research into Practice (TRIP) Fellowships, Early Career Fellowships and Postgraduate Scholarships.
In July 2009, NHMRC changed to a new electronic research grant management system (RGMS) and further development of the system occurred over the following year or so. The current RGMS is comprehensive and provides well-documented and defensible outcomes. However, there are still some areas that could be changed to streamline the competitive grant process and redress a number of issues, as outlined below.

The grant management process should therefore be streamlined with four objectives:

1. reduce the burden on the applicant
2. reduce the number of uncompetitive applications submitted and reviewed
3. streamline the evaluation process and criteria
4. ensure that high-risk/high-reward research is still supported.

4.3.2 Streamline NHMRC Grant Application Processes

RGMS allows researchers to maintain a CV, enter and submit grant applications, and manage their grants online. Researchers have provided feedback on the burdensome nature of the NHMRC assessment processes, difficulties with recent changes in IT platforms, and the growing burden on reviewers.

 Issue: The grant application process is complex and time-consuming for applicants. The NHMRC review process is comprehensive, with complex requirements for both applications and their evaluation. The application forms are detailed, submission requires live internet access and the submission process is complicated with, as expressed by researchers, excessive and unnecessary duplication of documents. An enormous amount of time and effort is required on the part of researchers when lodging grant proposals—time which could be more usefully spent doing research. While calls for a more simplified system increase, paradoxically the complexity of the application process also seems to increase.

“Australian researchers have been estimated to spend 25% of their time applying for (and reviewing) grants: in 2009, 180 years of researcher time was spent in applying for NHMRC research grants alone.

Victorian Government

Option: Redesign grant application e-forms to request only the key evaluation criteria for the category of grant being applied for. The NHMRC grant application processes should be reviewed to ensure that:

• data required for project grant evaluation is simplified down to key elements, and the e-forms indicate and request only the data actually required for each application type, and only provide those data in the material made available to reviewers;

• budget requests are simplified by considering quanta without specific salary levels (e.g. multiples of a fixed funding amount without specific budget justification details or discrimination between salaries and other expenditure); and

• the system moves away from requiring lengthy internet access to a process where applications can be largely completed offline and uploaded later.
4. Maintain Research Excellence

**Issue:** The NHMRC grant application system is not user-friendly or efficient. The RGMS system has never been particularly user-friendly, and has received substantial and sustained criticism from researchers, largely because of issues of inadequate computing infrastructure. However, criticisms of the application process itself have included statements that it is counter-intuitive, difficult to navigate, repetitious, tedious, and poorly integrated. Furthermore, constant changes to the funding schemes, application forms, and RGMS database have created inefficiency and frustration for researchers. In contrast, the ARC’s Grant Application Management System, although not without its own problems, is seen to be more efficient and user-friendly, as are electronic grant application systems in a range of other countries. The ARC system is specifically an application portal rather than an entire grants administration system.

**Option: Improve RGMS and harmonise with the ARC system.** NHMRC should continue to improve the functionality of RGMS for applicants and reviewers, preferably in consultation with end-users, and should ensure that it is supported by adequate computing hardware and an efficient web interface. As many researchers apply for grants from both NHMRC and ARC, unifying the ARC and NHMRC databases for recording personal researcher information could save time, avoiding the duplication of data input. At a minimum, the two systems should share a common CV form so that researchers do not need to update their CV in two places.

> “... two largest are the grants programs operated by the ARC and the NHMRC. Each requires the entry of significant amounts of information in a grant application. (There is scepticism in the research community about whether all the information submitted is relevant to the assessment process). Even where the applications are not similar, researchers who make applications to both agencies need to be familiar with both systems. Adoption by the two agencies of similar applications processes and the same grants administration system would significantly reduce the workload of researchers seeking grants. It would also reduce the cost associated with maintaining and further enhancing the system to improve performance and usability ...”

**Research Australia**

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>9a.1 Redesign, simplify and streamline NHMRC grant application forms to include only what is essential for assessment against the selection criteria within the paperwork provided to external assessors.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9a.2 Harmonise CV content between NHMRC RGMS, ARC systems and other key national funding agencies to ensure a single uniform CV is required for all project-based applications.</td>
<td>NHMRC, ARC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

### 4.3.3 Simplify NHMRC Grant Assessment Processes

There has been an annual increase in the number of applications submitted to NHMRC for over 10 years. Within the Project Grant scheme alone, this resulted in the submission of almost 4,000 Project Grants in the round of applications for funding commencing 2012, an average increase of 7% p.a. over the last ten years (Exhibit 4.6). While funding availability did increase following the implementation of the 1998 Wills Review, this has levelled, whereas application numbers continue to increase. This places a severe burden on the research community nationally and internationally to act as reviewers for such applications. Submissions to the Review suggested that the implementation of RGMS has added to the burden of the review process. This may ultimately place at risk the capacity to prioritise appropriately for funding those applications likely to have the greatest impact on health. Success rates have remained at an average of about 23% over the last decade.
**Exhibit 4.6**

Applications for NHMRC Project Grants have grown at 7% p.a. over the last 10 years, while success rates have remained around ~23%.

**NHMRC Project Grant Applications by Number of CIs on Grant**

<table>
<thead>
<tr>
<th># Applications</th>
<th>CAGR 01-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>931</td>
<td>7%</td>
</tr>
<tr>
<td>616</td>
<td></td>
</tr>
<tr>
<td>654</td>
<td></td>
</tr>
<tr>
<td>986</td>
<td></td>
</tr>
<tr>
<td>947</td>
<td></td>
</tr>
<tr>
<td>992</td>
<td></td>
</tr>
<tr>
<td>1,194</td>
<td></td>
</tr>
<tr>
<td>1,299</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>3,379</td>
<td></td>
</tr>
<tr>
<td>798</td>
<td></td>
</tr>
<tr>
<td>1,282</td>
<td></td>
</tr>
<tr>
<td>1,299</td>
<td></td>
</tr>
<tr>
<td>23%</td>
<td></td>
</tr>
<tr>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>23%</td>
<td></td>
</tr>
<tr>
<td>23%</td>
<td></td>
</tr>
</tbody>
</table>

Note: 1. CIs – Chief Investigators
Source: NHMRC data, 2012

**Issue: Increasing numbers of grant applications.** Several perverse drivers have caused this increase in application numbers, including incentives for the university sector to increase its share of NHMRC funding. There is a view among researchers that the selection process has an element of randomness, encouraging more applications in the belief that this will improve their individual chance of success. There is little to counter this trend because there is no limit on the number of applications per institution, there is no upfront charge for applying, any CI can hold up to six NHMRC Project grants and there is no penalty for lack of success. On the latter point, it is notable that of the 6521 applicants to all NHMRC schemes in 2011, 50% of applicants held no NHMRC Project Grant funding in the previous year (Exhibit 4.7), implying the possibility that a large number of applicants each year are not likely to be competitive.
4. Maintain Research Excellence

Exhibit 4.7

50% of NHMRC Project Grant applicants did not receive funding in the preceding year

Individuals Applying for NHMRC Project Grants

<table>
<thead>
<tr>
<th># Applications by Number of Grants Held by CIA(^1) in Previous Year</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3,288</td>
</tr>
<tr>
<td>1</td>
<td>1,775</td>
</tr>
<tr>
<td>2</td>
<td>768</td>
</tr>
<tr>
<td>3</td>
<td>386</td>
</tr>
<tr>
<td>4</td>
<td>197</td>
</tr>
<tr>
<td>5</td>
<td>89</td>
</tr>
<tr>
<td>6</td>
<td>18</td>
</tr>
</tbody>
</table>

% of Total (6,521) | 50% | 27% | 12% | 6% | 3% | 1% | 0%

Note: 1. CIA – Chief Investigator A and is the primary researcher on the grant application
Source: NHMRC data, 2012

A further driver for increasing grant applications in any given round is the success rate and the frequency of granting rounds. The success rate for NHMRC Project Grant applications in 2011 was 23%, meaning that on average four out of five people who applied for funding were unsuccessful for that particular application (though they may be successful in other applications or in other years). While comparable with other international granting schemes, this is not accompanied by longer grant durations or multiple rounds per year. Hence, this rate of success means that researchers must apply for multiple grants across multiple systems to ensure the continuation of their research, their career, and the careers of their team members.\(^96\) Unsuccessful applicants who must wait for one year to resubmit may be forced to abandon research careers, and to avoid this possibility, they make multiple submissions to increase their chance of success, further increasing demands on reviewers.

"The commonly held view that to obtain adequate levels of funding to undertake research in Australia requires 'multiple shots on goal' compels researchers to spend significant amounts of time away from the lab bench writing multiple grant applications each year."

Bio21 Cluster

\(^96\) For example, ‘…a survey of over 400 researchers who submitted an NHMRC Project Grant in March 2012 to ask them about their time spent preparing applications. We estimate that the 3737 grants that were submitted in 2012 cost 550 working years of chief investigator time (95% confidence interval: 513 to 589 years). Multiplying these years by the chief investigators' salaries gives an estimated annual cost of the submission process of $66 million. These very high figures demonstrate that valuable time is being wasted on the application process, particularly for those 75–80% applications that are not funded.’ Source: Stakeholder feedback to Consultation Paper, Adrian Barnett, Nicholas Graves, Philip Clarke and Danielle Herbert.
Option: Reduce the number of uncompetitive applications being submitted and reviewed. Given there are few drivers to reduce applications into the available schemes, consideration may be given to introducing a small administering institution submission fee for processing a grant application. This would address the growing costs of administering the schemes as well as encourage the applicants’ institutions to vet their applicants for competitiveness. While this may create risks for applications by new and early-career researchers, this should be mitigated by the previously proposed differentiation of selection criteria for New Investigators. By instituting a small fee, this would articulate the intent to discourage organisations from submitting large volumes of applications in the hope of receiving at least one grant. A tiered fee structure based on volume may also be considered so as to not disadvantage small organisations.

Issue: Reviewers are forced to undertake lengthy evaluation of applications which is currently a highly manual process. The work of assessors is too onerous and, with such a small pool of qualified assessors in Australia, all too frequent. This burden is particularly pertinent for international reviewers, given no fee is paid for service.

At the national level, reviewers are provided with a small set of grant applications to review, which is done in the absence of knowledge of other applications in the same round, and requires (literally) hours of thoughtful composition to provide fair assessment and objective comments to both the applicants and the committee members that have to integrate the information across the other applications in their purview … There is too much potluck and unproductive use of time.

Garvan Institute of Medical Research

Option: Streamline the evaluation process and criteria. To identify the best grants and give greater priority to merit and track record, reviewers should employ a new process with the following criteria.

- Grant Review Panels to triage applications based on significance and track record prior to seeking external reviews, to halve the total number of grants reaching final evaluation.
- Refine current criteria for selection to ensure adequate emphasis on potential for impact and ensure criteria are suitable for each of the major research areas (e.g. public health research).
- Adjust scoring to four bands—‘must fund’, ‘should fund’, ‘could fund’ and ‘not to be funded’, with the ‘could fund’ and ‘not to be funded’ culled prior to any external assessment.
- Remove the academy level of assignment to reduce the overall reviewer burden and have Grant Review Panels identify external assessors, but only for those applications passing the initial cull.
- Seek two external assessors against which the applicant can provide a rebuttal but do not require Grant Review Panel members to provide more than a score for each criterion post review of rebuttal.

Issue: High-risk/high-reward research applications are potentially unsuccessful due to their relatively low chance of success. There still needs to be recognition of high-risk applications which present an opportunity for high levels of reward, with a small proportion of dedicated funding set aside to support such research.

This system also militates against visionary applications, which often fall foul of skeptical reviewers and of committees that are not sufficiently confident (i.e. knowledgeable) to adjudicate in their favour.

Garvan Institute of Medical Research
4. Maintain Research Excellence

Option: Set aside a small portion of funding towards high-risk/high-reward research. The Panel suggests increasing the number of Marshall and Warren Awards to approximately 10 each year for high-risk/high-reward applications. Responsibility for this should remain with Grant Review Panels who would be expected to rank and then selectively assess unfunded applications based on their significance/potential for impact.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>9b.1 Streamline evaluation criteria through a process of elimination and assessment including having Grant Review Panels triage against significance and track record prior to seeking external reviews.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9b.2 Refine current criteria for selection to ensure adequate emphasis on potential for impact and ensure criteria are suitable for each of the major research areas (e.g. public health research).</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9b.3 Adjust scoring to four bands—‘must fund’, ‘should fund’, ‘could fund’ and ‘not to be funded’, and cull the ‘could fund’ and ‘not to be funded’ prior to any external assessment.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9b.4 Remove academy level of assignment to reduce the overall reviewer burden and have Grant Review Panels identify external assessors, but only for those applications passing the initial cull.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9b.5 Seek two external assessors against which the applicant can provide a rebuttal but do not require Grant Review Panels members to provide more than a score for each criterion post review of rebuttal.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9b.6 Increase the number of Marshall and Warren Awards to approximately 10 p.a. to identify the high risk/high-return applications. This could remain a task dealt with by Grant Review Panels with ranking based around significance of grants outside the funded rank.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

4.3.4 Move to Longer Quanta Grants

Project grants range in possible duration from one to five years; however, most applications tend to apply for and receive three years of funding, which results in the vast majority of competitively funded HMR in Australia being driven by a three-year funding cycle.

Issue: Short project grant cycle creates inefficiencies and career insecurity. The fundamental nature of HMR has changed in the last decade and many research projects are now quite complex, often involving a consortium of national and international researchers, and a suite of different technologies over several laboratories. What was appropriate a decade or more ago in terms of Project Grant duration—three years—is now only adequate for a limited number of grants. Typically, a new project in the current research environment may take the first year just to bring key stakeholders together, establish staffing and techniques, and gain significant momentum to start producing meaningful results. The second year is spent on writing research papers for publication in order to achieve sufficient track record to ensure continued funding in the next three-year cycle. Then, after two years, researchers must commence applying for their next grant, taking a significant amount of time and attention away from their project. Considerable time is also spent on strategic planning and on contingency planning. The final year entertains a debilitating element of uncertainty as researchers wait to know whether they have been successful in receiving further funding, and the stability of projects can be disrupted.
Short-term funding makes it difficult for research institutes to retain people of talent, especially those who are at the beginning of their research career. As a result, researchers spend too much time trying to secure their future career, rather than focusing on delivering high-quality research. In addition, it makes it difficult to plan and provide for medium to large infrastructure requirements. MRIs in particular need sustainable funding to provide access to state-of-art technologies and high-calibre people.

**Option: Move to mostly five-year NHMRC Project Grants.** The Wills Review recommended providing five-year Project Grant funding, and while this has been allowable for some time, it has not been broadly adopted. The proportion of grants funded for one through to five years currently varies between biomedical, clinical, public health and health services research. Prescribing five years for all grants is, of course, not sensible, particularly if a project only requires one or two years. Hence, not all grant applicants would be expected to apply for funding for a five-year term, particularly for research requiring fast turnaround times such as informing policy.

“To ensure that Australia builds and maintains a vibrant HMR workforce, the duration of most grants should increase to a minimum of 5 years. Students, researchers and clinicians will be attracted to HMR if it is seen as stable and not a gamble in terms of their careers. The current HMR workforce invests considerable time and funds in preparing research grants applications with decreasing success rates.”

The Australian Society for Medical Research

Five-year Project Grants would bring greater career security that would assist in stabilising and strengthening the workforce, and also leading to productivity increases both through less staff turnover and less time spent on grant application and administration matters. It would simultaneously encourage high-quality, innovative research, rather than incremental advances in knowledge, because the five-year timeframe would not demand immediate and low-impact outcomes. While this was a major issue highlighted by many submissions to the Review, the question is why this has not occurred, given the apparent lack of barriers to applications for five-year funding. This is likely to be the way in which grants are assessed, for two main reasons.

- It is more difficult to predict the outcomes over a five-year period and hence such applications may be viewed as having riskier feasibility profiles.
- Grant Review Panels may fear the consequences on overall success rate within the scheme of a significant shift to five-year projects.

The Review investigated the possible consequences on workforce, regional distribution and research areas supported of a substantial increase in the percentage of five-year Project Grants via retrospective analysis of previous NHMRC Project Grant rounds. Under a conservative estimate that the Project Grant budget were to remain at 2012 levels, it is estimated that while there would be a smaller number of grants awarded and possibly a lower success rate, the number of researchers who would continue to be supported would remain the same (Exhibit 4.8). In moving from largely three-year to five-year grants, there are also implications for the NHMRC Project Grant funding budget that would need to be managed to effect the transition until a steady state is reached by 2018. It should be noted that it is difficult to determine the impact of five-year grants on the number of applications submitted, and hence the impact on success rates are high-level estimates.
Exhibit 4.8

Five-year grants would reduce total grants awarded each year but would stabilise the research workforce

**Five-Year Grants Scenario**

2018 Steady State

<table>
<thead>
<tr>
<th></th>
<th>Status Quo</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ New Grants ($m)</td>
<td>140</td>
<td>83</td>
</tr>
<tr>
<td>Each Year</td>
<td>757</td>
<td>450</td>
</tr>
<tr>
<td># of New Grants</td>
<td>416</td>
<td>416</td>
</tr>
<tr>
<td>Each Year</td>
<td>2,248</td>
<td>2,248</td>
</tr>
<tr>
<td>$ Total Project</td>
<td>185</td>
<td>185</td>
</tr>
<tr>
<td>Grant Budget ($m)</td>
<td>555</td>
<td>925</td>
</tr>
<tr>
<td>Total # of Grants</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>in Portfolio</td>
<td>5,202</td>
<td>5,202</td>
</tr>
<tr>
<td># Researchers</td>
<td>925</td>
<td>555</td>
</tr>
<tr>
<td>Supported</td>
<td>5,202</td>
<td>5,202</td>
</tr>
</tbody>
</table>

Notes: 1. Assumes proposed changes implemented in 2013, fixed project grant budget (i.e. capped at 2012 levels of $418m), grant applications grow at 5% p.a., and average of 1.3 grants per CIA (based on 2011 historical data)

Source: NHMRC data, 2012; Pacific Strategy Partners analysis

The impact of moving to five-year grants is likely to ensure that the best grants will be funded and be of sufficient duration to deliver impact. Graves, Barnett and Clarke, using a statistical analysis of randomness, have concluded that the capacity for the current system to accurately identify the best research grant applications within the NHMRC processes was confined to the top 9% of grants. The impact of the transition is unlikely to have a significant impact on funding administered by research area, institution type and geography (Exhibit 4.9).

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97 N Graves, AG Barnett & P Clarke, ‘Funding grant proposals for scientific research: retrospective analysis of scores by members of grant review panel’, *British Medical Journal*, 2011, 343:d4797; URL: http://www.bmj.com/content/343/bmj.d4797.
Exhibit 4.9

Five-year grants would not significantly alter the research distribution by area, institution or state

Five-Year Grants Scenario
# New Grants Administered
2018 Steady State

By Broad Research Area

<table>
<thead>
<tr>
<th>Health Services</th>
<th>Public Health</th>
<th>Clinical</th>
<th>Biomedical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status Quo</td>
<td>757</td>
<td>31%</td>
<td>56%</td>
</tr>
<tr>
<td>Scenario</td>
<td>450</td>
<td>8%</td>
<td>57%</td>
</tr>
</tbody>
</table>

By Admin Institution

<table>
<thead>
<tr>
<th>University</th>
<th>Other MRI</th>
<th>Status Quo</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>77%</td>
<td>21%</td>
<td>757</td>
<td>450</td>
</tr>
<tr>
<td>75%</td>
<td>22%</td>
<td>5%</td>
<td>3%</td>
</tr>
</tbody>
</table>

By State

<table>
<thead>
<tr>
<th>VIC</th>
<th>NSW</th>
<th>QLD/SA</th>
<th>Other</th>
<th>Status Quo</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>7%</td>
<td>44%</td>
<td>12%</td>
<td>450</td>
<td>450</td>
</tr>
<tr>
<td>8%</td>
<td>8%</td>
<td>48%</td>
<td>8%</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Notes: 1. Assumes proposed changes implemented in 2013, fixed project grant budget (i.e. capped at 2012 levels of $418m), grant applications grow at 5% p.a., and average of 1.3 grants per CIA (based on 2011 historical data)
Source: NHMRC data, 2012; Pacific Strategy Partners analysis

Option: Administer grant budgets in quanta. Grant funding could be provided in quanta rather than as a variable budget line, as is current practice. A quanta approach is used within the NIH system with applicants allowed to request a specific number of quanta. For example, a funding quantum might be $50,000 p.a. and an applicant may request a four-quanta grant based upon the proposed project. The advantages of a quanta approach to funding with minimal budget justification include:

- reduced paperwork during the application process
- reduced assessment time during grant review
- a capacity to more accurately forward-project budgets from the NHMRC MREA
- greater alignment of researcher salary levels between NHMRC and research organisations.

For example, a simplified budget justification would provide an indicative split of expenditure, allowing GRPs to decide only on a number of quanta (e.g. a four-quanta grant with one quanta representing $50,000 p.a.) based on the number of people needed for the project and the nature of their work (near clinical research, wet lab research, dry lab research). Specific details of local salaries then remain the concern of the employer and employee rather than the NHMRC. Limits may have to be set for the range of quanta that can be requested and the scale of a single quantum. While moving to five-year standard quanta grants (assuming an average total value of $200,000 p.a.) is likely to reduce the number of grants awarded per year and possibly funding success rates, the total workforce supported is likely to remain consistent and more stable (Exhibit 4.10).
**Exhibit 4.10**

Provision of quanta funding would also reduce the number of grants awarded each year but would stabilise the workforce

**Five-Year Standard $200k Grants Scenario**

2018 Steady State

<table>
<thead>
<tr>
<th></th>
<th>Status Quo</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>$ New Grants ($m) Each Year</strong></td>
<td>140</td>
<td>83</td>
</tr>
<tr>
<td><strong># of New Grants Each Year</strong></td>
<td>757</td>
<td>416</td>
</tr>
<tr>
<td><strong>$ Total Project Grant Budget ($m)</strong></td>
<td>416</td>
<td>416</td>
</tr>
<tr>
<td><strong>Total # of Grants in Portfolio</strong></td>
<td>2,248</td>
<td>2,080</td>
</tr>
</tbody>
</table>

**Average Annual Grant Size ($k)**

<table>
<thead>
<tr>
<th></th>
<th>Status Quo</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>$ New Grants ($m) Each Year</strong></td>
<td>185</td>
<td>200</td>
</tr>
<tr>
<td><strong># of New Grants Each Year</strong></td>
<td>555</td>
<td>1,000</td>
</tr>
<tr>
<td><strong>$ Total Project Grant Budget ($m)</strong></td>
<td>22%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Total # of Grants in Portfolio</strong></td>
<td>5,202</td>
<td>5,202</td>
</tr>
</tbody>
</table>

Notes: 1. Assumes proposed changes implemented in 2013, fixed project grant budget (i.e. capped at 2012 levels of $418m), grant applications grow at 5% p.a., and average of 1.3 grants per CIA (based on 2011 historical data)

Source: NHMRC data, 2012; Pacific Strategy Partners analysis

### Implementation Tasks

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>9c.1 Increase the length of Project Grants to five years other than by requested exception (e.g. requests for one-year or two-year pilot studies, such as intervention trials). The target should be in the order of 85% of Project Grant applications as five-year grants.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>9c.2 Introduce quanta grant budgets, with a quantum of $50,000 p.a. The applicant would then propose a quanta level appropriate for the project and the panel would assess this against the budgeted resourcing and nature of the research.</td>
<td>NHMRC</td>
<td>2014–15</td>
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</table>
4.4 Rationalise Indirect Cost Funding for Competitive Grants

**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.

There are six major cost components in the conduct of research:

1. salaries (researchers, technicians, PhD students, etc)
2. laboratory maintenance and operational expenditure (consumables and laboratory supplies, minor equipment costs, access charges for equipment, animal house costs, etc)
3. facilities maintenance (rent, electricity, heating, air-conditioning, cleaning, waste removal, facilities management, etc)
4. administration costs (costs for salaries of administrative staff, IT support, business development offices, financial management, human resources and OH&S)
5. building construction costs
6. 'core' shared large equipment costs.

From a research funding perspective, however, costs are usually grouped into three major categories:

1. direct research costs (items 1 and 2), met by project-targeted grants
2. indirect research costs, also known as 'infrastructure support costs' or 'research support costs' (items 3 and 4)
3. capital costs (items 5 and 6).

Funding to cover research indirect and capital costs come from diverse sources and through diverse mechanisms, depending on where the work is conducted and which research agencies are funding the work. The costs associated with these categories can vary widely between research agencies, especially where research facilities are shared, where 'in-kind' or 'administration' cost-allocation arrangements are made, or where research and teaching overlap (e.g. in universities). Indirect costs can vary considerably as a proportion of the direct costs of the research: for example, 'wet' laboratory-based research programs are typically much more expensive than 'dry' office-based research programs involving desktop research or computer modelling.

“Independent research institutes are often affiliated with one or more Universities which may be accompanied by various arrangements that underpin staffing and flows of funds including infrastructure support. While these may be of mutual benefit, the specific relationship between the amounts of research funds attracted, the research being conducted and the infrastructure support provided, can become blurred. Further, claimant institutions may be able to utilise various administrative mechanisms to maximise advantage from the current funding schemes, which leads to the potential for cross- or double-funding of infrastructure from Commonwealth and State sources.

Department of Health Western Australia
When researchers at universities, MRIs and hospitals receive external grants from NHMRC, ARC, and sources such as philanthropic trusts, the funding usually only covers the direct research costs and does not cover indirect costs. Funding for indirect costs may be covered by two other major Australian Government funding schemes:

- Research Infrastructure Block Grants (RIBG) and the Sustainable Research Excellence in Universities (SRE) scheme, determined in part by the scale of research and postgraduate teaching activity, funded by DIISRTE, and provided exclusively to support university-based research
- the Independent Research Institutes Infrastructure Support Scheme (IRISS), funded by the Department of Health and Ageing (DoHA) and provided as a fixed fraction of direct research funding from NHMRC grants, with funds appropriated directly into MREA and administered by NHMRC.

“The research infrastructure funding landscape is complex. There are a myriad of programs administered by the Australian Government (e.g. IRISS, SRE, RIBG). State governments also fund a range of programs (e.g. in NSW, the Medical Research Support Program for MRIs and the Capacity-building and Infrastructure Grants Program for population and health services research groups). The NSW Health and Medical Research Strategic Research consultations identified that deficiencies in research infrastructure funding undermines the long-term interest of the research community by taking time from the main business of research and through impeding cross-sectoral collaboration. Further, differences in levels of infrastructure support (for universities, MRIs and health services) are considered by some to be divisive.

NSW Ministry of Health

Private and public hospital researchers are ineligible to access funding for indirect research costs through any of the above-mentioned schemes. If research support costs are provided by the researcher’s employing institution, it becomes an expense for that institution, which may otherwise have been put towards healthcare expenses. This is one of the primary reasons why healthcare institutions are reluctant to provide time to their health professional staff to conduct research. As a result, hospitals typically rely on academic staff holding conjoint appointments with universities or MRIs, with the associated institution nominally administering the grant and hence receiving the indirect research support funding, which may or may not find its way to the institution (i.e. hospital) where the research is actually conducted.

The major issue impeding translational clinical research at a research and teaching hospital like the Women’s is the lack of funds for indirect research costs, also called infrastructure costs. Hospitals have to provide resources for research such as staff time, pathology etc, access to patients and potentially extra care and diagnostic/pathology components of care (especially for clinical trials) and ethics approvals…There is no financial compensation for a hospital like that received by universities and independent MRIs for these services. The cost of these services comes essentially from the operating or service funds of the hospital … This is unfair and unjustifiable and a hindrance to translational research towards better patient outcomes and experiences.

Royal Women’s Hospital in Melbourne
For MRIs, the Association of Australian Medical Research Institutes (AAMRI) has estimated that indirect research costs are, on average, around 60 cents per direct research dollar and are comprised of laboratory costs at 25 cents, administrative costs at 20 cents, and building and facility costs at 15 cents (Exhibit 4.11). Actual costs of research in universities are not as well understood in aggregate, but are likely to be similar. Universities should also expect and receive explicit funding for indirect research costs of at least 60 cents on the same basis as all other research bodies.

While the Government has taken steps to alleviate this shortfall through the block grant schemes such as Research Infrastructure Block Grants (RIBG) and Sustainable Research Excellence (SRE), funding still falls well short of the real direct and indirect costs to the recipient. In terms of indirect costs, funding awarded under grant schemes does not cover, for example, infrastructure maintenance and research support services. Universities are, therefore, responsible for funding the gap between the amount awarded through the funding process and the true cost of undertaking the research from other revenue streams.

Universities Australia

Exhibit 4.11

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 RIBG
  - MRIs receive 20c via IIRISS
  - 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
**Issue: Insufficient and inefficient funding of indirect costs.** A number of significant problems stem from this complex system where the direct research costs (salaries/consumables) are paid by one agency and the indirect research costs are paid for by another agency (or perhaps several agencies) and, if provided at all, are provided inconsistently across direct cost providers and at a level inadequate to meet the actual indirect cost of the research. These problems have been commented on by most reviews touching the sector over the last decade including the 1998 Wills Review, the 2004 Grant Review, the 2008 Bradley Review, the 2008 Cutler Review, and the 2009 Bennett Report. Despite the many recommendations over the last 15 years (some of which have been implemented, but most of which have not), significant problems still exist with the funding of indirect costs.

The Australian Government’s response to the Bradley and Cutler Reviews was encapsulated in its Powering Ideas initiative, released with its May 2009 Budget, where it stated that it would progressively address the gap in funding for indirect research costs, starting by augmenting the RIBG scheme with the new SRE initiative. However, significantly, this scheme is only for universities and will make the relative position of MRIs and healthcare institutions worse. The prospective system will maintain three unintended consequences for the HMR sector:

- winning competitive grants will create budget problems for the most successful MRIs and, until indirect costs are fully covered, for the universities
- hospitals will have a major disincentive to win research projects, particularly those facing cost pressures from the health reforms
- institutions or researchers will maintain artificial university relationships simply to access indirect cost support.

The current system is also inequitable, with MRIs provided with IRIISS indirect support funding of 20 cents per dollar of research grant funding. Universities are eligible to apply for funding under the SRE measure combined with support from the RIBG scheme, which was recently revised (October 2012). Until the recent budget cutbacks, universities were expected to get up to 30c for indirect costs in 2013, with an increase to about 45c in 2016; however, this is no longer expected. In contrast to universities and MRIs, hospitals receive close to no indirect cost support funding. As a result of these inequalities, researchers applying for grants may end up doing so through a different administrative institution.

> This situation not only entrenches inequity, it presents unwelcome and distracting challenges for MRIs in patching together indirect funding support from a range of government sources. The lack of full funding for research also creates the necessity for MRIs, in particular, to seek philanthropic support for indirect costs.

Association of Australian Medical Research Institutes

In short, the current system of indirect research cost funding is inequitable and impedes research excellence. There are considerable disparities in what the various types of research institutions receive and in their various financial and taxation obligations. Indirect cost support schemes also vary across state and territory jurisdictions, further confusing the actual level of indirect cost support being provided. To create funding equity among the various types of research institutions, and improve the research effort overall, this situation should be resolved as soon as possible, preferably through provision of indirect costs for all competitively funded research and from a single agency.

Option A: Staple indirect cost of funding to NHMRC competitive grants. The most elegant option, recommended by the 2004 Grant Review, is to staple indirect cost funding to NHMRC competitive grants regardless of the receiving institution. This is somewhat problematic, however, as it would require:

1. Moving a proportion of the DIISRTE budget to NHMRC for grants to universities;
2. Moving a proportion of state and territory budgets from their HMR schemes to the NHMRC for grants to MRIs (and fully funding);
3. Moving a proportion of the DoHA budget to NHMRC for grants to hospitals (and fully funding); and
4. Implementing systems to ensure that indirect cost funding is spent as intended across these institutions.

Additionally, this option would discourage seeking funds from non-NHMRC sources as no indirect costs would be provided for such grants. The experience of the last decade is that reforms with so many stakeholders are difficult to achieve, even with strong executive endorsement.

“The adoption of a unified system of infrastructure funding at the Commonwealth level linked directly to research grant income could rectify some of the current issues of eligibility and incentives, and will also lead to a more transparent system of national infrastructure funding. This will also assist State Governments in their consideration of such funding, and will be important in the future when the TTR component in the national pricing framework comes into effect.”

Department of Health Western Australia

Option B: Provide indirect cost top-up funding to 60c per research dollar. A more pragmatic option, and the one recommended by the Panel is to separate out indirect cost support for universities and other researcher organisations. The system would be selective with a focus on institutions delivering excellent research and contributing to other proposed reforms.

For non-university research institutions, it is envisaged that these organisations could apply to be accredited for NHMRC indirect cost funding for up to 60 cents in the dollar of all competitively awarded national and international grant funds. NHMRC would continue to accredit institutions as eligible to apply for grants and to receive indirect funding with successful grants. This would include an additional requirement for audited accounts to be made publicly available.

Agreements would need to be made with those states and territories with MRI infrastructure schemes to redeploy their current indirect support funds to other agreed HMR uses. The hospital funding agreement for research would also need to allow for NHMRC indirect cost payments.

University institutions would also receive top-up funding up to 60 cents in the dollar of competitive grants, but should be funded via existing mechanisms such as the RIBG scheme. Clear guidelines for appropriate use of indirect funds would need to be developed, with retrospective spot checks on adequacy and use of indirect cost funds. The pledged increases in indirect costs for research performed within the university sector should be honoured and supplemented with additional funding to reach 60c in the dollar.

“The present arrangements for supporting research infrastructure costs are unsatisfactory. A simple transparent funding basis is needed, which provides equitable support regardless of where the research is undertaken, would be preferable to the present arrangements, and would remove incentives for artificial arrangements and "gaming" the system.”

The Group of Eight Limited

99 It is possible that shifting to grant administration via hospitals would be inefficient and may drive separation rather than integration of research effort.
## Implementation Tasks

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<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>10.1 For non-universities: continue to accredit institutions as eligible to apply for grants and to receive indirect funding with successful grants, including an additional requirement for audited accounts to be made publicly available.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>10.2 For non-universities: provide all institutions that receive competitive research funding, but are not eligible to receive funding under the RIBG scheme, with indirect top-up funding, starting with 40 cents in 2014–15 and building to 60 cents by 2019–20, based on the dollar value of competitive NHMRC national and international competitive grants. Make payments for indirect research costs to institutions based on and timed with aggregate competitive grants won.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>10.3 For non-universities: develop clear guidelines for appropriate use of indirect funds.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>10.4 For universities: provide university institutions through the RIBG scheme with indirect top-up funding for institutions that receive competitive research funding, starting with 40 cents in 2014–15 and building to 60 cents by 2019–20, based on the dollar value of competitive NHMRC national and international competitive grants.</td>
<td>DIISRTE</td>
<td>2014–15</td>
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<td>10.5 For universities: conduct retrospective spot checks on adequacy and use of indirect cost funds.</td>
<td>DIISRTE</td>
<td>2014–15</td>
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<tr>
<td>10.6 For state and territory governments: once indirect costs are supported by either university schemes or by NHMRC, ensure that previous state and territory government indirect cost support is redeployed to other agreed HMR activities (e.g. people support) to avoid any ‘double dipping’.</td>
<td>NHMRC, COAG SCoH</td>
<td>2014–15</td>
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### 4.5 Build Enabling Infrastructure and Capabilities

**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.
4.5.1 Introduction

Modern HMR is a complex activity that increasingly requires support from a broad range of enabling infrastructure and facilities, including biobanks, medical imaging, simulation technologies, micro and nano biotechnologies, high-resolution physical data-gathering instrumentation (e.g. photonics), proteomics, metabolomics and genomics. Key enabling areas of analytical expertise include computational biology, computer modelling, bioinformatics, biostatistics, health economics, health services research, and cognitive science in healthcare.

As drivers of HMR, these major enabling technologies themselves require support to build assets and capability. For the most part, these enablers do not require large infrastructure to be specifically constructed, but they do require secure long-term funding, and a skilled workforce. Specifically, to retain Australia’s research competitiveness in HMR, there is an urgent need for ownership and funding of a national health-data storage scheme, reinstatement of Australia’s national large-infrastructure scheme (the National Collaborative Research Infrastructure Strategy—NCRIS) or initiation of a similar program, increased support for genomics capacity, and increased support for a national biobank platform.

“Research infrastructure is a prime determinant of Australia’s ability to undertake excellent and world leading research. Long-term support for research infrastructure can bring about transformational change in the research system, allow development of a robust research workforce and provide a buffer for risk exposures resulting from a weaker economy. It can drive competitiveness and support economic growth by increasing private and public sector productivity, diversifying means of production and creating jobs.”

Department of Industry, Innovation, Science, Research and Tertiary Education

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

Issue: No long-term funding for major infrastructure from June 2013. In assessing major infrastructure needs for Australian research and innovation, the 2008 Cutler Review made two recommendations.

1. Establish a National Research Infrastructure Committee to advise on strategic directions in funding of national research infrastructure including landmark infrastructure.

2. Ensure a sustainable research infrastructure strategy into the future, extend funding for a successor program to NCRIS for 10 years, with capital and operational support of $150m to $200m per year.\(^\text{100}\)

The Australian Government’s response to the Cutler Review was contained, inter alia, in its 10-year reform agenda, \textit{Powering Ideas}, released in the May 2009 Budget.\(^\text{101}\) This document stated that the Government would continue to invest in research infrastructure to support collaboration and give Australian researchers access to the latest technology as guided by its most recent \textit{Strategic Roadmap for Australian Research Infrastructure}.\(^\text{102}\) The \textit{Strategic Roadmap}, of which there have been a number of iterations over the last seven years, is primarily concerned with national research infrastructure at a medium to large scale likely to have a strategic impact on research in Australia and generally requiring investment in the order of $20m to $100m over five years for each capability area.\(^\text{103}\) \textit{Powering Ideas} recommended a National Research Infrastructure Council—which was established in May 2009—provide strategic advice on Australian research infrastructure investment (thus fulfilling Cutler’s first recommendation).

100 DIISRTE, \textit{Venturous Australia—Building strength in innovation} (Cutler Review), Canberra, August 2008.
103 Note, national research priority areas were renamed ‘capability areas’ in the \textit{Roadmap}. 
The first Roadmap, developed in 2006, identified the priority capabilities for investments under NCRIS. The 2008 Roadmap formed the basis for the Australian Government's 2009 Super Science Initiative funded from the Education Investment Fund. According to the 2011 Roadmap, capability areas identified in previous Roadmaps had received substantial investment through NCRIS, the Super Science Initiative and the Education Investment Fund, and facilities established under those initiatives had delivered high-quality research infrastructure services to a broad base of users, a number of which have been recognised as world-leading initiatives. However, funding under NCRIS concluded on 30 June 2011 and funding from the Super Science Initiative, which has been fully allocated for some time, will conclude on 30 June 2013. To date, there have been no announcements of additional funding for national infrastructure programs.

The conclusion of NCRIS and the full allocation of Super Science Initiative funds is a cause of concern for the lack of new investment in major infrastructure in Australia. The 2012 crisis in funding for Australia’s synchrotron,\textsuperscript{104} where a funding-continuation agreement between the Australian and Victorian Governments was only reached two months before the agreement was due to expire, highlights the need not only for funding of new large-scale infrastructure on a nationally-coordinated basis, but for long-term, dedicated operating-cost funding for extant infrastructure.

An example of the difficulties caused by the lack of long-term infrastructure funding support was highlighted by state and territory government health departments:

“A recurring difficulty … is the discontinuity of funding for both infrastructure and researchers. At an infrastructure level, there can be significant investments by the Australian Government to establish facilities but without certainty of funds for long term maintenance. A current example, relevant to health services research, is the Australian Government investment in a national network of health data linkage facilities. Funding has been provided for a four year establishment phase but just as several of these facilities have reached a capacity to provide research datasets, there is uncertainty for continuing funds. There is a clear disincentive for researchers who are submitting grant applications for a project which is not only dependent on a novel facility but is also dependent on uncertain infrastructure funding.”

Northern Territory Government Department of Health

Option: Establish a NCRIS successor program which includes infrastructure for HMR. If the current infrastructure funding program is not deemed adequate for HMR purposes, the Panel recommends the initiation of a successor program to NCRIS, as recommended by the Cutler Review, for 10 years, including capital and operational support in the order of up to $150m to $200m p.a. for key major equipment infrastructure. The recently released National Research Investment Plan commits government to considering mechanisms to provide ongoing support for major national research infrastructure (Action 8).\textsuperscript{105}

“NCRIS introduced significant changes to the investment approach in research infrastructure by buttressing the importance of planning and focusing on collaboration across sectors. Pivotal to the NCRIS program’s success was its utilisation of a strategic process as opposed to a simple competition to determine funding allocation; a fundamental focus on collaboration; accessibility to infrastructure for all Australian researchers; and its ability to fund operating costs.”

Department of Industry, Innovation, Science, Research and Tertiary Education


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<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tr>
<td>11a.1 Create an infrastructure funding vehicle that provides funding of $150m to $200m p.a. for major infrastructure and key enabling technologies, including items discussed in Recommendations 11b, 11c and 11d. Ensure Integrated Health Research Centres and other quality institutions have sufficient access to infrastructure that allows Australia to maintain and further enhance its world-class HMR standing.</td>
<td>Leadership body</td>
<td>2017–18</td>
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### 4.5.3 Accelerate Efforts to Build and Support National Patient Databases

A critical factor in the advancement of medical research and its translation to better healthcare is the ease with which data can be amassed, integrated, analysed and disseminated, both within and across research and healthcare domains. Modern HMR has seen a proliferation of technologies and instruments capable of producing unprecedented volumes of data for analysis, plus new statistical techniques for data linking, data mining and meta-surveys. Throughout the research spectrum, from nanotechnology to population health, the ability to generate, store, manage, aggregate, analyse, share, make sense of, and disseminate reports from large volumes of data is rapidly growing in importance.

The introduction of the PCEHR has the capacity to significantly change Australia’s health and medical sector. The PCEHR has the potential to greatly inform researchers on health priorities at the population (or macro) level, as well as managing the delivery of health services at the ‘micro’ or patient level … The PCEHR can be a key enabler for the introduction of personalised medicine, where it will be possible to develop personalised treatment regimes based on a patient’s medical record. It should be a future priority to ensure that the PCEHR delivers meaningful population and patient level data. This will inform the overall health budget, including strategic research directions.

Department of Industry, Innovation, Science, Research and Tertiary Education

Yet there is a gap in long-term data storage, connection and discovery infrastructure. Patient datasets, collected in the process of delivering healthcare and monitoring health of individuals, patient groups and populations over the long term, are particularly important, and HMR will be seriously hampered without dedicated long-term support for infrastructure, integrated patient data collection associated with the delivery of healthcare and a significant investment in skilled people in these areas (refer to Section 4.5). This will be particularly critical in the integration of genomics into individual patient care and the evaluation of outcomes from all forms of healthcare.

**Issue: Up-take of personally-controlled electronic health records (PCEHR) may be limited.**

As part of its 2010–11 budget, and parallel to the accumulation of disciplinary databases, the Australian Government initiated a $467m investment over two years for a national PCEHR system for all Australians who choose to register, commencing in July 2012. The Government has established the National E-Health Transition Authority (NEHTA) to oversee, inter alia, implementation of the system nationally. The Government’s e-health initiative includes three identifiers: an individual healthcare identifier; a healthcare provider identifier for individuals; and a healthcare provider identifier for organisations.

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106 Also variously called a ‘patient held electronic health care record’ (PHEHCR) or a ‘patient held electronic health record’ (PHEHR).
The advent of ‘e-health’ and personalised electronic records offers a real opportunity for improved research and monitoring of health services at the population level.

Kirby Institute

All Australians who choose to do so can register for PCEHR, with information stored and shared in a network of connected systems. PCEHR will bring key health information from a number of different systems together and present it in a single view for that individual patient. As it matures, Australians who sign up will be able to share information with healthcare practitioners, who in turn will be able to access their patients’ records to support the delivery of healthcare regardless of where and when it is needed. Individuals will also eventually be able to add to the recorded information stored in their own PCEHR.

While there is significant potential for the PCEHR scheme to greatly empower the HMR sector, this is reliant upon two critical factors: (1) a sufficiently large up-take of the scheme by patients to create a critical mass of information; and (2) the availability of this data to researchers. NEHTA has not set any targets for patient uptake and does not appear to have visibility of historical rates of uptake. The opt-in nature of PCEHR will severely limit the power of the dataset by reducing it to a small percentage of the population. A greater opportunity lost is the fact that no consideration was made in the initial development of PCEHR to request approval for access for the purposes of research at the point of patient entry. There has been successful up-take of PCEHR in the Northern Territory indigenous population, where assisted registration has resulted in over 90% of the community having their records stored online. Despite this, there is currently no upfront request for approval for the use of patient data for research, and a lack of clarity surrounding access for researchers.

Option: Improve the coverage of PCEHR data through an opt-out registration process. The PCEHR system is expected to generate a long-term return to the Australian government of $11bn, for an estimated total investment of $700m. A limited up-take of PCEHR will limit the benefits it could yield through better medicines management and a reduction in unnecessary duplication of tests and referrals. Once the utility of PCEHR is established, it should become an opt-out system, with data available to be added retrospectively from current electronic sources. The Danish system, which covers 85% of its population, demonstrates the benefit that can be attained with an opt-out model (Case Study 4.1). There is also a need for public marketing campaigns to raise awareness of PCEHR.

Issue: PCEHR data are not readily accessible to researchers. The Panel notes that a CTAG recommendation was to ensure that clinical trials could take advantage of the developing e-health system, but that progress in implementing this recommendation has been very slow. Reports from the CTAG Coordination Group indicate that while a workshop to consider opportunities that PCEHR capabilities might present for clinical trials, common issues and consistent approaches for technologies and planning, was scheduled for March 2012, it was postponed until the 2012–13 financial year ‘given that the PCEHR is due to commence on 1 July 2012’. The ability of researchers to access the data held within the system is limited by the fact that it is fundamentally a patient-controlled database, plus there will not be linkages between the government PCEHR system and various other health records and population and health databases. Thus access to the PCEHR system for researchers has not been facilitated, with consumers not afforded the option to release de-identified records for HMR.

109 See CTAG Coordination Group meetings 6, 7 and 8 reported at: http://www.innovation.gov.au/Industry/ PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Pages/default.aspx.
Data linkage has a number of advantages as a tool for health and medical research. It maximises the use of existing data sets without any further burden on the respondents. It can include the whole population under study, or very large samples, and is thus also generally cost-effective, particularly compared with the resources required to conduct a survey or special study. … There is substantial public benefit to be gained from research using linked data. This research methodology can identify evidence of cause and effect and the nature and strengths of relationships over time and across traditionally separated domains of data collection. The demand to create and provide access to linked data is growing, and the number and breadth of projects in Australia involving data linkage is expanding rapidly.

Australian Institute of Health and Welfare

Option: Facilitate and ensure researchers have access to de-identified patient data. It is clear that privacy is a key issue in the healthcare sector, but this has largely been resolved in other industries through regulation and commercial terms and could be resolved in the health sector through routine use of electronic de-identification systems. It could also be resolved through policy reform and legislative changes by the states and territories, harmonised through COAG.

While the Panel accepts that the Government's PCEHR system was not established to facilitate research endeavours, NEHTA's progress in facilitating researcher needs in the design of the system and providing researchers with access to data has not been sufficient. While unique customer identifiers are now ubiquitous in most other industries, from banking to pizza delivery, the health sector lags in its ability to leverage customer data. The Panel believes that there is an urgent need to establish a research accessible system within the next couple of years, and this should be incorporated into the agreement between DoHA and NEHTA with a specified delivery target timeframe. This will also provide significant benefits for consumer recruitment and participation in clinical trials.

The implementation of personally controlled electronic health records (PCEHR) offer the opportunity to enhance community and consumer participation in medical research and have the potential to provide data to enhance recruitment into clinical trials for areas of need such as oncology, Aboriginal and Torres Strait Island and paediatric research.

The Royal Australasian College of Physicians

The Australian Institute of Health and Welfare (AIHW) can play a key role in facilitating health data access and offering expert advice for the HMR sector. The Panel notes that AIHW was one of the first agencies to be accredited as a Commonwealth Data Integrating Authority, is seen as a trusted intermediary, and could undertake the role of facilitating access to de-identified patient and other data (e.g. mortality data) for research agencies. Researchers should also acknowledge the data source to promote wider acceptance of benefits available from leveraging patient data and a move to an opt-out registration process. NEHTA should investigate potential designs and obstacles to promote secure access to electronic records for appropriately authorised researchers and clinical trials personnel.

Issue: PCEHR platform is not optimised for research use. Research-optimised PCEHR data will require significant input from the research sector, in conjunction with systems architects, to ensure the data are fit for purpose through the use of standardised data dictionaries. Further, PCEHR currently does not have an interrogation interface. Integrated patient datasets are also required. There have been recent efforts by the Population Health Research Network to build a national network that will enable existing health data from around the nation to be brought together and made available for HMR purposes. The Network comprises a program office located in Perth, a Centre for Data Linkage located at Curtin University in Western Australia, a remote Access Laboratory located at The Sax Institute in New South Wales and a network of project participants and data linkage units located in each Australian state and territory.
Option: Develop PCEHR specifications designed for research use in collaboration with the HMR community. Optimising the PCEHR system so that it could readily be used by health and medical researchers would significantly enhance the benefits from Government investment in a national health database. Further clinical research needs should be incorporated in future versions, and NEHTA should facilitate collaboration between researchers and systems architects to design specifications and implement changes so PCEHR data can be leveraged for research. Efforts to link datasets, particularly with the Medical Benefits Scheme and PBS, should be supported, accelerated and leveraged for research use.

"Australia has one of the most comprehensive collections of population based administrative data in the world, capturing complete information about use of services including those funded through Medicare (Medical Benefits Schedule [MBS] and Pharmaceutical Benefits Scheme [PBS]), public and private hospital services and community based and residential aged care. These are supplemented by other data that are routinely collected by government agencies, including vital statistics and disease registers, adverse incident reporting systems and surveys of patient satisfaction, and by a rich array of population based cohort studies … It is essential that research uses of data are considered as an integral part of the design of new e health systems, so that these data can be linked with existing administrative data to support powerful new studies of the outcomes of clinical care.

The Sax Institute

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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>11b.1 Conduct a public education campaign to raise awareness of the importance of</td>
<td>DoHA</td>
<td>2014–15</td>
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<td>health data collection, particularly through the Personally-Controlled Electronic</td>
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<td>Health Record (PCEHR) system in the wider community, and to reassure patients that</td>
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<td>their data would be de-identified and privacy guaranteed.</td>
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<tr>
<td>11b.2 Amend the current registration process for PCEHR to an opt-out system, to</td>
<td>DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>increase the scale and power of the data and maximise the return on investment.</td>
<td></td>
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<tr>
<td>11b.3 Facilitate researcher access to patient databases, particularly PCEHR, through</td>
<td>COAG SCoH, AHPMAC, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>legislative changes by the states and territories, harmonised through the Council of</td>
<td></td>
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<tr>
<td>Australian Governments Standing Council on Health (COAG SCoH).</td>
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<tr>
<td>11b.4 Optimise patient data for research use and charge the National E-Health</td>
<td>AHPMAC, NEHTA, AIHW</td>
<td>2014–15</td>
</tr>
<tr>
<td>Transition Authority (NEHTA) with facilitating the design and implementation of</td>
<td></td>
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<tr>
<td>research-friendly data and data interfaces. Ensure management of databases for</td>
<td></td>
<td></td>
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<tr>
<td>research is conducted in a systematic approach and uses accepted procedures.</td>
<td></td>
<td></td>
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<tr>
<td>11b.5 Institute a requirement that all research using patient data must</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>acknowledge its data source to promote wider acceptance of the benefits available</td>
<td></td>
<td></td>
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<tr>
<td>from leveraging consumer data.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11b.6 Accelerate efforts to integrate datasets.</td>
<td>AIHW</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
CASE STUDY 4.1

The Danish eHealth system covers over 85% of the population and links patient data with health services across the health system

**Background.** The official Danish eHealth portal (sundhed.dk) was established in 2003 and provides access to health records, health system information and administration services for citizens, patients, healthcare professionals and researchers (through the National Patient Registry). The portal allows patients to view information such as clinician notes, referrals, test results and submit prescription forms, as well as access educational material.

As information is held on over 85% of the Danish population, the Danish Health Data Network provides a valuable dataset for researchers to conduct population-level analysis. The system is also currently implementing a Shared Medical Record containing information about an individual's current medication, National Patient Index and National Health Record. This will provide a more complete and integrated view of patient data, including vaccinations, medications and medical test results.

**Danish eHealth System Structure**

**Key Lessons:**

1. National eHealth records improve the quality of patient data available for healthcare professionals. The Danish eHealth system brings together patient data from over 110 sources to provide a comprehensive view of a patient's medical and treatment history. As of 2011, over 85% of the population had an eHealth record. It is important to manage privacy, with patients able to see who has accessed their records.

2. Providing patients access to eHealth records enables better personal healthcare management. The number of unique visitors to the eHealth portal has increased from less than 90,000 in 2003 to over 350,000 in 2012. Providing tools that allow patients to manage their healthcare and evaluate healthcare services ensures that patients take an active role in managing their own health.

3. The Danish Health Data Network provides researchers with a robust data set for research. The widespread adoption of eHealth records provides a wealth of data for research.

Source: P Doupi et al, *eHealth Strategies: Denmark*, 2010; Denmark Health: www.sundhed.dk
4.5.4 Establish Clinical Registries

Clinical registries which systematically collect information on treatments and their outcomes from hospitals, across clinical practice guidelines, are one of the most effective means of monitoring and encouraging the uptake of medical and healthcare guidelines.

Issue: Lack of national clinical registries in Australia. There are only 28 identified clinical registries in Australia which collect patient-level, health-related data (including outcomes) across healthcare sites. Furthermore, of the 28 clinical registries, only five have national coverage.\textsuperscript{110} This compares to Sweden, where more than 70 clinical registries have been developed, and over 20 of these registries have greater than 85% patient coverage. Conditions tracked in these registries represent approximately 25% of national healthcare spending.\textsuperscript{111}

Option: Establish a national clinical registry program. The Panel notes that the Australian Commission on Safety and Quality in Health Care (ACSQHC) is developing a proposal for establishment of key registries in Australia and that this would require strengthened expertise in a range of related skill areas, including clinical epidemiology, biostatistics, ethics, governance, bioinformatics and data-management, as well as data linkage infrastructure. The next step would be for data collection and feedback mechanisms to be created for clinicians on their practice and performance. This could be supported by investment in change management expertise to incentivise and support healthcare professionals to create behavioural change and adopt evidence-based practices.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>11b.7 Develop a national clinical registry program and include mechanisms to provide clinicians with feedback.</td>
<td>ACSQHC, Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

4.5.5 Develop a National Biobank Strategy and Platform

Australia has developed a wide but fragmented array of biobanks.\textsuperscript{112} These vary from small to large, and from individual collections to networked ‘hub and spoke’ or ‘multiple distributed node’ facilities. They also vary by the materials collected, approaches to coding and privacy, and access for researchers.

Biobanks play a key role in accelerating research in that they are able to provide an immediate source of ‘research ready’ material and sufficient samples to give statistical significance to medical studies. Funding for biobanks currently comes from a mix of Australian Government, state and territory government, private sector, and philanthropic sources. Biobanks increase exponentially in value as their specimens accumulate. The demand for biobank services has increased considerably over the last decade, and will continue to increase in the future as biospecimen-based research expands and as associated analytical technologies develop. It is also likely that the types of biospecimens banked will also change as technology further advances.


\textsuperscript{111} EyeNetSweden, Handbook for establishing quality registries, Sweden, 2005.

Traditionally, many population studies have been limited to epidemiological research and produce limited, if any, biological research output. However, the genomic, proteomic, metabolomic and related bioinformatics revolution in recent years has exponentially improved our understanding of the links between basic and clinical science. Realising this opportunity requires large numbers of biospecimens to provide the required power for ground-breaking study—this is where biobanks become crucial. Instead of multiple studies over time, biobanks allow researchers to acquire thousands of disease-specific biological samples and linked data within weeks. Given the appreciable time taken to accumulate large (i.e. measured in the thousands) collections of biospecimens, biobanks promise to save many years in financial and infrastructure investment and fast-track the transition from benchtop to bedside.

Cancer Council NSW

In 2009, the Australasian Biospecimen Network, which comprises groups and individuals with an interest in tissue banking, established a set of biorepository protocols to assist in the adoption of standard operating procedures for the collection, processing, and storage of biospecimens. In 2010, NHMRC published a national biobanks information paper which was developed in response to recommendation 19-2 of the joint Australian Law Reform Commission and Australian Health Ethics Committee report, *Essentially Yours: The Protection of Human Genetic Information in Australia* of 2003 which required NHMRC as well as AHMAC to review the need for a nationally-consistent approach in relation to the collection, storage, use, disclosure of and access to human tissue collections, including pathology samples and banked tissue.

NHMRC has funded more than a dozen biobanks during the period of its Enabling Grants scheme, but has decided to phase out this scheme. The NHMRC Research Committee agreed to specifically support inclusion of fees for biobanking as part of support for research costs on successful NHMRC Project Grants. That is, applicants for NHMRC Research Project Grants would be asked to include biobanking specimen access costs as a direct research cost in their application budgets. Some biobanks previously funded under the Enabling Grants scheme have been given transition funding in 2012–13 to assist them with this shift, and some have initial funding that is not due to expire until the end of 2015. NHMRC is developing an indicative schedule of acceptable biobanking fees to assist applicants in preparing their budgets, and assessment panels in reviewing application budgets. However, it is financially impractical to maintain a biobank via prospective requests for specimen access on grant applications—the outcome of which takes nine months before announcement and has a success rate historically around 20%. Australia, therefore, remains without a coherent national biobank strategy and national funding mechanism to support the long-term availability of biobank resources.

**Issue: Australia’s biobanks are fragmented, inefficient and present difficulties for access and recruitment.** The *ad hoc* and diffuse nature of the development of biobanks in Australia has led to a number of issues. First, as long-term facilities, biobanks have ongoing maintenance costs plus costs associated with facilitating access to the material stored in them, but short-term investment in the form of traditional, peer-reviewed, competitive research grants is currently the norm. This is inefficient and ultimately not sustainable—a view endorsed by NHMRC in a recent position paper on biobanks.\(^{113}\) Second, researchers wanting to access biobank information must traverse multiple institutions, and their ethics committees, to access linked biospecimens. Conversely, biobanks themselves need assistance in the development and management of policies relating to best-practice governance and access.

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The majority of Australian biobanks … are solely tissue-based, have poor linkage to medical data and very limited linkage to lifestyle data, are too small to be high-quality research-effective, and/or have not been designed as a truly open source of access.

Cancer Council NSW

Other issues faced by biobanks include: recruitment of participants; adherence to the National Statement on Ethical Conduct in Human Research (2007); consent and reconsent; data management, including issues with respect to privacy and recontact; governance arrangements; legal and regulatory compliance; and access, commercialisation and benefit sharing.

Option: Accelerate a national biobank strategy, supported by national funding and national, government-endorsed protocols. The strategic development of biobanks in Australia has implications for HMR both in Australia and globally, and has the potential to assist Australia to remain globally competitive. Well-managed, large-scale or networked biobanks, providing open access to researchers, including international collaborators, offer economies of scale that are not possible to achieve with smaller, single-focus biobanks. Denmark is one of the leaders in biobanking and its initiative to link biobanks with national registries provides a data-rich source for research. The Canadian Tumour Repository Network which is representative of a spectrum of tumour banks across Canada delivers a federated biobanking model and has aspects which would be suitable for Australia.

The Australian approach should encompass:

- a national strategy on biobanks, focused on improvement in their consistency and accessibility
- a national biobanking network with linked access (rather than one centralised biobank), but with some scale and consolidation where feasible, supported by a national platform to link biobanks together with other health and medical data sets, and consistent data standards
- accreditation of all participating biobanks through the National Association of Testing Authorities, supported by the National Pathology Accreditation Advisory Council
- NHMRC-led certification of all Australian biobanking operations to ensure each resource is fit-for-purpose and continued support for biobanks indirectly though Project Grants
- development of a biobank hub, operating at international best-practice standards, to coordinate and optimise all biobanking resources and provide researchers with a single interface for all their biospecimen and data linkage needs, and establish national data protocols and specifications
- a sustainable and long-term funding stream, with associated development of funding models to maintain such networks (e.g. block funding initially, with a longer term move to user-pays and endowment income)
- encouragement of private sector involvement, especially private pathology companies
- development of policies that strongly encourage continued partnerships between users (industry in particular) and biobanks, aimed at producing high-quality research.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>11c.1</td>
<td>Develop a national biobank strategy based on a hub-and-spoke model, to coordinate all existing or newly created specimen-based biobanks in Australia with a major focus on accessibility, standardised clinical data dictionaries, record-keeping, quality control and cost neutrality.</td>
<td>NHMRC</td>
</tr>
</tbody>
</table>
CASE STUDY 4.2

The Danish National Biobank Initiative links biobanks with national registries and provides a rich source of data for researchers

**Background.** The Danish National Biobank was established in March 2012 by The Novo Nordisk Foundation, The Lundbeck Foundation and Danish Government Programme for Research Infrastructure, with a total investment of DKK179m (~A$30m). It links national registries with key biobanks, including a large state-of-the-art 3,000sqm² national biobank. Researchers will be able to access the national biobank register¹ which links detailed medical information from the Danish health system with biological samples at participating biobanks.

**Danish National Biobank Initiative**

**Structure**

<table>
<thead>
<tr>
<th>Participating Biobanks</th>
<th>Participating Registries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danish National Biobank (~6-7m samples²)</td>
<td>Danish National Civil Registration System</td>
</tr>
<tr>
<td>Patobanken (~7m samples)</td>
<td>Danish National Patient Registry</td>
</tr>
<tr>
<td>Danish Cancer Society Biobank (~57k samples)</td>
<td>Danish Family Relations Database</td>
</tr>
<tr>
<td>DNA Biobank at Rigshospitalet (~50k samples)</td>
<td>Danish Medical Birth Registry</td>
</tr>
<tr>
<td>Clinical Cancer Biobanks</td>
<td>National Pathology Registry</td>
</tr>
<tr>
<td>Other Biobanks³</td>
<td>Other Registries</td>
</tr>
</tbody>
</table>

**Researchers**

**Key Lessons:**

1. **A national registry which links biobanks and national registers provides a powerful tool for health researchers.** The Danish National Biobank Registry links patient information in participating biobanks with patient information in participating national registers (through a personal identification number which follows Danes from birth to death), providing a wealth of information for researchers to understand key causes of disease and impact of interventions.

2. **Creating a network of biobanks linked to a national registry provides researchers with efficient access to samples.** The Danish National Biobank is part of a network of national biobanks, linked by a national registry. This combines the economies of scale of the Danish National Biobank with the satellite biobanks, allowing for efficient access.

3. **Sustainable public/private funding of a national biobank program ensures long-term access.** The Danish National Biobank is jointly funded by private foundations and the Danish government, which will contribute to establishment and operating costs for 10 years. Plans for long-term cost neutrality are important to ensure a sustainable network.

**Notes:**

1. Under Danish law, there is an ‘opt-out register’ for individuals who do not want to be part of the national register
2. The Danish National Biobank is designed to hold in excess of 15m samples
3. Other biobanks include the Neonatal Screening Biobank (~2m samples) and the Danish National Birth Cohort (blood samples from 100,000 women)

**Source:** Danish National BioBank: www.biobankdenmark.dk/; Science Nordic: www.sciencenordic.com/new-biobank-will-make-research-easier
4.5.6 Increase Support Services Capacity

Issue: Skills shortages exist in enabling technologies and analytic services. There is a tendency in Australia to ignore the fact that investment is needed in human capacity-building in enabling technologies and analytical services. We simply do not have enough people who are educated and skilled in enabling technologies in Australia and this critical shortage is limiting the benefits that are gained from our primary investment in HMR. With the surge in quantity of genomic sequencing data being generated, there is an expanding need for expertise in areas such as molecular diagnostics, bioinformatics and computational biology. Despite this, the healthcare workforce is struggling to keep pace with advances in these areas.

"Biostatistical expertise is internationally recognised as essential to assuring high-quality health and medical research and practice. The importance of statistical expertise is increasing rapidly with the growing emphasis on prevention research and evidence-based healthcare, and the capacity to collect ever larger amounts of increasingly complex data, e.g. through health data linkage. This has helped change the perception of the discipline from that of an ancillary support group to one that is central to the integrity and quality of a very high proportion of research in the clinical and population health science. In Australia, the need for biostatistical expertise far exceeds the available supply."

Biostatistics Collaboration of Australia

The inability of Australia to generate a strong workforce in enabling technologies has two self-reinforcing drivers:

- the short-term nature of research funding which precludes security of employment of people with skills in these adjunct areas (they are often attached to research projects because of mandatory requirements, or subcontracted on a needs basis making these positions the least well supported in the research system)
- the limited availability of tertiary education and training courses for enabling technologies, such as health economics, biostatistics and bioinformatics.

The lack of skilled people hampers HMR projects which may be more sophisticated and competitive with the input of enabling technologies. Australia loses many skilled statisticians and bioinformaticians to overseas employment opportunities and to other sectors (such as IT), meaning that Australian research groups are forced to either outsource analytical services or place pressure on the few skilled individuals who choose to remain.

Education and training in enabling technologies and analytical services are also needed in the field of cross-platform research to enhance the integration and development of enabling services such as bioinformatics and information technology, particularly in the fields of genomics and personalised medicine.

"Health and medical research is no longer carried out in silos — most research projects cut across traditional discipline boundaries and continents. In addition to molecular and cell biology, pathology and physiology, many require new disciplines such as genomics, proteomics and bioinformatics and/or expertise in chemistry, psychology, physics, mathematics, social sciences and ethics."

Australian Academy of Science
Option: Fund enabling technology capacity. The Australian Government needs to specifically address the increasing requirement for human capacity-building in enabling technologies. There is a need to recognise that the career structures of enabling disciplines, such as bioinformatics or health economics, require nurturing within the HMR community. The Panel also recommends that building capacity in these areas could be addressed via targeted fellowships and scholarships from NHMRC (see Section 4.2.6). This could come from priority-area budgets or general people-support budgets, as the requirements for human capacity-building will vary between priority areas. The national leadership body needs to coordinate practical and theoretical training in underpinning technology innovations and enabling bioinformatics with a focus on translational medicine, and providing a bridge between the research community and the healthcare sector.

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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>11d.1 Develop NHMRC People Support Schemes to meet capacity-building requirements in en....</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>11d.2 Coordinate efforts to build capacity in enabling technologies and analytical services wi...</td>
<td>Leadership body, universities</td>
<td>2014–15</td>
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</table>
 Enhance Non-Commercial Pathway to Impact
5. ENHANCE NON-COMMERCIAL PATHWAY TO IMPACT

5.1 Introduction

As described in detail in Chapter 2, HMR delivers significant benefits for Australians and has an essential role to play in building a healthy and prosperous nation with the world’s best health system. The benefits include not only improved health outcomes, but economic, strategic and other non-quantifiable benefits. To achieve these benefits, however, research findings must first be translated through the health system into better individual and population health outcomes. This ensures that the benefits of the research are fully realised, and justifies the continued substantial public and private investment in research. The publication of research results in academic journals is just the very beginning of research translation, and there are many activities between publication of research results and the benefits that are ultimately derived by health consumers.

The US NIH 'T1 – T4 Research Translation Framework' provides a useful taxonomy for understanding research translation because it can be applied equally to commercial and non-commercial activities (Exhibit 5.1). The framework combines both clinical and public health approaches to translating scientific discoveries into effective, evidence-based approaches to treatment, prevention and control of human disease in populations. The four phases of translation in this framework are defined as:

• T1 – from discovery research to health applications (test, interventions)
• T2 – from health application to evidence guidelines
• T3 – from guidelines to health practice
• T4 – from health practice to population health outcomes.114

114 Note, the original paper from which this schema has been adapted, designated T0 as 'Description and discovery' research. See MJ Khoury, M Gwinn & JPA Ioannidis, 'The Emergence of Translational Epidemiology: From Scientific Discovery to Population Health Impact', American Journal of Epidemiology, 2010, 172:5, p.518; URL: http://aje.oxfordjournals.org/content/172/5/517.full.pdf+html.
5. Enhance Non-Commercial Pathway to Impact

Exhibit 5.1
The NIH Research Translation Framework can be applied to non-commercial translation

NIH Research Translation Framework

Non-Commercial Research Activity

- Clinical & population studies to develop insights and potential applications
- Observational & experimental studies on efficacy of interventions
- Studies assessing implementation of guidelines in practice
- Studies assessing policy proposals
- Outcomes research
- Population monitoring


The pathway from basic scientific discovery to improved individual or population health is usually complex and not necessarily linear, often involving an iterative process with feedback loops and tangential trails which may not necessarily lead to useful outcomes. Thus a strong translational research agenda is needed to ensure that the process moves effectively and efficiently from one stage to the next—from ‘bench to bedside’ and beyond.

The translation of research through the pathway to impact is motivated by two distinct though not mutually exclusive drivers:

1. non-commercial drivers, including individual and population health benefits such as those derived from limiting the spread of diseases
2. commercial drivers such as sales of pharmaceuticals, medical devices and diagnostic services.

This chapter focuses on non-commercial pathways to impact, while the following chapter (Chapter 6) focuses on the commercial pathways. Non-commercial research may have a significant economic outcome (for example, expenses saved to consumers and governments through reduced hospitalisations), but there may not be the potential for direct financial reward as there is in commercial pathways. This means that without active intervention there is a risk of under-investment in non-commercial translation.

Four key initiatives are needed (Exhibit 5.2):
- enhance public health research
- enhance health services research
- accelerate health system innovation
- inform policy with evidence.
Exhibit 5.2

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

Types of Non-Commercial Research and Translation

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

Each of these four areas comprises various types of research that vary in focus along the continuum of descriptive to impact-oriented research. An increased focus on research and translation that delivers impact in the health system and on population health outcomes is needed. This includes preventive programs, evidence-based strategies and translational research focused on implementation of evidence, plus change management programs to translate findings. It is also vital that health professionals, managers and policy makers are empowered with the right knowledge to facilitate these types of improvements. Evaluative research on areas such as public health programs and preventive measures, comparative cost-effectiveness of interventions, guideline adoption and health policy provides an important base of knowledge to facilitate translation. Naturally, this must be supported by more fundamental knowledge of population health, the health system, clinical practices and social and behavioural attributes.

Non-commercial translation tends to move slowly through the health system, particularly at the point of implementation. Indeed, there is evidence to suggest that a great deal of HMR stops just short of successful, widespread implementation. For example, as referenced in Chapter 2, although it has long been known that hand washing by clinicians is a key to reducing cross-infection rates, many healthcare settings, including leading hospitals, do not have rigorous hand-washing programs with systematic education and auditing of compliance. Hence, to deliver real impact in the health system, there is a need for greater emphasis on research and translation that is evaluative and impact-oriented.

With non-commercial translation, the economic benefits primarily come through cost savings, or better consumer outcomes for the same expenditure, rather than profits. Largely as a consequence of having limited commercial prospects, public-good innovations struggle to find a champion to drive the process through to effective up-take. They thus also struggle to find financial support to pay for translation activities which are often through expensive clinical trials, and knowledge transfer through dissemination, training and education. In such instances of market failure, financial support from government is required to ensure that the full potential of HMR can be unlocked.
5.2 Enhance Public Health Research

Recommendation 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.

Public Health Overview. While the focus of primary and clinical care is on treatment at the individual level, public health is aimed at the population level (and is thus often called population health) although the ultimate impact is, of course, on individuals. Public health activities include health promotion and preventive health activities, population-based interventions to reduce rates of disease, accidents and disability, and assistance in recovery. There is a greater focus on preventive measures rather than cure and treatment, and this often provides the most cost-effective approach to improving health outcomes. Public health programs have significant capacity to have positive impacts on a very broad cross-section of the population.

Public health has a strong track record of success in Australia, as demonstrated by a broad range of large-scale achievements—for example, smoking prevention, reduction and cessation; iodine and fluoride supplementation; screening for breast and prostate cancers; control of hydatid disease, malaria, dengue and tuberculosis; vaccination for prevention of epidemic childhood infections; compulsory seat belts, vehicle design and road safety campaigns; SIDS information; and safe-sex campaigns.

"Well-planned prevention programs have made enormous contributions to improving the quality and duration of our lives ... In the 1950s three-quarters of Australian men smoked. Now less than one-fifth of men smoke. As a result, deaths in men from lung cancer and obstructive lung disease have plummeted from peak levels seen in the 1970s and 1980s. Deaths from cardiovascular disease have decreased dramatically from all-time highs in the late 1960s and early 1970s to today. Road trauma deaths on Australian roads have dropped 80% since 1970, with death rates in 2005 being similar to those in the early 1920s."

National Preventative Health Strategy, June 2009

While such programs have a high chance of reducing expenditure within the health system and improving health outcomes for the population overall, there is a critical need to ensure that such programs are based on research evidence and that their outcomes are monitored to provide such evidence.

Most public health professionals work in state and territory government health departments and investigate the evidence base around which to develop or change policy, and it is through state and territory health departments that research findings are usually most efficiently disseminated. This workforce is integral to the delivery of key public health interventions such as immunisation, surveillance and monitoring of disease or epidemic outbreaks, and advising on environmental health issues (broadly described as disease control and health protection). Many of these staff, particularly at senior levels, work directly with policy makers (i.e. ministers and their staff), and are in a unique position to facilitate the translation of HMR evidence into health policy decisions. This is further discussed in Section 5.5.

Role of research in public health. Public health research is collaborative and inclusive rather than exclusive and, vitally, engages the community in a variety of ways. Public health research is usually multidisciplinary, accessing a range of supporting disciplines, such as the social sciences, anthropology, psychology, environmental sciences, education, marketing and economics. It also covers the evaluation of health and other interventions (including policies, programs and social changes—for example, aged care) to determine what works to keep populations healthy and free from disease.

Public health research … focuses on the health of whole populations and is concerned with documenting the incidence of disease, understanding the origins of disease, determining what factors make for healthy populations and evaluating the impact of measures (including policies, programs and social changes) that keep populations healthy and free from disease. Public health research is multi-disciplinary and includes epidemiology and the full range of social sciences (including sociology, psychology, economics, and anthropology). [It] focuses on how social, economic, physical and natural environments shape health and health-related behaviours.

Public Health Association of Australia Research Advisory Group

Public health research has a role to play in examining and addressing health disparities, particularly the social determinants of health (e.g. socioeconomic status, housing, the environment, education and social justice) which frequently determine lifestyle choices and, in turn, impact on health outcomes. It is increasingly extending beyond health into broader areas such as education, food control, and housing and urban planning, and this a trend is likely to continue.

The importance of the primary care interface in the delivery of population health policy should also not be overlooked, both in terms of its potential to facilitate preventive health outcomes and in terms of the need for research in this area. More research is also required on the evaluation of public health programs with a view to improving effectiveness of delivery.

The importance of preventive health cannot be overemphasized. The National Preventative Health Taskforce identified that 'smoking, obesity, harmful use of alcohol, physical inactivity and poor diet together with high blood pressure and high blood cholesterol cause approximately 32% of Australia’s burden of disease. To continue to effectively redress this situation, Australia needs to answer important policy and intervention questions through research.

Australian National Preventive Health Agency

Public health research has the potential to make a significant contribution to Australia’s various health priority areas, particularly in:

• determining the best methods for promotion of good health and disease prevention, and population health risk-management strategies
• improving management of and information about communicable diseases
• providing rapid and appropriate responses to emerging disease threats
• managing health issues related to an ageing population
• understanding which kinds of policies are best placed to support gains in population health and wellbeing and improve health equity
• elucidating the social determinants of physical and mental health and applying those understandings to improved individual and population health
• understanding, managing and preventing adverse health effects from potential environmental hazards
• understanding, managing and preventing the potential health consequences of climate change.
CASE STUDY 5.1

Water fluoridation is one of Australia's major public health achievements of the twentieth century

**Background.** Fluoride in drinking water protects against dental disease and may also have an indirect effect on reducing coronary heart disease risk, by reducing the incidence of periodontal disease. Global studies have shown that dental cavities affect between 60–90% of children and the majority of adults, and that water fluoridation reduces the prevalence of dental cavities by ~15%. Community water fluoridation was introduced in Australia in 1953, with fluoridated water available to over 70% of the Australian population by 2012.

In Australia, studies have shown that community water fluoridation has halved the prevalence of dental cavities from ~50% in the 1970s, to ~25% in the 1990s. In 2002, across the age range of 5–15 years, children from areas with higher concentrations of fluoride in drinking water had fewer dental cavities on average than children from areas with relatively low concentrations of fluoride in drinking water. Fluoridation also yielded significant economic benefits, with an economic cost-benefit analysis showing that community water fluoridation in the 1970s yielded a net benefit of $56 per person.

**Access to Fluoridated Community Water**
Percentage of Population in 2012

- <80%
- 80–89%
- 90–100%

Key Lessons:

1. **Health and medical research identified the prevalence of dental cavities and uncovered the potential benefits of fluoride in reducing dental disease.** Early research into water fluoridation at the start of the 20th century focused on naturally-occurring levels of fluoride in certain regions in the US, and the link with lower levels of dental cavities in children. Further research led to water fluoridation becoming national policy in the US in 1951 and Australia in 1953.

2. **Evidence-based policy has significant social and economic benefits.** Following the policy of introducing community water fluoridation in 1953, the prevalence of dental cavities has been significantly reduced, at a net economic benefit to Australians.

Enhanced and better-supported public health research can assist in guiding the development of Australia’s HMR priorities, and provide a view of how those priorities are regionally differentiated. Research programs aimed at improving population health are likely to make a significant contribution to Australia’s health. In addition, in terms of effective implementation of Australia’s recent health reforms, public health research could play a key role in evaluating the success of Medicare Locals and LHNs.

**Issue: Despite considerable growth in public health research over the last decade, further capacity-building is required.** Public health researchers include those trained in medicine or allied health, or science graduates, who then usually complete an advanced-studies course (e.g. Masters or PhD) in public health or epidemiology. They are mostly based in universities and research institutes which have a strong focus on public health (e.g. the Menzies School of Health Research and the Burnett Institute).

The Wills Review noted the need for significant capacity-building in the area of public health research to improve the health of the nation and recommended that NHMRC support increased public health research capacity. While NHMRC funding of public health research has grown at 16% per annum since 2002 compared to 13% across the total portfolio, public health research comprises less than 15% of total NHMRC expenditure. Given the potential for such research to reduce health expenditure and improve quality of life, there remains work to be done in expanding the public health workforce and increasing the proportion of expenditure on this type of research.

There is a need for increased funding support of research that is likely to significantly promote public and individual health, and translational research specifically aimed at implementing evidence. In addition, projects which include community and health provider partners on teams, which generally leads to improved translation, should be encouraged.

Key enabling infrastructure (discussed in Section 4.5) is of prime importance in ensuring rich, high-quality datasets that can be used for analysis. This includes access to large-scale national patient datasets and specialised research support staff such as bioinformaticists. NHMRC’s Partnership Project and Partnership Centres schemes are focused on bringing together larger multi-sector collaborations around specific public health issues, which can liaise directly with health departments, community groups and others to improve healthcare delivery. The Partnership Projects scheme, however, is currently undersubscribed and its establishment has involved protracted negotiations. Barriers to applications include getting sign-off and cash contributions from partners who are typically government agencies with frequent staff turnover, short-term funding and budget cycles that are vulnerable to changes in government. Currently there are two Partnership Centres (Cognitive and Related Functional Decline in Older People and Systems Perspectives on Preventing Lifestyle-Related Chronic Health Problems).

**Option: NHMRC to build capacity in public health research.** NHMRC should investigate opportunities to encourage participation in, and dissemination of findings from, research by the providers of public health services to attract and build a larger pool of public health researchers and to explore how current funding schemes can be further leveraged and enhanced in consultation with policy makers, ANPHA and the public health research community to deliver greater health impact.

**Issue: Public health intervention studies need a streamlined approach for competitive grant assessment.** Public health research is a particular area in which there is a strong justification for local research activity to make it relevant to the Australian population and health system. While competitive research funding in the area of public health, as for other types of research, should be assessed according to the accepted criteria of significance, scientific quality and track record, the nature of this research sector suggests the need for a different approach in the case of public health intervention studies. Such studies can be very expensive and hence require pilot data before larger-scale investments are made. These pilot studies may be only one-year or two-year projects with a requirement for completion before longer term funding is approved.
CASE STUDY 5.2

Obesity affects more than 63% of Australian adults and 25% of Australian children, and costs Australia $38bn annually

**Background.** With over 63% of Australians overweight or obese, including over 25% of children in 2012 (up from 11% in 1985), obesity has been identified as one of the most significant health problems affecting Australia. Obesity significantly increases the risk of cardiovascular diseases, Type 2 diabetes, osteoarthritis and certain forms of cancer. Should the current upward trend in obesity continue, recent projections indicate that there will be approximately 1.75 million deaths and more than 10 million years of life lost at ages 20-74 years in Australia from 2011 to 2050.

Research has shown that the prevention of obesity is the most cost-effective and realistic approach for dealing with obesity, due to the relative lack of success of treatment once obesity has been established. An analysis of obesity intervention programs has shown that preventive intervention, such as a combination of diet and physical exercise, yields the biggest net benefit of $1,764 per person, while pharmacological treatment yields a net benefit of $608 per person. Bariatric surgery has been shown to be significantly less cost-effective, at a net cost of $3,366 per person.

The National Partnership Agreement on Preventive Health (NPAPH) was established by the Council of Australian Governments in November 2008. A diverse range of programs is funded which target children and workplaces. Based on a success rate of 11% for preventive intervention, if a quarter of obese Australians improved their lifestyle, the Australian economy would incur a net benefit of $2bn through lower direct medical costs and increased productivity.

**Key Lessons:**

1. **Health and medical research has identified a link between obesity and chronic disease.** Obesity significantly increases the risk of cardiovascular diseases (such as coronary heart disease, stroke, heart failure and peripheral vascular disease), Type 2 diabetes, osteoarthritis and certain forms of cancer.

2. **Research has quantified the cost of obesity to Australia.** The estimated total cost of obesity to Australia is $38bn annually, consisting of $1.3bn in direct costs of treating obesity-related illnesses, $6.4bn in indirect costs such as productivity lost and $30bn in social and burden of disease costs (such as reduced life expectancy and quality of life).

3. **Preventive health initiatives can produce significant social and economic benefit.** Initiatives such as NPAPH are cost-effective and essential approaches to reducing the prevalence of obesity and chronic disease, through the promotion of preventive health activities and interventions.

Another issue is the way scientific quality and innovation is assessed where translation of existing knowledge into practice, usually via research on complex interventions, is evaluated. This means that excellent projects in this growing and developing field, including simulation modelling of the health economic impacts of addressing evidence-based practice gaps in a population, may be at a disadvantage based on current NHMRC Project Grant assessment criteria. Equally, some public health research requires long-term studies to provide evidence for outcomes. This does not fit into the current five-year framework for Project Grant funding. Such studies may be more appropriately dealt with in a distinct process more similar to those the Panel now suggests for clinical trials.

**Option: Streamline NHMRC Project Grant processes for public health intervention studies.** A streamlined NHMRC Project Grant process specifically for public health intervention studies should be investigated. In cases where such studies require more than five years of funding, proponents should also be encouraged to seek support from state and territory government health departments.

**Issue: Duplication of public health research grant assessment between NHMRC and ANPHA.** In addition to NHMRC competitive research funding, there is a budget for public health research specifically funded through ANPHA. Following a 2008 COAG initiative, ANPHA was established at the beginning of 2011 to strengthen Australia’s investment and infrastructure in preventive health. The Australian Government committed $872m over six years (commencing in 2009–10) under the COAG National Partnership Agreement on Preventive Health for a range of initiatives targeting the lifestyle risk factors of chronic disease. ANPHA received $133m of this funding over four years, allocated to social marketing campaigns ($102m), agency functions ($18m), a research fund ($13m) and a workforce audit ($0.6m). The allocation of funds for research projects by ANPHA may represent a duplication of assessment and administration activities given NHMRC's major role in HMR grant administration.

**Option: Align research strategy and leverage NHMRC competitive grant assessment processes for ANPHA research funding.** The Panel believes that ANPHA’s modest budget for research would be better aligned with the competitive assessment processes of NHMRC in a similar fashion to funding from specific charities which use NHMRC review processes to identify appropriate grant applications for funding. Regardless of this suggestion, there is a need for better alignment between ANPHA and NHMRC activities.

<table>
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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
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<tbody>
<tr>
<td>12a.1 Focus capacity-building using partnership schemes that allow the involvement of large teams from different sectors and leverage of funding from state and territory government health departments and also the private sector.</td>
<td>NHMRC, ANPHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>12b.1 Adjust the NHMRC Project Grant scheme to better accommodate short-term public health intervention pilot studies.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>12b.2 Ensure alignment between public health research efforts and ANPHA’s preventive health strategy and encourage ANPHA to procure research through NHMRC’s competitive grant processes.</td>
<td>Leadership body, ANPHA, NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>12c.1 Adopt new approaches to fund non-commercial clinical trials for long-term public health studies, (covered in Section 5.4.2), including convening specialised public health review panels.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
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</table>

CASE STUDY 5.3

Discoveries in public health research can significantly improve the quality of life for individuals

**Background.** Pellagra is nutritional deficiency that is clinically manifested by the 4 D’s: diarrhoea, dermatitis, dementia and death. Pellagra occurred in epidemic proportions in the American South in the early 1900s, persisting for four decades, with three million cases and 100,000 deaths. Poverty and a high consumption of corn were thought to be the highest risk factors, though the exact cause and cure were unknown.

Dr Joseph Goldberger of the US Public Health Service theorised that the condition was associated with dietary deficiency. This contradicted the conventional belief that pellagra was an infectious disease.

Goldberger undertook diet-restricted experiments in asylums, prisons and orphanages with the institutions agreeing to feed either a balanced or unbalanced diet. The evidence clearly demonstrated that an unbalanced diet resulted in a high likelihood of contracting pellagra, whilst those on a well-balanced diet experienced a recovery from symptoms or no contraction. Nonetheless, the discovery proved socially and politically unacceptable, and was broadly disregarded by the medical community.

Despite criticism, Goldberger continued to employ research to prove pellagra was a dietary disorder, not an infectious disease. By injecting himself and his assistant with a pellagrin’s blood and ingesting secretions and scabs, he was able to prove his theory was sound, with neither contracting the condition. This research was fundamental to a biochemist and doctor specialising in nutrition to ultimately make further discoveries proving niacin cured pellagra, and thereby improve the quality of life of the United States’ poorest citizens.

**Key Lessons:**

1. **Public health research has significant potential to improve the quality of life.** Research on public health issues such as nutritional deficiency improves health and wellbeing across the population.

2. **Collaboration is important to ensure discovery and translation of important health and medical research questions.** A public health doctor, statistician, nutrition doctor and biochemist combined over time to make this important discovery. Despite Goldberger’s findings being disregarded throughout his career, the strong case made by research stood to allow future discoveries to ultimately cure the condition.

5.3 Enhance Health Services Research

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.

Role of health services research. Health services research is characterised by T3 and T4 translation and is integral to delivering impact where a lack of commercial drivers exist. It examines the interplay between all components of the health system: its organisational structure, financing structure, governance structure, workforce dimensions and other human-resource contributions, policy environment, and relative contributions of the various subsectors (government, private and NFP). It examines efficiencies in the integrated whole, and in various sub-components of the sector, and how the sector relates to other sectors such as education and the environment. At a global level, health services research can also assist by drawing from overseas experience.

“Health services research is needed to address efficiency and costs. There is a recognition that innovation is required across health service delivery, to respond to three drivers: change in population health needs, increased demand, and rising costs of new treatments. … health services research is needed to determine appropriate, effective and efficient health operational strategies through this change.”

CSIRO

Health services research aims to improve equity of access, affordability and quality of health services for the entire population and has much to offer in terms of improving the consistency and quality of health outcomes for patients who may receive different treatments across the system, some of which may not be optimal. In particular, comparative evaluation of health interventions in terms of cost-effectiveness per QALY gained is an essential area for identifying potential opportunities for health system cost savings. Complementary to such research are change-management programs and evaluative research to realise any benefits identified.

In the face of rising healthcare costs, health services research holds significant potential to reduce health system costs. LHNs, Medicare Locals and GP Super Clinics are all areas where health services research has a key evaluative role to play. Health services research can play a pivotal role in health system improvement through evaluating cost-effectiveness of health services delivery arrangements and the efficiency of financing and funding mechanisms, and in identifying opportunities and developing strategies to improve health services delivery.

Comparative effectiveness research, which evaluates the cost-effectiveness of interventions and services, is of vital importance to ensure the sustainability of the health system. While processes used by the Pharmaceutical Benefits Advisory Committee and the Medical Services Advisory Committee have built up capability in this area, this activity is limited to items where there is a funding application. There is also a need for research into incentives across all parts of the health system, and how changes will impact on outcomes.

To evaluate health system impact, health services research draws heavily on health economics. Health economics play a valuable role in analysing future health-system costs, and ways of managing them. They are essential for the construction of effective and efficient health policy at all levels of government.
Every decision made by a policy maker or health professional commits scarce resources that have perhaps more beneficial alternative uses. The misallocation and inefficient use of resources costs lives. Many treatments continue to be provided which have been shown to be ineffective, inefficient or where the effectiveness of the treatment is not known … Health economics provides the tools to ensure that the way we spend the health care budget provides the best value for money and the most cost-effective health care.

Australian Health Economics Society

Identifying opportunities and developing strategies to improve health services delivery is another area where focused efforts are needed. Social and epidemiological research can bring about the necessary organisational and behavioural change required to deliver improved health services. For example, research on unwarranted clinical variations on hospital length of stay can lead to a better understanding of causes for lower performance and possible actions to address this.

Health services research can also provide an invaluable role in addressing problems relating to inequity in service delivery between Australia’s cities and its regional and rural areas, meeting the needs of women, families, ethnic and mobile populations better, and providing healthcare in non-hospital settings (including community-based care, home visiting, community groups and localised services). It could also be used to assist Australia’s Asia-Pacific neighbours in health service delivery.

Health services researchers deliver improvements in health areas not addressed by medical researchers such as staffing and workforce issues, patient treatments and interventions, safety, and quality aspects of health care to name just a few. Further, health services researchers develop improved treatments and models of care to enable Australian health organisations, community organisations and carers deal with the ever increasing burden of ill-health that will continue to be a consequence of an ageing population.

University of Technology Sydney

Issue: Australia’s capacity in health services and health economics research is under-funded, under-resourced and lacks cohesion. Health services and health economics research have never been adequately funded in Australia and consequently have low levels of human resource capacity. Health system research cannot be outsourced to another country because the research must be carried out within the context of Australia’s unique economic, political, social and healthcare environment. It is vital that Australia builds capacity in these areas as a matter of strategic priority.

In addition, it is also important to provide relevant training in research for people with clinical qualifications, providing them with the skills and theoretical context to lead change in health services. Research into the operation of the health system also requires expertise beyond health and medical researchers, with a consequent need to involve business professionals, particularly in the management and improvement of the health system. There is significant opportunity to improve health services delivery for patients by developing and implementing strategies to align organisational behaviour to ‘best practice’ and evidence-based models.

Concepts around business practices as they relate to health delivery may be better investigated through business people/management consultants rather than health researchers.

Australian Academy of Technological Sciences and Engineering

117 Australian Academy of Technological Sciences and Engineering response to the SRHMRA Consultation Paper.
CASE STUDY 5.4

In Canada, health services research has been used to evaluate and monitor improvements in the delivery of health services

**Background.** Hip and knee replacement procedures are associated with long waiting times to see an orthopaedic surgeon and to have the subsequent surgery. The care given to patients is variable, influenced by factors such as socioeconomic status, age and geographic location. Spiralling public healthcare costs have put pressure on resources and constrained the ability of the public system to meet growing demand driven by an ageing population and increasing incidences of obesity.

In 2003–2004, the Alberta Orthopaedic Society proposed a new continuum of care. This marked a fully integrated service offering delivered in a multidisciplinary environment, including assessment, diagnosis and non-surgical treatment. A pilot test trial occurred in 2006, which was the largest research evaluation project undertaken in Canada. This randomised controlled trial was conducted at the Alberta Bone and Joint Health Institute over a 12-month period on 3,400 patients. Individuals with similar conditions were allocated randomly to two or more treatment groups whose outcomes were compared after appropriate follow-up. The outcomes were then assessed against six dimensions of quality, with KPIs such as waiting time, cost or patient wellbeing.

**Key Pilot Results**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Current Approach</th>
<th>New Continuum of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessibility</td>
<td>Referral to being seen: 145 days&lt;br&gt;Being seen to surgery: 58 weeks</td>
<td>Referral to being seen: 21 days&lt;br&gt;Being seen to surgery: 7.5 weeks</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Surgery time: 119 minutes&lt;br&gt;Acute length of stay: 6 days</td>
<td>Surgery time: 109 minutes&lt;br&gt;Acute length of stay: 4.7 days&lt;br&gt;Cost change : c.15% (to hospital) and c.2% (to public healthcare)</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Long wait = decreased quality of life and increased cost</td>
<td>Reduced wait = minimal decrease in quality of life and cost</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Improved physical and social function and reduced pain</td>
<td>Greater increase in physical and social function and pain reduction</td>
</tr>
<tr>
<td>Safety</td>
<td>Joint-related adverse events: 4.8% &lt;30 days after surgery and 2.2% &gt;30 days after surgery</td>
<td>Joint-related adverse events: 4.1% &lt;30 days after surgery and 1.2% &gt;30 days after surgery</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>31% mobilised day of surgery &lt;br&gt;75% spinals</td>
<td>85% mobilised day of surgery &lt;br&gt;82% spinals &lt;br&gt;Discharge change: reduced use of surgical wound drains</td>
</tr>
</tbody>
</table>

**Key Lessons:**

1. **Health services research can evaluate and assess improvements in health services.** Improved processes can improve quality of care, patient satisfaction and cost effectiveness: patient waiting time is correlated to the overall case cost as a longer wait result in more services required of healthcare providers to help patients manage their symptoms.

Australia’s capacity in health services and health economics research is fractured and inadequate. Demand for health economists in particular over the last few decades has significantly exceeded supply and Australia has relied on the recruitment of overseas-trained health economists (mostly from UK), and generalist economists, mostly from universities and government departments. Continued under-investment in the education and training of health economists by Australia’s tertiary institutions will inhibit our ability to build world-class public health and health services research capability that can deliver the required level of impact in the health system and for Australians.

“In recent years, health economics has relied on senior health economists recruited mainly from the UK, and also from the involvement of economists from Departments of Economics. This has proved a successful strategy in the absence of a large locally-trained cohort of senior health economists. But this is not sustainable on its own in the longer term.

Australian Health Economics Society

Option: Provide targeted funding to build capacity. Health services research is ripe for priority funding through a targeted allocation of grants. While NHMRC has in the past developed targeted programs for health services research, this has not solved the problem of the shortage in capacity. What is needed is concerted action across education, research fellowships across all levels and research program and project funding with a longer term view.

While there have been economists, health services researchers and health policy researchers funded under NHMRC People Support Schemes, this needs to be opened more widely to get the investment in capacity needed. Consideration should also be given to providing targeted funding to build skills and leadership in these areas, and to support sustainable career pathways. This could take the form of a prestigious fellowship scheme to attract the best and brightest from around the world to build capacity in Australia, or more simply by expansion of the NHMRC People Support scheme to target health economics, health services research, and health policy research. Furthermore, the selection criteria for NHMRC Project Grants should be revised for health services research to reduce the significance of track record and introduce criteria around demonstrated and potential impact.

To ensure a steady flow of future researchers, a centre of excellence in teaching of health services and health economics research is needed in at least one Australian university, and preferably several across the nation. Capacity could also be built through development of training fellowships, a national postgraduate program, and integration of more health economics subjects into regular undergraduate economics courses as a way of attracting bright young minds to the field.

Issue: Need for initial pilot studies. There are several unique challenges in this sector. Research teams often involve a wide variety of people at different skill levels, making the track record of the team as a whole apparently less competitive in conventional grant review terms. Health services research, like public health research, often requires initial short-term and small-scale pilot studies which are potentially better assessed and funded locally rather than via a national competitive assessment process. For NHMRC Project Grant funding, an impediment to success for researchers in these fields is the way in which scientific quality and innovation are assessed, particularly the evaluation of translation or implementation of existing knowledge to practice (for example, via research on complex interventions). This means that excellent projects in this growing field (such as simulation modelling of the health economic impacts of addressing evidence-based practice gaps in a population) may be at a disadvantage given the current scoring criteria and weighting process for Project Grants.
CASE STUDY 5.5

Advancing evidence-based practice in neonatal care has significantly improved health outcomes and reduced healthcare delivery costs

**Background.** Preterm babies are at greater risk of death and disability. For instance, they are at high risk for nosocomial infections and a chronic lung disease linked to ventilator use called Bronchopulmonary Dysplasia (BPD). Preterm babies also account for a disproportionately high share of hospitals' postnatal care costs (Canadian studies show that babies born at less than 28 weeks gestation incurred an average hospital cost of C$84,200 compared to C$1,100 for full-term babies). More cases are occurring because many women are having children later in life or use in vitro fertilisation to conceive (two factors linked to higher incidence of preterm birth).

Dr Shoo K Lee of the Children's and Women's Health Centre of British Columbia began what eventually became known as Evidence-Based Practice of Improving Quality (EPIQ) in 2002 by adapting the Continuous Quality Improvement model used in the manufacturing sector. EPIQ works by combining a focus on the collection and analysis of data about care in Neonatal Intensive Care Units (NICUs), with tools for helping facilitate cultural changes within healthcare centres. For example, EPIQ experts train teams to conduct evidence reviews, gather and analyse data, create and refine process-of-care maps, manage change and measure outcomes. From 2003 to 2005, the NICUs using the new model demonstrated a 44% decrease in the incidence of nosocomial infections and a 15% decrease in BPD, which translated into a reduction of NICU patient stays across Canada of almost two days and a cost saving of almost C$2,500 per patient. If implemented nationally, the cost savings would amount to C$7.5m annually.

EPIQ II was then initiated to improve outcomes in BPD and nosocomial infections and three other major conditions that afflict preterm babies: intraventricular haemorrhage (bleeding in the brain that can cause brain damage), necrotising enterocolitis (a frequently deadly infection that kills intestinal tissue) and retinopathy of prematurity (abnormal blood vessel development in the retina that can lead to blindness). As a result, at Toronto's Sunnybrook Health Sciences Centre, NICU deaths fell by 75%, the incidences of retinopathy of prematurity and nosocomial infections were cut in half and BPD fell by 27%. The Foothills Medical Centre saw the incidence of necrotising enterocolitis drop from a 9% incidence rate down to about 2.5%.

**Key Lessons:**

1. **Health services research has the potential to evaluate and assess improvements in care.**
   
   EPIQ is currently operational in 30 NICUs across Canada, has been adopted by six Latin-American countries and 38 NICUs in Malaysia, and is being piloted in China. Preliminary analysis of the first two years of EPIQ II shows a reduction of nosocomial infection rates across Canada by 30%, retinopathy of prematurity by 20%, and necrotizing enterocolitis by 15%.

2. **Research can identify opportunities for advancing evidence-based healthcare practices.**
   
   Dr Lee says: 'The reality is, it's not so easy for uptake to happen. Sometimes people just don't believe the guidelines. Even when they do believe, sometimes they say, "It can't be done here". There sometimes can be a leadership problem. There are many reasons why these things don't happen.' To address that, EPIQ experts visit hospitals and conduct staff interviews, focus groups and surveys to assess organisational structure and culture, and identify potential barriers to change.

Source: Canadian Institutes of Health Research, 'EPIQ Results: Reconfiguring Neonatal Care Saves More Preterm Babies from Disability and Death', Show me the Evidence / Voici les faits, 1(2), 2012, pp.9-11.
5. Enhance Non-Commercial Pathway to Impact

Option: Revise NHMRC Project Grant criteria and encourage health services and health economics research activity in LHNs. NHMRC Project Grant criteria and assessment procedures for health services and health economics research should be more heavily weighted towards an assessment of outcomes and relevance, introducing criteria around health system impact and reducing the emphasis on track record. For short-term pilot studies, LHNs provide an ideal environment to conduct health services and health economics research, and should be encouraged to employ researchers in this area to assist in identifying opportunities for improving health service delivery and reducing costs. LHNs should also be encouraged to collaborate with researchers from universities and research institutes to further build capability in this area. To ensure a suitable environment in LHNs to facilitate this, it is important to ensure that the reforms to research activity in the health system detailed in Chapter 2 are implemented, particularly initiatives relating to increased accountability and tracking of research expenditure.

Issue: Overall investment and visibility of health services and health economics research is low. Despite numerous reviews pointing to the need for increased investment in these areas of research, there are currently very few funding opportunities. While the CAGR of NHMRC funding in health service research has been 26% since 2002, this only represents 5% of total NHMRC research expenditure (approximately $36m) and the success rate of Project Grant applications in health services is only 18%, which is significantly lower than all other sectors. This indicates a need for further capacity-building to create a more substantial health services research workforce.

Option: Establish an institute of health services research and increase visibility. There is strong merit in establishing an institute of health services research which would evaluate and monitor performance of key aspects of the health system, undertake policy research (including monitoring international developments) and promote policy debate, but with an evidence base as opposed to a vested interest or an ideological bias. Such an institute could also be charged with developing a system of rankings of research outputs and translation outcomes for LHNs, and encourage the use of the health system research funding being distributed to locally-selected health services for research pilot studies relevant to local applications. Health services research should be made more visible by identifying mechanisms and responsibilities for conducting research, starting with IHRCs, and establishing a LHN ranking of research outputs and translation outcomes, either through an external institute or NHMRC.

"Many health economics studies have established the returns on investment in research and developing new products and practices to reduce the impact of a specific disease. For example, a recent Victorian study showed that implementing a program of educational and skills sessions at a cost of $240 per patient, as part of the routine management of adult mental health patients, resulted in improved health and social functioning and reduced hospital admissions, resulting in a net cost saving of over $6000 per patient per year. In research funded in part by the Victorian Neurotrauma Initiative, an agency of the Victorian Transport Accident Commission, the infusion of albumin to manage large blood loss in trauma patients in intensive care (then standard practice) was compared with infusing saline. Saline was found to deliver better clinical outcomes, with almost 20% fewer trauma patients dying. Subsequent economic impact analysis established that the use of saline was considerably lower in cost than albumin and would generate lifetime savings of $688 million every year to the Australian health care system."

Victorian Government

118 For example, the 2009 Review of Health Technology Assessment in Australia.
CASE STUDY 5.6

A new criteria-led discharge protocol is helping WA Health improve patient flow and increase access to beds for patients

Background. The increased demand for limited hospital beds often results in elective cardiac procedures being delayed or cancelled. As part of the Research Translation Project, a WA Health research funding initiative, a criteria-led discharge protocol was developed and evaluated to improve patient flow in cardiovascular medicine wards in Western Australia.

The protocol allows for patients to be discharged by registered nurses without the need for final medical review. Nurses use a strict set of medically-approved criteria to assess if the patient is suitable for discharge, with any deviation from these resulting in the patient reverting back to a medically-led discharge.

Key Lessons:

1. **Research into healthcare delivery identifies areas for improvement.** The WA Health Research Translation Program was established to provide funding for research undertaken to improve the sustainability of the health system. Research conducted through this funding initiative has identified the inefficiencies in medically-led discharge in cases where criteria can be applied.

2. **Translating research into evidence-based practice has significant economic benefit and improves healthcare delivery.** The introduction of the protocol in a cardiovascular ward resulted in an estimated savings of $926,000 per year, based on patients with Acute Coronary Syndrome and arrhythmia, with $6 gained for every $1 invested. The criteria-led discharge protocol has also resulted in more efficient use of medical and nursing staff, reduction in patient length of stay, and increased availability of beds.

Source: Submission 237, Department of Health Western Australia, pp.1-5
5. Enhance Non-Commercial Pathway to Impact

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<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>13a.1 Build capacity in health services research through a targeted allocation of grants to understand and assist translation, identify opportunities to reduce healthcare costs and evaluate innovation.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>13a.2 Build health economist capacity to support both public health and health services research.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>13a.3 Establish a national health economics postgraduate program as a means of building capacity, and consider integrating more health economics subjects into regular undergraduate economics courses to increase visibility among students.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>13b.1 Revise the national selection criteria for NHMRC Project Grants in health services research to reduce the emphasis on track record and introduce criteria around impact.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<tr>
<td>13b.2 Encourage the use of the health system research funding being distributed to locally selected health services for research pilot studies that are relevant to local applications.</td>
<td>Leadership body</td>
<td>2014–15</td>
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<tr>
<td>13c.1 Establish an institute of health services research which would evaluate and monitor performance, undertake policy research, promote evidence-based policy and monitor international developments.</td>
<td>DoHA</td>
<td>2014–15</td>
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<tr>
<td>13c.2 Develop and monitor a Local Hospital Network ranking of research outputs and translation outcomes via the health services research institute or the leadership body.</td>
<td>NHPA, new health services research institute, leadership body</td>
<td>2014–15</td>
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</table>

5.4 Accelerate Health System Innovation

**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.

5.4.1 Deliver Evidence-Based Healthcare

**Innovation in commercial settings.** Areas of health that are fully private show ongoing innovation in both clinical procedures and business methods as the benefits of innovation can be partially internalised as increased profits. Given a competitive market, consumers also benefit from lower prices and improved quality in privately-delivered products and services. Prominent examples of commercially-driven innovation in Australia include:

- laser eye surgery
- Cochlear ear implants
- medically-led diagnostic practices
- in vitro fertilisation (Case Study 5.7).

Innovation works well with drugs and medical devices because the various commercial players drive licensing, pricing and uptake by marketing their products and services to health professionals.
This type of innovation delivers healthcare benefits for consumers, but tends to increase the cost of healthcare overall through active promotion of increasingly expensive products and services. In its report on *Impacts of advances in medical technology in Australia*, the Productivity Commission noted that advances in medical technology, although providing healthcare and cost benefits, were also ‘placing increasing pressures on the public and private health systems’.119

**Issue: Non-commercial settings lack incentives to drive innovation.** Much healthcare is necessarily provided in non-market settings (i.e. public health delivery), where it has been noted that procedural changes are slow and implementation is often *ad hoc*, depending on institutions and individual clinicians. Clinical decisions may be based on out-of-date information, personal preferences, or even intuitional directives, rather than the most up-to-date evidence. There is also a moral hazard in activities that constitute waste for the public healthcare system, but which provide revenue for some other participants (e.g. over-servicing through unnecessary diagnostic tests). Non-commercial research translation is therefore necessary to:

- ensure clinically-relevant research is undertaken in the first place;
- ensure that the need for innovation is accepted and adopted across the full breadth of the health sector with a multi-disciplinary approach;
- capture the health benefits of research through translation processes; and
- encourage innovation in the health system.

**Option: Provide incentives to generate clinically-relevant research evidence and institute KPIs which recognise contributions towards non-commercial translation activities.** Ongoing health system innovation therefore requires better incentives to generate clinically-relevant research evidence, adopt proven guidelines and seek better practice in all settings. Consumers would benefit from a greater focus on research that compares treatment options in various settings (comparative effectiveness research). Lateral innovation, such as adopting safety-check systems from other industries, can lead to significant improvements in non-commercial settings such as public hospitals.

As mentioned at the NHMRC Research Faculty Symposium held in October 2012, there is a ‘critical need to engage end-users and stakeholders throughout the whole cycle of research process to ensure evidence we generate can be implemented … even when conceptualising at the discovery level, or clinical or public health level”.120 Ensuring the most relevant questions are asked is obviously likely to increase the prospect of research leading to innovation. The importance of research-led innovation in health systems was emphasised by the NHHRC in its final report, *A Healthier Future For All Australians*, released in June 2009, that stated:

“We believe that our future health system should be driven by a strong focus on continuous learning and being able to readily apply new best knowledge to improve the delivery and organisation of health services. Innovation should be rewarded and recognised, at local and national levels, with clear strategies to share and embed successful local innovations across the whole health system. A vibrant culture of innovation and research should permeate health services, with effective linkages and partnerships across universities, research institutes, and hospitals and health services. Evidence should drive investment and disinvestment in particular healthcare services, as well as influencing the allocation of resources and the deployment of our health workforce.

National Health and Hospitals Reform Commission121

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120 NHMRC Research Translation Faculty Symposium, *Research Translation into Practice: Successful Examples and Key Learnings* chaired by Professor Helena Teede, October 2012.
CASE STUDY 5.7

Research advances in IVF have resulted in major improvements to success rates and significantly reduced costs for patients

**Background.** Research advances since 1980 have driven a major increase in success rates of in vitro fertilisation (IVF) and the reduction in the cost of IVF treatment in Australia.

As a result of research breakthroughs that allow embryos to be cultivated longer before implantation in the uterus, success rates for each cycle have increased from ~5% in 1980s, to ~45% today for women under 35. Research has led to steady declines in the cost of individual IVF cycles and the overall cost of IVF treatment for patients. Improvements have largely been driven by the commercial nature of the IVF industry, which is dominated by private clinics that have a strong incentive to increase the affordability of treatment to stimulate demand.

The improvement in IVF success rates has also reduced the need for multiple embryo transfers—a procedure which increases the likelihood of pregnancy but increases the risk of multiples or other health issues such as premature births, and leads to increased costs.

The increased success rate and reduced cost of successful single embryo transfer has reduced multiple embryo transfers from ~78% of transfers in 2003 to ~46% in 2007 which is one of the lowest multiple embryo transfer rates in the world.

**Key Lessons:**

1. **Research can drive innovation in healthcare practices leading to improved healthcare outcomes and lower costs.** As the success rate of each IVF cycle has increased dramatically, women no longer have to undertake multiple embryo transfers, reducing the chances of riskier twin, triplet or quadruplet pregnancies. The increased success rates and lower cost per cycle have made IVF treatment significantly more affordable. In the 1980s, the overall cost of a successful IVF delivery for a woman under 35 was $148,000 in current terms, while in 2010, the average cost of an IVF cycle was around $7,500, equating to an average of around $20,000 per successful IVF delivery.

2. **Commercial incentives can drive research advances that deliver improvements in treatment and lowers costs.** IVF clinics, which are largely privately owned and led by the 'invisible hand', have driven innovation in treatment which has increased affordability and stimulated increased demand.

Non-commercial translation requires an integrated approach, with investment across research organisations and health services providers to:

- build capacity in health services and public health research
- invest in research translation projects, which may require a different skill set to advise on priorities and assess investigator-initiated proposals
- ensure implementation of research findings
- conduct audits of evidence-based practice and clinical processes within the health system
- ensure ongoing research into clinical practices and reasons for observed adoption, or lack of adoption.

Non-commercial translation also requires support through formal recognition of research effort in this area. All guidelines should have an implementation plan and evaluation process. As noted in Section 5.3, track record criteria for researchers should recognise effort in non-commercial translation activities, plus KPIs should be more widely instituted in research agencies to similarly recognise non-commercial translation activities. NHPA should also consider including KPIs for research translation activities as part of reporting to monitor and track performance.

The Panel notes the establishment of the NHMRC Research Translation Faculty, aimed at the most significant gaps between research evidence and health policy and practice. This is an important step forward, and the underlying focus should be further built upon and extended more broadly, with involvement from health professionals in LHNs and other settings, and regulatory bodies charged with overseeing health service delivery standards, such as ACSQHC.

**Issue: Research output is typically not in an optimal format for the needs of various end-users.** Most research output is disseminated via an academic journal which has a specific style of scientific language aimed at a specific audience (other academic researchers), and not the general public, or even non-academic health professionals, who may be overwhelmed by the length and complexity of the information presented.\(^\text{122}\) Health professionals, policy makers and the general lay community require information that is readily available, easy to use, of high educational value, informative, relevant and accurate.\(^\text{123}\)

**Option: Encourage new guidelines to be written for wide dissemination and in a variety of formats for end-users.** Depending on the field of relevance, a greater focus on communication efficiency is required, including both the message and the media. Research findings that have potential for significant impact could also be published in the media to widen dissemination.

**Issue: Implementation of clinical guidelines is slow and inconsistent, and in some areas they are non-existent or inapplicable.** The main bridge between research and improved clinical practices is clinical practice guidelines. While there is considerable effort invested in the construction and publication of clinical guidelines in Australia (for example by NHMRC and the specialist medical colleges and societies), there are a number of issues that exist.

- Guidelines are not always distributed efficiently to reach their intended audience.
- Overall uptake of guidelines is sporadic and adherence is rarely evaluated.
- In some areas guidelines are non-existent, with health professionals left to rely on personal experience when treating patients.
- In other areas, guidelines are not applicable or readily accessible by health professionals in certain settings (e.g. primary-care).

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\(^{122}\) CA Higgins, Effective and Efficient Research Translation for General Audiences Literature Review and Recommendations, University of Kansas, Research and Training Center on Independent Living, 2001; URL: http://www2.ku.edu/~rtcil/products/RTCLIL%20publications/Media/Effective%20and%20Efficient%20Research%20Translation%20for%20General%20Audience%20Lit%20Review.pdf.

\(^{123}\) National Center for the Dissemination of Disability Research, Guides to improving practice: Improving the links between research and practice, Southwest Educational Development Laboratory, 1996.
CASE STUDY 5.8

Adopting safety checklist learnings from the aviation industry can lead to significant improvements in surgeries

Background. A recent World Health Organization (WHO) study drew on learnings from aviation safety research in the design of surgery checklists to focus in on ‘killer items’—tasks often overlooked but that potentially lead to significant increases in risk. The results were significant, with the incidence of major surgery complications falling from 11% of procedures to 7%. In addition, patient post-surgery deaths dropped from 1.5% to 0.8%. While the majority of the reduction of deaths was experienced in lower socioeconomic countries, it is still a dramatic decrease for the more developed nations.

The effectiveness of checklists is not limited to surgery and can be used in a variety of health-related contexts. For example, a study showed that the use of checklists when inserting catheters reduced the incidence of infection from 0.27% to 0%.

Key Lessons:

1. Adopting best practice from other industries can assist in driving a change in behaviour and culture to improve health outcomes and reduce healthcare costs. The WHO study showed how adopting a ‘killer items’ list from the aviation industry led to a reduction in major complications, deaths from surgery and other preventable errors. These safety improvements have the potential to reduce patient treatment costs dramatically, as approximately 50% of adverse events in hospitals start in surgery. Of these complications, 50% are avoidable and safety checklists could play a major role in prevention.

NHMRC could be much more active in the area of producing clinical and health services guidelines, using results of research that it funds, plus other international research evidence, to achieve more timely and systematic production of clinical practice guidelines.

Perhaps the most significant impediment to better practice is the delay between the publication of guidelines and their widespread adoption by clinicians, which is reinforced by a financial system that rewards delivery of treatments without systematic evaluation of their outcomes. Healthcare professionals are generally just ‘expected’ to know how to manage patients, while there are not in fact adequate systems to support their easy access to new knowledge. A cultural shift is needed towards making use of electronic access to the latest policies and procedures at the point of care to ensure uptake. E-health access systems are critical to this and provision of material for these should be an integral part of policy development (for example, when a lab test comes back suggestive of a diagnosis, an automatic e-link to the current guidelines for management of that problem should become available).

**Option: Implement new translation systems and processes and establish translation plans to monitor and promote the uptake of guidelines.** Knowledge translation systems and processes are required to ensure that the valuable evidence created reaches the end users who will benefit most from it. Such systems and processes will also accelerate the inevitable shift from traditional models of ‘publish and read’ to ‘publish, communicate and distribute electronically’. Implementation of new systems and processes in the health system requires support from the Australian and state and territory governments.

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<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>14a.1 Provide incentives to generate clinically-relevant research evidence and institute KPIs which recognise contributions towards non-commercial translation activities.</td>
<td>Leadership body, NHMRC</td>
<td>2014–15</td>
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<td>14a.2 Collaborate with ACSQHC to identify clinical practices which are not evidence-based that require research, and develop RFAs for NHMRC to seek research proposals.</td>
<td>Leadership body, ACSQHC</td>
<td>2014–15</td>
</tr>
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<td>14b.1 Ensure all guidelines have an implementation plan and evaluation process, and include research translation activity as part of LHN research reporting by the National Health Performance Authority (NHPA).</td>
<td>NHMRC, NHPA</td>
<td>2014–15</td>
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<tr>
<td>14b.2 Encourage new guidelines to be written for wide dissemination and in a variety of formats for various end-users, depending on the field of relevance.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>14b.3 Implement translation systems and processes to move from traditional ‘publish and read’ model to ‘publish, communicate and distribute electronically’.</td>
<td>NHMRC, ACSQHC</td>
<td>2014–15</td>
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**5.4.2 Support Non-Commercial Clinical Trials**

Commercial resources logically flow to areas of greatest market potential and these tend to be treatment for chronic diseases rather than implementing preventive measures. This fact simply reflects the legitimate operation of market forces within the healthcare system. Non-commercial clinical trials are, by their nature, trials which commercial organisations will not fund because due to a lack of potential for commercial benefit. This of course does not mean that they do not have significant potential to improve health outcomes or reduce health costs. Indeed, there are many research outcomes that have the potential to reduce morbidity and mortality, or to result in direct or indirect cost savings. Examples include time-saving advances in surgery practice, early intervention procedures such as cancer screening programs, the use of lower or less frequent drug dosages, and the introduction of better assessment processes to optimise the use of new technologies and pharmaceuticals.
... the investigator-led sector are more likely to conduct trials that contain medical inflation. Acceptance of this argument has led to substantial real investment in comparative effectiveness research in the United States and similar investment is warranted in Australia.

The Australian Clinical Trials Alliance

**Issue: Non-commercial trials are underfunded despite their significant potential benefits.**

The fact that commercial enterprises are not willing to take up clinical trials in some areas where clear benefits could reasonably be expected means that non-commercial clinical trials need to be supported through the public sector. However, support for non-commercial clinical trials is generally lacking in Australia. The main issues that prevent greater initiation of non-commercial clinical trials are:

- a lack of adequate government funding, exacerbated by a granting process that does not particularly favour the funding of non-commercial clinical trials
- a narrow definition of clinical research which needs to be broadened to include any interventions that involve health consumers, including preventive interventions
- a lack of resources in hospitals to assist in the conduct of clinical trials, and lack of protected time for hospital-based clinician researchers
- insufficient clarity on process and champions to ensure non-commercial clinical trials proceed.

In short, non-commercial clinical trials research needs to become a more integral part of Australian health service delivery in order to improve health outcomes and clinical practice. In addition, better communication to healthcare professionals and sometimes to consumers of non-commercial research outcomes is required, to replicate the marketing that would be provided for commercial translation.

**Option: Provide additional funding of $50m–$100m p.a. for 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 health services providers, both of which are lacking. The Panel’s view is that an additional $50m–$100m p.a. is required to support non-commercial clinical trials and infrastructure.

Strategies to improve the environment for the conduct of non-commercial public-good clinical trials include:

- creating an investment fund or providing grants to fund non-drug/device trials with both a strategic and investigator-initiated approach
- forming NHMRC panels with access to skills (directly or indirectly) to assess translation (e.g. clinicians, LHN executives, consumers)
- prioritising trials based on potential health benefits of interventions (i.e. same analysis a commercial organisation would undertake, but with public benefits such as QALYs as the target outcome)
- conducting trials at LHNs using streamlined governance processes initially.
CASE STUDY 5.9

Non-commercial clinical trials revealed that early treatment of dialysis is not beneficial to patients and incurs unnecessary costs

Background. While nearly three million people worldwide receive dialysis for final-stage kidney disease, little was known about the correct time to initiate dialysis treatment. In clinical practice, there is considerable variation in the timing of the initiation of dialysis for these patients, with an increasing practice of initiating dialysis earlier in the process.

It was previously thought that improved quality of life and survival outcomes could be gained by patients undergoing early treatment. This has further exacerbated rising health costs globally. Dialysis treatment is estimated to have cost $1,100bn globally between 2001–2010 and, in Australia, projections suggest an estimated $12bn cost to the Australian Government between 2009–2019.

Researchers conducted a randomised controlled trial study in 2010, and found that the earlier timing of dialysis treatment did not improve survival or clinical outcomes. Following this development, more recent observational data that is yet to be published suggests that starting dialysis early may lead to poorer health outcomes.

Key Lessons:

1. **Non-commercial clinical trials have a vital role to play in identifying clinical practices that are not beneficial or result in adverse health outcomes.** Randomised controlled trial evidence did not support the practice of early dialysis treatment. As a result, international practice has been changed to commence dialysis later.

2. **Non-commercial research can deliver significant healthcare cost savings.** Practitioners now commence dialysis later, resulting in reduced mortality and costs. This has led to a $1.7m saving per year in healthcare costs in Western Sydney.

A clinical trial study of serious infections in newborn babies found that treatment with costly IVIg resources to be of no benefit

**Background.** Infection in newborns is associated with serious complications, including brain damage and disability, particularly among preterm infants. Earlier research suggested that treatment with intravenous immunoglobulin (IVIg) could reduce mortality in babies with serious infection by ~50%. IVIg is an expensive resource extracted from donated human blood, and its administration carries risks of fluid overload, allergic reaction and the introduction of a healthcare-associated infection. This treatment had become common clinical practice, requiring significant time and effort to administer.

Australian researchers conducted a randomised controlled trial study of newborns globally. The study concluded that the rate of death or severe disability in newborns with suspected or proven neonatal sepsis who were given IVIg was the same as in those who were given the placebo (39%). The finding has resulted in changes in clinical practice guidelines globally, which now recommend against routine use of IVIg.

**Key Lessons:**

1. **Non-commercial clinical trials can identify interventions that do not provide clinical benefits and consume valuable health system resources.** This research proved clinical interventions to be ineffective and is expected to provide significant savings in health system costs globally by avoiding unnecessary expenditure on scarce and expensive human blood products. It will also remove the risk of intravenous line-associated infections, allergic reactions to IVIg and theoretical risk of blood product transfusion of an infectious agent.

### Implementation Tasks

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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tr>
<td>14c.1 Provide an additional $50m–$100m p.a. in competitive grants for non-commercial clinical trials through both 'top-down' strategic research and 'bottom-up' investigator-initiated proposals.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<td>14c.2 Prioritise funding for investigator-initiated non-commercial trials based on the potential health benefits of the proposed intervention, including cost/benefit analysis and public benefits (such as QALYS) in the assessment.</td>
<td>NHMRC</td>
<td>2014–15</td>
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<tr>
<td>14c.3 Revise NHMRC processes for the assessment of clinical trial applications to involve clinicians, Local Hospital Network executives and consumers, and to focus on potential outcomes, and path to implementation and impact.</td>
<td>NHMRC</td>
<td>2014–15</td>
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### 5.5 Inform Policy with Evidence

**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.

**Complexities of health policy.** The efficient allocation of public resources requires the application of appropriate public policy. However, health policy is complex because there are often strongly conflicting demands from sectoral interests and because decisions often need to be made in short timeframes, with limited or imperfect information. The Productivity Commission\(^\text{124}\) and the NHHRC\(^\text{125}\) have both noted that Australia often fails to use evidence from research to inform good policy-making. As stated by Productivity Commission Chairman, Gary Banks, in a 2009 paper *Evidence-based policy-making: What is it? How do we get it?:* 'It is as important that we have a rigorous evidence-based approach to public policy in Australia today as at any time in our history … the good news is that there is plenty of scope for improvement'.\(^\text{126}\)

> WA Health provides funding for short-term research undertaken within the policy setting of improving the evidence for a sustainable health system focussing on efficiencies and cost effectiveness, which can be translated into improved policy and practice. The research translation projects themselves are solution-driven and specifically directed at the end-users. They are investigator-initiated (‘bottom up’) and cover a wide range of areas relevant to WA Health. Projects are selected through a competitive peer review process. Key benefits and findings of this program, which is now into its sixth annual round, that are relevant to contributing to a more sustainable health system include: Cost savings and efficiencies demonstrated on the basis of research derived evidence: overall, the program is cost neutral and includes a few projects that have up to 6:1 return on research investment.

WA Department of Health

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\(^{125}\) NHHRC, 2009, op cit.

\(^{126}\) Productivity Commission, 2009, op cit.
As noted above, one of the areas where rapid benefits could be gained is the more widespread inclusion of health economics to inform resource analysis and trade-offs, and thus provide a better basis for policy decisions. As well as informing delivery of services, research also needs to inform ‘big picture’ health policy. While some aspects of healthcare provision, such as efficacy, quality and safety will benefit from research evidence produced at the level of service delivery, we also need evidence about how efficient, accessible and equitable the health system is.

“It is often not appreciated by policymakers that much of the existing corpus of clinical practice is not based on high-quality evidence and that many new therapies are adopted without robust evidence that the intervention improves lives in a cost-effective way. The investigator-led clinical trials sector has the potential to play a major role in assisting policymakers to meet future challenges.

The Australian Clinical Trials Alliance

Issue: Link between research evidence and policy is weak. There are several organisations focused on the interface between research and health policy, such as The Sax Institute, the Cochrane Collaboration and the Primary Health Care Research and Information Service. There have also been fragmented attempts over the years to address the need for evidence-based policy generation. Despite these efforts, further work is required to build a dynamic, coordinated and strong interface between research and health policy in Australia.

Although many academics have a strong desire for their research to ‘make a difference’, policy-relevant research is not always considered by academics to be well rewarded. Traditional metrics that inform career development (i.e. peer review income and publications) are less amenable to policy research. This is because policy research is often commissioned by agencies and primary research outputs are reports for government. With the increasing emphasis on the use of research evidence in policy and practice, there is a need to develop robust and meaningful impact measures to better reward policy-relevant research.

NSW Ministry of Health

Option: Identify policy gaps and build research capacity. There are various mechanisms through which policy gaps can be identified and appropriate research capacity provided:

• identify policy gaps via targeted research
• provide research capacity via NHMRC
• identify clinical evidence gaps and procure research
• provide researchers with a vehicle or body that could facilitate consideration of their research by the relevant policy makers
• fund embedded policy liaison officers
• build capacity in undertaking comparative-effectiveness research to provide evidence on effective practice
• provide an evidence portal for health practitioners
• encourage professionals from outside HMR to undertake research to assist in the provision of appropriate evidence and policy.

127 The Panel notes, for example, that at the Primary Health Care Research Conference, held in Canberra on 18-20 July 2012, which had the theme ‘Inform, influence, implement: Research improving policy and practice’, the vast majority of papers appear to have addressed ‘practice’ rather than ‘policy’, which reinforces the idea that translation of research to policy is not sufficiently well addressed in Australia.
The objective of these interventions is to help overcome the wide gulf between researchers and policy makers caused by their necessarily different methods and needs. In addition, incentives should be instituted to encourage researcher contribution to policy documents, particularly within their own health district. This could be achieved by recognising policy guidelines as a valuable form of publication and recording this in CVs; similarly, researcher contribution to evidence-based policy should be an important KPI for IHRCs to report against.

**Issue: Research guidelines do not sufficiently address the needs of policy makers.** The dissemination of the results of scientific research—including HMR—follows a well-known formula of publication through academic journals, or through academic conference presentations, posters and proceedings. However, academic publications disseminate information passively and, being primarily a reporting mechanism, do not usually advocate particular changes in practice for clinicians and healthcare professionals, although in some instances that need might be evident or implied. At a secondary stage, research results are aggregated, synthesised and published as health and medical guidelines, and it is at this point that practice changes are advocated—indeed, expected. A key aspect of NHMRC’s charter, for example, is the preparation and dissemination of health-practice guidelines.

> We acknowledge the importance of publishing health and medical research in scholarly journals. However, under the current system, there are few incentives for researchers to publish their work in other places that are more accessible to policymakers. To facilitate knowledge exchange, stronger incentives need to be put in place to encourage researchers to publish their work in non-peer reviewed formats that are more accessible and relevant to the needs of policymakers and/or practitioners.

*Australian Healthcare and Hospitals Association*

The information needs of policy makers, however, are entirely different from those of researchers, partly because their timeframes are so different. High-quality research seeks to be definitive, and the sheer volume of information can make it hard for policy makers to access key points, and translate them into policy implications. Consequently, even research commissioned by government typically falls short in delivering to the requirements of policy makers. This is in part due to a lack of structured processes around interactions between researchers and policy makers, which may happen in any of four broad ways.

1. **Researcher initiated** – This interaction is not common, and usually only applies where a research result has obvious public health benefits and cost savings for government, or where a research advocacy program such as ‘meet the scientist’ provides a direct interface between researchers and policy makers. The reason it is not common is that it is usually hard for researchers to get access to policy makers to inform them of their research and to follow-up potential policy changes.

2. **Policy maker initiated** – Politicians or government agencies may instigate a research project to provide information about a particular issue. As with all types of user-paid research, there is potential in this situation for research outcomes to be skewed towards that desired by the policy maker. Akin to this is where research which supports a policy announcement is deliberately selected by policy makers for just that reason, while other conflicting research is selectively ignored. Alternatively, research evidence can be used by policy makers to counter selective lobbying and provide checks and balances in the decision-making process.

3. **Research-policy cooperation** – Both researchers and policy makers are partners and involved from the project’s beginnings. Of the transfer pathways, this is the most productive (Case Studies 5.11 and 5.12), but unfortunately is also the least common because of the time, expense, strategic planning and cooperation involved. It is also less common because many policy problems, by their very nature, are vexed issues with no obvious solution, and research is often seen as further complicating the policy situation rather than actually solving the problem. These constraints are, of course, not reasons for ignoring this avenue of creating informed policy.
5. Enhance Non-Commercial Pathway to Impact

The most successful policy informative research comes from a synergy between researchers and policy makers, and by ensuring a culture of policy relevant research and research receptive policy.

Health Services Research Association of Australia and New Zealand

4. Systematic reviews – These are usually instigated by policy makers and set up with a specific charter or terms of reference. Examples include the Pharmaceutical Benefits Advisory Committee, Medicare Services Advisory Committee, NHMRC Clinical and Public Health Guidelines, the National Prescribing Service, ANPHA, ACSQHC and the various medical colleges.

The first two of these four approaches are very much ad hoc, while the third and fourth are very structured approaches. Each has its place in providing interactions between researchers and policy makers, but taken together they highlight the lack of a formal vehicle or body to facilitate and drive the development and implementation of evidence-based health policy in a systematic and inclusive manner.

Option: Establish a structured process within NHMRC and encourage closer interaction between researchers and policy makers. What is clearly needed is a structured mechanism for more regular and faster engagement between researchers and policy makers. The Panel believes this would best be facilitated through NHMRC given its proposed mandate and increased responsibilities as the potential candidate to assume sectoral leadership. There is also a need to encourage embedding of researchers within government policy departments in order to provide, at a minimum, a review of the evidence to assist with major policy decisions. In addition, greater involvement of policy makers, particularly in framing research questions and defining the required output, is required to ensure relevant and useable evidence is created.

Improving access to evidence from research requires mechanisms to support the rapid generation of reviews of existing evidence, in formats that meet the needs of policy makers. An example is The Sax Institute’s Evidence Check, a program that allows policy agencies to commission highly targeted evidence reviews from specialised researchers. A specialised ‘knowledge broker’ assists the policy maker to draft a brief which outlines specific policy relevant questions to be answered by a researcher in ways relevant and useful for the particular purpose.

The Sax Institute

Issue: Gaps between policy and evidence are not well known or monitored. Research surveillance on evidence-based policy and practice is not conducted and major gaps that have a major impact on health outcomes and expenditure are not well understood. This is in part due to a lack of incentives for researchers to be involved in policy-relevant research.

Option: Identify areas of policy lacking evidence-base and with greatest potential. Concerted efforts should be undertaken to conduct research on policymaker and clinician knowledge of and compliance with guidelines through ‘top-down’ requests for applications, with a focus on the policy areas that are likely have the largest impact.

There is potential for agencies to establish a formal requirement for the use of evidence in the development of policy and programs and to ensure that major policies and programs are rigorously evaluated. This could be achieved through inclusion in relevant performance agreements, policy development guidelines and through regular review and assessment.

NSW Ministry of Health
CASE STUDY 5.1

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
<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>15a.1 Enhance the capacity of NHMRC to supply evidence to: • support policy makers at state, territory and Australian Government level within four-week timeframes (i.e. literature search or meta-studies) and 1–2 year processes; • develop and review clinical guidelines with level 1–4 evidence, supported by an implementation plan; and • develop disease-specific prevention strategies in collaboration with the Australian National Preventive Health Agency.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>15a.2 Incentivise researcher contribution to policy documents, particularly within their own health district, by recognising policy guidelines as a valuable form of publication and recording this in CVs. Include this type of researcher contribution as one of the key performance indicators for Integrated Health Research Centres.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>15b.1 Encourage embedding of researchers within government for providing, at a minimum, a review of the evidence as a basis for major policy decisions.</td>
<td>Leadership body, DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>15c.1 Conduct research on policy maker and clinician knowledge of and compliance with guidelines via requests for applications.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
CASE STUDY 5.12

The SunSmart campaign has delivered significant health, economic and social benefits

Background. Australians suffer the highest rates of skin cancer in the world, largely as a result of Australia’s beach culture and higher UV levels than in other parts of the world. In 2008, there were more than 1,800 deaths from melanoma and non-melanoma skin cancer, with two of every three Australians diagnosed with skin cancer by the time they are 70.

The SunSmart program, first launched in Victoria in 1988, has become a national education and awareness campaign asserting that the benefits and risks of sun exposure. SunSmart aims to minimise the human cost of skin cancer through public awareness (e.g. the iconic Slip! Slop! Slap! campaign) and by providing leadership and innovation in ultraviolet radiation protection.

To date, the SunSmart program has prevented more than 100,000 skin cancers. The program’s focus on prevention has led to significant changes in health, including an observed downward trend in skin cancer rates in the under-40 age group who have grown up with SunSmart.

In addition to the health benefits, the program is extremely cost-effective, with research on the impact of the program indicating a $2.30 net saving for every $1 invested in promoting the campaign, making it one of Australia’s most cost-effective interventions.

Key Lessons:

1. Evidence-based policy improves population health outcomes. The SunSmart program was launched by the Victorian State Government to raise awareness of the effects of sun exposure on the incidence of skin cancer and encourage people to self-screen for skin cancer.

2. Research translation generates significant health and economic benefits. The campaign has been rated as one of the most cost-effective interventions and will deliver significant benefits to Australians now and in the future.

6. Enhance Commercial Pathway to Impact
6. ENHANCE COMMERCIAL PATHWAY TO IMPACT

6.1 Introduction

As described in Chapter 5, HMR can be translated into a range of health, economic and social benefits, for individuals, communities and governments. The two main pathways to these impacts—non-commercial and commercial—both have their place in driving benefits, and both have their difficulties. The framework for commercial translation is similar to the one for non-commercial translation described in the previous chapter, though with a different flow of activities. In commercial translation, the four phases of the framework are defined by NIH as:

- **T1** – basic science, and phase I and II clinical trials
- **T2** – observational studies, phase III and IV clinical trials, and guidelines for clinical practice
- **T3** – clinical education, conferences and marketing, and Therapeutic Goods Administration (TGA) approval, and Pharmaceutical Benefits Scheme (PBS) listing
- **T4** – studies assessing policy proposals.

Exhibit 6.1

**The NIH Research Translation Framework can be applied to commercial translation**

**NIH Research Translation Framework**

<table>
<thead>
<tr>
<th>Commercial Research Activity</th>
<th>Early Translation (T1)</th>
<th>Late Translation (T2)</th>
<th>Dissemination (T3)</th>
<th>Adoption (T4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic science</td>
<td>Observational studies</td>
<td>Phase IV clinical trials</td>
<td>Studies assessing policy proposals</td>
</tr>
<tr>
<td></td>
<td>Phase I &amp; II clinical trials</td>
<td>Phase III clinical trials</td>
<td>Clinical education and marketing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preclinical Studies</td>
<td>Guidelines for clinical practice</td>
<td>TGA approval/PBS listing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Animal Research</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Exhibit 6.1 diagram:

- **Early Translation (T1)**: Basic science, Phase I & II clinical trials.
- **Late Translation (T2)**: Guideline development, meta-analysis, systematic reviews.
- **Dissemination (T3)**: Clinical practice, timely and effective delivery of recommended care.
- **Adoption (T4)**: Evidence-based policy, inform policy, drive adherence and monitor impact.

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

The translation of research outcomes in the T1–T4 framework applies both to commercial research (e.g. drugs, medical devices) and to non-commercial research (e.g. health services, health economics). For example, in the stages of research and translation that brought about the cervical vaccine Gardasil, T1 was the discovery phase, T2 saw clinical trials that resulted in the production of guidelines for use, T3 saw adoption by clinicians and T4 was a government-sponsored vaccination program to the wider population. In a generalised epidemiological example, T1 assesses potential health applications by using clinical and population studies, T2 assesses...
the efficacy of interventions to improve health and prevent disease by using observational and experimental studies, T3 assesses the implementation and dissemination of guidelines into practice, and T4 assesses the effectiveness of interventions on health outcomes.\textsuperscript{128}

Within this framework, commercialisation is a necessary part of the process of delivering the benefits of research to the community. It can result in new and improved diagnostics, medical devices, therapeutic drugs, and a range of services. With commercial translation, financial benefits not only come to the commercialising entity through local sales and export income, but the processes and end products can also provide:

- high-value jobs in Australia;
- royalties to research institutions;
- returns to Australian shareholders of successful biotech and medical devices companies; and
- incentives and rewards to scientists and clinicians.

The process of commercialisation spans from proof-of-concept research to generating profits, and encompasses research organisations, clinical settings, business development offices, venture capital and innovation investment funds, and corporate entities. For commercialisation processes, the promise of profits means that champions may be far more numerous and forthcoming than for public-good translations. There remain, however, major barriers to the commercial translation of research into marketable drugs, devices and services, particularly in Australia. Further, it is important to ensure that researchers have a clear view of the end-user during research rather than as an afterthought.

**Benefits of commercialisation.** There is clear value in supporting the commercialisation of HMR in Australia along the developmental chain, especially in the preclinical and early clinical trial stages where appropriately-targeted support could provide the necessary stimulus to convert ideas into real products and services.

"**Australia is the leading location for biotechnology companies in the Asia-Pacific with over 1,000 biotechnology companies and 450 therapeutics and diagnostics and 600–1,000 medical technology companies ... As reported in February 2012 there were 100 ASX-listed life-sciences companies, with a market capitalisation of $31.4 billion. Australia offers world-class science, capacity for international partnerships, cost effectiveness, and a transparent and efficient regulatory system. In July 2011, Australia was ranked number five globally by Scientific American’s World View.**

**AusBiotech**\textsuperscript{129}

The combined biotechnology and pharmaceuticals sector currently provides over 40,000 Australian jobs,\textsuperscript{130} and there are over 10,000 people employed in the medical technology sector.\textsuperscript{131} The biomedical industry is Australia’s largest high-technology exporter with almost $4bn in export value in 2010–11,\textsuperscript{132} surpassing the size of the automotive industry, and is the highest manufacturing industry investor in R&D ($1bn in 2009–10).\textsuperscript{133} Publicly-listed life-sciences companies have consistently outperformed the broader equities market over the last 12 years.

Australia has clearly produced some great commercialisation successes such as CSL Limited, Resmed and Cochlear (Exhibit 6.2), but these have been too few and value creation is predominantly concentrated among these few large companies.

\textsuperscript{128} As described in MJ Khoury, M Gwinn and JPA Ioannidis, 2010, op cit.
\textsuperscript{129} Source: http://www.ausbiotech.org/content.asp?pageid=25.
\textsuperscript{131} AusBiotech URL: http://www.ausbiotech.org/content.asp?pageid=25.
\textsuperscript{132} ABS Catalogue 5368.0, International Trade in Goods and Services, Australia 2010–11.
\textsuperscript{133} ABS Catalogue 8104, Research and Experimental Development by Socioeconomic Objectives, Australia 2009–10.
Exhibit 6.2

Value creation remains highly concentrated, particularly in healthcare products and biotechnology

ASX All Ords HMR-related Sectors Market Capitalisation

$bn

<table>
<thead>
<tr>
<th>Sector</th>
<th>FY02</th>
<th>FY12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>5.5</td>
<td>2.6</td>
</tr>
<tr>
<td>Healthcare Products</td>
<td>5.7</td>
<td>10.8</td>
</tr>
<tr>
<td>Biotechnology</td>
<td></td>
<td>6.5</td>
</tr>
</tbody>
</table>

CAGR 02-12

-7.4% 6.6% 13.4%

Source: Bloomberg

The venture capital landscape has seen the largest injection of capital over the last six years in the healthcare and life sciences sector, with more than $400m invested over this period (Exhibit 6.3).

Exhibit 6.3

Healthcare and life sciences investment is the largest venture capital sector

Venture Capital Investment by Sector

2005–06 to 2011–12

$mn

<table>
<thead>
<tr>
<th>Sector</th>
<th>2005–06</th>
<th>2011–12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare &amp; Life Sciences</td>
<td>431</td>
<td>353</td>
</tr>
<tr>
<td>Technology &amp; Communications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business &amp; Industrial Products &amp; Services</td>
<td>52</td>
<td>46</td>
</tr>
<tr>
<td>Computer &amp; Consumer Electronics</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Energy &amp; Environment</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No. of Transactions

409 273 52 29 35 34

6. Enhance Commercial Pathway to Impact

It is clear that Australia has a very strong HMR capability and superior strengths in a number of specific health and biomedical research areas, yet Australia has a relatively poor record in the translation of this research into health and commercial benefits, both in the public-good arena (as discussed in Chapter 5) and in the commercial arena. Relative to the number of papers published and patents issued, Australia lags in key global commercialisation benchmarks and in creating significant public companies, commercial products, jobs and income. This means that, in addition to not gaining health benefits from those innovations, Australia misses out on the commercial and economic benefits that would also become available. The reasons for Australia's failure to sufficiently capitalise on the commercial benefits of its HMR include:

- a lack of funding for preclinical and early clinical research work
- the lack of a major pharmaceutical industry located within the country
- a relatively underdeveloped commercialisation environment in Australia, with limited knowledge of commercialisation principles among researchers, inadequate critical mass within university and MRI business development offices, and counter-productive practices relating to the protection of IP.

6.2 Support Research Commercialisation

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.

6.2.1 Introduction

Lack of 'D' in R&D. One of the major reasons Australia lags in research commercialisation is the very small proportion of funding by government to support research translation into commercial products compared to funding for basic and applied research—while over $8bn is spent annually in Australia on research across all sectors, government support for research commercialisation activities is less than 1.5% of this amount. Furthermore, many of the Australian Government-funded innovation support programs instituted over the last 10 years have been dropped for reasons mostly relating to their perceived or measured lack of impact. It is the Panel's view that further government support is required to support and accelerate commercialisation, but in a more appropriately targeted form.

134 The 2010 Excellence in Research for Australia (ERA) report found that disciplines in the health and medical sector which performed ‘well above world standard’ were: Cardiovascular Medicine and Haematology; Oncology and Carcinogenesis; Immunology; Medical Physiology; Human Movement and Sports Science; Clinical Sciences; and Pharmacology and Pharmaceutical Sciences. Source: ARC, Excellence in Research for Australia 2010 National Report, Canberra, 2010. URL: http://www.arc.gov.au/era/era_2010/outcomes_2010.htm.

135 For example, the 2012 INSEAD Global Innovation Index ranked Australia 23rd, behind smaller countries such as Estonia (19), New Zealand (13), and Ireland (9).

In the HMR commercialisation process, funding is required at three key stages—preclinical, early clinical and late clinical (Exhibit 6.4). It is at the first two stages that shortfalls in funding, or inappropriately targeted funding, are frequently experienced. Indeed, the problems at these two points are so profound that they are colloquially known as the twin ‘valleys of death’. Targeted government support at these points, in ways that leverage matching support from private sources, is critically needed.

Exhibit 6.4

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

Commercialisation Funding Stages

<table>
<thead>
<tr>
<th>Stage</th>
<th>Preclinical</th>
<th>Early Clinical</th>
<th>Late Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example</td>
<td>Research has identified potential new diagnostic/assay/drug via lab research, initial animal models, etc.</td>
<td>Research has discovered a molecule as drug candidate, evidenced by animal studies</td>
<td>‘In man’ clinical trials already through phases I and II (pilot), and addressable market scoped as commercially significant</td>
</tr>
<tr>
<td>Funding Required</td>
<td>No funding for further lab or animal trials available from grants, but too early for biotech, venture capital or industry investment</td>
<td>Funding for phases I and II (pilot) clinical trials to collect data that can support proposals to venture capital, biotechs and industry</td>
<td>Funding through phases II (well controlled) and III global clinical trials</td>
</tr>
<tr>
<td>Current Funding Sources</td>
<td>NHMRC Development Grants, Commercialisation Australia, ARC Linkage Projects scheme</td>
<td>Innovation Investment Fund (<del>$10m p.a.), MR CF (</del>$10m p.a.), Other private sector biotech fund managers (<del>$5–$10m p.a.), Small cap public biotechs (</del>$0–$20m p.a.)</td>
<td>Innovation Investment Fund, MR CF 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)</td>
</tr>
<tr>
<td>Recommended New Funding</td>
<td>$25m p.a.</td>
<td>At least $50m p.a.</td>
<td>Case for government investment not clear given scale; may be better suited to large biopharma investment</td>
</tr>
</tbody>
</table>

Notes: Includes drugs and devices
Source: Panel interviews

Because of the complexity and expense of translational activities through to proof-of-concept many potentially valuable projects fail to attract the level of resource required to progress further. For example, at CSL we look at over 100 opportunities each year. Of these, we choose 5-10% for full evaluation and then select only a handful for licensing. While many opportunities are declined because they are unsuitable for further development and commercialisation, we also have to turn down some potentially valuable and exciting projects simply because our available resources are fully allocated to other R&D projects. Some of these projects may be picked up by international companies but, in the process, opportunities to increase returns to Australia are lost.

CSL Limited

Funding at these two stages will help increase the outward flow of 'invisible ideas' that live within the research environment, and assist in unlocking their commercialisation potential (Case Study 6.1). In terms of the third, late-clinical stage, while Australia has an improving level of participation by large pharmaceutical industry investors and some private equity support, the Panel does not believe that there is a strong case for suggesting government funding for this stage, especially given the large cost involved (approximately $50m per project).
6.2.2 Bridge 'Valley of Death #1' – Preclinical Stage

Preclinical Stage Funding. The first funding 'valley of death' occurs during the development of ideas in the preclinical stage of research (discovery to proof-of-concept) where further funding for laboratory research is generally not available but the research is still too early in the development chain to attract biotech companies, venture capital or industry investment. The amount required at this point ranges from $200,000 to $2m per project. The Australian Government provides support for preclinical stage commercialisation through three different competitive grant programs. Modest funding is also provided by some MRIs, universities and privately-managed biotech funds.

- **NHMRC Development Grants scheme** – NHMRC Development Grants provide funding support for commercial development of products, processes, procedures or services that, if applied, would result in improved healthcare, disease prevention or provide health cost savings. In 2010–11, grants totalling $7.5m were awarded under the scheme.\textsuperscript{137}

- **Commercialisation Australia** – Launched in late 2009 as the successor to the Government's COMET scheme, Commercialisation Australia provides matched funding to bring IP to market for early-stage commercialisation. Funding of $50,000 to $2m over 24 months is matched on a one-to-one basis with the participant to encourage co-investment. This program has provided early-stage support for health and medical researchers in the fields of biotech, medical devices, software and online tools, supporting more than 64 projects with total grant funding of more than $25m to date.

- **ARC Linkage Projects scheme** – ARC also has a commercialisation funding scheme, Linkage Projects, which has been a productive translational mechanism for early-phase commercial development in all areas of industry. The scheme provides funding to eligible organisations to support R&D collaboration between higher education researchers and the industry, that is undertaken to acquire new knowledge and involves risk or innovation.

- **Other sources** – These include some discretionary funds from MRIs and industry investment from private sector biotech fund managers and the bio-pharmaceutical industry. While these investments are considered high risk, they are generally well deployed, particularly in larger research organisations with commercialisation expertise, and successful funds such as the Medical Research Commercialisation Fund (MRCF).

The aggregate of these sources of preclinical 'D' funding is estimated at no more than $25m p.a. The Panel considers this to be a seriously inadequate allocation in the R&D mix needed for any sustained improvement in the national HMR commercialisation pipeline. A conservative estimate of the funding gap at the preclinical stage is about $25m p.a. since these existing sources are less than optimally targeted and inadequate in scope.

**Issue: NHMRC Development Grants can be further leveraged.** An independent evaluation of the Development Grants Scheme commissioned by the NHMRC found that Development Grants have been successful.\textsuperscript{138} The study surveyed all completed and current Development Grants in the 2000–2008 period (estimated to be over 300), and selected 40 grants for further analysis, although the details of the 40 grants and criteria for selection have not been provided.

The Panel's concern, however, primarily lies within the positioning of the Development Grants. Several submissions to the Panel suggested that the commercial criteria required to be met by applicants to the scheme are too onerous and are unrealistic for such early-stage developments. In addition, the panels assessing these grants appear to place undue emphasis on track record. Very few researchers have achieved commercial success, and most will only do so once. As a result, the bar is inappropriately high and it remains unclear whether the scheme delivers the necessary 'development' part of the R&D process.

\textsuperscript{138} Ibid.
NHMRC Development Grants are designed to support individual researchers, research teams, or a company in partnership with a researcher/s to undertake work at the early proof-of-principle or pre-seed stage. While we support the intention of these grants, they are largely ineffective because:

- funding is too little and far too short a term to make a real difference: $100-300K per year over 2 years; and
- there is no requirement for the researcher to form links with a company capable of, and willing to, assist with advancing the project. A scheme like this needs to encourage strong links between the investigator and a commercial partner to drive it forward.

**Option: Institute a Matching Development Grants scheme.** An option to address the preclinical ‘valley of death’, particularly early on and prior to engaging a commercial partner, is to institute a Matching Development Grants program that provides, for example, 2% of a moving three-year average of NHMRC Project Grants to host organisations such as the 20 consistently most successful NHMRC peer-reviewed grant recipients. The grants would require host recipients to:

- match the stapled grant dollar-for-dollar with their own or third-party funds;
- have an established business development office or demonstrated use of an outsourced commercialisation service provider (and include a requirement to screen inventions for potential market relevance before filing patent applications);
- select proof-of-concept and development projects (instead of NHMRC); and
- audit funds to ensure they are only used for development purposes.

The advantages of this scheme include the potential to significantly increase the development funding for early-stage discovery and shifting the review and selection burden from the NHMRC back to the recipient organisations while maintaining or increasing the likelihood of success given the requirement for co-investment ‘skin in the game’. Small research institutes would not be excluded from accessing these grants, although they may need to collaborate with larger MRIs and university groups to access business development capability, or otherwise with third parties that have such skills (for example, large pharmaceutical companies, Commercialisation Australia or venture capital enterprises).

Funding for the new NHMRC Matching Development Grants scheme of up to $10m p.a., to be matched with $10m in development funding by recipient host organisations, could be expected to enable the advancement of up to 50 projects each year—projects that would otherwise languish and expire in the first ‘valley of death’. The scheme may be suitably funded by a modest reallocation of existing NHMRC funds while more than doubling the aggregate of development funding.

**Issue: Greater alignment between commercialisation schemes is needed.** There is also some overlap in activity between NHMRC Development Grants and Commercialisation Australia, and to some extent the ARC Linkage Projects scheme, all of which provide funding for preclinical proof-of-concept and development projects. Given the infancy of the Commercialisation Australia program, operating for just over three years, it is too early to comprehensively evaluate its performance. It is clear, however, that Commercialisation Australia has built capability and expertise in providing commercial development advice in addition to funding. This capability has strong potential to be leveraged by others involved in the development process.

Schemes such as NHMRC Development Grants, Commercialisation Australia and ARC Linkage Grants need to be complementary and support the translation of research without leaving gaps, particularly at the early stages of translation where there is often a gap between ‘discovery’ and ‘development’. These schemes need to be expanded to fill the void left by the critical shortage of venture capital in this country. Coordination between government agencies and departments is critical.
Option: Increase coordination between existing schemes. Increased alignment and coordination between existing schemes is recommended. As noted by the NHMRC Development Grants evaluation report recommendations, the NHMRC should consult with Commercialisation Australia and appropriate agencies in other jurisdictions on options for greater coordination between Development Grant projects and publicly-funded, early-stage, proof-of-concept opportunities. 139

Issue: ARC Linkage Project grants are no longer readily accessible to the HMR sector. ARC recently introduced significant restrictions to health and medical researchers' eligibility to apply for ARC funds. This rendered all preclinical research ineligible, completely discriminating against commercial development in this sector. In contrast to feedback on the NHMRC Development Grants, submissions to the Review suggested support for the partner-leveraged approach of the ARC Linkage Projects scheme which appears to have effectively supported preclinical development. Hence, the loss of ARC Linkage Projects grants to the HMR sector is significant as it shuts down a large section of early commercial translation.

Option: Restore access to ARC Linkage Project grants for HMR sector. Commercialisation of HMR as part of the DIISRTE portfolio is as important as commercialisation in any other sector. Maintaining HMR access to ARC Linkage Projects scheme grants is important, as many current medical devices and treatments were only enabled by the basic science discoveries that underpinned them. The Panel therefore recommends that DIISRTE ensures that the HMR sector has full access to ARC Linkage Projects grants, Cooperative Research Centre (CRC) funding and other DIISRTE development and commercialisation programs, particularly those relevant to multi-disciplinary projects spanning engineering, IT, HMR, physics, nanotechnology and other disciplines.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>16a.1 Institute a Matching Development Grants scheme for preclinical stage research that provides block-grant funding of $500,000 to each of the 20 largest NHMRC peer-review grant-recipient research organisations, as measured by the moving average of the most recent three years of grants. Ensure that recipients satisfy the following three criteria of: • appropriate internal business development resources • agreed access to NHMRC-approved external business development resources (e.g. Uniquest, Medical Research Commercialisation Fund) • providing matching cash commitments. Allow recipient organisations to select prospects for development and require them to submit annual acquittals to NHMRC. Encourage smaller organisations to collaborate with the larger block-grant recipients.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>16a.2 Evaluate the success of the Matching Development Grants program at the end of the first five-year period.</td>
<td>NHMRC</td>
<td>2019–20</td>
</tr>
<tr>
<td>16a.3 Increase coordination between existing commercialisation schemes, particularly NHMRC Development Grants and Commercialisation Australia.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>16b.1 Clarify that DIISRTE is the Australian Government department responsible for commercialising research and covers HMR.</td>
<td>DIISRTE</td>
<td>2014–15</td>
</tr>
<tr>
<td>16b.2 Ensure that HMR has access to and support from the ARC Linkage Projects scheme, CRC and other DIISRTE commercialisation programs.</td>
<td>DIISRTE</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

CASE STUDY 6.1

CSL is one of Australia’s greatest commercialisation stories and its success has been underpinned by sustained R&D investment

Background. CSL Limited is a global leader in the research and development of bio-pharmaceutical medicine and is Australia’s largest biotechnology company and one of the country’s greatest commercialisation success stories. CSL makes a significant contribution to the Australian economy with a market capitalisation of over $27bn,¹ sales revenue of over $500m and over 1,700 employees². Globally, CSL employs over 10,500 staff in more than 25 countries, generating sales of over $4.4bn in 2012—a 19% annual increase over the last 15 years.

Much of CSL’s success has been driven by its significant investment in R&D, which has grown from $37m in 1997 to $355m in 2012. CSL maintains a number of long-standing, strategic partnerships with Australian research organisations.

Through its Australian operations, CSL has pioneered a number of medical interventions that have had global impact, including:

- Gardasil – the first vaccine designed to prevent a cancer
- Panvax H1N1 – H1N1 influenza vaccine
- Fluvax – influenza vaccine
- Intragam P – immunoglobulin used to treat immunodeficiency
- Biostate – coagulation therapy

Key Lessons:

1. **Research commercialisation creates national wealth and new jobs.** CSL generated sales in Australia of over $510m in FY12 and currently employs more than 1,700 Australian workers.

2. **Sustained investment in health and medical research leads to innovation and wealth creation.** Investment in HMR ensures Australia continues to deliver internationally competitive research discoveries that can be translated to evidence-based care and maintains a critical mass of highly trained and skilled researchers to undertake basic research and foster translation.

Note: 1. As at 31 December 2012  
   2. Full-time equivalent employees  
   Source: CSL Limited: www.csl.com.au; Bloomberg
6.2.3 Bridge 'Valley of Death #2' – Early Clinical Stage

Current Funding Sources. In the early clinical development stages, funding is needed to collect data to support late clinical stage development proposals that would seek funding from venture capital, biotechnology and industry corporations. The current funding sources for early clinical stage work are estimated at $40m p.a. and comprise several sources.

- **Innovation Investment Fund (IIF) ($10m p.a.)** – The IIF is a co-investment scheme that uses a competitive process to license private sector fund managers and provide them with capital for investment at a matched ratio (currently 1:1). The program is not sector specific and investments are made in the field of expertise of the fund rather than the sector. Each fund manager pools their capital and invests in early-stage companies that are commercialising Australian R&D. The government also incentivises investors by allocating 90% of the profits of a successful exit to the private sector partner. Since its inception in 1998, the IIF has supported 47 HMR companies with $124m in investment, representing about 40% of the total fund.

- **Medical Research Commercialisation Fund (MRCF) ($10m p.a.)** – MRCF is managed by Brandon Capital and has been sponsored by state governments and private superannuation funds. It searches for potentially attractive research ideas for review and brings together member MRIs across the country to share technology and propose possible investment opportunities.

- **Other private sector biotech fund managers ($5–10m p.a.)** – Examples of biotech fund managers who provide support for early-stage development and commercialisation of medical technologies by bringing together research institutes, healthcare providers and investors include Starfish, Southern Cross, Coates Myer and GBS Ventures.

- **Small-cap public biotechnology company equity issues (up to $20m p.a.)** – While capital raisings also provide a source of investment at this stage, this is more towards the later end at which point the research has largely been proven.

**Issue: Insufficient funds to support early clinical stage ventures.** Funding for this stage is also considered to be inadequate, and a conservative estimate of the additional requirement is in the order of $50m p.a., supporting an average of five additional projects each year at $10m per project. While IIF has been successful and delivered returns to the Australian Government, it does not cover the second 'valley of death' gap in funding for HMR. The performance to date of bioscience funds in Australia has not been sufficient to warrant continued institutional support without additional risk-mitigation measures. There is therefore a compelling case for the Australian Government to provide a mechanism to stimulate private institutional investment.

**Option: Create a Translational Biotech Fund.** What is needed to bridge the second 'valley of death' is a Translational Biotech Fund (TBF) that would provide support from the end point of the NHMRC Matching Development Grants program (or ARC Linkage Projects scheme), through the early clinical stage (clinical trial phase I or II). The TBF would be a $250m fund seeded with class B equity capital of $125m by the Australian Government (callable over five years), and matched by industry sources (for example, large superannuation funds). The TBF should be styled along IIF lines, and managed by a well-qualified external manager with experience in the biosciences sector in Australia (and possibly in collaboration with off-shore bioscience venture capital firms).
CASE STUDY 6.2

Investment to commercialise research insights has taken VitroGro® from the lab to the cusp of delivering impact

**Background.** VitroGro® is the culmination of a commercial partnership between researchers at The Queensland University of Technology (QUT) and investment by Tissue Therapies. VitroGro® is a patented biomimetic scaffold comprised of portions of naturally-occurring proteins that facilitates attachment of skin cells and restores wound healing.

VitroGro® development began in 2001 at QUT but it was not until a chance meeting between Professor Upton of QUT and investor Greg Baynton at a Toronto biotechnology conference in 2002 that VitroGro® was set on the path to commercialisation. Mr Baynton arranged for seed funding of $250,000 and incorporated Tissue Therapies, the commercialisation vehicle for VitroGro®. Tissue Therapies was then publicly listed in 2004 and is currently in the final stages of gaining approval for VitroGro® in Europe with clinical trials expected to start in the US in 2013.

Tissue Therapies expects VitroGro® to be used in the treatment of chronic wounds, which are expensive to treat and can result in amputation. Each year more than 3,000 Australians are forced to undergo amputation as a result of diabetic ulcers, while in the US the cost of diabetic ulcer treatments is estimated at US$6bn annually, with amputations accounting for US$1bn.

**Key lessons:**

1. **Research leads to medical innovations that deliver better health outcomes and can reduce healthcare costs.** VitroGro® is designed to be applied to burns, ulcers and surgical wounds to replace the degraded wound matrix and restore healing. This new treatment can significantly improve the treatment of wounds, with a particular focus on treating chronic wounds, a condition that reduces quality of life and can lead to amputation, and is costly to treat.

2. **Investment during the early stages of commercialisation is critical to ensure translation of Australia’s health and medical discoveries.** The chance meeting between researcher and financier resulted in early-stage investment and the formation of Tissue Therapies to help VitroGro® navigate the commercial ‘valleys of death’ and provide funding support for animal and human trials to be conducted on VitroGro®.

Note: Image courtesy of the Institute of Health and Biomedical Innovation, Queensland University of Technology
The manager would:

- be selected via a competitive tender process to build a portfolio of investments with a target minimum of 25 proof-of-principle-in-man projects;
- be required to raise half of the $250m from superannuation funds or other private sources which would be issued class A equity, matching the Government dollar-for-dollar, but ranking ahead of class B for the first $125m in distributions from the fund; and
- receive a private equity-style fee of 2% p.a. on managed funds, plus 25% of net realised profits over the 15-year investment life of the fund.

The TBF proposal can be expected to receive strong support from the industry, including the Australian Private Equity and Venture Capital Association (AVCAL): ‘we strongly endorse the recommendation for a $250m early-stage development fund … we would recommend that the fund be administered in the form of a biomedical-dedicated round of the existing Innovation Investment Fund (IIF) co-investment program. The IIF program is well-understood by industry participants and would, in the long-term, enable the funds to be part of a revolving, self-sustaining program’.140

As noted by AVCAL, in addition to closing the funding gap, the TBF also has the potential to generate returns for the Australian Government that could be reinvested in the sector. The success of the TBF, and successful commercialisation of Australian biotechnology R&D as evidenced over time, should be evaluated within 10 years following establishment against its ability to:

- demonstrate the advancement of HMR projects from early clinical stage to commercially viable outcomes
- maximise IP returns in Australia
- accelerate growth in profits, exports, job creation (including in clinical trials activity) and taxation benefits
- achieve venture-capital-style investment returns for the investors in the fund.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>16c.1 Establish a new $250m Translational Biotech Fund (TBF) for early-stage development, funded by the Australian Government and the private sector on a matching basis, structured to incentivise superannuation fund investors but not require government investment until the third year (refer to detailed terms sheet in Exhibit 6.5), and managed by a selected fund manager from the biosciences sector.</td>
<td>Department of Health and Ageing, DIISRTE</td>
<td>2014–15</td>
</tr>
<tr>
<td>16d.1 Continue to support the Innovation Investment Fund and ensure access for HMR development projects.</td>
<td>DIISRTE</td>
<td>2014–15</td>
</tr>
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</table>

140 Response to Consultation Paper from the Australian Private Equity and Venture Capital Association.
Exhibit 6.5

Draft Terms Sheet

Proposed Translational Biotech Fund (TBF)

Purpose: Provision of venture capital for commercialisation of Australian medical research. Investment will be targeted to fund entities with projects at the phase I or II clinical trials stage with novel drug candidates or medical devices.

Size of Fund: $250m

Estimated average investment is expected to be $10m per project or portfolio company, with total number of investments expected to be 20 to 25. The TBF may invest in minority or majority voting and equity positions.

Term: The TBF has a 15-year vesting period, with an investment period of 7.5 years.

Structure: The TBF could be either a venture capital limited partnership or a managed investment trust, subject to final tax advice. This is designed to accommodate Australian and offshore investors.

Manager: The TBF will be managed by an experienced biotech fund manager pursuant to a competitive tender process. Criteria for selection will include:

• commercialisation track record and reputation;
• knowledge of the medical research and biotech sector;
• evidence of collaboration with offshore biotech venture managers; and
• experience in fund raising.

The Manager will be majority owned by Australian residents.

Investors: The Australian Government will be required to subscribe for $125m in the Fund. This will be in class A units subscribed as and when called by the Manager during the 7.5 year investment period. No government funding would be required until year three of the fund, estimated in 2015–16.

Institutional investors will be invited to subscribe for $125m in the Fund. This will be in class B units subscribed $ for $ with the A units.

Distributions: The B units enjoy preferred distribution rights over the A shares as follows:

• first $125m distributions made to B units
• next $250m distributions made to A & B units in ratio 50/50
• thereafter distributions made to A & B units in ratio of 25/75.

Manager Fees: Management fees will be 2% p.a. of committed capital for the first five years and 1.5% p.a. of invested capital for next five years.

Manager Carry: Manager’s carry will be 25% of net realised distributions (NRD) by the Fund. NRD is defined as distributions after all invested capital in the Fund compounded by the annual Reserve Bank rate together with the sum of all management fees have first been returned to the A&B class investors.

Governance: The investors will appoint an investment advisory board.
6.3 Enhance Commercialisation Environment

**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).

### 6.3.1 Introduction

Australia has a relatively underdeveloped culture for commercialisation of its innovation, with limited knowledge and skills among the research community. There is a lack of infrastructure to assist startups, including necessary incubation assets (for example, flexible shared space without requirements for major capital or cash-flow commitments). In addition to lack of funding support for commercialisation, these knowledge-based and infrastructure constraints further hamper business development in the HMR sector. Overall, Australia suffers from a lack of critical mass and the absence of a strong culture of innovation compared to other countries.

There are four key initiatives required:

- foster a culture of commercialisation
- leverage scale and expertise
- protect valuable intellectual property
- attract clinical trials.

While this is a broader issue, there are some actions 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 potential applications).

…” there is significant room for improvement in Australia’s commercialisation culture. Gains from basic research and proof-of-concept activities are still being lost because start-ups and small firms have inadequate access to advice and funding.

GlaxoSmithKline
6.3.2 Foster a Culture of Commercialisation

Commercialisation expertise among researchers. Despite a strong, government-supported push 10 to 15 years ago for Australia to move into the knowledge economy through establishment of Biotechnology Australia and other innovation-based initiatives, commercialisation skills and expertise are still in short supply. Many researchers are not commercially savvy, and are not focused on potential commercial applications for their research. Commercial outcomes of research are generally unpredictable and often arise from basic research that is not necessarily driven by a desire for a commercial outcome. The core skill set for scientists is obviously discovery, but if Australia is to capture more commercial benefits from its high level of investment in research, much more support is needed for researchers to help them recognise the practical application of their research, identify commercial opportunities and negotiate commercial outcomes.

Issue: Poor incentives for researchers to commercialise discoveries. There are few incentives for researchers to commercialise in Australia. Indeed, there are strong disincentives as the time taken for commercialisation activities reduces a researcher’s chances of producing high-impact publications that are essential for grant success. In addition, the commercialisation approaches in Australia often provide inadequate opportunity for investors to financially benefit. Brilliant research and successful commercialisation must not be viewed as mutually exclusive pursuits. The linkages between academic researchers and industry in Australia are weak. There is generally poor communication between the two groups and inconsistencies in approaches to commercialisation.

Compared with other countries, Australia and the UK are notably characterised by having the minority of their researchers employed in business relative to higher education, with a ratio of about 0.4 (Exhibit 6.6). Most developed countries have a ratio of around 2.

Exhibit 6.6

Australia and the UK have a minority of researchers employed in business relative to higher education

Researchers in Business vs. Higher Education
# Researchers per 1000 workers

Ratio of 2.0 researchers in business vs. education

Australia has a ratio of 0.4 researchers in business vs. education
Commercial investment in Australian Nanopatch technology is expected to revolutionise the delivery of vaccinations

**Background.** Vaxxas is a startup company established to commercialise the Nanopatch, originating from Professor Mark Kendall's research at The University of Queensland's Australian Institute for Bioengineering and Nanotechnology. Vaxxas' proprietary technology provides a needle-free vaccine solution, utilising a Nanopatch with thousands of projections which perforate the skin quickly and painlessly delivering the vaccine payload. This application varies markedly from the conventional needle and syringe injection approach, requiring as little as one hundredth of the dose and not requiring refrigeration during transportation and storage.

Vaxxas was founded by Professor Kendall in 2011 and UniQuest (UQ’s main commercialisation company) successfully negotiated the significant $15 million investment from OneVentures, with co-investors Brandon Capital, the Medical Research Commercialisation Fund (MRCF) and US-based HealthCare Ventures. This crucial investment will allow Vaxxas to advance their commercialisation process, growing a company that has the potential to impact the next generation of vaccines worldwide.

This investment allows Vaxxas to commercially advance the Nanopatch along the clinical testing and development pipeline towards becoming a next-generation, needle-free vaccine delivery device. Vaxxas’ focus is on translating the key Nanopatch benefits already observed in preclinical testing (e.g. improved immune responses, no need for vaccine refrigeration, no needle-stick injuries) to a clinically-proven product for widespread use. These translated benefits will improve the reach of vaccines and help reduce the annual death toll of infectious diseases of 17 million people. The Nanopatch could also have a significant impact on the multimillion dollar vaccine industry.

**Key lessons:**

1. **Commercial investment is crucial to develop research discoveries that deliver better health.** Vaxxas' ability to attract investment is a crucial achievement, allowing this technology to be developed further with the ultimate goal of distribution and use by consumers worldwide.

2. **Australia's commercialisation capability can attract global investment.** The global syndicate investment in Vaxxas is reflective of the potential opportunity for Australia’s research organisations to partner with global investors to transform research efforts into commercially-viable products. UniQuest's expertise in commercialisation of research has been crucial to this process.

**Note:** Image courtesy of UniQuest

**Source:** Vaxxas: http://www.vaxxas.com; Australian Institute for Bioengineering and Nanotechnology: http://www.aibn.uq.edu.au
Option: Establish stronger linkages between researchers and industry. Greater penetration of understanding of the research community by industry, and vice versa, is needed to facilitate commercial input at critical stages in the research process. A more collaborative approach, such as internships, is likely to foster mutual benefit and assist in the flow of funding from the commercial sector to the research sector. Other actions, such as developing a ranking of institutions on HMR commercialisation success and establishing awards and industry events for HMR commercialisation success, may also assist in fostering a stronger culture of commercialisation of HMR in Australia.

"Industry fellowships have been a success from CSL’s perspective. They have led to fruitful long term linkages between CSL and research organisations and have often been targeted specifically towards addressing the translational research gap described above. While important and adding significant value, these fellowships cannot be expected to address the full spectrum of translation activities. However, coupled with targeted translational research funding they can help develop specialised skills to support early stage commercial development of potential products."

CSL Limited

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>17a.1 Establish an internship program to enable freer interchange between researchers and the industry (in both directions), possibly targeting NHMRC overseas post-doctoral fellows.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
<tr>
<td>17a.2 Include HMR commercialisation success as one of the measures in sector-wide rankings.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>17a.3 Establish awards and industry events for HMR commercialisation success.</td>
<td>Leadership body</td>
<td>2014–15</td>
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6.3.3 Leverage Scale and Expertise

Need for scale and expertise. Over the last 15 years, many universities and MRIs have established their own commercialisation offices and have started to become more sophisticated in the way they manage commercialisation opportunities. Most, however, are still at a point below critical mass, where small commercialisation offices have neither the depth of expertise and experience, nor the resources to provide high-level advice, in a timely manner, to researchers who may have potentially commercialisable assets in their research portfolios. This means not only that smaller research agencies are disadvantaged in their ability to realise the commercial potential of research discoveries, but that Australia overall misses out.

"Many research innovations are not progressing beyond the lab because of the lack of expertise and resources to prepare them for investment in the development process. To improve the effective commercialisation of health research outcomes there needs to be improved resourcing and funding of technology transfer offices. The centralisation of these resources would allow for best practice through the provision of a critical mass of commercially experienced professionals, which ideally should be in the order of 20–30 people for maximum effect."

UniQuest
Issue: Many commercialisation offices are sub-scale. With a few exceptions (such as UniQuest – Case Study 6.4), commercialisation offices are sub-scale and do not have the required level of expertise to assess opportunities adequately in their own domain areas. The difference between the best and second-best resources can be decisive. The range of problems evident across university business development offices includes:

- over-valuation of initial discoveries
- a short-term mindset driven by the need for cost recovery of overheads
- lack of industry skill and understanding
- lack of international business development connections and acumen
- a general failure to recognise the diversity of commercial translation activities that lead to successful outcomes.

In addition, commercialisation skills are in short supply in Australia, particularly in the ability to choose and establish:

- products (molecules, devices, services) where partnerships with industry and licensing arrangements are needed; and
- platform technologies where a spin-off business development company may need to be established.

Option: Promote sharing of commercialisation capacity and resources. Because commercialisation skills are scarce, it is more efficient to have larger commercialisation resources that can be called upon by other institutions, than to have each small institution attempt to build end-to-end commercialisation capability. Some rationalisation is clearly needed. The obvious action is to promote the sharing of resources to leverage the scale of the more successful commercialisation offices. In addition, there needs to be much greater flexibility for researchers to allow them to move between research and commercial roles. Researcher career paths that move between universities, MRIs and industry need to be encouraged and rewarded, and pathways for re-entry to research from commercialisation activities in industry need to be improved. This matter is considered in more detail in Section 4.2.

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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>17b.1 Encourage research organisations with sub-scale or no business development offices to engage larger institutions/precincts for commercialisation requirements.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

6.3.4 Protect Valuable Intellectual Property

IP is clearly a valuable commodity in Australia's knowledge-based economy, and skilful IP protection is necessary to ensure inventions are safeguarded. A patent gives its owner the right to prevent others from making, using, importing or selling an invention based on that idea. For medical devices, however, patents are often not a viable source of protection due to the short life of a medical device product (usually 2–3 years). Medical device companies often use contractual methods of protection such as confidentiality agreements, and trade secrets.

Issue: Australia’s IP system is weak and not harmonised with international best practice. The best way to protect valuable IP is by ensuring Australia’s IP system is strong, stable, predictable and harmonised with international best practice. This cannot be achieved if policy makers implement undesirable reforms, such as the proposals to ban patents on biological materials and make it easier to obtain compulsory licences. It also cannot be achieved if efforts to harmonise IP standards with global best practice are inconsistent.
CASE STUDY 6.4

UniQuest is one of the largest commercialisation service providers in Australia, combining expertise and scale

**Background.** UniQuest is a leading Australian research commercialisation company which specialises in global technology transfer and facilitating access for all business sectors to world-class university expertise, intellectual property and facilities. Formed by The University of Queensland (UQ) in 1984, UniQuest was based on the model of university technology transfers in Silicon Valley and Cambridge, where the co-location of entrepreneurs, universities and industry led to a critical mass that resulted in significant technological outcomes.

Integrating public and private funding is essential to achieving translational research goals. Since 2000, UniQuest and its startups have raised more than $450m to take university technologies to market. Annual sales of products using UQ technology licensed by UniQuest are running at $3bn. Its innovation portfolio includes Australia’s first blockbuster vaccine Gardasil, pain therapy developer QRxPharma Ltd, the internationally-acclaimed Triple P Positive Parenting Program and UQ’s superconductor technology which is used in two-thirds of the world’s MRI machines.

UniQuest has commercialised an extensive range of ideas, developed more than 1,500 patents and created over 70 companies. This success is a direct consequence of the culture of collaboration embedded at UniQuest, which facilitates partnerships with Australia’s leading Life Sciences research institutions. Innovation and expertise are shared with both the public and private sectors. Ultimately, this leads to significant societal, economic and reputational benefits, both in Australia and abroad.

**Key Lessons:**

1. **Successful research commercialisation requires technical expertise, collaboration and scale.** UniQuest specialises in brokering commercial agreements between researchers and sources of funding. It is one of the largest technology transfer companies in the world.

2. **Public and private funding for university-based innovation is essential to achieve translational research goals.** UniQuest’s achievements demonstrate that improved health outcomes can be delivered sooner when governments, universities and industry interact and invest for a common purpose.

3. **Commercialisation delivers improved health outcomes and generates economic returns for researchers and investors.** UniQuest led the commercial effort to patent the cervical cancer vaccine that became Gardasil, the world’s first vaccine designed to prevent a cancer, and negotiated syndicated venture capital funding for QRxPharma, which raised $50m in its 2007 IPO.

Note: Image courtesy of UniQuest
Option: Strengthen and standardise Australia's IP system. There is a need for Australian governments to ensure the strength and stability of Australia's IP system through means such as:

- rejecting calls to exclude biological materials from patentable subject matter
- rejecting calls to make it easier to obtain compulsory licences
- extending the term of data exclusivity to harmonise an important element of the Australian IP system with international best practice.

Issue: Too many low-value patent applications are filed. With patents, timing is vital, and a balance needs to be struck between failing to recognise an idea that should be patented and filing too many patent applications, many of which are not commercially-valuable ideas. While on a global basis, Australia files relatively few health-related patents, too many patent applications are filed prematurely in Australia which wastes time and resources. In addition, by prematurely awarding patents, a monopoly is essentially achieved that actually slows the rate of innovation, collaboration and development. In other instances, over-patenting can be a perverse driver, hindering or preventing commercialisation, especially where it involves too many parties.

Option: Ensure greater rigour when assessing value of IP before patenting. There is thus a need to rigorously screen novel discoveries and inventions for potential market impact before filing for patents and attempting to commercialise them. Researchers should be encouraged to consult business development offices to ensure that IP is suitable for commercialisation before attempting to file a patent application. The assessment should be made by people with commercial experience in patenting.

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<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tr>
<td>17c.1 Strengthen Australia's intellectual property system and harmonise it with international best practice, to ensure that it appropriately supports and encourages investment in R&amp;D, particularly HMR.</td>
<td>DIISRTE</td>
<td>2014–15</td>
</tr>
<tr>
<td>17c.2 Encourage researchers to consult business development offices and ensure intellectual property is rigorously assessed for its commercial potential prior to filing patent applications.</td>
<td>NHMRC</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

6.3.5 Attract Clinical Trials

The US accounts for a large part of clinical trial activity and, together with Canada, represent approximately 50% of clinical trial sites worldwide.\[^{141}\] For historical, market and regulatory reasons, virtually all potentially commercial health and medical innovations undergo clinical trials in America, but they may also be trialled in overseas markets. For many years, Australia has been seen as a desirable place for clinical trials to be conducted because of its well-structured health sector, high level of research competence and strong competitive position in terms of time to completion.

For the various reasons described in Section 2.6.1, Australia is now at risk of losing its competitive position for global clinical trials. This is reflected in a recent survey of global companies that indicated expectation that Australia’s competitiveness will remain stagnant or decline (Exhibit 2.13). Furthermore, Australia is now one of the most costly countries for clinical trials (Exhibit 6.7). It is, therefore, imperative that clinical trial processes are reformed as a matter of urgency as proposed in Recommendation 5.

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 deliver translational results that improve health outcomes for Australians and to maximise the value of IP developed locally that builds national wealth and creates new jobs.
7. Attract Philanthropy and New Funding Sources
7. ATTRACT PHILANTHROPY AND NEW FUNDING SOURCES

7.1 Introduction

Non-government investment has an important role to play in supporting HMR. Traditional philanthropy has always been a significant contributor to HMR, a tangible expression of the public’s desire for greater investment in these fields. Recently, more innovative funding mechanisms have been explored and implemented—social bonds, lotteries, matching schemes and prizes have emerged globally. There are various additional approaches that can be drawn upon to attract more investment into the sector (Exhibit 7.1).

Exhibit 7.1

There are a number of additional sources of HMR funding which can be grouped into two main categories

Additional HMR Funding Sources – Examples

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attract Philanthropy</td>
<td>Large Global Philanthropy</td>
<td>Bill and Melinda Gates Foundation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Research budget of US$800m per annum</td>
</tr>
<tr>
<td></td>
<td>Wellcome Trust</td>
<td>Spends ~£600m on research annually</td>
</tr>
<tr>
<td></td>
<td>Atlantic Philanthropies</td>
<td>Total Australian HMR investment of $350m</td>
</tr>
<tr>
<td>Government Matched Funds</td>
<td>UKRPIF Matching Fund</td>
<td>Government matched funding of ~$220m</td>
</tr>
<tr>
<td></td>
<td>Arts Matching Funds</td>
<td>UK government matched funding of £80m</td>
</tr>
<tr>
<td>Collaboration, Scale and Innovation</td>
<td>EURORDIS/NORD Partnership</td>
<td>US/European collaboration on rare diseases</td>
</tr>
<tr>
<td></td>
<td>Cancer Australia</td>
<td>Priority-driven collaborative scheme</td>
</tr>
<tr>
<td>Identify New Funding Sources</td>
<td>Alternative Debt Financing</td>
<td>UK Social Bonds</td>
</tr>
<tr>
<td></td>
<td>NSW Social Bond Trial</td>
<td>Trialling social bonds (e.g. $7m for recidivism)</td>
</tr>
<tr>
<td></td>
<td>Future Health Institute</td>
<td>$2bn for translational HMR investment</td>
</tr>
<tr>
<td>Tax Rebates and Levies</td>
<td>R&amp;D Tax Rebates</td>
<td>Australian R&amp;D tax credits</td>
</tr>
<tr>
<td></td>
<td>Medicare Levy</td>
<td>1.5% taxable income levy to fund healthcare</td>
</tr>
<tr>
<td>Other Schemes (Prizes, Lotteries)</td>
<td>US Defense Grand Challenge</td>
<td>US$1m prize offered for driverless car</td>
</tr>
<tr>
<td></td>
<td>UK Health Lottery</td>
<td>Donates over 20% of revenue to health causes</td>
</tr>
</tbody>
</table>
These investment sources can be grouped into two broad funding categories, with each requiring a different leverage approach (Exhibit 7.2).

- **Attract philanthropy** – Australia can improve support from large local philanthropic sector, as well as become a more attractive destination for large international philanthropy.
- **Identify new funding sources** – There are some alternative methods to source public funds, match timing to benefits and tie funding to outcomes other than general taxation.

### Exhibit 7.2

**There are different ways to leverage additional sources of funding**

<table>
<thead>
<tr>
<th>Category</th>
<th>Segment</th>
<th>Opportunity</th>
<th>Approach to Best Leverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attract Philanthropy</td>
<td>Large Global Philanthropy</td>
<td>• Attract investment to tackle global and developing-world issues</td>
<td>• Make Australia more attractive destination for global philanthropy</td>
</tr>
<tr>
<td></td>
<td>Government Matched Funds</td>
<td>• Reduce gap in donations among high-net-worth individuals</td>
<td>• Incentivise large philanthropy with government matched funds</td>
</tr>
<tr>
<td></td>
<td>Collaboration, Scale and Innovation</td>
<td>• Encourage sector collaboration and scale to increase efficiency and effectiveness</td>
<td>• Facilitate collaboration and coordination within sector to increase efficiency</td>
</tr>
<tr>
<td>Identify New Funding Sources</td>
<td>Alternative Debt Financing</td>
<td>• Health bond/social bond schemes to match benefit timing or align outcomes</td>
<td>• Explore Treasury appetite for bond-type schemes and models</td>
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<td></td>
<td>Tax Rebates and Levies</td>
<td>• Focused funding on HMR aligned with public appetite</td>
<td>• Review potential opportunity based on fiscal environment</td>
</tr>
<tr>
<td></td>
<td>Other Schemes (Prizes, Lotteries)</td>
<td>• Prizes for measurable developments to encourage new research efforts and funding</td>
<td>• Explore/test prizes for key, measurable developments</td>
</tr>
</tbody>
</table>

### 7.2 Attract Philanthropy

**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.

#### 7.2.1 Attract Large Global Philanthropy

Australian HMR can attract large global philanthropic organisations by aligning with their global aims. Some of the largest and best-known global foundations focus on improving health such as the Bill and Melinda Gates Foundation, the Wellcome Trust and Atlantic Philanthropies. Australian researchers have successfully secured investment from each of these organisations and with a more focused effort from the Australian, state and territory governments, and coordination by NHMRC, this could lead to greater success.
CASE STUDY 7.1

The Bill and Melinda Gates Foundation delivers large-scale impact at a global health level and supports Australian health and medical research

Background. The Bill and Melinda Gates Foundation (BMGF) leverages its scale to deliver significant impact on global healthcare, with a focus on improving health through partnerships with health and medical researchers globally. BMGF donates over US$800m annually to global health programs such as AIDS, tuberculosis, malaria, polio and other global health initiatives. In Australia, BMGF has donated over US$50m for research in the areas of global public health and health issues.

BMGF has a number of partnerships with governments, financial institutions and other philanthropic bodies. For example, it has partnered with the Spanish Government, the Inter-American Development Bank and the Walter and Eliza Hall Institute to eliminate malaria in the Mesoamerican region. It also looks to leverage its philanthropies by partnering with governments to fund initiatives such as the Advance Market Commitment, which is a partnership with the governments of Canada, Italy, Norway, Russia and the United Kingdom. This initiative seeks to create a predictable market for new vaccines against pneumococcal disease—a leading killer of children in developing nations.

Australian recipients of grants have conducted research in the area of transmittable diseases, as well as family health issues including:

- HIV vaccine – Murdoch University (US$10m)
- elimination of dengue fever transmission by mosquitoes – The University of Queensland (US$7m)
- improving prevention of HIV AIDS and other sexually transmitted diseases in India – Australian International Health Institute (US$5m over five years)
- childhood pneumonia – Murdoch Children's Research Institute (US$1m)
- reducing maternal and child deaths in Asia Pacific – AusAID (US$4m)
- reduction in the incidence of maternal mortality caused by blood loss at birth – Monash University (US$1m).

Key Lessons:

1. Large global philanthropy can deliver a significant impact in global public health and global health research. BMGF has donated over US$1bn to fighting AIDS, tuberculosis and malaria. More than three million people have been provided with antiretroviral therapy, nine million cases of tuberculosis have been treated as well as almost 150 million insecticide-treated nets distributed in 2011 to aid in the prevention of malaria.

2. Australian HMR has an existing capability in global health research which can be leveraged to attract more global philanthropic funds. BMGF has supported Australian researchers through donations over $50m since 1994 and has called on Australian researchers to contribute to public health research initiatives.

3. Strategic alliances between governments and large philanthropic organisations can provide funding for global health research. BMGF has partnered with the Spanish government to eliminate malaria and reduce dengue fever in the Mesoamerican region.

Source: Bill and Melinda Gates Foundation: www.gatesfoundation.org
Atlantic Philanthropies has invested over US$385m to support health and medical research in Australia

**Background.** Through its Founding Chairman Programme, Atlantic Philanthropies has donated over US$300m to developing 25 biomedical research facilities across Australia. It has also contributed the largest single donation in Queensland history, at over $100m, towards the Translational Research Institute ($50m), the Smart State Medical Research Centre ($28m) and the Hub for Sustainable and Secure Infrastructure at the Queensland University of Technology ($25m). Atlantic Philanthropies has since completed its grant-making operations in Australia and is expected to conclude all its operations having donated a total of US$9bn.

**Atlantic Philanthropies Timeline**

1982 Atlantic Philanthropies established and first grants made

1984 Feeney endows Atlantic Philanthropies

1997 Public announcement of philanthropic efforts

2002 Atlantic Philanthropies becomes a limited life foundation

2009 $50m donation to the Translational Research Institute

2012-2016 Conclude grant-making

2020 Conclude all operations

**Key Lessons:**

1. **Global philanthropy provides a significant boost to Australian HMR.** Atlantic Philanthropies' donation of $50m is the largest from a non-government source to a single Australian medical research/higher education institute. This has resulted in the development of a world-class research and translational facility.

2. **Australia is well placed to make a significant contribution to global research efforts.** Australian biomedical research attracted more than US$385m in funding from Atlantic Philanthropies.

Source: Atlantic Philanthropies: www.atlanticphilanthropies.org; The Chronicle: www.chronicle.com/article/An-Australian-Smart-State/131540/
Although many MRIs and other research organisations have been highly successful in attracting philanthropic donations, Australia has the potential to substantially build the contribution of the local philanthropic sector to health and medical research. There is also an opportunity to better access support from global foundations such as the Gates Foundation, the Wellcome Trust and others...

*Association of Australian Medical Research Institutes*

Some examples of global philanthropic organisations are described below.

**Bill and Melinda Gates Foundation.** Founded in 1994, the Bill and Melinda Gates Foundation is the world’s largest transparently-operated private foundation which had an endowment of US$36bn in 2012. The Foundation donates over US$800m annually to global health programs such as AIDS, tuberculosis, malaria, polio and other developing-country initiatives. It has given $50m in grants to Australian researchers since its inception (Case Study 7.1). In 2008, the Foundation launched a US$100m Grand Challenges Explorations program to encourage ground-breaking global health and development research. The initiative uses an agile, accelerated grant-making process to identify funding candidates. Initial grants of US$100,000 are awarded biannually and successful projects have the opportunity to receive a follow-on grant of up to US$1m. The Foundation also partners with governments to deliver health and research programs, and represents an area of opportunity as a source of leveraged funding.

**The Wellcome Trust.** The Wellcome Trust is the largest non-government funding provider for scientific research in the UK, and spends approximately £600m annually. The Trust supports researchers in both the UK and globally through a number of grants, fellowships and training schemes and has donated funding to projects focused on biomedical research and research translation and development. The Wellcome Trust has also partnered with NHMRC and the Health Research Council of New Zealand to establish the International Collaborative Research Grants scheme, fostering collaborative research with low- and middle-income countries in the Asia-Pacific region. The £12m scheme (half of which was funded by the Wellcome Trust) addresses major health issues such as malaria, pesticide poisoning and human papilloma viruses study and vaccination. Such partnership schemes provide an effective avenue for leveraged funding in global HMR issues and strengthen Australia’s global links.

**Atlantic Philanthropies.** Since its inception in 1982, Atlantic Philanthropies has made grants over US$6bn through its Ageing, Children and Youth, Population Health, Reconciliation and Human Rights programs. Its Founding Chairman Programme, led by Charles ‘Chuck’ Feeney, grants funding for the building and development of facilities for centres of excellence in higher education and health. Atlantic Philanthropies has been a strong supporter of Australian HMR, donating over US$385m to support research that delivers health impact, including over $300m in developing and expanding 25 state-of-art biomedical research facilities across Australia (Case Study 7.2).

Leveraging Australia’s world-class HMR capability and track record of existing investment from large philanthropic organisations such as these will provide additional sources of investment for Australian HMR.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>18a.1 Create strategic alliances with global philanthropic organisations to leverage local research capability to contribute to global health and developing-world issues.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>18a.2 Encourage Australian researchers to apply for international philanthropic grants by providing a central point of information on new grants available for international research through international philanthropic funding bodies.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
7.2.2 Leverage Philanthropy with Government Matching

Overview of Australian HMR Philanthropy. HMR attracts significant philanthropic investment from private individuals, corporations, trusts, foundations, and high-net-worth individuals. The sector is also characterised by a large number of small charitable organisations that mostly raise funds for disease-specific research. While Australian volunteerism in terms of time spent is one of the highest in the world, and Australians are generally very generous with charity donations, high-end philanthropy is relatively underdeveloped in Australia. This is in contrast to the increasing global trend, particularly in the US.

HMR is generally regarded in Australia as a solid donor-support cause, and is highly popular for various causes and events (e.g. Red Nose Day, Walk for the Cure and Daffodil Day). Despite this, there is evidence that it is under-represented in the minds of the Australian giving population relative to its importance. Research Australia has published two comprehensive reports on individual philanthropy relating to HMR in Australia (in 2004 and 2011) both of which found that, as a nation, Australia has a relatively low level of charitable and philanthropic giving to HMR. When Australians make philanthropic donations, they are generally for causes other than HMR. Disease-specific organisations are the most likely to receive philanthropic support for HMR (55% of Australians donate to these organisations, compared to 37% to hospitals, 33% to MRIs and 4% to universities and academic institutes). Over the last decade, the number of Australians who give, and the size of their donations, has been rising, although the global financial crisis has slowed this rate during the last few years.

The preferred form of large philanthropic donation is for buildings. While providing much needed infrastructure, these donations have generally not been matched with funds for research support costs, leading to the frequent observation that there are plenty of new laboratories but, ironically, no money to turn the lights on. While naming rights are generally granted for new buildings, many consider that such rights are undervalued, and there is often insufficient leveraging to ensure that contributions to indirect research costs are included. Making indirect research costs more attractive for high-net-worth donors should be considered when donor proposals for large infrastructure are assessed. The other common form of large philanthropic donations is funds donated to research on personally-relevant diseases. This is useful to those disease areas, but does not necessarily contribute to research in a nationally strategic manner.

There is an opportunity for Governments to provide greater incentives for philanthropy. At present there is a perception that philanthropic funds are viewed by Government as a way of reducing their obligation. The Government must do more to encourage a culture of philanthropy towards the health and medical research, which could be achieved through additional tax incentives or through funding schemes which provide leveraging for philanthropic money …

Queensland Children’s Medical Research Institute

High-net-worth philanthropy is underdeveloped in Australia. Overall, Australian high-end philanthropy is weak and relatively underdeveloped, especially when compared with the culture driving large philanthropy among high-net-worth individuals (those with personal taxable income of more than $1m annually) in other countries (Exhibit 7.3). Aside from certain individuals, there has been relatively little high-net-worth support in Australia to date, and certainly no major HMR foundations established by wealthy individuals such as the Wellcome Trust in the UK or the Bill and Melinda Gates Foundation in the US. However, there are indications that high-net-worth support in Australia could be forthcoming given an appropriate catalyst for action.

142 A 2004 study found that, of the $5.7bn in donations made to not-for-profits during that year, more than 33% went to religious organisations such as churches, temples and mosques. Groups providing community and welfare services, international aid and development, and medical research, receive just over 10% each of the pool of donations. Source: Our Community–Giving Statistics; URL: http://www.ourcommunity.com.au/general/general_article.jsp?articleId=4381#a.

143 Research Australia, Shaping Up: Trends and Statistics in Funding Health and Medical Research, Occasional Paper Series: Two, Melbourne, 2011, pp.73-78.

Exhibit 7.3
The US is a leader in philanthropy, while Australia significantly lags the US and Canada in high-net-worth contributions

<table>
<thead>
<tr>
<th>National Giving Levels</th>
<th>High-Net-Worth Contribution Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Donations of GDP</td>
<td>% Donations of Pre-tax Income</td>
</tr>
<tr>
<td>2004</td>
<td>2004</td>
</tr>
<tr>
<td>US 1.67%</td>
<td>US 3.5%</td>
</tr>
<tr>
<td>UK 0.73%</td>
<td>Canada 3.2%</td>
</tr>
<tr>
<td>Canada 0.72%</td>
<td>Australia 0.69%</td>
</tr>
<tr>
<td>Australia 0.69%</td>
<td>South Africa 1.9%</td>
</tr>
</tbody>
</table>

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

Proposed government matched-funding program. The Panel recommends establishment of an annual government program, with funds in the order of $50m on a matching basis, to encourage HMR philanthropy. This funding would be administered by NHMRC and research projects considered appropriate under particular funding criteria would be eligible. A modest proportion of this funding might also be made available for initiatives to explore other ways in which the sector could raise significantly larger philanthropic funding. In the event that demand for this funding was relatively strong and exceeded the annual appropriation, NHMRC would give positive consideration to those applications offering a stronger ratio of private to public funding, as well as projects consistent with national priority areas. A minimum funding amount of $500,000 is recommended. Along with the amount of leverage, this minimum should be reviewed after several years.

“Priority areas and outcome-focussed research would also be attractive to philanthropic organisations or individuals—either for their own investments or through funding partnerships with Commonwealth agencies. Such support mechanisms should be fostered.”

Victorian Government

There are numerous examples where matched funding has been shown to be an effective means of stimulating investment. 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 (Case Study 7.3). To date, the Fund has contributed £300m to support over £600m in private funding for projects such as the University of Manchester Cancer Research Centre and the University College London Centre for Children’s Rare Disease Research.
The UK Research Partnership Investment Fund provides £300m in matched funds to stimulate private and philanthropic investment

Background. The UK Research Partnership Investment Fund is a £300m facility which leverages private and philanthropic investment to support research in the UK. The fund, which will be in effect from 2012 to 2015, is open to all UK higher education institutions (HEIs) and is designed to match private sector and philanthropic investment on a one-for-two basis. The objectives of the fund are to enhance the research facilities of HEIs, enhance strategic partnerships between HEIs and other organisations involved in research, stimulate investment in higher education-led research, and strengthen the contribution of research to economic growth.

To date, the fund has co-invested £220m, alongside £600m in private and philanthropic funding for projects, such as:

- Manchester Cancer Research Centre, a £38m partnership between the University of Manchester, Christie Hospital and Cancer Research UK
- Centre for Sustainable Chemistry, a £34m partnership between the University of Nottingham and GlaxoSmithKline
- Centre for Children’s Rare Diseases, a £85m initiative of the University College London’s Institute of Child Health and Great Ormond Street Hospital
- Centre for Experimental Medicine, a £32m collaboration between the Queen’s University Belfast and Atlantic Philanthropies, Wellcome Trust, Wolfson Foundation, Sir Jules Thorn Charitable Trust, Insight Trust for the Visually Impaired and Queen’s University of Belfast Foundation.

Key Lessons:

1. Matched funding is an effective means of stimulating private and philanthropic HMR investment. The Research Partnership Investment Fund was initially launched with a £100m limit but was increased to £300m due to the calibre of bids and level of interest from private and philanthropic organisations. In addition to the funding required to release government leverage, universities are also contributing an additional £70m in funding to support the research initiatives, bringing the total value of the projects to £1bn.

Matched funding has also been used in other sectors such as the arts. The Canada Cultural Investment Fund stimulates donations to the Canadian arts through a matching program. In 2011–12 the fund contributed almost C$19m to an endowment that donates funds to cultural programs across Canada. In the UK in 2010, the Arts Council England and the Department for Culture, Media and Sport announced a £80m matched-funds scheme to attract one-for-one donations to help create long-term financial sustainability for arts organisations. The matched funds scheme is part of a 10-point plan to promote greater philanthropy in the arts and consists of £50m from the Arts Council England and £30m from the Department of Culture, Media and Sport. In July 2011 the fund was boosted to £100m following a £20m injection from the Heritage Lottery Fund. The matching scheme has earmarked a portion of the funding (£40m) towards helping arts organisations raise money through philanthropy, while £55m will be made available for endowments.

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<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>18b.1 Allocate up to $50m p.a. for Australian Government matched philanthropic funding that leverages HMR opportunities and unlocks funding that may otherwise never have surfaced or would be directed to other causes. Select opportunities based on a set of factors including amount of leverage, relevance/impact, and alignment with the national HMR priority areas. Set a minimum funding amount (e.g. $500,000) to ensure focus on high-net-worth segment.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>18b.2 Review funding criteria and minimum funding amount after several years, and evaluate overall effectiveness of funding provided.</td>
<td>Leadership body</td>
<td>2018–19</td>
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7.2.3 Encourage Philanthropy Through Collaboration, Scale and Innovation

Philanthropy Australia estimates there are over 700,000 not-for-profit entities in Australia. Of these, however, just over 5% or 38,000 not-for-profit organisations employ staff, and approximately 22,000 organisations are classified by the Australian Tax Office as having Deductible Gift Recipient status which allows them to fundraise. While the exact number of HMR not-for-profit organisations in Australia is not known, it appears that there is a large number of small to medium charitable organisations raising funds.

A significant portion of research funding in Australia is provided by philanthropic organisations and charities … However, there are currently no guidelines or standards to guide non-government organisations in the best and most effective way to disperse their research funding. Many of these organisations are relatively small and have limited capacity/resources for the assessment of grant applications. Ideally a mechanism should exist whereby a single application by researchers could be considered for funding from all relevant funding sources.

Heart Foundation

Collaboration. Increased collaboration between charities in funding health research will assist in leveraging funding to deliver greater impact. The priority-driven Collaborative Cancer Research Scheme, an initiative of Cancer Australia, has achieved significant leverage of research investment since 2007. The success of this scheme demonstrates the feasibility and sustainability of pooling resources to fund research and focus funding on higher priority areas. Further, the collaboration of state-level cancer councils led to the establishment of a national body to oversee coordination across the nation.

146 Pro Bono Australia, Government 2.0 Taskforce Submission, 2009.
NHMRC projects that are deemed to be fundable, but fall under the ‘cut-off’ margin on competitive assessment, are prime examples of projects for which philanthropic organisations can assist in providing funding. While NHMRC does facilitate this today, this process should be further leveraged to pool more philanthropic donations towards competitively assessed projects. The recently established Rare Voices Australia is a national network of rare disease special interest groups that coordinates funding for research into rare diseases which meet the NHMRC peer-review standards but do not receive NHMRC grant funding (Case Study 7.4). The network pools sources of funding along common interests to generate funds for researchers that would normally only be able to access a subsection of philanthropic funding.

In addition, the total HMR philanthropic investment is not well understood or monitored. There is a lack of good data on charitable organisations that are HMR-focused or provide funding for HMR. Research Australia administers a regular survey which provides some insights, but further information and analysis is needed. Regular tracking of the amounts and types of donations to HMR in Australia is required to better understand Australia’s philanthropy milieu, to assess Australia’s giving environment relative to benchmark countries such as the US, UK and in Europe and to ensure the effectiveness and sustainability of such funding.

Scale. Many small medical research charities do not have sufficient economies of scale in fundraising and overheads. Charities perform three key activities that can all exhibit economies of scale.

- **Fund raising** – Larger charities tend to be better and more efficient at fundraising from the mass market. For example, many larger charities are able to execute highly successful street campaigns, some of which are managed by private marketing companies (e.g. Mission Australia, Red Cross).

- **Donor/participant management** – Managing and communicating with the donor base, and leveraging their interest and involvement is a complex process.

- **Fund distribution/granting** – Running a robust granting process is time consuming and difficult; there are significant fixed costs associated with developing a funding strategy and administering the process.

For these reasons and others, the plethora of small charities which raise funds for medical research should consider ways to achieve better economies of scale. While not wishing to diminish their efforts or enthusiasm for supporting their favoured causes, from a research perspective, the Panel believes it would be preferable if there were a smaller number of entities, with wider geographic coverage (e.g. eastern seaboard or national), that could better leverage their fundraising efforts and achieve a better ratio of funds raised to administration costs. Increasingly, smaller charitable organisations are recognising the potential to maximise investment through collaboration and coalescence, and such activity should be encouraged. Furthermore, state-based charities should be encouraged to become national so they can increase efficiency and access other funding sources (e.g. infrastructure).

> Voluntary amalgamation of smaller medical research trusts should be encouraged to achieve higher visibility and research impact.

*Australian Academy of Science*
CASE STUDY 7.4

Rare Voices Australia takes a collaborative approach to research and leverages scale to deliver greater impact

**Background.** Rare Voices Australia (RVA) was established in 2012 to unify and address the common interests of Australians living with a rare disease, with the ultimate aim of improving health outcomes for those affected. There are many rare diseases, and by virtue of their nature, rare disease groups are small. This leads to many small groups with low visibility competing for funding. This lack of cohesion and scale has resulted in poor visibility of rare disease prevalence and philanthropic funding for research. Unlike the US and Europe, there is no national plan for rare diseases and limited government funding.

Following the model of umbrella organisations such as the European Organization for Rare Diseases and the US National Organization for Rare Diseases, RVA was set up as a national network to identify common issues across rare diseases, raise public awareness and advocate and lobby government agencies, policy makers and politicians on the burden of rare disease agenda. Further, RVA plans to coordinate philanthropic support for research into chronic illnesses by connecting pharmaceutical corporations, corporate and individual philanthropists, philanthropic foundations and rare disease researchers through a single interface.

This network of philanthropic funding pools can be leveraged towards research into rare diseases that is aligned with the interests of philanthropists. RVA uses the NHMRC peer-review system to identify and fund research that is of a high standard but cannot be funded through NHMRC research grants.

**Key Lessons:**

1. **Collaboration improves awareness and leverages efforts to deliver greater impact.** By bringing together over 500 bodies advocating support for rare diseases, RVA has been able to lobby government to develop a national plan to address the burden of rare disease. This has led to the establishment of 'Rare Friends', a non-partisan network of WA politicians formed to raise awareness of rare disease.

2. **Collaboration leverages funding and achieves mutually beneficial outcomes.** RVA has aligned the interests of its network members with pharmaceutical companies and philanthropists to generate funding for rare disease research. As cancers constitute 20% of rare diseases, pharmaceutical companies have been encouraged to invest in research into rare diseases. By connecting pharmaceutical companies with philanthropists and researchers, RVA has been able to improve funding of rare disease research.

Source: Rare Voices Australia: www.rarevoices.org.au; H Dawkins et al, 'Awakening Australia to Rare Diseases: Symposium report and preliminary outcomes', Orphanet Journal of Rare Diseases, vol.6, 2011, p.57; C Molster et al, 'Key outcomes from stakeholder workshops at a symposium to inform the development of an Australian national plan for rare diseases', Orphanet Journal of Rare Diseases, vol.7, 2012, p.50
Innovation. Naming rights have been used by institutions, primarily in the US, UK and Europe, seeking to raise funds through philanthropic investment. A common philanthropic avenue used by institutions such as universities, schools, hospitals and research centres is offering naming rights that publicly recognise philanthropists who have donated significant funds. These funds are usually applied to significant capital investment programs such as buildings, research facilities and endowed chairs. Philanthropic naming rights are believed to have raised more than US$4bn in the United States in 2007,\textsuperscript{147} with recent examples in HMR including:

- Knight Cancer Institute at the Oregon Health and Science University, named after Nike founder Phillip Knight, who donated $100m
- Langone Medical Center at New York University, named after Home Depot co-founder Kenneth Langone, who has donated over $200m to the university
- Allen Institute for Brain Science in Seattle, named after its founder and Microsoft co-founder Paul Allen, who donated a further $23m in 2008
- Amplatz Children’s Hospital at the University of Minnesota, named after Kurt Amplatz, a former radiology professor, following a $50m donation from his family.

Endowing chairs and fellowships are also common fundraising mechanisms in the US, particularly among universities. These endowments, made available through philanthropic funds, typically cover the cost of a staff member or support the development of promising students. The endowment and selection process are usually overseen by a board of trustees which represent the interests of the donor. In addition, there is a greater culture of philanthropic giving within organisational boards in the US, which provides a significant source of funding and encourages consumers to donate knowing board members are actively invested in the cause.

\begin{tabular}{|l|l|l|}
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\textbf{Implementation Tasks} & \textbf{Responsibility} & \textbf{Timeframe} \\
\hline
18c.1 Coordinate the tracking of Australian HMR fundraising relative to international experience with a body such as Research Australia (and possibly Philanthropy Australia). & Leadership body & 2014–15 \\
\hline
18c.2 Encourage collaboration and coalescence of smaller not-for-profit institutions through stakeholder forums, particularly organisations that are aligned to the same disease. & Research Australia & 2014–15 \\
\hline
18c.3 Encourage philanthropic organisations to partner and fund NHMRC projects, particularly projects assessed to be fundable but under the 'cut-off' point (i.e. did not rank high enough to receive funding). & NHMRC & 2014–15 \\
\hline
18c.4 Drive philanthropic fund-raising innovation by encouraging measures such as naming rights, endowing chairs and board philanthropy. & Philanthropy Australia, Research Australia & 2014–15 \\
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7.3 Identify New Funding Sources

**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.

### 7.3.1 Consider Alternative Debt Financing

**Social Bonds.** Social bonds are a performance-based financial instrument that involves governments and sometimes non-government organisations that seek out investors to provide funding for initiatives which generate specific social outcomes and typically long-term cost savings. Initial capital is generally provided by private sector investors. In some cases, service providers act as lenders to government and are tasked with achieving a social outcome. Repayment of the initial capital invested, as well as a return on the investment, is contingent upon social outcomes. These performance-based bonds encourage governments to identify areas of spending that have the potential for significant future cost savings, which exceed the value of the return on investment demanded by lenders.

There are a number of benefits for governments in funding programs using social bonds. Social bonds introduce a new pool of funds for governments to access, rather than relying on taxes and traditional debt funding. Tying repayment of principal and return to a specific, measureable social outcome improves transparency for lenders and government. The nature of the investment also aligns the interests of governments and lenders to achieve social outcomes. Further, a measureable cost-saving outcome that exceeds the return on investment demanded by lenders is effectively paid for by the program and not by the government, with the onus of successful outcomes placed on the lender/service provider. Placing a dollar value on social outcomes and enforcing comparisons of potential social initiatives also encourages better allocation of government resources to more effective social initiatives.

Potential risks in using social bonds include the difficulty in accurately measuring social outcomes and measuring outputs instead of outcomes, shifting accountability away from governments and increased influence of investors/lenders. 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. In many cases, outcomes may not be easily measured and the nature of the payment structure reduces the accountability of government to invest in achievable outcomes. Further, as the investors enter the social bond with the intention of generating a return on their investment, they have a greater stake in the outcome and may seek to exert undue influence on governments.

**UK Social Bonds.** Social bonds have been used in the UK for initiatives such as supporting families and reducing recidivism. Local councils and charities throughout the UK have undertaken social bonds. Initial evaluations have identified opportunities for social bonds; however, the nature of the methodologies used to evaluate success of outcomes has been questioned.

**NSW Social Bonds Trial.** The NSW Government announced in its 2011–12 Budget that it will establish Australia’s first Social Benefit Bonds to address a range of social challenges facing the State. The Government announced three pilot programs that will enter into a Joint Development Phase. The programs include a $7m trial for recidivism, which will be sponsored by Social Finance and Mission Australia, a $10m bond sponsored by UnitingCare Burnside to assist children and families, and a $10m bond, sponsored by the Benevolent Society, Westpac and the Commonwealth Bank of Australia, to support 550 families for five years and reduce the number of days children spend in foster care. The Joint Development Phase is expected to include discussions of service delivery and cohort, financials and the evaluation and control of outcomes.
Capital Appreciation Bonds. School districts in California have utilised capital appreciation bonds to fund initiatives without having to raise taxes to meet interest payments. Capital appreciation bonds are structured such that interest payments are deferred until a future point, when the accrued interest is paid down in instalments. This effectively shifts the debt burden to future taxpayers, along with accrued interest on the loan that compounds throughout the life of the bond. This places a significant burden on future government finances.

A notable example of a recent capital appreciation bond is the US$105m 40-year Poway Unified School districts in California have utilised capital appreciation bonds to fund initiatives without having to raise taxes to meet interest payments. Capital appreciation bonds are structured such that interest payments are deferred until a future point, when the accrued interest is paid down in instalments. This effectively shifts the debt burden to future taxpayers, along with accrued interest on the loan that compounds throughout the life of the bond. This places a significant burden on future government finances.

Future Health Institute Health Bond. Another potential funding option, the Future Health Institute Health Bond, was brought to the Panel's attention during the Review. The purpose of this fund is to provide funding for health and medical translational research directed at reducing the cost and health burden caused by major chronic diseases such as cardiovascular disease, diabetes and asthma. An analysis by the proponents of the proposal suggests that the $2bn investment could achieve savings of approximately $40bn via reduction in lost workforce productivity and in direct costs to the health budget. The proposed bond is a zero coupon bond issuance of seven years maturity subscribed by institutional and other investors, with interest accruing until maturity date at the end of year seven and no cash outlay by government prior to this time. It has the advantages that research funding is targeted to areas that will increase productivity and mitigate increases in the health budget, and that government expenditure is better aligned to the timing of benefits.

Possible Trial of a Social Bond for a Chronic Disease. One option the Australian Government may wish to consider is to seek proposals for a social bond to manage the treatment of a single chronic disease, for example, juvenile diabetes. To be successful, the proposal will need to work with a defined population and deliver reductions in healthcare costs to justify the Government paying a coupon on the bonds. Accessing a verifiable source of data to provide evidence of reduced healthcare costs would be a key challenge.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.1 Examine Treasury's risk–return appetite for the Future Health Institute Health Bond as a way to focus research on productivity improvement and cost prevention areas and to better align government outlays with benefit timing.</td>
<td>Treasury, Leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>19.2 Explore a pilot social bond as a mechanism to fund investment in translational HMR. Accept applications from promoters around a single disease with verifiable benefits. Administration to be provided by NHMRC if a social bond program were to be pursued.</td>
<td>Treasury, Department of Health and Ageing</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
7.3.2 Support R&D Tax Incentives and Consider Levies

R&D Tax Incentives. Another means of stimulating industry investment is ensuring there are sufficiently attractive incentives to attract sources of global investment. The Australian Government provides support to companies undertaking R&D through the R&D Tax Incentive. This is the Government's flagship program for encouraging business investment in R&D activities. It is an entitlement-based and market-driven program that supports eligible companies in all industry sectors, including the health and medical sector.

The R&D Tax Incentive scheme applies to R&D activities conducted in income years commencing on or after 1 July 2011. The two key components of the program are:

- a 45% refundable R&D tax offset for small and medium enterprises (SMEs) with an aggregated turnover of less than $20m (‘refundable’ means that an eligible SME can access cash refunds if it is in tax loss); and
- a 40% non-refundable tax offset for other eligible R&D entities, increasing the base rate of support from 37.5 cents in the dollar to 40 cents in the dollar.

The health and medical industry sector has already benefited from the Government's R&D tax support under the previous R&D Tax Concession. In 2009–10, 380 companies undertaking medical and health science research were registered for the R&D Tax Concession with a reported R&D expenditure of $670m. The R&D Tax Incentive program should continue to be supported by the Australian Government and reviewed periodically to identify opportunities for further enhancement.

Levies. Levies, such as progressive tax initiatives, can be introduced with funding specifically earmarked for investment in health and medical research. This form of raising funds ensures funds are directed towards an investment designed to reap social benefits for the population and reduce the future burden placed on governments through debt financing. Australian governments have implemented a number of levies to support social programs. The most notable levy in operation is the Medicare levy, whereby 1.5% of taxable income (over a threshold) is nominally directed towards the Medicare scheme. At state and territory government level, levies include ambulance, emergency services and victims of crime. The Australian, state and territory governments are currently considering funding the National Disability Insurance Scheme through a similar levy. Levies have also been used as bridge financing in one-off situations, such as the Ansett levy, the firearms buyback levy and the flood levy. After the failure of Ansett, the Australian Government instituted a $5-per-seat levy on air travellers to ensure there was no exposure of taxpayers following a loan of $350m to administrators for the payment of employee entitlements. Similarly, when the Australian Government launched a firearms buyback in 1996, which cost $500m to purchase 600,000 firearms, a 1% levy on income tax was introduced for one year to raise funds. More recently, the Australian Government partially funded rebuilding efforts following the Queensland floods through a one-off progressive levy on individuals earning over $50,000, raising $1.8bn. Hence, the use of levies can be an effective means of raising government funding where there are clearly defined purposes and benefits to be gained. One possibility is for the Australian Government to place a $1 levy on all pharmaceuticals bought in Australia, with the revenue being directly allocated to HMR.

The issue with levies is that they are a form of additional taxation, made more palatable by being tagged for a ‘good’ purpose. Since money is fungible, the link between the levy and purpose is fictional. Since HMR delivers benefits to the whole population and needs to be a long-term activity, there is little rationale for it to be funded by a separate levy. The decision to tax a particular activity and invest the proceeds in another is separable and best optimised separately. Specific levies are therefore not recommended.
7.3.3 Explore Other Schemes

**Prizes.** 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, a prominent research organisation within the Department of Defense, launched its first Grand Challenge to develop a fully-automated vehicle. As the research arm of the Department, the Agency's goal is to bridge the gap between fundamental discoveries and military use through the sponsoring of revolutionary, high-payoff research. The first Grand Challenge offered US$1m to the team whose driverless car completed a 150-mile course. Since its inception, the Challenge has moved to an urban setting, resulting in the first driverless vehicle pioneered by Google, and the robotics world, where the Agency hopes to develop ground robotics capable of executing complex tasks. Another example is the National Aeronautics and Space Administration establishing a set of 'Centennial Challenges' in 2003 to stimulate and reward research efforts for major technological breakthroughs.

**Lotteries.** Lotteries have also been used as a source of alternative funding, albeit rather atypical. The Health Lottery was established in 2011 in the UK and donates over 20% of its revenue to health-related causes. The lottery is structured around 51 society lotteries, representing local authority areas in England, Scotland and Wales, and the donations are directed to the respective local authority areas and determined by the partner charity, the People's Health Trust. The UK National Lottery was used to fund Olympic endeavours and contributed £184m in investment to Olympic and Paralympic Sports. The Sydney Opera House was partially funded by a lottery which ran from 1957 to 1986. In Australia, companies already have exclusive rights to operate lotteries in most states, so developing a specific Australian health lottery would be problematic, and therefore not recommended.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.3 Explore suitability and impact of R&amp;D tax incentives to stimulate industry investment in HMR.</td>
<td>DoHA</td>
<td>2014–15</td>
</tr>
<tr>
<td>19.4 Design research prizes to stimulate interest and investment for key HMR challenges.</td>
<td>Leadership body</td>
<td>2014–15</td>
</tr>
</tbody>
</table>
8. Invest and Implement
8. INVEST AND IMPLEMENT

8.1 Introduction

As previously outlined, HMR is the R&D function of Australia's $135bn p.a. health system, and is therefore a critical component of the current health reform process. As previously covered in Chapter 2, HMR investment over the past few decades has been shown to generate an aggregate return on investment of 117%, through increased lifespan and better quality of life. The challenge for the sector is to ensure that incremental investment continues to deliver the highest possible returns, with a greater focus on translation and augmenting the health reform process. A robust implementation process is also required to ensure the recommendations and actions agreed by the Australian Government are implemented as intended.

8.2 Invest for the Future

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.

8.2.1 The Case for Increased Government HMR Investment

There are many competing priorities for government investment in Australia. The global financial crisis and its aftermath have left governments in Australia with a structural imbalance between tax receipts, the services the community expects and the cost of the public service that delivers them. In the longer term, Treasury has shown that an unreformed health system would require an increasingly greater share of national resources. Nevertheless, Australia has a strong national balance sheet, with financial, infrastructure, corporate and resource assets greatly exceeding public debt. Investment in HMR is therefore attractive, affordable and should be a priority for Australian governments, given the size and nature of the returns available.

The compelling rationale for Australian Government investment in research and innovation is well known, and was recently documented in the National Research Investment Plan.

- In the absence of government investment, neither the business nor non-business sector is likely to conduct the level of research and innovation that Australia needs to increase wellbeing.
- Government has a particular responsibility to sustain basic research capability.
- An excellent research capability strengthens Australia’s role in the global community.
- Government investment in research consistently provides high economic and social returns.

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The Productivity Commission highlights two main reasons why the government should invest in research and innovation:

- The existence of market failure in the form of ‘spillovers’, where those conducting the research are unable to capture the full economic benefit of their discoveries due to ideas being used or adapted cheaply by others. Such effects provide an incentive for the private sector to limit the amount and type of research they conduct. In this situation, additional public investment in support of R&D can provide a net benefit to the nation.149
- Governments need to invest in research and innovation to improve the products and services they offer and to better discharge their functions, as does the private sector. 150

**Addressing Market Failure.** There is a consensus in Australia that where market failure exists, governments are required to intervene and provide public goods such as health, education, defence and a welfare safety-net. Health investment provides positive feedback to other government programs, such as generational linkages between improved health, improved education and social inclusion. For example, early diagnosis of hearing issues and treatment with a Cochlear device could prevent a child falling behind in school and potentially facing reduced opportunities and increased expenses. HMR ensures that the health system will continue to have access to leading-edge therapies, and specific Australian health challenges, such as the Hendra virus, can be addressed. While there is also substantial business investment in HMR, public investment can be targeted to health challenges that will not be addressed by the private sector.

**Improving the Health System.** Investment in HMR plays an important role in delivering better health services for Australians. HMR investment has traditionally delivered high returns by improving the survival rate from illness, and hence overall life expectancy. Historically, this return has been achieved in waves. Public health and sanitation, followed by antibiotics and prevention/treatment of communicable diseases, then biochemistry and small molecule drugs are examples of these. The next waves are likely to focus on genomics, personalised medicine and lifestyle-disease prevention strategies.

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

The community has recognised that investment in HMR has resulted in better health outcomes, and has high approval of HMR as an appropriate priority for governments.

**Growing the Economy.** As described in detail in Chapter 1, HMR has significant benefits for the Australian economy. The health sector is unique in Australia in that it has a complete ‘ecosystem’ of researchers, clinicians, consumers, investors, global market-leading companies and associated service providers. The mining industry is similar, but relies on overseas consumers, so it is much more vulnerable to external shocks. Other sectors generally import IP to be consumed locally, and local industry can migrate offshore as economic conditions change. Health is different—it currently employs over one million people, and this workforce needs HMR to improve its productivity and effectiveness.

**Achieving R&D Benchmarks.** The causal links from innovation and investment to productivity growth and higher living standards are now well established and accepted across the political spectrum. As outlined in Section 2.2.4, OECD nations have set an average R&D benchmark of 3.2% of GDP for their economies to ensure their continued prosperity.

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The health sector has a unique set of characteristics that make it worthy of a specific policy focus around R&D investment.

- The health sector represents around 9% of the economy with $135bn in expenditure, and cannot migrate offshore to any substantial degree.
- It is a large employer with over one million jobs, and a high potential for process and technology improvements to raise productivity and effectiveness.
- Around 70% of health activity is managed by the public sector, giving governments the responsibilities, challenges and opportunities inherent in driving productivity improvement and other reforms.

For these reasons, health should have its own government R&D benchmark that is at least as high as the national benchmark. The Panel proposes it should be set at 3%–4% of Australian and state and territory government health spending.

### 8.2.2 Investment Strategy

**Future HMR investment can be better focused.** Future investment should therefore deliver the best possible returns by rebalancing the investment mix towards translation, particularly targeting health system productivity and effectiveness. The proposed investment program realigns existing investment in two ways.

- **NHMRC investment** – The existing $0.8bn p.a. MREA investment can be made more efficient through process reform and be better targeted around health priorities.
- **Health system investment** – The estimated $1.0–$1.5bn p.a. research investment in the health system can be optimised to provide greater control, transparency and accountability. This should also include early investment in health services research into efficiency measures that can deliver health system benefits.

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 (Exhibit 8.1). The new investment programs proposed, if successfully implemented in full, will help build a healthy and wealthy Australia.

1. **Optimise Current Investment** – Assumes the economic environment remains uncertain, where little or no additional government funding is available. No new investment would be made in real terms, and the focus would be on reallocation of existing NHMRC expenditure which includes reallocation to priority-driven research, supporting early investigators and development block grants. Research in state and territory hospitals would be partly funded by the Australian Government as per the NHRA formula, with greater transparency and control from IHPA, NHPA and NHMRC.

2. **Deliver Health System Impact Phase 1** – Assumes the economy remains strong, and modest new funds are made available for investment. In this phase, key recommendations would be implemented including establishing around 10–12 IHRCs by 2018–19, funding 200 clinician researchers by 2018–19, indirect research cost support phased in from 40c per dollar top-up funding in 2014–15 moving to 60c per dollar by 2018–19, and other initiatives implemented at pilot scale.

3. **Deliver Health System Impact Phase 2** – Assumes the economy returns to growth, with a surplus available for reinvestment. In this scenario, recommendations would be implemented in full including building to 15–20 IHRCs, supporting 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 3%–4% goal for total health system expenditure on HMR in the health system.
The Panel recommends two decision gates for investment. The first gate is in 2013–14 when the Australian Government decides on its response to the Review and whether to move from the path of optimising current investment to Phase 1 of investing to deliver health system impact. The second gate is in 2018–19, where the first four years of the investment program should be evaluated to determine effectiveness and health system impact. Investment could then be accelerated and moved to Phase 2 if the sector has demonstrated it can design and implement the proposed programs and some progress toward outcomes is evident. The program initiatives should be further refined based on this evaluation.

The proposed total government, business and NFP HMR investment will increase from $6bn in 2012–13 to $11bn in 2023–24 (Exhibit 8.2) under the third investment path (Deliver Health System Impact Phase 2), and can be divided into four areas.

1. **NHMRC and other initiatives** – Comprises existing NHMRC MREA funds, which under a model of indexation to health expenditure will grow to $1.3bn by 2023–24, and new investments, possibly funded outside the NHMRC MREA but with oversight from the leadership body (for example, to attract new commercial and philanthropic funding).

2. **Local Hospital Networks** – Currently research in LHNs is all block funded and not well tracked or monitored—the allocation for research as part of TTR needs to be determined and ring-fenced for use on defined research activity. This will ensure ‘research active’ LHNs have access to research funds, and can manage them appropriately. States and territories will be able to determine different strategies for research investment within agreed definitions and processes. In addition, a set of competitive schemes to drive an increased focus on research quality in the health system is needed. Competitive schemes will comprise a series of initiatives that will leverage health professionals to drive research activity across the health system to deliver better healthcare for Australians and improve the efficiency of the health system.

3. **University and other government** – Research conducted in the university sector and other government research institutions such as CSIRO will remain largely block funded by the Australian Government and continue to require support. Ideally, the research direction will be guided by the national HMR priority-setting process and aligned with developments such as IHRCs and within LHNs.

4. **Business and not-for-profit** – To support continued growth in HMR commercial investment and philanthropic donations, it is imperative that the environment for commercialisation and philanthropy is strengthened and specific initiatives aimed at stimulating funding from these sectors are deployed and sustained.
Exhibit 8.1

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

Investment Summary

$bn

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 full investment program will increase HMR above the target 3%–4% of government health expenditure over 10 years to 2023–24. This additional investment would increase the share of HMR in the economy from 0.4% to 0.6%, with the bulk of this increase focused on research within LHNs. The additional Australian Government support would comprise competitive schemes to augment the block funding that has already been agreed. The Australian Government would therefore be providing a significant incentive for states and territories to firstly improve their understanding and control of HMR within their own jurisdiction, and then to aspire to excellence, probably by focusing on areas of research with existing capacity or a natural advantage. The additional investment and associated control mechanisms would place downward pressure on total Australian and state and territory government health expenditure that is expected to rise from $95bn in 2011–12 to $170bn by 2023–24. To put the investment into perspective, a 1.7% reduction in the projected 2023–24 health expenditure would entirely fund the $2.8bn p.a. proposed incremental investment in that same year.
Exhibit 8.2

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

Total HMR Investment$bn

<table>
<thead>
<tr>
<th></th>
<th>Business &amp; NFP</th>
<th>State Gov’t</th>
<th>Australian Gov’t</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current System 2011–12 Estimate</strong></td>
<td>1.7</td>
<td>1.7</td>
<td>2.9</td>
</tr>
<tr>
<td>NHMRC</td>
<td>0.8</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>LHN</td>
<td>0.7</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>University &amp; Other</td>
<td>2.1</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>&amp; NFP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5.8</td>
<td>1.7</td>
<td>2.9</td>
</tr>
</tbody>
</table>

| **Future View 2023–24 Forecast** | 10.9           | 2.4         | 2.4              |
| NHMRC & Other         | 0.7            | 0.5         |                  |
| Initiatives           |                |             |                  |
| LHN                  | 3.5            | 0.9         |                  |
| University & Other    | 2.0            | 1.3         |                  |
| & NFP                |                |             |                  |
| Total                | 6.7            | 2.4         | 2.4              |

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

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 (Exhibit 8.3).

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.
### Exhibit 8.3

**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 Investment** ($m)

<table>
<thead>
<tr>
<th>#</th>
<th>Recommendation</th>
<th>FY19</th>
<th>FY24</th>
<th>FY15-24</th>
<th>Investment Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drive Research Activity in the Health System</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Refocus and better manage LHN HMR (reallocation of existing funds)</td>
</tr>
<tr>
<td>2</td>
<td>Establish Sector Leadership and Governance</td>
<td>6</td>
<td>10</td>
<td>72</td>
<td>Drive sector activity and reforms</td>
</tr>
<tr>
<td>3</td>
<td>Establish Integrated Health Research Centres</td>
<td>99</td>
<td>208</td>
<td>1,091</td>
<td>Lead research translation efforts to deliver impact</td>
</tr>
<tr>
<td>4</td>
<td>Build Health Professional Research Capacity</td>
<td>94</td>
<td>682</td>
<td>2,254</td>
<td>Ensure research is relevant and facilitate translation</td>
</tr>
<tr>
<td>5</td>
<td>Accelerate Clinical Trial Reforms</td>
<td>6</td>
<td>7</td>
<td>61</td>
<td>Reduce start up times and costs, and facilitate translation</td>
</tr>
<tr>
<td>6</td>
<td>Align Priority-Setting Process</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Drive strategic research (reallocation of existing funds)</td>
</tr>
<tr>
<td>7</td>
<td>Support a Range of Strategic Topics</td>
<td>0</td>
<td>14</td>
<td>65</td>
<td>Build capacity in key areas</td>
</tr>
<tr>
<td>8</td>
<td>Support Early Investigators and Review Schemes</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Train younger researchers and optimise funding (reallocation of existing funds)</td>
</tr>
<tr>
<td>9</td>
<td>Increase APA Stipends</td>
<td>23</td>
<td>49</td>
<td>269</td>
<td>Retain young research talent</td>
</tr>
<tr>
<td>10</td>
<td>Streamline Competitive Grant Processes</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Increase efficiency for applicants and assessors (use existing funding)</td>
</tr>
<tr>
<td>11</td>
<td>Rationalise Indirect Cost Funding</td>
<td>272</td>
<td>402</td>
<td>2,498</td>
<td>Support full costs of high-quality research</td>
</tr>
<tr>
<td>12</td>
<td>Build Enabling Infrastructure and Capabilities</td>
<td>75</td>
<td>266</td>
<td>1,240</td>
<td>Build infrastructure to support quality research</td>
</tr>
<tr>
<td>13</td>
<td>Enhance Public Health Research</td>
<td>38</td>
<td>223</td>
<td>899</td>
<td>Increase focus on preventive health and lower treatment costs</td>
</tr>
<tr>
<td>14</td>
<td>Enhance Health Services Research</td>
<td>38</td>
<td>223</td>
<td>899</td>
<td>Identify and evaluate opportunities to reduce healthcare costs</td>
</tr>
<tr>
<td>15</td>
<td>Accelerate Health System Innovation</td>
<td>54</td>
<td>145</td>
<td>657</td>
<td>Deliver better health outcomes and lower costs</td>
</tr>
<tr>
<td>16</td>
<td>Inform Policy with Evidence</td>
<td>6</td>
<td>21</td>
<td>96</td>
<td>Align policy with evidence and deliver better population health outcomes</td>
</tr>
<tr>
<td>17</td>
<td>Institute Matching Development Grants Scheme</td>
<td>12</td>
<td>14</td>
<td>111</td>
<td>Stimulate investment and devolve selection burden</td>
</tr>
<tr>
<td>18</td>
<td>Establish Translational Biotech Fund</td>
<td>30</td>
<td>0</td>
<td>154</td>
<td>Stimulate industry investment and build national wealth</td>
</tr>
<tr>
<td>19</td>
<td>Enhance Commercialisation Environment</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Increase commercialisation effectiveness (use existing funding)</td>
</tr>
<tr>
<td>20</td>
<td>Attract Philanthropy</td>
<td>36</td>
<td>69</td>
<td>453</td>
<td>Stimulate philanthropic investment</td>
</tr>
<tr>
<td>21</td>
<td>Identify New Funding Sources</td>
<td>2</td>
<td>3</td>
<td>24</td>
<td>Stimulate investment through prizes</td>
</tr>
<tr>
<td>22</td>
<td>Index NHMRC MREA to Increases in Health Expenditure</td>
<td>218</td>
<td>495</td>
<td>2,525</td>
<td>Ensure sufficient R&amp;D investment in health system</td>
</tr>
<tr>
<td>23</td>
<td>Action Report Recommendations</td>
<td>2</td>
<td>3</td>
<td>7</td>
<td>Ensure recommendations are implemented</td>
</tr>
</tbody>
</table>

**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). Refer to Appendix 9.3 for full 10-year view.
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 health services 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 largely investigator-driven research means that key challenges and areas with the greatest potential for impact will not be sufficiently addressed.

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 will also constrain sector productivity if not addressed.

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 with available technologies.

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.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>20a.1 Enhance, realign and better manage existing HMR investment programs, with extended oversight by the new leadership body.</td>
<td>Department of Health and Ageing (DoHA), leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>20a.2 Focus initial investment in the first four years on high-priority initiatives that deliver impact and improve the health system.</td>
<td>DoHA, leadership body</td>
<td>2014–15</td>
</tr>
<tr>
<td>20b.1 Evaluate investment program after four years and determine whether to accelerate, maintain or withdraw investment.</td>
<td>DoHA, leadership body</td>
<td>2018–19</td>
</tr>
<tr>
<td>20c.1 Index competitive research grant budgets (particularly the NHMRC Medical Research Endowment Account) to increases in health expenditure.</td>
<td>DoHA</td>
<td>2014–15 to 2023–24</td>
</tr>
</tbody>
</table>
8.3 Action Report Recommendations

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.

The majority of the 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, particularly where reforms cut across federal and state areas of responsibility. The process proposed in this Review draws on the previous experience of the sector and quality management techniques to ensure the recommendations deliver impact as intended.

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 established as quickly as possible to plan implementation and drive the process (e.g. January 2014). 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. This suggests some 15–20 members could be required, probably organised into sub-committees around specific implementation tasks although, where possible, tasks should be delegated to existing cross-jurisdictional committees.

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. Wherever possible, clear, measurable KPIs and actions should be committed to by the party responsible for implementation. Where several parties are required to cooperate, a single entity should be made accountable (e.g. DoHA or NHMRC). At an appropriate time, the committee should hand its role on to the leadership body recommended to oversee the sector.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>21a.1 Establish an implementation committee to plan, drive and monitor progress of implementation.</td>
<td>Minister for Health, DoHA</td>
<td>2013–14</td>
</tr>
<tr>
<td>21a.2 Develop an implementation plan which includes implementation of proposed recommendations, and aligns existing activity.</td>
<td>Implementation committee</td>
<td>2014–15</td>
</tr>
<tr>
<td>21a.3 Propose and seek agreement to a set of measureable, trackable actions with clear responsibility for implementation.</td>
<td>Implementation committee</td>
<td>2014–15</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>21a.4 Formal engagement of Australian Government and state and territory governments and relevant industry bodies required to implement recommendations.</td>
<td>Implementation committee</td>
<td>2014–15</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>21b.1 Set rewards and mechanisms to incentivise state and territory governments, departments and institutes responsible for delivery of specific actions within agreed timeframes.</td>
<td>Implementation committee/leadership body</td>
<td>2014–15 to 2023–24</td>
</tr>
</tbody>
</table>

### 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 range of actions proposed, an independent panel would be able to provide this check point most effectively.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>21c.1 Establish a follow-up review of implementation by an independent panel to assess initial outcomes of investment programs and determine whether investment should be accelerated, maintained or withdrawn.</td>
<td>DoHA</td>
<td>2018–19</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Implementation Tasks</th>
<th>Responsibility</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>21d.1 Evaluate and refine the planned actions to improve impact.</td>
<td>Leadership body</td>
<td>2018–19</td>
</tr>
</tbody>
</table>
9. Appendices
9. APPENDICES

9.1 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAHL</td>
<td>Australian Animal Health Laboratory</td>
</tr>
<tr>
<td>AAMRI</td>
<td>Association of Australian Medical Research Institutes</td>
</tr>
<tr>
<td>ABF</td>
<td>Activity Based Funding</td>
</tr>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
</tr>
<tr>
<td>AHMAC</td>
<td>Australian Health Ministers' Advisory Council</td>
</tr>
<tr>
<td>AHRCs</td>
<td>Advanced Health Research Centres (NHMRC)</td>
</tr>
<tr>
<td>AHSCs</td>
<td>Academic Health Science Centres</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>ANPHA</td>
<td>Australian National Preventive Health Agency</td>
</tr>
<tr>
<td>ANSTO</td>
<td>Australian Nuclear Science and Technology Organisation</td>
</tr>
<tr>
<td>APA(s)</td>
<td>Australian Postgraduate Award(s)</td>
</tr>
<tr>
<td>ARC</td>
<td>Australian Research Council</td>
</tr>
<tr>
<td>ASMR</td>
<td>Australian Society for Medical Research</td>
</tr>
<tr>
<td>ASX</td>
<td>Australian Stock Exchange</td>
</tr>
<tr>
<td>AusAID</td>
<td>Australian Agency for International Development</td>
</tr>
<tr>
<td>BERD</td>
<td>Business Expenditure on R&amp;D</td>
</tr>
<tr>
<td>BMGF</td>
<td>Bill and Melinda Gates Foundation</td>
</tr>
<tr>
<td>bn</td>
<td>billion</td>
</tr>
<tr>
<td>c.</td>
<td>circa (about)</td>
</tr>
<tr>
<td>CAGR</td>
<td>compound annual growth rate</td>
</tr>
<tr>
<td>CEO</td>
<td>chief executive officer</td>
</tr>
<tr>
<td>CIHR</td>
<td>Canadian Institutes of Health Research</td>
</tr>
<tr>
<td>CIs</td>
<td>Chief Investigators</td>
</tr>
<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
</tr>
<tr>
<td>CPI</td>
<td>Consumer Price Index</td>
</tr>
<tr>
<td>CRC(s)</td>
<td>Cooperative Research Centre(s)</td>
</tr>
<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
</tr>
<tr>
<td>CTAG</td>
<td>Clinical Trials Action Group</td>
</tr>
<tr>
<td>CV</td>
<td>curriculum vitae</td>
</tr>
<tr>
<td>DIISRTE</td>
<td>(Australian Government) Department of Industry, Innovation, Science, Research and Tertiary Education</td>
</tr>
<tr>
<td>DoHA</td>
<td>Department of Health and Ageing</td>
</tr>
<tr>
<td>EMCRs</td>
<td>early-mid career researchers</td>
</tr>
<tr>
<td>FTE</td>
<td>full-time equivalents</td>
</tr>
<tr>
<td>FY</td>
<td>financial year</td>
</tr>
<tr>
<td>GDP</td>
<td>gross domestic product</td>
</tr>
<tr>
<td>GERD</td>
<td>gross expenditure on R&amp;D</td>
</tr>
<tr>
<td>GOVERD</td>
<td>Government Expenditure on R&amp;D</td>
</tr>
<tr>
<td>GP(s)</td>
<td>general practitioner(s)</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>GRPs</td>
<td>grant review panels (of NHMRC)</td>
</tr>
<tr>
<td>HAIs</td>
<td>healthcare-associate infections</td>
</tr>
<tr>
<td>HERD</td>
<td>Higher Education Expenditure on R&amp;D</td>
</tr>
<tr>
<td>HMR</td>
<td>health and medical research</td>
</tr>
<tr>
<td>HoMER</td>
<td>Harmonisation of Multi-Centre Ethical Review</td>
</tr>
<tr>
<td>HPV</td>
<td>human papilloma virus</td>
</tr>
<tr>
<td>HREC(s)</td>
<td>Human Research Ethics Committee(s)</td>
</tr>
<tr>
<td>IHPA</td>
<td>Independent Hospital Pricing Authority</td>
</tr>
<tr>
<td>IHRCs</td>
<td>Integrated Health Research Centres (proposed)</td>
</tr>
<tr>
<td>IMGs</td>
<td>international medical graduates</td>
</tr>
<tr>
<td>IIF</td>
<td>Innovation Investment Fund</td>
</tr>
<tr>
<td>IP</td>
<td>intellectual property</td>
</tr>
<tr>
<td>IRIISS</td>
<td>Independent Research Institutes Infrastructure Support Scheme</td>
</tr>
<tr>
<td>KPIs</td>
<td>key performance indicators</td>
</tr>
<tr>
<td>LHNs</td>
<td>Local Hospital Networks</td>
</tr>
<tr>
<td>m</td>
<td>million</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council (UK)</td>
</tr>
<tr>
<td>MRCF</td>
<td>Medical Research Commercialisation Fund</td>
</tr>
<tr>
<td>MREA</td>
<td>Medical Research Endowment Account (NHMRC)</td>
</tr>
<tr>
<td>MRIs</td>
<td>medical research institutes</td>
</tr>
<tr>
<td>MRSA</td>
<td>methicillin-resistant Staphylococcus aureus</td>
</tr>
<tr>
<td>NCRIS</td>
<td>National Collaborative Research Infrastructure Strategy</td>
</tr>
<tr>
<td>NEAF</td>
<td>National Ethics Application Form</td>
</tr>
<tr>
<td>NEHTA</td>
<td>National E-Health Transition Authority</td>
</tr>
<tr>
<td>NFP</td>
<td>not for profit</td>
</tr>
<tr>
<td>NGOs</td>
<td>non-government organisations</td>
</tr>
<tr>
<td>NHFP</td>
<td>National Health Funding Pool</td>
</tr>
<tr>
<td>NHHRC</td>
<td>National Health and Hospitals Reform Commission</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NHPA</td>
<td>National Health Performance Authority</td>
</tr>
<tr>
<td>NHPAs</td>
<td>National Health Priority Areas</td>
</tr>
<tr>
<td>NHRA</td>
<td>National Health Reform Agreement</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health (US)</td>
</tr>
<tr>
<td>NIHR</td>
<td>National Institute for Health Research (UK)</td>
</tr>
<tr>
<td>NRD</td>
<td>net realised distributions</td>
</tr>
<tr>
<td>NRIP</td>
<td>National Research Investment Plan</td>
</tr>
<tr>
<td>NRPs</td>
<td>National Research Priorities</td>
</tr>
<tr>
<td>NSW</td>
<td>New South Wales</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>OH&amp;S</td>
<td>occupational health and safety</td>
</tr>
<tr>
<td>p.a.</td>
<td>per annum</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>PCEHR</td>
<td>personally controlled electronic health record</td>
</tr>
<tr>
<td>PhD</td>
<td>Doctor of Philosophy</td>
</tr>
</tbody>
</table>
9.2 Definitions

9.2.1 Classifications of Health and Medical Research Areas

A variety of terms has been used to classify different types of research endeavour. Wills described research as Fundamental research, Strategic research and Development and Evaluation research. Others use the terms Discovery, Delivery and Evaluation or basic, strategic and translational to describe the potential outcomes of the activity. Another approach is to distinguish the research activity based upon whether it is investigator-initiated or proposed or priority-driven (directed in response to a priority area).

These different classifications do not map easily across each other or clearly describe the type of research being performed, the skill set required or the likely outcomes from a health and medical perspective. For example, translational research can encompass everything from the development of a new drug through clinical trial to the implementation of a change in health system policy. In this report, the Panel has adopted the research area classification applied by the NHMRC during competitive grant and fellowship review. These are defined below with initial quotes from the Glossary of the Wills report.
Biomedical research

Biomedical research ‘is undertaken to address fundamental questions about the biological, behavioural and social mechanisms which underlie wellness and disease.’

Sometimes referred to as basic research, strategic basic research or fundamental research, biomedical research investigates the underlying biological principles of the normal and/or diseased cell, tissue or organism. This can include a wide range of biological disciplines including molecular biology, cell biology, structural biology, genetics, genomics, proteomics, physiology, biochemistry, genetics, immunology and others. As distinct from basic biological research or pure basic research, the long term outcomes of biomedical research are aligned with generating new knowledge that will be of significance to health. Biomedical research is predominantly performed by science or medical graduates and frequently has a high need for state of the art instrumentation and infrastructure. Outcomes include improved biological understanding of the basis of disease initiation or progression, discoveries pertinent to diagnosis or prognosis or novel compounds with potential as novel treatments. Translation from biomedical research involves subsequent clinical trials and often engagement with commercial partners. Australia has a proudly strong reputation in biomedical research and a large number of internationally recognised MRIs predominantly active in biomedical research.

Clinical research

‘Research involving clinical patients or tissues samples from patients. It is undertaken to find better ways of identifying and caring for people in ill health.’

Clinical research involves the study of disease in humans and includes clinical trials. Clinical research is performed predominantly by clinical and allied health professionals as well as science graduates frequently within or in association with a clinical delivery site. It is overtly aligned with specific disease states and may involve the administration of a treatment and monitoring of an outcome via the collection of data or material for biological assessment. Outcomes include the development of new treatment regimes or the refinement of current practice. Australia also has a long and distinguished reputation in clinical research with significant visibility in international publications including Lancet and NEJM publications.

Health services research

‘Research into health services to examine ways of improving delivery of health services, e.g. cost benefit studies of health programs.’

As distinct from public health research, health services research aims to evaluate the effectiveness of the healthcare delivery system, frequently focussing on the hospital sector rather than primary care or the community. Health service researchers include biostatisticians and health economists as well as science and allied health graduates. Outcomes include improved implementation of practice and increased economic rate of return within the health system. Such research has a capacity to rapidly influence health expenditure.
Public health research

'Research involving communities or populations…. undertaken to identify the factors which contribute to ill-health in populations and ways of influencing these factors to prevent disease.'

Public health research studies health and health outcome data from populations, often involving datasets from the community and from primary care. It relies heavily on access to data on disease onset, burden, progression and outcomes as well as social data on patient groups. Aims can include the evaluation of the effectiveness of treatments with respect to the patient group being treated to studies of the social determinants of health. Public health research activities include epidemiology, biostatistics, social and behavioural sciences and health economics and involves graduates from these areas as well as allied health. Studies can include longitudinal studies of population health as well as health intervention studies to investigate how treatment or behaviour modification at a population level may alleviate or associate with disease burden. The classical example of a public health intervention might be vaccination, but it might also include advertising or educational campaigns to raise awareness levels. The outcomes of public health research include health system policy recommendations. Public health research has a high capacity to improve QALY at low cost of intervention and is a key driver to savings within health expenditure.

9.2.2 General Definitions

Bioinformatics

The use of computer science, mathematics, and information theory to model and analyse biological systems, especially systems involving genetic material.

Biostatistics

Biostatistics is the application of statistical techniques to scientific research in health-related fields, including medicine and public health. Biostatisticians play essential roles in designing studies, using statistics to analyse data and creating methods to solve research problems.

Clinical trials

Set of procedures in medical research conducted to allow safety (or more specifically, information about adverse drug reactions and adverse effects of other treatments) and efficacy data to be collected for health interventions (e.g., drugs, diagnostics, devices, therapy protocols).

Commercialisation

Commercialisation is the process of patenting research findings, forming companies to own patents, and creating drugs, devices or therapies that generate revenue, jobs and improve health outcomes.

Health policy research

Concerns itself with how health policy is created, the critical appraisal of the evidence that is adduced in the formation of policy, the application of research evidence from clinical medicine and public health in the formation of policy, the behavioural and political science elements in the policy process, what enables, and what militates against, the formulation of quality policy and its implementation. It also includes evaluation research that concentrates upon assessing the achievements, failures, costs and consequences of health policy.

Innovation

Innovation is the application of fresh ideas that enable a business to better compete in the future. Such ideas can include any new or significantly improved goods or services and operational processes or managerial processes.
Infrastructure

Infrastructure for research consists of the essential institutional resources underpinning research such as buildings, lab space and major equipment, and is not covered by research grants. Infrastructure should be distinguished from indirect research costs which consist of supporting overheads required to operate infrastructure and conduct research.

Population health research

Investigation and analysis of factors that influence the health status of groups or whole populations, as well as the testing and evaluation of policies and interventions to improve population health outcomes.

Research and development

Research and development as defined according to the Organisation for Economic Co-operation and Development standard and adopted by Australian Bureau of Statistics, comprises creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

A research and development activity is characterised by originality. It has investigation as a primary objective, the outcome of which is new knowledge, with or without a specific practical application, or new or improved materials, products, devices, processes or services. Research and development ends when work is no longer primarily investigative.

Translational research

Refers to the process of using the findings of research to produce innovation in healthcare settings. This includes: treatment and intervention development (T1); testing efficacy and effectiveness of treatments and interventions (T2); and dissemination and implementation research for system-wide change (T3).
9.3 Investment Case

A detailed 10-year view of the investment required to implement initiatives is provided below for reference.

**Exhibit 9.1**

New investment should be progressively built up over a 10–year period

**Investment Summary (Deliver Health System Impact – Phase 2)**

<table>
<thead>
<tr>
<th>$m New Investment1</th>
<th>Financial Year2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theme</strong></td>
<td><strong>15</strong></td>
</tr>
<tr>
<td>II. Embed Research in the Health System</td>
<td></td>
</tr>
<tr>
<td>1. Drive Research Activity in the Health System</td>
<td>0</td>
</tr>
<tr>
<td>2. Establish Sector Leadership and Governance</td>
<td>0</td>
</tr>
<tr>
<td>3. Establish Integrated Health Research Centres</td>
<td>0</td>
</tr>
<tr>
<td>4. Build Health Professional Research Capacity</td>
<td>0</td>
</tr>
<tr>
<td>5. Accelerate Clinical Trial Reforms</td>
<td>0</td>
</tr>
<tr>
<td>III. Support Priority-Driven Research</td>
<td></td>
</tr>
<tr>
<td>6. Align Priority-Setting Process</td>
<td>0</td>
</tr>
<tr>
<td>7. Support a Range of Strategic Topics</td>
<td>0</td>
</tr>
<tr>
<td>IV. Maintain Research Excellence</td>
<td></td>
</tr>
<tr>
<td>8. Support Early Investigators and Review Schemes</td>
<td>0</td>
</tr>
<tr>
<td>9. Streamline Competitive Grant Processes</td>
<td>0</td>
</tr>
<tr>
<td>10. Rationalise Indirect Cost Funding</td>
<td>0</td>
</tr>
<tr>
<td>11. Build Enabling Infrastructure and Capabilities</td>
<td>77</td>
</tr>
<tr>
<td>V. Enhance Non-Commercial Pathway to Impact</td>
<td></td>
</tr>
<tr>
<td>12. Enhance Public Health Research</td>
<td>0</td>
</tr>
<tr>
<td>13. Enhance Health Services Research</td>
<td>0</td>
</tr>
<tr>
<td>14. Accelerate Health System Innovation</td>
<td>0</td>
</tr>
<tr>
<td>15. Inform Policy with Evidence</td>
<td>0</td>
</tr>
<tr>
<td>VI. Enhance Commercial Pathway to Impact</td>
<td></td>
</tr>
<tr>
<td>16. Institute Matching Development Grants Scheme</td>
<td>0</td>
</tr>
<tr>
<td>17. Enhance Commercialisation Environment</td>
<td>0</td>
</tr>
<tr>
<td>VII. Attract Philanthropy and New Funding Sources</td>
<td></td>
</tr>
<tr>
<td>18. Attract Philanthropy</td>
<td>0</td>
</tr>
<tr>
<td>19. Identify New Funding Sources</td>
<td>2</td>
</tr>
<tr>
<td>VIII. Invest and Implement</td>
<td></td>
</tr>
<tr>
<td>20. Index NHMRC MREA to Increases in Health Expenditure</td>
<td>39</td>
</tr>
<tr>
<td>21. Action Report Recommendations</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>157</strong></td>
</tr>
</tbody>
</table>

**Note:**
1. New incremental investment required (i.e. over and above the re-allocation of existing funds) in nominal dollars (i.e. new initiatives assume inflation of 3% p.a. over the 10-year period)
2. Financial year (e.g. 20 is FY19-20)
9.4 Terms of Reference

9.4.1 Terms of Reference

In establishing the review, the Government stated that it should take into account broader Government policy, including the Government's fiscal strategy, and focus on optimising Australia's capacity to produce world class health and medical research to 2020, including reference to the following matters:

1. The need for Australia to build and retain internationally competitive capacity across the research spectrum, from basic discovery research through clinical translation to public health and health services research.

2. Current expenditure on, and support for, health and medical research in Australia by governments at all levels, industry, non-government organisations and philanthropy; including relevant comparisons internationally.

3. Opportunities to improve coordination and leverage additional national and international support for Australian health and medical research through private sector support and philanthropy, and opportunities for more efficient use, administration and monitoring of investments and the health and economic returns; including relevant comparisons internationally.

4. The relationship between business and the research sector, including opportunities to improve Australia's capacity to capitalise on its investment in health and medical research through commercialisation and strategies for realising returns on Commonwealth investments in health and medical research where gains result from commercialisation.

5. Likely future developments in health and medical research, both in Australia and internationally.

6. Strategies to attract, develop and retain a skilled research workforce which is capable of meeting future challenges and opportunities.

7. Examine the institutional arrangements and governance of the health and medical research sector, including strategies to enhance community and consumer participation. This will include comparison of the NHMRC to relevant international jurisdictions.

8. Opportunities to improve national and international collaboration between education, research, clinical and other public health related sectors to support the rapid translation of research outcomes into improved health policies and practices. This will include relevant international comparisons.

9. Ways in which the broader health reform process can be leveraged to improve research and translation opportunities in preventative health and in the primary, aged and acute care sectors, including through expanded clinical networks, as well as ways in which research can contribute to the design and optimal implementation of these health reforms.

10. Ways in which health and medical research interacts, and should interact, with other Government health policies and programs; including health technology assessments and the pharmaceutical and medical services assessment processes.

11. Ways in which the Commonwealth's e-health reforms can be leveraged to improve research and translation opportunities, including the availability, linkage and quality of data.

12. The degree of alignment between Australia's health and medical research activities and the determinants of good health, the nation's burden of disease profile and national health priorities, in particular 'closing the gap' between indigenous and non indigenous Australians.

13. Opportunities for Australia's health and medical research activities to assist in combating some of the major barriers to improved health globally, especially in the developing world.
9.4.2 Aggregate Terms of Reference Questions

In seeking public and key stakeholder input to the Review, the Panel aggregated the 13 terms of reference under four major topic questions:

Q1 – Why is it in Australia’s interest to have a viable, internationally competitive health and medical research sector? (Terms of Reference 1 and 6)

Q2 – How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)

Q3 – What are the health and medical research strategic directions and priorities and how might we meet them? (Terms of Reference 5, 12 and 13)

Q4 – How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)
9.4.3 Cross-Reference to Terms of Reference

The Review has addressed the matters in the terms of reference as follows:

<table>
<thead>
<tr>
<th>Terms of Reference Matters</th>
<th>Addressed in Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The need for Australia to build and retain internationally competitive capacity across the research spectrum, from basic discovery research through clinical translation to public health and health services research.</td>
<td>4.2, 5.2, 5.3</td>
</tr>
<tr>
<td>2. Current expenditure on, and support for, health and medical research in Australia by governments at all levels, industry, non-government organisations and philanthropy; including relevant comparisons internationally.</td>
<td>1.4, 2.5, 7, 8</td>
</tr>
<tr>
<td>3. Opportunities to improve coordination and leverage additional national and international support for Australian health and medical research through private sector support and philanthropy, and opportunities for more efficient use, administration and monitoring of investments and the health and economic returns; including relevant comparisons internationally.</td>
<td>6.3, 7</td>
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<tr>
<td>4. The relationship between business and the research sector, including opportunities to improve Australia’s capacity to capitalise on its investment in health and medical research through commercialisation and strategies for realising returns on Commonwealth investments in health and medical research where gains result from commercialisation.</td>
<td>6</td>
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<tr>
<td>5. Likely future developments in health and medical research, both in Australia and internationally.</td>
<td>3.3.5</td>
</tr>
<tr>
<td>6. Strategies to attract, develop and retain a skilled research workforce which is capable of meeting future challenges and opportunities.</td>
<td>4.2</td>
</tr>
<tr>
<td>7. Examine the institutional arrangements and governance of the health and medical research sector, including strategies to enhance community and consumer participation. This will include comparison of the NHMRC to relevant international jurisdictions.</td>
<td>2.2, 2.5, 3</td>
</tr>
<tr>
<td>8. Opportunities to improve national and international collaboration between education, research, clinical and other public health related sectors to support the rapid translation of research outcomes into improved health policies and practices. This will include relevant international comparisons.</td>
<td>2.3</td>
</tr>
<tr>
<td>9. Ways in which the broader health reform process can be leveraged to improve research and translation opportunities in preventative health and in the primary, aged and acute care sectors, including through expanded clinical networks, as well as ways in which research can contribute to the design and optimal implementation of these health reforms.</td>
<td>2.2</td>
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<tr>
<td>10. Ways in which health and medical research interacts, and should interact, with other Government health policies and programs; including health technology assessments and the pharmaceutical and medical services assessment processes.</td>
<td>5.4, 5.5</td>
</tr>
<tr>
<td>11. Ways in which the Commonwealth's e-health reforms can be leveraged to improve research and translation opportunities, including the availability, linkage and quality of data.</td>
<td>4.5.2</td>
</tr>
<tr>
<td>12. The degree of alignment between Australia’s health and medical research activities and the determinants of good health, the nation's burden of disease profile and national health priorities, in particular 'closing the gap' between indigenous and non-indigenous Australians.</td>
<td>3</td>
</tr>
<tr>
<td>13. Opportunities for Australia’s health and medical research activities to assist in combating some of the major barriers to improved health globally, especially in the developing world.</td>
<td>3.3.4</td>
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## 9.5 Source of Quotations

The sources of quotations used in this report are listed in the following table.

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9.6 Strategic Review Process

9.6.1 Establishment of the Review

On 11 May 2011, the Minister for Mental Health and Ageing, the Hon Mark Butler MP announced a Strategic Review into Health and Medical Research (HMR) in Australia to develop a 10-year strategy for the sector.1 The Minister consulted with a range of key organisations in the formulation of the terms of reference for the review (see Appendix 9.4), including the Association of Australian Medical Research Institutes (AAMRI), Australian Academy of Science, The Australian Society for Medical Research (ASMR), the Group of 8 Universities, Medicines Australia, Public Health Association of Australia, Research Australia and Universities Australia. The composition of the Panel (see below) was announced by Minister Butler on 26 September 2011 and the Panel held its first meeting on 2 November 2011.

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1 Note: Minister Butler had at that time held responsibility for research in his part of the Health and Ageing portfolio. On 12 December 2012 this component was transferred to incoming Health Minister, the Hon Tanya Plibersek MP.
9.6.2 Submissions Received

The Review called for submissions on 4 February 2012, with a closing date of 30 March 2012, by which time 249 submissions had been received. The Panel continued to accept late submissions and a total of 348 submissions were received. A list of all respondents is provided at Appendix 9.7. Copies of all public submissions can be found on the review website at http://www.mckeonreview.org.au/10231/Submissions/. Of the 348 submissions, 122 came from individuals and 226 were submitted in a professional capacity or on behalf of an organisation; 18 respondents requested confidential status, with 15 for the whole submissions and three for part.

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<th>Submission Group</th>
<th>Professional</th>
<th>Individual</th>
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<td>Cooperative Research Centres</td>
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<td><strong>226</strong></td>
<td><strong>122</strong></td>
<td><strong>348</strong></td>
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</table>

Note: Classifications were based on what the respondent stated about themselves; the category ‘medical research institute’ was based on the word ‘institute’ in the organisation’s title.

In terms of states and territories, 150 came from Victoria, 74 from NSW, 39 from Queensland, 39 from the Australian Capital Territory, 18 from South Australia, 20 from Western Australia, three from Tasmania, three from Northern Territory, one was a joint submission from researchers in Queensland and Victoria, and one came from overseas (Switzerland).

Of those submissions from individuals, about one quarter (34) did not identify themselves in any way whatsoever. Of those who did, the vast majority showed either a university (45) or medical research institute affiliation (36). Of those submitted by people on behalf of an organisation, 77 came from peak bodies, 41 came from universities, 33 came from MRIs and 16 from government agencies.

9.6.3 Public Meetings and Private Stakeholder Consultations

The Panel commenced a series of public meetings which were held in every capital city from mid-April to early July 2012 (Appendix 9.8.1). The Panel also held a series of private stakeholder consultations across Australia in conjunction with the public meetings (Appendix 9.8.2). These meetings included over 175 different stakeholder groups and more than 200 individuals. A number of other private discussions were held with Government ministers, shadow ministers and representatives of key agencies (Appendix 9.8.3).
9.6.4 Consultation Paper

In early October, the Panel publicly released its Consultation Paper Summary: Issues and Proposed Recommendations (Draft for Public Comment). By early December, 201 responses had been received.

9.7 List of Submissions

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<th>Name, Organization</th>
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<td>State and Territory managers of breast, cervical and bowel cancer screening programs</td>
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<td>Cahill Lambert, Ms Anne, et al</td>
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9.8 List of Consultations

9.8.1 Public Meetings
Public meetings were held in:
Hobart – 18 April 2012
Canberra – 19 April 2012
Melbourne – 1 May 2012
Darwin – 8 May 2012
Brisbane – 29 May 2012
Adelaide – 5 June 2012
Perth – 6 June 2012
Sydney – 5 July 2012

9.8.2 Stakeholder Consultations
Consultations were held with the following stakeholder groups

1. Hobart — 18 April 2012
Department of Health and Human Services (Tasmanian Government)
• Dr Craig White, Chief Medical Officer, Tasmanian Department of Health and Human Services
• Mr John Milbourne, Director, Office of the Chief Health Officer, Tasmanian Department of Health and Human Services
The University of Tasmania and Menzies Research Institute
• Prof James Vickers, Head, School of Medicine, University of Tasmania
• Prof Andrew Robinson, Associate Dean (Research), Faculty of Health Science
• Prof Haydn Walters, NHMRC – The 'Breathe Well' CRE
• Prof Richard Wood-Baker, NHMRC - The 'Breathe Well' CRE
• Dr Lisa Foa, Senior Lecturer (Medicine)
• Prof Alison Venn, Acting Director MRI (epidemiologist)
• Prof Heinrich Korner, Immunologist
• Assoc Prof Tracey Dickson, Neuroscientist
Royal Hobart Hospital
• Prof Mary Fitzgerald, Midwifery
• Prof Matthew Jose, Consultant Nephrologists
• Assoc Prof Peter Dargaville, Assoc Prof of Paediatrics and Child Health
Menzies Research Institute
• Professor Bruce Taylor, Principal Research Fellow

2. Canberra — 19 April 2012
Department of Health and Ageing (Australian Government)
• Mr David Butt, Deputy Secretary
• Prof Chris Baggoley, Chief Medical Officer
John Curtin School Medical Research
- Prof Chris Parish, A/g Director and A/g Head, Dept of Immunology
- Prof Carola Vinuesa, Head, Dept of Pathogens and Immunity
- Prof Thomas Preiss, Dept of Genome Biology
- Prof Caryl Hill, Acting Head, Dept of Neuroscience
- Prof Klaus Mattheai, Acting Head, Dept of Translational Biosciences

Medicines Australia
- Ms Deborah Monk, Director, Innovation and Industry Policy
- Mr Andrew Simpson, Government Affairs Manager
- Mr Omar Ali Khan, Policy Officer

National Rural Health Alliance
- Ms Lesley Barclay, Chairperson
- Mr Gordon Gregory, Executive Director
- Ms Helen Hopkins, Policy Advisor

Academy of Science
- Prof Suzanne Cory, President
- Prof Bob Williamson, Secretary (Science Policy)

Public Health Association of Australia
- Mr Michael Moore, Chief Executive Officer
- Ms Melanie Walker, Deputy Chief Executive Officer

Royal College of Nursing Australia
- Adj/Prof Penny Newsome, Director, Membership Services
- Ms Stacey Murphy, Policy Manager

Australian College of Mental Health Nurses
- Ms Kim Ryan, Chief Executive Officer

Australian College of Midwives
- Jan Taylor, Executive Officer

Department of Innovation, Industry, Science and Research (Australian Government)
- Ms Julia Evans, General Manager, Research Funding and Policy Branch

Australian Women's Health Network
- Dr Gwendolyn Gray, Convenor

Consumers Health Forum of Australia
- Carol Bennett, Chief Executive Officer
- Anna Greenward, Deputy Chief Executive Officer

Council of Academic Public Health Institutions
- Assoc Prof Lyndall Strazdins, Fellow
- Dr Joe Hlubucek, Project Manager

Universities Australia
- Ms Belinda Robinson, Chief Executive Officer

Australian Research Council
- Ms Leanne Harvey, Acting Chief Executive Officer
3. Melbourne — 1 & 2 May 2012

Melbourne University
- Prof Arthur Shulkes, Associate Dean (Research) and NHMRC Research
- Prof Dick Strugnell, Pro Vice-Chancellor (Graduate Research)
- Prof Peter Ebeling, Chair Of Medicine (Western Health)
- Prof Terry Nolan, Head, Melbourne School of Population Health

Monash University
- Prof Gail Risbridger, Faculty of Medicine, Nursing and Health Sciences
- Professor Margaret O’Connor, Chair in Palliative Care Nursing
- Dr Maggie Kirkman, Senior Research Fellow, Jean Hailes Research Unit

Deakin University
- Ms Alison Hadfield, Director Research and Research Training
- Ms Rose Firkin, Executive Officer, Research Grants and Contracts

Universities Australia
- Prof Michael Calford, Chair, DVCs Committee (Research)

CASS Foundation Ltd
- Mr Daniel Rechtman, Chair of Directors

Philanthropy Australia
- Mr Bruce Argyle, Director, Partnerships and Membership

Peter MacCallum Cancer Centre
- Prof John Zalcberg, Executive Director, Cancer Medicine
- Prof Joe Trapani, Executive Director, Cancer Research

Ludwig Institute for Cancer Research
- Prof Andrew Scott, Director, Melbourne-Austin Branch

St Vincent’s Institute of Medical Research
- Prof Tom Kay, Director
- Dr Anne Johnston, Grants Manager
- Dr Mai Krishnasami, Director of Cancer, Nursing Practise & Research

Prince Henry’s Institute of Medical Research
- Prof Matthew Gillespie, Director
- Prof Peter Fuller, Associate Director

Florey Neurosciences Institute
- Prof Geoffrey Donnan, Director
- Dr Henry De Aizpurua, Deputy Director

Walter and Eliza Hall Institute of Medical Research (WEHI)
- Prof Douglas Hilton, Director
- Dr Julian Clark, Head of Business Development
- A/Prof Lynn Corcoran, Laboratory Head, Faculty Member and Co-Chair Gender Equity Committee
- Dr Sandra Nicholson, Laboratory Head, Faculty Chairperson
- Prof Nicos Nicola, Ex-Deputy Director, Co-Head of the Division of Cancer and Hematology
- Ms Maureen O’Keefe, Chief Operating Officer
- Dr Matt Ritchie, President of WEHI Post-doctorate Association
• Prof Ian Wicks, Head of Division of Inflammation, Head of Division of Inflammation, Head of Rheumatology Unit at the Royal Melbourne Hospital and Director of the AFV Centre for Rheumatic Diseases at the University of Melbourne.

Murdoch Children's Research Institute
• Prof Terry Dwyer, Director

Baker IDI Heart and Diabetes Institute
• Mr Peter Scott, Chairman, Board of Directors (from April 2012)
• Prof Garry Jennings, Director and Chief Executive Office
• Prof Bronwyn Kingwell, Executive Director, Science Policy and Head, Metabolic and Vascular Physiology
• Mr David Lloyd, Deputy Director and Chief Operating Officer

Macfarlane Burnet Institute for Medical Research and Public Health
• Prof Brendan Crabb, Executive Director and CEO
• Mr Paul Rathbone, Executive Officer

Clinical Oncological Society of Australia
• Prof John Zalcberg, Executive Committee

Cancer Council Victoria
• Prof Ron Borland, Nigel Gray Distinguished Fellow for Cancer Prevention
• Ms Woody McPherson, Head, Research Management Unit

Victorian Cancer Centre
• Prof Joe Sambrook, Distinguished Fellow of the Research Division


Lowitja Institute
• Dr David Thomas, Associate Director, Research and Innovation

Department of Health (Northern Territory Government)
• Dr Steven Guthridge, Director, Health Gains Planning
• Dr Barbara Paterson, Chief Health Officer
• Ms Wendy Ah Chehin, Executive Director, Aboriginal Policy and Stakeholder Engagement

Royal Darwin Hospital
• Dr Sara Watson, Director, Medical Services and Education

Menzies School of Health Research
• Prof Jonathan Carapetis, Director
• Ms Heather D’Antoine, Associate Director, Indigenous Programs

Aboriginal Medical Services Alliance NT (Indigenous health groups)

Mr Chips Mackinolty, Manager, Research Policy and Advocacy
• Dr Liz Moore, Public Health Medical Officer
• Ms Sarah Haythornthwaite, Clinical Support and Supervision Officer
• Mr Rob Curry, Programs Manager
• Dr David Cooper, Research /Advocacy and Policy Unit

Central Australian Aboriginal Congress
• Ms Stephanie Bell, Chief Executive Officer
• Dr John Boffa, Medical Campaigner
5. Melbourne — 14 May 2012

GBS Ventures
- Dr Joshua Funder, Partner

Starfish Ventures
- Dr Michael Panaccio, Investment Principal
- Mr Nick Peace, Investment Director

Scientia Capital
- Lawrence Gozlan, Chief Executive Officer

Medical Research Commercialisation Fund
- Dr Chris Nave, Principal Executive

National Heart Foundation
- Dr Lyn M Roberts, CEO, National
- Dr Akiko Ono, National Director, Research

National Stroke Foundation
- A/Prof Julie Bernhardt, Director,
- Mr Scott Stirling, Government Relations Advisor

College of Intensive Care Medicine
- Prof Rinaldo Bellomo, Director of Intensive Care Research, Austin Health

Royal Australasian College of Surgeons
- Prof Julian Smith, Head, Department of Surgery

Royal Australian College General Practitioners
- A/Prof Marie Pirotta, Chair, RACGP National Standing Committee, Research

RANZ College of Psychiatrists
- Dr Anne Ellison, General Manager, Practice, Policy and Projects Unit

Monash Medical Centre
- Ms Malar Thiagarajan, Director, Research Services, Southern Health
- Prof Stephen Holdsworth, Director, Research Strategy, Southern Health

Royal Melbourne Hospital
- Prof Ingrid Winship, Executive Director, Research, Melbourne Health

Alfred Hospital
- Prof Stephen Jane, Director, Research

Austin Health
- Prof Neville Yeoman, Austin Life Sciences
- A/Prof Christine McDonald, Director, Department of Respiratory and Sleep Medicine, and CEO, Institute for Breathing and Sleep

Royal Women’s Hospital
- Prof Jock Findlay, Director, Research, and NHMRC Senior Principal Research Fellow at Prince Henry’s Institute

Early-Mid Career Researcher Forum
- Dr Marguerite Evans-Galea, Chair
- Dr Darren Saunders, Representative – Group Leader at the Garvan Institute of Medical Research
- Dr Andrew Siebel, Representative – Senior Research Officer
CSL Limited
• Mr Andrew Cuthbertson, R&D Director and Chief Scientist
Mesoblast Limited
• Dr Paul Simmons, Executive Vice-President of Corporate Research and Product Development
Australasian Leukaemia and Lymphoma Group
• Mr Peter Kempen, Chairman
• Prof Andrew Roberts, Director
• Ms Delaine Smith, Chief Executive Officer

6. **Brisbane — 29 and 30 May 2012**

Queensland Institute of Medical Research
• Prof Frank Gannon, Director and CEO
• David Whiteman, Medical Epidemiologist
• James McCarthy, Senior Scientist

Institute for Molecular Bioscience
• Prof Brandon Wainwright, Director

Queensland Brain Institute
• Prof Pankaj Sah, Deputy Director
• Prof Geoff Goodhill, Director, Computational Neuroscience
• Prof Juergen Gotz, Foundation Chair Centre for Age and Dementia Research

University of Queensland Centre for Clinical Research
• Prof Murray Mitchell, Director

Mater Medical Research Institute
• Prof John Prins, CEO and Institute Director
• A/Prof Mark Bowles, Deputy Director, Operations
• Prof Michael McGuckin, Deputy Director, Research

Association of Australian Medical Research Institutes (AAMRI)
• Prof Julie Campbell, President,
• Prof Garry Jennings, Board Member and Past President
• Prof Moira Clay, Chair of the AAMRI Working Group
• Dr Nicole Den Elzen, Executive Officer

University Queensland, ARC Centre of Excellence for Functional Nanomaterials
• Prof Max Lu, Senior Deputy Vice-Chancellor
• Prof Nick Fisk, Executive Dean

Griffith University
• Prof Ned Pankhurst, Director
• Prof Lyn Griffiths, Director, Griffith Health Institute
• Dr Vicki Pattemore, Dean, Research (Health), Director, Genomics Research Centre

Queensland University of Technology, Research and Commercialisation
• Prof Andrew Wilson, Executive Dean
• Prof Arun Sharma, Deputy Vice-Chancellor

Royal Brisbane and Women's Hospital
• Dr David Alcorn, Executive Director
Princess Alexandra Hospital, Research Development and Ethics
- David Thiele, Director
- Ms Areti Gavrilidis, Director
- Prof Ken Ho, Chair of Princess Alexander Hospital
- Dr John O'Donnell, Chief Executive Officer, Mater Health Services

Australian Centre for Health Services Innovation, Queensland University of Technology
- Prof Nicholas Graves, Academic Director
- A/Prof Adrian Barnett, Principal Research Fellow, Faculty of Health, School Public Health and Social Work

Baker IDI Alice Springs
- Dr Alex Brown, Head, Research Program

Australian Society for Medical Research
- Dr Paul Dawson, President
- A/Prof Naomi Rogers, President-elect and Regional Events Convenor

Institute of Health Biomedical Innovation
- Prof Ross Young, Executive Director

Diamantina Institute and Institute of Molecular Biosciences
- Prof Matt Brown, Director

Australian Institute for Bioengineering and Nanotechnology
- Prof Peter Gray, Director
- A/Prof Christine Wells, Group Leader

Translational Research Institute
- Dr Kate Johnston, Chief Operating Officer

Department of Health (Queensland Government)
- Dr Jane Jacobs, Director, Research Ethics and Coordination, Office of Health and Medical Research

Department of Science, IT, Innovation and the Arts
- Ms Beth Woods, Deputy Director-General (Science)
- Mr Mark Jacobson, General Manager

Department of Education, Training, Employment and Skills
- Dr Sue Coke, Acting Director

Implicit
- Mr Gary Redlich, Managing Director and Chief Executive Officer

Magic Pudding
- Peter Andrews, Chairman

Life Sciences Queensland
- Mr Mario Pennisi, Chief Executive Officer

Institute for Molecular Bioscience
- Prof Mark Smythe, Head
7. Adelaide — 5 June 2012

Department for Health and Ageing (South Australian Government)
• Mr Andrew Stanley, Chief Executive
• Sarah Lawson, Director, Office for Research Development
• Tony Woollacott, Director
• Heather Petty, Principal Project Officer

Hanson Institute and Cancer Biology
• Prof Heddy Zola, Research Director
• Prof Angel Lopez, Co-Director

South Australian Health and Medical Research Institute
• Prof Steven Wesselingh, Executive Director

Australian Institute of Tropical Medicine
• Prof Juergen Reichardt, Associate Dean Research

Sansom Institute for Health Research
• A/Prof Pat Buckley, Director

CSIRO
• Prof Richard Head, Director, Preventative Health Flagship
• Dr Lynne Cobiac, Director, Preventative Health Flagship

Royal Adelaide Hospital
• Prof Guy Ludbrook, Professor of Anaesthesia
• Oksana Holubowycz, Epidemiologist

Women’s and Children’s Hospital
• Ms Gail Mondy, Chief Executive Officer
• Dr Andrea Avis, Director of Women’s and Children’s Health Research

Flinders University
• Prof Michael Kidd, Executive Dean, Faculty of Health Sciences
• Prof Jeff Fuller, Associate Dean (Research)
• Prof Jennene Greenhill, Director/ Associate Dean, Flinders University Rural Clinical School
• Prof Keryn Williams, Principled Research Fellow
• Prof John Coveney, Associate Dean, Flinders Prevention Promotion & Primary Health Care
• Prof Fran Baum, Director

University of Adelaide
• Prof David Findlay, Deputy Head

University of South Australia
• Prof Sakkie Pretorius, DVC, Research and Innovation
• Prof Allan Evans, Pro Vice Chancellor
• Dr Tracey Swift, Director

Bio Innovation SA
• Dr Jurgen Michaelis, Chief Executive
8. Perth — 6 June 2012

Department of Health (Western Australian Government)
- Dr Andy Robertson, A/g Chief Medical Officer
- Mr Babu Simon, Research Development Unit
- Dr Neil Lynch, Senior Policy Advisor

The University of Western Australia
- Prof Robyn Owens, DVC Research
- Prof Alistar Robertson, Pro Vice-Chancellor (Research)
- Prof Ian Puddey, Dean, Faculty of Medicine, Dentistry and Health Sciences
- Dr Campbell Thomson, Director (Research Services)

Curtin University
- Prof Gary Allison, Dean, Research & Graduate Studies

Murdoch University
- Prof David Morrison, DVC Research

Notre Dame University
- Prof Richard Berlach, Professor of Education
- Prof Gavin Frost, Dean of Medicine
- Prof Kathryn Hird, Dean of Medicine

Edith Cowan University
- Dr Margaret Jones, Director of Research and Innovation

Western Australian Institute for Medical Research
- Prof Peter Klinken, Director

Telegenic Institute for Child Health Research
- Prof Moira Clay, Director of Academic and Research Services
- Dr Rebecca Glauert, Manager
- Brad Farrant, Protectoral Fellow
- Kim Carter, Senior Fellow
- Anne Mckenzie, Team Investigator

Lions Eye Institute
- Prof David A Mackey, Managing Director
- Prof Mariaimpia Degli-Esposti, Director of Research

Western Australia Institute of Medical Research
- W/Prof Lin Fritchi, Head of Epidemiology Group
- John Fitzgerald, Director of Strategic Research

Royal Perth Hospital
- Prof Peter Leedman, Director of Research
- Sharon Olgie, Research Governance at Royal Perth Hospital
- Ms Bonnie McLeod, Research Governance Officer

Sir Charles Gairdner Hospital
- Prof Peter Thompson, Director, Research Development
- Lynell Belardo, Coordinating Research Manager (no title)
- Nola Mammatt, Research Governance – Project Education Officer
- Diana Forster, Executive Officer, Ethics Committee
9. Appendices

St John of God Hospital
• Ms Gorette De Jesus, Executive Officer, Ethics Committee

Visiomed
• Prof Fiona Wood, Director

Yuwa Capital LP Dimerix Bioscience –
• Dr James Williams, Investment Director

Giving West
• Mr Kevin MacDonald, Chief Executive Officer


BUPA
• Dr Stan Goldstein, Head of Clinical Advisory

HCF
• Ms Karen Beatty, Manager, Health and Medical Research Foundation

MJA Clinical Trials Research Summit
• Dr Annette Katelaris, Editor
• Prof John Simes, Director
• Prof Alan Cass, Senior Research Fellow
• Prof Anthony Keech, Deputy Director

Prince Henry’s Institute (Melbourne)
• Prof John Funder, Senior Fellow

Neuroscience Research Australia
• Prof Peter Schofield, CEO and Executive Director

Schizophrenia Research Institute
• Prof Vaughan Carr, CEO
• Ms Liesl Duffy, Acting Director of Operations

Hunter Medical Research Institute
• Emeritus Prof Peter Dunkley, Conjoint Professor

Centenary Institute of Cancer Medicine and Cell Biology
• Prof Wolfgang Weninger, Head, Immune Imaging Group

Garvan Institute of Medical Research
• Prof John Mattick, Executive Director

The Victor Chang Cardiac Research Institute
• Prof Robert Graham, Executive Director
• Ms Britt Granath, Senior Policy Officer

Westmead Millennium Institute
• Prof Tony Cunningham, Executive Director

Heart Research Institute
• Prof Philip Barter, Executive Director

The George Institute, Australia
• Prof Fiona Turnbull, Principal Director
• Prof Bruce Neil, Senior Director
Children's Cancer Institute Australia
- Prof Michelle Haber, Executive Director
- Dr Peter Wejborna, Head, Research Development and Operations

Children's Medical Research Institute
- Prof Roger Reddel, Director

Woolcock Institute of Medical Research
- Prof Carol Armour, Director
- Dr Greg King, Chair, Research Committee
- Dr David Andrews, Chief Operating Officer

Sydney University
- Prof Graham Mann, Associate Dean (Research), Sydney Medical School
- Prof John Simes, Director, NHMRC Clinical Trials Centre

University of NSW
- Prof Les Field, Vice-President and Deputy Vice-Chancellor
- Prof Terry Campbell, Senior Associate
- Ms Bronwyn Greene, Dean, Faculty of Medicine

University of Newcastle
- Prof John Rostas, Deputy Head of Faculty Research (Health)

Macquarie University
- Prof Dominic Rowe, Australian School of Advanced Medicine
- Prof Janey Greeley, Executive Dean, Faculty of Human Sciences
- Mr Evan Rawstron, Chief Operating Officer, Macquarie University Hospital & Health Policy Advisor, Australian School of Advanced Medicine

University of Wollongong
- Prof Ian Wilson, Associate Dean (Learning and Teaching), Graduate School of Medicine

University of Technology, Sydney
- Prof Attila Brungs, Deputy Vice-Chancellor and Vice-President (Research)
- Prof Ian Charles, Director, ithree institute

Royal Prince Alfred Hospital
- Mr Ken Cahill, Executive Director
- Prof Warwick Britton, Director of Research

St Vincent's Hospital
- Ms Sarah Charlton, HREC Executive Officer

Royal North Shore Hospital
- Ms Tegan Cox, A/g Chief Operating Officer

The Prince of Wales Hospital
- Ms Helen Fraser, Manager, Research Support Office
- Prof Robyn Ward, Clinical Associate Dean
- Prof Margaret Rose, Area Director of Research

Macquarie University Hospital
- Mr Evan Rawstron, Chief Operating Officer
St John of God (Perth)
- Prof Nik Zeps, Research Collaborator
Novartis
- Ms Christine Black, Senior Manager
Cochlear
- Dr Chris Roberts, CEO and President
HammondCare
- Ms Jan Gralton, Research Governance Officer
Uniting Care
- Mr Steve Teulan, Director
Southern Star Research
- Dr David Lloyd, Managing Director
Bellberry Limited
- Ms Imelda Lynch, Chief Executive
- Mr Malcolm Crompton, Director
Members of the Pharmaceuticals Industry Council Research and Development Taskforce and industry representatives of the CTAG Coordination Group
- Ms Deborah Monk, Director, Innovation and Industry Policy, Medicines Australia
- Mr Mitch Kirkman, Development QA Manager, Novartis Pharmaceuticals Australia
NSW Health (NSW Government)
- Professor David Currow, Chief Executive Officer
- Dr Rohan Hammett, Deputy Director General, Strategic Development and Procurement
- Dr Tony Penna, A/g Director, Office of Health and Medical Research
- Ms Anne O'Neill, Associate Director, Office for Medical Research
- Mr Ron Phillips, Chair, Sydney Local Health District
- A/Prof Sarah Thackway, Director, Centre for Epidemiology and Evidence
Research Australia
- Ms Elizabeth Foley, CEO
- Mr Greg Mullins, Head of Policy
- Mr Peter Wills, Deputy Chairman
Garvan Research Foundation
- Andrew Giles, Chief Executive Officer
Cancer Council Australia
- Prof Ian Olver, CEO
- Mr Paul Grogan, Advocacy Director
NSW Cancer Council
- Ms Libby Topp, Senior Lecturer
Alzheimer's Australia
- Glenn Rees, CEO
- Dr Chris Hatherly, National Research Officer
- Ms Joan Jackman, Consumer
Diabetes Australia
• Prof Paul Williams, Director

Australian Lung Health Alliance
• Mr William Darbishire, Chief Executive Officer
• Prof Gary Anderson, National Council Member
• Prof Paul Reynolds, National Council Member

Royal College of Pathologists of Australasia
• Dr Stephen Adelstein, Senior Staff Specialist and Head of Department
• Dr Nicholas Zeps, Research Collaborator
• Dr Dan Catchpool, Head of the Tumour Bank

Royal Australian and New Zealand College of Radiologists
• Prof Michael Barton, Research Director

Royal Australasian College of Physicians
• Prof Phillip Bardin, Clinician Researcher
• Alex Lynch, Regional Policy Officer (NSW)

Sax Institute
• Prof Sally Redman, CEO
• Prof Louisa Jorm, Principal Scientist

Health Services Research Association
• Prof Marion Haas, Vice President
• Prof Jane Hall, Director

Australian Health Economics Society
• A/Prof Rosalie Viney, President
• Prof Philip Clarke, Chair of Economics

Royal North Shore Hospital
• Prof Carol Pollock, Chair, Northern Sydney Local health District

Kolling Institute of Medical Research
• Prof Jonathan Morris, Director

Garvan Institute of Medical Research
• Prof John Mattick, Executive Director
## 9.8.3 Other Key Meetings

Meetings were held with the following key individuals:

<table>
<thead>
<tr>
<th>Name and Title</th>
<th>Position/Function</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Deans of Medicine Group of Eight</td>
<td>6 Feb 2012</td>
<td></td>
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<tr>
<td>Professor Alain Beaudet CEO, Canadian Institutes of Health Research</td>
<td>30 May 2012</td>
<td></td>
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<tr>
<td>Prof Ian Chubb AC Chief Scientist</td>
<td>27 Jun 2012 &amp; 27 Nov 2012</td>
<td></td>
</tr>
<tr>
<td>Mr David McCann (Deputy Chief of Staff) and Mr Len Hatch (Advisor)</td>
<td>Office of the Minister for Mental Health and Ageing</td>
<td>27 Jun 2012</td>
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<tr>
<td>The Hon Mark Butler MP Minister for Mental Health and Ageing, Minister for Social Inclusion, Minister Assisting the Prime Minister on Mental Health Reform</td>
<td>3 Jul 2012</td>
<td></td>
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<tr>
<td>Ms Jane Halton PSM Secretary, Department of Health and Ageing</td>
<td>5 Jul 2012, 20 Aug 2012 &amp; 7 Nov 2012</td>
<td></td>
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<tr>
<td>The Hon Tanya Plibersek MP Minister for Health and Ageing</td>
<td>19 Jul 2012</td>
<td></td>
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<tr>
<td>The Hon Peter Dutton MP Shadow Minister for Health and Ageing</td>
<td>19 Jul 2012</td>
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<tr>
<td>Prof Carol Pollock Chairman, Northern Sydney Local Health District</td>
<td>19 Jul 2012</td>
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<tr>
<td>Prof Jonathan Morris Director, Kolling Institute of Medical Research</td>
<td>19 Jul 2012</td>
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<tr>
<td>Prof John Mattick Executive Director, Garvan Institute of Medical Research</td>
<td>19 Jul 2012</td>
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<tr>
<td>Dr Megan Clark Chief Executive, CSIRO</td>
<td>20 Aug 2012</td>
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<tr>
<td>Prof Warwick Anderson CEO, NHMRC</td>
<td>20 Aug 2012 &amp; 7 Nov 2012</td>
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<tr>
<td>Prof Aidan Byrne CEO, ARC</td>
<td>4 Sep 2012</td>
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<tr>
<td>Ms Elizabeth Foley CEO, Research Australia</td>
<td>5 Nov 2012</td>
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<tr>
<td>Dr Diane Watson CEO, National Health Performance Authority</td>
<td>7 Nov 2012</td>
<td></td>
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<tr>
<td>Mr Shane Solomon &amp; Dr Tony Sherbon Chair and CEO, Independent Hospital Pricing Authority</td>
<td>12 Nov 2012</td>
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<tr>
<td>The Hon Jillian Skinner MP &amp; Dr Tony Penna NSW Minister for Health &amp; Director of the Office of Health and Medical Research</td>
<td>20 Nov 2012</td>
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<tr>
<td>Prof Tony Cunningham &amp; Prof Stephen Leeder Westmead Millennium Institute for Medical Research</td>
<td>21 Nov 2012</td>
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<tr>
<td>Ms Louise Sylvan CEO, ANPHA</td>
<td>27 Nov 2012</td>
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<tr>
<td>The Hon Greg Combet AM MP Minister for Industry and Innovation</td>
<td>27 Nov 2012</td>
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<tr>
<td>Mr Alan Bean (Chief of Staff) and Mr Dane Atkinson (Senior Advisor)</td>
<td>Office of the Minister for Industry and Innovation</td>
<td>27 Nov 2012</td>
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<tr>
<td>Dr Pradeep Philip &amp; Dr Amanda Caples Secretary, Department of Health Deputy Secretary, Department of Business &amp; Innovation, Victoria</td>
<td>29 Nov 2012</td>
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<tr>
<td>Mr Peter Fleming CEO, National E-Health Transition Authority</td>
<td>5 Dec 2012</td>
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<tr>
<td>Prof Debora Picone AM CEO, Australian Commission on Safety and Quality in Health Care</td>
<td>5 Dec 2012</td>
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<tr>
<td>Mr Doron Ben-Meir CEO, Commercialisation Australia</td>
<td>6 Dec 2012</td>
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<tr>
<td>The Hon Malcolm Turnbull MP Shadow Minister for Communications and Broadband</td>
<td>7 Dec 2012</td>
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