Strategic Review of Health and Medical Research

Henry Brodaty
Key Findings

• Vision for ‘Better Health Through Research’
  – Opportunity is to build a healthy and wealthy Australia with the world’s best health system
  – Research has a vital role in improving the health system and creating national wealth

• Embed Research in the Health System
  – Bring research into the system as part of healthcare delivery
  – Establish 10-20 ‘Integrated Health Research Centres’ to drive excellence
  – Build health professional researcher capacity with 1,000 practitioner fellowships
Key Findings

• Build HMR Capability
  – Establish a set of national HMR priorities and leverage ‘top-down’ and ‘bottom-up’ research
  – Streamline granting processes to reduce administrative inefficiencies
  – Fund indirect costs and infrastructure to support high quality research
Key Findings

• Accelerate Translation
  – Build capacity in public health & health services research
  – Drive health system innovation and evidence-based policy to deliver better health outcomes
  – Support research commercialisation with matched development grants and a ‘Translational Biotech Fund’
Key Findings

• Optimise Investment
  – Attract philanthropy with matched government funding and examine new funding sources
  – Invest over 10 years and implement recommendations to deliver health system impact
The Review proposes a 10-year strategy built upon a number of themes.

**HMR Strategy Framework**

1. Better Health Through Research

<table>
<thead>
<tr>
<th>Build HMR Capability</th>
<th>Accelerate Translation</th>
<th>Optimise Investment</th>
</tr>
</thead>
</table>

2. Embed Research in the Health System
Total HMR investment is estimated at ~$6bn in 2011–12e

Total HMR Investment ¹
$bn 2011-12e

<table>
<thead>
<tr>
<th>Source</th>
<th>NHMRC</th>
<th>LHN</th>
<th>University &amp; Other Government</th>
<th>Business &amp; NFP</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.8</td>
<td>1.1</td>
<td>1.7</td>
<td>1.7</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Note: 1. Nominal dollars (assumes 5% forecast growth FY12-FY23 for existing HMR funding and new initiatives inflation adjusted at 3%); FY is financial year
Source: Treasury; DoHA; NHMRC; ABS; AIHW; Pacific Strategy Partners analysis

HMR of Health System Spend
(0.8+1.5) / 93.4 = 2.0%
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

$bn

<table>
<thead>
<tr>
<th>Sector</th>
<th>CAGR 1991-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicinal and Pharmaceutical Products</td>
<td>12%</td>
</tr>
<tr>
<td>Vehicles</td>
<td>6%</td>
</tr>
<tr>
<td>Specialised Industrial Machinery</td>
<td>7%</td>
</tr>
<tr>
<td>General Industrial Machinery</td>
<td>7%</td>
</tr>
<tr>
<td>Transport Equipment</td>
<td>4%</td>
</tr>
</tbody>
</table>

Note: 1. CAGR – compound annual growth rate
Source: Australian Bureau of Statistics
The current trajectory of projected Australian Government health expenditure is unsustainable.

Treasury Projections of Australian Government Health Expenditure

<table>
<thead>
<tr>
<th>Year</th>
<th>% of GDP</th>
<th>$bn</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-10</td>
<td>4%</td>
<td>51</td>
</tr>
<tr>
<td>2019-20</td>
<td>4%</td>
<td>68</td>
</tr>
<tr>
<td>2029-30</td>
<td>5%</td>
<td>89</td>
</tr>
<tr>
<td>2039-40</td>
<td>6%</td>
<td>166</td>
</tr>
<tr>
<td>2049-50</td>
<td>7%</td>
<td>257</td>
</tr>
</tbody>
</table>

Impact of aging and population effects only

Impact of increasing demand for higher standard of care

Note: 1. Excludes state and territory Government health expenditure

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
Percentage of Respondents

1. **Improving Hospitals and the Health System**
   - Keeping the National Economy Strong: 91%
   - Improving Education Standards and Outcomes: 87%
   - Improving National Infrastructure: 86%
   - Improving Employment Opportunities: 85%
   - Doing More to Keep Prices and the Cost of Living Down: 84%
   - Providing Strong Leadership: 84%
   - Creating More Skilled Jobs and Apprenticeships: 82%
   - More Funding for Health and Medical Research: 81%
   - Increasing Funding for Preventative Health Care: 80%
   - Deliver improvements to hospitals and the health system: 78%

Note: 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*
Australia’s health system delivers good outcomes for reasonable cost

Life Expectancy vs. Health Expenditure 2010

Note: 1. Australia’s GDP per capita is above US$35k
2. PPP – purchasing power parity

Source: OECD, Pacific Strategy Partners Analysis
Health outcomes are driven by the productivity and cost-effectiveness of interventions

Health System Performance

<table>
<thead>
<tr>
<th>Health Outcome (e.g. QALYs)</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination</td>
<td></td>
</tr>
<tr>
<td>Preventative health campaigns</td>
<td></td>
</tr>
<tr>
<td>I. High Value Intervention</td>
<td></td>
</tr>
<tr>
<td>II. Routine Treatment</td>
<td></td>
</tr>
<tr>
<td>III. Low Value Intervention</td>
<td></td>
</tr>
<tr>
<td>IV. Waste</td>
<td></td>
</tr>
<tr>
<td>V. Adverse Events</td>
<td></td>
</tr>
<tr>
<td>Renal Dialysis</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy for most Cancers</td>
<td></td>
</tr>
<tr>
<td>Screening Programs</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
Source:
43% of Australians do not receive appropriate, evidence-based care

A study found that about 43% of people are not receiving appropriate care based on best practice or evidence.

Lowest levels of appropriateness of care were alcohol dependence, antibiotics and obesity.

Health services research can identify areas of healthcare lacking evidence-base and develop strategies to address this.

Source: Runciman, W. et al, (2012), CareTrack: Assessing the Appropriateness of Health Care Delivery in Australia, Medical Journal Australia, pp 100-105
1. The vision calls for strengthened partnerships between researchers, health professionals and the community.
2. 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

- Leadership
- Investment
- Excellence
- Processes
- Capability

Drive Research Activity in the Health System
Accelerate Clinical Trials Reforms
Establish Sector Leadership
Establish Integrated Health Research Centres
Build Health Professional Research Capacity
Better Health for Consumers
3. 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**

**Align HMR Priority-setting Processes**

- HMR Priority-Setting Process
- National HMR Priorities
- Expert Panels
- ‘Top-down Research via RFAs’
- Bottom-up Investigator-Initiated Research

**Support a Range of Strategic Topics**

- Focused HMR Capacity
  - Indigenous
  - Rural and Remote
  - Global Health
  - Genomics
Improvements are required across the four main components of the research delivery system:

- **Research Workforce**
  - Monitor and manage
  - Support early investigators
  - Retain researchers
  - Build capacity in key areas

- **Granting Processes**
  - Re-engineer granting processes
  - Establish longer, quanta grants

- **Enabling Infrastructure**
  - Project Funding
    - Indirect costs
    - Direct costs
  - Rationalise indirect cost funding

- **Supporting Services**
  - Establish infrastructure fund

**Research Delivery System**
1. Drive Research Activity in Health System

- Optimise current HMR investment
- Monitor and manage 3%–4% of total government health expenditure on HMR

  a. Manage current state/territory government LHN HMR investment, using National Health Reform Agreement to strengthen and build upon approx. $1.0–$1.5bn p.a. estimated HMR and set research KPIs for LHNs and hospital CEOs

  b. Additional $1.5bn pa for HMR within 10 yrs

  c. National health R&D investment target 3–4% of government health expenditure
2. Establish Sector Leadership and Governance

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
Rec. 3. Establish Integrated Health Research Centres

• IHRCs combine hospital and community-care, universities, & research organisations such as MRIs
  a. Establish clear set of criteria: integration, excellence, translation, strategy, leadership and governance
  b. Initially select 4–8 IHRCs; funding of < $10m pa each for 5 years, and add 1–2 IHRCs every 1–2 years → total 10–20 over 10 years
  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
Recommendation 4: 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 ≤ 1,000 over 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
Australia is one of the most expensive locations in the world for clinical trials

Clinical Trial Costs\(^1\)
Cost Index\(^2\)
2011-12

<table>
<thead>
<tr>
<th>Country</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>46</td>
</tr>
<tr>
<td>China</td>
<td>53</td>
</tr>
<tr>
<td>Mexico</td>
<td>60</td>
</tr>
<tr>
<td>Russia</td>
<td>63</td>
</tr>
<tr>
<td>France</td>
<td>79</td>
</tr>
<tr>
<td>Canada</td>
<td>88</td>
</tr>
<tr>
<td>Hollande</td>
<td>91</td>
</tr>
<tr>
<td>UK</td>
<td>95</td>
</tr>
<tr>
<td>Brazil</td>
<td>100</td>
</tr>
<tr>
<td>US</td>
<td>107</td>
</tr>
<tr>
<td>Italy</td>
<td>108</td>
</tr>
<tr>
<td>Germany</td>
<td>113</td>
</tr>
<tr>
<td>Aus</td>
<td>132</td>
</tr>
<tr>
<td>Japan</td>
<td>132</td>
</tr>
</tbody>
</table>

Note: 1. Based on operating costs of a clinical trials management firm
2. Indexed to the US

Decline in International Competitiveness

- Australia second most expensive country (Japan 1\textsuperscript{st})
- Rising relative value of Australian dollar
- Rapid increase in capacity of low-cost countries
- Complex, time consuming and costly approvals processes for ethics and governance review
- Lack of standardised costs across Australia
- Lack of appropriate clinical trial support infrastructure
- Difficulty in recruiting participants driven by limited access to patients by healthcare providers
- Lack of national patient data infrastructure to identify participants
Rec. 5: Accelerate Clinical Trial Reforms
Build on Clinical Trials Action Group

a. Develop an online approval workflow system and enhance existing consumer recruitment portal
b. Establish 8–10 national ethics committees to replace the proliferation of local committees
   - currently >250 HRECs in Australia (vs 87 in UK)
c. Implement a national clinical trials liability insurance scheme
d. Create a national clinical trials office within the HMR leadership body to drive reforms
Clinical trials deliver...

- Better patient outcomes for hospitals that participate
- A source of income for the hospitals involved, but need infrastructure and involves ethical and legal risks
- Clinical trials provide export income
- Est. value in Australia ≈ $1bn pa
- ≈600 new trials reported by TGA in 2011
  – (Nº trials stagnant over last 5 yrs)
6. Establish, fund and create a structure around a set of national HMR priorities

a. Set national HMR priority areas through the leadership body and Council of Australian Governments Standing Council on Health triennially

b. Allocate 10%–15% of the NHMRC budget to priority areas for 'top-down strategic research'

c. Create a panel of experts for each priority area to set research agenda, leverage funding and evaluate outcomes
Strategic, government-led research into the Hendra virus quickly led to an understanding of its causes and subsequent treatment

• Collaboration between health departments and researchers led to identification only two weeks after its first incidence

• CSIRO AAHL identified bats as the source of virus, but focused on the end solution, horses for the treatment

• Identified prevention and treatment for humans and animals, including the Equivac HeV vaccine

In Sept 1994, a Qld horse trainer and 14 of his horses caught an unidentified illness and were dead within days
Hendra Virus Case Study: Key Lessons

1. Strategic, responsive research can rapidly address urgent disease outbreaks. Focusing on an end-solution accelerated the development of a treatment.

2. Collaborative research efforts are important to deliver better quality and timely interventions. AIBN, QLD Health, PA Hospital and US researchers produced antibodies for emergency treatment of humans exposed to virus.

3. Investment in world-class research facilities consolidates Australia’s global role in health and medical research. AAHL is world-renowned centre for research into exotic and emerging animal diseases with international links.

Source: Desktop research
7. Support Range of Strategic Topics

a. Build Indigenous research capacity through a virtual Integrated Health Research Centre (IHRC)
b. Establish a virtual rural and remote IHRC
c. Support global health research, esp. focus on Asia
d. Develop capacity and capability in genomics through a national HMR network, ongoing training, NHMRC People Support Schemes and data infrastructure investment
A targeted approach to cerebral palsy resulted in significantly improved clinical practices and outcomes

Background

• Cerebral Palsy Alliance launched a strategic review process in 2007 which identified 33 areas of priority research

• Research findings disproved the link between neonatal oxygen deprivation at birth and cerebral palsy

• Translated into two new clinical procedures of cooling of the brain and using magnesium sulphate, reducing incidence of cerebral palsy by 5% and 30% in premature infants

Source: Cerebral Palsy Alliance Research Foundation; Schofeild, S. “How do I know if my intervention was cost effective?” Perinatal Society Annual Conference 2012.
A targeted approach to cerebral palsy resulted in significantly improved clinical practices and outcomes.

Key Lessons

1. A targeted approach enriches medical significance of research being conducted.

2. Strategic approach focused research efforts and disproved the link between clinical procedures and cerebral palsy.

3. Translation of research into evidence-based practice leads to significantly improved health outcomes.

4. For every case of cerebral palsy prevented, $2m saved over the child’s first 18 years of life – a substantial return on the investment of less than $200k per case for prevention.

Source: Cerebral Palsy Alliance Research Foundation; Schofeild, S. “How do I know if my intervention was cost effective?” Perinatal Society Annual Conference 2012.
Research workforce
NHMRC people support schemes experienced solid growth up until 2009 and have since been flat to in decline.

NHMRC People Support Schemes
# Researchers

<table>
<thead>
<tr>
<th>Year</th>
<th>PhD Scholarships</th>
<th>Senior Fellowships</th>
<th>Career Development Fellowships</th>
<th>Postdoctoral Fellowships</th>
<th>Other Fellowships</th>
<th>PhD Scholarships</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>884</td>
<td>48</td>
<td>228</td>
<td>353</td>
<td>249</td>
<td>1,043</td>
</tr>
<tr>
<td>2003</td>
<td>1,043</td>
<td>81</td>
<td>263</td>
<td>429</td>
<td>249</td>
<td>280</td>
</tr>
<tr>
<td>2004</td>
<td>1,215</td>
<td>115</td>
<td>309</td>
<td>481</td>
<td>309</td>
<td>289</td>
</tr>
<tr>
<td>2005</td>
<td>1,373</td>
<td>142</td>
<td>361</td>
<td>544</td>
<td>36</td>
<td>298</td>
</tr>
<tr>
<td>2006</td>
<td>1,491</td>
<td>186</td>
<td>421</td>
<td>550</td>
<td>37</td>
<td>323</td>
</tr>
<tr>
<td>2007</td>
<td>1,543</td>
<td>201</td>
<td>434</td>
<td>539</td>
<td>36</td>
<td>356</td>
</tr>
<tr>
<td>2008</td>
<td>1,734</td>
<td>240</td>
<td>539</td>
<td>538</td>
<td>36</td>
<td>373</td>
</tr>
<tr>
<td>2009</td>
<td>1,783</td>
<td>250</td>
<td>549</td>
<td>536</td>
<td>61</td>
<td>386</td>
</tr>
<tr>
<td>2010</td>
<td>1,764</td>
<td>261</td>
<td>553</td>
<td>467</td>
<td>75</td>
<td>380</td>
</tr>
<tr>
<td>2011</td>
<td>1,761</td>
<td>266</td>
<td>547</td>
<td>447</td>
<td>97</td>
<td>380</td>
</tr>
</tbody>
</table>

Source: NHMRC data, 2012
NHMRC people support schemes support ~1,760 researchers with ~$159m in funding

<table>
<thead>
<tr>
<th>People Support Schemes</th>
<th>2011</th>
<th>Number of Recipients</th>
<th>Funding ($m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Principal Research Fellow</td>
<td>68</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Principal Research Fellow</td>
<td>84</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Senior Research Fellow B</td>
<td>107</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Senior Research Fellow A</td>
<td>121</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Career Development Fellow</td>
<td>266</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Postdocoral Fellow</td>
<td>547</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>PhD Scholar</td>
<td>447</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Practitioner Fellow</td>
<td>75</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Australian Fellowship(^1)</td>
<td>37</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Translating Research into Practice Fellow</td>
<td>9</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,761</strong></td>
<td><strong>159</strong></td>
<td></td>
</tr>
</tbody>
</table>

Notes: 1. Australian Fellowships are no longer offered (represents expenditure from existing applications)
Source: NHMRC, Customised data request, 2012
8. Train, Support and Retain Workforce

a. Actively monitor HMR workforce and NHMRC People Support Schemes

b. Support career entry with higher Australian PG Award stipends and 'early investigator' grants

c. Retain more researchers with flexibility for career breaks or P/T 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 & contributions

e. Build capacity in key enabling areas (eg genomics, health economics)
9. Streamline Competitive Grant Processes

a. Streamline NHMRC grant application processes 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 standard Project Grant duration of 5 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.
Indirect costs are on average 60c per dollar of research, leaving current research organisations underfunded

Average MRI Indirect Research Costs
Cents per dollar
2008

- 25c
- 20c
- 15c
- 60c

• Currently research organisations receive varying levels support but all are below 60c
  - Universities receive 30c via SRE and RIBG
  - MRIs receive 20c via IRISS
  - Hospitals receive no indirect cost support

• Top-up funding to the actual costs of research of 60c should be provided, coupled with NHMRC competitive grant funding

Note: 1. SRE – Sustainable Research Excellence Program and RIBG – Research Infrastructure Block Grant
2. IRISS – Independent Research Institutes Infrastructure Support Scheme
Source: AAMRI, Australian MRI Indirect Cost Funding, 2010
11. Build Enabling Infrastructure and Capabilities

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
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 & evaluate translation
  b. Refine NHMRC selection criteria to encourage health services research
  c. Establish an influential institute of health services research
Health Services Research examples

• Fully integrated orthopaedic service for surgery
  – Reduced waiting times
  – Decreased time in hospitals
  – Increased mobilisation rates on day of surgery
  – Decreased adverse events

• Chemotherapy for cancer
  – 3 months equal to 6 months \(\Rightarrow\) cost\(\downarrow\) and AEs\(\downarrow\)
Health Research Translation
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
   - 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

Cumulative Health Outcome (e.g. QALYs)

Cost ($)
Implementing hand-washing programs can reduce hospital infection rates that cost health system ~$1-2bn pa

Hand-washing Non-compliance in Hospitals
% Non-compliance Rate

- Infections result from poor hygienic practices such as hand washing
- Over 200,000 incidents p.a. (5%–15% of all hospital admissions)
- Total cost of $1-2bn p.a.
- Hand hygiene programs have yielded $9 for every $1 invested

Note: 1. Initial observation that handwashing can reduce infection rates – Ignaz Semmelweis;
14: 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
US NIH T1 – T4 Public Health Research Translation Framework

- **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

Public health examples
- Fluoride in water
- Tackling obesity
- Pellagra
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
Identify policy gaps and build research capacity

• Targeted research
• Establish structured process within NHMRC to encourage closer interaction between researchers and policy makers
• Fund embedded policy liaison officers
• Build capacity to undertake comparative-effectiveness research → evidence
• Provide evidence portal for health practitioners
• Encourage professionals from outside HMR to undertake research to assist in the provision of appropriate evidence and policy
Enhance Non-Commercial Pathway to Impact

- Build capacity in health services research through targeted allocation of grants
- Build health economist capacity
- Establish national health economics PG program
- Revise selection criteria for NHMRC Project Grants
- Encourage LHNs to use health system research funds
- Establish an institute of health services research
- Develop and monitor Local Hospital Networks’ ranking of research outputs and translation outcomes
Commercial vs non-commercial

Innovation in commercial settings:

• Laser eye surgery
• Cochlear ear implants
• Medically-led diagnostic practices
• In vitro fertilisation

These deliver benefits but drive up cost of health care

Non-commercial settings lack incentives to drive innovation
Non-commercial trials underfunded despite significant potential benefits

- Lack of adequate government funding
- Granting process does not favour funding of non-commercial clinical trials
- Narrow definition of clinical research
- Lack of resources in hospitals for clinical trials
- Lack of protected time for hospital-based clinician researchers
- Insufficient clarity on process and champions to ensure non-commercial clinical trials proceed
Options

• Provide additional funding of $50m–$100m p.a. for non-commercial clinical trials, eg
  – early dialysis for renal patients not beneficial
  – IV Ig not beneficial for neonates with infections

• NHMRC panels with skills to assess translation

• Prioritising trials based on potential health benefits of interventions (with public benefits such as QALYs)

• Conduct trials at LHNs using streamlined governance processes initially
Benefits of commercialisation

- Biotech and pharma provides > 40,000 Australian jobs
- > 10,000 people employed in medical technology
- Biomedical industry is Australia's largest high-tech exporter with ≤ $4bn in export > automotive industry
- Highest manufacturing R&D investor ($1bn 2009/10)
- Publicly-listed life-sciences companies consistently outperformed broader equities market over last 12 y
- Commercialisation successes
  - CSL, Resmed, Cochlear, Mesoblast
Poor incentives for researchers to commercialise discoveries

- Ratio of Australia and UK researchers employed in business relative to higher education $\approx 0.4$
- In most developed countries, ratio $\approx 2$
- Government support for research commercialisation activities $< 1.5\%$ of $> 8$bn spent annually in Australia on research across all sectors
- Funding is required at three key stages—preclinical, early clinical and late clinical
Leading OECD countries adopted R&D targets of > 3% of GDP

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

The National Research Investment Plan (2012) recommends an R&D target of 3% of GDP

Source: Australian Government, National Research Investment Plan, 2012; OECD; UNESCO
Bridge 'Valley of Death #1' – Preclinical Stage

• Current
  – NHMRC Development Grants scheme
  – Commercialisation Australia
  – ARC Linkage Projects scheme
  – Medical Research Commercialisation Fund (MRCF)

• Options
  – Institute a matching development grants scheme ≤ $10m pa to be matched with $10m by recipient to enable advancement of ≤ 50 projects each year
  – Increase coordination between existing schemes
  – Restore access to ARC Linkage Project grants for HMR
Bridge 'Valley of Death #2' – Early Clinical Stage

• Innovation Investment Fund (IIF) ($10m pa)
  – a co-investment scheme uses a competitive process to license private sector fund managers
  – Provides 1:1 matched investment (40% in HMR)
• Medical Research Commercialisation Fund (MRCF) ($10m pa)
• Small-cap public biotech company equity issues ($20m pa)

Option: Create a Translational Biotech Fund: $250m seeded with class B equity capital of $125m by Australian Gov. and matched by industry sources (eg superannuation) → support five projects per year @ $10m ea
Rec. 16: Support Research Commercialisation
Provide funding for twin 'valleys of death' in commercialising research

a. Matching Development Grants scheme $0.5m pa ea. to 20 consistently most successful NHMRC grant recipient organisations, contingent on matching commitments and access to business development

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 Australian Government and private sector on one-to-one match

d. Continue to support the Innovation Investment Fund
Recommendation 17: Enhance Commercialisation Environment. Improve commercialisation capability, culture and practices

• Foster a culture of commercialisation
• Leverage scale and expertise
• Protect valuable intellectual property
• Attract clinical trials
Collaboration led to development of HPV vaccine technology that prevents cervical and other cancers

- HPV technology developed by researchers to immunise against four HPV strains that cause cervical and other cancers
- Technology licenced through UniQuest to CSL, who on-licensed to Merck & GSK to develop & commercialise
- 75% reduction of HPV-related diseases
- Similar rate expected for cervical cancer incidence over next 30 years

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
# HPV Development

## Basic Research

1980-1989
Evidence that HPV induces anogenital cancers gathered worldwide

1989-1991
Synthesis of particles to mimic HPV at UQ leads to the creation of a VLP in Australia

## Development

1991-1995
UniQuest patents VLP technology in 1991

1995-2006
CSL sub-licenses to Merck and GSK, who scale up technology and pursue vaccine clinical trials

## Immunisation Program

2007
Gardasil added to the National Immunisation Program for 12-13 year old girls

2013
Gardasil added to the National Immunisation Program for 12-13 year old boys

## Health System Impact

2013-2050
HPV related diseases in women expected to drop by 92% by 2050.

Vaccinations of men expected to consolidate a herd effect and further reduce HPV infection rates and associated diseases

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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*
Key Lessons from HPV vaccine

1. Collaborative research can deliver ‘breakthrough’ discoveries of interventions to prevent major illnesses.

2. The link between the HPV and pre-cancerous cells led to the HPV technology development.

3. Commercialisation expertise is key to ensure translation of breakthrough discoveries. Commercialisation of vaccine technology was supported by UniQuest, CSL, Merck and GSK.

4. Evidence-based policy leads to significantly improved healthcare outcomes for the broader population. Infection rates are expected to drop by 92% by 2050.

S Tabrizi et al, ‘Fall in human papillomavirus prevalence following a national vaccination program’, J. Infectious Diseases, 19 October 2012, pp.1-7; National Immunisation Program, Fact Sheet: HPV Vaccination for Boys, 2013
Rec 18 Attract Philanthropy

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

National Giving Levels
% Donations of GDP
2004

<table>
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<tr>
<th>Country</th>
<th>2004 Percentage</th>
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<tr>
<td>US</td>
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<tr>
<td>UK</td>
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High Net Worth Contribution Rate
% Donations of Pre-Tax Income
2004

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<tr>
<th>Country</th>
<th>2004 Percentage</th>
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<td>Canada</td>
<td>3.2%</td>
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<tr>
<td>Australia</td>
<td>1.9%</td>
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Source: Philanthropy Australia, Strategies for Increasing High Net Worth and Ultra High Net Worth Giving, 2011
Recommendations 19-21

• 19. Identify New Funding Sources. Identify other possible funding sources. e.g., alternative debt finance, R&D tax incentives and levies, research prizes

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

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

<table>
<thead>
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<th>Business &amp; NFP</th>
<th>State Gov’t</th>
<th>Australian Gov’t</th>
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<tr>
<td>Total HMR Investment</td>
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Current System 2011–12 Estimate

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Future View 2023–24 Forecast

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<tr>
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<td>University &amp; Other</td>
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<td>Business &amp; NFP</td>
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<td>Total</td>
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Note:
1. Nominal dollars (assumes 5% forecast growth over period 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. Additional investment would be progressively built up over a ten year period based on decision gates in 2013–14 and 2018–19.

**Investment Summary**

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<th>$bn</th>
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Note: 1. Nominal dollars inflation adjusted at 3%
2. FY is financial year (e.g. FY13 is 2012-13)

Source: ABS, AIHW, NHMRC, DoHA, Pacific Strategy Partners Analysis

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**Decision Gate A**
Invest to improve the health system

**Decision Gate B**
Refine and invest in success

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3. Deliver Health System Impact – Phase 2 (Path 3)
2. Deliver Health System Impact – Phase 1 (Path 2)
1. Optimise Current Investment

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3-4% Benchmark Range
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
Thank you

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