



Australian Academy of Science

**SUBMISSION TO THE MCKEON STRATEGIC REVIEW
OF HEALTH AND MEDICAL RESEARCH**

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EXECUTIVE SUMMARY

Health and medical research has great intrinsic social and economic value. It produces knowledge and resources that change medical and public health practice, resulting in better health for the community. It also leads to the commercial development of improved medicines, vaccines, medical devices and healthcare technologies, thereby contributing to economic growth.

Australia is strong in health and medical research, thanks to its excellent education and training of health care professionals and scientists, and historically strong research support from Government to Universities, Medical Research Institutes and CSIRO.

While numerous landmark discoveries impacting on community health have been made in Australia, such as the development of a vaccine to prevent cervical cancer, some areas of community need, such as age-related illnesses, mental health and Aboriginal health, are still relatively neglected and require further attention.

The fact that Australia has a vibrant medical research sector allows us to access and benefit from medical research advances made internationally. Furthermore, our strong international reputation enables us to attract an increasing number of very bright postgraduate and postdoctoral trainees from overseas. Many settle here and further enhance our capability, while others retain strong collaborative links after returning to their countries of origin.

Factors limiting the sector include the conflict between Commonwealth and State health responsibilities, and the relatively low contribution by State governments to research funding. Funding from the private sector and from philanthropic funding is also low in Australia in comparison to the United Kingdom and the United States.

Recommendations

1. Australia should continue to support health and medical research strongly, because this will guarantee that we improve the health of our community; give attention to Australian health issues; preserve a strong clinical, public health and research workforce; and ensure continued growth of allied Australian industries.
2. Funding of health and medical research (basic, translational and clinical) should be steadily increased in Australia, to reach a target of 2% of the health budget by 2025. While a proportion of this increase should come from Commonwealth, the States should also contribute strongly, particularly in the area of clinical research funding.
3. Public sector research, both in Medical Research Institutes and Universities, should be properly funded for indirect costs as well as direct costs.
4. Barriers discouraging collaborations between sectors (universities, medical research institutes, CSIRO, DSTO and biotech companies) should be removed. Policy settings and funding opportunities that further promote interdisciplinary collaborations should be developed.

5. Further tax reform and other incentive measures should be considered by Government to increase charitable donations. Voluntary amalgamation of smaller medical research trusts should be encouraged to achieve higher visibility and research impact.
6. Funding for clinical translation and public health research should be increased, without reducing the budget for basic research, which underpins future applications. A new peer-reviewed competitive grants scheme for clinical and public health research should be established, funded by the Department of Health and Ageing (DOHA), in conjunction with the State Departments of Health. This could be administered by a new agency within DOHA or, alternatively, by the NHMRC via a separate, protected budget.
7. Areas of unmet community need, such as Aboriginal health, mental health and age-related illnesses, should receive increased attention and resources.
8. Government should give careful consideration to further R&D tax incentives for biotechnology, medical technology and allied companies, especially during the start-up and early development phases.
9. Government should consider policy measures and regulatory support to encourage increased private sector investment in bio-medical industries, perhaps through investment from superannuation funds and/or private health insurance funds.
10. Government should remove unnecessary barriers to international research collaborations in health and biomedical research, and establish a new strategic plan to enhance and facilitate international research collaborations.
11. The career structure for health and medical research researchers should be expanded and reformed to ensure that the sector continues to attract and retain the brightest and best graduates, both national and international.
12. Government agencies should take a measured look at how approval processes, reporting and regulation can be minimised and streamlined to reduce unnecessary time expenditure by researchers.

1. HEALTH AND MEDICAL RESEARCH IS A KEY ENTERPRISE FOR AUSTRALIA

The international environment

There is an increasing emphasis globally on growing health and medical research. 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.

The major funding body in the United States, the National Institutes of Health (NIH), has a budget of over US\$30 billion pa. American researchers also have access to major charitable, non-government organisation funds and philanthropic donations. The US recently established a new National Center for Advancing Translational Science (NCATS) within the NIH budget. President Obama has commented often that the US Government sees health and medical research as both an economic investment and a social benefit, and has pledged to increase R&D investment to 3% GDP, alongside the United Kingdom's 2.5% (by 2014) and European Union's 3% targets. In France, of the total 35 billion Euro budget allocated to improving competitiveness and innovation after the GFC, 21.9 billion was allocated to medical and scientific research and higher education¹. In Asia, the interests of a rapidly growing middle class ensure that above average investment in scientific research in general includes health and medical sciences, in many cases led by Singapore.

In the UK, despite severe economic pressures from the Global Financial Crisis (GFC), the Government has created a new translational research fund of approximately £1 billion pa, to be disbursed using competitive peer-review mechanisms through the National Health Service and, at the same time, has increased the budget of the Medical Research Council, which is focusing on more fundamental research on which long-term advances will be based.

It is essential that Australia remains a competitive collaborative scientific partner, especially in Asia. We need to ensure access to the 98% of science produced internationally and continue to make effective use within our system of Australian and international researchers.

Justification for continued investment in Australia

Health and medical research is a key enterprise for Australia that should continue to be supported strongly. Amongst the many reasons, the Australian Academy of Science wishes to focus on three.

- Firstly, as a highly developed and wealthy nation, with a strong health care system and an excellent world record in general health and life expectancy for most of our people, it is important that we participate in generating further cost-effective improvements in health care for both our own and the international community. The strength of our research underpins our ability to attract and maintain a highly skilled and motivated clinical community, even among those who do not directly participate in the research endeavour.

¹ Science 10 February 2012: 644-645 €22 Billion Stimulus Brings Worries About Egalit , Barbara Casassus

- Secondly, health and medical research is a generator of wealth in our society and worldwide, both through the excellence in education and clinical practice that is generated through cutting-edge research, and through the activities of the growing biotechnology and related industries.
- Thirdly, there are many problems (unusual viruses, the impact of drought and flood on public health, the issues in the poor health status of Aboriginal Australians) that are unique to our country, and for which we need to find Australian solutions.

Strong past performance

Health and medical research in Australia performs well by international standards. With only 0.3% of the world-population, we produce approximately 3% of the world's publications in this field². Highlighting our strength in medical research, of the eleven Australians who have won a Nobel Prize – the highest accolade in science - seven have been health and medical researchers.

A major factor in the success of the sector has been relatively strong support by Government, especially over the last 10 years, which has seen an increase in the National Health and Medical Research Council (NHMRC) budget from \$290 million in 2001 to \$790 million in 2011.

There are many examples where health care has benefitted from the strength of basic research performed in Australia. These include:

- The demonstration that the likelihood of a death from SIDS is reduced markedly if babies sleep on their backs;
- The discovery that infection by *Helicobacter pylori* plays a key role in causing stomach ulcers
- The discovery of hormones for white blood cell production that have benefitted over 10 million cancer patients world-wide
- The development of the anti-flu drug Relenza
- The development of the cochlear implant
- The development of Gardasil, the vaccine that prevents infection with cervical-cancer causing human papilloma viruses
- The development and manufacture of sleeping masks for individuals suffering from sleep-disordered breathing

Australian context

In considering improvements to the Australian health and medical research sector, it is important to compare it with best practice internationally. At the same time, the particularities of the Australian context must also be considered. These include:

- Our hospitals (including most of the major research-oriented “teaching Hospitals”) are run by the States, but research (through NHMRC) and primary care/public health are run by the Commonwealth. This creates conflicting issues in the support of translational

² Research Australia, 2011, July, Occasional Paper Series, *Shaping Up: Trends and Statistics in Funding Health and Medical Research*.

research (“bench-to-bedside” research that is directed to practical outcomes to meet health problems in the community) and its implementation into standard clinical practice.

- Much of the best health and medical research in Australia is performed by full-time researchers in Medical Research Institutes (MRIs), which are quasi-independent but have close affiliations with local Universities and Hospitals.
- The real cost of doing research includes both direct costs³ and indirect costs⁴. Indirect costs vary between research sectors but are widely agreed to amount to ~60 cents for every direct research dollar⁵ and are verifiable by audit. NHMRC and Australian Research Council (ARC) research grants fund only the direct costs of research, while comparable funding agencies in the US and UK also provide substantial funding for indirect costs. Funding mechanisms for indirect costs in Australia are inadequate and inequitable, varying considerably between organisations.
- While Australia benefits from many small philanthropic trusts, it does not have multi-billion dollar private charitable organisations comparable to those that provide so much support for medical research in the UK (Wellcome Trust, Cancer Research UK) and USA (Howard Hughes, Bill and Melinda Gates Foundation).
- Unlike the USA, UK or Europe, Australia does not have highly developed biotechnology or pharmaceutical sectors that support biomedical basic or translational research.
- Our capital cities, which contain most of the population, are very distant from each other, posing significant logistical and political problems for research collaboration, access to resources and major research infrastructure. Australian researchers also have to import many of their specialised reagents from overseas, adding significantly to their research costs.

Recommendations:

1. Australia should continue to support health and medical research strongly, because this will guarantee that we improve the health of our community; give attention to Australian health issues; preserve a strong clinical, public health and research workforce; and ensure continued growth of allied Australian industries.
2. Funding of health and medical research (basic, translational and clinical) should be steadily increased in Australia, to reach a target of 2% of the health budget by 2025. While a proportion of this increase should come from Commonwealth, the States should also contribute strongly, particularly in the area of clinical research funding.
3. Public sector research, both in Medical Research Institutes and Universities, should be properly funded for indirect costs as well as direct costs.

³ Direct Costs include expenses related for example to salaries, salary on-costs, smaller items of equipment and consumables

⁴ Indirect Costs include expenses related for example to administration, maintenance, library, engineering, IT, research support services, translation/commercialisation services, legal and patent and depreciation

⁵ May RM, Sarson SC (1999) Revealing the hidden costs of research. Nature 398:457

4. Barriers discouraging collaborations between sectors (universities, medical research institutes, CSIRO, DSTO and biotech companies) should be removed. Policy settings and funding opportunities that promote interdisciplinary collaborations should be developed.

5. Further tax reform and other incentive measures should be considered by Government to increase charitable donations. Voluntary amalgamation of smaller medical research trusts should be encouraged to achieve higher visibility and research impact.

2. ENHANCING CLINICAL TRANSLATION AND PUBLIC HEALTH RESEARCH

Australia should move to a system where research is seen as an essential part of the training of every health care professional, whether employed at a Hospital, University or Medical Research Institute, or in primary care.

In order to introduce improved and cost-effective treatment and preventative measures, it is vital to attract and retain innovative clinicians, clinician-scientists and public health researchers and to nurture research-supportive teaching hospitals.

It is also vital to increase Australia's capability for mounting the clinical and public health trials essential to translate discoveries into clinical practice, not all of which will be attractive to large pharmaceutical companies that currently support most such trials.

Clinical, translational and public health research are currently underfunded and should be increased, but without reducing the budget for basic research, which underpins our understanding of how these treatments work and informs their safe application.

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.

Improving Aboriginal health should remain a top priority. Greater progress is also urgently required in the fields of age-related illnesses and mental health. Responsibility for the frail elderly, and for the mentally ill, is currently divided between several agencies - Commonwealth, State and private. While there is much research into problems that affect the elderly (e.g. cancer), other areas need increased attention. In the case of mental health, a welcome increase in service provision has not been matched by an influx of funds for new research projects.

Recommendations:

6. Funding for clinical translation and public health research should be increased, without reducing the budget for basic research, which underpins future applications. A new peer-reviewed competitive grants scheme for clinical and public health research should be established, funded by the Department of Health and Ageing (DOHA), in conjunction with the State Departments of Health. This could be administered by a new agency within DOHA or, alternatively, by the NHMRC via a separate, protected budget.

7. Areas of unmet community need, such as Aboriginal health, mental health and age-related illnesses, should receive increased attention and resources.

3. ENHANCING INNOVATION AND COMMERCIAL TRANSLATION

It is widely agreed that Australia's achievements in basic science are not yet matched by comparable achievements in commercial translation of discoveries. In the field of medical research, however, there have been some highly impressive success stories:

- The stockpiling of Relenza by governments to protect against bird flu and swine flu brought in A \$63.7 million in royalties for the Melbourne-based company Biota in the 2009-10 Financial Year.
- Cochlear implants have earned hundreds of millions of dollars in profit for the Australian company Cochlear.
- The cumulative sales of Gardasil are more than A \$5 billion, resulting in royalty returns to CSL of around A \$600 million.
- The Australian company ResMed, which manufactures masks for sleeping disorders, has more than 1300 employees in Australia, with revenues of \$1.1 billion and profit before tax of A \$261 million in 2010.

Further attention should be given by Government to strengthening this sector.

Recommendations:

8. Government should give careful consideration to further R&D tax incentives for biotechnology, medical technology and allied companies, especially during the start-up and early development phases.

9. Government should also implement measures to encourage increased private sector investment in biomedical industries, perhaps through investment from superannuation funds and/or private health insurance funds.

4. ENHANCING INTERNATIONAL FUNDING AND LINKAGES

The strong international reputation of the Australian medical research sector enables it to attract an increasing number of very bright postgraduate and postdoctoral trainees from overseas. Many settle here and further enhance our capability, while others retain strong collaborative links with Australia after returning to their countries of origin.

Although Australia is too small to participate in every research arena, our reputation for excellence guarantees that we have a respected place in the international research community, with access to advances made in other countries, including those in health and medicine.

Australia's strong reputation in health and medical research presents great opportunities for enriching Australia's international relationships and for developing new opportunities in medical

and scientific training of overseas students, vaccine and drug development, public health education and practice, and clinical trials.

It is vital to foster international relationships by establishing government-to-government agreements which can fund international research workshops, exchanges and programs, and which remove formal bureaucratic barriers. Regrettably, the Commonwealth's International Science Linkages program came to an end in June 2011. The Academy has recommended a new A \$250 million strategy over the next ten years to improve Australia's competitiveness, awareness and governance of international science programs and science diplomacy⁶.

Recommendation:

10. Government should remove unnecessary barriers to international research collaborations in health and biomedical research, and establish a new strategic plan to enhance and facilitate international research collaborations.

5. WORKFORCE ISSUES:

Career development

The health and medical research workforce is amongst the most highly educated in Australia. In addition to their undergraduate science degree, most have PhDs, or comparable higher degrees, with arduous and lengthy postgraduate and postdoctoral training (typically >10 years), often in multiple fields.

Australia has excellent undergraduate degree courses that underpin health and medical research, particularly in basic sciences such as immunology and genetics, as well as excellent undergraduate and postgraduate courses in medicine, nursing and allied health fields (including public health). These courses are also very popular for overseas students, particularly those from the Australasian region, and fees from international students are now critical for the financial viability of our universities.

Approximately 4,000 students per annum obtain PhDs from Australian Universities. The training in biomedical sciences received by PhD graduates is primarily relevant to academic research. However, while many do proceed to research careers in universities, medical research institutes or government research agencies, the majority (>80%) end up in a different career such as teaching, business or administration. The Academy supports these varied career paths and believes that a PhD is an excellent qualification for any high level position. However, to better facilitate the transition to these other roles, we believe every PhD student should receive mentoring and professional skills development (via short courses) in areas such as finance, governance, media, human resources, and research conduct (and misconduct), in addition to their research training.

There are many opportunities for our PhD graduates to continue research training in excellent laboratories either in Australia or abroad. Typically, this important post-PhD training phase is supported by a postdoctoral fellowship or by a grant held by the research supervisor/mentor.

⁶ Australian Academy of Science, 2011 Position Paper, *Australian science in a changing world: innovation requires global engagement* <http://www.science.org.au/reports/documents/Innovationrequiresglobalengagement.pdf>.

However, after this early postdoctoral training phase, opportunities contract significantly, because academia and government research organisations have insufficient mid- and senior-level research positions for the demand and opportunities in allied industries such as biotechnology are still very limited in this country.

It should be noted that this mid-career stage is the time (typically early 30s) when the best and brightest should be starting to run their own groups. It is also the time when many couples are starting to raise families and many women scientists leave the workforce.

The Academy's "Early-Mid-Career Researchers Forum" has made a detailed set of recommendations on these very important workforce issues, in a separate submission.

Over-regulation

Every scientist accepts that he/she must justify their tax-funded research funding and that research should be regulated by Government to ensure both personal and environmental safety. In today's scientific milieu, however, grant writing, and regulation compliance and reporting have ballooned out of proportion. In the US, it is estimated that such activities now consume 42% of a scientist's time⁷ and the time taken in Australia is similar. This is counter-productive, greatly erodes scientific creativity, and ultimately reduces research output.

Recommendations:

11. The career structure for health and medical research researchers should be expanded and reformed to ensure that the sector continues to attract and retain the brightest and best graduates, both national and international.
12. Government agencies should take a measured look at how approval processes, reporting and regulation can be minimised and streamlined to reduce unnecessary time expenditure by researchers.

6. CONCLUDING REMARKS

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. Driven by the genome revolution, the potential for evidence-based changes over the next 25 years is truly remarkable. However, if Australia is to participate in and benefit from this transformation, we need to increase our investment. Responsible action would ensure that we have a highly talented, stable, research-oriented workforce; flexible well-supported research institutions that are appropriately integrated with clinical and public health research; and hospitals that are committed to timely implementation of evidence-based, cost-effective care.

⁷ Science, 11 November 2011: 738. Editorial, *Rethinking the Science System*, Alan I. Leshner